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ANTI-DIABETIC ACTIVITY AND ANTI-HYPERLIPIDEMIC ACTIVITY OF BARLERIA LONGIFLORA

KUTHATI THIRUPATHAMA[1]*, K. CHAITANYA PRASAD[2], B. SUDHAKAR[3]
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Abstract:

Objective *- To investigate the anti diabetic and anti Hyperlipidemic activity of methanol extract of Barleria longiflora in male Wistar rats.*

Material & method: *- In this model of Hyperlipidemia 30 adult male wistar rats (150-200gms) were equally divided into 5 groups in both groups. Group-1 and Group-2 served as untreated and model controls respectively, while Group-3, 4 and 5 were the treatments groups which were simultaneously treated with standard, 200 and 400 mg/kg extract respectively along with High Fat Diet and Triton x 100. On last day, blood samples for biochemical parameters, were obtained under inhaled diethyl anaesthesia.*

In the model of anti diabetic animals were evenly divided into 5 groups.

Group-1 and Group-2 served as untreated and model controls respectively, while Group-3, 4 and 5 were the treatments groups which were simultaneously treated with standard, 200 and 400 mg/kg extract respectively after glucose loading.

Results: *- HFD and Triton x 100 treatment caused Hyperlipidemia as evidenced by marked elevation in Cholesterol, Triglycerides, LDL, VLDL and decrease in HDL levels. Co-administration of extract with HFD and Triton x 100 decreased rise Cholesterol, Triglycerides, LDL, VLDL and increase in HDL levels.*

Glucose loading caused hyperglycemia by elevation of glucose which was significantly reduced by treatment with standard and extract.

Conclusion: *It was observed that the methanol extract of Barleria longiflora conferred anti diabetic and Anti- Hyperlipidemia activity by biochemical observation against HFD and Triton x 100 induced Hyperlipidemia in rats. In the near future could constitute a lead to discovery of a novel drug for treatment of drug induced Hyperlipidemia and diabetes.*

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RESEARCH ARTICLE

Formulation and Evaluation of Sotalol Gastrorententive Tablets

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ABSTRACT:
The objective of this study was to formulate floating tablets (GRDDS) of Sotalol using direct compression method to increase its bioavailability and the gastric residence time of the dosage form. The Sotalol tablets were prepared by direct compression method. The tablets were prepared by using different types of polymers i.e.; Sodium CMC, Chitosan and Psyllium Husk which act as a release retardant polymer. Sodium bi carbonate ($NaHCO_3$) was used as a gas degenerating agent and MCC (Micro crystalline cellulose) was used as a diluent. The prepared formulation were subjected to some evaluation parameters like hardness, friability, weight variation, drug content, buoyancy property, drug release study etc. In the FT-IR study it was revealed that there is no interaction between the drug and excipients. The formulation which containing Chitosan polymer and Sodium bicarbonate shows good drug release pattern with less floating lag time and good floating duration. The *in vitro* drug release pattern of Sotalol floating tablets was fitted to different kinetic models which showed the highest regression for Higuchi order kinetics. Thus, it can be concluded that the floating drug delivery system of Sotalol using the appropriate polymers in right amount may enhance the activity of the drug by prolonging the gastric residence time or reducing the floating lag time.

KEYWORDS: Sotalol and Floating Tablets.

INTRODUCTION:

The aim of drug delivery system is to afford therapeutic amount of drug to the proper site in the body to attain promptly and then maintain desired drug concentration. Theoral route is increasingly being used for the delivery of therapeutic agents because the low cost of the therapy and ease of administration lead to high levels of patient compliance. More than 50% of the drug delivery systems available in the market are oral drug delivery systems [1-4].

Gastric emptying of dosage forms is an extremely variable process and ability to prolong and control the emptying time is a valuable asset for dosage forms, which reside in the stomach for a longer period of time than conventional dosage forms. Several difficulties are faced in designing controlled release systems for better absorption and enhanced bioavailability. One of such difficulties is the inability to confine the dosage form in the desired area of the gastrointestinal tract. The relatively brief gastric emptying time (GET) in humans which normally averages 2-3 h through the major absorption zone, i.e., stomach and upper part of the intestine can result in incomplete drug release from the drug delivery system leading to reduced efficacy of the administered dose. Sustained releases are dosage forms that provide medication over an extended period of time. Controlled release denotes that the system is able to provide some actual therapeutic control [5]. Controlled release (modified release) dosage forms are growing in popularity. These more sophisticated systems can be used as a means of altering the pharmacokinetic behavior

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PHARMACOLOGICAL EVALUATION OF ANTIDEPRESSANT AND ANTIANXIETY ACTIVITY OF BUPLEURUM FALCATUM IN ANIMAL MODELS

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Abstract:
Bupleurum falcatum, belongs to the family Apiaceae. Anxiety and Depression are wide spread psychiatric disorders affecting around 5% of the population. Furthermore, it is difficult to predict which patient will respond to any given treatment. In the traditional systems of medicine, many plants have been used to treat anxiety and depression for thousands of years. The present study was designed to evaluate the antianxiety and antidepressant activity of the alcoholic and aqueous extracts of Bupleurum falcatum leaves in rodents. Antianxiety activity was tested by exposing rats to unfamiliar aversion in different methods like elevated plus maze, hole board and actophotometer. The results infer that reduced aversion fear elicits antianxiety activity. The antidepressant activity was tested by using forced swim test and tail suspension test. The results infer that reduced immobility time evicts antidepressant activity. It was concluded that alcoholic and aqueous extracts of Bupleurum falcatum leaves having antianxiety and antidepressant activity. Alcoholic extract of Bupleurum falcatum leaves showing more significant activity over the aqueous extract.

Keywords: *Bupleurum falcatum, Antianxiety activity, Antidepressant activity, Elevated plus maze, Actophotometer, Forced swim test, Tail Suspension Test.*

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Research

NEWER RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF DILOXANIDE FUROATE, TINIDAZOLE IN DOSAGE FORM

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Abstract

A rapid and precise reverse phase high performance liquid chromatographic method has been developed for the validated of Diloxanide and Tinidazole, in its pure form as well as in tablet dosage form. Chromatography was carried out on a Phenomenex Gemini C18 (4.6 x 150mm, 5µm) column using a mixture of Methanol: Water (25:75% v/v) as the mobile phase at a flow rate of 1.0ml/min, the detection was carried out at 240 nm. The retention time of the Tinidazole and Diloxanide was 2.256, 5.427 ±0.02min respectively. The method produce linear responses in the concentration range of 5-25mg/ml of Tinidazole and 25-125mg/ml of Diloxanide. The method precision for the determination of assay was below 2.0%RSD. The method is useful in the quality control of bulk and pharmaceutical formulations.

Keywords: Diloxanide, Tinidazole, RP-HPLC, validation.

INTRODUCTION

Analytical chemistry is a scientific discipline used to study the chemical composition, structure and behaviour of matter. The purposes of chemical analysis are together and interpret chemical information that will be of value to society in a wide range of contexts. Quality-control in manufacturing industries, the monitoring of clinical and environmental samples, the assaying of geological specimens, and the support of fundamental and applied research are the principal applications. Analytical chemistry involves the application of a range of techniques and methodologies to obtain and assess qualitative, quantitative and structural information on the nature of matter.

- **Qualitative analysis** is the identification of elements, species and/or compounds present in sample.
- **Quantitative analysis** is the determination of the absolute or relative amounts of elements, species or compounds present in sample.

Structural analysis is the determination of the spatial arrangement of atoms in an element or molecule or the identification of characteristic groups of atoms (functional groups). An element, species or compound that

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Reference citation should start from introduction section with superscript number in ascending order EX: 1,2,3....

oxygen, which include free radicals such as superoxide ions (O_2^-) and hydroxyl radicals (OH), as well as non-free radical species such as hydrogen peroxide (H_2O_2). These ROS plays an important role in degenerative or pathological processes, such as aging, cancer, coronary heart disease, Alzheimer's disease, neurodegenerative disorders, atherosclerosis, cataracts and inflammation. In living organism various ROSs were formed in different ways, through normal aerobic respiration lead to the stimulation of

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Review

Procedure And Regulations For Drug Registration In UK

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Abstract

MHRA (Medicines And Health Products Regulatory Agency) is the regulatory authority body for pharmaceuticals approval in the UK union. MHRA is formed by the merging of two separate agencies in 2003 i.e., Medicines Control Agency and Medical Device Agency. This agency works to maintain safety, quality and efficacy of the drug product before it enters into the country. The main aim of this work is to know about the practice and the regulatory requirements for the registration of a drug in the UK as per the regulations of MHRA. They are responsible for ensuring that the medicines and medical devices are acceptably safe and don't cause any harm to the patients. MHRA provides a license which is a marketing authorization to the manufacturer, required before a drug is being used by the patients of that country. Good Manufacturing Practice (GMP) is the minimum requirement that a manufacturer should possess during the period of production of the drug product. New drugs are being invented and also being distributed as per the needs of the patients. It is known that no drug product is completely safe or is 100% safe for use, but MHRA tries to minimize as many problems regarding the drug so that patients will be provided with the best drug with minimal risk.

Keywords: MHRA, United Kingdom, Product license, eCT, CTD

INTRODUCTION

The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK. MHRA is an executive agency, sponsored by the Department of Health and Social Care. MHRA (Medicines And Health Products Regulatory Agency) is the regulatory authority body for pharmaceuticals approval in the UK union. MHRA is formed by the merging of two separate agencies in 2003 i.e., Medicines Control Agency and Medical Device Agency. This agency works to maintain safety, quality and efficacy of the drug product before it enters into the country. The main aim of this work is to know about the practice and the regulatory requirements for the registration of a drug in the UK as per the regulations of MHRA. They are responsible for ensuring that the medicines and medical devices are acceptably safe and don't cause any harm to the patients. MHRA provides a license which is a marketing authorization to the manufacturer, required before a drug is being used by the patients of that country. Good Manufacturing Practice (GMP) is the minimum requirement that a manufacturer should possess during the period of production of the drug product. New drugs are being invented and also being distributed as per the needs of the patients. It is

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Research

A New Analytical Method Development And Validation For Quantitative Estimation Of Spironolactone And Furosemide In Bulk And Tablet Dosage Form By Using Rp-Hplc

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Abstract

A rapid and precise reverse phase high performance liquid chromatographic method has been developed for the validated of Spironolactone and Furosemide, in its pure form as well as in pharmaceutical dosage form. Chromatographic separation was carried out on a Symmetry C18 (4.6 x 150mm, 5µm) column using a mixture of Methanol: TEA Buffer pH 4.2 (40:60v/v) as the mobile phase at a flow rate of 1.0ml/min, the detection was carried out at 272 nm. The retention time of the Spironolactone and Furosemide was 2.781, 4.048 ±0.02min respectively. The proposed method was validated for various ICH parameters like linearity, limit of detection, limits of quantification, accuracy, precision, range and specificity. The method produce linear responses in the concentration range of 5-25mg/ml of Spironolactone and 9.375-46.875 mg/ml of Furosemide. The method precision for the determination of assay was below 2.0%RSD. The proposed method is applicable to routine analysis of Spironolactone and Furosemide in bulk and pharmaceutical formulations.

Keywords: Spironolactone, Furosemide, RP-HPLC, Accuracy, Robustness.

INTRODUCTION

Analytical chemistry is a scientific discipline used to study the chemical composition, structure and behaviour of matter. The purposes of chemical analysis are together and interpret chemical information that will be of value to society in a wide range of contexts. Quality control in manufacturing industries, the monitoring of clinical and environmental samples, the assaying of geological specimens, and the support of fundamental and applied research are the principal applications. Analytical chemistry involves the application of a range of techniques and methodologies to obtain and assess qualitative, quantitative and structural information on the nature of matter.

Qualitative analysis is the identification of elements, species and/or compounds present in sample.

Quantitative analysis is the determination of the absolute or relative amounts of elements, species or compounds present in sample.

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Research

ASSESSMENT OF DRUG RELATED PROBLEMS IN THE PATIENTS OF CARDIOLOGY DEPARTMENT IN A TERITIARY ROHINI HOSPITAL

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Abstract

Cardiovascular diseases are the biggest killers in the world according to WHO, of which stroke and ischemic heart disease are main diseases, which nearly cause 15 million deaths. Drug Related Problems are defined as a circumstance or an event which involves the pharmacotherapy or the drug treatment that interferes with the optimum outcome of medical care of a patient. DRP'S are classified into 4 categories according to PCNE classification V.5.01 which are the Problems, Causes, Interventions and the Outcome of intervention. The main aim of the study is to detect the drug related problems among the patients with cardiovascular diseases admitted to the hospital in a tertiary Rohini hospital. A cross sectional observational study with a sample size of 100 patients in a period of 6 months was included as per inclusion criteria and exclusion criteria. All the case record sheets of patients above 18 years are collected to assess the drug related problems. Of all the 100 case records collected,44 DRP'S were found in 39 patients. The major DRP identified is Drug interactions-26 followed by ADR'S-15, Therapeutic duplication-2 and Wrong dose-1. Mainly the 33 DRP'S were found in 29 male patients with an incidence rate of 41.4% when compared to females,11 DRP'S in 10 patients with an incidence rate of 33.3%. The drug related problems have higher incidence rate in male patients than in female patients. Most common drug related problems observed are Drug Interactions followed by the Adverse Drug Reactions. Interventions are generally made at the prescriber level and the outcome of intervention in most of the cases is totally solved.

Keywords: Drug Related Problems, Cardiovascular Diseases, Drug Interactions, Adverse Drug Reactions.

INTRODUCTION

Cardiovascular illness (CVDs) area is unit hunch of disorders of the guts and blood vessels and that they embody arteria disease, vessel illness, peripheral blood vessel illness, rheumatic heart condition, inborn heart condition, deep vein occlusion and embolism and stroke(1).

Cardiovascular diseases (CVDs) have currently become the leading reason behind mortality in Asian nation. 1 / 4 of all mortality is as a result of CVD. Anaemia, heart condition and stroke area unit the predominant causes and area unit answerable for >80% of CVD deaths. The worldwide burden of illness study estimate of age-standardized CVD death rate of 272 per 100000 population in Asian nation is beyond the

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REVIEW ARTICLE

Formulation and Evaluation of Bosentan Pulsatile Drug Delivery System by Using Press Coated Technique

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ABSTRACT:
In the present research work, we have designed a pulsatile formulation of Bosentan to treat High blood pressure as per the chronotherapeutic pattern of the disease. Core tablets were prepared by incorporating different concentration of disintegrants and were compressed in between different concentration of polymers. The core and compression coated tablets were subjected to pre-formulation, physicochemical and *In-vitro* drug release studies. FTIR studies revealed that there was not any chemical reaction between pure drug Bosentan and polymers. The pre and post-compressional parameters of tablets were also found to be within limits. Our optimized formulation F-6 releases Bosentan after a lag time of 2 hours and 98.01 % up to 12 hours. Formulations were stable for at least 3 months under standard long-term and accelerated storage conditions.

KEYWORDS: Pulsatile formulation, Bosentan, and press coated tablets.

INTRODUCTION:

Bosentan is chemically, 4-tetrabutyl-N-[6-(2-hydroxyethoxy)-5-(2-methoxyphenoxy)-2-(pyrimidin-2-yl) pyrimidin-4-yl] benzene-1-sulfonamide2. (Fig.1).It is a white crystalline powder .chemical formula C27H29N5O6S, and Molecular weight of551.6.[1] Bosentan is used to lower the pulmonary hypertension by blocking the action of endothelin-1 molecules responsible for narrowing the blood vessels and elevates high blood pressure[2].

Bosentan monohydrate was selected active therapeutic agent which is having 50% absolute bioavailability and 5 hours of terminal elimination half-life. The innovator Trachleer is successful brand tablet formulation of Bosentan monohydrate US manufactured by PatheonInc and marketed by Acteleon pharmaceuticals US was found to be expensive and exhibits high cost benefit ratio.[3]

Anti-hypertensive agents hold a major share of drug market as hypertension is a major cause of health problems. The estimated market share of anti-hypertensive agents is $30 billion by 2016. As a consequence, the chances of adulteration increases due to increased market needs. Adulteration in any form is not acceptable for any drugs, especially for Anti-hypertensive agents.[4] Hypertension is a condition in

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Research article Clinical research

Nephro protective activity of *plumbago zeylanica* extract on gentamicin induced nephrotoxicity in rats

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ABSTRACT

Herbal medicine is the oldest form of healthcare known to mankind and most cultures have long folk medicine histories that include the use of plants. Nephrotoxicity is one of the most common kidney problems and occurs when the body is exposed to a drug or toxin that causes damage to the kidneys. To investigate the Nephroprotective activity of ethanol extract of *Plumbago zeylanica* on Gentamicin induced Nephrotoxicity in male Wistar rats. In this model of Nephrotoxicity, 30 adult male wistar rats (150-200gms) were evenly divided into 5 groups. Group-1 and Group-2 served as untreated and model controls respectively, while Group-3, 4 and 5 were the treatments groups which were simultaneously treated with standard, 200 and 400 mg/kg extract respectively, after each dose Gentamicin (80 mg/kg, i.p.) for 10 day. On 11th day, blood samples for biochemical parameters, while the rats kidneys for histology were obtained under inhaled diether anaesthesia. Gentamicin treatment caused Nephrotoxicity as evidenced by marked elevation in blood urea, uric acid and Creatinine. Co-administration of extract with *Plumbago zeylanica* decreased rise in blood urea, uric acid and Creatinine. Apart from these, histopathological changes also showed the protective nature of extract against Gentamicin induced necrotic damage of renal tissues. It was observed that the ethanol extract of conferred nephroprotective activity by histopathological and biochemical observation against Gentamicin induced Nephrotoxicity in rats. In the near future could constitute a lead to discovery of a novel drug for treatment of drug induced Nephrotoxicity.

Keywords: *Plumbago zeylanica*, Nephrotoxicity, Nephroprotective activity, Gentamicin

INTRODUCTION

Kidney

Anatomy and physiology of kidney

Kidney is an important excretory organ in the human body. The function of kidney is not only to excrete the metabolic waste products, but also to maintain the acid base balance and endocrine functions like erythropoietin production (which stimulates the bone marrow to produce red blood cells), active form of vitamin D (calcitriol or 1, 25 dihydroxy-vitamin D which regulates absorption of calcium and phosphorus from food, promoting formation of strong bone), renin (which regulates blood volume and blood pressure). The kidney receives blood supply from the renal artery, the branch of abdominal aorta and the venous drainage occurs through renal vein. The urine formed in the kidney gets drained through ureter into the urinary bladder. Kidneys are situated retroperitonially in abdominal cavity and has outer cortex and inner hypertonic medulla. The structural and functional unit of the kidney is nephron. Each human kidney has approximately about 1.3 million nephrons. Each nephron has glomerulus and renal tubules. The glomerulus is formed by invagination of tuft of capillaries into the dilated blind end of the nephron (Bowman's capsule); the capillaries are supplied by an afferent arteriole and drained by an efferent arteriole. The blind end of the nephron continues as the proximal convoluted tubule of 15 mm long and 55nm diameter. The convoluted portion of the proximal tubule drain into the straight portion which forms the first part of the loop of henle. The loop of henle continues with ascending loop of henle and further as distal convoluted tubule which opens into the collecting duct[1].

In the resting adult, the kidney receives 1.2 to 1.3 liters of blood per minute. Glomerular filtrate is formed by the blood in the glomerular capillaries by hydrostatic and osmotic pressure gradients. The glomerular membrane permits free passage of neutral substances with particle size up to 4nm in

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Research

SIMULTANEOUS ESTIMATION OF NEW ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF DABRAFENIB AND TRAMETINIB BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY

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Abstract

An accurate, precise, simple, efficient and reproducible, isocratic Reversed Phase-High Performance Liquid Chromatography (RP-HPLC) method was developed and validated for the simultaneous estimation of Dabrafenib and Trametinib in bulk and combined pharmaceutical tablet dosage forms. Dabrafenib and Trametinib were separated by using a Symmetry ODS C18 (4.6mm×150mm) 5µm Particle Size: Waters Alliance e2695 HPLC system with 2998 PDA detector and the mobile phase contained a mixture of Methanol: 0.1% Orthophosphoric acid (64:36% v/v). The flow rate was set to 1ml/min with the responses measured at 224nm. The retention time of Dabrafenib and Trametinib was found to be 2.808min and 3.880min respectively with resolution of 5.68. Linearity was established for Dabrafenib and Trametinib in the range of 20-100µg/ml for Dabrafenib and 60-140µg/ml for Trametinib with correlation coefficient 0.999. The percentage recovery was found to be is 100.30% for Dabrafenib and 100.21% for Trametinib respectively. Validation parameters such as specificity, linearity, precision, accuracy and robustness, limit of detection (LOD) and limit of quantitation (LOQ) were evaluated for the method according to the International Conference on Harmonization (ICH) Q2 R1 guidelines. The developed method was successfully applied for the quantification of bulk and active pharmaceutical ingredient present and in combined tablet dosage form.

Keywords: Dabrafenib and Trametinib, RP-HPLC, Validation, Accuracy, Precision

INTRODUCTION

Analytical chemistry[1] is the branch of chemistry involved in separating, identifying and determining the relative amounts of the components making up a sample of matter. It is mainly involved in the qualitative

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oxygen, which include free radicals such as superoxide ions (O_2^-) and hydroxyl radicals (OH), as well as non-free radical species such as hydrogen peroxide (H_2O_2). These ROS plays an important role in degenerative or pathological processes, such as aging, cancer, coronary heart disease, Alzheimer's disease, neurodegenerative disorders, atherosclerosis, cataracts and inflammation. In living organism various ROSs were formed in different ways through normal aerobic respiration lead to the stimulation of

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RESEARCH ARTICLE

Reverse Phase High Performance Liquid Chromatography Method for Simultaneous Estimation of Aspirin and Caffeine in Pure and Tablet

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ABSTRACT:
A new, simple, rapid, accurate and precise Reverse Phase High Performance Liquid Chromatographic method has been developed for the validated of Aspirin and Caffeine, in Active pharmaceutical Ingredient form as well as in combined tablet dosage form. Chromatography was carried out on Symmetry ODS C18 (4.6mm × 250mm, 5µm) column using a mixture of Methanol: Acetonitrile (35:65v/v) as the mobile phase at a flow rate of 1.0ml/min, the detection was carried out at 273 nm. The retention time of the Aspirin and Caffeine, was 2.085, 5.262 ± 0.02min respectively. The method produce linear responses in the concentration range of 30-70mg/ml of Aspirin and 6-14mg/ml of Caffeine.. The mean % assay of marketed formulation was found to be 100.04%, and % recovery was observed in the range of 98-102%. Relative standard deviation for the precision study was found <2%.The developed method is simple, precise and rapid, making it suitable for estimation of Aspirin and Caffeinein API and combined tablet dosage form. The method is useful in the quality control of bulk and pharmaceutical formulations.

KEYWORDS: Aspirin and Caffeine, RP-HPLC, Validation, ICH Guidelines.

INTRODUCTION:

High performance liquid chromatography (HPLC) is a technique used for analysis of drug substance, drug product and determination and quantification of known as well as unknown impurities at lower level, food and drug administration (FDA) also trust on the purity method of analysis by using HPLC, because of high accuracy and reproducibility of results[1].

The importance of chromatography is increasing rapidly in pharmaceutical analysis for the exact differentiation, selective identification, quantitative determination of structurally closely related compounds.

Another important field of application of chromatographic methods is the purity testing of final products and the intermediates[2].

Aspirin, 2-(acetyloxy) benzoic acid, acts as an inhibitor of cyclooxygenase which results in the inhibition of the biosynthesis of prostaglandins. It also inhibits platelet aggregation and is used in the prevention of arterial and venous thrombosis [3]. Aspirin is also used for long-term, at low doses, to help prevent heart attacks, strokes, and blood clot formation in people at high risk for developing blood clots [4].

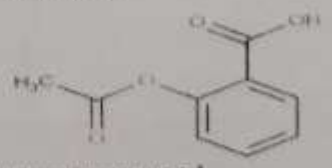

Fig 1: Chemical Structure of Aspirin[5]

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Research

FORMULATION DEVELOPMENT AND *IN VITRO* CHARACTERIZATION OF FLURBIPROFEN SUSTAINED RELEASE MATRIX TABLETS

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Abstract

In the present work, an attempt has been made to develop Sustained release tablets of Flurbiprofenby selecting natural polymers Tragacanth, Acacia gum, and Xanthan gum as retarding polymers. All the formulations were prepared by direct compression method. The blend of all the formulations showed good flow properties such as angle of repose, bulk density, tapped density. The prepared tablets were shown good post compression parameters and they passed all the quality control evaluation parameters as per I.P limits. Among all the formulations F2 formulation showed maximum % drug release i.e., 95.19% in 12 hours hence it is considered as optimized formulation F2 which contains Tragacanth(100 mg). Optimized formulation F2 was followed Higuchi release kinetics mechanism.

Keywords: Flurbiprofen, Tragacanth, Acacia gum, Xanthan gum and sustained release tablets.

INTRODUCTION

All the pharmaceutical products formulated for systemic delivery via the oral route of administration irrespective of the mode of delivery (immediate, sustained or controlled release) and the design of dosage forms (either solid dispersion or liquid), must be developed within the intrinsic characteristics of GI physiology, pharmacokinetics, pharmacodynamics and formulation design is essential to achieve a systemic approach to the successful development of an oral pharmaceutical dosage form. Sustained-release medications are usually labeled with "SR" at the end of their name. These medications prolong the medication's release from a tablet or capsule so that you'll get the medication's benefits over a longer period of time. Sustained-release medications should not be used alone to adjust or titrate a patient's uncontrolled pain. Using them for titration unduly prolongs the process to

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oxygen, which induce free radicals such as superoxide ions (O_2^-) and hydroxyl radicals (OH), as well as non-free radical species such as hydrogen peroxide (H_2O_2). These ROS plays an important role in degenerative or pathological processes such as aging, cancer, coronary heart disease, Alzheimer's disease, neurodegenerative disorders, atherosclerosis, cataracts and inflammation. In living organism various ROSs were formed in different ways, through normal aerobic respiration lead to the stimulation of

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Research

Life Cycle of Drug Regulation

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Abstract

Pharmaceutical regulations across the world play an important role in ensuring the safety and efficacy of the approved drugs. They not only regulate the pricing of drugs but the quality as well. The regulations are required both for new innovations and already existing products, in order to improve health status. An important agenda of pharmaceutical companies is the establishment of therapeutic area strategies, drug modality, and geographic strategies for research and development. It is worthwhile to understand the changes in therapeutic area, modality and internationalization of the top-selling pharmaceutical drugs over the past. Hence, the purposes of this study are to investigate changes in therapeutic area, modality and internationalization of the top-selling drugs and to identify their life cycle patterns. We compared the top-selling drugs between 2011 and 2017, and found that the percentages of nichebuster cancer drugs and home region-oriented drugs have increased whereas the proportions of traditional blockbuster cardiovascular drugs and global drugs have decreased. We compared product life cycle patterns via a Kruskal–Wallis test, and identified the features of product life cycle patterns per therapeutic area and modality. We performed a case study on drugs in the same class with the same pharmacological mechanism but found no differences across cases. Our results provide insights into therapeutic area strategies that consider life cycle patterns and geographic strategies that consider the competitive advantages of home region-oriented drugs. Finally, we presented new and simple models of life cycle patterns. This approach may help such enterprises establish and maintain sustainable growth.

Keywords: (FDA), the European Medicines Agency (EMA) and the Japanese Pharmaceutical and Medical Devices Agency (PMDA).

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Research

FORMULATION DEVELOPMENT AND *IN VITRO* CHARACTERIZATION OF FLURBIPROFEN SUSTAINED RELEASE MATRIX TABLETS

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Abstract

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Keywords: Flurbiprofen, Tragacanth, Acacia gum, Xanthan gum and sustained release tablets.

INTRODUCTION

All the pharmaceutical products formulated for systemic delivery via the oral route of administration irrespective of the mode of delivery (immediate, sustained or controlled release) and the design of dosage forms (either solid dispersion or liquid), must be developed within the intrinsic characteristics of GI physiology, pharmacokinetics, pharmacodynamics and formulation design is essential to achieve a systemic approach to the successful development of an oral pharmaceutical dosage form. Sustained-release medications are usually labeled with "SR" at the end of their name. These medications prolong the medication's release from a tablet or capsule so that you'll get the medication's benefits over a longer period of time. Sustained-release medications should not be used alone to adjust or titrate a patient's uncontrolled pain. Using them for titration unduly prolongs the process to bring the pain under control. However, once the pain is controlled, changing to a sustained-release product may enhance the patient's quality of life and improve compliance and adherence due to the decreased frequency of dosing.

Advantages of administering a single dose of a drug that is released over an extended period of time, instead of numerous doses, have been obvious to the Pharmaceutical industry for some time. The desire to maintain a near-constant or uniform blood level of a drug often translates into

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Research

Principle And Guidelines For Be Studies For Approval Of ANDA

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Abstract

The present study was aimed to study the requirements of bioequivalence for the registration of pharmaceutical products. Before going into bioequivalence studies it is essential for the pharmaceutical industry to study the guidelines of bioequivalence for the respective country where the industry wants to market its products and thus enter into generic market. This study reviews the requirements of bioequivalence with study parameters such as study design, fasting or fed state studies, volunteers recruitment, study dose, sampling points, analytical method validation parameters, moieties to be measured in plasma, pharmacokinetic parameters, criteria for bioequivalence, which are needed for the pharmaceutical industry to carry out bioequivalence studies and to file ANDA. Test products and reference products are needed for this study. Test products are usually manufactured by a sponsor and reference products are provided by the government laboratories of the respective countries. Sampling points also vary with respect to the regulatory guidelines of a country.

Keywords: Raphia hookeri, total antioxidant

INTRODUCTION

Bioequivalence studies are special type of studies where two drugs or two sets of formulation of the same drug are compared to show that they have nearly equal bioavailability and PK/PD parameters. These studies are often done for generic drugs or when a formulation of a drug is changed during development.

Generally, demonstration of bioequivalence (BE) is the most appropriate method of ensuring therapeutic equivalence between two medicinal products. Bioequivalence studies should be conducted for comparison of medicinal products containing same active substance. Such studies need to be carefully designed to take into account biopharmaceutical, ethical, medical, pharmacokinetic, analytical and statistical considerations. The studies should be aimed to critically assess the possibility of alternate use of these products. In the 2003 United States Food and Drug Administration (FDA) guidance, bioequivalence is defined as: "the absence of a significant difference in the rate

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Research

Current trends in regulatory actions against misbranding and adulteration

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Abstract

Adulteration has led to many mild, moderate, severe adverse reactions in our body. They Can Be Life Threatening as Well. Adulteration Is Done with The Use of Other Crude Drugs Which Consists of Similar Properties. Every country is the victim of misbranded or adulterated drugs, which result in life threatening issues, financial loss of consumer and manufacturer and loss in trust on health system. For minimizing adulterated and misbranding drugs or not of standard quality drugs, there is urgent requirement of more stringent regulation and legal action against the problem. The adulteration and substitution of crude drug is a burning problem. substitution is helpful in places where unavailability of particular crude drug and or unwanted adverse effects of desired crude drug are there and have a choice of other drug with similar pharmacological effect and less unwanted after effects. But in most cases, it is unacceptable because the conversion of authentic drug into substandard drug may cause variety of adverse effects from mild and moderate to severe life threatening reactions. So, understanding of all the ways of adulteration and substitution is necessary to rectify. this illegal act and maximizing consumers' safety. However, India has taken some preventive steps in the country to fight against the poor quality of regulatory organization drugs for protecting and promoting the public health.

Keywords: Adulteration, Crude drug, Misbranding drugs.

INTRODUCTION

An Introduction to Adulteration of drugs

A treatise published two centuries ago (in 1820) on adulterations in food and culinary materials is a proof for this practice as an age-old one. Due to adulteration, faith in herbal drugs has declined. Adulteration in market samples is one of the greatest drawbacks in promotion of herbal products. Many researchers have contributed in checking adulterations and authenticating them. It is invariably found that the adverse event reports are not due to the intended herb, but rather due to the presence of an unintended herb. Medicinal plant dealers have discovered the 'scientific' methods in creating adulteration of such a high quality that without microscopic and chemical analysis, it is very difficult to trace these adulterations.[1]

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Research

Planning and execution of dossier compilation of countries Germany, Canada and Australia

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Abstract

To prepare and compile the Dossier required for Registration of Pharmaceutical Products as per the requirements of each countries which shall be acceptable internationally to develop one regulatory approach. To avoid variation in the documents submitted in the form of dossier for registration of Pharmaceutical Products in the different countries of the world it's important to know the requirements of Regulatory Authorities of each countries in which the Dossier is filled for the smooth Registration. When submitting your drug benefit assessments to the German Authority or other (foreign) regulatory agencies, you need to provide your reports in a specific format. . Drug regulatory affairs in pharma industries have mandated two types of dossier namely CTD (Common Technical Dossier) and ACTD (Asean Common Technical Dossier). Regulated pharma markets (eg.USA, Europe) markets require submission of dossier in CTD format which has to provide clinical trial and bioequivalence studies. As against this, semi-regulated pharma markets (South East Asian) require ACTD format which does not require exhaustive details like CTD. For industries, it has eliminated the need to reformat the information for submission to the different ICH regulatory authorities.

Keywords: CTD, ACTD, Dossier

INTRODUCTION

Pharmaceutical Dossier

Pharmaceutical Dossier defines the collection of detailed documents containing information about a particular drug which require extensive data to be attached on the dossier for submission to Regulatory Authority for grant of Regulatory Approval in any country with which a Licensed Product must be registered or approved for the Manufacturing, Marketing, Use, Distribution or Sale of such Licensed Product in the Field. Commonly called as Marketing Authorization Application (MAA) for European Union and New Drug Application (NDA) for United Nation.

Dossier is required to prepare as per the internationally accepted format i.e. CTD & ACTD so as to reduce the time and extra working for registration of single Drug Product in Multiple countries. There is huge contribution of ICH in this for standardizing and bringing the concept of Internationally acceptable format

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Review

Global process for generic drug approval

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Abstract

Drug approval standards in the United States are considered by many to be the most demanding in the world. Developing a new drug requires great amount of research work in discovery, development, preclinical research, clinical research. Reviewers in regulatory agencies throughout the world bear the responsibility of evaluating whether the research data support the safety, effectiveness and quality control of a new drug product to serve the public health. Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue the guidelines to regulate the marketing of the drugs. This work focuses on drug approval process in different countries like USA, Europe and India.

Keywords: API, FDA, INN

INTRODUCTION

Generic Drug

A generic drug is a pharmaceutical drug that contains the same chemical substance as a drug that was originally protected by chemical patents. Generic drugs are allowed for sale after the patents on the original drugs expire. Because the active chemical substance is the same, the medical profile of generics is believed to be equivalent in performance.[1,2] A generic drug has the same active pharmaceutical ingredient (API) as the original, but it may differ in some characteristics such as the manufacturing process, formulation, excipients, color, taste, and packaging.[2]

Although they may not be associated with a particular company, generic drugs are usually subject to government regulations in the countries in which they are dispensed. They are labeled with the name of the manufacturer and a generic non-proprietary name such as the United States Adopted Name (USAN) or International Nonproprietary Name (INN) of the drug. A generic drug must contain the same active ingredients as the original brand-name formulation. The U.S. Food and Drug Administration (FDA) requires generics to be identical to or within an acceptable bioequivalent range of their brand-name counterparts, with respect to pharmacokinetic and pharmacodynamic properties.[3] (The FDA's use of the word "identical" is a legal interpretation, not literal.)

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Review

Current regulations for herbal products

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Abstract

Officinal plants and their products have great social and economic consequences, and today they are used in four principal sectors: food, cosmetics, health and medicine. The medicinal use of the herbal drugs, Phytotherapy, is differently controlled in different countries, but with only marginal differences because phytotherapeutic products must possess quality, safety and efficacy. The use of herbs as health foods, as well as food supplements, complicates the formulation of regulations by countries throughout the world. The increasing supply of herbal products to international markets makes it necessary for international organizations, such as the World Health Organization (WHO) to develop standards relative to their commercialization throughout the world. The classification of drugs varies from country to country, with active foods, dietary supplements and traditional medicines being included in certain categories. The stability of those products is also unknown and complex to the critical problem in the analysis of herbal products that this is a complex ingredient combination, as well as the elements responsible for the treatment effects. In order to identify the changes to the newly introduced regulations or regulations, detailed literary searches and online searches for herbal medicinal products regulations have been made in South-east Asia and European countries.

Keywords: Harmonization, herbal medicine, herbal products

INTRODUCTION

Herbal medicine (also herbalism) is the study of pharmacognosy and the use of medicinal plants, which are a basis of traditional medicine.[1] There is limited scientific evidence for the safety and efficacy of plants used in 21st century herbalism, which generally does not provide standards for purity or dosage.[2,3] The scope of herbal medicine commonly includes fungal and bee products, as well as minerals, shells and certain animal parts. Herbal medicine is also called phytomedicine or phytotherapy.[1]

Paraherbalism describes alternative and pseudoscientific practices of using unrefined plant or animal extracts as unproven medicines or health-promoting agents.[1,2,3,4] Paraherbalism relies on the belief that preserving various substances from a given source with less processing is safer or more effective than manufactured products, a concept for which there is no evidence.[4]

Herbal medicines are the natural plants and their parts which are being used for medicinal purpose. This is one of the oldest types of medicine in human history. Herbal medicine is still widely practiced all over

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Review

Electronic Regulatory Submissions

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Abstract

This document represents the Agency's current thinking on regulatory submissions in electronic format. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An elective methodology might be utilized assuming such methodology fulfils the necessities of the material resolution, guidelines, or both. This is one in a progression of direction records expected to help you while making administrative entries in electronic organization to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA). This direction talks about broad issues normal to a wide range of electronic administrative entries. Now and again, the direction for one focus varies from that for the other focus due to contrasts in systems and in the PC frameworks in the focuses. We will attempt to limit these distinctions at every possible opportunity. Organization direction archives on electronic administrative entries will be refreshed routinely to mirror the developing idea of the innovation in question and the experience of those utilizing this innovation.

Keywords: Regulatory, Review, FDA, CDER, CBER.

INTRODUCTION

Introduction to Regulatory submission

Regulatory submissions are packages of information and data needed by a regulatory agency to establish whether a regulated healthcare product can progress to clinical testing or whether it is safe and effective for marketing.

A regulatory submission for a healthcare product includes any documentation or information submitted to a regulatory agency for review, for notification or in response to a request for additional information related to a healthcare product. The format can be paper or electronic, or both. The amount of information involved and its required complexity can vary significantly. A licensing application for a drug or biological product may contain hundreds of paper volumes whereas a response to an agency's question for a clarification may involve a single page. Due to the enormous amount of information presented in a marketing application, agencies are

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PHYTOCHEMICAL SCREENING AND PHARMACOLOGICAL EVALUATION OF ANTICANCER ACTIVITY OF METHANOLIC EXTRACT OF MAYTENUS EMARGINATA (WILLD) IN RATS

VURIMETLA SHRUTHI[1]*, DR.D.SWATHI[2],DR.NAGASREE[3],DR.Y.SIRISHA[4]
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Abstract:

Cancer is one of the most serious health problems that affect the duration and quality of the individual's life. Enormous efforts are invested to cope with this problem, but unfortunately limited success has ever been achieved with most of the therapeutic strategies. These efforts are usually complicated with the need for well experienced surgeons, lack of specificity and high cost, as well as being usually accompanied with a wide range of side effects.

As the conventional therapeutic strategies fail to fulfill the major requirements for a successful cancer therapy, the use of naturally developed anticancer agents has evolved as an alternative safe, low-cost and convenient one. Therefore, the use of plant extracts with potential anticancer therapeutic effects might be particularly significant, especially in Palestine, which is rich in thousands of plant species known for their medical uses. Moreover, the lack of expertise, the scarce economical resources and the complicated political situation in Palestine don't allow the application of sophisticated surgical, chemo- and radio-therapies to cure cancer.

Therefore, the current study, investigates the effect of crude methanolic extracts from Maytenus emarginata, Fig on cell lines derived from different human tissue origins (Hep3b: Hepatocellular carcinoma; Hela: cervical epithelial cancer; and A549: human lung adrenal cancer).

The results showed a concentration-dependent reduction in the final number of cancer cells in consequence to treatment with the aforementioned methanolic extracts. Two kinds of anticancer effects were evaluated and found to contribute to this reduction, the antiproliferation effect (decreased number of metabolically active cells) and cytotoxicity (decreased number of live cells).

This extract possess both of the effects with variable degrees. Maytenus emarginata possess the strongest and most profound effects on the three cell lines, mainly by suppression of cell growth.

Further studies are needed to assess the active ingredients of Maytenus emarginata, involved in the antiproliferative or cytotoxic effects of these plants. These studies must involve the establishment of in vivo animal models and the application of more efficient extraction and fractionation techniques.

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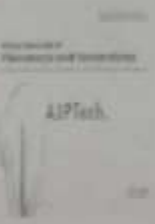

RESEARCH ARTICLE

Formulation and Evaluation of Sumatriptan Succinate Microspheres by Using Different Polymers

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ABSTRACT:
In the present work, Microspheres of Sumatriptan Succinate using PLGA, Ethyl cellulose and HPMC K4M as polymers were formulated to deliver Sumatriptan Succinate via oral route. The results of this investigation indicate that solvent evaporation method can be successfully employed to fabricate Sumatriptan Succinate microspheres. In this work an effort was made to formulate microsphere of Sumatriptan Succinate by using different polymers. Prepared formulations are evaluated for bulk density, tapped density, precent mucoadhesion, Percent compressibility, hausners ration, percentage yield, size and interaction study by Differential scanning calorimeter and *in vitro* drug release. Formulation which passed all the evaluation parameters was considered as best formulation of Sumatriptan Succinate. The present study conclusively that Sumatriptan Succinate microsphere could be prepared successfully and formulation F5 was shows satisfactory result.

KEYWORDS: Sumatriptan Succinafe, PLGA, Ethyl cellulose and HPMC K4M and Microspheres.

INTRODUCTION:
Sumatriptan is a selective serotonin agonist with good vasoconstrictor properties used in the treatment of migraine drug of triptan class. It is chemically known as 3-[2-(Dimethylamino) ethyl] –N-methyl-1H indole -5-methane sulphonamide succinate (1:1) base. Sumatriptan is rapidly but incompletely absorbed following oral administration and undergoes first pass metabolism resulting in a low absolute bioavailability of 14% with biological half life of 2.5 hours. It is official in British Pharmacopoeia[1-4].

Poly (lactide-co-glycolide) (PLGA):
L-lactide and DL-lactide have been used for copolymerization with glycolic acid monomers. Different ratios of poly (lactide-co-glycolide) have been commercially developed. Amorphous polymers are obtained for a 25L: 75G monomer ratio. A copolymer with a monomer ratio of 80L: 20G is semi-crystalline[5]. PLGA is the most commonly used FDA approved polymer[6].

For many decades, medication of an acute disease or a chronic disease has been accomplished by delivering drugs to the patients via various pharmaceutical dosage forms like tablets, capsules, pills, creams, ointments, liquids, aerosols, injectables and suppositories as carriers[7]. Oral controlled release (CR) dosage forms (DFs) have been developed over the past three decades due to their considerable therapeutic advantages such as

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REVIEW ARTICLE

Formulation Development and *In vitro* Characterisation of Stavudine Extended Release Matrix Tablets

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ABSTRACT:
The aim of the present study was to develop Stavudine extended release tablets to maintain constant therapeutic levels of the drug for over 12 hrs. Xanthan gum, Sodium CMC and HPMC 15cps were used as polymers. All the formulations were passed various physicochemical evaluation parameters such as Bulk Density, Tapped Density, Carr's Index, Hausners Ratio, Angle Of Repose, Weight Variation, Hardness, Thickness, Friability And Drug Content. From the dissolution studies it was evident that the formulation F6 showed better and desired drug release pattern i.e., 99.12 % in 12 hours. It contains the Sodium CMC as polymer. It followed Kars Mayer peppas release kinetics mechanism.

KEYWORDS: Stavudine, Xanthan gum, Sodium CMC and HPMC 15 cps and Extended release tablets.

INTRODUCTION:

Extended release dosage forms are designed to achieve a prolonged therapeutic effect by continuously releasing drug over an extended period of time after administration of a single dose[1]. To achieve better therapeutic action various types of drug delivery systems are available, out of which extended release systems are gaining much importance because of their wide advantages over others like ease of administration, convenience and non-invasiveness [2].

Extended release formulation is an important program for new drug research and development to meet several unmet clinical needs.

There are several reasons for attractiveness of these dosage forms viz. provides increase bioavailability of drug product, reduction in the frequency of administration to prolong duration of effective blood levels, Reduces the fluctuation of peak trough concentration and side effects and possibly improves the specific distribution of the drug [3]. The rationale for development of an extended-release formulation of a drug is to enhance its therapeutic benefits, minimizing its side effects while improving the management of the diseased condition [4].

The sustained plasma drug levels provided by extended release products often at times eliminate the need for night dosing which benefits not only the patient but also the caregiver [5]. The extended release systems are the methods that can achieve therapeutically effective concentrations of drug in systemic circulation over an

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RESEARCH ARTICLE

Preparation and Evaluation of Niosomal Transdermal Patch of Clozapine

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ABSTRACT:
Niosomes are the non-ionic surfactant vesicles obtained on hydration of synthetic non-ionic surfactants. These are the promising vehicles for effective transdermal drug delivery. The present research work was aimed to develop niosomal-based transdermal Clozapine patch containing a stable formulation with improved drug permeation. Niosomes were prepared by solvent casting method. All the formulations were evaluated for vesicle size, zeta potential and percent entrapment efficiency. All the patches were then characterized for thickness, folding endurance, drug content determination, Flatness, and *in vitro* permeation studies. F3 formulation having optimum vesicle size (2.6 µm), highest zeta potential (-32.56 mV) and maximum percent entrapment efficiency (98.09 %) was selected as optimized formulation. The transdermal patch was prepared using solvent casting method from the optimised niosomes formulation F3 formulation. The prepared optimised niosomes F3 formulation were loaded into the patch formulation. Patches loaded with niosomes (F3NT3) showed 95.78 % cumulative amount of drug permeated. The optimized formulation (F3NT3) followed first order release kinetics.

KEYWORDS: Transdermal patches, Clozapine and Niosomes.

INTRODUCTION:

Clozapine is benzodiazepine derivative and use in treatment of schizophrenia. The IUPAC name of Clozapine is 8-Chloro-11-(4-methyl-1-piperazinyl)-5H-dibenzo [b, e] [1, 4] diazepine.[1] Clozapine acts as an antagonist of dopamine receptors in the mesolimbic system5. The binding ratio of clozapine to serotonine (5-HT2A) receptor and dopamine (D2) receptor is higher than other conventional antipsychotic drugs.[2] Clozapine is used to suppress both positive and negative symptoms of schizophrenia and many neuroleptic responses. Compared with the atypical antipsychotics, and be effective for residual positive symptoms in the treatment of refractory patients.[3]

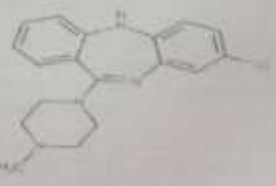

Fig 1: Chemical structure of Clozapine[4]

Vesicular systems are noval means of delivering drug in controlled manner to enhance bioavailability and to get therapeutic effect over a longer period of time. Vesicular systems are lamellar structures made up of amphiphilic molecules surrounded by an aqueous compartment. Vesicular systems useful for the delivery of both drug (hydrophobic and hydrophilic) which are encapsulated into the interior hydrophilic compartment and the outer lipid layer respectively. They have longer shelf life, stability and ability to delivery drug at target site in controlled or sustained manner which enchance bioavailability. Non-ionic are used due to enhance

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RESEARCH ARTICLE

A New Analytical Rp-Hplc Method for the Estimation of Letrozole in Pure and Tablet form

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ABSTRACT:
A simple, rapid, specific and accurate reverse phase high performance liquid chromatographic method has been developed for the validated of Letrozole in bulk as well as in marketed pharmaceutical dosage form. This separation was performed on a Symmetry ODS C18 (4.6×250mm, 5µm) column with Methanol: Phosphate Buffer (35:65) V/V as mobile phase at a flow rate of 1.0 mL min−1 with UV detection at 240 nm; the constant column temperature was Ambient. The runtime under these chromatographic conditions was less than 8 min. The retention time of Letrozole was found to be 2.252. The calibration plot was linear over the concentration range of 6–14µg mL−1 with limits of detection and quantification values of 1.2 and 3.6ng mL−1 respectively. The mean % assay of marketed formulation was found to be 99.86%, and % recovery was observed in the range of 98-102%. Relative standard deviation for the precision study was found <2%.The developed method is simple, precise, specific, accurate and rapid, making it suitable for estimation of Letrozole in bulk and marketed pharmaceutical dosage formdosage form.

KEYWORDS: Letrozole, RP-HPLC.

INTRODUCTION:

HPLC is also being automated which involve automated sampling, separation, detection, recording, calculation and printing of results. HPLC offers a wide choice of chromatographic separation methodologies from normal to reverse phase and whole range of mobile phases using isocratic or gradient elution techniques [1]. The packing material of the column is the basic feature for the growth of this technique which directly responsible for the chromatographic separations.

The principle of separation of compounds is given by Van Deemter equation, which is an empirical formula that describes the relationship between linear velocity (flow rate) and plate height [2].

Letrozole 4,4l-(1H-1,2,4-triazol-1- ylmethylene) bisbenzonitrile[3], is a potent, specific, non-steroidal, third generation aromatase inhibitor, used therapeutically to treat hormone-sensitive breast cancer in postmenopausal women[4].

Cancer is a fatal disease. It can be cured if detected in an early stage[5]. The incidence of breast cancer is rising in every country of the world especially in developing country such as India. There has been no improvement in

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REVIEW ARTICLE

HPLC Analytical Method Development and Validation for Estimation of Cytarabine and Daunorubicin in API and Pharmaceutical Formulation

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ABSTRACT:
A rapid and precise reverse phase high performance liquid chromatographic method has been developed for the validated of Cytarabine and Daunorubicin, in its pure form as well as in pharmaceutical dosage form. Chromatography was carried out on an Altima C18 (4.6mm x 150mm, 5µm) column using a mixture of ACN, Methanol and Phosphate buffer pH-4.6 (10:25:65 v/v) as the mobile phase at a flow rate of 1.0ml/min, the detection was carried out at 265nm. The retention time of the Cytarabine and Daunorubicin was 2.088, 6.068±0.02 min respectively. The method produces linear responses in the concentration range of 10-50mg/ml of Cytarabine and 20-100mg/ml of Daunorubicin. The method precision for the determination of assay was below 2.0%RSD. The method is useful in the quality control of bulk and pharmaceutical formulations.

KEYWORDS: Cytarabine, Daunorubicin, RP-HPLC, Validation, Accuracy, ICH Guidelines.

INTRODUCTION:

High performance liquid chromatography (HPLC) is a technique used for analysis of drug substance, drug product and determination and quantification of known as well as unknown impurities at lower level, food and drug administration (FDA) also trust on the purity method of analysis by using HPLC, because of high accuracy and reproducibility of results. By using this technique we can separate drug related process impurities, degradation impurities as well as reactants [1].

According to the principle of separation of HPLC, as the particle size of column material decreases, the efficiency of the chromatographic separation, speed and resolution also increases. The HPLC is the most simple, economic, reliable and worldwide used technique in the pharmaceutical analysis [2].

Cytarabine, is cytosine arabinoside (ara-C), is a chemotherapeutic agent used to treat acute myeloid leukemia (AML), acute lymphocytic leukemia (ALL), non-Hodgkin's lymphoma, and chronic myelogenous leukemia (CML). It is administered via injection, under the skin, or into the cerebrospinal fluid. There is a pharmaceutical liposomal formulation for which there is tentative evidence of enhanced outcomes in lymphoma including the meninges [3]. Cancer is a group of diseases characterized by the disregulate proliferation of

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Research article | Medical research

Evaluation of anti ulcer activity of *eclipta alba* extract in experimental animal model

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ABSTRACT

The cause of ulceration in patients is mainly due to hyper secretion of gastric juice and also due to hyper secretion of pepsin. In traditional system of medicine a number of herbal preparations have been used for the treatment of peptic ulcers. There are various medicinal plants has been used for the treatment of gastrointestinal disorders. In view of this, in present study we have to evaluate the anti-ulcer activity of *Eclipta Alba*. Study was carried out, by using three methods i.e., alcohol, paracetamol and stress induced ulcers in rats pretreated with the doses of 250 mg/kg AQEA and ALEA, 10mg/kg Omeoprazole and 50 mg/kg Ranitidine.
To evaluate the antiulcer activity of aqueous and alcoholic extracts of *Eclipta Alba* leaves (AQEA and ALEA) at 250 doses using different experimentally induced gastric ulcer models in rats. Gastric ulcers were induced in rats by 80% alcohol, paracetamol and forced immersion stress induced methods. In alcohol induced ulcer model, paracetamol induced ulcer model and stress induced model the ulcer index was determined. Where as in stress induced ulcers stress plays an important role in ulcerogenesis.In alcohol-induced ulcers, AQEA and ALEA were effective in reducing lesion index and increasing the gastric mucus content. It was also effective in decreasing ulcer index in paracetamol-induced ulcers. All the results obtained with *Eclipta Alba* were dose dependent. The results suggest that AQEA and ALEA possesses significant and dose dependent antiulcer activity. The antiulcer activity of AQEA and ALEA can be attributed to its cytoprotective and antisecretory action.

Keywords: *Eclipta Alba*, antisecretory, cytoprotective, gastric ulcer, alcohol induced ulcers, paracetamol-induced ulcers and stress induced ulcers.

INTRODUCTION

Peptic ulcer and other acidic symptom affect up to ten percentages of the humans with sufficient severity to prompt victims to seek medical attention. The more significant disease condition requiring medical fuscous is ulcer and gastro esophagealdisease1. In the US, approximately 4 million people have peptic ulcer (duodenal and gastric types), and 350 thousand new patient are diagnosed in each year, around 180 thousand peoples are admitted to hospital and treated with drugs yearly, and about five thousand patient from this case die each year as a result of ulcer condition. The lifetime of human being developing a peptic ulcer is about 10 percentages for Americans males and four percentages for female population2.
Peptic ulcers is wound in the lesions that are most often affected in younger to older adults population, but this may diagnosed in young adult life. They often appear without obvious sign and symptom, after a period of days to months of active phase of disease, it may heal with or without drug treatment. It also affect because of bacterial infections with H. Pylori.

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RESEARCH ARTICLE

Formulation and Characterization of Transdermal Patches for Controlled Delivery of Cyproheptadine

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ABSTRACT:
The purpose of this research was to develop a matrix-type transdermal therapeutic system containing drug Cyproheptadine with different ratios of polymeric systems by the Solvent evaporation technique by using Dibutyl phthalate to the polymer weight, incorporated as plasticizer. Dimethylsulphoxide were used to enhance the transdermal permeation of Cyproheptadine. The physicochemical compatibility of the drug and the polymers studied by infrared spectroscopy suggested absence of any incompatibility. Formulated transdermal patches were physically evaluated with regard to thickness, weight variation, drug content, flatness, tensile strength and folding endurance. *In-vitro* drug studies of formulations were performed by using Franz diffusion cells. The results followed the release profile of Cyproheptadine followed mixed peppas release kinetics. However, the release profile of the optimized formulation F3 (98.51% at 12hr) indicated that the permeation of the drug from the patches was governed by a diffusion mechanism.

KEYWORDS: Cyproheptadine, Transdermal drug delivery and solvent evaporation technique.

INTRODUCTION:

Cyproheptadine hydrochloride (CYP) chemically known as 4-(5H dibenzo[a,d]-cyclohepten-5-ylidene)-1-methyl-piperidine HCl. Cyproheptadine is an antihistamine used to relieve allergy symptoms such as watery eyes, runny nose, itching eyes/nose, sneezing, hives, and itching. It works by blocking a certain natural substance (histamine) that our body makes during an allergic reaction. This medication also blocks another natural substance in your body(serotonin).[1]

Transdermal delivery of drugs through the skin to the systemic circulation provides a convenient route of administration for a variety of clinical indications. Pharmaceutical scientists have accepted the challenge of transdermal drug delivery over the last 25 years.[2] Transdermal delivery system is currently available for the treatment of various diseases such as cardiovascular diseases, Parkinson's disease, Alzheimer's disease, depression, anxiety and attention deficit hyperactivity disorder (ADHD), skin cancer, female sexual dysfunction, post-menopausal bone loss and urinary incontinence.[3] The transdermal route of administration cannot be employed for a large number of drugs, only a small number of drug products are currently available via transdermal delivery. In many cases, a drug's physical properties, including molecular size and polarity, have limited its capacity to be delivered transdermally. Similarly, the biological properties of drug molecules, including dermal irritation and insufficient bioavailability, have been problematic.[4] Transdermal drug delivery systems have recently developed to achieve the objective of systemic medication through topical application. The transdermal route of drug delivery is becoming popular because large

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RESEARCH ARTICLE

Quantitative Estimation of Roxithromycin and Ambroxol in Bulk and Tablet Dosage Forms by Rp-Hplc Method

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ABSTRACT:
A Rapid and Precise Reverse Phase High Performance Liquid Chromatographic method has been developed for the validated of Roxithromycin and Ambroxol, in its pure form as well as in tablet dosage form. Chromatography was carried out on Altima C18 (4.6 x 150mm, 5µm) column using a mixture of ACN, Methanol and Phosphate buffer pH4.6 (10:25:65 v/v) as the mobile phase at a flow rate of 1.0ml/min, the detection was carried out at 215 nm. The retention time of the Roxithromycin and Ambroxol was 2.344, 3.286 ±0.02min respectively. The method produce linear responses in the concentration range of 10-50mg/ml of Roxithromycin and 2.5-12.5mg/ml of Ambroxol. The method precision for the determination of assay was below 2.0%RSD. The method is useful in the quality control of bulk and pharmaceutical formulations.

KEYWORDS: Roxithromycin, Ambroxol, RP-HPLC, validation.

INTRODUCTION:

Analytical chemistry plays a vital role in maintaining the quality of drugs. It consists of Qualitative and Quantitative estimations[1]. To develop a new HPLC method for any drug, knowledge of its molecular weight, polarity, ionic character, pK_a values, wavelength of absorption, purity of compound and the solubility should be known. Method development involves considerable effort and time.[2]

Acute respiratory infections (ARI) may cause inflammation of the respiratory tract anywhere from nose to alveoli, with a wide range of combination of symptoms and signs. ARI is often classified by clinical syndromes depending on the site of infection and is referred to as ARI of upper (AURI) or lower (ALRI) respiratory tract.[3] Upper respiratory tract comprises of the airways from nostrils to the vocal cords in the larynx, plus the paranasal sinuses and the middle ear. Upper respiratory tract infection (URTI) includes the common cold, laryngitis, pharyngitis/tonsillitis, acute rhinitis and acute otitis media. The lower respiratory tract includes the furtherance of the airways from the trachea and bronchi to the bronchioles and the alveoli. Lower respiratory tract infection (LRTI) includes acute bronchitis, bronchiolitis and pneumonia[4].

WHO reported more than four million deaths a year from acute respiratory infections in the developing world quarters. Mortality may be greater in developing countries because of low resistance of children due to malnutrition, overcrowding and poor environmental circumstances such as indoor air pollution[5]. Respiratory problems are responsible for a large proportion of pediatric admissions and outpatient attendance. Children are an embodiment of our dreams and hopes of the future.[6]

Roxithromycin macrolide category wide spectrum antibacterial drug that inhibits bacterial protein biosynthesis by

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Research article | Medical research

Screening of antidepressant activity of *bouganvillae spectabillis* in wistar albino rats

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ABSTRACT

Viburnum opulus Belongs to the family Adoxaceae. Depressions are widespread psychiatric disorders affecting around 5% of the population. Furthermore, it is difficult to predict which patient will respond to any given treatment. In the traditional systems of medicine, many plants have been used to treat anxiety and depression for thousands of years. The present study was designed to evaluate the antidepressant activity of the alcoholic and aqueous extracts of *Viburnum opulus* leaves in rodents. The antidepressant activity was tested by using forced swim test and Open Field Test. The results infer that reduced immobility time elicits antidepressant activity. It was concluded that alcoholic and aqueous extracts of *Viburnum opulus* leaves having antidepressant activity. Alcoholic extract of *Viburnum opulus* leaves showing more significant activity over the aqueous extract.

Keywords: *Viburnum opulus*, Antidepressant activity, forced swim test, Open Field Test

INTRODUCTION

Medicinal plants are various plants thought by some to have medicinal properties, but few plants or their phytochemical constituents have been proven by rigorous science or approved by regulatory agencies such as the United States Food and Drug Administration or European Food Safety Authority to have medicinal effects. World Health Organization (WHO) has provided a definition of medicinal plants, that is "A medicinal plant is any plant which, in one or more of its organs, contains substances that can be used for therapeutic purposes or which are precursors for synthesis of useful drugs."[1]

World Health Organization (WHO) reported that 80% of the world's population depends on medicinal plants for their primary health care. In the Plant Kingdom, Medicinal plants form the largest single grouping of plants. It is estimated that 30,000 species worldwide fall in this group, of which around 33% are trees [2] Plants are known to be the source of many chemical compounds. Medicinal plants were used by people of ancient cultures without knowledge of their active ingredients. The common practice of taking crude extract orally is laden with hazards as the extracts may contain some toxic constituents. There is an ever increasing need to limit toxic clinical drugs.In modern times, the active ingredients and curative actions of medicinal plants were first investigated through the use of European Scientific methods[3]. The most important ingredients present in plant communities turn out to be alkaloids, terpenoids, steriods, phenols glycosides and tannins[2].

The information obtained from extracts of medicinal plants makes pharmacological studies possible. The mode of action of plants producing therapeutic effects can also be better investigated if the active ingredients are characterized. Infectious diseases are the leading cause of death worldwide. The clinical efficiency of many existing antibiotics is being threatened by the emergence of multidrug resistant pathogens. Bacterial pathogens have evolved numerous defense mechanisms against antimicrobial agents and resistance to old and newly produced drug is on the rise. The increasing failure of chemotherapeutics and antibiotic resistance exhibited by pathogenic microbial infectious agents has led to the screening of several medicinal plants for their potential antimicrobial activity[4].

There are several reports in the literature regarding the antimicrobial activity of crude extracts prepared from plants

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RESEARCH ARTICLE

Validated RP-HPLC Method for Simultaneous Estimation of Perphenazine and Amitriptyline in Bulk and Tablet Dosage form

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ABSTRACT:
A new, simple, precise, rapid, selective and stability reversed-phase high performance liquid chromatographic (RP-HPLC) method has been developed and validated for the simultaneous quantification of Perphenazine and Amitriptylinein pure form and its pharmaceutical dosage form. The method is based on Phenomenex Gemini C18 (4.6×250mm) 5µ column. The separation is achieved using isocratic elution by Methanol: TEA Buffer in the ratio of 65:35% v/v, pumped at flow rate 1.0mL/min and UV detection at 230nm. The column is maintained at 40°C throughout the analysis. The total run time is about 6min. The method is validated for specificity, accuracy, precision and linearity, robustness and ruggedness, system suitability, limit of detection and limit of quantitation as per International conference of harmonization (ICH) Guidelines. The method is accurate and linear for quantification of Perphenazine, Amitriptylinebetween 10 - 50µg/mL and 20 - 100µg/mL respectively.Further, satisfactory results are also established in terms of mean percent- age recovery (100.37% for Perphenazine and 100.34% for Amitriptyline, intra-day and inter-day precision (<2%) and robustness.The advantages of this method are good resolution with sharper peaks and sufficient precision.The results indicate that the method is suitable for the routine quality control testing of marketed tablet formulations.

KEYWORDS: Perphenazine and Amitriptyline.

INTRODUCTION:

In HPLC, separation occurs due to partitioning between a stationary phase contained in a column and a liquid phase, which is pumped under pressure through this column. Each of the components will have a certain affinity for the stationary phase and a certain affinity for the mobile phase. Provided there is sufficient difference between the analytes in their relative affinities for the two phases, then in HPLC system they will separate [1].

The components themselves are first dissolved in a solvent and then required to flow (via the mobile phase) complete a column (stationary phase) in high pressure. The mixture is determined into its components within the column and the amount of resolution is dependent upon the interaction between the solute components and the column stationary phase and liquid phase. The interaction of the solute with the mobile and stationary phases can be worked through different choices of both solvent and stationary phases [2].

Schizophrenia is a disorder that affects the way a person acts, thinks, and sees the world. People with schizophrenia have an altered perception of reality and may withdraw from the outside world and or act out in confusion and fear [3]. Schizophrenia strikes without regard to gender, race, social class or culture [4]. Pharmacological therapies and psychosocial interventions play a role in the prognosis of schizophrenia as an essential component of a comprehensive schizophrenia treatment [5].

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Research

ANTIDIABETIC ACTIVITY OF METHANOLIC EXTRACTS OF LEAVES OF SAMANEA SAMAN ON ALLOXAN INDUCED DIABETES IN RATS

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Abstract

Samanea Saman, belongs to the family Fabaceae, have pharmacological actions like Antioxidant, Antimicrobial, anti-inflammatory , anti-ulcer.
Objetive: To investigate Antidiabetic activity of methanolic leaf extract of Samanea Saman, on alloxan induced diabetic rats.
Methods: Alloxan is administered as an inducer for diabetes. Thirty Wistar albino rats were randomly divided into five groups. Either sex of Wister strains of albino rats were divided in to 5 groups were Group 1 served as normal control, Group 2 served as alloxan control, Group 3 were administered with standard drug (Glibenclamide), Group 4 and Group 5 were administered to different doses of methanolic extract of Samanea Saman, (i.e. 200 and 300 mg/kg/Kg body weight) The anti-diabetic activity was determined by glucometer in both normal and alloxan-induced diabetic rats. The methanolic extract of *Samanea Saman* showed significant reduction in blood glucose levels due to the presence of phytochemicals such as alkaloids in extracts.
Results: Altered levels of the FBGL and OGTT in alloxan induced rats were brought back to normal on treatment with methanolic extract of Samanea Saman., Thus the positive results suggest that *Samanea Saman* extract should be further studied to determine the bioactive chemical compounds as well as to understand the possible mechanism of action and evaluate their toxicity looking towards pharmaceutical actions.
Conclusion: It was concluded from the result that the methanolic extract of Samanea Saman., showed significant antidiabetic activity in a dose dependent manner.

Keywords: Samanea Saman., Antidiabetic activity, Glibenclamide, FBGL and OGTT.

INTRODUCTION

Diabetes Mellitus (DM)

Diabetes is one of the most common non-communicable diseases and a serious life-long condition appearing worldwide. The etiology of diabetes is a complex interaction of genetic and environmental factors. It is a heterogeneous group of metabolic disorders characterized physiologically by dysfunction of pancreatic beta cells and deficiency in insulin secretion or insulin activity and clinically by hyperglycemia or impaired glucose

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Research article

Clinical research

Evaluation of anti hyperlipedimic activity of Pterocarpus marsupium extract in experimental animal model

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ABSTRACT

To investigate the anti Hyperlipidemic activity of methanol extract of *Pterocarpus marsupium s* in male Wistar rats. In this model of Hyperlipidemia, 30 adult male wistar rats (150-200gms) were evenly divided into 5 groups in both groups. Group-1 and Group-2 served as untreated and model controls respectively, while Group-3, 4 and 5 were the treatments groups which were simultaneously treated with standard, 200 and 400 mg/kg extract respectively along with High Fat Diet and Triton x 100. On last day, blood samples for biochemical parameters, were obtained under inhaled diether anaesthesia. In the model of anti diabetic animals were evenly divided into 5 groups. Group-1 and Group-2 served as untreated and model controls respectively, while Group-3, 4 and 5 were the treatments groups which were simultaneously treated with standard, 200 and 400 mg/kg extract respectively after glucose loading. HFD and Triton x 100 treatment caused Hyperlipidemia as evidenced by marked elevation in Cholesterol, Triglycerides, LDL, VLDL and decrease in HDL levels. Co-administration of extract with HFD and Triton x 100 decreased rise Cholesterol, Triglycerides, LDL, VLDL and increase in HDL levels. It was observed that the methanol extract of *Pterocarpus marsupium* conferred Anti- Hyperlipidemia activity by biochemical observation against HFD and Triton-x-100 induced Hyperlipidemia in rats. In the near future could constitute a lead to discovery of a novel drug for treatment of drug induced Hyperlipidemia.

Keywords: *Pterocarpus marsupiums*, Hyperlipidemia, anti diabetic, HFD and Triton-x-100.

INTRODUCTION

Hyperlipidemia is a condition when abnormally high levels of lipids i.e.the fatty substance are found in the blood. This condition is also called hypercholesterolemia/ hyperlipoproteinemia[1]. Human body is complex machinery and for maintaining the homeostasis of various organ and organ system. Any undesirable change will disturb the balance resulting in diseased state. Lipids are fats in the blood stream, commonly divided into cholesterol and triglycerides. Cholesterol circulates in the bloodstream and is involved in the structure and function of cells. Triglycerides(TG) are best viewed as energy that is either used immediately or stored in fat cells.TG are manufactured in the liver from the foods or by being absorbed from the intestine[3]. Virchow in 19thcentury who identified cholesterol crystals in atherosclerotic lesion and stated that endothelial cell injury initiates atherogenesis2. In a modification of this hypothesis it was proposed that the endothelium normally influences the behaviour of arterial smooth muscle cells by providing a barrier to the passage of plasma proteins, and that the major effect of haemodynamic or other factors that injure endothelium is to reduce the effectiveness of the barrier[4].Arteries are normally smooth and unobstructed on the inside, but in case of increased lipid level, a sticky substance called plaque is formed inside the walls of arteries. This leads to reduced blood flow, leading to stiffening and narrowing of the arteries. It has been proved that elevated plasma levels of cholesterol and of LDL are responsible for atherosclerosis in man, and epidemiological data suggests that elevated plasma levels of HDL have a protective effect[5]

Classification of Lipid Concentrations

The cholesterol along with some other types of fats cannot be dissolved in the blood. Moreover, in order to be

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RESEARCH ARTICLE

Preparation and Evaluation of Viloxazine Hydrochloride Bilayer Matrix Tablets

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ABSTRACT:
Aim of study was to develop bilayer drug delivery for treatment of attention deficit hyperactivity disorder (ADHD) by delivering loading and maintenance dose for fast achievement of peak plasma concentration and maintaining the same respectively. The prepared drug loaded bilayer tablets were evaluated for pre and post compression parameters. The tablets were prepared by direct compression and wet granulation method. The loading dose was delivered in the form of immediate release layer prepared by different super-disintegrations and maintenance dose was delivered through sustained release layer prepared by using polymers like Ethyl cellulose and Carbopol. Both the immediate release layer and sustained release layers were separately optimized and then combined to optimize the bilayer tablets. No interactions were found between drug and excipients. Formulation containing Cross Carmellose shows immediate drug release. Formulation Containing Carbopol shows sustained release action and bilayer formulations F5 shows releases up to 12 hours. Bilayer tablets with release characteristics offer critical advantages such as, site specificity with improved absorption and efficacy.

KEYWORDS: Viloxazine hydrochloride, Ethyl Cellulose, Carbopol p934, immediate release tablets, sustain release tablet and Bilayer tablet.

INTRODUCTION:

Introduction of matrix tablet as Controlled release (SR) has given a new breakthrough for novel drug delivery system in the field of Pharmaceutical technology. It excludes complex production procedures such as coating and Pelletization during manufacturing and drug release rate from the dosage form is controlled mainly by the type and proportion of polymer used in the preparations.[1] Drug release through various matrix system is determined by Water penetration, Polymer swelling, Drug dissolution, Drug diffusion, Matrix erosion have been utilized as formulation sustained release drug delivery.[2] Matrix systems made of swellable or nonswellable polymers[3].

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Matrix devices, due to their chemical inertness, drug embedding ability and drug release character, have gained steady popularity for sustaining the release of a drug.[4]

Advantages of Matrix Tablets: Easy to manufacture, Versatile, and effective, It has low cost, Can be made to release high molecular weight compounds, Suitable for both non degradable and degradable systems, No danger of dose dumping in case of rupture, Can be fabricated in a wide range of sizes and shapes.[5]

Matrix tablet was chosen as dosage form because of cost effectiveness. The effect of various grades of HPMC on formulation parameters was evaluated.[6]

Matrix tablets are considered to be the commercially feasible sustained action dosage forms that involve the least processing variables, utilize the conventional facilities and accommodate large doses of drug.[7]

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Research

A New Analytical Method Development And Validation For Quantitative Estimation Of Spironolactone And Furosemide In Bulk And Tablet Dosage Form By Using Rp-Hplc

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Abstract

A rapid and precise reverse phase high performance liquid chromatographic method has been developed for the validated of Spironolactone and Furosemide, in its pure form as well as in pharmaceutical dosage form. Chromatographic separation was carried out on a Symmetry C18 (4.6 x 150mm, 5µm) column using a mixture of Methanol: TEA Buffer pH 4.2 (40:60v/v) as the mobile phase at a flow rate of 1.0ml/min, the detection was carried out at 272 nm. The retention time of the Spironolactone and Furosemide was 2.781, 4.048 ±0.02min respectively. The proposed method was validated for various ICH parameters like linearity, limit of detection, limits of quantification, accuracy, precision, range and specificity. The method produce linear responses in the concentration range of 5-25mg/ml of Spironolactone and 9.375-46.875 mg/ml of Furosemide. The method precision for the determination of assay was below 2.0%RSD. The proposed method is applicable to routine analysis of Spironolactone and Furosemide in bulk and pharmaceutical formulations.

Keywords: Spironolactone, Furosemide, RP-HPLC, Accuracy, Robustness.

INTRODUCTION

Analytical chemistry is a scientific discipline used to study the chemical composition, structure and behaviour of matter. The purposes of chemical analysis are together and interpret chemical information that will be of value to society in a wide range of contexts. Quality control in manufacturing industries, the monitoring of clinical and environmental samples, the assaying of geological specimens, and the support of fundamental and applied research are the principal applications. Analytical chemistry involves the application of a range of techniques and methodologies to obtain and assess qualitative, quantitative and structural information on the nature of matter.

- **Qualitative analysis** is the identification of elements, species and/or compounds present in sample.
- **Quantitative analysis** is the determination of the absolute or relative amounts of elements, species or compounds present in sample.

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STABILITY INDICATING RP-HPLC METHOD FOR THE ESTIMATION OF TRICLABENDAZOLE AS API AND ESTIMATION IN TABLET DOSAGE FORM

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Article Received: July 2023 Accepted: August 2023 Published: September 2023

Abstract:

A novel specific, accurate, rugged, precise reversed-phase high performance liquid chromatographic (RP-HPLC) method has been developed for the quantitative determination of Triclabendazole in active pharmaceutical ingredients and in its Pharmaceutical dosage form by using Phenomenex Luna C18 (250mm x 4.6mm, 5µm) column with a mobile phase containing a mixture of Acetonitrile and Potassium dihydrogen phosphate buffer adjusted to pH-2.8 with ortho phosphoric acid in the ratio of 25:75%v/v. The flow rate was 1.0 ml/min and effluent were monitored at 254 nm and a peak eluted at 3.174 min and column oven temperature was maintained ambient. Calibration curve was plotted with a range from 10- 30 µg/ml. The LOD and LOQ values of Triclabendazole were found to be 1.3µg/ml and 3.9 µg/ml respectively. The percentage recovery of the Triclabendazole was found to be within the limits. The developed RP-HPLC method was validated according to the current International Conference on Harmonization (ICH) guidelines for specificity, LOD, LOQ, linearity, accuracy, precision, intermediate precision and robustness. The results of the study showed that the proposed RP-HPLC method is simple, rapid, precise and accurate which is useful for the routine determination of Triclabendazole in bulk drug and in its pharmaceutical dosage form. The proposed method was applied for the analysis of tablet formulations, to improve QC and assure therapeutic efficacy.

Keywords: *Triclabendazole, RP-HPLC, Accuracy, Validation, ICH Guidelines.*

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A VALIDATED REVERSE PHASE-HPLC-PDA METHOD AND OPTIMIZATION OF METHOD AND ITS VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF SULFADOXINE AND PYRIMETHAMINE IN PURE AND PHARMACEUTICAL DOSAGE FORM

BOTTA SUPRIYA[1]*, K.CHAITANYA PRASAD[2], B.SUDHAKAR[3], R.MOUNIKA[4]
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Article Received: July 2023 Accepted: August 2023 Published: September 2023

Abstract:
A new, simple and accurate, precise RP-HPLC method was developed for simultaneous determination of Sulfadoxine and Pyrimethamine in bulk and in combined pharmaceutical dosage form. The separation of Sulfadoxine and Pyrimethamine was achieved within 8 minutes on an Agilent Zorbax (C18(150mm x 4.6mm, 5µm) column using Methanol: Acetate Buffer pH-3.8 (24:76v/v) as the mobile phase. Detection was carried out using wavelength at 262nm. The method showed adequate sensitivity concerning linearity, accuracy and precision over the ranges 100-500ng/ml and 30-70ng/ml for Sulfadoxine and Pyrimethamine, respectively. Careful validation proved advantages of high sensitivity, accuracy, precision, wherein, robust and satisfactory for quality control laboratories. The developed method was robust as the %RSD was within the range and without effecting system suitabilities parameters. The proposed method is suitable for simultaneous determination of Sulfadoxine and Pyrimethamine in bulk and pharmaceutical dosage form.

Keywords: *Sulfadoxine and Pyrimethamine, RP-HPLC, Validation, Precision, Robustness.*

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RESEARCH ARTICLE

Analytical Method Development and Validation for the Simultaneous Estimation of Bilastine and Montelukast by RP-HPLC

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ABSTRACT:
A new, simple, rapid and precise reverse phase high performance liquid chromatographic method has been developed for the validation of Bilastine and Montelukast in its pure form as well as in combined marketed formulation. Chromatography was carried out on a Phenomenex Luna C18 (4.6mm×250mm) 5µm particle size column using a mixture of Methanol: Phosphate Buffer (pH-4.2) (37:63% v/v) as the mobile phase at a flow rate of 1.0ml/min, thedetection was carried out at 260 nm. The retention time of the Bilastine and Montelukast was found to be was 2.133, 3.692±0.02 min respectively. The method was validated according to ICH guidelines for linearity, sensitivity, accuracy, precision, specificity and robustness. The method produce linear responses in the concentration range of 20-60mg/ml of Bilastine and 10-30mg/ml of Montelukast.The inter-day and intra-day precisions were found to be within limits. The method precision for the determination of assay was below 2.0%RSD. The method is useful in the quality control of bulk and pharmaceutical formulations.

KEYWORDS: Bilastine and Montelukast, RP-HPLC, Validation, Accuracy, Precision.

INTRODUCTION:

High Performance Liquid Chromatography (HPLC) is the fastest growing analytical technique for the analysis of drugs. Chromatographic separation in HPLC is the result of specific interaction between sample molecules with both the stationary and liquid mobile phases. HPLC has been rapidly developed with the introduction of new pumping methods, more reliable columns and wide range of detectors.[1] In the era of developed and modified chromatographic techniques, the HPLC is still the simplest, most reliable, easy handling and worldwide used technique in the various stages of drug development[2].

Bilastine or 2-[4-[2-[4-[1-(2-ethoxyethyl) benzimidazol-2-yl]piperidin-1-yl]ethyl]phenyl]-2-methylpropionic acid, is selective Histamine H1 receptor antagonist, leading to decreased nasal congestionand urticaria.[3] The absorption of Bilastine is fast, linear and dose proportional; it appears to be safe and well tolerated at all doses levels in healthy population [4].

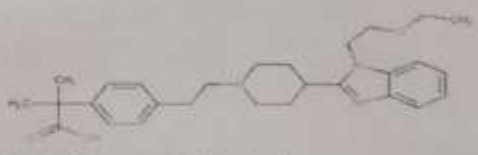

Fig. 1: Chemical structure of bilastine[5]

Bilastine is an antiallergenic agent, which helps alleviate allergic symptoms such as nasal inflammation and urticarial by combining and preventing H1 receptor activation. Bilastine has decreased the severity of allergic effects due to histamine release from mast cells [6].

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Acceptance Letter

HPLC ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR ESTIMATION OF TRAMETINIB IN API AND PHARMACEUTICAL FORMULATION

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2 Department of Pharmacy, University College of Technology, Osmania University, Hyderabad, Telangana, 500007, India

Dear Prof/Dr./Mr.

I have immense pleasure to inform you that your paper have been accepted and the editorial board agrees to publish your paper in the forthcoming issue of *Bulletin of Environment, Pharmacology and Life Sciences Volume 11/11 october 2022.*

Thank You

Date: 15.12.2022
Place: AGRA

Manish Kumar

Dr. Manish Kumar
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Acceptance Letter

SIMULTANEOUS ESTIMATION OF TRIFLURIDINE AND TIPIRACIL HYDROCHLORIDE IN BULK AND TABLET DOSAGE FORM BY USING RP-HPLC METHOD

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2 Department of Pharmacy, University College of Technology, Osmania University, Hyderabad, Telangana, 500007, India.

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Acceptance Letter

ANTIDIABETIC ACTIVITY AND PHYTOCHEMICAL SCREENING OF EXTRACTS OF THE LEAVES OF COLOCASIA ESCULENTA ON ALLOXAN-INDUCED DIABETIC MICE

P.Aravinda reddy 1* , Javvaji Pravalika 1 , Ramya Sri Sura 2
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2 Department of Pharmacy, University College of Technology, Osmania University, Hyderabad-Telangana, 500007, India. **Dear Prof/Dr./Mr.**

I have immense pleasure to inform you that your paper have been accepted and the editorial board agrees to publish your paper in the forthcoming issue of *Bulletin of Environment, Pharmacology and Life Sciences Volume 11/11 october 2022.*

Thank You

Date: 15.12.2022
Place: AGRA

Manish Kumar

Dr. Manish Kumar
[BEPLS]

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Acceptance Letter

NEW ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR ESTIMATION OF PREGABALIN AND MECOBALAMIN IN BULK AND TABLET BY RP-HPLC

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Acceptance Letter

PREPARATION AND EVALUATION OF SOLID LIPID NANOPARTICLES FOR TAVABOROLE TRANSDERMAL GEL

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Research article | Medical research

Screening of antidepressant activity of *marsilea minuta* in wistar albino rats

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ABSTRACT

Depression is a widely prevalent form of mental illnesses worldwide. It is commonly associated with sad mood, loss of interest or pleasure, feelings of guilt or low self-worth, disturbed sleep or appetite, and low energy. *Marsilea minuta* has many medicinal properties, and are used in traditional medicine in the treatment of various medical conditions. This study was conducted to better understand the antidepressant activity of *Marsilea minuta*. To evaluate the *in vivo* antidepressant activity of Methanolic extract of *Marsilea minuta* leave in Swiss albino mice. Methanolic extract of *Marsilea minuta* (MEMM) leaves was prepared by a continuous method using Soxhlet apparatus. The extract was subjected to phytochemical screening followed by acute oral toxicity studies in mice. MEMM in the doses of 100mg/Kg, 200mg/Kg and 400mg/Kg mg/kg body weight was administered to test groups Group 3, 4 and 5 respectively. Imipramine hydrochloride 15mg/kg body weight was administered to Standard group by oral route. Test group 3 received 100mg/kg (p.o). Control group received Normal saline 10ml/kg body weight. Antidepressant activity was identified by using modified Forced Swimming Test (FST) and Tail Suspension Test (TST). Period of immobility was observed in both the models which was indicative of anti depressant activity. Standard statistical methods were used to evaluate the results. The results showed significant dose dependent antidepressant effect of EASL in Swiss albino mice for both the models in all the test groups (Test group I, II and III). MEMM possess significant antidepressant activity. However, further investigations are required to determine its active constituents and molecular level of target mechanism of the extract for further use in humans.

Keywords: *Marsilea minuta*, Antidepressant activity, forced swim test, Open Field Test.

INTRODUCTION

Depression: It is basically acknowledged as illness with symptoms such as anxiety and sleep disturbances. It can be a persistent, recurring illness that can cause many personal suffering for individuals and their families. At present, disability caused by depression is estimated to be the fourth most important cause of worldwide loss of life years. This has resulted into a requirement of search for effective treatments, including antidepressant drugs, herbal remedies, psychotherapy and electroconvulsive shock therapy.

THE NEUROBIOLOGY AND PHARMACOLOGY OF DEPRESSION

Neurotransmitter Systems

Within the central nervous system (CNS), the catecholamines, adrenaline, noradrenaline and dopamine forms the adrenergic systems. Out of these, few of the adrenergic neurons are radiating from the ancient limbic system and plays to role of discharging the catecholamines within the frontal cortex. Thus, the catecholaminergic pathways are claimed to be responsible for mood, alertness and stress responses. The primary neurotransmitter, which modulates the excitatory catecholamine systems of the CNS is Serotonin. The Serotonin neurons are responsible for the control of memory, mood, sex drive and appetite.[1] The systems of serotonin and noradrenaline are the important their main cell small bodies in brainstem areas that serve as headquarters for shipping axonal projections by the brains in specific pathways that mediate specific functions (See Figure No. 1 for an illustration of the serotonin projections and Figure No. 2 for an illustration of the noradrenergic projections). Multiple serotonergic and noradrenergic

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RESEARCH ARTICLE

Analytical Method Development and Validation for Estimation of Spironolactone and Hydrochlorothiazide in Bulk and Tablet Dosage form by High Performance Liquid Chromatography

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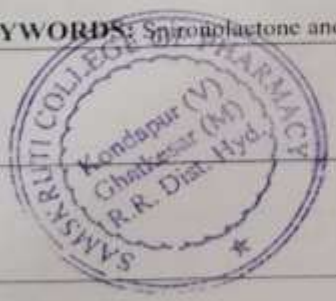
ABSTRACT:
Analytical Method Development and Validation for Spironolactone and Hydrochlorothiazide in bulk and Combined Dosage Form by RP-HPLC. New method was established for simultaneous estimation of Spironolactone and Hydrochlorothiazideby RP-HPLC method. The chromatographic conditions were successfully developed for the separation of Spironolactone and Hydrochlorothiazideby using Inertsil C18 (4.6mm ×250mm, 5µm particle size), flow rate was 1.0 ml/min, mobile phase ratio was (55:45% v/v) Methanol: Phosphate buffer pH 4.8 (pH was adjusted with ortho phosphoricacid), detection wavelength was 282nm. The instrument used was WATERS Alliance 2695 separation module, Software: Empower 2, 996 PDA detector. The retention times were found to be 1.688mins and 3.282mins. The % purity of Spironolactone and Hydrochlorothiazidewas found to be 99.86%. The system suitability parameters for Spironolactone and Hydrochlorothiazidesuch as theoretical plates and tailing factor were found to be 7586, 1.69 and 6235 and 1.58, the resolution were found to be 10.85. The analytical method was validated according to ICH guidelines (ICH, Q2 (R1)). The linearity study ofSpironolactone and Hydrochlorothiazidewas found in concentration range of 100µg-500µg and 30µg-70µg and correlation coefficient (r2) was found to be 0.999 and 0.999, % recovery was found to be 100.112% and 100.16%, %RSD for repeatability was 0.1702 and 0.043 respectively. The precision study was precise, robust, and repeatable. The LOD value was found to be 2.1µg/ml and 1.28µg/ml, and LOQ value was 6.3µg/ml and 3.84µg/ml for Spironolactone and Hydrochlorothiaziderespectively. Hence the suggested RP-HPLC method can be used for routine analysis of Spironolactone and Hydrochlorothiazide in API and Pharmaceutical dosage form.

KEYWORDS: Spironolactone and Hydrochlorothiazide, Accuracy, Precision, ICH Guidelines.



INTRODUCTION:

High-performance liquid chromatography (HPLC) is the fastest growing analytical technique for analysis of drugs. Its simplicity, high specificity, and wide range of sensitivity make it ideal for the analysis of many drugs in both dosage forms and biological fluids [1].

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