LIST OF ACTIVITIES UNDERGONE DURING THE LAST 5 YEARS(2016-2021)		
I. LIST OF ACTIVITIES UNDERGONE IN 2020-2021 ACADEMIC YEAR		
S.NO	**ACTIVITY**	**VALUES**
1	.FREE MEDICAL CAMP	PROFESSIONAL ETHICS
2	GROCERIES DISTRIBUTION DURING COVID PANDEMIC	HUMAN VALUES
3	COVID TEST DRIVE	HUMAN VALUES
4	HETERO CAMPUS DRIVE	PROFESSIONAL ETHICS
5	PERSONALITY DEVELOPMENT PROGRAM	HUMAN VALUES
6	HEALTH CAMP AT KORUKONDA	PROFESSIONAL ETHICS
7	. VACCINATION DRIVE	PROFESSIONAL ETHICS
8	COVID ISOLATION WARD	PROFESSIONAL ETHICS
9	WEBINARS DURING THE PANDEMIC	PROFESSIONAL ETHICS
	II. LIST OF ACTIVITIES UNDERGONE IN 2019-2020 ACADEMIC YEAR	
S.NO	**ACTIVITY**	**VALUES**
1	INTERNATIONAL WOMEN'S DAY	GENDER
2	FAREWELL PARTY CELEBRATIONS	ENVIRONMENT & SUSTAINABILITY
3	WORLD ENVIRONMENT DAY	ENVIRONMENT & SUSTAINABILITY
4	HETERO CAMPUS DRIVE	PROFESSIONAL ETHICS
5	GANESH NAVARATI CELEBRATIONS	HUMAN VALUES
6	GRADUATION DAY CEREMONY	PROFESSIONAL ETHICS
7	WORLD PHARMACIST DAY	PROFESSIONAL ETHICS
8	GUEST LECTURE	ENVIRONMENT & SUSTAINABILITY
9	FRESHER'S PARTY CELEBRATIONS	HUMAN VALUES
10	.BLOOD DONATION CAMP	HUMAN VALUES
11	NEC AP STATE ROUND COMPETITION	PROFESSIONAL ETHICS
12	ORIENTATION PROGRAMME	PROFESSIONAL ETHICS
13	58th NATIONAL PHARMACY WEEK CELEBRATIONS	PROFESSIONAL ETHICS
14	PERSONALITY DEVELOPMENT PROGRAMME	HUMAN VALUES

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15	SEMI CHRISTMAS CELEBRATIONS	HUMAN VALUES
16	INDUSTRY ORIENTED TRAINING PROGRAMME FROM PTI	PROFESSIONAL ETHICS
17	BEST LOCAL BRANCH AWARD -5TH TIME CONSECUTIVELY (IPA)	PROFESSIONAL ETHICS
18	SANKRANTHI CELEBRATIONS	HUMAN VALUES
19	ARTIFICIAL INTELLIGENCE IN HEALTH CARE	PROFESSIONAL ETHICS
20	MOU WITH KONKUK UNIVERSITY SEOUL, SOUTH KOREA	PROFESSIONAL ETHICS
21	NATIONAL SERVICE SCHEME (NSS) SPECIAL CAMP	HUMAN VALUES
22	.Mock Aircraft Crash	HUMAN VALUES

III. LIST OF ACTIVITIES UNDERGONE IN 2018-2019 ACADEMIC YEAR

S.NO	ACTIVITY	VALUES
1	FELICITATION TO Dr.T.V.NARAYANA	HUMAN VALUES
2	INTERNATIONAL YOGA DAY	ENVIRONMENT & SUSTAINABILITY
3	THREE DAYS WORKSHOP ON " TRAINING IN FORMULATIONS, QA& QC"	PROFESSIONAL ETHICS
4	DENTAL CAMP	PROFESSIONAL ETHICS
5	MEGA BLOOD DONATION CAMP	PROFESSIONAL ETHICS
6	RELIEF FUND FOR KERALA FLOOD VICTIMS	HUMAN VALUES
7	WORLD PHARMACIST DAY	PROFESSIONAL ETHICS
8	DENGUE AWARENESS PROGRAM	PROFESSIONAL ETHICS
9	57th NATIONAL PHARMACY WEEK CELEBRATIONS	PROFESSIONAL ETHICS
10	AWARENESS RALLY ON NATIONAL VOTERS DAY	HUMAN VALUES
11	69th REPUBIC DAY CELEBRATIONS	ENVIRONMENT & SUSTAINABILITY
12	10th NATIONAL IPA STUDENT CONGRESS	PROFESSIONAL ETHICS

IV. LIST OF ACTIVITIES UNDERGONE IN 2017-2018 ACADEMIC YEAR

S.NO	ACTIVITY	VALUES
1	ANTIMICROBIAL RESISTANCE AWARENESS WALK	PROFESSIONAL ETHICS
2	9th IPA STUDENT CONGRESS	PROFESSIONAL ETHICS
3	ORIENTATION PROGRAMME FOR I B.PHARM AND PHARM.D STUDENTS AND PARENTS	PROFESSIONAL ETHICS
4	WORLD PHARMACIST DAY CELEBRATIONS	PROFESSIONAL

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		ETHICS
5	WORLD ANTOBIOTIC AWARENESS WEEK	PROFESSIONAL ETHICS
6	56th NATIONAL PHARMACY WEEK	PROFESSIONAL ETHICS
7	BLOOD DONATION CAMP	HUMAN VALUES
8	. NSS MEGA CAMP	HUMAN VALUES
9	POSTER PRESENTATION COMPETITION	PROFESSIONAL ETHICS
10	WORLD TB DAY	HUMAN VALUES

V. LIST OF ACTIVITIES UNDERGONE IN 2016-2017 ACADEMIC YEAR

S.NO	ACTIVITY	VALUES
1	ORIENTATION PROGRAMME FOR B.PHARM AND PHARM.D STUDENTS	PROFESSIONAL ETHICS
2	WORLD PHARMACIST DAY CELEBRATIONS	PROFESSIONAL ETHICS
3	PERSONALITY DEVELOPMENT PROGRAM	PROFESSIONAL ETHICS
4	NATIONAL PHARMACY WEEK CELEBRATIONS	PROFESSIONAL ETHICS
5	LOC MEETING OF 68th IPC	PROFESSIONAL ETHICS
6	WORKSHOP ON ANTICOAGULATION CLINIC: ROLE OF PHARMACY PROFESSIONALS	PROFESSIONAL ETHICS
7	KEY ROLE IN 68TH IPC	PROFESSIONAL ETHICS
8	ANTICANCER CAMPAIGN ON WORLD CANCER DAY	HUMAN VALUES
9	GUEST LECTURE ON COMMUNITY PHARMACY	HUMAN VALUES
10	BLOOD DONATION CAMP	HUMAN VALUES
11	GUEST LECTURE BY DR. A.RAMKISHAN	PROFESSONAL ETHICS

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Dr.T.V.NARAYANA
PRINCIPAL

LIST OF ACTIVITIES UNDERGONE IN 2020-2021 ACADEMIC YEAR.

1.FREE MEDICAL CAMP:

Students of Vikas Institute of Pharmaceuticals sciences Rajahmundry in association with PHC Dowleswaram, organized a free medical camp at konthamuru area , Rajahmundry. Financially weaker sections of the area were given free medicines at the government school. Students of 4th and 5th Pharm.D actively participated in the camp. Mr.T.Ch.Subba Rao, Chairman VIPS and Dr.G.Sumalatha, Vice Principal , VIPS inaugurated the medical camp.

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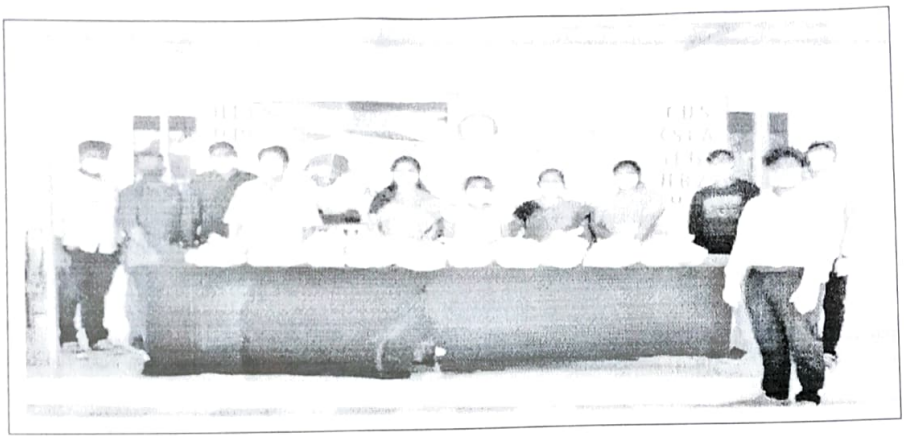
2.GROCERIES DISTRIBUTION DURING COVID PANDEMIC :



To help the poor during the pandemic and to take social responsibility in supporting the needy during this financial meltdown, Vikas Institute of Pharmaceutical Sciences and A & I foundation distributed groceries the people in the villages nearby and also to the workers and sweepers at the college. They have also extended their helping hand do the people in the quarantine region. All the students volunteered for the program.

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3.COVID TEST DRIVE:

A three day COVID test drive was organized at Vikas Institute of Pharmaceutical Sciences in the month of December 2020 from 10th to 12th. The tests were performed for all the students and staff of the college. Medical staff of PHC Dosakayalapalli village have helped in making the drive a successful one. Dr.G.Sumalatha, Secretary IPA Rajahmundry Local branch, vice principal, Vikas Institute of Pharmaceutical Sciences and Dr. S.Muralidhar HOD, Dept of Pharmaceutics, Vikas Institute of Pharmaceutical Sciences, Rajahmundry and other teaching staff of the college have corporated for the success of the drive

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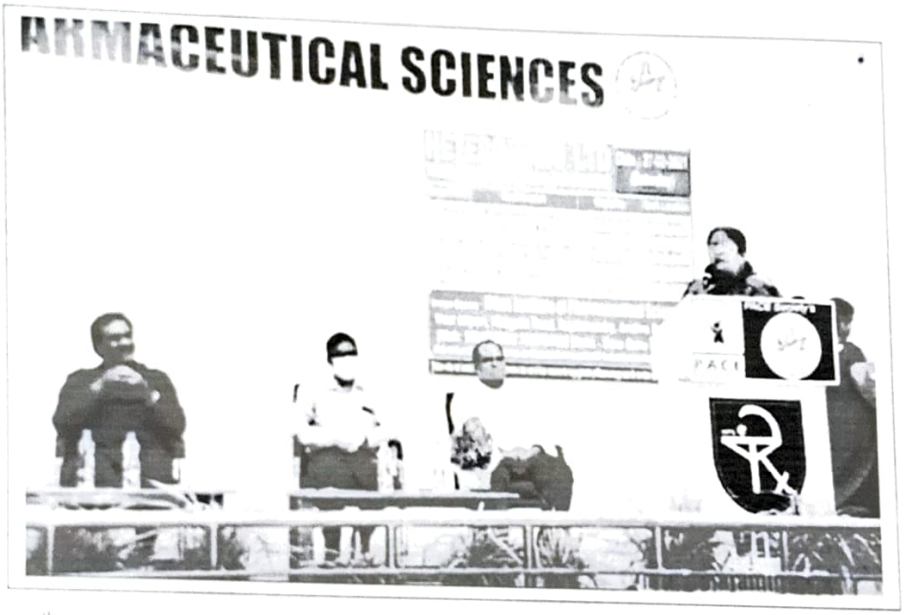
4.HETERO CAMPUS DRIVE:



On 27th of February 2021, Campus Drive was organized by Vikas Institute of Pharmaceutical Sciences, Rajahmundry. The campus drive was conducted by Hetero Labs Ltd (API Division, Visakhapatnam). Around 200 pharmacy students from different colleges in and around Rajahmundry have attended the interviews conducted for various departments such as Production, QA, QC and technical services. Mrs.Jakkampudi Vijaya Laksmi Central Executive member of YSRCP was the chief guest for the inauguration of the programme. Dr. I V Narayana, President IPA , Principal and director VIPS, Rajahmundry have also graced the occasion. North zone DSP and CI of North zone joined for the valedictory and have extended their greetings to the candidates who have successfully cracked the interview and were selected.

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5. PERSONALITY DEVELOPMENT PROGRAM:

Vikas Institute of Pharmaceutical sciences have conducted a 3- day workshop on personality development program to the 1st year students of B.Pharm, Pharma.D and M..Pharm from 23rd - 25th March 2021. The students were trained by Dr. Jagannath Rao, a renowned motivational speaker and soft skill & life skill trainer. On the last day of the program all the students were awarded with the certificates. Dr.T.V.Narayana, President IPA and Principal and director VIPS, Rajahmundry have also graced the occasion.

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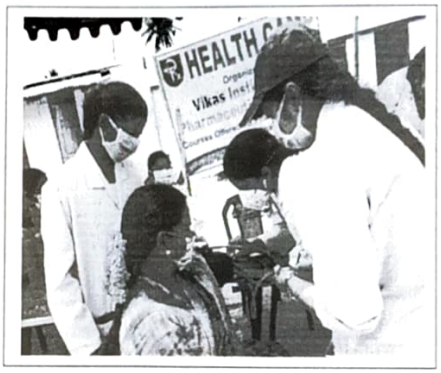
6. HEALTH CAMP AT KORUKONDA :



Vikas Institute of Pharmaceutical Sciences, Rajahmundry on March 25th to 27th 2021, organized a health camp at Korukonda temple, where a 3 day temple fair is organized every year and is attended by large number of devotees. Students of 4th and 5th year Pharm.D have actively participated in the camp. The health camp was organized to provide basic medical services required for the devotees. The health camp was inaugurated by Dr. G.Sumalatha, Vice principal Vikas Institute of Pharmaceutical Sciences, Rajahmundry.

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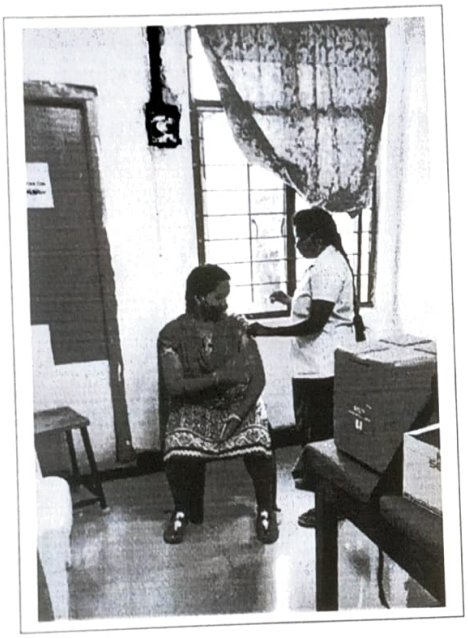
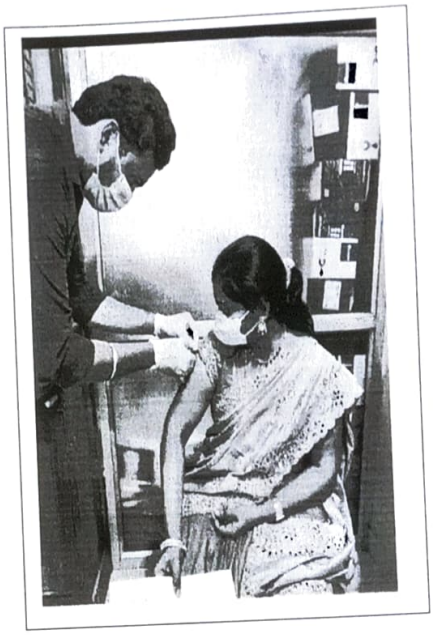
7. VACCINATION DRIVE:





To gear up the teaching from online to offline classroom mode and to continue with the regular academics at the college, Vikas Institute of Pharmaceutical Sciences has initiated a vaccination drive. As a part of this initially all the teaching and non-teaching staff were vaccinated with COVAXIN/ COVISHIELD vaccines by taking the support from PHC, Dosakayalapalli village. Later the drive was extended to all the people of several villages around the college.

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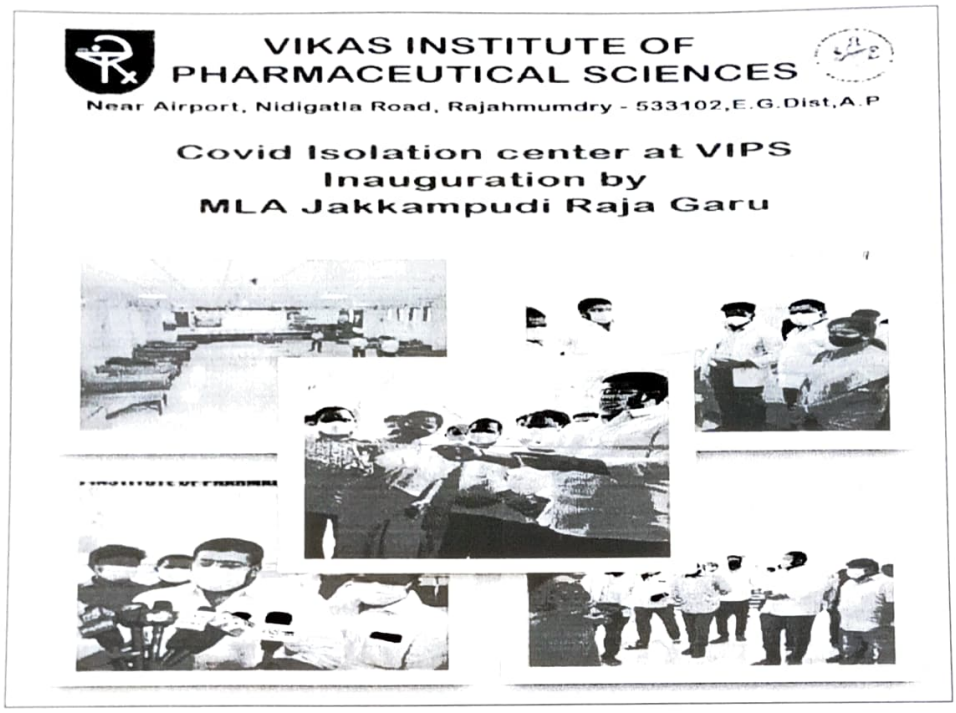
8. COVID ISOLATION WARD :



With the advent of 2nd wave of COVID 19, the increase in number of cases and the limited number of beds at the hospitals was the major issue faced. Ideally the COVID patients are to be housed in single rooms. But it was not possible with the prevailing conditions. To extend a helping hand to the people of the villages around Vikas Institute of Pharmaceutical Sciences Rajahmundry has set up a COVID isolation ward at the main auditorium of the college on 11th of June 2021. All the guidelines as given by the Government was followed. The COVID isolation center was inaugurated by Sri Jakkampudi Raja, MLA, Rajanagram and Dr. G.Sumalatha, Vice principal, VIPS.

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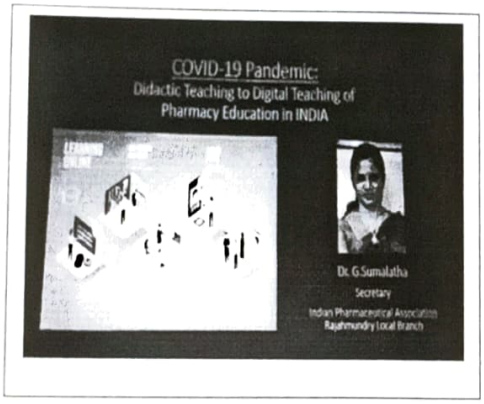
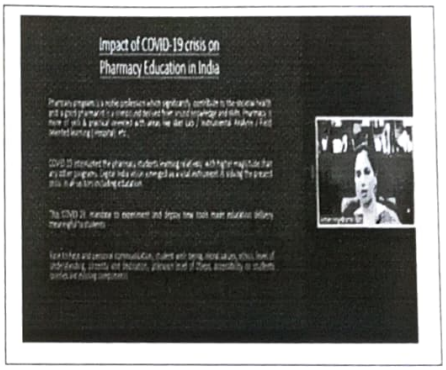
9. WEBINARS DURING THE PANDEMIC:





During the pandemic continuous learning was one of the major challenges faced. Webinars compromised a major avenue for the education/ continuous learning during COVID 19 pandemic. Vikas Institute of Pharmaceutical Sciences, Rajahmundry with a motto of continuous learning have organized various webinars. All the participants of these webinars were provided with An e-certificate. Apart from webinars, various quizzes were also conducted to improve the knowledge about COVID-19. The list of webinars conducted are as follows

S.no	Date	Topic of Webinar
1	09-Jun-20	Webinar by Dr Surya Kiran Kadali, Head Global Pharmacovigilance MSN Laboratories Private Limited, Hyderabad. Topic: Drug Safety and Pharmacovigilance
2	29-Jun-20	Webinar by P.Vijayalakshmi, Senior Scientist FR & D, Dr.Reddy's Laboratories, Hyderabad. Topic:Generic Drug Development -International Regulatory Perspective
3	11-Jul-20	Webinar by Dr. Karthik Rakman, President of Pharmacon Society for Pharmacy Practice (PSPP). Topic: Inspiring Professional Journeys-Pharm D Success Stories.
4	16-Jul-20	Webinar by Himaja Brahmapur Dept. of Chemistry, School of Science and Humanities,VIT Vellore Topic: Feasible Methods To Explore Alternative Medicines From Edible Plants
5	20-Jul-20	Webinar by Dr Krishnaveni Nagappan Professor & HOD Dept of Pharmaceutical Analysis, JSS School of Pharmacy, Ooty

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		Topic: Forced degradation studies and its Importance in Impurity Profiling of Pharmaceuticals
6	21-Jul-20	Webinar by Dr C V S Subrahmanyam Dept Of Pharmaceutics Gokaraju Rangaraju College of Pharmacy, Osmania University Hyderabad Topic: Drug Absorption Simulations-ACAT Model
7	22-Jul-20	Wbinar by Mrs. V. Sumalatha (Ph.D) Asst.Prof, Department of Statistics University College for Woman, Osmania University, Hyderabad Topic: Statistical Tools and Their Application in Pharmacy
8	23-Jul-20	Webinar by Dr K Siva Rama Raju Post Doc Associate University of Florida, USA Topic: Pharmacokinetics And Drug Metabolism
9	27-Jul-20	Webinar by Dr. Suresh Choudary Dept. of Pharmaceutical Chemistry Alwar Pharmacy College,Alwar Topic: Career Prospects After Pharmacy An Insight: To Espouse becoming an Entrepreneur
10	29-Jul-20	Webinar by Mr Pavan Kumar Achanta M Pharm Sr Clinical Data Analyst, PPD .Inc. Bengaluru Topic: Basics of Clinical Research and career in Clinical Data Management
11	04-Aug-20	Webinar by Dr. V. Gopal Principal & Head of the department of Pharmacognosy College of Pharmacy, In-Charge, School of Indian Systems of Medicine, Puduchery Topic: Anxiety management for COVID-19
12	06-Aug-20	Webinar by Mr C S Mujeebuddin Founder & CEO Clinosol Research Pvt, Ltd Topic: An Overview of Trendsetting Jobs in Pharma-IT Field
13	07-Aug-20	Webinar by Dr. Paresh Kumar C. Dave Founder & MD IP Moments Services Dwaraka, New Delhi Topic: Current Scenario of Intellectual Property Rights (IPR's)
14	10-Aug-20	Webinar by Dr. Ashok Kumar D Head of the Department of Pharmacognosy Dr. H.L.Thimmegowda College of Pharmacy Kengal, Chennapatna, Bangalore Topic: Role of Nutraceuticals in Health Benefits - Let food be your Medicine
15	12-Aug-20	Webinar by Dr. G.Harinath Reddy Ex-Head of Dept. Regulatory Affairs - Sun Pharma and Granules- USA Regulatory Consultant - USA, USA Topic: Introduction to Regulatory Affairs Function – Generic Drugs

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16	13-Aug-20	Webinar by Dr K S Nataraj Professor, Dept. of Pharmaceutical Analysis Shri Vishnu College of Pharmacy Bhimavaram, Andhra Pradesh Topic: Advanced Pharmaceutical Analytical Procedures
17	16-Aug-20	Webinar by Dr. Isha Patel Department of Pharmacy Practice Marshall University, West Virginia, USA Topic: COVID- 19: Lessons Learned
18	19-Aug-20	Webinar by Dr Krishna Devarakonda President Arcay Scientific LLC, USA Topic: Drug Discovery and Development Concepts and Challenges
19	02-Dec-20	FIP: Regional needs and drivers for transforming vaccination SEAR Moderator Dr G. Sumalatha
20	23-Jul-21	Webinar by Mr. Krishnan Certified Financial and Corporate Trainer. Topic: Wealth Awareness Program "Startup and Innovation"
21	28-Aug-21	Webinar by Dr Vasudeva Rao Avupali E-Learning Lead, School of Pharmacy, Senior lecturer, Dept.of Pharmaceutical Chemistry, International Medical University (IMU), Malaysia Topic: Fostering Digital transformation in Higher-Education: Perspective in strategic planning amid COVID-19

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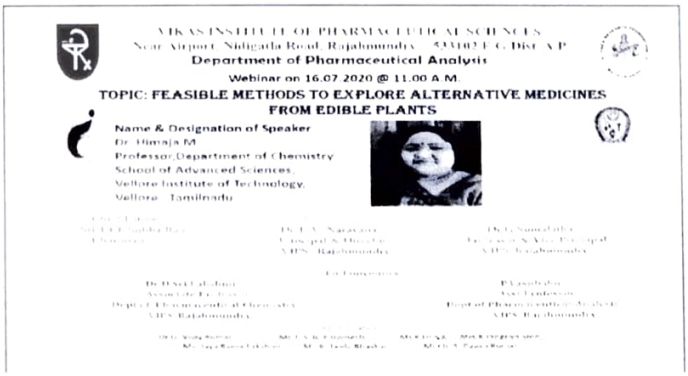
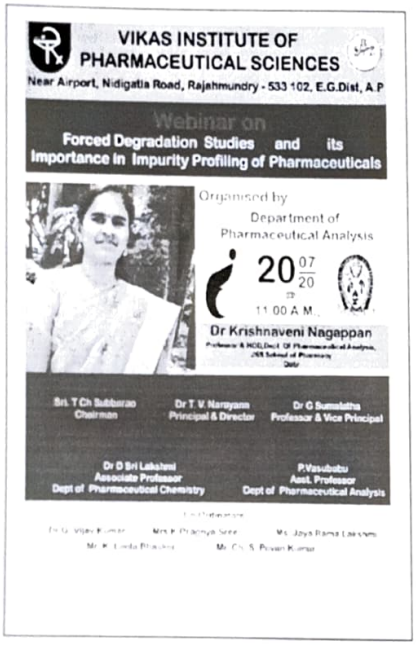
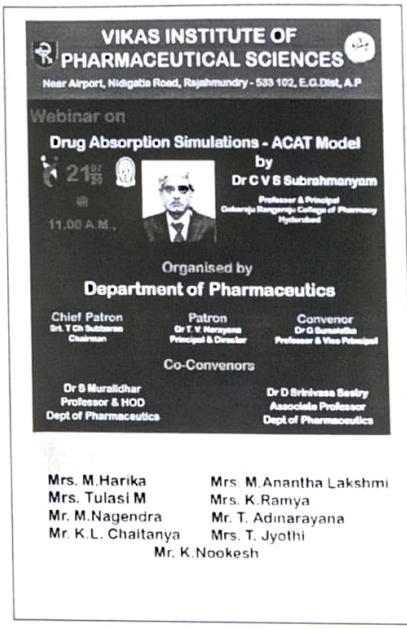

VIKAS INSTITUTE OF PHARMACEUTICAL SCIENCES
Near Airport, Nidigatla Road, Rajahmundry - 533102 E.G.Dist. A.P.
Department of Pharmaceutical Analysis
Webinar on 16.07.2020 @ 11.00 A.M.
TOPIC: FEASIBLE METHODS TO EXPLORE ALTERNATIVE MEDICINES FROM EDIBLE PLANTS
Name & Designation of Speaker
Dr. Himaja M
Professor, Department of Chemistry
School of Advanced Sciences
Vellore Institute of Technology,
Vellore - Tamilnadu





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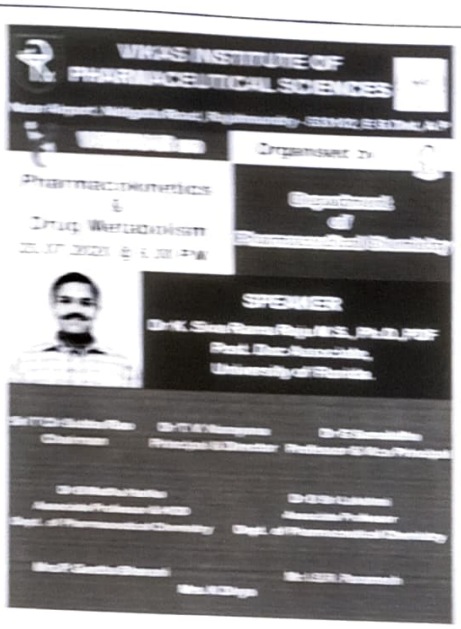

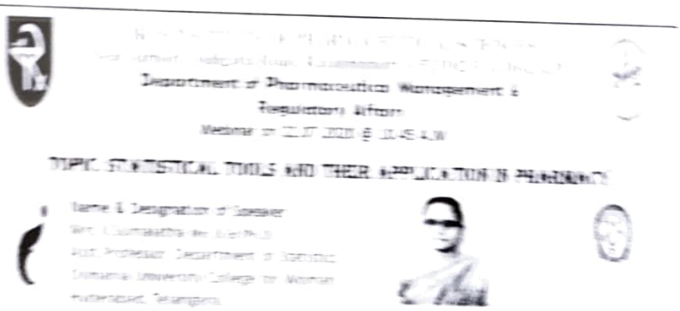

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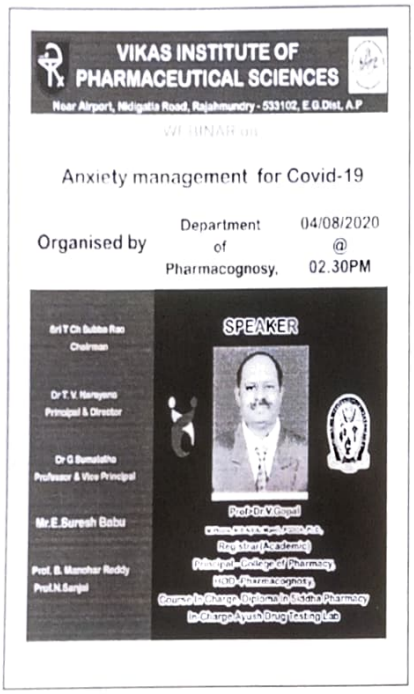

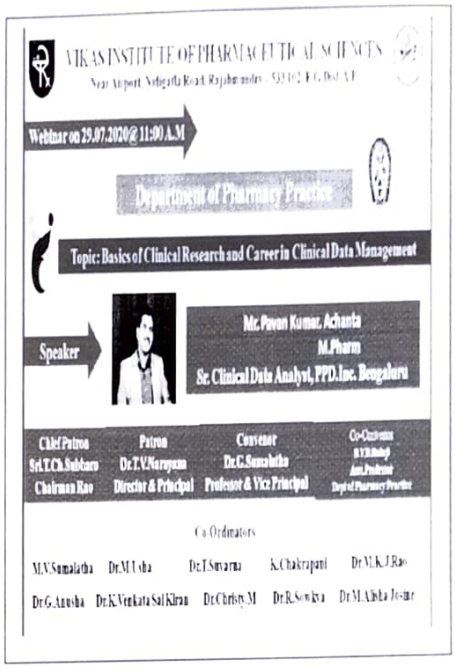

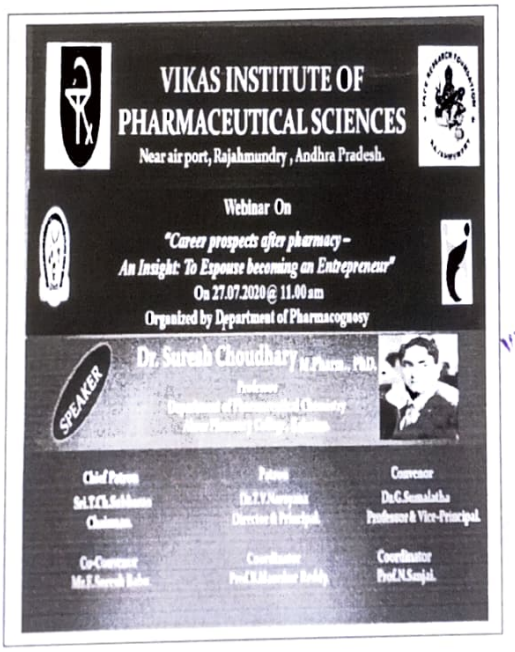

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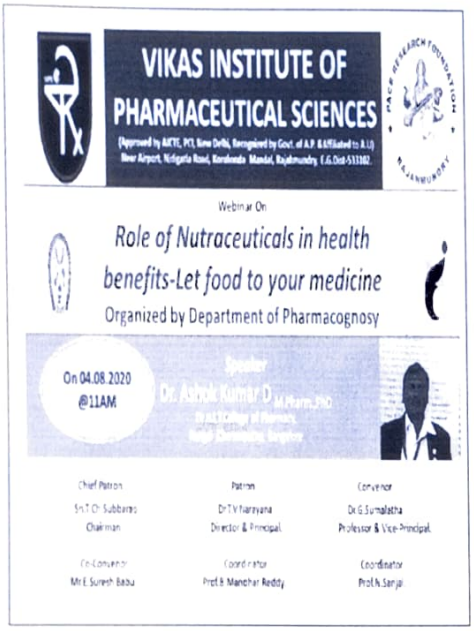

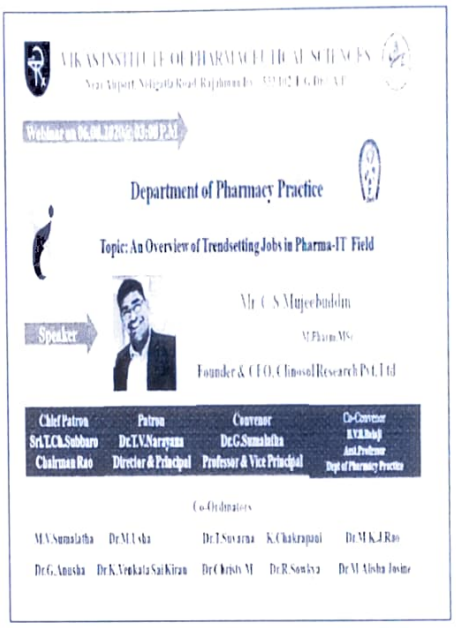

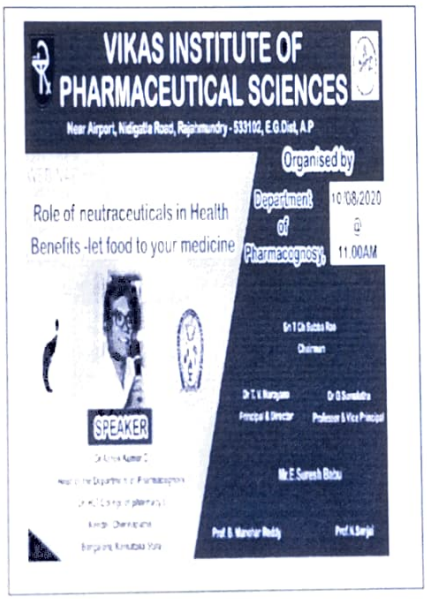

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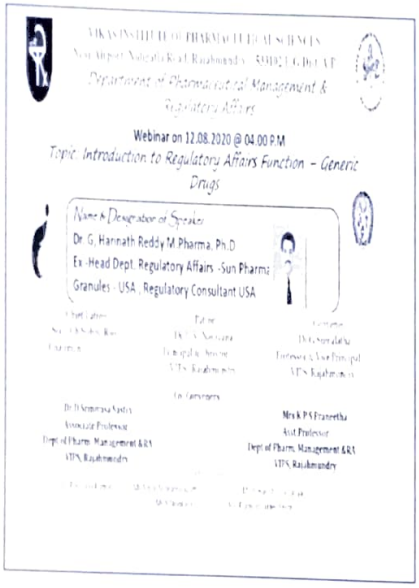
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Near Airport, Nidigatla Road, Rajahmundry - 533102 E.G.Dist. A.P.
Department of Pharmaceutical Management & Regulatory Affairs

Webinar on 12.08.2020 @ 04.00 P.M
Topic: Introduction to Regulatory Affairs Function – Generic Drugs

Name & Designation of Speaker
Dr. G. Hannath Reddy M.Pharma, Ph.D
Ex-Head Dept. Regulatory Affairs -Sun Pharma
Granules - USA. Regulatory Consultant USA

Chief Patron
Sri T.C.h.Subbarao
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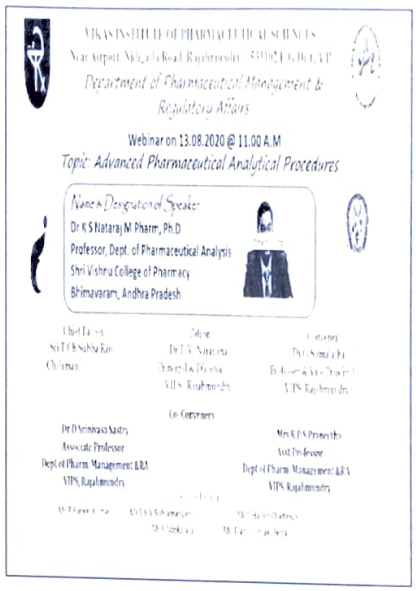
Mrs.K.P.S.Pranavitha
Asst.Professor
Dept. of Pharm. Management &RA
VIPS, Rajahmundry


VIKAS INSTITUTE OF PHARMACEUTICAL SCIENCES
Near Airport, Nidigatla Road, Rajahmundry - 533102 E.G.Dist. A.P.
Department of Pharmaceutical Management & Regulatory Affairs

Webinar on 13.08.2020 @ 11.00 A.M
Topic: Advanced Pharmaceutical Analytical Procedures

Name & Designation of Speaker
Dr.K.S.Nataraj M.Pharm, Ph.D
Professor, Dept. of Pharmaceutical Analysis
Shri Vishnu College of Pharmacy
Bhimavaram, Andhra Pradesh

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Sri T.C.h.Subbarao
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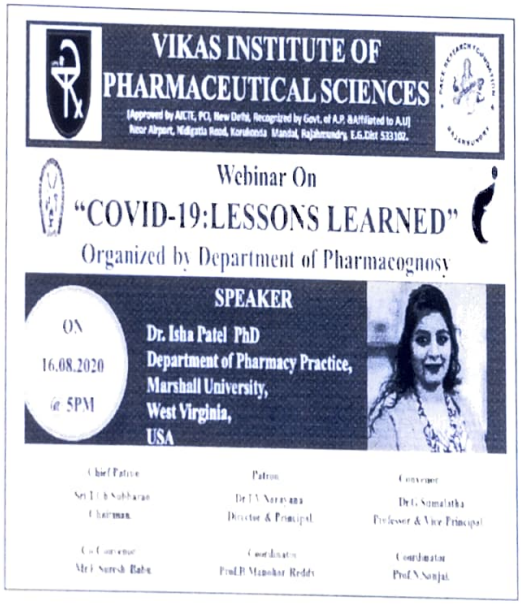
VIKAS INSTITUTE OF PHARMACEUTICAL SCIENCES
(Approved by AICTE, PCI, New Delhi, Recognized by Govt. of A.P. &Affiliated to AU)
Near Airport, Nidigatla Road, Korukonda Mandal, Rajahmundry, E.G.Dist 533102.

Webinar On
"COVID-19:LESSONS LEARNED"
Organized by Department of Pharmacognosy

SPEAKER
Dr. Isha Patel PhD
Department of Pharmacy Practice,
Marshall University,
West Virginia,
USA

ON
16.08.2020
@ 5PM

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Sri T.C.h.Subbarao
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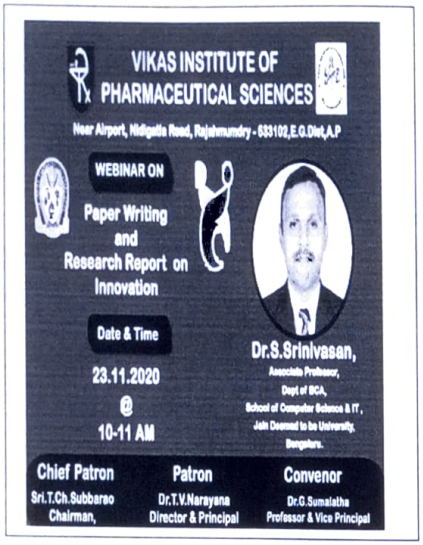

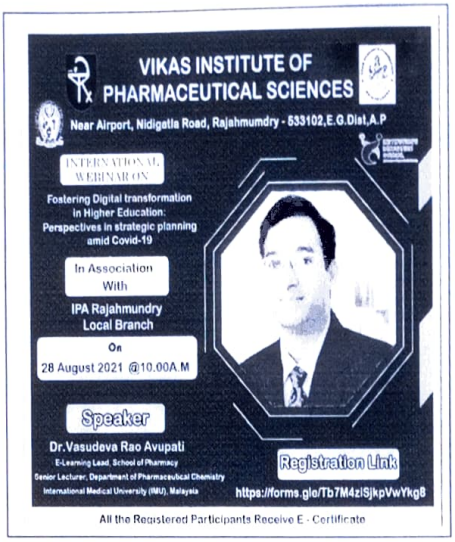

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Dr.T.V.NARAYANA
PRINCIPAL

II.LIST OF ACTIVITIES UNDERGONE IN 2019-2020 ACADEMIC YEAR

1.International Women's Day

On the extravaganga of International Women's Day the Vice-Principal of Vikas Institute of Pharmaceutical Sciences Dr.G.Sumalatha have received "Elite Women Award" in best communication category sponsored by V team entertainments for East and West Godavari regions in Andhra Pradesh. This delightful and blissful event was hosted at River Bay, Rajahmundry and the award swearing ceremony was carried over by the playback singer cum anchor Suneetha. In this regard the entire fraternity of Vikas Institute of Pharmaceutical Sciences congratulated her for her achievement.

2.Farewell Party Celebrations

A splendid and ravishing "Farewell Party" was conducted to the outgoing batch of B.Pharm for the year 2015-19 at Vikas Institute of Pharmaceutical Sciences .The Students have shared treasures of memories and experiences during their Education at Vikas Institute of Pharmaceutical Sciences. Dr.T.V.Narayana . Principal cum Director of Vikas Institute of Pharmaceutical Sciences have been delivered his valuable address to all the gathering about the farewell Ceremony. He also pointed out the milestones that the outgoing batch has achieved in their academic pursuit. The Chief guest of the programme Mr.Ajay Bhupati – a flim director has witnessed the joy and celebrations of the students and Dr.N.S Rama Raju Director KIMS Hospital also motivated students with his experiences in life.

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3.World Environment day

On the occasion World Environment day the students and staff of Vikas Institute of Pharmaceutical Sciences have planted 1000 plant saplings in and around the premises of the college along with the adopted villages nearby the college. The students of all years of B.Pharm and Pharm.D have participated in a huge manner to which made the programme successful.

4.Hetero Campus Drive

Hetero Group of Industries conducted a guest lecture on "How to imbibe Industrial knowledge and Technical aspects in industry", to all final year B.Pharm and M.Pharm students at Vikas Institute of Pharmaceutical Sciences .Followed by the session they have conducted a campus recruitment drive and many of the students of B.Pharm and M.Pharm were selected for Quality assurance and Quality Control Departments.

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5.Ganesh Navarati Celebrations

At our college Vikas Institute of Pharmaceutical Sciences the entire fraternity celebrated Ganesh Chaturdhi very enthusiastically.The concept of eco-friendly ganesh idol making is to protect environment from harmful chemicals. The idols are made of clay, natural fibers, paper and other biodegradable materials. These idols, when immersed in water degrade faster and do not harm the environment as much as the ones made of POP. Many co-curricular and cultural programmes were conducted in our campus.

6.Graduation Day Ceremony

The much awaited event in every student's life the Graduation Ceremony for Pharm.D and M.Pharm respectively was conducted in Vikas Institute of Pharmaceutical Sciences in association with IPA-Rajahmundry Local Branch. The students of Pharm.D and M.Pharm have shared their precious and valuable memories to the august gathering. Distinguished guests Dr.T.V.Narayana, President of IPA, Principal cum Director of Vikas Institute of Pharmaceutical Sciences, Dr.Rao Vadlamudi, President, Commonwealth Pharmacists Association (CPA) and Dr. Sakaram garale have delivered their convocation address to all the students and parents in Dhanvanthri auditorium at Vikas Institute of Pharmaceutical Sciences. The chief guest Dr Sakaram garale was felicitated by Sri.T.Ch.Subba Rao and other diginarities on that auspicious day.

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7.World Pharmacist Day

A rally was organized from Burugupudi Gate to Dosakhyalapalli Village with all the students of B.Pharm, Pharm.D and M.Pharm on the occasion of World Pharmacist Day by Vikas Institute of Pharmaceutical Sciences. By justifying the theme ***"Safe and effective medicines for all"*** the students distributed various pamphlets among villagers about the safety use of medicines. On behalf of World Pharmacist Day the students have created awareness campaign about safety use of medicines in Gadala Panchayat School and Konthamuru RCM School

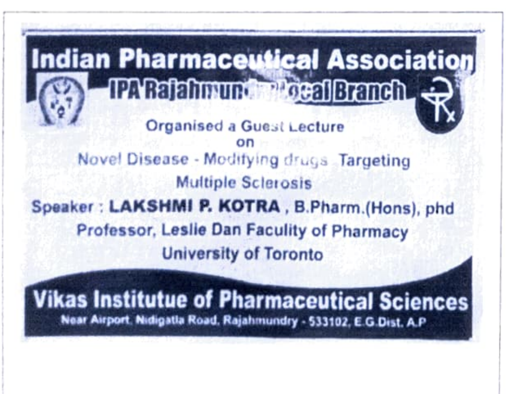

4 గురువారం 28-11-2019

'వికాస్'లో జాతీయ ఫార్మసీ వారోత్సవం

[illegible]

8.Guest Lecture

A guest lecture was conducted on " Novel Disease –Modifying drugs targeting Multiple Sclerosis" by Lakshmi P.Kotra, Professor of Medicinal Chemistry, Lesile Dan, Faculty of Pharmacy . University of Toronto in Vikas Institute of Pharmaceutical Sciences. The Speaker highlighted the importance of drugs targeting Multiple sclerosis. Many of the Pharm.D & B.Pharm students utilised the session in accordance to their regular curriculum. Later, the speaker was felicitated for his extensive lecture.



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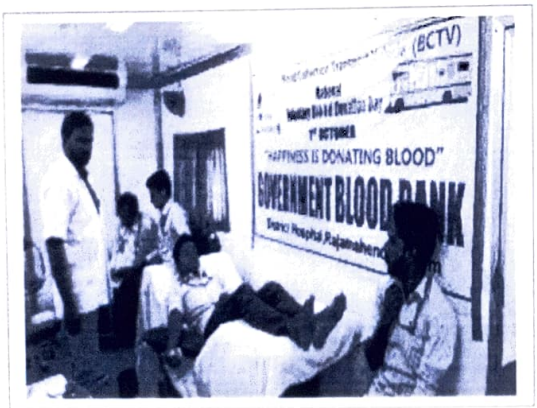
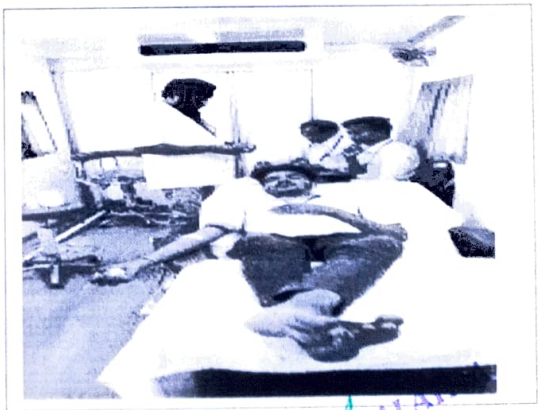
9.Fresher's Party Celebrations

Fresher's party is a way to welcome new comers into college, and it is considered particularly amazing when it comes to VIKAS INSTITUTE OF PHARMACEUTICAL SCIENCES. The Fresher's party isn't just a day for the new comers JOURNEE DES FRIAS but is also important and special for the seniors. Fresher's as by ritual is organised by the seniors and IPA president Dr.T.V.Narayana is the spotlight of the event. All the freshers actively participated in all the games and competitions like there's no tomorrow and enjoyed as it is their last day (even though it is the first one) and made Fresher's Party the official beginning of their journey as a memorable, because that day is actually a new beginning in the college life.

10. Blood Donation Camp

A blood donation camp was organized by IPA Local branch Rajahmundry in association with Government general hospital at Vikas Institute of Pharmaceutical Sciences .All the students of the college participated actively in the blood donation camp. Nearly 50 students donated blood. Teaching and non-teaching staff have also assisted and participated in the event.





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11.NEC AP State Round Competition

National Elocution Competition 2019 State Round Competition was conducted at Vikas Institute Of Pharmaceutical Sciences. This programme is highlighted by the very presence of Jakkampudi Raja, MLA, Rajanagaram. The competition was based on the topic "Your Medication Counselor" for a duration of 6+2 minutes and was judged by staff from 3 different departments Managing skills, English and Pharmacy. It was a well-organized, planned and perfectly executed event that provided a wonderful platform for pharmacy students to exhibit their talent. Dr.T.V.Narayana, President of IPA congratulated the fabulous achievement of the students.

12.Orientation Programme

An orientation programme for freshers was conducted in Vikas Institute of Pharmaceutical Sciences in association with IPA Local Branch Rajahmundry. The Chief guest of the Orientation programme Dr.Divakar Goli, Editor, Indian Journal of Pharmaceutical Sciences motivated and sharpened students with his inspirational words. The occasion was also graced by Sri.T.Ch.Subba Rao, Dr.T.V.Narayana, Dr.G.Sumalatha and Dr.S.Muralidhar . The students and the parents were given detailed information about both the B.Pharm and Pharm.D Courses.

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Week **Celebrations** **CARUM**

(Campaign for awareness on responsible use of medicines)

The 58th National Pharmacy Week Celebrations were conducted with lots of enthusiasm and professionalism by Indian Pharmaceutical Association Rajahmundry in association with Vikas Institute of Pharmaceutical Sciences. The week was celebrated with enthusiasm and zeal under the guidance of Dr.I.V.Narayana, President of IPA and Dr.G.Sumalatha, Secretary IPA Rajahmundry Local Branch. During the weeklong celebrations many competitions were organized in order to spread awareness in the society about the theme of 58th National Pharmacy Week ***"Pharmacist: Your Medication Counsellor"***.

Day 1: **Inauguration:**

Inauguration was held at Vikas Institute of Pharmaceutical Sciences, Rajahmundry in November in the college Dhanvanthri auditorium. Dr.G.Sumalatha, Secretary IPA Rajahmundry Local Branch welcomed the gathering. She highlighted the objectives of the Pharmacy week and various event chalked out for the week long celebrations such as elocution, competition on innovative ideas on Pharmaceutical Science and Technology and Pharmacy Practice , health awareness campaign and rally. The program was inaugurated by I.Sri.Ch.Subba Rao, Chairman, Vikas Institute of Pharmaceutical Sciences

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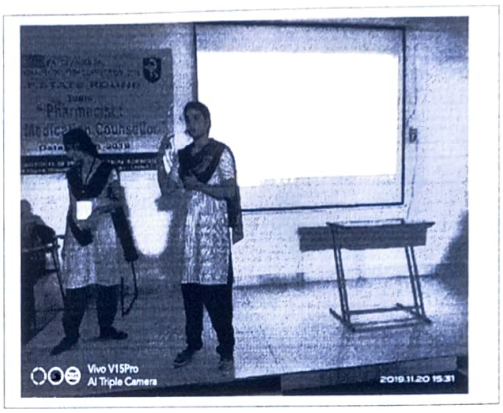
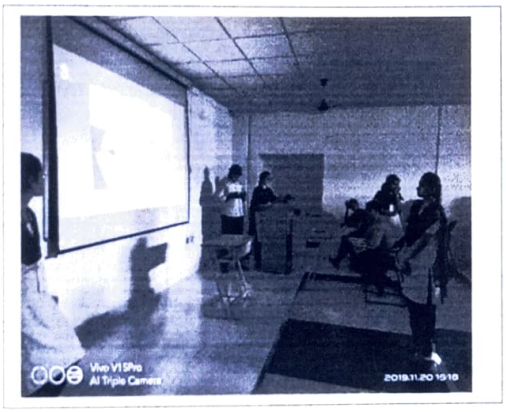
Day 2: **Elocution Competition**

NPW elocution competitions were held at the college. The topic of the events was – ***"Pharmacist: Your Medication Counsellor."*** The elocution competition was judged by Dr.B.Madhu Harika and Mr.P.Vasubabu of Vikas Institute of Pharmaceutical Sciences.



Day 3: **Competition on Innovative Ideas:**

On the 3rd day a competition on innovative ideas on Pharmaceutical Science and technology and Pharmacy practice was held in the auditorium of the college. Students expressed their ideas in various fields such as pharmaceutics , analysis and pharmacy practice.



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15.4 Day 4: Health Campaign

Day 4: **Health Campaign**

A health awareness camp was organized on the 4th day. Students of various years of B.Pharm and Pharm.D visited the village madhurapudi. A door to door health campaign was conducted by the students. The villagers were enlightened on the various preventive and management steps to control contagious diseases. All the villagers were also distributed with information leaflets in the local language regarding the regular habits to be inculcated and maintenance of sanitation .

Day 5: **Rally**

A Rally was organized on the 5th day of National Pharmacy Week Celebrations by Vikas Institute of Pharmaceutical Sciences. It was started from Anamkalakendhram to Kambalcheruvu. Rajahmundry with all the students and staff by displaying the placards about the theme ***"Pharmacist: Your Medication Counsellor.***

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Institute of Pharmaceutic...
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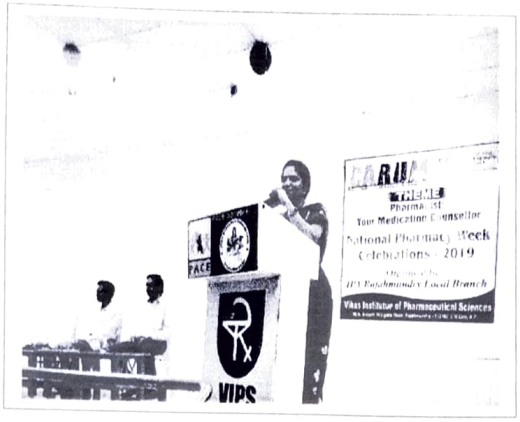
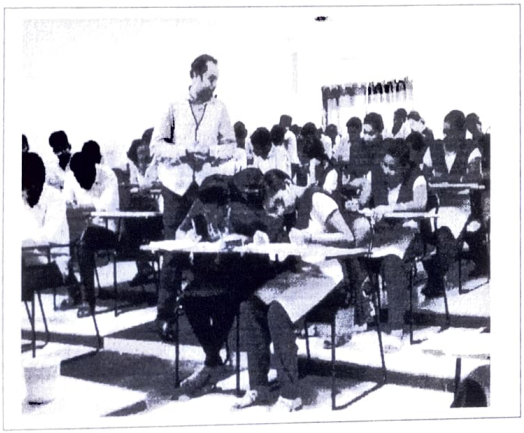
Day 6: **Valedictory**

The week long celebrations were concluded by the valedictory function. Prizes were distributed to the winners and runners of various competitions held . The prizes were distributed by T.Sri.Ch.Subba Rao , Chairman, Dr.G.Sumalatha Vice-Principal Vikas Institute of Pharmaceutical Sciences. Vote of thanks was proposed by Mrs.D.Anupama , Vikas Institute of Pharmaceutical Sciences.



14.Personality Development Programme

A personality development programme was organised and conducted at Vikas Institute of Pharmaceutical Sciences in association with a dynamic personality and Orator Dr.Jagannath Rao who has mastered " The art of inspiring exclusively student community". He inspired and motivated the 1st year B.Pharm.,M.Pharm and Pharm.D students in order to thrive for their goals. Further Dr.Jagannath Rao was felicitated by Vikas Institute of Pharmaceutical Sciences Chairman Sri.T.Ch.Subbarao for his valuable contribution to the student community.



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15.Semi Christmas Celebrations

Christmas is the season of joy, expressing love ,gift-giving and families getting United. VIPS family promotes Unity in diversity that focusses oneness in the varieties. The Christmas celebrations took place in college campus on 16th Dec 2019.On Christmas day,a special mass was conducted in the dhanvantari auditorium.The celebrations included a rhythmic performance from college choir and an add-on surprise by santa Claus.

16.Industry Oriented Training Programme from PTI

A three day Industrial training programme was conducted by Pharma Training Institute (PTI) to all final year B.Pharm at Vikas Institute of Pharmaceutical Sciences . The students have been benefited and also focused on various regulatory aspects pertaining to Quality Assurance, Quality Control & Production Departments. They have also demonstrated about current Good Manufacturing Practices (CGMP) and Good documentation practices (GDP). To strengthen and improve the skills of the students they have given meritorious certificates to the students.

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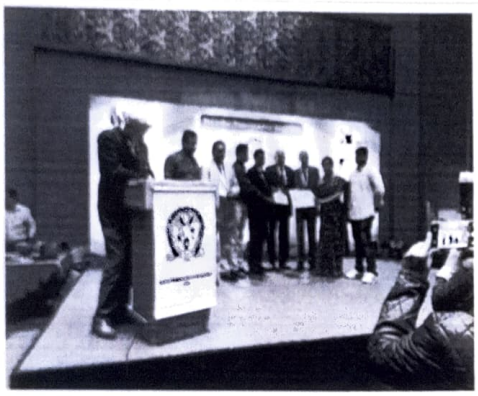
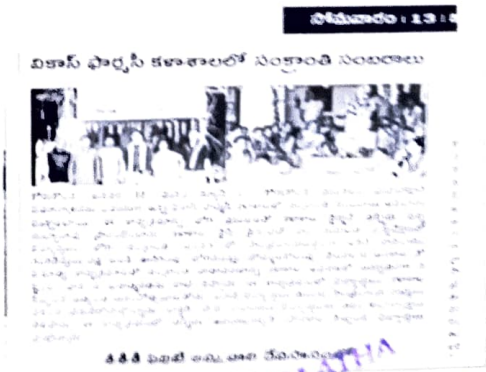
17. BEST LOCAL BRANCH AWARD -5TH TIME CONSECUTIVELY (IPA)

We are extremely delighted to share that Vikas Institute of Pharmaceutical Sciences was awarded best local branch from IPA consecutively for the fifth time from 2015 onwards. By implementing cross cutting issues relevant to the professional ethics, gender equity, human values etc VIPS organised many curricular and co curricular and extra curricular activities . Vikas Institute of Pharmaceutical Sciences also immensely glad to share that our Research Director Prof.K.P.R.Chowdary have received Eminent Pharmacist Award by the IPA President Dr. I.V.Narayana in 2019 for his pioneering work in research.



18.Sankranthi Celebrations

With a fresh and good start of the New Year 2020 at our college we have celebrated the harvest festival *Pongal* with all the students and staff of Vikas Institute of Pharmaceutical Sciences with great devotion and myth. It signified the over flowing of prosperity, integrity and love between nature and humans for each other. Students from different disciplines have participated and enjoyed the celebrations.



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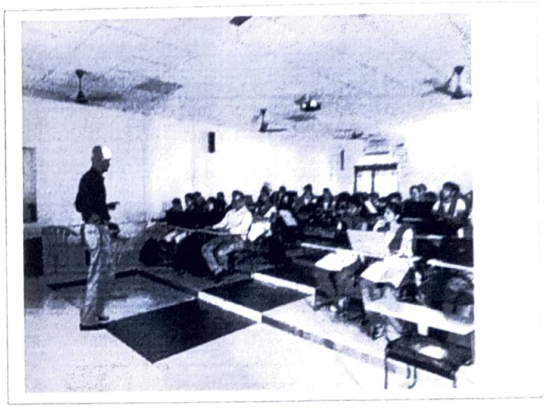
19.Artificial Intelligence in Health Care

Artificial Intelligence in Health Care is a session that includes a wide range of theoretical and practical aspects that helps students in their career development programmes. Artificial Intelligence is a use of algorithms and software's to approximate human cognition in the analysis of complex medical data. This was organised by Shastra Event IIT- Madras at Vikas Institute of Pharmaceutical Sciences.

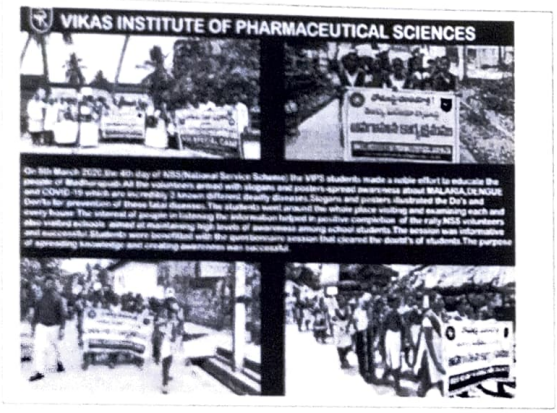


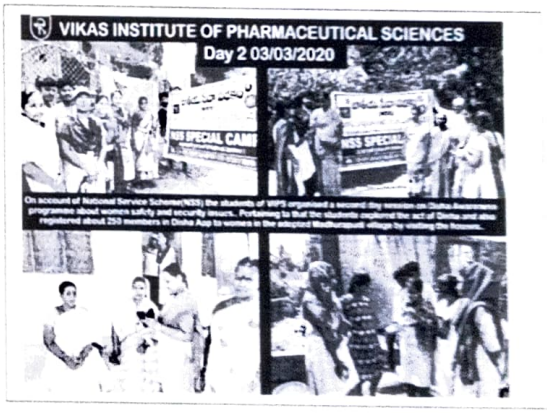
20.MOU with Konkuk University Seoul, South Korea

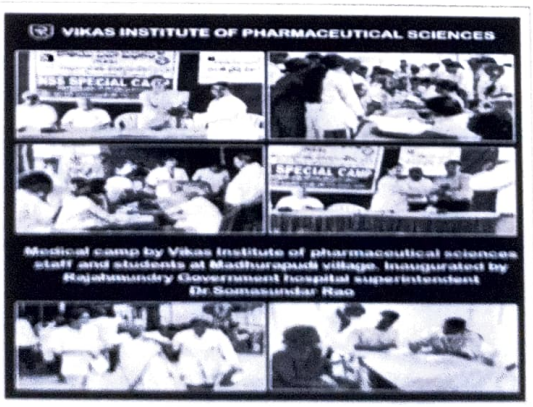
At Vikas Institute of Pharmaceutical Sciences inaugurated Research and Development (R&D) cell in collaboration with Konkuk University, South Korea, Seoul by Professor Susrutha Koppula Department of Biotechnology Konkuk University. His lecture focussed on the importance of Research and development and also discussed various research strategies in the present scenario of drug discovery. The Programme was highlighted by the chief guest Dr.Rao Vadlamudi , President, Commonwealth Pharmacists Association (CPA) and Dr.T.V.Narayana, President of IPA.

21. National Service Scheme (NSS) Special Camp

On account of National Service Scheme(NSS) special camp the students of Vikas Institute of Pharmaceutical Sciences organised a first day session on Disha awareness programme about women safety and security issues. Pertaining to that the students explored the act of Disha and also registered about 250 members in Disha App to women in the adopted Madhurapudi village by visiting the houses. Vikas Institute of Pharmaceutical Sciences students make a noble effort to educate the people of Madhurapudi. All the volunteers armed with slogans and posters and they spread awareness about Malaria, Dengue and COVID-19 which are incredibly three known different deadly diseases. Slogans and posters illustrated the Do's and Don't s for prevention of these fatal diseases. Medical camp was organised by Vikas Institute of Pharmaceutical Sciences staff and students at Madhurapudi village, inaugurated by Dr.Somasundar Rao, Superintendent, Government Hospital, Rajahmundry. Hitherto NSS campaign had succeeded in virtue through straining of hidden talents in elementary students by co-curricular activities that provoked young champs in Mandal Parishat school of adopted Madhurapudi village.







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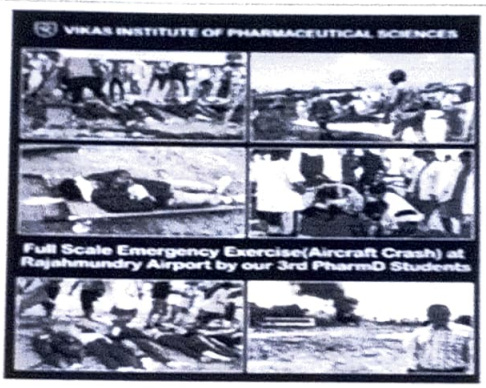
22. Mock Aircraft Crash

On 9th march 2020, Rajahmundry Airport has successfully conducted it's full scale aerodrome emergency exercise which simulated an air crash to ensure preparedness at all times. As a part of simulated exercise, a domestic passenger aircraft crashed on approach path of runway due to an engine failure. The drill lasted from 10am to 2pm. Nearly 120 personnel of key emergency responders- state disaster management authority, rajahmundry fire brigade, National disaster response force, rajahmundry police, rajahmundry government hospital, ambulance services and 15 young pharmacists of Vikas Institute of Pharmaceutical Sciences served the victims with the first aid kits provided. Various agencies of airport and airlines were also deployed as observers to critically evaluate the response by the agencies to combat such emergencies in real time. The students of Vikas Institute of Pharmaceutical Sciences have witnessed the simulated exercise with all the precautionary measures in disaster management.



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Dr. T.V.NARAYANA
PRINCIPAL

LIST OF ACTIVITIES UNDERGONE IN 2018-2019 ACADEMIC YEAR

1.FELICITATION TO Dr.T.V.NARAYANA

Vikas Institute of Pharmaceutical Sciences in association with all the East & West Godavari private pharmacy college managements and staff felicitated Dr.T.V.Narayana on being elected unanimously as 36th IPA President at LA Hospin Hotel, Rajahmundry. The felicitation was done under the Presidentship of Hon Gollapalli SuryaRao , MLA Shri Sesha Reddy (Aditya Colleges) and Dr.Chaitanya Raju (GIET College). Dr.P.Rajeswara Rao Principal, Lydia College of Pharmacy and other pharmacy college Principals and Staff members attended in the programme.

2.INTERNATIONAL YOGA DAY

At Vikas institute of pharmaceutical sciences conducted yoga session on the eve of International day of Yoga on June 21th 2018 from 10.30 am to 12.30 am. Almost 100 participants took part in the event. Dr G. Sumalatha Secretary, IPA Rajahmundry local branch, Dr S. Muralidhar, and other staff members along with students participated in the event.

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3. THREE DAYS WORKSHOP ON " TRAINING IN FORMULATIONS, QA& QC"

A Three Day Workshop on " TRAINING IN FORMULATIONS, QA& QC" was at Vikas Institute of Pharmaceutical Sciences Rajahmundry. All the final year Students of B.Pharmacy & M.Pharmacy students attended the workshop along with staff of the college.The workshop was inaugurated by Dr.I.V.Narayana , IPA President. Renowed stallwarts in the Pharmaceutical Industry field Sri.Uma Nandan Misra ,Mr.Ashutosh Dixit & Mr.Venu Gopal Rao trained the students on various aspects of Pharmaceutical Industry. The Programme was organised by Dr.G.Sumalatha. Vice -Principal. Mr.T.Ch.SubbaRao. Chairman Vikas Institute of Pharmaceutical Sciences. have also graced the occasion. Students were trained on different topics such as Manufacturing. cGMP.Product Development.Drug Design.Handling of Market Complaints.Change Control Management and were also trained on Instrumentation. Principle and handling of various Analytical Instruments . On the 3rd Day Certifiacte of Training was given to all the students participating in the workshop.

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Vikas Institute of Pharmaceutical Sciences
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Dr. G. SUNDARATHA
PRINCIPAL
Vikas Institute of Pharmaceutical Sciences
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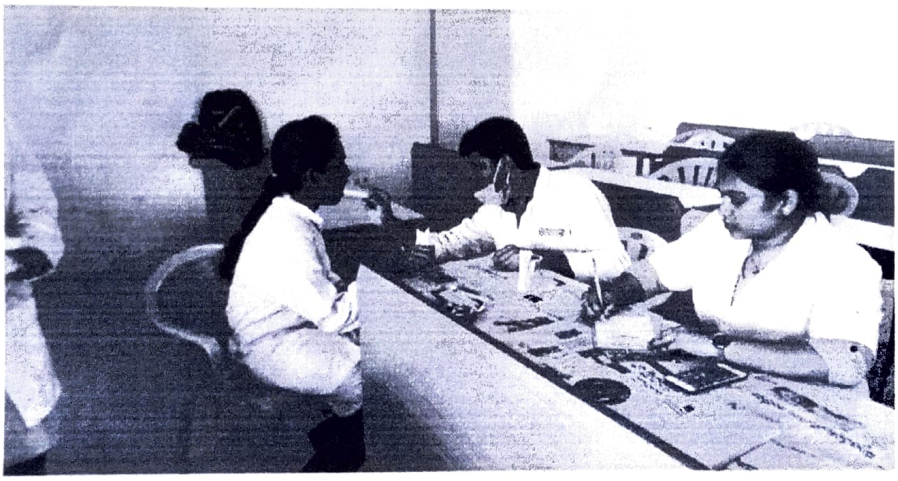
4. DENTAL CAMP

NSS unit of Vikas institute of pharmaceutical sciences organized a camp on Dental Checkup on the college premises on 12th July 2018. The Dental Checkup was done by **Prof. Dr.VishwaPrakash Shetty** from KLR LENORA Institute of Dental sciences, Rajahmundry. The camp was inaugurated with a special talk on Dental awareness and Oral health. The doctor spoke about some common Dental ailments and preventive measures to maintain good oral

hygiene. Around 200 Students were benefitted by the camp. Dr. G. Sumalatha Vice-Principal inaugurated the camp and Dr.S. Muralidhar and the team of volunteers made all the arrangement for the successful conduct of the camp.



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5. MEGA BLOOD DONATION CAMP

Vikas institute of pharmaceutical sciences organized a blood donation camp in collaboration with blood bank of Rajahmundry government hospital, on 16 th July 2018. The camp began at 10.00 am with short inaugural function where in Dr. Suhasini and her five members team was given a floral welcome. Dr. Suhasini expressed her gratitude to VIPS for its continuous endeavour in this regard. The camp was inaugurated by Dr. G.Sumalatha,Vice-

Principal, Dr. S. Muralidhar Professor, CH.S. Phani Kumar Associate professor, P. Vasubabu. Asst professor and D. Anupama, Asst Professor 40 volunteers came forward to donate blood during the camp which included other teaching and non-teaching staff and students. At the end 36 units of blood was collected.

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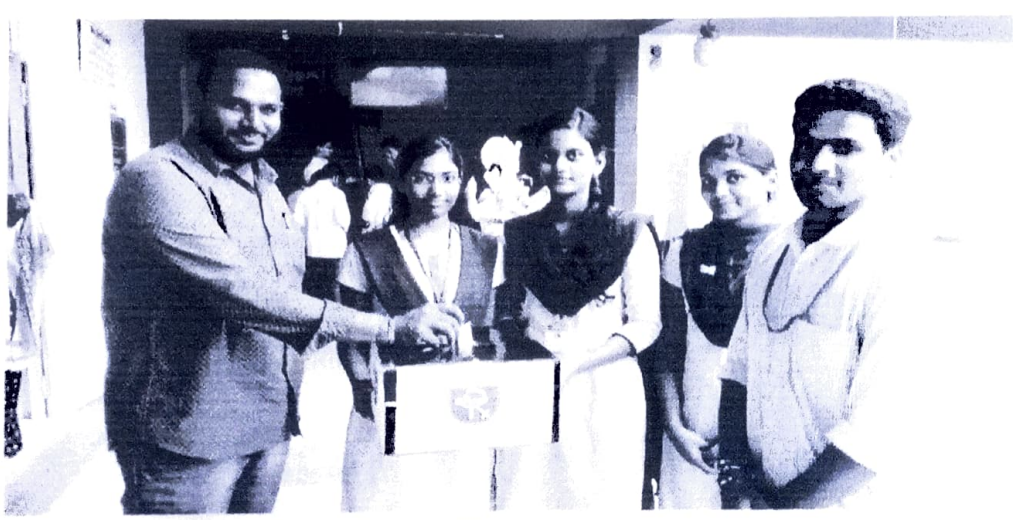
6. RELIEF FUND FOR KERALA FLOOD VICTIMS

Vikas institute of pharmaceutical sciences collected the money from various people for the purpose of helping people in KERALA and KODAGU flood affected areas. To students participated in the Activity on 25th Aug 2018 under the guidance of Dr. G.Sumalatha,vice-principal. A total amount of Rs. was collected and was handed over to the collector of Rajahmundry



7. WORLD PHARMACIST DAY

World Pharmacist Day was celebrated on 25- Sep-2018 with tremendous joy by all Staff & Students of Vikas institute of pharmaceutical sciences, Rajahmundry in association with IPA Rajahmundry local branch. The theme of World Pharmacists Day 2018 is "Pharmacists: your medicines experts." It is meant to emphasize that pharmacists are a trusted source of knowledge and advice, not just for patients, but also for healthcare professionals. A rally was organized on

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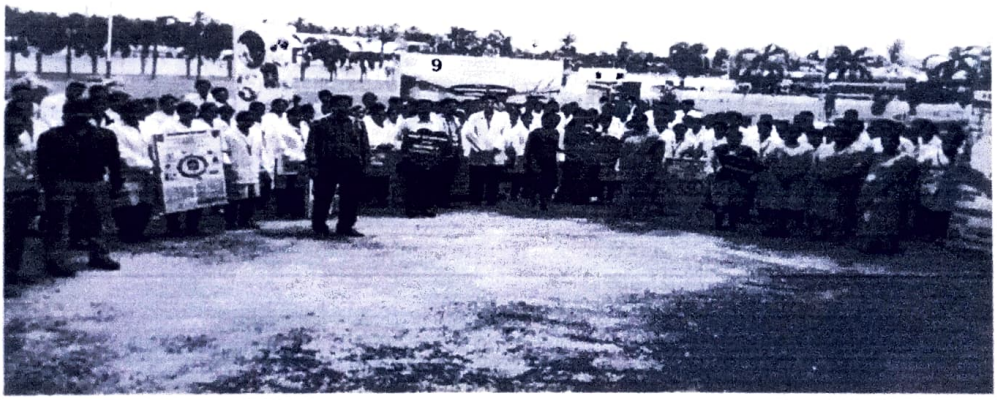
world pharmacist day at Dosakayapalli village where around 100 students participated and educated the people by telling the role of pharmacist in society.



8. DENGUE AWARENESS PROGRAM

Vikas institute of pharmaceutical sciences students took out a rally created awareness among the common public on dengue and other viral fevers in Gummuluru village on 13 October 2018. The rally was flagged off by Dr. G. Sumalatha vice-principal and Dr. Muralidhar. The student carrying placards and banners marched through the village street areas by saying the slogans urging people to keep their surrounding clean and free from mosquito breeding sources.

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9. 57TH NATIONAL PHARMACY WEEK CELEBRATIONS

VIPS has been celebrating National Pharmacy Week (NPW) every year during the third week of November. Vikas Institute of Pharmaceutical Sciences celebrated National pharmacy week with great zeal and enthusiasm. The major focus of the celebrations was to create awareness amongst the public, other health care providers and authorities about NPW theme. The theme for this year was "Pharmacists for healthy India". As a part of week long celebrations various activities such as pharma quiz, health campaign, rally and poster presentation events were conducted.

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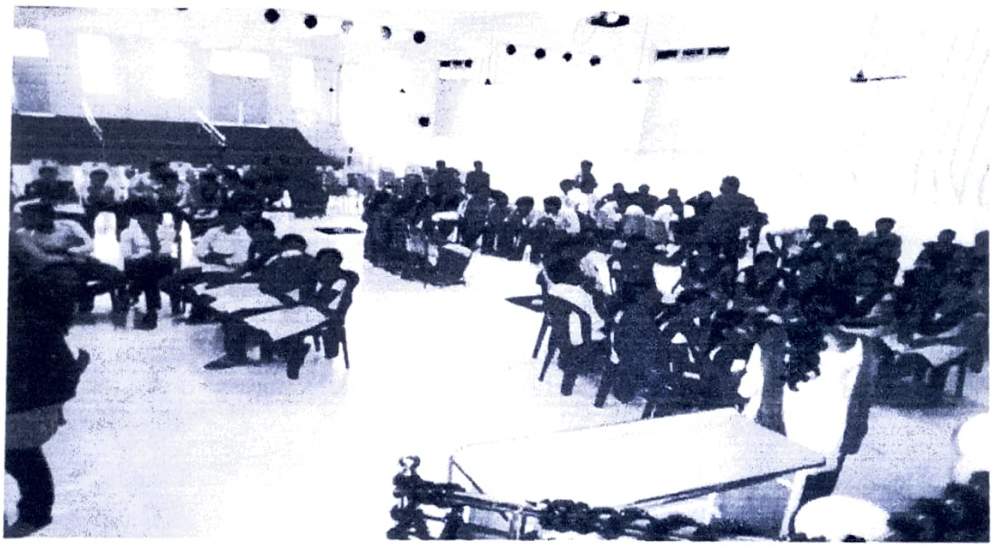

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10 AWARENESS RALLY ON NATIONAL VOTERS DAY

Vikas Institute of pharmaceutical sciences conducted an awareness Rally on Voter's Day on 25th January 2019 in and around the village. The theme for this year was "No voter to be left behind" .As part of this all the students made a rally in the village and interacted with the community and created awareness among the public about the importance of the voting. And also informed all the young people to enroll themselves as voters.

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11. 69TH REPUBIC DAY CELEBRATIONS

Vikas institute of pharmaceutical sciences celebrated 69th Republic Day in the campus. I.CH.Subba Rao, Chairman, Vikas Institute of Pharmaceutical Sciences hoisted the national flag. Dr.G.Sumalatha,Secretary, Vice-Principal delivered a talk on the integrity in diversity, Swaach Bharat and Swasth Bharat and emphasized in the role of Pharmacist in Swasth Bharath moment.

12.10TH NATIONAL IPA STUDENT CONGRESS

The 10th National IPA student congress was hosted by IPA Rajahmundry local branch which was organized at Vikas Institute of Pharmaceutical Sciences during 16th – 17th February 2019 with the theme "Need based education: Changes envisaged". In the two day mega program many events such as oral presentation, dispensing event, Innovative ideas event, Patient counseling event, dance competition, poster presentation were conducted. Each event winners were given a cash prize of 1 lakh rupees. Total cash prize of worth 9 lakhs was awarded to the winners of all competitions. Along with this IIT program was also conducted.

The 10th IPA-Students' Congress mainly focus on patient counseling event , clinical skills event, pharma quiz, placement conclave, innovative ideas and panel discussions blended with a cultural evening .

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The congress brought together over 2200+ delegates from 90 colleges across the nation from various states like Tamilnadu, Kerala, Karnataka,Delhi, West Bengaland Maharashtra to participate in the workshops and competitions to share their experiences, to learn from one another and to debate regarding the current and future pharmacist roles.

The congress was inaugurated by DR.B Suresh, president (Pharmacy Council of India) and vice chancellor JSS University.

This event was blessed by the presence of DR.Krishna. Ella, MD Bharath biotech and DR.Subhodh Priolkar, Wincore limited, Mumbai. Along with 5 former presidents of IPA DR.C.K.Kokate sir, DR. J.A.S Giri, DR. Rao Vadlamudi.

MR. Lee li from Shanghai, DR. M.D Karvekar, E.C member, Pharmacy Council of India: DR. T V Narayana,President IPA and Director Vikas institute of pharmaceutical sciences: DR. S Vidhyadhara, Chairman Indian Pharmaceutical Association- Educational division: Prof. KPR Chowdary - SSC Convener IPCA graced the occasion.MR. Dilip Kumar, President AIDCOC: DR. T. Ch. Subbarao- Chairman VIPS: DR. A. Ramakishan, Deputy Drugs Controller graced the event as well.

MS. Pragna Ella, Chairperson IPASF(Indian Pharmaceutical Association Students' Forum) gave the welcome address and this was followed by inspirational speeches by the dignitaries on the dais and felicitation to the President (Pharmacy council of India), and keynote speaker DR. Krishna Ella and all other guests.

The theme for the congress is 'Need Based Education------Changes Envisaged' Exactly justifying the theme, the congress truly explains about the need of outcome based education in the panel discussion by eminent personalities from practice, academia, Industry like DR. Rao Vadlamudi, DR. Naresh Sharma, DR. Sunil Attavar and etc. They also clarify so many doubts raised from students'side in their discussion.

Students' congress served as a best platform to share and showcase a students' research work. 776 posters were presented in all and out of which 10 best posters were selected for e-poster competition. Besides, 40 participants participated in the oral presentation.

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- The patient counselling event was a platform through which pharmacy students can practice with one another and develop their patient counselling skills. 40+ participants participated in this event.
- Clinical Skills Event focused on using clinical knowledge / referring authentic content to solve and to improve patient's therapeutic outcome. 54+ participants participated in the event.
- Compounding event raised the awareness about the importance of compounding and quality/security measures regarding the production of compounded pharmaceutical products. 32+ participants participated in this event.
- These three events(Patient counselling, Clinical Skills, Compounding)are mentored by DR. T. K Ravi;DR Sriram shanmugam
- 50+ teams participated in Pharma Quiz .
- 12 teams from different colleges participated in the dance competition and was a treat to eye. And 15 teams from various colleges participated in innovative ideas competition.

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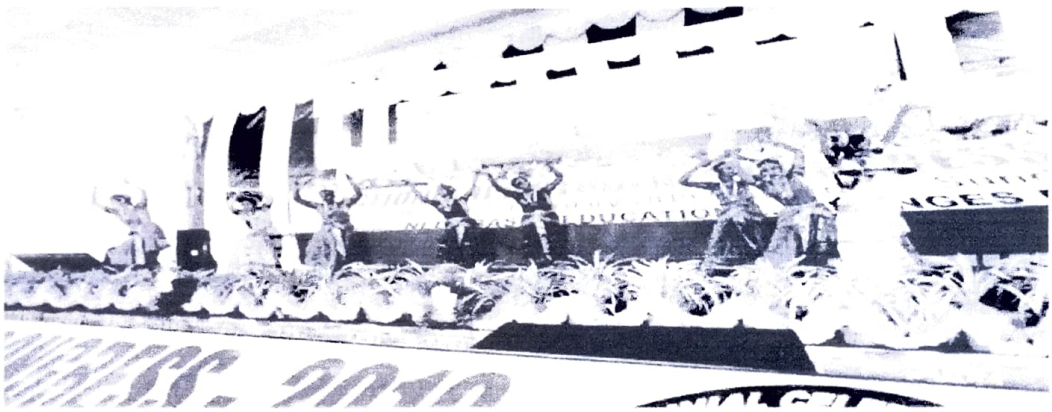

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Dr.T.V.NARAYANA
PRINCIPAL

LIST OF ACTIVITIES UNDERGONE IN 2017-2018 ACADEMIC YEAR

1.ANTIMICROBIAL RESISTANCE AWARENESS WALK

On 4th of April 2017, a rally was organized in association with AP Drug control Administration, AP Pharmacy council and Seemandhra Drug dealers Association. All the students and staff from various Pharmacy colleges participated in the rally. The main theme of the rally was "Antimicrobial resistance awareness walk". Students prepared placards bearing the information about the antimicrobial drugs and information about the development of resistance and its effect. The rally started at Anamkalkendram and continued to walk for a distance of about 2 km till hi- tech bus stop .

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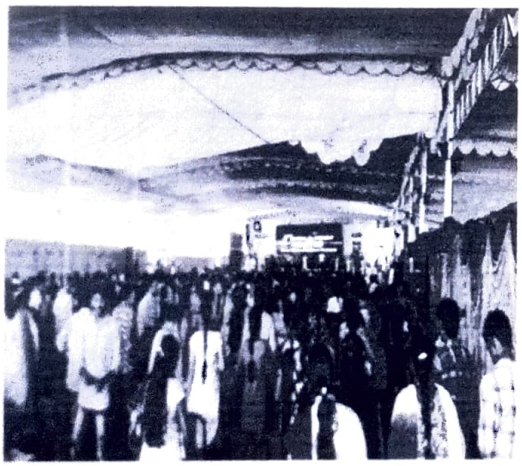
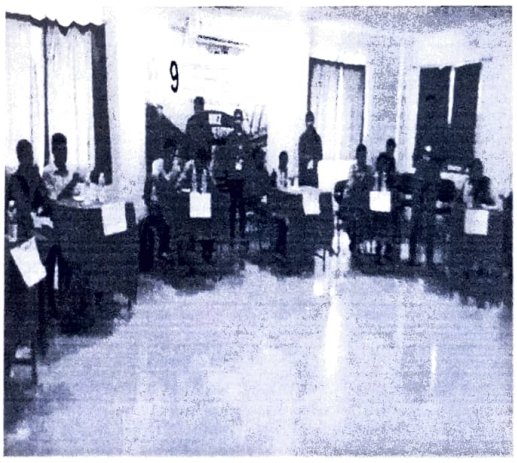
2. 9th IPA STUDENT CONGRESS

9th national IPA student congress was held at Vikas institute of pharmaceutical sciences. This national event was hosted by IPA Rajahmundry local branch, and organized by IPA Mumbai, IPA education division and IPA students forum. The programme was inaugurated by Director of National Institiute of Biology (NIB) Surinder Singh. Many eminent and pioneers of Pharmacy profession Dr.K.Chinna Swamy, Dr.RaoV.S.V.Vadlamudi, Dr. T.V.Narayana have graced the two day seminar. Various events were organized for the students such as poster and oral presentation, patient counseling competition, compounding competition, clinical skill competition, Dance competition , interaction and workshop. A prize money of 1 lakh was given to the winners of the competition of each event.





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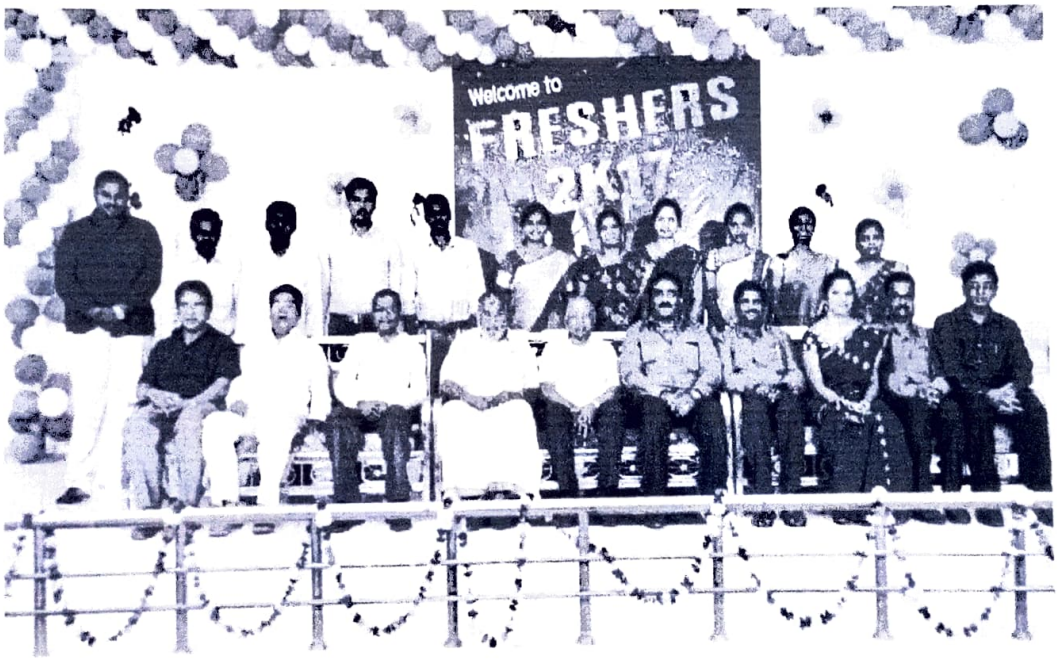
3. ORIENTATION PROGRAMME FOR I B.PHARM AND PHARM.D STUDENTS AND PARENTS



An orientation programme for freshers was conducted on th September 2017 in Vikas Institute of Pharmaceutical Sciences in association with IPA local branch Rahjahmundry. Chief guest for the orientation programe was Dr.MD. Karvekar, Dr.K.Chinna Swamy , Dr.D.Satyanarayana, Prof.K.P.R.Chowdary, Dr.T.V.Narayana, Dr.G.Sumalatha graced the occasion. The students and the parents were given a detailed information about both the B.pharm and pharm.D courses .

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4. WORLD PHARMACIST DAY CELEBRATIONS

A rally was organized on the occasion of world pharmacist day by Vikas Institute of Pharmaceutical Sciences in association with IPA local branch Rajahmundry and East Godavari pharmacist association. All the pharmacists of Rajahmundry , students and staff of various pharmacy colleges participated in the event. The theme was "From research to health care , Your pharmacist is at your service". Mr T.Srinivas Murthy, assistant director , drug controller was the chief guest. D.Prasad , A.P Pharmacy council member was the guest of honor. Soon after the rally a meeting was held which was attended by all the participants of the rally, principals of various pharmacy colleges, members of Rajahmundry chemists and druggist association. University rankers of the academic year 2016-17 were given certificates on this occasion.

5. WORLD ANTOBIOTIC AWARENESS WEEK

On the occasion of "World Antibiotic Awareness Week", an initiation by WHO with Vikas Institute of Pharmaceutical Sciences have organized antibiotic awareness week. World antibiotic awareness week aims to increase awareness of global antibiotic resistance and to encourage best practices among the general public, health workers to avoid the further emergence and spread of antibiotic resistance. On this occasion, an essay writing competition was held on 14th November 2017 where the students were given the topic " Antibiotic resistance". The top 5 students were selected and were rewarded.

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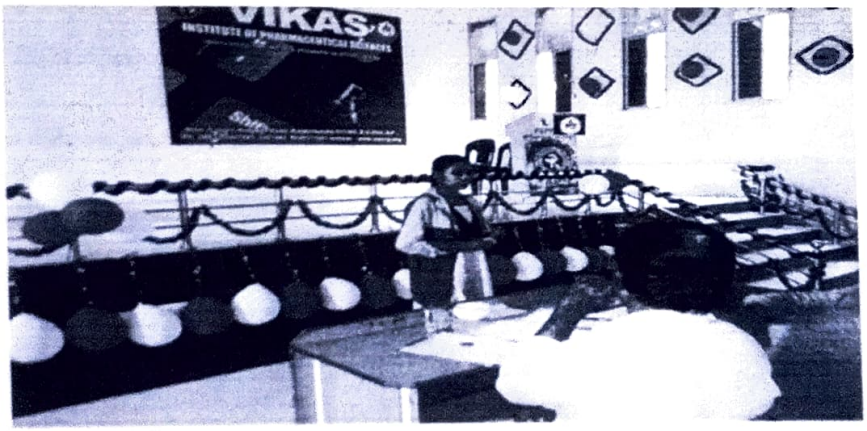
6 56th NATIONAL PHARMACY WEEK

The 56th National Pharmacy Week celebrations were conducted with lots of enthusiasm and professionalism with Vikas Institute of Pharmaceutical Sciences, from 19th November to 25th November, 2017. The week was celebrated with enthusiasm and zeal under the guidance of Dr.T. V. Narayana, Chairman, IPA education division and Prof. K. P. R. Chowdary, President IPA Rajahmundry local branch. During the weeklong celebrations many competitions were organized in order to spread awareness in the society about the theme of 56th National Pharmacy Week- Know your medicines: Ask your pharmacist"

6.1 Day 1: INAUGURATION

Inauguration was held at Vikas Institute of Pharmaceutical Sciences, Rajahmundry in association with IPA local branch on 19th November 2017 in the college auditorium. Dr.T. V. Narayana, Chairman, IPA education division welcomed the gathering. He highlighted the objectives of the pharmacy week and various events chalked out for the week long celebrations such as, elocution, competition on innovative ideas on pharmaceutical science and technology and pharmacy practice, health awareness campaign, Caricature competition. The program was inaugurated by Prof. K. P. R. Chowdary, President , IPA Rajahmundry local branch.

6.2 Day 2 : ELOCUTION COMPETITION



NPW elocution competitions were held at the college. The topic for the events was " Know your medicines: Ask your pharmacist". These competition was judged by , Dr.S.Muralidhar, Dr.B.J.Mahendra Kumar and Mr.T.Uday Bhaskar of Vikas Institute of Pharmaceutical Sciences.

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6.3 Day 3: COMPETITION ON INNOVATIVE IDEAS

On the 3rd day a competition on innovative ideas on pharmaceutical science and technology and pharmacy practice was held in the auditorium of t he college. Students expressed their ideas in various fields such as pharmaceutics, analysis and pharmacy practice .

6.4 Day 4 : HEALTH CAMPAIGN

A health awareness camp was organized on the fourth day. Students of various years of B.Pharm and Pharm.D visited the village Madhurapudi. A door to door health campaign was conducted by the students. The villagers were enlightened on the various preventive and management steps to control contagious diseases. All the villagers were also distributed with information leaflets in the local language regarding the regular habits to be inculcated and maintenance of sanitation

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6.5 Day 5 : CARICATURE

A caricature competition was held on the 5th day. The topic given was the theme of the year " Know your medicines: Ask your Pharmacist"

6.6 Day 6: VALEDICTORY

The week long celebrations were concluded by the valedictory function. Prizes were distributed to the winners and runners of various competitions held. The prizes were distributed by Prof. K. P. R. Chowdary, President, IPA Rajahmundry local branch. T.Ch.Subba Rao, Chairman VIPS, Dr.G.Sumalatha, Secretary, IPA Rajahmundry local branch. Vote of thanks was proposed by Mr.T.Uday Bhaskar, Vikas Institute of Pharmaceutical Sciences.

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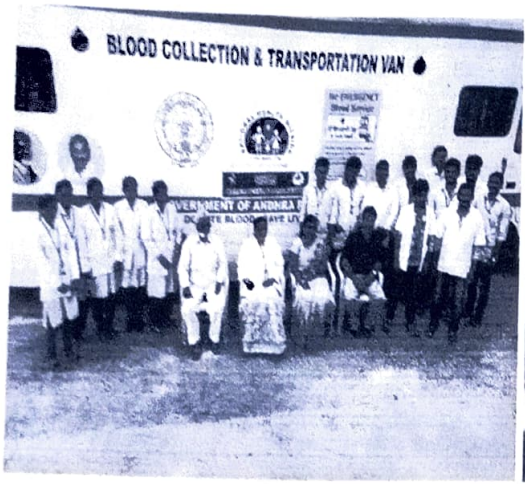
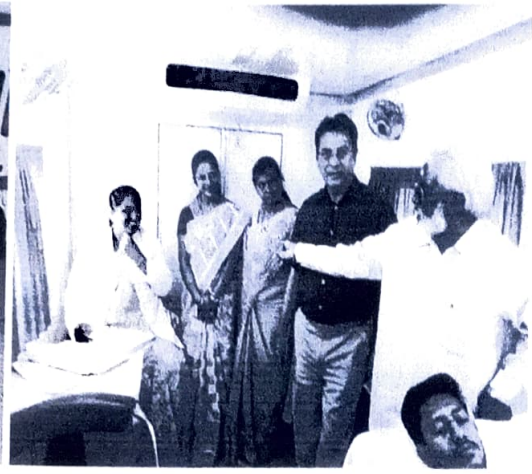
7. BLOOD DONATION CAMP





A blood donation camp was organized in association with Government general hospital at Vikas Institute of Pharmaceutical Sciences on 12th February 2018. All the students of the college participated actively in the blood donation camp. Nearly 50 students donated blood. Teaching and non teaching staff have also assisted and participated in the event.

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8. NSS MEGA CAMP

A one week mega NSS camp was conducted by Andhra University in association with IPA local branch Rajahmundry. In this mega camp students from all the pharmacy colleges of Rajahmundry have participated. The service was done at Divancheruv area of Rajahmundry.

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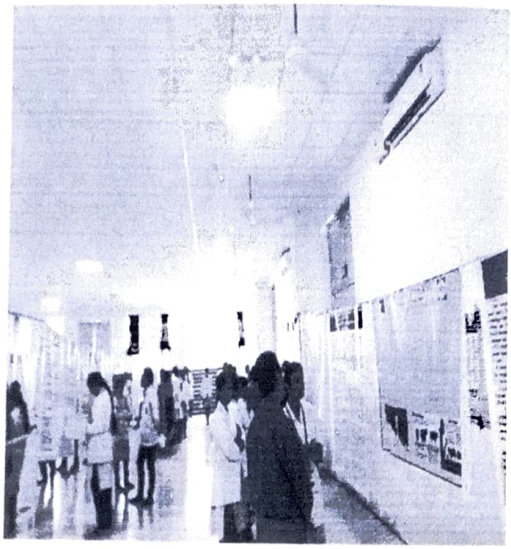
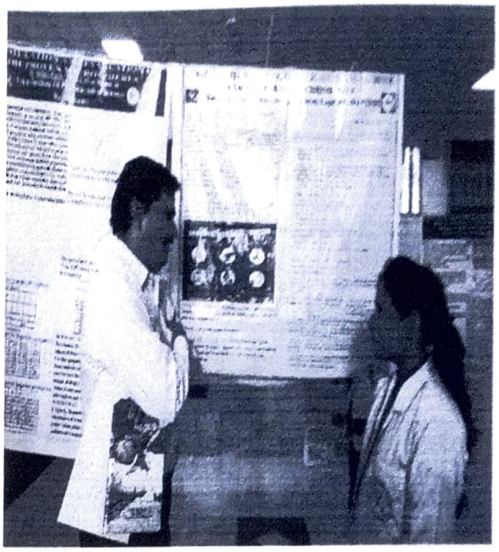
9. POSTER PRESENTATION COMPETITION





A poster presentation competition was held at Vikas Institute of Pharmaceutical Sciences . The competition was conducted for the final year and 3rd year B.pharm students on the innovatives in Pharmacey field. The competition was inaugurated by Dr.G.Sumalatha. HODs of various departments of Vikas Institute of Pharmaceutical Sciences have judged the presentations.

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10. WORLD TB DAY

Every year March 24th is commemorated as World TB day. On this occasion Vikas Institute of Pharmaceutical Sciences organised a rally to raise public awareness about the devastating health, social and economic impact of tuberculosis and to urge acceleration of efforts to end the global TB epidemic. The awareness rally was organised from Government General hospital, Rajahmundry to Kambalcheruv. Dr. Ramesh Kishore, superintendent, Government general hospital, Rajahmundry inaugurated the rally. All the students, staff of Vikas Institute of Pharmaceutical Sciences and Doctors of Government general hospital, Rajahmundry have actively participated. During the rally, holding the banners with the theme ' Wanted:Leaders for a TB free world', students orated slogans to create awareness on TB.

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Dr.T.V.NARAYANA
PRINCIPAL

LIST OF ACTIVITIES UNDERGONE IN 2016-2017 ACADEMIC YEAR

1.ORIENTATION PROGRAMME FOR B.PHARM AND PHARM.D STUDENTS

An orientation programme for freshers was conducted on 11th September 2016 in Vikas Institute of Pharmaceutical Sciences. Chief guest for the orientation program was C.Uma Maheswara Reddy professor , Sri Rama Chandra Medical University,Chennai,Tamilnadu . Dr.D.Satyanarayana, Prof.K.P.R.Chowdary, Dr.T.V.Narayana, Dr.G.Sumalatha graced the occasion. The students and the parents were given a detailed information about both the IPA and its activities. Dr. G.Sumaltha, Vice-Principal advised the students to take life membership in IPA.

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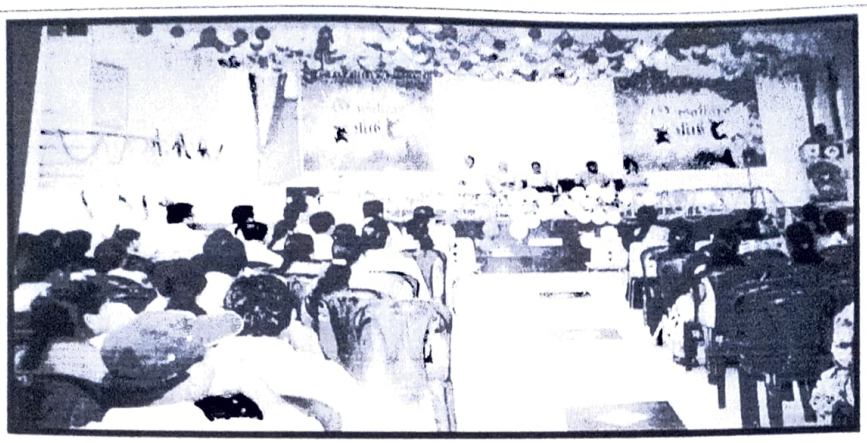

2. WORLD PHARMACIST DAY CELEBRATIONS

VIPS conducted a rally on the eve of world pharmacist day, Sep 26th 2016. Pharmacist awareness rally was organised from 9am to 12 noon with the theme "Pharmacist caring for you". The rally was conducted from Gokavaram bus stand to Y junction at Rajahmundry. Students from all the pharmacy colleges and staff of all the pharmacy colleges in Rajahmundry participated in the event. D.Prasad Reddy, member, state pharmacy council, Dr.G.Sumalatha ,secretary, Indian Pharmaceutical Association Rajahmundry also participated in the Rally . The rally was inaugurated by Ms.Raja Kumari, Urban Superintendent of police Rajahmundry.

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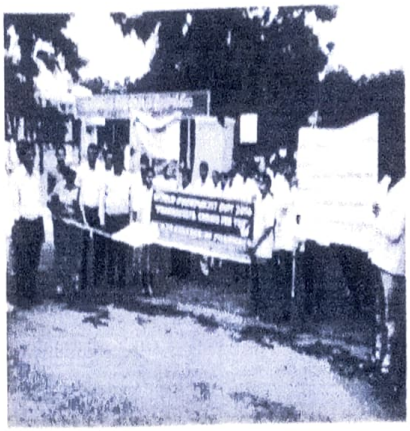
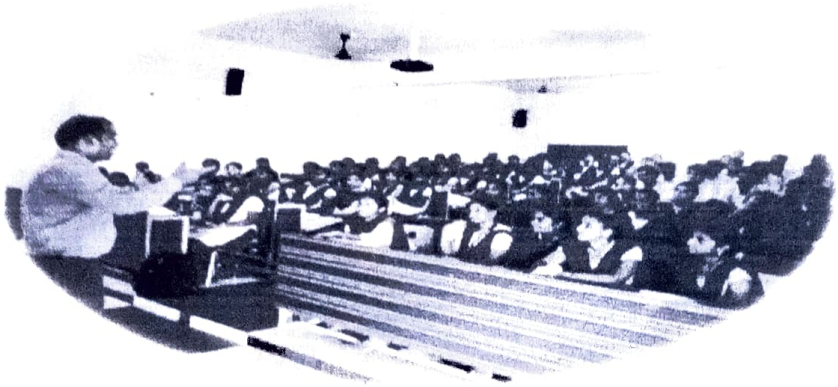


3.PERSONALITY DEVELOPMENT PROGRAM

VIPS conducted a 3 day Personality development workshop from 28th September to 30th September 2016 in Vikas Institute of Pharmaceutical sciences for the B.pharm and pharm.D students. Dr.Jaganath Rao addressed the students. They were trained on various personality development areas such as memory improving techniques , success formula, elimination of stage fear and time management.



4. NATIONAL PHARMACY WEEK CELEBRATIONS

The 55th National Pharmacy Week celebrations were conducted with lots of enthusiasm and professionalism by Indian Pharmaceutical Association Rajahmundry in association with Vikas Institute of Pharmaceutical Sciences, from 20th November to 26 th November, 2016. The week was celebrated with enthusiasm and zeal under the guidance of Dr.T. V. Narayana, Principal and Prof. K. P. R. Chowdary, Research Director VIPS. During the weeklong celebrations many competitions were organized in order to spread awareness in the society about the theme of 54th National Pharmacy Week- Role of pharmacist for a healthy India : Role in prevention and management of diabetes.

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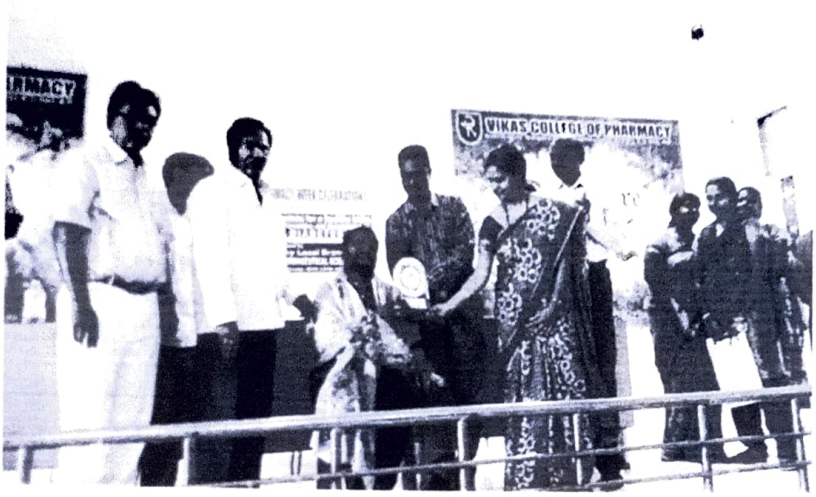
Day 1: INAUGURATION

Inauguration was held at Vikas Institute of Pharmaceutical Sciences, Rajahmundry in association with IPA local branch on Monday , 21st November 2016 in the college auditorium. Dr. I. V. Narayana, Chairman, IPA education division welcomed the gathering. He highlighted the objectives of the pharmacy week and various events chalked out for the week long celebrations such as rally, health awareness campaign, elocution, essay writing and quiz. The program was inaugurated by the chief guest Dr. M.V.S.Murthy, AIDS Nodal officer, Rajahmundry region and Prof. K. P. R. Chowdary, President , IPA Rajahmundry local branch.



Dr. M.V.S.Murthy spoke on the role of pharmacist in patient care. The program was co-ordinated by Dr.D.Satyanarayana, Emeritus Professor, VIPS, Dr.S.Muralidhar, professor VIPS, Dr.G.Sumalatha, Secretary, IPA Rajahmundry local branch, Dr.B.J.Mahendra Kumar, HOD Pharmacy practice department.

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Day 2 : PHARMA RALLY

The second event organized during NPW was a " Pharma Rally" in a nearby village Korukonda. The rally was inaugurated by Prof. K. P. R. Chowdary, President , IPA Rajahmundry local branch, T.Ch.Subba Rao, Chairman VIPS and other dignitaries. All the students of the college in their lab coats and faculty members took out the rally for a distance of around 3km along the main temple street of the village. The students orated various slogans and also displayed the banners and placards containing the information regarding prevention and management of diabetes.

Day 3 : HEALTH CAMPAIGN

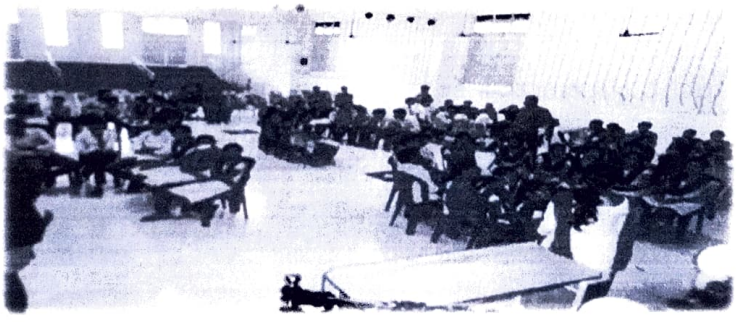
A health awareness camp was organized on the third day. Students of various years of B.Pharm and Pharm.D visited the village Madhurapudi. A door to door health campaign was

conducted by the students. The villagers were enlightened on the various preventive and management steps to control diabetes. All the villagers were also distributed with information leaflets in the local language regarding the diet to be followed and the regular habits to be inculcated to prevent diabetes and to manage it.

Day 4 : ELOCUTION & ESSAY WRITING

On the fourth day of NPW celebrations elocution and essay writing competitions were held at the college. The topic for both the events was " Role of pharmacist in management of diabetes. These competitions were judged by , Dr.S.Muralidhar, Dr.B.J.Mahendra Kumar and Mr.T.Uday Bhaskar of Vikas Institute of Pharmaceutical Sciences.

Day 5: Quiz



A pharma quiz was conducted on 5th day as a part of NPW celebrations. The students were divided into 5 groups. Three rounds were conducted. First being the multiple choice round followed by visual round and finally abbreviation round. All the students participated very enthusiastically.

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Day 6 VALEDICTORY

The week long celebrations were concluded by the valedictory function. Prizes were distributed to the winners and runners of various competitions held . the prizes were distributed by Dr.T. V. Narayana, Chairman, IPA education division, Prof. K. P. R. Chowdary, President , IPA Rajahmundry local branch, T.Ch.Subba Rao, Chairman VIPS, Dr.G.Sumalatha, Secretary, IPA Rajahmundry local branch. Vote of thanks was proposed by Mr.T.Uday Bhaskar, VikasInstitute of Pharmaceutical Sciences.

5. LOC MEETING OF 68th IPC ON 3RD DECEMBER 2016

A zonal LOC meeting comprising 68th IPC committee members and organizing committee members was held at Vikas Institute of Pharmaceutical Sciences in association with IPA local branch , Rajahmundry.

Around 500 volunteers of 68th IPC participated in the meeting. In this meeting Dr.T.V.Narayana, Gen. Sec, IPC, LOC chairman highlighted the record breaking online registrations done for the IPC to be held at Andhra University, Visakhapatnam and also informed to the gathering that honorable C.M of Andhra Pradesh has given consent to attend the conference as chief patron. Speaking on this occasion, Dr.Rao Vadlamudi went down his memory lane and shared that in 1977 IPC was held at Andhra University under the leadership of his father Dr.Vadlamudi Subba Rao and it gives him an immense pleasure to be the LOC chairman for 68th IPC. Prof K.P.R.Chowdary , chairman , scientific session spoke that for the first time 2900 scientific papers were selected to be presented at IPC. Principals, directors from various colleges of the zone have attended the meeting. Mr T.Bharat Vikas, IPASF secretary, Dr.Anu Rao, IPASF chairman also attended the meeting. Later a training session was held for the student volunteers by Dr.G.Jagannadh Rao. A rehearsal was done on bar coding system that was going to be introduced for the first time at IPC.

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6.WORKSHOP ON ANTICOAGULATION CLINIC; ROLE OF PHARMACY PROFESSIONALS

A one day workshop was held on 8th to 10th December 2016, at Vikas institute of pharmaceutical sciences in association with IPA local branch, Rajahmundry. The aim of the workshop is to provide a platform for Pharm.D professionals who would be competent and capable of performing safe and effective practice of the health care services. Scott Gier , R.Ph., Pharm.D (USA) and M.Chandra Shekar R.Ph. PhD. FAPhA (USA) were the resource persons who enlightened pharm.D and pharmacy practice students and faculty members from various colleges with better understanding on anticoagulation and Coumadin clinic.

Mr.Pendurti Venkatesh , MLA, Rajanagram constituency was the chief guest and Dr. K.Vijay Kumar, Sai hospitals, Rajahmundry was the guest of honour on this ocassion. The workshop started with an inaugural note by Dr.T.V.Narayana, chairman IPA education division, Prof. K.P.R.Chowdary, president, IPA local branch , Rajahmundry. Other dignitaries Dr. Jayapal Reddy , Chairman , St.Peter's Institute of pharmaceutical sciences, Warangal, Dr. Suresh Bandari, principal, St.Peter's Institute of pharmaceutical sciences, Warangal, Dr.G.Sumalatha, secretary, IPA local branch , Rajahmundry, Dr. S.Muralidhar and Dr.B.J.Mahendra kumar graced the workshop. The workshop focused especially on agents used to prevent clot formation, parentral anticoagulants, review on atrial fibrillations, venous thromboembolism, anticoagulation clinic, patient education, warfarin genetics, drug interactions with warfarin and its management. A live demonstration was given for the students on patients taking warfarin therapy. Participants of the workshop at the end spoke about the importance and benefits of the program to the student community.

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7. KEY ROLE IN 68[TH] IPC

The 68th Indian Pharmaceutical Congress (IPC), was held at Andhra University Campus, Visakhapatnam, Andhra Pradesh from December 16-18, 2017. The IPC was inaugurated on December 16, 2016, by the Honorable AP State Minister for HRD, Mr. Ganta Srinivasa Rao. The scientific sessions were inaugurated by honorable chief minister Mr.N.Chandra Babu Naidu. During the three day event many programs were held such as scientific sessions, leader ship training, cultural dance fest and many other to list. IPA local branch Rajahmundry played a key role in organizing many events. Dr. T.V.Narayana, Director, Vikas Institute of Pharmaceutical Sciences received "EMINENT PHARMACIST AWARD" from honorable Chief Minister. Prof. K.P.R.Chowdary, president, IPA local branch Rajahmundry was Chairman for scientific committee, LOC. Under his able guidance all the scientific sessions were held in a unique way. All the scientific papers evaluation was done at IPA local branch, Rajahmundry at Vikas institute of Pharmaceutical Sciences

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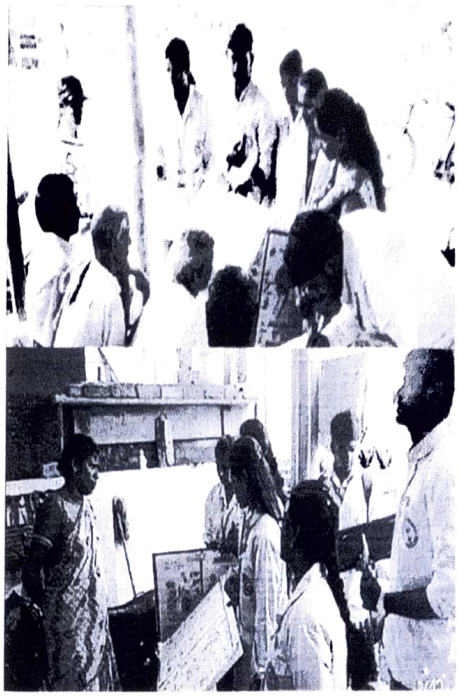
8. ANTICANCER CAMPAIGN ON WORLD CANCER DAY ON 4TH FEBRUARY 2017



On the eve of world cancer day, 4th February 2017, Vikas Institute of Pharmaceutical Sciences, Rajahmundry in collaboration with IPASF have organised an anti cancer campaign at a nearby village Burugupudi. The programme was inagurated by Dr.G.Sumalatha, principal , Vikas Institute of Pharmaceutical Sciences.Rajahmundry. With an objective to educate the villages, the students under the guidence of Ms.Samhitha Reddy, IPASF member , have prepared charts and placards containing pictoral information about various cancers occuring in females, males and in common.The students were divided into four groups containing six volunteers and a group head in each.Each group got divided into different directions and gathered villages in little groups and educated them about the majorly occuring cancers , their symptoms, stages associated and the methods for early diagnosis of cancer.The villages were also educated on various life style modifications to be made as a preventive measure.

9. GUEST LECTURE ON COMMUNITY PHARMACY

Vikas institute of pharmaceutical sciences has organized a guest lecture on community pharmacy on 21st February 2017. Mr. A.Gundu Rao, president, Karnataka Pharmacy Council and Y.V.Gauda, member , Karnataka pharmacy council were the speakers. The program was inaugurated by Dr.G.Sumalatha with a welcome note to the gathering. Mr.A.Gundu Rao addressed the pharm.D and Pharm.D (PB) students and explained them the importance of community pharmacy. Speaking on this occasion Mr. Y.V.Gauda highlighted the role played by a pharmacist and especially pharm.D students as a community pharmacist. Dr.B.J.Mahendra Kumar proposed vote of thanks.

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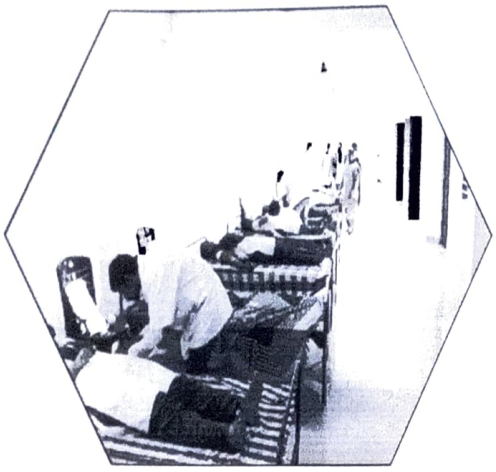
10. BLOOD DONATION CAMP ON 6TH MARCH 2017



A blood donation camp was organized by IPA local branch Rajahmundry in association with Vijaya sree blood bank at Vikas Institute of Pharmaceutical Sciences on 6th March 2017. All the students of the college participated actively in the blood donation camp. Nearly 50 students donated blood. Teaching and non teaching staff have also assisted for the event.

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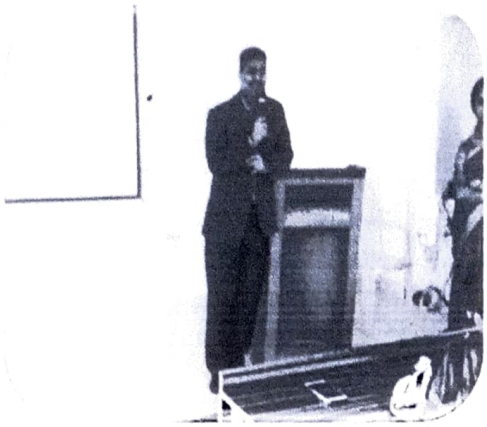
13.GUEST LECTURE BY DR. A.RAMKISHAN



A guest lecture was organised by IPA local branch Rajahmundry at Vikas Institute of Pharmaceutical Sciences by Dr. A .Ramkishan, Deputy Drug Controller (India). CDSCO was the chief guest of the event. Dr.A.Ramkishan addressed the gathering and gave a brief idea of CDSCO and its role and also sppoke on the origin and history of D and C act. All the staff and students of the college attended the lecture and Dr. A.Ramkishan was felicitated by Dr.G.Sumalatha, secretary , IPA local branch rajahmundry and other staff members of the college.

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Dr.T.V.NARAYANA
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1.3.1 DESCRIPTION OF COURSES

Gender:

1.Human anatomy and physiology

2.Pharmaceutics

The above courses explain fundamental knowledge on the structure and functions of the various systems of the human being also explain the formulation of suitable dosage form for the different sex. Gender Related Issues are discussed in seminars, rallies under the NSS, like Beti bachao Beti padhao, Yoga Day, Sports, Women entrepreneurship awareness program, Personality Development Programme and International Women's Day.

Environmental and Sustainability:

The following courses address Environmental and sustainability .

1.Pharmacognosy and Phytochemistry

2.Herbal drug technology

3.Pharmaceutical Biotechnology

4.Pharmaceutical Microbiology

5.Pharmaceutical chemistry(Natural products)

Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment. The institute organized various programmes to aware the students regarding the protection of environment such as, Tree Plantation, Swachata Abhiyan, and Water Day.

Human Values and Professional Ethics:

The following courses describe the Human values.

1.Communication Skills

2. Pharmaceutical Jurisprudence

3.Regulatory Affairs

4.Industrail Pharmacy

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5.Hospital pharmacy

6.Community pharmacy

7.Clinical pharmacy

Pharmaceutical Jurisprudence is the study of legislations relating to the Pharmaceutical profession and their implications in development and marketing along with code of ethics during pharmaceutical practice, manufacturing, sale or distribution. It provides the professional ethics to be followed to become a pharmacy professional. Also it includes the prevention of cruelty to animals which goes far beyond the human values. Other than, The institute organizes interaction of eminent personalities from social world to inculcate human values and professional ethics such as- Celebration of Sanvidhan Day, Pharmacy Day, also our college regularly organizes lectures, seminars pertaining to human values, soft skills and personality development to have professionalism ingest in the students.

The courses mentioned below provide the information about **Health determinants.**

1.Pharmaceutics

2.Pharmacology

3.Pharmaceutical Biochemistry

4.Human anatomy and physiology

5.Clinical Toxicology

The above courses describe the details with a formulation of various dosage form and their effects on the various organs and systems of human body and also its relation with human physiology.

Right To Health And Emerging Demographic Issues

1. Hospital and Clinical Pharmacy

2. Hospital And Community Pharmacy

3. Pharmacotherapeutics

4.Clinical Pharmacy

5.Clinical Research And Pharmacovigilance

6.Biopharmaceutics and Pharmacokinetics

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7.Clinical Pharmacokinetics &Therapeutic Drug Monitoring

These courses create awareness about healthcare issues facing the society. The college organizes awareness activities like Aids day, Pharmacist Day. The College organizes campaign about prevention and misuse of medicines.

DETAILED DESCRIPTION OF THE COURSES THAT INTEGRATES CROSS CUTTING ISSUES RELEVANT TO PROFESSONAL ETHICS,HUMAN VALUES,ENVIRONMENT AND SUSTAINABILITY INTO CURRICULUM

1. **Health Education & Community pharmacy:**

- Health Education is the principle by which individuals and groups of people learn to behave in a manner conducive to the promotion, maintenance, or restoration. And community pharmacy is a pharmacy that deals directly with people in the local area. It has responsibilities including compounding, counselling, checking and dispensing of prescription drugs to the patients with care, accuracy, and legality.

- This course deals with scientific study of concept of health including physical, mental, social, spiritual and all details including indicators of health also the concept of prevention of diseases.

2. Hospital and Clinical Pharmacy:

- This course is designed to impart the basic knowledge about hospital and clinical pharmacy including definition, functions, classification based on various criteria, organization, management and health delivery system in India.

- This course deals with functions and objectives of hospital pharmaceutical services, location, layout, different principles of drug distribution and manufacturing related to that.

3. Human Anatomy And Physiology :

- This course is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The course provides the basic knowledge required to understand the various disciplines of pharmacy.

- This course deals with introduction to human body, cellular level of organization, tissue level of organization, integumentary system: including skeletal system and joints. Body

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fluids and blood, lymphatic system, peripheral nervous system and special senses cardiovascular system.

4. Pharmaceutical Biochemistry:

- Biochemistry, sometimes called Biological Chemistry, is the study of chemical processes within and relating to living organism. Biochemical processes give rise to the complexity of life. Biochemistry is closely related to molecular biology, the study of molecular mechanism of biological process.

- Biochemistry focuses on understanding how biological molecule give rise to the processes that occur within the living cell and between cells, which in turn relate greatly to the study and understanding of tissues, organs, and organism structure and function.

5. Pharmaceutics:

- This course gives knowledge about pharmacy that deals with the process of turning a new chemical entity or old drug into a medication to be used safety and effectively by patient. It is also called the science of dosage form design.

- Pharmaceutics helps relate the formulation of drug to their delivery and disposition in the body. Pharmaceutics deals with the formulation of a pure drug substances into a dosage form. The pharmaceutical industry discover, develops,produce,and market drug or pharmaceutical drug for use as medication to be administered to patient.

6. Communication Skills:

- This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

- This course deals with communication skills, barriers to communication, and perspectives in communication, elements of communication including communication styles.

Basic listening skills, effective written communication, writing effectively, interview skills including presentation skills. Group discussion.

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7. Pharmacognosy:

• Phamacognosy is the study of plant or natural sources as a possible source of drug. The study of the physical, chemical, biochemical ,and biological properties of drug, drug subtances of natural origin as well as the search for new drug from natural sources.

• Pharmacognosy involve the identification, physiochemical characterization, cultivation, extraction, preparation, quality control, and biological assessment of drug.

8. Pharmacology:

• Pharmacology is defined as study of drugs. Also consisting of the drug composition and properties, synthesis and drug design, molecular and cellular mechanisms, organ/systems mechanisms, signal transduction/cellular communication, molecular diagnostics, interactions, chemical biology, therapy, and medical applications and antipathogenic capabilities.

• The two main areas of this course are pharmacodynamics and pharmacokinetics. Pharmacodynamics studies the effects of a drug on biological systems, and pharmacokinetics studies the effects of biological systems on a drug.

9. Hospital And Community Pharmacy :

• This course is designed to prescription orders which compounded and dispensed and also patient care, drug monitoring, extemporaneous preparation and organization or department of the hospital to manage the procurement, storage, preservation, packaging, sterilization, compounding, preparation, dispensing or distribution of medicine in the hospital. • This course deals with community pharmacy management, community pharmacies in primary health care services, application of computers in pharmacy, patient counselling, introduction to hospitals and hospital pharmacy, hospital pharmacy, hospital formulary, hospital committees' constitution and function, hospital manufacturing, drug distribution systems, controlled drugs dispensing (narcotic drugs), sterilization.

10. Clinical Pharmacy:

• This course is designed to drug information, drug utilization, drug evaluation and selection, medication therapy management, formal education and training programs, disease state management.

• This course deals with definition, scope, history and development of clinical pharmacy, introduction to daily activities of a clinical pharmacist, patient data analysis, prescribing guidelines for pediatric patients, geriatric patients, pregnancy and breast feeding, clinical

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pharmacokinetics, designing and conducting of clinical trials, monitoring of drug therapy, adverse reactions to drug, pharmacogenetics, drug interaction.

11. Clinical Pharmacotherapeutics:

- This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

- This course deals with cardiovascular system, respiratory system, haematological diseases, gastrointestinal system, renal system, endocrine system, neuro-psychiatric disorders, infectious diseases, toxicology.

12. Regulatory Affairs:

- Regulatory affairs is a profession within regulated industries, such as pharmaceutical, medical devices, agrochemical etc. Regulatory affairs also has a very specific meaning within the healthcare industries.

- The main objectives of regulatory affairs is to provide the basis for the assurances of high quality of food product which can increase consumer interest for ensuring the efficacy, quality, and safety. Ensuring that their companies comply with all of the regulation and laws pertaining to their business.

13. Hazards And Safety Management:

- Hazard management is a continuous process that is used to improve the health and safety off all workplaces. It ia essentially a problem solving process aimed at defining problem, gathering information about them and solving them.

- Safety hazard are unsafe working condition that can cause injury, illness, and death. Safety hazard are the most common workplace hazard.

14. Clinical Research And Pharmacovigilance:

- Clinical Research is a branch of healthcare science that determine the safety and effectiveness of medication, devices, diagnostic products and treatment regimen intended for human use. They may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease.

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• Pharmacovigilance (PV) Drug safety it is the pharmacological science relating to the collection ,assessment, detection, monitoring, and prevention of adverse reaction with pharmaceutical product.

15. Pharmaceutical Jurisprudence:

• Pharmaceutical jurisprudence is the study of laws regulating the profession of pharmacy in India. It includes all the acts and rules there of mentioned in the constitution of India. E.g. Drug and cosmetic act and rules.

• Jurisprudence or legal theory is the theoretical study of law. Scholars of jurisprudence seek to explain the nature of law in its most general form and provide a deeper understanding of legal reasoning, legal system, legal institutions, and the role of law in society.

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Dr.T.V.NARAYANA
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B.PHARM (2013) SYLLABUS AND REGULATIONS

INDEX:

1. Admission, instruction and attendance
2. Examinations: Sessional and Year-end
3. Declaration of results and classification
4. Practical training.
5. Guidelines for paper setting and model papers.

1.1 The degree of Bachelor of Pharmacy of Andhra University will be conferred on a candidate who has satisfied the following conditions.

1.2 The candidate must have passed the (i) Intermediate examination of the Board of Intermediate Education, Government of Andhra Pradesh, or Diploma in Pharmacy examination of the Dept. of Technical Education, Govt. of Andhra Pradesh or any other examination recognized by the academic senate as equivalent thereto with Physics, Chemistry and Mathematics or Biology as group subjects and must have qualified in the Entrance Exams as prescribed by the University for being eligible to join I semester of B.Pharm course.

1.3.1 The candidate must have, after passing the qualifying examination pursued a regular course of study for not less than four academic years(three academic years in the case of diploma in pharmacy holders who are admitted directly in to 2nd year(3rd semester) of B.Pharm) and satisfied the academic requirements as prescribed thereafter. The scope of subject matter in each course and periods of study shall be as indicated in the syllabus and the scheme of instruction.

1.3.2 Instruction and examination in each academic year is spread over two semesters with a minimum of 90 working days in each semester (180 in any given academic year). However in the case of semesters I and II of B.Pharm the instruction and examination shall be organized simultaneously spread over the entire academic year of 180 days to save time that may be lost due to possible delays in the admission process.

1.4 Each period of instruction is of 45 minutes duration. Eight periods of instruction are provided on each day and there are six working days in a week (Monday to Saturday).

1.5 Attendance Requirements: A regular course of study during an academic semester means a minimum of average attendance of 75% of all the courses of the semester computed by totaling the number of periods of lectures and practicals, as the case may be, held in every course. In special cases where sufficient causes were shown, the Vice-Chancellor may on the recommendation of the Principal and Head of the Department concerned condone the deficiency in the average attendance to an extent of 9% for reasons such as ill health, if the application for condonation is submitted at the time of actual illness and is supported by certificate of; authorized Medical officer approved by the Principal. However, in the case of students, who participate in activities like N.S.S., N.C.C., Inter-Collegiate tournaments

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conducted by Andhra University, Inter-University tournaments conducted by Inter-university Board and any such other activities involving the representation of the College/University with the prior approval of the principal, the candidate may be deemed to have attended the college during the period solely for the purpose of the examination.

1.6 A candidate who cannot satisfy the attendance requirements in clause 1.5 because of late admission under special circumstances reasonable and acceptable to the University on the basis of document, shall fulfill the following conditions; Average attendance: A candidate shall have attended at least a total of 90% of the periods-lectures/practicals as the case may be held from the date of admission and also shall attend at least 50% of the total working days during that academic semester (Late admission means, admissions made after 45 days from date of commencement of the academic semester for the course).

1.7 If any candidate fails to satisfy the regulation under 1.5 or 1.6 she/he shall not be allowed for the University Examinations at the end of the semester, and he/she shall not be allowed for promotion to the next higher class of study. He/she shall be required to repeat the regular course of study of that academic semester along with the next regular batch.

2.0 Assessment for the award of degree shall consists of (a) Internal evaluation for 20 marks in each of the theory and practical courses separately except in course 101 A and B Biology theory and practical (bridge course). For course 101A and B the sessional marks shall be 10 and 10 respectively as detailed in the scheme of examination. (b) Semester-end examination as detailed in the scheme of examination for 80 marks in each of the theory and practical, except for 101 A and B Biology theory and practical (bridge course) for which the semester-end examination marks shall be 40 and 40 respectively.

2.1 Regulations concerning sessional examination: (a) Three shall be two sessional examinations in each theory course and the best of the two shall be taken; (b) the marks for the internal evaluation for the practical are awarded based on the continuous assessment of the performance of the candidate at the practical classes and the records. The marks certificate issued to the candidate by the University shall show separately the sessional marks, the semester-end examination marks and the aggregate of both; (c) The teacher who teaches the subject shall ordinarily to be internal examiner, (d) There shall be no provision for the improvement of the sessional marks.

2.2 Regulations concerning semester-end examination: (a) There shall be one semester-end examination in each theory course based on the question paper set by an external paper setter and it shall be evaluated by an internal examiner. There shall be one semester-end examination in each practical course and the setting and evaluation shall be done jointly by two examiners, one internal and one external. The duration of the practical examination may be of 4 to 6 hours as prescribed. There shall be no supplementary examination except for the final semester-end examinations. A candidate shall not be allowed to appear for the sixth semester end examination unless he passes in all the courses of the first and second semester end examinations and the eighth semester-end examinations unless he passes in all the courses of the third and fourth semester-end examinations.

3.1 A candidate shall be declared to have passed the examination in each semester if he obtains (i) not less than 40% marks in each theory and 50% in each practical of the semester-end examinations.

3.1a. A candidate may be permitted to improve his performance in semester-end examination of any semester only after completing the entire eight semester course of study by appearing again for the whole examinations of that semester only during four subsequent years after completion of the study of the entire course. Such an improvement can be availed only once for each one of the semester examinations of the entire course of study. When considered in its totality the better of the two performances as whole at the I, II, III, IV, V, VI, VII or VIII semesters as the case may be shall be taken into consideration for the purpose of awarding the grade.

3.1b. The courses 101 A Mathematics, 101 B Biology theory are bridge courses for candidates with only biology and with only mathematics background respectively at the intermediate level. Candidates with Diploma in Pharmacy have to take course 101 Mathematics. The respective candidates shall have to pass in these courses. The marks awarded in these courses shall not be considered for calculation of SGPA and CGPA.

3.2 Any candidate who carried a backlog at any stage will not be eligible for rank, medal or prizes to be awarded by the University. First attempt means appearance at the first examinations conducted for the particular batch.

4.0 Every candidate shall undergo practical training for at least one month in pharmaceutical factory at the end of the final semester of the course.

Grading system:
Appropriate letter grades are awarded in each theory and practical subject to only such candidates who have passed in the university examinations. Internal assessment marks and university examination marks put together will be taken into account for the letter grading system in each subject separately.

A candidate registered for the university examination but fails to appear or fails to score the minimum required 40% marks in the university examination will get a grade 'F', indicating failure or grade of incompletion.

A subject successfully completed cannot be repeated. Final evaluation of each subject (theory and practical separately) will be carried out on a 10- point grading system corresponding to the marks obtained in that subject. Each subject letter grade is converted into a specific grade value associated with the letter grade as given below (Table)

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Table: 10-Point grading system:

S. No.	Range of marks	Grade	Grade points
1	≥75%	O	10.0
2	65% - 74%	A	9.0
3.	60% - 64%	B	8.0
4	55% - 59%	C	7.0
5.	50% - 54%	D	6.0
6.	40% - 49%	E	5.0
7.	< 40%	F(Fail)	0.0
8.	The grade W represents failure due to insufficient attendance in the semester or year	W	0.0
9.	Incomplete (subsequently to be changed into pass or E or O or F grade in the same semester)	I	0.0

Semester Grade point average (SGPA):

The grade pointsare weighted in accordance with the number of credits assigned to a theory or practical subject and it is a product of credit and grade value. The semester grade point average (SGPA) is the weighed average of grade points awarded to a candidate

$$SGPA = \frac{\text{Total grade points of a particular semester}}{\text{Total number of credits of the semester}}$$

Performance in the non credit courses in which a pass (i.e., 35% or more) is sufficient will not be considered for calculation of SGPA.

SGPA (semester grade point average) for each semester will be calculated for those candidates who have passed all the subjects of that particular semester of the course.

D. Pharm holders, who take direct admission to third semester B.Pharm, are exempted from First and second semester B.Pharm credits.

Cumulative Grade Point Average (CGPA):

The weighed average of SGPA's of all Semesters that the student has completed at any point of time is the cumulative grade point average (CGAP) at that point of time

CGAP up to a semester will be calculated only for those students who have passed all the subjects up to that semester. Generally, CGPA is calculated after the successful completion of the entire B.Pharm course

$$CGPA = \frac{\sum(\text{SGAP of each semester} * \text{corresponding number of credits})}{\text{Sum of the entire course credits}}$$

After the results are declared, grade cards will be issued to each student, which will contain the list of subjects for that semester and grades obtained by the student

For Diploma holders, who take direct admission to third semester of B.Pharm, only six semester course credits i.e., 3rd to 8th semesters of B.Pharm will be considered for CGPA calculation.

5. Guidelines for paper setting and model papers.

5.1 Guidelines for paper setting:

1. The semester end question paper in each theory course is to be set for a total of 80 marks by an external paper setter as per the general model given below
2. 1 The question paper in each theory course is to be divided into parts A and B
2. 2 Part A consists of 10 short answer questions each carrying 4 marks out of which 8 questions are to be answered by the candidate. Thus the total of part A is 32 marks
2. 3 Part B consists of six long answer questions each carrying 12 marks out of which 4 questions are to be answered by the candidate. Thus the total of part B is 48 marks
2. 4 The question given in parts A and B should be spread over the entire syllabus in an even manner
2. 5 The question paper in each semester and practical examination is to be set jointly by two examiners, one external and one internal as per the general model provided below.

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5.2 MODEL PAPERS

Model question paper for practical course:

Course No
Title of the course
Date of examination

1. Synopsis	10 marks
2. Major experiment	35 marks
3. Minor experiment	20 marks
4. Viva voce	15 marks
	Total: 80 marks

Model question paper for theory course:

Course No
Title of the course
Time: 3Hrs

Max Marks:80

Part A

Answer any **eight** questions 8 X 4 =32

1
2
3
4
5.
6.
7
8.
9
10

Part B

Answer any **four** questions 4 X 12 = 48

11
12
13
14
15
16

SCHEME OF INSTRUCTION AND EXAMINATION

Course No.	Subject	Periods per week		Exam. duration (Hrs.)	Marks			Credits
		Theory	Practical		Sessional	Semester end	Total	
I/IV B.PHARM I SEMESTER								
101A	Mathematics (Bridge course) For Bi.P.C.	4	...	3	20	80	100	N.C
101B	Biology (Bridge course) For M.P.C	4	...	3	20	80	100	N.C
102	English	2	...	3	20	80	100	N.C
103	Soft skills	---	6 (2 x 3)	3	20	80	100	N.C
104	Pharm. Chemistry-I (Inorganic)	4	...	3	20	80	100	4
105	Pharm. Chemistry-II (Organic-I)	4	...	3	20	80	100	4
106	Pharm. Chemistry-II (Organic-I) Practical	...	6 (2 x 3)	4	20	80	100	2
107	Computer Applications	4	...	3	20	80	100	2
108	Computer Applications Practical	...	6 (2 x 3)	4	20	80	100	2
	TOTAL						**800**	**14**
I/IV B.PHARM II SEMESTER								
201	General & Dispensing Pharmacy	4	...	3	20	80	100	4
202	General & Dispensing Pharmacy Practical	...	6 (2 x 3)	4	20	80	100	2
203	Physical Pharmacy-I	4	...	3	20	80	100	4
204	Physical Pharmacy-I Practical	...	6 (2 x 3)	4	20	80	100	2
205	Human Physiology & Health Education-I	4	...	3	20	80	100	4
206	Environmental Sciences	4	...	3	20	80	100	2
	TOTAL						**600**	**18**

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II/IV B.PHARM III SEMESTER

301	Human Physiology & Health Education-II	4	...	3	20	80	100	4
302	Human Physiology & Health Education-II Practical	--	6 (2 x 3)	4	20	80	100	2
303	Pharm. Analysis-I	4	...	3	20	80	100	4
304	Pharm. Analysis-I Practical	...	6 (2 x 3)	4	20	80	100	2
305	Physical Pharmacy-II	4	...	3	20	80	100	4
306	Physical Pharmacy-II Practical	...	6 (2 x 3)	4	20	80	100	2
307	Pharm. Chemistry-III (Organic-II)	4	...	3	20	80	100	4
	TOTAL						**700**	**22**

II/IV B.PHARM IV SEMESTER

401	Applied Statistics	4	...	3	20	80	100	2
402	Pharm. Engineering-I	4	...	3	20	80	100	4
403	Pharm. Microbiology	4	...	3	20	80	100	4
404	Pharm. Microbiology Practical	...	6 (2 x 3)	4	20	80	100	2
405	Applied Biochemistry	4	...	3	20	80	100	4
406	Applied Biochemistry Practical	...	6 (2 x 3)	4	20	80	100	2
407	Pharmacognosy & Phytochemistry-I	4	...	3	20	80	100	4
408	Pharmacognosy & Phytochemistry-I Practical	...	6 (2 x 3)	4	20	80	100	2
	TOTAL						**800**	**24**

III/IV B.PHARM V SEMESTER

501	Pharm. Biotechnology	4	...	3	20	80	100	4
502	Pharm. Biotechnology Practical	...	6 (2 x 3)	6	20	80	100	2
503	Medicinal Chemistry-I	4	...	3	20	80	100	4
504	Medicinal Chemistry-I Practical	...	6 (2 x 3)	6	20	80	100	2
505	Pharm. Engineering-II	4	...	3	20	80	100	4
506	Pharm. Engineering-II Practical	...	6 (2 x 3)	6	20	80	100	2
507	Hospital & Community Pharmacy and Industrial Management	4	...	3	20	80	100	2
	TOTAL						**700**	**20**

III/IV B.PHARM VI SEMESTER

601	Pharmacology-I	4	...	3	20	80	100	4
602	Pharmacology-I Practical	...	6 (2 x 3)	6	20	80	100	2
603	Medicinal Chemistry-II	4	...	3	20	80	100	4
604	Medicinal Chemistry-II Practical	...	6 (2 x 3)	6	20	80	100	2
605	Industrial Pharmacy& Cosmetic Technology	4	...	3	20	80	100	4
606	Industrial Pharmacy & Cosmetic Technology Practical	...	6 (2 x 3)	6	20	80	100	2
607	Pharmaceutical Jurisprudence	4	...	3	20	80	100	4
	TOTAL						**700**	**22**

IV/IV B.PHARM VII SEMESTER

701	Pharm. Chemistry (Natural products)	4	...	3	20	80	100	4
702	Pharm. Chemistry-V (Natural products) Practical	...	6 (2 x 3)	6	20	80	100	2
703	Pharmacology-II	4	...	3	20	80	100	4
704	Pharmacology-II Practical	...	6 (2 x 3)	6	20	80	100	2

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705	Pharmacognosy & Phytochemistry-II	4	...	3	20	80	100	4
706	Pharmacognosy & Phytochemistry-II Practical	...	6 (2 x 3)	6	20	80	100	2
707	GMP & Validation	4	...	3	20	80	100	4
708	Professional Training *	Viva-Voce and Project Report		One month	20	80	100	4
*Industrial or Hospital or Community Pharmacy								
	TOTAL						800	26

IV/IV B.PHARM VIII SEMESTER

801	Pharm. Analysis-II	4	...	3	20	80	100	4
802	Pharm. Analysis-II Practical	...	6 (2 x 3)	6	20	80	100	2
803	Biopharmaceutics& Pharmacokinetics	4	...	3	20	80	100	4
804	Biopharmaceutics& Pharmacokinetics Practical	...	6 (2 x 3)	6	20	80	100	2
805	Clinical Pharmacy &Therapeutics	4	..	3	20	80	100	4
806	Novel Drug Delivery Systems	4	..	3	20	80	100	4
	TOTAL						600	20
	I SEMESTER						800	14
	II SEMESTER						600	18
	III SEMESTER						700	22
	IV SEMESTER						800	24
	V SEMESTER						700	20
	VI SEMESTER						700	22
	VI I SEMESTER						800	26
	VIII SEMESTER						600	20
	GRAND TOTAL						5700	164

B.PHARM I SEMESTER

COURSE NO 101A: MATHEMATICS
(BRIDGE COURSE FOR BIOLOGY STUDENTS)

Learning objectives: This is an introductory course in mathematics upon completion of which the student shall be able to solve different types of problems in matrices, trigonometry, co-ordinate geometry, differentiation and integration. He/she can also implement the applications of mathematics in pharmacy.

Units	Contents	Hrs
Unit-1:	**Algebra:** Functions, mapping, one-one function or injection, onto function or surjection, bijection, identity function, constant function, inverse function, composite function, real valued functions, addition and multiplication of real valued functions. Quadratic expressions in one variable, extreme value change in sign and magnitude, quadratic expressions in two variables, summation series involving A.P., G.P., H.P. Expression of $^{n}P_{n}$and $^{n}C_{r}$ and their definitions.	09
Unit-2:	**Matrices:** Definition, types of matrices, addition and multiplication of matrices, transpose of a matrix-properties, determinant, inverse of a matrix, solution of simultaneous linear equations in two and three variables.	08
Unit-3:	**Trigonometry:** Fundamentals of trigonometry, general definition of trigonometric ratios, sign of the trigonometric ratios as the angle varies from 0 to 2π, trigonometric ratios of the angles of -θ, 90°± θ, 180°± θ, 270°± θ in terms of those of θ, graphs and periodicity of trigonometric ratios, inverse trigonometric functions, expressions for sin2x, cos2x, tan2x in terms x, hyperbolic functions, inverse hyperbolic functions.	06
Unit-4:	**Co-ordinate geometry 1:** Translation and rotation of axis, locus and its equation. Straight line - equations to a straight line in point-slope form, slope-intercept form, perpendicular form, two point form, intercept form, symmetric form. The straight line and the equation a+b x=0. Families of lines (one parameter), point of intersection of two straight lines, angle of intersection of two straight lines, condition of parallelism and perpendicularity of lines.	07
Unit-5:	**Co-ordinate geometry 2:** Pair of straight lines, homogenous equation of second degree in x and y, angle between the lines and the combined equation of the bisectors of the angles between the lines, respectively, by the above equation, general second degree equation	07

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	in x and y, point of intersection and the angle between the lines.	
Unit-6:	**Limits and Continuity:** Concept of intervals and neighborhood, definition of limit, standard limits, continuity of a function.	05
Unit-7:	**Differential Calculus:** Derivatives of composite, implicit, parametric, inverse circular, hyperbolic functions, logarithmic differentiation, derivative of a function with reference to another function, applications of differentiation, partial differentiation, computation of first and second order partial derivatives.	09
Unit-8:	**Integral Calculus:** Integration as the inverse processes of differentiation, indefinite and definite integral, standard integral covering algebraic, trigonometric exponential and hyperbolic functions. Measures of integration, substitution methods, integration by parts, properties of definite integral and its equations, trapezoidal and Simpson's rules for approximate integration area under the curves, formation of differential equations.	09

COURSE NO 101 B: PHARMACEUTICAL BIOLOGY
(BRIDGE COURSE FOR MATHEMATICS STUDENTS)

Learning objectives:

1. To understand the nature of biological population.
2. To provide general knowledge of environmental effects and behavior.
3. To introduce the learner towards the organizational and functional aspects of lower animals.
4. To introduce students towards the structural and functional aspects of plant kingdom.

Units	Contents	Hrs
Unit-1:	Structure of the plant and animal cells. The functions of cell components. Cell division-mitosis and meiosis. The animal kingdom outline, classification with salient features and examples of each phylum. Principles of the histology of animal tissues.	08
Unit-2:	Amphibian (frog) Physiology with reference to cardiovascular system, nervous system and muscle contraction.	06
Unit-3:	Parasitology- Introduction to the important protozoa and helminthes in man. Outline of the life history of plasmodium, Trypnasoma, Liver fluke, tapeworm and round worm. The structure and life history and physiology	12
	of amoeba and mosquito (Anopheles and Culex)	
Unit-4:	Anintroduction to the classification of plants with specific examples, Characterization of the following medicinally important plant families with specific examples. Leguminosae, Rutaceae, Apocyanaceae, Solanaceae, Liliaceae, Rubiaceae, Scrophulariaceae, Compositae, Umbelliferae and Papaveraceae.	12
Unit-5:	Study of general morphological and histological characters of stem, flower, root, seed and fruit. Fertilization and methods of propagation of plants.	10

Books suggested:

1.Text book of Botany –Vignan series
2. Text book of Zoology –Vignan series

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COURSE NO 102: ENGLISH

Learning objectives:

1. To teach the fundamental of English language- Grammar, Vocabulary, Synonyms, usage etc.
2. To teach the skills of communication and correspondence in English.
3. To teach the methods of acquiring fluency and proficiency in English language.
4. To acquiring them with models of English prose and teach the skills of writing in English.
5. To facilitate practices of target language in class room.

Units	Contents	Hrs
Unit-1:	Role and importance of communication, verbal and nonverbal communication, group communication, effective communication, barriers to communication, communication media, participating in discussions, conduct of seminars, conferences etc., making presentations through collection, evaluation, organizing the information, interacting with learners and teachers, role of wit and humor in communication.	03
Unit-2:	Spoken English Vs written English, reading method, formal/informal English(one way two way) British /American/Indian English, how two introduce one self and others, how to tender apology, how to thank in different ways, greetings, some polite expressions.	05
Unit-3:	Agreements and disagreements, how to use a dictionary, how to use a thesaurus, vocabulary development, synonyms and antonyms, one word substitutes, comprehension.	03
Unit-4:	Communication through letters, official and personal letters, letters of complaint, letters of enquiries and responses, writing memos, circulars and notices, what to avoid while writing, paragraph writing.	02
Unit-5:	Scientific technical report writing, drafting and delivering a speech, resume writing and interview techniques.	03
Unit-6:	Grammar: sequence of tenses, voice, articles, direct and indirect speech, degrees of comparison, common errors in English made by Indian learners of English.	04
Unit-7:	***Concepts of learning and listening, types and methods of learning and listening, learning and listening of knowledge, attitudes, skills and practices.***	04
Unit-8:	***The following four essays from "selections from modern English" prose edited by Haladhar panda are prescribed.*** 1. Our own civilization-C.E.M joad 2. Andrew Carnegie-E.H carter 3. The secret of work-swami Vivekananda 4. The generation gap-Benjamin spock	04

Textbooks:

1. "bussiness correspondence and report writing" R.C.sharma and Krishna mohan Tata Megrawhillpublishers,New Delhi
2. Communicative English,E.SureshKumar,RajKamalPublications,Hyd.
3. "Selections of Modern English Prose"Ed by HladharPanda,Published by Universities Press(India)PvtLtd,Hyd.
4. A hand book of English for professionals, 2nd edition by P.Elliah Published by Pharma book syndicate

COURSE NO 103: SOFT SKILLS

Learning objectives:

1. To introduce the students to the basics of phonology, pronunciation, and way of expressing .....
2. To develop general skills for clear and effective communication by using appropriate vocabulary and grammar.
3. To teach techniques for improving memory for better communication.
4. To teach the skills time management for effective utilization of time.
5. To teach methods of managing stress in the work place.
6. To identify and focus on goals to be achieved by using effective communication methods.
7. To teach the art and skills of listening and derive the right information.
8. To teach the use of non verbal communication as a supplement to verbal forms.

Units	Contents	Hrs
Unit-1:	**Effective Communication**: Elements of Communication,7Cs of Communication, Types of Communication, Speaking and Listening, Non Verbal Communication, Writing Skills, Body Language, Improvement of Communication Skills.	06

Unit-2:	**Effective Public Speaking:** Audience Analysis, Choosing the Subject, Preparation of Speech, Presentation, Use of various Aids, Launching Pad, Evaluation, How to overcome Stage fear.	06
Unit-3:	**Memory Techniques:** Memory Testing, Process of Learning, How to train your observation, retention of information, link method of memory, importance of memory, absent-mindedness, memory demonstration.	06
Unit-4:	**Human relations:** Understanding people and human nature, communication barriers, skillful talk, listening to people, influencing and convincing people, making good impression, final thoughts.	06
Unit-5:	**Decision making:** crisis, identification and understanding the problem, writing possible solutions and selecting the best one, implementation.	06
Unit-6:	**Stress management:** causes of stress, understanding human nature, mood, temperament, needs, behavior, reactions, stress at home, work place, relaxation techniques.	06
Unit-7:	**Time management:** importance of time, identifying time wasters, four chambers of time management, steps for proper management of time. **Goal setting:** introduction, identifying goals, SWORT analysis, SMART goals, short term and long term goals, writing of mission statement, evaluation.	06
Unit-8:	**Team management:** identifying goals, setting targets, delegating tasks, monitoring and coordination. **Interview facing:** preparation of the bio-data, preparation for the interview, attire, postures and gestures, right way of answering questions.	06

Recommended books

1. Quick and easy way to effective speaking by Dale Carneige.
2. How to develop a super power memory by Harry Lorayne, Gaurav publishing house, New Delhi.
3. Improve your memory by Ran Fry.
4. Skill with people by Les Gibilin,Printmedia,New Delhi.
5. How to develop self-confidence and influence people by public speaking by Dale Carneige.
6. Coping with stress at work by J.M. Atkinson.
7. How to make successful decisions by A. Hardingham.
8. Communicative competence by Varanasi BhaskaraRao Published by Pharma book syndicate.
9. Personal and emotional competence by Varanasi BhaskaraRao Published by Pharma book syndicate.

COURSE 104: PHARMACEUTICAL CHEMISTRY- I (INORGANIC) THEORY

Learning objectives:

1. To impart the knowledge on the concept of inorganic pharmaceuticals and their applications.
2. To make the student understand about the sources of impurities and limit tests and purity tests for various inorganic chemicals.
3. To gain the knowledge on the electrolytes and their role in human body.
4. To gain the knowledge on the use of inorganic compounds as gastrointestinal, topical agents, dental products and other miscellaneous agents.
5. To impart knowledge on the use of inorganic compounds as pharmaceutical aids.

Units	Contents	Hrs
Unit-1:	1) General introduction to pharmaceutical inorganic chemistry. 2) Classification of inorganic pharmaceuticals based on their applications with examples. 3) Sources of impurities in pharmaceutical substances. 4) Principle and procedure for the limit tests of chlorides, sulphates, iron, lead, heavy metals and arsenic.	12
Unit-2:	**Test for purity of following:** 1) Neutralization capacity of Aluminium hydroxide gel. 2) Bulkiness in barium sulphate. 3) Limit test of copper and silver in bismuth subcarbonate. 4) Sucrose and reducing sugars in calcium gluconate. 5) Sedimentation volume, swelling power, coarse particles of bentonite. 6) Stability of hydrogen peroxide. 7) Absorption power and swelling power of kaolin.	04
Unit-3:	**Electrolytes:** Description, preparation and uses of following: 1) Sodium and potassium replenishers – sodium chloride, compound sodium chloride, potassium chloride, oral rehydration salts. 2) Calcium replenishers : calcium gluconate, dibasic calcium phosphate, calcium chloride. Acid base regulators: sodium bicarbonate, sodium lactate, sodium citrate, sodium acetate, ammonium chloride, potassium citrate.	08
Unit-4:	**Gastro intestinal agents** Properties, preparation and uses of the following:	09

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	1) Acidifying agents: Hydrogen chloride, sodium acid phosphate. 2) Antacids: aluminium hydroxide gel, sodium carbonate, magnesium carbonate (light and heavy) milk of magnesia, magnesium trisilicate, magnesium oxide. 3) Protectives and adsorbents: Boric acid, zinc oxide, kaolin(light and heavy), calamine, charcoal. 4) Laxatives: Magnesium sulphate sodium phosphate, sodium potassium tartarate.	
Unit-5:	**Topical agents** Definition, classification, mechanism of action, preparation and uses of the following: 1) Astringents: zinc sulphate, calcium hydroxide, zinc oxide, bismuth subcarbonate. 2) Topical protectants: zinc oxide, zinc stearate, talc, calamine, titanium dioxide 3) Anti-infectives: hydrogen peroxide, potassium permanganate, silver nitrate, Iodine, Boric acid, selniumsulphide, yellow mercuric oxide.	07
Unit-6:	**Miscellaneous inorganic pharmaceutical agents** Preparations and uses: 1) Heamatinics: ferrous sulphate, ferrous fummerate, ferrous gluconate, ferric ammonium citrate, iodinized dextrose 2) Halogens: iodine, iodides. 3) Antidotes: sodium thiosulphate, sodium nitrite. 4) Expectorants: ammonium chloride, potassium chloride. 5) Emetics: potassium antimony tartarate, copper sulphate. Importance of essential and non-essential trace ions: essential ions-iron, copper, zinc, manganese, sulphur; Non-essential- lithium, lead, mercury, bromide, chloride, gold.	12
Unit-7:	**Dental products** Introduction, classification with examples. Preparations and uses: 1. Flourides- Sodiumfluoride, sodium monofluorophosphate, stannous fluoride.	06
	2. Oral antiseptics and astringents -hydrogen peroxide, magnesium peroxide, zinc peroxide, mouth washes. 3. Dentrifices: - calcium carbonate, dibasic calcium phosphate, calcium phosphate, sodium metaphosphate and strontium chloride.	
Unit-8:	**Pharmaceutical Aids:** properties, preparation (wherever applicable) and uses 1. Excipents: dicalcium phosphate, magnesium stearate, Talc, calcium carbonate. 2. Suspending agents: bentonite, colloidal silica, aluminium stearate 3. Colorants: Titanium oxide, Ferric oxide.	04

Text books:

1) Bentley and Driver's text book of pharmaceutical chemistry Ed: L.M.Atherden, 1983. Oxford university press, Delhi.

2) Inorganic Medicinal and pharmaceutical chemistry; J.H. Block, E.B. Roche, T.O. Soine, C.V.Wilson, 1986, Varghese publishing house.

3) Inorganic pharmaceutical chemistry; P. GunduRao, Vallabhprakashan 1995, Delhi.

Reference Books:

1) Pharmacopoeia; (Indian, British, US and European)

2) Remington Pharmaceutical Sciences; 20th Edition Lippincott Wilfiams and Wilkins.

3) Martindale: The Extra Pharmacopoeia; 31StEdn, 1996, The Royal pharmaceutical society.

4) Hand book of pharmacy and health care Ed: Robin.J. Haiwan 1990, The Pharm Press, UK.

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COURSE 105: PHARMACEUTICAL CHEMISTRY-II(ORGANIC-I)THEORY

Learning objectives:

This course is designed to impart a very good knowledge about

1. IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
2. Some important physical properties of organic compounds and their role in biological system as well as chemical reactivity;
3. Free radical/ nucleophyllic [alkyl/ acyl/ aryl] /electrophyllic substitution, free radical/ nucleophyllic / electrophyllic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
4. Some named organic reactions with mechanisms; and
5. Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.
6. Identification, naming of stereo chemical centers. Stereochemistry and its importance in bioactivity of an organic compound.

Units	Contents	Hrs
Unit-1:	**Structure and properties of organic molecules:** Polarity of bonds and molecules; Intra and inter molecular forces, influence of electromeric, inductive, mesomeric (resonance), hyperconjugation effects on physical properties. Modern theories of acids and bases. Interpretation of acidity and basicity based on inductive effect. Significance of resonance energy. Importance of equivalent and non equivalent resonance structures in resonance stabilization. Electrophiles and nucleophiles. Carbocations: formation, stability and rearrangement and reactions. Carbanions: formation, stability and reactions. Steric effects and their influence on reactivity.	06
Unit-2:	**Alkanes**: Nomenclature, General methods of preparation, reactions of alkanes with special reference to free radical substitution. Rotation about carbon-carbon single bonds and conformational isomerism. **Cyclo alkanes**: Nomenclature, General preparation, Bayer's strain theory, chair and boat conformations of cyclohexane, axial and equatorial bonds.	08
Unit-3:	**Stereo chemistry**: Concepts of isomerism and its comparision to stereo isomerism. Optical isomerism (enantiomerism), planes of symmetry, centre of symmetry, chirality and other characteristics of optical isomers. Racemic mixture, resolution of racemic mixture; Diastereomer: properties and optical activity. Optical rotation and specific rotation, mesoforms.	08
	Configuration-Relative configuration (D&L system), absolute configuration (R&S system), sequence rules. Geometric isomerism- Cis-trans isomerism and E&Z nomenclature.	
Unit-4	**Halo alkanes**: Nomenclature, general methods of preparation. Significance of nucleophilic substitution of alkyl halides. S_N1 and S_N2 mechanisms; evidences in favour of these reactions; S_N1 vs S_N2 E1 and E2 mechanisms; evidences in favour of these reactions. Saytzeff rule and Hofmann's rule for eliminations, E1 vs E2 and Substitution vs elimination.	08
Unit-5:	**Alkenes and dienes**: Nomenclature, general methods of preparation. Electrophilic and nucleophilic addition to –C=C- and allylic substitution. Markovnikon's rule, peroxide effect, ozonolysis. Dienes- Introduction to alkadienes, stability of conjugated dienes.	08
Unit-6:	**Alkynes**: Nomenclature, general methods of preparation. Reactions of alkynes. Acidity of alkynes. Stereospecific reduction of alkynes.	05
Unit-7:	**Organometallic compounds**- Grignard reagents-preparation and nucleophilic addition and nucleophilic substitution reactions of Grignard reagent and their applications in synthetic chemistry.	04
Unit-8:	**Alcohols**- Nomenclature, general methods of preparation. Industrial preparation of ethanol and methanol. Preparation of absolute alcohol. Reactions of alcohols, importance of iodoform and lucas test. **Ethers**- Nomenclature, Williamson's-synthesis and acid cleavage of ethers.	08

COURSE NO 106: PHARMACEUTICAL CHEMISTRY-II (ORGANIC- I)PRACTICAL

1. Experiments to provide practice to the students in the uses of organic chemistry laboratory techniques such as crystallization, distillation (at normal pressure and under reduced pressure), sublimation, determination of physical constants like melting point and boiling point.
2. Identification of mono and multi functional organic compounds by systematic qualitative organic analysis (carboxylic acid, phenols, amines, aldehydes and ketones, alcohols, esters, hydrocarbons, nitro compounds and anilides).
3. Preparation of simple organic compounds such as nitrobenzene, iodoform, acetanilide, aspirin, sulphanilic acid, benzoic acid and benzanilide.

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4 Building organic molecules (ethane, isobutanol, tartaric acid, cyclohexane in chair and boat form) using steric model sets.

TEXT BOOKS:

1. Organic Chemistry By Morrison and Boyd
2. Bently and Driver's Textbook of Pharmaceutical Chemistry
3. Organic Chemistry, Vol. I by I.L. Finar.

COURSE NO 107: COMPUTER APPLICATIONS

Learning objectives:

1. To educate students in basics of computer hardware.
2. To educate the students about the different operating systems.
3. To teach the students use of MS office and its applications.
4. To teach the students the use of C language and its applications.
5. To impart knowledge on the use of MATLAB software and its applications.

Units	Contents	Hrs
Unit-1:	**COMPUTER ARCHETECTURE:** Evolution of Microprocessors and Digital Computers – Computer Generations –Architecture of the General Purpose Computer–Memories –Semiconductor memory – Optical Disks –Cache Memory -- Buses –Input/output Devices – Number Systems – Assemble languages– Machine languages.	04
Unit-2:	**MS DOS- DISK OPERATING SYSTEM:** Introduction – Need of Operating System – Function of Operating system –Introduction to MS-Dos – Disk Drivers –Loading of Dos into main memory – Files and File Naming Conventions –Types of Dos commands – Directory Structure of MS-Dos –Concept of path – Dos Internal commands – External Commands.	06
Unit-3:	**MS OFFICE APPLICATIONS.** Introduction of MS Word – Word control functions – Editing Document – Find and Replace –Tab Stops – Formatting the document – Spell Check –Tables & Graphs preparation – Graphics – Advanced Tools.	06
Unit-4:	**MS OFFICE APPLICATIONS.** Introduction of MS Excel – Excel Basics – Editing cell contents – worksheet – Command for worksheet. Introduction of MS PowerPoint –Steps to a Presentation – Adding new slides –Editing & Formatting new slides – Creating slide show.	08
Unit-5:	**C LANGUAGE & APPLICATIONS:** Introduction to C language – Difference between High level & low level language–Constants – variables – arithmetic operators – Integer expressions – Floating point – compound statement – conditional statement -- while loop – for loop – do while loop – logical operators – precedence rules for logical operators – switch & brake statements.	06
Unit-6:	**MATLAB -SCIENTIFIC ORIENTED PROGRAMMING:** Introduction to MATLAB –workspace – Command Window --	06

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	Arrays of Numbers – Creating and Executing a Script file –Function files – Matrices and Vector operations -- Graphics – 2D plots – 3D plots – Multiple Curves -- Input/output Functions -- Special effects of graphs – Generating and executing .M files.	
Unit-7:	**DATA BASE APPLICATIONS USING MATLAB:** Reading in the Data – Operating with the data – Counter and Bar Graphs – Frequencies and Histograms – Multivariate Tables -- Scatter Plots– Measures of Location/speed/shape – Hypothesis Test.	06
Unit-8:	**ANOVA APPLICATIONS USING MATLAB:** Introduction to the Analysis of Variance –Testing Mean – Testing Variance – One way ANOVA – Two way ANOVA	06

REFERENCE BOOKS:

1. Fundamentals of Microprocessors &Microcomputer by B.RAM.
2. Computer Applications by SUMITA ARORA; DhanapatRai& Co publications.
3. Computer Programming in C by V. RAJARAMAN; PHI publications.
4. Let us C by YESWANTH KANITKAR; BPB publications.
5. Programming In ANSI-C by E.Balaguruswamy.
6. Getting Started with MATLAB by RUDRA PRATHAP SHING
7. Applied Statistics using SPSS, STATISTICS& MATLAB by JOAQUIM P. MARQUE

ONLINE REFERENCES:

1. http://www.tutorialspoint.com/cprogramming/
2. http://www.cprogramming.com/tutorial.html
3. http://www.learnonline.com/
4. http://www.mathworks.in/academia/
5. http://www.mathworks.in/help/matlab/

COURSE NO 108: COMPUTER APPLICATIONS (PRACTICAL)

CYCLE 1: MS-DOS.

CYCLE 2: MS-OFFICE.

CYCLE 3: C–LANGUAGE.

CYCLE 4: MATLAB PROGRAMMING.

B.PHARM II SEMESTER

COURSE NO 201: GENERAL AND DISPENSING PHARMACY

Learning objectives:

Units	Contents	Hrs
Unit-1:	History of Pharmacy, Pharmacy Profession and Evolution of Pharmacy – Pharmacy in India – Pharmacopoeias of India, B.P., U.S.P. and International Pharmacopoeia – Metrology – Weights and Measures – Balances – Types and Care.	04
Unit-2:	**Dosage Forms** – Classification – Definition and Essential Characteristics – Formulation and its purpose – Formulation additives. A study of principles, formulation, general methods of preparation, dispensing and uses of the following types of preparations including a study of official (IP/BP) and other popular products under each category.	08
Unit-3:	**Liquids for External Use:** Lotions, Liniments, Glycerins, Collodions, Paints, Gargles, Mouth Washes, Ear Drops. Liquids for Internal Use: Waters, Solutions, Spirits, Elixirs, Syrups.	06
Unit-4:	**Emulsions and Suspensions.**	08
Unit-5:	**Powders, Semisolids**: Ointments, Creams, Pastes, Gels, Suppositories.	08
Unit-6:	**Galenicals:** A Study of Maceration, Percolation and Continuous Hot Extraction. Method of Preparation and Uses of the Following Galenicals: Compound Tincture of Benzoin, Liquid Extract of Belladonna, Dry Extract of Nux Vomica.	06
Unit-7:	Prescription, Types, Latin term terms in prescriptions – General principles of Dispensing, Accuracy and Care in Dispensing and Administrating Medicines, Labelling and Packing. Pharmaceutical Calculations on Percentage Solutions, Doses, Posology, Alligation, Proof Strength.	06
Unit-8:	**Incompatibility**: Physical, Chemical and Therapeutic – Methods of Overcoming and Handling Incompatible Prescription.	08

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Text Books:

1. Introduction to Pharmaceutical Dosage Forms by H. C. Ansel;
2. Bently's Textbook of Pharmaceutics by E. A. Rawlins;
3. I.P., B.P. and B.P.C (Current Editions);
4. Textbook of Professional Pharmacy by N.K. Jain and S.N. Sharma;
5. Cooper and Gunn's Dispensing Pharmacy;
6. Tutorial Pharmacy by Cooper and Gunn;
7. The Science and Practice of Pharmacy by Remingtons.
8. Modern dispensing pharmacy by N.K. Jain and G.D.Gupta published by Pharma book syndicate.

COURSE NO 202: GENERAL AND DISPENSING PHARMACY PRACTICALS

Preparation of atleast 60 Pharmaceutical Products Covering Various Types of Dosage Forms (25) and Aromatic waters (3), Solutions (4), Syrups (3), Elixirs (3), Lotions (2), Liniments (2), Galenicals (1), Glycerins (3), Ointments (2), Creams (2), Mixtures (8), Powders (6), Emulsions (6), Suppositories (2), Incompatibilities (10), Paints, Gargles, Mouth Washes (3), Prescriptions related to: mixtures of different classes in each (4), Powders in eutectic and effervescent preparations, physical and chemical incompatibilities each (2).

COURSE NO 203: PHYSICAL PHARMACY I – THEORY

Learning objectives:

Units	Contents	Hrs
Unit-1:	**Intermolecular forces and state of matter:** Binding forces between molecules, the states of matter, the gaseous state, the liquid state, solids and the crystalline state phase equilibria and the phase rule	08
Unit-2:	**Thermodynamics:** Basic principles of first, second and third laws of thermodynamics, modification of first law under different thermodynamic conditions differential and integral heat of solutions, entropy and its significance, applications of three laws of thermodynamics in Pharmacy, Gibbs and Helmholtz free energy functions.	08
Unit-3:	**Solutions of non-electrolytes:** Concentration expressions: molarity, molality, normality, mole fraction percentage by weight, volume, their relative advantages and disadvantages, Roults Law and its applications, ideal and real solutions. Colligative properties and their significance in Pharmacy.	08
Unit-4:	**Solutions of electrolytes:** Properties of electrolytic solutions, conductance and equivalent conductance. Arrhenius theory of strong electrolytes and its merits and demerits. Degree of dissociation and Van'tHoffs factor. Activity and activity coefficients. Debye-HuckelTheory ionic strength, coefficients for expressing the colligative properties	08
Unit-5:	**Ionic equilibria:** Ionization of water, weak acids and weak bases, Sorensen's pH scale and interconversion of ionic concentrations to pH and vice-versa. pH calculations involving proton balance equations. Acidity conditions and their significance	07
Unit-6:	**Electrodes** Electromotive force and oxidation – reduction systems. Electrochemical cells, electrometric determination of pH and redox.	07
Unit-7:	**Buffers:** Buffers and buffered isotonic systems. The buffer equation,	07

	buffer capacity, buffers in pharmaceuticals and biologics, buffered isotonic, methods of adjusting tonicity and pH.	
Unit-8:	**Physical properties:** Study of the following principles with emphasis on problem solution, wherever applicable.Viscosity and Poisseulli's formulae for liquids, experimental determination of viscosity, Ostwald's viscometer, comparison of viscosities. Surface Tension: Definition, method of determination. Significance in Pharmacy. Dielectric constant, induced polarization, dipole moment, refractive index and molar refraction. Optical rotation, optical rotatory dispersion.	09

Martin C V S Subrahmanyam

COURSE NO 204: PHYSICAL PHARMACY-PRACTICAL

1. Determination of viscosity of liquids such as water, glycerin, liquid paraffin – light and heavy;
2. Determination of surface tension of water and a surfactant solution;
3. Determination of density of a solid;
4. Phase Rule: Construction of phase diagram for phenol – water system;
5. Construction of Phase diagram for triethanolamine – water system;
6. Rast camphor method: Determination of molecular weight of a substance (benzoic acid and aspirin);
7. Elevation of boiling point – determination of vant Hoff's factor;
8. Determination of refractive index and molar refractivity of liquids such as water, acetone, carbon tetrachloride and alcohol;
9. Quatitative applications of refractive index – determination of strength of alcohol or acetone;
10. Determination of specific rotation of dextrose solution and estimation of dextrose in solution by polarimetry;
11. Calibration of pH meter and determination of pH of solutions;
12. Acid – base titrations using pH meter;
13. Determination of pKa by half – neutralization method;
14. Preparation of selected buffers and determination of buffer capacity of acetate buffer.

Suggested Books:

1. Physical Pharmacy by Alfred Martin.
2. Bentley's Textbook of Pharmaceutics by E.A. Rawlins.
3. Remington's Pharmaceutical Sciences.
4. Physical pharmacy Practical text by Guru Prasad Mohanta and Prabal Kumar Manna Published by Pharma book syndicate.
5. Essentials of physical pharmacy by Derle D.V. published by pharma book syndicate

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COURSE NO 205: HUMAN PHYSIOLOGY -1
(INCLUDING HEALTH EDUCATION AND PATHOPHYSIOLOGY)

Learning objectives:

1. To impart fundamental knowledge of the structure and functions of the human body.
2. To understand homeostasis mechanisms and its relation with various body systems.
3. To gain the knowledge regarding various tissues and organs of different systems of human body.
4. To impart a thorough knowledge of pathophysiological aspects of various diseases.
5. The knowledge imparted should help the students to understand the pharmacology of drugs.

Units	Contents	Hrs
Unit-1:	Fundamentals of anatomy of different systems of body including skeleton. Extracellular fluid-internal environment. Difference between extracellular fluid and intracellular fluids. Membrane potentials, action potentials. Homeostatic mechanisms, electrolytes, pH and buffers. Classification of tissues and their functions, neuromuscular junction, mechanism of muscle contraction and its electrical and metabolic correlates. Muscle function during exercise. Knowledge of myasthenia gravis, spasticity, tetanus.	10
Unit-2:	Composition and the functions of blood. Genesis and regulation of red blood cells production, blood groups, transfusion of blood. Leukocytes, properties of white blood cells, tissue macrophages. Blood coagulation, Formation and circulation of lymph. Diseases related to blood: anemia and blood dyscrasias like purpura, agranulocytosis, thrombocytopenia, leukemias, leucopenia, hemophilia and polycythemia.	06
Unit-3:	Cardiovascular system: Structure and functions of heart and blood vessels. Excitatory and conductive system of the heart, Action potentials in cardiac muscle, cardiac cycle, Nervous regulation of the heart. Systemic, pulmonary, coronary and hepatic blood circulation, cardiac output, blood pressure in different blood vessels, blood pressure regulation and measurement. E.C.G of heart, abnormal rhythms of the heart, congestive heart failure, hypertension, atherosclerosis, arteriosclerosis, angina pectoris, IHD.	12
Unit-4:	Structure and functions of different parts of gastrointestinal tract. Motility of alimentary canal and its regulation. Gastrointestinal secretions, their composition, function and regulation. Digestion of food in mouth, stomach and small intestine and its absorption. Balanced diet and deficiency disorders. Structure and functions of Liver. Diseases related to GIT: emesis, pyloric stenosis, hyperacidity, peptic and duodenal ulcer, dyspepsia, colic, constipation and diarrhea, piles, jaundice, cirrhosis, diabetes.	10
Unit-5:	Respiratory organs and their physiology. Mechanisms of respiration. Molecular aspects of cellular respiration. Transport of gases between lungs and tissues. Artificial respiration methods. Diseases related to respiratory tract: asthma, bronchitis and pulmonary tuberculosis.	04
Unit-6:	Kidney: structure and function of nephron, formation of urine and renal mechanisms for concentrating and diluting the urine, regulation of acid-base balance. Renin-angiotensin-aldosterone system, Regulation of blood volume, extracellular fluid volume. Diseases related to kidney: Nephritis, crystalluria, edema, nephrogenic diabetes insipidus, and acute renal failure.	04
Unit-7:	Spread and prevention of contagious diseases, venereal diseases, leprosy, droplet's infection, water and air-borne diseases, diseases caused by insects.	06
Unit-8:	Population problem, family planning programme. The role of pharmacist in motivating public in the implementation of family planning programme, Principles of family planning methods, contraceptives and their use. First aid for fractures of limbs, joints, bleeding, drowning and snakebite, burns, scalds and poisoning.	06

Suggested Books:

1. Medical Physiology by Tortora.
2. Shambu lingam- Essentials of Physiology.
3. Ross & Wilson- Anatomy & Physiology in health and illness- Anne Waugh, Allison Grant.
4. First Aid to the injured- Published by Saint John Ambulance Association.
5. A Treatise on Hygiene and Public Health, B.N. Ghosh, Calcutta Scientific Publishing Company.

Reference Books:

1. Text Book of Medical Physiology- Arthur.C Guyton
2. Samson Wright's Applied Physiology.

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COURSE NO 206: ENVIRONMENTAL SCIENCES

Name of the Course: Environmental Sciences		
Course No. 206	Semester II	
Duration: 60 Hrs	Maximum Marks: 100	
Teaching Scheme	Examination Scheme	
Theory: 04 Hrs/week	Mid Semester Exam: 20 Marks	
Practical: Not Applicable	End Semester Exam: 80 Marks	
Credits: 04		
Aim: Impart environmental awareness for the rational utilization of resources and protection of the environment		
Objectives:		
1.	To impart knowledge on the importance of environmental resources for humanity	
2.	To create awareness on local and global environmental problems	
3.	To make the students understand the environmental impacts of developmental activities taking place in various sectors	
4.	To provide basic knowledge on the connection between economy and environment	
5.	To make the students understand the social issues related to environmental pollution	
6.	To provide basic knowledge on the governance and regulations regarding the environment	
7.	To provide field knowledge in order to enable the students to understand the state of ecology, environment and natural resources	
Pre-Requisite:		
1.	10 + 2 level qualification	

Units	Contents	Hrs
Unit - 1	Introduction: definition, scope and importance of environment. Types, characteristics, structure and function of forest, grassland, desert and aquatic (lakes, rivers and estuaries) ecosystems.	05
Unit - 2	Natural resources (land, water, forest and energy) management: Land degradation, soil erosion and desertification, impacts of modern agriculture Water use and over-utilization of surface and ground water, water conflicts, floods, droughts, water logging and salinity Forest use, abuse and over-use, impacts of mining and dams on forests and tribal people Energy needs, renewable and non-renewable energy sources, alternate energy sources, impacts of energy use on environment.	10
Unit - 3	Biodiversity and its conservation and management: Social, ethical, aesthetic, commercial and medicinal values of biodiversity, India as a mega diversity center, threats to biodiversity (Hot spots, Habitat loss, Wildlife poaching, Species loss), *In-situ* and *Ex-situ* conservation and management of biodiversity.	05
Unit - 4	Global environmental problems: Causes, effects and control measures of air pollution, water pollution, soil pollution, marine pollution, noise pollution and thermal pollution; Nuclear hazards, acid rain, ozone depletion, global warming and climate change; Solid waste management, organic compost; Urban and industrial wastes, recycling and re-use.	10
Unit - 5	Environmental problems of India: Drinking water, sanitation and public health; effects of urbanization, transportation, industrialization and green revolution on the quality of environment; water scarcity and ground water depletion; rain water harvesting, cloud seeding and watershed management. Controversies on major dams – resettlement and rehabilitation of people, problems and concerns.	08
Unit - 6	Economy and Environment: Economics of development, preservation and conservation; sustainability – theory and practice; Equitable use of resources for sustainable lifestyles; environmental impact assessment. Environmental education, environmental movements and environment versus development.	05
Unit - 7	Institutional governance and environmental regulations: Government regulations, monitoring and enforcement; environmental governance, environmental acts (Water Act, Air Act, Environment Protection Act, Wildlife Protection Act, Forest Conservation Act and Coastal Zone Regulations); Institutions and Policies relating to India. International Conventions – Stockholm Conference 1972; Earth Summit 1992; World Commission for Environmental Development.	07
Unit - 8	Case Studies: Chipko movement, Narmada BachaoAndolan, Silent Valley Project, Madhura Refinery and TajMahal, Industrialization of Pattancheru, Hyderabad, Nuclear Reactor at NagarjunaSagar, Tehri Dam, Ralegaon Siddhi (Anna Hazare), Kolleru Lake Aquaculture and Florosis in Andhra Pradesh Field Work: Study of local flora and fauna; hill, river and pond ecosystems; Field knowledge on local industries, water treatment plants, and effluent treatment plants.	10
	Total	60

Text Books:

1. G. Tyler Miller and S. Spoolman 2010. Environmental Science, 13th Edition, Cengage Learning, USA. ISBN-13: 9780495560166
2. Arvind Kumar 2004. A Text Book of Environmental Science. APH Publishing, ISBN 817648590X
3. Robert M. Schoch 1996. Case Studies in Environmental Science. Jones & Bartlett Publishers, ISBN 0314203974

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4.	Energy Primer – Solar, Water, Wind and Biofuels 1974. Published by Portola Institute, USA. ISBN 0-91477400-X.
5.	Richard T.W. and Bernard J.N. 2002. Environmental Sciences: Toward a sustainable future. 8th Edition, Prentice Hall Publisher, ISBN 10.0130325384.
6.	Daniel B.B. and Edward A.K. 2002. Environmental Sciences: Earth as a Living Planet. Wiley Publishers, ISBN 10.0471389145.
7.	Christopher, A.S. 2006. Alternative energy Political, Economic and Social Feasibility. Rowman& Littlefield, Maryland. ISBN 0-7425-4909-7.
8.	Krishnamurthy, K.V. 2003. Text Book of Biodiversity, Scientific Publishers Inc., USA. ISBN 1-57808-325-7
9.	Singh, R.B. and Suresh M. 1996. Environmental Law in India: Issues and Responses. Concept Publishing Company, New Delhi. ISBN 81-7022-575-2.
10.	Goodstein, E.S. 2011. Economics and the Environment. John Wiley & Sons Inc., USA ISBN 13-978-0-470-56109-6.

B.PHARM III SEMISTER

COURSE NO 301: HUMAN PHYSIOLOGY II

Learning objectives:

1. To impart the knowledge of the functions of endocrine glands and their role in various disease states and reproduction.
2. To understand the physiology of respiration and functioning of kidneys.
3. To develop the knowledge regarding functioning of central nervous system and peripheral nervous systems.
4. The knowledge imparted should help the students to understand the pharmacology of drugs.

Units	Contents	Hrs
Unit-1:	Endocrine glands: Adrenal, thyroid, parathyroid, pituitary, thymus and gonads,their hormones and physiology Knowledge on addison's disease, Hirsutism, Cretinism, Goiter, Myxedema, tetany, acromegaly	08
Unit-2:	Physiology of male and female reproductive systems, Production of gametes, sex differentiation, fundamental knowledge on puberty, menstrual cycle, conception, parturition and menopause knowledge on common chromosomal abnormalities.	06
Unit-3:	Central nervous system (CNS): Membrane potentials, nerve excitation and conduction, neurons, neuronal transmission, receptors. Fundamentals of anatomy of brain and spinal cord. Reflex action and reflex arc.	10
Unit-4:	Functions of cerebrum, cerebellum, thalamus, hypothalamus, midbrain, pons, medulla oblongata and cranial nerves. spinal cord and spinal nerves	08
Unit-5:	Reticular activating system, limbic system and their functions, sleep, EEG, ventricles of the brain, cerebrospinal fluid (CSF) and its circulation, blood brain barrier, epilepsy, anxiety, schizophrenia, depression, sleep, insomnia, parkinsonism	07
Unit-6:	Autonomic nervous system (ANS): Parasympathetic and sympathetic divisions of ANS. Fundamentals of anatomy of ANS – Physiology of ANS. Neurotransmittors-Chemical transmission, cholinergic and adrenergic nerves. Organs of special senses- taste, smell, touch, hearing and vision. Glaucoma, mydriasis, miosis, conjunctivitis, deafness.	08

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Unit-7:	Metabolism of carbohydrates, proteins, fats and minerals. Metabolic disorders- diabetes, thermoregulation- pyrexia, pain – inflammation-arthritis.	06
Unit-8:	Immune systems. Immuno component cells and their development – autoimmune disorders.	07

COURSE NO 302: HUMAN PHYSIOLOGY II PRACTICAL

Learning Objectives:

- **To impart knowledge practically on theory based aspects (tissues of various organ systems, microscopical knowledge, membrane potentials, nature of nerve and muscles, neurotransmitters and their role, Blood chemistry etc)**

List of Experiments:

1. Identification of permanent slides of heart ,liver ,lung ,pancreas ,stomach, small intestine, uterus, ovary ,testes ,skin ,eye, tongue, thyroid, adrenal gland ,T.S. of artery and vein ,kidney.
2. Microscopic examination of epithelial cells, muscular tissue, nerve fiber, cartilage.

Determination of following parameters in human blood and other experiments related on different organ systems:

3. Hemoglobin.
4. Blood group.
5. Coagulation time and bleeding time.
6. R.B.C.count.
7. W.B.C.count.
8. Differential leukocyte count.
9. Erythrocyte sedimentation rate (ESR)
10. Determination of fragility range of sheep R.B.C. in hypotonic saline.
11. Graphical recording of simple muscle twitch (SMT) with frog's gastronomous-sciatic muscle nerve preparation.
12. Effect of fatigue on SMT
13. Effect of cold Ringer(10 degrees centigrade) on SMT
14. Effect of warm ringer(forty degrees centigrade) on SMT
15. Genesis of tetanus on SMT
16. Determination of arterial blood pressure by Sphygmomanometer.
17. Determination of vital capacity of lungs.
18. Recording of normal heart beat of frog in situ
19. Recording of body temperature of humans with clinical thermometer.

Suggested Books:

1. Shambu lingam- Essentials of Physiology
2 .Ross & Wilson- Anatomy & Physiology in health and illness-Anne Waugh, Allison Grant
3. First Aid to the injured- Published by Saint John Ambulance Association.
4. A Treatise on Hygiene and Public Health, B.N. Ghosh, Calcutta Scientific Publishing Company.

Reference Books:

1. Text Book of Medical Physiology-Arthur.C Guyton
2. Samson Wright's Applied Physiology

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COURSE NO 303: PHARMACEUTICAL ANALYSIS –I (THEORY)

Learning objectives:

1. To emphasize the importance of quality in drugs & pharmaceuticals.
2. To establish the fundamental conventional methods of drug analysis used in laboratories.
3. To provide the knowledge regarding the principles of titrimetry and gravimetric techniques.
4. To give the basic principles of other analytical techniques used in analytical chemistry.
5. To teach applications of these analytical methods to drugs & pharmaceuticals.

Units	Contents	Hrs
Unit-1:	A general introduction to pharmaceutical analysis and general aspects of standardization of pharmaceutical chemicals and formulated products mentioned in Indian pharmacopoeia. Importance of proper sampling and general books for pharmaceutical standards like pharmacopoeias, National formularies. computation of analytical results, significant numbers, rejection of doubtful values with reference to volumetric and gravimetric analysis, sources of errors and calibration of analytical equipment used in volumetric and gravimetric analysis.	06
Unit-2:	Acid-Base titrations: theoretical basis of neutralization reactions including electrolytic dissociation, application of law of mass action, relative strength of acids and bases, hydrolysis of salts and buffer solutions, theory of neutralization indicators and factors involved in the selection of indicators for different types of acid-base titrations. Procedures involved in different types of titrations using strong acid, week base, strong base, week base and back titration with blank determination.	10
Unit-3:	Oxidation-reduction titrations: theoretical considerations including standard potentials, calculation of redox potentials, redox indicators, principle and procedure involved in different types of redox titrations using potassium permanganate, iodine. Titrations of released iodine and back titration of excess iodine, potassium iodate, ammonium ceric sulphate and titanous chloride. Precipitation titrations: principles and procedures involved in argentimetry, use of silver nitrate and ammonium thocyanate. Indicators used in precipitation titrations including adsorption indicators, Mohr's and volhard's methods with examples.	10
Unit-4:	Complexometric titrations: basic principles of complexometric analysis including theories of complex ions, chelating agents, properties of metal complexes with particular reference to EDTA. Basic principles of complexometric analysis including theories of complex formation. Werener's coordination number and structure of complex ions, chelating agents, properties of metal complexes with particular reference to EDTA, various examples of titrations of metal ions using disodium acetate, indicators and end point detection using indicators and by physical methods, masking and demasking agents, pharmaceutical applications of complexometry with particular reference to I.P.	08
Unit-5:	Non-aqueous titrations: principles, advantages and pharmaceutical applications, solvents reagents and indicators used in nonaqueoustitrimetry, other methods of detecting end points. Examples of titrations of alkali metal and alkaline earth metal salts of organic acids, primary, secondary and tertiary amines, halogen acid salts of bases, titration of acidic substances.	06
Unit-6:	Principles and procedures involved and application of nitrite titrations, titrations using 2, 6-dichlorophenol-indophenol. Aquametry including use of Karl-fisher reagent and moisture balances. Drying and distillation, oxygen flask combustion method of analysis.	06
Unit-7:	A detailed study of gravimetric analysis including principles involved, critical factors and typical methods involving precipitation, coagulation, digestion, filtration and incineration procedures with suitable examples. Advantages and disadvantages, sources of errors and their elimination in gravimetric analysis.	06
Unit-8:	Gas analysis: principles of gas analysis, use of hempel's gas burette and pipette, nitrometer, haldome's and orset's gas analysis apparatus and their operations. Examples of gas analytical methods of pharmaceutical significance.	06

Text books:

1. Indian pharmacopoeia
2. practical pharmaceutical chemistry by A.H. Becket and Stenlake.

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COURSE NO 304: PHARMACEUTICAL ANALYSIS –I (PRACTICAL)

Acid-base titrations
1. Standardization of HCl 2. Standardization of H_2SO_4 3. Standardization of NaOH
4. Assay of boric acid 5. Assay of sodium bicarbonate 6. Assay of borax 7. Assay of calcium hydroxide 8. Assay of zinc oxide 9. Assay of calcium carbonate 10. Assay of acetyl salicylic acid 11. Assay of formaldehyde 12. Assay of NaOH in presence of sodium carbonate.

Redox titrations:
13. Standardization of iodine 14. Standardization of $KMnO_4$
15. Assay of ferrous sulphate 16. Assay of hydrogen peroxide 17. Assay of sodium nitrate18. Estimation of ascorbic acid with 2,6-dichlorophenol indophenol 19. Assay of mercuric chloride 20. Assay of sodium metabisulphite 21. Assay of copper sulphate

Precipitation titrations
22. Standardization of silver nitrate
23. Assay of potassium chloride 24. Assay of ammonium thiocyanate 25. Assay of mercuric oxide

Complexation titrations
26. Standardization of EDTA
27. Assay of calcium gluconate injection/tablets 28. Assay of aluminiumsulphate

Non-aqueous titrations
29. Assay of thiamine hydrochloride

Gravimetry
30. Determination of sulphate as barium sulphate 31. Estimation of magnesium as magnesium pyrophosphate 32. Determination of thiamine as silico tungstate

Limit tests
33. Limit test for chlorides 34. Limit test for sulphates
35. Limit test for iron

COURSE NO 305: PHYSICAL PHARMACY – II

A study of the applications of physico – chemical properties to pharmacy with special reference to the following

Learning objectives:
1. To acquaint the students with the fundamental principles & their applications with reference to Pharmacy.
2. To study the Solubility, distribution and interfacial phenomena of liquids.
3. To impart the knowledge onthe rheology and micromeritics.
4. To study kinetics and methods of stabilization and accelerated stability

Units	Contents	Hrs
Unit-1:	Solubility and distribution phenomena: Solvent – solute interactions, solubility of gases in liquids, liquids, solids – factors influencing solubility – methods of increasing solubility, distribution coefficient significance of distribution coefficient.	08
Unit-2:	Complexation: Types of complexes, methods of analysis. Complexation and drug action.	06
Unit-3:	Kinetics: Rates and orders of reactions, determinations of order of a reaction influence of temperature and other factors on reaction. Decomposition of medicinal agents. Methods and principles of stabilization. Accelerated stability analysis – principles and methods. An introduction to ICH guidelines.	08
Unit-4:	Interfacial phenomena: Liquid interfaces, adsorption at liquid interfaces. Surface active agents classification, properties, applications HLB. Adsorption at solid interfaces. Electric properties at interfaces – Zeta potential and its importance.	08
Unit-5:	Colloids. Types, methods of preparation, properties, protective colloid action, Solublization. Gels, Structure, properties and applications.	07
Unit-6:	Coarse dispersions: Emulsions, Suspensions and semisolids. Suspensions – interfacial properties of suspended particles, setting in suspensions. Formulation and evaluation of flocculated and deflocculated suspensions. Emulsions: Theories of emulsification, physical stability of emulsions, preservation of emulsions, rheological properties of emulsions, suspensions and semisolids.	09

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Unit-7:	Rheology: Newtonian systems. Thixotropy measurement and its applications in pharmacy. Determination of viscosity, viscometer.	06
Unit-8:	Micromeritics: Particle size and size distribution, methods of determining particle size particle shape, particle number, surface area – methods of determining surface area, derived properties of powders – their significance.	08

Text Books:

1. Physical Pharmacy by Alfred Martin; 2. Tutorial Pharmacy by Cooper and Gunn, edited by S.J. Carter, 3. Remington's Practice of Pharmaceutical Sciences.

COURSE NO 306: PHYSICAL PHARMACY – II – PRACTICAL

1. Determination of solubility of drugs in single and mixed solvents; 2. Construction of phase diagram for the system of methyl salicylate – isopropanol water; 3. Determination of partition coefficient of benzoic acid in peanut oil – water system, 4. Influence of additives (glycerol in aqueous phase) on the partition coefficient; 5.Study of Complexation of copper and glycine by pH titration method; 6.Determination of rate constant of a first order reaction, 7.Determination of rate constant of second order reaction, 8.Determination of surface and interfacial tensions; 9.Determination of CMC of a surfactant by capillary rise principle; 10.Determination of HLB of a surfactant; 11.Determination of Cloud and Kraft point, 12.Study of adsorption of oxalic acid on charcoal – construction of adsorption isotherms, 13.Influence of suspending agent on the sedimentation parameters in a suspension; 14.Determination of degree of flocculation in a suspension; 15.Determination of particle size by gravity sedimentation Andreason's Apparatus; 16.Determination of globule size and size distribution in an emulsion; 17.Study of physical stability of selected emulsions; 18.Preparation of colloids 9 (lyophilic and lyophobic) and study of protective colloidal action; 19.Determination of bulk and true density (by liquid displacement method) of crystalline solids; 20.Micromeritic studies on tablet granulations – determination of bulk and granule densities, angle of repose, compressibility index, influence of glidants on flow properties.

COURSE NO 307: PHARMACEUTICAL CHEMISTRY-III (ORGANIC-II) THEORY

Learning objectives:

1. To develop the linkage between organic molecules and their transformation to the drug molecule.
2. To develop the ability to name drugs having various structural features
3. To expose students towards different chemical classes of compounds and their relationships according to their biological activity.

Units	Contents	Hrs
Unit-1:	Benzene and aromaticity: Modern structure of benzene aromaticity. Huckels rule, Nomenclature of benzene derivatives, Electrophilic substitution reactions – mechanisms of nitration, halogenation, sulphonation and Friedel-crafts alkylation, Theory of reactivity and orientation in mono substituted benzenes, preparation and uses of gamma benezene hexachlorilde, saccharine and chloramines-T.	10
Unit-2:	Aldehydes and Ketones: Nomenclature, general methods of preparation, structure versus reactivity, Nucleophilic addition reactions, acidity of alpha-hydrogens and carbanion addition reactions. Haloform reaction of methyl ketones. Preparation and uses of formaldehyde, paraformaldehyde, acetaldehyde, paraldehyde, acetone, chloral hydrate, benzaldehyde, cinnamaldehyde, vanillin	10
Unit-3:	Sulphonic acids. Methods of preparation and uses of alkyl and aryl Sulphonic acids – sodium lauryl sulphate	05
Unit-4:	Functional derivatives of carboxylic acids – Nucleophilic acyl substitution reactions; preparation of acid chlorides, amides, anhydrides and ester from acids. Nucleophilic acyl substitution reactions – preparation and uses of ethyl acetate, diethyl phthalate, methyl salicylate, ethyl acetate and aspirin. Preparation and synthetic uses of malonic ester and aceto acetic ester.	08
Unit-5:	Phenols. General methods of preparation, acidity, characteristic reactions. Preparation and uses of phenol, catechol, resorcinol, hydroquinone and pyrogallol. Aryl-halides – Nucleophilic aromatic sybstitution. General methods of preparation, reactivity of aryl halides, nucleophilic aromatic substitution reactions.	08
Unit-6:	Amines: General methods of preparation, basicity of amines, characteristic reactions of amines, separation of different classes of amines, Ring substitution in aromatic amines, quaternary ammonium compounds, preparation and uses of ethonalamine, aniline, acetanilide, urea and tetrabutyl ammonium hydroxide, cetyltrimethyl	08

	ammonium bromide.	
Unit-7:	Diazonium compounds: preparation, reactions and uses. Polynuclear aromatic compounds: structure and reactions of naphthalene, anthracene and phenanthrene.	06
Unit-8:	Name reactions: Mannich reaction Micheal addition, Beckmann rearrangement, Fries rearrangement, Bayer-villiger oxidation.	05

TEXT BOOKS:

2. Organic chemistry by Morrison and Boyd
3. Bently and Dirver's Textbook of pharmaceutical Chemistry
4. Organic Chemistry, Vol. I, by I.L. Finar.

B.PHARM IV SEMESTER

COURSE NO 401: APPLIED STATISTICS

Learning objectives:

1. To provide the knowledge on the applications of statistics.
2. To impart the knowledge in performing general calculations involved in various disciplines of Pharmacy using spread sheet.
3. To provide the information on correlation and regression
4. To provide the knowledge on the probability and its distributions.
5. To enable students to understand about the hypothesis testing, utilization of parametric and non parametric tests.

Units	Contents	Hrs
Unit-1:	A study of the following with reference to Pharmaceutical Sciences Applications of statistics in pharmaceutical sciences Scales of measurement (nominal, ordinal, interval, ratio)	08
Unit-2:	Definitions, Concept, Applications, merits and demerits of mean, median, mode, standard deviation, relative standard deviation, variance, coefficient of variation, skewness, kurtosis.	10
Unit-3:	Definition and concept of precision, accuracy, mean error, relative error, significant numbers. Concept, applications, properties, calculations involved in correlation (Pearson's correlation coefficient, Spearman's rank correlation coefficient) and regression (linear regression, least square method)	10
Unit-4:	Probability: Definitions (Random event, Elementary event, Exhaustive event, mutually exclusive events, complementary events, independent events, classical and modern definitions of probability, random variable.)	07
Unit-5:	Addition theorem, Multiplication theorem, Baye's theorem	05
Unit-6:	Probability distributions such as normal, binomial and poisson distributions. Sampling distribution, standard error, confidence limits.	06
Unit-7:	Elements of sampling theory: Definitions and concepts of population, sample, discrete variable, continuous variable, different sampling methods	07
Unit-8:	Testing of hypothesis: Definition and concept of null hypothesis, types of error, level of significance, criterion value, Z test and t test	07

Text Books:

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1. Comprehensive Statistical Methods, by P.N.Arora, SumeetArora, and S. Arora (S. Chand & company)
2. Miller & Freund's Probability and statistics for engineers by Richard A. Johnson, (Pearson Education Publishers)
3. Statistics – Theory, Methods and Application by DC Sancheti and VK Kapoor()(Sulthan and chand&sonsPublishers)

Reference Book:

1. Pharmaceutical Statistics by S. Bolton
2. Biostastics and computer applications by G N.Rao and N.K Tiwari published by pharma book syndicate.

K. Sambha murthy, CVS, Paradhar

COURSE NO 402: PHARMACEUTICAL ENGINEERING – I

A study of the following topics with particular reference to pharmaceutical industry.

Learning objectives:

1. To create awareness regarding the unit operations involved in Pharmaceutical industry.
2. To provide overview of Pharmaceutical machineries.
3. To enable students in selecting proper equipment for material processing in Pharma. Industry
4. To educate learners about hazards and safety aspects in industrial environment.

Units	Contents	Hrs
Unit-1:	Fluid Flow: Definitions, Material balance, energy balance, Bernoulli's equation, stream line and turbulent flow, Reynolds number, roughness of pipe surfaces, energy loses in flowing fluids through pipes. Measurement of pressure and fluid flow. Different types of manometers, orifice meter, venture meter, pilot tube and Rotameter. Solutions to simpler numerical problems.	08
Unit-2:	Transportation of fluids: Pipe fittings and valves. Pumping equipment, reciprocating pumps, diaphragm pumps, centrifugal pumps, rotary pumps and compressors. Use of compressed air, air lift pumps, screw pumps, monopump and peristaltic pump. Water supply and maintenance of water at different temperatures.	08
Unit-3:	Heat transfer: Introduction, conduction, Fourier's law, conduction through plain and cylindrical surfaces, compound resistances. Heat transfer from condensing vapours. Drop wise and film type condensation. Properties of steam, Heat exchangers. Parallel and counter current flow. Radiation, Stephan's and Kirchoff law, Physical nature of surfaces. Heat conservation and insulation. Requirements of a good conductor.	10
Unit-4:	Evaporation: General principles, methods of supply of heat, types of evaporators, jacketed evaporators, film evaporators, forced circulation evaporators, evaporator accessories, wet and dry condensers, vacuum pumps, gauzes, steam traps.	06
Unit-5:	Distillation: Theory applied to binary mixtures, boiling point and equilibrium diagrams, constant boiling mixtures, equilibrium distillation, differential distillation, steam distillation, rectification, distillation stills, automatic water stills, molecular distillation and its application.	08
Unit-6:	Filtration: Filtration media and filter aids, types of filters, filter presses, rotary continuous filter and Meta filters. Sterile filtration of liquids, air filters. Filter operation, effect of pressure and temperature on rate of filtration, compressibility of filter cake, elementary theory of filtration, solutions of simpler numerical problems. Centrifuges, theory and equipment and applications.	08
Unit-7:	Materials of construction. Consideration of mechanical properties, corrosion and contamination. Consideration of ferrous metals and their alloys. Non – ferrous metals like copper, tin, lead, nickel, zinc, silver and platinum.	06
Unit-8:	Non – metallic materials like stone ware, wood, glass, rubber and plastics. Materials of Pharmaceutical packaging; Industrial hazards and safety precautions; Mechanical, chemical, electrical, fiber and dust hazards. Safety requirements, fire extinguishers, industrial dermatitis.	06

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Text Books:

1. Introduction to Chemical Engineering by Water L. Badger and Julius T. Banchero; 2. The Theory and Practice of Industrial Pharmacy by Leon Lachman, H.A Lieberman and Joseph L. Kanig; 4. Tutorial Pharmacy – Cooper and Gunn 5. Pharmaceutics, The Science of Dosage Form Design, edited by Michael E.Aulton.

COURSE NO 403: PHARMACEUTICAL MICROBIOLOGY

Learning objectives:

1. To emphasize microbiological aspects of Pharmaceutical importance.
2. To deal with the various aspects of microorganisms, their classification cultivation, identification etc.
3. To provide the thorough knowledge of disinfection and sterilization methods.
4. To give an idea regarding immunological aspects, their significance.
5. To outline the importance of subject in useful diagnostic tests.
6. To provide the knowledge about the use of microbiological techniques in quantification/standardization of selected Pharmaceuticals.
7. To help in providing idea about infectious diseases diagnosis and their control.

Units	Contents	Hrs
Unit-1:	History, branches of microbiology and importance of pharmaceutical Microbiology. Contribution of Antony Van Leeuwenhoek, Robert Koch, Louis Pasteur and Alexander Fleming. Microscopy – Principle and description of light microscopes and electron microscope	06
Unit-2:	Structure of procaryotic and eucaryotic cells and their comparison. Theory of staining, simple, Gram's, acid fast, negative, flagella and spore staining methods. Study of morphology, broad classification of bacteria, yeasts, actinomycetes, fungi, viruses and life cycle of bacteriophage. Types and preparation of media for bacterial, fungal and actinomycete cultures.	08
Unit-3:	Different methods of isolation and preservation of microbial cultures. System of identification of bacteria – preliminary criteria for identification, some biochemical tests – Fermentation of carbohydrates, nitrate reduction, starch hydrolysis and gelatin liquefaction, H_2S production. Study of bacterial growth – Growth, generation time, growth rate and growth curve. Techniques for quantitative measurement of bacterial growth (viable and total counts). Synchronous and continuous growth. Effect of UV light, temperature, pH, osmotic pressure, salt concentration and metal ions on bacterial growth.	10
Unit-4:	Sterilization methods: Moist heat, dry heat, filtration, gaseous and radiation methods. Sterilization indicators. Principle and significance of test for sterility. Concept of asepsis and maintenance of aseptic conditions. General principles of antibiotics, clinically useful antibiotics, mode of action, sensitivity tests and antibiotic resistance. Dynamics of disinfection, merits and demerits of different disinfectants, commonly used disinfectants, their mechanism of action. Evaluation of	10

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	disinfectants (Rideal Walker and Chick Martin coefficients and their limitations)Introduction to microbiology of water and milk. Bacteriological examination for assessment of the quality of milk and water.Microbial limit tests for *E. coli* and *Pseudomonas*.	
Unit-5:	Immunity: Definition of antigen and antibody, types of antigens and antibodies, classification of immunoglobulins, types of immunity. Antigen-antibody reactions (agglutination, precipitation, neutralization and complement fixation). Hyper sensitive types of reactions. Definition of infection, non-specific defence mechanisms, bacterial toxins, virulence and virulence factors and attenuation.	07
Unit-6:	Methods of transmission of communicable and infectious diseases, carriers, vectors and reservoirs.General methods of immunization against diseases.	06
Unit-7:	Study of etiology, diagnosis, sources of infection, mode of trasmission, immunization methods, prevention and control of the following diseases, Bacillary dysentery, typhoid, cholera, amoebiasis. syphilis, gonorrhoea, AIDS, tetanus, diphtheria, tuberculosis, leprosy, food poisoning and infective hepatitis.	07
Unit-8:	Genetic recombination – Bacterial conjugation, transformation and transduction. Mutation, mutagens, mechanism of mutation, types of mutations, isolation of nutritional and antibiotic resistant mutants.	06

COURSE NO 404: PHARMACEUTICAL MICROBIOLOGY - PRACTICALS

List of experiments:

1.Preparation of nutrient broth; 2. Preparation of nutrient agar; 3.Inoculation of bacteria; 4.Isolation of pure cultures; 5.simple staining; 6. Gram's staining; 7.Motility of bacteria; 8.Spore staining; 9.Oligodynamic action of copper; 10.Liquefaction of gelatin; 11. Starch hydrolysis; 12. Nitrate reduction;13. H_2S production 14.Phenol coefficient; 15.Chick Martin coefficient;16.Viable count; 17.Fermentation of carbohydrates; 18.Microbiology of water; 19.Microbiology of milk; 20.Antibiotic sensitivity test; 21. Morphology of yeast, fungi and actinomycetes

Text books and Reference books:

1. Microbiology by Pelczar, M.J. Reid, R.D. and Chan, E.S. Tata McGraw Hill Publishing Co. Ltd.,
2. Medical microbiology edited by Robert Cruick Shank. ELBS edition.
3. Bentley's text book of pharmaceutics
4. Pharmaceutical microbiology by Harrish M. Baillere, Tindal and Co., London.
5. Tutorial Pharmacy by Cater S.J. Kothari Book Depot, Bombay.
6. Pharmaceutical microbiology edited by Hugo and Russel, P.g. publishing company Ltd., New Delhi

COURSE NO 405: APPLIED BIOCHEMISTRY

Learning objectives:

1. To impart broad understanding of molecular level of chemical process associated with living cells
2. To develop the knowledge regarding enzymes and its related issues.
3. To provide idea about metabolic processes involved in illnesses.

Units	Contents	Hrs
Unit-1:	Brief chemistry of carbohydrates, lipids, proteins and nucleoproteins and detailed metabolism of the above.	10
Unit-2:	Outlines of the mechanism of protein synthesis, metabolism and genetic regulation	08
Unit-3:	Outlines of biochemistry of cell division and metastasis	06
Unit-4:	Biochemistry of important body fluids	06
Unit-5:	Principles involved and apparatus used in the analysis of blood and urine and interpretation of results	10
Unit-6:	Enzymes: Classification, mode of action, factors affecting the enzyme action and co-enzymes.	08
Unit-7:	Brief outline of energy and phosphate metabolism and detoxification mechanisms of the body. Principles involved in biological oxidation.	08
Unit-8:	The biochemical role of vitamins and hormones-principles of nutrition and dietetics	08

Books suggested

1. Review of Physiological Chemistry by Harold,A Harper;
2. Textbook of Biochemistry by West, Todd, Manson, Van Bruggen.

Reference Books:

1. Hawk's Physiological Chemistry by Bernard L.Oser;
2. Biochemistry by Albert Lehninger.

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COURSE NO 406: APPLIED BIOCHEMISTRY PRACTICAL

1. General tests for identification of carbohydrates, proteins and lipids;
2. Qualitative examination of urine for normal and abnormal constituents;
3. Quantitaive estimation of glucose in urine
5. Quantitaive estimation of glucose in blood ;
8. Quantitative estimation of cholesterol in blood;
9. Estimation of triglycerides in blood ;
10. Estimation of blood urea nitrogen;
11. Estimation of SGPT and SGOT in blood ;
12. Estimation of bile pigments in blood ;
13. Effect of temperature, pH and inhibitors on amylase enzyme activity

COURSE NO 407: PHARMACOGNOSY AND PHYTOCHEMISTRY-I

Learning objectives:

1. To train the students in medicinal plants cultivation, collection, processing and storage of crude drugs.
2. To introduce the microscopical and morphological charactars, chemical nature, tests for identification, adulterants, substituents and uses of the following drugs Leaves, Flowers, Barks and seeds

Units	Contents	Hrs
Unit-1:	Introduction ,development, present status and future scope of pharmacognosy; Classification of crude drugs : Alphabetical, morphological, taxonomical, chemical and therapeutic; Cultivation, collection, processing and storage of crude drugs. Factors influencing cultivation of medicinal plants. Types of soils and fertilizers of common use.	12
Unit-2:	A study of mineral drugs, fossil organisms, Diatomite, chalk, kaolin, bentonite, Fuller's earth. A study of commercial fibers, their sources, preparation, characters, chemical tests, uses, etc.-Cotton, cellulose, regenerated cellulose, Jute, Wool, Silk, Nylon; Starch – manufacture and general characteristics of wheat, potato, maize and rice starches, soluble starch, dextran.	08
Unit-3:	Microscopical and macroscopical characters, varieties, cultivation, collection, principal, constituents, chemical nature, tests for identification, adulterants, substituents and uses of the following drugs. **Leaves**: Eucalyptus, senna, adhatoda, digitalis, squill and datura.	06
Unit-4:	Microscopical and macroscopical characters, varieties, cultivation, collection, principal, constituents, chemical nature, tests for identification, adulterants, substituents and uses of the following drugs **Flowers**: Cloves, pyrethrum, saffron	06
Unit-5:	Microscopical and macroscopical characters, varieties, cultivation, collection, principal, constituents, chemical nature, tests for identification, adulterants, substituents and uses of the following drugs **Fruit** : Fennel, cumin, coriander, ajowan, dill, caraway, orange, lemon and capsicum.	08
Unit-6:	Powders of natural occurrence: Lycopodium,pollen,kamala,lupulin; Entire organisms:Carrageenan,ergot,penicillin,ephedra,belladonna,lobelia,pepper mint,vinca and leech.	07
Unit-7:	Microscopic characters, cultivation, collection, commercial varieties, adulterants, chemical constituents and uses of the following drugs. **Barks** : Cinchona, cinnamon, cascara segrada, kurchi, wild cherry,quillaia.	06
Unit-8:	Microscopic characters, cultivation, collection, commercial varieties,	07

	adulterants, chemical constituents and uses of the following drugs Seeds: Nux vomica, strophanthus, linseed, ispaghula, castor,areca nut, colchicum.Woods: Quassia, Sandal.	

Recommended Books:

1. Atal,CK and Kappor,BM.Cultivation and Utilisation of Medicianl Plants.
3. Trease,CE and Evans,WC. Textbook of Pharmacognosy.11th to 14th Editions. Tindal L., U.K.
4. Tyler,VC Brady, LR and Robers JE.Pharmacognosy.8th Edition, Lea &Febeger, Philadelphia.
5. Wallis,TE. Textbook of Pharmacognosy,5thEdition,J&A,ChurchillLimited,U.K.
6. Kokate,CKPurohit,AP. And Gokhale,SB.Pharmacognosy.

COURSE NO 408: PHARMACOGNOSY AND PHYTOCHEMISTRY-I PRACTICAL

Organoleptic examination, description and microscopical examination of the drugs mentioned below

Powders: Lycopodium, Kamala; Starches: Wheat, potato, rice and maize; Leaves: Eucalyptus, senna, datura, adhatoda and digitalis; Barks:Cinnamon,cinchona,cascara and kurchi, Wood: Quassia;Seeds: Nux-vomica, linseed; Fruit: Fennel, coriander, cumin, cloves.

Identification of crude drugs studied in theory in their "entire" and "broken" condition by their gross characters and by qualitative tests.

Books Recommended.

1.Wallis,TE AnalyticalMicroscopy,J&A,ChurchillLimited,U.K.
2. Kokate,CK. Practical Pharmacognosy.
3.Lalla,PK. Practical Pharmacognosy,Lina,Calcutta,1981.

B.PHARM V SEMISTER

COURSE NO 501: PHARMACEUTICAL BIOTECHNOLOGY

objectives:

1. To impart knowledge on various biological products, preparation, storage and uses.
2. To gain knowledge on preparation, storage and useof blood and blood products. To impart the knowledge on preparation, standardization and storage of various immunological preparations.
3. To impart knowledge on fermentative production, recovery and uses of selected products.
4. Knowledge on sterility testing and its importance, RIA, and ELISA techniques.
5. Fundamentals of microbial production of useful enzymes and immobilization of enzymes, microbial transformations.
6. Basics of recombinant DNA technology, hybridoma technology- their application in production of therapeutically useful products.
7. Introduction to bioinformatics.

Units	Contents	Hrs
Unit-1:	Animal products: I) Insulin – Extraction, Purification and types of formulations II) Preparation and uses of Pancreatin, Pepsin, Heparin, Thyroid and Liver preparations as per I.P Blood products & Plasma substitutes: Prepartion, uses and storage of the following, Whole human blood, Dried human plasma, human gamma globulins, clinical dextran and absorbable haemostats.	06
Unit-2:	Immunological products Preparation & standardization of the following; Vaccines – BCG, DPT, Poliomyelitis and Typhus. Toxoids – Diphtheria and Tetanus. Antitoxins – Diphtheria and Gas-gangrene	10
Unit-3:	**Fermentation Products** Introduction to fermentation, aerobic and anaerobic, surface, submerged and solid state fermentations and fermentation media. Design and operation of industrial fermenter. Fermentative production, recovery and uses of the following. I) Antibiotics - Penicillin and Streptomycin II) Organic acids - Citric and Lactic acids III) Solvents - Alcohol IV) Vitamins - Vitamin-B_{12} V) Miscellaneous - Lactobacillus spores	10

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Unit-4:	Test for sterility: Sterility testing media, sampling, neutralization of various antimicrobial substances in dosage forms, conducting the tests for injections, surgical sutures (Catgut), cotton, tubings and bottles. Principles of microbiological assay of amino acids, vitamins and antibiotics. Detailed assay of lysine, vitamin-B_{12} and penicillin.	**09**
Unit-5:	Radioimmunoassay (RIA): Principle and applications. Estimation of insulin in blood by RIA. ELISA: Principle and applications	**04**
Unit-6:	Enzymes, Enzyme immobilization and microbial transformations 1. Enzymes: Sources and general methods of preparation Preparation of fungal diastase. Applications in pharmaceutical industry, therapeutics and clinical assays 2. Immobilization: Advantages and limitations, techniques of immobilization of enzymes and cells. 3. Microbial transformations. Advantages, different types of microbial and steroid Conversions	**7**
Unit-7:	**Recombinant DNA technology** 1. Introduction to genetic engineering. Brief description of (a) Restriction of DNA (b) Ligation of DNA (c) Introduction into host cells (d) Recombinant selection (e) Use of the plasmids and bacteriophages as cloning vehicles, artificial plasmid vectors, cosmids and phasmids (f) Agarose gel electrophoresis, southern, northern and western blotting. 2. Applications of R-DNA technology: Production of human insulin and hepatitis B vaccine. Hybridoma technology. Production of monoclonal antibodies and their applications.	**10**
Unit-8:	Bioinformatics. Introduction, scope and applications	**04**

Text books and Reference books:

1. Bentley's text book of pharmaceutics by Herold Davis - 7th and Latest edition
2. The microbiological assay of Vitamin B-complex and amino acids by E. C. Barton – Wright, Sir Issac Pitman and Sons Ltd., London
3. Analytical microbiology by Kavanagh, Academic press
4. Tutorial pharmacy by Cooper and Gunn
5. Indian Pharmacoepoeia, Volume-I, 2010 Edition
6. Remington's Pharmaceutical Sciences
7. Pharmaceutical biotechnology by Vyas and Dixit. BS Publications & distributors. New Delhi.
8. Pharmaceutical Biotechnology by K.Sambamurthy&Ashutoshkar, New age international publishers.
9. Industrial microbiology by L.E. Casida JR., New age international publishers
10. Principles of gene manipulation by Primrose, Twyman, 6th Edition, Blackwell
11. Foundation in Pharmaceutical Biotechnology by B.P. Nagori and Roshanlssarani published by Pharma book syndicate.

COURSE NO 502: PHARMACEUTICAL BIOTECHNOLOGY PRACTICALS

List of experiments.

1. Sterilization by autoclaving and test for sterility;
2. Sterilization by dry heat and test for sterility.
3. Sterilization by heating with bactericide and test for sterility.
4. Sterilization by gas and test for sterility;
5. Test for sterility of commercial dextrose injection I.P
6. Test for sterility of preparation containing sulphanilamide.
7. Preparation and standardization of a bacterial vaccine
8. Fermentative production of penicillin/Neomycin (Demonstration)
9. Fermentative production of glutamic acid (Demonstration);
10. Microbiological assay of penicillin including construction of standard curve.
11. Test for presence of fungi in tap water.
12. Determination of minimum inhibitory concentration of phenol;
13. Immobilization of microbial cells by entrapment in sodium alginate;
14. Isolation of DNA from bacteria (Demonstration).

COURSE NO 503: PHARMACEUTICAL CHEMISTRY-IV (MEDICINAL CHEMISTRY - I) THEORY

Learning objectives:

1. To develop the linkage between organic molecules and their transformation into the drug molecule

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2. To develop the ability to name drugs having various structural features.
3. To expose students towards different chemical classes of compounds and their relationships according to their biological activity

Units	Contents	Hrs
Unit-1:	History, introduction and development of medicinal chemistry, nomenclature of drugs. Heterocyclic compounds. Nomenclature and numbering of heterocyclic systems, general methods of preparation and important reactions of five membered and six membered heterocyclic systems-pyrrole, furan, thiophene, pyridine, quinoline, isoquinoline and indole	06
Unit-2:	Acquaintance with the following heterocyclic systems commonly encountered in therapeutic agents with suitable examples Aziridine, thiadiazole, oxazole, isoxazole, thiazole, imidazole, pyrazole, pyridazine, pyrimidine, piperazine, piperidine, benzothiazole, purine, benzimidazole, indole, benzothiadiazine, pteridine, pthalazine, quinazoline, quinoline, isoquinoline, benzopyran, benzodiazipines, phenothiazine, aciridine, thiaxanthene	10
Unit-3:	Study of the classification, mode of action, structural activity realationship (wherever applicable) and synthesis of specified members of the following classes of drugs. General anaesthetics: Halothane, thiopental sodium and diethyl ether Sedatives and hypnotics. Phenobarbital, buspirone, diazepam, alprazolam Anticonvulsants: phenytoin, valproic acid, etho suximide, carbamazepine . Central voluntary muscle relaxants: mefenecin, methocarbamol	10
Unit-4:	Study of the classification, mode of action, structural activity realationship (wherever applicable) and synthesis of specified members of the following classes of drugs. Analgesics. Narcotic analgesics-derivatives of morphin, morphinan, phenylpiperidine, benzazocine, diphenyl propylamine and isosters. Narcotic antagonists-morphine derivatives, miscellaneous compounds, antitussives and expectorants. Synthesis of meperidine, methadone, pethidine and propoxiphen.	08
Unit-5:	A study of the classification, mode of action, structural activity realationship (wherever applicable) and synthesis of specified members of the following classes of drugs Nonsteroidal anti-inflammatory analgesics and antipyretics-paracetamol, asprin, indomethacin, diclophenac sodium, ibuprofen and piroxicam	06
Unit-6:	A study of the classification, mode of action, structural activity realationship (wherever applicable) and synthesis of specified members of the following classes of drugs. Analeptics: Nikethamide, picrotoxin, pentelene tetrazole, ethamiban, doxapram Antipsychotic agents: chloropromazine, promethazine, thiothexene and haloperidol. Antidepressants: imipramine, desipramine, amitryptiline, isocarboxazide phenelzine	07
Unit-7:	A study of the classification, mode of action, structural activity realationship (wherever applicable) and synthesis of specified members of the following classes of drugs 1. Diagnostic agents: Radio-opaques, agents for kidney function and liver function tests, miscellaneous agents. 2. Local anaesthetics: benzocaine, procaine, lignocain and dibucaine.	07
Unit-8:	A study of the classification, mode of action, structural activity realationship (wherever applicable) and synthesis of specified members of the following classes of drugs Antihistaminic agents diphenhydramine HCl, chloropheniramine, chlorcyclizine, cetrizine, meperamine, ranitidine and omeprazole Antidiabetic agents: Insulin and its preparations, tolbutamide and glibenclamide	06

TEXT BOOKS:

1. Wilson and Gisvold, Textbook of organic, Medicinal and Pharmaceutical Chemistry
2. Bently and Driver's Textbook of Pharmaceutical Chemistry
3. Remington's Practice of Pharmaceutical Sciences.
4. Medicinal chemistry by Nadendla Rama Rao Published by Pharma book syndicate.

Reference Books

1. Organic Chemistry, Vol. I. By I.L.Final
2. Essentials of Medicinal Chemistry by Karlkovas
3. Medicinal Chemistry, Vol. I,II and III. By A.Burger

Indian Pharmacopoeia

(MEDICINAL-II)

PRACTICALS

1. Preparation of drugs including heterocyclic compounds involving two or more steps like: Benzimidazole, 3,4-dihydroxy-4-oxo-phthalazine, Benztriazole, 1,2,3,4-tetrahydrocarbazole, 6-methyl uracil, 7-hydroxy-4-methyl coumarin,3-methyl-1-phenyl-5-pyrazolone, Benzoin, Diphenylhydantoin, Chlorbutol.
2. Identification tests for selected drugs.
3. Analysis of formulations containing selected drugs like meprobamate, phenytoin, ibuprofen, chlorpromazine, lignocaine, oxyphenbutazone, diphenhydramine.

COURSE NO 505: PHARMACEUTICAL ENGINEERING – II

A study of the following unit operations as applied to Pharma Industry.

Learning objectives:

1. To create awareness regarding the unit operations involved in Pharmaceutical industry.
2. To provide overview of equipment used in a pharmaceutical industry.
3. To enable students in selecting proper equipment for material processing in Pharma. Industry
4. To educate learners about hazards and safety aspects in industrial environment.

Units	Contents	Hrs
Unit-1:	Drying: Introduction, classification of drying equipment - static bed, moving bed and fluidized bed systems – spray dryer, infrared drying, freeze drying, choice of dryers. Factors influencing the rate of drying, Mechanism of drying with carrier gas, typical drying curve.	10
Unit-2:	Crystallization : Crystal forms and Crystal habbit – supersaturation and formation of crystals and crystal growth. Mier's supersaturation theory of Crystallization and its limitations, solubility curves	08
Unit-3:	Mixing: Solid – solid mixing mechanism of mixing. Mixers: V type, drum, paddle and Rotocube mixers – selection of mixer, mixing of viscous masses: kneading machines and ointment mills.	07
Unit-4:	Liquid – liquid and gas – liquid mixing equipment. Impellers – their characteristics and field of operation.	07
Unit-5:	Size reduction : Classification of equipment – cutting roll, edge runner and end runner mills, disintegrators, hammer mills, ball and tube mills, colloid mills – impact mills, fluid energy mill,	07
Unit-6:	Choice of size reduction machinery – theory of size reduction. Energy for size reduction. Size separation: Screens and screening equipment – air and hydraulic separators, sedimentation, particle size distribution and its measurement – representation of data.	07
Unit-7:	Refrigeration: Principles and equipment, choice of refrigerant, coefficient of performance. Humidity control: Definition, methods of monitoring and drying gases – air conditioning, cooling towers – wet and dry bulb hygrometry, study of air handling systems.	07
Unit-8:	Extraction: Principles of solid – liquid and liquid – liquid extraction, equipment, diffusion batteries – extraction of towers – Podbielniak extraction	07

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Text Books

1. Introduction to Chemical Engineering by Walter L. Badger and Julius T. Banchero.
2. Elementary Chemical Engineering by Max S. Peters.
3. The theory and practice of Industrial Pharmacy by Leon Lachman, H.A. Lieberman and Joseph L. Kanig.
4. Pharma ceutical engineering by K.Sambamurthy published by New age international (P) LTD. Publishers
5.

COURSE NO 506: PHARMACEUTICAL ENGINEERING – II

PRACTICAL

I. Determination of radiation constant of brass, iron, unpainted and painted glass (4 experiments).
II. Steam distillation – To calculate the efficiency of steam distillation.
III. To determine the overall heat transfer coefficient.
IV. Construction of drying curves (for calcium carbonate and starch).
V. Determination of moisture content and loss on drying.
VI. Determination of humidity of air – i) From wet and dry bulb temperatures – use of humidity chart, II) Dew point method.
VII. Surface evaporation – To calculate the mass transfer coefficient from water to air.
VIII. Size analysis by sieving – To evaluate size distribution of tablet granulations – construction of various size frequency curves including arithmetic and logarithmic probability plots.
IX. Size reduction : To verify the laws of size reduction using ball mill.
X. Demonstration of colloid mill, fluidized bed dryer, freeze dryer and such other major equipments.

Text books:

1. Pharmaceutical engineering Practical manual (unit operations) by Sudhakara Reddy published by Pharma book syndicate.

COURSE NO 507: HOSPITAL & COMMUNITY PHARMACY AND INDUSTRIAL MANAGEMENT

Learning objectives:

1. To understand the organization of a pharmacy unit in a hospital and the responsibilities of a hospital pharmacist.
2. To have knowledge on the organization of a community pharmacy
3. To understand the managerial aspects in running a pharmaceutical industry

Units	Contents	Hrs
Unit-1:	Hospital Pharmacy – Definition, Hospital organization, Pharmacy organization and personnel, Location and layout of a hospital pharmacy unit in a hospital, responsibilities of a hospital pharmacist. Pharmacy and therapeutics committee, Hospital formulary. Dispensing to inpatients (a) Floor stock system, (b)Individual prescription order system, (c) Combination of (a) and (b), Dispensing to out patients	10
Unit-2:	Drug information center, Central sterile supply, Intravenous drug admixture, Unit dose dispensing, prepackaging in the hospital, Patient counseling- theory, counseling for analgesics and antipyretics, antidiabetics, antibiotics and antihypertensive drugs.	08
Unit-3:	Purchase and inventory control in hospitals and in community pharmacy: Vendor development, Buying techniques, Types of discount, Selection of right source of supply, Purchasing Procedure (Purchase request form, Purchase order form), Receipt of materials and maintenance of records. Factors influencing inventory control, Selective inventory control methods (ABC , VED, SOS), Lead Time, Stockouts, Safety Stocks, Reorder Quantity methods, Economic Order Quantity, Reorder point methods	07
Unit-4:	Community Pharmacy:– selection of site, space, lay-out, and legal requirements for starting and maintaining a drug store as per Drugs and Cosmetics Act 1940, Maintenance of registers for drugs of different schedules, Use of computers, Business and healthcare softwares	08
Unit-5:	**Meaning and Evolution of Management; Planning, organizing, staffing, Directing, Co-ordinating, Reporting and Budgeting; Functions of management with reference to pharmaceutical management.**	07
Unit-6:	Understanding Organisation: Types of organizational structures, line, line & staff & matrix organizational structure. Resistance to change, authority and responsibility	08
Unit-7:	Sales promotion: Market research-salesmanship, qualities of a salesman, advertising and window display. Recruitment, training,	06

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	evaluation of pharmacists and compensation to the pharmacist.	
Unit-8:	Pharmacy finance: Budgeting, budgetary control, types of budgets, Capital requirements, sources of pharmacy capital, Risk management and insurance.	06

Reference Books:

1. Merchant and Qadry's text book of hospital pharmacy revised by Dr. Ramesh K Goyal and RK Parikh; BS Shah Prakashan Publications.
2. Hospital Pharmacy by William E Hassan, Lea & Febiger, Philadelphia
3. Pharmacy management for students and practitioners, by C. Patrick Tharp and Pedro J Leeca.
4. Pharmaceutical Production and Management by C.V.S. Subrahmanyam, Vallabh Prakashan Publications

B.PHARM VI SEMISTER

COURSE NO 601: PHARMACOLOGY-I THEORY

Learning objectives:

1. To understand pharmacokinetic and pharmacodynamic principles involved in the use of drugs.
2. To understand and identify the various factors that can affect the action of drugs
3. To know the various routes of drug administration.
4. To know the effect of drugs on different systems of the body.
5. To know the drugs used in systemic illness.
6. To understand the methods in experimental pharmacology to correlate drug effects with receptors.

Units	Contents	Hrs
Unit-1:	General pharmacology: How do drugs act? Receptor and non receptor mechanisms of drug action. Brief introduction to structure activity relationship. Normal and unwanted activities of drugs. Factors influencing drug action.	08
Unit-2:	Drugs acting on Central Nervous System: Central depressants- ethyl alcohol, general anesthetics, basal narcotics, hypnotics, analgesic hypnotics, anxiolytics, antipyretic analgesics. CNS stimulants and analeptics.	10
Unit-3:	Psychopharmocological agents: Neuroleptics, antidepressants, anxiolytics, hallucinogens. Habit forming drugs and drugs of addiction	08
Unit-4:	Drugs acting on Autonomic Nervous System: Parasympathomimetic and parasympathetic blocking agents.	06
Unit-5:	Drugs acting on Autonomic Nervous System Sympathomimetic and sympathetic blocking agents.	06
Unit-6:	Drugs acting on Ganglionic stimulants and blockers, skeletal muscle relaxants	06
Unit-7:	Drugs acting on Cardiovascular system: Coagulants, anticoagulants, Drugs acting on blood forming organs, antihypertensive agents, vasodilators, antianginal agents, antiarrhythmics, cardiotonics, plasma substitutes, antihyperlipidemic agents	10
Unit-8:	Drugs acting on the kidney: Diuretics, antidiuretics, drugs useful in urinary tract infections.	06

cardiac glycosides (digitoxin)

Text Books:

1. Textbook of Pharmacology by Rang and Dale.
2. Essentials of Medical Pharmacology. -KD Tripathi.
3. Lippincort's illustrated pharmacology.
4. Pharmacology and pharmacotherapeutics by Satoshkar and Bandarkar

Reference Books:

Pharmacological basis of Therapeutics by Goodman and Gillman.
Text book of clinical pharmacology –Bertram C.Katzung

COURSE NO 602: PHARMACOLOGY-I PRACTICAL

1. Excretion of drugs in urine, sweat, saliva in humans.
2. Role of acetylcholine in ciliary movement of frog's oesophagus.
3. Drug action on the eye of rabbit- (miotic and-mydriatic).
4. Drug antagonism with pilocarpine and atropine in rabbits.
5. To study the analgesic effect of morphine in mice using Tail Flick method
6. Effect of Adrenaline and Acetylcholine on frogs rectum in situ.
7. Drug action on intact frog heart.
8. Action of acetylcholine and nicotine on the rectus abdominis muscle of frog.
9. Dose response curve (DRC) with acetylcholine on rectus abdominis muscle of frog
10. Potentiation of acetylcholine response but not of nicotine by eserine on rectus abdominis muscle of frog

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11. Inhibition of acetylcholine response by curare/procaine/quinidine/pethidine on rectus abdominis muscle of frog.
12. Different stages of general anaesthesia using ether in mice.
13. Effect of different ions(Ca^{+2}, K^{+}) on isolated perfused frog heart.
14. Effect of digoxin on normal and hypodynamic heart.
15 To evaluate Antiepileptic Activity of Drugs (Diazepam or Sodium Valproate) against Chemoshock Induced by Pentylenetetrazole or Picrotoxin in Mice
16 To study the Anticonvulsant Activity of Diphenylhydantoin Sodium (Dilantin Sodium) against Maximal Electroshock Seizures (MES) in Mice.

COURSE NO 603: PHARMACEUTICAL CHEMISTRY-V (MEDICINAL CHEMISTRY-II)

Learning objectives:
1. To give an understanding regarding the use of different name reactions in preparation of some useful compounds for synthesis of simple drug molecules.
2. To train the students in safe handling of very reactive chemical reagents by givingsuitable reactions.

Units	Contents	Hrs
Unit-1:	Physico-chemical properties and biological activity: Influence of partition coefficient, covalent bonding, hydrogen bonding, surface activity, redox potentials, chelation, enantiomeris, and geometrical isomerism on biological activity.	08
Unit-2:	Factors affecting absorption, transport, distribution and elimination of drugs, protein binding of drugs. Introduction to the concepts of prodrugs, soft drugs and targeted drugs. Introduction to principles of chemotherapy, chemotherapeutic index, drug resistance, super infection.	07
Unit-3:	A study of the classification, mode of action, uses and synthesis of specified members in each of the following categories. Antiinfective agents: (a) Ectoparasiticides: Lindane, pyrethrins, sulfurated compounds, benzyl benzoate (b)	07
Unit-4:	A study of the classification, mode of action, uses and synthesis of specified members in each of the following categories. Antiseptics and disinfectants: alcohol, formaldehyde, resorcinol, hydrogen peroxide, benzalkonium chloride, gentian violet; methyline blue and furazolidone.	08
Unit-5:	Sulphonamides: sulfisoxazole, sulphamethazole and sulphathiazole. Antimycobacterial agents: (a)Antitubercular agents..PASA, isoniazid (b) antileprotic agents: dapsone Anthelmintics: diethyl carbamazine citrate, mebendazole, tinidazole, thiabendazole and pyrantel pamoate	08
Unit-6:	Antimalarials: chloroquine, primaquine, mefloquine and pyrimethamine Antiamoebic agents: metronidazole, diloxanide furoate and carbarsone. Antifungal agents: clotrimazole, ketocanazole and tolnaftate. Antiviral agents: acyclovir, zidovudine, idoxuridine and adamantine Cytostatic agents: chlorambucil, cyclophospamide, lomustine, methotrexate, 5-flouro uracil and mercaptopurine	07
Unit-7:	Adrenergic drugs: Biosynthesis and metabolism of catecholamines, direct and indirect sympathomimetics, mode of action and structure activity relations, adrenergic blocking agents, synthesis of amphetamine, phenyl ethylamine and isoproterneol. Cholinergic agents and anticholinesterases: Structural features of acetylcholine, cholinergic agonists, anticholinesterases, synthesis of carbachol, physostigmine, neostigmine and dicyclomine.	08
Unit-8:	Diuretics: acetazolamide, furosemide, ethacrynic acid and hydrochlorthiazide Antihypertensives: methyldopa, amlodipine, prazocin and propranolol.	07

TEXT BOOKS:
1. Wilson and Gisvold, Textbook of organic, Medicinal and Pharmaceutical Chemistry
2. Bently and Driver's Textbook of Pharmaceutical Chemistry
3. Remington's Practice of Pharmaceutical Sciences.

Reference Books
1.Organic Chemistry, Vol. I. By I.L.Final
2.Essentials of Medicinal Chemistry by Karlkovas
3.Medicinal Chemistry, Vol. I,II and III. By A.Burger
4.Indian Pharmacopoeia.

COURSE NO 604: PHARMACEUTICAL CHEMISTRY-VI (DRUG ANALYSIS-II)

PRACTICALS

1. Preparation of synthetic drugs involving two or three steps such as benzilic acid , methaqualone, cinchophen, phenolphthalein. barbituric

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2. Identification of drugs.
3. Analysis of formulations containing drugs studied in theory such as Chloroquine phosphate, metronidazole, diethyl carbamazine, pentobarbitone, dapsone, isoniazid, tolbutamide, sulpha drugs.

COURSE NO 605: INDUSTRIAL PHARMACY & COSMETIC TECHNOLOGY

Learning objectives:

1. To understand the formulation and production technology of different dosage forms
2. To understand the formulation and production technology of different cosmetics

Units	Contents	Hrs
Unit-1:	Pre – formulation: Objectives – Protocols –solubility studies (pKa determinations, pH solubility profile and common ion effects, effect of temperature, solubilization, partition coefficient, dissolution), bulk characterization (crystallinity and polymorphism, hygroscopicity, micromeritic properties, particle characterization, density and porosity and powder flow properties), stability analysis (solution stability, solid state stability, drug-excipient compatibility).	10
Unit-2:	A study of the formulation, process and equipment used in the large scale manufacture, evaluation, and quality control of the following dosage forms. (i)Suspensions (ii) Emulsions (iii) Liquid orals (Syrups and Elixirs) (iv) Semisolids.	10
Unit-3:	A study of the formulation, process and equipment used in the large scale manufacture, evaluation, and quality control of the following dosage forms. Tablets, Tablet coating –sugar, film and enteric coating, Capsules – hard and soft	08
Unit-4:	A study of the formulation, process and equipment used in the large scale manufacture, evaluation, and quality control of the following dosage forms. (i) Parenterals (ii) Other sterile products – eye ointments, eye drops.	07
Unit-5:	(i)Sustained release products (drug complexes, encapsulated granules, slow release granules, tableted slow release granules, matrix tablets) (ii) Microencapsulation and microcapsules (iii) Aerosol preparations	08
Unit-6:	Formulation and preparation of the following Cosmetics – Hand lotions and creams, face powders, baby and bath powders,	08
Unit-7:	Formulation and preparation of the following Cosmetics -dentifrices, shampoo, lipstick, shaving preparations and hair dyes and creams, skin creams.	06
Unit-8:	Case studies: Formulation of (i) An antacid product (ii) An ampicillin product for Paediatric use (iii) An antibacterial product for a child (iv) Pain balm (v) An anti-inflammatory gel.	05

Text Books:

1. The theory and practice of Industrial Pharmacy by Leon Lachman, H.A. Lieberman and Joseph L. Kanig, CBS Publishers and Distributors.
2. Pharmaceutics, The Science of Dosage Form Design, edited by Michael E. Aulton.
3. Science and Technology of Cosmetics by Sagarin.
4. Remington's Practice of Pharmaceutical Sciences.
5. Cosmetics a practical manual by Swarnalata saraf and shailendra saraf published by pharma book syndicate.
6. Handbook of Pharmaceutical Manufacturing Formulations, Uncompressed solid products, Volume 2, Sarfaraz K Niazi, CRC Press

COURSE NO 606: INDUSTRIAL PHARMACY & COSMETIC TECHNOLOGY PRACTICAL

Formulation, preparation and quality control of pharmaceutical products (25) covering dosage forms listed in theory. The number of products under each category is as follows

Tablets – 6, Liquid orals – 4, Emulsions – 3, Capsules – 2, Parenterals – 4, SR Tablets – 2, Cosmetics – 4.

Text Books:

7. The theory and practice of Industrial Pharmacy by Leon Lachman, H.A. Lieberman and Joseph L. Kanig.
8. Pharmaceutics, The Science of Dosage Form Design, edited by Michael E. Aulton.
9. Science and Technology of Cosmetics by Sagarin.
10. Remington's Practice of Pharmaceutical Sciences.

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11. Cosmetics a practical manual by Swarnalata saraf and shailendra saraf published by pharma book syndicate.

COURSE NO 607: PHARMACEUTICAL JURISPRUDENCE

Learning objectives:

1. The subject exposes the student to important legislations related to Pharmacy profession in India.
2. It imparts knowledge about the Drug and Cosmetic Act and its Rules.
3. It provides the basic idea regarding DPCO drug policies and patenting in India.

Units	Contents	Hrs
Unit-1:	Pharmacy Act	10
Unit-2:	Drugs and Cosmetic Act and Rules	10
Unit-3:	Narcotic Drugs and Psychotropic Substances Act (1986)	07
Unit-4:	Drugs and Magic Remedies Act	06
Unit-5:	Drugs (Price Control) Order 2013	07
Unit-6:	Medicinal and Toilet Preparations (Excise duties) Act and Rules.	07
Unit-7:	Patents Act and Intellectual Property Rights	07
Unit-8:	Medical Termination of Pregnancy Act, Code of Pharmaceutical Ethics	06

Suggested Books

1. Original Laws Published by Government of India.
2. Forensic Pharmacy by B.M.Mithal, 5th Edition, National Book Centre, 1997.
3. Forensic Pharmacy by N.K.Jain, 6th Edition, Vallabh Prakashan, 2003.
4. Forensic Pharmacy by C.K. Kokate and S.B. Gokale, Pharmamed Press, 2008.
5. Intellectual Property Law by R.K. Nagarajan, Jain Book Depot, 2004.

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OP Agarwal. (Vol - I
Vol - II)

B.PHARM VII SEMESTER

COURSE NO 701: PHARMACEUTICAL CHEMISTRY-VI (NATURAL PRODUCTS)

Learning objectives:

1. To let students to understand the role of natural chemistry in drug discovery
2. To make students understand the intricacies of natural product isolation and identification using chemical tests, degradative methods and spectroscopy
3. To expose students towards different chemical classes of natural products and their relationships according to their biological activity

Units	Contents	Hrs
Unit-1:	Carbohydrates: Classification and general properties. Knowledge of structure including stereochemistry of glucose, fructose, and sucrose. General treatment of pharmaceutically important carbohydrates-maltose, lactose, starch, cellulose, dextrin, and glycosides.	08
Unit-2:	Amino acids and proteins: Classification and general reactions of amino acids and their relationship to proteins and polypeptides. Methods of preparation of amino acids, classification and general reactions of proteins, degradation of proteins-hydrolysis and end group analysis-protein hormones, oxytocin	10
Unit-3:	Purines and xanthine derivatives: Structure and synthesis of uric acid, Theo bromine, theophylline, and caffeine. General aspects of nucleoproteins and nucleic acids. Lipids: Fixed oils and fats. Fatty acids: chemistry and analysis of oils and fats.	08
Unit-4:	Terpenes: Occurrence, general methods of isolation and classification, chemistry of citral, limonene, α-terpeneol, carvone, camphor and menthol. Preparation, general composition, properties and analysis of essential oils of I.P. Alkaloids: Classification, general methods of isolation, chemical tests for alkaloids, Chemistry and uses of ephedrine, nicotine, papaverine and atropine.	08
Unit-5:	Vitamins: Classification, chemistry, physiological role and uses of thiamine, riboflavin and ascorbic acid. Skeletal structures of vitamins official in I.P. Steroids: Nomenclature and skeletal structures of ergosterol, stigmasterol, cholsterol and bile acids. Chemical tests for steroids Calciferols and Sapogenins – diosgenin, hecogenin	07

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Unit-6:	Hormones: Sex hormones, structure and physiological properties of testosterone, progesterone, estrone, estriol and estradiol. Their synthesis from cholesterol or diosgenin. Synthetic estrogens. Introduction to oral contraceptives. Cortisones; prednisolone, aldosterone, synthesis of cortisone. Steroidal anti-inflammatory drugs: structures and their therapeutic uses.	06
Unit-7:	Glycosides: Enzymatic and hydrolysis reactions of glycosides, mechanism of action, SAR, therapeutic uses and toxicity of glycosides. Cardiac glycosides of digitalis, bufa and squill. Structure of salicin, hesperidin and rutin.	07
Unit-8:	Antibiotics: A general study of antibiotics, isolation or synthesis, chemistry and uses of penicillin, chloramphenicol and streptomycin, general introduction to tetracycline and other antibiotics included in I.P. Spectroscopy and structure: an introductory treatment of U.V., I.R. and NMR spectroscopy in structure deterimination.	06

SUGGESTED BOOKS

1. Organic chemistry, Vol. II. By I.L. Finar
2. Wilson and Gisvold, Textbook of Organic, Medicinal and Pharmaceutical Chemistry
3. Bently and Driver's Textbook of Pharmaceutical chemistry
4. Remington's Prtactice of Pharmaceutical Sciences
5. Indian Pharmacopoeia.

COURSE NO 702: PHARMACEUTICAL CHEMISTRY-II (NATURAL PRODUCTS)

PRACTICAL

1. Determination of acid value
2. Determination of saponification value
3. Determination of iodine value
4. Determination of unsaponifiable matter
5. Determination of Eugenol in clove oil
6. Estimation of cineole in eucalyptus oil
7. Estimation of citral in lemon grass oil
8. Determination of aminophylline
9. Determination of caffeine citrate
10. Estimation of strychnine hydrochloride
11. Tests for absence of arachis oil, cottonseed oil and sesame oil in other oils
12. Reactions of carbohydrates, glycosides, alkaloids, amino acids (including Xanthine alkaloids), sterols and vitamins
13. Identification of selected natural products
14. Preparation of caffeine from Tea dust
15. Preparation of caseine and estimation of nitrogen
16. Soxhelt extraction of a crude drug
17. Assay of tincture Nux vomica/Tincture Belladona

COURSE NO 703: PHARMOCOLOGY-II- THEORY

Learning objectives:

1. To make student understand drug development and concepts of drug action
2. To know the drugs used in infections and chemotherapy with mechanism of action and pharmacokinetics, uses, side-effects.
3. To know peptides as drugs and role of autocoids in various process and drugs acting on them.

Units	Contents	Hrs
Unit-1:	Chemotherapy: sulphonamides, antibiotics, antiviral, antifungal agents and antineoplastics. Drug treatment in tuberculosis, leprosy, venereal diseases, malaria, filaria, leishmaniasis, trypnasomiasis, amoebiasis and helmenthiasis.	12
Unit-2:	Vitamins and hormones: vitamins, thyroid, parathyroid, adrenal cortex, insulin and oral antidiabetic drugs	08
Unit-3:	Pharmacology of drugs acting on sex organs: Oral Contraceptives, oxytocic agents and uterine relaxants.	06
Unit-4:	Immunity and biological standardisation: vaccines and immune sera, immunosuppressive agents.	07
Unit-5:	Methods of biological assay, principles of bioassays, fundamentals of biometric analysis. Detailed study of the official bioassay methods for adrenaline, posterior pituitary, insulin, gonadotrophic hormones, cholera vaccine and diphtheria antitoxin. Tests for pyrogens: LAL Test & rabbit method.	10
Unit-6:	Pharmocology of local anaesthetics.	05
Unit-7:	Drugs acting on respiratory system: cough suppressants, bronchodilators, drugs used in asthma. Miscellaneous: chelating agents, demulcents, counter-irritants, diagnostic agents.	06
Unit-8:	Drugs acting on GI tract: digestants, antispasmodics, anti-diarrhoeal agents, cathartics, emetics, antiemetics, drugs used in inflammatory bowel syndrome, antacids and drugs used in gastric ulcers.	06

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Text Books:

1. Textbook of Pharmocology by Rang and Dale
2. Essentials of Medical Pharmacology. -KD Tripathi
3. Lippincort's illustrated pharmacology
4. Pharmacology and pharmacotherapeutics by Satoshkar and Bandarkar.

Reference Books:

1. Pharmacological basis of Therapeutics by Goodman and Gillman.
2. Text book of clinical pharmacology –Bertram.C.Katzung
3. Indian Pharmacopoeia.

COURSE NO 704: PHARMOCOLOGY-II- PRACTICAL

List of Practicals:

1. Effect of Adrenaline and Acetylcholine on the rabbit intestine.
2. Effect of Atropine on the action of Acetylcholine on the rabbit intestine
3. Effect of anti-histaminics on the action of histamine on guineapig ileum.
4. Drug antagonism studies on isolated smooth muscle strips Adrenaline × propranolol (receptor antagonism) of rabbit intestine.
5. Bioassay of acetylcholine by Comparative method using Rat Ileum.
6. Bioassay of acetylcholine by Graphical method using Rat Ileum (Indirect Bioassay)
7. Three-point bioassay: Bioassay of acetylcholine by using isolated Rat Ileum Preparation
8. To find out the Potency ratio between the Standard and test sample of Acetylcholine solution by four point bioassay method using isolated rat ileum
9. Bioassay of histamine on guineapig ileum.
10. Action of drugs on rabbits eye (local anaesthetics).
11. Action of drugs on mice (CNS stimulants).
12. Action of drugs on mice (CNS depressants).
13. Test for Pyrogens: Determination of the Existence of Pyrogens in Parenteral preparations (rabbit method).
14. Hypoglycemic effect of insulin in rabbits.

COURSE NO 705: PHARMACOGNOSY AND PHYTOCHEMISTRY II

Learning objectives:

1. To study the generation of biodrugs in plants as a result of metabolism.
2. To impart knowledge about important chemical classes of compounds having bio activity

Units	Contents	Hrs
Unit-1:	General Pharmacognosy: Advantages and disadvantages of obtaining drugs from cultivated and wild plants. Variability of drug constituents due to exogenous and endogenous factors like altitude, temperature, rain fall, light, propagation by seed vegetative means, mutation, hybridization;	08
Unit-2:	Deterioration of crude drugs during storage by insects, pests and enzymes. Factors influencing the storage of crude drugs. Methods of storage. Evaluation of crude drugs: Identity, purity and quality of crude drugs by organoleptic microscopic, physical, chemical and biological evaluation;	10
Unit-3:	Methods of adulteration, detection and identification of adulterants types and significance of standards for crude drugs included in I.P and B.P. Quantitative pharmacognosy.	06
Unit-4:	A detailed study of the following drugs, their classification methods of preparation, commercial varieties, active principles, their chemical nature, identification, tests and uses; Roots and rhizomes :Male fern, valerian, rhubarb, podophyllum, liquorice, turmeric ,ginger, ipecac, rauwolfia, aconite and jalap; Unorganised drugs: opium, aloes, kino, gambier, agar, alginates, gelatin.	07
Unit-5:	A detailed study of the following drugs, their classification methods of preparation, commercial varieties, active principles, their chemical nature, identification, tests and uses Resins, gum resins, oleoresins-colophony, benzoin, shellac, myrrh, galbanum asafetida, turpentine, balsam of Tolu, balsam of Peru and storax;	08
Unit-6:	A detailed study of the following drugs, their classification methods of preparation, commercial varieties, active principles, their chemical nature, identification, tests and uses Glands and glandular secretions-thyroid, pituitary, adrenal, pancreas and musk; Gums and saccharin substances: acacia, tragacanth and honey.	08
Unit-7:	Chromatography and some related terms. Classification and a study of various chromatographic methods. Column, paper, thin layer and gas chromatography, HPLC and their applications to natural products.	07
Unit-8:	Biogenesis, Pathways leading to formation of plant products; Historical development of plant tissue culture, types of cultures	06

	nutritional requirements, growth and their maintenance, applications of plant tissue culture in production of pharmaceutically important secondary metabolites.	

Recommended Books :

1. Atal CK and Kapoor BM. Cultivation and utilization of Aromatic Plants CSIR Publications;
2.Tyler,VC,Brady,LR and Robers,JE.Pharmacognosy.,11th to 14th Editions;
3.Wallis,TE.Textbook of Pharmacognosy,5th Edition,J & A,Churchill Limited, U.K. 4. Kokate, CK Purohit, AP. and Gokhale, SB. Pharmacognosy;
5.Ross,MF. And Brain,KR.An introduction to Phytopharmacy,Pitman Medical –Kent; 6. Deinvert,J. and BajajYPS.Applied and Fundamental Aspects of Plant Cell ,Tissue and Organ Culture,Berlin.

COURSE NO 706: PHARMACOGNOSY AND PHYTOCHEMISTRY II (PRACTICAL)

1.Identification of powdered crude drugs and their combinations with the help of organoleptic, microscopic and chemical tests;2.Determination of leaf constants such as stomatal index, stomatal number, vein islet number and palisade ratio; 3.Thin layer chromatographic studies of extracts from crude drugs.

Recommended Books:

1.Pharmacopoeia of India,1985;
2.Practical Pharmacognosy,3rd Edition, By Kokate,C.K ;
3.Practical Pharmacognosy by Lala,P.K.,Lina,Calcutta,198.

COURSE NO 707: GMP AND VALIDATIONS

Learning objectives:

1. To understand the standard specifications and procedures required in the manufacture of dosage forms
2. To understand the modern concepts of validation, quality assurance and statistical quality control

Units	Contents	Hrs
Unit-1:	CGMP: A detailed study of GMP as prescribed in Schedule M of Drugs and Cosmetics Act and Rules. Requirements regarding premises, sanitation, personnel, equipment and building, documentation and records and processes.	10
Unit-2:	Control of Production Procedures: Manufacturing Control – In – Process Quality Control for solids, liquids, semisolids and parenteral products – packaging control	08
Unit-3:	Control of Finished Products: Tablets , Capsules, parenterals, semisolids, liquid orals	06
Unit-4:	Validation: Types and Protocols of Validations – A study of Process Validation. Validation of Equipments	06
Unit-5:	Cleaning Validation, Analytical Method Validation – Procedures and Examples.	08
Unit-6:	Quality Assurance: Principles and General Concepts – Duties and Responsibilities of Quality Assurance Departments in a modern Pharmaceutical Concern – Sources of Quality Variation, Control of Quality Variation (Raw Material Control (active materials, inactive materials), In- process items control	08
Unit-7:	Quality Assurance before Start – up (environmental and microbiological control and sanitation, Manufacturing working formula procedures, Raw materials, manufacturing equipment); Quality assurance at Start – up (Raw materials processing,	07

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	compounding, Packaging Materials and Labels control, finished product control).	
Unit-8:	Concept of Statistical Quality Control – Quality Control Charts (control charts by variables, control charts by attributes), quality level and inherent variability – Sampling and Sampling Plans.	07

Recommended Books:

1. The Theory and Practice of Industrial Pharmacy by Leon Lachman, H.A. Liberman and Joseph L. Kanig, 3rd Edition, Lea & Febiger publishers, Philadelphia.
2. Quality Assurance of Pharmaceuticals Vol. I and Vol. II published by Pharma book syndicate
3. Pharmaceutical Product Development by N.K. Jain, CBS Publishers & Distributors Pvt. Ltd. Tablets – Vol. I, II and III by Leon Lachman et al.

Reference Books:

1. Pharmaceutical Dosage Forms, Tablets – Vol. I, II and III edited by H.A. Lieberman and Leon Lachman, Marcel Dekker, Inc.
2. Modern Pharmaceutics by Banker

COURSE NO 708: Professional Training

Training in Industrial, Hospital and Community Pharmacy

B.PHARM VIIIth SEMESTER

COURSE NO 801: PHARMACEUTICAL ANALYSIS –II (THEORY)

Learning objectives:

1. To emphasize the importance of quality in drugs & pharmaceuticals.
2. To establish the fundamental conventional methods of drug analysis used in laboratories
3. To provide the knowledge regarding the principles of Instrumentation.
4. To give the basic principles of other analytical techniques used in Pharma Industries.
5. To teach applications of these analytical methods to drugs & pharmaceuticals

Units	Contents	Hrs
Unit-1:	Physicochemical aspects of analytical chemistry with special reference to pharmaceutical analysis. Chromatographic methods-I: Principles, theories, instrumentation and applications Involved in a) Column chromatography b) Paper chromatography c) Thin layer chromatography	08
Unit-2:	Chromatographic methods-I: Principles, theories, instrumentation and applications Involved in (i)HPTLC (ii) Ion-exchange and gel filtration techniques	08
Unit-3:	Chromatographic methods-II: Principles, theories, instrumentation and applications Involved in a) Gas chromatography (GC) b) High performance liquid chromatography (HPLC)	08
Unit-4:	Spectrophotometric analysis: A discussion of basic principles including interaction of matter with electro-magnetic radiation, absorption, emission, luminescence and scattering phenomena, units of measurement and definition of terms: a) absorptiometry: quantitative consideration of absorption phenomena including Beer and Lambert,s laws and their mathematical expression, deviations from the laws and methods used in absorption spectrophotometry (visible, UV and IR) including sources, monochromators, detectors, preparation of calibration curves and pharmaceutical applications. Sources of errors and their correction and validation of spectrophotometric methods.	08
Unit-5:	Basic principles, equipment and methods used and pharmaceutical applications of flame photometry, photofluorimetry, turbidimetry and nephlometry.	06

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Unit-6:	Electrochemical Analysis: A discussion of basic principles involved in electrochemical analysis, electrochemical cells and half-cells, electrodes, electrode reactions and electrode potentials:a) Potentiometry: basic principles involved in measurement of EMF and pH , Nernest equation, typical equipment and their construction, factors influencing EMF of cell, portable, stationary and on-line equipment for pH measurement, applications.	08
Unit-7:	Potentiometric titrations including principles involved, methods for detection pf end point including dead stop mend point, applications in neutralization, redox and precipitation titrations, equipment used, exploration of titration curves obtained with acids and bases of different strength and mixture of acids. c) Conductometric titrations: basic principles, titrations, equipment and applications.	07
Unit-8:	Polarography: basic principles, titrations, equipment and applications in qualitative and quantitative analysis.e) amperometric titrations: basic principles, titrations, equipment and applications, Basic principles, definition of terms, equipment and their working and applications of – NMR and Mass spectrometry. Thermal methods of analysis and radioimmunoassay assay.	07

Reference books:

1. Pharmaceutical chemistrty by L.G. Chatten (Marcel Dekker)
2. A text book of pharmaceutical analysis by K.A. Connors (John Willey)
3. Pharmaceutical analysis- modern methods by J.W. Munson (Marcel Dekker)
4. Instrumental methods of analysis by Willard, Merritt, Dean and Settle (CBS publishers)
5. Text book of analytical chemistry by Y.Anjaneyalu, K.Chandra sekhar and Valli manickam.
6. Introduction to Instrumental analysis by Robert D.Braun Published by Pharma book syndicate.

COURSE NO 802: PHARMACEUTICAL ANALYSIS –II (PRACTICAL)

1. Separation of plant materials by column chromatography 2. Separation and identification of flavonoids/sulphonamides by paper chromatography 3. Separation and identification of sulphonamides by paper chromatography 4. Separation and identification of amino acids by TLC methods 5. Separation and identification of barbiturates by TLC methods 6. Determination of λ max.,($KMnO_4$ and methylene blue solutions).7. Demonstration experiments in HPLC and GLC 8. Assay of sulphadiazine tablets by visible spectrophotometry 9. Assay of sulphadiazine tablets by UV spectrophotometry 10. Demonstration experiments in IR spectrophotometry injcluding interpretation of given spectra. 11. Fluorimetric estimation of quinine sulphate in formulations 12. Fluorimetric estimation of riboflavin in formulations 13. Flame photometric estimation of sodium and potassium ions 14. Potentiometric analysis a) Determination of pH of two solutions b) Titration of strong acid against strong base c) Titration of strong base against weak acid d) Simultaneous determination of strong acid and weak acid in a mixture e) Potentiometric assay of any two formulations from I.P. 15. Conductometric titration of NaOH with HCl 16. Polarographic estimation of drug official in I.P. 17. Determination of concentration of sugar solution by polarimetry 18. Determination of critical micellar concentration (butyric acid in water using abbe refractometer.19. Demonstration experiments in detection of polymorphism and pseudo polymorphism in pharmaceuticals by DTA and DSC 20. Assay of an ointment and cream official in I.P. 21. Complete testing and assay of any two drugs as per I.P. monograph.

Reference books:

1. A text book of pharmaceutical analysis by K.A. Connors (John Willey).

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COURSE NO 803: BIOPHARMACEUTICS AND PHARMACOKINETICS

Learning objectives:

1. The student will be able to understand the mechanism, factors influencing the absorption, distribution, metabolism and excretion of drugs (ADME)
2. With the understanding of the ADME pathways the student will be able to calculate the pharmacokinetic and pharmacodynamic parameters
3. The student will be able to design suitable dosage forms using the knowledge of physico-chemical, biological and other properties studied

Units	Contents	Hrs
Unit-1:	**Biopharmaceutics**: Definition and introduction to biopharmaceutics, Fundamental principles of pharmacokinetics and pharmacodynamics, concepts of absorption, distribution, metabolism and elimination. Definitions and explanation of the terms connected with the study of biopharmaceutics. Basic pharmacokinetic models viz. compartment, catenary and mammillary models.	06
Unit-2:	**Physiological factors related to drug absorption**: Structure of cell membrane and its significance in drug absorption. Mechanisms of drug absorption, per oral routes of administration, anatomical and physiological considerations of the gastrointestinal tract, absorption of drugs from gastrointestinal tract and factors governing gastrointestinal drug absorption, first pass effect and its significance. Fick's first law of diffusion and *in vivo* sink condition	08
Unit-3:	**Biopharmaceutical considerations in dosage form design**: Rate limiting steps in drug absorption, introduction to BCS (biopharmaceutical classification system), physico-chemical factors of drug, pharmaceutical factors, formulation factors effecting drug absorption and bioavailability. Theories of dissolution and *in vitro* dissolution testing, *in vitro* sink condition, compendial methods of dissolution testing of different dosage forms.	08
Unit-4:	**Drug distribution**: Physiological barriers for drug distribution, plasma protein binding of drugs, its significance and kinetics, factors influencing the drug distribution, apparent volume of distribution and its significance.	07
Unit-5:	**Metabolism and excretion of drugs**: Significance of biotransformation, factors influencing biotransformation, hepatic metabolism, microsomal and non microsomal metabolism, effects of enzyme induction and inhibition on biotransformation, phase I and phase II biotransformation reactions, renal and non-renal routes of drug excretion, concept of clearance, total body clearance, renal clearance, non-renal clearance, clearance ratio, factors effecting the clearance of drugs, glomerular filtration rate, tubular reabsorption	08
Unit-6:	**Bioavailability and bioequivalence**: Definitions of different types of bioavailability and bioequivalence, objectives of bioavailability studies, methods for improving the bioavailability of drugs. Methods for assessing bioavailability, experimental design and evaluation of bioavailability studies, *in vitro* and *in vivo* correlation methods.	08
Unit-7:	**Pharmacokinetics**: Introduction to pharmacokinetics, their importance in bioavailability and clinical practice. Concepts, definition and explanation of terminologies used. Compartment models- concepts and their importance in the study of pharmacokinetics. One compartment open model - Determination of pharmacokinetic parameters from plasma and urine data after i.v. injection and oral administration. Percent absorbed time plot and absorption rates based on one compartment model. Non-compartmental analysis.	10
Unit-8:	**Non-Linear Pharmacokinetics, individual and optimization of drug dosage regimens:** Causes of non-linearity, detection of non-linearity, Michaeles Menton equation and calculation of Michaeles Mentón constant and maximum metabolic rate. Basic concepts relating to individualization of dosage with reference to pediatric, geriatric, liver and renal impaired patients.	10

Recommended Books

1. Biopharmaceutics and Pharmacokinetics-A Treatise - D.M. Brahmakar, Sunil. B. Jaiswal, 2nd Edition, Vallabh Prakashan, 2012.
2. Biopharmaceutics and Pharmacokinetics, V. Venkateswarlu. 2nd Edition, Pharma Book Syndicate, 2010.
3. Biopharmaceutics and Clinical Pharmacokinetics, Milo Gibaldi. 4th Edition, Pharma Book Syndicate, 2005.
4. Applied Biopharmaceutics & Pharmacokinetics, Shargel and Andrew Yu, 6th Edition, Mc GrawHill Professional, 2012.

COURSE NO 804: BIOPHARMACEUTICS AND PHARMACOKINETICS PRACTICALS

1. Dissolution testing of conventional marketed tablet containing drugs like aspirin, paracetamol, theophylline
2. Dissolution testing of controlled/sustained release dosage forms containing drugs like theophylline, diclofenac sodium, aceclofenac sodium
3. Dissolution testing of enteric coated tablets like aspirin
4. Effect of particle size on dissolution rate of drugs using drugs like aspirin
5. Effect of surfactant on dissolution rate of drugs using drugs like nimesulide, sulfamethoxazole
6. Plasma protein binding studies of drug using egg albumin by dialysis sac method for drugs having plasma protein binding

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7. Calculation of pharmacokinetic parameters using different pharmacokinetic approaches by using plasma, urinary and salivary data (Not less than 5 problems.
8. Calculations of bioavailability and bioequivalence using theoretical data
9. Writing the experimental protocol for bioavailability and bioequivalence studies for the given formulation

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COURSE NO 805: CLINICAL PHARMACY & THERAPEUTICS

Learning objectives:

1. To understand the dosage calculations appropriate for the patient and be able to select the proper drug.
2. To understand the adverse drug reactions and drug interactions of various classes of drugs.
3. To understand the importance of rational prescribing of drugs and concept of essential drugs
4. To impart the knowledge on the therapy of various disorders

Units	Contents	Hrs
Unit-1:	General concept: Clinical pharmacokinetics, drug interactions, adverse drug reactions, parenteral nutrition.	06
Unit-2:	Pharmacoeconomics, Pharmacogenomics, Pharmacovigilance, Therapeutic drug monitoring, Neutraceuticals, essential drugs and rational drug usage.	07
Unit-3:	Age related drug therapy: concept of posology, drug therapy for neonates, pediatrics and geriatrics. Drugs used in pregnancy and lactation.	07
Unit-4:	Drug therapy for neurological and psychological disorders.	06
Unit-5:	Drug therapy in infections of respiratory system, urinary system, infective meningitis, TB, HIV, malaria and filaria..	09
Unit-6:	Drug therapy for thyroid and parathyroid disorders, diabetes mellitus, menstrual cycle disorders, menopause and male sexual dysfunction.	08
Unit-7:	Drug therapy for malignant disorders like leukemia, lymphoma and solid tumors.	10
Unit-8:	Drug therapy for rheumatic, eye and skin disorders.	07

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COURSE NO 806: NOVEL DRUG DELIVERY SYSTEMS THEORY

Learning objectives:

1. To understand the concepts of controlled drug delivery and targeting
2. To understand the design of controlled and targeted drug delivery systems

Units	Contents	Hrs
Unit-1:	Introduction to novel drug delivery systems, Basic Concepts in sustained and controlled release, advantages and disadvantages of controlled release products. Factors influencing the design and performance of controlled release products.	10
Unit-2:	Targeting, passive and active, mechanisms and basic techniques used.	6
Unit-3:	Design, preparation and characterization of Oral Controlled Release products (Matrix Tablets, Coated Pellets, OROS, microcapsules, gastro retentive systems).	10
Unit-4:	Design, preparation and characterization of Parenteral controlled release products (Microspheres, Emulsions, suspensions).	08
Unit-5:	Design, preparation and characterization of Transdermal Therapeutic Systems (TTS) (Drug in adhesive type, matrix type, reservoir type, membrane matrix hybrid type, microreservoir type).	8
Unit-6:	Design, preparation and characterization of Implants and implantable devices, osmotically controlled drug delivery systems.	08
Unit-7:	Design, preparation and characterization of Liposomes, resealed erythrocytes.	10
Unit-8:	Design, preparation and characterization of Nanoparticles.	08

Recommended Text Books:

1. Lachman Lieberman's The Theory and Practice of Industrial Pharmacy, Fourth Edition, Editors, Roop K khar, SP Vyas, Farhan J Ahmad and Gaurav K Jain, CBS Publishers and Distributors Pvt. Ltd.
2. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K. Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012
3. Modern Pharmaceutics by Banker.
4. Oral drug delivery technology by Aukunaru Jithan Published by Pharma Book Syndicate.

Pharmacy Council of India
New Delhi

Rules & Syllabus for the Bachelor of Pharmacy (B. Pharm) Course

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[Framed under Regulation 6, 7 & 8 of the Bachelor of Pharmacy (B. Pharm) course regulations 2014]

CHAPTER- I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the B. Pharm. Degree Program (CBCS)of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by Pharmacy Council of India.

2. Minimum qualification for admission

2.1 First year B. Pharm:

Candidate shall have passed 10+2 examination conducted by the respective state/central government authorities recognized as equivalent to 10+2 examination by the Association of Indian Universities (AIU) with English as one of the subjects and Physics, Chemistry, Mathematics (P.C.M) and or Biology (P.C.B / P.C.M.B.) as optional subjects individually. Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

2.2. B. Pharm lateral entry (to third semester):

A pass in D. Pharm. course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

3. Duration of the program

The course of study for B.Pharm shall extend over a period of eight semesters (four academic years) and six semesters (three academic years) for lateral entry students. The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semestershall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, tutorial hours, practical classes, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and /or tutorial (T) hours, and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and tutorial hours, and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having three lectures and one tutorial per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

7.2. Minimum credit requirements

The minimum credit points required for award of a B. Pharm. degree is 208. These credits are divided into Theory courses, Tutorials, Practical, Practice School and Projectover the duration of eight semesters. The credits are distributed semester-wise as shown in Table IX. Courses generally progress in sequences, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

The lateral entry students shall get 52 credit points transferred from their D. Pharm program. Such students shall take up additional remedial courses of 'Communication Skills' (Theory and Practical) and 'Computer Applications in Pharmacy' (Theory and Practical) equivalent to 3 and 4 credit points respectively, a total of 7 credit points to attain 59 credit points, the maximum of I and II semesters.

8. Academic work

A regular record of attendance both in Theory and Practical shall be maintained by the teaching staff of respective courses.

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9. Course of study

The course of study for B. Pharm shall include Semester Wise Theory & Practical as given in Table – I to VIII. The number of hours to be devoted to each theory, tutorial and practical course in any semester shall not be less than that shown in Table – I to VIII.

Table-I: Course of study for semester I

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP101T	Human Anatomy and Physiology I– Theory	3	1	4
BP102T	Pharmaceutical Analysis I – Theory	3	1	4
BP103T	Pharmaceutics I – Theory	3	1	4
BP104T	Pharmaceutical Inorganic Chemistry – Theory	3	1	4
BP105T	Communication skills – Theory *	2	-	2
BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics – Theory*	2	-	2
BP107P	Human Anatomy and Physiology – Practical	4	-	2
BP108P	Pharmaceutical Analysis I – Practical	4	-	2
BP109P	Pharmaceutics I – Practical	4	-	2
BP110P	Pharmaceutical Inorganic Chemistry – Practical	4	-	2
BP111P	Communication skills – Practical*	2	-	1
BP112RBP	Remedial Biology – Practical*	2	-	1
	Total	**32/34$/36#**	**4**	**27/29$/30#**

#Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.

$Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course.

* Non University Examination (NUE)

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Table-II: Course of study for semester II

Course Code	Name of the course	No. of hours	Tutorial	Credit points
BP201T	Human Anatomy and Physiology II – Theory	3	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	3	1	4
BP203T	Biochemistry – Theory	3	1	4
BP204T	Pathophysiology – Theory	3	1	4
BP205T	Computer Applications in Pharmacy – Theory *	3	-	3
BP206T	Environmental sciences – Theory *	3	-	3
BP207P	Human Anatomy and Physiology II –Practical	4	-	2
BP208P	Pharmaceutical Organic Chemistry I– Practical	4	-	2
BP209P	Biochemistry – Practical	4	-	2
BP210P	Computer Applications in Pharmacy – Practical*	2	-	1
	Total	**32**	**4**	**29**

*Non University Examination (NUE)

Table-III: Course of study for semester III

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP301T	Pharmaceutical Organic Chemistry II – Theory	3	1	4
BP302T	Physical Pharmaceutics I – Theory	3	1	4
BP303T	Pharmaceutical Microbiology – Theory	3	1	4
BP304T	Pharmaceutical Engineering – Theory	3	1	4
BP305P	Pharmaceutical Organic Chemistry II – Practical	4	-	2
BP306P	Physical Pharmaceutics I – Practical	4	-	2
BP307P	Pharmaceutical Microbiology – Practical	4	-	2
BP 308P	Pharmaceutical Engineering –Practical	4	-	2
	Total	**28**	**4**	**24**

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Table-IV: Course of study for semester IV

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP401T	Pharmaceutical Organic Chemistry III– Theory	3	1	4
BP402T	Medicinal Chemistry I – Theory	3	1	4
BP403T	Physical Pharmaceutics II – Theory	3	1	4
BP404T	Pharmacology I – Theory	3	1	4
BP405T	Pharmacognosy and Phytochemistry I– Theory	3	1	4
BP406P	Medicinal Chemistry I – Practical	4	-	2
BP407P	Physical Pharmaceutics II – Practical	4		2
BP408P	Pharmacology I – Practical	4	-	2
BP409P	Pharmacognosy and Phytochemistry I – Practical	4	-	2
	Total	**31**	**5**	**28**

Table-V: Course of study for semester V

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3	1	4
BP502T	Industrial PharmacyI– Theory	3	1	4
BP503T	Pharmacology II – Theory	3	1	4
BP504T	Pharmacognosy and Phytochemistry II– Theory	3	1	4
BP505T	Pharmaceutical Jurisprudence – Theory	3	1	4
BP506P	Industrial PharmacyI – Practical	4	-	2
BP507P	Pharmacology II – Practical	4	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4	-	2
	Total	**27**	**5**	**26**

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Table-VI: Course of study for semester VI

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III – Theory	3	1	4
BP602T	Pharmacology III – Theory	3	1	4
BP603T	Herbal Drug Technology – Theory	3	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3	1	4
BP605T	Pharmaceutical Biotechnology – Theory	3	1	4
BP606T	Quality Assurance –Theory	3	1	4
BP607P	Medicinal chemistry III – Practical	4	-	2
BP608P	Pharmacology III – Practical	4	-	2
BP609P	Herbal Drug Technology – Practical	4	-	2
	Total	**30**	**6**	**30**

Table-VII: Course of study for semester VII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3	1	4
BP702T	Industrial PharmacyII – Theory	3	1	4
BP703T	Pharmacy Practice – Theory	3	1	4
BP704T	Novel Drug Delivery System – Theory	3	1	4
BP705P	Instrumental Methods of Analysis – Practical	4	-	2
BP706PS	Practice School*	12	-	6
	Total	**28**	**5**	**24**

* Non University Examination (NUE)

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Table-VIII: Course of study for semester VIII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3	1	4
BP802T	Social and Preventive Pharmacy	3	1	4
BP803ET	Pharma Marketing Management	3 + 3 = 6	1 + 1 = 2	4 + 4 = 8
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardization of Herbals			
BP807ET	Computer Aided Drug Design			
BP808ET	Cell and Molecular Biology			
BP809ET	Cosmetic Science			
BP810ET	Experimental Pharmacology			
BP811ET	Advanced Instrumentation Techniques			
BP812ET	Dietary Supplements and Nutraceuticals			
BP813PW	Project Work	12	-	6
	Total	**24**	**4**	**22**

Table-IX: Semester wise credits distribution

Semester	Credit Points
I	**27/29$/30#**
II	29
III	26
IV	28
V	26
VI	26
VII	24
VIII	22
Extracurricular/ Co curricular activities	01*
Total credit points for the program	**209/211$/212#**

* The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

$Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics course.

#Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology course.

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10. Program Committee

1. The B. Pharm. program shall have a Program Committee constituted by the Head of the institution in consultation with all the Heads of the departments.

2. The composition of the Program Committee shall be as follows:

   A senior teacher shall be the Chairperson; One Teacher from each department handling B.Pharm courses; and four student representatives of the program (one from each academic year), nominated by the Head of the institution.

3. Duties of the Program Committee:

   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Program Committee shall meet at least thrice in a semester preferably at the end of each Sessionalexam (Internal Assessment) and before the end semester exam.

11. Examinations/Assessments

The scheme for internal assessment and end semester examinations is given in Table – X.

11.1. End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to VIII shall beconducted by the university except for the subjects with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

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Tables-X: Schemes for internal assessments and end semester examinations semester wise

Semester I

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
BP101T	Human Anatomy and Physiology I– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP102T	Pharmaceutical Analysis I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP103T	Pharmaceutics I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP104T	Pharmaceutical Inorganic Chemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP105T	Communication skills – Theory *	5	10	1 Hr	15	35	1.5 Hrs	50
BP106RBT BP106RMT	Remedial Biology/ Mathematics – Theory*	5	10	1 Hr	15	35	1.5 Hrs	50
BP107P	Human Anatomy and Physiology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP108P	Pharmaceutical Analysis I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP109P	Pharmaceutics I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP110P	Pharmaceutical Inorganic Chemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP111P	Communication skills – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
BP112RBP	Remedial Biology – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
	Total	**70/75$^{\$}$/80$^{\#}$**	**115/125$^{\$}$/130$^{\#}$**	**23/24$^{\$}$/26$^{\#}$ Hrs**	**185/200$^{\$}$/210$^{\#}$**	**490/525$^{\$}$/ 540$^{\#}$**	**31.5/33$^{\$}$/ 35$^{\#}$ Hrs**	**675/725$^{\$}$/ 750$^{\#}$**

$^{\#}$Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.

$^{\$}$Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course.

* Non University Examination (NUE)

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3. Duties of the Program Committee:

   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Program Committee shall meet at least thrice in a semester preferably at the end of each Sessionalexam (Internal Assessment) and before the end semester exam.

11. Examinations/Assessments

The scheme for internal assessment and end semester examinations is given in Table – X.

11.1. End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to VIII shall beconducted by the university except for the subjects with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

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Semester II

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP201T	Human Anatomy and Physiology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP202T	Pharmaceutical Organic Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP203T	Biochemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP204T	Pathophysiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP205T	Computer Applications in Pharmacy – Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP206T	Environmental sciences – Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP207P	Human Anatomy and Physiology II –Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP208P	Pharmaceutical Organic Chemistry I– Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP209P	Biochemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP210P	Computer Applications in Pharmacy – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
	Total	**80**	**125**	**20 Hrs**	**205**	**520**	**30 Hrs**	**725**

* The subject experts at college level shall conduct examinations

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Semester III

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP301T	Pharmaceutical Organic Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP302T	PhysicalPharmaceuticsI –Theory	10	15	1 Hr	25	75	3 Hrs	100
BP303T	Pharmaceutical Microbiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP304T	Pharmaceutical Engineering – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP305P	Pharmaceutical Organic Chemistry II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP306P	Physical Pharmaceutics I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP307P	Pharmaceutical Microbiology – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP308P	Pharmaceutical Engineering – Practical	5	10	4 Hr	15	35	4 Hrs	50
	Total	**60**	**100**	**20**	**160**	**440**	**28Hrs**	**600**

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Semester IV

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP401T	Pharmaceutical Organic Chemistry III– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP402T	Medicinal Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP403T	Physical Pharmaceutics II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP404T	Pharmacology I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP405T	Pharmacognosy I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP406P	Medicinal Chemistry I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP407P	Physical Pharmaceutics II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP408P	Pharmacology I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP409P	Pharmacognosy I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**70**	**115**	**21 Hrs**	**185**	**515**	**31 Hrs**	**700**

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Semester V

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP501T	Medicinal Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP502T	Industrial PharmacyI– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP503T	Pharmacology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP504T	Pharmacognosy II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP505T	Pharmaceutical Jurisprudence – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP506P	Industrial PharmacyI– Practical	5	10	4 Hr	15	35	4 Hrs	50
BP507P	Pharmacology II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP508P	Pharmacognosy II – Practical	5	10	4 Hr	15	35	4 Hrs	50
	Total	**65**	**105**	**17 Hr**	**170**	**480**	**27 Hrs**	**650**

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Semester VI

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP601T	Medicinal Chemistry III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP602T	Pharmacology III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP603T	Herbal Drug Technology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP605T	Pharmaceutical Biotechnology– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP606T	Quality Assurance– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP607P	Medicinal chemistry III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP608P	Pharmacology III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP609P	Herbal Drug Technology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
	Total	**75**	**120**	**18 Hrs**	**195**	**555**	**30 Hrs**	**750**

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Semester VII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP701T	Instrumental Methods of Analysis – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP702T	Industrial Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP703T	Pharmacy Practice – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP704T	Novel Drug Delivery System – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP705 P	Instrumental Methods of Analysis – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP706 PS	Practice School*	25	-	-	25	125	5 Hrs	150
	Total	**70**	**70**	**8Hrs**	**140**	**460**	**21 Hrs**	**600**

* The subject experts at college level shall conduct examinations

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Semester VIII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP801T	Biostatistics and Research Methodology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP802T	Social and Preventive Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP803ET	Pharmaceutical Marketing – Theory	10 + 10 = 20	15 + 15 = 30	1 + 1 = 2 Hrs	25 + 25 = 50	75 + 75 = 150	3 + 3 = 6 Hrs	100 + 100 = 200
BP804ET	Pharmaceutical Regulatory Science – Theory							
BP805ET	Pharmacovigilance – Theory							
BP806ET	Quality Control and Standardization of Herbals – Theory							
BP807ET	Computer Aided Drug Design – Theory							
BP808ET	Cell and Molecular Biology – Theory							
BP809ET	Cosmetic Science – Theory							
BP810ET	Experimental Pharmacology – Theory							
BP811ET	Advanced Instrumentation Techniques – Theory							
BP812PW	Project Work	-	-	-	-	150	4 Hrs	150
	Total	**40**	**60**	**4 Hrs**	**100**	**450**	**16 Hrs**	**550**

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CHAPTER - II: SYLLABUS

Semester I

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Evaluation of Dissertation Book:

Objective(s) of the work done	15 Marks
Methodology adopted	20 Marks
Results and Discussions	20 Marks
Conclusions and Outcomes	20 Marks
Total	**75 Marks**

Evaluation of Presentation:

Presentation of work	25 Marks
Communication skills	20 Marks
Question and answer skills	30 Marks
Total	**75 Marks**

Explanation: The 75 marks assigned to the dissertation book shall be same for all the students in a group. However, the 75 marks assigned for presentation shall be awarded based on the performance of individual students in the given criteria.

22. Industrial training (Desirable)

Every candidate shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. After the Semester – VI and before the commencement of Semester – VII, and shall submit satisfactory report of such work and certificate duly signed by the authority of training organization to the head of the institute.

23. Practice School

In the VII semester, every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the program committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college leveland grade point shall be awarded.

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24. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the B.Pharm program shall not be eligible for award of ranks.Moreover, the candidates should have completed the B. Pharm program in minimum prescribed number of years, (four years) for the award of Ranks.

25. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

26. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

27. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

No condonation is allowed for the candidate who has more than 2 years of break up period and he/she has to rejoin the program by paying the required fees.

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Note: Grade ABshould be considered as failed and treated as one head for deciding academic progression. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course.The letter grades and their corresponding grade points are given in Table – XII.

Table – XII: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of ABand a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtainedin all the courses by the student during the semester. For example, if a student takes five courses(Theory/Practical) in a semester with credits C1, C2, C3, C4 and C5 and the student's grade pointsin these courses are G1, G2, G3, G4 and G5, respectively, and then students' SGPA is equal to:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4 + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

The SGPA is calculated to two decimal points.It should be noted that, the SGPA for any semester shall take into consideration the F and ABSgrade awarded in that semester. For example if a learner has a F or ABS grade in course 4, theSGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * ZERO + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the VIII semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all VIII semesters and their courses. The CGPA shall reflect the failed statusin case of F grade(s),till the course(s) is/are passed. When the course(s)is/are passedby obtaining a pass grade on subsequent examination(s) theCGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4 + C_5S_5 + C_6S_6 + C_7S_7 + C_8S_8}{C_1 + C_2 + C_3 + C_4 + C_5 + C_6 + C_7 + C_8}$$

where $C_1, C_2, C_3, \ldots$ is the total number of credits for semester I,II,III,.... and $S_1, S_2, S_3, \ldots$ is the SGPA of semester I,II,III,.... .

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction	= CGPA of. 7.50 and above
First Class	= CGPA of 6.00 to 7.49
Second Class	= CGPA of 5.00 to 5.99

21. Project work

All the students shall undertake a projectunder the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of five students). The projects shall be evaluated as per the criteria given below.

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Table-XIII: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I, III, V and VII	November / December	May / June
II, IV, VI and VIII	May / June	November / December

Question paper pattern for end semester theory examinations

For 75 marks paper

I. Multiple Choice Questions(MCQs) = 20 x 1 = 20
OR OR
Objective Type Questions (10 x 2) = 10 x 2 = 20
(Answer all the questions)
II. Long Answers (Answer 2 out of 3) = 2 x 10 = 20
III. Short Answers (Answer 7 out of 9) = 7 x 5 = 35

Total = 75 marks

For 50 marks paper

I. Long Answers (Answer 2 out of 3) = 2 x 10 = 20
II. Short Answers (Answer 6 out of 8) = 6 x 5 = 30

Total = 50 marks

For 35 marks paper

I. Long Answers (Answer 1 out of 2) = 1 x 10 =10
II. Short Answers (Answer 5 out of 7) = 5 x 5 = 25

Total = 35 marks

Question paper pattern for end semester practical examinations

I. Synopsis = 5
II. Experiments = 25
III. Viva voce = 5

Total = 35 marks

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16. Academic Progression:

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. Academic progression rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I, II and III semesters till the IV semester examinations. However, he/she shall not be eligible to attend the courses of V semester until all the courses of I and II semesters are successfully completed.

A student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of I, II, III and IV semesters are successfully completed.

A student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of I, II, III, IV, V and VI semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to VIII semesters within the stipulated time period as per the norms specified in 26.

A lateral entry student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of III and IV semesters are successfully completed.

A lateral entry student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of III, IV, V and VI semesters are successfully completed.

A lateral entry student shall be eligible to get his/her CGPA upon successful completion of the courses of III to VIII semesters within the stipulated time period as per the norms specified in 26.

Any student who hasgiven more than 4 chances for successful completion of I / III semester courses and more than 3 chances for successful completion of II / IV semester courses shall be permitted to attend V / VII semester classes ONLY during the subsequent academic year as the case may be. In simpler terms there shall NOT be any ODD BATCH for any semester.

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Semester	For Regular Candidates	For Failed Candidates
I, III, V and VII	November / December	May / June
II, IV, VI and VIII	May / June	November / December

Question paper pattern for end semester theory examinations

For 75 marks paper

I. Multiple Choice Questions(MCQs)	=	20 x 1 = 20
OR		OR
Objective Type Questions (10 x 2)	=	10 x 2 = 20
(Answer all the questions)		
II. Long Answers (Answer 2 out of 3)	=	2 x 10 = 20
III. Short Answers (Answer 7 out of 9)	=	7 x 5 = 35
	Total =	75 marks

For 50 marks paper

I. Long Answers (Answer 2 out of 3)	=	2 x 10 = 20
II. Short Answers (Answer 6 out of 8)	=	6 x 5 = 30
	Total =	50 marks

For 35 marks paper

I. Long Answers (Answer 1 out of 2)	=	1 x 10 =10
II. Short Answers (Answer 5 out of 7)	=	5 x 5 = 25
	Total =	35 marks

Question paper pattern for end semester practical examinations

I. Synopsis	=	5
II. Experiments	=	25
III. Viva voce	=	5
	Total =	35 marks

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For subjects having Non University Examination

I. Long Answers (Answer 1 out of 2)	=	1 x 10 = 10
II. Short Answers (Answer 4 out of 6)	=	4 x 5 = 20
	Total =	30 marks

Question paper pattern for practical sessional examinations

I. Synopsis	=	10
II. Experiments	=	25
III. Viva voce	=	05
	Total =	40 marks

12. Promotion and award of grades

A student shall be declared PASSand eligible for getting gradein a course of B.Pharm.program if he/she secures at least 50% marks in that particular course including internal assessment.For example, to be declared as PASS and to get grade, the student has to secure a minimum of 50 marks for the total of 100 including continuous mode of assessment and end semester theory examination and has to secure a minimum of 25 marks for the total 50 including internal assessment and end semester practical examination.

13. Carry forward of marks

In case a studentfails to secure the minimum 50% in any Theory or Practical course as specified in 12,then he/she shall reappear for the end semester examinationof that course. However his/her marks of the Internal Assessmentshallbe carried overand he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A studentshall have the opportunity to improvehis/her performance only oncein the Sessional exam component of the internal assessment. The re-conduct of the Sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Re-examination of end semester examinations

Reexamination ofend semester examinationshall be conducted as per the schedule given in table XIII. The exact dates of examinations shall be notified from time to time.

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11.2. Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table-XI:Scheme for awarding internal assessment: Continuous mode

Theory		
Criteria	**Maximum Marks**	
Attendance (Refer Table – XII)	4	2
Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	3	1.5
Student – Teacher interaction	3	1.5
Total	**10**	**5**
Practical		
Attendance (Refer Table – XII)	2	
Based on Practical Records, Regular viva voce, etc.	3	
Total	**5**	

Table- XII: Guidelines for the allotment of marks for attendance

Percentage of Attendance	**Theory**	**Practical**
95 – 100	4	2
90 – 94	3	1.5
85 – 89	2	1
80 – 84	1	0.5
Less than 80	0	0

11.2.1. Sessional Exams

Two Sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical Sessional examinations is given below. The average marks of two Sessional exams shall be computed for internal assessment as per the requirements given in tables – X.

Sessional exam shall be conducted for 30 marks for theory and shall be computed for 15 marks. Similarly Sessional exam for practical shall be conducted for 40 marks and shall be computed for 10 marks.

Question paper pattern for theory Sessional examinations

For subjects having University examination

I. Multiple Choice Questions (MCQs)	=	10 x 1 = 10
OR		OR
Objective Type Questions (5 x 2)	=	05 x 2 = 10
(Answer all the questions)		
I. Long Answers (Answer 1 out of 2)	=	1 x 10 = 10
II. Short Answers (Answer 2 out of 3)	=	2 x 5 = 10
	Total =	30 marks

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BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the various experiments related to special senses and nervous system.
5. Appreciate coordinated working pattern of different organs of each system

Course Content:

Unit I **10 hours**

- **Introduction to human body**
  Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.
- **Cellular level of organization**
  Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine
- **Tissue level of organization**
  Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.

Unit II **10 hours**

- **Integumentary system**
  Structure and functions of skin
- **Skeletal system**
  Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system
  Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction

- **Joints**
  Structural and functional classification, types of joints movements and its articulation

Unit III **10 hours**

- **Body fluids and blood**
- Body fluids, composition and functions of blood, hemopoeisis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system.
- **Lymphatic system**

  Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system

Unit IV **08 hours**

Peripheral nervous system:
Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system.
Origin and functions of spinal and cranial nerves.

- **Special senses**
  Structure and functions of eye, ear, nose and tongue and their disorders.

Unit V **07 hours**

- **Cardiovascular system**
  Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones

6. Introduction to hemocytometry.
7. Enumeration of white blood cell (WBC) count
8. Enumeration of total red blood corpuscles (RBC) count
9. Determination of bleeding time
10. Determination of clotting time
11. Estimation of hemoglobin content
12. Determination of blood group.
13. Determination of erythrocyte sedimentation rate (ESR).
14. Determination of heart rate and pulse rate.
15. Recording of blood pressure.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA
4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.

6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books (Latest Editions)

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

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BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones

6. Introduction to hemocytometry.
7. Enumeration of white blood cell (WBC) count
8. Enumeration of total red blood corpuscles (RBC) count
9. Determination of bleeding time
10. Determination of clotting time
11. Estimation of hemoglobin content
12. Determination of blood group.
13. Determination of erythrocyte sedimentation rate (ESR).
14. Determination of heart rate and pulse rate.
15. Recording of blood pressure.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA
4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.

BP102T. PHARMACEUTICAL ANALYSIS (Theory)

45 Hours

Scope: This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

Objectives: Upon completion of the course student shall be able to

- understand the principles of volumetric and electro chemical analysis
- carryout various volumetric and electrochemical titrations
- develop analytical skills

Course Content:

UNIT-I **10 Hours**

(a) Pharmaceutical analysis- Definition and scope

i) Different techniques of analysis

ii) Methods of expressing concentration

iii) Primary and secondary standards.

iv) Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate

(b)Errors: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures

(c)Pharmacopoeia, Sources of impurities in medicinal agents,limit tests.

UNIT-II **10 Hours**

- **Acid base titration**: Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves
- **Non aqueous titration**: Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl

UNIT-III **10 Hours**

- **Precipitation titrations**: Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride.
- **Complexometric titration**: Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.
- **Gravimetry**: Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate.
- Basic Principles,methods and application of diazotisation titration.

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UNIT-IV **08 Hours**

Redox titrations

(a) Concepts of oxidation and reduction

(b) Types of redox titrations (Principles and applications)

Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate

UNIT-V **07 Hours**

- **Electrochemical methods of analysis**
  - **Conductometry**- Introduction, Conductivity cell, Conductometric titrations, applications.
  - **Potentiometry** - Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.
  - **Polarography** - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications

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BP108P. PHARMACEUTICAL ANALYSIS (Practical)

4 Hours / Week

I **Limit Test of the following**
- (1) Chloride
- (2) Sulphate
- (3) Iron
- (4) Arsenic

II **Preparation and standardization of**
- (1) Sodium hydroxide
- (2) Sulphuric acid
- (3) Sodium thiosulfate
- (4) Potassium permanganate
- (5) Ceric ammonium sulphate

III **Assay of the following compounds along with Standardization of Titrant**
- (1) Ammonium chloride by acid base titration
- (2) Ferrous sulphate by Cerimetry
- (3) Copper sulphate by Iodometry
- (4) Calcium gluconate by complexometry
- (5) Hydrogen peroxide by Permanganometry
- (6) Sodium benzoate by non-aqueous titration
- (7) Sodium Chloride by precipitation titration

IV **Determination of Normality by electro-analytical methods**
- (1) Conductometric titration of strong acid against strong base
- (2) Conductometric titration of strong acid and weak acid against strong base
- (3) Potentiometric titration of strong acid against strong base

Recommended Books: (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry
5. John H. Kennedy, Analytical chemistry principles
6. Indian Pharmacopoeia.

BP103T. PHARMACEUTICS- I (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

Objectives: Upon completion of this course the student should be able to:

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

Course Content:

UNIT – I **10 Hours**

- **Historical background and development of profession of pharmacy**: History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.
- **Dosage forms:** Introduction to dosage forms, classification and definitions
- **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.
- **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

UNIT – II **10 Hours**

- **Pharmaceutical calculations**: Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.

- **Powders:** Definition, classification, advantages and disadvantages,Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.

- **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

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BP108P. PHARMACEUTICAL ANALYSIS (Practical)

4 Hours / Week

I **Limit Test of the following**
- (1) Chloride
- (2) Sulphate
- (3) Iron
- (4) Arsenic

II **Preparation and standardization of**
- (1) Sodium hydroxide
- (2) Sulphuric acid
- (3) Sodium thiosulfate
- (4) Potassium permanganate
- (5) Ceric ammonium sulphate

III **Assay of the following compounds along with Standardization of Titrant**
- (1) Ammonium chloride by acid base titration
- (2) Ferrous sulphate by Cerimetry
- (3) Copper sulphate by Iodometry
- (4) Calcium gluconate by complexometry
- (5) Hydrogen peroxide by Permanganometry
- (6) Sodium benzoate by non-aqueous titration
- (7) Sodium Chloride by precipitation titration

IV **Determination of Normality by electro-analytical methods**
- (1) Conductometric titration of strong acid against strong base
- (2) Conductometric titration of strong acid and weak acid against strong base
- (3) Potentiometric titration of strong acid against strong base

Recommended Books: (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry
5. John H. Kennedy, Analytical chemistry principles
6. Indian Pharmacopoeia.

UNIT – III **08 Hours**

- **Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.
- **Biphasic liquids:**
- **Suspensions:** Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.
- **Emulsions:** Definition, classification, emulsifying agent, test for the identification of type ofEmulsion, Methods of preparation & stability problems and methods to overcome.

UNIT – IV **08 Hours**

- **Suppositories**: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.
- **Pharmaceutical incompatibilities**: Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

UNIV – V **07 Hours**

- **Semisolid dosage forms:** Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms

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BP109P. PHARMACEUTICSI (Practical)

3 Hours / week

1 . Syrups

a) Syrup IP'66

b) Compound syrup of Ferrous Phosphate BPC'68

2. Elixirs a) Piperazine citrate elixir

b) Paracetamol pediatric elixir

3.Linctus a) Terpin Hydrate Linctus IP'66

b) Iodine Throat Paint (Mandles Paint)

4. Solutions

a) Strong solution of ammonium acetate

b) Cresol with soap solution

c) Lugol's solution

5. Suspensions

a) Calamine lotion

b) Magnesium Hydroxide mixture

c) Aluminimum Hydroxide gel

6. Emulsions a) Turpentine Liniment

b) Liquid paraffin emulsion

7. Powders and Granules

a) ORS powder (WHO)

b) Effervescent granules

c)Dusting powder

d)Divded powders

8. Suppositories

a) Glycero gelatin suppository

b) Coca butter suppository

c) Zinc Oxide suppository

8. Semisolids

a) Sulphur ointment

b) Non staining-iodine ointment with methyl salicylate

c) Carbopal gel

9. Gargles and Mouthwashes

a) Iodine gargle

b) Chlorhexidine mouthwash

Recommended Books: (Latest Editions)

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy,Lea& Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

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BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

45 Hours

Scope: This subject deals with the monographs of inorganic drugs and pharmaceuticals.

Objectives: Upon completion of course student shall be able to

- know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals
- understand the medicinal and pharmaceutical importance of inorganic compounds

Course Content:

UNIT I **10 Hours**

- **Impurities in pharmaceutical substances:** History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

  General methods of preparation, assay for the compounds superscripted with **asterisk (*),** properties and medicinal uses of inorganic compounds belonging to the following classes

UNIT II **10 Hours**

- **Acids, Bases and Buffers:** Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.
- **Major extra and intracellular electrolytes**: Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance.
- **Dental products**: Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

UNIT III **10 Hours**

- **Gastrointestinal agents**

  Acidifiers: Ammonium chloride* and Dil. HCl

  Antacid: Ideal properties of antacids, combinations of antacids, Sodium

Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture

Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite

Antimicrobials: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations

UNIT IV **08 Hours**

- **Miscellaneous compounds**

  Expectorants: Potassium iodide, Ammonium chloride*.

  Emetics: Copper sulphate*, Sodium potassium tartarate

  Haematinics: Ferrous sulphate*, Ferrous gluconate

  Poison and Antidote: Sodium thiosulphate*, Activated charcoal, Sodium nitrite333

  Astringents: Zinc Sulphate, Potash Alum

UNIT V **07 Hours**

- **Radiopharmaceuticals**: Radio activity, Measurement of radioactivity, Properties of α, β, γ radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide I^{131}, Storage conditions, precautions & pharmaceutical application of radioactive substances.

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BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)

4 Hours / Week

I **Limit tests for following ions**
- Limit test for Chlorides and Sulphates
- Modified limit test for Chlorides and Sulphates
- Limit test for Iron
- Limit test for Heavy metals
- Limit test for Lead
- Limit test for Arsenic

II **Identification test**
- Magnesium hydroxide
- Ferrous sulphate
- Sodium bicarbonate
- Calcium gluconate
- Copper sulphate

III **Test for purity**
- Swelling power of Bentonite
- Neutralizing capacity of aluminum hydroxide gel
- Determination of potassium iodate and iodine in potassium Iodide

IV **Preparation of inorganic pharmaceuticals**
- Boric acid
- Potash alum
- Ferrous sulphate

Recommended Books (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4th edition.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition
4. M.L Schroff, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
7. Indian Pharmacopoeia

BP105T.COMMUNICATION SKILLS (Theory)

30 Hours

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

Objectives:

Upon completion of the course the student shall be able to

1. Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
2. Communicate effectively (Verbal and Non Verbal)
3. Effectively manage the team as a team player
4. Develop interview skills
5. Develop Leadership qualities and essentials

Course content:

UNIT – I **07 Hours**

- **Communication Skills:** Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context
- **Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers
- **Perspectives in Communication:** Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

UNIT – II **07 Hours**

- **Elements of Communication:** Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication
- **Communication Styles:** Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

UNIT – III **07 Hours**

- **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations
- **Effective Written Communication:** Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication
- **Writing Effectively:** Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

UNIT – IV **05 Hours**

- **Interview Skills:** Purpose of an interview, Do's and Dont's of an interview
- **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

UNIT – V **04 Hours**

- **Group Discussion:** Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

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BP111P.COMMUNICATION SKILLS (Practical)

2 Hours / week

Thefollowing learning modules are to be conducted using wordsworth® English language lab software

Basic communication covering the following topics

Meeting People

Asking Questions

Making Friends

What did you do?

Do's and Dont's

Pronunciations covering the following topics

Pronunciation (Consonant Sounds)

Pronunciation and Nouns

Pronunciation (Vowel Sounds)

Advanced Learning

Listening Comprehension / Direct and Indirect Speech

Figures of Speech

Effective Communication

Writing Skills

Effective Writing

Interview Handling Skills

E-Mail etiquette

Presentation Skills

Recommended Books: (Latest Edition)

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1stEdition, Oxford Press, 2011
3. Organizational Behaviour, Stephen .P. Robbins, 1stEdition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1stEdition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5thEdition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2ndEdition, New arrivals – PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1stEdition, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, 1stEdition, Mc Graw Hill Education, 2011
11. Effective communication, John Adair, 4thEdition, Pan Mac Millan,2009
12. Bringing out the best in people, Aubrey Daniels, 2ndEdition, Mc Graw Hill, 1999

BP 106RBT.REMEDIAL BIOLOGY (Theory)

30 Hours

Scope: To learn and understand the components of living world, structure and functional system of plant and animal kingdom.

Objectives: Upon completion of the course, the student shall be able to

- know the classification and salient features of five kingdoms of life
- understand the basic components of anatomy & physiology of plant
- know understand the basic components of anatomy & physiology animal with special reference to human

UNIT I **07 Hours**

Living world:

- Definition and characters of living organisms
- Diversity in the living world
- Binomial nomenclature
- Five kingdoms of life and basis of classification. Salient features of Monera, Potista, Fungi, Animalia and Plantae, Virus,

Morphology of Flowering plants

- Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.
- General Anatomy of Root, stem, leaf of monocotyledons & Dicotylidones.

UNIT II **07 Hours**

Body fluids and circulation

- Composition of blood, blood groups, coagulation of blood
- Composition and functions of lymph
- Human circulatory system
- Structure of human heart and blood vessels
- Cardiac cycle, cardiac output and ECG

Digestion and Absorption

- Human alimentary canal and digestive glands
- Role of digestive enzymes
- Digestion, absorption and assimilation of digested food

Breathing and respiration

- Human respiratory system
- Mechanism of breathing and its regulation
- Exchange of gases, transport of gases and regulation of respiration
- Respiratory volumes

UNIT III **07 Hours**

Excretory products and their elimination

- Modes of excretion
- Human excretory system- structure and function
- Urine formation
- Rennin angiotensin system

Neural control and coordination

- Definition and classification of nervous system
- Structure of a neuron
- Generation and conduction of nerve impulse
- Structure of brain and spinal cord
- Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

Chemical coordination and regulation

- Endocrine glands and their secretions
- Functions of hormones secreted by endocrine glands

Human reproduction

- Parts of female reproductive system
- Parts of male reproductive system
- Spermatogenesis and Oogenesis
- Menstrual cycle

UNIT IV **05 Hours**

Plants and mineral nutrition:

- Essential mineral, macro and micronutrients
- Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

Photosynthesis

- Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.

UNIT V **04 Hours**

Plant respiration: Respiration, glycolysis, fermentation (anaerobic).

Plant growth and development

- Phases and rate of plant growth, Condition of growth,Introduction to plant growth regulators

Cell - The unit of life

- Structure and functions of cell and cell organelles.Cell division

Tissues

- Definition, types of tissues, location and functions.

Text Books

a. Text book of Biology by S. B. Gokhale
b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books

a. A Text book of Biology by B.V. Sreenivasa Naidu
b. A Text book of Biology by Naidu and Murthy
c. Botany for Degree students By A.C.Dutta.
d.Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Ananthakrishnan.
e. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

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BP112RBP.REMEDIAL BIOLOGY (Practical)

30 Hours

1. Introduction to experiments in biology
   a) Study of Microscope
   b) Section cutting techniques
   c) Mounting and staining
   d) Permanent slide preparation
2. Study of cell and its inclusions
3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues pertinent to Stem, Root Leaf, seed, fruit and flower
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Reference Books

1. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.
2. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.
3. Biology practical manual according to National core curriculum .Biology forum of Karnataka. Prof .M.J.H.Shafi

BP 106RMT.REMEDIAL MATHEMATICS (Theory)

30 Hours

Scope: This is an introductory course in mathematics. This subject deals with the introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.

Objectives: Upon completion of the course the student shall be able to:-

1. Know the theory and their application in Pharmacy
2. Solve the different types of problems by applying theory
3. Appreciate the important application of mathematics in Pharmacy

Course Content:

UNIT – I **06 Hours**

- **Partial fraction**

Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction , Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics

- **Logarithms**

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.

- **Function**:

Real Valued function, Classification of real valued functions,

- **Limits and continuity** :

Introduction , Limit of a function, Definition of limit of a function ($\in$ - δ definition) , $\lim_{x \to a} \frac{x^n - a^n}{x - a} = na^{n-1}$, $\lim_{\theta \to 0} \frac{\sin\theta}{\theta} = 1$,

UNIT –II **06 Hours**

- **Matrices and Determinant:**

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants , Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix , Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley–Hamilton theorem,Applicationof Matrices in solving Pharmacokinetic equations

UNIT – III **06 Hours**

- **Calculus**

Differentiation : Introductions, Derivative of a function, Derivative of a constant, Derivative of a product of a constant and a function , Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two functions (Quotient formula) – **Without Proof**, Derivative of x^n *w.r.t*x,where *n* is any rational number, Derivative of e^x,, Derivative of $\log_e x$, Derivative of a^x,Derivative of trigonometric functions from first principles **(without Proof)**, Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point. Application

UNIT – IV **06 Hours**

- **Analytical Geometry**

Introduction: Signs of the Coordinates, Distance formula,

Straight Line : Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope – intercept form of a straight line

Integration:

Introduction, Definition, Standard formulae, Rules of integration , Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

UNIT-V **06 Hours**

- **Differential Equations** : Some basic definitions, Order and degree, Equations in separable form , Homogeneous equations, Linear Differential equations, Exact equations, **Application in solving Pharmacokinetic equations**
- **Laplace Transform** : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, **Application in solving Chemical kinetics and Pharmacokinetics equations**

Recommended Books (Latest Edition)

1. Differential Calculus by Shanthinarayan
2. Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa Gowda D.H.
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr.B.S.Grewal

Semester II

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BP 201T. HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to:

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.
5. Appreciate coordinated working pattern of different organs of each system
6. Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Course Content:

Unit I **10 hours**

- **Nervous system**

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters.

Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid.structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts,reflex activity)

Unit II **06 hours**

- **Digestive system**

Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine

and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

- **Energetics**

  Formation and role of ATP, Creatinine Phosphate and BMR.

Unit III **10 hours**

- **Respiratory system**

  Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration

  Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

- **Urinary system**
  Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

Unit IV **10 hours**

- **Endocrine system**
  Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal
  gland, pancreas, pineal gland, thymus and their disorders.

Unit V **09 hours**

- **Reproductive system**

  Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

- **Introduction to genetics**

  Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

1. To study the integumentary and special senses using specimen, models, etc.,
2. To study the nervous system using specimen, models, etc.,
3. To study the endocrine system using specimen, models, etc
4. To demonstrate the general neurological examination
5. To demonstrate the function of olfactory nerve
6. To examine the different types of taste.
7. To demonstrate the visual acuity
8. To demonstrate the reflex activity
9. Recording of body temperature
10. To demonstrate positive and negative feedback mechanism.
11. Determination of tidal volume and vital capacity.
12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
13. Recording of basal mass index .
14. Study of family planning devices and pregnancy diagnosis test.
15. Demonstration of total blood count by cell analyser
16. Permanent slides of vital organs and gonads.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA

4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books:

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)

45 Hours

Scope: This subject deals with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions and methods of preparation of these compounds. The syllabus also emphasizes on mechanisms and orientation of reactions.

Objectives: Upon completion of the course the student shall be able to

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. identify/confirm the identification of organic compound

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT-I **07 Hours**

- **Classification, nomenclature and isomerism**

  Classification of Organic Compounds

  Common and IUPAC systems of nomenclature of organic compounds

  (up to 10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds

UNIT-II10 Hours

- **Alkanes*, Alkenes* and Conjugated dienes***

  SP^3 hybridization in alkanes, Halogenation of alkanes, uses of paraffins.

  Stabilities of alkenes, SP^2 hybridization in alkenes

  E_1 and E_2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E_1 verses E_2 reactions, Factors affecting E_1 and E_2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.

  Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement

UNIT-III10 Hours

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- **Alkyl halides***

  SN_1 and SN_2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

  SN_1 versus SN_2 reactions, Factors affecting SN_1 and SN_2 reactions

  Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.

- **Alcohols***- Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol

UNIT-IV10 Hours

- **Carbonyl compounds* (Aldehydes and ketones)**

  Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde.

08 Hours

UNIT-V

- **Carboxylic acids***

  Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids ,amide and ester

  Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid

- **Aliphatic amines*** - Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine

BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)

4 Hours / week

1. Systematic qualitative analysis of unknown organic compounds like
    1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
    2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
    3. Solubility test
    4. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
    5. Melting point/Boiling point of organic compounds
    6. Identification of the unknown compound from the literature using melting point/ boiling point.
    7. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
    8. Minimum 5 unknown organic compounds to be analysed systematically.
2. Preparation of suitable solid derivatives from organic compounds
3. Construction of molecular models

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
9. Reaction and reaction mechanism by Ahluwaliah/Chatwal.

BP203 T. BIOCHEMISTRY (Theory)

45 Hours

Scope: Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

Objectives: Upon completion of course student shell able to

1. Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.
2. Understand the metabolism of nutrient molecules in physiological and pathological conditions.
3. Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

Course Content:

UNIT I **08 Hours**

- **Biomolecules**

  Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins.

- **Bioenergetics**

  Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential.

  Energy rich compounds; classification; biological significances of ATP and cyclic AMP

UNIT II **10 Hours**

- **Carbohydrate metabolism**

  Glycolysis – Pathway, energetics and significance

  Citric acid cycle- Pathway, energetics and significance

  HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency

  Glycogen metabolism Pathways and glycogen storage diseases (GSD)

  Gluconeogenesis- Pathway and its significance

  Hormonal regulation of blood glucose level and Diabetes mellitus

- **Biological oxidation**

  Electron transport chain (ETC) and its mechanism.

Oxidative phosphorylation & its mechanism and substrate level phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers

UNIT III **10 Hours**

- **Lipid metabolism**

  β-Oxidation of saturated fatty acid (Palmitic acid)

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Formation and utilization of ketone bodies, ketoacidosis

De novo synthesis of fatty acids (Palmitic acid)

Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D

Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

- **Amino acid metabolism**

General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders

Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia)

Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline

Catabolism of heme; hyperbilirubinemia and jaundice

UNIT IV **10 Hours**

- **Nucleic acid metabolism and genetic information transfer**

Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease

Organization of mammalian genome

Structure of DNA and RNA and their functions

DNA replication (semi conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

UNIT V **07 Hours**

- **Enzymes**

  Introduction, properties, nomenclature and IUB classification of enzymes

  Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

  Enzyme inhibitors with examples

  Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation

  Therapeutic and diagnostic applications of enzymes and isoenzymes

  Coenzymes –Structure and biochemical functions

BP 209 P. BIOCHEMISTRY (Practical)

4 Hours / Week

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.

Formation and utilization of ketone bodies; ketoacidosis

De novo synthesis of fatty acids (Palmitic acid)

Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D

Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

- **Amino acid metabolism**

General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders

Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia)

Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline

Catabolism of heme; hyperbilirubinemia and jaundice

UNIT IV **10 Hours**

- **Nucleic acid metabolism and genetic information transfer**

Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease

Organization of mammalian genome

Structure of DNA and RNA and their functions

DNA replication (semi conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

UNIT V **07 Hours**

- **Enzymes**

  Introduction, properties, nomenclature and IUB classification of enzymes

  Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

  Enzyme inhibitors with examples

  Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation

  Therapeutic and diagnostic applications of enzymes and isoenzymes

  Coenzymes –Structure and biochemical functions

BP 209 P. BIOCHEMISTRY (Practical)

4 Hours / Week

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.

Recommended Books (Latest Editions)

1. Principles of Biochemistry by Lehninger.
2. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
3. Biochemistry by Stryer.
4. Biochemistry by D. Satyanarayan and U.Chakrapani
5. Textbook of Biochemistry by Rama Rao.
6. Textbook of Biochemistry by Deb.
7. Outlines of Biochemistry by Conn and Stumpf
8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
11. Practical Biochemistry by Harold Varley.

BP 204T.PATHOPHYSIOLOGY (THEORY)

45Hours

Scope: Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes.This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

Objectives: Upon completion of the subject student shall be able to –

1. Describe the etiology and pathogenesis of the selected disease states;
2. Name the signs and symptoms of the diseases; and
3. Mention the complications of the diseases.

Course content:

Unit I **10Hours**

- **Basic principles of Cell injury and Adaptation:**
  Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury,Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage),Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia),Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis &Alkalosis,Electrolyte imbalance

- **Basic mechanism involved in the process of inflammation and repair:** Introduction, Clinical signs of inflammation, Different types of Inflammation,Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's,Mediators of inflammation,Basic principles of wound healing in the skin,Pathophysiology of Atherosclerosis

10Hours

Unit II

- **Cardiovascular System:** Hypertension, congestive heart failure, ischemic heart disease (angina,myocardial infarction, atherosclerosis and arteriosclerosis)
- **Respiratory system:**Asthma, Chronic obstructive airways diseases.
- **Renal system:**Acute and chronic renal failure .

10Hours

Unit II

- **Haematological Diseases:** Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia
- **Endocrine system:** Diabetes, thyroid diseases, disorders of sex hormones
- **Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.
- **Gastrointestinal system:** Peptic Ulcer
-

8 Hours

Unit IV

- Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.
- **Disease of bones and joints:** Rheumatoid arthritis, osteoporosis and gout
- **Principles of cancer:** classification, etiology and pathogenesis of cancer
- **Diseases of bones and joints:**Rheumatoid Arthritis, Osteoporosis,Gout
- **Principles of Cancer:** Classification, etiology and pathogenesis of Cancer

7 Hours

Unit V

- **Infectious diseases:**Meningitis,Typhoid, Leprosy, Tuberculosis

Urinary tract infections

- **Sexually transmitted diseases:**AIDS, Syphilis, Gonorrhea

Recommended Books (Latest Editions)

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins &Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. William and Wilkins, Baltimore;1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston;Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

Recommended Journals

1. The Journal of Pathology. ISSN: 1096-9896 (Online)
2. The American Journal of Pathology. ISSN: 0002-9440
3. Pathology. 1465-3931 (Online)
4. International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171 (Online)
5. Indian Journal of Pathology and Microbiology. ISSN-0377-4929.

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BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)

30 Hrs (2 Hrs/Week)

Scope: This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

Objectives: Upon completion of the course the student shall be able to

1. know the various types of application of computers in pharmacy
2. know the various types of databases
3. know the various applications of databases in pharmacy

Course content:

UNIT – I **06 hours**

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement ,Two's complement method, binary multiplication, binary division

Concept of Information Systems and Software : Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

UNIT –II **06 hours**

Web technologies:Introduction to HTML, XML,CSS and Programming languages, introduction to web servers and Server Products

Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

UNIT – III **06 hours**

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

UNIT – IV **06 hours**

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

UNIT-V **06 hours**

Computers as data analysis in Preclinical development:
Chromatographic dada analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMS)

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BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3. Retrieve the information of a drug and its adverse effects using online tools
4. Creating mailing labels Using Label Wizard , generating label in MS WORD
5. Create a database in MS Access to store the patient information with the required fields Using access
6. Design a form in MS Access to view, add, delete and modify the patient record in the database
7. Generating report and printing the report from patient database
8. Creating invoice table using – MS Access
9. Drug information storage and retrieval using MS Access
10. Creating and working with queries in MS Access
11. Exporting Tables, Queries, Forms and Reports to web pages
12. Exporting Tables, Queries, Forms and Reports to XML pages

Recommended books (Latest edition):

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi - 110002

BP 206 T. ENVIRONMENTAL SCIENCES (Theory)

30 hours

Scope: Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

Objectives: Upon completion of the course the student shall be able to:

1. Create the awareness about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the environment.
4. Motivate learner to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature.

Course content:

10hours

Unit-I

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

10hours

Unit-II

Ecosystems

- Concept of an ecosystem.
- Structure and function of an ecosystem.
- Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

10hours

Unit- III

Environmental Pollution: Air pollution; Water pollution; Soil pollution

Recommended Books (Latest edition):

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clanderson Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

SEMESTER III

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BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)

45 Hours

Scope: This subject deals with general methods of preparation and reactions of some organic compounds. Reactivity of organic compounds are also studied here. The syllabus emphasizes on mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

Objectives: Upon completion of the course the student shall be able to

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. prepare organic compounds

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT I **10 Hours**

- **Benzene and its derivatives**
  - **A.** Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule
  - **B.** Reactions of benzene - nitration, sulphonation, halogenation-reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.
  - **C.** Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction
  - **D.** Structure and uses of DDT, Saccharin, BHC and Chloramine

UNIT II **10 Hours**

- **Phenols*** - Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols
- **Aromatic Amines*** - Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts
- **Aromatic Acids*** –Acidity, effect of substituents on acidity and important reactions of benzoic acid.

UNIT III

10 Hours

- **Fats and Oils**

a. Fatty acids – reactions.

b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.

c. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

UNIT IV **08 Hours**

- **Polynuclear hydrocarbons:**

a. Synthesis, reactions

b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

UNIT V **07 Hours**

- **Cyclo alkanes***

Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only

BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

4 Hrs/week

I Experiments involving laboratory techniques

- Recrystallization
- Steam distillation

II Determination of following oil values (including standardization of reagents)

- Acid value
- Saponification value
- Iodine value

III **Preparation of compounds**

- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
- 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
- Acetanilide by halogenation (Bromination) reaction.
- 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
- Benzoic acid from Benzyl chloride by oxidation reaction.
- Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- 1-Phenyl azo-2-napthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
- Cinnammic acid from Benzaldehyde by Perkin reaction
- *P*-Iodo benzoic acid from *P*-amino benzoic acid

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.

BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

4 Hrs/week

I Experiments involving laboratory techniques

- Recrystallization
- Steam distillation

II Determination of following oil values (including standardization of reagents)

- Acid value
- Saponification value
- Iodine value

III **Preparation of compounds**

- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
- 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
- Acetanilide by halogenation (Bromination) reaction.
- 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
- Benzoic acid from Benzyl chloride by oxidation reaction.
- Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- 1-Phenyl azo-2-napthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
- Cinnammic acid from Benzaldehyde by Perkin reaction
- *P*-Iodo benzoic acid from *P*-amino benzoic acid

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.

8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

BP302T. PHYSICAL PHARMACEUTICS-I (Theory)

45Hours

Scope: The course deals with the various physica and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

Objectives: Upon the completion of the course student shall be able to

1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
2. Know the principles of chemical kinetics & to use them for stability testing nad determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Content:

UNIT-I **10 Hours**

Solubility of drugs: Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications

UNIT-II **10Hours**

States of Matter and properties of matter: State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols – inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid-crystalline, amorphous & polymorphism.

Physicochemical properties of drug molecules: Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determinations and applications

UNIT-III **08 Hours**

Surface and interfacial phenomenon: Liquid interface, surface & interfacial tensions,

surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solid interface.

UNIT-IV **08Hours**

Complexation and protein binding: Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stability constants.

UNIT-V **07 Hours**

pH, buffers and Isotonic solutions: Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.

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BP306P. PHYSICAL PHARMACEUTICS – I (Practical)

4 Hrs/week

1. Determination the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in CCl_4 and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of surface tension of given liquids by drop count and drop weight method
7. Determination of HLB number of a surfactant by saponification method
8. Determination of Freundlich and Langmuir constants using activated char coal
9. Determination of critical micellar concentration of surfactants
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin
2. Experimental Pharmaceutics by Eugene, Parott.
3. Tutorial Pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical Calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C and ManavalanR.
8. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
9. Physical Pharmaceutics by C.V.S. Subramanyam
10. Test book of Physical Phramacy, by Gaurav Jain & Roop K. Khar

BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)

45Hours

Scope:

- Study of all categories of microorganisims especially for the production of alchol antibiotics, vaccines, vitamins enzymes etc..

Objectives: Upon completion of the subject student shall be able to;

1. Understand methods of identification, cultivation and preservation of various microorganisms
2. To understand the importance and implementation of sterlization in pharmaceutical processing and industry
3. Learn sterility testing of pharmaceutical products.
4. Carried out microbiological standardization of Pharmaceuticals.
5. Understand the cell culture technology and its applications in pharmaceutical industries.

Course content:

Unit I **10 Hours**

Introduction, history of microbiology, its branches, scope and its importance.
Introduction to Prokaryotes and Eukaryotes
Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).
Study of different types of phase constrast microscopy, dark field microscopy and electron microscopy.

Unit II **10 Hours**

Identification of bacteria using staining techniques (simple, Gram's &Acid fast staining) and biochemical tests (IMViC).

Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous,radiation and mechanical method of sterilization.

Evaluation of the efficiency of sterilization methods.

Equipments employed in large scale sterilization.

Sterility indicators.

Unit III **10 Hours**

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses.

Classification and mode of action of disinfectants

Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions

Evaluation of bactericidal & Bacteriostatic.

Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

Unit IV **08 Hours**

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.
Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.
Assessment of a new antibiotic.

Unit V **07Hours**

Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage.

Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.

Growth of animal cells in culture, general procedure for cell culture. Primary, established and transformed cell cultures.

Application of cell cultures in pharmaceutical industry and research.

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BP 307P.PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hrs/week

1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4. Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test.

Recommended Books (Latest edition)

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the art and science of various unit operations used in pharmaceutical industry.

Objectives: Upon completion of the course student shall be able:

1. To know various unit operations used in Pharmaceutical industries.
2. To understand the material handling techniques.
3. To perform various processes involved in pharmaceutical manufacturing process.
4. To carry out various test to prevent environmental pollution.
5. To appreciate and comprehend significance of plant lay out design for optimum use of resources.
6. To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

Course content:

UNIT-I **10 Hours**

- **Flow of fluids:** Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer.
- **Size Reduction:** Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.
- **Size Separation:** Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.

UNIT-II **10 Hours**

- **Heat Transfer:** Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.

- **Evaporation:** Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator& Economy of multiple effect evaporator.

- **Distillation:** Basic Principles and methodology of simple distillation,flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

UNIT- III **08 Hours**

- **Drying:** Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.

- **Mixing:** Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier,

UNIT-IV **08 Hours**

- **Filtration:** Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.
- **Centrifugation:** Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

UNIT- V **07 Hours**

- **Materials of pharmaceutical plant construction, Corrosion and its prevention:** Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and there prevention. Ferrous and nonferrous metals, inorganic and organic non metals, basic of material handling systems.

Recommended Books: (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson- Latest edition.
3. Unit operation of chemical engineering – Mcabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

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BP308P - PHARMACEUTICAL ENGINEERING (Practical)

4 Hours/week

I. Determination of radiation constant of brass, iron, unpainted and painted glass.
II. Steam distillation – To calculate the efficiency of steam distillation.
III. To determine the overall heat transfer coefficient by heat exchanger.
IV. Construction of drying curves (for calcium carbonate and starch).
V. Determination of moisture content and loss on drying.
VI. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
VII. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
VIII. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic andlogarithmic probability plots.
IX. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.
X. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such othermajor equipment.
XI. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
XII. To study the effect of time on the Rate of Crystallization.
XIII. To calculate the uniformity Index for given sample by using Double Cone Blender.

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SEMESTER IV

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BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)

45 Hours

Scope: This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important hetero cyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

Objectives: At the end of the course, the student shall be able to

1. understand the methods of preparation and properties of organic compounds
2. explain the stereo chemical aspects of organic compounds and stereo chemical reactions
3. know the medicinal uses and other applications of organic compounds

Course Content:

Note: To emphasize on definition, types, mechanisms, examples, uses/applications

UNIT-I **10 Hours**

Stereo isomerism

Optical isomerism –

Optical activity, enantiomerism, diastereoisomerism, meso compounds

Elements of symmetry, chiral and achiral molecules

DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers

Reactions of chiral molecules

Racemic modification and resolution of racemic mixture.

Asymmetric synthesis: partial and absolute

UNIT-II **10 Hours**

Geometrical isomerism

Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems)

Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane.

Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity.

Stereospecific and stereoselective reactions

UNIT-III **10 Hours**

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Heterocyclic compounds:

Nomenclature and classification

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrrole, Furan, and Thiophene

Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene

UNIT-IV **8 Hours**

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrazole, Imidazole, Oxazole and Thiazole.

Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine

Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

UNIT-V **07 Hours**

Reactions of synthetic importance

Metal hydride reduction ($NaBH_4$ and $LiAlH_4$), Clemmensen reduction, Birch reduction, Wolff Kishner reduction.

Oppenauer-oxidation and Dakin reaction.

Beckmanns rearrangement and Schmidt rearrangement.

Claisen-Schmidt condensation

Recommended Books (Latest Editions)

1. Organic chemistry by I.L. Finar, Volume-I & II.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl.
3. Heterocyclic Chemistry by Raj K. Bansal
4. Organic Chemistry by Morrison and Boyd
5. Heterocyclic Chemistry by T.L. Gilchrist

BP402T. MEDICINAL CHEMISTRY – I (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: Upon completion of the course the student shall be able to

1. understand the chemistry of drugs with respect to their pharmacological activity
2. understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. know the Structural Activity Relationship (SAR) of different class of drugs
4. write the chemical synthesis of some drugs

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

10 Hours

UNIT- I

Introduction to Medicinal Chemistry

History and development of medicinal chemistry

Physicochemical properties in relation to biological action

Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism.

Drug metabolism

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

10 Hours

UNIT- II

Drugs acting on Autonomic Nervous System

Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

Sympathomimetic agents: SAR of Sympathomimetic agents

Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine,

Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

- Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.
- Agents with mixed mechanism: Ephedrine, Metaraminol.

Adrenergic Antagonists:

Alpha adrenergic blockers: Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

Beta adrenergic blockers: SAR of beta blockers, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

UNIT-III **10 Hours**

Cholinergic neurotransmitters:

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic agents: SAR of Parasympathomimetic agents

Direct acting agents: Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible): Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, Echothiophate iodide, Parathione, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

Solanaceous alkaloids and analogues: Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*.

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

UNIT- IV **08 Hours**

Drugs acting on Central Nervous System

A. Sedatives and Hypnotics:

Benzodiazepines: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem

Barbiturtes: SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital

Miscelleneous:

Amides & imides: Glutethmide.

Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

Phenothiazeines: SAR of Phenothiazeines - Promazine hydrochloride, Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.

Ring Analogues of Phenothiazeines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

C. Anticonvulsants: SAR of Anticonvulsants, mechanism of anticonvulsant action

Barbiturates: Phenobarbitone, Methabarbital. **Hydantoins:**

Phenytoin*, Mephenytoin, Ethotoin **Oxazolidine diones:**

Trimethadione, Paramethadione **Succinimides:**

Phensuximide, Methsuximide, Ethosuximide* **Urea and**

monoacylureas: Phenacemide, Carbamazepine*

Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid , Gabapentin, Felbamate

UNIT – V **07 Hours**

Drugs acting on Central Nervous System

General anesthetics:

Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.

Ultra short acting barbitutrates: Methohexital sodium*, Thiamylal sodium, Thiopental sodium.

Dissociative anesthetics: Ketamine hydrochloride.*

Narcotic and non-narcotic analgesics

Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anilerdine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate.

Narcotic antagonists: Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride.

Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepriac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

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BP406P. MEDICINAL CHEMISTRY – I (Practical)

4 Hours/Week

I	**Preparation of drugs/ intermediates**
1	1,3-pyrazole
2	1,3-oxazole
3	Benzimidazole
4	Benztriazole
5	2,3- diphenyl quinoxaline
6	Benzocaine
7	Phenytoin
8	Phenothiazine
9	Barbiturate
II	**Assay of drugs**
1	Chlorpromazine
2	Phenobarbitone
3	Atropine
4	Ibuprofen
5	Aspirin
6	Furosemide
III	**Determination of Partition coefficient for any two drugs**

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.

रजिस्ट्री सं. डीएल (एन)-04/0007/2003—05 REGISTERED No. DL(N)—04/0007/2003—05

भारत का राजपत्र
The Gazette of India

साप्ताहिक/WEEKLY

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No. 19] NEW DELHI, SATURDAY, MAY 10—MAY 16, 2008 (VAISAKHA 20, 1930)

इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
(Separate paging is given to this Part in order that it may be filed as a separate compilation)

भाग III—खण्ड 4
[PART III—SECTION 4]
[सांविधिक निकायों द्वारा जारी की गई विविध अधिसूचनाएं जिसमें कि आदेश, विज्ञापन और सूचनाएं सम्मिलित हैं]
[Miscellaneous Notifications including Notifications, Orders, Advertisements and Notices issued by Statutory Bodies]

भारतीय रिज़र्व बैंक

मुंबई-400001, दिनांक 9 अप्रैल 2008

सदर्भ : बैंपविवि. सं. आईबीडी.-14241/23.13.048/2007-08--भारतीय रिज़र्व बैंक अधिनियम, 1934 (1934 का 2) की धारा 42 की उप-धारा (6) के खण्ड (ग) के अनुसरण में भारतीय रिज़र्व बैंक इसके द्वारा निदेश देता है कि उक्त अधिनियम की दूसरी अनुसूची में निम्नलिखित परिवर्तन किये जाएं :--

''अरब बांगलादेश बैंक लिमिटेड'' शब्दों के स्थान पर ''एबी बैंक लिमिटेड'' शब्द होंगे।

आनन्द सिन्हा
कार्यपालक निदेशक

[PUBLISHED IN THE GAZETTE OF INDIA, No.19, PART III, SECTION 4]

Ministry of Health and Family Welfare
(Pharmacy Council of India)

New Delhi, 10th May, 2008.

Pharm.D. Regulations 2008

Regulations framed under section 10 of the Pharmacy Act, 1948 (8 of 1948).

(As approved by the Government of India, Ministry of Health vide, letter No.V.13013/1/2007-PMS, dated the 13th March, 2008 and notified by the Pharmacy Council of India).

No.14-126/2007-PCI.— In exercise of the powers conferred by section 10 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government, hereby makes the following regulations, namely:-

CHAPTER-I

1. Short title and commencement. – (1) These regulations may be called the Pharm.D. Regulations 2008.

   (2) They shall come into force from the date of their publication in the official Gazette.

2. Pharm.D. shall consist of a certificate, having passed the course of study and examination as prescribed in these regulations, for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948.

CHAPTER-II

3. Duration of the course. –

a) Pharm.D: The duration of the course shall be six academic years (five years of study and one year of internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of six years duration is divided into two phases –

Phase I – consisting of First, Second, Third, Fourth and Fifth academic year.

Phase II – consisting of internship or residency training during sixth year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision so that he or she may become capable of functioning independently.

b) Pharm.D. (Post Baccalaureate): The duration of the course shall be for three academic years (two years of study and one year internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases –

Phase I – consisting of First and Second academic year.
Phase II – consisting of Internship or residency training during third year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services, and acquires skill under supervision so that he or she may become capable of functioning independently.

4. Minimum qualification for admission to. –

a) Pharm.D. Part-I Course – A pass in any of the following examinations -

(1) 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the following subjects:

Mathematics or Biology.

(2) A pass in D.Pharm course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

(3) Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

Provided that a student should complete the age of 17 years on or before 31st December of the year of admission to the course.

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

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b) Pharm.D. (Post Baccalaureate) Course -

A pass in B.Pharm from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act:

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

5. Number of admissions in the above said programmes shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted as below –
   i) Pharm.D. Programme – 30 students.
   ii) Pharm.D. (Post Baccalaureate) Programme – 10 students.

6. Institutions running B.Pharm programme approved under section 12 of the Pharmacy Act, will only be permitted to run Pharm.D. programme. Pharm.D. (Post Baccalaureate) programme will be permitted only in those institutions which are permitted to run Pharm.D. programme.

7. Course of study. – The course of study for Pharm.D. shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

TABLES

First Year :

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
1.1	Human Anatomy and Physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medicinal Biochemistry	3	3	1
1.4	Pharmaceutical Organic Chemistry	3	3	1
1.5	Pharmaceutical Inorganic Chemistry	2	3	1
1.6	Remedial Mathematics/ Biology	3	3*	1
	Total hours	**16**	**18**	**6 = (40)**

* For Biology

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Second Year:

S.No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
2.1	Pathophysiology	3	-	1
2.2	Pharmaceutical Microbiology	3	3	1
2.3	Pharmacognosy & Phytopharmaceuticals	3	3	1
2.4	Pharmacology-I	3	-	1
2.5	Community Pharmacy	2	-	1
2.6	Pharmacotherapeutics-I	3	3	1
	Total Hours	**17**	**9**	**6 = 32**

Third Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
3.1	Pharmacology-II	3	3	1
3.2	Pharmaceutical Analysis	3	3	1
3.3	Pharmacotherapeutics-II	3	3	1
3.4	Pharmaceutical Jurisprudence	2	-	-
3.5	Medicinal Chemistry	3	3	1
3.6	Pharmaceutical Formulations	2	3	1
	Total hours	**16**	**15**	**5 = 36**

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Fourth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
4.1	Pharmacotherapeutics-III	3	3	1
4.2	Hospital Pharmacy	2	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics	3	3	1
4.6	Clinical Toxicology	2	-	1
	Total hours	**15**	**12**	**6 = 33**

Fifth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Clinical Research	3	-	1
5.2	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	-	1
5.4	Clerkship *	-	-	1
5.5	Project work (Six Months)	-	20	-
	Total hours	**8**	**20**	**4 = 32**

* Attending ward rounds on daily basis.

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Sixth Year:

Internship or residency training including postings in speciality units. Student should independently provide the clinical pharmacy services to the allotted wards.

(i) Six months in General Medicine department, and

(ii) Two months each in three other speciality departments

8. Syllabus. – The syllabus for each subject of study in the said Tables shall be as specified in Appendix -A to these regulations.

9. Approval of the authority conducting the course of study. – (1) No person, institution, society or university shall start and conduct Pharm.D or Pharm.D. (Post Baccalaureate) programme without the prior approval of the Pharmacy Council of India.

(2) Any person or pharmacy college for the purpose of obtaining permission under sub-section (1) of section 12 of the Pharmacy Act, shall submit a scheme as prescribed by the Pharmacy Council of India.

(3) The scheme referred to in sub-regulation (2) above, shall be in such form and contain such particulars and be preferred in such manner and be accompanied with such fee as may be prescribed:

Provided that the Pharmacy Council of India shall not approve any institution under these regulations unless it provides adequate arrangements for teaching in regard to building, accommodation, labs., equipments, teaching staff, non-teaching staff, etc., as specified in Appendix-B to these regulations.

10. Examination. – (1) Every year there shall be an examination to examine the students.

(2) Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.

(3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables below :

TABLES

First Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Human Anatomy and Physiology	70	30	100	70	30	100
1.2	Pharmaceutics	70	30	100	70	30	100
1.3	Medicinal Biochemistry	70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100
1.6	Remedial Mathematics/ Biology	70	30	100	70*	30*	100*
				600			600 = 1200

* for Biology.

Second Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
2.1	Pathophysiology	70	30	100	-	-	-
2.2	Pharmaceutical Microbiology	70	30	100	70	30	100
2.3	Pharmacognosy & Phytopharmaceuticals	70	30	100	70	30	100
2.4	Pharmacology-I	70	30	100	-	-	-
2.5	Community Pharmacy	70	30	100	-	-	-
2.6	Pharmacotherapeutics-I	70	30	100	70	30	100
				600			300 = 900

Third Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
3.1	Pharmacology-II	70	30	100	70	30	100
3.2	Pharmaceutical Analysis	70	30	100	70	30	100
3.3	Pharmacotherapeutics-II	70	30	100	70	30	100
3.4	Pharmaceutical Jurisprudence	70	30	100	-	-	-
3.5	Medicinal Chemistry	70	30	100	70	30	100
3.6	Pharmaceutical Formulations	70	30	100	70	30	100
				600			500 = 1100

Fourth Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
4.1	Pharmacotherapeutics-III	70	30	100	70	30	100
4.2	Hospital Pharmacy	70	30	100	70	30	100
4.3	Clinical Pharmacy	70	30	100	70	30	100
4.4	Biostatistics & Research Methodology	70	30	100	-	-	-
4.5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
4.6	Clinical Toxicology	70	30	100	-	-	-
				600			400 = 1000

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Fifth Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
5.1	Clinical Research	70	30	100	-	-	-
5.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
5.4	Clerkship *	-	-	-	70	30	100
5.5	Project work (Six Months)	-	-	-	100**	-	100
				300			200 = 500

* Attending ward rounds on daily basis.

** 30 marks – viva-voce (oral)
70 marks – Thesis work

11. Eligibility for appearing Examination.— Only such students who produce certificate from the Head of the Institution in which he or she has undergone the Pharm.D. or as the case may be, the Pharm.D. (Post Baccalaureate) course, in proof of his or her having regularly and satisfactorily undergone the course of study by attending not less than 80% of the classes held both in theory and in practical separately in each subject shall be eligible for appearing at examination.

12. Mode of examinations.— (1) Theory examination shall be of three hours and practical examination shall be of four hours duration.

(2) A Student who fails in theory or practical examination of a subject shall re-appear both in theory and practical of the same subject.

(3) Practical examination shall also consist of a viva –voce (Oral) examination.

(4) Clerkship examination – Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

13. Award of sessional marks and maintenance of records.— (1) A regular record of both theory and practical class work and examinations conducted in an institution imparting training for Pharm.D. or as the case may be, Pharm.D. (Post Baccalaureate) course, shall be maintained for each student in the institution and 30 marks for each theory and 30 marks for each practical subject shall be allotted as sessional.

(2) There shall be at least two periodic sessional examinations during each academic year and the highest aggregate of any two performances shall form the basis of calculating sessional marks.

(3) The sessional marks in practicals shall be allotted on the following basis:-

(i) Actual performance in the sessional examination (20 marks);

(ii) Day to day assessment in the practical class work, promptness, viva-voce record maintenance, etc. (10 marks).

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14. Minimum marks for passing examination.— A student shall not be declared to have passed examination unless he or she secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in each of the practical examinations including sessional marks. The students securing 60% marks or above in aggregate in all subjects in a single attempt at the Pharm.D. or as the case may be, Pharm. D. (Post Baccalaureate) course examination shall be declared to have passed in first class. Students securing 75% marks or above in any subject or subjects shall be declared to have passed with distinction in the subject or those subjects provided he or she passes in all the subjects in a single attempt.

15. Eligibility for promotion to next year.— All students who have appeared for all the subjects and passed the first year annual examination are eligible for promotion to the second year and, so on. However, failure in more than two subjects shall debar him or her from promotion to the next year classes.

16. Internship.— (1) Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquires skills under the supervision so that he or she may become capable of functioning independently.

    (2) Every student has to undergo one year internship as per Appendix-C to these regulations.

17. Approval of examinations.— Examinations mentioned in regulations 10 to12 and 14 shall be held by the examining authority hereinafter referred to as the university, which shall be approved by the Pharmacy Council of India under sub-section (2) of section 12 of the Pharmacy Act, 1948. Such approval shall be granted only if the examining authority concerned fulfills the conditions as specified in Appendix–D to these regulations.

18. Certificate of passing examination.— Every student who has passed the examinations for the Pharm.D. (Doctor of Pharmacy) or Pharm.D. (Post Baccalaureate) (Doctor of Pharmacy) as the case may be, shall be granted a certificate by the examining authority.

CHAPTER-III
Practical training

19. Hospital posting.— Every student shall be posted in constituent hospital for a period of not less than fifty hours to be covered in not less than 200 working days in each of second, third & fourth year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.

20. Project work.— (1) To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.

    (2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.

21. Objectives of project work.— The main objectives of the project work is to—

    (i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and

    (ii) develop the students in data collection, analysis and reporting and interpretation skills.

22. Methodology.— To complete the project work following methodology shall be adopted, namely:—

    (i) students shall work in groups of not less than *two* and not more than *four* under an authorised teacher;

    (ii) project topic shall be approved by the Head of the Department or Head of the Institution;

    (iii) project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics;

    (iv) project work shall be approved by the institutional ethics committee;

    (v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and

    (vi) two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

23. Reporting .— (1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorised teacher, Head of the Department as well as by the Head of the Institution

(2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-tiles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14.

(3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

24. Evaluation.— The following methodology shall be adopted for evaluating the project work—

(i) Project work shall be evaluated by internal and external examiners.

(ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).

(iii) Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.

(iv) Evaluation shall be done on the following items:

	Marks
a) Write up of the seminar	(7.5)
b) Presentation of work	(7.5)
c) Communication skills	(7.5)
d) Question and answer skills	(7.5)
Total	(30 marks)

(v) Final evaluation of project work shall be done on the following items:

	Marks
a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)
c) Communication skills	(17.5)
d) Question and answer skills	(17.5)
Total	(70 marks)

Explanation.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

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APPENDIX-A

(See regulation 8)

PHARM.D. SYLLABUS

First Year

1.1 HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and Objectives:** This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.

2. **Upon completion of the course the student shall be able to:**
   a. describe the structure (gross and histology) and functions of various organs of the human body;
   b. describe the various homeostatic mechanisms and their imbalances of various systems;
   c. identify the various tissues and organs of the different systems of the human body;
   d. perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
   e. appreciate coordinated working pattern of different organs of each system; and
   f. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

3. **Course materials:**

   Text books

   a. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology Publisher Harpercollins college New York.
   b. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology. Publisher: Churchill Livingstone, Edinburg.

   Reference books

   a. Guyton arthur, C. *Physiology of human body*. Publisher: Holtsaunders.
   b. Chatterjee,C.C. *Human physiology*. Volume 1&11. Publisher: medical allied agency, Calcutta.
   c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
   d. *Gray's anatomy*. Publisher:Churchill Livingstone, London.

4. Lecture wise program :

Topics

1 Scope of anatomy and physiology, basic terminologies used in this subject (Description of the body as such planes and terminologies)

2 Structure of cell – its components and their functions.

3 Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics

4 a) Osseous system - structure, composition and functions of the Skeleton. (done in practical classes - 6hrs)
b) Classification of joints, Types of movements of joints and disorders of joints (Definitions only)

5 Haemopoetic System
a) Composition and functions of blood
b) Haemopoesis and disorders of blood components (definition of disorder)
c) Blood groups
d) Clotting factors and mechanism
e) Platelets and disorders of coagulation

6 Lymph
a) Lymph and lymphatic system, composition, formation and circulation.
b) Spleen: structure and functions, Disorders
c) Disorders of lymphatic system (definition only)

7 Cardiovascular system
a) Anatomy and functions of heart
b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
c) Electrocardiogram (ECG)
d) Cardiac cycle and heart sounds
e) Blood pressure – its maintenance and regulation
f) Definition of the following disorders
Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias

8 Respiratory system
a) Anatomy of respiratory organs and functions
b) Mechanism / physiology of respiration and regulation of respiration
c) Transport of respiratory gases
d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.

9 Digestive system
a) Anatomy and physiology of GIT
b) Anatomy and functions of accessory glands of GIT
c) Digestion and absorption
d) Disorders of GIT (definitions only)

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10 Nervous system
a) Definition and classification of nervous system
b) Anatomy, physiology and functional areas of cerebrum
c) Anatomy and physiology of cerebellum
d) Anatomy and physiology of mid brain
e) Thalamus, hypothalamus and Basal Ganglia
f) Spinal card: Structure & reflexes – mono-poly-planter
g) Cranial nerves – names and functions
h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.

11 Urinary system
a) Anatomy and physiology of urinary system
b) Formation of urine
c) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
d) Clearance tests and micturition

12 Endocrine system
a) Pituitary gland
b) Adrenal gland
c) Thyroid and Parathyroid glands
d) Pancreas and gonads

13 Reproductive system
a) Male and female reproductive system
b) Their hormones – Physiology of menstruation
c) Spermatogenesis & Oogenesis
d) Sex determination (genetic basis)
e) Pregnancy and maintenance and parturition
f) Contraceptive devices

14 Sense organs
a) Eye
b) Ear
c) Skin
d) Tongue & Nose

15 Skeletal muscles
a) Histology
b) Physiology of Muscle contraction
c) Physiological properties of skeletal muscle and their disorders (definitions)

16 Sports physiology
a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
c) Drugs and athletics

1.1 HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

General Requirements: Dissection box, Laboratory Napkin, muslin cloth, record, Observation book(100pages), Stationary items, Blood lancet.

Course materials:

Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune
Anderson Experimental Physiology, Latest edition, Publisher: NA

List of Experiments:

1. Study of tissues of human body
   (a) Epithelial tissue.
   (b) Muscular tissue.
2. Study of tissues of human body
   (a) Connective tissue.
   (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
   (a) Erythrocyte Sedimentation Rate.
   (b) Hemoglobin content of Blood.
   (c) Bleeding time & Clotting time.
8. Determination of
   (a) Blood Pressure.
   (b) Blood group.
9. Study of various systems with the help of charts, models & specimens
   (a) Skeleton system part I-axial skeleton.
   (b) Skeleton system part II- appendicular skeleton.
   (c) Cardiovascular system.
   (d) Respiratory system.

(e) Digestive system.
(f) Urinary system.
(g) Nervous system.
(h) Special senses.
(i) Reproductive system.

10. Study of different family planning appliances.

11. To perform pregnancy diagnosis test.

12. Study of appliances used in experimental physiology.

13. To record simple muscle curve using gastroenemius sciatic nerve preparation.

14. To record simple summation curve using gastroenemius sciatic nerve preparation.

15. To record simple effect of temperature using gastroenemius sciatic nerve preparation.

16. To record simple effect of load & after load using gastroenemius sciatic nerve preparation.

17. To record simple fatigue curve using gastroenemius sciatic nerve preparation.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.2 PHARMACEUTICS (THEORY)

Theory : 2 Hrs. /Week

1. **Scope and objectives:** This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.

2. **Upon the completion of the course the student should be able to:**
   a. know the formulation aspects of different dosage forms;
   b. do different pharmaceutical caluculation involved in formulation;
   c. formulate different types of dosage forms; and
   d. appreciate the importance of good formulation for effectiveness.

3. **Course materials:**

   Text books
   a. Cooper and Gunns Dispensing for pharmacy students.
   b. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

   Reference books
   a. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
   b. Remington's Pharmaceutical Sciences.
   c. Register of General Pharmacy by Cooper and Gunn.
   d. General Pharmacy by M.L.Schroff.

4. **Lecture wise programme:**

   Topics

   1 a. Introduction to dosage forms - classification and definitions
   b. Prescription: definition, parts and handling
   c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.
   2 Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.
   3 Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
   4 Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.
   5 Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
   6 Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

7 Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
8 Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
9 Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.
10 Pharmaceutical calculations.
11 Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.
12 Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

1.2 PHARMACEUTICS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. **Syrups**
   a. Simple Syrup I.P
   b. Syrup of Ephedrine Hcl NF
   c. Syrup Vasaka IP
   d. Syrup of ferrous Phosphate IP
   e. Orange Syrup
2. **Elixir**
   a. Piperizine citrate elixir BP
   b. Cascara elixir BPC
   c. Paracetamol elixir BPC
3. **Linctus**
   a. Simple Linctus BPC
   b. Pediatric simple Linctus BPC
4. **Solutions**
   a. Solution of cresol with soap IP
   b. Strong solution of ferric chloride BPC
   c. Aqueous Iodine Solution IP
   d. Strong solution of Iodine IP
   e. Strong solution of ammonium acetate IP

5. **Liniments**
   a. Liniment of turpentine IP*
   b. Liniment of camphor IP
6. **Suspensions***
   a. Calamine lotion
   b. Magnesium Hydroxide mixture BP
7. **Emulsions***
   a. Cod liver oil emulsion
   b. Liquid paraffin emulsion
8. **Powders♣**
   a. Eutectic powder
   b. Explosive powder
   c. Dusting powder
   d. Insufflations
9. **Suppositories♣**
   a. Boric acid suppositories
   b. Chloral suppositories
10. **Incompatibilities**
    a. Mixtures with Physical
    b. Chemical & Therapeutic incompatibilities

* colourless bottles required for dispensing ♣ Paper envelope (white), butter paper and white paper required for dispensing.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.3 MEDICINAL BIOCHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells.Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases.

2. **Objectives of the Subject** (Know, do, appreciate) :

   The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to –

   a. understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
   b. know the metabolic process of biomolecules in health and illness (metabolic disorders);
   c. understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
   d. know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
   e. do the qualitative analysis and determination of biomolecules in the body fluids.

   Text books (Theory)

   a. Harpers review of biochemistry - Martin
   b. Text book of biochemistry – D.Satyanarayana
   c. Text book of clinical chemistry- Alex kaplan &Laverve L.Szabo

   Reference books (Theory)

   a. Principles of biochemistry -- Lehninger
   b. Text book of biochemistry -- Ramarao
   c. Practical Biochemistry-David T.Plummer.
   d. Practical Biochemistry-Pattabhiraman.

3. **Lecture wise programme:**

   Topics

   1 **Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.

   2 **Enzymes**: Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.

   3 **Carbohydrate metabolism**: Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.

4 **Lipid metabolism:** Oxidation of saturated (β-oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atheroslerosis, fatty liver, hypercholesterolmiea).

5 **Biological oxidation:** Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;

6 **Protein and amino acid metabolism:** protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.

7 **Nucleic acid metabolism:** Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.

8 **Introduction to clinical chemistry: Cell**; composition; malfunction; Roll of the clinical chemistry laboratory.

9 **The kidney function tests:** Role of kidney; Laboratory tests for normal function includes-
   a) Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)
   b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)
   c) Urine concentration test
   d) Urinary tract calculi. (stones)

10 **Liver function tests:** Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.
   a) Test for hepatic dysfunction-Bile pigments metabolism.
   b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
   c) Dye tests of excretory function.
   d) Tests based upon abnormalities of serum proteins.
   Selected enzyme tests.

11 **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.

12 **Immunochemical techniques** for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.

   Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)

13 **Electrolytes:** Body water, compartments, water balance, and electrolyte distrubution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

1.3 MEDICINAL BIOCHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

1 Qualitative analysis of normal constituents of urine.*
2 Qualitative analysis of abnormal constituents of urine.*
3 Quantitative estimation of urine sugar by Benedict's reagent method.**
4 Quantitative estimation of urine chlorides by Volhard's method.**
5 Quantitative estimation of urine creatinine by Jaffe's method.**
6 Quantitative estimation of urine calcium by precipitation method.**
7 Quantitative estimation of serum cholesterol by Libermann Burchard's method.**
8 Preparation of Folin Wu filtrate from blood.*
9 Quantitative estimation of blood creatinine.**
10 Quantitative estimation of blood sugar Folin-Wu tube method.**
11 Estimation of SGOT in serum.**
12 Estimation of SGPT in serum.**
13 Estimation of Urea in Serum.**
14 Estimation of Proteins in Serum.**
15 Determination of serum bilirubin**
16 Determination of Glucose by means of Glucoseoxidase.**
17 Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
18 Study of factors affecting Enzyme activity. (pH & Temp.)**
19 Preparation of standard buffer solutions and its pH measurements (any two)*
20 Experiment on lipid profile tests**
21 Determination of sodium,calcium and potassium in serum.**
** indicate major experiments & * indicate minor experiments

Assignments:

Format of the assignment

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and objectives**: This course is designed to impart a very good knowledge about
   a. IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
   b. Some important physical properties of organic compounds;
   c. Free radical/ nucleophyllic [alkyl/ acyl/ aryl] /electrophyllic substitution, free radical/ nucleophyllic / electrophyllic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
   d. Some named organic reactions with mechanisms; and
   e. Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

2. **Course materials:**

   Text books

   a. T.R.Morrison and R. Boyd - Organic chemistry,
   b. Bentley and Driver-Text book of Pharmaceutical chemistry
   c. I.L.Finer- Organic chemistry, the fundamentals of chemistry

   Reference books

   a. Organic chemistry – J.M.Cram and D.J.Cram
   b. Organic chemistry- Brown
   c. Advanced organic chemistry- Jerry March, Wiley
   d. Organic chemistry- Cram and Hammered, Pine Hendrickson

3. **Lecture wise programme :**

   Topics

   1 Structures and Physical properties:
      a. Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
      b. Acids and bases, Lowry bronsted and Lewis theories
      c. Isomerism

   2 Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides And Cycloalkanes.

   3 Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability

   4 Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.

   5 Nuclophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN_2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents.

6 Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.

7 Electrophillic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophillic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydin formation, mechanism of free radicals additon, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.

8 Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparision of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.

9 Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophyllic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substituion in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.

10 Elecrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, friedel craft alkylation, friedel craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogination of alkyl benzene, resonance stabilization of benzyl radical.

11 Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of caboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.

12 Mechanism of aldol condensation, claisen condensation, cannizzaro reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.

13 Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer tieman's reactions.

14 Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.

15 Oxidation reduction reaction.

16 Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihyrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl pthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

1. Acetanilde / aspirin (Acetylation)
2. Benzanilide / Phenyl benzoate (Benzoylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-napthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 – Antharaquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenone oxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotolune
14. Preparation of cyclohexanone from cyclohexanol

II. Identification of organic compounds belonging to the following classes by :

Systematic qualitative organic analysis including preparation of derivatives Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones, Alcohols, esters, hydrocarbons, anilides, nitrocompounds.

III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope and objectives:** This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.

2. **Upon completion of the course student shall be able to:**
   a. under stand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
   b. know the analysis of the inorganic pharmaceuticals their applications; and
   c. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

3. **Course materials:**

   Text books
   a. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
   b. A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol-I & Vol-II
   c. Inorganic Pharmaceutical Chemistry III-Edition P.Gundu Rao

   Reference books
   a. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
   b. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
   c. Analytical chemistry principles by John H. Kennedy
   d. I.P.1985 and 1996, Govt. of India, Ministry of health

4. **Lecture wise programme:**

   Topics
   1 Errors
   2 Volumetric analysis
   3 Acid-base titrations
   4 Redox titrations
   5 Non aqueous titrations
   6 Precipitation titrations
   7 Complexometric titrations
   8 Theory of indicators
   9 Gravimetry
   10 Limit tests
   11 Medicinal gases
   12 Acidifiers
   13 Antacids
   14 Cathartics
   15 Electrolyte replenishers

16 Essential Trace elements
17 Antimicrobials
18 Pharmaceutical aids
19 Dental Products
20 Miscellaneous compounds
21 Radio Pharmaceuticals

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

1. **Limit test (6 exercises)**
   a. Limit test for chlorides
   b. Limit test for sulphates
   c. Limit test for iron
   d. Limit test for heavy metals
   e. Limit test for arsenic
   f. Modified limit tests for chlorides and sulphates

2. **Assays (10 exercises)**
   a. Ammonium chloride- Acid-base titration
   b. Ferrous sulphate- Cerimetry
   c. Copper sulpahte- Iodometry
   d. Calcilugluconate- Complexometry
   e. Hydrogen peroxide – Permanganometry
   f. Sodium benzoate – Nonaqueous titration
   g. Sodium chloride – Modified volhard's method
   h. Assay of KI – KIO_3 titration
   i. Gravimetric estimation of barium as barium sulphate
   j. Sodium antimony gluconate or antimony potassium tartarate

3. **Estimation of mixture (Any two exercises)**
   a. Sodium hydroxide and sodium carbonate
   b. Boric acid and Borax
   c. Oxalic acid and sodium oxalate

4. **Test for identity (Any three exercises)**
   a. Sodium bicorbonate
   b. Barium sulphate
   c. Ferrous sulphate
   d. Potassium chloride

5. **Test for purity (Any two exercises)**
   a. Swelling power in Bentonite
   b. Acid neutralising capacity in aluminium hydroxide gel
   c. Ammonium salts in potash alum
   d. Adsorption power heavy Kaolin
   e. Presence of Iodates in KI

6. **Preparations (Any two exercises)**
   a. Boric acids
   b. Potash alum
   c. Calcium lactate
   d. Magnesium suphate

Scheme of Practical Examination :

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment1&2	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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1.6 REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory : 3 Hrs. /Week

REMEDIAL MATHEMATICS :

1. **Scope and objectives**: This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.

2. **Upon completion of the course the student shall be able to : –**
   a. Know Trignometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
   b. solve the problems of different types by applying theory; and
   c. appreciate the important applications of mathematics in pharmacy.

3. **Course materials:**

   Text books
   a. Differential calculus By Shantinarayan
   b. Text book of Mathematics for second year pre-university by Prof.B.M.Sreenivas

   Reference books
   a. Integral calculus By Shanthinarayan
   b. Engineering mathematics By B.S.Grewal
   c. Trigonometry Part-I By S.L.Loney

4. **Lecture wise programme :**

   Topics

   1 **Algebra :** Determinants, Matrices
   2 **Trigonometry :** Sides and angles of a triangle, solution of triangles
   3 **Analytical Geometry :**Points, Straight line, circle, parabola
   4 **Differential calculus:** Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables
   5 **Integral Calculus:** Definite integrals, integration by substitution and by parts, Properties of definite integrals.
   6 **Differential equations:** Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.
   7 **Laplace transform:** Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

BIOLOGY :

1. **Scope and objectives**: This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduces to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

2. **Course materials:**

Text books

a. Text book of Biology by S.B.Gokhale
b. A Text book of Biology by Dr.Thulajappa and Dr. Seetaram.

Reference books

a. A Text book of Biology by B.V.Sreenivasa Naidu
b. A Text book of Biology by Naidu and Murthy
c. Botany for Degree students By A.C.Dutta.
d. Outlines of Zoology by M.Ekambaranatha ayyer and T.N.Ananthakrishnan.
e. A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

3. **Lecture wise programme :**

Topic

PART – A

01 Introduction
02 General organization of plants and its inclusions
03 Plant tissues
04 Plant kingdom and its classification
05 Morphology of plants
06 Root, Stem, Leaf and Its modifications
07 Inflorescence and Pollination of flowers
08 Morphology of fruits and seeds
09 Plant physiology
10 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae
11 Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

01 Study of Animal cell
02 Study animal tissues
03 Detailed study of frog
04 Study of Pisces, Raptiles, Aves
05 Genearal organization of mammals
06 Study of poisonous animals

1.6 BIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title:

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

Scheme of Practical Examination :

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

Second year

2.1 PATHOPHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.

2. **Objectives of the Subject :** Upon completion of the subject student shall be able to –
   a. describe the etiology and pathogenesis of the selected disease states;
   b. name the signs and symptoms of the diseases; and
   c. mention the complications of the diseases.

   Text books (Theory)
   a. Pathologic basis of disease by- Cotran, Kumar, Robbins
   b. Text book of Pathology- Harsh Mohan
   c. Text book of Pathology- Y.M. Bhinde

   Reference books (Theory)
   a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

3. **Detailed syllabus and lecture wise schedule :**

   Chapter

   1 **Basic principles of cell injury and Adaptation**
   a) Causes, Pathogenesis and morphology of cell injury
   b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases

   2 **Inflammation**
   a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
   b) Repairs of wounds in the skin, factors influencing healing of wounds

   3 **Diseases of Immunity**
   a) Introduction to Tand B cells
   b) MHC proteins or transplantation antigens
   c) Immune tolerance
   - Hypersensitivity
     Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs
   - Autoimmunity
     Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.
   - Acquired immune deficiency syndrome (AIDS)

- Amylodosis

4 **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.

5 Types of shock, mechanisms, stages and management

6 Biological effects of radiation

7 Environmental and nutritional diseases
   i) Air pollution and smoking- SO2,NO, NO2, and CO
   ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.

8 Pathophysiology of common diseases
   a. Parkinsonism
   b. Schizophrenia
   c. Depression and mania
   d. Hypertension,
   e. Stroke (ischaemic and hemorrhage)
   f. Angina, CCF, Atherosclerosis, Myocardial infarction
   g. Diabetes Mellitus
   h. Peptic ulcer and inflammatory bowel diseases
   i. Cirrhosis and Alcoholic liver diseases
   j. Acute and chronic renal failure
   k. Asthma and chronic obstructive airway diseases

9 Infectious diseases :
   Sexually transmitted diseases (HIV,Syphilis,Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.

4. Assignments :

Title of the Experiment

1 Chemical Mediators of inflammation
2 Drug Hypersensitivity
3 Cigarette smoking & its ill effects
4 Biological Effects of Radiation
5 Etiology and hazards of obesity
6 Complications of diabetes
7 Diagnosis of cancer
8 Disorders of vitamins
9 Methods in Pathology-Laboratory values of clinical significance
10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

1 Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

2.2 PHARMACEUTICAL MICROBIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** Microbiology has always been an essential component of pharmacy curriculum. This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future.
   This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. Its also discusses with sterilization of pharmaceutical products, equipment, media etc. The course further discusses the immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

2. **Objectives of the Subject :**
   Upon completion of the subject student shall be able to –
   a. know the anatomy, identification, growth factors and sterilization of microorganisms;
   b. know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
   c. do estimation of RNA and DNA and there by identifying the source;
   d. do cultivation and identification of the microorganisms in the laboratory;
   e. do identification of diseases by performing the diagnostic tests; and
   f. appreciate the behavior of motility and behavioral characteristics of microorganisms.

Text books (Theory)

a. Vanitha Kale and Kishor Bhusari " Applied Microbiology " Himalaya Publishing house Mumbai.
b. Mary Louis Turgeon " Immunology and Serology in Laboratory Medicines" 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
c. Harsh Mohan, " Text book of Pathology" 3rd edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

Reference books (Theory)

a. Prescot L.M., Jarley G.P Klein D.A "Microbiology" 2nd- edition Mc Graw Hill Company Inc
b. Rawlins E.A."Bentley's Text Book of Pharmaceutics" B ailliere Tindals 24-28 London 1988
c. Forbisher " Fundamentals of Microbiology" Philidelphia W.B. Saunders.
d. Prescott L.M. Jarley G.P., Klein.D.A. " Microbiology."2nd edition WMC Brown Publishers, Oxford. 1993
e. War Roitt, Jonathan Brostoff, David male, " Immunology"3rd edition 1996, Mosby-year book Europe Ltd, London.
f. Pharmacopoeia of India, Govt of India, 1996.

3. Detailed syllabus and lecture wise schedule :

Title of the topic

1 Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.

2 Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.

3 Nutritional requirements, growth and cultivation of bacteria and virus. Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures.

4 Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria -Total and Viable counting techniques.

5 Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations . Brief information on Validation.

6 Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic, , virucidal activities, evaluation of preservatives in pharmaceutical preparations.

7 Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity(active and passive) . Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.

8 Diagnostic tests : Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantaux Peripheral smear. Study of malarial parasite.

9 Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B_2 and B_{12}. Standardisation of vaccines and sera.

10 Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.

2.2 PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

1 Study of apparatus used in experimental microbiology*.

2 Sterilisation of glass ware's. Preparation of media and sterilisation.*

3 Staining techniques – Simple staining ; Gram's staining ; Negative staining**

4 Study of motility characters*.

5 Enumeration of micro-organisms (Total and Viable)*

6 Study of the methods of isolation of pure culture.*

7 Bio chemical testing for the identification of micro*-organisms.

8 Cultural sensitivity testing for some micro-organisms.*
9 Sterility testing for powders and liquids.*
10 Determination of minimum inhibitory concentration.*
11 Microbiological assay of antibiotics by cup plate method.*
12 Microbiological assay of vitamins by Turbidometric method**
13 Determination of RWC.**
14 Diagnostic tests for some common diseases, Widal, malarial parasite.**

* Indicate minor experiment & ** indicate major experiment

Assignments:

1 Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
2. Visit to milk dairies (Pasturization) and microbial laboratories(other sterization methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments
   a. Report of recent microbial techniques developed in diagnosing some common diseases.
   b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and objectives:** This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occurring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.

2. **Upon completion of the course student shall be able to:**
   a. under stand the basic principles of cultivation, collection and storage of crude drugs;
   b. know the source, active constituents and uses of crude drugs; and
   c. appreciate the applications of primary and secondary metabolites of the plant.

3. **Course materials:**

   Text books
   a. Pharmacognosy by G.E. Trease & W.C.Evans.
   b. Pharmacognosy by C.K.Kokate,Gokhale & A.C.Purohit.

   Reference books
   a. Pharmacognosy by Brady &Tyler.E.
   b. Pharmacognosy by T.E.Wallis.
   c. Pharmacognosy by C.S. Shah & Qadery.
   d. Pharmacognosy by M.A. Iyengar.

4. **Lecture wise programme:**

   Topics

   1 Introduction.
   2 Definition, history and scope of Pharmacognosy.
   3 Classification of crude drugs.
   4 Cultivation, collection, processing and storage of crude drugs.
   5 Detailed method of cultivation of crude drugs.
   6 Study of cell wall constituents and cell inclusions.
   7 Microscopical and powder Microscopical study of crude drugs.
   8 Study of natural pesticides.
   9 Detailed study of various cell constituents.
   10 Carbohydrates and related products.
   11 Detailed study carbohydrates containing drugs.(11 drugs)
   12 Definition sources, method extraction, chemistry and method of analysis of lipids.
   13 Detailed study of oils.
   14 Definition, classification, chemistry and method of analysis of protein.
   15 Study of plants fibers used in surgical dressings and related products.
   16 Different methods of adulteration of crude drugs.

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

Practical : 3 Hrs./Week

General Requirements: Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box.

List of experiments:

1 Introduction of Pharmacognosy laboratory and experiments.
2 Study of cell wall constituents and cell inclusions.
3 Macro, powder and microscopic study of Datura.
4 Macro, powder and microscopic study of Senna.
5 Macro, powder and microscopic study of Cassia.cinnamon.
6 Macro, powder and microscopic study of Cinchona.
7 Macro, powder and microscopic study of Ephedra.
8 Macro, powder and microscopic study of Quassia.
9 Macro, powder and microscopic study of Clove
10 Macro, powder and microscopic study of Fennel.
11 Macro, powder and microscopic study of Coriander.
12 Macro, powder and microscopic study of Isapgol.
13 Macro, powder and microscopic study of Nux vomica.
14 Macro, powder and microscopic study of Rauwolfia.
15 Macro, powder and microscopic study of Liquorice.
16 Macro, powder and microscopic study of Ginger.
17 Macro, powder and microscopic study of Podophyllum.
18 Determination of Iodine value.
19 Determination of Saponification value and unsaponifiable matter.
20 Determination of ester value.
21 Determination of Acid value.
22 Chemical tests for Acacia.
23 Chemical tests for Tragacanth.
24 Chemical tests for Agar.
25 Chemical tests for Starch.
26 Chemical tests for Lipids.(castor oil,sesame oil, shark liver oil,bees wax)
27 Chemical tests for Gelatin.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

2.4 PHARMACOLOGY – I (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

2. **Objectives of the Subject :** Upon completion of the subject student shall be able to (Know, do, appreciate) –
   a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
   b. handle and carry out the animal experiments;
   c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
   d. correlate and apply the knowledge therapeutically.

Text books (Theory) (Author, Title, Edition, Publication Place, Publisher, Year of Publication)

a. Tripathi, K. D. Essentials of medical pharmacology. 4th Ed, 1999. Publisher: Jaypee, Delhi.
b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
c. Rang, H.P. & Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)(Author, Title, Edition, Publication Place, Publisher, Publication Year)

a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher Mc Graw Hill, Pergamon press.
b. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co
c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
d. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

Text books (Practical) :

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical)

a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.

Dr. C. S. [illegible] REDDY
PRINCIPAL
Vikas Institute of Pharmaceutical Science
RAJAHMUNDRY-533 102.

b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule :

Title of the topic

1. **General Pharmacology**
   a) Introduction, definitions and scope of pharmacology
   b) Routes of administration of drugs
   c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
   d) Pharmacodynamics
   e) Factors modifying drug effects
   f) Drug toxicity - Acute, sub- acute and chronic toxicity.
   g) Pre-clinical evaluations
   h) Drug interactions

   Note: The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.

2. **Pharmacology of drugs acting on ANS**
   a) Adrenergic and antiadrenergic drugs
   b) Cholinergic and anticholinergic drugs
   c) Neuromuscular blockers
   d) Mydriactics and miotics
   e) Drugs used in myasthenia gravis
   f) Drugs used in Parkinsonism

3. **Pharmacology of drugs acting on cardiovascular system**
   a) Antihypertensives
   b) Anti-anginal drugs
   c) Anti-arrhythmic drugs
   d) Drugs used for therapy of Congestive Heart Failure
   e) Drugs used for hyperlipidaemias

4. **Pharmacology of drugs acting on Central Nervous System**
   a) General anesthetics
   b) Sedatives and hypnotics
   c) Anticonvulsants
   d) Analgesic and anti-inflammatory agents
   e) *Psychotropic drugs*
   f) Alcohol and methyl alcohol
   g) CNS stimulants and cognition enhancers
   h) Pharmacology of local anaesthetics

5. **Pharmacology of Drugs acting on Respiratory tract**
   a) Bronchodilators
   b) Mucolytics
   c) Expectorants
   d) Antitussives
   e) NasalDecongestants

6. **Pharmacology of Hormones and Hormone antagonists**
   a) Thyroid and Antithyroid drugs
   b) Insulin, Insulin analogues and oral hypoglycemic agents
   c) Sex hormones and oral contraceptives
   d) Oxytocin and other stimulants and relaxants

7. **Pharmacology of autocoids and their antagonists**
   a) Histamines and Antihistaminics
   b) 5-Hydroxytryptamine and its antagonists
   c) Lipid derived autocoids and platelet activating factor

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2.5 COMMUNITY PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope**: In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.

2. **Objectives:** Upon completion of the course, the student shall be able to –
   a. know pharmaceutical care services;
   b. know the business and professional practice management skills in community pharmacies;
   c. do patient counselling & provide health screening services to public in community pharmacy;
   d. respond to minor ailments and provide appropriate medication;
   e. show empathy and sympathy to patients; and
   f. appreciate the concept of Rational drug therapy.

   Text Books:
   a. Health Education and Community Pharmacy by N.S.Parmar.
   b. WHO consultative group report.
   c. Drug store & Business management by Mohammed Ali & Jyoti.

   Reference books:
   a. Handbook of pharmacy – health care.Edt. Robin J Harman. The Pharmaceutical press.
   b. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

   Special requirements:
   1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
   2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. **Scheme of evaluation (80 Marks)**
   1. Synopsis 10
   2. Major Experiment 30
      (Counselling of patients with specific diseases – emphasis should be given on Counselling introduction, content, process and conclusion)
   3. Minor Experiment(Ability to measure B.P/ CBG / Lung function) 15
   4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management) 15
   5. Viva – Voce 10

4. Lecture wise programme :

Topics

1 **Definition, scope, of community pharmacy**
Roles and responsibilities of Community pharmacist

2 **Community Pharmacy Management**
a) Selection of site, Space layout, and design
b) Staff, Materials- coding, stocking
c) Legal requirements
d) Maintenance of various registers
e) Use of Computers: Business and health care soft wares

3 **Prescriptions** – parts of prescription, legality & identification of medication related problems like drug interactions.

4 **Inventory control in community pharmacy**
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock

5 **Pharmaceutical care**
Definition and Principles of Pharmaceutical care.

6 **Patient counselling**
Definition, outcomes, various stages, barriers, Strategies to overcome barriers
Patient information leaflets- content, design, & layouts, advisory labels

7 **Patient medication adherence**
Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.

8 **Health screening services**
Definition, importance, methods for screening
Blood pressure/ blood sugar/ lung function and Cholesterol testing

9 **OTC Medication- Definition, OTC medication list & Counselling**

10 **Health Education**
WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.
Commonly occurring Communicable Diseases, causative agents,
Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy,
Syphilis, Gonorrhea and AIDS
Balance diet, and treatment & prevention of deficiency disorders
Family planning – role of pharmacist

11 **Responding to symptoms of minor ailments**
Relevant pathophysiology, common drug therapy to,
Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Opthalmic symptoms, worms infestations.

12 **Essential Drugs concept and Rational Drug Therapy**
Role of community pharmacist

13 **Code of ethics for community pharmacists**

2.6 PHARMACOTHERAPEUTICS - I (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
   a. the pathophysiology of selected disease states and the rationale for drug therapy;
   b. the therapeutic approach to management of these diseases;
   c. the controversies in drug therapy;
   d. the importance of preparation of individualised therapeutic plans based on diagnosis;
   e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
   f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
   g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
   h. discuss the controversies in drug therapy;
   i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
   j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
d. Applied Therapeutics:The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
f. Relevant review articles from recent medical and pharmaceutical literature.

3. **Detailed syllabus and lecture wise schedule :**

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

1 **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias

2 **Respiratory system :** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis

3 **General prescribing guidelines for**
a. Paediatric patients
b. Geriatric patients
c. Pregnancy and breast feeding

4 **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial

5 **Introduction to rational drug use**
Definition, Role of pharmacist Essential drug concept Rational drug formulations

2.6 PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Dr. G. SUMALATHA
PRINCIPAL
Vikas Institute of Pharmaceutical Science
RAJAHMUNDRY-533 102.

Third Year

3.1 PHARMACOLOGY – II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autocoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamines, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

2. **Objectives of the Subject Upon completion of the subject student shall be able to:**
   a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
   b. carry out the animal experiments confidently,
   c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
   d. correlate and apply the knowledge therapeutically.

Text books (Theory)

a. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.
b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
c. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)

a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Text books (Practical)

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical) :

a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Pharmacology of Drugs acting on Blood and blood forming agents**
   a) Anticoagulants
   b) Thrombolytics and antiplatelet agents
   c) Haemopoietics and plasma expanders

2. **Pharmacology of drugs acting on Renal System**
   a) Diuretics
   b) Antidiuretics

3. **Chemotherapy**
   a) Introduction
   b) Sulfonamides and co-trimoxazole
   c) Penicillins and Cephalosporins
   d) Tetracyclins and Chloramphenicol
   e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
   f) Quinolines and Fluroquinolines
   g) Antifungal antibiotics
   h) Antiviral agents
   i) Chemotherapy of tuberculosis and leprosy
   j) Chemotherapy of Malaria
   k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
   l) Pharmacology of Anthelmintic drugs
   m) Chemotherapy of cancer (Neoplasms)

4 **Immunopharmacology**
Pharmacology of immunosuppressants and stimulants

5. **Principles of Animal toxicology**
Acute, sub acute and chronic toxicity

6. **The dynamic cell: The structures and functions of the components of the cell**

a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies

b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.

c) DNA replication: General, bacterial and eukaryotic DNA replication.

d) The cell cycle: Restriction point, cell cycle regulators and modifiers.

e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors.

The Gene: Genome structure and function:

a) Gene structure: Organization and elucidation of genetic code.

b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.

c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

RNA processing: rRNA, tRNA and mRNA processing.
Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events
Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes.
The gene sequencing, mapping and cloning of human disease genes.
Introduction to gene therapy and targeting.
Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

Books:

1 Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD, 3rd edition.
2 Molecular Cell Biology By Lodish, H., Baltimore, D., Berk, A et al., 5th edition.
3 Molecular Biology by Turner, PC., McLennan, AG., Bates, AD and White MRH 2nd edition.
4 Genes VIII by Lewin, B., (2004)
5 Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)
6 Recombinant DNA by Watson, JD., Gilman, M., et al., (1996)
7 Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)

3.1 PHARMACOLOGY – II (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
    a) Analgesic property of drug using analgesiometer.
    b) Antiinflammatory effect of drugs using rat-paw edema method.
    c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
    d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
    e) Locomotor activity evaluation of drugs using actophotometer and rotorod.
    f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
Max Marks	**20**	**70**
Duration	**3hrs**	**4hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.2 PHARMACEUTICAL ANALYSIS (THEORY)

Theory : 3 Hrs. /Week

1. **Quality Assurance:**
   a. Introduction, sources of quality variation, control of quality variation.
   b. Concept of statistical quality control.
   c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
   d. GLP, ISO 9000.
   e. Total quality management, quality review and documentation.
   f. ICH- international conference for harmonization-guidelines.
   g. Regulatory control.

2. **Chromatography:**

   Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.

   a. **Column Chromatography**: Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
   b. **TLC**: Introduction, principle, techniques, R_f value and applications.
   c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
   d. **Ion-exchange chromatography**: Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
   e. **HPLC**: Introduction, theory, instrumentation, and applications.
   f. **HPTLC**: Introduction, theory, instrumentation, and applications.
   g. **Gas Chromatography**: Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors- Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
   h. **Electrophoresis**: Principles of separation, equipment for paper and gel electrophoresis, and application.
   i. **Gel filtration** and **affinity chromatography**: Introduction, technique, applications.

3. **Electrometric Methods:**

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

a. **Potentiometry**: Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.

b. **Conductometry**: Introduction, conductivity cell, conductometric titrations and applications.

c. **Polarography**: Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.

d. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

4. **Spectroscopy:**

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:

a. **Absorption Spectroscopy:**

- Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.
  Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

- **Infrared Spectroscopy**: Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation–IR spectrometer – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors– Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.

- **Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.

b. **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.

c. **Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications.

d. **Atomic Emission Spectroscopy**: Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.

e. **NMR & ESR (introduction only):** Introduction, theoretical aspects and applications.

f. **Mass Spectroscopy**: **(Introduction only)** – Fragmentation, types of ions produced mass spectrum and applications.

g. **Polarimetry: (Introduction only)** – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.

h. **X-RAY Diffraction: (Introduction only)** – Theory, reciprocal lattice concept, diffraction patterns and applications.

i. **Thermal Analysis**: Introduction, instrumentation, applications, and DSC and DTA.

3.2 PHARMACEUTICAL ANALYSIS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of a acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Supha drugs using BMR reagent.

11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

Reference Books:

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.
19. USP - Mack Publishing Co., Easton, PA.
20. The Extra Pharmacopoeia – The Pharm. Press, London.

Practicals

Title of the Experiment:

1 Study of agonistic and antagonistic effects of drugs using Guinea-pig ileum preparation.**
2 To study the effects of drugs on intestinal motility using frog's esophagus model*
3 To study the effects of drugs using rat uterus preparation.**
4 To study the anticonvulsant property of drugs (any one model).*
5 To study antihistaminic property of drug using histamine induced anaphylactic reaction in guinea pigs.
6 To study the apomorphine-induced compulsive behaviour (stereotypy) in mice.*
7 To study the muscle relaxant property of diazepam in mice using rotarod apparatus.*
8 To study the antiinflammatory property of indomethacin against carrageenan-induced paw oedema.**
9 To study the anxiolytic effect of diazepam in mice using mirrored-chamber apparatus.**
10 To demonstrate the effect of various drugs on the blood pressure and respiration of anaesthetized dog.
11 To study the effect of anthelmintics on earthworms.
12 To study the taming effect of chlorpromazine.*
13 To study the effects of drugs on vas deferense of the male rat.**
14 To study the effect of drugs on pesticide toxicity using rats as model.
15 To study the effect of drugs on heavy metal toxicity.

** indicate major experiment & * indicate minor experiment

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.3 PHARMACOTHERAPEUTICS – II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

2. **Objectives of the Subject Upon completion of the subject student shall be able to –**
   a. know the pathophysiology of selected disease states and the rationale for drug therapy
   b. know the therapeutic approach to management of these diseases;
   c. know the controversies in drug therapy;
   d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
   e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

   Text books (Theory)
   Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

   Reference books (Theory)
   a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
   b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
   c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

3. **Detailed syllabus and lecture wise schedule :**

   Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –

   Title of the topic

   1. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonarrhoea and Syphillis
   2 **Musculoskeletal disorders**
   Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
   3 **Renal system**
   Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

4 **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis

5 **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

3.3 PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.

2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, and appreciate) –
   a. practice the Professional ethics;
   b. understand the various concepts of the pharmaceutical legislation in India;
   c. know the various parameters in the Drug and Cosmetic Act and rules;
   d. know the Drug policy, DPCO, Patent and design act;
   e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
   f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
   g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

   Text books (Theory)

   Mithal , B M. Textbook of Forensic Pharmacy. Calcutta :National; 1988.

   Reference books (Theory)

   a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
   b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
   c. Reports of the Pharmaceutical enquiry Committee
   d. I.D.M.A., Mumbai. DPCO 1995
   e. Various reports of Amendments.
   f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
   g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3. **Detailed syllabus and lecture wise schedule:**

   Title of the topic

   1. **Pharmaceutical Legislations** – A brief review.
   2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
   3. **Drugs and Cosmetics Act, 1940,and its rules 1945.**
      Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.
      Sales, Import, labeling and packaging of Drugs And Cosmetics Provisions Relating to Indigenous Systems.
      Constitution and Functions of DTAB,DCC,CDL.
      Qualification and duties –Govt. analyst and Drugs Inspector.

4. **Pharmacy Act –1948.**
   Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.
5. **Medicinal and Toilet Preparation Act –1955.**
   Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations.
6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**. Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.
7. **Study of Salient Features of Drugs and magic remedies Act and its rules.**
8. **Study of essential Commodities Act Relevant to drugs price control Order.**
9. **Drug Price control Order & National Drug Policy (Current).**
10. **Prevention Of Cruelty to animals Act-1960.**
11. **Patents & design Act-1970.**
12. **Brief study of prescription and Non-prescription Products.**

4. Assignments:

Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

3.5 MEDICINAL CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

   A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

2. Anti-infective agents
   a) Local anti-infective agents
   b) Preservatives
   c) Antifungal agents
   d) Urinary tract anti-infectives
   e) Antitubercular agents
   f) Antiviral agents and Anti AIDS agents
   g) Antiprotozoal agents
   h) Anthelmentics
   i) Antiscabies and Antipedicular agents
3. Sulphonamides and sulphones
4. Antimalarials
5. Antibiotics
6. Antineoplastic agents
7. Cardiovascular agents
   a) Antihypertensive agents
   b) Antianginal agents and vasodilators
   c) Antiarrhythmic agents
   d) Antihyperlipidemic agents
   e) Coagulants and Anticoagulants
   f) Endocrine
8. Hypoglycemic agents
9. Thyroid and Antithyroid agents
10. Diureties
11. Diagnostic agents
12. Steroidal Hormones and Adrenocorticoids

3.5 MEDICINAL CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

Reference Books:

a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.

b. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.

c. Burgers, Medicinal Chemistry, M.E.,Welly Med.Chemistry M.E. Walffed Johnwilley and Sons, Wiley-interscience Publication, New York, Toranto.

d. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.

e. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.

f. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.

g. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.

h. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.

i. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

3.6 PHARMACEUTICAL FORMULATIONS (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.

2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
   a. understand the principle involved in formulation of various pharmaceutical dosage forms;
   b. prepare various pharmaceutical formulation;
   c. perform evaluation of pharmaceutical dosage forms; and
   d. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

   Text books (Theory)
   a. Pharmaceutical dosage forms, Vol, I,II and III by lachman
   b. Rowlings Text book of Pharmaceutics
   c. Tutorial Pharmacy – Cooper &Gun

   Reference books (Theory)
   a. Remington's Pharmaceutical Sciences
   b. USP/BP/IP

3. **Detailed syllabus and lecture wise schedule:**

   Title of the topic

   1. Pharmaceutical dosage form- concept and classification
   2. **Tablets**: Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
   3. **Capsules**; Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.
   4. **Liquid orals**: Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
   5. **Parenterals** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization
   6. **Ophthalmic preparations (Semi – Solids)**: Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging
   7. Definition and concept of **Controlled and novel Drug delivery systems** with available examples, viz. parentral, trans dermal, buccal, rectal, nasal, implants, ocular

3.6 PHARMACEUTICAL FORMULATIONS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments :

1. **Manufacture of Tablets**
   - **a.** Ordinary compressed tablet-wet granulation
   - **b.** Tablets prepared by direct compression.
   - **c.** Soluble tablet.
   - **d.** Chewable tablet.
2. **Formulation and filling of hard gelatin capsules**
3. **Manufacture of parenterals**
   - **a.** Ascorbic acid injection
   - **b.** Calcium gluconate injection
   - **c.** Sodium chloride infusion.
   - **d.** Dextrose and Sodium chloride injection/ infusion.
4. **Evaluation of Pharmaceutical formulations (QC tests)**
   - **a.** Tablets
   - **b.** Capsules
   - **c.** Injections
5. **Formulation of two liquid oral preparations and evaluation by assay**
   - **a.** Solution: Paracetamol Syrup
   - **b.** Antacid suspensions- Aluminum hydroxide gel
6. **Formulation of semisolids and evaluation by assay**
   - **a.** Salicyclic acid and benzoic acid ointment
   - **b.** Gel formulation Diclofenac gel
7. **Cosmetic preparations**
   - **a.** Lipsticks
   - **b.** Cold cream and vanishing cream
   - **c.** Clear liquid shampoo
   - **d.** Tooth paste and tooth powders.
8. **Tablet coating (demonstration)**

Scheme of Practical Examination :

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Fourth Year

4.1 PHARMACOTHERAPEUTICS – III (THEORY)

Theory : 3 Hrs. /Week

1. **Scope :** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
   a. the pathophysiology of selected disease states and the rationale for drug therapy;
   b. the therapeutic approach to management of these diseases;
   c. the controversies in drug therapy;
   d. the importance of preparation of individualised therapeutic plans based on diagnosis;
   e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
   f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
   g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
   h. to discuss the controversies in drug therapy;
   i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
   j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
f. Relevant review articles from recent medical and pharmaceutical literature.

4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical : 3 Hrs./Week

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
5 Pain management including Pain pathways, neuralgias, headaches.
6 Evidence Based Medicine

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.2 HOSPITAL PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope**: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.

2. **Objectives:** Upon completion of the course, the student shall be able to –
   a. know various drug distribution methods;
   b. know the professional practice management skills in hospital pharmacies;
   c. provide unbiased drug information to the doctors;
   d. know the manufacturing practices of various formulations in hospital set up;
   e. appreciate the practice based research methods; and
   f. appreciate the stores management and inventory control.

   Text books: (latest editions)
   a. Hospital pharmacy by William .E. Hassan
   b. A text book of Hospital Pharmacyby S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

   References:
   a. WHO consultative group report.
   b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
   c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

3. **Lecture wise programme :**

   Topics

   1 **Hospital - its Organisation and functions**
   2 **Hospital pharmacy-Organisation and management**
   a) Organizational structure-Staff, Infrastructure & work load statistics
   b) Management of materials and finance
   c) Roles & responsibilities of hospital pharmacist
   3 **The Budget – Preparation and implementation**
   4 **Hospital drug policy**
   a) Pharmacy and Therapeutic committee (PTC)
   b) Hospital formulary
   c) Hospital committees
   - Infection committee
   - Research and ethical committee

   d) developing therapeutic guidelines
   e) Hospital pharmacy communication - Newsletter

5 Hospital pharmacy services

a) Procurement & warehousing of drugs and Pharmaceuticals
b) Inventory control
   Definition, various methods of Inventory Control
   ABC, VED, EOQ, Lead time, safety stock
c) Drug distribution in the hospital
   i) Individual prescription method
   ii) Floor stock method
   iii) Unit dose drug distribution method
d) Distribution of Narcotic and other controlled substances
e) Central sterile supply services – Role of pharmacist

6 Manufacture of Pharmaceutical preparations

a) Sterile formulations – large and small volume parenterals
b) Manufacture of Ointments, Liquids, and creams
c) Manufacturing of Tablets, granules, capsules, and powders
d) Total parenteral nutrition

7 Continuing professional development programs

Education and training

8 Radio Pharmaceuticals – Handling and packaging

9 Professional Relations and practices of hospital pharmacist

4.2 HOSPITAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.3 CLINICAL PHARMACY (THEORY)

Theory : 3 Hrs. /Week

1. **Objectives of the Subject :**

Upon completion of the subject student shall be able to (Know, do, appreciate) –

a. monitor drug therapy of patient through medication chart review and clinical review;
b. obtain medication history interview and counsel the patients;
c. identify and resolve drug related problems;
d. detect, assess and monitor adverse drug reaction;
e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

References

a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. **Detailed syllabus and lecture wise schedule:**

Title of the topic

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
   a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
   b. Ward round participation
   c. Adverse drug reaction management
   d. Drug information and poisons information
   e. Medication history
   f. Patient counseling
   g. Drug utilisation evaluation (DUE) and review (DUR)
   h. Quality assurance of clinical pharmacy services

3. **Patient data analysis**
   The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
   a. Haematological, Liver function, Renal function, thyroid function tests
   b. Tests associated with cardiac disorders
   c. Fluid and electrolyte balance
   d. Microbiological culture sensitivity tests
   e. Pulmonary Function Tests
5. **Drug & Poison information**
   a. Introduction to drug information resources available
   b. Systematic approach in answering DI queries
   c. Critical evaluation of drug information and literature
   d. Preparation of written and verbal reports
   e. Establishing a Drug Information Centre
   f. Poisons information- organization & information resources
6. **Pharmacovigilance**
   a. Scope, definition and aims of pharmacovigilance
   b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
   c. Reporting, evaluation, monitoring, preventing & management of ADRs
   d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

a. Answering drug information questions (4 Nos)
b. Patient medication counselling (4 Nos)
c. Case studies related to laboratory investigations (4 Nos)
d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. Detailed syllabus and lecture wise schedule

1 **Research Methodology**

a) Types of clinical study designs:
Case studies, observational studies, interventional studies,

b) Designing the methodology

c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study

d) Report writing and presentation of data

2 **Biostatistics**

2.1 a) Introduction

b) Types of data distribution

c) Measures describing the central tendency distributions- average, median, mode

d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 **Data graphics**

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarthimic plots

2.3 **Basics of testing hypothesis**

a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.

b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)

c) Level of significance (Non-parametric data)- Sign test, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one way ANOVA)

d) Linear regression and correlation- Introduction, Pearsonn's and Spearmann's correlation and correlation co-efficient.

e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 **Statistical methods in epidemiology**

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy

Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature Retrieval

Use of Computerized Retrieval

Reference books:

a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.

b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory : 3 Hrs. /Week

1. Biopharmaceutics

1. Introduction to Biopharmaceutics
   a. Absorption of drugs from gastrointestinal tract.
   b. Drug Distribution.
   c. Drug Elimination.

2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
   a. Mathematical model
   b. Drug levels in blood.
   c. Pharmacokinetic model
   d. Compartment models
   e. Pharmacokinetic study.

3. One compartment open model.
   a. Intravenous Injection (Bolus)
   b. Intravenous infusion.

4. Multicompartment models.
   a. Two compartment open model.
   b. IV bolus, IV infusion and oral administration

5. Multiple – Dosage Regimens.
   a. Repititive Intravenous injections – One Compartment Open Model
   b. Repititive Extravascular dosing – One Compartment Open model
   c. Multiple Dose Regimen – Two Compartment Open Model

6. Nonlinear Pharmacokinetics.
   a. Introduction
   b. Factors causing Non-linearity.
   c. Michaelis-menton method of estimating parameters.

7. Noncompartmental Pharmacokinetics.
   a. Statistical Moment Theory.
   b. MRT for various compartment models.
   c. Physiological Pharmacokinetic model.

8. Bioavailability and Bioequivalence.
   a. Introduction.
   b. Bioavailability study protocol.
   c. Methods of Assessment of Bioavailability

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical : 3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of Ka, Ke, $t_1/2$, Cmax, AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxzole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

References:

a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.
c. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
f. Biopharmaceutics; By Swarbrick
g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
h. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

4.6 CLINICAL TOXICOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –
   a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
   b) Opiates overdose.
   c) Antidepressants
   d) Barbiturates and benzodiazepines.
   e) Alcohol: ethanol, methanol.
   f) Paracetamol and salicylates.
   g) Non-steroidal anti-inflammatory drugs.
   h) Hydrocarbons: Petroleum products and PEG.
   i) Caustics: inorganic acids and alkali.
   j) Radiation poisoning
8. Clinical symptoms and management of chronic poisoning with the following agents – Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

a) CNS stimulants :amphetamine
b) Opioids
c) CNS depressants
d) Hallucinogens: LSD
e) Cannabis group
f) Tobacco

References:

a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

Fifth year

5.1 CLINICAL RESEARCH (THEORY)

Theory : 3 Hrs. /Week

1. **Drug development process:**
   Introduction
   Various Approaches to drug discovery
   1. Pharmacological
   2. Toxicological
   3. IND Application
   4. Drug characterization
   5. Dosage form

2. **Clinical development of drug:**
   1. Introduction to Clinical trials
   2. Various phases of clinical trial.
   3. Methods of post marketing surveillance
   4. Abbreviated New Drug Application submission.
   5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
   6. Challenges in the implementation of guidelines
   7. Ethical guidelines in Clinical Research
   8. Composition, responsibilities, procedures of IRB / IEC
   9. Overview of regulatory environment in USA, Europe and India.
   10. Role and responsibilities of clinical trial personnel as per ICH GCP
       a. Sponsor
       b. Investigators
       c. Clinical research associate
       d. Auditors
       e. Contract research coordinators
       f. Regulatory authority
   11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
   12. Informed consent Process
   13. Data management and its components
   14. Safety monitoring in clinical trials.

References :

a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.

b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.

g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

5.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory : 3 Hrs. /Week

1. **Pharmacoepidemiology :**

Definition and scope:
Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology
Outcome measure and drug use measures
Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

Concept of risk in pharmacoepidemiology
Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods
Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods
Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Sources of data for pharmacoepidemiological studies
Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology
Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. **Phrmacoeconomics:**

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation
Outcome assessment and types of evaluation
Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:
Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. **Applications of Pharmacoeconomics**

Software and case studies

5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory : 2 Hrs. /Week

1. **Introduction to Clinical pharmacokinetics.**

2. **Design of dosage regimens:**
   Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.

3. **Pharmacokinetics of Drug Interaction:**
   a. Pharmacokinetic drug interactions
   b. Inhibition and Induction of Drug metabolism
   c. Inhibition of Biliary Excretion.

4. **Therapeutic Drug monitoring:**
   a. Introduction
   b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs).
   c. Indications for TDM. Protocol for TDM.
   d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
   e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

5. **Dosage adjustment in Renal and hepatic Disease.**
   a. Renal impairment
   b. Pharmacokinetic considerations
   c. General approach for dosage adjustment in Renal disease.
   d. Measurement of Glomerular Filtration rate and creatinine clearance.
   e. Dosage adjustment for uremic patients.
   f. Extracorporeal removal of drugs.
   g. Effect of Hepatic disease on pharmacokinetics.

6. **Population Pharmacokinetics.**
   a. Introduction to Bayesian Theory.
   b. Adaptive method or Dosing with feed back.
   c. Analysis of Population pharmacokinetic Data.

7. **Pharmacogenetics**
   a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
   b. Genetic Polymorphism in Drug Transport and Drug Targets.
   c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

APPENDIX-B

(See regulation 9)

CONDITIONS TO BE FULFILLED BY THE ACADEMIC TRAINING INSTITUTION

1) Any authority or institution in India applying to the Pharmacy Council of India for approval of courses of study for Pharm.D. and Pharm.D. (Post Baccalaureate) under sub-section (1) of section 12 of the Pharmacy Act, 1948 shall comply with the infrastructural facilities as prescribed by the Pharmacy Council of India from time to time.

2) Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be conducted only in those institutions which -

   a) are approved by the Pharmacy Council of India for B.Pharm course as provided under section 12 of the Pharmacy Act, 1948;

   b) have 300 bedded hospital attached to it.

(i) Hospital Details

1. Institution with their own hospital of minimum 300 beds.
2. Teaching hospital recognised by the Medical Council of India or University, or a Government hospital not below the level of district headquarter hospital with 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
3. Corporate type hospital with minimum 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
4. Number of institutions which can be attached to one hospital shall be restricted by the student pharmacist to bed ratio of 1:10.

(ii) Speciality

a) Tertiary care hospitals are desirable

b) Medicine[compulsory], and any three specialization of the following

1. Surgery
2. Pediatrics
3. Gynecology and obstetrics
4. Psychiatry
5. Skin and VD
6. Orthopedics

(iii) Location of the Hospital

Within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.

3) TEACHING STAFF REQUIREMENT

i) Staff Pattern : All faculty shall be full time. However part time perceptors in hospital shall be allowed.

ii) Subject wise specialisation of the Teaching Staff :

S.No.	Subject	Specialisation required
1.	Pharmacy Practice	M.Pharm in Pharmacy Practice or Pharmacology or Pharmaceutics.
2.	Human Anatomy & Physiology	M.Pharm in Pharmacology or Pharmacy practice
3.	Pharmaceutics (Dispensing & General Pharmacy)	M.Pharm in Pharmaceutics
4.	Pharmacognosy-I	M.Pharm in Pharmacognosy
5.	Pharmaceutical Organic Chemistry-I	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
6.	Pharmaceutical Inorganic Chemistry	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
7.	Pharmaceutical microbiology	M.Pharm in Pharmaceutics or Pharmaceutical Biotechnology
8.	Pathophysiology	M.Pharm Pharmacy practice or Pharmacology
9.	Applied Biochemistry & Clinical Chemistry	M.Pharm in Pharmacology or Pharmacy practice or Pharmaceutical chemistry
10.	Pharmacology-I	M.Pharm in Pharmacology or Pharmacy practice
11.	Pharmaceutical Jurisprudence	M.Pharm in Pharmaceutics
12.	Pharmacology-II	M.Pharm in Pharmacology or Pharmacy practice
13.	Pharmaceutical Dosage Forms	M.Pharm in Pharmaceutics or Industrial Pharmacy
14.	Pharmacotherapeutics –I, II and III	M.Pharm Pharmacy practice or Pharmacology
15.	Community Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
16.	Hospital Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
17.	Clinical Pharmacy	M.Pharm in Pharmacy practice
18.	Computer Science or Computer Application in pharmacy	MCA
19.	Mathematics	M.Sc. (Maths)

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iii) Teaching Staff :

Department/Division	Name of the post	No.
Department of Pharmaceutics	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmaceutical Chemistry (Including Pharmaceutical Analysis)	Professor	1
	Asst. Professor	1
	Lecturer	3
Department of Pharmacology	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmacognosy	Professor	1
	Asst. Professor	1
	Lecturer	1
Department of Pharmacy Practice	Professor	1
	Asst. Professor	2
	Lecturer	3

iv) Prescribed qualifications and experience for Professor, Assistant Professor, Lecturer and others :

Sl. No.	CADRE	QUALIFICATIONS	EXPERIENCE
1.	Lecturer	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) First Class Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm)	No minimum requirement.
2.	Assistant Professor	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm)	Three years experience in Teaching or Research at the level of Lecturer or equivalent.

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		iv) Ph.D. degree (with First Class degree either at Bachelor's or Master's level) in the appropriate branch of specialization in Pharmacy.	
3.	Professor	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm). iv) Ph.D. degree (with first Class either at Bachelor's or Master's level) in appropriate branch of specialization in Pharmacy.	i) Ten years experience in Teaching or Research. ii) Out of which five years must be as Assistant Professor.
4.	Director or Principal or Head of institute	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm) iv) Ph.D. degree (with first Class degree either at Bachelor's or Master's level in the appropriate branch of specialization in Pharmacy.	i) Fifteen years experience in Teaching or Research. ii) Out of which five years must be as Professor or above in Pharmacy. Desirable : Administrative experience in responsible position. The maximum age for holding the post shall be 65 years.

Note : If a class or division is not awarded at Master's level, a minimum of 60% marks in aggregate or equivalent cumulative grade point average shall be considered equivalent to first class or division, as the case may be.

v) Workload of Faculty :

Professor – 8 hrs. per week

Assistant Professor – 12 hrs. per week

Lecturers – 16 hrs. per week

vi) Training of Pharmacy Practice Faculty :

a) Teaching staff will be trained as per the module prescribed by the Central Council.

b) Duration of training – Minimum 3 months.

c) Training sites – Institutions running pharmacy practice or Programmes for atleast five years.

d) Trainer – Professor or Assistant Professor with minimum of five years of clinical pharmacy teaching and practice experience.

4) NON-TEACHING STAFF :

Sl.No.	Designation	Required (Minimum)	Required Qualification
1	Laboratory Technician	1 for each Dept	D. Pharm
2	Laboratory Assistants or Laboratory Attenders	1 for each Lab (minimum)	SSLC
3	Office Superintendent	1	Degree
4	Accountant	1	Degree
5	Store keeper	1	D.Pharm or a Bachelor degree recognized by a University or institution.
6	Computer Data Operator	1	BCA or Graduate with Computer Course
7	Office Staff I	1	Degree
8	Office Staff II	2	Degree
9	Peon	2	SSLC
10	Cleaning personnel	Adequate	---
11	Gardener	Adequate	---

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5) ACCOMMODATION :

Suitable and sufficient accommodation with adequate ventilation, lighting and other hygienic conditions should be provided to the rooms for Principal or the Head of the department, office, class rooms, library, staff, staff common room, students common room, museum, laboratories, stores, etc.

At least two lecture halls alongwith eight laboratories as specified below should be provided for: —

1. Pharmaceutics and Pharmacokinetics Lab - 2
2. Life Science (Pharmacology, Physiology, Pathophysiology) - 2
3. Phytochemistry or Pharmaceutical Chemistry - 2
4. Pharmacy Practice - 2

Total = 8

In addition to the laboratories, balance room, aseptic room or cabinet, animal house and a machine room shall also be provided.

Floor area of the laboratory should not be less than 30 square feet per student required to work in the laboratory at any given time subject to a minimum of 750 square feet.

Laboratories should be fitted and constructed in a manner that these can be kept reasonably clean. Gas and water fittings, shelves, fuming cupboards be provided wherever necessary.

6. EQUIPMENT AND APPARATUS :

Department wise list of minimum equipments

A. DEPARTMENT OF PHARMACOLOGY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscopes	15
2	Haemocytometer with Micropipettes	20
3	Sahli's haemocytometer	20
4	Hutchinson's spirometer	01
5	Spygmomanometer	05
6	Stethoscope	05
7	Permanent Slides for various tissues	One pair of each tissue Organs and endocrine glands One slide of each organ system
8	Models for various organs	One model of each organ system
9	Specimen for various organs and systems	One model for each organ system
10	Skeleton and bones	One set of skeleton and one spare bone

11	Different Contraceptive Devices and Models	One set of each device
12	Muscle electrodes	01
13	Lucas moist chamber	01
14	Myographic lever	01
15	Stimulator	01
16	Centrifuge	01
17	Digital Balance	01
18	Physical /Chemical Balance	01
19	Sherrington's Kymograph Machine or Polyrite	10
20	Sherrington Drum	10
21	Perspex bath assembly (single unit)	10
22	Aerators	10
23	Computer with LCD	01
24	Software packages for experiment	01
25	Standard graphs of various drugs	Adequate number
26	Actophotometer	01
27	Rotarod	01
28	Pole climbing apparatus	01
29	Analgesiometer (Eddy's hot plate and radiant heat methods)	01
30	Convulsiometer	01
31	Plethysmograph	01
32	Digital pH meter	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Folin-Wu tubes	60
2	Dissection Tray and Boards	10
3	Haemostatic artery forceps	10
4	Hypodermic syringes and needles of size 15,24,26G	10
5	Levers, cannulae	20

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

B. DEPARTMENT OF PHARMACOGNOSY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscope with stage micrometer	15
2	Digital Balance	02
3	Autoclave	02

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4	Hot air oven	02
5	B.O.D.incubator	01
6	Refrigerator	01
7	Laminar air flow	01
8	Colony counter	02
9	Zone reader	01
10	Digital pH meter	01
11	Sterility testing unit	01
12	Camera Lucida	15
13	Eye piece micrometer	15
14	Incinerator	01
15	Moisture balance	01
16	Heating mantle	15
17	Flourimeter	01
18	Vacuum pump	02
19	Micropipettes (Single and multi channeled)	02
20	Micro Centrifuge	01
21	Projection Microscope	01

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Reflux flask with condenser	20
2	Water bath	20
3	Clavengers apparatus	10
4	Soxhlet apparatus	10
6	TLC chamber and sprayer	10
7	Distillation unit	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

C. DEPARTMENT OF PHARMACEUTICAL CHEMISTRY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Hot plates	05
2	Oven	03
3	Refrigerator	01
4	Analytical Balances for demonstration	05
5	Digital balance 10mg sensitivity	10
6	Digital Balance (1mg sensitivity)	01
7	Suction pumps	06
8	Muffle Furnace	01

9	Mechanical Stirrers	10
10	Magnetic Stirrers with Thermostat	10
11	Vacuum Pump	01
12	Digital pH meter	01
13	Microwave Oven	02

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Distillation Unit	02
2	Reflux flask and condenser single necked	20
3	Reflux flask and condenser double/ triple necked	20
4	Burettes	40
5	Arsenic Limit Test Apparatus	20
6	Nesslers Cylinders	40

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

D. DEPARTMENT OF PHARMACEUTICS :

I. Equipment:

S.No	Name	Minimum required Nos.
1	Mechanical stirrers	10
2	Homogenizer	05
3	Digital balance	05
4	Microscopes	05
5	Stage and eye piece micrometers	05
6	Brookfield's viscometer	01
7	Tray dryer	01
8	Ball mill	01
9	Sieve shaker with sieve set	01
10	Double cone blender	01
11	Propeller type mechanical agitator	05
12	Autoclave	01
13	Steam distillation still	01
14	Vacuum Pump	01
15	Standard sieves, sieve no. 8, 10, 12,22,24, 44, 66, 80	10 sets
16	Tablet punching machine	01
17	Capsule filling machine	01
18	Ampoule washing machine	01
19	Ampoule filling and sealing machine	01

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20	Tablet disintegration test apparatus IP	01
21	Tablet dissolution test apparatus IP	01
22	Monsanto's hardness tester	01
23	Pfizer type hardness tester	01
24	Friability test apparatus	01
25	Clarity test apparatus	01
26	Ointment filling machine	01
27	Collapsible tube crimping machine	01
28	Tablet coating pan	01
29	Magnetic stirrer, 500ml and 1 liter capacity with speed control	05 EACH 10
30	Digital pH meter	01
31	All purpose equipment with all accessories	01
32	Aseptic Cabinet	01
33	BOD Incubator	02
34	Bottle washing Machine	01
35	Bottle Sealing Machine	01
36	Bulk Density Apparatus	02
37	Conical Percolator (glass/copper/ stainless steel)	10
38	Capsule Counter	02
39	Energy meter	02
40	Hot Plate	02
41	Humidity Control Oven	01
42	Liquid Filling Machine	01
43	Mechanical stirrer with speed regulator	02
44	Precision Melting point Apparatus	01
45	Distillation Unit	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Ostwald's viscometer	15
2	Stalagmometer	15
3	Desiccator*	05
4	Suppository moulds	20
5	Buchner Funnels (Small, medium, large)	05 each
6	Filtration assembly	01
7	Permeability Cups	05
8	Andreason's Pipette	03
9	Lipstick moulds	10

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

E. DEPARTMENT OF PHARMACEUTICAL BIOTECHNOLOGY :

S.No.	Name	Minimum required Nos.
1	Orbital shaker incubator	01
2	Lyophilizer (Desirable)	01
3	Gel Electrophoresis (Vertical and Horizontal)	01
4	Phase contrast/Trinocular Microscope	01
5	Refrigerated Centrifuge	01
6	Fermenters of different capacity (Desirable)	01
7	Tissue culture station	01
8	Laminar airflow unit	01
9	Diagnostic kits to identify infectious agents	01
10	Rheometer	01
11	Viscometer	01
12	Micropipettes (single and multi channeled)	01 each
13	Sonicator	01
14	Respinometer	01
15	BOD Incubator	01
16	Paper Electrophoresis Unit	01
17	Micro Centrifuge	01
18	Incubator water bath	01
19	Autoclave	01
20	Refrigerator	01
21	Filtration Assembly	01
22	Digital pH meter	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

F. DEPARTMENT OF PHARMACY PRACTICE :

Equipment:

S.No.	Name	Minimum required Nos.
1	Colorimeter	2
2	Microscope	Adequate
3	Permanent slides (skin, kidney, pancreas, smooth muscle, liver etc.,)	Adequate
4	Watch glass	Adequate
5	Centrifuge	1
6	Biochemical reagents for analysis of normal and pathological constituents in urine and blood facilities	Adequate
7	Filtration equipment	2
8	Filling Machine	1
9	Sealing Machine	1

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10	Autoclave sterilizer	1
11	Membrane filter	1 Unit
12	Sintered glass funnel with complete filtering assemble	Adequate
13	Small disposable membrane filter for IV admixture filtration	Adequate
14	Laminar air flow bench	1
15	Vacuum pump	1
16	Oven	1
17	Surgical dressing	Adequate
18	Incubator	1
19	PH meter	1
20	Disintegration test apparatus	1
21	Hardness tester	1
22	Centrifuge	1
23	Magnetic stirrer	1
24	Thermostatic bath	1

NOTE:

1. **Computers and Internet connection (Broadband), six computers for students with internet and staff computers as required.**
2. **Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and the department.**

G. CENTRAL INSTRUMENTATION ROOM :

S.No.	Name	Minimum required Nos.
1	Colorimeter	01
2	Digital pH meter	01
3	UV- Visible Spectrophotometer	01
4	Flourimeter	01
5	Digital Balance (1mg sensitivity)	01
6	Nephelo Turbidity meter	01
7	Flame Photometer	01
8	Potentiometer	01
9	Conductivity meter	01
10	Fourier Transform Infra Red Spectrometer (Desirable)	01
11	HPLC	01
12	HPTLC (Desirable)	01
13	Atomic Absorption and Emission spectrophotometer (Desirable)	01
14	Biochemistry Analyzer (Desirable)	01
15	Carbon, Hydrogen, Nitrogen Analyzer (Desirable)	01
16	Deep Freezer (Desirable)	01
17	Ion- Exchanger	01
18	Lyophilizer (Desirable)	01

APPENDIX-C

(See regulation 16)

INTERNSHIP

1) **SPECIFIC OBJECTIVES :**

i) to provide patient care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.

ii) to manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.

iii) to promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an interprofessional team of health care providers.

iv) to demonstrate skills in monitoring of the National Health Programmes and schemes, oriented to provide preventive and promotive health care services to the community.

v) to develop leadership qualities to function effectively as a member of the health care team organised to deliver the health and family welfare services in existing socio-economic, political and cultural environment.

vi) to communicate effectively with patients and the community.

2) **OTHER DETAILS :**

i) All parts of the internship shall be done, as far as possible, in institutions in India. In case of any difficulties, the matter may be referred to the Pharmacy Council of India to be considered on merits.

ii) Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.

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iii) Every candidate shall be required, after passing the final Pharm.D. or Pharm.D. (Post Baccalaureate) examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of twelve months so as to be eligible for the award of the degree of Pharm.D. or Pharm.D. (Post Baccalaureate) as the case may be.

3. ASSESSMENT OF INTERNSHIP :

i) The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.

ii) Satisfactory completion of internship shall be determined on the basis of the following:-

(1) Proficiency of knowledge required for each case management SCORE 0-5

(2) The competency in skills expected for providing Clinical Pharmacy Services SCORE 0-5

(3) Responsibility, punctuality, work up of case, involvement in patient care SCORE 0-5

(4) Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0-5

(5) Initiative, participation in discussions, research aptitude. SCORE 0-5

Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship.

APPENDIX-D

(See regulation 17)

CONDITIONS TO BE FULFILLED BY THE EXAMINING AUTHORITY

1. The Examining Authority shall be a statutory Indian University constituted by the Central Government/State Government/Union Territory Administration. It shall ensure that discipline and decorum of the examinations are strictly observed at the examination centers.

2. It shall permit the Inspector or Inspectors of the Pharmacy Council of India to visit and inspect the examinations.

3. It shall provide:-
   (a) adequate rooms with necessary furniture for holding written examinations;
   (b) well-equipped laboratories for holding practical examinations;
   (c) an adequate number of qualified and responsible examiners and staff to conduct and invigilate the examinations; and
   (d) such other facilities as may be necessary for efficient and proper conduct of examinations.

4. It shall, if so required by a candidate, furnish the statement of marks secured by a candidate in the examinations after payment of prescribed fee, if any, to the Examining Authority.

5. It shall appoint examiners whose qualifications should be similar to those of the teachers in the respective subjects as shown in Appendix–B.

6. In pursuance of sub–section (3) of section 12 of the Pharmacy Act, 1948, the Examining Authority shall communicate to the Secretary, Pharmacy Council of India, not less than six weeks in advance the dates fixed for examinations, the time-table for such examinations, so as to enable the Council to arrange for inspection of the examinations.

7. The Examining Authority shall ensure that examiners for conducting examination for Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be persons possessing pharmacy qualification and are actually involved in the teaching of the Pharm.D. and Pharm.D. (Post Baccalaureate) programmes in an approved institution.

(ARCHNA MUDGAL)
Registrar-cum-Secretary
Pharmacy Council of India
New Delhi – 110002

ANDHRA UNIVERSITY

MASTER OF PHARMACY

(2020)

Regulations and Syllabus

Four semester pattern

With effect from 2020-21

M.PHARM (2020) REGULATIONS AND SYLLABUS

INDEX:

1. Admission, instruction and attendance
2. Examinations - Sessional and Semester - end
3. Eligibility criteria for appointment as examiner for M.Pharm examination
4. Regulations for pursuing M.Pharm III and IV Semester project
5. Declaration of results and classification:
6. Grading system:
7. Guidelines for paper setting and model papers.

1. Admission, instruction and attendance

The degree of Master of Pharmacy of the Andhra University will be conferred on a candidate who has satisfied the following conditions:

1.1. The candidate must have passed the B.Pharm. Degree examination of this University or B.Pharm. Degree examinations of any other University recognized by the Academic Council as equivalent thereto in First or Second class; and must have qualified in any entrance examination, if prescribed.

1.2. Every student, selected for admission to PG Pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

1.3. The candidate should have undergone a regular course of study as prescribed hereunder extending over a period of four semesters, ordinarily consecutive, and satisfied the academic requirements as prescribed hereinafter. The course of instruction and periods of study shall be as given in the scheme of instruction and in the syllabus.

1.4. The subjects of specializations for Master of Pharmacy Course shall be as follows:

1. Pharmaceutical Analysis
2. Pharmaceutical Chemistry
3. Pharmaceutics
4. Pharmaceutical Biotechnology
5. Pharmacology
6. Pharmacognosy
7. Pharmaceutical Regulatory Affairs
8. Pharmaceutical Quality Assurance
9. Industrial Pharmacy
10. Pharmacy Practice

1.5. Instruction and examination in each academic year is spread over two semesters with a minimum of 96 working days in each semester (192 in any given academic year). The odd semesters shall be conducted from the month of July to November and the even semesters shall be conducted from the month of December to April.

1.6. Each period of instruction is of 45 minutes duration. Eight periods of instruction are provided on each day and there are six working days in a week (Monday to Saturday).

1.7. Attendance Requirements: A regular course of study during an academic semester means a minimum of average attendance of 80% of all the courses of the semester computed by totaling the number of periods of lectures and practicals, as the case may be, held in every course. In special cases where sufficient causes were shown, the Vice-

Chancellor may on the recommendation of the Principal concerned condone the deficiency in the average attendance to an extent of 9% for reasons such as ill health, if the application for condonation is submitted at the time of actual illness and is supported by certificate of; authorized Medical officer approved by the Principal. However, in the case of students, who participate in activities like N.S.S., N.C.C., Inter-Collegiate tournaments conducted by Andhra University, Inter-University tournaments conducted by Inter-university Board and any such other activities involving the representation of the College/University with the prior approval of the principal, the candidate may be deemed to have attended the college during the period solely for the purpose of the examination.

1.7. A candidate who cannot satisfy the attendance requirements in clause 1.5 because of late admission under special circumstances reasonable and acceptable to the University on the basis of document, shall fulfill the following conditions; Average attendance: A candidate shall have attended at least a total of 90% of the periods-lectures/practicals as the case may be held from the date of admission and also shall attend at least 50% of the total working days during that academic semester (Late admission means, admissions made after 45 days from date of commencement of the academic semester for the course).

1.8. If any candidate fails to satisfy the regulation under 1.5 or 1.6 she/he shall not be allowed for the University Examinations at the end of the semester, and he/she shall not be allowed for promotion to the next higher class of study. He/she shall be required to repeat the regular course of study of that academic semester along with the next regular batch.

1.9. A regular record of attendance in theory, practical, seminar, assignment, journal club, discussion with the supervisor, research work presentation and dissertation shall be maintained by the department/teaching staff of respective courses.

2. Examinations – Internal assessment and Semester-end

2.1. Assessment for the award of degree shall consists of (a) internal assessment for 30 marks in each of the theory and practical courses separately. (b) Semester-end examination as detailed in the scheme of examination for 70 marks in each of the theory and practical separately.

2.2. Regulations concerning internal assessment: Internal assessment consist of continuous mode (10 marks for theory and 15 marks for practical) and sessional examinations (20 marks for theory and 15 marks for practical)

2.2.1. Scheme for awarding continuous mode marks for theory and practical

Theory-Criteria	**Marks**
Attendance	5
Student-Teacher Interaction	5
Theory sessional examination	20
Total theory internal assessment	**30**
Practical-Criteria	
Attendance	5
Record + Viva-voce	10
Practical sessional examination	15
Total practical internal assessment	**30**

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2.2.1.1. Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory/Practical
95 -100	5
90-94	4
85-89	3
80-84	2
Less than 80	0

2.2.1.2. Guidelines for allotment of marks for Student-Teacher interaction

The teacher shall create some interactive sessions for theory topics and every student shall interact on the given topic relating to its application in pharmacy. The teacher should assess the student capacity for understanding of the concept taught. It shall not be like seminars.

2.2.1.3. Guidelines for allotment of marks Record + Viva-voce

The teacher should conduct viva-voce at the end of each practical and evaluate the record on continuous mode and shall award these marks.

2.2.4. Guidelines for sessional examinations

Two sessional examinations shall be conducted for each theory/practical course. The average marks of the two shall be computed.

The teacher who teaches the subject shall ordinarily to be the internal examiner.

There shall be no provision for the improvement of the sessional marks.

There is no minimum mark prescribed for sessional examination for pass in the end semester examination.

If any student is absent for a single or both sessional examinations, the candidate will be awarded "ZERO" in the respective examination.

The theory average sessional mark shall be finally computed for 20 marks and average practical sessional mark shall be finally computed for 15 marks.

2.3. Regulations concerning M.Pharm I and II semester evaluation pattern:

2.3.1. There shall be one semester end examination in each theory course based on the question paper set by an external paper setter and there shall be single valuation. There shall be one semester end examination in each practical course as per the scheme of examination and valuation shall be done by examiner. The duration of the practical examination is of 6 hours as prescribed.

2.3.2. However the student may apply for revaluation of any subject in theory papers after declaring the results as per University examination guide lines.

2.3.3. Seminar

A seminar at the end of first and second semesters is separately conducted keeping in view of the enrichment of required communication, presentation and explanatory skills. A minimum of four seminars shall be given during the semester before the Program Committee and other students and documented separately for record in a Semester Seminar Register.

2.3.4. Comprehensive viva

At the end of II Semester comprehensive viva will be conducted for all the subjects

covering the theory subjects of I & II semesters by the external examiner and eligible internal examiners (at least two from the college) who taught these subjects. The candidate should obtain minimum of 50% marks for passing the examination.

2.3.4. Journal Club

In case of Journal Club, based on the research proposal, each student shall collect a minimum of 5 research papers (published in a reputed journal with impact factor of Thomson & Reuters of not less than 1.0) and should discuss in a Programme Committee (consisting of Head of the Department, Research Supervisor and other Senior faculty members) and documented separately for record in a Journal Club Register.

2.3.5. A student shall be eligible to carry forward all the courses of I, II semesters. However, he/she shall not be eligible to attend the courses of IV semester until the candidate clears III semester Midterm Project Review.

2.4. Regulations concerning M. Pharm. III and IV Semester evaluation pattern:

2.4.1. Evaluation of the seminar on the objectives and work plan of the proposed project is to be completed within one month from the commencement of the project date with three examiners from the same college consisting of research guide, another teacher in the concerned specialization and third teacher from different specialization. These teachers must fulfill the eligibility criteria laid down in Section 3.

2.4.2. Evaluation of the M.Pharm III Semester Mid-term project review and seminar on selected topic will be done by the research guide and external examiner. The seminar on the selected topic shall not be the one connected with the topic of the thesis work but should be related to concerned specialization.

2.4.3. A candidate shall submit four copies of his/her thesis either printed or typed, embodying the results of research work done by him under direction of an approved research director following the specific guidelines as stipulated under Section 5. All the candidates must submit their thesis within the prescribed date as per the academic calendar.

2.4.4. The thesis submitted by the candidate shall be examined by a Board of Examiners consisting of an External Examiner and the research director and shall have to be approved after holding a viva voce examination to test the knowledge of the candidate in the subject. The thesis will be evaluated independently by the external examiner and research director and in case the difference between examiners is more than 20%, the thesis shall be sent to a second external examiner whose award shall be the final. The viva-voce examination will be jointly conducted both by the external examiner and research director. A candidate can re-submit the thesis in a revised form after further work, if required to do so.

2.4.5. A candidate desires of improving his/her class shall take either or both of the first two semesters as a whole.

2.5. Guidelines for writing the thesis

The thesis should have the following pages in order:

1. Title page highlighting the title, name of the candidate, reg. no., guide name, college name and month and year of submission.
2. The inner title page containing the same details on white background.
3. Certificate from the Head of the institution
4. Certificate from the Research Director
5. Certificate from the ethical committees for approval of study, if any

6. Declaration by the student
7. Acknowledgements
8. Index highlighting chapter titles and sections titles
9. Index for tables, figures and plates, if any
10. Abbreviations and symbols
11. Materials used in the investigation with their procurement details like name of the company, batch number etc.
12. Equipment used in the study with the model number and other details
13. The thesis should contain the following chapters:
    a) Aim and objectives of the investigation
    b) Introduction and literature survey
    c) Description: Methods and Materials, etc.
    d) Experimental work
    e) Results and discussion
    f) Summary and conclusions
    g) References (The references may be included at the end of each chapter or at the end of the thesis according to the convenience)

2.5.1. The thesis should be typed in times new roman in 12 font size with 1.5 line spacing from the beginning of the thesis including titles to the chapters and sections. Bold font may be used wherever necessary. The students are expected to follow scientific grammar for writing *in vivo* etc. which should be in italics.

2.5.2. The citation of references should be done carefully by citing the complete reference i.e. name of all the authors. Usage of et al. is not allowed in the citation of reference. The students are expected to give the primary references rather than secondary or higher levels of references. The presentation of reference must be in Vancouver style.

2.5.3. No code names or numbers are allowed to be written in the thesis for the materials used in the project.

2.5.4. The examiners of thesis evaluation are expected to verify all this and appropriate corrections are to be made before conducting the viva-voce examination.

2.5.5 Project Work/IV Semester Assessment – Division of Marks:

Course 402 -Thesis Evaluation (Max. Marks – 150)

Criteria of Evaluation	**Marks**
Seminar/Presentation of work	20
Objective(s) of the work done	20
Methodology adopted	40
Results and Discussion	40
Conclusions and Outcomes	30
Total	**150**

The division of marks shall be clearly indicated for every candidate in the marks statement being sent to the University.

2.6. End Semester examinations

The End Semester examination for each theory, practical and other courses through

semesters I to IV shall be conducted by the University except for the subject with asterisk symbol (*) in the tables of the each specialization courses (Non University Examinations) for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University. In case of theory examinations, the question paper of the corresponding subject shall be mailed (Official mail id) to the Controller of Examinations and Chairman, BOS with signature of the Head of the Institute in PDF format within twenty four hours after completion of the examination.

3. Eligibility criteria for appointment as examiner for M.Pharm examination

3.1. In order to eligible to be appointed as an internal examiner for the semester end examination in the respective specialization, a teacher shall have M. Pharm. or Ph.D. in the respective specialization with at least three years of M.Pharm teaching experience for the course concerned.

3.2. The eligibility of a teacher for guiding the M.Pharm III and IV semester project is as follows:

3.2.1. The teacher must have M.Pharm/Ph.D. in the respective specialization with an experience of minimum 3 years of Post Graduate teaching in the respective specialization.

3.2.2. The eligibility of such teachers qualified for guiding M.Pharm projects must be ratified by the Board of Studies before commencement of M.Pharm guidance.

3.2.3. The recognized M.Pharm guides are not eligible to guide more than **6** students in one academic year including joint guidance.

4. Regulations for pursuing M.Pharm III and IV Semester project

4.1. Students desirous of pursuing M.Pharm III and IV semester projects outside college are required to get the approval from the college before one month from the commencement of the project work. The research work can be carried out in a GMP compliant industry (as approved by WHO, USFDA etc.) and Central research laboratories like IICT, CDRI, NIH etc. or DSIR and Drug Control Administration recognized laboratories. A certificate to that effect must be incorporated in the M.Pharm thesis indicating the duration of stay. If the duration of stay is less than nine months the remaining period of stay in the college should be certified by the research supervisor and the Principal.

4.2. All the students should present a seminar on the objectives of their work, work plan, etc. within one month from the commencement of the project. The students should attend a mid-term review seminar in the presence of a committee consisting of one external examiner, research director. The suggestions made by the committee are to be taken into consideration for further work and should be presented in the thesis.

5. Declaration of results and classification:

5.1. A candidate shall be declared to have passed the examination held at the end of each semester if obtains i) not less than 40% in the each theory and 50% in each practical, seminar, comprehensive viva, thesis and thesis viva-voce at the end of each semester end examination and ii) an aggregate of 50% of all examinations of that semester including sessoinals. There are no minimum marks prescribed for sessional examination.

5.2. A candidate who has successfully completed the examination in a course by securing not less than 50% of marks shall not be permitted to retake the examination in that course.

5.3. A candidate who fails to secure 50% of marks on the aggregate but secures 50% or

more in some courses and between 40-49% in the other courses, he/she shall be required to retake the semester and supplementary examination in one or more of the courses in which he/she secures less than 50% of marks as per his/her choice to satisfy the requirement of 50% aggregate.

5.4. Declaration of class

The classes shall be awarded on the basis of CGPA as follows

First Class with Distinction = CGPA of 7.50 and above

First Class = CGPA of 6.00 to 7.49

Second Class = CGPA of 5.00 to 5.99

6. Grading system:

6.1. Appropriate letter grades are awarded in each theory and practical subject to only such candidates who have passed in the university examinations. Internal assessment marks and university examination marks put together will be taken into account for the letter grading system in each subject separately.

6.2. A candidate registered for the university examination but fails to appear or fails to score the minimum required 40% marks in the university examination will get a grade 'F', indicating failure or grade of incompletion.

6.3. A subject successfully completed cannot be repeated. Final evaluation of each subject (theory and practical separately) will be carried out on a 10- point grading system corresponding to the marks obtained in that subject. Each subject letter grade is converted into a specific grade value associated with the letter grade as given below (Table).

6.4. Grading of performances

Based on the performance, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given below.

10-Point grading system

Percentage of marks	Grade	Grade points
90.00 - 100	O	10.0
80.00 - 89.99	A	9.0
70.00 – 79.99	B	8.0
60.00 – 69.99	C	7.0
50.00 – 59.99	D	6.0
40.00 – 49.99	E	5.0
< 40.00	F (Fail)	0.0
The grade W represents failure due to insufficient attendance in the semester or year	W	0.0
Incomplete (subsequently to be changed into pass or E or O or F grade in the same semester)	I	0.0

6.5 The Semester grade point average (SGPA):

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the

grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$\mathbf{SGPA} = \frac{C1G1+C2G2+C3G3+C4G4}{C1+C2+C3+C4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and AB grade awarded in that semester. For example if a learner has F or AB grade in course 4, the SGPA shall then be computed as:

$$\mathbf{SGPA} = \frac{C1G1+C2G2+C3G3+C4*ZERO}{C1+C2+C3+C4}$$

The credits allotted to each course are given in the respective specialization **Tables 1-10**.

6.6. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/ are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$\mathbf{CGPA} = \frac{C1S1+C2S2+C3S3+C4S4}{C1+C2+C3+C4}$$

Where $C_1, C_2, C_3, C4$.... is the total number of credits for semester I, II, III and IV and S1, S2, S3 and S4 are the SGPA of semester I, II, III and IV.

7. Guidelines for paper setting and model papers.

7.1. Guidelines for theory paper setting for semester end examinations

7.1.1. The semester end question paper in each theory course is to be set for a total of 70 marks by an external paper setter as per the general model given below.

7.1.2. Question paper consists of 5 questions each carrying 5 marks out of which 4 questions are to be answered by the candidate and 7 questions each carrying 10 marks out of which 5 questions are to be answered by the candidate for a total of 70 marks. Each main question may contain subsections like a, b, c etc.

7.1.3. The questions given should be spread over the entire syllabus in an even manner covering all the units as per the pattern of the question paper given below.

7.1.4. Model question paper for theory course:

Course No.

Specialization Name:

Title of the course:

Time: 3 Hours **Max. Marks: 70**

Part A (Question Numbers 1-5)

Answer any **four** questions out of five questions 4X5=20

One question has to be set from each unit.

Part B

Answer any **five** questions out of **seven** questions (Question Numbers 6-12) 5X10=50

Five questions are to be set from five units and the remaining two should cover at least four out of five units. The main questions may contain sub question like 6(a), 6(b) etc.

7.2. Guidelines for practical paper setting for semester end examination

7.2.1. The question paper in each semester end practical examination is to be set jointly by two examiners and evaluated, one external and one internal as per the general model provided below.

7.2.2. Model question paper for practical course:

Course No.

Title of the course

Time: 6 hrs.

1. Synopsis	10 marks
2. Major experiment	30 marks
3. Minor experiment	20 marks
4. Viva voce	10 marks
	Total: 70 marks

7.3. Guidelines for theory/practical sessional examination paper setting:

Question paper pattern for theory Sessional examinations

Max. Marks: 30

Time: 2 Hours

Part A

Answer any **two** questions out of three questions 2X5=10

Part B

Answer any **two** questions out of three questions 2X10=20

Each of the sessional examination question paper should cover at least half the units of the syllabus.

Question paper pattern for practical sessional examinations

Max. Marks: 30

Time: 4 hours

1. Synopsis	5 Marks
2. Experiment	20 Marks
3. Viva	5 Marks
	Total: 30 Marks

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Table 1: Pharmaceutical Analysis (MPA)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MPA 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MPA 102T	Advanced Pharmaceutical Analysis	4	4	10	20	30	70	100
MPA 103T	Pharmaceutical Validation (Common paper for MPA and MQA)	4	4	10	20	30	70	100
MPA 104T	Food Analysis	4	4	10	20	30	70	100
MPA 105P	Pharmaceutical Analysis Practical - I	2	6	15	15	30	70	100
MPA 106P	Pharmaceutical Analysis Practical - II	2	6	15	15	30	70	100
MPA 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	---	---	---	---	**650**
II Semester								
MPA 201T	Advanced Instrumental Analysis	4	4	10	20	30	70	100
MPA 202T	Modern Bio-Analytical Techniques	4	4	10	20	30	70	100
MPA 203T	Quality Control and Quality Assurance (Common paper for MPA and MQA)	4	4	10	20	30	70	100
MPA 204T	Herbal and Cosmetic Analysis	4	4	10	20	30	70	100
MPA 205P	Pharmaceutical Analysis Practical - III	2	6	15	15	30	70	100
MPA 206	Comprehensive Viva	2	---	---	---	---	---	50
MPA 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	---	---	---	---	**600**

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Table 3: Pharmaceutics (MPH)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MPH 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MPH 102T	Advanced Biopharmaceutics & Pharmacokinetics (Common paper for MPH and MIP)	4	4	10	20	30	70	100
MPH 103T	Modern Pharmaceutics	4	4	10	20	30	70	100
MPH 104T	Regulatory Affairs	4	4	10	20	30	70	100
MPH 105P	Pharmaceutics Practical – I	2	6	15	15	30	70	100
MPH 106P	Pharmaceutics Practical – II	2	6	15	15	30	70	100
MPH 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**
II Semester								
MPH 201T	Molecular Pharmaceutics (Nano Technology and Targeted DDS)	4	4	10	20	30	70	100
MPH 202T	Drug Delivery Systems (DDS)	4	4	10	20	30	70	100
MPH 203T	Computer Aided Drug Development (CADD)	4	4	10	20	30	70	100
MPH 204T	Pharmaceutical and Cosmetic Product Development	4	4	10	20	30	70	100
MPH 205P	Pharmaceutics Practical - III	2	6	15	15	30	70	100
MPH 206	Comprehensive Viva	2	---	---	---	---	---	50
MPH 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	**---**	**---**	**---**	**---**	**600**

Table 3: Pharmaceutics (MPH) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MPH 302	Journal Club*	2	2	50	---	---	---	50
MPH 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MPH 304	Seminar on selected topic	4	4	---	---	---	100	100
MPH 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	---	---	---	---	**400**
IV Semester								
MPH 401	Journal Club*	2	2	50	---	---	---	50
MPH 402	Thesis evaluation	12	20	---	---	---	150	150
MPH 403	Thesis viva	4	---	---	---	---	50	50
	Total:	**20**	**22**	---	---	---	---	**250**

* Non-University Examination

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Table 7: Pharmaceutical Regulatory Affairs (MRA)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MRA 101T	Good Regulatory Practices	4	4	10	20	30	70	100
MRA 102T	Documentation and Regulatory Writing	4	4	10	20	30	70	100
MRA 103T	Clinical Research Regulations	4	4	10	20	30	70	100
MRA 104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals, Herbals & Food and Neutraceuticals in India & Intellectual Property Rights	4	4	10	20	30	70	100
MRA 105P	Regulatory Affairs Practical - I	2	6	15	15	30	70	100
MRA 106P	Regulatory Affairs Practical - II	2	6	15	15	30	70	100
MRA 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	---	---	---	---	**650**

Table 7: Pharmaceutical Regulatory Affairs (MRA) continued

II Semester								
MRA 201T	Regulatory Aspects of Drugs & Cosmetics	4	4	10	20	30	70	100
MRA 202T	Regulatory Aspects of Herbal & Biologicals	4	4	10	20	30	70	100
MRA 203T	Regulatory Aspects of Medical Devices	4	4	10	20	30	70	100
MRA 204T	Regulatory Aspects of Food & Neutraceuticals	4	4	10	20	30	70	100
MRA 205P	Regulatory Affairs Practical - III	2	6	15	15	30	70	100
MRA 206	Comprehensive Viva	2	---	---	---	---	---	50
MRA 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	---	---	---	---	**600**
III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MRA 302	Journal Club*	2	2	50	---	---	---	50
MRA 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MRA 304	Seminar on selected topic	4	4	---	---	---	100	100
MRA 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	---	---	---	---	**400**
IV Semester								
MRA 401	Journal Club*	2	2	50	---	---	---	50
MRA 402	Thesis evaluation	12	20	---	---	---	150	150
MRA 403	Thesis viva	4	---	---	---	---	50	50
	Total:	**20**	**22**	---	---	---	---	**250**

* Non-University Examination

Table 9: Industrial Pharmacy (MIP)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MIP 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MIP 102T	Advanced Biopharmaceutics & Pharmacokinetics (Common paper for MPH and MIP)	4	4	10	20	30	70	100
MIP 103T	Novel Drug Delivery Systems	4	4	10	20	30	70	100
MIP 104T	Intellectual Property Rights	4	4	10	20	30	70	100
MIP 105P	Industrial Pharmacy Practical - I	2	6	15	15	30	70	100
MIP 106P	Industrial Pharmacy Practical - II	2	6	15	15	30	70	100
MIP 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	---	---	---	---	**650**
II Semester								
MIP 201T	Scale Up and Technology Transfer	4	4	10	20	30	70	100
MIP 202T	Pharmaceutical Production Technology	4	4	10	20	30	70	100
MIP 203T	Entrepreneurship Management	4	4	10	20	30	70	100
MIP 204T	Pharmaceutical Formulation Development	4	4	10	20	30	70	100
MIP 205P	Industrial Pharmacy Practical - III	2	6	15	15	30	70	100
MIP 206	Comprehensive Viva	2	---	---	---	---	---	50
MIP 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	---	---	---	---	**600**

Table 9: Industrial Pharmacy (MIP) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MIP 302	Journal Club*	2	2	50	---	---	---	50
MIP 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MIP 304	Seminar on selected topic	4	4	---	---	---	100	100
MIP 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MIP 401	Journal Club*	2	2	50	---	---	---	50
MIP 402	Thesis evaluation	12	20	---	---	---	150	150
MIP 403	Thesis viva	4	---	---	---	---	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

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PHARMACEUTICAL ANALYSIS (MPA)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

(Note: Common paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect and applications of UV-visible spectroscopy.

b. IR spectroscopy: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier-Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 2:

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **10 Hours**

Unit 3:

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. **10 Hours**

Unit 4:

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** High Performance Liquid chromatography **g)** Ultra High Performance Liquid chromatography **h)** Affinity chromatography **i)** Gel Chromatography. **14 Hours**

Unit 5:

a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing.

b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake. Vol 2. 4th ed. CBS Publishers, New Delhi
5. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B – J.W. Munson. Vol 11. Marcel-Dekker Series.
8. Spectroscopy of Organic Compounds - P.S. Kalsi. 2nd ed. Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis – K.A. Connors. 3rd ed. John Wiley & Sons.

ADVANCED PHARMACEUTICAL ANALYSIS (MPA 102T)

Unit 1:

Impurities and stability studies: Definition, classification of impurities in drug substance or active pharmaceutical ingredients and quantification of impurities as per ICH guidelines – Q3A & Q3D. Impurities in new drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products.

Impurities in residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents.

12 Hours

Unit 2:

Impurity profiling and degradent characterization (ICH Q2A & Q2B): Stability studies accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, stability zones.

Elemental impurities: Basics of impurity profiling and degradent characterization with special emphasis. Method development and concepts of validation. Element classification, control of elemental impurities, Potential Sources of elemental impurities, Identification of potential elemental impurities, analytical procedures, instrumentation & C, H, N and S analysis. (Ref: USP 38 NF 33, Vol. I, 2015, Chapter 232 & 233). **14 Hours**

Unit 3:

Stability testing protocols (ICH Q1A): Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates with practical considerations. Photostability testing guidelines, ICH stability guidelines for biological products (ICHQ5C).

Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity. **12 Hours**

Unit 4:

Biological tests: Preservative challenging test, disinfectant efficacy test and its validation. Neutralizer efficacy test, membrane filter integrity test, bacterial endotoxin test & microbial limit test. Container–closure integrity test for sterile products. **12 Hours**

Unit 5:

Immunoassays (IA): Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA (ELISA), Fluoro IA, Luminescence IA, Quantification and applications of IA. **10 Hours**

REFERENCES

1. Vogel's Textbook of Quantitative Chemical Analysis - Jeffery J Bassett, J. Mendham, R. C. Denney. 5th ed. ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake. Vol 2, 4th ed. CBS Publishers, New Delhi.
3. Textbook of Pharmaceutical Analysis – K.A. Connors. 3rd ed. John Wiley & Sons, 1982
4. Pharmaceutical Analysis - Higuchi, 2nd ed. Wiley – Inter Science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi, 3rd ed. CBS Publishers, New Delhi.
6. Pharmaceutical Analysis- Modern Methods – J.W. Munson – Part B. Volume 11, Marcel Dekker.
7. The Quantitative Analysis of Drugs – D.C. Carratt. 3rd ed. CBS Publishers, New Delhi, 1964.
8. Indian Pharmacopoeia 2007, 2010, 2014 & 2018.
9. Methods of Sampling and Microbiological Examination of Water, First Revision, BIS
10. Analytical Profiles of Drug Substances – Klaus Florey. Vol 1 – 20, Elsevier, 2005
11. Analytical Profiles of Drug Substances and Excipients – Harry G Brittain. Volume 30, Elsevier, 2005.
12. The Analysis of Drugs in Biological Fluids - Joseph Chamberlain. 2nd ed. CRC Press,
13. ICH Guidelines for Impurity Profiles and Stability Studies

PHARMACEUTICAL VALIDATION (MPA 103T)

(Note: Common paper for MPA and MQA specializations)

Unit 1:

Introduction to validation: Definition of calibration, qualification and validation, scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of validation, scope of validation, organization for validation, validation master plan, types of validation, streamlining of qualification & validation process and validation master plan.

Qualification: User requirement specification, design qualification, factory acceptance test (FAT)/site acceptance test (SAT), installation qualification, operational qualification, performance qualification, re-qualification (Maintaining status-calibration preventive maintenance, change management). **12 Hours**

Unit 2:

Qualification of analytical instruments/Equipment: Training & qualification of analyst. qualification of UV-visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, and dissolution test apparatus. **10 Hours**

Unit 3:

Validation of utility systems: Pharmaceutical water system, HVAC system, compressed air and nitrogen. Facility qualification, AHU validation, clean room validation.

Cleaning validation: Cleaning method development, sampling techniques, validation of analytical method used in cleaning. Cleaning of equipment, cleaning of facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant.

Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5, LIMS, audit trail and data integrity. **12 Hours**

Unit 4:

Process validation: Concept, process and documentation of process validation. Prospective, concurrent & retrospective validation, re validation criteria, process validation of various formulations (coated tablets, capsules, ointment/creams, liquid orals and aerosols).

Aseptic filling: Media fill validation, USFDA guidelines on process validation- A life cycle approach.

Analytical method validation: General principles, validation of analytical method as per ICH guidelines (Q2A) and USP. Preparation & qualification of working standards and reference standards. **12 Hours**

Unit 5:

General principles of intellectual property: Concepts of intellectual property (IP), intellectual property protection (IPP), intellectual property rights (IPR); economic importance, mechanism for protection of intellectual property – patents, copyright, trademark; factors affecting choice of IP protection; penalties for violation; role of IP in pharmaceutical industry; global ramification and financial implications. Filing a patent application; patent application forms and guidelines. Types of patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; rights and responsibilities of a patentee; practical aspects regarding maintaining of a patent file; patent infringement meaning and scope. Significance of transfer of technology (TOT), IP and ethics-positive and negative aspects of IPP; societal responsibility, avoiding unethical practices. **14 Hours**

REFERENCES

1. Pharmaceutical Process Validation - B. T. Loftus & R. A. Nash. Drugs and Pharm Sci. Series, Vol. 129, 3rd ed. Marcel Dekker.
2. The Theory & Practice of Industrial Pharmacy - Leon Lachman, Herbert A Lieberman & Joseph L Kanig. 3rd ed. Varghese Publishing House, Bombay.
3. Validation of Aseptic Pharmaceutical Processes - Carleton & Agalloco. 2nd ed. Marcel Dekker.
4. Pharmaceutical Process Scale-Up - Michael Levin. Drugs and Pharm. Sci. Series. Vol. 157. 2nd ed. Marcel Dekker.
5. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries - Syed Imtiaz Haider.
6. Validation of Pharmaceutical Processes: Sterile Products - Frederick J Carlton and James Agalloco. 2nd ed. Marcel Dekker.
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook - Phillip A Cloud. Interpharm Press.
8. Analytical Method Validation and Instrument Performance Verification - Churg Chan, Heiman Lam, Y.C. Lee & Yue. Zhang. Wiley Inter Science.

9. Validation Master Plan - Terveeks or Deeks. Davis Harwood International Publishing.

FOOD ANALYSIS (MPA 104T)

Unit 1:

Carbohydrates: Classification and properties of food carbohydrates, general methods of analysis of food carbohydrates, changes in food carbohydrates during processing, digestion, absorption and metabolism of carbohydrates. Dietary fiber, crude fiber and application of food carbohydrates.

Proteins: Chemistry and classification of amino acids and proteins, physico-chemical properties of protein and their structure, general methods of analysis of proteins and amino acids. **12 Hours**

Unit 2:

Lipids: Classification, general methods of analysis, determination of adulteration in fats and oils, various methods used for measurement of spoilage of fats and fatty foods.

Vitamins: Classification of vitamins, principle & microbial assays of vitamin-B_1, B_2 & B_{12}. **12 Hours**

Unit 3:

Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.

Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, non-permitted synthetic dyes used by industries, method of detection of natural, permitted and non-permitted dyes. **12 Hours**

Unit 4: General analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar. **12 Hours**

Unit 5:

Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA. FSSAI guidelines-special emphasis on mycotoxins, microbiology, antibiotic residues in foods. HACCP (Biological, Physical & Chemical hazards), Regulatory aspects of CODEX Alimentarius. **12 Hours**

REFERENCES

1. The Chemical Analysis of Foods – David Pearson. 7th ed. Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical Analysis of Foods – S. Nielsen. Jones & Bartlett Publishers, Boston, London, 1994.
3. Official Methods of Analysis of AOAC International. 6th ed. Volume 1 & 2. 1997.
4. Analysis of Food Constituents – Multon. John Wiley & Sons.
5. Official methods of analysis of AOAC International - Dr. William Horwitz. 18th ed. 2005.

PHARMACEUTICAL ANALYSIS PRACTICAL - I (MPA 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV-Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry

3. Experiments based on HPLC
4. Experiments based on gas chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs

PHARMACEUTICAL ANALYSIS PRACTICAL - II (MPA 106P)

1. Calibration of glassware
2. Calibration of pH meter
3. Calibration of UV-Visible spectrophotometer
4. Calibration of FTIR spectrophotometer
5. Calibration of GC instrument
6. Calibration of HPLC instrument
7. Cleaning validation of any one equipment
8. Determination of total reducing sugar
9. Determination of proteins
10. Determination of saponification value, iodine value, peroxide value, acid value in food products
11. Determination of fat content and rancidity in food products
12. Analysis of natural and synthetic colors in food
13. Determination of preservatives in food
14. Determination of pesticide residue in food products
15. Analysis of vitamin content in food products
16. Determination of density and specific gravity of foods
17. Determination of food additives.
18. Analysis of vanillin content in foods
19. Analysis of oxalate content in guava fruit
20. ELISA & CLIA – demonstration
21. IMVIC test - Indole test, methyl red test, Voges-Proskauer test, citrate utilization test

Second Semester

ADVANCED INSTRUMENTAL ANALYSIS (MPA 201T)

Unit 1:

HPLC: Principle, analytical method development, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, new developments in HPLC-role and principles of ultra, nano liquid chromatography, and preparative HPLC in pharmaceutical analysis. Advancement in enantiomeric separations, Immobilized polysaccharide CSP's and HILIC approaches. **12 Hours**

Unit 2:

Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles - stationary phases and mobile phases.

Gas chromatography: Derivatization, head space sampling, analytical method development and quantification. **12 Hours**

Unit 3:

Super critical fluid chromatography: Principle, instrumentation, pharmaceutical applications.

Capillary electrophoresis: General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation & its applications.

12 Hours

Unit 4:

Mass spectrometry: LC-MS hyphenation and DART MS analysis. Mass analyzers (Quadrupole, Time of flight, FT-ICR, Ion Trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF; Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap. **12 Hours**

Unit 5:

NMR spectroscopy:

Brief outline of principles of NMR &FT-NMR. Spin-spin and spin-lattice relaxation phenomenon. 13C NMR, 1-Dand 2-D NMR, NOESY and COSY techniques, interpretation and qualitative and quantitative applications of NMR spectroscopy. LC-NMR hyphenations. ICP-MS, ICP-OES, PES, TOC Analysis, KF titration, melting point determination using advanced instrumentation. **12 Hours**

REFERENCES

1. Spectrometric Identification of Organic Compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
5. Quantitative Analysis of Pharmaceutical Formulations by HPTLC – P.D. Sethi. CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi.
7. Pharmaceutical Analysis- Modern Methods – Part B – J.W. Munson. Vol 11, Marcel Dekker Series.
8. Organic Spectroscopy - Donald L Paviya. 5th ed.

MODERN BIO-ANALYTICAL TECHNIQUES (MPA 202T)

Unit 1:

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the bioanalytical methods such as protein precipitation, liquid - liquid extraction and solid phase extraction and other novel sample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines. **12 Hours**

Unit 2:

Biopharmaceutical consideration: Introduction, in vitro: dissolution and drug release

testing, alternative methods of dissolution testing. Solubility: experimental methods. permeability: in-vitro, in-situ and in-vivo methods. **12 Hours**

Unit 3:

Pharmacokinetics and toxicokinetics: Basic consideration, drug interaction (PK-PD interactions), the effect of protein-binding interactions, the effect of tissue-binding interactions, toxicokinetics-toxicokinetic evaluation in preclinical studies, importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

12 Hours

Unit 4:

Metabolite identification: In vitro/in vivo approaches, protocols and sample preparation. Microsomal approaches (rat liver microsomes (RLM) and human liver microsomes (HLM) in Met-ID - Regulatory perspectives. In vitro assay of drug metabolites & drug metabolizing enzymes. **12 Hours**

Unit 5:

Drug product performance: In vivo: bioavailability and bioequivalence. Drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, generic biologics (biosimilar drug products), clinical significance of bioequivalence studies. **12 Hours**

REFERENCES

1. Analysis of Drugs in Biological Fluids - Joseph Chamberlain. 2nd ed. CRC Press.
2. Principles of Instrumental Analysis - Doglas A Skoog. 5th ed. Eastern Press, Bangalore.
3. Pharmaceutical Analysis - Higuchi, Brochmman & Hassen. 2nd ed. Wiley Interscience
4. Pharmaceutical Analysis - Modern methods – Part B – J.W. Munson. Vol 11, Marcel Dekker.
5. Practical HPLC Method Development – Snyder & Kirkland. 2nd ed. John Wiley & Sons.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics. 2nd ed. Marcel Dekker.
7. Chromatographic Methods in Clinical Chemistry & Toxicology – Roger L Bertholf & Ruth E Winecker. John Wiley & Sons, New Jersey, USA, 2007.
8. Good Laboratory Practice Regulations - Sandy Weinberg. Vol. 69. 2nd ed. Marcel Dekker.
9. Good laboratory Practice Regulations – Allen F. Hirsch. Vol. 38. Marcel Dekker, 1989.
10. ICH, USFDA & CDSCO Guidelines.

QUALITY CONTROL AND QUALITY ASSURANCE (MPA 203T)

(Common paper for MPA and MQA specializations)

Unit 1:

Introduction: Concept and evolution of quality control and quality assurance. Good laboratory practice, GMP, overview of ICH guidelines - QSEM, with special emphasis on Q-series guidelines.

Good laboratory practices: Scope of GLP, definitions, quality assurance unit, protocol for conduct of non-clinical testing.

CPCSEA guidelines: Control on animal house, report preparation and documentation.

12 Hours

Unit 2:

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, clean room validation, control of contamination. sterility assurance, AHU system & qualification, and Good Warehousing Practice. **12 Hours**

Unit 3:

Developing specification (ICH Q6 and Q3), sampling methods for raw and packing materials. Purchase specifications, vendor qualification and maintenance of stores for various materials.

Testing of primary packing materials as per IP & USP: Glass containers, plastics, rubber.

Analysis of raw materials, packaging materials: In-process quality control and finished products quality control for following formulations in pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products. Quality control test for containers, closures and secondary packing materials. **12 Hours**

Unit 4:

Documentation in pharmaceutical industry: Three tier documentation, policy, procedures and work instructions, and records (Formats), basic principles - how to maintain, retention and retrieval etc. Standard operating procedures (how to write), Master Formula Record, Batch Manufacturing Record, quality audit plan and reports. Specification and test procedures, protocols and reports. distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). **12 Hours**

Unit 5:

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging. **12 Hours**

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India. 3rd Revised ed. Vol 1 & 2, Mumbai, 1996.
2. Good Laboratory Practice Regulations - Sandy Weinberg. Vol. 69. 2nd ed. Marcel Dekker.
3. Quality Assurance of Pharmaceuticals - A compendium of Guidelines and Related Materials. Vol 1 & 2. 2nd ed. WHO Publications, 1999.
4. How to Practice GMP's – P.P. Sharma. Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – Vol. I, II, III, IV & V - General Methods of Analysis and Quality Specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd ed. WHO, Geneva, 2005.
6. Good Laboratory Practice Regulations – Allen F Hirsch. Vol 38. Marcel Dekker.
7. ICH guidelines
8. ISO 9000 and Total Quality Management

9. The Drugs and Cosmetics Act 1940 – Deshpande & Nilesh Gandhi. 4th ed. Susmit Publishers.
10. QA Manual – D.H. Shah 1st ed. Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals; A Plan for Total Quality Control – Sidney H. Willig. Vol. 52. 3rd ed. Marcel Dekker.
12. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers - Steinborn L (Volume 1 - With Checklists and Software Package). 6th ed. Taylor & Francis.
13. Quality Systems and Controls for Pharmaceuticals – D.K. Sarker. John Wiley & Sons, 2008.

HERBAL AND COSMETIC ANALYSIS (MPA 204T)

Unit 1:

Herbal remedies: Toxicity and regulations: Herbals vs. conventional drugs, Efficacy of herbal medicine products, validation of herbal therapies, pharmacodynamics and pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

12 Hours

Unit 2:

Adulteration and deterioration: Introduction, types of adulteration/substitution of herbal drugs, causes and measure of adulteration, sampling procedures, determination of foreign matter, DNA finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations.

12 Hours

Unit 3:

Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, adulterant screening using modern analytical instruments, stability testing of natural products, protocol. Monographs of herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American Herbal Pharmacopoeia, British Herbal Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

12 Hours

Unit 4:

Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

12 Hours

Unit 5:

Evaluation of cosmetic products: Determination of moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

Schedule S: Standards for cosmetics. Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

12 Hours

PHARMACEUTICS (MPH)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

(Note: Common paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect and applications of UV-visible spectroscopy.

b. IR spectroscopy: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier-Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 2:

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **10 Hours**

Unit 3:

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. **10 Hours**

Unit 4:

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** High Performance Liquid chromatography **g)** Ultra High Performance Liquid chromatography **h)** Affinity chromatography **i)** Gel Chromatography. **14 Hours**

Unit 5:

a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing.

b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy

and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A. Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake. Vol 2. 4th ed. CBS Publishers, New Delhi
5. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B – J.W. Munson. Vol 11. Marcel-Dekker Series.
8. Spectroscopy of Organic Compounds - P.S. Kalsi. 2nd ed. Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis - K.A. Connors. 3rd ed. John Wiley & Sons.

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 102T)

(Common paper for MPH and MIP specializations)

Unit 1:

Drug absorption from the gastrointestinal tract and other routes of administration: Mechanisms and factors affecting drug absorption from different routes, influence of pH–partition theory on drug absorption. Factors affecting dissolution rate and its process, Noyes-Whitney equation. dissolution testing methods for solids - tablets, capsules and for suspensions. Correlation of in vivo and in vitro dissolution data. **12 Hours**

Unit 2:

Biopharmaceutical considerations in drug product design and in vitro drug product performance. Introduction - biopharmaceutical factors affecting bioavailability, rate limiting steps in drug absorption, physicochemical nature of drug, formulation factors affecting drug product performance. In vitro dissolution and drug release testing, dissolution test apparatus and methods as per IP and USP for different types of drug delivery systems, design of dissolution testing for conventional and controlled release products. Data handling and correction factor, bio relevant media, similarity and dissimilarity factors f_1 & f_2, alternative methods of dissolution testing, problems of variable control in dissolution testing performance of drug products. Drug product stability during dissolution testing, in vitro evaluation of drug release from different dosage forms. **12 Hours**

Unit 3:

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model - IV bolus, IV infusion, extra-vascular. Multi compartment models in brief, calculation of parameters in two compartment models. Non-linear pharmacokinetics: causes of non-linearity, Michaelis – Menten equation, estimation of k_m and V_{max}. Concept of clearance and its applications. Problems related to the above. **12 Hours**

Unit 4:

Drug Product Performance: Bioavailability and bioequivalence, drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods, protocol design for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, cross over study designs, evaluation of the data, bioequivalence example, study submission and drug review process. In vitro - in vivo correlations in protocol

design, levels of correlation, biopharmaceutical classification system, methods. Permeability: Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies. **12 Hours**

Unit 5:

Application of pharmacokinetics: Modified-release drug products, targeted drug delivery systems and biotechnological products. Significance of pharmacokinetic and pharmacodynamic drug interactions in the design of the modified release products. **12 Hours**

REFERENCES

1. Pharmacokinetics - Milo Gibaldi. 2nd ed.
2. Applied Biopharmaceutics and Pharmacokinetics - Leon Shargel. 5th ed.
3. Biopharmaceutics and Clinical Pharmacokinetics - Robert E Notari. 4th ed.
4. Modern Pharmaceutics - Gilbert S. Banker, Christopher T Rhodes. 4th ed.
5. Clinical Pharmacokinetics & Pharmacodynamics - Malcolm Rowland & Tozer. 4th ed. Lippincott Publications.
6. Drug Disposition and Pharmacokinetics - Stephen H Curry. 3rd ed.
7. Current Concepts in the Pharmaceutical Sciences : Biopharmaceutics - James Swarbrick
8. Current Concepts in the Pharmaceutical Sciences:Dosage Form Design and Bioavailability - James Swarbrick.

MODERN PHARMACEUTICS (MPH 103T)

Unit 1:

Preformulation Concepts – Drug excipient interactions-different methods, kinetics of stability, stability testing. Theories of dispersion and pharmaceutical dispersion (emulsions and suspensions, SMEDDS) preparation and stability. Large and small volume parenterals – physiological and formulation consideration, manufacturing and evaluation.

Optimization techniques in pharmaceutical formulation: Concept and parameters of optimization. Optimization techniques in pharmaceutical formulation and processing. Statistical design, response surface method, contour designs, factorial designs and application in formulation. **12 Hours**

Unit 2:

Validation: Introduction to pharmaceutical validation, scope & merits of validation. Validation and calibration of master plan, ICH & WHO guidelines for calibration and validation of equipment, validation of specific dosage form, types of validation. Government regulations, manufacturing process model, user requirement specifications (URS), design qualification (DQ), installation qualification (IQ), operational qualification (OQ) & performance qualification (PQ) of facilities. **12 Hours**

Unit 3:

cGMP & industrial management: Objectives and policies of current good manufacturing practices (cGMP), layout of buildings, services, equipment and their maintenance. Production management, production organization, materials management, handling and transportation, inventory management and control, production and planning control, sales forecasting, budget and cost control, industrial and personal relationship. Concept of total quality management (TQM). **12 Hours**

Unit 4:

Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Heckel plots, Strain gauges, evaluation of forces, energy consumption, factors influencing consolidation parameters.

12 Hours

Unit 5:

Drug release characteristics and modeling: Diffusion parameters, evaluation of matrix and reservoir systems and swelling matrix tablets, burst effect, modeling of drug release using different equations (Higuchi model, Peppas model, Hixson Crowell, zero order & first order). Linearity, concept of significance, standard deviation, Chi square test, students T-test, ANOVA test. **12 Hours**

REFERENCES

1. Encyclopedia of Pharmaceutical Technology - James Swarbrick. 3rd ed. Informa Healthcare Publishers.
2. Pharmaceutical Dosage Forms : Tablets - Herbert A Lieberman & Leon Lachman, Volume 1 - 3. Marcel Dekker, Inc.
3. The Theory and Practice of Industrial Pharmacy - Roop K Khar, S.P. Vyas, Farhan J Ahmad, Gaurav K Jain. 4th ed. CBS Publishers, New Delhi.
4. Martin's Physical Pharmacy and Pharmaceutical Sciences - Patrick J Sinko. 6th ed. BI Publications Pvt. Ltd.
5. Pharmaceutical Dosage Forms : Disperse Systems - Herbert A Lieberman, Martin M Rieger & Gilbert S Banker. Vol 1 – 3. Informa Healthcare.
6. Pharmaceutical Dosage Forms : Parenteral Medication – Sandeep Nema & John Ludwig, Vol 1 – 3. 3rd ed. Informa Healthcare.
7. Aulton's Pharmaceutics – The Design and Manufacture of Medicines - M.E. Aulton & M.G. Kevin Taylor. 5th ed. Elsevier.
8. Remington – The Science and Practice of Pharmacy – Loyd V Allen. 22nd ed.

REGULATORY AFFAIRS (MPH 104T)

Unit 1:

Documentation in pharmaceutical industry: Master formula record, DMF drug master file (DMF), distribution records. Generic drugs product development, introduction, Hatch-Waxman Act and amendments, Code of Federal Regulations (CFR), drug product performance in vitro, ANDA regulatory approval process, NDA approval process. **12 Hours**

Unit 2:

Bioequivalence and drug product assessment: Scale up post approval changes, post marketing surveillance, outsourcing BA and BE to CRO. Regulatory requirement for product approval, active pharmaceutical ingredient (API), biologics, novel therapies by obtaining NDA, ANDA generic drugs. Pharmaceutical product development (Q8), quality risk management (Q9) and pharmaceutical quality systems (Q10). Quality by design (Q_bD), principles in pharmaceutical development, regulatory and industry views on Q_bD, elements of Q_bD, ANDA applications and examples. **12 Hours**

Unit 3:

Critical manufacturing controls (CMC), post approval regulatory affairs: Regulation for combination products and medical devices. CTD and eCTD format, industry and FDA liaison. ICH - Guidelines of ICH - Q, S, E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. **12 Hours**

Unit 4:

Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier (IMPD) and investigator brochure (IB).

Clinical trials: Developing clinical trial protocols. Institutional review board/independent ethics committee - Formulation and working procedures, informed consent process and procedures. HIPAA- new requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. **12 Hours**

Unit 5:

General principles of intellectual property rights (IPR): IP protection, economic importance, mechanism of protection. Patents, criteria, types of patent application-steps, trademarks and copy rights. **12 Hours**

REFERENCES

1. The Theory and Practice of Industrial Pharmacy - Leon Lachman, H.A. Lieberman & Joseph L Kanig. 3rd ed. Varghese Publishing, 1991.
2. Lachman/Lieberman's The Theory and Practice of Industrial Pharmacy - Roop K Khar, S.P. Vyas, Farhan J Ahmad & Gaurav K Jain. 4th ed. CBS Publishers, New Delhi.
3. Quality Assurance of Pharmaceuticals – WHO. Vol. 1 & 2. Pharma Book Syndicate.
4. Pharmaceutical Product development - N.K. Jain. CBS Publishers, New Delhi.
5. Law relating to Drugs & Cosmetics - Vijay Malik. Eastern Book Company.

PHARMACEUTICS PRACTICAL - I (MPH 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV - Visible spectrophotometer.
2. Colorimetric analysis of aspirin.
3. Kinetic studies of aspirin degradation.
4. Molecular weight determination of polymers by viscosity method.
5. Preparation of granules, drying by conventional dryer and fluidized bed dryer and comparing the granules by their flow property.
6. HPLC analysis of any one drug.
7. GMP audit requirements as per CDSCO.
8. Preparation of check-lists for registration of IND as per ICH CTD format.
9. Preparation of check-lists for registration of NDA as per ICH CTD format.
10. Preparation of check-lists for registration of ANDA as per ICH CTD format.
11. To carry out pre formulation studies of tablets.
12. To study the effect of Compression force on tablets disintegration time.

PHARMACEUTICS PRACTICAL - II (MPH 106P)

1. Improvement of dissolution of drugs by solid dispersions, cyclo dextrin complexation etc.
2. Effect of ointment base on drug diffusion using agar plate method and diffusion membrane.
3. To study the effect of particle size on dissolution of a tablet.
4. To study the effect of binders on dissolution of a tablet.
5. To plot Heckel plot, Higuchi and Peppas plot and determine similarity factors.
6. Improvement of dissolution characteristics of slightly soluble drug by solid dispersion technique.
7. Protein binding studies of a highly protein bound drug and poorly protein bound drug.

8. Absorption kinetics of paracetamol in goat intestine (ex vivo study)
9. Pharmacokinetic and IVIVC data analysis by WinNonlin® Software (Demo).
10. In vitro cell studies for permeability and metabolism (Demo).
11. Effect of surfactant on drug dissolution using BCS II drugs.

Second Semester

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (MPH 201T)

Unit 1:

Targeted drug delivery systems: Concepts, events and biological process involved in drug targeting. Tumor targeting and brain specific delivery. **12 Hours**

Unit 2:

Targeting Methods: Introduction, preparation, evaluation and application of nano particles & liposomes. **12 Hours**

Unit 3:

Micro capsules/micro spheres: Types, preparation, evaluation and applications of monoclonal antibodies, niosomes, aquasomes, phytosomes, electrosomes. **12 Hours**

Unit 4:

Pulmonary drug delivery systems: Aerosols, metered dose inhalers, dry powder inhalers, propellants, containers, types, preparation and evaluation. Intra nasal route delivery systems; types, preparation and evaluation. **12 Hours**

Unit 5:

Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex vivo & in vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and non viral gene transfer). Liposomal gene delivery systems. Bio distribution and pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future. **12 Hours**

REFERENCES

1. Novel Drug Delivery Systems – Y.W. Chien. 2nd ed. (Revised and expanded). Marcel Dekker.
2. Controlled Drug Delivery: Concepts and Advances - S.P. Vyas & R.K. Khar. 1st ed. Vallabh Prakashan, New Delhi.
3. Controlled and Novel Drug Delivery - N.K. Jain. 1st ed. CBS Publishers, New Delhi, 1997.

DRUG DELIVERY SYSTEMS (MPH 202T)

Unit 1:

Sustained release (SR) and controlled release (CR) formulations: Introduction & basic concepts, advantages/disadvantages, factors influencing, physicochemical & biological approaches for SR/CR formulation, mechanism of drug delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application. Dosage Forms for personalized medicine: Introduction, definition, pharmacogenetics, categories of patients for personalized medicines. Customized drug delivery systems, bioelectronic medicines, 3D printing of pharmaceuticals, tele pharmacy. **12 Hours**

Unit 2:

Rate controlled drug delivery systems: Principles & fundamentals, types, activation; Modulated drug delivery systems; mechanically activated, pH activated, enzyme activated, and osmotic activated drug delivery systems, feedback regulated drug delivery systems;

principles & fundamentals. **12 Hours**

Unit 3:

Gastro retentive drug delivery systems: Principle, concepts, advantages and disadvantages. Modulation of GI transit time, approaches to extend GI transit. Buccal drug delivery systems: Principle of mucoadhesion, advantages and disadvantages, mechanism of drug permeation, methods of formulation and evaluation. **12 Hours**

Unit 4:

Ocular drug delivery systems: Barriers of drug permeation, methods to overcome barriers. Transdermal drug delivery systems: Structure of skin and barriers, penetration enhancers, formulation and evaluation. **12 Hours**

Unit 5:

Protein and Peptide Delivery: Barriers for protein delivery. Formulation and evaluation of delivery systems of proteins and other macromolecules.

Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

Medical devices: Materials and their requirements for manufacture of specialized medical devices-disposable hypodermic needles and syringes, prefilled syringes, drug eluting stents, orthopedic implants and intra ocular lenses. **12 Hours**

REFERENCES

1. Novel Drug Delivery Systems – Y.W. Chien. 2nd ed. (Revised and expanded). Marcel Dekker.
2. Controlled Drug Delivery Systems - J. R. Robinson & V.H.L. Lee. Marcel Dekker, Inc.
3. Encyclopedia of Controlled Delivery - Edith Mathiowitz. John Wiley and Sons, Inc.
4. Controlled Drug Delivery: Concepts and Advances - S.P. Vyas & R.K. Khar. 1st ed. Vallabh Prakashan, New Delhi.
5. Controlled and Novel Drug Delivery - N.K. Jain. 1st ed. CBS Publishers, New Delhi, 1997.

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

Unit 1:

Computers in pharmaceutical research and development: A general overview: History of computers in pharmaceutical research and development.

Statistical modeling in pharmaceutical research and development: Descriptive versus mechanistic non parametric and parametric modeling. Statistical parameters, estimation, confidence regions, nonlinearity at the optimum, sensitivity analysis, optimal design, population modeling. **12 Hours**

Unit 2:

Computational modeling of drug disposition: Introduction, modeling techniques: Drug absorption, solubility, intestinal permeation, drug distribution, drug excretion, active transport; P-gp, BCRP, nucleoside transporters, hPEPT1, ASBT, OCT, OATP, BBB-choline transporter. **12 Hours**

Unit 3:

Computer-aided formulation development: Solid dosage forms, disperse systems such as suspensions, emulsions and micro emulsion drug carrier system with examples. Legal protection of innovative uses of computers in R&D, the ethics of computing in pharmaceutical research. Computers in clinical development: Clinical data collection and management, computers in market analysis. **12 Hours**

Unit 4:

Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, theoretical background, model construction, parameter sensitivity analysis, virtual trial, fed vs. fasted state, in vitro dissolution and in vitro–in vivo correlation, biowaiver considerations

Computer simulations in pharmacokinetics and pharmacodynamics: Introduction. Computer simulation: Whole organism, isolated tissues, organs, cell, proteins and genes.

12 Hours

Unit 5:

Artificial intelligence (AI): Concepts and applications, robotics. Computational fluid dynamics: General overview and applications. Pharmaceutical automation, pharmaceutical applications, advantages and disadvantages. Current challenges and future directions.

12 Hours

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development - Sean Ekins. John Wiley & Sons, 2006.
2. Computer-Aided Applications in Pharmaceutical Technology - Jelena Djuris. 1st ed. Woodhead Publishing.
3. Encyclopedia of Pharmaceutical Technology - James Swarbrick & James G Boylan. Vol 13. Marcel Dekker Inc, New York, 1996.

PHARMACEUTICAL AND COSMETIC PRODUCT DEVELOPMENT (MPH 204T)

Unit 1:

Preformulation studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies by TLC, DTA, DSC and TGA spectral studies, formulation additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. **12 Hours**

Unit 2:

Solubility: Importance, experimental determination, phase solubility analysis, pH-solubility profile, techniques to improve solubility of drugs and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy, methods of characterization. **12 Hours**

Unit 3:

Product stability: Mechanisms of degradation and protection, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf-life assignment. Stability protocols, reports and ICH guidelines. **12 Hours**

Unit 4:

Herbal Cosmetics : Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics. **12 Hours**

Unit 5:

Cosmetics: Formulation, manufacturing and quality control methods of following cosmetic products. Hair care products - Shampoos, hair dyes, shaving products and depilatories. Dental hygiene products: Tooth paste, mouth washes. Skin care products: Hand cream, cleansing

PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

First Semester

GOOD REGULATORY PRACTICES (MRA 101T)

Unit 1:

Current Good Manufacturing Practices (cGMP): Introduction, US cGMP Part 210 and Part 211. EC principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force (GHTF) Guidance docs. **12 Hours**

Unit 2:

Good Laboratory Practices (GLP): Introduction, USFDA GLP Regulations (Subpart A to Subpart K). Controlling the GLP inspection process, documentation, audit, goals of Laboratory Quality Audit, Audit tools. Future of GLP regulations, relevant ISO and Quality Council of India (QCI) Standards. **12 Hours**

Unit 3:

Good Automated Laboratory Practices (GALP): Introduction to GALP, principles of GALP, GALP requirements, SOPs of GALP, Training Documentation, 21 CFR Part 11, General check list of 21 CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards. **12 Hours**

Unit 4:

Principles, personnel, documentation, premises and equipment, deliveries to customers, returns, self-inspection, provision of information, stability testing principles, WHO Good Distribution Practices. USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards. **6 Hours**

Unit 5:

Quality management systems: Concept of quality, Total Quality Management, quality by design, six sigma concept, Out of Specifications (OOS), change controls.

Validation: Types of validation, Types of qualification, validation master plan (VMP), analytical method validation. validation of utilities, [compressed air, steam, water systems, heat ventilation and air conditioning (HVAC)] and cleaning validation. The International Council for Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Schedule M-III and other relevant CDSCO regulatory guidance documents.

ICH Guidelines: Emphasis on Q2, Q3, Q7, Q8, Q9, Q10 & Q11 (draft Form) **18 Hours**

REFERENCES

1. Good Laboratory Practice Regulations - Sandy Weinberg, 4th ed. Drugs and The Pharmaceutical Sciences, Vol.168.
2. How to Practice GLP – P.P. Sharma. Vandana Publications.
3. Laboratory Auditing for Quality and Regulatory Compliance - Donald C Singer. Drugs and The Pharmaceutical Sciences, Vol. 150.
4. Drugs & Cosmetics Act, Rules & Amendments, Government of India.
5. Good Pharmaceutical Manufacturing Practice, Rationale and Compliance - John Sharp. CRC Press.
6. Establishing a cGMP Laboratory Audit System, A Practical Guide - David M Bleisner. Wiley.

DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

Unit 1:

Documentation in pharmaceutical industry: Exploratory Product Development Brief (EPDB) for drug substance and drug product, Product Development Plan (PDP), Product Development Report (PDR), master formula record, batch manufacturing record and its calculations, batch reconciliation, batch packaging records, print pack specifications, distribution records, Certificate of Analysis (CoA), site master file and Drug Master Files (DMF). **12 Hours**

Unit 2:

Dossier preparation and submission: Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements. Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO. Pharmaceutical Inspection & Convention Scheme and Pharmaceutical Inspection & Cooperation Scheme (PIC/S), ASEAN Pharmaceutical harmonization on initiative. **12 Hours**

Unit 3:

Audits: Introduction, definition, summary, types of audits, GMP compliance audit, audit policy, internal and external audits, second party audits, external third party audits, Auditing strategies, preparation and conducting audit, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485. **12 Hours**

Unit 4:

Inspections: Pre-approval inspections, inspection of pharmaceutical manufacturers, inspection of drug distribution channels, quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, root cause analysis, corrective and preventive action (CAPA)

12 Hours

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Unit 5:

Product life cycle management: ICH life cycle management (Q12), post approval labeling changes, lifecycle management, FDA inspection and enforcement, Establishment Inspection Report (EIR), warning letters, recalls, seizure and injunctions. ISO risk management standard. **12 Hours**

REFERENCES

1. Laboratory Auditing for Quality and Regulatory Compliance - Donald C Singer, Raluca-loana Stefan & Jacobus F Van Staden. Taylor and Francis, 2005.
2. Handbook of Microbiological Quality Control - Rosamund M Baird, Norman A Hodges & Stephen P Denyar. CRC Press, 2000.
3. Juran's Quality Handbook - Joseph M Juran & Joseph A De Feo. 6th ed. ASQ Publications.
4. Compliance Auditing for Pharmaceutical Manufacturers - Karen Ginsbury & Gil Bismuth. Interpharm/CRC, Boca Raton, London New York, Washington D.C.
5. Pharmaceutical Manufacturing Handbook: Regulations and Quality - Shayne Cox Gad. Wiley-Interscience, A John Wiley and Sons, Inc., Publications.

6. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results - Al Endres. Wiley, 2000.
7. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases - Jiju Antony. David Preece, Routledge, 2002.
8. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report - Edward E Lawler III, Susan Albers Mohrman & George Benson. Jossey-Bass, 2001.
9. Corporate Culture and the Quality Organization - James W Fairfield-Sonn. Quorum Books, 2000.
10. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery & Diane Zabel. Routledge, 1997.
11. The Quality Toolbox - Nancy R Tague. 2nd ed. ASQ Publications.
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action - Duke Okes. ASQ Publications.
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP).

CLINICAL RESEARCH REGULATIONS (MRA 103T)

Unit 1:

Clinical drug development process: Different types of clinical studies. Phases of clinical trials, clinical trial protocol. Phase 0 studies, Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug– drug interaction, PK endpoints. Phase II studies (proof of concept or principle studies to establish efficacy). Phase III studies (Multi ethnicity, global clinical trial, registration studies). Phase IV studies (Post marketing studies - PMS), clinical investigation and evaluation of medical devices & IVDs different types of studies, key concepts of medical device, clinical evaluation, key concepts of clinical investigation. **12 Hours**

Unit 2:

Ethics in clinical research: Historical perspectives: Nuremberg code, thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki· Origin of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines. The ethics of randomized clinical trials. The role of placebo in clinical trials. Ethics of clinical research in special population. Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data. Data safety monitoring boards. Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research. Ethical principles governing informed consent process. Patient information sheet and informed consent form the informed consent process and documentation. **12 Hours**

Unit 3:

Regulations governing clinical trials in India: Clinical research regulations in India – Schedule Y & Medical Device Guidance USA: Regulations to conduct drug studies in USA (FDA). NDA505(b)(1) of the FD&C Act (Application for approval of a new drug) NDA505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant). ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product). FDA Guidance for Industry - Acceptance of foreign clinical studies. FDA Clinical Trials Guidance Document: Good Clinical Practice EU: Clinical Research regulations in European Union (EMA). **12 Hours**

Unit 4:

Clinical research related guidelines: Good Clinical Practice Guidelines (ICHGCP E6), Indian GCP Guidelines. ICMR Ethical Guidelines for biomedical research. CDSCO guidelines GHTF study group 5 guidance documents, Regulatory guidance on efficacy and safety ICH Guidance's · E4 – Dose response information to support drug registration. E7 – Studies in support of general population: geriatrics. E8 – General considerations of clinical trials. E10 – Choice of control groups and related issues in clinical trials. E 11 – Clinical investigation of medicinal products in the pediatric population. General biostatistics principle applied in clinical research. **12 Hours**

Unit 5:

USA & EU Guidance: FDA Guidance. CFR 21 Part 50: Protection of human subjects. CFR 21 Part 54: Financial disclosure by clinical investigators. CFR 21 Part 312: IND Application. CFR 21 Part 314: Application for FDA Approval to market a new drug. CFR 21 Part 320: Bioavailability and bioequivalence requirements. CFR 21 Part 812: Investigational device exemptions. CFR 21 Part 822: Post-market surveillance. FDA safety reporting requirements for INDs and BA/BE Studies. FDA Med Watch. Guidance for industry: Good pharmacovigilance practices and pharmacoepidemiologic assessment.

European Union: EMA Guidance, EU Directives 2001 EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use. EU Annual Safety Report (ASR) Volume 9A – Pharmacovigilance for medicinal products for human use. EU MDD with respect to clinical research · ISO 14155. **12 Hours**

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance - Fay A Rozovsky & Rodney K Adams.
2. FDA Regulatory Affairs: a Guide for Prescription Drugs, Medical Devices, and Biologics - Douglas J Pisano & David Mantus. CRC Press, USA.
3. New Drug Approval Process: The Global Challenge – Guarino & A. Richard. Marcel Dekker Inc.
4. HIPAA and Human Subjects Research: A Question and Answer Reference Guide - J.D. Mark Barnes & J.D. Jennifer Kulynych.
5. Principles and Practices of Clinical Research, John I Gallin & Frederick P Ognibene. 2nd ed.
6. Reviewing Clinical Trials: A Guide for the Ethics Committee - Johan P E Karlberg & Marjorie A Speers. Hong Kong.
7. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy - Anthony C Cartwright. Taylor & Francis Inc., USA.

REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS, HERBALS, FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (MRA 104T)

Unit 1:

Drugs Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments): 1) Drugs and Cosmetics Act 1940 and Rules 1945: Schedule M, DPCO & NPPA. 2) Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India Other relevant Acts: Narcotic Drugs and Psychotropic Substances Act; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act. **12 Hours**

Unit 2:

Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities. Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. Format and contents of Regulatory dossier filing Clinical trial/investigations. **12 Hours**

Unit 3:

Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards. Regulations for packaging material, packaging requirements & labeling requirements as per Rules 94, 95, 96, 97 & 105 D& C Rules 1945. **12 Hours**

Unit 4:

Bioavailability and bioequivalence data (BA &BE), BCS classification of drugs, regulatory requirements for bioequivalence study. Stability requirements: ICH and WHO guidelines for drug testing in animals/preclinical studies animal testing: Rationale for conducting studies, CPCSEA guidelines. Ethical guidelines for human participants. ICMR-DBT guidelines for stem cell research. **12 Hours**

Unit 5:

Intellectual property rights: Patent, trademark, copyright, industrial designs and geographical indications, Indian patent scenario, IPR vs regulatory affairs. **12 Hours**

REFERENCES

1. Manual of Patent Practice & Procedure - The Patent Office of India. 3rd ed.
2. Patent Failure How Judges, Bureaucrats, and Lawyers put Innovators at Risk - James Bessen & Michael J Meurer.
3. Principles and Practice of Clinical Trial Medicine - Richard Chin & Bruce Y. Lee.
4. Ethical Guidelines for Biomedical Research on Human Participants - Indian Council of Medical Research, New Delhi, 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the Purpose of Control and Supervision on Experiments on Animals (CPCSEA).
6. ICH E6 Guidelines — Good Clinical Practice - ICH Harmonised Tripartite.
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation).
9. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO.
10. Guidelines for Import and Manufacture of Medical Devices – CDSCO.
11. Guidelines from official website of CDSCO.

REGULATORY AFFAIRS PRACTICAL – I (MRA 105P)

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices
2. Documentation for in- process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand & generics
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India

8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application
13. Preparation of checklist for registration of IND as per ICH CTD format
14. Preparation of checklist for registration of NDA as per ICH CTD format
15. Preparation of checklist for registration of ANDA as per ICH CTD format

REGULATORY AFFAIRS PRACTICAL – II (MRA 106P)

1. Case studies on response with scientific rationale to USFDA Warning Letter
2. Preparation of submission check list of IMPD for EU submission
3. Comparison study of marketing authorization procedures in EU
4. Comparative study of DMF system in US, EU and Japan
5. Preparation of regulatory submission using eCTD software
6. Preparation of Clinical Trial Application (CTA) for US submission
7. Preparation of Clinical Trial Application (CTA) for EU submission
8. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form
9. Regulatory requirements check list for conducting clinical trials in India
10. Regulatory requirements check list for conducting clinical trials in Europe
11. Regulatory requirements check list for conducting clinical trials in USA
12. Writing Stability Protocols as per ICH
13. Writing Validation Protocol of Water & AHU Systems
14. Writing & Compiling a Dossier
15. Writing & Compiling Site Master File

Second Semester

REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T)

Unit 1:

USA & Canada: Organization and functions of FDA. Federal register and Code of register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US. Regulatory approval process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA). Regulatory requirements for orphan drugs and combination products, Changes to an approved NDA/ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada. **12 Hours**

Unit 2:

European Union & Australia: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU. Content and approval process of IMPD. Marketing authorization procedures in EU (centralized procedure, decentralized procedure, mutual recognition procedure and national procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, variations & extensions, compliance of European

Pharmacopoeia (CEP)/Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia. **12 Hours**

Unit 3:

Emerging market: Introduction, countries covered, study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC). WHO GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and country specific (India, South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana. **12 Hours**

Unit 4:

Brazil, ASEAN, CIS and GCC Countries: ASIAN Countries, introduction to ACTD, regulatory requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) region i.e., Vietnam, Malaysia, Philippines, Singapore and Thailand. **12 Hours**

Unit 5:

CIS (Commonwealth Independent States): Regulatory prerequisites related to marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries. **12 Hours**

REFERENCES

1. Generic Drug Product Development: Solid Oral Dosage Forms - Leon Shargel. Marcel Dekker Series, Vol. 143.
2. The Pharmaceutical Regulatory Process - Ira R Berry. Marcel Dekker Series, Vol.144.
3. Guidebook for Drug Regulatory Submissions - Sandy Weinberg. John Wiley & Sons. Inc.
4. New Drug Approval Process: Accelerating Global Registrations - Richard A Guarino, Vol 190. 5th ed. Drugs and the Pharmaceutical Sciences.
5. Drugs and the Pharmaceutical Sciences. Vol.185. Informa Health Care Publishers.
6. Drugs: From Discovery to Approval – N.G. Rick. 2nd ed.
7. New Drug Development: A Regulatory Overview - Mark Mathieu. 8th ed.
8. Pharmaceutical Risk Management - Jeffrey E Fetterman, Wayne L Pines & Gary H Slatko.
9. Preparation and Maintenance of the IND Application in eCTD Format - William K Sietsema.
10. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/List MRAWebsites
11. Roadmap to an ASEAN economic community - Denis Hew. ISEAS Publications. Singapore, 2005.
12. ASEAN - Rodolfo C. Severino. ISEAS Publications, Singapore.
13. Building a Future with Brics: The Next Decade for Offshoring - Mark Kobayashi-Hillary.
14. Outsourcing to India: The Offshore Advantage - Mark Kobayashi-Hillary. Springer Trade Performance and Regional Integration of the CIS Countries - Lev Freinkman.
15. The World Bank, Washington DC.
16. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World - Frederick M Abbott & Graham Dukes. Edward Elgar Publishing Inc.
17. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low

& Lorraine Carlos Salazar. ISEAS Publishing.
18. Doing Business in the Asean Countries - Balbir Bhasin. Business Expert Press.
19. Realizing the ASEAN Economic Community: A Comprehensive Assessment - Michael G Plummer & Chia Siow Yue. Published by Institute of Southeast Asian studies, Singapore.
20. Country Specific Guidelines from official websites.

REGULATORY ASPECTS OF HERBAL AND BIOLOGICS (MRA 202T)

Unit 1:

India: Introduction, applicable regulations and guidelines , principles for development of similar biologics. Data requirements for preclinical studies, data requirements for clinical trial application, data requirements for market authorization application. Post market data for similar biologics, pharmacovigilance. GMP and GDP. **12 Hours**

Unit 2:

USA & European Union: Introduction to biologics; biologics, biological and biosimilar, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labeling and packing of biologics in USA and EU. **12 Hours**

Unit 3:

Vaccine regulations in India, US and European Union: Clinical evaluation, marketing authorization, registration or licensing, quality assessment, pharmacovigilance, additional requirements. Blood and blood products regulations in India, US and European Union.

12 Hours

Unit 4:

Regulatory Requirements of Blood and/or its components including blood products, label requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemo vigilance Network). **12 Hours**

Unit 5:

Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union. **12 Hours**

REFERENCES

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics - Douglas J. Pisano & David S Mantus. Taylor and Francis, 2008.
2. Biological Drug Products: Development and Strategies - Wei Wang. Wiley, 2013.
3. Development of Vaccines: From Discovery to Clinical Testing - Manmohan Singh. Wiley, 2011.
4. www.who.int/biologicals/en
5. www.fda.gov/Biologics Blood Vaccines/Guidance Compliance Regulatory Information/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. www.cdsco.nic.in
10. www.ema.europa.eu›scientific guidelines›Biologicals

REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)

Unit 1:

Medical devices: Introduction, definition, risk based classification and essential principles of medical devices and IVDs. Differentiating medical devices, IVDs and combination products from that of pharmaceuticals. History of medical device regulation. Product Life cycle of medical devices and classification of medical devices.

IMDRF/GHTF: Introduction, organizational structure, purpose and functions, regulatory guidelines, working groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN). **12 Hours**

Unit 2:

Ethics: Clinical investigation of medical devices, clinical investigation plan for medical devices. Good clinical practice for clinical investigation of medical devices (ISO 14155:2011), Quality system regulations of medical devices (ISO 13485), Quality risk management of medical devices (ISO 14971). Validation and verification of medical device, adverse event reporting of medical device. **12 Hours**

Unit 3:

USA: Introduction, classification, regulatory approval process for medical devices (510k). Premarket notification, Pre Market Approval (PMA), Investigational Device Exemption (IDE) and in vitro diagnostics, Quality System Requirements (21 CFR Part 820), labeling requirements (21 CFR Part 801). Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of in vitro diagnostics, classification and approval process.

12 Hours

Unit 4:

European Union: Introduction, classification, regulatory approval process for medical devices (Medical Device Directive, Active Implantable Medical Device Directive) and in vitro diagnostics (In Vitro Diagnostics Directive). CE certification process. Basics of in vitro diagnostics, classification and approval process. **12 Hours**

Unit 5:

ASEAN, China & Japan: Medical devices and IVDs, regulatory registration procedures. Quality system requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents. Medical Devices Act, 2017 Regulations. **12 Hours**

REFERENCES

1. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices - John J Tobin & Gary Walsh.
2. Medical Device Development: A Regulatory Overview - Jonathan S Kahan.
3. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics - Carmen Medina.
4. Country Specific Guidelines from official websites.

REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS (MRA 204T)

Unit 1:

Nutraceuticals: Introduction, history of Food and Nutraceutical Regulations, meaning of nutraceuticals, dietary supplements, functional foods, medical foods. Scope and opportunities in nutraceutical market. **12 Hours**

Unit 2:

Global aspects: WHO guidelines on nutrition. NSF International, its role in the dietary supplements and nutraceuticals industries, NSF certification, NSF standards for food and

dietary supplements. Good Manufacturing Practices for nutraceuticals, Hazard Analysis & Critical Control Point (HACCP). **12 Hours**

Unit 3:

India: Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and functions, regulations for import, manufacture and sale of nutraceutical products in India. Recommended dietary allowances (RDA) in India. **12 Hours**

Unit 4:

USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements. Labeling requirements and label claims for dietary supplements, Recommended dietary allowances (RDA) in the U.S. **12 Hours**

Unit 5:

European Union: European Food Safety Authority (EFSA), Organization and Functions. EU directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labeling. European regulation on novel foods and novel food ingredients. Recommended dietary allowances (RDA) in Europe. **12 Hours**

REFERENCES

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective - Clare M Hasler. Wiley Online Library.
2. Nutraceutical and Functional Food Regulations in the United States and Around the World - Debasis Bagchi. Academic Press, Elsevier.
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOLSTU (2015)536324_EN.pdf
5. Handbook of Nutraceuticals - Yashwant Pathak. CRC Press.
6. Food Regulation: Law, Science, Policy and Practice - Neal D Fortin. Wiley.
7. Country Specific Guidelines from official websites.

REGULATORY AFFAIRS PRACTICAL – III (MRA 205P)

Case studies on:

1. Change Management/ Change control. Deviations
2. Corrective & Preventive Actions (CAPA)
3. Documentation of raw materials analysis as per official monographs
4. Preparation of audit checklist for various agencies
5. Preparation of submission to FDA using eCTD software
8. Preparation of submission to EMA using eCTD software
9. Preparation of submission to MHRA using eCTD software
10. Preparation of Biologics License Applications (BLA)
11. Preparation of documents required for Vaccine Product Approval
12. Comparison of clinical trial application requirements of US, EU and India of Biologics.
13. Preparation of Check list for Registration of Blood and Blood Products
14. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization

INDUSTRIAL PHARMACY (MIP)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MIP 101T)

(Note: Common Paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect and applications of UV-visible spectroscopy.

b. IR spectroscopy: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier-Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 2:

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **10 Hours**

Unit 3:

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. **10 Hours**

Unit 4:

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** High Performance Liquid chromatography **g)** Ultra High Performance Liquid chromatography **h)** Affinity chromatography **i)** Gel Chromatography. **14 Hours**

Unit 5:

a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing.

b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A. Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake. Vol 2. 4th ed. CBS Publishers, New Delhi
5. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B – J.W. Munson. Vol 11. Marcel-Dekker Series.
8. Spectroscopy of Organic Compounds - P.S. Kalsi. 2nd ed. Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis - K.A. Connors. 3rd ed. John Wiley & Sons.

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP 102T)

(Common paper for MPH and MIP specializations)

Unit 1:

Drug absorption from the gastrointestinal tract and other routes of administration: Mechanisms and factors affecting drug absorption from different routes, influence of pH–partition theory on drug absorption. Factors affecting dissolution rate and its process, Noyes-Whitney equation. dissolution testing methods for solids - tablets, capsules and for suspensions. Correlation of in vivo and in vitro dissolution data. **12 Hours**

Unit 2:

Biopharmaceutical considerations in drug product design and in vitro drug product performance. Introduction - biopharmaceutical factors affecting bioavailability, rate limiting steps in drug absorption, physicochemical nature of drug, formulation factors affecting drug product performance. In vitro dissolution and drug release testing, dissolution test apparatus and methods as per IP and USP for different types of drug delivery systems, design of dissolution testing for conventional and controlled release products. Data handling and correction factor, bio relevant media, similarity and dissimilarity factors f_1 & f_2, alternative methods of dissolution testing, problems of variable control in dissolution testing performance of drug products. Drug product stability during dissolution testing, in vitro evaluation of drug release from different dosage forms. **12 Hours**

Unit 3:

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model - IV bolus, IV infusion, extra-vascular. Multi compartment models in brief, calculation of parameters in two compartment models. Non-linear pharmacokinetics: causes of non-linearity, Michaelis – Menten equation, estimation of k_m and V_{max}. Concept of clearance and its applications. Problems related to the above. **12 Hours**

Unit 4:

Drug Product Performance: Bioavailability and bioequivalence, drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods, protocol design for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, cross over study designs, evaluation of the data, bioequivalence

example, study submission and drug review process. In vitro - in vivo correlations in protocol design, levels of correlation, biopharmaceutical classification system, methods. Permeability: Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies. **12 Hours**

Unit 5:

Application of pharmacokinetics: Modified-release drug products, targeted drug delivery systems and biotechnological products. Significance of pharmacokinetic and pharmacodynamic drug interactions in the design of the modified release products. **12 Hours**

REFERENCES

1. Pharmacokinetics - Milo Gibaldi. 2nd ed.
2. Applied Biopharmaceutics and Pharmacokinetics - Leon Shargel. 5th ed.
3. Biopharmaceutics and Clinical Pharmacokinetics - Robert E. Notari. 4th ed.
4. Modern Pharmaceutics - Gilbert S. Banker, Christopher T. Rhodes. 4th ed.
5. Clinical Pharmacokinetics & Pharmacodynamics - Malcolm Rowland & Tozer. 4th ed. Lippincott Publications.
6. Drug Disposition and Pharmacokinetics - Stephen H Curry. 3rd ed.
7. Current Concepts in the Pharmaceutical Sciences:Biopharmaceutics - James Swarbrick
8. Current Concepts in the Pharmaceutical Sciences:Dosage Form Design and Bioavailability - James Swarbrick.

NOVEL DRUG DELIVERY SYSTEMS (MIP 103T)

Unit 1:

Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.

Carriers for drug delivery: Polymers/co-polymers, introduction, classification, characterization, polymerization techniques, application in CDDS/NDDS, biodegradable & natural polymers. **12 Hours**

Unit 2:

Study of various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, mucoadhesive DDS (buccal, nasal, pulmonary) pulsatile, colon specific, liquid sustained release systems, ocular delivery systems

Transdermal drug delivery systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems. **12 Hours**

Unit 3:

Targeted drug delivery systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions. **12 Hours**

Unit 4:

Protein/peptide drug delivery systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.

Biotechnology in drug delivery systems: Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy. **12 Hours**

Unit 5:

New trends for personalized medicine: Introduction, definition, pharmacogenetics, categories of patients for personalized medicines: customized drug delivery systems, bioelectronic medicines, 3D printing of pharmaceuticals, telepharmacy.

Sub micron cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc. and their regulatory aspects. **12 Hours**

REFERENCES

1. Novel Drug Delivery Systems - Y.W. Chein. Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery: Fundamentals and Applications – Joseph R Robinson & Vincent H L Lee. Vol 29. Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications – Y.W. Chein. Vol 31. Marcel Dekker, New York.
4. Bioadhesive Drug Delivery Systems - E. Mathiowitz. Vol 98. Marcel Dekker, NY.
5. Nasal System Drug Delivery - K.S.E. Su. Vol 39. Marcel Dekker, NY.
6. Drug Delivery Devices – P. Tyle. Vol 32. Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery - P.J. Tarcha. CRC Press.
8. Pharmaceutical Biotechnology - S.P.Vyas and V.K. Dixit. CBS Publishers, New Delhi.
9. Biotechnology of Industrial Antibiotics - E.J. Vandamme. Marcel Dekker, NY.
10. Protein Formulation & Delivery - E.J. McNally. Vol 99. Marcel Dekker, NY.
11. Drug Targeting - M.H. Rubinstein. John Wiley, NY.

INTELLECTUAL PROPERTY RIGHTS (MIP 104T)

Unit 1:

Patents: Definition, need for patenting, types of patents. Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in patent. **12 Hours**

Unit 2:

Role of GATT, TRIPS, and WIPO **12 Hours**

Unit 3:

Brief introduction to Trademark protection and WHO Patents. IPR's and its types. Major bodies regulating Indian Pharmaceutical sector. **12 Hours**

Unit 4:

Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA **12 Hours**

Unit 5:

Regulatory requirements for contract research organization. Regulations for biosimilars. **12 Hours**

REFERENCES

1. Pharmaceutical Process Validation - Fra R Berry & Robert A Nash. Vol 57. 2nd ed. Marcel Dekker, NY.
2. Applied Production and Operation Management – James R Evans. 4th ed.
3. GMP for Pharmaceuticals Material Management - K.K. Ahuja. CBS Publishers, New Delhi.
4. ISO 9000-Norms and explanations

5. GMP for Pharmaceuticals: A Plan for Total Quality Contorl – S.H. Willing. Marcel Dekker.

INDUSTRIAL PHARMACY PRACTICAL - I (MIP 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV-visible spectrophotometer
2. Estimation of riboflavin/quinine sulphate by fluorimetry
3. Estimation of sodium/potassium by flame photometry
4. Effect of surfactants on the solubility of drugs
5. Effect of pH on the solubility of drugs
6. Stability testing of solution and solid dosage forms for photo degradation
7. Stability studies of drugs in dosage forms at 25°C, 60% RH 40°C, 75% RH
8. Compatibility evaluation of drugs and excipients (DSC & FTIR).
9. Preparation and evaluation of different polymeric membranes

INDUSTRIAL PHARMACY PRACTICAL - II (MIP 106P)

1. Formulation and evaluation of sustained release oral matrix tablet/oral reservoir system
2. Formulation and evaluation of microspheres/microcapsules
3. Formulation and evaluation of transdermal drug delivery systems
4. Design and evaluation of face wash, body wash, creams, lotions, shampoo, toothpaste, lipstick
5. Electrophoresis of protein solution
6. Preparation and evaluation of liposome delivery system
7. Experiments based on HPLC/GC
8. Simultaneous estimation of multi component containing formulations by UV spectrophotometry

Second Semester

SCALE UP AND TECHNOLOGY TRANSFER (MIP 202T)

Unit 1:

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations.

Scale up: Importance, technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products – stress on formula, equipment, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology **12 Hours**

Unit 2:

Validation: General concepts, types, procedures & protocols, documentation. Validation Management Forum (VMF). Analytical method validation. Cleaning validation and vender qualification. **12 Hours**

Unit 3:

Equipment qualification: Importance, IQ, OQ, PQ for equipment – autoclave, dry heat sterilization, membrane filter, rapid mixer granulator, cone blender, fluidized bed dryer, tablet compression machine, liquid filling and sealing machine. Aseptic room validation. **12 Hours**

Unit 4:

Process validation: Importance, validation of mixing, granulation, drying, compression,

tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control. **12 Hours**

Unit 5:

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, their. monitoring & prevention systems. Industrial effluent testing and treatment. Control of environmental pollution. **12 Hours**

REFERENCES

1. Pharmaceutical Process Validation - Fra R. Berry & Robert A. Nash. Vol 57. 2nd ed. Marcel Dekker, NY.
2. Pharmaceutical Production Facilities, Design and Applications – G.C. Cole. Taylor and Francis.
3. Pharmaceutical Project Management - T.Kennedy. Vol 86. Marcel Dekker, NY.
4. The Theory & Practice of Industrial Pharmacy, 3rd ed. Leon Lachman, Herbert A Lieberman & Joseph L Karig, Varghese Publishing House, Bombay.
5. Tablet Machine Instruments in Pharmaceuticals – P.R. Watt. John Wiley & Sons.
6. Pharmaceutical Dosage Forms: Tablets - Herbert A Lieberman & Leon Lachman, Volume 1 - 3. Marcel Dekker, Inc.
7. Pharmaceutical Dosage Forms : Disperse Systems - Herbert A Lieberman, Martin M Rieger & Gilbert S Banker, Vol 1 – 3. Informa Healthcare.
8. Pharmaceutical Dosage Forms : Parenteral Medication – Sandeep Nema & John Ludwig, Vol 1 – 3. 3rd ed. Informa Healthcare.
9. Pharmaceutical Production and Management – C.V.S. Subrahmanyam. Vallabh Prakashan, Dehli, 2007.

PHARMACEUTICAL PRODUCTION TECHNOLOGY (MIP 202T)

Unit 1:

Improved tablet production: Tablet production process, unit operation improvements, granulation and pelletization equipment, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered. **12 Hours**

Unit 2:

Parenteral production: Area planning and environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. **12 Hours**

Unit 3:

Lyophilization and spray drying technology: Principles, process, freeze-drying and spray drying equipment. **12 Hours**

Unit 4:

Capsule production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.

Disperse systems production: Production processes, applications of mixers, mills, disperse equipment including fine solids dispersion, problems encountered. **12 Hours**

Packaging technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms. **12 Hours**

Unit 5:

Air handling systems: Study of air handling units (AHUs), humidity and temperature control, air filtration systems, dust collectors.

Water treatment process: Techniques and maintenance – RO, DM, ultra – filtration, water for injection. **12 Hours**

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, 3rd ed. Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
2. Modern Pharmaceutics - Gilbert S. Banker, Christopher T. Rhodes. 4th ed.
3. Pharmaceutical Dosage Forms: Tablets - Herbert A. Lieberman and Leon Lachman, Volume 1 - 3. Marcel Dekker, Inc..
4. Pharmaceutical Dosage Forms : Disperse Systems - Herbert A Lieberman, Martin M Rieger & Gilbert S Banker, Vol 1 – 3. Informa Healthcare.
5. Pharmaceutical Dosage Forms : Parenteral Medication – Sandeep Nema & John Ludwig, Vol 1 – 3. 3rd ed. Informa Healthcare.
6. Pharmaceutical Production Facilities, Design and Applications – G.C. Cole. Taylor and Francis.
7. Product Design and Testing of Polymeric Materials - N.P. Chezerisionoff.
8. Pharmaceutical Project Management - T.Kennedy. Vol 86. Marcel Dekker, NY.
9. Packaging of Pharmaceutical and Health Care - H. Lockhart & F.A. Paine.
10. Quality Control of Packaging Materials in the Pharmaceutical Industry – Kenneth Harburn. Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products - L. Ray. Vol 96. Marcel Dekker, NY.
12. Tablet Machine Instruments in Pharmaceuticals – P.R. Watt. John Wiley & Sons.

ENTREPRENEURSHIP MANAGEMENT (MIP 203T)

Unit 1:

Conceptual frame work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprises, merits and demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management. **12 Hours**

Unit 2:

Entrepreneur: Entrepreneurial motivation, dynamics of motivation. Entrepreneurial competency, concepts. Developing entrepreneurial competencies, requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role. **12 Hours**

Unit 3:

Launching and organizing an enterprise: Environment scanning, information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT analysis. Resource mobilization - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation. **12 Hours**

Unit 4:

Growth strategies and networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future growth – techniques of expansion and diversification, vision strategies. Concept and dynamics.

methods, Joint venture, co-ordination and feasibility study. **12 Hours**

Unit 5:

Preparing project proposal to start on new enterprise project work – feasibility report. Planning, resource mobilization and implementation. **12 Hours**

REFERENCES

1. Entrepreneurship for Women in India - M.M.P. Akhauri. NIESBUD, New Delhi, 1990.
2. The Women Entrepreneurs - R.D. Hisrich, & C.G. Brush. D.C. Health & Co., Toranto, 1996.
3. Entrepreneurship: Starting, Developing and Managing a New Enterprise – Robert A Hisrich & Michael P Peters. 4th ed. McGraw Hill Education, 1997.
4. Practice of Entrepreneurship – G.G. Meredith, Robert E Nelson & Philip A Neck. ILO, Geneva, 1982.
5. Women Entrepreneurship – Developing New Entrepreneurs - V.C. Patel. Entrepreneurship Development Institute of India, Ahmedabad, 1987.

PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP 204T)

Unit 1:

Preformulation studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination. **12 Hours**

Unit 2:

Formulation additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development. **12 Hours**

Unit 3:

Solubility: Importance, experimental determination, phase- solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy. **12 Hours**

Unit 4:

Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, in vitro and in vivo correlations, levels of correlations. **12 Hours**

Unit 5:

Product stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines. **12 Hours**

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, 3rd ed. Leon Lachman, Herbert A Lieberman & Joseph L Karig. Varghese Publishing House, Bombay.
2. Martin's Physical Pharmacy and Pharmaceutical Sciences - Patrick J Sinko. 6th ed. BI Publications Pvt. Ltd.

3. Pharmaceutical Dosage Forms: Tablets - Herbert A Lieberman & Leon Lachman. Volume 1 - 3. Marcel Dekker, Inc.
4. Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances - Ellis Horwood Ltd., England, 1998.
5. Techniques of Solubilization of Drugs – S.H. Yalkowsky. Vol - 12. Marcel Dekker Inc., New York, 1981.
6. Pharmaceutical Dissolution Testing – J. Dressman & J. Kramer. Saurah Printers Pvt. Ltd., New Delhi, 2005.
7. Drug Stability Principles and Practices – J.T. Carstensen & C.T. Rhodes. CBS Publishers, New Delhi, 2005.
8. Stability of Drugs and Dosage Forms – S. Yoshioka & V.J. Stella. Springer (India) Pvt. Ltd., New Delhi, 2006.
9. Modern Pharmaceutics - Gilbert S. Banker, Christopher T Rhodes. 4th ed.
10. Stability Testing of Drug Products - W. Grimm.
11. International Stability Testing – D.J. Mazzo. Eastern Press Pvt. Ltd., Bangalore,
12. Indian Pharmacopoeia-2018. Controller of Publication. Delhi.
13. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2017.
14. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2019.
17. Encyclopedia of Pharmaceutical Technology – James Swarbrick. Vol 1-3.
18. Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances - J. I. Wells. Ellis Horwood Ltd. England, 1988.

INDUSTRIAL PHARMACY PRACTICAL - III (MIP 205P)

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique
2. Comparison of dissolution of two different marketed products /brands
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
4. Bioavailability studies of paracetamol (Animal)
5. Pharmacokinetic and IVIVC data analysis by WinNolin® software
6. In vitro cell studies for permeability and metabolism
7. Formulation and evaluation of tablets
8. Formulation and evaluation of capsules
9. Formulation and evaluation of injections
10. Formulation and evaluation of emulsion
11. Formulation and evaluation of suspension
12. Formulation and evaluation of enteric coating tablets
13. Preparation and evaluation of a freeze dried formulation
14. Preparation and evaluation of a spray formulation

PHARMACY PRACTICE (MPP)

First Semester

CLINICAL PHARMACY PRACTICE (MPP 101T)

Unit 1:

Introduction to clinical pharmacy: Definition, evolution and scope of clinical pharmacy. International and national scenario of clinical pharmacy practice, pharmaceutical care.

Clinical pharmacy services: Ward round participation, Drug therapy review - drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions. **12 Hours**

Unit 2:

Clinical pharmacy services: Patient medication history interview, basic concept of medicine and poison information services. Basic concept of pharmacovigilance, hemovigilance, materiovigilance and active surveillance of adverse events following immunization (AEFI). Patient medication counselling, drug utilization evaluation. Documentation of clinical pharmacy services, quality assurance of clinical pharmacy services. **12 Hours**

Unit 3:

Patient data analysis & practice skills: Patient's case history – its structure and significances in drug therapy management. Common medical abbreviations and terminologies used in clinical practice. Communication skills - verbal and non-verbal communications, their applications in patient care services. **12 Hours**

Unit 4:

Lab data interpretation: Hematological tests, renal function tests, liver function tests. Tests associated with cardiac disorders, pulmonary function tests, thyroid function tests. Fluid and electrolyte balance, microbiological culture sensitivity tests. **12 Hours**

Unit 5:

Medicines information services: Definition and need for medicine information service, medicine information resources. Systematic approach in answering medicine information queries. Preparation of verbal and written response. Establishing a drug information centre.

Poison information service: Definition, need, organization and functions of poison information centre. **12 Hours**

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential Concepts and Skills – G. Parthasarathi, Karin Nyfort-Hansen & Milap Nahata.
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
3. Basic Skills in Interpreting Laboratory Data – L.T. Scott. American Society of Health System Pharmacists Inc.
4. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS-I (MPP 102T)

Etiopathogenesis and pharmacotherapy of diseases associated with following systems:

Unit 1:

Cardiovascular system: Hypertension, congestive cardiac failure, acute coronary syndrome, arrhythmias, hyperlipidemias. **12 Hours**

Unit 2:

Respiratory system: Asthma, chronic obstructive airways disease, drug induced pulmonary diseases

Third Semester

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

(Note: Common Paper for all specializations)

Unit 1:

General research methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques. **12 Hours**

Unit 2:

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (Wilcoxan rank tests, analysis of variance, correlation, Chi-square test), null hypothesis, P values, degree of freedom, interpretation of P values. **12 Hours**

Unit 3:

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-malfeasance, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality. **12 Hours**

Unit 4:

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals. **12 Hours**

Unit 5:

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care. **12 Hours**

REFERENCES

1. Pharmaceutical Statistics: Practical and Clinical Applications - Stanford Bolton & Charles Bon. 5th ed. CRC Press.
2. Biostatistics: A Foundation for Analysis in the Health Sciences - Wayne W Daniel. 10th ed. John Wiley & Sons.
3. Introduction to Research in the Health Sciences - Stephen Polgar & Shane Thomas. 7th ed. Elsevier.
4. www.cpcsea.nic.in
5. www.wma.net

1. PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

FIRST SEMESTER

Course Nos. 1101, 2101, 3101, 4101, 5101, 6101, 7101, 8101, 9101, 10101 and 11101

Course Nos. 1101 BIOSTATISTICS (THEORY)

(Common paper for all specialisations)

LEARNING OBJECTIVES:

Learning this subject must help the student

1. To perform easily the calculations involved in all the statistical procedures, to properly understand all the concepts involved in testing of hypothesis and experimental design.
2. To apply the knowledge gained through this subject in the design, data collection and analysis involved in his/her research project in second year M.Pharm.
3. To interpret properly the experimental data in an industry or research setting in his/her future career and to take decisions in a more scientific manner.

UNIT I Introduction to biostatistics and applications of biostatistics in pharmaceutical and medical research. Tests of significance: Testing hypotheses- principle and applications of Z, t test and F tests. **8 hours**

UNIT II Analysis of Variance: 1-way, 2-way and 3-way classification. **8 hours**

UNIT III Non-parametric tests: Chi square test, sign test, Wilcoxon signed rank test, Wilcoxon rank sum test, Kruskal Wallis test, run test and median tests. **8 hours**

UNIT IV Design of Experiments: Principles of randomization, replication and local control;CRD, RBD, LSD - their applications and analysis of data. **8 hours**

UNIT V Factorial Experiments-Principles and applications; Use of software such as design expert and origin in the design of experiment **8 hours**

UNIT VI Probit analysis-Dose-effect relationships, calculation of LD_{50}, ED_{50} **8 hours**

UNIT VII Regression and correlation: Method of least squares, Correlation Coefficient, rank correlation and multiple regression. **8 hours**

UNIT VIII Optimization Techniques: Basic principles and advantages of optimization, Optimization using factorial design, the simplex lattice and sequential optimization. **8 hours**

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REFERENCE BOOKS

1. Statistics (Theory, Methods & Application) by D.C. Sancheti and V.K. Kapoor ; Sultan Chand & Sons; Educational Publishers, New Delhi
2. Comprehensive Statistical Methods by P.N. Arora, Sumeeth Arora and S.Arora;S.Chand Publication
3. Biostatistics- An Introductory Text by Avram Goldstein; The Macmillan Company, New York
4. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, Charles Bon; Marcel Dekker Inc.

Course No. 1102 ADVANCED PHARMACEUTICAL ANALYSIS I (THEORY)

LEARNING OBJECTIVES:

This subject is aimed

1. To train students in advanced qualitative and quantitative aspects of different spectroscopic methods and separation techniques.
2. After learning this subject the student must be able to apply these concepts in various steps like sample preparation, routine quality control analysis, development and validation of analytical methods useful in pharmaceutical industry.

UNIT I

UV-Visible & Derivative Spectroscopy

Brief review of electromagnetic spectrum, UV-Visible range, Energy wavelength-colour relationships. Interaction of electro - magnetic radiation (UV-Vis) and matter and its effects, Chromophores and their interaction with EMR, Woodward-Fischer rule, Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs, Beer-Lambert's law, Shifts and their interpretation (including solvent effects). Principles, Instrumentation- including sources, monochromators, detectors, preparation of calibration curves and pharmaceutical applications including assay of official compounds and formulations used in the structure determination, Multicomponent analysis, Derivative spectroscopy. Source of errors and their corrections and validation of spectrophotometric methods.Pharmaceutical Applications

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Infrared Spectroscopy

Nature of Infra-red radiation, Molecular or infra-red spectra, origin of infra red spectra, vibrational energies of diatomic molecules, Interaction of IR radiation with organic molecules and effects on bonds, Brief outline of classical IR instrumentation and interpretation of spectra, including sample preparation for spectroscopy, qualitative interpretation of IR Spectra, influence of substituent's, ring size, hydrogen bonding, vibrational coupling and field effect on frequency, quantitative methods, FT-IR and applications. Recent advances in IR Spectroscopy (FT-NIR), Interpretation of IR spectra- Characteristic group frequencies of organic molecules.Pharmaceutical Applications.

9 hours

UNIT II

Fluorimetry and Phosphorimetry

Concept of Fluorescence and Phosphorescence, factors effecting Fluorescence and Phosphorescence. Quenching-Internal conversion and external conversion, relation between intensity of fluorescence and concentration, calculation of results and measurement of fluorescence, filter fluorometers, spectrofluorometers, principles, instrumentation and applications; electro-chemiluminescence, resonant ionization and laser-enhanced ionization

Atomic Emission Spectroscopy and Plasma Emission Spectroscopy

Introduction, theory of signal generation-Atomic spectra, Molecular Spectra, continuum, instrumentation-atomic emission source-Inductively Coupled Plasma (ICP), Direct Current Plasma (DCP), Microwave Induced Plasma (MIP) and capacitively coupled microwave plasma (CMP, Optical System and detectors) Pharmaceutical Applications.

7 hours

UNIT III

H^1 NMR and C^{13} NMR Spectroscopy

Nuclear spin and magnetic moment, nuclear magnetic- resonance-origin of NMR spectra, theory of NMR spectroscopy, Nuclear resonance: saturation-relaxation process in NMR, Flipping –origin of signal, factors effecting -chemical shift and spin spin splitting. Double resonance-spin spin decoupling and nuclear overhauser effect (NOE). One dimensional and two dimensional NMR spectroscopy- comparisons between one dimensional and two dimensional NMR, C^{13} NMR-natural abundance of C^{13}, resolution and multiplicity FT mode, RF mode, uses of proton coupled, decoupled and off resonance decoupling techniques, deuterium substitution, chemical equivalence in peak assignment, chemical shift. Effect of

substitution on chemical shifts, position of alkanes, alkenes, alkynes and benzene spin coupling and c^{13}-H^1 coupling – other techniques like COSY, HETCOR, NOESY TOCSY AND ROESY. Interpretation of NMR Data. Pharmaceutical applications.

Electron Spin Resonance Spectroscopy

Introduction, factor affecting g-value, limitations of ESR, Difference between ESR and NMR, Instrumentation, electron nucleus coupling or electron nucleus interaction.Hyperfine interactions- isotopic and anisotopic coupling constants. Spin Hamiltonian, Electronic structure and hyperfine splitting-spin densities and McConnel relationship. triplet states-Zero field splitting and Kramer's degeneracy. Choice of solvents, sensitivity, quantitative analysis, applications of ESR-Study of free radicals, determination of reaction rates and mechanisms by ESR, structural determination by ESR, study of inorganic compounds, transition elements by ESR and pharmaceutical Applications. **7 hours**

UNIT IV

Mass Spectroscopy

Basic principles and instrumentation (components and their significance).Ionization techniques (FAB, MALDI, SELDI, APCI, APPI, ESI and DART).Mass analyzers [Quadrupole, Ion Trap, FT-ICR, TOF and tandem mass (MS-MS)].High resolution mass spectroscopy. Concepts of interpretation of mass spectra: Mass spectrum, molecular ion, metastable ions, fragmentation patterns α fission, β fission. Mac Lafferty rearrangement, Retro Diels Alder rearrangement.Pharmaceutical applications.

Hyphenated techniques of Mass Spectroscopy

Hyphenated techniques-GC-MS/MS, LC-MS/MS- including recent advances in MS, fast atom bombardment mass spectroscopy; Pharmaceutical Applications.

8 hours

UNIT V

High performance liquid chromatography and Derivative methods

Theoretical principles involved in HPLC, discussion of typical equipment including pumps, columns, injection systems, detectors, packing materials and solvent systems, pharmaceutical applications, advantages and disadvantages. Precolumn and post column derivatization, detection methods, reagents for coloured and UV absorbing derivatives, reagents for UV/Visible detection, fluorimetric detection, fluorescent derivatives, electrochemical

derivatives, chiral derivatization reagents. Introduction to UPLC and pharmaceutical applications

7 hours

UNIT VI

Gas chromatography

Basic principles, instrumentation, columns, detectors, Van Deemter equation, Kovats retention index and HETP and temperature programming, qualitative and quantitative applications in Pharmacy, combination of GLC with other methods, advantages and disadvantages.Derivatization techniques – acylation, silylation, alkylation and esterification. Introduction to head space GC and pharmaceutical applications.

Super critical fluid chromatography

Introduction, theory, important properties of supercritical fluids, fluid extraction solvents, Categorization of SFC, instrumentation and pharmaceutical applications.

7 hours

UNIT VII

Ion Exchange Chromatography

Introduction, principle, theory, Cationic and Anionic exchange Columns, Instrumentation, Pharmaceutical Applications.

Vapour phase chromatography Introduction, theory, instrumentation, factors effecting the elution time and resolution power, Applications in pharmaceutical industries

Affinity chromatography Introduction, matrix, spacer arm, ligand binding, elution, ligand coupling, pre-activated matrices. Purification steps, media selection of media and buffers, sample preparation Purification of specific groups of molecules, components of an affinity medium, designing affinity media using pre-activated matrices. Sample preparation- fractional precipitation, ammonium sulphate precipitation, resolubilization of protein precipitates, buffer exchange and desalting, sample stability, sample clarification.Pharmaceutical applications.

7 hours

UNIT VIII

Optical Rotatory dispersion and Circular Dichroism: Basic principles, Instrumentation and pharmaceutical applications of ORD and CD spectroscopy

X-ray Diffraction: Bragg's Equation, concept of crystal and x-rays, Basics of crystallography, production of X-rays, instrumentation and pharmaceutical applications of XRD.

Thermal methods of analysis: Basic principles, instrumentation and pharmaceutical applications of DTA (Differential thermal analysis), DSC (Differential scanning calorimetry), TGA (Thermogravimetric analysis).

8 hours

REFERENCE BOOKS:

1. Marvin C. McMaster, "LC/MS: A practical user's guide", John Wiley and Sons, 2005
2. Marvin C. McMaster, "GC/MS: A practical user's guide",Second edition, John Wiley and Sons, 2008.
3. ManMohan Srivastava , "High performance thin layer chromatography", Springer, 2011.
4. Silverstein RM, Webstar FX. Spectrometric identification of organic compounds. 6th ed., John Wiley &Sons (Asia) Pvt, Ltd., Singapore, 2005
5. Donald L. Pavia, Gary M. Lampman, George S. Kriz and James A. Vyvyan, "Introduction to spectroscopy", Fourth edition, Cengage Learning, 2009.
6. Skoog, D.A., "Principles of Instrumental Analysis", 3rd Edition, Saunders College Publishing, 1985
7. Willard, H.H., Merritt. L.L., Dean J.A., and Settle, F.A., "Instrumental Methods of Analysis", 7th Edition, CBS Publishers, 2004.
8. Wim Kok.,"Capillary Electrophoresis : Instrumentation and Operation" Vol.51, Stefanie Hoffmann, 2000.

Course No. 1103 ADVANCED PHARMACEUTICAL ANALYSIS I (PRACTICAL)

1. Determination of λ max,(KMnO4 and methylene blue solutions)
2. Assay of sulphadiazine tablets by Visible Spectrophotometry.
3. Assay of sulphadiazine tablets by UV spectrophotometry.
4. Demonstration experiments in IR spectrophotometry including interpretation of given spectra.
5. Flourimetric estimation of quinine sulphate in formulations.
6. Flourimetric estimation of riboflavin in formulations.
7. Flame photometric estimation of sodium ions.
8. Flame photometric estimation of potassium ions Losartan Potassium.

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9. Separation of plant materials by column chromatography.
10. Separation and identification of flavonoids/sulphonamides by paper chromatography.
11. Separation and identification of sulphonamides by paper chromatography.
12. Separation and identification of amino acids by TLC methods.
13. Separation and identification of barbiturates by TLC methods.
14. Demonstration experiments in HPLC.
15. Demonstration experiments in GLC.

Course No. 1104 VALIDATION OF INSTRUMENTAL METHODS OF ANALYSIS (THEORY)

LEARNING OBVJECTIVES:

1. After learning this subject student should understand the scope and functional importance of documentation and validation in pharmaceutical field.
2. The student must be able to apply these concepts in various steps like development and validation of new analytical method, calibrations, validation of equipment, cleaning, sterilization and utilities; use of validation in pharmaceutical industry.

UNIT I Validation

a. Introduction, history, definition
b. Types of validation, prospective validation, retrospective validation, concurrent validation, revalidation
c. Validation Master Plan **8 hours**

UNIT II Process Validation of Solid Dosage forms

a. Process validation of low dose tablet manufacturing process
b. Uniformity of blend (US FDA guideline) for tablets subjected to content uniformity test as per USP
c. Process validation of compression machine giving details of control charts **8 hours**

UNIT III Sterilization Validation

a. Process validation of terminally sterilized product. Validation of sterilization process including heat distribution, heat penetration studies, and sterility assurance level.
b. Process validation of aseptically filled product with special emphasis on media fill test.

8 hours

UNIT IV Cleaning Validation

a. Validation of cleaning process.

b. Elements of validation protocol.

c. Determination of acceptable limits for cleaning process.

d. Factors to consider in setting the limits.

e. Numerical calculation of limits. **7 hours**

UNIT V Utilities Validation

a. Validation of water system- for production of demineralised (DM) water, distilled water

b. Validation of Air handling Units- classification of environment (class 100, 10,000, 1,00,000)

c. Performance qualification & parameter of cleanliness such as no. of airborne particles, microbes filter integrity test of HEPA filter, air velocity, air flow pattern, no. of air changes, pressure differentials etc. **8 hours**

UNIT VI Analytical Method Validation

a. Recommendation of ICH guideline- Definition of accuracy, precision, linearity, LOD, LOQ, range, robustness, ruggedness, specificity, system suitability test.

b. USP requirement of analytical validation- different category of assays.

c. Stability indicating methods.

d. Bio analytical method validation **7 hours**

UNIT VII Instruments calibration

a. Analytical balance calibration.

b. Calibration of weight box.

c. Calibration of UV-spectrophotometer.

d. Calibration of IR spectrophotometer.

e. Calibration of HPLC system.

f. Calibration of Gas Chromatography instrument.

g. Performance check of HPLC/GC column.

h. Out of Calibration. **8 hours**

UNIT VIII Equipment Validation

a. Definition of DQ, IQ, OQ, PQ

b. Comparison of different types of liquid filling machines (vacuum / volumetric)

c. Process capability of filling machines

d. Performance qualification of bottle washing/ ampoules washing machines - challenge test. **6 hours**

REFERENCE BOOKS:

1. R. Nash and Wachter, "Pharmaceutical Process Validation". Volume 129, Latest Edition. Marcel Dekker Inc., New York
2. K.L. Williams, "Microbial Contamination Control in Parenteral Manufacturing". Latest Edition. Marcel Dekker Inc., New York
3. Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice-USFDA
4. J.T. Carstensen, C.T. Rhodes, "Drug stability: principles & Practices". Latest Edition. Marcel Dekker Inc., New York
5. www.ich.org – Q7 a guideline
6. www.fda.org
7. United State Pharmacopoeia
8. US-FDA guideline for bio-analytical studies. Dekker Inc., New York
9. It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers

Course No. 1105 VALIDATION OF INSTRUMENTAL METHODS OF ANALYSIS (PRACTICAL)

LIST OF LABORATORY EXPERIMENTS:

1. Calibration of pH meter
2. Calibration of UV spectrophotometer
3. Calibration of HPLC instrument
4. Calibration of IR spectrophotometer
5. Demonstration and calibration of GC, Spectrofluorimeter, LC-MS wherever possible.

Course No.1106 Comprehensive Viva

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PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

SECOND SEMESTER

Course Nos. 1207, 2207, 3207, 4207, 5207,6207,7207,8207,9207,10207 and 11207

Course No. 1207 MODERN ANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

LEARNING OBVJECTIVES:

1. This subject should train the students in advanced qualitative and quantitative aspects of different spectroscopic methods, thermal methods and separation techniques.
2. The student must be able to apply these concepts in various steps like sample preparation, characterization of excipients, structural analysis, routine quality control analysis, development and validation of analytical methods useful in pharmaceutical industry.

UNIT I UV SPECTROSCOPY

Theory – Beer and lambert's law and its limitations–energy levels and selection rules, wood ward Fieser, Fieser Kuhn and Nelson rules – Influence of substituent, ring size and strain on spectral characteristics –solvent effects, stereo chemical effects –Non conjugated interactions, spectral correlation with structure– Applications of UV spectroscopy. **7 hours**

UNIT II INFRA RED SPECROSCOPY

Molecular spectra – Origin of IR spectra – Harmonic oscillator model – Electronic band spectra – Pre dissociation spectra – Vibrations coupling – Instrumentation – Fourier transform spectrometer – Dispersive instruments – Non dispersive instruments – Mid infra red absorption spectrometry – Factors influencing vibrational frequencies –Spectral regionsin IR – Environmental effects – Applications of IR spectroscopy. **8 hours**

UNIT III HIGH PRESSURE LIQUID CHROMATOGRAPHY

Theory of chromatography – Principle –Instrumentation– column efficiency (theoretical plates), HETP, selectivity, resolution – tailing and fronting – Applications and recent trends in chromatography. **8 hours**

UNIT IV GAS LIQUID CHROMATOGRAPHY

Gas chromatography– Basic principle,instrumentation – selection of liquid stationary phases Derivatization in GC – GC detectors – Applications. **7 hours**

UNIT V NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY

Theory of NMR – Magnetic properties of nuclei and the spin number – Chemical equivalence – chemical shift – shielding and deshielding – Spin-Spin coupling, pascal's triangle, coupling constant – decoupling– local diamagnetic shielding – magnetic anisotropy, nuclear overhauser effect–Applications. **8 hours**

UNIT VI MASS SPECTROMETRY

Principle – reactions inside the mass spectrometer – resolution – principle of measuring ofion currents – electron impact – chemical ionization – Instrumentation and ionization methods(FAB, ESI, MALDI, FID, etc) – Plasma desorption mass spectrometry –fragmentation –rearrangements –Applications of mass spectrometry. **8 hours**

UNIT VII X RAY AND ELECTRON SPECTROSCOPY

X-ray diffraction – Bragg's law – Diffraction of X-rays – production and detection of X-rays – sample preparation – identification of powder diffraction patterns – quantitative analysis – principle, instrumentation and applications of XRD, SEM and TEM. **7 hours**

UNIT VIII THERMAL ANALYSIS

Theory – Instrumentation of TGA, DTA and DSC and its role in the characterization of drugs and excipients. **7 hours**

REFERENCE BOOKS:

1. Skoog DA, Holler FJ, Crouch SR. Principles of instrumental analysis. 6th ed., Baba Barkha Nath printers, Haryana, 2007
2. Silverstein RM, Webstar FX. Spectrometric identification of organic compounds. 6th ed., John Wiley &Sons (Asia) Pvt, Ltd., Singapore, 2005
3. Willard HR, Merritt LL, Dean JA, Settle FA. Instrumental methods of analysis, 7th ed., CBS Publishers &distributors, New Delhi, 1986
4. Ewing GW. Instrumental methods of chemical analysis, 5th ed., McGraw Hill Book Company, New York, 1985
5. Schirmer RE. Modem methods of pharmaceutical analysis, Vol. I &II, 2nd ed., CRC Press, Florida, 2000
6. Whoston C. X-ray methods, John Wiley & Sons, New York, 1987
7. Lee DC, Webb M. Pharmaceutical Analysis, Blackwell publishing, Australia, 2004
8. Gurdeep R. Chatwal, Instrumental Methods of Chemical Analysis, Himalaya Publishing House, 2006.

Course Nos. 1208, 2208, 3208, 4208, 5208,6208,7208,8208,9208,10208 and 11208

Course No. 1208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS (THEORY)

(Common paper for all specializations)

LEARNING OBJECTIVES:

On learning this subject the student must

1. Understand the concepts and procedures involved in quality assurance, GMP, and validation.
2. Be thorough in the drug development process and the drug registration process in India and in the United States of America.

UNIT I The concepts of quality assurance, GMP, TQM- Principles and objectives, process control, sources and control of quality variation, statistical quality control, in process quality control, dosage forms control, specifications.

8 hours

UNIT II GMP- A study of Schedule M of Drugs and Cosmetics Act, WHO specifications, US FDA guidelines. The study shall include special emphasis on premises, personnel, sanitation, equipment, manufacturing operations and documentation.

8 hours

UNIT III Validation: Types of validation, protocol for process validation, cleaning validation, validation of air handling, validation of equipment and facilities in sterile and non-sterile areas. Analytical method validation

8 hours

UNIT IV Ware housing for materials and products; complaints and recalls- evaluation of complaints and recall procedures; finished product release-Quality review-Quality audits-Handling of returned goods, recovered materials and reprocessing.

8 hours

UNIT V Documentation related to Product Development, standard operating procedures, standard test procedures, cleaning methods, quality control documents, batch release document, distribution records, complaints and recalls records, retention of records.

4 hours

UNIT VI Drug Regulatory Affairs: A study of the Drugs and Cosmetics Act with relevance to new drug development and approval; Part 10A of the Act Schedule Y and the Appendices I, II,

III, IV and V. Intellectual Property Rights, Patents, and non-infringing patents. Guidelines for Bioavailability and Bioequivalence studies as per Central Drugs Standard Control Organization (CDCSO, Govt. of India).

12 hours

UNIT VII New Drug Approval Process – Investigational New Drug (IND)- New Drug Application (NDA) – Abbreviated New Drug Applications (ANDA), Hatch-Waxman Act.

4 hours

UNIT VIII ICH for technical requirements for registration of biopharmaceuticals for human use- History and constitution of ICH, ICH guidelines relating to quality, safety, efficacy and multi disciplinary topics and detailed study of

Q1-Stability testing of new drug substances and products

Q3- Impurities in new drug substances and new drug products

S3- Toxicokinetics and Pharmacokinetics

S7- Pharmacology studies **12 hours**

REFERENCE BOOKS:

1. Leon Lachman, H. A. Lieberman & J. L. Kanig : "The Theory and Practice of Indusrtrial Pharmacy", 3rd edition, Varghese Publishing House, Bombay, 1991.
2. Quality Assurance of Pharmaceuticals Vol. I and Vol. II published by Pharma book syndicate.
3. Lachman/Lieberman's The Theory and Practice of Industrial Pharmacy, Fourth Edition, Editors, Roop K khar, SP Vyas, Farhan J Ahmad and Gaurav K Jain, CBS Publishers and Distributors Pvt. Ltd.
4. Pharmaceutical Product development by N. K. Jain, CBS Publishers and distributors Pvt. Ltd.
5. Law relating to Drugs & Cosmetics by Vijay Malik, Eastern Book Company.

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Course No.1209 BIO-ANALYTICAL METHODS (THEORY)

LEARNING OBVJECTIVES:

This course is aimed

1. To train students in qualitative and quantitative analysis of drugs and endogenous substances in biological samples.
2. To acquaint the student about the applications of bio-analytical methods in pharmacokinetics, toxicokinetics and bioequivalence.

The student must be able to apply these concepts in various steps like bioassays of drugs, clinical trials, therapeutic drug monitoring, and routine quality control analysis in pharmaceutical industry.

UNIT I PRINCIPLES OF BIOLOGICAL STANDARDIZATION

Methods of biological assay, Principles of biological assays with certain examples as per IP and BP. Development of new bioassay methods. Alternatives to animal screening procedures: Cell-Line, Patch-Clamp Techniques, In-Vitro Models, molecular biology techniques. Principles of toxicity evaluations, ED50, LD50 and TD values. Regulations for laboratory animal care and ethical requirements: Organization of screening. International guidelines (ICH recommendations). **8 hours**

UNIT II BIOASSAYS

Statistical methods in biological assays, Antibiotics-microbiological assays, Test for freedom from undue Toxicity, test for pyrogens, Determination of potency of diphtheria antitoxin, Determination of potency of Gas – Gangrene antitoxin (oedematiens), Determination of potency of Gas – Gangrene antitoxin (Septicum), Determination of potency of Gas – Gangrene antitoxin (perfringens), Determination of potency of tetanus antitoxin, Biological assay of Plague vaccine, , Biological assay of old tuberculin, test for potency of vaccine Lymph, Determination of ABO group and of RH group.

8 hours

UNIT III BIOASSAYS

Biological assay of cobra and viper venoms, Biological assay of chorionic Gonadotrophin, Biological assay of Serum Gonadotrophin, Biological assay of corticotrophin, Biological assay of insulin, The Mouse Method, Biological assay of protamine Zinc insulin,

Biological assay of posterior pituitary injection, Biological assay of Adrenaline, Biological assay of heparin sodium. **7 hours**

UNIT IV HUMAN DRUG METABOLISM

Phase-I metabolic reactions- cytochrome P450 enzyme system, Non-microsomal oxidation, Reduction, Hydrolysis, Phase-II metabolic reactions (conjugation)- Glucuronidation, Glutathione conjugation, Acetylation, Sulphation, methylation, Amino acid conjugation. Biomimetic modell systems in the drug metabolism studies- Synthetic porfirines, The Fenton-reaction, electrochemical oxidation Experimental setups for the investigation of Phase-I and II reactions. **7 hours**

UNIT V HUMAN DRUG METABOLISM

In vitro and ex vivo techniques in the drug metabolism studies, Supersomes, Human Liver Microsomal, Cytosolic and S9 fractions (HLM, HLC, HLS9), Immobilized Enzyme Reactors (IMER), Liver cell lines, HepG2 cell line, Transgenic cell lines, Hepatocytes, Liver slices, isolated perfused liver, Integrated discrete Multiple Organ Co-culture system (IdMOC).

8 hours

UNIT VI BIOAVAILABILITY AND BIOEQUIVALENCE

Bioequivalence and its determination, study design for the assessment of bioavailability and bioequivalence, factors influencing bioavailability and bioequivalence. Correlation of in vitro dissolution & in vivo bioavailability.Statistical concepts in estimation of bioavailability and bioequivalence. **8 hours**

UNIT VII SAMPLE PREPARATION TECHNIQUES

Protein precipitation, Liquid –Liquid extractions, Solid-Liquid extraction, Hybrid extraction techniques. Solvents used for extraction procedures, Identification of drug metabolites in biological fluids using qualitative spectroscopic and chromatographic techniques. **7 hours**

UNIT VIIII DENTIFICATION OF DRUG METABOLITES IN BIOLOGICAL FLUIDS

Objectives of metabolite isolation – Bioavailability of drug metabolites – Principles of isolation of metabolites – Influence of Biological matrix in isolation – Principles of Metabolite identification – Use of Tandem mass spectrometry (MS-MS) in metabolite identification –

Isotopically labeled compounds in metabolite identification – Practical aspects for the identification of metabolites by mass spectrometry. **7 hours**

REFERENCE BOOKS:

1. H. G. Vogel: "Drug Discovery and Evaluation-Pharmacological Assays", 2nd edition, Springer Verlag, Berlin, Germany, 2002.
2. Robert A.Turner: "Screening Methods in Pharmacology"
3. M. N. Ghosh: "Fundamentals of Experimental Pharmacology", 2nd edition, Scientific Book Agency, Calcutta, India, 1984.
4. D. R. Laurence and A.L. Bacharach: "Evaluation of Drug Activities: Pharmacometerics", Vol. 1, Academic Press, London, U.K., 1964.
5. David R. Gross: "Animal Models in Cardiovascular Research", 2nd edition, Kluwer Academic Publishers, London, U.K., 1994.
6. A handbook of Bioanalysis and Drug metabolismby Gary Evans
7. Shargel, L., Wu-Pong, S. and Yu, B.C.A., "Applied Biopharmaceutics and Pharmacokinetics" 5th Edition, McGraw-Hill, 2004.
8. Gibaldi. M. and Perrier, D., "Pharmacokinetics", 2nd Edition, Marcel Dekker Inc., 1982.
9. Pharmacopoeia of India, 3rd edition, volume –II, 1985.
10. Pharmacopoeia of India, 2nd edition, 1996, appendix XXXV.
11. Modern analytical techniques in the pharmaceutical- and bioanalysis by Dr. Istvan Bak.

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Course No.1210 ADVANCED PHARMACEUTICAL ANALYSIS II (THEORY)

LEARNING OBVJECTIVES:

The subject is aimed

1. To train students in advanced qualitative and quantitative analytical principles of sampling techniques, colorimetric reagents, quality control of excipients & packaging materials, stability tests and impurity profiling.
2. The student must be able to apply these concepts in various steps like stability testing of raw materials & finished drug products, sample preparation, routine quality control analysis and characterization of impurities in active pharmaceutical ingredients and pharmaceutical drug products in pharmaceutical industry.

UNIT I Analysis of Drugs in Dosage Forms

A detailed study of principles and procedure involved in various physicochemical methods of analysis including instrumental methods, (biological and microbiological methods to be completely excluded) of pharmaceutical preparations and dosage forms include in the Indian pharmacopoeia containing the following class of drugs.

a) Anti Malarial drugs b) Anti Neoplastic Drugs

c) Antibiotics d) Anti viral drugs **9 hours**

UNIT II Analysis of Drugs in Dosage Forms

A detailed study of principles and procedure involved in various physicochemical methods of analysis including instrumental methods, (biological and microbiological methods to be completely excluded) of pharmaceutical preparations and dosage forms include in the Indian pharmacopoeia containing the following class of drugs.

a) Steroidal Harmones b) Vitamins

c) Anti tubercular drugs d) Sulfonamides **6 hours**

UNIT III Analysis of Drugs in Dosage Forms

A detailed study of principles and procedure involved in various physicochemical methods of analysis including instrumental methods, (biological and microbiological methods to be completely excluded) of pharmaceutical preparations and dosage forms include in the Indian pharmacopoeia containing the following class of drugs.

a) Adrenergic drugs b) Diuretics

c) Anti hypertensive drugs **6 hours**

UNIT IV Analysis of Drugs in Dosage Forms

A detailed study of principles and procedure involved in various physicochemical methods of analysis including instrumental methods, (biological and microbiological methods to be completely excluded) of pharmaceutical preparations and dosage forms include in the Indian pharmacopoeia containing the following class of drugs.

a) Drugs acting on CNS (Local anesthetics, Sedatives and hypnotics, Anti depressants, Anti psychotics)

b) Analgesics and Anti Pyretics **6 hours**

UNIT V Reagents and Functional Group Based Analysis of Active Pharmaceutical Ingredients (API)

Principles and procedures involved in quantitative determination of the following functional groups a) Hydroxy b) Aldehyde c) Ketone d) Amine e) Methoxyl f) Ester g) Carboxyl

Analytical principles, procedures and applications involved in the use of the following reagents.

a) MBTH (3-methyl-2-benzothiazoline hydrazone).
b) Folin – Ciocalteu (FC) reagent.
c) 2,6- Dichloroquinone chlorimide.
d) 2,3,5- Triphenyl tetrazolium salt.
e) 1,2- naptho quininone -4- sulfonate.
f) Bratton-Marshall reagent.
g) *p*-Dimethyl amino cinnamaldehyde (PDAC) reagent. **8 hours**

UNIT VI Quality Control Tests of Pharmaceutical Dosage forms

a) Tablets b) Capsules c) Parentrals d)Liquid orals e) Ointments **7 hours**

UNIT VII Quality Control of Excipients & Packaging Materials

Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), gelling temperature, swelling temperature, loss on drying, residue on ignition, conductivity, congealing range, readily carbonizable substances and readily oxidizable substances, melting point and melting range. Excipients of interest, disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

Containers and Closures: Glass light transmission, chemical resistance – glass containers, powdered glass test, water attack test. Biological tests – plastics and other polymers: physicochemical tests – plastics, polyethylene containers, single unit containers and unit dose containers for non sterile solids and liquid dosage forms, customized patient medication packages, containers – permeation, metal containers, and rubber closures.

8 hours

UNIT VIII

Stability Testing

Solid state drug stability, accelerated stability studies, physical degradation of pharmaceutical products, prolonging the shelf life, effect of packaging materials on dosage form on stability, ICH guidelines- ICH basic principles, stability testing of new drug substance and formulations, photostability testing, Containers. WHO stability guidelines.Forced Degradation.

Impurity Profiling

Sources of impurities and their effect on drug stability and therapeutic action – Determination of impurities in bulk drugs: Isolation, characterization, and analytical methods – Formulation related impurities: Isolation, characterization, and analytical methods. ICH and WHO guidelines for impurity and related substances in the drugs.

10 hours

REFERENCE BOOKS:

1. Hiaguchi T, Brochmann E, Hanssen H, Hanseen H. Pharmaceutical analysis, CBS publishers &distributors, New Delhi, 2004.
2. Rowe RC, Sheskey PJ, Owen SC. Handbook of Pharmaceutical excipients. 5th ed., Pharmaceutical press, Britain, 2006.
3. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1987.
4. Ahuja S, Alsante KM. Handbook of isolation and characterization of impurities in pharmaceuticals. Academic press, California, 2003.
5. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publishers &distributors, New Delhi, 2008.
6. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I &II. 4th ed., CBS publishers &distributors, New Delhi, 2004.
7. Remington: The science and practice of pharmacy. 21st ed., vol. I &II, Lippincatt Willams &Wilkings, New Delhi, 2005.

8. Indian Pharmacopoeia. Controller of Publication. Delhi, 2007.
9. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
10. United States Pharmacopoeia. United States Pharmacoepial Convention, Inc, USA, 2006.
11. Methods of Drug Analysis by Gearin and Grobowski
12. Text book of Pharm Analysis by K.A.Connors.(John wiley
13. Spectroscopy by Silverstein.
14. Phamaceutical Analysis-Modern Methods by J.W.Munson(Marcel Dekker)
15. Pharmaceutical chemistry by L.G.Chatten(Marcel Dekker)

Course No. 1211 ADVANCED PHARMACEUTICAL ANALYSIS II (PRACTICAL)

1. Utility of MBTH reagent for the assay of Aldehyde drugs.
2. Utility of FC reagent for the assay of phenolic and amine drugs
3. Utility of DCQC reagent for the assay of phenolic drugs
4. Utility of 2,3,5, tri phenyl tetrazolium salt for the assay of drugs
5. Utility of 1,2- naptho quininone -4- sulfonate for the assay of amine drugs
6. Utility of BM reagent for the assay Primary aromatic amine drugs
7. Utility of PDAB and PDAC reagent for the assay of amine drugs.
8. Assay of Antibiotics
9. Assay of Vitamin
10. Assay of steroids
11. Assay of Sulfonamides
12. Assay of Adrenergic drugs
13. Assay of Diuretics
14. Assay of Anti neoplastic drug
15. Assay of Barbiturates
16. Assay of Antipyretic and analgesics
17. Assay of Antiviral drugs
18. Assay of Anti hypertensive drugs
19. Stability indicating assay method of any one drug.

Course No. 1212 comprehensive viva

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THIRD SEMESTER

Course No. 1313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No. 1314 Mid-term project review at the end of third semester.

Course No. 1315 Seminar on the selected topic

FOURTH SEMESTER

Course No. 1416 Thesis evaluation

Course No. 1417 Thesis viva-voce

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3. PHARMACEUTICAL TECHNOLOGY

FIRST SEMESTER

Course No. 3101 BIOSTATISTICS (THEORY)

(Common paper for all specializations)

Course No. 3102 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

LEARNING OBJECTIVES:

1. The course will help the student in understanding the various factors that contribute towards the bioavailability of a drug.
2. The student would gain knowledge on topics like drug interactions and pharmacokinetics. The student would be able to correlate *in vitro* and *in vivo* data and design experimental models for bioavailability studies.

UNIT I Drug Absorption, Distribution, Biotransformation and Excretion: Absorption of drugs, Significance of metabolisms involved in the absorption and bio transformation of drugs. Effects of Physico-Chemical, Pharmaceutical and Biological Factors on absorption, distribution, metabolism and excretion. Renal and Non renal Excretion Concept of clearance. **10 hours**

UNIT II Bioavailability and Bioequivalence of Drug Products: Factors-Assessment-Experimental designs and protocol for bioavailability and bioequivalence studies as per CDSCO, Schedule Y guidelines and GCP guidelines, *in-vitro and in-vivo* correlation of bioavailability, methods to enhance bioavailability. Statistical considerations in comparative bioavailability studies. **8 hours**

UNIT III Drug Interactions: Interaction of drugs with food, Classification of food drug interactions, models for estimation of pharmacokinetic parameters in food drug interaction studies. Effect of alcohol, smoking on drugs. Drug-Drug Interactions: factors contributing to drug interactions, Mechanisms of drug interactions with emphasis on pharmacokinetic interactions. **8 hours**

UNIT IV Pharmacokinetics: Basic consideration, pharmacokinetic models, Pharmacokinetic Parameters, Compartment modeling: One compartment model- IV bolus, IVinfusion, Extra-vascular; MultiCompartmentmodels; Twocompartmentmodel- IV bolus, IV infusion, Extra-vascular. Application of pharmacokinetics in new drug development and designing of dosage forms and novel drug delivery systems. Kinetics of multiple dosing-dosage regimens-

loading and maintenance doses of sustained release and continuous blood levels. Concepts of software used in the pharmacokinetic analysis Win Nonlin® and Kinetica. **10 hours**

UNIT V Non-linear and Clinical Pharmacokinetics: Concepts of linear and non-linear pharmacokinetics, Michaelis - Menten Kinetics characteristics. Basic kinetic parameters, possible causes of non-induction, non-linear binding, non-linearity of pharmacological responses. **7 hours**

UNIT VI Time Dependent Pharmacokinetics: Introduction, classification, physiologically induced time dependency, Chromo pharmacokinetics. **6 hours**

UNIT VII Non Compartmental Analysis based on Statistical Moment Theory Statistical Moments, Bioavailability, Clearance, half-life, Absorption kinetics, Apparent volume of distribution, fraction metabolites, Predicting Steady State Concentrations, Predicting time to steady state. **7 hours**

UNIT VIII Clinical Pharmacokinetics: Altered Kinetics in Paediatrics, Geriatrics, Kinetics in GI, Liver, Cardiac, Renal and Pulmonary Disease State. **7 hours**

REFERENCE BOOKS:

1. Pharmacokinetics, Milo Gibaldi, 2nd Ed.
2. Applied Biopharmaceutics and Pharmacokinetics, Leon Shargel, 5th Ed.
3. Biopharmaceutics and Clinical Pharmacokinetics, Robert E. Notari, 4th Ed.
4. Modern Pharmaceutics, Gilbert S. Banker, Christopher T. Rhodes, 4th Ed.
5. Clinical Pharmacokinetics and Pharmacodynamics – Concepts and Applications, Malcolm Rowland and Thomas N. Tozer, 4th Ed.
6. Drug Disposition and Pharmacokinetics, Stephen H. Curry, 3rd Ed.
7. Current concepts in the Pharmaceutical Sciences-Biopharmaceutics, James Swarbrick
8. Current concepts in the Pharmaceutical Sciences-Dosage Form Design and Bioavailability, James Swarbrick

Course No. 3103 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

1. Effect of particle size on the drug dissolution using drugs like aspirin, salicylic acid, nitrofurantoin
2. Effect of surfactant on the drug dissolution using drugs like sulfamethoxazole, nefidipine.
3. Effect of ointment base on drug diffusion using agar plate method and diffusion membrane.

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4. Determination of protein binding effect on drugs by using dialysis sac method using protein bound drugs.
5. Improvement in the dissolution of drugs by solid dispersion, cyclodextrin complexation etc.
6. To study the effect of sink condition on dissolution of drugs using discriminatory dissolution medium
7. To study the effect of permeation enhancers on drug diffusion using Franz-diffusion cell using suitable biomembranes.
8. Calculation of pharmacokinetic parameters using reported data.
9. Calculation of bioavailability and bioequivalence from the given data using different approaches.
10. In vitro-in vivo correlations using experimental data.
11. Preparation of experimental protocols for carrying out pharmacokinetic, pharmacodynamic, bioavailability and bioequivalence studies using suitable experimental designs for the given data.

Course No.3104 ADVANCED PHYSICAL PHARMACEUTICS (THEORY)

LEARNING OBJECTIVES:

On learning this subject, the student must understand

1. The concepts of solubility, solubilization, dissolution, compression, granulation, stability, stability testing, polymers and biodegradable polymers.
2. The student must be able to apply these concepts in preparing dosage forms that have enhanced dissolution and bioavailability, and in performing operations like tablet compression, stability testing and polymer characterization, required in the industry.

UNIT I Solubilisation of drugs in aqueous media:

Solubility, ideal solubility, activity coefficient, Hildebrand solubility approach, solubility parameter, estimating solubility and dissolution rate, apparent solubility enhancement from different solid phases, pH control, salt formation, buffers, cosolvents, dependence of solubilisation on solute properties, dependence of solubilisation on cosolvent properties, multiple cosolvents, surfactants, complexation, self-association and stacking complexation, inclusion complexes, combination of pH and complexation. **8 hours**

UNIT II Solubilising excipients in pharmaceutical formulations:

Introduction, oral formulations(water soluble organic solvents, surfactants, water insoluble organic solvents, water insoluble solids, cyclodextrins, microemulsion oral formulations); injectable formulations (water soluble organic solvents, surfactants, cyclodextrins, phospholipids, emulsions), oily injectable formulations and transdermal formulations.

8 hours

UNIT III Granulation and tablet characteristics: Granule formation and structure, particle size measurement and interpretation, shape determination, surface area, densities and packings, granule strength and friability, electrostatic properties, flow properties, ease of consolidation and mechanisms; control of tablet characteristics, such as , size and shape, tablet thickness, hardness, friability, disintegration, weight variation and content uniformity. **8 hours**

UNIT IV Compression: properties of tablets influenced by compression (elastic deformation, plastic deformation, brittle fracture, micro squashing, density and porosity, hardness and strength, specific surface, disintegration, dissolution); measurement of compressional force, energy expenditure, transmission of force. Consolidation, role of moisture, compression and consolidation under high loads, effect of friction, force distribution, development of radial force die wall lubrication, Heckle plots, energy involved in compaction, force-displacement curves, instrumentation of tablet machines, single station presses, multistation presses and signal processing.

8 hours

UNIT V Stability: physical, chemical and microbiological stability, quantitation of rate of degradation (zero order kinetics, first order kinetics, shelf life calculation), factors influencing reaction rate(temperature, pH, ionic strength, dielectric constant), methods of stabilizing dosage forms.

8 hours

UNIT VI Stability testing: ICH guidelines for stability testing, selection of batches and container closure systems, matrixing and bracketing design, storage conditions and testing frequency, climatic zones concept, stability testing in different stages of drug product life cycle, specific stability tests for various dosage forms. Photo stability studies, expiration dating, overages calculation.

8 hours

UNIT VII Polymers: Definitions, molecular weight averages, determination of molecular weight from solution viscosity, polymers as thickening agents, polymers in solutions, preparing

polymer solutions, thermodynamics of polymer solutions, gel formation, coacervation and microencapsulation, Pharmaceutical application of polymers.

8 hours

UNIT VIII Hydrogels (over view, synthesis, structure and properties, swelling ratio and water content, use in drug delivery, mucoadhesive hydrogels, sensitivity to pH changes, Polyethylene oxides), lipids(physical and chemical properties, applications in drug delivery), Biodegradable polymers as drug carriers (overview, factors affecting selection of polymer, factors affecting drug release, degradation mechanisms, polyesters, polyanhydrides). **8 hours**

REFERENCE BOOKS:

1. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third Edition, Informa Healthcare publishers.
2. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
3. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop k Khar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt. Ltd.
4. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.

Course No. 3105 ADVANCED PHYSICAL PHARMACEUTICS (PRACTICAL)

1. Stability studies on commercial tablets containing drugs like aspirin over two months at room temperature, 37°C and 45°C.
2. Stability studies on suspensions containing drugs like aspirin over 20 days at room temperature, 37°C and 45°C.
3. Determination of molecular weight by viscosity method, by Mark- Houwink equation for gelatin, methyl cellulose and polyvinyl alcohol.
4. Effect of temperature on the decomposition of bromophenol blue at three temperatures and two pH values
5. Effect of pH on the decomposition of aspirin.
6. Preparation of granules, drying by conventional dryer and fluidized bed dryer and comparing the granules by their flow properties.

7. Preparation of tablets by two different sets of granules with different flow properties; and finding the effect of variability in flow rate of granules on the weight variation of resultant tablets using drugs like Metronidazole.
8. Drawing the coacervation curve on a three component system graph (gelatin, sodium sulphate and water) for gelatin, sodium sulphate system.
9. Determination of bloom strength of gelatin.
10. Preparation of liquid paraffin emulsion in a colloid mill; determining the effect of duration of milling (up to 10 minutes), on the heat developed in the emulsion (temperature) and on the extent of micronization (globule size analysis).
11. Visiting a pharmaceutical industry and observing the modern equipment used in production and quality control.
12. Carrying out accelerated stability studies of disperse systems using freeze thaw technique and centrifugation techniques and prediction of shelf life.

Course No. 3106 Comprehensive viva

PHARMACEUTICAL TECHNOLOGY
SECOND SEMESTER

Course No. 3207 MODERN ANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

Course No. 3208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS (THEORY)(Common paper for all specializations)

Course No. 3209 NOVEL DRUG DELIVERY SYSTEMS (THEORY)

LEARNING OBJECTIVES:

On learning this subject, the student will understand the concepts in parenteral controlled release and will be able to design sustained or controlled or novel drug delivery systems

UNIT I Introduction to Parenteral Drug Delivery: Basic requirements of Parenteral Controlled release products; release profiles and biofate of intravenously administered systems and intramuscularly administered systems. **4 hours**

UNIT II Targeted Drug Delivery: Concepts of Targeting, Rationale of Drug Targeting, Carriers, Passive Targeting, Inverse Targeting, Active Targeting, First, Second, and Third order Targeting, Ligand Mediated Targeting, Physical Targeting, Dual Targeting, Double Targeting, Combination Targeting and problems associated with Targeted Delivery Systems. **4 hours**

UNIT III Targeting to the Brain, Targeting to the tumour and Targeting to the colon. **4 hours**

UNIT IV Sustained release formulations (encapsulated slow release granules, tableted slow release granulations, matrix tablets, drug complexes, ion activated systems, pH independent systems, altered density systems, colonic release systems). **8 hours**

UNIT V Controlled release formulations (osmotic pressure activated systems, hydrodynamic pressure activated systems, hydrodynamically balanced systems, the synchron system, the Penn kinetic system and bio adhesive system); *In vitro* and *in vivo* product evaluation and testing. **10 hours**

UNIT VI Design and Evaluation of Novel drug delivery systems: Ocuserts, transdermal drug delivery systems, *In situ* gelling systems, stimuli-sensitive "smart" polymers as drug delivery systems, glucose-responsive insulin delivery, polymer drug conjugates. **10 hours**

UNIT VII Novel carriers for controlled targeted drug delivery: Liposomes, Niosomes, Ethosomes, Transferosomes, Virosomes, polymeric nanoparticles, solid lipid nanoparticles, inorganic nanoparticles. **10 hours**

UNIT VIII Supra molecular systems, micelles/reverse micelles, lipoproteins, liquid crystals, resealed erythrocytes, carbon nanotubes, self-emulsifying drug delivery systems, Aquasomes, DQA somes, nanosuspension, nanocapsules. **10 hours**

REFRENCE BOOKS:

1. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K. Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
2. Lachman/Lieberman's The Theory and Practice of Industrial Pharmacy, Fourth Edition, Editors: Roop K Khar, S P Vyas, Farhan J Ahmed, and Gaurav K Jain, CBS Publishers and Distributors Pvt ltd, 2013.

Course No.3210: PRODUCT FORMULATION AND DEVELOPMENT (THEORY)

LEARNING OBJECTIVES:

The course gives a foundation on

1. Pre-formulation aspects involved in product development.

2. The student will be able to carry out the functions in the production division of a pharmaceutical industry by understanding the production, scale up techniques, quality control and packaging aspects of large scale manufacture of different dosage forms like oral liquids, tablets, capsules, parenterals etc.

UNIT I Pharmaceutical Product Development: Introduction to product development. Goals of preformulation, preformulation drug characterization in a structured program for different dosage forms. Influence of the parameters like intrinsic solubility, dissociation constant (pK_a), salts, solvents, partition coefficient, dissolution, polymorphism, particle size, shape and surface area, bulk density, flowability, hygroscopicity, stability indicating assays, and stability.

10 hours

Formulation Development of the following dosage forms:

UNIT II Oral Liquids: Monophasic Systems, Solutions: Vehicles, Additives Used in Formulation of Solutions, Oral Solution Products, Equipment, and Compounding, Filling of Liquids.

Biphasic Systems: Suspensions: Formulation and Manufacture of Suspension, Evaluation of Stability.

Emulsions: Microemulsions, Multiple Emulsions, Nanoemulsions Theories of Emulsification, Preparation of Emulsion, Equipment's Used for Emulsification, Stability, evaluation of Emulsions and their applications in drug delivery. **8 hours**

UNIT III Tablets: Types of Tablets, Components of a Tablets, Excipients, Granulation Methods, Mechanisms and Equipment, Processing Problems of Tablets, working of tablet Machines.

Tablet Coating: Comparison of different coating techniques procedures. Problems involved in each coating and trouble shooting. Equipment used for sugar coating, film coating, aqueous film coating, compression coating, enteric coating. Novel Drug Delivery. Technologies: Mouth Dissolving Tablets (Orasolv, Durasolv and Zydis Oral Fast Dissolving Dosage Forms), Oral Controlled Release Drug Delivery Systems, Osmotically Controlled release dosage forms, Nanocrystal Technology, IDD Formulations, Self-Repairing Tablets, Effervescent Tablets, Dissocubes. **10 hours**

UNIT IV Capsules and Microencapsulation: Types of gelatin and excipients used in the preparation of soft and hard gelatin capsules. Related advantages of soft and hard gelatin

capsules. Methods and equipment involved in the manufacturing of soft and hard gelatin capsules. Powder Filling, Choice of Excipients, Non Powder Filling, Storage, packaging and Stability Considerations of hard gelatin capsules. Micro encapsulation: Methods and Applications of Microencapsulation. **10 hours**

UNIT V Parenteral Products: Routes of administration, categories of Parenteral Products based on volume, formulation additives, development of Parenteral Products, Important parameters for Parenterals development, manufacturing of Parenterals, Quality Control requirements for Parenterals. **7 hours**

UNIT VI Opthalmic Products: Absorption of drugs in the Eye, product development of ophthalmic products, general safety considerations, conventional ophthalmic dosage forms, Packaging and Storage, approaches for efficient drug delivery.

Ophthalmic implants and shunts, Inserts, Non erodible ocular inserts, Erodible Ocular inserts, Contact lens, recent development of contact lenses (bandage lenses, therapeutic contact lenses in drug delivery, Silicone hydrogel based lenses), Collagen Shields and Implants, An anopthalmos and orbital implants, glaucoma shunts, particulate based drug carriers. **6 hours**

UNIT VII Topical Products: Structure of skin, Mechanisms of skin penetration, Percutaneous Absorption, Design of topical drug products (Gels, Liquid-Preparations, powders, Ointments), Novel Drug Delivery Systems for topical Drug Delivery (Micro emulsion, liposome, Transferons, Ethosones, Hydrogels), Evaluation of topical dosage forms.Rectal Products: Advantages, Rectal preparations. **6 hours**

UNIT VIII Pharmaceutical Packaging: Packaging Materials, Glass, Plastic, Metals, Rubber, Evaluation of Packaging materials. Special problems of container product interactions, pharmacopoeial specifications tests and standards for packaging materials. **6 hours**

REFERENCE BOOKS:

1. Lachmen/Liberman - Theory and Practice of Industrial Pharmacy, Roop K. Khar, S.P. Vyas, Farhan J. Ahmad, Gaurav K. Jain, 4th Ed.
2. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B. Popovich, Howard C. Ansel, 9th Ed.

3. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton, 3rd Ed.
4. Remington – The Science and Practice of Pharmacy, 20th Ed.
5. Encyclopedia of Pharmaceutical Technology, James Swarbrick, 3rd Ed.
6. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman and Joseph B. Schwartz
7. Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R. and Gilbert S. Banker.
8. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis and H.A. Libermann.

Course No. 3211 PRODUCT FORMULATION AND DEVELOPMENT (PRACTICAL)

1. Preformulation studies of drugs like aspirin, sulfamethoxazole, nefidipine etc. using different excipients as per ICH guidelines.
2. Preparation and evaluation of matrix controlled drug delivery systems using suitable drugs like theorphylline, diclofenac, aceclofenac.
3. Formulation and evaluation of oral disintegrating tablets using suitable drugs.
4. Formulation and evaluation of transdermal patches
5. Preparation and evaluation of microcapsules using techniques like coacervation-phase separation, ionic gelation method.
6. Formulation of dry syrup and its evaluation.
7. Formulation and evaluation of gastric floating drug delivery system
8. Comparison of different gels using diclofenac/aceclofenac like drugs
9. Formulation of liposomes and their characterization using microscopy.
10. Formulation and evaluation of suspensions containing suitable drugs.
11. Studies on effect of emulsifying agents on the stability of emulsion.

Course No. 3212 Comprehensive Viva

THIRD SEMESTER

Course No.3313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No.3314 Mid-term project review at the end of third semester.

Course No.3315 Seminar on the selected topic.

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FOURTH SEMESTER

Course No.3416 Thesis evaluation.

Course No.3417 Thesis viva-voce.

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7. PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS

FIRST SEMESTER

Course No. 7101 BIOSTATISTICS (THEORY)

(Common paper for all specializations)

Course No. 7102 PHARMACEUTICAL ORGANIZATION AND PRODUCTION MANAGEMENT (THEORY)

LEARNING OBJECTIVES:

Through this course a thorough understanding about various facets of

1. Business development and organization like budgeting, entrepreneurship and management of personnel will be possible.
2. Understanding of an organization, operational management automation requirements are also explained. **75 hours**

UNIT I Meaning and Evolution of Management; Planning, Organizing, Staffing, Directing, Co-Ordinating, Reporting & Budgeting(POSDCORB),functions of management with reference to pharmaceutical management. Introduction to budgeting, budgetary control, types of budgets, entrepreneurship development, types of entrepreneurs & characteristics of entrepreneurs. **8 hours**

UNIT II Understanding Organization: Types of organization structures; line, line & staff & matrix organizational structure. Resistance to change; Authority& Responsibility; Organizational conflicts, Organizational Communication system. Theory –X, Theory –Y and theory-Z. Motivational Aspects, Maslow's hierarchy of needs, Hedge Berg two factor theory, group dynamics. **8 hours**

UNIT III Personnel management: Recruitment & selection, training & development, compensation, transfer, promotion, demotion policies, job evaluation, performance appraisal, industrial relations, grievance handling, stress management. Handling strikes, gheraos, arbitration and negotiations, enforcement of discipline, lay off and discharge. **9 hours**

UNIT IV Role of personnel manager: Professional Mangers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management. Rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. -Stress management. **9 hours**

UNIT V Operational Management: Nature and scope of production management: Types of manufacturing systems – batch production and selection: Process planning: Aggregate planning and Master production scheduling: Project management – project planning, scheduling Program Evaluation Review Technique (PERT) and Critical Path Method (CPM) use. **8 hours**

UNIT VI Materials Management: An introduction to materials management. Material requirement Purchase management, Inventory control, Material handling: Vendor selection Make or buy decision Negotiation: Cost – reduction techniques – Standardization codification and variety reduction: waste management: Value analysis. **9 hours**

UNIT VII Formulation and Production Management: Locating production and service facilities - layout planning and analysis. Material handling for various pharmaceutical products, service facilities and preventive maintenance in pharmaceutical companies-group and individual replacement. Introduction to automation requirements: supervisory control and data acquisition (SCADA) and programmable logic controller (PLC) based process controls. **9 hours**

UNIT VIII Introduction to accounting, book keeping, Systems of accounting, journal, ledger, trial balance and final accounts. Study of computer based systems for accounting with examples. **8 hours**

REFERENCE BOOKS:

1. The theory and practice of Industrial Pharmacy Leon Lachman, Ph.D., Lachamn Consultant Services, Inc. Garden City, New York. Herbert A. Lieberman, Ph.D., H.H. Lieberman Associates Inc. Consultant Services, Livingstom, New Jersey, Joseph L. Kanig, Ph.D, Kanig Consulting and Research Associates, Inc Ridgefield Connecticut. Third Edition (Indian Edition) Varghese Publishing House, Hind Rajasthan Building, Dadar Bombay 400017.1987.
2. Pharmaceutical Dosage Forms and Drug Delivery Systems Fifth Edition Howard C. Ansel, Ph.D., Professor and Dean, College of Pharmacy, The University of Georgia. Nicholas G. Popovich , Ph.d., Professor, School of Pharmacy and Pharmaceutical Sciences, Purdue University. Published by Lea & Febiger, Philadelphia, London. 1990.
3. Selected Topics in Industrial Pharmacy, Dr. N. Udupa, 1992, II Edition Varghese Publishing House, Bombay.
4. Admn. E.E. and Ebert RJ: Production and Operations Management, 6th Edition, New Delhi, Prentice Hall of India 1995.

5. Chunawalla and Patel: Production and Operations Management, Himalaya Publishing House.
6. Gopalakrishnan.P and Sudarshan M Hand Book Materials Management New Delhi Prentice Hall of India. 1994.
7. Dutta A.K. Integrated Materials Management New Delhi PhI1986.
8. Buffa E.S. and Sareen: Modern Production Management, New York, John Wiley 2002.
9. Koonz, Weihrich and Aryasri: "Principles of Management", Tata Mc Graw Hill.
10. Daft : "The Era of Management ",Cengage Learning, New Delhi.
11. K.Aswathappa: "Organizational Behavior – Text, Cases and games", Himalaya Publishing House, New Delhi,2008,
12. Aswathappa K: "Production and Operation Management", Himalaya Publishing House, Mumbai.
13. R.Panneerselvam:"Productions and operations Management",PHI Learning private limited,New Delhi,2009.
14. Modern Pharmaceutics, Second Edition, Revised & Expand (Volume40) Edited by Gilbert S. Banker, University of Minnesota, Minneapoils, Minnesota; Chistopher T. Rhodes, University of Rhode Island, Kingston, 1990 Marcel Dekker Inc., 270 Madison Avenue, New York 10016.
15. GMP for Pharmaceuticals forth edition by S. Willing, J. Stocker Marcel Decker series 1997.
16. I.P.., B.P., U.S.P. International Pharmacopoeia.

JOURNALS:

Journals related to National and International status to cover the syllabus.

Course No. 7103 PHARMACEUTICAL ORGANIZATION AND PRODUCTION MANAGEMENT (PRACTICAL)

1. Organization/ Business case presentations.
2. Survey of market research to collect information regarding management of a given disease and/or disorder.
3. Group discussions and case studies based on theory.
4. Layouts for production of API and Pharmaceutical formulations (Tablets, capsules, ophthalmic, parenteral and other formulations)

5. Preparation of trial balance, preparation of final accounts, inventory measurement methods

Course No. 7104: INDIAN DRUG REGULATORY AFFAIRS (THEORY)

LEARNING OBJECTIVES:

This course is aimed at giving all the required information regarding

1. The regulatory bodies in India, patenting and intellectual property rights.
2. Information regarding good clinical practices and WHO certification is also covered in the course.

UNIT I A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts / Laws (with latest amendments)

- Package commodities act
- Competition council of India
- Right to information act
- National Pharmaceutical Pricing Authority (NPPA) – Power to fix the maximum sale prices of bulk drugs specified in the First Schedule, calculation of retail price of formulation, power to revise price of bulk drugs and formulations, display of prices of non-scheduled formulations and price list thereof. Study of different forms to be used for submission of these approvals. **8 hours**

UNIT II Introduction to IPRs : Intellectual property (IP) versus conventional property. Introduction to 8 different IP mechanisms – patents, industrial designs, and layout designs, plant varieties, geographical indications, copyright, trademark, trade secrets; their characteristics, properties. usefulness of patents for researchers. Factors affecting choice of IP protection; penalties for violation / infringement.IPRs vs. Regulatory affairs- similarities and differences.

Patenting in India : Development of IP law in India. Patent legislation and introduction to current IP laws in India. Amendments in Indian Patent laws and their significance; Requirement for patenting- novelty, inventive step (non obviousness) and industrial application (utility). Patent specification & claims, patent infringement.Procedure for filing patent in India-provisional, complete, divisional, additional and conventional patent applications; forms and fee.Prior art search and sources of patent information – free and paid databases.Patent analysis and land-scaping.Patent Search Maps.Infringement analysis.Concepts of Patent writing in India. Patent cooperation treaty (PCT) route of filing for International patents. **8 hours**

UNIT III Schedule M, M1, M2 & U general requirements and special provisions, DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal provisions related to production of Active Pharmaceutical Ingredients (APIs), other raw materials (including packaging materials) used in drugs & cosmetics.

Schedule M, M1, M2 &U general requirements and special provisions, DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal provisions related to production aspects of various drugs & cosmetic formulations (solid, parenteral and semi solid preparations).

Pilot plant scale- up techniques: Pharmaceutical pilot plant, pilot plant design, case studies for above preparations. Basic requirements for design of product, facility, equipment selection and personnel. **9 hours**

UNIT IV Schedule M, M1, M2 &U general requirements and special provisions DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal provisions related to quality control & quality assurance aspects of various drugs & cosmetic formulations (solid, parenteral and semi solid preparations). **9 hours**

UNIT V General requirements and special provisions, DCGA & Central Drugs Standard Control Organization (CDSCO) regulatory requirements and other legal provisions related to marketing of various drugs & cosmetic formulations (solid, parenteral and semi solid preparation). Introduction to uniform code of marketing practices for the Indian pharmaceutical industry (UCPMP). **8 hours**

UNIT VI Indian Good Clinical Practices guidelines: National regulatory requirements for pharmaceutical development regarding clinical research practices. Current issues in GCP; standards for design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. Schedule Y of Indian Drugs and Cosmetics Act 1940, Role of Regulatory affairs in Developing clinical trial protocols, Clinical phase, Preclinical Phase, Manufacturing phase and Marketing Phase. **9 hours**

UNIT VII Hierarchy and working flow of DCGA in India. Regulations and documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls. **9 hours**

UNIT VIII WHO certification, Trademarks and copyrights. National Accreditation Board for testing and Calibration Laboratory (NABL) certification and accreditation procedure. The International Organization for Standardization (ISO) 9000 series of quality systems standards, ISO 14000. **8 hours**

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REFERENCE BOOKS:

1. Drugs and Cosmetics Act, 1940 and its rules, published by Ministry of health and family welfare, Government of India.
2. Pharmaceutical Jurisprudence, G.K. Jani.
3. The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin
4. Medical Product Regulatory Affairs: Pharmaceutical, Diagnostics, Medical Devices – John J. Tobin and Gary Walsh.
5. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 2nd ed. – Douglas J. Pisano and David S. Mantus
6. Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu.
7. Pharmaceutical Patent Law – John R. Thomas.
8. Original laws published by Govt. of India.
9. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
10. Laws of Drugs in India by Hussain.
11. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.

Course No.7105 INDIAN DRUG REGULATORY AFFAIRS (PRACTICAL)

1. Testing of glass, rubber, plastic & metal packaging materials and preparing document for submission for approval.
2. Stability testing of an API, a pharmaceutical excipient, pharmaceutical dosage forms (solid, parenteral & semi solid) as per regulatory requirements and preparing required documents for submission
3. Quality control testing of finished product (solid, parenteral & semi solid dosage forms) as per Indian Pharmacopoeial requirements and preparing required documents for submission.
4. Patent writing for a given modification in the composition of a dosage form (minimum of 2 protocols).
5. Preparation of documents for submitting a patent file through Patent cooperation treaty (PCT) route.
6. Preparation of Dossiers to be submitted to the CDSCO/DCGA for a solid/parenteral/ semi solid dosage forms.

Course No.7106 Comprehensive Viva

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PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS

SECOND SEMESTER

Course No.7207 MODERN ANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

Course No. 7208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS (THEORY) (Common paper for all specializations)

Course no.7209 PHARMACEUTICAL MANAGEMENT SCIENCE (THEORY)

75 hours

LEARNING OBJECTIVES:

Through this course a thorough understanding about various facets of

1. Business development and organization like budgeting, entrepreneurship and management of personnel will be possible.
2. Understanding of an organization, operational management automation requirements are also explained.

UNIT I History, growth of Indian Pharmaceutical Industry. Global scenario of Indian pharmaceutical Industry and pharmaceutical market past and present. **8 hours**

UNIT II Pharmaceutical marketing : Introduction of pharmaceutical marketing, evolution of marketing concept; production oriented, sales oriented, promotion oriented and consumer oriented modern concept); market segmentation; concept of marketing mix, role of 7 P's (product, price, promotion, place, physical evidence, process, people) in pharmaceutical marketing management, corporate planning & strategy, pharmaceutical industrial marketing management. pharmaceutical marketing environment. E-Pharma marketing. **8 hours**

UNIT III Supply Chain Management : Scientific purchasing, quality control, problems of productivity, stores organization, location of stores, receiving, inspection of materials, issue from the store, control of stores and stocks, store accounting and records. ABC analysis, VED (Vital, Essential, Desirable), Fast moving, Dormant moving & Obsolete (FDO), Economic Order Quantity (EOQ). **9 hours**

UNIT IV Product design planning: Selection of product, new product development and product differentiation, pricing, promotion.

Marketing research: definition and importance, Pharmaceutical marketing research techniques, marketing information systems, pharmaceutical market research area.

9 hours

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UNIT V Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.

Legal Environment of Business: Need for government regulations; financial regulations, Equity market & SEBI, BIFR, FEMA and others, Contract Act and Sale of Goods Act, Company Act, Corporate tax laws -Direct and Indirect. **8 hours**

UNIT VI Market demands and sales forecasting: major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales forecasting. Social and legal and ethical issue of pharma marketing, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) code of pharmaceutical marketing practices, pharma guidelines for Direct-to-consumer advertising (DTC advertising) and Organization of Pharmaceutical Producers of India (OPPI) guidelines for Pharmaceutical marketing in India. **8 hours**

UNIT VII Strategic marketing : SWOT Analysis, GAP Analysis, Porter's five-force model, Ansoffs Matrix. Role of customer in marketing, importance of consumer behavior, customer relationship management (CRM). Nature of international marketing, evaluating international marketing, develop international marketing objectives, Formulate product marketing strategies, market entry and overseas distribution system, pricing. **9 hours**

UNIT VIII Functions of finance management; performance evaluation through ratio analysis & funds flow statement; project preparation, other ethical aspects of Pharmaceutical promotion and advertisement. Effect of Competition Council of India (CCI) on Pharma industry. **9 hours**

REFERENCE BOOKS:

1. Phillip Kotler: "Marketing Management", 11/e, Pearson Publishers, New Delhi, 2003
2. K Aswathappa: "Human Resource and Personnel Management", Tata McGraw Hill, New Delhi, 2007.
3. Aswathappa K: "Production and Operation Management", Himalaya Publishing House, Mumbai.
4. I.M Pandey: "Financial Management", 9/e, Vikas Publishing, 2004
5. Rajan Saxena: "Marketing Management, 2/edition, Tata McGraw Hill, New Delhi, 2008.
6. Shashi K Gupta & Sharma, Financial Management, Kalyani Publishers
7. Buffa, Production and Operations management
8. Business Environment, Francis Cherunilam, Himalaya Publications

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Course No. 7210 INTERNATIONAL DRUG REGULATORY ASPECTS (THEORY)

LEARNING OBJECTIVES:

This course covers all the regulatory aspects in

1. Product design including generic product designing. It covers the international drug regulatory aspects in its entirety right from the product approvals to stability testing, quality evaluation and batch release.
2. Regulations put on excipients used in the formulation development.

UNIT I Generic drug product development: Introduction, Hatch-Waxman update, Drug product performance- in vitro, Abbreviated New Drug Application (ANDA) Regulatory Approval Process, paragraph IV drug product application. Bioequivalence and drug product assessment- in vivo, scale- up, post approval changes, post marketing surveillance, outsourcing Bioavailability and Bioequivalence studies to Contract Research organizations. Formats for marketing authorization submission to WHO, USFDA, EU. Data privacy Protection, Pharmaceutical Labeling, Advertising and Promotion, Risk Management in regulatory affairs.

9 hours

UNIT II Regulatory requirements for product approvals: Active Pharmaceutical Ingredients, Biologics, novel therapies, special categories [Over - the - counter (OTC) products, herbal medicines and Homeopathics]. Obtaining New Drug Application (NDA), ways and means of US Registration for foreign drugs, Chemistry, Manufacturing and controls (CMC), Post approval Regulatory affairs, Regulation for combination products (Controlled release systems), medical devices, Environmental concerns and regulations. 21 Code of Federal Regulations (CFR) Part 11 and LIMS (Laboratory Information Management System). **8 hours**

UNIT III FDA Approval indications and other considerations: Data procession for Global submission, Text and Tabular exposition- Common Technical Document (CTD)/ electronic Common Technical Document (eCTD) format, working with contract research organization (CRO), industry and FDA liaison, role of European Commission Competent Authorities and Notified Bodies and USFDA authorities. **9 hours**

UNIT IV Nonclinical drug development: Global submission of Investigational New Drug application (IND), New Drug application (NDA), Abbreviated New Drug Application (ANDA), Investigational medicinal product Dossier (IMPD) & Investigator Brochure (IB), new product applications for global pharmaceutical product approvals, US NDA vs. Global CTD Formats, ANDA & Supplemental Abbreviated New Drug Application (SNDA), CTD and eCTD for registration of pharmaceuticals for Human use, combination products & controlled release systems. **8 hours**

UNIT V Centralized procedure for marketing authorization: legal basis – scope. Procedure for submission of application – preauthorization, inspections (GMP inspection) – pre authorization inspection (GCP inspection) – Scientific evaluation of the application – CPMP (Committee for Proprietary Medicinal Products) opinion and follow up action. **8 hours**

UNIT VI Harmonization of regulatory requirements- The International Conference on Harmonization (ICH) process, guidelines to establish quality, safety and efficacy (carcinogenicity studies - need for carcinogenicity studies of pharmaceuticals and testing for carcinogenicity of pharmaceuticals, Genotoxicity- a standard battery for Genotoxicity testing of pharmaceuticals) of drug substances and products. Study of ICH common technical documents, harmonization of pharmacopoeial standards. Health Insurance Portability and Accountability Act of 1996 (HIPAA)- A new requirement to clinical study process, Code of Federal Regulations (CFR)/ International Conference on Harmonization (ICH) / EU GCP obligations of Investigators, sponsors & monitors. **9 hours**

UNIT VII Stability Testing of New Drug Substances and Products Stability Testing: Photo-stability testing of new drug substances and products, stability testing for new dosage forms, bracketing and matrixing designs for stability testing of new drug substances and products. Evaluation of stability data, impurities in new drug substances, impurities in new drug products, guidelines for residual solvents. **8 hours**

UNIT VIII Quality evaluation and batch release: change control, deviation-(planned and unplanned), corrective action and preventive action (CAPA), Handling of non-conformance, vendor evaluation process, out of specification (OOS), batch reconciliation and finished goods release, market recalls & market complaints.

Joint International Pharmaceutical Excipients Council (IPEC) – Pharmaceutical Quality Group (PQG) Good Manufacturing Practices guidelines for pharmaceutical excipients. **8 hours**

REFERENCE BOOKS :

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series,Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition, Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.

5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams
8. HIPAA and Human Subjects Research: A Question and Answer Reference Guide by Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
9. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
10. Drugs: From Discovery to Approval, Second Edition by Rick Ng
11. New Drug Development: A Regulatory Overview, Eighth Edition by Mark Mathieu
12. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
13. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
14. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
15. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh

Course No.7211 INTERNATIONAL DRUG REGULATORY ASPECTS (PRACTICAL)

1. The general stages of drug development from R & D to marketing.
2. List the various types of manufacturer – FDA interactions that can occur during the drug development process.
3. Requirements for registration of ANDA as per ICH CTD/eCTD format.
4. Preparation of documents required for paragraph IV drug product application.
5. The general process by which new molecular entities (NMEs) are identified through pharmaceutical approaches.
6. Types of IND applications and structures of each type.
7. Requirements to complete an IND application and IND review process.
8. Requirements for a new drug application (NDA) & NDA submission process.
9. FDA's review of submitted NDA application/FDA's requirements for changes to an approved NDA
10. Clinical trial protocol preparation / clinical data requirements for approval of controlled release NDA

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11. Post NDA approval responsibilities of a sponsor.
12. General study of ICH guidelines with special reference to ICH Q7, Q8, Q9 and Q10
13. Compliance requirements for bioavailability & bioequivalence studies.
14. Patent challenge/ non infringement case studies.
15. Qualification of disintegration test apparatus/friability test apparatus/dissolution test apparatus
16. Qualification of UV-Vis spectrophotometer.
17. Comparison of D & C Act with that of other regulations such as USFDA, UKMCA, EDQM, South Africa MCC, Brazilian ANVISA, Australian TGA

Course No.7212 Comprehensive Viva

THIRD SEMESTER

Course No. 7313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No. 7314 Mid-term project review at the end of third semester.

Course No. 7315 Seminar on the selected topic.

FOURTH SEMESTER

Course No. 7416 Thesis evaluation.

Course No. 7417 Thesis viva-voce.

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8. PHARMACEUTICAL ANALYSIS AND QUALITY CONTROL

FIRST SEMESTER

Course No. 8101 BIOSTATISTICS (THEORY)

(Common paper for all specializations)

Course No. 8102 ADVANCED PHARMACEUTICAL ANALYSIS I (THEORY) (Paper common with Pharmaceutical Analysis and Quality Assurance)

Course No. 8103 ADVANCED PHARMACEUTICAL ANALYSIS I (PRACTICAL) (Paper common with Pharmaceutical Analysis and Quality Assurance)

Course No. 8104 QUALITY CONTROL OF PHARMACEUTICALS (THEORY)

LEARNING OBVJECTIVES:

1. To train students in advanced qualitative and quantitative analytical techniques in 1.Sampling, quality control of excipients, inprocess quality control and analysis of herbal products.
2. The student must be able to apply these concepts in various steps like analysis of raw materials & finished drug products, sample preparation, routine quality control and different phases of validation in quality control lab or pharmaceutical industry.

UNIT I Sample collection and Preparation for Analysis

Importance of sampling techniques – Sampling techniques – Random, stratified, systematic, cluster, for quality control – Sample preparation – Separating analyte from interferants – Extraction – Automated extraction – Solid phase extraction – Solid phase micro extraction – Super critical fluid extraction and microwave assisted extraction. **7 hours**

UNIT II In Process Quality Control

In process control during component manufacture – Solid dosage forms – Liquid dosage forms – Semi solid dosage forms – Inhalations – Sterile solutions – Novel drug delivery systems – Various IP, BP, USP Methods. **8 hours**

UNIT III Process Analytical Technology (PAT)

Implementation of process analytical technologies in the industrial settings – Generalized process analytical works – PAT applications – Chemometrics – Online applications in pharmaceutical industries. **7 hours**

UNIT IV Performance Evaluation Methods

In vitro dissolution studies for solid dosage forms – In vitro drug dissolution testing models – method interpretation of dissolution data – Bioavailability studies and bioavailability testing

protocol and procedures – In vivo methods of evaluation and statistical treatment – In vitro invivo correlation (F2 Factor) – Various in-vitro and in- vivo models. **7 hours**

UNIT V Quality Control of following

a. Liquid Oral Dosage Forms& Parenterals

b. Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), gelling temperature, swelling temperature, loss on drying, residue on ignition, conductivity, congealing range, readily carbonizable substances and readily oxidizable substances, melting point and melting range.

c. Types And Tests assuring Quality Of Glass **8 hours**

UNIT VI Herbal Products Analysis

Study of method procedure, drugs of formulations standard requirements of herbal medicines, traditional and folk remedies, preparation & their quality, safety and efficaly assessment & use for acceptance by FDA. **8 hours**

UNIT VII Biological Standardization

Biological Standardization: General Principles, Scope & limitations of Bioassays. Bio- assays of some Official Drugs. Pyrogen - chemistry and properties of bacterial pyrogens and endotoxins.

Mechanisms of action of pyrogens. Pharmaceutical aspects, pyrogen test of IP compared to that of BP & USP. Interpretation of data, Comparison of LAL and other pyrogen tests.

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. Microbiological Limit Tests, Tests for effectiveness of antimicrobial preservatives . **8 hours**

UNIT VIII Bioassays

Detailed study of principles & procedures involved in bio assay of.

(a) Heparin, insulin, posterior pituitary

(b) Diphtheria, typhoid

Principles and Procedures involved in Biological tests of the following.

(i) Living contaminants in vaccines.

(ii) Histamine like substances

(iii) Determine of toxic elements **7 hours**

REFERENCE BOOKS:

1. Brewer, R. F., "Design of Experiments for Process Improvement and Quality Assurance", Narora Publishing House, 1996.
2. Sethi,P.D., "Quantitative Analysis of Drugs in Pharmaceutical Formulations", 3rd Edition, C.B.S. Publishers and Distributors, 2003.
3. Bakeev, K.A., "Process Analytical Technology", Blackwell Publishers, 2006
4. Indian and British Pharmacopoeia

Course no. 8105 QUALITY CONTROL OF PHARMACEUTICALS (PRACTICAL)

(Practicals based on Theory)

Course No. 8106 Comprehensive viva

PHARMACEUTICAL ANALYSIS AND QUALITY CONTROL
SECOND SEMESTER

Course No.8207 MODERN ANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

Course No. 8208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS (THEORY)(Common paper for all specializations)

Course no. 8209 VALIDATION OF INSTRUMENTAL METHODS OF ANALYSIS (THEORY)

LEARNING OBVJECTIVES:

Learning this subject should make student understand the scope and functional importance of

1. Documentation and validation in pharmaceutical field.
2. The student must be able to apply these concepts in various steps like development and validation of new analytical method, validation of equipment, cleaning validation, and utilities validation useful in pharmaceutical industry.

UNIT I Validation

a. Introduction, history, definition,
b. Types of validation, prospective validation, retrospective validation, concurrent validation, revalidation,
c. Validation Master Plan **8 hours**

UNIT II Process Validation of Solid Dosage forms

a. Process validation of low dose tablet manufacturing process
b. Uniformity of blend (US FDA guideline) for tablets subjected to content uniformity test as per USP
c. Process validation of compression machine giving details of control charts.

8 hours

UNIT III Sterilization Validation

a. Process validation of terminally sterilized product. Validation of sterilization process including heat distribution, heat penetration
b. studies, and sterility assurance level
c. Process validation of aseptically filled product with special emphasis on media fill test.

8 hours

UNIT IV Cleaning Validation

a. Validation of cleaning process.
b. Elements of validation protocol.
b. Determination of acceptable limits for cleaning process.
c. Factors to consider in setting the limits.
d. Numerical calculation of limits. **7 hours**

UNIT V Utilities Validation

a. Validation of water system- for production of DM water, distilled water
b. Validation of Air handling Units- classification of environment (class 100, 10,000, 1,00,000)
c. Performance qualification & parameter of cleanliness such as no. of airborne particles, microbes filter integrity test of HEPA filter, air velocity, air flow pattern, no. of air changes, pressure differentials etc. **8 hours**

UNIT VI Analytical Method Validation

a. Recommendation of ICH guideline- Definition of accuracy, precision, linearity, LOD, LOQ, range, robustness, ruggedness, specificity, system suitability test.
b. USP requirement of analytical validation- different category of assays.
b. Stability indicating methods.
c. Bio analytical method validation **7 hours**

UNIT VII Instruments calibration

a. Analyticalbalance calibration.
b. Calibration of weight box.

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b. Calibration of UV-spectrophotometer.
c. Calibration of IR spectrophotometer.
d. Calibration of HPLC system.
e. Calibration of Gas Chromatography instrument.
f. Performance check of HPLC/GC column.
g. Out of Calibration.

8 hours

UNIT VIII Equipment Validation

a. Definition of DQ, IQ, OQ, PQ.
b. Comparison of different types of liquid filling machines (vacuum / volumetric),
c. process capability of filling machines,
d. Performance qualification of bottle washing/ ampoules washing machines - challenge test.

6 hours

REFERENCE BOOKS:

1. R. Nash and Wachter, "Pharmaceutical Process Validation". Volume 129, Latest Edition. Marcel Dekker Inc., New York.
2. K.L. Williams, "Microbial Contamination Control in Parenteral Manufacturing". Latest Edition. Marcel Dekker Inc., New York.
3. Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice-USFDA.
4. J.T. Carstensen, C.T. Rhodes, "Drug stability: principles & Practices". Latest Edition. Marcel Dekker Inc., New York
5. www.ich.org – Q7 a guideline
6. www.fda.org
7. United State Pharmacopoeia
8. US-FDA guideline for bio analytical studies. Dekker Inc., New York
9. It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.

Course No. 8210 ADVANCED PHARMACEUTICAL ANALYSIS II (THEORY)

(Paper common with Pharmaceutical Analysis and Quality Assurance)

Course No. 8211 ADVANCED PHARMACEUTICAL ANALYSIS II (PRACTICAL)

(Paper common with Pharmaceutical Analysis and Quality Assurance)

Course No. 8212 comprehensive viva

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THIRD SEMESTER

Course No. 8313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No. 8314 Mid-term project review at the end of third semester.

Course No. 8315 Seminar on the selected topic

FOURTH SEMESTER

Course No. 8416 Thesis evaluation

Course No. 8417 Thesis viva-voce

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9. PHARMACEUTICS

FIRST SEMESTER

Course No. 9101 BIOSTATISTICS (THEORY)

(Common paper for all specialisations)

Course No. 9102 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)(Paper common with Pharmaceutical Technology and Industrial Pharmacy)

Course No. 9103 BIOPHARMACEUTICSAND PHARMACOKINETICS (PRACTICAL)(Paper common with Pharmaceutical Technology and Industrial Pharmacy)

Course No. 9104 ADVANCED PHYSICAL PHARMACEUTICS (THEORY)

(Paper common with Pharmaceutical Technology)

Course No. 9105 ADVANCED PHYSICAL PHARMACEUTICS (PRACTICAL) (Paper common with Pharmaceutical Technology)

Course No. 9106 Comprehensive Viva

PHARMACEUTICS

SECOND SEMESTER

Course No. 9207 MODERN ANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

Course No. 9208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS (THEORY)

(Common paper for all specializations)

Course No. 9209 INDUSTRIAL PHARMACY II (THEORY)

(Paper common with Industrial Pharmacy)

Course No. 9210 NOVEL DRUG DELIVERY SYSTEMS (THEORY)

(Paper common with Pharmaceutical Technology and Industrial Pharmacy)

Course No. 9211 NOVEL DRUG DELIVERY SYSTEMS (PRACTICAL)

(Paper common with Industrial Pharmacy)

Course No. 9212 Comprehensive Viva

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THIRD SEMESTER

Course No. 9313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No. 9314 Mid-term project review at the end of third semester.

Course No. 9315 Seminar on the selected topic

FOURTH SEMESTER

Course No. 9416 Thesis evaluation

Course No. 9417 Thesis viva-voce

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10. INDUSTRIAL PHARMACY

FIRST SEMSTER

Course No. 10101 BIOSTATISTICS(THEORY)

(Common paper for all specializations)

Course No. 10102 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)(Paper common with Pharmaceutical Technology and Pharmaceutics)

Course No. 10103 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL) (Paper common with Pharmaceutical Technology and Pharmaceutics)

Course No. 10104 INDUSTRIAL PHARMACY I (THEORY)

LEARNING OBJECTIVES:

This course gives a complete knowledge on

1. Formulation designing of various dosage forms like solid dosage forms, powder dosage forms, liquid dosage forms, semi-solid dosage forms, parenterals and aerosols.
2. The student will have a thorough understanding on the concepts of formulation design right from the stage of preformulation to scale – up.

UNIT I Pre-formulation studies:

a) Goals of preformulation, preformulation parameters, Methodology, Solid state, Properties, Solubility and Partition coefficient, Solubility, Drug excipient Compatibility.

b) Excipients used in pharmaceutical dosage forms:

c) Properties and selection criteria for various excipients like surfactant, viscosity Promoters, diluents, coating materials, plasticizers, preservatives, flavors and Colours.

Industrial unit operations relating to the manufacture of the following dosage forms:

UNIT II Solid dosage forms: Improved production techniques for tablets: New materials, process, equipments improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development , physics of tablet compression, computerization for in process quality control of tablets, types of tablets and their manufacture. Formulations, production and evaluation of hard and soft gelatin capsules.

UNIT III Powder dosage forms: Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms.

UNIT IV Liquid and Semi-solid dosage forms: Recent advances in formulation aspects and manufacturing of monophasic dosage forms. Recent advances in formulation aspects and manufacturing of suspensions, dry syrups and semi-solid dosage forms.

UNIT V Parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilizers and aseptic processing. Manufacturing of small and large volume parenterals and quality control.

UNIT VI Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosol formulation, Manufacture and quality control.

UNIT VII Aseptic processing operation: Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, Microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.

UNIT VIII Plant Design: Design of manufacturing facility as per current good manufacturing practices for the bulk production of the above mentioned dosage forms

REFERENCE BOOKS:

1. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third Edition, Informa Healthcare publishers.
2. Pharmaceutical Dosage Forms, Tablets, Volume I and II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
3. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop k Khar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt. Ltd.
4. The Theory and Practice of Industrial Pharmacy, Leon Lachman, H.A.liberman & J.L.Kanig; Varghese publishing House, Bombay.
5. Pharmaceutical Product Development, N.K.Jain, CBS Publishers and Distributors Pvt.ltd.
6. Law relating to Drugs & Cosmetics by Vijay Malik, Eastern Book Company.

Course No.10105 INDUSTRIAL PHARMACY I (PRACTICAL)

(Practicals based on Theory)

1. Preformulation studies of drugs like aspirin, sulfamethoxazole, nefidipine etc. using different excipients as per ICH guidelines.
2. Formulation and evaluation of oral disintegrating tablets using suitable drugs.
3. Preparation and evaluation of microcapsules using techniques like coacervation-phase separation, ionic gelation method.
4. Formulation of dry syrup and its evaluation.
5. Comparison of different gels using diclofenac/aceclofenac like drugs

6. Formulation and evaluation of suspensions containing suitable drugs.
7. Studies on effect of emulsifying agents on the stability of emulsion
8. Visiting a pharmaceutical industry and observing the modern equipment used in production and quality

Course No. 10106 Comprehensive Viva

INDUSTRIAL PHARMACY
SECOND SEMESTER

Course No. 10207 MODERNANALYTICAL TECHNIQUES (THEORY)

(Common paper for all specializations)

Course No. 10208 QUALITY ASSURANCE AND DRUG REGULATORY AFFAIRS (THEORY)(Common paper for all specializations)

Course No. 10209 INDUSTRIAL PHARMACY II (THEORY)

LEARNING OBJECTIVE:

This is an industry oriented course with information regarding the various aspects of

1. Equipment handling like working, validation and maintenance.
2. The student would understand the production, planning, control and documentation involved in an industry. Pharma promotion management and human resource development will also be covered in this course

UNIT I Pharmaceutical Equipment: Installation, Validation, Maintenance and working of the following:

Tablet Machines: Rotary tablet, Multi punch Coating Equipment : Pans, fluidized bed Dryers: Freeze, spray, fluidized bed and tray dryer Granulators: Rapid mixer, extruder-spheronizer Mixers/Milling: Planetary, double cone, triple roller mill, colloidal mill Filters: Plate and frame press, membrane filters, air filtration system (Laminar flow) and Aseptic Room Sterilization: Autoclave Homogenizers and High Pressure Homogenizer.

UNIT II Pilot Plant Scale-up techniques: Significance, Pilot study of some important dosage forms like tablets, capsules, sustained release dosage forms and liquid orals. Discussion of parameters like formula, equipment, product uniformity, raw material processing, physical layouts, personal requirements and reporting responsibilities.

UNIT III Quality Control: Process controls involved in manufacturing process of pharmaceutical dosage forms, statistical quality control charts and their applications in process control. Testing program and methods for testing quality of pharmaceutical dosage forms.

UNIT IV Stability studies: Introduction to ICH guidelines and ICH stability protocols for different pharmaceutical dosage forms.

UNIT V Industrial Safety: Industrial hazards due to fire accidents, mechanical and electrical equipment, chemicals and pharmaceuticals. Monitoring and prevention systems and maintenance of accident records.

UNIT VI Applications of optimization techniques: Optimization parameters, statistical design and techniques in product development and evaluation. Production optimization and its importance.

UNIT VII Production, Planning, Control and documentation: Production scheduling, forecasting, Vendor development, Capacity assessment, Production management, Production organization, Productivity, guide to manufacturing facilities of tablets, liquid orals and capsules.

UNIT VIII Pharma Promotion Management and Human resource development: Strategic issues in Pharma marketing, consumer behaviour in pharmaceuticals, market research, sales management, Brand management, supply chain management. Personnel training, job specification, job enlargement, labour welfare and training. Business leadership.

REFERENCE BOOKS:

1. Leon Lachman, H. A. Lieberman & J. L. Kanig : "The Theory and Practice of Indusrtrial Pharmacy", 3rd edition, Varghese Publishing House, Bombay, 1991.
2. Lachman/Lieberman's The Theory and Practice of Industrial Pharmacy, Fourth Edition, Editors, Roop K khar, SP Vyas, Farhan J Ahmad and Gaurav K Jain, CBS Publishers and Distributors Pvt. Ltd.
3. Pharmaceutical Product development by N. K. Jain, CBS Publishers and distributors Pvt. Ltd.
4. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, Charles Bon; Marcel Dekker Inc.
5. Pharmaceutical Production And Management by C.V.S.Subrahmanyam, Vallabh Prakasan Publishers
6. Pharmaceutical Dosage Forms, Tablets, Volume I and II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.

Course No.10210NOVEL DRUG DELIVERY SYSTEMS (THEORY)

(Paper common with Pharmaceutical Technology and Pharmaceutics)

Course No.10211 NOVEL DRUG DELIVERY SYSTEMS (PRACTICAL)

1. Preparation and evaluation of microcapsules with different polymeric coats
2. Preparation and evaluation of slow release granules
3. Preparation and evaluation of matrix tablets using different polymers
4. Preparation and evaluation of gastro retentive systems
5. Preparation and evaluation of transdermal patches
6. Preparation and evaluation of liposomes
7. Preparation and evaluation of mucoadhesive systems
8. Study of marketed novel drug delivery products

Course No.10212 Comprehensive Viva

THIRD SEMESTER

Course No. 10313 Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project.

Course No. 10314 Mid-term project review at the end of third semester.

Course No. 10315 Seminar on the selected topic

FOURTH SEMESTER

Course No. 10416 Thesis evaluation

Course No. 10417 Thesis viva-voce

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