

Phytochemical investigation and antihelmintic activity of *Operculina turpethum* roots

Pulipaka Shankaraiah^{1*}, Anasuri Santhosh², M. Ravi Kumar³, Bharat Bhusan Mahapatra⁴

ABSTRACT

The present study was aimed at the investigation of the roots of the traditional Indian medicinal plant *Operculina turpethum* for pharmacologically active chemical constituents and *in vitro* evaluation of the fraction (or) extracts that shown to contain maximum constituents for anthelmintic activity against adult Indian earthworms (*Pheretima posthuma*) using albendazole as the reference standard. The collected and authenticated roots were dried under shade and extracted with water, ethanol, and ethyl acetate by maceration. The obtained extracts were investigated for the presence of various biologically active ingredients by qualitative methods. Ethanolic and ethyl acetate extracts that were shown to possess maximum constituents were tested for anthelmintic activity by measuring parameters such as time taken for paralysis and death of the worms. Results were compared with that were obtained with albendazole. From the results, it was found that the ethanolic extract of the roots taken for the study possesses significant activity at the concentrations of 150 mg/ml. However, more study is recommended for further investigation in this regard.

KEY WORDS: Albendazole, Anthelmintic activity, Extracts, *Operculina turpethum*, Phytochemical investigation, Roots

INTRODUCTION

The human being appears to be afflicted with more diseases from the early ages, taking advantages of plants growing around them to alleviate their sufferings from injury or disease with hopes for remedies in chronic diseases generated new enthusiasm in the research workers to develop herbal medicines.

Herbal medicine offers a greater scope for the future treatment of various pathological conditions.

The effectiveness of medicinal plant lies in the varying complex chemical substances such as alkaloids, glycosides, corticosteroids, and essential oils which are the starting material for a vast number of synthetic drugs.^[1,2]

Helminthiasis is one of the most important animal diseases worldwide that can cause heavy production

losses in grazing animals. The disease is prevalent all over the world, especially in developing countries, and is always associated with poor management practices and inadequate and inappropriate control strategies. An integrated approach is required for the effective control of helminths which includes strategic and tactical use of anthelmintics which remains the cornerstone to this end and careful management of grazing lands including control of stocking rates and appropriate rotation strategies.

Role of vaccinations is also vital for the control of various parasitic diseases as in the case of lungworms. However, various problems have emerged with the use of anthelmintics, and among them, resistance against various species of helminthes is of utmost importance to different anthelmintic compounds and classes, as well as chemical residue and toxicity problems.

In addition, recognition of the antigenic complexity of parasites has slowed vaccine development. For these various reasons, interest in the screening of medicinal plants for their anthelmintic activity remains of great scientific significance despite extensive use

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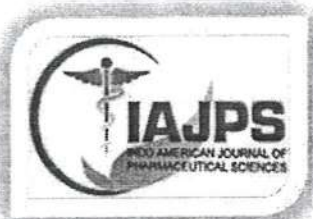
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Research Article

**DESIGN AND INVITRO CHARACTERIZATION OF
RIVASTIGMINE TRANSDERMAL PATCHES**P.Umadevi ^{1*}, I.Nagaraju ² and K. Ravi kumar ³¹Department of Pharmaceutics, Geethanjali College of Pharmacy, Keesara, Hyderabad²Assistant Professor, Department of Pharmaceutics Geethanjali College of Pharmacy, Keesara, Hyderabad³Principal, Geethanjali College of Pharmacy, Keesara, Hyderabad**Abstract**

In present study transdermal drug delivery of Rivastigmine was developed to overcome the first pass metabolism and to reduce frequency of dosing compared to oral route. Matrix type of transdermal patches was developed by using polymers HPMCK₄M and HPMCK₁₅M. Transdermal patches were prepared by employing solvent casting method. Propylene glycol and Tween80 were selected as permeation enhancer and plasticizer. Formulations were prepared with the varying concentrations polymers ranging from F1-F12. Moisture content and Swelling study and all the results were found to be with in the pharmacopeial limits. invitro drug release studies by using dialysis membrane. Among all the 12 formulations F6 formulation which contain HPMC K4M 300mg and Eudragit L-100 60mg had shown 94% cumulative drug release with in 12 hours. And compared to HPMC K15M, HPMC K4M showed better drug release profile. For F6 formulation release kinetics were plotted and the Regression coefficient value was found to be high for Korsmeyer-peppas release model i.e., 0.9892.

Key words: Rivastigmine, transdermal patches, HPMCK₄M and HPMCK₁₅M**Corresponding author:****P.Umadevi**Department of Pharmaceutics,
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**FORMULATION AND EVALUATION OF VORICONAZOLE PATCHES FOR BUCCAL
DRUG DELIVERY SYSTEM**

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ABSTRACT

Voriconazole is a triazole antifungal drug that generally used to treat serious, invasive fungal infections. These are generally seen in patients who are immune compromised, and include invasive candidacies, invasive aspergillosis, and certain emerging fungal infections. In the present study buccal drug delivery of Voriconazole was developed to overcome the first pass metabolism and to reduce the frequency of dosing compared to oral route. Matrix type of buccal patches was developed by using polymers HPMCK4M and HPMCK100M. Buccal patches were prepared by employing solvent casting method. Propylene glycol and Tween80 were selected as permeation enhancer and plasticizer. Drug excipient compatibility studies were carried out by using FTIR, and it was observed that there were no interactions. The formulations were prepared with the varying concentrations of polymers ranging from F1-F6, and all the formulations were evaluated for various parameters like Physical appearances, Flatness, Weight variation, Thickness, Folding endurance, Drug content, Moisture uptake, Moisture content and Swelling study and all the results were found to be within the pharmacopeial limits, *invitro* drug release studies is done by using dialysis membrane. Among all the 6 formulations F6 formulation which contain HPMC K100M 500mg had shown 94.7% cumulative drug release within 12 hours. For F6 formulation release kinetics were plotted and the Regression coefficient value was found to be high for Korsmeyer-peppas release model i.e., 0.989.

KEYWORDS: Voriconazole, HPMCK4M, HPMCK100M, Buccal Patches and Buccal Drug Delivery.

INTRODUCTION

There are several routes of drug administration for delivering the drug. Among them in recent years, many investigations are done in the field for delivering the drug locally to the tissues in the oral cavity, especially for treating bacterial and fungal infections, and periodontal treatments. Bioadhesive drug delivery plays an important role in delivering drug locally in the oral cavity as it retains the drug at the site of action. Adhesive material may be natural or synthetic. Surface of adhesion can be either epithelial tissue or mucous coat of the tissue. If adhesion is to a mucous coat, then it is referred as mucoadhesion. Over the decades mucoadhesion has become popular for its potential to optimize localized drug delivery, by retaining a dosage form at the site of action (e.g. within the gastrointestinal tract) or systemic delivery by retaining the formulation in intimate contact with the absorption site (e.g. buccal cavity).^[1]

Mucoadhesive polymers have greater application in buccal drug delivery system. Recently, many mucoadhesive forms have been developed like patches, films, disks, strips, ointments, tablets, gels etc. However, buccal patch offers greater flexibility and comfort than

the other forms. Apart from it buccal patches can overcome problems like short residence time as that of gels which is easily washed away by saliva.^[2]

Buccal route of drug delivery provides high bioavailability as it has direct access to the systemic circulation through the jugular vein bypassing the first pass hepatic metabolism. Apart from it, it has excellent accessibility, low enzymatic activity, suitable for drugs or excipients that mildly and reversibly damage or irritate the mucosa. Other advantages include painless drug administration, easy withdrawal. Facility to include permeation enhancer / enzyme inhibitor or pH modifier in the formulation, versatility in designing as multidirectional or unidirectional release system for local or systemic action.^[3] Voriconazole is a triazole anti fungal drug which is used to treat serious fungal infections. It has a very low aqueous solubility and extensively metabolized by the liver. Buccal route offers several advantages as it bypasses first pass metabolism, easy withdrawal, rapid absorption. Hence it leads to significant reduction of dose and related side effects. Here in the present work, an attempt was made to formulate and evaluate voriconazole buccal patches for

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EVALUATION OF MUSCLE RELAXANT AND LOCOMOTOR ACTIVITY OF *PHYLLANTHUS EMBLICA* ON SWISS ALBINO MICE

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ABSTRACT

Phyllanthus emblica is perhaps the single most often mentioned herb in "Charak Samhita", the Ayurvedic medicine literature (500 BC). It is a wonder herb and one of the precious gifts of nature to humans. It is known as "Divya" and "Amrut" or AmritPhala in Sanskrit, which literally means fruit of heaven or nectar fruit. One Indian plant stands out as being exceptional for its ethnic, ethnobotanical and ethno pharmaceutical use. The main components of *P. emblica* vitamin C (richest source) emblicanin A & B, puniglucanin, pedunculagin, glutamic acid, proline, aspartic acid, alanine, lysine, ellagic acid, and hexahydroxy-diphenic acid. It is an indispensable part of the ayurvedic and unani system with amazing remedial qualities. In Sanskrit, it is called Amalaki or Dhartiphala. Here dried fruits were powdered and extracted with Soxhlet Extractor using methanol. Two different doses of same extract were used on Swiss albino mice to study muscle relaxant and locomotor activity against Diazepam as the standard drug. It was observed that *Phyllanthus emblica* possess significant skeletal muscle relaxant activity and locomotor activity comparable to the standard one. Hence same extract can be used to isolate pure compound which can be utilized for rational designing of drugs for muscle relaxation and altering locomotor activity.

Keywords: *Phyllantusemblica*, Euphorbiaceae, Wonder herb, Muscle relaxation, Locomotion.

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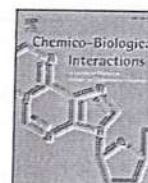
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INTRODUCTION

The world craves new ideas and looks to the Far East and Asia for inspiration and innovation. One Indian plant stands out as being exceptional for its ethnic,

ethnobotanical and ethno pharmaceutical use. There is a wealth of technical data to support the safe use of this plant and in this review a monograph will be produced that justifies the use of this plant in a wide range of personal care applications. Latin names of the plant: *Phyllanthus emblica* Linn., *Emblica officinalis* Gaertn., *Phyllanthus laxifolius* Don., *Cicca emblica* Kurz, *Dichelastina nodicaulis* Hance. Family: Euphorbiaceae *Emblica* fruits are one of three "myrobalans," a term deriving from the Greek for acorn, which is a well-known astringent used in tanning. In fact, both emblicmyrobalans and chebulicmyrobalans (*Terminalia chebula*) are relied upon for their high content of tannins; chebulicmyrobalans have long been used for tanning leather. The third fruit, bclericmyrobalans, is a close relative of the chebulicmyrobalans (*Terminalia belerica*) and this too is a tanning agent. These three fruits together make up the popular remedy "Triphala," a rejuvenating formula that is often applied to treating intestinal disorders (inflammation, infection, diarrhoea and constipation). In order to better understand the Ayurvedic system of



Isolated mangiferin and naringenin exert antidiabetic effect via PPAR_γ/GLUT4 dual agonistic action with strong metabolic regulation

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ABSTRACT

In this study, we isolated two compounds from the leaves of *Salacia oblonga* (SA1, mangiferin and SA2, naringenin), and their structures were confirmed by infrared spectroscopy, nuclear magnetic resonance (NMR) spectroscopy, and mass spectrometry. SA1 and SA2 were orally administered to streptozotocin-induced diabetic rats at 50 and 100 mg/kg daily for 15 days. Blood glucose level, serum lipid profile, oxidative stress parameters, histopathology, docking, molecular parameters, and NMR-based metabolic perturbation studies were performed to investigate the pharmacological activities of SA1 and SA2. Results suggested that both compounds reduced blood glucose level, restored body weight, and normalized lipid concentrations in the serum and oxidative stress biomarkers in the liver and pancreas. In addition, the docking study on several diabetes-associated targets revealed that both compounds had a strong binding affinity towards peroxisome proliferator-activated receptor gamma (PPAR_γ) and glucose transporter type 4 (GLUT4). Further real-time reverse transcription polymerase chain reaction and western blot analyses were performed to confirm the gene and protein expression levels of PPAR_γ and GLUT4 in the pancreatic tissues. Data obtained from the molecular studies showed that both compounds exhibited antidiabetic effects through dual activation of PPAR_γ/GLUT4 signaling pathways. Finally, the NMR-based metabolic studies showed that both compounds normalized the diabetogenic metabolites in the serum. Altogether, we concluded that SA1 and SA2 might be potential antidiabetic lead compounds for future drug development.

1. Introduction

Type-2 diabetes is one of the major factors responsible for the ever-growing incidence of cardiovascular diseases, particularly coronary heart diseases [1]. Several studies have suggested that deposition of lipids in the skeletal muscles, pancreas, kidneys, and liver plays an important role in diabetes pathology [2,3]. Unlike synthetic compounds, natural products have a wide range of structural diversity; therefore, they are extensively involved in the discovery of lead compounds for new drug development [4]. Natural products have been shown to play important roles in the regulation of pathophysiological signaling pathways, particularly in diabetes [5].

Salacia oblonga Wall. (SO) has been used from thousands of years in

Ayurveda medicine [6] for treatment and cure of various human diseases, including type-2 diabetes (also known as non-insulin-dependent diabetes mellitus) [6,7]. Various active constituents, such as friedelan-type triterpenes, eudesmane-type sesquiterpene, norfriedelan-type triterpene, glycosides, and polyphenols, have been isolated from this plant [7]. Importantly, numerous active compounds, such as salacinol and kotalanol, have been isolated from the roots and barks of SO, and most of them showed antidiabetic effects via α -glycosidase inhibition. Besides, SO has several pharmacological activities, including antidiabetic, cardioprotective, anti-inflammatory, antimicrobial, neuroprotective, and antimutagenic activities [7].

A previous study showed that the leaves of SO are rich in flavonoids and xanthonoid glycosides [8,9]. They have been shown to exhibit

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Formulation and Evaluation of Montelukast Sodium Fast Dissolving Tablets

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Abstract: The demand for fast dissolving tablet (FDT) has been growing during the last decade especially for elderly and children who have swallowing difficulties. Montelukast is a leukotriene receptor antagonist (LTRA), anti-asthmatic used for the maintenance treatment of asthma and to relieve symptoms of seasonal allergies. It is effective in relieving nasal congestion, particularly in patients with allergic rhinitis. In present work an attempt has been made to prepare fast dissolving tablets of montelukast sodium with increased rate of dissolution may leads to increase bioavailability. In present work fast dissolving tablet of montelukast sodium prepared using crosscarmellose sodium, sodium starch glycolate and kollidon cl-m as superdisintegrants by direct compression method. The tablets were evaluated for various parameters like weight variation, hardness, friability, *in-vitro* dispersion time, drug-polymer interaction, drug content water absorption ratio, wetting time, *in-vitro* drug release. The tablet prepared by direct compression method passes weight variation was found in the range 113 to 121 mg which is below $\pm 7.5\%$, hardness, 3.69 ± 0.25 to 3.51 ± 0.27 kg/cm², percentage friability of 0.22 to 0.37%, *in-vitro* disintegration time of 51 to 17 sec, drug content uniformity was in between 98.23 to 98.75%, water absorption ratio were found between 61 to 38% and wetting time between 58.23 to 21.12 seconds, maximum drug release 87.75 to 98.75% shows within 10 min. FTIR study showed that there was no drug interaction with formulation additives of the tablet.

INTRODUCTION

Oral administration is the most popular route due to ease of ingestion, pain avoidance, versatility (to accommodate various types of drug candidates) and most importantly, patient compliance. Also, solid oral delivery systems do not require sterile conditions and therefore, less expensive to manufacture. Several novel technologies for oral delivery have recently become available to address the physicochemical and pharmacokinetic characteristics of drugs, while improving patient compliance.^[1]

The most desirable formulation for use by the elderly is one that is easy to swallow and easy to handle. Taking these requirements in to consideration, attempts have been made to develop a rapid dissolving tablet. Since such a tablet can disintegrate in only a small amount of water in the oral cavity, it is easy to take for any age patient, regardless of time or place. For example, it can be taken anywhere at any time by anyone who do not have easy access to water. It is also easy to dose the aged, bed-ridden patients or infants who have problems in swallowing tablets and capsules. Recently, many companies have researched and developed various types of fast-disintegrating dosage form technologies with the potential to accommodate various physicochemical, pharmacokinetic and pharmacodynamic characteristics of drugs.^[2,3]

Asthma is a chronic inflammation of the bronchial tubes (airways) that cause swelling and narrowing (constriction) of the airways. The result is difficulty breathing. The symptoms of asthma vary from person to person and in any individual from time to time. It is important to remember that many of these symptoms can be subtle and similar to those seen in other conditions. All of the symptoms mentioned below can be present in other respiratory and

sometimes, in heart conditions. This potential confusion makes identifying the settings in which the symptoms occur and diagnostic testing very important in recognizing this disorder.^[4]

Therefore, in the present study an attempt waws made to formulate Fast dissolving tablets of montelukast sodium is (R,E)-2-[1-[[[1R]-1-{3-[[E]-2(7-chloroquinoline-2-yl) eththnyl]phenyl} -3-[2-(2hydroxypropan2yl)phenyl]propyl] sulfanyl)methyl] cyclopropanyl] aceticacid. Montelukast is a leukotriene receptor antagonist (LTRA), anti -asthmatic used for the maintenance treatment of asthma and to relieve symptoms of seasonal allergies.

MATERIALS AND METHODS

Montelukast sodium was supplied by Ranbaxy lab. Ltd. New Delhi, India. Sodium starch glycolate, Croscarmellose sodium and Kollidon cl-m were procured from S D fine chemical Ltd. Mumbai. All solvents used were of analytical grade.

Drug-Excipients Compatibility Study by FTIR

The spectrum analysis of pure drug and physical mixture of drug and different excipients which are used for preparation of tablets was studied by FTIR. FTIR spectra were recorded by preparing potassium bromide (KBr) disks using a Shimadzu Corporation (Japan) facility (model - 8400S). Potassium bromide (KBr) disks were prepared by mixing few mg of sample with potassium bromide by compacting in a hydrostatic press under vacuum at 6-8 tons pressure. The resultant disc was mounted in a suitable holder in IR spectrophotometer and the IR spectrum was recorded from 399.193 cm⁻¹ to 4000.6 cm⁻¹ in a scan time of 12 minutes. The resultant spectrum was compared for any spectral changes. They were observed for the presence of characteristic peaks for the respective functional group in the compound.^[5,6]

Preparation of Mixed Blend of Drug and Excipients

All the ingredients were passed through mesh no #60. Required quantity of each ingredient was taken for each

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INVITRO EVALUATION AND OPTIMIZATION OF CONTROLLED RELEASE FLOATING DRUG DELIVERY SYSTEM OF GLIPIZIDE

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ABSTRACT

The floating microspheres have been utilized to obtain prolonged and uniform release in the stomach for development of a once daily formulation. The major advantage of the preparation technique includes short processing time, the lack of exposure of the ingredients to high temperature, and high encapsulation efficiencies. In the present study, preparation of Glipizide floating microspheres, evaluation of Floating Drug Delivery System (FDDS) *in vitro*, prediction of the release, and optimization of floatation and drug release pattern to match target release profile was observed. Floating microspheres were prepared by non-aqueous emulsification solvent evaporation technique using Ethyl cellulose as the rate controlling polymer and 250 mg of Glipizide per batch and its *in vitro* performance was evaluated by the usual pharmacopoeial and other tests such as drug polymer compatibility (FTIR scan), yield (%), particle size analysis, drug entrapment efficiency, surface topography, and *in vitro* floatation and release studies. Results showed that the mixing ratio of components in the organic phase affected by the size, size distribution (250-1000 μm), drug content (61 – 133% of theoretical load), yield (58 – 87%) and drug release of microspheres (47 – 86% after 8 h), floating time (> 8 hr) and the best results were obtained at the ratio of drug: polymer: solvent (250:750:12 and 250:146.45:9 [mg: mg: ml]), when both the batches were mixed in equal proportions. In most cases good *in vitro* floating behavior was observed and a broad variety of drug release pattern could be achieved by variation of the polymer and solvent ratio, which was optimized to match target release

Gender Development And The Status Of Tribal Women: A Case Study Of Telangana State

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Abstract

The scheduled tribes (Tribal) constitute, according to 2011 census about 9.3 % of the total population in Telangana. Moreover, this tiny southern state presents a bewildering collection of tribal groups. Out of the 9(Nine) enlisted tribes found in the state, (i.e, Lambada,Koya,Gond,Yerukala,Pardhan,Kolam,Chenchus,KondaReddi and Thota) are regarded as the original settlers. In tribal communities, the role of women is substantial and crucial. They constitute about half the total population, but in tribal society women are more important than in other social groups, because they work harder and the family economy and management depend on them. Even after industrialization and the resultant commercialization swamped the tribal economy, women continued to play a significant role. Mostly women and children do collection of minor forest produce. Many also work as laborers in industries, households and construction, contributing to their family income. However, tribal women are still marginalized and deprived group in Tribal society. Gender equality among tribal groups is a complex phenomenon that needs to be addressed in the context of various issues of tribal life. The Gender dimension

of the tribal communities of India also has a bearing on the need for tribal development. This Research work focuses on the nature and dimensions of change in the lives and status of tribal women in Telangana and also focuses how the Socioeconomic changes during the last few decades have introduced new gender and class issues into the purportedly egalitarian society of the Tribal's.

Keywords: Gender equality,Gender discrimination,Tribal community,Development and Tribal Women in Telangana.

Introduction

Telangana is the only southern Indian state with tribal populations of 9.34%, and having boundaries with neighboring states of is bordered by the states of Maharashtra to the north and northwest, Chhattisgarh, Odisha to the northeast, Karnataka to the west and Andhra Pradesh to the east and south^[1]. It has a geographical area of 112,077 sq. km. The population of our State is 35, 193978, out of that, the population belongs to Tribals is 30, 66,802 of the total population according to 2011 census^[2]. The scheduled tribes (Tribal) constitute about 9.3 % of the total population in Telangana^[3]. Moreover, this tiny eastern state presents a bewildering

**FORMULATION AND EVALUATION OF SUSTAINED RELEASE
TABLETS OF TRAMADOL****B. Ganesh*, L. Thirupathi, T. Vijayakumari, B. Chandulal and T. Mangilal**

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Pharmacy, Cheeryal,
Keesara, Medchal,
Telangana, India.**ABSTRACT**

The main aim of the proposed work was to develop Tramadol matrix tablets, sustained release dosage form. Tramadol is a narcotic analgesic proposed for moderate to severe pain Sustained release formulation is the drug delivery system that is designed to achieve a prolonged therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose. The sustained release tablets were prepared by direct compression method using Hydroxypropyl methyl cellulose as a K100M grade, Karayagum and Guar gum in varying ratios. Tablets blends were evaluated for Bulk density, Tapped density, compressibility index and angle of

repose, shows satisfactory results. The compressed tablets were then evaluated for various physical tests like diameter, thickness, uniformity of weight, hardness, friability and drug content. The granules exhibited satisfactory rheological demeanor. The results of all these tests were found to be satisfactory. The *in-vitro* dissolution study was carried out for 12 hours using the paddle method in phosphate buffer (pH 6.8) as dissolution media. Formulation F1, to F9 direct compression method, sustain release and among all the formulation. This finding reveals that above a particular concentration of HPMCK100M, Karayagum and Guar gum and Magnesium stearate are capable of providing sustained drug release. Sustained release, HPMC-K100M, Karayagum, Guar gum, Magnesium stearate, Microcrystalline cellulose.

INTRODUCTION

Oral drug delivery is the most widely utilized routes of administration among all the routes of administration that has been explored for systemic delivery of drugs via pharmaceutical products of different dosage form.^[1] Oral route is considered more natural, uncomplicated, convenient and safe due to its ease of administration, patient compliance and cost effective



Research Article

FORMULATION AND *IN VITRO* EVALUATION OF SIMETHICONE TABLETS AS GASRTO RETENTIVE DRUG DELIVERY SYSTEM

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ABSTARCT

The aim of the present study was to develop a delayed release formulation of Simethicone to maintain constant therapeutic levels of the drug for over 12 hrs. Various grades of HPMC polymers and accrual were employed as polymers. Simethicone dose was fixed at 62.5 mg. The total weight of the tablet was considered as 300 mg. Polymers were used in the concentration of 10, 20 and 30 mg concentration and accrual concentration used in the formulations were optimized according to the floating properties of the formulations. All the formulations were passed various physicochemical evaluation parameters like hardness, bulk density, friability, weight variation etc. and they were found to be within limits and also the drug and excipient studies showed that there is no incompatibility between pure drug and excipient. Whereas from the dissolution studies, it was evident that the optimized formulation (F₆) showed better and desired drug release pattern i.e., 98.17 % in 12 hours. The optimized formulation dissolution data were subjected to release kinetics; from the release kinetics data it was evident that the formulation followed Higuchi mechanism of drug release.

Keywords: Simethicone, Accrual, HPMC, Hardness, Bulk density, Friability, Weight variation, Incompatibility and Higuchi mechanism.

INTRODUCTION

The oral 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 systems¹. Controlled-release drug delivery systems (CRDDS) provide drug release at a predetermined, predictable and controlled rate. Controlled-release drug delivery system is capable of achieving the benefits like maintenance of optimum therapeutic drug concentration in blood with predictable and reproducible release rates for extended time period², enhancement of activity of duration for short half-life drugs, elimination of side effects, reducing frequency of dosing and wastage of drugs, optimized therapy and better patient compliances³. The successful development of oral controlled drug delivery systems requires an understanding of the three aspects of the system, namely: 1. The physicochemical characteristics of the drug, 2. Anatomy and physiology of GIT and Characteristics of Dosage forms⁴ Good fundamental understanding of the anatomic and physiological characteristics of the human GIT is required to modulate the gastrointestinal transit time of a drug through FDDS for maximal gastrointestinal absorption of drugs and site-specific delivery⁵. The aim of the study is to formulate and evaluate Simethicone non effervescent floating tablets using different polymers HPMC K100M, HPMC K15M, HPMC K4M and Magnesium Stearate, Talc in different ratios.

MATERIALS AND METHODS

Simethicone procured from Natco Laboratories Pvt Ltd,

Hyderabad, and Telangana, India. HPMC K4M from Merck Pvt Ltd, Mumbai, India. HPMC K4M, HPMC K15M, K100M and Talc from SD fine chemical, Mumbai, India. Magnesium stearate and Micro crystalline cellulose from Heligent Pharma, Mumbai, India and other chemicals were consumed of laboratory grade.

Determination of Absorption maxima: A solution containing the concentration 10 µg/ml drug was prepared in 0.1N HCl UV spectrum was taken using Double beam UV/VIS spectrophotometer. The solution was scanned in the range of 200 – 400⁶.

Preparation of calibration curve: 100mg of the Simethicone pure drug was dissolved in 100ml of 0.1N HCl (stock solution) 10ml of solution was taken and make up with 100ml of 0.1N HCl (100µg/ml). From this 10ml was taken and make up with 100 ml of 0.1N HCl (10µg/ml). The above solution was subsequently diluted with 0.1N HCl to obtain a series of dilutions Containing 1,2,3,4 and 5µg/ml of Simethicone per ml of solution. The absorbance of the above dilutions was measured at 266 nm by using UV-Spectrophotometer taking 0.1N HCl as blank. Then a graph was plotted by taking Concentration on X-Axis and Absorbance on Y-Axis which gives a straight line Linearity of standard curve was assessed from the square of the correlation coefficient (R²) which determined by least-square linear regression analysis⁷.

Drug – excipient compatibility studies

Fourier transform infrared (FTIR) spectroscopy: The physical properties of the physical mixture were compared with those of plain drug. Samples were mixed thoroughly with 100mg

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Research Article

**FORMULATION AND EVALUATION OF POLY HERBAL
COSMETIC FACE CREAM**Anusha V^{*1}, Vineela M², Priyanka Odela³, Dr.T.Mangilal⁴^{*1}Department of Pharmaceutics, Vignan Institute of Pharmaceutical Sciences, Hyderabad, India.²Department of Pharmaceutics, Bharat Institute of Technology, Hyderabad India.³Department of Pharmaceutics, G Pulla Reddy College of Pharmacy, Hyderabad, India.⁴Gcop, Cheeryal, Keesara, Medchal-501301, Telangan, India.**Abstract:**

Natural remedies are safer with fewer side effects than the synthetic ones. The present work deals with the Formulation development and evaluation of the poly herbal skin cream containing hydro-alcoholic extract of Liquorice, ashwagandha, Nagarmotha, Terminalia Chebula, carrot and aloe Vera along with the cream base ingredients liquid paraffin, cetyl alcohol, stearic acid in various concentrations along with other ingredients and preservatives in various trials F1-F5. The present study proposes to make use of hydroalcoholic extract of these plant materials to make the cream more effective as these plants have been reported in the literature to exhibit good anti- microbial, anti-oxidant and anti-inflammatory properties. Various trials of polyherbal creams F1 to F5 were formulated by incorporating different concentrations of ingredients, then they were evaluated for various parameters like pH, viscosity, spreadability, Washability, consistency, irritancy, etc., Based on the results trial F3 was found to be optimized as it exhibited excellent properties mandatory for cream. Formulation F3 showed good spreadability, good consistency, homogeneity, appearance, pH with no evidence of phase separation and it shows no redness, inflammation and irritation during irritancy studies, hence it is was optimized and identified as a safe formulation to be used for skin and the formulation F3 proves it is stable when subjected for stability test.

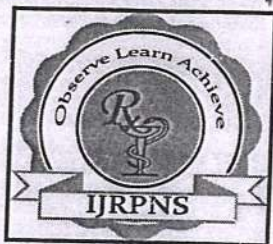
Key words: Extracts, Cream, Stability, Consistency and Viscosity.**Corresponding author:****Mrs. Anusha V,**Department of Pharmaceutics,
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**LANSOPRAZOLE MICROSPHERES FOR IMPROVEMENT IN DISSOLUTION
RATE AND SUSTAINED RELEASE PROPERTY**

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ABSTRACT

Different batches of lansoprazole loaded ethyl cellulose and HPMC K4M microspheres were prepared using W/O/O double emulsification-solvent diffusion method, to overcome the problem of low encapsulation efficiency of lansoprazole using span-80 as a stabilizer with constant stirring by a magnetic stirrer (Model-1 MLA, Remi motors, vasai, Mumbai, India) at 750- 1000 rpm for 5 hours and centrifuged by cooling centrifuge (Hittich, Zentrifugen, model-1195 a, Mikro 220R, Germany). The prepared microspheres were evaluated and characterized for particle size, percentage yield, drug entrapment efficiency, surface morphology by scanning electron microscopy (SEM), drug-excipient compatibility studies by Fourier transform infrared (FTIR), solid state properties (crystalline or amorphous) by differential scanning calorimetry (DSC), *In-vitro* drug release studies and release kinetics were determined. The optimized formulation F5 was characterized for particle size and surface morphology using optical microscopy method and scanning electron microscopy. Lansoprazole drug release rate was observed highest and improved dissolution rate, with the increase in concentration of HPMC K4M and decreased particle size of microspheres and showed sustained release property of the drug by ethyl cellulose in pH 1.2 up to 92-98.3% were releases within a period of 12 hrs. From the formulation F1 to F5, F5 showed a high dissolution rate of 98.3% and compared with the percentage drug release of pure drug. The data obtained from the dissolution profiles were compared to the different release kinetics models and the regression coefficients. The drug release profile follows zero order release and Higuchi model kinetics, it was found that the optimized formulation of lansoprazole microspheres showed sustained release property and drug release was found to be diffusion controlled mechanism, the n value of Korsmeyer-peppas equation indicated non-fickian type of diffusion.

KEYWORDS

Lansoprazole, Hydroxyl propyl methyl cellulose, Ethyl cellulose, Span-80, Sustained release, Microspheres, Double emulsification-solvent diffusion method, Zero order release and Higuchi model kinetics.

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INTRODUCTION

For decades an acute or chronic illness is being clinically treated through delivery of drugs to the patients in form of some pharmaceutical dosage forms like tablets, capsules, liquids, creams, pills, aerosols, inject able, and suppositories with their main discrepancy to maintain drug levels within the



**FORMULATION AND EVALUATION OF VORICONAZOLE PATCHES FOR BUCCAL
DRUG DELIVERY SYSTEM**

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ABSTRACT

Voriconazole is a triazole antifungal drug that generally used to treat serious, invasive fungal infections. These are generally seen in patients who are immune compromised, and include invasive candidacies, invasive aspergillosis, and certain emerging fungal infections. In the present study buccal drug delivery of Voriconazole was developed to overcome the first pass metabolism and to reduce the frequency of dosing compared to oral route. Matrix type of buccal patches was developed by using polymers HPMCK4M and HPMCK100M. Buccal patches were prepared by employing solvent casting method. Propylene glycol and Tween80 were selected as permeation enhancer and plasticizer. Drug excipient compatibility studies were carried out by using FTIR, and it was observed that there were no interactions. The formulations were prepared with the varying concentrations of polymers ranging from F1-F6, and all the formulations were evaluated for various parameters like Physical appearances, Flatness, Weight variation, Thickness, Folding endurance, Drug content, Moisture uptake, Moisture content and Swelling study and all the results were found to be within the pharmacopeial limits, *in vitro* drug release studies done by using dialysis membrane. Among all the 6 formulations F6 formulation which contain HPMC K100M 500mg had shown 94.7% cumulative drug release within 12 hours. For F6 formulation release kinetics were plotted and the Regression coefficient value was found to be high for Korsmeyer-peppas release model i.e., 0.989.

KEYWORDS: Voriconazole, HPMCK4M, HPMCK100M, Buccal Patches and Buccal Drug Delivery.

INTRODUCTION

There are several routes of drug administration for delivering the drug. Among them in recent years, many investigations are done in the field for delivering the drug locally to the tissues in the oral cavity, especially for treating bacterial and fungal infections, and periodontal treatments. Bioadhesive drug delivery plays an important role in delivering drug locally in the oral cavity as it retains the drug at the site of action. Adhesive material may be natural or synthetic. Surface of adhesion can be either epithelial tissue or mucous coat of the tissue. If adhesion is to a mucous coat, then it is referred as mucoadhesion. Over the decades mucoadhesion has become popular for its potential to optimize localized drug delivery, by retaining a dosage form at the site of action (e.g. within the gastrointestinal tract) or systemic delivery by retaining the formulation in intimate contact with the absorption site (e.g. buccal cavity).^[1]

Mucoadhesive polymers have greater application in buccal drug delivery system. Recently, many mucoadhesive forms have been developed like patches, films, disks, strips, ointments, tablets, gels etc. However, buccal patch offers greater flexibility and comfort than

the other forms. Apart from it buccal patches can overcome problems like short residence time as that of gels which is easily washed away by saliva.^[2]

Buccal route of drug delivery provides high bioavailability as it has direct access to the systemic circulation through the jugular vein bypassing the first pass hepatic metabolism. Apart from it, it has excellent accessibility, low enzymatic activity, suitable for drugs or excipients that mildly and reversibly damage or irritate the mucosa. Other advantages include painless drug administration, easy withdrawal. Facility to include permeation enhancer / enzyme inhibitor or pH modifier in the formulation, versatility in designing as multidirectional or unidirectional release system for local or systemic action.^[3] Voriconazole is a triazole anti fungal drug which is used to treat serious fungal infections. It has a very low aqueous solubility and extensively metabolized by the liver. Buccal route offers several advantages as it bypasses first pass metabolism, easy withdrawal, rapid absorption. Hence it leads to significant reduction of dose and related side effects. Here in the present work, an attempt was made to formulate and evaluate voriconazole buccal patches for



ROLE OF THE GENE HP0102 ENCODING A CONSERVED LPS GLYCOSYLTRANSFERASE IN THE PATHOGENESIS OF HELICOBACTER PYLORI

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ABSTRACT

Helicobacter pylori are a major human pathogen and are associated with chronic gastric inflammation, peptic ulcer disease and gastric cancer. Contact with host cells is recognized as a signal capable of triggering expression of bacterial genes important for host pathogen interaction. Adherence of *H. pylori* to the gastric epithelial cell lines AGS and MKN45 strongly upregulated expression of a gene HP0102 in the adhered bacteria as determined by qRT-PCR. In silico analysis suggested that HP0102 shows tremendous sequence conservation among different strains of *H. pylori* including several Indian clinical isolates and was predicted to encode for a glycosyltransferase enzyme. To elucidate the role of HP0102, a HP0102 knockout strain was constructed (Δ HP0102) and analyzed. The gene was found to be associated with two distinct phenotypes related to pathogenicity. In AGS cell-adhered *H. pylori*, it has a role in upregulation of *cag A*, a major virulence factor and consequent induction of the hummingbird phenotype in the infected AGS cells. HP0102 was also found to be involved in the glycosylation of bacterial lipopolysaccharides (LPS) by glycostaining analysis. Bacterial LPS is a major virulence factor triggering the expression of cytokines via TLR 2 and TLR4 dependent signaling cascades. Results of a cytokine array using the cell culture supernatants of MKN45 cells (expressing both TLR2 and TLR4) infected with either *H. pylori* wild type or the Δ HP0102 strain suggested that the HP0102 mutant was impaired in inducing the expression of several cytokines including the proinflammatory cytokine IL-8. Further work is under progress to identify more specific functions of HP0102 and also identify other signaling networks that may be affected by LPS and its glycosylation state during the pathogenesis of *H. pylori*.

KEYWORDS: *Helicobacter pylori* Peptic ulcer disease, Gastric cancer and Cytokine array.

INTRODUCTION

Helicobacter pylori are a Gram-negative, microaerophilic bacterium which is specialized in colonization of the gastric mucosa.^[1] Between 1979- 82, Australian pathologist, Robin Warren and Australian gastroenterologist, Barry Marshall, identified *H. pylori* and suggested a link to the development of stomach ulcers. *H. pylori* are slow growing microorganisms but act as a dominant pathogen that can cause peptic ulcers and gastritis that can lead to gastric cancer.^[2] Human stomach acts as a reservoir providing most suitable environment for the growth of the *H. pylori*. Its name refers to both its spiral shape and the area of the lower stomach which it habitually colonizes between the stomach and small intestine.^[3] The adaptation to such a harsh and acidic environment in human stomach reduces its competition with other bacterium and enhances its ability to cause chronic infection.^[4] This makes *H. pylori* one of the most successful human bacterial parasites,

which colonizes more than 50% of the human population.

The link between *Helicobacter pylori* and peptic ulcer, first recognized by Barry Marshall and Robin Warren in 1982, provided major insight into human gastric pathology. Colonization ranges from 50-100%, making *Helicobacter pylori* the most common infectious agent of humans in the world today.^[4] Because of the prevalence and importance of *Helicobacter pylori* infection, understanding the mechanisms by which it colonizes the gastric mucosa and causes disease has received intense interest. *Helicobacter pylori* possess several putative colonization factors, including urease, various adhesins and flagellar motility, some of which have been shown to be necessary for gastric colonization. The most severe *Helicobacter pylori* mediated disease states are attributed to strains harbouring the *cag* pathogenicity island (*cag* PAI), a 40 kb DNA element. Analysis of the *cag* PAI sequence suggested that it encodes a putative secretion



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Preparation and evaluation of poly herbal anti-aging cream by using different synthetic polymers

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Abstract

Herbal formulations have growing demand in the world market and the plants have been reported in the literature having good anti- microbial, anti-oxidant and anti-inflammatory activity. In this study cream was formulated based on the anti-oxidant potential of herbal extracts and its evaluation. Green tea leaves were a shade dried and extracted using a Soxhlet extraction method. The cream was formulated with Neem oil, Jamul seed powder, olive oil of different concentrations namely F₁, F₂, F₃ and F₄. The cream was stable during stability studies according to ICH guidelines 30±2 °C / 50±5% RH and 40±2 °C / 75±5% RH for two months. The evaluations of all formulations were done on different parameters like pH, spreadability, stability etc. Formulations F₃ and F₄ showed good spreadability, good consistency, homogeneity with good appearance, pH, and no evidence of phase separation and ease of removal. The formulation F₃ and F₄ shows no redness, edema, inflammation and irritation to the skin during irritancy studies. These studies suggest that the composition of extracts and base of cream of F₄ is more stable and safe, it may produce synergistic action. It can be concluded that herbal cream without side effects having anti-oxidant property can be used as provision of a barrier to protect the skin and avoid aging of the skin.

Keywords: Herbal cream, anti-aging, green tea, antioxidant and polyherbal

1. Introduction

Skin aging is the result of a continual deterioration process because of damage to cellular DNA and protein. The ageing process is classified into two distinct types i.e. "Sequential Skin Aging" and "Photo Aging". Both types have distinct Clinical and Historical features. Sequential Skin Aging is the universal and predictable process characterized by physiological alteration in skin function. In the aging process keratinocytes are unable to form a functional stratum corneum and rate of formation of neutral lipids slows down, resulting in dry and pale skin with wrinkle [1]. In contrast, Photo Aging is caused by over exposure to UV rays from sunlight. It is characterized by dry, pale and sallow skin, displaying fine wrinkles as well as deep furrows caused by the disorganization of epidermal and dermal components associated with elastosis and heliodermatis. Herbs and plants have already proved useful as tool in complementary medicine [2].

Cosmetic products are used to protect against exogenous and endogenous harmful agents, and enhance the beauty and attractiveness of skin [3]. The use of cosmetics not only developing an attractive external appearance, but towards achieving longevity of good health by reducing skin disorders [4]. The synthetic or natural ingredients present in a skin care formulation that supports the health, texture, integrity of skin, moisturizing, maintaining the elasticity of skin by reduction of type I collagen, photo protection etc. This property of cosmetics is due to presence of ingredients in skin care formulations, because it helps to reduce the production of free radicals in the skin and manage the skin properties for a long time [5]. The cosmetic products are the best choice to reduce skin disorders such as hyperpigmentation, skin ageing, skin wrinkling, rough skin texture etc. The demand of herbal cosmetic is rapidly expanding. Olive oil contains abundant amounts of Vitamin A. It acts as a very good anti-oxidant which slows down the process of ageing. Vitamin C produces collagen in the body which is essential protein for making our skin elastic and it also prevents wrinkles on skin [6].

The literature shows that anti-oxidant substances of that living organism always acts as a "protective chain", that is, different anti-oxidant substances possess a synergistic effect and protect each other from direct destruction in the reactions of neutralization of the free radicals and other reactive species [7-8]. The poly herbal cosmetic formulation is recommended for management of skin properties for a long time and their effects are also well accepted in the community of different countries. The selected herbal extract described in present investigation has been utilized medicinally in crude extract to treat various skin diseases.



BIOANALYTICAL METHOD DEVELOPMENT, VALIDATION AND QUANTIFICATION OF BOSENTAN BY HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY IN RAT PLASMA

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ABSTRACT

A Simple and rapid bioanalytical high performance liquid chromatographic (HPLC) method for the determination of Bosentan using Losertan as an internal standard was developed and validated as per regulatory requirements. Sample preparation was accomplished through liquid phase extraction and chromatographic separation on a reverse phase column. The mobile phase consists of mixture of methanol and water in the ratio of 50:50 at a flow rate of 1ml/min. The wavelength used for the detection of bosentan was 225nm with a total run time of 6minutes. The retention times of bosentan and losertan were found to be 2 and 4 respectively. The method was developed and tested for the linearity range of 250-750ng/ml. The method was validated for accuracy, precision, linearity and recovery in compliance

to international regulatory guidelines.

KEYWORDS: Bosten, HPLC, Validation.

Abbreviations: CV: Coefficient Variation; HPLC: High Performance Liquid Chromatography; IS: Internal Standard; LC: Liquid Chromatography; LLOQ: Lower Limit of Quantitation; LQC: Low Quality Control; MQC: Medium Quality Control; HQC: High Quality Control; PK: Pharmacokinetics; QC: Quality Control; RP: Reverse Phase, UV: Ultraviolet spectrophotometry; C_{max}: the maximum plasma concentration of the drug.

Pharmacodynamic and Pharmacokinetic Interactions of Piperine on Gliclazide in Animal Models

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ABSTRACT

Back Ground: The objective of the present study was to find out the pharmacodynamic and pharmacokinetic interactions of piperine on gliclazide in rats and rabbits. **Methods:** Influence of piperine on the activity of gliclazide was determined by conducting single- and multiple-dose interaction studies in rats (normal and diabetic) and diabetic rabbits. Blood samples collected at predetermined time intervals from experimental animals were used for the estimation of glucose and insulin levels by using automated clinical chemistry analyzer and radioimmunoassay method, respectively. β -cell function was determined by homeostasis model assessment. Additionally, serum gliclazide levels in rabbits were analyzed by high-performance liquid chromatography. **Results:** Gliclazide showed significant reduction in blood glucose levels in diabetic rats and rabbits. Similarly, piperine also showed significant reduction in blood glucose levels in animals. Additionally, samples analyzed from all time points in combination with piperine showed peak reduction in blood glucose in diabetic rats and rabbits. The pharmacokinetics of gliclazide was also altered by single- or multiple-dose piperine treatments in rabbits. **Conclusion:** The interaction of piperine with gliclazide upon single and multiple-dose treatment was pharmacodynamic and pharmacokinetic in nature, indicating the need for periodic monitoring of glucose levels and dose adjustment as necessary when this combination is prescribed to diabetic patients.

Key words: Diabetes, Drug interaction, Gliclazide, Piperine.

INTRODUCTION

Diabetes mellitus is the most severe metabolic disorder characterized by absolute or relative insufficiency in insulin secretion and/or its action.¹ Gliclazide (second generation sulfonylurea derivative) is the preferred choice of drug.² Piperine is an alkaloidal compound and is an active constituent of black and long peppers. It has been found to have anti-diabetic activity per se. Piperine can improve the bioavailability of many drugs and decrease the elimination of the drugs and finally improves the biological effectiveness. Piperine is known to inhibit human CYP2C9, CYP3A4 and P-glycoprotein.^{3,4} But the influence of piperine on diabetic patients who are under the treatment with Gliclazide is not proved yet. Hence, the present study was designed to find out the pharmacodynamic and pharmacokinetic interactions of piperine on gliclazide in rats and rabbits.

MATERIALS AND METHODS

Drugs and chemicals

Gliclazide was obtained as a gift sample from Dr Reddy's Laboratories (Bachupally, Hyderabad, Telangana, India). Piperine was purchased from HiMedia Laboratories private limited, Mumbai. Alloxan monohydrate was purchased from Loba Chemie (Mumbai, Maharashtra,

India). All reagents and chemicals used in the study were of analytical grade.

Gliclazide solution Gliclazide solution was prepared by dissolving in few drops of 0.1 N sodium hydroxide and the final volume was made with water.⁵

Preparation of Piperine solution

Piperine solution was prepared in 2% Gum acacia solution.

Preparation of alloxan solution

Alloxan monohydrate 110 mg/Kg was dissolved in sterile saline and injected by subcutaneous route immediately within five min to avoid degradation.⁶

Animals

Eight to 9-week-old male albino rats weighing between 170 and 250 g and 3-month-old male albino rabbits weighing between 1 and 1.5 kg were procured from M/s Mahavir Enterprises, Hyderabad. They were maintained under controlled room temperature (24±2°C; relative humidity 60-70%) in a 12h light - dark cycle. The animals were given a standard laboratory diet and water *ad libitum*. The animals were acclimatized before the study.

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Research Article

PREPARATION AND *IN VITRO* EVALUATION OF TORSEMIDE MATRIX TABLETS USING DIFFERENT SODIUM ALGINATE GRADES

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■ ABSTRACT

The objective of this study was to design oral controlled release matrix tablets of torsemide using different viscosity grades of sodium alginates as release rate retardants. The study mainly focus on effect of various formulation factors such as polymer content, polymer type, and compression force on the *in vitro* release of drug. The *in vitro* drug release studies were performed using a USP Type II dissolution apparatus. The dissolution medium was 900 ml of 6.8 pH phosphate buffer for 16 h. The temperature of dissolution medium was maintained at 37°C ± 0.5°C. The data of dissolution were fitted to various kinetics models. *In vitro* release studies showed that the release rate decreased with increase in polymer concentration and viscosity of the polymer. The matrix tablets containing sodium alginate LF 5/60 was extended the drug release form 13 to 17 h. The matrix tablets containing sodium alginate LF 10/60 was extended the drug release form 10 to 14 h. The matrix tablets containing sodium alginate LF 240 D was extended the drug release form 11 to 17 h. The data of the release kinetics showed the first-order release with diffusion mechanism. The differential scanning calorimetry and Fourier-transform infrared study showed no drug-polymer interaction.

Key Words: Differential scanning calorimetry, Fourier-transform infrared, matrix tablets, sodium alginate, Torsemide

■ INTRODUCTION

Conventional dosage forms are the most preferred and convenient option for drug delivery. However, it has poor patient compliance with ensuing undesirable toxicity and poor efficiency. A major challenge thus lies in optimizing the properties of the drug and its delivery mechanism in producing safe and efficient drugs. Consequently, there is a need for new drug delivery systems and they represent one of the Frontier research areas.^[1-3]

Torsemide is a new generation loops diuretic belonging to pyridine-sulfonylurea class and has been used for the treatment of both acute and chronic congestive heart failure, liver cirrhosis, and arterial hypertension. It exerts longer duration of action with a bioavailability of 80% and elimination half-life of 3-4 h compared with other loop diuretics.^[4-9] The conventional formulation of Torsemide shows rapid absorption after oral administration which leads to high plasma concentration and fluctuations resulting more frequency of administration.^[10] Hence, the need for the design and evaluation of the controlled



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Research Article

**BIOANALYTICAL METHOD DEVELOPMENT, VALIDATION
AND QUANTIFICATION OF METAXALONE BY LIQUID
CHROMATOGRAPHY TANDEM MASS SPECTROMETRY IN
RAT PLASMA**Nallakumar P^{1*} and Siva Kumar R²¹Department of Pharmaceutical Analysis, Srivenkateshwara College of Pharmacy and Research Centre, Madhapur, Hyderabad - 500081, India.²Department of Pharmaceutical Analysis, Geethanjali College of Pharmacy, Cheeryal vill, Keesara mdi, RR dist. India.**Abstract:**

A simple, highly sensitive, precise and accurate high-performance liquid chromatographic (LCMSMS) method with mass detection was developed and validated for the rapid quantification of metaxalone (CAS Registry No, 1665-48-1) in rat plasma samples. The chromatographic separation was achieved with a reverse phase column Agilent XDB C18 (4.6×100 mm, 5µ) and the mobile phase consisted of methanol and 5 mM ammonium acetate buffer (80:20 v/v) as eluent, at a low rate of 0.6 mL/min. Phenytoin (CAS Registry no, 57-41-0) was used as an internal standard. The effluent was ionized by positive electrospray ionization and measured by mass spectrometry. The retention time of metaxalone and phenytoin were found to be 1.60 and 1.83 min respectively. The calibration curve was linear ($r^2 > 0.99$) ranging from 0.98 to 998 ng/ml and the lower limit of quantification was 0.98 ng/mL. Interday and intraday precision were lower than 5% (CV) and accuracy ranged from 90 to 110% in terms of percent accuracy. Mean extraction recovery was found to be above 82%. The method was successfully demonstrated for evaluation of pharmacokinetic profile of metaxalone in male Sprague dawley rats and validated for excellent selectivity, accuracy, precision, recovery and stability.

Keywords: Electrospray Ionization; Metaxalone; HPLC; Mass detection; Rat plasma; Validation.**Corresponding Author:****Nallakumar P,**Department of Pharmaceutical Analysis,
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UNDERSTANDING TECHNICAL BARRIERS TO TRADE AGREEMENT

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REVIEW ARTICLE

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ABSTRACT

Signing of formation of World Trade Organization has transformed trade, services and intellectual property into a mutual, predictable exchange of trade and intellectual property protection among member countries. Countries who have become members of WTO have accepted simultaneously several agreements that are multi-lateral or plurilateral. The current article is relating to one of the WTO's imbibed agreement relating to technical barriers to trade emphasizing its role on Good Regulatory Practice.

Keywords: WTO Agreement Series, Technical Barriers to Trade, Good Regulatory Practice (GRP)

INTRODUCTION

The objectives of formation and administrative structure of WTO (GATT) were discussed earlier^{1, 2}. Currently, WTO has a total of 164 countries as members and India has become an initial member to GATT in 1948 and continued its membership even after GATT transformed to WTO in 1995. A single WTO agreement led to understanding and agreeing of about 60 multilaterals and several plurilateral. The word 'technical' means 'aspects involved or concerned to applied and industrial sciences'. Relating to pharmaceuticals technical aspects are relating to national or international legislations, guidelines, standards set for quality of products, various protocols for application, scrutiny and approval processes etc.

The fundamental concept of economics runs on two words that are 'need' and 'want' leading to manufacturing of a product, leading to trade, leading to economic growth of the individual/company as well as the country. In pharmaceuticals need and want of legislations raised due to past bitter experiences of lethality of drug products availability in the market. This led to vesting, implementation of legislations. In due course drug regulatory authority, establishment of pharmacopoeia and their role were well defined. Countries like India have pioneered in manufacture of quality

pharmaceuticals that comply not only to national but also with international levels. The current article is an understanding of how already established legislations, guidelines, protocols are fine tuning towards harmonization and to some extent uniformity.

Objectives of Technical Barriers to Trade (TBT) agreement:

With the prime objective of protection of human, animal or plant life or health, of the environment, the agreement is an international understanding to improve efficiency of production, facilitate international trade, develop and encourage international standards and conformity assessment systems, does not create unnecessary obstacles to international trade with respect to technical regulations and standards, no member country should not be prevented from taking measures necessary to ensure the quality of its exports with simultaneous monitoring of deceptive practices at the levels the country considers appropriate, prevent discrimination between countries, respecting countries for taking measure for protection of its essential security interest, respecting international standardization that can make transfer of technology from developed to developing countries, assisting developing countries by developed countries in achieving technical regulations. It is also indicated that purchasing or procurement by government

A Study on Ash Values and Pharmacopoeial Assay Methods in Herbal Pharmaceuticals

Dr. Bayya Subba Rao

Abstract: Herbal pharmaceuticals are usually called crude drugs, which are classified as organized or un-organized drugs, apart from geleniums and various formulations. Ash values helps in understanding the levels of cations (basic radicals) in a crude drug. Indian Pharmacopoeia indicates limit tests as a means of knowing the levels of cations and anions. An attempt is made to enlighten the role of ash values and various Indian Pharmacopoeia 2014 assay methods prescribed for herbals that are crude drugs or their formulations.

Introduction

Herbal (Ayurveda) system of medicine is well known since ages in India. Herbal products available as such as entire plant or parts of a plant or their powder form are called as organized drugs whereas secretions of the plant are usually called as un-organized drugs.

Calcium oxalate is the most commonly and naturally formed crystals in living cells. Majority of the minerals have their role in tissue growth. Indian pharmacopoeia prescribes the limits of anions and cations so as to overcome toxicity problems as well as formulation problems. Limit tests are usually considered as both quantitative and semi-quantitative whereas ash values helps in knowing the quantitative values of especially the cations. ICH guidelines' Q3A to Q3D emphasizes on impurities. Impurities are organic, in-organic or solvents that are imparted from manufacturing equipment, catalysts, reagents, starting materials, intermediates, degraded products, by-products, isomers, solvents, packing materials etc. In case of herbal crude drugs impurities are imparted also from air, water, soil sources etc.

As per ICH guidelines, residual solvents are categorized into class 1 (solvents to be avoided-carcinogenic, environmental hazard-benzene, halocarbons), class 2 (solvents to be limited-suspected of other significant but reversible toxicities-acetonitrile, chloroform, ethylene glycol, methanol, nitro methane, pyridine, tetrahydrofuran, toluene, xylene etc.), class 3 (solvents with low toxic potential-acetic acid, heptane, 1-butanol, dimethylsulphoxide

(DMSO), ethanol, ether, pentane, propanol). The guideline mentions the concentration of class 2 solvent limits by using the formula:

$$\text{Concentration (ppm)} = 1000 \times \frac{\text{Permitted Daily Exposure (PDE)}}{\text{dose}}$$

Class	Elemental Impurities	Necessity of Risk Assessment
Class 1	As, Cd, Hg, and Pb	Yes
Class 2A	Co, Ni and V	Yes
Class 2B	Ag, Au, Ir, Os, Pd, Pt, Rh, Ru, Se and Tl	Yes only if intentionally added
Class 3	Ba, Cr, Cu, Li, Mo, Sb, and Sn	Dependent upon route of administration
Other elements	Al, B, Ca, Fe, K, Mg, Mn, Na, W and Zn	Not addressed in the current guideline. Needs to be assessed based on regional/ other guidelines.

Table 1: Classification of Elemental Impurities (ICH Q3D)

ICH guideline Q3D, Table 2, illustrates and insists on assessing a product.

The guideline provides with the procedure how to establish exposure limits, PDE for elemental impurities. Table 3, illustrates the Permitted Daily Exposure (PDE) limits for various elements with respect to routes of administration.

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Phytochemical investigation and antihelmintic activity of *Operculina turpethum* roots

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ABSTRACT

The present study was aimed at the investigation of the roots of the traditional Indian medicinal plant *Operculina turpethum* for pharmacologically active chemical constituents and *in vitro* evaluation of the fraction (or) extracts that shown to contain maximum constituents for anthelmintic activity against adult Indian earthworms (*Pheretima posthuma*) using albendazole as the reference standard. The collected and authenticated roots were dried under shade and extracted with water, ethanol, and ethyl acetate by maceration. The obtained extracts were investigated for the presence of various biologically active ingredients by qualitative methods. Ethanolic and ethyl acetate extracts that were shown to possess maximum constituents were tested for anthelmintic activity by measuring parameters such as time taken for paralysis and death of the worms. Results were compared with that were obtained with albendazole. From the results, it was found that the ethanolic extract of the roots taken for the study possesses significant activity at the concentrations of 150 mg/ml. However, more study is recommended for further investigation in this regard.

KEY WORDS: Albendazole, Anthelmintic activity, Extracts, *Operculina turpethum*, Phytochemical investigation, Roots

INTRODUCTION

The human being appears to be afflicted with more diseases from the early ages, taking advantages of plants growing around them to alleviate their sufferings from injury or disease with hopes for remedies in chronic diseases generated new enthusiasm in the research workers to develop herbal medicines.

Herbal medicine offers a greater scope for the future treatment of various pathological conditions.

The effectiveness of medicinal plant lies in the varying complex chemical substances such as alkaloids, glycosides, corticosteroids, and essential oils which are the starting material for a vast number of synthetic drugs.^[1,2]

Helminthiasis is one of the most important animal diseases worldwide that can cause heavy production

losses in grazing animals. The disease is prevalent all over the world, especially in developing countries, and is always associated with poor management practices and inadequate and inappropriate control strategies. An integrated approach is required for the effective control of helminths which includes strategic and tactical use of anthelmintics which remains the cornerstone to this end and careful management of grazing lands including control of stocking rates and appropriate rotation strategies.

Role of vaccinations is also vital for the control of various parasitic diseases as in the case of lungworms. However, various problems have emerged with the use of anthelmintics, and among them, resistance against various species of helminthes is of utmost importance to different anthelmintic compounds and classes, as well as chemical residue and toxicity problems.

In addition, recognition of the antigenic complexity of parasites has slowed vaccine development. For these various reasons, interest in the screening of medicinal plants for their anthelmintic activity remains of great scientific significance despite extensive use

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METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF DESLORATADINE AND MONTELUKAST SODIUM BY RP-HPLC

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ABSTRACT

A novel, precise, accurate, rapid and cost effective isocratic Reverse-Phase High Performance Liquid Chromatographic (RP-HPLC) method was developed, optimized and validated for the simultaneous estimation of Desloratadine and Montelukast Sodium in pharmaceutical dosage forms. The drugs were estimated using Imp Sil, C₁₈HS(250 mm x 4.6 mm i.d, 5µm)column. The mobile phase composed of Acetonitrile, Methanol, water with ratio of 15:80:05 v/v, at a flow rate of 1.0 ml/min was used for the separation. Detection was carried out at 280 nm. The linearity range obtained was 2-10 µg/ml for Desloratadine and 10 – 50 µg/ml for Montelukast with retention times of 2.46 min and 3.73 min for Desloratadine and Montelukast respectively. The correlation coefficient values were found to be

0.9994 and 0.9998. Precision studies showed % RSD values less than 2% for both the drugs in all the selected concentrations. The percentage recoveries of Desloratadine and Montelukast were in the range of 99.32% - 99.58% and 99.38%- 109% respectively. The limit of detection (LOD) and limit of quantification (LOQ) were 0.522µg/ml, 0.584µg/ml for Desloratadine and 1.384µg/ml 1.268µg/ml for Montelukast respectively. The method was validated as per the International Conference on Harmonization (ICH) guidelines. The proposed validated method was successfully used for the quantitative analysis of commercially available tablet dosage forms.

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DETERMINATION OF CARISOPRODOL IN HUMAN PLASMA BY LIQUID CHROMATOGRAPHY TANDEM MASS SPECTROMETRY

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ABSTRACT

A liquid chromatographic tandem mass spectrometry (LC-MS/MS) method was developed and validated for the determination of carisoprodol in human plasma. Carisoprodol d3 was used as an internal standard (IS). The plasma samples were extracted by simple liquid liquid extraction method. These samples were then chromatographed on a Zorbax XDB phenyl column by using a mixture of 0.1% formic acid in water and acetonitrile (20:80, v/v) as the mobile phase. The method was validated in the range of 25-3000 ng/mL with $r^2 \geq 0.99$. The intra-day and inter-day precision and accuracy results in four validation batches across five concentration levels were well within the acceptance limits.

KEYWORDS: Carisoprodol; Human Plasma; Liquid-liquid Extraction (LLE); LC-MS/MS.

INTRODUCTION

Chemically, carisoprodol is a 2-[[[(aminocarbonyl)oxy]methyl]-2-methylpentyl isopropyl carbamate and its chemical formula is C₁₂H₂₄N₂O₄. Carisoprodol is a centrally acting skeletal muscle relaxant indicated for the relief of discomfort associated with acute

**METHOD DEVELOPMENT AND VALIDATION FOR
SIMULTANEOUS ESTIMATION OF TOLPERISONE AND
PARACETAMOL BY RP-HPLC**

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ABSTRACT

A simple, sensitive, accurate, precise and rapid reverse phase high performance liquid chromatographic method has been developed and validated for the simultaneous determination of Tolperisone and Paracetamol from synthetic mixture. The chromatographic separation was performed on Imo Sil 5 C18 column (250 mm × 4.6 mm i.d, 5 µm particle size). Mobile phase consisted of a Acetonitrile and methanol in the ratio of 25:75, v/v at a flow rate of 1.0 ml/min. The detection wavelength was set at 261nm. The proposed method was validated for linearity, accuracy, precision, LOD and LOQ. The calibration was linear over the concentration range of 10-30 µg/ml for Tolperisone and 5-15 µg/ml for Paracetamol. The retention times were found to be 5.3 + 0.14min for Paracetamol and 2.4 + 0.13min for Tolperisone. The

mean recoveries were 100.5 ± 0.34 and 98.2 ± 0.80 for Tolperisone and Paracetamol, respectively. The method can be easily adopted for quality control analysis.

KEYWORDS: Tolperisone, Paracetamol, HPLC, Validation.

INTRODUCTION

Tolperisone (R,S)-2-methyl-1-(4-methyl phenyl)-3-propane-1-one, is a centrally acting muscle relaxant. Acts at reticular formation in the brain stem by inhibiting voltage gated Na⁺⁺

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DETERMINATION OF CARISOPRODOL IN HUMAN PLASMA BY LIQUID CHROMATOGRAPHY TANDEM MASS SPECTROMETRY

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**METHOD DEVELOPMENT AND VALIDATION FOR
SIMULTANEOUS ESTIMATION OF DESLORATADINE AND
MONTELUKAST SODIUM BY RP-HPLC**R. Naga Kishore^{1*}, N. Anjaneyulu¹, A. Teja Sri², B. Vani swetha¹ and M. Bhavani¹¹Department of Pharmaceutical Analysis, Geethanjali College of Pharmacy, Cheeryal,
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A novel, precise, accurate, rapid and cost effective isocratic Reverse-Phase High Performance Liquid Chromatographic (RP-HPLC) method was developed, optimized and validated for the simultaneous estimation of Desloratadine and Montelukast Sodium in pharmaceutical dosage forms. The drugs were estimated using Imp Sil.C₁₈HS(250 mm x 4.6 mm i.d. 5µm)column. The mobile phase composed of Acetonitrile, Methanol, water with ratio of 15:80:05 v/v, at a flow rate of 1.0 ml/min was used for the separation. Detection was carried out at 280 nm. The linearity range obtained was 2-10 µg/ml for Desloratadine and 10 – 50 µg/ml for Montelukast with retention times of 2.46 min and 3.73 min for Desloratadine and Montelukast respectively. The correlation coefficient values were found to be

0.9994 and 0.9998. Precision studies showed % RSD values less than 2% for both the drugs in all the selected concentrations. The percentage recoveries of Desloratadine and Montelukast were in the range of 99.32% - 99.58% and 99.38%- 109% respectively. The limit of detection (LOD) and limit of quantification (LOQ) were 0.522µg/ml, 0.584µg/ml for Desloratadine and 1.384µg/ml 1.268µg/ml for Montelukast respectively. The method was validated as per the International Conference on Harmonization (ICH) guidelines. The proposed validated method was successfully used for the quantitative analysis of commercially available tablet dosage forms.



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Research Article

STUDY OF THE ANTI-ASTHMATIC ACTIVITIES ON *A. MARMELOS*, *S. URENS* & *V. NEGUNDO* IN ANIMAL MODELSR. Naga Kishore^{*1}, G. Vidyasagar² and R. K. Jat¹¹Department of Pharmacy, JJTU, Jhunjhunu, Rajasthan, India.²Principal, Srinivasarao College of Pharmacy, Vizag, A.P, India.**Abstract:**

The present study was undertaken to evaluate the effects of antiasthmatic on *A. marmelos*, *S.urens* and *V. negundo*. Leaves of alcoholic extracts of *A. marmelos*, *S. urens*, *V. negundo* were subjected for the antiasthmatic evaluation for Histamine induced paw edema (HIPE), Milk Induced leucocytosis (MIL), Clontidine Induced Catalepsy (CIC). Adult albino mice (25-30gms) of either sex were used for the study. The animals were divided into three groups containing of 6 animals of each group-1 received normal saline, group-2 received standard drug and group-3 received test drug aqueous extract of Plant extract maintained in a well-ventilated room with 12:12 hour light/dark cycle in polypropylene cages. Treatments were administered and observed for specific periods, all results showed significant value when compared to standard treatment group. From the above findings it can be confirmed that *A. marmelos*, *S.urens* and *V. negundo* has antiasthmatic activity. However further studies are required to know the exact mechanism of actions.

Keywords: Leucocytosis, Catalepsy, *A. marmelos*, *S.urens* & *V. negundo***Corresponding Author:****R. Naga Kishore,**
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**ANTI-DIARRHEAL ACTIVITY OF LEAVES EXTRACTS OF *LINUM USITATISSIMUM* IN ANIMAL MODELS**

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Department of Pharmacy,
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Jaipur, India.**ABSTRACT**

The purpose of the present study was to evaluate scientifically the anti-diarrheal effect of *Linum usitatissimum* using castor oil-induced diarrhoea model. The anti-diarrheal effect of aqueous and alcoholic extract of leaves of *Linum usitatissimum* was studied against castor oil-induced-diarrhea model in rats. The gastrointestinal transit rate was expressed as the percentage of the longest distance traversed by the charcoal divided by the total length of the small intestine. The weight and volume of intestinal content induced by castor oil were studied by enteropooling method. Like atropine (3mg/kg, i.p.) there were

significant reductions in fecal output and frequency of droppings when the plant extracts of aqueous 100 and 200 mg/kg doses were administered intraperitoneally compared with castor oil treated rats. All doses of the plant extract significantly retarded the castor-oil induced enteropooling and intestinal transit. The remarkable anti-diarrheal effect of *Linum usitatissimum* extract against castor oil-induced diarrhea model attests to its utility in a wide range of diarrheal states.

KEYWORDS: *Linum usitatissimum*pusillus, Anti-Diarroheal, Castor oil, Atropine.

INTRODUCTION

Diarrhea is a condition that involves the frequently passing of liquid faeces with or without blood or mucus; it is one of the leading causes of mortality in developing countries and major cause of this disease is malnutrition.^[1-3] WHO has encouraged studies for treatment and prevention of diarrheal diseases depending on traditional medicinal practices.

Linum (flax) is a genus of approximately 200 species in the flowering plant family Linaceae. They are native to temperate and subtropical regions of the world. The genus includes the

Research Article

Pharmacological
Evaluation Of
Anti-Depressant Activity
Of *Linum Usitatissimum* In
Mice Model

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Abstract

Objective: The present study was designed to investigate the anti-depressant activity of the *Linum usitatissimum*. **Methods:** Anti-depressant activity is evaluated by forced swim test, tail suspension test and open field test. Healthy albino mice (6-7 week old) weighing 20-40 grams were used. Potency of the test sample was compared with the standard fluoxetine drug. **Results:** Results showed that the administration of the *Linum usitatissimum* produced adiminution of immobility time in mice exposed to the both forced swimming and tail suspension tests. In the present study, *Linum usitatissimum* (100mg/kg) administered to mice, produced significant anti-depressant like effect in both TST and FST and efficacy was found to be comparable to fluoxetine (20 mg/kg, ip). **Conclusion:** Further studies would be necessary to evaluate the contribution of *Linum usitatissimum* for the observed anti-depressant activity as it still remains to be determined for the side effects.

Key words: *Linum usitatissimum*, anti-depressant activity.

INTRODUCTION

Depression is characterized primarily by changes of mood, rather than by thought disturbances. Depressive disorders are common; approximately 15% of the population experiences a depressive episode at some point of life. It may range from a very mild condition to severe depression, accompanied by hallucinations and delusions. Two types of depressive illness can be distinguished, namely unipolar depression, in which the mood swings are always in the same direction, and bipolar affective disorder, in which depressive episodes alternate with mania⁽¹⁾. An antidepressant is a psychiatric medication used to alleviate mood disorders, such as major depression and dysthymia and anxiety disorders such as being social. The main types of anti-depressant drugs are TCA, selective serotonin reuptake inhibitors (SSRI), MAOI and atypical anti-depressants. Lithium is used as mood stabilizer in manic-depressive illness (bipolar depression). The Selective serotonin reuptake inhibitors (SSRIs) are the class of anti-depressants commonly used as the first line treatment for depression because they have a favorable side-effect profile and low toxicity. The atypical antidepressants act like the TCA, but have a different chemical structure^(2,3). Study drug, *Linum usitatissimum* resembles pharmacological features of typical anti-depressants. Therefore we undertook the study to evaluate the anti-depressant action of *Linum usitatissimum*⁽⁴⁾.

MATERIALS AND METHODOLOGY:

Plant material

Leaves of *Linum usitatissimum* were collected from locally in Hyderabad, Andhra Pradesh. These were authenticated at the department of Pharmacognosy department.

Preparation of the ethonolic extract

The leaves of *Linum usitatissimum* were collected, washed thoroughly in water and air dried at 35-40°C for a week. Dried leaves were pulverized by using electric grinder to obtain a fine powder. The powder was defatted with petroleum ether. Later it was extracted with ethanol extraction was done by using soxhlet apparatus. The filtrate was evaporated to dryness at 40°C.

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**FORMULATION AND EVALUATION OF VORICONAZOLE PATCHES FOR BUCCAL
DRUG DELIVERY SYSTEM**

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ABSTRACT

Voriconazole is a triazole antifungal drug that generally used to treat serious, invasive fungal infections. These are generally seen in patients who are immune compromised, and include invasive candidacies, invasive aspergillosis, and certain emerging fungal infections. In the present study buccal drug delivery of Voriconazole was developed to overcome the first pass metabolism and to reduce the frequency of dosing compared to oral route. Matrix type of buccal patches was developed by using polymers HPMCK4M and HPMCK100M. Buccal patches were prepared by employing solvent casting method. Propylene glycol and Tween80 were selected as permeation enhancer and plasticizer. Drug excipient compatibility studies were carried out by using FTIR, and it was observed that there were no interactions. The formulations were prepared with the varying concentrations of polymers ranging from F1-F6, and all the formulations were evaluated for various parameters like Physical appearances, Flatness, Weight variation, Thickness, Folding endurance, Drug content, Moisture uptake, Moisture content and Swelling study and all the results were found to be within the pharmacopeial limits, *in vitro* drug release studies done by using dialysis membrane. Among all the 6 formulations F6 formulation which contain HPMC K100M 500mg had shown 94.7% cumulative drug release within 12 hours. For F6 formulation release kinetics were plotted and the Regression coefficient value was found to be high for Korsmeyer-peppas release model i.e., 0.989.

KEYWORDS: Voriconazole, HPMCK4M, HPMCK100M, Buccal Patches and Buccal Drug Delivery.

INTRODUCTION

There are several routes of drug administration for delivering the drug. Among them in recent years, many investigations are done in the field for delivering the drug locally to the tissues in the oral cavity, especially for treating bacterial and fungal infections, and periodontal treatments. Bioadhesive drug delivery plays an important role in delivering drug locally in the oral cavity as it retains the drug at the site of action. Adhesive material may be natural or synthetic. Surface of adhesion can be either epithelial tissue or mucous coat of the tissue. If adhesion is to a mucous coat, then it is referred as mucoadhesion. Over the decades mucoadhesion has become popular for its potential to optimize localized drug delivery, by retaining a dosage form at the site of action (e.g. within the gastrointestinal tract) or systemic delivery by retaining the formulation in intimate contact with the absorption site (e.g. buccal cavity).^[1]

Mucoadhesive polymers have greater application in buccal drug delivery system. Recently, many mucoadhesive forms have been developed like patches, films, disks, strips, ointments, tablets, gels etc. However, buccal patch offers greater flexibility and comfort than

the other forms. Apart from it buccal patches can overcome problems like short residence time as that of gels which is easily washed away by saliva.^[2]

Buccal route of drug delivery provides high bioavailability as it has direct access to the systemic circulation through the jugular vein bypassing the first pass hepatic metabolism. Apart from it, it has excellent accessibility, low enzymatic activity, suitable for drugs or excipients that mildly and reversibly damage or irritate the mucosa. Other advantages include painless drug administration, easy withdrawal. Facility to include permeation enhancer / enzyme inhibitor or pH modifier in the formulation, versatility in designing as multidirectional or unidirectional release system for local or systemic action.^[3] Voriconazole is a triazole anti fungal drug which is used to treat serious fungal infections. It has a very low aqueous solubility and extensively metabolized by the liver. Buccal route offers several advantages as it bypasses first pass metabolism, easy withdrawal, rapid absorption. Hence it leads to significant reduction of dose and related side effects. Here in the present work, an attempt was made to formulate and evaluate voriconazole buccal patches for



Original Article

Evaluation of Anti-Quorum Sensing Activity and Anti-Biofilm Activity of *Prunus Avium* Fruit Extract

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ABSTRACT

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Bacteria inhabit dense, surface-bound communities, termed biofilms, within which they communicate and respond to local cell density through a process known as quorum sensing. Biofilms are estimated to be associated with 80% of microbial infections and the growth of micro-organisms in biofilms can enhance their resistance to antimicrobial agents. Targeting the bacterial communication system (quorum sensing, QS) can be chosen as one of the novel strategy to combat anti microbial resistance. In this work, *Prunus avium* fruit extract was prepared using sox let extraction. *Escherichia Coli* culture was maintained on nutrient agar medium and transferred on to LB broth and bacterial extract is prepared using Orbital shaker incubator. *Escherichia Coli* Bio film was prepared on cover slips and slides. The intensity of bio film was measured by crystal violet assay method. The extra cellular polysaccharide was extracted. Anti quorum sensing activity of *Prunus avium* fruit extract was estimated using disk diffusion method. The anti biofilm activity was measured by crystal violet assay method. In this study *Prunus avium* fruit extract has shown promising anti quorum sensing activity against *Escherichia coli*. *Prunus avium* fruit extract was tested against urinary catheter infected with *Escherichia Coli* biofilm. There is a significant decrease in the intensity of the bio film of *Escherichia coli* after a period of 3 days.

Key words: Quorum sensing, biofilm, *Prunus avium*, anti biofilm agents and *Escherichia coli*

1. INTRODUCTION

Biofilm is a group of microorganisms in which microbial cells stick to each other irreversibly (not removed by gentle rinsing) and they often adhere to a surface. Bacteria exhibit this type of behavior by chemically signaling to one another by a process called quorum sensing¹. Quorum sensing bacteria releases a chemical molecule called auto inducers; these auto inducers modulate gene expression². Biofilms acts as a mechanism towards bacterial resistance³. Growth of micro-organisms in biofilms can enhance their resistance to antimicrobial agents. As a consequence antimicrobial therapy often fails to eradicate biofilms from the site of

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Process optimization for the cultivation of anti-cancer *Pseudomonas aeruginosa* (MTCC 647) bacterial strains

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ABSTRACT

Cancer is one of the most dangerous diseases worldwide. Bacterial products such as proteins and endotoxins (Lipo polysaccharides) have been tested for cancer treatment. In this work an effort was made to increase the biomass and total protein content of *Pseudomonas aeruginosa* extract by using Asparagine proline broth and optimum growth conditions. Bacterial strains of *Pseudomonas aeruginosa* MTCC no 647 collected from MTCC, Chandigarh. AP broth was optimized by addition of copper sulphate, methylamine and aluminum sulphate. Modified Asparagine proline broth (AP1 to AP5) was prepared and the effect of graded amounts of copper sulphate and aluminum sulphate were analyzed. Asparagine proline broth supplemented with 0.03% of copper sulphate and 0.02 % of aluminum sulphate (AP3) was selected as it has shown high cell growth rate. Influences of various culture conditions such as temperature, P^H, Incubation time on cultivation of *Pseudomonas aeruginosa* in modified Asparagine proline broth were studied. The highest protein production was achieved at 43°C, at pH 8 for a period of 48hrs.

Keywords: Asparagine proline broth; Bacterial proteins; biomass; Media optimization and *Pseudomonas aeruginosa*.

INTRODUCTION

Cancer is one of the most dangerous diseases worldwide. Cancer development is a multi-factorial process (Shappell et al., 2004; Lakritz et al., 2014), its evolution depending on the micro and macro environment. According to International Agency for Research on Cancer (IARC) (WHO) Global burden rises to 14.1 million new cases and 13.3 million people are likely to die annually of cancer by 2030.

Conventional anticancer therapies are affected by development of drug resistance and side effects in patients with advanced solid and liquid borne tumors. Hence, there is a strong need of alternative cancer therapies. Nowadays, multi-targeted approaches have gained greater importance in cancer therapy. New generation of drugs is urgently needed to achieve the concept of multi-targeted therapy (Chakrabarty AM et.al, 2014).

Bacterial products such as proteins and endotoxins (Lipo polysaccharides) have been tested for cancer treatment. Bacterial proteins are used for tumor de-

struction. Purified bacterial products are also gaining relevance as new classes of bioactive products to treat and prevent cancer growth and metastasis. Some of these products have proven to cause significant and promising results, such as tumor regression through growth inhibition, cell cycle arrest or even apoptosis induction (Fialho AM et.al, 2012). In future, cancer vaccines can be produced based on proteins and immunotoxins of bacterial origin (Bernardes N et al., 2010).

Bacteria can be used as vectors to deliver anticancer drugs specifically to tumor cells. Spores of anaerobic bacteria can be used for the aforementioned strategies because only spores that reach an oxygen starved area of a tumor will germinate, multiply and become active. The use of genetically modified bacteria for selective destruction of tumors, and bacterial gene-directed enzyme prodrug therapy have shown promising potential.

Bacterial redox protein such as Azurin complex with p53 protein, stabilize and increase its intracellular level and produce apoptosis. Azurin protein transduction domain specifically penetrates cancer cells and produce cytostatic and cytotoxic effects (Divya K. Damania, 2016).

Proteins of *P. aeruginosa* strain reduce toxic effects in regression of cancer treatment. Previous study reveals that the blue copper protein azurin with cytochrome c can be synthesized from different microbial sources, specifically from *P. aeruginosa* (Parr SR et.al.1979; Go-

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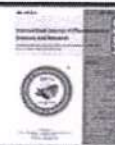
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PREPARATION AND EVALUATION OF PARACETOMOL MUCOADHESIVE BUCCAL PATCHES USING TAMARIND SEED POLYSACCHARIDE AS A NATURAL BINDER

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Keywords:

Tamarind Gum, Buccal Patches,
Tamarind Seed Polysaccharide,
Solvent Casting Method and
Mucilage Binder

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ABSTRACT: Mucoadhesive buccal patches provide a wide variant of therapeutic effect via mucosa and buccal region of the mouth. They provide zero first pass metabolism and high bioavailability providing patient compliance. In the present study, buccal patches of paracetamol were developed to improve the bioavailability and half life of the drug. In the process of its preparation binder plays a greater role in holding the drug. One of such is Tamarind seed polysaccharide (TSP) isolated from the kernels of *Tamarindus indica* seeds was used as a binder in the preparation of paracetamol mucoadhesive buccal patches. Here, solvent casting method was employed and performed various evaluation parameters. Mucilage extracts at 0.5, 1, 1.5, 2, 2.5% concentrations were used. All the patches were shown smooth surface and elegant texture. The weights of (10 mm) patches were in the range of 21.6 to 26.8 mg. The results indicate that the formulation with 2% mucilage extract shows maximum drug release. Among the five formulations (F1 to F5), F4 formulation showed maximum percentage of drug release.

INTRODUCTION: Oral drug delivery has been known for decades as the most widely utilized route of administration among all the routes that have been explored for systemic drug delivery of drugs via various pharmaceutical products of different dosage forms. ¹ Pharmaceutical products designed for oral delivery are mostly the immediate-release type, which are designed for immediate drug absorption. Recently, a new generation of pharmaceutical products called controlled-release drug delivery systems received regulatory approval for marketing and their pharmaceutical superiority and clinical benefits over the sustained-release and immediate release pharmaceutical products ².

Buccal patches: Buccal route of drug delivery is a good alternative, amongst the various routes of drug delivery ³. Within the oral mucosal cavity, the buccal region offers an attractive route of administration for systemic drug delivery and offer distinct advantages over oral administration for systemic drug delivery such as possible bypass of first pass effect, avoidance of pre-systemic elimination within the GI tract, these factors make the oral mucosal cavity a very attractive and feasible site for systemic drug delivery. Buccal mucosa has rich blood supply and it is relatively permeable ⁴.

In this project, it is proposed to use tamarind as a natural gum. Tamarind (*Tamarindus Indica* L.) is amongst the most common and commercially important, large evergreen tree that grows abundantly in dry tracks of central and south Indian states, also in other south East Asian countries. The pulpy portion of fruit is mainly used as acidulant in Indian recipes ⁵.

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Anti-Anxiety Activity of *Tradescantia spathacea* Assessed Using Different Experimental Anxiety Models

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Abstract: The point of present examination was to investigate the anti-anxiety activity of hydroalcoholic extracts of *Tradescantia spathacea* utilizing different animal models (elevated plus maze, open field test, light and dark test and social interaction test) of anxiety in mice. Diazepam (0.5 mg/kg) was utilized as the standard and measurement of hydroalcoholic extract of *T. spathacea* (50, 100 and 200 mg/kg) was chosen according to OECD rules. Results recommended that concentrate of *T. spathacea* at 100 and 200 mg/kg dose produced anti-anxiety effects almost similar to diazepam and at 50 mg/kg dosage did not create against anti-anxiety activity on any of the paradigm used. Additionally ponders are expected to recognize the anxiolytic mechanism(s) and the phytoconstituents responsible for the observed central effects of the hydroalcoholic extract of *T. spathacea*.

INTRODUCTION

Anxiety affects simple fraction of the whole population worldwide and has become a crucial space of analysis interest in pharmacology throughout this decade. [1] Benzodiazepines are the most important category of compounds utilized in anxiety and that they have remained the foremost unremarkably prescribed treatment for anxiety. [2] However, the belief that benzodiazepines gift a slim margin of safety between the anxiolytic impact and people inflicting unwanted aspect effects has prompted several researchers to judge new compounds within the hope that different anxiolytic medicine can have less undesirable effects. [3] The popularity of anxiolytic effects of non-benzodiazepine azapirone agents, which act as 5-HT_{1A} partial agonists, like buspirone, gepirone and ipsapirone and their therapeutic role in clinical anxiety and mood disorders has any targeted attention on the 5-HT_{1A} receptor. [4] Though the azapirone move with different neurochemical systems, like the dopaminergic and noradrenergic, they show nanomolar affinity for 5-HT_{1A} receptor sites. [5] However, the anxiolytic effects of azapirone follow a time course determined with antidepressants wherever therapeutic effects are delayed for 3-4 weeks, that is in contrast to the speedy effects determined with anxiolytic drug anxiolytics. [6] Thus, there's a requirement of strong anxiolytic compounds that have lesser aspect effects than benzodiazepines and additional immediate onset of action than presently out there 5-HT_{1A} receptor acting medicine. [7]

Tradescantia spathacea Swartz (syn. *Rhoeo discolor* L. H'er Hance, *Rhoeo spathacea* (Swartz) Stearn) is a plant of India that is in use in traditional medicine. This plant belongs to the Commelinaceae family. [8] In the Southeastern of Mexico, it is known as "Maguey Morado" (Purple Maguey) and the decoction of the leaves is daily free-consumed as curative of cancer, without existing

scientific evidence of such property. [9] It is known that the aqueous extract of *T. Spathacea* blocks the antiadrenergic action of bretylium [10] and is contraceptive in rats. [11] The extracts of *T. Spathacea* have been incorporated in cosmetics to improve the appearance of skin. [12] Some chemicals detected in *T. Spathacea* are flavonoids, anthocyanins, saponins, carotenoids, waxes, terpenoids and coumarinic and steroidal compounds. [13, 14] On the other hand, *T. Spathacea* ethanolic crude extract evaluated in an *in-vitro* system, showed antioxidative activities [15] and antimicrobial properties. [16]

Due to the absence of scientific reports *in-vivo* that corroborate the anxiolytic activity property of *T. Spathacea*, it is evident the importance of the exploration of this plant. They additionally assessed the spontaneous activity and neuromuscular coordination. Other than this, no model(s) for anxiety (except EPM) has been used for further evaluation of anxiolytic activity of *T. Spathacea* extract, to our knowledge. The aim of the present study was to explore the anti-anxiety activity of hydroalcoholic extract of *T. Spathacea* totally different animal models (EPM, open field (OF) test, light and dark test and social interaction test) of anxiety in mice.

MATERIALS AND METHODS

Animals

Swiss albino mice (males; 20–25 g) were used in the present study. Divided into 5 groups of 6 animals per cage were used. Animals were maintained under standard laboratory aseptic conditions (12-h light/dark cycle, 24 hrs). The food in the form of dry pellets and water is provided *ad libitum*. The animals were acclimatized to the laboratory conditions before experiments. Experimental protocol was approved by Institutional Animal Ethics Committee. Care of the animals was taken as per guidelines of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) Government of India. Experiment protocol was approved by Institutional Animal Ethics Committee (Reg No: 1648/PO/A/12/CPCSEA).

Plant Material

The plant *Tradescantia spathacea* was collected within the month of Feb. 2017 from medicinal gardens of Geethanjali

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Hepatoprotective Activity of *Talinum portulacifolium* forsk, Extract against Paracetamol Induced Hepatic Damage in Rats

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ABSTRACT

Talinum portulacifolium Forsk (family: Portulacaceae) has been traditionally used in Indian medicine as a result of its curative results of hepatitis, gonorrhoea and diabetes. No systemic study has been conducted on the protective effect of *Talinum portulacifolium* forsk to treat hepatic diseases. Therefore, claims can be made for the protective efficacy of *Talinum portulacifolium* forsk to treat hepatic diseases. The present study focused on investigating the role of methanolic extract of *Talinum portulacifolium* forsk (METP). METP at a dose level of 250mg/kg p.o and 500mg/kg p.o significantly produced ($p < 0.05$) hepatoprotection by decreasing the level of serum Aspartate amino transferase (AST), Alanine amino transferase (ALT), alkaline phosphatase (ALP) and Total serum bilirubin (SB) However, they significantly increased the level of glutathione (GSH) in a dose dependent manner. The effects of METP were comparable to that standard drug, silymarin. Histopathological observations confirmed the beneficial role of METP against Paracetamol (PCM) - induced liver injury in rats. The result suggests that the methanolic extract of *Talinum portulacifolium* forsk possesses significant potential as a hepatoprotective agent.

Keywords: Hepatoprotective, *Talinum portulacifolium* forsk, Paracetamol, Lipid Peroxidation, Glutathione radicals.

1. INTRODUCTION

Talinum portulacifolium forsk is an annual herb which belongs to the family Portulacaceae¹ that mainly grows in India, W. Peninsula, China and Ceylon. In India, it is found in Andhra Pradesh and Tamil Nadu¹. *T. Portulacifolium* forsk has been frequently used as an alternative, astringent to the bowels, worms, itching, and it is useful in gonorrhoea^{1, 2}. The juice of the leaves of the plant is used for the treatment of diabetes, cures ulcers and is traditionally used for the treatment of antioxidant²⁻⁴. No

scientific data are available to justify the traditional hepatoprotective potential of the plant.

Acetaminophen (N-acetyl-p-aminophenol, Paracetamol) is usually used as an analgesic and antipyretic drug⁵. Extensive use of PCM for therapeutic functions leads to severe hepatic damage. Toxic doses of PCM could induce changes in the morphology and function of liver mitochondria⁶. Formation of N-acetyl-p-benzoquinone imine (NAPQI) is responsible for liver injury through the depletion of glutathione (GSH) even as it binds to cellular proteins⁷. PCM induced hepatotoxicity is known to involve liver cytochrome P₄₅₀ (CYPs) together CYP2E1, CYP3A4, and CYP1A2 and it also inhibits the mitochondrial oxidative phosphorylation, reduces

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Method Development and Validation for Simultaneous Estimation of Raltegravir and Lamivudine by Using RP-HPLC in Bulk and Pharmaceutical Dosage Form

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Abstract: High performance liquid chromatography is at present one of the classiest tool of the analysis. The estimation of raltegravir and lamivudine was done by RP-HPLC. The Phosphate buffer was pH 3.0 and the mobile phase was optimized with consists of acetonitrile: phosphate buffer mixed in the ratio of 45:55 % v/v. Inertsil ODS 3V C₁₈ column (4.6 x 150 mm, 5 μm) or equivalent chemically bonded to porous silica particles was used as stationary phase. The detection was carried out by using PDA detector at 275 nm. The solutions were chromatographed at a constant flow rate of 1.0 ml/min. the linearity range of raltegravir and lamivudine were found to be from 150-450 μg/ml of raltegravir and 50-150 μg/ml of lamivudine. Linear regression coefficient was not more than 0.999. The values of % RSD are less than 2% indicating accuracy and precision of the method. The percentage recovery varies from 100.36 and 100.30% of raltegravir and lamivudine. LOD and LOQ were found to be within limit.

INTRODUCTION

Raltegravir (RAL) is chemically N-[(4-Fluorophenyl)methyl]-1, 6- dihydro-5-hydroxy-1-methyl-2[1-methyl-1-[(5- methyl-1, 3, 4-oxadiazol-2-yl) carbonyl] amino] ethyl]-6-oxo-4 pyrimidine carboxamide. It is a human immunodeficiency virus (HIV) integrase strand transfer inhibitor. [1, 2] The chemical structure of RAL was shown in figure-1. Researchers found proof that few analytical methods such as UV, [3-6] HPLC, [7-12] UPLC, [13] LC-MS [14-15] and HPTLC [12] methods have been reported in either alone or combined dosage form and biological sample.

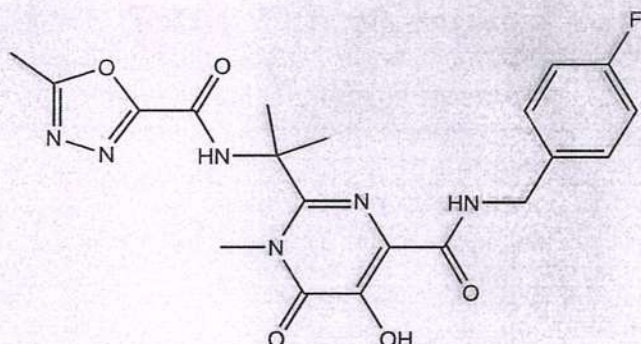


Figure 1: Chemical structure of raltegravir

Lamivudine (LAM) is chemically 4-amino-1-[(2R, 5S)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]-1,2-dihydropyrimidin-2-one. It is an HIV-1 nucleoside analogue reverse transcriptase and HBV polymerase inhibitor. [1, 16] The chemical structure of RAL was shown in Figure 2. Researchers reveals that very few analytical methods have been reported for the determination of LAM which includes UV, [17-22] HPLC, [17, 23-27] HPTLC [17, 28] and LC-MS [29, 30] are available for the estimation of LAM either individually or combined dosage form and biological sample.

Correspondingly, this manuscript described the optimization of an isocratic RP-HPLC method for the

routine quality control analysis of LAM and RAL in laboratory prepared binary mixture. In spite of that Development and optimization of isocratic RP-HPLC method is a tedious process that involves instantaneous determination of several factors. [31-36] It is recognized to provide risk-based understanding of the analytical as well as major factors affecting the performance of analytical method. [37-39] Furthermore, it provided thorough understanding of the possible risk and associated with interaction among the method variables, respectively. [40] Therefore, the aim of present study was to develop, optimize and validate sensitive and cost-effective RP-HPLC method for estimation of LAM and RAL in laboratory prepared binary mixtures.

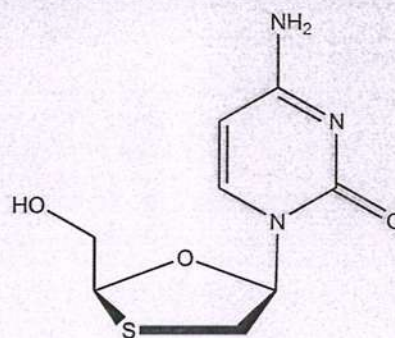


Figure 2: Chemical structure of lamivudine

MATERIALS AND METHODS

Chemicals

Pure drugs LAM (99.95%) and RAL (99.95%) were kindly supplied by Richer Pharmaceuticals, Prasanthinagar, Hyderabad, India and Emcure Pharmaceuticals, Pune, India respectively. The Pharmaceuticals LAM and RAL (DUTREBIS, Tablets: 150 mg lamivudine and 325.8 mg raltegravir potassium) were purchased from local pharmacy (Meda Pharmaceuticals/ Hyderabad, India). Dipotassium hydrogen phosphates (AR Grade), Ortho phosphoric acid (AR Grade), acetonitrile (HPLC Grade) were purchased from E. Merck (India) Ltd. Worli, Mumbai, India. The 0.45 μm nylon filters were purchased from Advanced Micro Devices Pvt. Ltd., Chandigarh, India.

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ANTIDEPRESSANT AND ANXIOLYTIC EFFECTS OF ALCOHOLIC EXTRACT FROM *TEPHROSIA PUMILA* (L.) PERS

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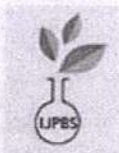
ABSTRACT

Tephrosia pumila (L.) Pers (Leguminosae (Fabaceae)), is an herbaceous climber that has been generally utilized in Indian traditional medicine for the treatment of different central nervous system (CNS) disorders. Nevertheless, the available scientific information about this species is rare and there are no reports identified with its conceivable impact on the CNS. In this work, the effects of ethanolic extract of *Tephrosia pumila* (L.) Pers (TPP) were assessed in rats utilizing behavioral tests sensitive to clinically effective antidepressant and anxiolytic effects compounds. The extract (200 and 400mg/kg), administered intraperitoneally, was able to decrease the immobility time of rats dose-dependently when subjected to both tail

suspension and forced swim tests for antidepressant activity and elevated Pluse maze test, actophotometer test for anxiolytic effect and the effects are comparable to that of standard drugs i.e., Diazepam (20mg/kg). Neither the extracts of TPP and Diazepam, at the doses tested, produced significant effects on locomotor activity when subjected to open field behavioral test. These results demonstrated that TPP had specifically antidepressant effects *in vivo*. In conclusion, the present study recommended that TPP extracts possessed potential antidepressant and anxiolytic effects which could be of therapeutic interest for using in the treatment of patients with depressive disorders.


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BIOASSAY GUIDED ISOLATION AND IDENTIFICATION OF THE ANTIOXIDANT CONSTITUENT FROM *HOLOSTEMMA* *ADA-KODIEN SHCULT*

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ABSTRACT

Holostemma ada-kodien shcult (Syn: *Holostemma annulare*) is a traditionally used in Indian herbal medicine. The objective of this study is to investigate the antioxidant activity of a bioassay-guided fractionation and its active components/compounds. Compounds were isolated by high performance thin layer chromatography (HPTLC) and preparative high performance liquid chromatography (pre-HPLC) and their structures were established by mass spectrometry (MS), Nuclear magnetic resonance (NMR) and fourier transform infrared spectroscopy (FT-IR) spectroscopic analyses. The antioxidant activity of ethyl acetate extract of *Holostemma ada-kodien shcult* and its fractions (CE, CF, EAF, MF and AF) were investigated using free radical scavenging activity, superoxide radical-scavenging assay, hydroxyl radical scavenging assay and assay of FeCl₃ power. The results revealed that the antioxidant activity of different fractionations such as CE and EAF showed prominent activity when compared with butylated hydroxytoluene (BHT) in a dose-dependent manner. Two compounds were isolated from Fraction -D among them quercetin and acacetin were reported for the first time in *H. ada-kodien*. Quercetin showed a more prominent antioxidant activity potential at concentrations (10, 20, 30, 40 and 50µg/mL) when compared with the other compounds. In conclusion the ethyl acetate fraction proved to have significant therapeutic potential for antioxidant effect.

KEYWORDS: Antioxidant activity, *Holostemma ada-kodien shcult*, Butylated Hydroxytoluene, Quercetin, Acacetin



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Method Development and Validation for Simultaneous Estimation of Dasatinib and Lenvatinib by Using RP-HPLC in Pharmaceutical Dosage Form

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Abstract: High performance liquid chromatography is at present one of the most sophisticated tool of the analysis. The estimation of dasatinib and lenvatinib was done by RP-HPLC. The phosphate buffer was pH 3.0 and the mobile phase was optimized which consists of methanol: phosphate buffer mixed in the ratio of 70:30 % v/v. Inertsil ODS C₁₈ column (4.6 x 150 mm, 5 μm) or equivalent chemically bonded to porous silica particles was used as stationary phase. The detection was carried out using PDA detector at 260 nm. The solutions were chromatographed at a constant flow rate of 0.8 ml/min. The linearity range of dasatinib and lenvatinib were found to be from 100-500 μg/ml of dasatinib and 1-5 μg/ml of lenvatinib. Linear regression coefficient was not more than 0.999. The values of % RSD are less than 2% indicating accuracy and precision of the method. The percentage recovery varies from 98-102% of dasatinib and lenvatinib. LOD and LOQ were found to be within limit.

INTRODUCTION

Dasatinib is an oral medication used for treating chronic myeloid leukemia and acute lymphoblastic leukemia. It is classified as a kinase inhibitor. [1] Kinase inhibitors prevent the growth of tumors by reducing the action of proteins that control cell division, growth and survival. [2] These proteins are usually present in larger quantities or are more active in cancer cells. By reducing the activity of these proteins, growth and survival of cancer cells are reduced. The chemical name for dasatinib is N-(2-Chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)-1-piperazinyl]-2-methyl-4-pyrimidinyl] amino]-5-thiazolecarboxamide monohydrate (Figure 1). The molecular formula is C₂₂H₂₆ClN₇O₂S.H₂O, which corresponds to a formula weight of 506.02 (monohydrate). [3] The anhydrous free base has a molecular weight of 488.01. Dasatinib is a white to off-white powder and has a melting point of 280°- 286°C. The drug substance is insoluble in water and slightly soluble in ethanol and methanol. [4] Dasatinib is an inhibitor of multiple tyrosine kinases. [1-2] Researchers found proof that few analytical methods such as HPLC, [5-6] LC-MS [7-11] and UPLC [12] methods have been reported for the estimation of dasatinib.

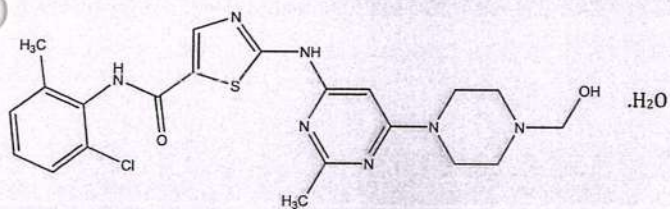


Figure 1: Chemical structure of dasatinib

Lenvatinib is a multiple receptor tyrosine kinase (RTK) inhibitor indicated for the treatment of thyroid cancer. Lenvatinib restrains kinase activities of vascular

endothelial growth factor receptors. It also simultaneously restrains other receptors involved in the tumour angiogenesis and proliferation of thyroid cancer including fibroblast growth factor and the platelet derived growth factor receptor alpha. [13] Lenvatinib is chemically known as 4-[3-chloro-4-(cyclopropyl carbamoyl amino)phenoxy]-7-methoxyquinoline-6-carboxamide is shown in Figure 2. Researchers reveals that very few analytical methods have been reported for the determination of lenvatinib which includes high performance liquid chromatography, [14] Liquid chromatography-mass spectroscopy [15-17] and pharmacokinetics studies. [18-22]

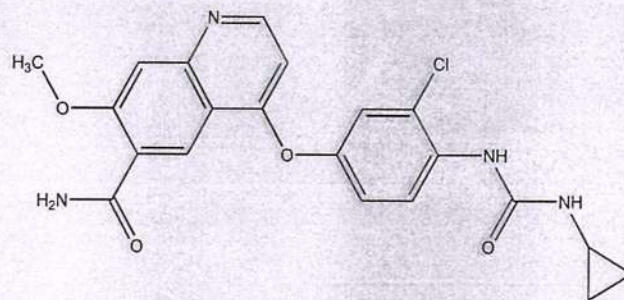


Figure 2: Chemical structure of lenvatinib

Literature review reveals that no analytical methods have been reported for the determination of simultaneous estimation of dasatinib and lenvatinib drugs which includes RP-HPLC in pharmaceutical dosage form. The present study was aimed to develop a simple and accurate RP-HPLC method for the estimation of dasatinib and lenvatinib drug according to ICH guidelines. [23-24]

MATERIALS AND METHODS

Chemicals

Dasatinib was purchased from Mylon Laboratory, Hyderabad, Telangana, India. Lenvatinib was purchased from Cipla, Hyderabad, Telangana, India. Dipotassium Hydrogen Phosphates (AR Grade), Ortho Phosphoric Acid (AR Grade), Acetonitrile (HPLC Grade) were purchased from E. Merck (India) Ltd., Worli, Mumbai, India. The 0.45 μm nylon filters were purchased from Advanced Micro Devices Pvt. Ltd., Chandigarh, India.

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Antidepressant and Anxiolytic Effects of Alcoholic Extract from *Tephrosia maxima* (L.) Pers

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Abstract: *Tephrosia maxima* (L.) Pers (Leguminosae (Fabaceae)), is an herbaceous climber that has been generally utilized in Indian traditional medicine for the treatment of different central nervous system (CNS) disorders. Nevertheless, the available scientific information about this species is rare and there are no reports identified with its conceivable impact on the CNS. In this work, the effects of ethanolic extract of *Tephrosia maxima* (L.) Pers (TMP) were assessed in rats utilizing behavioral tests sensitive to clinically effective antidepressant and anxiolytic effects compounds. The extract (200 and 400 mg/kg), administered intraperitoneally, was able to decrease the immobility time of rats dose-dependently when subjected to both tail suspension and forced swim tests for antidepressant activity. Anxiolytic effect to determine by elevated plus maze test and actophotometer test models and the effects are comparable to that of standard drugs i.e., Diazepam (20 mg/kg). Neither the extracts of TMP and diazepam at the doses tested, produced significant effects on locomotor activity when subjected to open field behavioral test. These results demonstrated that TMP had specifically antidepressant effects *in-vivo*. In conclusion, the present study recommended that TMP extracts possessed potential antidepressant and anxiolytic effects which could be of therapeutic interest for using in the treatment of patients with depressive disorders.

INTRODUCTION

As indicated by the World Health report, [1] approximately 450 million people suffer from a mental or behavioral disorder. This amounts to 12.3% of the global burden of disease and will rise to 15% by 2020. [2, 3] Depression is the most prevailing mental disorder and depression is recognized to be symptomatically, psychologically and biologically heterogeneous. [4] The disorder was characterized by apathy, loss of energy, retardation of thinking and activity, as well as profound feelings of gloominess, despair and suicidal ideation. [5] In spite of the accessibility of antidepressant drugs like tricyclic antidepressants, selective reversible inhibitors of monoamine oxidase-A (MAO-A), selective serotonin reuptake inhibitors (SSRIs) and selective noradrenaline reuptake inhibitors (SNRIs), depression maintain to be a major medical problem. [6] Fundamental neuroscience offers the promise of improving our understanding of disease pathophysiology, identifying novel mechanisms that can be targeted by more effective pharmacotherapies and screening of herbal sources of drugs. These considerations implicate the search for new antidepressant agents that have a fast onset of action, with less side effects and a wider safety margin. Various plants are being utilized in complementary and alternative medicines for management of mood disorders. [7]

The plants of *Tephrosia maxima* (L.) Pers (TMP) (Family : Leguminosae (Fabaceae)) [8, 9] was chosen for evaluating its anxiolytic and antidepressant activity due to its traditional use in the management of anxiety, stress, insomnia, hysteria, skin inflammation, cough and fever. The

literature reports that antimicrobial activities, antiprotozoal activity, anticancer activity, anti-inflammatory activity. [10] The experimental documents reports that chemical constituents in TMP include flavonoids and alkaloids. [11-13] A few reports have pointed out the flavonoids and alkaloids as the bioactive constituents of TMP, one of the species of *Tephrosia* that have been extensively studied chemically and biologically. [14] So far there has been no scientific report in literature about the antidepressant activity (in experimental animal models) of this plant. Therefore, the present study has been undertaken to investigate the effect of ethanolic extract of *Tephrosia maxima* (L.) Pers depression in rats.

MATERIALS AND METHODS

Plant Material

The plants of *Tephrosia maxima* (L.) Pers (TMP) was gathered from Ranga Reddy dist, Telangana State in the month of August and was identified and authenticated from Department of Botany Osmania University, Hyderabad, Telangana State. The plant material was cleaned, reduced to small fragments, air dried under shade at room temperature and coarsely powdered in a blender. The powdered material was stored or taken up for extraction process.

Drugs and Chemicals

Diazepam (Nicholas Piramal Ltd, India) and Ethanol (Changshu Yangyuan Chemicals, China.) were used reference standards for antidepressant activity.

Experimental Animals

Healthy adult albino wistar rats weighing 200-250 grams of either sex were chosen for the study. Animals were housed in appropriate cages in uniform hygienic conditions and fed with standard pellet diet (Amrul Laboratory Animal Diet) and water *ad-libitum*. They were fasted overnight before the day of test. Animals were housed within the departmental animal house and the room temperature was maintained at 27°C. Animal studies had approval of IAEC. An authority regulating animal experiments and was

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Formulation and Evaluation of Montelukast Sodium Fast Dissolving Tablets

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Abstract: The demand for fast dissolving tablet (FDT) has been growing during the last decade especially for elderly and children who have swallowing difficulties. Montelukast is a leukotriene receptor antagonist (LTRA), anti-asthmatic used for the maintenance treatment of asthma and to relieve symptoms of seasonal allergies. It is effective in relieving nasal congestion, particularly in patients with allergic rhinitis. In present work an attempt has been made to prepare fast dissolving tablets of montelukast sodium with increased rate of dissolution may leads to increase bioavailability. In present work fast dissolving tablet of montelukast sodium prepared using croscarmellose sodium, sodium starch glycolate and kollidon cl-m as superdisintegrants by direct compression method. The tablets were evaluated for various parameters like weight variation, hardness, friability, *in-vitro* dispersion time, drug-polymer interaction, drug content water absorption ratio, wetting time, *in-vitro* drug release. The tablet prepared by direct compression method passes weight variation was found in the range 113 to 121 mg which is below $\pm 7.5\%$, hardness, 3.69 ± 0.25 to 3.51 ± 0.27 kg/cm², percentage friability of 0.22 to 0.37%, *in-vitro* disintegration time of 51 to 17 sec, drug content uniformity was in between 98.23 to 98.75%, water absorption ratio were found between 61 to 38% and wetting time between 58.23 to 21.12 seconds, maximum drug release 87.75 to 98.75% shows within 10 min. FTIR study showed that there was no drug interaction with formulation additives of the tablet.

INTRODUCTION

Oral administration is the most popular route due to ease of ingestion, pain avoidance, versatility (to accommodate various types of drug candidates) and most importantly, patient compliance. Also, solid oral delivery systems do not require sterile conditions and therefore, less expensive to manufacture. Several novel technologies for oral delivery have recently become available to address the physicochemical and pharmacokinetic characteristics of drugs, while improving patient compliance.^[1]

The most desirable formulation for use by the elderly is one that is easy to swallow and easy to handle. Taking these requirements in to consideration, attempts have been made to develop a rapid dissolving tablet. Since such a tablet can disintegrate in only a small amount of water in the oral cavity, it is easy to take for any age patient, regardless of time or place. For example, it can be taken anywhere at any time by anyone who do not have easy access to water. It is also easy to dose the aged, bed-ridden patients or infants who have problems in swallowing tablets and capsules. Recently, many companies have researched and developed various types of fast-disintegrating dosage form technologies with the potential to accommodate various physicochemical, pharmacokinetic and pharmacodynamic characteristics of drugs.^[2,3]

Asthma is a chronic inflammation of the bronchial tubes (airways) that cause swelling and narrowing (constriction) of the airways. The result is difficulty breathing. The symptoms of asthma vary from person to person and in any individual from time to time. It is important to remember that many of these symptoms can be subtle and similar to those seen in other conditions. All of the symptoms mentioned below can be present in other respiratory and

sometimes, in heart conditions. This potential confusion makes identifying the settings in which the symptoms occur and diagnostic testing very important in recognizing this disorder.^[4]

Therefore, in the present study an attempt was made to formulate Fast dissolving tablets of montelukast sodium is (R,E)-2-[1-({[(1R)-1-{3-[(E)-2(7-chloroquinoline-2-yl) ethynyl]phenyl} -3-[2-(2hydroxypropan-2-yl)phenyl]propyl] sulfanyl)methyl] cyclopropanyl] acetic acid. Montelukast is a leukotriene receptor antagonist (LTRA), anti-asthmatic used for the maintenance treatment of asthma and to relieve symptoms of seasonal allergies.

MATERIALS AND METHODS

Montelukast sodium was supplied by Ranbaxy lab. Ltd. New Delhi, India. Sodium starch glycolate, Croscarmellose sodium and Kollidon cl-m were procured from S D fine chemical Ltd. Mumbai. All solvents used were of analytical grade.

Drug-Excipients Compatibility Study by FTIR

The spectrum analysis of pure drug and physical mixture of drug and different excipients which are used for preparation of tablets was studied by FTIR. FTIR spectra were recorded by preparing potassium bromide (KBr) disks using a Shimadzu Corporation (Japan) facility (model - 8400S). Potassium bromide (KBr) disks were prepared by mixing few mg of sample with potassium bromide by compacting in a hydrostatic press under vacuum at 6-8 tons pressure. The resultant disc was mounted in a suitable holder in IR spectrophotometer and the IR spectrum was recorded from 399.193 cm⁻¹ to 4000.6 cm⁻¹ in a scan time of 12 minutes. The resultant spectrum was compared for any spectral changes. They were observed for the presence of characteristic peaks for the respective functional group in the compound.^[5,6]

Preparation of Mixed Blend of Drug and Excipients

All the ingredients were passed through mesh no #60. Required quantity of each ingredient was taken for each

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Development and Characterization of Colon pH Triggered Multiparticulate Drug Delivery System for Ulcerative Colitis

Shiva Kumar Yellanki^{1*}, B Mamatha²

Abstract: The purpose of the present study was to develop and characterize mesalamine microsphere to target colon for ulcerative colitis. Mesalamine is a drug with low solubility so in order to increase its solubility the solid dispersions of mesalamine were prepared by using kneading method with three different carriers, poly vinyl pyrrolidone (PVP K-30), poly ethylene glycol (PEG 4000) and β -cyclodextrin and evaluated for solubility determination. The solid dispersion (F15) drug: β -cyclodextrin (1:3) was selected for further formulation of microspheres due to its high solubility (4.268 \pm 0.031 mg/ml). The microspheres were prepared by using solvent evaporation method. The polymers used were Eudragit L 100 and Eudragit S 100 and glutaraldehyde is used as cross linking agent. The prepared formulations of microspheres were characterized for various parameters like particle size analysis, Scanning electron microscopy, micromeritic properties, percentage yield, drug content, entrapment efficiency, *in-vitro* release studies and stability studies. The micromeritic properties like angle of repose, Hausner's ratio and Carr's index showed good flow properties for all the formulations. The particle size of all formulations was in the range of 203 \pm 14 to 437 \pm 24 μ m. The *in-vitro* studies revealed that the M6 formulation showed the drug release of 95.12% in a controlled manner up to 14 hrs and the best fit model was Hixson and Crowell which shows that drug release is mainly by dissolution.

INTRODUCTION

Delivery of drugs to the colon, via Oral route is valuable in treating diseases of the colon (Ulcerative colitis, amoebiasis, crohn's disease, carcinoma and infections) where high local concentration of drug can be achieved with fewer side effects and the most critical challenge in one such approach is to protect the dosage form in the upper GIT and also to prevent unnecessary systemic absorption. [1] By targeting the drug to the colon, the maximum concentration of drug reaches and increases the residence time of drug in the colon. [2] The various approaches in targeting the drug to the colon include pH dependent system, time dependent system, microbially triggered approach. [3] The newly developed approaches include pressure controlled DDS, osmotic controlled DDS, CODES™ system, Ticking capsule, Enterion capsule etc.

Many techniques are available for enhancing the dissolution characteristics of slightly water soluble drugs such as Micronization, formation of solvates, complexes, adsorbates, solid dispersion. Solid dispersion refers to a group of solid products consisting of atleast two different components generally hydrophilic carrier and a hydrophobic drug. [4] The different methods of preparation of solid dispersions are Solvent evaporation method, fusion/ melting method, Kneading method, Physical mixture method, super critical fluid technology. [5]

Microencapsulation technique has been mostly used for the lipophilic drugs since hydrophilic drugs show low loading efficiency. [6] Microspheres can be defined as solid approximately spherical particles, ranging in size from 1 to 1000 μ m. [7]

Ulcerative colitis is a form of IBD which is a chronic inflammatory disorder of the colonic mucosa, which starts

in the rectum and generally extends proximally in a continuous manner through part of, or the entire, colon. [8] The various drugs used for the treatment of ulcerative colitis are aminosalicylates, corticosteroids, immuno suppressants, mono clonal antibodies. [9] Mesalamine is a 5-Amino salicylic acid, an anti-inflammatory drug used for the treatment of Ulcerative colitis. It is the active moiety of sulfasalazine. Its $t_{1/2}$ is 5 hours and it is 20 to 30% orally absorbed.

The aim of the present study was to formulate and evaluate the multiparticulate DDS of Mesalamine. Firstly the solid dispersion of mesalamine was prepared by using PVP K-30, PEG 4000, β -Cyclodextrin to enhance the solubility. The solubility was determined for all the formulations. The formulations with highest solubility were used to prepare microspheres by using Eudragit L 100 and Eudragit S 100 polymers and were characterized for various parameters.

MATERIALS AND METHODS

The drug Mesalamine, β -cyclodextrin and Glutaraldehyde was purchased from ALM Laboratories, Warangal. Eudragit L 100 and Eudragit S 100 were obtained as a gift sample from Evonik, Degussa, Mumbai. PEG 4000 was gifted by Tablets India, Chennai. PVP K-30 from Priyadarshini College of Pharmaceutical Sciences, Ghatkesar. All solvents used were of analytical grade.

Preparation of Solid Dispersion

Mesalamine and the various water soluble carriers (PVP K-30, PEG4000 and β Cyclodextrin) were weighed in different ratio and transferred to mortar were taken and mixed for 5 min and then kneaded for 45 min using hot water. To maintain paste like consistency sufficient hot water was added. The paste was then dried in hot air oven at 45°C for 24 hours. The dried products were crushed, pulverized and passed through sieve No. 60. The prepared dispersions were stored in glass vials and the solubility of the solid dispersions was determined. The ratios of solid dispersion were shown in Table 1.

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Anti-Anxiety Activity of *Tradescantia spathacea* Assessed Using Different Experimental Anxiety Models

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Abstract: The point of present examination was to investigate the anti-anxiety activity of hydroalcoholic extracts of *Tradescantia spathacea* utilizing different animal models (elevated plus maze, open field test, light and dark test and social interaction test) of anxiety in mice. Diazepam (0.5 mg/kg) was utilized as the standard and measurement of hydroalcoholic extract of *T. spathacea* (50, 100 and 200 mg/kg) was chosen according to OECD rules. Results recommended that concentrate of *T. spathacea* at 100 and 200 mg/kg dose produced anti-anxiety effects almost similar to diazepam and at 50 mg/kg dosage did not create against anti-anxiety activity on any of the paradigm used. Additionally ponders are expected to recognize the anxiolytic mechanism(s) and the phytoconstituents responsible for the observed central effects of the hydroalcoholic extract of *T. spathacea*.

INTRODUCTION

Anxiety affects simple fraction of the whole population worldwide and has become a crucial space of analysis interest in pharmacology throughout this decade. [1] Benzodiazepines are the most important category of compounds utilized in anxiety and that they have remained the foremost unremarkably prescribed treatment for anxiety. [2] However, the belief that benzodiazepines gift a slim margin of safety between the anxiolytic impact and people inflicting unwanted aspect effects has prompted several researchers to judge new compounds within the hope that different anxiolytic medicine can have less undesirable effects. [3] The popularity of anxiolytic effects of non-benzodiazepine azapirone agents, which act as 5-HT_{1A} partial agonists, like buspirone, gepirone and ipsapirone and their therapeutic role in clinical anxiety and mood disorders has any targeted attention on the 5-HT_{1A} receptor. [4] Though the azapirone move with different neurochemical systems, like the dopaminergic and noradrenergic, they show nanomolar affinity for 5-HT_{1A} receptor sites. [5] However, the anxiolytic effects of azapirone follow a time course determined with antidepressants wherever therapeutic effects are delayed for 3-4 weeks, that is in contrast to the speedy effects determined with anxiolytic drug anxiolytics. [6] Thus, there's a requirement of strong anxiolytic compounds that have lesser aspect effects than benzodiazepines and additional immediate onset of action than presently out there 5-HT_{1A} receptor acting medicine. [7]

Tradescantia spathacea Swartz (syn. *Rhoeo discolor* L. H'er Hance, *Rhoeo spathacea* (Swartz) Stearn) is a plant of India that is in use in traditional medicine. This plant belongs to the Commelinaceae family. [8] In the Southeastern of Mexico, it is known as "Magüey Morado" (Purple Magüey) and the decoction of the leaves is daily free-consumed as curative of cancer, without existing

scientific evidence of such property. [9] It is known that the aqueous extract of *T. Spathacea* blocks the antiadrenergic action of bretylium [10] and is contraceptive in rats. [11] The extracts of *T. Spathacea* have been incorporated in cosmetics to improve the appearance of skin. [12] Some chemicals detected in *T. Spathacea* are flavonoids, anthocyanins, saponins, carotenoids, waxes, terpenoids and coumarinic and steroidal compounds. [13, 14] On the other hand, *T. Spathacea* ethanolic crude extract evaluated in an *in-vitro* system, showed antioxidative activities [15] and antimicrobial properties. [16]

Due to the absence of scientific reports *in-vivo* that corroborate the anxiolytic activity property of *T. Spathacea*, it is evident the importance of the exploration of this plant. They additionally assessed the spontaneous activity and neuromuscular coordination. Other than this, no model(s) for anxiety (except EPM) has been used for further evaluation of anxiolytic activity of *T. Spathacea* extract, to our knowledge. The aim of the present study was to explore the anti-anxiety activity of hydroalcoholic extract of *T. Spathacea* totally different animal models (EPM, open field (OF) test, light and dark test and social interaction test) of anxiety in mice.

MATERIALS AND METHODS

Animals

Swiss albino mice (males; 20–25 g) were used in the present study. Divided into 5 groups of 6 animals per cage were used. Animals were maintained under standard laboratory aseptic conditions (12-h light/dark cycle, 24 hrs). The food in the form of dry pellets and water is provided *ad libitum*. The animals were acclimatized to the laboratory conditions before experiments. Experimental protocol was approved by Institutional Animal Ethics Committee. Care of the animals was taken as per guidelines of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) Government of India. Experiment protocol was approved by Institutional Animal Ethics Committee (Reg No. 164B/PO/A/12/CPCSEA).

Plant Material

The plant *Tradescantia spathacea* was collected within the month of Feb. 2017 from medicinal gardens of Geethanjali

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STABILITY INDICATING RP-LC ASSAY METHOD FOR CARISOPRODOL

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ABSTRACT

Objective: A reverse phase stability-indicating HPLC method was developed for the determination of Carisoprodol in pharmaceutical dosage forms. The chromatographic elution was achieved on C18, 250 mm × 4.6 mm, 5-µm particle size column.

Methods: The mobile phase contains a mixture of water and acetonitrile in ratio of 60:40 v/v. The flow rate was 1.0 ml min⁻¹ and was detected by Refractive index detector.

Results: The method was proven to be linear over a range of 1 to 4 mg/ml with a mean correlation coefficient of 0.99998. The %mean recovery is in the range of 100.55% to 101.11% and %RSD was less than 1.0% between preparations. The % RSD for Assay results of initial sample preparation in different intervals of 0hr, 24 h, 30 h and 48 h was less than 1.0%. To establish stability-indicating capability of the method, drug product was subjected to the stress conditions of acid, base, oxidative, hydrolytic, thermal and photolytic degradation. The degradation products were well resolved from Carisoprodol.

Conclusion: The developed method was validated as per international ICH guidelines with respect to specificity, linearity, accuracy, precision and robustness.

Keywords: Carisoprodol, Stability-Indicating HPLC Method, Stress Conditions

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INTRODUCTION

Carisoprodol is chemically (1-Methylethyl) carbamic acid 2-(((amino-carbonyl)oxy)methyl)-2-methyl pentyl ester marketed under the brand name soma since 1959 and is used as skeletal muscle relaxant [1-2]. It belongs to the class of carbamates and produces effects associated with barbiturates [3-4]. Mechanism of the activity of carisoprodol of relieving discomfort associated with acute painful musculoskeletal condition has not been clearly known. In animal studies, muscle relaxation induced by carisoprodol was found to be associated with altered inter-neuronal activity in the spinal cord and in the descending reticular formation of the brain, resulting in blocking pain sensations between the nerves and the brain [4].

Literature review reveals few reports for carisoprodol assay. They include liquid chromatography-tandem mass spectrometry [5-6], gas chromatography [7-8], high-performance thin-layer chromatography [9] and homogeneous immunoassay [10]. All these analytical techniques have been employed for carisoprodol determination in biological samples such as urine and serum of equine and urine and plasma of human. Furthermore the reported methods are cumbersome and require sophisticated equipment. Drugs in bulk and pharmaceutical dosage forms can be analysed in quality control laboratories and cost effective methods like uv/visible spectroscopic method or HPLC with UV/Visible detector. Three extractive spectrophotometric methods for the quantification of carisoprodol in pure and pharmaceutical formulations were determined by Ravi *et al.* [11], which were based on formation of colored chloroform extractable ion-pair complexes with dyes like bromocresol green, bromothymol blue and bromophenol blue in acidic medium. However, these methods suffer from one or the other disadvantage such as extraction of ionpair complex, poor sensitivity, unstable color and rigid experimental conditions.

Assay of carisoprodol and its impurities with 2-methyl-2-propylpropane-1, 3-diyl dicarbamate and N-isopropyl-2-methyl-2-propyl-3-hydroxy propyl carbamate using UV-HPLC was presented by Rohith *et al.* [12], but has drawbacks in terms of precision, accuracy, retention time (16.855 min) and run time (50 min). In

addition, the gradient mode of elution increases the use of solvents and the method is more concentrated on the characterization of impurities rather than the assay of carisoprodol. The main objective of the present investigation is to develop and validate a simple, sensitive, cost effective, selective and reproducible stability indicating HPLC method with UV detector for quantitative determination of carisoprodol and also to study the stability of carisoprodol. The present study is aimed to develop a reverse phase HPLC assay which is specific, precise, linear and accurate that can be used for routine analysis and stability study.

MATERIALS AND METHODS

Materials

HPLC grade acetonitrile was purchased from Merck India Limited, Mumbai, India. Analytical grade potassium dihydrogen phosphate, hydrochloric acid, sodium hydroxide and hydrogen peroxide were from Sdfine-Chem limited, Mumbai, India. Milli-Q-water was used throughout the process. The 2-Methyl-2-propyl-1,3-prpanediol; Carisoprodol Impurity A CRS Lot no: 1; Carisoprodol Sample and USP Carisoprodol RS were donated by Lee pharma as gift sample.

Instrumentation

Separation and quantization of carisoprodol was performed on a High Pressure Liquid Chromatography (Waters, HPLC) equipped with 2345 Quaternary gradient pump and 2414 RI detector. The HPLC data were processed using Empower soft ware.

Chromatographic conditions

The present study was aimed to carry out by reversed-phase chromatography to determine Carisoprodol; the column used was Sunfire-C₁₈ column (250 mm × 4.6 mm, 5 µm) at 30°C, mobile phase was prepared by mixing water with acetonitrile in the ratio 60:40v/v and refractive index detector at 30°C. The mobile phase was delivered at a flow rate of 1.0 ml per min. The mobile phase was filtered through a Millipore membrane filter paper and sonicated for 15 min for degassing prior to use.

Method Development and Validation for Simultaneous Estimation of Raltegravir and Lamivudine by Using RP-HPLC in Bulk and Pharmaceutical Dosage Form

Sunil Junapudi^{1*}, P Nagaraju¹, K Ganesh¹, M Nagesh¹

Abstract: High performance liquid chromatography is at present one of the classiest tool of the analysis. The estimation of raltegravir and lamivudine was done by RP-HPLC. The Phosphate buffer was pH 3.0 and the mobile phase was optimized with consists of acetonitrile: phosphate buffer mixed in the ratio of 45:55 % v/ v. Inertsil ODS 3V C₁₈ column (4.6 x 150 mm, 5 μm) or equivalent chemically bonded to porous silica particles was used as stationary phase. The detection was carried out by using PDA detector at 275 nm. The solutions were chromatographed at a constant flow rate of 1.0 ml/min. the linearity range of raltegravir and lamivudine were found to be from 150-450 μg/ml of raltegravir and 50-150 μg/ml of lamivudine. Linear regression coefficient was not more than 0.999. The values of % RSD are less than 2% indicating accuracy and precision of the method. The percentage recovery varies from 100.36 and 100.30% of raltegravir and lamivudine. LOD and LOQ were found to be within limit.

INTRODUCTION

Raltegravir (RAL) is chemically N-[[[4-Fluorophenyl]methyl]-1, 6- dihydro-5-hydroxy-1-methyl-2[[1-methyl-1-[[[5- methyl-1, 3, 4-oxadiazol-2-yl] carbonyl] amino] ethyl]-6-oxo-4 pyrimidine carboxamide. It is a human immunodeficiency virus (HIV) integrase strand transfer inhibitor. [1, 2] The chemical structure of RAL was shown in figure-1. Researchers found proof that few analytical methods such as UV, [3-6] HPLC, [7-12] UPLC, [13] LC-MS [14-15] and HPTLC [12] methods have been reported in either alone or combined dosage form and biological sample.

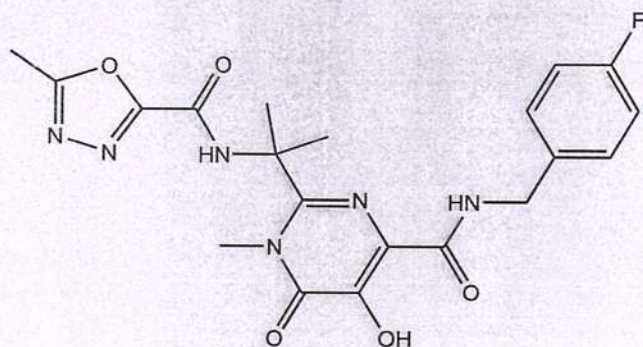


Figure 1: Chemical structure of raltegravir

Lamivudine (LAM) is chemically 4 amino 1 [(2R, 5S) 2 (hydroxymethyl)-1,3-oxathiolan-5-yl]-1,2-dihydropyrimidin-2-one. It is an HIV-1 nucleoside analogue reverse transcriptase and HBV polymerase inhibitor. [4, 16] The chemical structure of RAL was shown in Figure 2. Researchers reveals that very few analytical methods have been reported for the determination of LAM which includes UV, [17-22] HPLC, [17, 23-27] HPTLC [17, 28] and LC-MS [29, 30] are available for the estimation of LAM either individually or combined dosage form and biological sample.

Correspondingly, this manuscript described the optimization of an isocratic RP-HPLC method for the

routine quality control analysis of LAM and RAL in laboratory prepared binary mixture. In spite of that Development and optimization of isocratic RP-HPLC method is a tedious process that involves instantaneous determination of several factors. [31-36] It is recognized to provide risk-based understanding of the analytical as well as major factors affecting the performance of analytical method. [37-39] Furthermore, it provided thorough understanding of the possible risk and associated with interaction among the method variables, respectively. [40] Therefore, the aim of present study was to develop, optimize and validate sensitive and cost-effective RP-HPLC method for estimation of LAM and RAL in laboratory prepared binary mixtures.

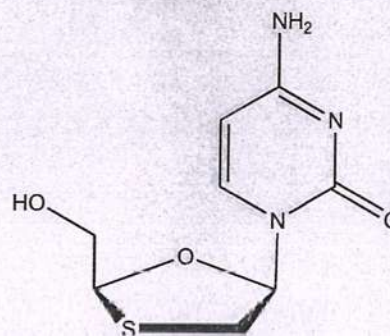


Figure 2: Chemical structure of lamivudine

MATERIALS AND METHODS

Chemicals

Pure drugs LAM (99.95%) and RAL (99.95%) were kindly supplied by Richer Pharmaceuticals, Prasanthinagar, Hyderabad, India and Emcure Pharmaceuticals, Pune, India respectively. The Pharmaceuticals LAM and RAL (DUTREBIS, Tablets: 150 mg lamivudine and 325.8 mg raltegravir potassium) were purchased from local pharmacy (Meda Pharmaceuticals/ Hyderabad, India). Dipotassium hydrogen phosphates (AR Grade), Ortho phosphoric acid (AR Grade), acetonitrile (HPLC Grade) were purchased from E. Merck (India) Ltd. Worli, Mumbai, India. The 0.45 μm nylon filters were purchased from Advanced Micro Devices Pvt. Ltd., Chandigad, India.

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**RUTF (READY-TO-USE THERAPEUTIC FOODS) TREATMENT FOR KWASHIORKOR****Lahari Samudrala*¹, Pooja Agarwal², T. Ramya Krishna³ and B. Priyanka⁴**

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ABSTRACT

Kwashiorkor, also known as “edematous malnutrition” is a nutritional disorder most often seen in regions experiencing extreme scarcity of food. It is a form of malnutrition caused by a lack of protein in the diet. These conditions are responsible for a lack of food, which leads to malnutrition. Kwashiorkor is very rare in children in the United States. The World Health Organization (WHO) defines malnutrition as “the cellular imbalance between the supply of nutrients and energy and the body's demand for them to ensure growth, maintenance, and specific functions. If kwashiorkor is identified early it can be treated with either specially formulated milk-based feeds or ready-to-use therapeutic food (RUTF). RUTF is typically made up of peanut butter, milk powder, sugar, vegetable oil, and added vitamins and minerals. More intensive

treatment in hospital will be needed in severe cases or where there are already complications, such as infections. Hospital treatment will usually involve: Treating or preventing low blood glucose. Keeping the person warm – kwashiorkor can make it harder to generate body heat. Treating dehydration with specially formulated rehydration solution. Treating infections with antibiotics – kwashiorkor greatly increases the risk of infections. Treating vitamin and mineral deficiencies – vitamin supplements are usually included in the special milks or RUTF.

KEYWORDS: Protein Deficiency, Malnutrition, Kwashiorkor, Therapeutic Foods.

KWASHIORKOR

Kwashiorkor, also known as “edematous malnutrition” is a nutritional disorder most often seen in regions experiencing extreme scarcity of food. It is a form of malnutrition caused by a

GERMANY PATENT SYSTEM – AN OVERVIEW

Available online at www.ijdra.com

REVIEW ARTICLE

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ABSTRACT

Patent is one of the intellectual property rights, by which the innovator gets exclusive rights or legal monopoly granted to an individual or a firm to make use or sell or reproduce and excluding others from doing so. The Germany patent act came into existence on June 21st 1976, which was taken from the European patent convention of October 5, 1973. Germany stands in 2nd place in filing patents and it shares 16% of total application in 2016 and 25,086 application are filed, grant of patent applications are 18,728. In this paper discussed about Germany patent system.

Keywords: Germany, Patent filing, Monopoly rights, Federal court.

INTRODUCTION

Patent is one of the intellectual property right, by which the innovator gets exclusive rights or legal monopoly granted to an individual or a firm to make use or sell or reproduce and excluding others from doing so.(1,2) The Germany patent act came into existence on June 21st 1976, which was taken from the European patent convention of October 5, 1973.(3) Germany stands in 2nd place in filing patents and it shares 16% of total application in 2016 and 25,086 application are filed, grant of patent applications are 18,728. In this paper discussed about Germany patent system. (4)

Germany patent law came into effect from June 21st 1976, is has become a member of PCT on 24th January 1978. (5) It was stipulated in the patent law in 25 May 1877 and named as the Kaiserliches Patentamt (imperial patent office) started to operate in Berlin on July 1st 1877 and the first Germany patent granted for the "production process of red ultramarine color" invented by Johann Zeltner of Numberger Ultramarine Fabrik. After a lot of changes now, it became as Deutsches patent-und markenam (DPMA) on November 1st 1998. It celebrated its 60th anniversary in Munich on October 1st 2009.(6) German intellectual property law mainly consists of the Copyright Act (UrhG),

Patent Act (PatG), Trademark Act (MarkenG), Utility Model Act (GebrMG) and Design Rights Act (GeschMG), flanked by some provisions of the Civil Code (BGB) and the Act Against Unfair Competition (UWG).(7) Generally, Patent term is 20 years.

GERMANY PATENT SYSTEM

A patent grants exclusive rights to a new process (or) product (or) invention in order to reproduce, sell, make etc., to the inventor. It is generally governed by Germany patent system and European patent convention. Germany patent system is one of the few system in this patent infringement and patent validity are dealt with different courts or routes. The patent infringement is dealt with Federal Patent Court and it is known as bifurcation system.

Types of Patent applications

- National patent application: It is a direct application done with German Patent and Trademark Office i.e., DPMA (Deutsches Patent- und Markenamt) Patent granted by DPMA have effect on the Federal Republic of Germany.
- European Patent application: it is a single direct national filing and it is applicable in European member states and granted by European Patent office.



A REVIEW ON NEW DRUG APPROVAL PROCESS IN INDIA

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ABSTRACT

A regulatory process, by which a person/organization/sponsor/innovator gets authorization to launch a drug in the market, is known as drug approval process. In general, a drug approval process comprises of various stages: application to conduct clinical trials, conducting clinical trials, application to marketing authorization of drug and post-marketing studies. 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 the drug approval process in India. The new drug approval process in India is standardized and well controlled, involving multiple steps and organizations. At the central level, DCGI, under the Ministry of Health and Family Welfare, approves the drug or medical device for marketing. Manufacturing licenses are approved at the state level by state drug control authorities. Monitoring is also performed by state agencies in coordination with the CDSCO.

KEYWORDS: Drug approval process, Clinical trials, Marketing.

INTRODUCTION

NDA is an application submitted to the FDA for permission to market a new drug. To obtain this permission a sponsor submits preclinical and clinical test data to NDA for analyzing the drug information, description of manufacturing procedures.

After NDA received by the agency, it undergoes a technical screening. This evaluation ensures that sufficient data and information have been submitted in each area to justify "filing" the application that is FDA formal review. At the conclusion of FDA review of an NDA, there are three possible actions that can send to sponsor:

Not approvable - This letter consists of list of deficiencies.

Approvable - It means that the drug can be approved but minor deficiencies that can be corrected like-labeling changes and possible request commitment to do post-approval studies.

Approval - It state that the drug is approved. If the action taken is either an approvable or a not approvable, then FDA provides applicant with an opportunity to meet with agency and discuss the deficiencies.^[1]

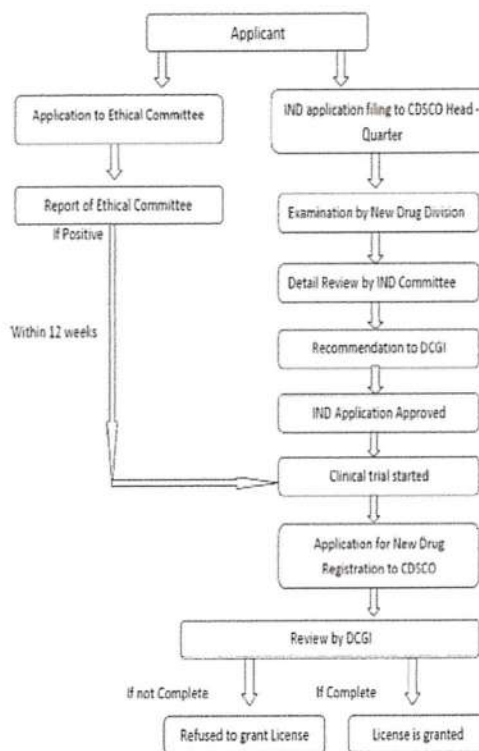


Figure 1: Drug Approval Process In India.

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**SGLT2 INHIBITORS: A NEW CLASS OF DRUGS FOR TYPE-II
DIABETES MELLITUS****Lahari Samudrala*¹, T. Ramya Krishna², V. Sireesha³ and Pooja Agarwal⁴**

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ABSTRACT

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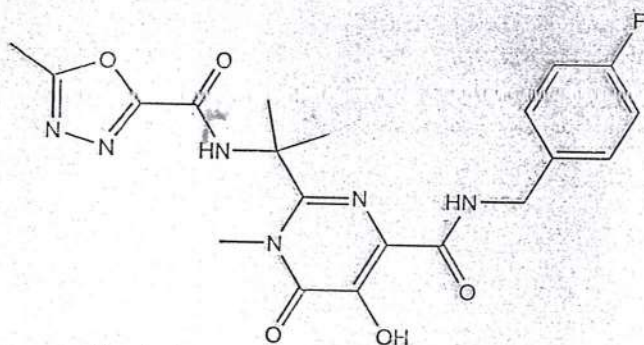


Figure 1: Chemical structure of raltegravir

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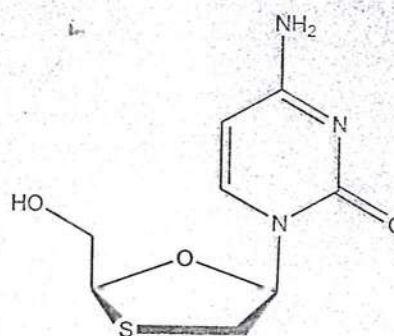


Figure 2: Chemical structure of lamivudine

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FORMULATION AND EVALUATION OF SUSTAINED RELEASE TABLETS OF TRAMADOL

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ABSTRACT

The main aim of the proposed work was to develop Tramadol matrix tablets, sustained release dosage form. Tramadol is a narcotic analgesic proposed for moderate to severe pain Sustained release formulation is the drug delivery system that is designed to achieve a prolonged therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose. The sustained release tablets were prepared by direct compression method using Hydroxypropyl methyl cellulose as a K100M grade, Karayagum and Guar gum in varying ratios. Tablets blends were evaluated for Bulk density, Tapped density, compressibility index and angle of

repose, shows satisfactory results. The compressed tablets were then evaluated for various physical tests like diameter, thickness, uniformity of weight, hardness, friability and drug content. The granules exhibited satisfactory rheological demeanor. The results of all these tests were found to be satisfactory. The *in-vitro* dissolution study was carried out for 12 hours using the paddle method in phosphate buffer (pH 6.8) as dissolution media. Formulation F1, to F9 direct compression method, sustain release and among all the formulation. This finding reveals that above a particular concentration of HPMCK100M, Karayagum and Guar gum and Magnesium stearate are capable of providing sustained drug release. Sustained release, HPMC-K100M, Karayagum, Guar gum, Magnesium stearate, Microcrystalline cellulose.


INTRODUCTION

Oral drug delivery is the most widely utilized routes of administration among all the routes of administration that has been explored for systemic delivery of drugs via pharmaceutical products of different dosage form.^[1] Oral route is considered more natural, uncomplicated, convenient and safe due to its ease of administration, patient compliance and cost effective

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PRINCIPAL

**SGLT2 INHIBITORS: A NEW CLASS OF DRUGS FOR TYPE-II
DIABETES MELLITUS**Lahari Samudrala*¹, T. Ramya Krishna², V. Sireesha³ and Pooja Agarwal⁴

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Anti-Anxiety Activity of *Tradescantia spathacea* Assessed Using Different Experimental Anxiety Models

D Tirumala^{1*}, Junapudi Sunil¹, M Sangeetha², Ch Hari Prasad Murthy³, Pulipaka Shankaraiah¹

Abstract: The point of present examination was to investigate the anti-anxiety activity of hydroalcoholic extracts of *Tradescantia spathacea* utilizing different animal models (elevated plus maze, open field test, light and dark test and social interaction test) of anxiety in mice. Diazepam (0.5 mg/kg) was utilized as the standard and measurement of hydroalcoholic extract of *T. spathacea* (50, 100 and 200 mg/kg) was chosen according to OECD rules. Results recommended that concentrate of *T. spathacea* at 100 and 200 mg/kg dose produced anti-anxiety effects almost similar to diazepam and at 50 mg/kg dosage did not create against anti-anxiety activity on any of the paradigm used. Additionally ponders are expected to recognize the anxiolytic mechanism(s) and the phytoconstituents responsible for the observed central effects of the hydroalcoholic extract of *T. spathacea*.

INTRODUCTION

Anxiety affects simple fraction of the whole population worldwide and has become a crucial space of analysis interest in pharmacology throughout this decade. [1] Benzodiazepines are the most important category of compounds utilized in anxiety and that they have remained the foremost unremarkably prescribed treatment for anxiety. [2] However, the belief that benzodiazepines gift a slim margin of safety between the anxiolytic impact and people inflicting unwanted aspect effects has prompted several researchers to judge new compounds within the hope that different anxiolytic medicine can have less undesirable effects. [3] The popularity of anxiolytic effects of non-benzodiazepine azapirone agents, which act as 5-HT_{1A} partial agonists, like buspirone, gepirone and ipsapirone and their therapeutic role in clinical anxiety and mood disorders has any targeted attention on the 5-HT_{1A} receptor. [4] Though the azapirone move with different neurochemical systems, like the dopaminergic and noradrenergic, they show nanomolar affinity for 5-HT_{1A} receptor sites. [5] However, the anxiolytic effects of azapirone follow a time course determined with antidepressants wherever therapeutic effects are delayed for 3-4 weeks, that is in contrast to the speedy effects determined with anxiolytic drug anxiolytics. [6] Thus, there's a requirement of strong anxiolytic compounds that have lesser aspect effects than benzodiazepines and additional immediate onset of action than presently out there 5-HT_{1A} receptor acting medicine. [7]

Tradescantia spathacea Swartz (syn. *Rhoeo discolor* L. H'er Hance, *Rhoeo spathacea* (Swartz) Stearn) is a plant of India that is in use in traditional medicine. This plant belongs to the Commelinaceae family. [8] In the Southeastern of Mexico, it is known as "Maguey Morado" (Purple Maguey) and the decoction of the leaves is daily free-consumed as curative of cancer, without existing

scientific evidence of such property. [9] It is known that the aqueous extract of *T. Spathacea* blocks the antiadrenergic action of bretylium [10] and is contraceptive in rats. [11] The extracts of *T. Spathacea* have been incorporated in cosmetics to improve the appearance of skin. [12] Some chemicals detected in *T. Spathacea* are flavonoids, anthocyanins, saponins, carotenoids, waxes, terpenoids and coumarinic and steroidal compounds. [13, 14] On the other hand, *T. Spathacea* ethanolic crude extract evaluated in an *in-vitro* system, showed antioxidative activities [15] and antimicrobial properties. [16]

Due to the absence of scientific reports *in-vivo* that corroborate the anxiolytic activity property of *T. Spathacea*, it is evident the importance of the exploration of this plant. They additionally assessed the spontaneous activity and neuromuscular coordination. Other than this, no model(s) for anxiety (except EPM) has been used for further evaluation of anxiolytic activity of *T. Spathacea* extract, to our knowledge. The aim of the present study was to explore the anti-anxiety activity of hydroalcoholic extract of *T. Spathacea* totally different animal models (EPM, open field (OF) test, light and dark test and social interaction test) of anxiety in mice.

MATERIALS AND METHODS

Animals

Swiss albino mice (males; 20–25 g) were used in the present study. Divided into 5 groups of 6 animals per cage were used. Animals were maintained under standard laboratory aseptic conditions (12-h light/dark cycle, 24 hrs). The food in the form of dry pellets and water is provided *ad libitum*. The animals were acclimatized to the laboratory conditions before experiments. Experimental protocol was approved by Institutional Animal Ethics Committee. Care of the animals was taken as per guidelines of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) Government of India. Experiment protocol was approved by Institutional Animal Ethics Committee (Reg No: 1648/PO/A/12/CPCSEA).

Plant Material

The plant *Tradescantia spathacea* was collected within the month of Feb. 2017 from medicinal gardens of Geethanjali

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Review on Screening of Pharmacological Activities of Plant Mediated Solid Nanoparticles

Abstract

Herbal medicines have been broadly utilized everywhere throughout the world since ancient times and have been perceived by doctors and patients for their better remedial value as they have less adverse effects compared with present-day medicines. Phytotherapeutics require a scientific approach to deliver the components in a sustained manner to increase patient compliance and avoid repeated administration. This can be accomplished by planning novel drug delivery systems (NDDS) for natural constituents. NDDSs not just decrease the rehashed organization to defeat rebelliousness, yet additionally, help to expand the therapeutic value by diminishing lethality and expanding the bioavailability. One such novel methodology is nanotechnology. Nano-sized drug delivery systems of herbal medications have a potential future for upgrading the movement and overcome issues related to plant drugs. Hence, integration of the nanocarriers as an NDDS in traditional medicine system is basic to conflict more chronic diseases like asthma, diabetes, malignant growth, and others. With the usage of nanotechnological production methods, it is possible to meet the high demand for artemisinin for malaria sickness treatment and cancer chemotherapy also. Utilizing nanotechnology, the specialists found that another natural medication compound had the capacity to enter disease cells without harming the healthy cells of the human body. Ongoing advances in drug delivery systems of camptothecin (an anticancer specialist) have enhanced this current medication's effectiveness because of improvement in nano-sized dose types of camptothecin-determined medications. DNA topoisomerase is one of medication focuses on malignant growth treatment.

Key words: Herbal drugs, nanotechnology, novel drug delivery systems, nanoparticles

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Introduction

The term nanotechnology was derived from greek word 'nanos', it means dwarf. It is the new technology in drug discovery and it has property of self targeting. Nanotechnology is an advanced scientific technique in 21st century. The size of particle is less than 100nm [1]. Herbal medicines have been widely used worldwide since ancient times and have been recognized by physicians and patients for their better therapeutic values as they have fewer adverse effects as compared to modern medicines. Medicinal plants are currently obtaining a lot of attention than ever as a result of they need potential of providing large advantages to society or so to all or any human race, particularly within the line of drugs. The herbal treatment helps to extend the therapeutic value

by reducing the toxicity and side effects of medicine at a similar time it additionally will increase the bioavailability. In this approach nanotechnology plays an excellent role and therefore the use of nanotechnology in herbal drugs and more specifically in drug delivery is ready to spread quickly. Nano herbal drug delivery systems have a potential future for enhancing the activity and overcoming the problems associated by medicinal plants. So, the herbal nanocarriers help to treat the dangerous diseases like cancer, Diabetes etc. Herbal medicines weren't thought-about for development of novel formulations because of lack of scientific justification and process difficulties however modern phytopharmaceutical analysis will solve the scientific desires (such as determination of pharmacokinetics, mechanism of action, site of



Phytochemical investigation and antihelmintic activity of *Operculina turpethum* roots

Pulipaka Shankaraiah^{1*}, Anasuri Santhosh², M. Ravi Kumar³, Bharat Bhusan Mahapatra⁴

ABSTRACT

The present study was aimed at the investigation of the roots of the traditional Indian medicinal plant *Operculina turpethum* for pharmacologically active chemical constituents and *in vitro* evaluation of the fraction (or) extracts that shown to contain maximum constituents for anthelmintic activity against adult Indian earthworms (*Pheretima posthuma*) using albendazole as the reference standard. The collected and authenticated roots were dried under shade and extracted with water, ethanol, and ethyl acetate by maceration. The obtained extracts were investigated for the presence of various biologically active ingredients by qualitative methods. Ethanolic and ethyl acetate extracts that were shown to possess maximum constituents were tested for anthelmintic activity by measuring parameters such as time taken for paralysis and death of the worms. Results were compared with that were obtained with albendazole. From the results, it was found that the ethanolic extract of the roots taken for the study possesses significant activity at the concentrations of 150 mg/ml. However, more study is recommended for further investigation in this regard.

KEY WORDS: Albendazole, Anthelmintic activity, Extracts, *Operculina turpethum*, Phytochemical investigation, Roots

INTRODUCTION

The human being appears to be afflicted with more diseases from the early ages, taking advantages of plants growing around them to alleviate their sufferings from injury or disease with hopes for remedies in chronic diseases generated new enthusiasm in the research workers to develop herbal medicines.

Herbal medicine offers a greater scope for the future treatment of various pathological conditions.

The effectiveness of medicinal plant lies in the varying complex chemical substances such as alkaloids, glycosides, corticosteroids, and essential oils which are the starting material for a vast number of synthetic drugs.^[1,2]

Helminthiasis is one of the most important animal diseases worldwide that can cause heavy production

losses in grazing animals. The disease is prevalent all over the world, especially in developing countries, and is always associated with poor management practices and inadequate and inappropriate control strategies. An integrated approach is required for the effective control of helminths which includes strategic and tactical use of anthelmintics which remains the cornerstone to this end and careful management of grazing lands including control of stocking rates and appropriate rotation strategies.

Role of vaccinations is also vital for the control of various parasitic diseases as in the case of lungworms. However, various problems have emerged with the use of anthelmintics, and among them, resistance against various species of helminthes is of utmost importance to different anthelmintic compounds and classes, as well as chemical residue and toxicity problems.

In addition, recognition of the antigenic complexity of parasites has slowed vaccine development. For these various reasons, interest in the screening of medicinal plants for their anthelmintic activity remains of great scientific significance despite extensive use

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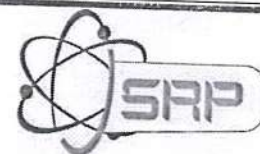
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Research Article

Full Proceeding Paper

IN-VITRO ALDOSE REDUCTASE AND ADVANCED GLYCATION END PRODUCTS INHIBITORY ACTIVITY OF THE LEAVES OF CARICA PAPAYA LINNAnasuri Santhosh ^{1*}, Pulipaka Shankaraiah ², Gopi Swapna ³¹ Department of Pharmacognosy, Avanthi Institute of Pharmaceutical Sciences, Hyderabad, Telangana, INDIA.² Department of Pharmacognosy, Geethanjali College of Pharmacy, Hyderabad, Telangana, INDIA.³ Department of Pharmaceutical Chemistry, Avanthi Institute of Pharmaceutical Sciences, Hyderabad, Telangana, INDIA.

Received on: 05-10-2017; Revised and Accepted on: 08-11-2017

ABSTRACT

Objective: To study the in-vitro Aldose reductase and Advanced glycation end products formation inhibitory activities of the crude ethanolic extract of the leaves of *Carica papaya*. **Methods:** In-vitro Aldose reductase inhibitory activity was studied by using isolated rat lens and kidney Aldose reductase by UV-Visible spectro photo metric method by in comparison with Quercetin as reference compound. In-vitro Advanced glycation end products inhibitory activity was estimated by using laboratory test reaction with protein and sugars by spectro fluorimetric method by comparing with Aminoguanidine as reference compound. Statistical analysis of the results was done by using graphpad prism software. **Results:** The plant extract was found to possess significant Aldose reductase and Advanced glycation end products formation inhibitory activity in-vitro. **Conclusions:** More study is required for isolation and characterization of the chief chemical constituents responsible for the biological activity of the plant extract.

KEYWORDS: Aldose Reductase, Advanced Glycation end Products, Complications of Diabetes mellitus, *Carica papaya*, Crude extract, Quercetin, Aminoguanidine.

INTRODUCTION

Diabetes mellitus (DM) is an important metabolic disorder leading to several complications such as Diabetic-neuropathy, nephropathy, retinopathy and cataracts in severe and untreated conditions which require a special medical attention. Most of these occur in the tissues of insulin independent uptake of glucose such as nerves, kidneys, lens etc. via Polyol Pathway (POP) of glucose metabolism. Aldose Reductase (AR, ALR2, EC 1.1.1.21) is a NADP⁺, alditol, oxidoreductase, a member of aldoketoreductase superfamily that plays a key role in POP. ALR2 converts the glucose in the first step of POP into sorbitol which gets accumulated in such tissues due to the poor permeability of the tissues and the slow rate of the second step of POP where, the sorbitol is converted to fructose by another enzyme Sorbitol Dehydrogenase (SD, EC 1.1.1.2). As a result of accumulation of sorbitol, the normal physiology of the tissues was altered and leading to several complications [1]. Advanced Glycation End Products (AGE) are the reactive, fluorescent compounds produced in severe and untreated conditions of DM. These are mainly derived from the products of POP such as fructose and even from the sugars like glucose via non-enzymatic glycation reaction with tissue proteins and aminoacids-Millard's reaction and Amodari rearrangement and Schiff's base formation. The AGE's are further more reactive with tissue proteins and cause irreversible damage to such tissues and increase the severity of the complications of DM [2].

Inhibition of ALR2 and the formation of AGE's is a promising and novel approach for the treatment of such complications of DM. Certain synthetic compounds such as spirohydantoin derivatives like sorbinil and carboxylic acid derivatives like epalrestat are well reported for AR inhibitory activity. But most of the synthetic compounds are also found to possess unwanted effects and poor pharmacokinetic parameters and less effective *in-vivo* [1].

Several natural products are reported to be the safe and effective as AR, AGE formation inhibitors such as, *Nelumbo nucifera*-Leaves [2], Extracts from *Hops-Humulus lupulus* [3] etc. Most of these are also reported for antidiabetic activity and contains flavanoids or other antioxidant chemicals.

The primary objective of the present work is to study the AR and AGE formation inhibitory potential of the crude extract of the ancient Indian medicinal plant *Carica papaya* in an attempt to discover safe and effective natural products as AR and AGE formation inhibitors. Various parts including leaves of the plant were reported to contain different Pharmacologically important compounds like flavonoids, saponins, glycosides, alkaloids, vitamins, minerals, enzymes like papain and chymopapain, proteins and aminoacids, carbohydrates etc., [4-10]. Different parts specifically, leaves of the same plant also scientifically proved to possess several Pharmacological activities like, antidiabetic, antifungal, anti-inflammatory, antifertility, anticancer, immunomodulatory, antimicrobial, hepatoprotective, antimalarial, anthelmintic, antioxidant, diuretic antiprotozoal etc., [11-18].

Quercetin possesses significant AR inhibitory and AD activities [19, 20] Aminoguanidine well known to be an AGE Inhibitor and AD agent [21, 22] were taken as the reference compounds for the study,

MATERIALS AND METHODS**Plant materials:**

The leaves the plant was procured from authentic source in the medicinal plant garden of our college. The collected leaves were shade dried and pulverized and sieved through standard sieve to obtain

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REVIEW ON THE PHYTOCHEMICAL AND PHARMACOLOGICAL PROPERTIES OF *OPERCULINA TURPETHUM*Pulipaka Shankaraiah ^{1*}, Anasuri Santhosh ², M. Vyshnavi ³, Y. Shravana Gowri ³, K. Prathika ³¹ Assistant Professor, Geethanjali College of Pharmacy, Hyderabad, Telangana, INDIA.² Assistant Professor, Avanthi Institute of Pharmaceutical Sciences, Hyderabad, Telangana, INDIA.³ B. Pharmacy Final year, Geethanjali College of Pharmacy, Hyderabad, Telangana, INDIA.

Received on: 05-10-2017; Revised and Accepted on: 08-11-2017

ABSTRACT

The current review aimed to present the Phytopharmaceutical and Pharmacological importance of the traditional Indian Ayurvedic medicinal plant *Operculina turpethum*. It was reported scientifically that, various parts possess several Phytopharmaceutical agents like glycosides and different parts and their extracts or products were reported for several Pharmacological activities like anti-diabetic, anti-cancer activities. So, it can be concluded that the plant possesses various chemical compounds most of which need to be isolated and characterized both chemically and biologically to make them as safe and effective Pharmaceutical agents.

KEYWORDS: *Operculina Turpethum*, Phytochemical and Pharmacological.

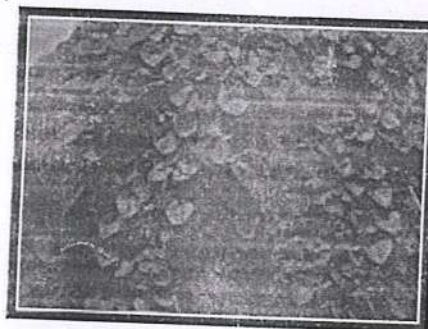
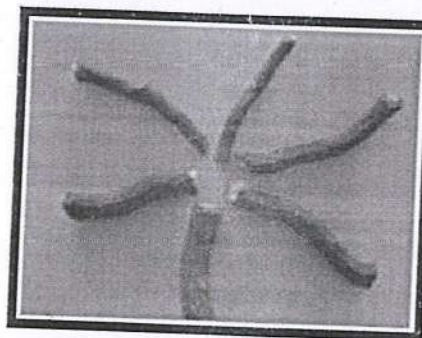
INTRODUCTION

Complimentary of alternative medicine is rapidly increasing worldwide to meet the market demands for herbs that are lightly to remain high due the bioactive constituents present in them and yet cannot be prepared synthetically [1]. Medicinal plants play a vital role in all most all the traditional system of medicine and folklore practices. In concordance, India has rich bio diversity with flourished heritage of tradition medicines. One such example constitutes Artemisinin an active anti-malarial compound isolated from *Artemisia annua*. Conventional as well as western medicine comprises mostly medicinal components that are derived from plants. In the present scenario, around 88% of the global population focus on plant derived medicines as first line defense in combating dreadful diseases of the day. Traditional medicine has not however been incorporated in most of the national health systems and the potential of service provided by the traditional medical practitioner is not fully utilized. *Operculina turpethum* Linn. Belonging to family *convulvaceae* is widely distributed throughout India, China, Sri Lanka and Australia. The plant is commonly known as Trivrit and exists in 2 varieties namely Aruna or Shweta (*Operculina Turpethum*) and Shyama (*Ipomea Petaloides*) [2]. Root of Trivrit is used on a large scale in disorders like skin peptic acid disorders and constipation. In Ayurveda this has been included among the 10 purgative herbs (i.e. *Bhedaniya Mahakashaya*), group of 'ten antidote herbs' (i.e. *Vishaghna Mahakashaya*), group of 'ten herbs supportive for therapeutic enema' (i.e. *Ashthapanopag Mahakashaya*), group of colon cleanser, antitumor & antidote herbs, (i.e. *Shyamadi Gana*), and in the group of 'herbs eliminating the toxins (i.e. vitiated Doshas) from lower half of the body' (i.e. *Adhobhagahar Gana*) [3]. Basically the bark of this plant is used as a purgative whereas the leaves are used as cardiotoxic. Probably the

roots, bark and seeds contain cardiac glycosides such as neriodorin, neriodorein and karabin. The fresh juice of leaves finds use in ophthalmia as inducer of lacrimation [4].

Plant Profile:

Operculina turpethum is a perennial climber with long fleshy roots and long twisting pubescent stems that turns very tough and brown when old [5].

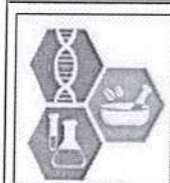
Fig. 1: *Operculina turpethum* PlantFig. 2: *Operculina turpethum* Roots

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Phytochemical investigation and antimicrobial anthelmintic activities of the leaves of *Rubus moluccanus* Linn

Santhosh Anasuri, Uma Shankar Damu, Shankaraiah Pulipaka and Madhuri Tekurala

Abstract

Objective: To evaluate the leaves of the endangered traditional Indian medicinal plant *Rubus moluccanus* for its pharmacologically active chemical constituents and assessment of its antimicrobial and anthelmintic activities.

Methods: Shade dried and pulverized leaves of the plant were macerated with different solvents to get the respective extracts that were used for chemical examination using simple test tube chemical reactions. The extract that shown to possess maximum chemical constituents was selected for Physicochemical and Pharmacological investigation. Antibacterial and antifungal activities were studied by agar disc diffusion method in comparison with standard drugs amoxicillin and ketoconazole respectively against antimicrobial sensitive and resistant, pathogenic strains of microorganisms say *Bacillus subtilis*, *Escherichia coli*, *Staphylococcus aureus*, *Aspergillus niger* and *Candida albicans*. The anthelmintic activity was studied by using adult Indian earthworms *Pheretima postuma* using parameters like, time taken for paralysis and death of the worms and compared with standard albendazole drug.

Results: The ethanolic extract of the leaves of the plant was selected for Physicochemical and Pharmacological evaluation as it was found to possess maximum chemical constituents. The crude plant extract was known to illustrate the significant antimicrobial and anthelmintic activities in comparison with reference drugs.

Conclusion: More studies are recommended for isolation and chemical, pharmacological characterization of the chief chemical constituents responsible for the above discovered activities of the plant extract.

Keywords: *Rubus moluccanus*, leaves, ethanolic extract, antimicrobial and anthelmintic activity.

Introduction

Bacterial, fungal and helminthic infections of human beings, animals and plants emerging as a major threat to the productivity and food security of the world especially, the third world group of developing countries such as India due to poor management practices and lack of awareness. Conventional especially, the synthetic drugs become noneffective against several pathogenic microbes and helminths and these drugs also possess several unwanted adverse effects and drug interactions. Therefore, it is challenging for the scientific world to discover safe and effective drugs to deal with this threat. The nature provided us with enormous resources containing wide range of Pharmaceutical agents that are able to cure several ailments of all the types. Several natural products from plants and other natural sources were scientifically proven to be safe and effective antimicrobial and anthelmintic agents raised the hopes for the future scientific world to discover novel drugs [1-4]. The present study is an attempt in this regard to study an endangered Indian medicinal plant *Rubus moluccanus* of family Rosaceae leaves for its Phytochemical and Pharmacological screening to scientifically establish it as a lead for future discovery of safe and effective drugs.

Materials and Methods

Plant material: The leaves of *Rubus moluccanus* were collected from Nilgiri hills region of Tamilnadu state. The collected leaves were shade dried and subjected to pulverization and sieving to get powder of uniform size. The powdered plant material was extracted by using different menstruum say Formaldehyde, Ethyl alcohol, Acetic acid and Chloroform by maceration for seven days. Dried extracts were prepared by desiccation after evaporation of the solvents from filtered extracts in rotary evaporator. The plant material was authenticated by department of Botany, Osmania University, Hyderabad.

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PHYTOCHEMICAL INVESTIGATION AND *IN-VITRO*
ANTHELMINTIC ACTIVITY OF THE LEAVES OF *GYNURA*
LYCOPERSICIFOLIA LINN

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ABSTRACT

Introduction: The present study is aimed at phytochemical investigation and evaluation of the *in-vitro* anthelmintic activity of the leaves of the medicinal plant *Gynura lycopersicifolia* which was not reported earlier in an attempt to develop natural products as safe and effective alternatives for synthetic drugs that possess challenges like, antimicrobial resistance and side effects. **Methods:** Dried leaves of the plant was used for extraction with water, ethanol and ethylacetate as menstrum and the extracts thus obtained were used for phytochemical qualitative analysis for different phytopharmaceutical agents like alkaloids and flavanoids. The extracts which were found to possess maximum constituents were selected for biological evaluation for

anthelmintic activity using Indian earth worms *in-vitro*. Albendazole was taken as reference standard. Time taken for paralysis and death of the worms was taken as criteria for the efficacy of standard and extracts. **Results:** Both the ethanolic and ethyl acetate extracts were found to contain various phytochemicals of pharmaceutical importance such as alkaloids and flavanoids. Both the extracts were also known to exhibit anthelmintic activity *in-vitro* against Indian earth worms at concentrations 30 mg/ml comparable to reference standard 10 mg/ml. **Conclusions:** Ethanolic and ethyl acetate extracts of the leaves of the plant *Gynura lycopersicifolia* contains significant phytochemicals of pharmaceutical importance can be used for the biological evaluation for different pharmacological activities. Both the extracts were found to possess significant anthelmintic activity against Indian earth worms *in-vitro*.

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EVALUATION OF ETHANOLIC EXTRACT OF ORYZA SATIVA (VAR. JOHA RICE) FOR ANTI DIABETIC ACTIVITY IN STREPTOZOCIN INDUCED DIABETIC RATS

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ABSTRACT

The present study evaluated the anti-diabetic activity of the ethanolic extracts of *Oryza sativa* (var. Joha rice) (Ethanolic Extract of Joha Rice) on blood glucose of albino rats. Ethanolic Extract of Joha Rice was administered at doses of 200 and 400 mg/kg body weight respectively on Streptozocin induced diabetic rats for 17 days. Diabetic rats had much reduced body weight than normal rats. Administration of the extracts at the dose of 200 & 400 mg/kg body wt. /day resulted in a marked decrease in the levels of fasting blood glucose, with a concomitant increase in body weight. Streptozocin induced diabetic rats treated with Ethanolic Extract of Joha Rice (200 & 400 mg/kg) significantly reversed all these changes to near normal. Quantification of antioxidants of the Ethanolic Extract of Joha Rice revealed that Joha rice had high antioxidant property. These results suggest that Ethanolic Extract of Joha Rice possess anti diabetic in Streptozocin induced diabetic rats.

KEY WORDS

Ethanolic extract, streptozocin, joha rice, fasting blood glucose, antioxidant property

INTRODUCTION

Diabetes mellitus type 1 (also known as **type 1 diabetes**) is a form of diabetes mellitus in which not enough insulin is produced. This results in high blood sugar levels in the body. The classical symptoms are frequent urination, increased thirst, increased hunger, and weight loss.

Diabetes mellitus type 2 (also known as **type 2 diabetes**) is a long-term metabolic disorder that is characterized by high blood sugar, insulin resistance, and relative lack of insulin. Common symptoms include increased thirst, frequent urination, and unexplained loss. Symptoms may also include increased hunger, feeling tired, and sores that do not heal.

Gestational diabetes mellitus (GDM) is defined as glucose intolerance of variable degree with onset or first recognition during pregnancy. A study found this

condition to be associated with persistent metabolic dysfunction in women at 3 years after delivery, separate from other clinical risk factors.

Prescribing pattern: Rational use of the drugs is a defined as follows: "That patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time and at the lowest cost to them and their community". Rational use of the drugs in populations can be effectively evaluated with drug utilization studies.

Drug utilization studies seek to monitor, evaluate and implement remedies in the prescribing practice with the aim of making the medical care rational and effective.

Signature of
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Evaluation of *Oryza Sativa* (Var. Joha Rice) for Anti-Hyperlipidemic Activity in Rats

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Abstract:

The present study evaluated the anti-hyperlipidemic activity of the ethanolic extracts of *Oryza sativa* (var. Joha rice) (EEJR) on blood cholesterol of albino rats. Ethanolic extract of joha rice was administered at doses of 200 and 400 mg/kg body weight respectively on cholesterol induced hyperlipidemic rats for 7 days. Hyperlipidemic rats had much reduced body weight than normal rats. Administration of the extracts at the dose of 200 & 400 mg/kg body wt. /day produced a significant effect on lipid profile, which had shown anti hyperlipidemic activity on cholesterol induced hyperlipidemic rats. Cholesterol induced hyperlipidemic rats treated with Ethanolic extract of joha rice (200 & 400 mg/kg) significantly reversed all these changes to near normal. These results suggest that Ethanolic extract of joha rice possess anti hyperlipidemic activity in cholesterol induced hyperlipidemic rats.

Keywords: joha rice, hyperlipidemia, cholesterol, albino rats, lipid profile.

I. INTRODUCTION:

Cardiovascular disease is the leading cause of mortality all over the world and is a major health concern of the public nowadays. Hyperlipidemia is described as the contributing risk factor for cardiovascular disease (Brown & Goldstein 1986). Hyperlipidemia is also the primary cause of atherosclerosis, ischemic cerebrovascular disease, coronary heart disease and peripheral vascular diseases (Hardman & Limbard 2001). Hyperlipidemia is characterized by cluster of abnormalities like elevated serum total cholesterol, serum triglyceride, low density lipoprotein-cholesterol levels and reduced high density lipoprotein-cholesterol levels. It is well known that various factors such as lipid abnormalities, oxidative stress (Yokoyama 2004) and inflammation (Hansson 2005) have been associated in the development of atherosclerosis and subsequent cardiovascular diseases. There exists a wide consensus that hyperlipidemia in human and animals is produced by the influence of dietary cholesterol. Diet plays a pivotal role in maintenance of ideal body weight, body fat and normal levels of blood lipids (Loo et al 1991). Numerous research reports have been demonstrated in understanding the pathophysiology of hyperlipidemia.

Growing evidence suggests that prevention or treatment of atherosclerosis and cardiovascular diseases is possible through targeting hyperlipidemia by diet or drugs (LaRosa et al 1990). Hyperlipidemia disease has afflicted humankind since antiquity. In 2002, coronary heart Epidemiological evidence strongly supported the positive correlation between blood lipids, hyperlipidemia and its complications, mainly CHD. This relationship has been shown between and within cultures. The hyperlipidemia is traditionally defined as conditions in which the concentration of *cholesterol* or *triglyceride*-carrying *lipoprotein* s in plasma exceeds an arbitrary normal limit. These

lipoproteins deposit in the interstitial space of arteries arising from aorta, restricting the blood supply to the heart. This phenomenon is known as atherosclerosis. Higher deposition of lipoproteins completely blocked the blood supply to the heart, and thus myocardial infarction (MI) occurs, which is commonly known as heart attack.

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The predisposing factors associated with hyperlipidemia constitute (Bethesda 1991; Marshall 1992; Lipmann et al 2000)

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9. Physical inactivity
10. Obesity or overweight
11. Overactive adrenal gland
12. Increased levels of c-reactive proteins
13. Increased Lipoprotein (a) levels
14. Liver and kidney problems
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Types of Hyperlipidemia

Hyperlipidemia is broadly classified into two types:

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Primary Hyperlipidemia This occurs as an outcome of high consumption

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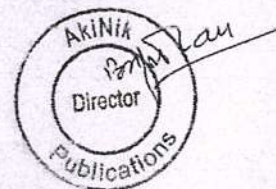
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RUTF (READY-TO-USE THERAPEUTIC FOODS) TREATMENT FOR KWASHIORKOR

Lahari Samudrala*¹, Pooja Agarwal², T. Ramya Krishna³ and B. Priyanka⁴

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ABSTRACT

Kwashiorkor, also known as “edematous malnutrition” is a nutritional disorder most often seen in regions experiencing extreme scarcity of food. It is a form of malnutrition caused by a lack of protein in the diet. These conditions are responsible for a lack of food, which leads to malnutrition. Kwashiorkor is very rare in children in the United States. The World Health Organization (WHO) defines malnutrition as “the cellular imbalance between the supply of nutrients and energy and the body's demand for them to ensure growth, maintenance, and specific functions. If kwashiorkor is identified early it can be treated with either specially formulated milk-based feeds or ready-to-use therapeutic food (RUTF). RUTF is typically made up of peanut butter, milk powder, sugar, vegetable oil, and added vitamins and minerals. More intensive

treatment in hospital will be needed in severe cases or where there are already complications, such as infections. Hospital treatment will usually involve: Treating or preventing low blood glucose. Keeping the person warm – kwashiorkor can make it harder to generate body heat. Treating dehydration with specially formulated rehydration solution. Treating infections with antibiotics – kwashiorkor greatly increases the risk of infections. Treating vitamin and mineral deficiencies – vitamin supplements are usually included in the special milks or RUTF.

KEYWORDS. Protein Deficiency, Malnutrition, Kwashiorkor, Therapeutic Foods.

KWASHIORKOR

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**SGLT2 INHIBITORS: A NEW CLASS OF DRUGS FOR TYPE-II
DIABETES MELLITUS****Lahari Samudrala*¹, T. Ramya Krishna², V. Sireesha³ and Pooja Agarwal⁴**

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ABSTRACT

Diabetes is on the rise. No longer a disease of predominantly rich nations, the prevalence of diabetes is steadily increasing everywhere, most markedly in the world's middle-income countries. Sodium-glucose co-transporter-2 (SGLT2) inhibitors are a new group of oral medications used for treating type II Diabetes Mellitus. The drugs work by helping the kidneys to lower the blood glucose levels. Globally, an estimated 422 million adults were living with diabetes in 2014, compared to 108 million in 1980. The global prevalence of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% in the adult population. This reflects an increase in associated risk factors such as being overweight or obese. Over the past decade, diabetes prevalence has risen faster in low- and middle-income countries than in

high-income countries. The present therapeutic classes of anti-diabetic drugs are not adequately effective in maintaining long-term glycemic control in the most patients. Sodium glucose transporter-2 (SGLT2) inhibitors including Dapagliflozin, Canagliflozin and Empagliflozin act by a novel insulin-independent mechanism by blocking glucose reabsorption in the proximal convoluted tubule resulting in markedly increased glycosuria, and blocking the formation of proteins.

KEYWORDS: Canagliflozin, Dapagliflozin, Empagliflozin, Sodium Glucose Co-Transporter-2 Inhibitors.

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EVALUATION OF ETHANOLIC EXTRACT OF ORYZA SATIVA (VAR. JOHA RICE) FOR ANTI DIABETIC ACTIVITY IN STREPTOZOCIN INDUCED DIABETIC RATS

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ABSTRACT

The present study evaluated the anti-diabetic activity of the ethanolic extracts of *Oryza sativa* (var. Joha rice) (Ethanolic Extract of Joha Rice) on blood glucose of albino rats. Ethanolic Extract of Joha Rice was administered at doses of 200 and 400 mg/kg body weight respectively on Streptozocin induced diabetic rats for 17 days. Diabetic rats had much reduced body weight than normal rats. Administration of the extracts at the dose of 200 & 400 mg/kg body wt. /day resulted in a marked decrease in the levels of fasting blood glucose, with a concomitant increase in body weight. Streptozocin induced diabetic rats treated with Ethanolic Extract of Joha Rice (200 & 400 mg/kg) significantly reversed all these changes to near normal. Quantification of antioxidants of the Ethanolic Extract of Joha Rice revealed that Joha rice had high antioxidant property. These results suggest that Ethanolic Extract of Joha Rice possess anti diabetic in Streptozocin induced diabetic rats.

KEY WORDS

Ethanolic extract, streptozocin, joha rice, fasting blood glucose, antioxidant property

INTRODUCTION

Diabetes mellitus type 1 (also known as type 1 diabetes) is a form of diabetes mellitus in which not enough insulin is produced. This results in high blood sugar levels in the body. The classical symptoms are frequent urination, increased thirst, increased hunger, and weight loss.

Diabetes mellitus type 2 (also known as type 2 diabetes) is a long-term metabolic disorder that is characterized by high blood sugar, insulin resistance, and relative lack of insulin. Common symptoms include increased thirst, frequent urination, and unexplained loss. Symptoms may also include increased hunger, feeling tired, and sores that do not heal.

Gestational diabetes mellitus (GDM) is defined as glucose intolerance of variable degree with onset or first recognition during pregnancy. A study found this

condition to be associated with persistent metabolic dysfunction in women at 3 years after delivery, separate from other clinical risk factors.

Prescribing pattern: Rational use of the drugs is a defined as follows: "That patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time and at the lowest cost to them and their community" Rational use of the drugs in populations can be effectively evaluated with drug utilization studies.

Drug utilization studies seek to monitor, evaluate and implement remedies in the prescribing practice with the aim of making the medical care rational and effective.



Evaluation of *Oryza Sativa* (Var. Joha Rice) for Anti-Hyperlipidemic Activity in Rats

R.Umadevi¹, T.Anoosha²

Assistant professor^{1,2}

Department of pharmaceutical chemistry
Geethanjali College of pharmacy, Hyderabad, India

Abstract:

The present study evaluated the anti-hyperlipidemic activity of the ethanolic extracts of *Oryza sativa* (var. Joha rice) (EEJR) on blood cholesterol of albino rats. Ethanolic extract of joha rice was administered at doses of 200 and 400 mg/kg body weight respectively on cholesterol induced hyperlipidemic rats for 7 days. Hyperlipidemic rats had much reduced body weight than normal rats. Administration of the extracts at the dose of 200 & 400 mg/kg body wt. /day produced a significant effect on lipid profile, which had shown anti hyperlipidemic activity on cholesterol induced hyperlipidemic rats. Cholesterol induced hyperlipidemic rats treated with Ethanolic extract of joha rice (200 & 400 mg/kg) significantly reversed all these changes to near normal. These results suggest that Ethanolic extract of joha rice possess anti hyperlipidemic activity in cholesterol induced hyperlipidemic rats.

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**FORMULATION AND EVALUATION OF SUSTAINED RELEASE
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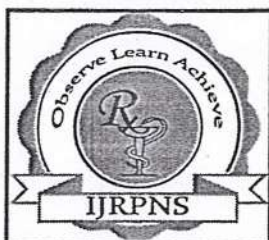
ABSTRACT

The main aim of the proposed work was to develop Tramadol matrix tablets, sustained release dosage form. Tramadol is a narcotic analgesic proposed for moderate to severe pain Sustained release formulation is the drug delivery system that is designed to achieve a prolonged therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose. The sustained release tablets were prepared by direct compression method using Hydroxypropyl methyl cellulose as a K100M grade, Karayagum and Guar gum in varying ratios. Tablets blends were evaluated for Bulk density, Tapped density, compressibility index and angle of

repose, shows satisfactory results. The compressed tablets were then evaluated for various physical tests like diameter, thickness, uniformity of weight, hardness, friability and drug content. The granules exhibited satisfactory rheological demeanor. The results of all these tests were found to be satisfactory. The *in-vitro* dissolution study was carried out for 12 hours using the paddle method in phosphate buffer (pH 6.8) as dissolution media. Formulation F1, to F9 direct compression method, sustain release and among all the formulation. This finding reveals that above a particular concentration of HPMCK100M, Karayagum and Guar gum and Magnesium stearate are capable of providing sustained drug release. Sustained release, HPMC-K100M, Karayagum, Guar gum, Magnesium stearate, Microcrystalline cellulose.

INTRODUCTION

Oral drug delivery is the most widely utilized routes of administration among all the routes of administration that has been explored for systemic delivery of drugs via pharmaceutical products of different dosage form.^[1] Oral route is considered more natural, uncomplicated, convenient and safe due to its ease of administration, patient compliance and cost effective



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RATE AND SUSTAINED RELEASE PROPERTY**

T. Vijayakumari¹, B. Ganesh¹, P. Uma Devi¹ and T. Mangilal²

¹Geethanjali College of Pharmacy, Cheeryal, Keesara, Medchal, Telangana, India.

²College of Technology (A), Osmania University, Hyderabad, Telangana, India.

ABSTRACT

Different batches of lansoprazole loaded ethyl cellulose and HPMC K4M microspheres were prepared using W/O/O double emulsification-solvent diffusion method, to overcome the problem of low encapsulation efficiency of lansoprazole using span-80 as a stabilizer with constant stirring by a magnetic stirrer (Model-1 MLA, Remi motors, vasai, Mumbai, India) at 750- 1000 rpm for 5 hours and centrifuged by cooling centrifuge (Hittich, Zentrifugen, model-1195 a, Mikro 220R, Germany). The prepared microspheres were evaluated and characterized for particle size, percentage yield, drug entrapment efficiency, surface morphology by scanning electron microscopy (SEM), drug-excipient compatibility studies by Fourier transform infrared (FTIR), solid state properties (crystalline or amorphous) by differential scanning calorimetry (DSC), *In-vitro* drug release studies and release kinetics were determined. The optimized formulation F5 was characterized for particle size and surface morphology using optical microscopy method and scanning electron microscopy. Lansoprazole drug release rate was observed highest and improved dissolution rate, with the increase in concentration of HPMC K4M and decreased particle size of microspheres and showed sustained release property of the drug by ethyl cellulose in pH 1.2 up to 92-98.3% were releases within a period of 12 hrs. From the formulation F1 to F5, F5 showed a high dissolution rate of 98.3% and compared with the percentage drug release of pure drug. The data obtained from the dissolution profiles were compared to the different release kinetics models and the regression coefficients. The drug release profile follows zero order release and Higuchi model kinetics, it was found that the optimized formulation of lansoprazole microspheres showed sustained release property and drug release was found to be diffusion controlled mechanism, the n value of Korsmeyer-peppas equation indicated non-fickian type of diffusion.

KEYWORDS

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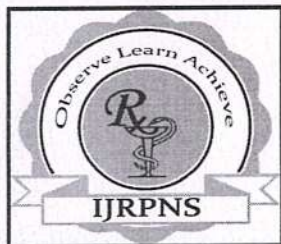
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Research Article

**DESIGN AND INVITRO CHARACTERIZATION OF
RIVASTIGMINE TRANSDERMAL PATCHES**P.Umadevi ^{1*}, I.Nagaraju ² and K. Ravi kumar ³¹Department of Pharmaceutics, Geethanjali College of Pharmacy, Keesara, Hyderabad²Assistant Professor, Department of Pharmaceutics Geethanjali College of Pharmacy, Keesara,
Hyderabad³Principal, Geethanjali College of Pharmacy, Keesara, Hyderabad**Abstract**

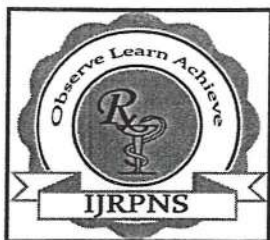
In present study transdermal drug delivery of Rivastigmine was developed to overcome the first pass metabolism and to reduce frequency of dosing compared to oral route. Matrix type of transdermal patches was developed by using polymers HPMCK4M and HPMCK15M. Transdermal patches were prepared by employing solvent casting method. Propylene glycol and Tween80 were selected as permeation enhancer and plasticizer. Formulations were prepared with the varying concentrations polymers ranging from F1-F12. Moisture content and Swelling study and all the results were found to be with in the pharmacopeial limits. invitro drug release studies by using dialysis membrane. Among all the 12 formulations F6 formulation which contain HPMC K4M 300mg and Eudragit L-100 60mg had shown 94% cumulative drug release with in 12 hours. And compared to HPMC K15M, HPMC K4M showed better drug release profile. For F6 formulation release kinetics were plotted and the Regression coefficient value was found to be high for Korsmeyer-peppas release model i.e., 0.9892.

Key words: Rivastigmine, transdermal patches, HPMCK4M and HPMCK15M**Corresponding author:**

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P. Umadevi^{1*}, Suryawanshi Harinath¹ and Teelavath Mangilal²

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ABSTRACT

The floating microspheres have been utilized to obtain prolonged and uniform release in the stomach for development of a once daily formulation. The major advantage of the preparation technique includes short processing time, the lack of exposure of the ingredients to high temperature, and high encapsulation efficiencies. In the present study, preparation of Glipizide floating microspheres, evaluation of Floating Drug Delivery System (FDDS) *in vitro*, prediction of the release, and optimization of floatation and drug release pattern to match target release profile was observed. Floating microspheres were prepared by non-aqueous emulsification solvent evaporation technique

using Ethyl cellulose as the rate controlling polymer and 250 mg of Glipizide per batch and its *in vitro* performance was evaluated by the usual pharmacopoeial and other tests such as drug polymer compatibility (FTIR scan), yield (%), particle size analysis, drug entrapment efficiency, surface topography, and *in vitro* floatation and release studies. Results showed that the mixing ratio of components in the organic phase affected by the size, size distribution (250-1000 μm), drug content (61 – 133% of theoretical load), yield (58 – 87%) and drug release of microspheres (47 – 86% after 8 h), floating time (> 8 hr) and the best results were obtained at the ratio of drug: polymer: solvent (250:750:12 and 250:146.45:9 [mg: mg: ml]), when both the batches were mixed in equal proportions. In most cases good *in vitro* floating behavior was observed and a broad variety of drug release pattern could be achieved by variation of the polymer and solvent ratio, which was optimized to match target release

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FORMULATION AND IN VITRO EVALUATION OF PIOGLITAZONE
HYDROCHLORIDE MOUTH DISSOLVING TABLETSBandi Anitha*¹ and Polepaka Ajaykumar²¹Pulla Reddy Institute of Pharmacy, Domadugu (V) Gummadidala (M) Sangareddy-502313.²Princeton College of Pharmacy, Ghatkesar- Rangareddy (D)-501301.

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ABSTRACT

The purpose of this research work was to develop antidiabetic mouth dissolving tablets of Pioglitazone HCL thereby enhancing the dissolution rate. Tablets containing Pioglitazone, sodium starch glycolate & crospovidone, Croscarmellose sodium as superdisintegrants were prepared by wet granulation & direct compression techniques. The tablets were evaluated for weight variation, hardness, percentage friability, wetting time and disintegration time were showed acceptable results. Formulations F5 and F9 showed disintegration time of 23 and 22 sec respectively. Dissolution was performed in pH 1.2 Hcl buffer and formulations F5 showed maximum drug release within 30 min and drug release from F9 was more than that of the marketed drug. Hence, it could be concluded that formulation F9 showed good drug release than marketed drug. The results compared for both the technologies showed that the Pioglitazone HCL tablets prepared using wet granulation was found to have good technological properties and satisfying and reproducible drug dissolution profiles. Moreover the drug release was found to be comparable to the marketed dispersible tablet.

KEYWORDS: Mouth dissolving tablets, Pioglitazone, Direct compression, Wet granulation, dissolution enhancement.

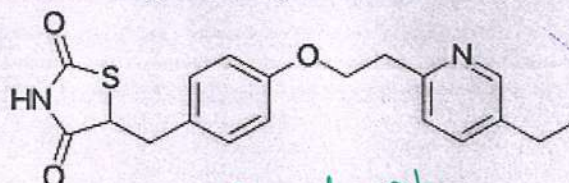
INTRODUCTION

Pioglitazone hydrochloride is an oral hypoglycemic agent, which is a commonly prescribed drug for the treatment of patients with type II diabetes mellitus. Pioglitazone hydrochloride is a basic (pKa = 12.06) which is practically insoluble in water and alkaline buffer solutions, but as per the Biopharmaceutical Classification System (BCS) Pioglitazone categorized as class II drug. The oral absorption is uniform, rapid and complete with a bioavailability of nearly 100% and an elimination half-life of 3-7 hrs. Delivery Systems (NDDS) aim for the same by formulating a dosage form, convenient to be administered so as to achieve better patient compliance. One such approach is oral dispersible tablet. Solid dosage forms are popular because of ease of administration, accurate dosage, self-medication, pain avoidance and most importantly the patient compliance. Mouth dissolving tablets are also called as fast dissolving tablets, melt-in mouth tablets, Orodispersible tablets, rapid melts, porous tablets, quick dissolving etc. Mouth dissolving tablets are those when put on tongue disintegrate instantaneously releasing the drug which dissolves or disperses in the saliva the faster the drug into solution, quicker the absorption and onset of clinical effect. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is

significantly greater than those observed from conventional tablets dosage form.

Diabetes Mellitus (DM) is a group of syndromes and chronic metabolic disorder characterized by hyperglycemia, altered metabolism of lipids, carbohydrates and proteins because of a lack of or ineffective use of the hormone insulin and associated with reduced life expectancy, significant morbidity due to specific diabetes related micro vascular complications and diminished quality of life. A fasting blood glucose level of 126 mg/dl and 200 mg/dl post prandial (oral Glucose load) is considered as indication of DM. In present work, an investigation was made to use crospovidone and sodium starch glycolate, Croscarmellose sodium as superdisintegrants in the design of mouth dissolving tablets.

Structure: Pioglitazone Hydrochloride.



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ORODISPERSIBLE TABLETS - A REVIEW

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ABSTRACT

Orally disintegrating tablets (ODTs) are solid dosage forms containing drugs along with superdisintegrants and other common tablet excipients that disintegrate in the oral cavity within less than 1 minute leaving an easy-to-swallow residue. Over the past three decades, orally disintegrating tablets (ODTs) have gained considerable attention as a preferred alternative to conventional tablets and capsules due to better patient compliance. New ODT technologies address many pharmaceutical and patient needs, ranging from enhanced life-cycle management to convenient dosing for paediatric, geriatric, and psychiatric patients with dysphagia. ODT is a good choice of drug delivery for pediatric and geriatric patients because it troubleshoots the problem of dysphagia. The European Pharmacopoeia adopted the term orodispersible tablet for a tablet that disperses or disintegrates within <3 minutes in the mouth before swallowing. The current article is focused on ideal characteristics, advantages and disadvantages, limitations, superdisintegrants and their selection, various technologies developed for ODT, evaluation methods along with recent research and future potential.

Keywords: Orodispersible tablets, Mechanism of disintegration, improved bioavailability, patented technologies, recent research.

INTRODUCTION

Solid dosage forms are most common, popular, preferred and advantageous because of low cost, ease of administration, accurate dosage, self-medication, pain avoidance, and the most importantly the patient compliance. The most popular solid dosage forms are being tablets and capsules^{1,2}. One important drawback of such dosage forms is Dysphagia, or difficulty in swallowing is common among all age groups due to size, surface, and taste of tablets. Geriatric and paediatric patients and traveling patients, who may not have ready access to water, are most in need of easy swallowing dosage forms³. To fulfill these medical needs, pharmaceutical technologists have developed a novel oral dosage form known as ODTs which disintegrate rapidly in saliva, usually within a matter of seconds, without the need to take it with water. Drug dissolution and absorption, as well as onset of clinical effect and drug bioavailability, may be significantly greater than those as compared with conventional dosage forms^{4,5}. ODTs releases the medicament in the mouth for absorption through local oromucosal tissue and through pre-gastric (oral cavity, pharynx, and

esophagus), gastric (stomach), and post-gastric (small and large intestine) segments of gastrointestinal tract (GIT)⁷.

Orodispersible tablets (ODTs) are also known as "Mouth dissolving tablets", (MDTs) "Orally disintegrating tablets", "Melt-in-mouth", "Orodispersible drug delivery systems" (ODDS), "Rapimelts tablets", "Porous tablets", "Quick dissolving tablets" (QDTs), "fast dissolving tablets" (FDTs) that disintegrate in the oral cavity in easy swallow residue.. Recently ODT terminology has been approved by United State Pharmacopoeia, British Pharmacopoeia, and Centre for Drug Evaluation and Research (CDER). US FDA defined ODT tablets as "A solid dosage form containing medicinal substances which disintegrates rapidly usually within a matter of seconds, when placed upon the tongue". European pharmacopoeia also adopted the term "orodispersible tablet" as a tablet that is to be placed in the mouth where it disperses, rapidly before swallowing despite various terminologies used³. Recently, ODT have started gaining popularity and acceptance as new drug delivery systems, because they are easy to administer and lead to better patient compliance especially in Geriatric and pediatrics. In order to allow orodispersible tablets to dissolve in the mouth, they are made of either very porous and soft-moulded matrices or compressed into tablets with very low compression force, which makes the tablets friable

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Research Article

DESIGN AND INVITRO CHARACTERIZATION OF RIVASTIGMINE TRANSDERMAL PATCHES

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Abstract

In present study transdermal drug delivery of Rivastigmine was developed to overcome the first pass metabolism and to reduce frequency of dosing compared to oral route. Matrix type of transdermal patches was developed by using polymers HPMCK4M and HPMCK15M. Transdermal patches were prepared by employing solvent casting method. Propylene glycol and Tween80 were selected as permeation enhancer and plasticizer. Formulations were prepared with the varying concentrations polymers ranging from F1-F12. Moisture content and Swelling study and all the results were found to be with in the pharmacopeial limits. invitro drug release studies by using dialysis membrane. Among all the 12 formulations F6 formulation which contain HPMC K4M 300mg and Eudragit L-100 60mg had shown 94% cumulative drug release with in 12 hours. And compared to HPMC K15M, HPMC K4M showed better drug release profile. For F6 formulation release kinetics were plotted and the Regression coefficient value was found to be high for Korsmeyer-peppas release model i.e., 0.9892.

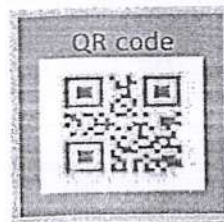
Key words: Rivastigmine, transdermal patches, HPMCK4M and HPMCK15M

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Research Article

Pharmacokinetic and Pharmacodynamic Interaction of Quercetin with Saxagliptin in Normal and Diabetic Rats

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Abstract

Background and Objective: People often take different herbs in combination with prescribed modern medication therapy in diabetes and such herbal preparations often contains quercetin that can inhibit cytochrome P450 (CYP)3A4. This enzyme is responsible for metabolizing saxagliptin, which is a potent and specific DPP-4 inhibitor used as anti-diabetic agent. The aim of the present study was that the quercetin may influence the both pharmacokinetic (PK) and pharmacodynamic (PD) interaction of saxagliptin, which could be particularly crucial, as any increment in its plasma levels may raise safety concerns. **Materials and Methods:** The effect of quercetin on the pharmacokinetics and pharmacodynamics of saxagliptin in normal as well as in streptozotocin (STZ) induced diabetic rats were studied. The data were statistically evaluated using one-way analysis of variance (ANOVA) followed by *post hoc* Dunnett's t multiple comparison test using GraphPad Prism 5. **Results:** In normal and diabetic rats, the combination of saxagliptin with quercetin, significantly increased all the pharmacokinetic parameters, such as C_{max}, AUC_{0-n}, AUC_{total}, t_{1/2} and mean residence time and decreased the clearance, V_d, markedly as compared with the control group whereas, PD activity was also altered. **Conclusion:** The results suggesting that quercetin led to the PK/PD changes because of saxagliptin increased bioavailability and the inhibition of CYP3A4 enzyme. In conclusion, add on preparations containing quercetin may increase the bioavailability of saxagliptin and hence should be cautiously used.

Key words: Saxagliptin, quercetin, diabetic rats, herb drug interaction, pharmacokinetic, pharmacodynamic


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Competing Interest: The authors have declared that no competing interest exists.

Data Availability: All relevant data are within the paper and its supporting information files.


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**SGLT2 INHIBITORS: A NEW CLASS OF DRUGS FOR TYPE-II
DIABETES MELLITUS****Lahari Samudrala*¹, T. Ramya Krishna², V. Sireesha³ and Pooja Agarwal⁴**

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ABSTRACT

Diabetes is on the rise. No longer a disease of predominantly rich nations, the prevalence of diabetes is steadily increasing everywhere, most markedly in the world's middle-income countries. Sodium-glucose co-transporter-2 (SGLT2) inhibitors are a new group of oral medications used for treating type II Diabetes Mellitus. The drugs work by helping the kidneys to lower the blood glucose levels. Globally, an estimated 422 million adults were living with diabetes in 2014, compared to 108 million in 1980. The global prevalence of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% in the adult population. This reflects an increase in associated risk factors such as being overweight or obese. Over the past decade, diabetes prevalence has risen faster in low- and middle-income countries than in

high-income countries. The present therapeutic classes of anti-diabetic drugs are not adequately effective in maintaining long-term glycemic control in the most patients. Sodium glucose transporter-2 (SGLT2) inhibitors including Dapagliflozin, Canagliflozin and Empagliflozin act by a novel insulin-independent mechanism by blocking glucose reabsorption in the proximal convoluted tubule resulting in markedly increased glycosuria, and blocking the formation of proteins.

KEYWORDS: Canagliflozin, Dapagliflozin, Empagliflozin, Sodium Glucose Co-Transporter-2 Inhibitors.

INTRODUCTION

Diabetes is on the rise. No longer a disease of predominantly rich nations, the prevalence of diabetes is steadily increasing everywhere, most markedly in the world's middle-income

RUTF (READY-TO-USE THERAPEUTIC FOODS) TREATMENT FOR KWASHIORKOR

Lahari Samudrala^{*1}, Pooja Agarwal², T. Ramya Krishna³ and B. Priyanka⁴

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ABSTRACT

Kwashiorkor, also known as “edematous malnutrition” is a nutritional disorder most often seen in regions experiencing extreme scarcity of food. It is a form of malnutrition caused by a lack of protein in the diet. These conditions are responsible for a lack of food, which leads to malnutrition. Kwashiorkor is very rare in children in the United States. The World Health Organization (WHO) defines malnutrition as “the cellular imbalance between the supply of nutrients and energy and the body's demand for them to ensure growth, maintenance, and specific functions. If kwashiorkor is identified early it can be treated with either specially formulated milk-based feeds or ready-to-use therapeutic food (RUTF). RUTF is typically made up of peanut butter, milk powder, sugar, vegetable oil, and added vitamins and minerals. More intensive

treatment in hospital will be needed in severe cases or where there are already complications, such as infections. Hospital treatment will usually involve: Treating or preventing low blood glucose. Keeping the person warm – kwashiorkor can make it harder to generate body heat. Treating dehydration with specially formulated rehydration solution. Treating infections with antibiotics – kwashiorkor greatly increases the risk of infections. Treating vitamin and mineral deficiencies – vitamin supplements are usually included in the special milks or RUTF.

KEYWORDS: Protein Deficiency, Malnutrition, Kwashiorkor, Therapeutic Foods.

KWASHIORKOR

Kwashiorkor, also known as “edematous malnutrition” is a nutritional disorder most often seen in regions experiencing extreme scarcity of food. It is a form of malnutrition caused by a

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GERMANY PATENT SYSTEM – AN OVERVIEW

Available online at www.ijdra.com

REVIEW ARTICLE

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ABSTRACT

Patent is one of the intellectual property rights, by which the innovator gets exclusive rights or legal monopoly granted to an individual or a firm to make use or sell or reproduce and excluding others from doing so. The Germany patent act came into existence on June 21st 1976, which was taken from the European patent convention of October 5, 1973. Germany stands in 2nd place in filing patents and it shares 16% of total application in 2016 and 25.086 application are filed, grant of patent applications are 18,728. In this paper discussed about Germany patent system.

Keywords: Germany. Patent filing, Monopoly rights, Federal court.

INTRODUCTION

Patent is one of the intellectual property right, by which the innovator gets exclusive rights or legal monopoly granted to an individual or a firm to make use or sell or reproduce and excluding others from doing so.(1,2) The Germany patent act came into existence on June 21st 1976, which was taken from the European patent convention of October 5, 1973.(3) Germany stands in 2nd place in filing patents and it shares 16% of total application in 2016 and 25.086 application are filed, grant of patent applications are 18,728. In this paper discussed about Germany patent system . (4)

Germany patent law came into effect from June 21st 1976, is has become a member of PCT on 24th January 1978. (5) It was stipulated in the patent law in 25 May 1877 and named as the Kaiserliches Patentamt (imperial patent office) started to operate in Berlin on July 1st 1877 and the first Germany patent granted for the "production process of red ultramarine color" invented by Johann Zeltner of Numberger Ultramarine Fabrik. After a lot of changes now, it became as Deutsches patent-und markenam (DPMA) on November 1st 1998. It celebrated its 60th anniversary in Munich on October 1st 2009.(6) German intellectual property law mainly consists of the Copyright Act (UrhG),

Patent Act (PatG), Trademark Act (MarkenG), Utility Model Act (GebrMG) and Design Rights Act (GeschMG), flanked by some provisions of the Civil Code (BGB) and the Act Against Unfair Competition (UWG).(7) Generally, Patent term is 20 years.

GERMANY PATENT SYSTEM

A patent grants exclusive rights to a new process (or) product (or) invention in order to reproduce, sell, make etc., to the inventor. It is generally governed by Germany patent system and European patent convention. Germany patent system is one of the few system in this patent infringement and patent validity are dealt with different courts or routes. The patent infringement is dealt with Federal Patent Court and it is known as bifurcation system.

Types of Patent applications

- National patent application: It is a direct application done with German Patent and Trademark Office i.e., DPMA (Deutsches Patent- und Markenamt). Patent granted by DPMA have effect on the Federal Republic of Germany.
- European Patent application: it is a single direct national filing and it is applicable in European member states and granted by European Patent office.

Method Development and Validation for Simultaneous Estimation of Raltegravir and Lamivudine by Using RP-HPLC in Bulk and Pharmaceutical Dosage Form

Sunil Junapudi^{1*}, P Nagaraju¹, K Ganesh¹, M Nagesh¹

Abstract: High performance liquid chromatography is at present one of the classiest tool of the analysis. The estimation of raltegravir and lamivudine was done by RP-HPLC. The Phosphate buffer was pH 3.0 and the mobile phase was optimized with consists of acetonitrile: phosphate buffer mixed in the ratio of 45:55 % v/v. Inertsil ODS 3V C₁₈ column (4.6 x 150 mm, 5 µm) or equivalent chemically bonded to porous silica particles was used as stationary phase. The detection was carried out by using PDA detector at 275 nm. The solutions were chromatographed at a constant flow rate of 1.0 ml/min. the linearity range of raltegravir and lamivudine were found to be from 150-450 µg/ml of raltegravir and 50-150 µg/ml of lamivudine. Linear regression coefficient was not more than 0.999. The values of % RSD are less than 2% indicating accuracy and precision of the method. The percentage recovery varies from 100.36 and 100.30% of raltegravir and lamivudine. LOD and LOQ were found to be within limit.

INTRODUCTION

Raltegravir (RAL) is chemically N-[[4-Fluorophenyl]methyl]-1, 6- dihydro-5-hydroxy-1-methyl-2[[1-methyl-1-[[[(5- methyl-1, 3, 4-oxadiazol-2-yl) carbonyl] amino] ethyl]-6-oxo-4 pyrimidine carboxamide. It is a human immunodeficiency virus (HIV) integrase strand transfer inhibitor. [1, 2] The chemical structure of RAL was shown in figure-1. Researchers found proof that few analytical methods such as UV, [3-6] HPLC, [7-12] UPLC, [13] LC-MS [14-15] and HPTLC [12] methods have been reported in either alone or combined dosage form and biological sample.

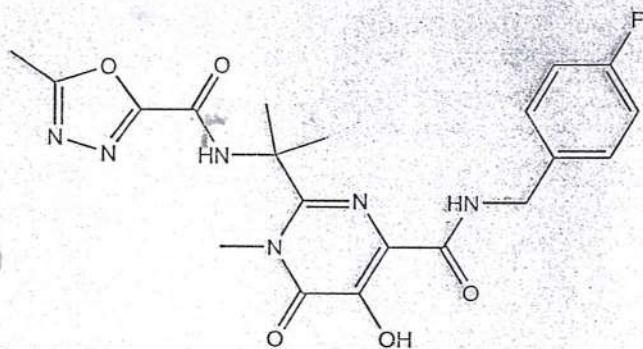


Figure 1: Chemical structure of raltegravir

Lamivudine (LAM) is chemically 4-amino 1-[[[2R, 5S]-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]-1,2-dihydropyrimidin-2-one. It is an HIV-1 nucleoside analogue reverse transcriptase and HIV polymerase inhibitor. [4, 16] The chemical structure of RAL was shown in Figure 2. Researchers reveals that very few analytical methods have been reported for the determination of LAM which includes UV, [17-22] HPLC, [17, 23-27] HPTLC [17, 28] and LC-MS [29, 30] are available for the estimation of LAM either individually or combined dosage form and biological sample.

Correspondingly, this manuscript described the optimization of an isocratic RP-HPLC method for the

routine quality control analysis of LAM and RAL in laboratory prepared binary mixture. In spite of that Development and optimization of isocratic RP-HPLC method is a tedious process that involves instantaneous determination of several factors. [31-36] It is recognized to provide risk-based understanding of the analytical as well as major factors affecting the performance of analytical method. [37-39] Furthermore, it provided thorough understanding of the possible risk and associated with interaction among the method variables, respectively. [40] Therefore, the aim of present study was to develop, optimize and validate sensitive and cost-effective RP-HPLC method for estimation of LAM and RAL in laboratory prepared binary mixtures.

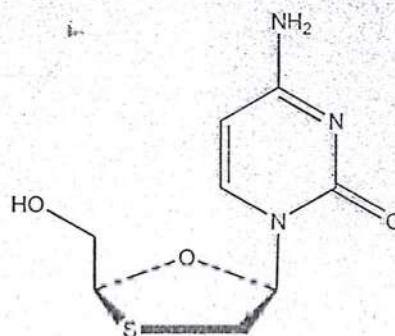


Figure 2: Chemical structure of lamivudine

MATERIALS AND METHODS

Chemicals

Pure drugs LAM (99.95%) and RAL (99.95%) were kindly supplied by Richer Pharmaceuticals, Prasanthinagar, Hyderabad, India and Emcure Pharmaceuticals, Pune, India respectively. The Pharmaceuticals LAM and RAL (DUTREBIS, Tablets: 150 mg lamivudine and 325.8 mg raltegravir potassium) were purchased from local pharmacy (Meda Pharmaceuticals/ Hyderabad, India). Dipotassium hydrogen phosphates (AR Grade), Ortho phosphoric acid (AR Grade), acetonitrile (HPLC Grade) were purchased from E. Merck (India) Ltd. Worli, Mumbai, India. The 0.45 µm nylon filters were purchased from Advanced Micro Devices Pvt. Ltd., Chandigarh, India.

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FORMULATION AND EVALUATION OF SUSTAINED RELEASE TABLETS OF TRAMADOL

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ABSTRACT

The main aim of the proposed work was to develop Tramadol matrix tablets, sustained release dosage form. Tramadol is a narcotic analgesic proposed for moderate to severe pain Sustained release formulation is the drug delivery system that is designed to achieve a prolonged therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose. The sustained release tablets were prepared by direct compression method using Hydroxypropyl methyl cellulose as a K100M grade, Karayagum and Guar gum in varying ratios. Tablets blends were evaluated for Bulk density, Tapped density, compressibility index and angle of

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repose, shows satisfactory results. The compressed tablets were then evaluated for various physical tests like diameter, thickness, uniformity of weight, hardness, friability and drug content. The granules exhibited satisfactory rheological demeanor. The results of all these tests were found to be satisfactory. The in-vitro dissolution study was carried out for 12 hours using the paddle method in phosphate buffer (pH 6.8) as dissolution media. Formulation F1, to F9 direct compression method, sustain release and among all the formulation. This finding reveals that above a particular concentration of HPMCK100M, Karayagum and Guar gum and Magnesium stearate are capable of providing sustained drug release. Sustained release, HPMC-K100M, Karayagum, Guar gum, Magnesium stearate, Microcrystalline cellulose.

INTRODUCTION

Oral drug delivery is the most widely utilized routes of administration among all the routes of administration that has been explored for systemic delivery of drugs via pharmaceutical products of different dosage form.[1] Oral route is considered more natural, uncomplicated, convenient and safe due to its ease of administration, patient compliance and cost effective

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