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PHARMACOECONOMIC ANALYSIS OF END STAGE RENAL DISEASED PATIENTS UNDERGOING HEMODIALYSIS

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ABSTRACT

The increased prevalence of end stage renal disease (ESRD) in India and the treatment options are dialysis or kidney transplantation. The availability and affordability are two important issues in treatment of ESRD. Hemodialysis (HD) is inaccessible and not affordable by majority of population in India. To assess the direct and indirect cost of hemodialysis patients. This was a prospective, observational and interventional study conducted for 5 months period in a secondary care hospital. Patients undergoing hemodialysis were selected for the study. A 25 members undergoing hemodialysis were selected and the data was obtained along with cost details of 1025 sessions were studied. Health cost analyzed which includes medical (dialysis, erythropoietin, medications and investigations) and nonmedical costs (wages, food and transportation). The total cost per session was found to be 4265, total 1025 sessions were studied. In that 52% contributes direct medical costs, 19% contributes non-medical costs and 29% contributes indirect medical costs, since the patients were paying from their own pockets only the middle class people can undergo Hemodialysis. The health cost of treating a patient on HD in India is around Rupees 10,000-12,000 per month in subsidized dialysis units, and in private hospitals the health cost of treating a patient is around Rupees 20,000 and 30,000. This study concludes that medical cost spent more than other cost in patients undergoing hemodialysis units.

Key Words: Hemodialysis, End Stage Renal Disease, Erythropoietin, Pharmacoeconomic, Cost analysis.

INTRODUCTION

Pharmacoeconomic can be defined as the study of how individuals choose to allocate scarce pharmaceutical and health resources among competing alternatives and opt to distribute the product and services among members of the society. Newer diagnostic and therapeutic measures have emerged because of the advances of the medical field (Stejin J *et al.*, 2012). This prolongs the life span of human as well as increases the burden on chronic illness such as diabetes, hypertension and renal failure etc (Dhivya PS *et al.*, 2014). Reported that chronic renal failure becomes one of the public health problem world's wide bbecause of its incidence and prevalence economic burden and poor quality of life. The world wide incidence of chronic renal failure has doubled in the last 18 years and its progression to end stage disease has been expected to be doub'ed in next 15 years (Suja A, 2012). It is evident from the world wide data that more than one million end stage renal diseases. Patients are on renal replacement therapy, where as two million patients in need of that.[9] In India it is reported that the progression of chronic kidney diseases to ESRD is rapid due to the factors Such as lack of medical facilities poor control of risk factors and delayed referral to nephrologists (Ballal HS, 2007). The prevalence of CKD and ESRD are estimated as 8500 and 2070 per million respectively majority of the patients about 60% will discontinue the therapy with in four months it is estimated that in India about 120000 person suffering from ESRD

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ASSESSMENT OF DRUG-DRUG INTERACTIONS IN TREATMENT CHARTS OF HOSPITALIZEDPATIENTS

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ABSTRACT

Drug-drug interactions (DDIs) are common in drug therapy which can be avoidable and manageable if detected. Pharmacist plays an important role in identifying, resolving and preventing DDIs. A retrospective, observational study conducted in a tertiary care super speciality hospital, Rajahmundry, India from April to September 2015. The objective of the study was to assess the drug-drug interactions in treatment charts of hospitalized patients. Data of 95 patient's treatment charts were collected and recorded in the patient profile form, which consists of demographic details, case history, medical history, laboratory details and treatment details. DDI's were screened using Medscape, Micromedex, and Drugs.com. The age of patient's age ranges from 12-80 years and the majority of the patients were 18-60 years. We found 72 DDI's, major 33(45.30%), moderate 36(50.00%), minor 01(01.33%) and contraindicated 02(02.70%). The most common DDI's pairs were ciprofloxacin-Ondansetron, Cefopodoxime proxetil-ranitidine, and Ondansetron-Tramadol. This signifies the necessity of pharmacist to manage DDI's.

Key Words: Drug-drug interactions, ciprofloxacin-Ondansetron, Cefopodoxime proxetil-ranitidine, Ondansetron-Tramadol.

INTRODUCTION

A potential drug-drug interaction (pDDI) is related to the possibility of a drug to alter the effect of another drug when simultaneously administered. It is predictable and thus avoidable and manageable if detected at the early stage. (Almeida *et al.*, 2007). It is estimated that drug interaction occur in patients between 3% to 5% who receive few drugs and 20% drug interaction in patients who receive 10 to 20 drugs.(Ferreira Sobrinho *et al.*, 2006). The incidence of drug interactions is directly proportional to the increase in the number of drugs prescribed (Matos *et al.*, 2009). The number of drugs (poly pharmacy) use has been increased, due to multiple co-morbidities and complexity in drug treatment options for specific individuals. This leads to drug related problems such as adverse drug reactions (ADRs) and drug interactions. No drug is absolutely free from harmful effects. Drug-drug interactions can also cause partial or complete abolishment of treatment efficacy. The potential drug-drug interactions is considered in the benefit-risk evaluation of a medicinal product and can negatively impact on this balance either through increased incidence of adverse events or reduced efficacy. Risk factors for drug interactions related to the drug involved are high doses, route of administration, long time drug therapies, drugs with self-induced or saturable metabolism, substances with identical or similar pharmacological profile and drugs with steep dose-response curves for which moderate changes in plasma concentration may lead to significant increases in the drug effect.

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SIMULTANEOUS ESTIMATION OF ALISKIREN AND AMLODIPINE BY RP-HPLC AND ITS VALIDATION

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ABSTRACT

A simple, accurate, economical and precise reverse phase high performance liquid chromatographic (RP-HPLC) method has been developed for the simultaneous determination of Aliskiren and Amlodipine. The separation was achieved on Intersil C18 column (250 x 4.6 mm, 5 µm) as stationary phase with a mobile phase comprising of Methanol: KH_2PO_4 (80:20) in an isocratic mode, at a flow rate of 1 ml/min. The detection was monitored at 239 nm. The retention time of Aliskiren and Amlodipine were 2.869 min and 3.942 min respectively. The linearity was found to be in the range of 20-80 µg/ml for Aliskiren and Amlodipine respectively with correlation coefficient of 0.999. The proposed method was validated according to ICH guidelines for parameters like linearity, accuracy, precision and specificity. All validation parameters were within the acceptable range. The developed method was successfully applied for the estimation of Aliskiren and Amlodipine in pure and pharmaceutical dosage form.

KEYWORDS: Aliskiren, Amlodipine, RP-HPLC, Validation, Simultaneous estimation, ICH guidelines.

INTRODUCTION

Aliskiren (Figure 1) (2(*S*),4(*S*),5(*S*),7(*S*)-*N*-(2-carbamoyl-2-methylpropyl)-5-amino-4-hydroxy-2, 7-diisopropyl-8- [4-methoxy-3-(3-methoxypropoxy)phenyl]-octanamide hemifumarate[1] is used alone or together with other medicines to treat high blood pressure (hypertension). Aliskiren is a direct renin inhibitor, decreasing plasma renin activity (PRA)

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FORMULATION AND *INVITRO* COMPARATIVE EVALUATION OF ORODISPERSIBLE TABLETS OF OMEPRAZOLE

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ABSTRACT

In the present work, an attempt has been made to formulate oral dispersible tablets of omeprazole by three different methods. Conventional tabletting procedure was followed for the preparation of tablets. Nine batches of tablets were prepared and evaluated for general appearance and physical parameters, drug content, *in vitro* disintegration, *in vitro* dispersion, *in vitro* drug release, kinetic and stability studies. Formulations prepared by superdisintegrants addition method emerged as the best formulations, as they showed rapid *in vitro* disintegration time, *in vitro* dispersion time and drug release at the end of 5 min, apart from taste and excellent mouth feel compared to formulations prepared by sublimation and effervescent methods. It was concluded that oral dispersible tablets of omeprazole can be successfully formulated and will be used as a novel drug dosage form for pediatrics and geriatrics with improved patient compliance.

Keywords: Omeprazole, Orodispersible tablets, Superdisintegrants, Effervescent, Sublimation.

INTRODUCTION

Recent developments in technology have presented viable dosage alternatives for patients who have difficulty in swallowing the tablets or liquids. Traditional tablets and capsules administered with an 8-oz. glass of water may be inconvenient or impractical for some patients. Dysphagia or chewing solid dosage forms, which is a common problem of all age groups, particularly pediatrics and geriatrics, because of physiological changes associated with these groups [1]. Dysphagia is also associated with the number of medical conditions, including stroke, Parkin-son's disease, AIDS, head and neck radiation therapy and other neurological disorders, including cerebral palsy. Other categories that experience problems using conventional oral dosage forms include are mentally ill, uncooperative and nauseated patients, those with motion sickness, sudden episodes of allergic attack or coughing [2], sometimes, it may be difficult to swallow the conventional products due to unavailability of water [3]. These problems cause the need for delivering drugs to patients efficiently, and with few side effects have prompted pharmaceutical companies to engage in the development of new drug delivery systems. Oral dispersible tablets (ODT) are perfect fit for all this kind of patients. ODT is those solid dosage forms when put on the tongue, disintegrate or dissolve instantaneously, releasing the drug, within a few seconds without the need of water. When this type of tablet is placed into the mouth, the saliva will serve to rapidly disintegrate the tablet. The faster the drug into solution, quicker the absorption and onset of clinical effect. ODT release drug in the mouth for absorption through local oral mucosal tissues and through pregastric (i.e., oral cavity, pharynx and oesophagus), gastric (i.e., stomach) and post gastric (i.e., small and large intestine) [4]. In such cases, the bioavailability of some drugs may be increased due to absorption of drugs in oral cavity and also due to pregastric absorption of saliva containing dispersed drugs that pass down significantly greater than those observed from conventional dosage forms [5]. ODT are also known as

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Development and Validation of Stability Indicating RP-HPLC method for simultaneous estimation of Sacubitril and Valsartan in bulk and tablet dosage form

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ABSTRACT

The proposed study, a new stability- indicating RP-HPLC method has been developed for estimation of Sacubitril and Valsartan in bulk and tablet dosage form. The present method was a sensitive, precise, and accurate RP-HPLC method for the analysis of Sacubitrii and Valsartan. To optimize the mobile phase, various combinations of buffer and organic solvents were used on Kromasil-(250x4.6mm, 5µ) column. Then the mobile phase containing a mixture of Perchloric acid: Acetonitrile in the ratio of 50:50% v/v was selected at a flow rate of 1.0 ml/min for developing the method and the peaks with good shape and resolution were found resulting in short retention time, baseline stability and minimum noise. The retention times of Sacubitril and Valsartan were found to be 2.438min and 3.709min respectively. Quantitative linearity was obeyed in the concentration range of 24.25-145.25 and 25.8-154.8 µg/mL of Sacubitril and Valsartan respectively. The limit of detection and limit of quantification were found to be 0.090 µg/mL and 0.274 µg/mL (Sacubitril); 0.06 µg/ mL and 0.19 µg/mL (Valsartan) respectively, which indicates the sensitivity of the method. The high percentage recovery indicates that the proposed method is highly accurate. No interfering peaks were found in the chromatogram indicating that excipients used in injection formulations didn't interfere with the estimation of the drugs by the proposed HPLC method.

Keywords: RP-HPLC, Sacubitril, Valsartan, Validation.

1. INTRODUCTION

Sacubitril [1-3] is the first novel angiotensin receptor neprilysin inhibitor used along with angiotensine II receptor blockers in the treatment of heart failure and hypertension. Under normal conditions, neprilysin which is found in most of the tissues abounded in kidney breaks down some neutral endo peptidases (NEP) such as atrial natriuretic peptide, brain natriuretic peptide and c-type natriuretic peptide [4-7]. These peptides are released into theblood and activate receptors leading to vasodilatation, natriuresis and diuresis. Sacubitril is a prodrug, once metabolized it produce active metabolite which inhibits the neprilysin leading to increased circulation of vasopeptides and produce both vasodilation and vasoconstriction. Therefore, therapy that increases circulating concentrations of NPs through inhibition of neprilysin (neutral endopeptidase, NEP), the enzyme responsible for breaking down NPs, is considered an attractive therapeutic approach for a number of cardiovascular (CV) diseases, such as hypertension (HTN) and HF. The chemical structure of Sacubitril was given in fig 1.

Valsartan is new potent, highly selective angiotensin II receptor blocker [8-9], used as anti-hypertensive agent to treat hypertension, systolic dysfunction, heart failure, myocardial infarction and coronary artery diseases. Angiotensin II is produced from angiotensin I peptide and receptor stimulation leads to

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Original Article

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Development and Validation of Stability Indicating RP-HPLC method for simultaneous estimation of Epalrestat and Pregabalin in bulk and tablet dosage form

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ABSTRACT

The proposed study, a new stability- indicating RP-HPLC method has been developed for estimation of Epalrestat and Pregabalin in bulk and tablet dosage form. The present method was a sensitive, precise, and accurate RP-HPLC method for the analysis of Epalrestat and Pregabalin. To optimize the mobile phase, various combinations of buffer and organic solvents were used on Xterra-(150x4.6mm, 5µ) column. Then the mobile phase containing a mixture of Ammonium acetate buffer (pH 10): ACN 70:30 % v/v was selected at a flow rate of 1.0 ml/min for developing the method and the peaks with good shape and resolution was found resulting in short retention time, baseline stability and minimum noise. The retention times of Epalrestat and Pregabalin were found to be 2.516 min and 3.132 min respectively. Quantitative linearity was obeyed in the concentration range of 37.5-225 and 18.75-112.5 µg/mL of Epalrestat and Pregabalin respectively. The limit of detection and limit of quantification were found to be 0.19µg/mL and 0.57µg/mL (Epalrestat); 0.50µg/ mL and 1.51 µg/mL (Pregabalin) respectively, which indicates the sensitivity of the method. The high percentage recovery indicates that the proposed method is highly accurate. No interfering peaks were found in the chromatogram indicating that excipients used in injection formulations didn't interfere with the estimation of the drugs by the proposed HPLC method.

Key Words: Stability RP-HPLC, Epalrestat and Pregabalin, Validation

INTRODUCTION

Epalrestat[1-8] is a carboxylic acid derivative and a noncompetitive and reversible used for the treatment of which is one of the most common long-term complications in patients. Chemically, Epalrestat is 4-[4-(4-chlorophenyl)-4-hydroxypiperidin-1-yl]-1-(4-fluorophenyl) butan-1-one. Chemically, Epalrestat is unusual in that it is a drug that contains a group. Aldose reductase is the key enzyme in the polyol pathway whose enhanced activity is the basis of diabetic neuropathy. Aldose reductase inhibitors (ARI) target this enzyme. Out of the many ARIs developed, ranirestat and fidarestat are in the trial stage. Others have been discarded due to unacceptable adverse effects or weak efficacy. Epalrestat is the only ARI commercially available. It is easily absorbed into the neural tissue and inhibits the enzyme with minimum side effects.The chemical structure of Epalrestat was given in fig 1.

Pregabalin[9-17] is an anticonvulsant drug used for neuropathic pain, as an adjunct therapy for partial seizures, and in generalized anxiety disorder. It was designed as a more potent successor to gabapentin. Chemically it is (3S)-3-(aminomethyl)-5-methylhexanoic acid. Pregabalin is marketed by Pfizer under the trade name Lyrica. It is considered to have a dependence liability if misused and is classified as a Schedule V drug in the U.S. The chemical structure of Pregabalinwas given in fig 2.

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A PROSPECTIVE OBSERVATIONAL STUDY ON PRESCRIPTION PATTERN, DRUG UTILIZATION AND AUDIT FOR THE TREATMENT OF TUBERCULOSIS IN A TERTIARY CARE HOSPITAL IN ANDHRA PRADESH

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Abstract:

Introduction: *TB ranks as the second leading cause of death from an infectious disease worldwide, after the human immunodeficiency virus (HIV). Tuberculosis is caused by a bacteria called Mycobacterium tuberculosis that most often affects the lungs. Tuberculosis is a curable and preventable disease. Early diagnosis and adequate treatment of infectious patients with pulmonary TB are necessary to reduce transmission of tuberculosis and ultimately to achieve elimination of TB. If TB is detected early and properly treated using a combination of medicines for 6 to 9 months, the patients quickly become noninfectious and are eventually cured.* ***Objective:*** *The objective of the observational study is to evaluate the prescription pattern, drug utilization and the audit of anti-TB drugs usage in a tertiary care hospital in Rajahmundry, Andhra Pradesh.* ***Methodology:*** *The study design is a prospective observational study. A total of 80 cases related to treatment of TB were investigated. The inclusion and exclusion criteria include patients with pulmonary TB admitted as in patients in the hospital, patients with age group 15-80years of both men and women, patients with active or inactive TB taking anti-tubercular treatment and pregnant and lactating women. The data sources include patient case sheets, prescriptions issued and discharge medication sheet, WHO guidance on essential drugs and by interacting with physicians and patients.* ***Results and Conclusions:*** *Men are more prone(62.5%) to TB than women(37.5%). In all age groups men are more than females among the TB patients. Hypertension ,diabetes, COPD and thyroid are more prevalent co-morbid diseases in TB patients. 4-drug combinations consisting of rifampicin, isoniazid, ethambutol and pyrazinamide are most widely prescribed(86.25%). WHO suggested 7 essential drugs for TB out of which only 4 drugs were prescribed in the hospital. In most of the cases of mono drug therapy and combination therapy, the drugs are used at larger doses than the WHO suggested doses. Hence it is suggested that the WHO recommended all essential drugs may be used either alone or in combinations at the doses suggested*

Key Words: *Prospective observational study, Prescription pattern, Drug utilization, Prescription audit, Anti tubercular drugs.*

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Available online at: http://www.iajps.com **Research Article**

A PROSPECTIVE OBSERVATIONAL STUDY ON PRESCRIPTION PATTERN DRUG UTILIZATION AND AUDIT FOR THE TREATMENT OF DIABETIES MELLITUS IN A TERTIARY CARE HOSPITAL IN ANDHRA PRADESH.

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Abstract:

Introduction: *Diabetes is the most common metabolic disorder in Indian community. It is a silent disease that has become more prevalent with increased age. Despite the advances in understanding the disease and its management, the mortality and morbidity of the disease is increasing* ***Objective:*** *The objective of the study is to evaluate the prescription pattern, drug utilization and audit for the treatment of diabetes mellitus in a tertiary care hospital in Rajahmundry.* ***Methodology:*** *The study design is a prospective observational study. A total of 150 cases related to anti diabetic treatment were investigated in a tertiary care hospital in Rajahmundry, Andhra Pradesh. Inclusion and Exclusion Criteria include patients with diabetes mellitus admitted as in-patients in the hospital and Patients with age group 20-70 years of both men and women are included. Pregnant and lactating women are excluded from the study and Patients who are unconscious, mentally retarded and who were suffering with psychiatric diseases are excluded from the study. The data sources include patient case sheets, prescriptions issued and discharge medication sheet, WHO guidance on essential drugs and by interacting with physicians and patients.* ***Results and Conclusions:*** *The diabetes is more prevalent among women than in men. Patients in the age group 51-60 years are more prone to diabetes than other age groups. The comorbid diseases in diabetic patients majorly include Hypertension, Hyperlipidemias, Thyroid, and Obesity. Cataract, Chronic foot ulcer, Neuropathy and Mild hypoglycemia are the major clinical manifestations in diabetic patients. Mono drug therapy in 36.6% cases, two drug therapies in 44.6% cases and three drug therapies in 18.6% cases is followed for the treatment of diabetes in the hospital. WHO suggested 18 drugs for mono therapy and 6 two drug combinations for diabetes. Only three drugs(Insulin, Metformin, Glimepiride) out of 18 suggested were used in mono therapy and only one 2 drug combination was used among the 6 suggested by WHO. Three 2 drug combinations other than those suggested by WHO are also used in the hospital. Anti diabetic drugs other than those suggested by WHO are also used to a large extent in the hospital. Hence, it is suggested that the WHO suggested Essential drugs be prescribed to the hospital for better patient care, safety and efficacy.*

Key words: *Prospective observational study, Prescription pattern, Drug utilization, Prescription audit, Anti-diabetic drugs.*

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A PROSPECTIVE OBSERVATIONAL STUDY ON PRESCRIPTION PATTERN UTILIZATION AND AUDIT OF ANTIBIOTIC DRUGS IN GOVERNMENTAL AND NON-GOVERNMENTAL HOSPITALS IN RAJAHMUNDRY

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Abstract:

Introduction: *Antibiotics are currently the most commonly prescribed drugs in hospitals worldwide. Healthcare is through both public and private sector facilities. About 80% of the healthcare in India is provided by the private sector and 93% of hospitals are private.* ***Objective:*** *The objective of the study is to evaluate prescription pattern, utilization & audit of antibiotic drugs in governmental and non-governmental hospitals in Rajahmundry, AP.* ***Methodology:*** *The study design is a prospective observational study. A total of 150 cases related to antibiotic treatment were investigated in Governmental and Non-governmental hospitals in Rajahmundry, AP. Inclusion and Exclusion Criteria include Patients who were hospitalized due to infections and were on antibiotic treatment were enrolled in the study. Patients in all age groups of both men and women are included. Patients who are unconscious mentally retarded and who were suffering with psychiatric diseases are excluded from the study. Pregnant and Lactating women are excluded from the study. The data sources include patient case sheets, prescriptions issued and discharge medication sheet. WHO guidance on essential drugs and by interacting with physicians and patients.* ***Results and Conclusions:*** *The antibiotic usage is higher in Non-governmental hospitals in the departments of General Medicine (47.44%), and Pulmonary (33.33%) when compared to the Governmental hospitals. 43% in General Medicine and 20.8% in pulmonary department. In the department of Trauma the antibiotic usage is more in Governmental hospital (12.5%) than in Non-governmental hospital (3.8%). The antibiotic usage is more in the age group 41-60 years in both Governmental (35.8%) and Non-governmental (43.59%) hospital. A total of 26 Antibiotic drugs are prescribed either alone or in combination in both Governmental and Non-governmental hospitals. Out of 44 WHO essential drugs only 13 drugs (29.5%) were in usage in governmental as well as non- government hospitals. About 18.7% and 40.9% of antibiotics used respectively in Governmental and Non-governmental hospitals are other than WHO suggested drugs. Non Steroidal Anti-inflammatory drugs, Antacids and Multivitamins are most frequently prescribed along with antibiotics in about 90-100% prescriptions. It is suggested that the WHO prescribed antibiotic drugs are only to be used in the doses prescribed to avoid possible Drug interactions and Adverse Drug Reactions.*

Key words: *Prospective observational study, Prescription pattern, Drug utilization, Prescription audit, Antibiotic drugs.*

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A PROSPECTIVE OBSERVATIONAL STUDY ON PRESCRIPTION PATTERN DRUG UTILIZATION AND AUDIT FOR THE TREATMENT OF WOMEN DISORDERS IN A TERTIARY CARE HOSPITAL IN RAJAHMUNDRY

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Abstract:

Introduction: *Women and men share many similar health problems but, women also have their own health issues which deserves special considerations. Many diseases affect both men and women alike but some diseases occur in women at high frequency.* ***Objective:*** *The objective of the study is to evaluate prescription pattern, drug utilization & audit for the treatment of women disorders in a tertiary care hospital in Rajahmundry.* ***Methodology:*** *The study design is a prospective observational study. A total of 86 cases related to women disorders were investigated in a tertiary care hospital in Rajahmundry, Andhra Pradesh. Inclusion and Exclusion Criteria include Patients who were hospitalized due to women disorders were enrolled in the study, Women patients of all age groups are included. Patients who are unconscious/mentally retarded and who were suffering with psychiatric diseases are excluded from the study.* ***Results and Conclusions:*** *Women disorders are more prevalent in the age groups 21-30 years and 31-40 years .PCOD and Ovarian cyst are the most prevalent diseases among women of 21-40 years of age. Diabetes, hypertension, thyroid, appendicitis, and CVS problems are most commonly observed co-morbid diseases associated with women disorders. Pain , irregular menstruation , bleeding with clots and heavy bleeding are commonly observed clinical manifestations . 5. For all women disorders hormones , anti-microbials, vitamin and mineral supplements are prescribed. Among the hormones Human chorionic gonadotropin (HCG) 5000units , Allylsternol 5mg , Medroxy progesterone 5mg are prescribed to a large extent. Among the anti-microbials metronidazole 100mg , cefiriaxone 250mg are prescribed widely. Only 5 out of 12 hormones and 8 out of 16 anti-microbials were as suggested by WHO. Drugs other than those suggested by WHO are also used to a large extent in the hospital. Hence,it is suggested that the WHO suggested Essential drugs be prescribed in the hospital for better patient care ,safety and efficacy.*

Key words: *Prospective observational study, Prescription patters, Drug utilization, Prescription audit, Women disorder.*

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DEVELOPMENT OF A NEW STABILITY INDICATING RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF SAXAGLIPTINE AND DAPAGLIFLOZIN AND ITS VALIDATION AS PER ICH GUIDELINES

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Abstract:

A new stability indicating RP HPLC method has been developed and validated for simultaneous estimation of Saxagliptine and Dapagliflozin in bulk and dosage forms. The method involves separation on XTerra C 18 column (150mm x 4.6mm x5µm particle size). The optimized mobile phase consists of phoaphate buffer (pH 4) and Acetonitrile (50:50v/v) with a flow rate of 1ml/min and UV detection at 225nm. Retention time was 2.1min (Saxagliptine), 2.8min (Dapagliflozin). Linearity range was 20-60ug/ml (Saxagliptine), 40-120ug/ml (Dapagliflozin). Accuracy was in the range of 99.99-100.50% for both drugs. Precision was 0.78% and 0.44% for Saxagliptine and Dapagliflozin. LOD and LOQ are 1.63ug/ml and 5.39ug/ml for Saxagliptine, 1.94ug/ml and 6.50ug/ml for Dapagliflozin. The method developed is more sensitive, accurate and precise than the methods reported earlier. Retention time and run time were also less and hence the method is economical. When applied for tablet assay, drug content was within 100.24-100.43 % of labeled content. Forced degradation studies indicated the suitability of the method for stability studies.

Key Words: *Saxagliptine, Dapagliflozin, RP-HPLC Method, Simultaneous estimation, Validation as per ICH guidelines, Forced degradation studies.*

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FORMULATION DEVELOPMENT AND OPTIMIZATION OF TELMISARTAN TABLETS EMPLOYING βCD STARCH 1500 AND SOLUPLUS

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Abstract:

The objective of the present study is optimization of telmisartan tablet formulation employing βCD, Starch 1500, and Soluplus by 2^3 factorial design to achieve NLT 85% dissolution in 10 min. Eight telmisartan tablet formulations were prepared using selected combinations of the three factors as per 2^3 factorial design. Telmisartan tablets were prepared by direct compression method and were evaluated.

The individual and combined effects of the three factors, βCD, Starch 1500 and Soluplus are highly significant ($P < 0.01$) in influencing the dissolution rate of Telmisartan tablets. Telmisartan tablet formulations F_5 and F_6 disintegrated rapidly in 20 and 40 seconds and gave very rapid dissolution of telmisartan, 96.1% and 95.8% in 10 min respectively. The increasing order of dissolution rate (K_1) observed with various formulations was $F_4 < F_1 < F_8 < F_2 < F_3 < F_7 < F_5 < F_6$. The polynomial equation describing the relationship between the response, percent drug dissolved in 10min (Y) and the levels of βCD (X_1), Starch 1500 (X_2) and Soluplus (X_3) based on the observed results was found to be $Y = 55.33 + 3.61(X_1) + 35.07(X_2) - 9.18(X_1 X_2) - 3.76(X_3) - 3.31(X_1 X_3) + 2.06(X_2 X_3) + 1.77(X_1 X_2 X_3)$ Based on the above equation, the formulation of optimized telmisartan tablets with NLT 85% dissolution in 10 min require βCD at 1:3.5 ratio of drug: βCD, Starch 1500 at 27.82% of drug and βCD content, and Soluplus at 1% of drug and βCD content. The optimized telmisartan tablet formulation gave 85.5% dissolution in 10min fulfilling the target dissolution requirement. Formulation of telmisartan tablets with NLT 85% dissolution in 10 min could be optimized by 2^3 factorial design.

Key words: *Formulation Development, Telmisartan tablets, Optimization, Factorial Design, βCD, Starch 1500, Soluplus*

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*Please cite this article in press as N.Tirumalesh and K. P. R. Chowdary, **Formulation Development and Optimization of Telmisartan Tablets Employing βcd Starch 1500 and Soluplus** , Indo Am. J. P. Sci, 2017; 4(06).*

Original Research Paper

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Clinical Research

A PROSPECTIVE OBSERVATIONAL STUDY ON SELF-MEDICATION PRACTICES AMONG UNDERGRADUATE PHARMACY COLLEGE STUDENTS

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B. Mary Prasanna Kumari

Kuchipudi Harinadh Baba

Ch. Sri Pavan Kumar

ABSTRACT The selection and use of medicines by individuals to treat self-recognized illness or symptoms. Self-medication includes the use of non-prescription drugs and a range of different alternative medicines such as traditional products food supplements and herbal remedies

Material and Methods

This was a prospective observational study done among 270 pharmacy students. Of all the years of undergraduate pharmacy students. It's a questionnaire based study and history of self-medication in last six was taken.

Study duration: January to June 2017

Study setting: The study was done in pharmacy colleges of Rajahmundry, AP, India.

Inclusion criteria: of sound mind, can communicate by one of the means viz. speaking or writing, inhabitant of study area, consuming any category of medication without prescription, being medication for family members without prescription.

Exclusion criteria: Inhabitant outside the study area, of insane mind, unable to communicate, faculty, drug consumers with valid prescription, pregnant students, chronic illness students.

Results & discussion: In this study we have taken 360 students out of which 270 pharmacy are willing to fill the questionnaire. Out of 270 students in which there are 162 males and 108 female students are carried out in our study, in this 243 students are single and 27 were married, and all are ethnicity of India only, this program me was conducted with 270 students and family history of employed were 162 and unemployed were 108. The most frequently requested category of drugs in this study were analgesics/antipyretics and other classes of drugs, there is not any argument against the use of analgesics and antipyretics on self-medication provided they are given with proper advice and not taken as treatment continuously as evidenced by other studies.

During an illness episode individuals commonly seek information and advice from a referral networks and this affects self diagnosis and treatment by providing reference points for perceptions of illness, by contributing knowledge by gained through experience and by sharing of medications.

Conclusion:

The study concluded that self-medication is found to be a common practice among the pharmacy graduates. Commonly used drugs are pain relievers, cough remedies; cold, creams etc are highly used by the students. The highlights the importance of impressing the students about the danger of self-medication. Nonetheless awareness should be constantly provided to the students for continuous safe self-medication.

KEYWORDS : Self medication, illness, perception, communicate, suppliments, analgesics, antipyretics

Introduction:

Self medication can be defincd as the use of drugs to treat self diagnosed disorders or symptoms, or the intermittent or continuous use of prescribed drugs for chronic or recurrent disease or symptoms.[1] It is a growing trend of self-care which has its positive and negative aspects.

In India, the drugs and cosmetics act 1940 (DCA), drugs and cosmetics rules 1945.DCA regulates the import, manufacture, distribution and sale of drugs and cosmetics.[2] Self medication is the first line of action which makes self medication a common practice worldwide.[3] When self medication ispracticed responsibly it reduces the load on medical services, decreases the time spent in waiting to see the physician and saves cost in especially in economically deprived countries with limited health care resources.[4] However this requires a certain level of knowledge and health orientation. [5] Additionally self medication practices are is exposed to the risk of increasing the burden and expensive it may results in ADH effects that will require medical attention. [15]

Self care: Self care behavior is not new but rather the oldest and mostly widely used of all forms of behavior that effects the health of individuals .however the use of the terms of health field is now the contemporary, self care is a response of developments and attitudes regarding the role of individuals that occur over the past 100 years and the rapid change in the organization content and delivery of forms helps survives also suggest another reason for maintaining the term self care and developing associated theory and concepts.[7,8]

Self care concepts: It is defined as substitute, supplementary or additive to personal care, or as a discrete component in the health care delivery system. As there are many authors and professionals concerned with health and self-care, self care is active; it is participatory rather than passive receiving of care or direction given by professionals.[9]

Products consumed during self medication:

Some products mark the underline disease and may cause several adverse effects of fatalities. For example in GERD gastro esophagus reflux disease, antacids can neutralize acid in the esophagus, but don't significantly affect gastric PH or prevent subsequent heart burn episodes. [5] Histamine receptor 2 antagonists (eg: ranitidine) also rapidly develop tolerance with repeated dosing, and exhibit an analgesic effect that may provide heartburn relief which leaving the esophagus exposed to the acid.[10]

Importance of self medication:

Students are willing and able to take more responsibility for their own health and by so doing a significant amount of resources could be utilized more in perusing areas than patient receiving consultation and prescription for minor alignments.[12]

ORIGINAL RESEARCH PAPER

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A STUDY ON ASSESSMENT OF HEALTH RELATTED QUALITY OF LIFE IN DIABETIC PATIENTS

Pharmaceutical

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Cherla Phani Sita Radhika Madhuri* Pharmacy Practice Department, Vikas Institute of Pharmaceutical Sciences, Rajahmundry *Corresponding Author

KEYWORDS

INTRODUCTION:

Diabetes mellitus is a chronic disorder that has been recognised by the Indian government as a major public health problem with far reaching consequences. Every diabetic patient's life is unique. Many cannot effectively control their disease but all patients are unanimous in their opinion that diabetes has had a huge impact on their lives. They feel psychologically overwhelmed by the numerous rules that the disease requires them to follow. An added burden for them is the micro- and macro-vascular complications associated with both short-term and long-term diabetes management. Assessing the quality of life (QoL) of patients is very difficult, due to the fact that each individual has their own subjective view on their physical, emotional and social well-being. This subjective opinion includes a cognitive element satisfaction; as well as emotional component happiness. A declining QoL and depression can strongly influence a patient's commitment towards controlling their disease

METHODOLOGY:

This was a prospective survey based study conducted for a period of six months to assess the quality of life of patients with diabetes, surveyed in a location of Rajahmundry jurisdiction by using a health related quality of life general questionnaire that is SF-36 which has the domains of physical functioning, role limitations due to physical health, bodily pain, general health, vitality, social functioning, role limitations due to emotional health, and mental health. . Quality- of-Life Questionnaire (SF-36) was applied to surveyed patients to collect their satisfaction towards the specific domain questionnaire. The questionnaire contains 36 questions under 8 domains. The score range from 0 to 100. In addition to dimension scores, two summary scales (the Physical Components Summary [PCS] and the Mental Components Summary [MCS]) can be derived from the scales, and the summary quality-of-life dimensions are also used in this study. Data were analyzed using simple mathematical equations.

RESULTS:

Out of 50 patients interviewed males are 52% and females are 48%. The economic status of the people were found to be 8% are with lower income, 58% with average income and 34% with higher income as we collected data in a multispecialty hospital lower income people found less as they unable to afford the hospital charges. In the total patients n=50 smokers were 10% and non- smokers were 90%. The patients who interviewed were 48% lower education, 20% higher education, 26% are graduates and 6% are postgraduates. The age grouped from 40-80years, a gap of 10 years between the groups. Out of 50 patients 26% are in range of 40-50 group, 34% in range of 50-60 group, 24% in range of 60-70,and 16% in range of 70-80group. The co- morbid conditions with the patients are found to be 52% with hypertension and 2% with cardiovascular disorder.

Out of fifty diabetic patients surveyed, male 26(52%) and female 24(48%). The score ranges were 0-100, zero indicates least quality of life and 100 indicate maximum quality of life. The mean scores found in wellbeing 17.53, social 59.29, physical 56.35, physical health 31.75, pain 61.65, general health 54, energy 55.58 and emotional problems 26. The reasons may be due to economic, social and personnel problems

Table No. Demographics details of surveyed population (n=50)

Parameter	Number (Percentage)
Gender	
Male	26 (52%)
Female	24 (48%)
Age	
40-50	13(26%)
50-60	17(34%)
60-70	12(24%)
70-80	08(16%)
Education status	
Lower	24(48%)
Higher	10(20%)
Graduation	13(26%)
Post graduation	03(06%)
Economic	
Lower	04 (08%)
Middle	29 (34%)
Higher	17 (58%
Smoking	
Smoker	05 (10%)
Non smoker	45 (90%)
Co-morbidities	
Hypertension	26 (52%)
Cardiovascular –disorder	02 (04%)

Table No 2: Comparison of mean score of Quality Of Life domains (n=50)

Domains	Mean Score (0-100)	Standard Deviation (±)
Physical functioning	56.35	36.76
Physical health	31.75	12.02
Emotional problems	66.66	26.00
Energy /Fatigue	55.58	14.14
Emotional wellbeing	17.53	17.53
Social functioning	59.29	20.80
Pain	61.65	11.95
General health	54.00	19.09

CONCLUSION:

This study demonstrated that the diabetic patient has different quality of life in different domains due to various reasons. Clinical Pharmacist identifies the reasons and prevents to improve the quality of life.

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A Survey on Home Storage of Medicines in South India

Ch PSR Madhuri, Mahendra Kumar BJ

Abstract: *Medicines are kept in households worldwide for first aid, treatment of minor ailments such as cold, fever, headache, diarrhoea, pain, and minor wounds and injuries. These medicines are either prescribed by health professionals or obtained over-the counter in the communities. The presence of medicines in households is a risk factor for irrational drug use mainly due to the easy access. In most communities of developing countries, there is limited knowledge among the population on the safety of drugs commonly in homes. In addition to this, controlling the use of drugs stored at home is a great task especially from unintentional users such as children which increases the risk of accidental poisoning. Moreover, presence of medicines at home has also been associated with sharing of drugs which further increase the risk of inappropriate drug use and hence the emergence of antimicrobial resistance. The burden of increasing diseases especially in developing countries, desire for quick recovery from illness and the acceptance of self-medication among communities influence home storage of drugs. Challenges in healthcare delivery such as inadequate access, lack of medical personnel and frequent drug stock outs common in developing countries may also influence communities to store drugs in homes. Many studies in Africa identified a high prevalence of drug storage at home. In Sudan, about 98% of investigated families had at least one drug product stored at home. Study conducted in Uganda also showed that about 40% of the surveyed households kept medicines at home and 30% of identified anti-bacteria's found in surveyed households were kept for future use. In Ethiopia, a study conducted almost two decades ago in Addis Ababa revealed that 20% of the studied households were found hoarding drugs, and drug sharing was practiced by 17% of the respondents . Apart from this study, little has been done to characterize drugs stored in households in south India. Therefore, this study aimed at generating data on the prevalence and factors associated with home storage of medicines in south India. The challenges of having medicines in homes include poor storage conditions such as humidity, and temperature are not regulated. This increases the risk of deterioration and expiry of medicines. Due to lack of capacity to detect expired drugs in households; these medicines are in most cases taken by the residents, increasing the risk of adverse effects. People are not mainly aware of storage of the medicines, they may keep the medicines everywhere not at particularly defined places which may cause drug deterioration. Health professionals often focus on giving patients information on medicine use with limited information offered on storage and their disposal. The medicines that inevitably remain after most treatments are disposed in various ways such as throwing in garbage pits and latrines/toilets. This inappropriate disposal of medicines poses danger to the community and the environment.*

Keywords: Medicine Box, home storage, clinical pharmacist

1. Background

Medicines are kept in households worldwide for first aid, treatment of minor ailments such as cold, fever, headache, diarrhoea, pain, and minor wounds and injuries. These medicines are either prescribed by health professionals or obtained over-the counter in the communities. The presence of medicines in households is a risk factor for irrational drug use mainly due to the easy access. In most communities of developing countries, there is limited knowledge among the population on the safety of drugs commonly in homes. In addition to this, controlling the use of drugs stored at home is a great task especially from unintentional users such as children which increases the risk of accidental poisoning. Moreover, presence of medicines at home has also been associated with sharing of drugs which further increase the risk of inappropriate drug use and hence the emergence of antimicrobial resistance.

The burden of increasing diseases especially in developing countries, desire for quick recovery from illness and the acceptance of self-medication among communities influence home storage of drugs. Challenges in healthcare delivery such as inadequate access, lack of medical personnel and frequent drug stock outs common in developing countries may also influence communities to store drugs in homes.

Many studies in Africa identified a high prevalence of drug storage at home. In Sudan, about 98% of investigated families had at least one drug product stored at home. Study conducted in Uganda also showed that about 40% of the surveyed households kept medicines at home and 30% of identified anti-bacteria's found in surveyed households were kept for future use. In Ethiopia, a study conducted almost two decades ago in Addis Ababa revealed that 20% of the studied households were found hoarding drugs, and drug sharing was practiced by 17% of the respondents . Apart from this study, little has been done to characterize drugs stored in households in south India. Therefore, this study aimed at generating data on the prevalence and factors associated with home storage of medicines in south India.

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Research Article

DEVELOPMENT AND VALIDATION OF STABILITY INDICATING RP-HPLC METHOD FOR ESTIMATION OF TOLPERISONE HYDROCHLORIDE IN PHARMACEUTICAL FORMULATIONS

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ABSTRACT

A simple, sensitive, precise and accurate stability indicating RP-HPLC method has been developed and validated for estimation of Tolperisone hydrochloride in bulk drug and pharmaceutical formulation. Chromatographic separation was achieved on Zorbax C18 (150 mm × 4.6 mm I.D., 5 µm particle size) column with a mobile phase composed of 10 mM phosphate buffer: water:acetonitrile in the ratio of 60:20:20 v/v/v and a flow rate of 1.0 mL/min. The detection wave length was set at 265 nm. An excellent linearity was observed for Tolperisone hydrochloride in the concentration range of 5-250 µg/mL with a correlation coefficient of 0.999. The run time was 8 min and retention time was 5.236 min. The mean percentage recovery of Tolperisone hydrochloride was 99.72%. The developed method was validated for linearity, precision, accuracy and forced degradation studies like acid, alkali, peroxide and thermal stress conditions were performed as per ICH guidelines. The results demonstrated that the method was suitable for routine quality control analysis of Tolperisone hydrochloride in bulk and pharmaceutical dosage form.

KEYWORDS: Tolperisone, HPLC, Estimation, Stability.

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Research Article

DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF PARACETAMOL AND LORNOXICAM IN BULK AND PHARMACEUTICAL DOSAGE FORM

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Keywords:
Paracetamol, Lornoxicam, Estimation, HPLC.

ABSTRACT

A simple, rapid, accurate and precise isocratic reversed phase high performance liquid chromatographic method has been developed and validated for simultaneous estimation of Paracetamol and Lornoxicam in tablet dosage form. The chromatographic separation was carried out on Zorbax C18 column (150 mm x 4.6 mm I.D., 5 µm particle size) with a mixture of 20 mM ammonium acetate pH 3.2 buffer and acetonitrile in the ratio of 60:40 v/v as a mobile phase at a flow rate of 1.0 mL/min. UV detection was performed at 265 nm. The retention times were 2.74 minutes and 5.36 minutes for Paracetamol and Lornoxicam respectively. Calibration plots were linear (r^2=0.999 for both Paracetamol and Lornoxicam respectively) over the concentration range of 6.25-250 µg/mL for Paracetamol and 0.1-4 µg/mL for Lornoxicam. The method was validated for linearity, precision, accuracy, ruggedness and robustness. The proposed method was successfully used for simultaneous estimation of Paracetamol and Lornoxicam in tablet dosage form. Validation studies revealed that the proposed method is specific, rapid, reliable and reproducible. The high % recovery and low % RSD confirms the suitability of the proposed method for routine quality control analysis of Paracetamol and Lornoxicam in bulk and tablet dosage form.

INTRODUCTION

Paracetamol (Fig. 1) is a non-selective COX inhibitor and has weak activity on prostaglandin synthetase in the inflamated peripheral tissues [1]. Paracetamol is used to treat many conditions such as headache, muscle ache, arthritis, backache, toothache, cold and fever. Chemically it is N-acetyl-p-amino phenol [2].

Lornoxicam (Fig. 2) is a potent analgesic with excellent anti inflammatory properties in a range of painful and inflammatory conditions, including postoperative pain and rheumatoid arthritis [3]. Chemically it is 6-chloro-4-hydroxy-2-methyl-N-2-pyridinyl-2*H*-thieno[2,3-e]-1,2-thiazine-3-carboxamide1,1-ioxide [4].

Literature survey reveals that few analytical methods using spectrophotometry [5-7], HPLC [8-10] and HPTLC [11-13] have been reported for the simultaneous determination of Paracetamol and Lornoxicam in combined dosage forms. Therefore, an attempt has been made to develop a novel, rapid, accurate and precise RP-HPLC method for simultaneous estimation of Paracetamol and Lornoxicam in tablet dosage form and validated in accordance with ICH guidelines [14].

MATERIALS AND METHODS

Instrumentation

To develop a high performance liquid chromatographic method for simultaneous estimation of Paracetamol and Lornoxicam using Waters 2695 HPLC system on a Zorbax C-18 (150 mm × 4.6 mm I.D., 5 µm particle size) column was used. The instrument is equipped with pump-515,

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PRELIMINARY PHYTOCHEMICAL INVESTIGATION AND BIOLOGICAL EVALUATION OF THE LEAVES OF *NEOLAMARCKIA CADAMBA*

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ABSTRACT

Natural compounds can be a lead compounds, allowing the design and rational planning of new drugs, biomimetic synthesis development and the discovery of new therapeutic properties not yet attributed to known compounds (S.M.K. Rates, 2011). The present study has made an attempt to evaluate the microscopic characters of *Neolamarckia cadamba* by determining leaf constants, trichomes and stomata, Phytochemical screening by using Qualitative chemical tests & column chromatography. The study includes biological evaluation of antibacterial and antifungal activity. Phytochemical screening of the crude methanolic extract of the leaves of *Neolamarckia cadamba* showed the presence of Alkaloids, Tannins, Saponins, Steroids and Glycosides. In Biological Evaluation, the antibacterial and antifungal activities of extracts (50, 75, 100 µg/ml) of *Neolamarckia cadamba* were tested against Gram-positive—*Staphylococcus aureus,* Gram-negative—*Escherichia coli.* Zone of inhibition of extracts were compared with that of standards like Amikacin for antibacterial activity and fluconazole for antifungal activity Post hoc analysis showed the remarkable inhibition of the bacterial growth was shown against the anti-bacterial organisms and a minute inhibition for anti-fungal organism.

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HYPOLIPIDEMIC ACTIVITY OF *AEGLE MARMELOS* LEAVES EXTRACT ON ALBINO WISTAR RATS

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Abstract:

Aegle marmelos commonly known as bael, wood apple and stone apple, belongs to the family Rutaceae. It is a deciduous shrub. Young leaves are pale green or pinkish, finely hairy while mature leaves are dark green and completely smooth and are used extensively in the indigenous system of medicine as an anti-diabetic agent and also as hypolipidemic agent. This study is aimed to evaluate the hypolipidemic activity of aqueous leaf extract of Aegle marmelos. The hypolipidemic activity of the plant were studied by administering aqueous leaf extract on Albino Wistar rats, using serum lipid profile i.e., high density lipo-protein (HDL), very low-density lipo-protein (VLDL), total cholesterol (TC) and triglyceride (TG) profile. The animals were divided into six groups, each group consists of six rats and the study is designed by following standard protocol for the evaluation of hypolipidemic activity. In this study, the treatment with standard hypolipidemic drug Pioglitazone is compared with the treatment of aqueous leaf extract of Aegle marmelos at dose levels of 100, 200 and 400mg kg body weight. Hypolipidemic activity was observed best with all the dose levels based on lipid profiles (VLDL, HDL, TC and TG).

Key words: *Aegle marmelos, Hypolipidemic activity, VLDL, HDL, TC and TG.*

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Original Article

Formulation and evaluation of fast dissolving tablets of ketoprofen

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ABSTRACT

Ketoprofen is non-steroidal anti-inflammatory drug mainly used for osteoarthritis and rheumatoid arthritis. The major problem with this drug is its very low solubility in biological fluids which results in poor solubility after oral administration. Therefore solid dispersion of Ketoprofen with PEG-6000 and PVP K30 in different weight ratios were prepared with a view to increase it's water solubility. The solid dispersions were evaluated by solubility study, drug content, in-vitro drug release study, dissolution efficiency and characterized by FT-IR. The Ketoprofen SD with PVP K30 (1:3) ratio showed maximum amount of drug release hence it was selected for Fast Dissolving Tablet formulation. The Fast Dissolving Tablets of Ketoprofen were prepared by direct compression technique by addition of different concentrations of superdisintigrants like Sodium starch glycolate, Crosscarmalose sodium and Crospovidone. The prepared tablets were evaluated for Pre-Compression and Post- Compression Parameters among all the formulations F15 showed least disintegration time and % drug release. Stability study of F15 was carried out at 40^0c and 75% RH for three months. Stability study confirms there is no significant change in the formulation of F15.

Keywords: Ketoprofen, Solid dispersion, Direct compression, Fast dissolving Tablets, Superdisintigrants, Stability Study.

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EFFECT OF POST AND PRE INDUCED TREATMENT WITH HESPERIDIN IN N-METHYL N-NITROSOUREA (MNU) INDUCED MAMMARY GLAND CANCER IN FEMALE SPRAGUE-DAWLEY RATS

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Evaluation of tumour suppressor activity of naringin in N-methyl N-Nitrosourea (MNU) induced mammary cancer in female Sprague-Dawley rats

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Formulation and evaluation of fast dissolving tablets of ketoprofen

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Keywords: Ketoprofen, Solid dispersion, Direct compression, Fast dissolving Tablets, Superdisintigrants, Stability Study.

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Review Article

A REVIEW ON CORE SHELL TECHNOLOGY IN HIGH PERFORMANCE LIQUID CHROMATOGRAPHY: DRUG ANALYSIS

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ABSTRACT

Column is the heart of the chromatographic systems. Now a days in order to increase the separation efficiency a new technology of column packed with core shell particles was used in HPLC .The core shell particles revolutionized the chromatography industry by providing faster methods without sacrificing resolution .this specialized particles provides higher efficiency and through put which leads to a reduction in solvent consumption. The literature here by describe the performance difference between the core shell particles column and traditional HPLC columns and the results shows that core shell columns are a promising toll in drug analysis.

KEYWORDS: *Core Shell, HPLC, Column and Separation Efficiency.*

INTRODUCTION

1. Core shell technology:

Among different types of chromatography, high performance liquid chromatography (HPLC) has been most widely used as an essential analysis tool for research, manufacturing, clinical tests, and diagnostics. This is due to its universal applicability and remarkable assay precision [1]. The column is the heart of chromatographic system, common secret among all chromatographers. The challenges in HPLC are highly efficient and fast separation with high resolution and ideally low back pressure for various types of samples, e.g., in pharmaceuticals, food, life science, environmental and also the daily analysis in research labs. In general there are two types of columns, i.e., packed column and monolithic column, have been used as stationary phases for routine HPLC. Silica microspheres are the mostly used packing materials for packed columns. While for monolithic columns, both porous silica and cross linked polymers are frequently used [2]. Porous monoliths containing highly interconnected pores are widely used as monolithic columns for fast separation with low back pressure [3,4]. The large pores are in the category of macro-pores (>50 nm, around 1m for polymer monolith). For silica monoliths, in addition to the macrospores, mesopores (2–50 nm) are present in the silica wall. The highly interconnected porosity results into high permeability and hence low back pressure even at high flow rates. Satisfying performance has been achieved particularly for large biomolecules [5,6]. The main obstacles for the wider use of monolithic columns are the reproducibility of the pore structures and the delicate cladding procedure to fit the monolith into a column. As a result, the analysis performance of monolithic columns may varies from batch to batch. Furthermore, the mechanical stability is generally weak for monolithic columns. There is an additional issue with polymer monoliths, i.e., the potential swelling problems in the presence of solvents. Packed columns with silica microspheres are still dominating the market and most widely used. Although various polymer and ceramic microspheres have been used as packing materials, silica microspheres are the mostly investigated and used materials. Both nonporous and porous silica microspheres have been used. For small nonporous particles, the separation occurs on the particle surface and band-broadening is alleviated because of the short diffusion path, thus allowing faster mass transfer [7]. However, due to the low surface area, retention, selectivity and therefore resolution are limited. The loading capacity is also a critical issue. For porous silica microspheres, in addition to the particle surface, the pore surface provides more sites to interact with analyte. For liquid phase separation, the pore sizes are required to be greater than 7 nm to allow sufficient mass transport. For separation of large biomolecules, large pores up to 100 nm may be required for efficient separation [4]. The size of silica particles and the packing quality can significantly affect the performance of the packed columns. Mono disperses silica particles with smaller diameters are employed to achieve high performance separation. However, coming with the use of smaller particles is the considerably increased back pressure [8]. Half of the particle size may double the separation performance (in terms of theoretical plate numbers) but can also quadruple the back pressure at the same time [4]. Micro-spheres are currently the state-of-art on the market for porous silica microspheres. To achieve fast separation on silica microspheres of certain size, a straightforward approach is to increase the flow rate and therefore the pressure drop across the column. Ultrahigh pressure liquid chromatography is thus developed and used. This technique places much stricter requirement on the pumping system and the whole flow system due to the very high operation pressure. In recent years, core–shell silica particles (solid core and porous shell or superficially porous) have been increasingly used for highly efficient separation with fast flow rate and relatively low back pres-sure [9]. The solid core plus the porous shell gives a larger particle and thus low operating back pressure while the porous shell and small solid core can provide higher surface area for the separation to occur. [10]. The advantage with the core–shell particles as packing materials is that the smaller pore volume reduces the volume present for broadening from longitudinal diffusion (B term in the van Demeter equation). The short diffusion path length can reduce the contribution of the C term due to the fast mass transfer [8, 11]. Particle characteristics such as particle size and porous shell thickness can significantly influence separation parameters [12]. As the thickness of the porous shell decreases, the faster mass transfer can lead to improved column efficiency and fast elution time [13, 14]. For chromatographic

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FORMULATION DEVELOPMENT OF SUSTAINED RELEASE FLOATING TABLETS OF VALSARTAN: OPTIMIZATION BY 2^2 FACTORIAL DESIGN

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Abstract:

The objective of the present study is optimization of valsartan SR floating tablet formulation by 2^2 factorial design. SR floating tablets of valsartan (80 mg) were formulated employing HPMCK100M as matrix forming polymer, sodium bicarbonate as gas generating agent and beeswax and ethyl cellulose as floating enhancers. Valsartan is an orally active anti-hypertensive drug, majorly absorbed from stomach and upper small intestine. Formulation of sustained release floating tablets of valsartan is needed because of its poor oral bioavailability and short biological half-life. Valsartan floating tablets were formulated as per 2^2 factorial design and were evaluated. Valsartan SR floating tablets prepared as per 2^2 factorial design were non-disintegrating in water and aqueous acidic (pH 1.2) and alkaline (pH 7.4) fluids and were of good quality with regard to drug content, hardness, friability and suitable for controlled release. The individual effect of sodium bicarbonate (factor B) and combined effect of HPMCK100M and sodium bicarbonate (AB) on the floating lag time are significant (P < 0.05). Formulations Fb and Fab exhibited excellent floating over > 12 h with a floating lag time in the range 15-45 seconds. Higher levels (20 %) of sodium bicarbonate gave shorter floating lag time. Valsartan release from the floating tablets prepared was slow and spread over 12 h and dependent on the composition of the tablets. Valsartan release from the floating tablets prepared was by non-fickian diffusion mechanism in all the cases.

Optimization of valsartan sustain release floating tablet formulation was done taking release rate (K0) as the parameter for optimization. For optimization, release rate (K0) was taken as response (Y) and level of HPMCK100M as (X1) and level of sodium bicarbonate as (X2). The polynomial equation describing the relationship between the response, Y and the variables, X1 and X2 based on the observed data was found to be $Y = 8.05 - 1.25 (X1) + 0.75 (X2) - 0.25 (X1 X2)$ by multiple regression analysis. Based on the polynomial equation developed, the optimized valsartan sustain release floating tablet formulation with the desired release rate (K0) of 7.4 mg/hr could be formulated employing HPMCK100M (200 mg/tablet) and sodium bicarbonate (53.35 mg/tablet). The optimized formulation (Fopt) exhibited a floating time of > 12 h with a lag time of 21 seconds and gave a release rate (K0) of 7.45 mg/hr fulfilling the target release rate (K0) set indicated validity of the optimization technique employed. The optimized formulation (Fopt) exhibited a slow release of Valsartan over 12h. As such, formulation Fopt is considered as the best floating tablet formulation of valsartan suitable for b.i.d administration.

Key words: *Formulation development, Floating tablets, Valsartan, Optimization, Factorial design, Sustained release.*

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PREPARATION AND EVALUATION OF STARCH ACETATE-GLICLAZIDE MICROPARTICULATE DRUG DELIVERY SYSTEMS FOR ORAL CONTROLLED RELEASE: *INVITRO* STUDIES

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Abstract:

Recently much emphasis is being laid on the development of microparticulate DDS in preference to single unit systems because of their potential benefits such as increased bioavailability, reduced risk of systemic toxicity, reduced risk of local irritation and predictable gastric emptying. The objective of the present study is to prepare and characterize starch acetate and to evaluate its application in the preparation of microparticulate drug delivery systems for oral controlled release of gliclazide. Starch acetate was prepared by acetylation of potato starch with acetic anhydride. The prepared starch acetate was characterized and evaluated.

Starch acetate with a degree of substitution 2.75 could be prepared by acetylation of potato starch with acetic anhydride. The starch acetate prepared was fechy soluble in chloroform and insoluble in several aqueous fluids and organic solvents. Chloroform could be used as solvent for starch acetate in the preparation of microparticles, microcapsules and in film coating Spherical starch acetate- Gliclazide microparticles could be prepared by the emulsification-solvent evaporation method. The method is industrially feasible as it involves emulsification and removal of the solvent, which can be controlled precisely. The emulsification solvent evaporation method was reproducible with regard to size and size distribution of the microparticles. About 65-70% of microparticles in each batch were in the size range 35-50 mesh (398.5μm). Encapsulation efficiency was in the range 96.0-99.3 % in the preparation of microparticles.

Gliclazide release from the starch acetate microparticles was slow and spread over longer periods of time. The drug release depended on the proportion of core:coat in the microparticles. A good linear relationship (R^2 = 0.826) between percent coat and release rate (k_1) was observed. The relationship could be expressed by the linear equation, y = 12.18-0.173x where x is percent coat and y is release rate (k_1). Gliclazide release from the starch acetate microparticles was by non fickian (anomalous) diffusion. Formulation F2 prepared using a Core :coat ratio of 8 :2 gave slow, controlled and complete release(100%) of Gliclazide over 12 hours. As such formulation F2 is considered as a promising microparticulate DDS for oral control release of Ghelazide over 12 hours for b.i.d administration.

Key words: *Multiparticulate drug delivery systems, Starch acetate, Gliclazide, Oral controlled release*

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Research Article

Preparation and Evaluation of Micro particulate Drug Delivery Systems of Gliclazide Employing Starch Acetate

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Abstract

Recently much emphasis is being laid on the development of micro particulate DDS in preference to single unit systems because of their potential benefits such as increased bioavailability, reduced risk of systemic toxicity, reduced risk of local irritation and predictable gastric emptying. The objective of the present study is to prepare and evaluate micro particulate drug delivery systems of Gliclazide using starch acetate, a new modified starch for oral controlled release. The starch acetate (DS 2.75) was freely soluble in chloroform and insoluble in several aqueous fluids and organic solvents. Chloroform could be used as solvent for starch acetate in the preparation of micro particles, microcapsules and in film coating Spherical starch acetate- Gliclazide micro particles could be prepared by the emulsification-solvent evaporation method. The method is industrially feasible as it involves emulsification and removal of the solvent, which can be controlled precisely. The emulsification solvent evaporation method was reproducible with regard to size and size distribution of the micro particles. About 65-70% of micro particles in each batch were in the size range 35/50 mesh (398.5µm) Encapsulation efficiency was in the range 96.0-99.3 % in the preparation of micro particles.

Gliclazide release from the starch acetate micro particles was slow and spread over longer periods of time. The drug release depended on the proportion of core: coat in the micro particles. A good linear relationship (R^2=0.826) between percent coat and release rate (k_o) was observed. The relationship could be expressed by the linear equation, y=12.18-0.173x where x is percent coat and y is release rate (k_o). Gliclazide release from the starch acetate micro particles was by non fickian (anomalous) diffusion. Formulation F2 prepared using a Core: coat ratio of 8:2 gave slow, controlled and complete release (100%) of Gliclazide over 12 hours. As such formulation F2 is considered as a promising micro particulate DDS for oral cor.trol release of Gliclazide over 12 hours for b.i.d administration

Keywords: Multi particulate drug delivery systems; Starch acetate; Gliclazide; Oral controlled release

Introduction

The design of micro particulate drug delivery systems is an efficient technique to provide the sustained & controlled delivery of drugs over long periods of time. Micro particulate drug delivery systems [1] consist of small particles of solids or small droplets of liquids surrounded by walls of natural & synthetic polymer films of varying thickness & degree of permeability acting as a release rate controlling substance & have a diameter up to the range of 0.1µm-200µm. Micro particulate dosage forms [2] are pharmaceutical formulations in which the active substance is present in a number of small independent subunits. To deliver the recommended total dose, these subunits are filled into capsules, encapsulated or compressed into a tablet. Micro particulate drug delivery systems contain discrete particles that make up a multiple-unit system. They provide many advantages over single-unit systems because of their small size. Multi particulates are less dependent on gastric empty time, resulting in less inter and intra-subject variability in

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ENHANCEMENT OF DISSOLUTION RATE OF EFAVIRENZ BY SOLID DISPERSION IN STARCH 1500 AND SOLUPLUS ALONE AND IN COMBINATION

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Abstract:

Efavirenz, a widely prescribed antiretroviral drug belongs to class II under BCS and exhibit low and variable oral bioavailability due to its poor aqueous solubility. As such it needs enhancement in the dissolution rate and bioavailability to derive its maximum therapeutic efficacy. The objective of the present study is to prepare and evaluate solid dispersions of Efavirenz in Starch 1500 and Soluplus alone and in combination for enhancing the dissolution rate and dissolution efficiency of Efavirenz. The individual and combined effects of the two carriers, Starch 1500 and Soluplus in enhancing the dissolution rate and dissolution efficiency of Efavirenz were evaluated in a 2^2 factorial study. Solid dispersions of Efavirenz in Starch 1500 alone were prepared using four ratios of drug: carrier namely 2:1, 1:1, 1:2 and 1:3 by solvent evaporation method. Solid dispersions of Efavirenz in Soluplus alone were prepared at three concentrations namely 0.5, 1.0 and 2% by common solvent method. Solid dispersions of Efavirenz in combined carriers namely Starch 1500 and Soluplus were prepared as per 2^2 factorial design. All the solid dispersions prepared were evaluated for drug content uniformity, dissolution rate and dissolution efficiency in comparison to Efavirenz pure drug.

The dissolution rate and dissolution efficiency of Efavirenz could be significantly enhanced by solid dispersion in Starch 1500 and Soluplus alone and in combination. The individual and combined effects of Starch 1500 and Soluplus in enhancing the dissolution rate and dissolution efficiency of Efavirenz are highly significant ($P < 0.01$). Soluplus gave significant enhancement in the dissolution rate of Efavirenz at very low concentrations where as a large proportion of Starch 1500 is required for a similar enhancement in the dissolution rate of Efavirenz. Combination of Starch 1500 and Soluplus resulted in a much higher enhancement in the dissolution rate and dissolution efficiency of Efavirenz than is possible with them individually. Combination of Starch 1500 and Soluplus is recommended for enhancing the dissolution rate and dissolution efficiency of Efavirenz.

Key words: *Efavirenz, Solid dispersion, Dissolution Rate, Starch 1500, Soluplus, Factorial study.*

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Method development and validation for Simultaneous Estimation of Telmisartan and Nebivolol by using RP-HPLC Method

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Abstract

A simple rapid reversed- phase high performance liquid chromatographic method has been developed and validated for estimation of Telmisartan and Nebivolol in tablet dosage form. The estimation was carried out on TYPE MG 5µm, SIZE 4.6mm x 250mm with a mixture of Acetonitrile: phosphate buffer(3.1) 60:40 (v/v) as mobile phase. UV detection was performed at 280 nm. The method was validated for linearity, accuracy, precision, specificity and sensitivity as per ICH norms. The developed and validated method was successfully used for the quantitative analysis of commercially available dosage form. The retention time was 2.172 and 2.448 min for Telmisartan and Nebivolol respectively and total run time was 10 min at a flow rate of 1.0 mL/ min. The assay of Telmisartan and Nebivolol was performed with tablets and the % assay was found to be 98.41and 99.8 which shows that the method is useful for routine analysis. The linearity of Telmisartan and Nebivolol was found to be linear with a correlation coefficient of 0.999 and 0.999, which shows that the method is capable of producing good sensitivity. The acceptance criteria of precision is RSD should be not more than 2.0% and the method show precision 1.5 and 0.1 for Telmisartan and Nebivolol which shows that the method is precise. The LOD was performed for Telmisartan and Nebivolol was found to be 52000 and 10044 respectively. The LOQ was performed for Telmisartan and Nebivolol was found to be 158180 and 31643 respectively. The method robust even by change in mobile phase ±5% of Organic composition. The acceptance criteria of intermediate precision is RSD should be not more than 2.0% and the method show precision 1.9 and 0.1 for Telmisartan and Nebivolol which shows that the method is repeatable when performed in different days also.

Keywords: Telmisartan, Nebivolol HCl, RP-HPLC, Validation

Introduction

Telmisartan is an angiotensin receptor antagonist (ARB) used in the management of hypertension generally, angiotensin || receptor blocker (ARBs) such as telmisartan bind to the angiotensin || receptor with high affinity, causing inhibition of the action of angiotensin || on vascular smooth muscle, ultimately leading to a reduction in arterial blood pressure. Recent studies suggest that telmisartan may also have PP-AR-gamma agonistic properties that could potentially confer beneficial metabolic effect.

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A New stability indicating RP-HPLC method for simultaneous estimation of Escitalopram and L-methylfolate in bulk and tablet dosage form

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Abstract

The Present Study, A New Stability- Indicating RP-HPLC Method Has Been Developed For Simultaneous Estimation Of Escitalopram And L-Methylfolate In Bulk And Tablet Dosage Form. The Developed Method Was Considered A Sensitive, Precise, And Accurate RP-HPLC Method For The Analysis Of Escitalopram And L-Methylfolate. To Optimize The Mobile Phase, Various Combinations Of Buffer And Organic Solvents Were Used On Kromosil-250x4.6mm, 5µ Column. Then The Mobile Phase Containing A Mixture Of 0.1% OPA (Ph 4.0) And Acetonitrile 60:40 % V/V Was Selected At A Flow Rate Of 1.0 Ml/Min For Developing The Method And The Peaks With Good Shape And Resolution Were Found Resulting In Short Retention Time, Baseline Stability And Minimum Noise. The Retention Times Of Escitalopram And L-Methylfolate Were Found To Be 3.045min And 3.661min Respectively. No Interfering Peaks Were Found In The Chromatogram Indicating That Excipients Used In Formulations Didn't Interfere With The Estimation Of The Drugs By The Proposed HPLC Method.

Keywords: Stability RP-HPLC, Epalrestat And Pregabalin, Validation.

Introduction

Escitalopram [1-9]. The S-Enantiomer Of Citalopram, Belongs To A Class Of Antidepressant Agents Known As Selective Serotonin-Reuptake Inhibitors (Ssris). Despite Distinct Structural Differences Between Compounds In This Class, Ssris Possess Similar Pharmacological Activity. As With Other Antidepressant Agents, Several Weeks Of Therapy May Be Required Before A Clinical Effect Is Seen. Ssris Are Potent Inhibitors Of Neuronal Serotonin Reuptake. They Have Little To No Effect On Norepinephrine Or Dopamine Reuptake And Do Not Antagonize A- Or B-Adrenergic, Dopamine D2 Or Histamine H1 Receptors. Chemically, Escitalopram Is (1S)-1-[3-(Dimethylamino) Propyl]-1-(4-Fluorophenyl)-1, 3-Dihydro-2-Benzofuran-5-Carbonitrile. The Antidepressant, Antiobsessive-Compulsive, And Antibulimic Actions Of Escitalopram Are Presumed To Be Linked To Its Inhibition Of CNS Neuronal Uptake Of Serotonin.

Escitalopram Blocks The Reuptake Of Serotonin At The Serotonin Reuptake Pump Of The Neuronal Membrane, Enhancing The Actions Of Serotonin On 5HT1A Autoreceptors. Ssris Bind With Significantly Less Affinity To Histamine, Acetylcholine, And Norepinephrine Receptors Than Tricyclic Antidepressant Drugs.

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Research Article

Formulation And Evaluation Of Fast Dissolving Tablets By Addition Of Different Concentrations Of Superdisintegrant And By Effervescent Technology.

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Abstract

Ketoprofen is NSAID drug used for osteoarthritis and rheumatoid arthritis. The major problem with this drug is very low solubility in biological fluids. Therefore solid dispersion of Ketoprofen with PVP K30 in different weight ratios were prepared to increase its water solubility. The solid dispersions were evaluated by solubility study, drug content, in-vitro drug release, dissolution efficiency and characterized by FT-IR. The Ketoprofen SD with PVP K30 (1:4) ratio showed maximum amount of drug release it was selected for Fast Dissolving Tablet formulation. The Tablets were prepared by by addition of different concentrations of superdisintigrant and By Effervescence Technology, The tablets were evaluated for Pre-Compression and Post-Compression Studies, among all the formulations F5 showed least disintegration time and 99.60% of drug release in 20 minutes. Stability study of F5 was carried out at 40°c and 75% RH for three months. it confirms there is no significant change in the formulation.

Keywords: Ketoprofen, Solid dispersion, Fast dissolving Tablets, Superdisintigrant, Effervescence Technology.

Introduction

Fast dissolving tablets disintegrate or dissolve quickly in the oral cavity, or swallowed without the need for the administration of water. leading to an increase in bioavailability by avoiding first pass liver metabolism. Fast disintegrating tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people.These tablets are also called as mouth-dissolving tablets, melt-in mouth tablets, rapimelts, porous tablets, quick dissolving etc. Recent developments in fast-dissolving tablets provide a convenient solution for patients who have difficulties in swallowing conventional tablets. These FDT turn into a soft paste or liquid form for easy swallowing and thus it is free of suffocation risk[1,2]. The primary beneficiaries for FDTs are pediatric and geriatric patients, bedridden or developmentally disabled patients. The key properties of FDTs are fast absorption of water in to the core of the tablets and disintegration of associated particles into individual components for fast dissolution[3,4]. Ketoprofen [5-10] Thus, its availability seems to be dissolution rate limited. Ketoprofen is practically insoluble in water, The rate of dissolution can be increased by increasing the surface area of available drug by various methods like Micronization, Complexation and Solid dispersion [11] (SD). hence present study was carried out to enhance solubility and dissolution properties of Ketoprofen through the preparation of Solid Dispersions (SD) using PVP[12] as carriers at various proportions (1:1,1:2,&1:4) by using Solvent evaporation technique and the addition of different concentration of superdisintegrant such as crospovidone[13] and Effervascent agents like Citric acid and Sodium bicarbonate in combination in (2:3 ratio) were studied. U.V. Spectrophotometer method was selected for assay as well as in-vitro dissolution studies. The FTIR was used to characterize the solid state of

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Original Research Paper

Pharmaceutical

METHOD DEVELOPMENT AND VALIDATION BY RP-HPLC FOR SIMULTANEOUS ESTIMATION OF GLIMEPIRIDE AND ROSIGLITAZONE IN BULK AND TABLET DOSAGE FORM

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ABSTRACT The proposed study, a new method development and validation by RP-HPLC has been developed for estimation of Glimepiride and Rosiglitazone in bulk and tablet dosage form. The present method was a sensitive, precise and accurate RP-HPLC method. To optimize the mobile phase, various combinations of buffer and organic solvents were used on Inertsil ODS-150x4.6mm, 5µ column. Altima-150x4.6mm, 5µ Then the mobile phase containing a mixture of phosphate buffer (pH 4.0) and Acetonitrile 60:40 %v/v were selected at a flow rate of 1ml/min for developing the peaks with good shape and resolution was found resulting in short retention time, baseline stability and minimum noise. Retention times of Glimepiride and Rosiglitazone were found to be 2.109min and 4.657min respectively. Quantitative linearity obeyed in the concentration range of 10-60 µg/ml and 20-120 µg/ml of Glimepiride and Rosiglitazone respectively. The limit of detection and limit of quantification were found to be 0.002 µg/ml and 0.06 µg/ml (Glimepiride) and 0.23 µg/ml and 0.70 µg/ml (Rosiglitazone) respectively, which indicates the sensitivity of the method. The high percentage recovery indicates that the proposed method is highly accurate. No interfering peaks were found indicating the excipients used in formulations didn't interfere with the estimation of the drugs.

KEYWORDS : Glimepiride and Rosiglitazone, RP-HPLC, Validation.

INTRODUCION

Glimepiride (1-10) is the first III generation sulphonyl urea it is a very potent sulphonyl urea with long duration of action. Chemically, Glimepiride is 3-ethyl-4-methyl-N-{2-[4-({[(4-methylcyclohexyl) carbamoyl] amino) sulfonyl) phenyl] ethyl}-2-oxo-2, 5-dihydro-1H-pyrrole-1-carboxamide. which increases the release of insulin from pancreatic beta cells, in addition, Glimepiride increases the activity of intracellular insulin receptors. Studies conducted on adiposities and skeletal muscle suggest that Glimepiride induces the PI3 kinase (PI3K) and Akt pathway, along with insulin receptor substrate-1/2 and endothelial nitric oxide synthase. Glimepiride also increases osteoblast proliferation and differentiation, which is thought to be related to its ability to activate the PI3K and Akt pathway. The chemical structure of Glimepiride was given in (Fig. 1).

Rosiglitazone (11-24) is an anti-diabetic drug in the thiazolidinedione class of drugs. Like other thiazolidinediones, the mechanism of action of Rosiglitazone is by activation of the intracellular receptor class of the peroxisome proliferator-activated receptors (PPARs), specifically PPARγ. Rosiglitazone is a selective ligand of PPARγ, and has no PPARα-binding action. Apart from its effect on insulin resistance, it appears to have an anti-inflammatory effect: nuclear factor kappa-B (NFκB) levels fall and inhibitor (IκB) levels increase in patients on Rosiglitazone. Recent research has suggested that Rosiglitazone may also be of benefit to a subset of patients with Alzheimer's disease not expressing the ApoE4 allele. This is the subject of a clinical trial currently underway. Chemically it is 5-[(4-{2-[methyl (pyridin-2-yl) amino] ethoxy} phenyl) methyl]-1, 3-thiazolidine-2, 4- dione. The chemical structure of Glimepiride was given in (Fig. 2).

The review of literature (25-30) revealed that several analytical methods have been reported for Glimepiride and Rosiglitazone in spectrophotometry, HPLC, HPTLC, and LC/MS individually and in combination. To date, there have been no published reports about the simultaneous estimation of Glimepiride and Rosiglitazone by RP-HPLC in bulk and tablet dosage forms. This present study reports for the first time method development and validation by RP-HPLC for simultaneous estimation of Glimepiride and Rosiglitazone in bulk and tablet dosage forms.

MATERIALS AND METHODS

Chemicals and reagents: Glimepiride and Rosiglitazone were obtained as gift sample from Spectrum Pharma Research laboratory in Hyderabad. Tablets (Avandaryl, GlaxoSmithKline.) containing Glimepiride -4mg and Rosiglitazone-8 mg Marketed formulation was purchased from local market. Acetonitrile, Water HPLC grade (Merck. Mumbai, India) Potassium dihydrogen ortho phosphate, Triethylamine (RANKEM, Mumbai, India.). Ortho Phosphoric Acid HPLC (Merck., Mumbai, India) All solvents used in this work are HPLC grade.

Instrument and chromatographic conditions: A Waters 2695 RP-HPLC separation module (Waters Corporation, Milford, USA) equipped with PDA detector having back pressure 5000psi, automatic injector and the chromatographic separation was achieved on Inertsil ODS-150x4.6mm, 5µ column using phosphate buffer (pH 4.0) and Acetonitrile 60:40 %v/v as mobile phase at a flow rate of 1ml/min. The injection volume was 10 µl and the total runtime was set as 8min. The determination of analytes was carried out at 235nm.

Preparation of samples and solutions:

Preparation of mobile phase: Preparation of 0.1M Phosphate buffer (pH 4.0): Accurately 13.6gms of KH_2PO_4 in a 1000ml of volumetric flask add about 900ml of milli-Q water added and degas to sonicate and finally make up the volume with water. Then adjust pH 4.0 with ortho phosphoric acid. Sonicate to degas.

Preparation of glimepiride stock solution: Accurately Weighed and transferred 4mg of Glimepiride in to 10ml of clean dry volumetric flask, add 7ml of diluent, then sonicated for 10min and make up the volume with diluent.

Preparation of rosiglitazone stock solution: Accurately weighed 8mg of Rosiglitazone and transferred into 10ml of clean dry volumetric flask, add 7ml of diluent, then sonicated for 10 min and make up the final volume with diluent.

Preparation of glimepiride standard solution: From the above Glimepiride stock solution 1ml was pipette out into 10ml of clean dry volumetric flask and make up the final volume with diluent.

Preparation of rosiglitazone standard solution: From the above

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SYNTHESIS AND CHARACTERIZATION OF 2, 3-DISUBSTITUTED QUINAZOLINE-4(3H)-ONES AND THEIR POTENTIAL BIOLOGICAL ACTIVITY

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ABSTRACT

In the present study all the compounds of 2, 3-disubstituted quinazoline -4(3H)-ones from (7a-7g & 8a-8g) were synthesized, characterized and screened for their anti-tubercular and antibacterial activity. The results of anti-tubercular activity revealed that title compounds 7a-e and 8a-c exhibited significant activity. These compounds have amido, thioamido, imidamido, N, N- dimethyl guanidinyl and N-pyridoyl moieties at 3rd position of quinazolinone ring. The study revealed the necessity of synthesizing many more compounds having these moieties. Such compounds may emerge as much more potent anti-tubercular agents. The results of anti-bacterial activity revealed that title compounds 7g and 8d exhibited significant activity against Gram positive bacteria. This may be due to the presence of N-phenyl (7g) and N, N-dimethyl guanidinyl moieties at 3rd position, methyl (7g) and phenyl (8d) at 2nd positions of quinazolinone ring system. From the results, it was observed that none of the title compounds exhibited significant inhibitory activity on the growth of Gram negative bacteria.

KEYWORDS: Quinazoline, 2, 3 Disubstituted Quinazoline, Quinazoline-4(3H)-ones, anti bacterial, anti tubercular.

INTRODUCTION

Benzopyrimidine is usually called Quinazoline. It is a bicyclic compound consisting of a pyrimidine system fused at 5th, 6th positions with benzene ring. chemical formula is

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PRECLINICAL PHARMACOKINETIC EVALUATION OF STARCH ACETATE AND CHITOSAN MICROPARTICLES OF GLIPIZIDE

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ABSTRACT

Recently much emphasis is being laid on the development of microparticles because of their potential benefits such as increased bioavailability, reduced risk of systemic toxicity, reduced risk of local irritation and predictable gastric emptying. The preparation and *in vitro* (drug release) evaluation of microparticles of glipizide using i) starch acetate, a new modified starch and ii) chitosan, a new mucoadhesive polymer are reported earlier. The microparticles prepared using both the polymers exhibited good *in vitro* controlled release of glipizide over 12 h. The objective of the present study is preclinical pharmacokinetic evaluation of selected glipizide microparticles (SAF2 and CHF3) in comparison to glipizide pure drug in healthy rabbits (n=6). The products were tested orally at a dose equivalent to 0.4 mg/kg of glipizide. Plasma glipizide concentrations were determined by a reported and revalidated HPLC method. The biological half life ($t_{1/2}$) of glipizide pure drug estimated (3.45 h) was in good agreement with the literature value of 2-5 h. The $t_{1/2}$ of glipizide was slightly elongated with microparticles. The absorption of Glipizide was very rapid when administered as pure drug and was slow from both the microparticles tested. Based on $(AUC)_0^{\alpha}$, the relative bioavailability (BA) of glipizide from microparticles SAF2 and CHF3 was 105.41 % and 113.95% respectively when compared to glipizide pure drug (100%). A good level A correlation was observed between percent drug released (*in vitro)* and $(AUC)_0^{\alpha}$ (*in vivo*) with both the microparticles. Thus, the results of preclinical pharmacokinetic studies indicated that glipizide was absorbed slowly

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SIMULTANEOUS DETERMINATION OF ALOGLIPTINE, PIOGLITAZONE AND ITS ACTIVE METABOLITE IN HUMAN PLASMA BY LC-MS/MS METHOD AND ITS PHARMACOKINETIC APPLICATION

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ABSTRACT

A simple, rapid and sensitive liquid chromatography-tandem mass spectrometric (LC–MS/ MS) assay method has been developed and fully validated for the simultaneous quantification of Alogliptine, Pioglitazone and Hydroxy Pioglitazone. The analytes were extracted from human plasma via protein precipitation using acetonitrile. The reconstituted samples were chromatographed on a Alltima HP C18 column by using a 60:40 (v/v) mixture of acetonitrile and 10 mM ammonium acetate (pH 3.0) as the mobile phase at a flow rate of 1.1 mL/min. The calibration curves obtained were linear over the concentration range of 3.05-250.29 ng/mL for Alogliptine, 15–2500.50 ng/mL for Pioglitazone and 7–1500 ng/mL for Hydroxy Pioglitazone. The API-4000 LC–MS/MS in multiple reaction monitoring (MRM) mode was used for detection. The results of the intra- and inter-day precision and accuracy studies were well within the acceptable limits. All the analytes were found to be stable in a battery of stability studies. The method is precise and sensitive enough for its intended purpose. The developed assay method was successfully applied to a pharmacokinetic study in human volunteers.

KEYWORDS: Alogliptine, Pioglitazone, Hydroxy Pioglitazone, Human plasma, LC-MS/MS, pharmacokinetic study.

RESEARCH ARTICLE

Synthesis Characterization of Novel Benzimidazole Derivatives as Anthelmintic

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Abstract: Some substituted benzimidazole derivatives were synthesized by condensation of o-phenylenediamine with aromatic acids in presence of water. A total of six compounds have been synthesized and the chemical structures were identified by spectral analysis. The synthesized compounds were screened for their *in-vitro* antibacterial activity against standard strains by cup plate method and also for anthelmintic activity and all the compounds showed good activities when compared with the standard except compound 4 of the series of compounds.

INTRODUCTION

Benzimidazole derivatives have occupied a prominent place in medicinal chemistry because of their significant properties as therapeuticsin clinical applications. Benzimidazole is a versatile pharmacophore producing a diverse range of biological activities. Benzimidazoles and its derivatives represent one of the most biologically active class of compounds, possessing a wide spectrum of activities. [1-4] Benzimidazole containing compounds have numerous medical and biological activities, such as anthelmintic, anti-tumor, anti-bacterial, anti-fungal, anti-viral, anti-convulsant, anti-depressant, analgesic, anti-inflammatory and anti-diabetic properties. Microbial drug resistance is the common problem as there are increasing number of strains are becoming resistant to multiple antimicrobial agents, with some bacteria now being resistant to all available antibiotics. [5-8] There is thus a critical need to develop new drugs with novel mechanisms of action. The optimization of benzimidazole derivatives based on their structures has resulted in various potent drugs that are now being currently practiced in the market, like albendazole, mebendazole, etc. [8-10] Owing to the importance and in continuation of our ongoing project work on benzimidazole derivatives, it was felt worthwhile to synthesize some novel substituted benzimidazole derivatives and screen them for their anti bacterial and anthelmintic activities. [11-12]

MATERIALS AND METHODS

All chemicals and reagents were of synthetic grade and commercially procured from S.D Fine Chem. Ltd. India. The melting points were determined using open capillary tubes and are uncorrected, silica gel chromatographic plates were used for TLC and solvent systems were ethanol: chloroform: acetone (1:4:5) for all compounds. The purity of the compounds was checked by TLC and spots were visualised by HCl solution. IR spectra were recorded on JASCO FTIR 410 using KBr disk method. 1 H NMR was recorded on VNMRS-500 AGILENT make.

Synthesis of 2-Phenyl Benzimidazole

Take 0.03 mol of O-phenylenediamine and 0.09 mol of benzoic acid and then added 20 ml of distilled water to the above reaction mixture. Reflux the reaction mixture for 45 mins under tap water and remove from the heating add slowly liquid ammonia with continues stirring until the product turns to basic then add ice cold water, collect the precipitate and allow to dry and recryllised from 10% ethanol. Yield: 85.39%. Melting range: 160-165°C.Rf: 0.93. IR (KBr) Cm^{-1}, 3172.30 (C-H stretching), 1582.87 (C=C stretching), 1125.97 (C-N stretching), 1667.25 (C=N stretching), 1451.50 (aromatic benzene ring). 1HNMR (DMSO): M δ 7.45-7.971 Aromatic (9H), S δ 6.508 (NH) protons.

Synthesis of P-Nitro Benzimidazole

Take 0.03mol of O-phenylenediamine and 0.09mol of P-nitro benzoic acid and then added 20 ml of distilled water to the above reaction mixture. Reflux the reaction mixture for 45 mins under tap water and remove from the heating add slowly liquid ammonia with continues stirring until the product turns to basic then add ice cold water, collect the precipitate and allow to dry and recryllised from 10% ethanol. Yield: 75.03%. Melting range: 174-178°C.Rf: 0.82. IR (KBr) cm^{-1}, 3113.6 (C-H stretching), 1540.85 (C=C stretching), 1106.87 (C-N stretching), 1603.81 (C=N stretching), 1449.23 (aromatic benzene ring). 1HNMR (DMSO): M δ 7.95-8.3 Aromatic (9H), S δ 6.52 (NH) protons.

Synthesis of Hydroxy Benzimidazole

Take 0.03mol of O-phenylenediamine and 0.09mol of salicylic acid and then added 20 ml of distilled water to the above reaction mixture. Reflux the reaction mixture for 45 mins under tap water and remove from the heating add slowly liquid ammonia with continues stirring until the product turns to basic then add ice cold water, collect the precipitate and allow to dry and recrystallised from 10% ethanol. Yield: 77.77%. Melting range: 220-225°C.Rf: 0.87. IR (KBr) cm^{-1}, 3238.10 (C-H stretching), 1449.23 (C=C stretching), 1197.59 (C-N stretching), 1606.11 (C=N stretching), 1426.97 (aromatic benzene ring). 1HNMR (DMSO): M δ 6.87-7.8 Aromatic (9H), S δ 6.64 (OH) protons, S δ 6.52 (NH) protons.

Synthesis of Carboxy Benzimidazole

Take 0.03mol of O-phenylenediamine and 0.09mol of pthallic acid and then added 20 ml of distilled water to the above reaction mixture. Reflux the reaction mixture for 45 mins under tap water and remove from the heating add slowly liquid ammonia with continues stirring until the

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Robo substitutes life in COVID-19: A Review

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ABSTRACT

Coronavirus pandemic has wreaked havoc around the world,pushing people indoors into isolation. Novel Corona Virus disease(COVID-19) is a disease caused by SARS-CoV-2(severe acute respiratory syndrome corona virus2)spreads mainly through respiratory droplets produced by an infected person. Treatment strategies include paracetamol, hydroxychloroquine, dexamethasone, favipiravir and remdesivir but no vaccine is currently available. The key preventive measure of COVID-19 is physical distancing. In this battle of COVID-19 the frontline health care warriors are overworking to stem the tide of COVID-19 and doing longshifts in suboptimal conditions, which puts them at highest risk of disease that has sickened and killed in a little over 3months. Furnishing the future and a fast paced shift towards digitalisation one of the best initiative was robotic technology. Robots in laboratory, pharmacy, lifesciences and pharmaceutical applications perform tasks at rates beyond human capability.Robots are slim,quick,flexible and can perform a 96hour project in 10hours with the highest quality. Robots can work 24hours a day,7days a week without stopping or tirirng and work effectively, without wasting movement of time and reduced chances of contamination but can also cause dangers too. Robots can act as an interface between a doctor and a patient where in they can carryout diagnostic and treatment processes, decreased rate of dispensing errors and optimised stock management, reducing human contact and risk of contamination of infection. During the coronavirus pandemic robots can also be advocated in the development of vaccine to cure COVID-19 by examining virus components. Stepping in where humans should not, robots are being used for jobs such as sanitising hospitals, delivering food and medicines to patients and people who are in quarantines and measure their temperature.

Key words: COVID-19, Corona virus, Corona warriors, Robotic technology.

I.INTRODUCTION

Corona virus , the name being derived from the outer fringe, or "CORONA" of embedded envelope protein can lead to COVID-19.The virus has now spread to countries and territories across the globe and WHO stated as pandemic on 11th march 2020

According to WHO, COVID-19 is a disease caused by SARS -COV-2 (Severe acute respiratory syndrome corona virus 2) spreads mainly through respiratory droplets produced by an infected person when sneeze or cough i.e., person to person contact that can spread to lungs and cause infection reduces oxygen supply to blood stream. Meanwhile, immune system causes inflammation throughout the body due to fight off the infection. This inflammation leads to drop in blood pressure. An infection in lungs or pneumonia causes lungs to become inflamed and fluid filled. This makes the situation becomes more worsen. People with pre-existing comorbid conditions can lead to fatal.

Diagnosis of COVID-19 covers preanalytical and analytical stages, where preanalytical stage involves collecting the proper respiratory tract specimen and analytical stage in real time reverse transcription- polymerase chain reaction(RT-PCR) assays remains the molecular test of choice for etiologic diagnosis of SARS-COV-2 infection while antibody based techniques are being introduced as supplemental tools[3].

There is no specific antiviral treatment recommended for covid-19 and no vaccine is currently available. The treatment is symptomatic. The treatment strategies varies from country to country and patient to patient. The selection is based on patient age, health status, severity of disease and availability of drug. Some treatment plans include hydroxychloroquine, dexamethasone, paracetamol, favipiravir and remedesivir [4].

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Tale of SARS: A Novel Cousin Causes Covid-19

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ABSTRACT

Both human corona viruses (SARS-CoV& SARS-CoV-2) have been reported as pathogens that cause severe symptoms in respiratory tract infections. They belong to the family coronaviridae and order nidovirales and genus betacorona virus. Up to date six corona virus species have been identified to infect humans and cause diseases. Among them 229E,OC43,NL63 and HKU1infections are frequently mild, mostly cause common cold symptoms. The other two species, Severe acute respiratory syndrome corona virus(SARS-CoV, 2003) and Middle east respiratory syndrome corona virus(MERS-CoV,2012) ,might cause fatal illness. SARS-CoV2 (novel Covid-19) is the seventh member of the corona viruses that infects humans. This novel corona virus was named as the severe acute respiratory syndrome corona virus 2 (SARS-CoV-2, 2019-nCoV) due to its high homology (~80%) to SARS-CoV which cause acute respiratory distress syndrome (ARDS) and high mortality during 2002- 2003. Due to the outbreak of SARS-CoV and SARS-CoV-2 resulting wide spread of fear among public and concern and leaves a pandemic situation to the world. The main motto of this article is to present SARS-CoV and SARS-CoV -2 in aspects of their virus incubation, originations, diagnosis, and treatment methods, genomic and proteomic sequences and pathogenic mechanisms.

Keywords: Corona viruses,SARS-CoV,SARS-CoV-2,MERS-CoV, Genomic comparison, Proteomic sequences, Pathogenic comparison.

I.INTRODUCTION

Corona viruses (CoVs) are a group of viruses that co-infect humans and other vertebrate animals. The infections caused by these viruses affects the respiratory tract, GIT, liver and central nervous system of humans, livestock, birds, bats, mice and many other wild animals. These viruses caused by the zoonotic transmission. In the case of SARS CoV-virus identified in 2003,which was thought to be an animal virus from an uncertain animal reservoir, perhaps bats ,that spread to other animals (civet cats) and first infected human case was reported in the Guangdong province of southern China in 2002. During this epidemic period the total reported confirmed cases were found to be 8,000 and the total confirmed deaths were found to be 774[9]. Where as in case of MERS CoV which was identified in the year 2012,and was thought to be an zoonotic virus that has repeatedly entered the human population via direct or indirect contact with infected dromedary camels in the Arabian peninsula. At the end of the November2019,a total of 2,494 laboratory confirmed cases of Middle east respiratory syndrome (MERS),including 858 associated deaths were reported globally[7]. Coming to the novel corona virus which was identified in December2019 and though to be emerged in Hunan seafood market at wuhan, south china and rapidly spread throughout world[20]. As of recent data 30 June 2020,the total confirmed cases 10.5M, recovered cases -5.34M, deaths-511 K was reported [19]

II.EPIDEMOLOGY

The epidemiology of these viruses depends on many factors including age, health conditions and sex ratio.

Death Rate By Age: Death rate =no. of deaths /no. of cases=probability of dying if infected by the virus (%).In both cases of SARS-CoV and SARS-CoV-2,many studies increasingly clear that death rate increases with age (over 80 years) and those with chronic diseases are the most vulnerable. The fatality rate starts to increase for those over 50 years of age . Those under 50 years, who are infected have a death rate of 0.40%, while for those 50-59 years its 1.3%.For those 60-69 years its 3.60%, for 70-79 years its 8% and for those over 80 years of age, it is 14.8% [20].

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A Review - Anosmia & Ageusia Biomarkers for COVID -19

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ABSTRACT

On 11th march 2020, World Health Organization(WHO) declared novel corona virus disease(COVID-19) caused by severe acute respiratory syndrome corona virus 2(SARS-COV2) as a pandemic and reiterated the call for countries to take immediate action and scale up response to treat, detect and reduce transmission to save people lives. Early diagnosis plays vital role in control of COVID-19, recognition of early signs such as anosmia or ageusia might be very useful in diagnosis of COVID-19 and isolation of patients. Patients confirmed with anosmia and ageusia were validated with olfactory and gustatory test. Security and prevention departments of the university hospital of Sassari, university hospital of salerno and Bologna Maggiore-Belloria hospital provides a framework summary of patient general and clinical features where 33 COVID-19 were participated in the study. The threshold and identification test scores, after being analyzed separately were finalized as mild,moderate and severe COVID-19 positive. These findings support anosmia and ageusia had the highest positive predictive value for COVID-19. Awareness has to be created on chemo sensitive dysfunction prediction, but instead suggests that those with more severe disease neglect such symptom in setting of severe respiratory disease. Future concentration on anosmia and ageusia rely as biomarker for COVID-19.

Keywords: Ageusia, Anosmia, gustatory, olfactory.

INTRODUCTION

COVID-19 outbreak caused by severe acute respiratory syndrome corona virus2(SARS-COV2) is a pandemic life threatening disease where an explosive increase in number of new cases, hospital bed shortage became a challenge to the healthcare system.

Clinical presentation of COVID-19 presents high fever, cough and in some cases viral pneumonia develops and progresses resulting in shortness of breath. Muscle ache, confusion, headache, sore throat, rhinorrhea, chest pain, diarrhea, nausea/vomiting, congectival congestion, nasal congestion, sputum production, fatigue, hemoptysis chills appears to be common[1]. Acute smell and taste disorders are related to a wide range of respiratory viral infections.

Health care team developed and employed remote telephone severity scoring system which is used to check, the status of patients who were staying at home on a daily basis[3]. They reported the interview results to the team arranging hospitalization or facility isolation based on their performance, found that a significant number of the patient stated experiencing acute loss of smell(anosmia) or loss of taste (ageusia). A literature patients confirming with anosmia & ageusia were validated with olfactory & gustatory test review revealed the importance of anosmia or ageusia as symptoms of COVID-19.

The pathogenic mechanism underlying anosmia &Ageusia in COVID-19 are as follows-

Invasion & multiplication of SARS – COV2 damages olfactory nerve causes anosmia, where ageusia is caused by the binding & penetration of SARS – COV2 with the angiotensin converting enzyme2 receptor, which is the main host cell receptor widely expressed on epithelial cells of oral mucosa[2].

Early diagnosis place vital role in control of COVID-19, recognition of early science such as anosmia or ageusia might be very useful for diagnosis of COVID-19 & isolation of patience this telephone severity scoring system had a limitation regarding the accuracy of assessment of patience. However, anosmia andAgeusia are not ambiguous symptoms but focuses on that time pattern on the recovery of these symptoms.

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A REVIEW ON INTELLECTUAL PROPERTY RIGHTS WITH AN EMPHASIS ON PATENTS, COPYRIGHTS AND TRADE MARKS

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ABSTRACT

Intellectual property or Intellectual Property Right have been expounded as inventions, creative expressions based on public willingness to vouchsafe on status of the property and it is also referred as a legal protection to certain inventions or creations of the mind. There are several types of IPR's such as Patents, Copyrights, Trademarks, Trade Secrets, Geographical Indications, Industrial Designs, Plant Varieties etc. IPR provides certain exclusive rights on particular property of the inventor in order to procure benefits from their efforts. Patent is a proprietary right granted in recognition of an invention, which is novel and satisfies the non-obviousness and industrial application. Patent also protects the commercial inventions such as new product or process. Patents are accompanied by diagrammatic representation through chemical structures, drawings of electrical, mechanical and also by textual descriptions. IPR is prerequisite for the identification, planning, rendering, commercialization and protection of creativity or an invention. The role of IPR's is to provide incentives to discover develop and market new drugs. In this review article we are providing the information about IPR with a special note on Patents, Copy rights and Trademarks.

KEYWORDS: IPR's, Patents, Copy Rights, Trade Marks.

INTRODUCTION

Intellectual Property Right (IPR) are the rights given to the persons over the creation of their minds, inventions, literary, artistic work, symbols, names and images used in commerce. They usually give the creator an exclusive right over the use of his/her creation for a certain

A REVIEW ON INTRAUTERINE DEVICES - FOR BIRTH CONTROL

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Abstract: Unintended pregnancy remains a public health concern. It is either due to failure to use contraception, failure to use contraception correctly or failure of the contraception method itself. The purpose of this review is to give a detail note on one of the most often preferred contraceptive method i.e. IUD's (Intra uterine devices), types of IUD's available in the market, their advantages and disadvantages, mechanism of action. This article gives an idea about what to expect during insertion and removal of IUD's. Also helps people to make their own birth control choice.

Index Terms – Intrauterine devices, IUD's, Birth control, Contraceptive devices

I. INTRODUCTION:

The percentage of unintended pregnancies is highest in teens younger than 18 years, followed by women in the age group of 20 to 24 years. Emergency contraception (EC) may be used shortly after unprotected intercourse. There are two main types of EC methods, oral methods (as a pill) and intrauterine devices (IUD's). The most commonly used oral methods are levonorgestrel and ulipristal acetate (UPA) 30 mg given as single doses. The second method is the insertion of an intrauterine device. These IUD's act as Sustained and controlled-release devices for drug delivery in the vaginal and uterine areas. The advantages in administration by this route are - Prolonged release, minimal systemic side effects, and an increase in bioavailability-allow for less total drug than with an oral dose.

The usage of IUD is increasing year on year as women find IUD the most convenient, safe, and effective form of contraception.

Until the 1960s, IUDs and condoms were the only artificial method for the control of fertility. The mix of available methods has greatly expanded and the insertion of an IUD is now the second most prevalent method of family planning used worldwide (13.6%), after female sterilization (20.5%), among women of reproductive age who are married or cohabiting (United Nations, 2006). The total number of current IUD users is estimated at over 150 million women worldwide, of which 100 million are in China. The majority of devices used are copper devices but reliable data on the use of different types of devices are not available. The levonorgestrel-releasing intrauterine system (LNG-IUS) has been used by over 10 million users in 113 countries, since it was first marketed in 1990. The proportion of IUD users among married or cohabiting women of reproductive age is nearly 2-fold higher in the developing world (14.5%) than the developed world (7.6%). Prevalence of IUD use is the greatest in the Democratic People's Republic of Korea, where it is used by 78% of contraceptive users, in the Central Asian Republics (63–76%), and in certain countries in the Middle East and Latin America (Egypt, 63%; Cuba, 59%) (United Nations, 2006). In contrast, IUD prevalence is below 2% among women of reproductive age in sub Saharan Africa and in North America.

ADVANTAGES OF IUD's:

- Cost-effectiveness over time
- Ease of use
- Lower risk of ectopic pregnancy
- No interruption of foreplay or intercourse

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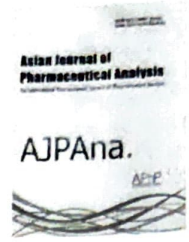

RESEARCH ARTICLE

Development and Validation of Stability Indicating UPLC Method for the Simultaneous Estimation of Drugs in Combined Dosage Forms using Quality by Design Approach

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ABSTRACT:

UPLC is a modern technique which gives a new direction for liquid chromatography. UPLC refers to ultra performance liquid chromatography, which enhance mainly in three areas: speed, resolution and sensitivity. Ultra performance liquid chromatography (UPLC) applicable for particle less than 2µm in diameter to acquire better resolution, speed, and sensitivity compared with high-performance liquid chromatography (HPLC). The concept of "Quality by Design" (QbD) is an approach which covers a better scientific understanding of critical process and product qualities, designing controls and tests based on the scientific limits of understanding during the development phase and using the knowledge obtained during the life-cycle of the product to work on a constant improvement environment.

KEYWORDS: Ultra performance liquid chromatography, resolution.

INTRODUCTION:

A precise measurement of drug levels both in a pharmaceutical industry's perspective and health care setup is the need of the hour. Pharmaceutical companies spend extravagantly and also untiringly, day in and day out, to delineate a single successful drug moiety from thousands of lead compounds. In this pursuit, they rely on bio-analytical techniques which could help them in separating the most active elements from the crude mixtures.

And also, later on in pre-clinical and clinical testing accurate measurement of drug levels in biological tissues using suitable Liquid chromatography are indispensable. Moreover, a treating physician depends on drug levels especially for those drugs with narrow therapeutic margin. Though the qualitative and quantitative analytical methods existing today are more sophisticated and complex, they actually originated and evolved from the roots of chromatography. Hence, chromatography still prevails as the most significant analytical method in molecular chemistry despite being primitive. This current indisputable status of chromatography is reflected by the fact that majority of the present techniques is based on the principle of chromatography.

ORIGINAL RESEARCH PAPER

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INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

DEVELOPMENT AND VALIDATION OF STABILITY INDICATING RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF HALOPERIDOL AND BENZHEXOL IN BULK AND TABLET DOSAGE FORM

Pharmacy

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ABSTRACT

The proposed study development and validation of stability indicating RP-HPLC method has been developed for simultaneous estimation of Haloperidol and Benzhexol in bulk and tablet dosage forms. The developed new method was a sensitive, precise and accurate RP-HPLC method for estimation of Haloperidol and Benzhexol. An isocratic RP-HPLC system was used for analysis of samples at 30°C column oven temperature. The chromatographic separation was achieved on Kromasil C18, 5 micron column using 0.1% perchloric acid and acetonitrile 50:50 as mobile phase at a flow rate of 1 ml/min. The injection volume was 10 µl and the total run time was set as 10 mins. The detection of analytes was carried out at 210 nm using PDA detector. The developed method was validated for linearity, precision, accuracy and forced degradation studies as per ICH guidelines. The results demonstrated that the method was suitable for quality control analysis of combination of haloperidol and benzhexol both in bulk and tablet dosage forms.

KEYWORDS

RP-HPLC, Haloperidol, Benzhexol, Method development, Validation

INTRODUCTION:

Haloperidol [1-3] is a phenyl-piperidinyl-butyrophenone that is used primarily to treat schizophrenia and other psychoses. Chemically, Haloperidol is 4-[4-(4-chlorophenyl)-4-hydroxypiperidin-1-yl]-1-(4-fluorophenyl) butan-1-one [figure 2.1]. Haloperidol is a psychotropic agent indicated for the treatment of schizophrenia. It also exerts sedative and antiemetic activity. Benzhexol [4-10] is an anti cholinergic used in the symptomatic treatment of all etiologic groups of Parkinsonism and drug induced extrapyramidal reactions (except tardive dyskinesia). Benzhexol possesses both anti cholinergic and antihistaminic effects, although only the former has been established as therapeutically significant in the management of Parkinsonism. Chemically it is 1-cyclohexyl-1-phenyl-3-(piperidin-1-yl) propan-1-ol. Most of the Pharmaceutical industries utilize sophisticated equipments like HPLC, HPTLC and LC-MS for qualitative analysis of various drugs. These equipments also used in analyzing the raw material to ensure the obtained product is pure and also to determine how much amount of the drug is present in the final product.

Among all analytical methods, the modern method of choice for drug analysis is Chromatographic technique which requires highly sophisticated equipment, trained personal, high purity chemicals and proper maintenance. Reverse Phase High Performance Liquid Chromatography (RP-HPLC) is assuming one of the best analytical equipment for various categories of pharmaceutical drugs. An extreme literature survey revealed that very few analytical methods have been reported for Haloperidol, Benzhexol in individual and combination and other drugs. Therefore it was thought of interest in development and validating a new and advanced sensitive, specific, precise, accurate stability indicating RP-HPLC method for simultaneous estimation of Haloperidol and Benzhexol in bulk drug and in pharmaceutical dosage form.

MATERIALS AND METHODS:

Drugs and chemicals: Haloperidol and Benzhexol were obtained as gift sample from Spectrum Pharma Research laboratory in Hyderabad. Tablets (Hexidol Forte, Torrent Pharmaceuticals Ltd, Secundrabad, Telangana, India.) containing Haloperidol-10 mg and Benzhexol-2 mg Marketed formulation was purchased from local market. Acetonitrile, Water HPLC grade were obtained from Merck, Mumbai, India and Potassium dihydrogen ortho phosphate, Triethylamine from RANKEM, Mumbai, India. All solvents used in this work are HPLC grade.

Instrument: A Waters 2695 RP-HPLC separation module (Waters Corporation, Milford, USA) equipped with PDA detector having back pressure 5000psi, automatic injector and Kromasil-250x4.6mm, 5µ. Single pan Balance (Mettler Toledo), Control Dynamics PH meter (Mettler Toledo), Sonicator (Labindia Instruments).

Chromatographic conditions: An isocratic RP-HPLC system was used for analysis of samples at 30 °C column oven temperature. The chromatographic separation was achieved on Kromasil-250x4.6mm, 5µ column using (0.1%) Perchloric acid and Acetonitrile 50:50 %v/v as mobile phase at a flow rate of 1ml/min. The injection volume was 10 µl and the total runtime was set as 10min. The determination of analytes was carried out at 210nm using PDA detector.

Preparation of Samples and Solutions

Preparation of Mobile Phase: Accurately 1ml of Perchloric acid in a 1000ml of volumetric flask adds about 900ml of milli-Q water added and degasses to sonicate and finally make up the volume with water.

Preparation of Haloperidol stock solution: Accurately Weighed and transferred 10mg of Haloperidol in to 10ml of clean dry volumetric flask, add 7ml of diluent, then sonicated for 10min and make up the volume with diluent.

Preparation of Benzhexol stock solution: Accurately weighed 2mg of Benzhexol and transferred into 10ml of clean dry volumetric flask, add 7ml of diluent, then sonicated for 10 min and make up the final volume with diluent.

Preparation of Haloperidol standard solution: From the above Haloperidol stock solution 1ml was pipette out into 10ml of clean dry volumetric flask and make up the final volume with diluent.

Preparation of Benzhexol standard solution: From the above Benzhexol stock solution 1ml was pipette out into a 10ml clean dry volumetric flask and make up the final volume with diluent.

RESULTS AND DISCUSSION

Optimized chromatographic conditions: A Reverse Phase C8 and C18 columns were tried initially to separate the analytes. After several systemic trials, a suitable C18 column was selected and good separation of the compounds was achieved with mobile phase consisting Perchloric acid and Acetonitrile in the ration of 50:50 %v/v. Finally, a simple precise, sensitive, accurate, precise and economic RP-HPLC method has been developed for performing stability studies and simultaneous estimation of Haloperidol and Benzhexol. The optimized chromatographic conditions were given in the below table.

Optimized chromatographic conditions

Parameter	Condition
RP-HPLC	Water 2695 separation module with PDA detector
Mobile phase	Perchloric acid: ACN 50:50%v/v
Column	Kromasil-250x4.6mm, 5µ column
Column Temperature	30°C
Wavelength	210nm
Diluents	Water: ACN (50:50)
Injector volume	10µl
Flow rate	1ml/min
Runtime	7min
Retention time	Haloperidol-2.139min and Benzhexol-3.151min
Theoretical Plates	Haloperidol-2919 and Benzhexol - 7217

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RJPT

RESEARCH ARTICLE

Q-Analysis and Simultaneous Equation method for Estimation of Domperidone and Naproxen by UV Spectrophotometry in bulk and Tablet Dosage Form

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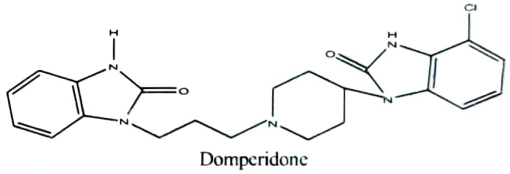
ABSTRACT:

An accurate, specific and precise UV spectrophotometric method was developed for the simultaneous determination of domperidone (DOM) and naproxen (NAP) in tablet dosage form. The optimum conditions for the analysis of the drug were established. The maximum wavelength (λmax) was found to be 286nm for DOM and 270nm for NAP respectively. The linearity of the proposed method was found in the range of 10-50µg/ml and 5-25µg/ml for DOM and NAP respectively. Calibration curves showed a linear relationship between the absorbance and concentration. The line equation for DOM Y = 0.020X + 0.005 with r^2 of 0.999 and for NAP Y = 0.022X + 0.003 with r^2 of 0.999 was obtained. Validation was performed as per ICH guidelines for linearity, accuracy, precision, LOD and LOQ. The LOD and LOQ were found to be with in the range. The proposed method was simple, sensitive, precise, accurate, quick and useful for routine analysis of DOM and NAP in bulk and tablet dosage forms.

KEYWORDS: Simultaneous equation method, Validation, Domperidone, Naproxen, UV spectrophotometry.

INTRODUCTION:

Domperidone acts as a gastrointestinal emptying (delayed) adjunct and peristaltic stimulant. The gastroprokinetic properties of domperidone are related to its peripheral dopamine receptor blocking properties. Domperidone facilitates gastric emptying and decreases small bowel transit time by increasing esophageal and gastric peristalsis and by lowering esophageal sphincter pressure. Antiemetic: The antiemetic properties of domperidone are related to its dopamine receptor blocking activity at both the chemoreceptor trigger zone and at the gastric level. It has strong affinities for the D2 and D3 dopamine receptors, which are found in the chemoreceptor trigger zone, located just outside the blood brain barrier, which - among others - regulates nausea and vomiting.[1]



Domperidone

Figure No 1

As with other non-selective NSAIDs, naproxen exerts it's clinical effects by blocking COX-1 and COX-2 enzymes leading to decreased prostaglandin synthesis.[3] Although both enzymes contribute to prostaglandin production, they have unique functional differences.[3] The COX-1 enzymes is constitutively active and can be found in normal tissues such as the stomach lining, while the COX-2 enzyme is inducible and produces prostaglandins that mediate pain, fever and inflammation.[4] The COX-2 enzyme mediates the desired antipyretic, analgesic and anti-inflammatory properties offered by Naproxen, while undesired adverse effects such as gastrointestinal upset and renal toxicities are linked to the COX-1 enzyme.[2]

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COVID-19 SPECIAL COLLECTION

RESEARCH ARTICLE

Pharmacy education during and beyond COVID-19 in six Asia-Pacific countries: Changes, challenges, and experiences

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Abstract

The COVID-19 pandemic shifted pharmacy education to remote teaching and learning (T&L) strategies. To share changes, challenges, and experiences in pharmacy education among member countries, the Federation of Asian Pharmaceutical Associations hosted a 1.5-hour webinar on 15th May 2020. Questions collected during registration and the live webinar were coded using thematic analysis. A total of 794 participants from 18 countries/territories registered, while 346 attended the webinar. Of 445 questions, 392 were from the registration form and 53 from the webinar. All questions were coded to four major themes: new normal pharmacy education, ethics and safety, material accessibility, and teaching and evaluation methods. Questions during registration were mostly on new normal adaptation (n=79), T&L formats (n=65), and access/resources/sustainability (n=59). Webinar questions were mainly on assessment format (n=13), laboratory skills (n=9), and access/resources/sustainability (n=9). The webinar provided an opportunity to quickly identify issues regarding pharmacy education during the COVID-19 pandemic for prompt actions and further research.

Introduction

The coronavirus disease 2019 (COVID-19) pandemic has pushed higher institutions of learning to quickly adjust their teaching and learning (T&L) strategies in order to comply with international and national safety measures, including reduced movements of staff and students due to lockdowns, movement control orders (MCO), and international border closures. Hence, institutions employed online-based T&L using various information technology (IT) platforms. Staff and students faced challenges to ensure seamless delivery of synchronous