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Original Article

STUDY OF POTENTIAL DRUG INTERACTIONS AMONG EIGHT MAJOR DEPARTMENTS-GENERAL MEDICINE, ORTHOPEDICS, GYNECOLOGY, PULMONOLOGY, GENERAL SURGERY, PSYCHIATRY, OTOLARYNGOLOGY AND DERMATOLOGY OF A TERTIARY CARE TEACHING HOSPITAL IN SOUTHERN INDIA

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ABSTRACT

Objective: To identify frequency, type, severity and predictors of potential drug-drug interactions(pDDIs), potential drug-food interactions(pDFIs), potential drug-alcohol interactions(pDAIs) and potential drug-tobacco interactions(pDTIs) and most frequently interacting drug combination pairs in hospitalized patients from departments(depts) of General Medicine(GM), Orthopedic(Ortho), Gynecology(OBG), Pulmonology(Pulmo), General Surgery (GS), Psychiatry (Psych), Otolaryngology(ENT) and Dermatology (Derm) of study population.

Methods: A Prospective Observational Study was conducted in eight major dept's of a tertiary care teaching hospital for a period of 6 mo. A sample size of 650 prescriptions reflecting admission no's for each department were used.

Results: A total of 650 patients were included in the study. Among them, 282(43.4%) were males and 368(56.6%) were females. The mean age of the study population was 39.67±15.23. A total of 487 pDDIs, 734 pDFIs, 586 pDAIs and 159 pDTIs were found out of 650 hospitalized episodes. OBG showed the highest pDDIs and pDAIs. Highest pDFIs and pDTIs were seen in Pulmo. The majority of DDIs were minor, DFIs and DAIs were moderate and DTIs were of major in severity. Pharmacokinetic types of interactions were seen in the majority of the depts. Logistic regression analysis showed that Polypharmacy was associated with the occurrence of DIs. Most of the DIs repeated several times in particular depts and a list of these combinations was prepared.

Conclusion: With the high occurrence of overall DIs and characteristic patterns of DIs combination pairs among different departments of the hospital, the presence of clinical pharmacists in hospitals can play a great role, especially in developing nations like India where their role in hospitalized settings is always controversial.

Keywords: Drug interactions, Drug-drug interactions, Drug-food interactions, Drug-alcohol interactions, Drug-tobacco interactions, Departments, Drug combination pairs, Clinical Pharmacist

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INTRODUCTION

Drug interactions(DIs) are one of the most common causes of adverse drug reactions and continues to be a public health challenge in both developed and developing countries in the world. These DIs can be defined as an alteration in the efficacy or toxicity of a drug caused by concomitant administration with other drugs, food, beverages, and other supplements [1]. With thousands of drugs available worldwide and a substantial increase in drug discovery processes, the range of possibilities for drug interactions is considerable. It is reported that elderly patients with their increased complexity of the disease and therapeutic regimen are more susceptible to the occurrence of DIs [2].

However, these DIs may also occur independently in patients of all age groups. As the pattern of medications received by patients of different age groups and in different departments in a hospital is more complex, it is not easy to estimate the occurrence of DIs accurately. The prescriptions having 3 or more drugs had increased from 11.8% in 1988-1994 to 20.08% in 2007-2010 and having 5 or more drugs have increased from 4% to 15.01% during the same time period in the United States [3, 4].

The mechanism implicated in the occurrences of DIs can be Pharmacokinetic (PK) with alteration in the absorption, distribution, metabolism, and excretion of object drug or Pharmacodynamic (PD) in which interaction is close to the target organ and has an additive or antagonistic effect on the pharmacological action of the object drug [5].

About 30% of all adverse drug events increasing the hospital stay and healthcare cost of patients are related to DIs [6, 7].

Therefore, reviewing the therapy by the clinical pharmacist based on the physiological conditions of the patient and considering the type of allergies, medication history, and social habits of the patient, the clinical pharmacist may play a key role in preventing different types of DIs and adverse events.

Not much data is available on the distribution pattern of DIs in different department's (dept's) of the hospital. There are several published data regarding the pattern of DIs in a particular department of the hospital or the overall interactions found in particular age groups [2, 8]. Further, the literature has mainly focused on drug-drug interactions (DDIs), while there are also risks of occurrence of DIs with food, alcohol, and tobacco [9-11]. There are some very well-known potential drug-food interactions that are potentially dangerous and may result in therapeutic failure. With an increasing population taking alcohol and tobacco, many drugs interact adversely with them. Hence this study aims to find out the frequency, type, severity, and predictors of potential drug-drug interactions (pDDIs), potential drug-food interactions (pDFIs), potential drug-alcohol interactions (pDAIs) and potential drug-tobacco interactions (pDTIs) and the most frequently interacting drug combination pairs in hospitalized patients from departments (depts) of General medicine (GM), Orthopedic (Ortho), Pulmonology (Pulmo), General Surgery (GS), Psychiatry (Psych), Otolaryngology (ENT) and Dermatology (Derm) of the study population, which will help the doctor to be aware of these

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DEVELOPMENT, CHARACTERIZATION AND PRE CLINICAL EVALUATION OF POLYHERBAL SYRUP FOR ANTIOXIDANT AND HEP ATOPROTECTIVE ACTIVITY

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ABSTRACT

The liver problems are on rise which necessitates development of better remedies to contain them. Hence the present study was intended to develop, characterize and evaluate polyherbal syrup containing *Cicer arietinum, Tabebuia argentea, Acacia leucophloea, Biophytum sensitivum* for its hepatoprotective and antioxidant activity. Polyherbal syrup was prepared by taking equal proportions of methanolic extracts of selected plants and simple syrup in 1:5 proportions. The formulation was then characterized for its organoleptic parameters, physicochemical parameters, stability testing and refractive index. It was later evaluated for hepatoprotective and antioxidant activity in CCl_4 induced hepatotoxicity model. The formulation showed significant hepatoprotective and antioxidant activity by restoring altered biochemical and antioxidant enzyme levels in both the models which proved its efficacy in alleviating liver disorders. The study provides a better remedy for liver disorders which needs further substantiation in clinical studies.

KEY WORDS: ***Hepatotoxicity, Polyherbal formulation, Oxidative stress.***

1. INTRODUCTION

Liver diseases have turned into a global concern worldwide[1]. The exposure to various organic compounds (drugs, chemicals, etc.) and environmental pollutants, to form highly reactive substances like reactive oxygen species (ROS) directly or through metabolic activation, which results change in anatomy or functions of liver[2]. The management of liver disorders is a big challenge to the modern medicine. The modern allopathic drugs are unsatisfactory in alleviation of hepatic ailments and some of these drugs adversely affect the liver function. The traditional system of medicine like ayurveda and siddha system of medicine have a crucial role in curing of liver aliments[3].Owing to good safety profile, use of herbal medicine for various diseases have received much attention in worldwide and in India[4]. The herbal formulations that have attained widespread acceptability as therapeutic agents include antidiabetics, hepatoprotective agents, and lipid-reducing agents[5]. However, there are many limitations such as collection, storage, doses, and duration regarding the safety and efficacy of these preparations. A research has been carried out to evaluate hepatoprotective and antioxidant activity of herbal agents as formulation[6]. The formulation contains methanolic extracts of aerial parts except seeds and seed coat of *Cicer arietinum* (Fabaceae), leaves of *Tabebuia argentea* (Bignoniaceae), *Biophytum sensitivum* (Oxalidaceae) and bark of *Acacia leucophloea* (Mimosaceae).

2. MATERIALS AND METHODS

2.1. Preparation of formulation

All the plant materials were collected and authentication was done by Dr. K. Madhava Chetty, Assistant professor, Department of Botany, Sri Venkateshwara University, Tirupati, Andhra Pradesh. Methanolic extracts of each plant prepared by using continuous hot percolation method. These extracts of each plant in equal proportions were mixed with simple syrup in 1:5 v/v ratio. The final liquid dosage form was then subjected to evaluation of quality and Pharmacological activity of the formulation as per official standards.

2.2. Chemicals

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FORMULATION AND EVALUATION OF FELODIPINE HOLLOW MICROSPHERES

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ABSTRACT
Felodipine is a calcium channel blocker which is used for the treatment of high blood pressure to prevent heart stroke. In the current research work hollow microspheres of Felodipine with better absorption in gastric pH was formulated by using various polymers. Drug polymer compatibility was characterized by FT-IR. Microspheres were prepared by emulsion solvent diffusion technique by using different polymers such as ethyl cellulose, carbopol 934, eudragit and sodium alginate at varying concentrations. The formulations were evaluated for micromeritic properties, buoyancy, percentage yield, entrapment efficiency, *in vitro* studies and stability stuides. SEM photographs showed outer surface of microspheres was smooth and dense where as internal surface was porous which helped to prolong floating. Optimized F2 formulation exhibited higher release rate 95.55%. *In vitro* drug release studies showed controlled release of Felodipine for over 8h. Stability studies indicated the F2 formulation was stable with respect to its drug release.

KEYWORDS: Felodipine hollow microspheres, polymers, emulsion solvent diffusion technique, FTIR Studies, floating time, *in vitro* drug release studies.

INTRODUCTION
Oral drug delivery has been known for decades as the most widely used route of administration among all the routes. The reasons that the oral route achieved such popularity may be in part attributed to its ease of administration as well as the traditional belief. Pharmaceutical product designed for oral delivery which are currently available in the market mostly immediate-release or conventional release, which maintains the drug concentration within the therapeutically effective range only, when administered several times a day. This results in a significant fluctuation in the drug level.[1,2] An effective drug therapy not only depends on the inherent therapeutic activity of the drug molecule but also the efficiency of its delivery at the site of action. Drug absorption at the desired rate means, first, to reach the effective plasma level within an acceptable short time period; second, to avoid an overshoot in the case of rapidly absorbed drugs and third, to maintain effective plasma levels over the desired time period. To develop a drug delivery system for oral administration, it is necessary to optimize not only the release rate of an active ingredient from the system but also the residence time of the system in the gastrointestinal tract.[3] One of the most feasible approaches for achieving a prolonged and predictable drug delivery in the GI tract is to control the gastric residence time (GRT), by using gastro-retentive dosage forms (GRDFs).[4,5] Floating systems were first described by Davis in 1968. FDDS is an effective technology to prolong the gastric residence time in order to improve the bioavailability of the drug. FDDS are low-density systems that have sufficient buoyancy to float over the gastric contents and remain in the stomach for a prolonged period. Floating systems can be classified as follows. The various buoyant preparation include hollow microsphere (micro balloons), granules powder, capsule, tablet (pills) laminated films. Hollow microspheres float immediately upon contact with gastric fluid and gives promising approaches for increasing the bioavailability of drugs with absorption windows in upper small intestine and stomach. However, immediate floating can only be achieved, when the density of the device is lower than gastric fluid 1.004 gm/cm^3.[6,7] Hollow microspheres of non-steroidal anti-inflammatory drugs are very effective for controlled release, and reduce the major side effect of gastric irritation. For example, floating microspheres of indomethacin are quite beneficial for rheumatic patients.[8,9] Hollow microspheres can greatly improve the pharmacotherapy of the stomach through local drug release, leading to

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DESIGN AND *IN-VITRO* EVALUATION STUDIES OF TELMISARTAN LIPOSOMAL FORMULATIONS

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ABSTRACT
The aim of the present study was to develop a liposomal gel formulation for antihypertensive drug telmisatran. Liposomal carriers are well known for their topical drug delivery system with an advantage to overcome serious gastrointestinal complications for steroidal or non steroidal drugs given in oral route. Liposomes with various concentrations of cholesterol were prepared using thin film hydration technique (vacuum rotatory evaporator). The liposomal formulation was incorporated in gel (carbopol) and characterized. The SEM analysis showed surface morphology of liposomal formulation was achieved. The FTIR analysis showed there is no specific interaction between drug and excipients. The in-vitro studies revealed that liposomal gel formulation exhibits increased permeation showing sustain. The future studies are warranted to develop commercial liposomal gel formulation for the treatment of hypertension.

KEYWORDS: Liposomes, Telmisatran, FTIR & in-vitro studies.

INTRODUCTION
Telmisartan is a nonpeptide angiotensin-II receptor (type AT1) antagonist. It blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin-II by selectively blocking its binding to the AT1 receptor in adrenal gland and smooth muscles of vasculature.[1,2] In the past few decades, considerable attention has been focused on the development of new drug delivery system (NDDS). The NDDS should ideally fulfill two prerequisites. Firstly, it should deliver the drug at a rate directed by the needs of the body, over the period of treatment. Secondly, it should channel the active entity to the site of action. Conventional dosage forms including prolonged release dosage forms are unable to meet none of these. At present, no available drug delivery system behaves ideally, but sincere attempts have been made to achieve them through various novel approaches in drug delivery. In recent years, vesicles have become the vehicle of choice in drug delivery. Lipid vesicles were found to be of value in immunology, membrane biology, diagnostic techniques, and most recently, genetic engineering. Vesicles can play a major role in modelling biological membranes, and in the transport and targeting of active agents. Vesicular drug delivery reduces the cost of therapy by improved bioavailability of medication, especially in case of poorly soluble drugs. They can incorporate both hydrophilic and lipophilic drugs. These systems delay drug elimination of rapidly metabolizable drugs and function as sustained release systems and solve the problems of drug insolubility, instability and rapid degradation. Consequently, a number of vesicular delivery systems such as liposomes, proliposomes, transferosomes, pharmacosomes, niosomes or proniosomes etc, were developed.[3] Most commonly used materials for the formation of vesicles are phospholipids cholesterol and non-ionic surfactants. Vesicular system offers number of advantages in drug delivery through the skin such as biocompatibility, non-toxicity, incorporated both hydrophilic and lipophilic drugs, controlled drug delivery rate and extent, act as a depot formation for sustained release of drug, increased permeation of drugs through the skin and penetration enhancer because of their unique composition etc.[4,5] Liposome can be defined as "a colloidal, vesicular structures composed of one or more lipid bilayers surrounding a number of aqueous compartments".[6] Liposomes can be composed of naturally-derived phospholipids with mixed lipid chain like egg phosphatidylethonalimine or of pure components like DOPE (dioleolylphosphatidyl ethanolamine) and cholesterol.[7] A number of evidences demonstrated the ability of liposomes to enhance the efficiency of drug delivery via several routes of administration.[8] Liposome as a vesicular system offers a number of advantages,

DEVELOPMENT AND CHARACTRIZATION OF GRANISETRON FAST DISSOLVING TABLETS

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ABSTRACT

The aim of work is to characterization and evaluation of fast dissolving tablet of Granisetron hydrochloride using super disintegrates like crosscarmellose sodium and sodium starch glycolate. FTIR studies revealed that there was no physico-chemical interaction between granisetron and other excipients. Tablet containing sodium starch glycolate showed excellent disintegration time and drug release as compared to other formulations. Granisetron is a selective 5HT3 receptor antagonist, which may have beneficial therapeutic ef fects in the treatment of vomiting and nausea resulting from cancer therapy. In the present work fast dissolving tablets of Granisetron have been prepared by direct compression method. Formulations were evaluated for precompressional parameters such as angle of repose, % compressibility and Hausner's ratio. The prepared tablets were evaluated for post compressional parameters such as hardness, friability, thickness, invitro dispersion time, wetting time, and water absorption ratio. From this study it is concluded that fast dissolving tablets could be prepared by direct compression method using different superdisintegrants enhanced dissolution will lead to improved bioavailability, improved effectiveness of Granisetron.

Keywords: Granisetron, superdisintegrants, FTIR studies, direct compression technique, in-vitro drug release studies.

1.INTRODUCTION

The FDT technology, which makes tablets dissolve or disintegrate in the mouth without additional water intake. The FDT formulation is defined by the Food and Drug Administration (FDA) as "a solid dosage form containing medical substances whish disintegrates rapidly, usually within a seconds, when placed upon the tongue.[1] The basic approach in development of FDT is the use of superdisintegrants, which provide instantaneous disintegration of tablet after putting on tongue, their by release the drug in saliva [2].The fast dissolving tablets are rapidly dissolved or disintegrate by the use of superdisintegrants. Fast dissolution"""" or fast disintegration typically requires dissolution or disintegrationof a tablet within one minute[3.] Granisetron hydrochloride is a selective 5-HT_3 receptor antagonist, which may have beneficial therapeutic effects in the treatment of vomiting and nausea resulting from cancer therapy[4,5] Granisetron hydrochloride undergoes extensive hepatic first pass metabolism with a Bioavailability of 60%. The terminal elimination half-life is 3 to 14 hours after oral administration. Granisetron hydrochloride is about 65% bound to plasma proteins. In the present study, an attempt was made to develop

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Open Access Review Article

Therapeutic Considerations for Docetaxel and Paclitaxel in Metastatic Breast Cancer

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ABSTRACT

Breast cancer is the main source of death among women. Currently, 77% of women diagnosed with breast cancer are age 50 and older; however, it is projected that approximately 66% of the new cases diagnosed will occur in women younger than 65. Taxanes are one of the most effective class of drugs among all the chemotherapeutic agents. They are crucial in the adjuvant therapy of lymph node fantastic or high risk/lymph node poor breast cancer. Several clinical trials have assessed the wellbeing and adequacy of taxanes along with their tolerability in patients with metastatic cancer (MBC) The overview of these Paclitaxel and Docetaxel, the mechanism of action, pharmacokinetics and pharmacodynamics, dose and administration, adverse effects, clinical potency, and sufferable profiles combination therapies, the pathological complete response of these taxanes are included. The different novel formulations of taxanes are formulated from nanoparticles, polyglutamate, liposomes to improve the wellbeing and adequacy taxanes to reduce their toxicities. Single-agent research located with docetaxel and paclitaxel in metastatic breast most cancers show clinically huge antitumor motion even in the advanced stage, heavily pretreated, safe, as properly as in refractory diseases. This action is likewise clear with taxane-based combination regimens. Serious hematologic and nonhematologic toxicities are incompatible, with different toxicities noted dependent on the portion and weekly regimen selected. Weekly docetaxel and paclitaxel regimens speak to important helpful treatment options for women suffering from metastatic breast cancer and have entered assessment as a major aspect of adjuvant treatment for this disease Toxicity associated with taxanes chemotherapy are based totally on the dose schedules and weekly regimen selected and the most frequent toxicities related with these marketers include myalgia, peripheral neuropathy, neutropenia, etc Docetaxel retains in tumor cells for longer duration when compared to paclitaxel because of its slow efflux and large amounts of uptake into the cell which explains its more benefits when compared to paclitaxel. Clinical studies conducted so far suggested a more benefit to risk ratio for docetaxel when compared to paclitaxel. This article reviews mainly different actions exhibited by taxanes in the therapy of metastatic breast cancer and others on stages of cancer along with the toxicities associated with these agents.

Keywords: Metastatic breast cancer, Taxanes, Paclitaxel, Docetaxel, Single-agent, Combination regimen.

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INTRODUCTION:

Worldwide, breast cancer is leading cancer in females. Neoadjuvant chemotherapy administered before medical surgery is the possible treatment option for various breast cancer patients [1]. Preoperative chemotherapy diminishes the primary tumor thereby facilitating breast conservation [2, 3].

Preoperative chemotherapy administration on open tumors before the medical procedure likewise gives the chance to quickly measure tumor reaction and identify the patients who responded to the therapy. It also helps in attaining pathological complete response (pCR) which is often described by the destruction of all malignant cells from the breast and also from axillary lymph nodes, which is the primary endpoint for disease-free tolerance after neoadjuvant therapy, particularly in triple-negative breast tumor [4, 5].

Clinical parameters, for example, estrogen receptor-negative status, excessive histological evaluation, and high proliferative fame are associated with excessive affectability to chemotherapy [5, 6]. Of all the new anti-

Research Article

Formulation and Evaluation of a Novel Capsule-in-a-Capsule Technology of Anti-tubercular Drugs

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ABSTRACT

The present investigation aims to develop a novel capsule-in-a-capsule technology using multiple unit mini-tablets for targeting and sustaining the release of rifampicin and isoniazid in stomach and intestine respectively. Before developing the batches, drugs and polymers were checked for compatibility studies. For preparing the formulation, rifampicin was developed as liquid dispersions and floating mini-tablets using various solvent mixtures and hydrophilic polymers respectively. Whereas, isoniazid was developed as intestinal targeted mini-tablets using pH-dependent polymers. Moreover, the capsule-in-a-capsule formulation was developed by first filling five isoniazid mini-tablets into a smaller sized capsule (i.e. size "3") and then smaller mini-tablets-filled capsule of isoniazid and ten rifampicin mini-tablets into a bigger sized capsule (i.e. size "0"). FTIR and DSC studies confirm that there was no interaction between drug and polymers. From the separate in-vitro dissolution studies, it was found that rifampicin floating mini-tablets containing 30% concentration of HPMCK-4M and HPMC-K100M polymers in 1:4 ratio and intestinal targeted isoniazid mini-tablets containing 50% concentration of eudragit-S100 polymer were considered as the most optimized batches. Whereas, capsule-in-a-capsule formulation released 96.92±1.14 % of rifampicin at the end of 4 hours and 4.17±1.68 %, 99.06±1.88 % of isoniazid at the end of 2 and 6 hours respectively. This formulation was also found to be stable as per the ICH guidelines. The developed capsule-in-a-capsule formulations have successfully released rifampicin and isoniazid in the pH of stomach and small intestine respectively as observed from the in-vitro results.

Keywords: Rifampicin; Isoniazid; Capsule-in-a-capsule technology; Liquid dispersions; Floating mini-tablets; Intestinal targeted mini-tablets.

INTRODUCTION

Tuberculosis is a deadly and common infectious disease which is caused by mycobacterium, mainly mycobacterium tuberculosis.[1] Since past forty years, rifampicin and isoniazid has been majorly used in tuberculosis therapy.[2,3] It is because isoniazid is a first-line anti-tubercular drug and it acts by inhibiting the mycolic acid synthesis in the mycobacterium cell wall. Isoniazid is never used alone to treat active tuberculosis because of its quick resistance to the body. Whereas, rifampicin is a novel and only anti-tubercular drug which has the unique ability to kill dormant tubercular bacilli. It acts by inhibiting DNA-dependent RNA polymerase in the bacterial cells by binding to its beta-subunit, thereby preventing RNA transcription and subsequent proteins translation.[4]

Isoniazid and rifampicin are widely prescribed as combination product for tuberculosis treatment. But since past years, two critical problems have been observed from such combination products of isoniazid and rifampicin. That includes 1) The impaired and varying bioavailability of rifampicin from combination formulation with isoniazid and 2) Poor rifampicin stability containing combination formulation with Isoniazid.[5-7] The possible reason for such problem is that the rifampicin interacts with isoniazid in the acidic media of stomach to form inactive 3-formyl rifamycin isonicotinyl hydrazone. Thus, the use of substandard combination formulations ultimately results in the emergence of drug resistant tuberculosis and hence treatment failure.[8] Moreover, it has also been found that rifampicin is highly soluble between 1-2 pH and well absorbed from the stomach. Whereas, isoniazid is well absorbed from all the three sections of small intestine (i.e. duodenum, jejunum and ileum).[9] Thus, there is a necessity to modify the combination formulation in such a way that rifampicin and isoniazid are not released simultaneously in the stomach.

Thus, the innovative thinking has transformed towards the novel concept of capsule-in-a-capsule technology of Anti-tubercular drugs with improved functionality. It is because capsule-in-a-capsule drug delivery systems are ideally suited for combination or dual release products. They can be used to combine incompatible active pharmaceutical ingredients and to deliver compounds to two different regions of gastro-intestinal tract. The best advantage of this novel technology is that it offers several

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CORONAVIRUS: ORIGIN, SPREAD, DIAGNOSTIC TESTS, LIFE CYCLE, TREATMENT AND PREVENTIVE MEASURES FOR COVID-19

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ABSTRACT

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).It was first identified in December 2019 in Wuhan, China, and has since spread globally, resulting in an ongoing pandemic. The World Health Organization (WHO) on March 11, 2020, has declared the novel coronavirus (COVID-19) outbreak a global pandemic. According to the CDC Trusted Source, SARS-CoV-2 has an incubation period of 2 to 14 days. This means that someone who's carrying the virus may come into contact with many people before symptoms begin. The virus is primarily spread between people during close contact, often via small droplets produced by coughing,sneezing, and talking.To date, there are no specific vaccines or medicines for COVID-19 but by using some anti-viral and anti malarial drugs such as hydrochlroquine and chloroquine it can be treated out. The epidemic preventive measures are epidemic lockdown and social distancing.

Keywords: COVID-19, SARS-CoV-2, epidemic prevention and control, social distancing, epicenter lockdown.

INTRODUCTION

Corona viruses belong to the class:-pisoniviricetes, family:Corona viridae, kingdom:-orthornavirae and are characterized by causing respiratory tract infections ranging from mild diseases such as common cold to pneumonia with a lethal outcome.The SARS-CoV-2 virus is a single-stranded RNA beta-coronavirus, similar to SARS-CoV and MERS-CoV.Researchers first identified a coronavirus in 1937, isolating one that was responsible for a type of bronchitis in birds that had the potential to devastate poultry stocks.Scientists found evidence of human coronaviruses in the 1960s, in the noses of people with the common cold. In the context of human coronaviruses, it was thought that they caused only mild self-limitinginfections until the SARS-CoV outbreak in 2002–2003 [2]. Two humanα-coronaviruses (HCoV-229Eand HCoV-NL63) and twoβ-coronaviruses (HCoV-OC43 and HCoV-HKU1) were identified asendemic in human populations, responsible for 15%–30% of annual respiratory tract infections.However, a more severe disease has been detected in neonates, elderly people and in individuals withpre-existing illnesses

Human coronaviruses that are particularly prevalent include 229E, NL63, OC43, and HKU1.The name "coronavirus" comes from the crown-like projections on their surfaces. "Corona in Latin means "halo" .

Origin and cause

The coronavirus likely originated in bats or pangolins. The first transmission to humans was in Wuhan, China. Since then, the virus has mostly spread through person-to-person contact.

Coronaviruses are a group of viruses that can cause disease in both animals and humans. The most common in certain species of animals, such as cattle and camels. Although the transmission of coronaviruses from animals to humans is rare, this new strain likely came from bats, though one study suggests pangolins may be the origin. The severe acute respiratory syndrome (SARS)

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Research Article

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A NEW HPLC METHOD DEVELOPMENT AND VALIDATION FOR THE DETERMINATION OF SOFOSBUVIR IN TABLET DOSAGE FORM

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ABSTRACT

A simple, accurate, rapid and precise isocratic reverse phase high performance liquid chromatographic method has been developed and validated for the determination of Sofosbuvir in tablet dosage form. The chromatographic separation was carried out with a Kromosil analytical column (250×4.6mm,5µm), a mixture of 0.1% ortho phosphoric acid: acetonitrile in the ratio of 30:70 as mobile phase, at a flow rate of 1.0 ml/minute maintaining the temperature at 30ºc. UV detection was performed at 260 nm. The retention time was 2.576 for Sofosbuvir. The method was validated according to ICH guidelines and the acceptance criteria of results for accuracy, precision, linearity, robustness, limit of detection, limit of quantification and ruggedness were met in all cases. The % RSD values for Sofosbuvir in precision study was found to be 0.70%. The linearity of the calibration curve for each analyte in the desired concentration range was good (r^2>0.999). The high recovery and value of low relative standard deviation confirm the suitability of the method for routine evaluation of Sofosbuvir in pharmaceutical dosage forms.

KEYWORDS: Sofosbuvir, HPLC, Method development, validation.

INTRODUCTION

Sofosbuvir (SBR) is a pro drug.[1-5] nucleotide analog, an important part used as combination therapy to treat cases like hepatitis C virus (HCV) infection, co-infection of HIV and HCV. After its metabolism to the active antiviral agent 2'-deoxy-2'-α-fluoro-β-C-methyluridine-5'-triphosphate (commonly known as GS-461203), the triphosphate generally serves as a defective substrate for the protein NS5B, an RNA-dependent RNA polymerase which required for replication of viral RNA. The drug SBR and other nucleotide inhibitors of the HCV RNA polymerase exhibit a very high barrier to resistance development. Markedly, this is an important advantage relative to HCV drugs that target other certain viral enzymes such as the protease, for which rapid resistance development has proved to be an important cause of therapeutic failure.

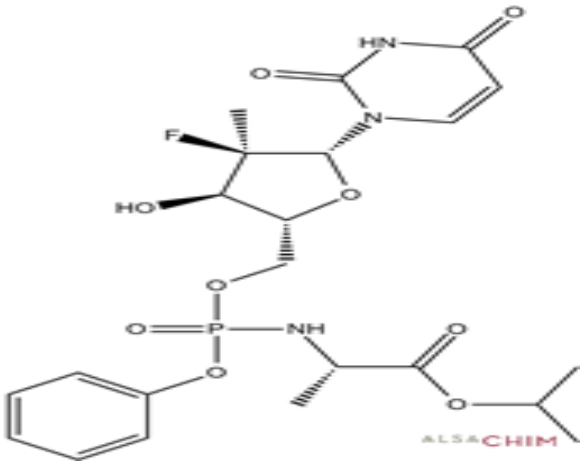

Fig 1: Chemical structure of Sofosbuvir.

Literature survey,[4-10] helps us to get motivated and go for the present research work. There are certain assay methods available for this compound. Kalpana Nekkala, Shanmukha Kumar J V, Ramachandran D developed a method for the simultaneous estimation of sofosbuvir

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RESEARCH ARTICLE

Development and Validation of UPLC method for the determination of Lenvatinib in Capsule formulation

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ABSTRACT:
A new, simple and selective method was developed to estimate Lenvatinib pharmaceutical dosage form by UPLC. Ideal Chromatographic peak of separation was attained on a Acquity BEH C18 (50*3.0mm. 1.7µm) using mobile phase consisting 0.1% Orthophosphoric acid: ACN (60:40) v/v with detection of 248 nm. Linearity of the drug was observed in the concentration range 60-140 µg /ml (r^2 =0.994). From the results, the developed method was simple, sensitive, precise and accurate and it can successfully be applied for the determination of API in the commercial formulations of Lenvatinib in quality control laboratories.

KEYWORDS: Lenvatinib, development, validation, ICH guidelines, UPLC method.

INTRODUCTION:
Lenvatinib is chemically 4-[3-chloro-4-(cyclopropylcarbamoylamino)phenoxy]-7-methoxyquinoline-6-carboxamide as shown in figure 1 with the molecular formula $C_{21}H_{19}clN_4O_4$ and molecular weight of 426.857g/mol[1]. It is an anticancer agent which acts by inhibiting VEGFR (vascular endothelial growth factor) as well as FGFR (fibroblast growth factor receptors) and also platelet derived growth factor receptor (PDGFR)[2]. Hence, used in the treatment of thyroid cancer[3][4][5] Hepatocellular cancer (HCC)[6][7] and renal carcinoma.[8]

Literature study shows very few validation methods for determining Lenvatinib such as spectroscopy and HPLC method[9], LC-MS/MS method[10][11] as well as RP-HPLC method[12][13]. However, in the present research study, a new and precise UPLC method was established for determination of Lenvatinib in capsule formulation and validated as per ICH guidelines[14].

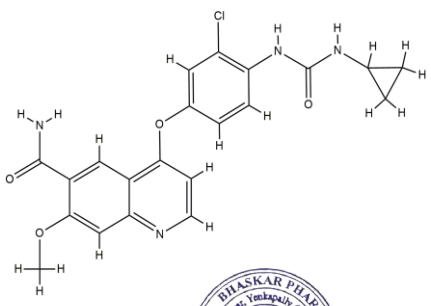

Figure 1: Structure of Lenvatinib

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NEW METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS DETERMINATION OF ASPIRIN, ATORVASTATIN AND CLOPIDOGREL IN CAPSULE DOSAGE FORM BY HPLC

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Abstract:

A simple, accurate, rapid and precise isocratic reverse phase high performance liquid chromatographic method has been developed and validated for simultaneous determination of aspirin, atorvastatin and clopidogrel in capsule dosage form. The chromatographic separation was carried out on an Inertsil ODS analytical column (250×4.6mm,5µm) with a mixture of solvents phosphate buffer (pH 3.15 adjusted with o-phosphoric acid), acetonitrile and methanol (40:40:20 v/v/v) as mobile phase, at a flow rate of 1.0 ml/minute maintaining the temperature at 30ºc. UV detection was performed at 240 nm. The retention times were 2.4, 3.5 and 4.5 for atorvastatin, aspirin and clopidogrel respectively. The method was validated according to ICH guidelines and the acceptance criteria of results for accuracy, precision, linearity, robustness, limit of detection, limit of quantification and ruggedness were met in all cases. The % RSD values for atorvastatin, aspirin and clopidogrel were found to be 0.101%, 0.547% and 0.515% respectively. The linearity of the calibration curve for each analyte in the desired concentration range was good (r^2>0.999). The high recovery and value of low relative standard deviation confirm the suitability of the method for routine evaluation of aspirin, atorvastatin and clopidogrel in pharmaceutical dosage forms.

Keywords: *Aspirin, atorvastatin, clopidogrel, simultaneous, HPLC.*

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Research article *Open Access*

Method development and validation of combination of sofosbuvir and velpatasvir by RP-HPLC method

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ABSTRACT

Objective

The objective of the present research work was to develop a innovative, simple, and economic method for estimation of Sofosbuvir and Velpatasvir in bulk and dosage form by RP-HPLC.

Methods

The chromatographic conditions were performed on Develosil ODS HG-5 RP C_{18}, 5µm, 15cmx4.6mm i.d. as stationary phase and mobile phase was prepared with a mixture of Potassium Dihydrogen Phosphate buffer (adjusted with 1% Orthophosphoric acid, pH- 3.5) (0.05M) : Acetonitrile with (70:30 v/v), flow 1.0 ml/min, with Injection Volume 10µl, at detection wavelength 257 nm and run time at 10.0 mins

Results

The analytical method is valid for estimation of Sofosbuvir and Velpatasvir over a range of 6 µg/ml – 14 µg/ml and 12 µg/ml – 28 µg/ml. The results of system suitability test, linearity, precision and accuracy, robustness, specificity, LOD and LOQ and stabilities presented in this report are within the acceptance range.

Conclusion

A specific, sensitive, economic method estimation of Sofosbuvir and Velpatasvir has been developed based on ICH Guidelines with bulk and dosage forms.

Keywords: Sofosbuvir and Velpatasvir, HPLC, Method Development, ICH, Validation, Accuracy, Precision.

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Research article *Open Access*

Method development and validation of raltegravir by RP-HPLC method

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ABSTRACT

Objective

The objective of the present research work was to develop an innovative, simple, and economic method for estimation of Raltegravir in bulk and dosage form by RP-HPLC.

Methods

The chromatographic conditions were performed on Symmetry Develosil ODS HG-5 RP C_{18}, 5µm, 15cmx4.6mm i.d. as stationary phase and mobile phase was prepared with a mixture of Phosphate buffer (pH=3.0) : Methanol with 30:70, flow 1.0 ml/min, with Injection Volume 10µl, at detection wavelength 246 nm and run time at 5.0 min.

Results

The analytical method is valid for estimation of Raltegravir over a range of 20 µg/ml–70 µg/ml. The results of system suitability test, linearity, precision and accuracy, robustness, specificity, LOD and LOQ and stabilities presented in this report are within the acceptance range.

Conclusion

A specific, sensitive, economic method estimation of Raltegravir has been developed based on ICH Guidelines with bulk and dosage forms.

Keywords: Raltegravir, HPLC, Method Development, ICH, Validation, Accuracy, Precision.

INTRODUCTION

Raltegravir (RAL), sold under the brand name Isentress, is an antiretroviral medication used, together with other medication, to treat HIV/AIDS. [1] It may also be used, as part of post exposure prophylaxis, to prevent HIV infection following potential exposure. It is taken by mouth. [2] Common side effects include trouble sleeping, feeling tired, nausea, high blood sugar, and headaches. [3] Severe side effects may

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EVALUATION OF ANTIDIABETIC ACTIVITY OF *SWERTIA CHIRAYITA* AND *PANAX GINSENG*

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ABSTRACT

Diabetes mellitus, one of the most common endocrine disorders has caused significant morbidity and mortality due to macro vascular and micro vascular complications. Currently available therapies for diabetes include insulin and various oral anti diabetic drugs have number of serious adverse effect; therefore the search for more effective and safer hypoglycemic agents is one of the important areas of investigation. Some medicinal plants have been reported to be useful in diabetes worldwide. The herbs like *swertia chirayata* shown to protect the liver. It contains xanthones which is reputedly effective against Malaria, Tuberculosis. It also cures constipation and used for treating dyspepsia with all other properties the *swertia chirayita* shows good anti diabetic activity. The other herb which was used to carry out the experiment *panax ginseng* is well effective in case of anti-sterility in men, it prevents cancer and fight chemical dependency (anti proliferative). The study was conducted to examine the possible antidiabetic activity of *swertia chirayata and panax ginseng* leaf extraction on male wistar rats. Gold thio glucose method was used to induce diabetes in rats. Initially blood glucose levels were increased abruptly after induction. After giving the oral administration of ethanolic extract of *swertia chirayat* (100mg/ Kg, 200mg/kg) and *panax gingseng* (250mg/kg, 100mg/kg). Finding of this research showed that ethanolic extract of a plant *swertia* possess phytochemicals like steroids, alkaloids, tannins, flavonoids and *panax ginseng* possess alkaloids, carbohydrates, flavonoids and tannins significant ($P < 0.05$) anti diabetic activity. The results were compared with standard drug metformin (400mg/kg).

KEYWORDS: *Swertia chirayita*, *panax ginseng*, Antidiabetics.

INTRODUCTION

DIABETES MELLITUS

Diabetes mellitus is a chronic metabolic disorder characterized by high blood glucose concentration (hyperglycemia) caused by insulin deficiency often combined with insulin resistance (Rang and Dale, 2008). Diabetes mellitus refers to the group of diseases that leads to high blood glucose level due to defect in either insulin secretion or insulin action in the body (Rother, 2007).

Hyperglycemia occurs because of uncontrolled hepatic glucose output and reduced uptake of glucose by skeletal muscle with reduced glycogen synthesis. When the renal threshold for glucose reabsorption is exceeded, glucose spills over into the urine (glycosuria) and causes an osmotic diuresis (polyuria), which in turn results in dehydration, thirst and increased drinking of water (polydipsia).

The characteristic symptoms of diabetes mellitus are polyuria, polydipsia, polyphagia (increased hunger), blurred vision, these symptoms may be absent if the blood sugar is only mildly elevated.

IMPORTANT TYPES OF DIABETES MELLITUS

A. TYPE I DIABETES MELLITUS

Type I diabetes mellitus is characterized by loss of the insulin producing beta cells of the islets of Langerhans in the pancreas leading to insulin deficiency. Type I diabetes can be further classified as immune mediated or idiopathic. Type I diabetes is majorly of the immune mediated variety, where beta cell loss is a T-cell mediated auto immune attack (Rother, 2007). Type I diabetes is also called as juvenile diabetes (childhood) or insulin dependent diabetes mellitus (IDDM).

There is no preventive measure that can be taken against this type I diabetes. Diet and exercise cannot reverse or prevent type I diabetes. Sensitivity and responsiveness to insulin are usually normal especially in early stages.

B. TYPE II DIABETES MELLITUS

Type II diabetes mellitus is characterized differently and it is due to insulin resistance or reduced insulin sensitivity and it may be absolutely due to reduced insulin secretion in some of the cases. Insulin receptor sensitivity decreases or insulin receptors.

Research Article

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QUANTITATIVE DETERMINATION OF QUERCETIN A BIOMARKER IN METHANOLIC EXTRACT OF *LAGERSTROEMIA LANCEOLATA* AND *LAGERSTROEMIA PARVIFLORA* LEAVES BY HPTLC METHOD

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ABSTRACT

In Indian Ayurvedic system, *Lagerstroemia lanceolata* (*L. lanceolata*) and *Lagerstroemia parviflora* (*L. parviflora*) are well-known plants used for major and minor ailments. Quercetin identified from the vast plethora of plant extracts has proved to possess ethno pharmacological relevance. The present investigation is to estimate biologically active flavonoid compound, quercetin in methanolic leaves extract of *L. lanceolata* and *L. parviflora* by using high-performance thin-layer chromatography (HPTLC). After extraction and phytochemical screening, the extracts were subjected to quantification for the presence of quercetin by HPTLC. Pre coated silica gel 60 F254 is used as a stationary phase and toluene: ethyl acetate: formic acid in ratio of 7: 5: 1 is used as a mobile phase. Densitometric estimation and quantification of quercetin was carried out at 254 nm. The standard Rf value of quercetin is 0.64. The total peak area of the standard, quercetin was compared and the corresponding peak areas of *L. lanceolata* and *L. parviflora* extracts were estimated to be 390.6 and 5442.8 respectively. A good linear relationship 0.988 was obtained between the concentration ranges of 0.2-1.0 µg. This HPTLC method was found to be simple and convenient for rapid screening of active compounds and quantification of the investigated flavonoids in *L. lanceolata* and *L. parviflora*.

Keywords: *Lagerstroemia lanceolata*, *Lagerstroemia parviflora,* HPTLC, Flavonoid compounds, Quercetin.

INTRODUCTION

Nature still obliges as the man's primary source for the cure of his ailments. Research in preventive medicine showed the importance of functional nutrition in reducing the risk factor of certain chronic diseases. Innate defense system of the human body may be insufficient for the damage caused by continued oxidative stress[1]. Flavonoids are a group of polyphenolic compounds, which are extensively dispersed throughout the plant kingdom. Till date about 300 varieties of flavonoids are known[2]. Herbal medicines have situated the test of time for their efficacy, safety, cultural suitability and smaller side effects. Flavonoids are classified as flavonones, flavones, flavonols, flavanols, flavan-3-ols and isoflavones according to the locations of the substitutes present on the parent molecule. Quercetin and other flavonoids have the structure to act as powerful antioxidants and have often proven so *in vitro*. Quercetin, being a major constituent of the flavonoid intake, could be a key in fighting several chronic degenerative diseases[3]. Growing scientific evidence has shown adverse side effects, like liver damage and mutagenesis, of synthetic antioxidant[4]. Therefore, recently there has been an upsurge of interest in natural products as antioxidants, as they inhibit the free radical reactions and protect human body from various diseases, such as cancer and diabetes. Recent studies showed that a number of plant products including poly phenolic substances (e.g., gallocatechins, delphinidin, cyanidin, gallic acid, ellagic acid, pelargonidin and sitosterol) and various plants or herbal extracts exert potent antioxidant actions, which are very well known for their healing powers[5]. Quercetin 5, 7, 3', 4', -tetrahydroxy flavonol exhibit anti-inflammatory, antihepatotoxic[6], antiulcer[7], anti-allergic and antiviral actions and some of them provides protection against cardiovascular mortality[8,9]. Quercetin in combination with other flavonoids, inhibits a number of enzymes like bradykinin[10], tyrosine kinase[11]and 5'- nucleotidase activity[12]. *L. lanceolata* Wall (Lythraceae) is a moderate to large deciduous tree, sometimes attaining 30 meters in height and 2.4 to 3.0 meters in girth with a clean cylindrical bole of 12 to 15 meters. It is found from Bombay to Kerala and in the hills of Deccan Peninsula up to an altitude of 1,200 meters. Bark is smooth, greenish or yellowish white, exfoliating in papery strips; leaves elliptic- lanceolate or broadly ovate, 6.2 to 10.0 cm x 1.8 to 5.0 cm, coriaceous, glabrous, shining above, usually white or grayish blue; flowers small, white, in large panicles; capsules ellipsoid; seeds winged[13]. *L. lanceolata* has been used in the treatment of asthma, diabetes mellitus, chronic bronchitis, cold and cough. Seeds have been documented for its multiple pharmacological activities including narcotic principle. Steroid, terpenoids, phenols, flavonoids, alkaloids, ellagic acid and tannins are the major components present in the plant[14]. *L. parviflora* Roxb (Lythraceae) is a medium-sized deciduous plant indigenous to India and available even up to a height of 900 m in the Himalayas. The plant is used for the treatment of syphilis, sores and carbuncles[15]. Mazumder *et al.* (2003)[16] reported the antibacterial activities of the leaves of the plant and Bhakuni *et al.* (1969)[17] reported the anti-asthmatic activity of the flowers of *L. parviflora*. The leaf juice of this plant is used in traditional medicine to treat fever in Jharkhand, India[15]. *L. lanceolata* and *L. parviflora* contain quercetin as an important active constituent and is predictable by HPLC method. Phytochemical assessment is one of the tools for the quality evaluation, which includes preliminary phytochemical screening, chemo profiling and marker compound analysis using current analytical techniques. In the last two decades HPTLC method has appeared as a significant tool for the qualitative and quantitative

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EVALUATION OF ANTI INFLAMMATORY AND ANALGESIC ACTIVITIES OF THE EXTRACT PREPARED FROM *ALOYSIA POLYSTACHYA* IN EXPERIMENTAL ANIM ALS

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ABSTRACT

Aloysia polystachya used as an appetite suppressant herb for millennia. It also has antioxidant, ant diabetic, and nootropic actions. It is proved that it is a natural anti obesogenic agent and is widely consumed in India. Its actions like anti-atherosclerotic is of high medicinal value. The phytochemical screening of extract shows the presence of alkaloids, phytosterols, phenolic compunds and tannins using various methods. In the present work an attempt has been made to evaluate the anti inflammatory, analgesic activities of ethanolic extract of *aloysia polystachya* (100mg/kg, 200mg/kg) and the results were found to be positive. The results were compared with the standard drug indomethacin (10mg/kg), pentazocin (10mg/kg) and aspirin (10mg/kg). Hence, *aloysia polystachya* contains anti inflammatory and analgesic activity. The present work was done to demonstrate the anti inflammatory and analgesic activity of the ethnolic extract obtained from the leaves of *aloysia polystachya* (verbenaceae). Inflammation was induced by carrageenan induced paw edema and pain was induced by eddy's hot plate and tail flick method. Thermal and radiant heat is used in hot plate and tail flick method respectively.

KEYWORDS: *Aloysia polystachya*, analgesic, anti inflammatory activity.

1. INTRODUCTION

Pain is the most common reason for physician consultation. It is a major symptom in many medical conditions. It can significantly interfere with a person's quality of life and general functioning.[1] It is a part of the body's defence system, producing are flexiveretraction from the painful stimulus, and tendencies to protect the affected body part while it heals, and avoid that harmful situation in the future.[2,3] Pain is the most common reason for using complementary and alternative medicine.[4,5] Pain is primarily managed with analgesics. Opioid analgesics are commonly used for treatment of pain. Although opioids are strong analgesics, there are other drugs used for the treatment of pain.

Inflammation is the body's immediate response to damage to its tissues and cells by pathogens, noxious stimuli such as chemicals, or physical injury.[6] It is a protective attempt by the organism to remove the injurious stimuli as well as initiate the healing process for the tissue. Inflammation can be classified as either acute or chronic status depending on onset time. Acute inflammation is the primary response of the body to injurious stimuli and it involves the local vascular and immune response. On the other hand, chronic inflammation is a pathological condition characterized by progressive destruction and recovery of the injured tissue from the inflammatory response.[7]

Though a variety of chemical mediators or signalling molecules such as histamine, serotonin, leukotrienes, prostaglandins are involved in the inflammatory response the mechanism of inflammation injury is attributed to release of ROS (reactive oxygen species) from activated neutrophils and macrophages. The over production of ROS by macrophages causes oxidative damage to membrane lipids, DNA, proteins and lipoproteins.[8] In addition, ROS propagate inflammation by stimulating release of cytokines such as interleukin-1, tumor necrosis factor and interferon which stimulate recruitment of additional neutrophils and macrophages. Further ROS activates Nuclear Factor ƙ-β(NF-ƙ-β) which regulates various cellular genes involved in immune and acute phase inflammatory responses and in cell survival. Thus free radicals are important mediators that provoke or sustain inflammatory processes and consequently, their neutralization by antioxidants and radical scavengers can attenuate inflammation.

2. MATERIAL AND METHODS

2.1 Material

Drugs and chemicals

1. Pentazocine inj. (Ranbaxy laboratories limited).

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Prevalence of electrolyte imbalance in hospitalized patients and relationship to outcome and duration of stay in orthopaedic department

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Abstract
Background: Electrolyte imbalance is a severe and life-threatening condition, but its investigation and evaluation is often inadequate and inappropriate. The aim of the study is to identify the prevalence of electrolyte imbalance (Na & K) in hospitalized patients and to evaluate the relationship to their outcome and duration of stay in orthopedic department in a tertiary care hospital.
Materials and methods: 150 patients of both genders and all age groups excluding pediatric and neonate patients were evaluated. Study was carried out in Udai Omni hospital, Hyderabad between mid-december 2018 to march 2019.
Results: 150 patients were evaluated during the study period and electrolyte imbalance was found in 38 patients that is prevalence of electrolyte imbalance was 25.33%. This study has shown equal gender distribution of electrolyte imbalance (19 cases each) and are most commonly seen in elderly patients of age >60years (52.63%). The most common comorbid conditions seen in these 38 patients are Diabetes mellitus (DM), Hypertension (HTN), Hypothyroidism, Chronic kidney disease (CKD) etc. Most of the cases are seen with combined DM and HTN. Among all the electrolyte imbalance cases, the most commonly seen type of electrolyte imbalance are Hyponatremia and Hypokalemia (11 cases each). Most of the cases of electrolyte imbalance are seen pre-operatively. This study showed almost equal gender distribution of Hyponatremia. Distribution of Hypokalemia cases is relatively high in males. Out of 38 cases, 10 (26%) cases have shown increased duration of stay due to electrolyte imbalance. Among 38 cases, most commonly observed cause of electrolyte imbalance is CKD followed by these of diuretics. In this study most common presenting symptoms are constipation, nausea, vomiting, headache, confusion, weakness, dizziness and some patients were asymptomatic.
Conclusion: In this prospective, observational study on orthopaedic patients, prevalence of different electrolyte imbalance are seen, in which Hyponatremia and Hypokalemia are more common in hospitalized patients. Electrolyte imbalance complicates the health conditions of the patients and leads to increased falls and fractures and duration of hospital stay.

Keywords: Prevalence, electrolyte imbalance, orthopaedic, duration of stay, causes, symptoms

Introduction

Electrolytes are minerals that carry an electric charge. These electrolytes are essential for various bodily functions or processes, like proper nerve and muscle function, maintaining acid-base balance and keeping body hydrated.

The concentration of cations and anions is different in ICF and ECF. The ICF has a high concentration of potassium, magnesium (cations) and phosphates (anions). Whereas the concentration of sodium and chloride ions are relatively low in ICF. ECF has high concentrations of sodium and the main anions present are chloride and bicarbonates. For electrolyte homeostasis, the electrolyte concentration in both the cell and the plasma should be within normal limits. This normal limit of serum electrolyte concentrations can be maintained by proper balancing on the four processes – electrolyte intake, absorption, distribution and excretion. Any disturbances in these four processes can lead to electrolyte imbalances [1]. Electrolyte imbalance is a severe and life threatening condition, but its investigation and evaluation is often inadequate and inappropriate. The important electrolyte imbalances that are seen most commonly in clinical practice are of Sodium and Potassium [2]. Sodium Normal range is 136-145 mmol/L. Conditions that occur due to imbalanced sodium levels are: Hyponatremia (low sodium levels) and Hypernatremia (high sodium levels). Hyponatremia when under-recognized, incorrectly investigated and sub optimally managed, can lead to poor patient outcomes. Frequently insufficient diagnostic testing or investigations can affect both management and outcome of the patients [3]. Failure to correct the condition of hyponatremia may lead to delay or prevention of both patient outcomes and hospital length of stay [4, 5]. Potassium Normal range is 3.5 – 5.0 mmol/L. Conditions occur due to imbalance in potassium levels are: Hypokalemia and Hyperkalemia [1]. Common causes of electrolyte imbalance may include vomiting, diarrhea, excessive sweating, renal diseases, poor diet, acid base imbalance in the body, congestive cardiac failure, cancer treatment, old age, stress, use of some drugs such as diuretics, antidepressants, anti-epileptics etc and post-operative surgery patients are more

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Formulation and Evaluation of Valsartan Floating Tablets

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Abstract

The present research work was an attempt to formulate and evaluate floating tablet containing valsartan in the form of tablets using polymers like HPMC K100M, Ethyl cellulose, $NaHCO_3$ as gas generating agent. Valsartan, an antihypertensive drug, with an oral bioavailability 23%, short half-life (6 hr) and largely present in unionized form in acidic pH, have been designed to increase gastric residence time and therapeutic efficacy. This can be achieved by fabricating floating tablets which retain in stomach for prolonged time to release the drug. The tablets were formulated by direct compression method. The effect of sodium bicarbonate and citric acid on drug release profile and floating properties were investigated. The tablets were characterized for the pre and post compression parameters such as friability, hardness, thickness, drug content, weight variation, *in-vitro* buoyancy studies and *in-vitro* drug release studies and the results were within the limits. The *in-vitro* drug release studies were carried out in a USP type-II apparatus in 0.1N HCl. Optimized formulation (F1) revealed that tablet was constantly floating in the stomach region of the rabbit, thereby indicating improved gastric retention time for more than 8 h. Consequently, all the findings and outcomes have showed that developed valsartan matrix tablets could be effectively used for floating drug delivery system.

Keywords

Valsartan, polymers, sodium bi carbonate and citric acid, FTIR studies, direct compression technique.

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INTRODUCTION:

Valsartan is an angiotensin receptor blocker widely prescribed for hypertension. It's absorbed from the upper part of gastrointestinal tract [1, 2]. The oral route is considered as the most convenient and extensive route of drug delivery among all the routes

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FORMULATION AND EVALUATION OF DELAYED RELEASE TABLETS OF LANSOPRAZOLE

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ABSTARCT
The objective of the study was an attempt to formulate and evaluate delayed release tablets of lansoprazole which is a benzimidazole anti ulcer agent and is one of the most widely used drugs for treating mild and severe ulcers. The stability of lansoprazole a proton pump inhibitor is a function of pH and it rapidly degrades in acidic medium of the stomach, but has acceptable stability in alkaline conditions. The present study demonstrates that the lansoprazole tablets could be successfully intestine targeted by using pH dependent polymers in different concentrations. The drug and excipient compatibility study was performed by FT-IR and study revealed that there was no interaction between drug & excipient. The tablets were evaluated for various parameters like hardness, friability, weight variation, percentage drug content and *in-vitro* disintegration time, *in-vitro* dissolution study, drug release kinetic study and stability study. By observing the dissolution profile for all the formulations, F1 was the better formulation. From the result of this study it may be concluded that the colon targeted drug delivery tablets using a combination of two polymers in optimized concentrations can be used to increase the delayed action of drug release to deliver the drug in a delayed manner.

KEYWORDS: Lansoprazole, polymers, direct compression technique, FTIR & *in-vitro* studies.

INTRODUCTION

The term "drug delivery" can be defined as "the techniques that are used to get the therapeutic agents inside the body". The Oral Solid Dosage forms are the preferred route of administration for many drugs and most widely used formulations for new and existing modified release products. Indeed, for controlled release systems, the oral route of administration has by far received the most attention with respect to research on physiological and drug constraints as well as design and testing of products. This is because there is more flexibility in dosage form design for the oral route than there is for the parental route.[1-4] Delayed Release Drug Delivery System involves release of drugs only at a specific site in the gastrointestinal tract. The drugs contained in such a system are those that are.[5-6]

i) Destroyed in the stomach or by intestinal enzymes
ii) Known to cause gastric distress
iii) Absorbed from a specific intestinal site or
iv)Meant to exert local effect at a specific gastrointestinal site

The two types of delayed release systems are:
1. Intestinal release systems
2. Colonic release systems

MATERIAL AND METHODS

Materials

Lansoprazole was obtained from Chandra labs, Hyderabad. Microcrystalline cellulose, Cross povidone and Magnesium stearate were purchased from S. D. Fine Chemicals, Mumbai. Cross caramellose sodium and Sodium starch glycolate were procured from Mylan Chem. Ltd, Mumbai and Talc was obtained from ESSEL fine chem, Mumbai, India.

Methods

Preformulation studies

Pre formulation studies are performed to investigate the physical and chemical properties of a drug substance alone and also when combined with other substances such as excipient. It is the first step in the rational development of dosage forms.

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Research Article

A New Simple RP-HPLC Method Development and Validation of Empagliflozin in Bulk and it's Tablet Dosage Form

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ABSTRACT

The primary important objective of the present research work is to develop simple, specific, rapid, accurate and sensitive reverse phase HPLC method and validated for the qualitative and quantitative determination of empagliflozin in its active pharmaceutical ingredient and tablet dosage form according to ICH guidelines. An isocratic separation was done by using Phenomenex C18 column possess 75 x 4.6 mm, 2.6 µ,100 A0 dimensions with a mobile phase composition of water: acetonitrile (10:90% v/v) at a flow rate of 1ml/min and response detected by using 261 nm wavelength as absorption maximum. The Retention time of empagliflozin was found to be 2.84 minutes, LOD and LOQ were observed at 1.5 µg/ml and 4.6 µg/ml concentration respectively, linear curve was observed in the concentration range of 10-60 µg/ml with correlation coefficient of 0.99. The percentage recovery (accuracy) was in the range of 98.3- 102% and the % RSD was observed to be less than 2%. The proposed method was validated for accuracy, precision, sensitivity, linearity and robustness and successfully employed for quantitative determination of empagliflozin in tablet dosage form in quality control department of pharmaceutical industry.

Keywords: RP-HPLC, Retention Time, Limit of detection, Limit of quantification, Robustness.

INTRODUCTION

Chemically empagliflozin is (1S)-1,5-Anhydro-1-(4-chlor-3-{4-[(3S)-tetrahydro-3-furanyloxy]benzyl} phenyl)-D-glucitol works as sodium-glucose co-transporter 2 (SGLT2) inhibitors offer an insulin-independent component for improving blood glucose levels, since they advance urinary glucose discharge (UGE) by restraining glucose reabsorption in the kidney. Notwithstanding glucose control, SGLT2 inhibitors are related with weight reduction and circulatory strain decreases, and don't build the danger of hypoglycemia[1].

On extensive literature review revealed that, different analytical methods have been reported for the qualitative and quantitative analysis of empagliflozin in bulk and pharmaceutical dosage forms using UV–visible spectroscopy[2,3] and reverse phase- high performance liquid chromatography (RP-HPLC). In depth literature survey reveals that even though so many numbers of RP-HPL C methods were reported, but there is no RP- HPLC method with less retention time with simple mobile phase system was not reported for quantitative estimation of empagliflozin in bulk drugs and pharmaceutical dosage forms[4,5,6].

The objective of the present research work was to develop and validate simple, precise, sensitive and accurate analytical method with less retention time and simple cost-effective solvent system for the estimation of empagliflozin in pure and commercially available tablets for regular analysis in pharmaceutical industry. Chromatographic method is the most effective popular method for the analysis of drug substance and drug product; hence a new RP- HPLC method was developed and validated for the estimation of empagliflozin.[7]

MATERIALS AND METHODS

The empagliflozin reference standard (claim 99.18%) was provided by HETERO Drugs. Tablets of empagliflozin (JARDIANCE -10mg) were purchased from a local pharmacy. HPLC grade acetonitrile was obtained from Finar Chemicals Limited, Ahmadabad, India. All the glass wares used in this research work were made of Borosilicate glass and the solvents and prepared solutions were filtered by using Nylon (0.45µm) filters.

Chromatography

RP-HPLC method was performed with Cyberlab HPLC equipment with UV detector and manual injector with a 10 µL loop. The equipment was connected to data-processing system (LC- Solution software). The chromatographic system was performed using C_{18} (250 x 4.6mm, 2.6µ,100 A^0) column. Separation was successfully achieved using a mobile phase composition of Acetonitrile: Water (90:10 v/v) at a flow rate of 1 ml/min. The eluent was measured using UV detection at a wavelength of 261nm.The column temperature was maintained at 25°C±2 and the injection volume of 10 µL was injected. The prepared mobile phase was filtered through a 0.45 µm nylon filter prior to use.

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NUTRITIONAL ASSESSMENT AND MANAGEMENT IN CHRONIC LIVER DISEASE

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ABSTRACT

Liver plays major role in metabolism of nutrients their distribution and absorption. Malnutrition is common in patients with chronic liver disease and it is an important prognostic indicator. The aim of the study was to assess the nutritional status of the patients with chronic liver disease by using Assessment parameters like MNA (mini nutrition assessment tool that classify nutritional status of the patient into three: normal nutritional status, at risk of malnutrition, malnourished, and also based Anthropometric measurements (BMI, MAC, calf circumference), laboratory and cinical findings. The present study is prospective observational study. The patients are recruited from gastroenterology department Apollo hospitals, jubilee hills from October to march 2018. The sample of study composed of 70 patients who fulfilled inclusion criteria. The study revealed that 25.7% of the patients have good nutritional status, 54.5% of the patients are at risk of malnutrition, 20% of the patients were malnourished based on MNA Screening score. 21.4% of the patients have good nutritional status, 54.3% are at risk of malnutrition and 24.3% are malnourished based on MNA Indicator score. Based on the BMI 1.75% of males and 23.07 percent of females were underweight, 52.63% males and30.79 females were normal weight, 26.31% males and others were less likely overweight and obese. Based on MUAC and Calf circumference most of their nutritional status was well nourished and moderately nourished. Assessment of nutritional statuus based on laboratory parameters showed that serum Albumin, Pre albumin,