DEVELOPMENT AND METHOD VALIDATION OF STABILITY INDICATING ASSAY METHOD OF DUTASTERIDE BY USING UV-VIS SPECTROSCOPY

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ABSTRACT

The objective of the present study was to develop and validate stability indicating method to generate reliable, precise, cost effective UV-VIS spectroscopy method and accurate data for dutasteride regardless of whether it is for acceptance, release, stability or pharmacokinetic study. The solvent used was methanol and the absorption maximum λ max of the drug was found to be at 241nm. A linear response was observed in the range of 1-100μg/mL. Linear regression of absorbance on concentration gave the equation y = 0.0194x + 0.0099 with a regression co-efficient (R^2) of 0.997. The method was then validated for different parameters as per the ICH guidelines. Dutasteride was subjected to stress degradation under different conditions as recommended by ICH guidelines. The degradation studies were carried out by using the developed method. The method is useful for the determination of dutasteride in bulk and pharmaceutical formulations.

Keywords: Dutasteride, validation, stress degradation studies, UV-Vis spectroscopy

INTRODUCTION

Dutasteride is a white to pale yellow power with the chemical name α-5α-N-(2,5 bis (trifluoromethyl) phenyl)-3-oxo-4-azandrost-1-ene-17β-carboxamide. Its CAS number is 164656-23-9.The chemical formula is $C_{27}H_{30}F_6N_2O_2$ and the molecular weight of dutasteride is 528.53 g/mol[1]. Dutasteride is used to treat benign prostatic hyperplasia[1,2,3] in men having an enlarged prostate gland and in the treatment of male pattern baldness. It belongs to a class of drugs called 5α-reductase inhibitors, which competitively and specifically inhibit type 1 (active in the sebaceous glands of most regions of skin and liver) and type 2 (primarily active in the reproductive tissues like prostate, seminal vesicles, epididymides, hair follicles and liver) isoforms of 5α-reductase, an intracellular enzyme that converts testosterone to 5α-dihydrotestosterone. The decrease in dihydrotestosterone levels may mitigate or prevent enlargement of the prostate gland. Dutasteride does not bind to the human androgen receptor[2]. A limited number of analytical techniques have been reported for the quantitative determination of dutasteride. These techniques are UPLC[2], LC–MS–MS[3,4], liquid chromatography–tandem mass spectrometry assay[5], HPTLC[6], enzyme-linked immunosorbent assay[7] and stability-indicating RP-HPLC[8,9].

In order to commercialize an active pharmaceutical ingredient, it is mandatory requirement from regulatory authorities to show the proper qualification of its degradation pathways and characterization of known degraded products that are present. Degradation can arise during the storage of the drug substances and their acceptance upto certain limits are based on pharmaceutical studies or known safety data. In the present study, we describe an ideal stability indicating spectroscopic method which can estimate the drug and also be able to resolve the drug from its degradation products. An attempt has been made to develop an accurate, rapid and reproducible method for the determination of dutasteride in presence of its degradation products for its content analysis in pharmaceutical dosage form as per ICH guidelines[13,14].

MATERIALS AND METHODS

Chemicals

Samples of dutasteride were obtained as gift samples from Wockhardt Pharma Ltd. (Aurangabad, India). HPLC grades methanol, analytical reagents grade concentrated hydrochloric acid, sodium hydroxide and sodium hypochlorite (4-6% W/V available chlorine) were

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A Review on Natural Radio-protective Agents

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Abstract

Radioprotectors play crucial role in safeguarding biological system from various damages to DNA (Deoxyribonucleic acid), protein molecules, lipids by peroxidation as well as hematopoietic, gastrointestinal, reproductive and central nervous system exposed to radiation dose especially against radiation injury in cancer survival patients undergoing radiotherapy. As over 40% patients require this therapy, during the treatment where ionizing radiation is used to shrivel tumors and exterminate cancer cells by disrupting their DNA. The present review intimately chronicles the rich intellectual, pharmacological story of natural radioprotectors. In this article, for the first time we have discussed the impact of radioprotectors on different signaling pathways in cells, which will create a basis for scientific community working in this area to develop novel molecules with better therapeutic efficacy. Therefore to enhance therapeutic ratio (ratio of cancer killing cells to normal cells toxicity with the given dose) radioprotective agents are gaining significant interest.

Keywords: *Applications, examples, mechanism of action, natural radio-protective agents, pharmacology*

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INTRODUCTION

Ionizing radiation in the form of x-rays, gamma rays are frequently used in cancer therapy as these rays have the capacity to penetrate tissues fragmenting chemical bonds, withdrawing electrons from the atoms. Large doses of radiation are required for considerable period of time to terminate the growth of tumor as well reduce the signs and symptoms produced by tumor. But over exposure to ionizing radiation leads to mutagenesis, cell death and clinical manifestations depends on the vulnerable body part and the dose [1].

Radiation damage to biological tissues of living organisms is categorized as lethal, sub-lethal and potentially lethal damage [2].

Lethal damage is defined as irreversible, irreparable leading to death of cells;

Sub-lethal damage is defined as type of damage which can be repaired in some hours except additional sub-lethal damage won't be added further and eventually end up to lethal damage and

Potentially lethal damage is defined as repair when living cells are allowed to persist in a non-dividing phase.

Thus, there is a need of radioprotection especially for cancer patients to enhance quality of life along with increase in cancer curability and in professional groups exposed to diagnostic radiation, energy sectors, nuclear accidents and terror attacks [3]. Radioprotection covers all the measures involved in securing humans and environment against ill effects of ionizing radiations such as beta, gamma, UV, or by radio nucleotides (e.g., americium-241, cesium-137, radium,

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Review Article

Antimicrobial Drug Resistance: A Review

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ABSTRACT

Problems of antimicrobial drug resistance are presently serious and desperate. The principal areas of concern are twofold: multiresistant opportunist bacteria that affect vulnerable patients in high dependency areas of hospitals major problem for developing countries like India. There is multidrug resistance among the classic pathogens. Almost 1/3rd population on the earth are infected by mycobacterium tuberculosis, salmonella typhi, Shigella spp., Neisseria gonorrhea and plasmodium falciparum. Number of drugs available for the treatment of viral, fungal and parasite infections is comparatively less; moreover very little is known about resistance. In recent years; concern has increased that the golden antibiotic era might be coming to an end. This is attributed to the rate of production of new antimicrobial agents has reduced. Moreover, different parasites are showing great inventiveness in devising mechanisms for overcoming the lethal activity of such agents. If antimicrobial chemotherapy is preserved for future; prescribers must learn to use these powerful tools with greater discretion and their use worldwide must be regulated effectively.

Keywords: Antimicrobial Drug; Drug Resistance; Parasites

INTRODUCTION

There should be awareness among the health professional and the public. They should be emphasis on infection and antimicrobial in medical curriculum. It is a need of time to discuss the issue at length to avoid mammoth problem of drug resistance. Drug resistance is a state of insensitivity or of decreased sensitivity to drugs that ordinarily cause growth inhibition or cell death.

Types of drug resistance: There are two types of bacterial resistance: Inherent and acquired.

1. Inherent; Gram negative bacteria as a group are inherently resistance to number of important antibiotics that are very effective against gram positive organism. Further, pseudomonas aeuruginosa presents high intrinsic resistance too many antibiotics among the gram negative organisms. This inherent resistance of gram negative organism is associated with the impermeability of the complex outer layers of the cell envelop to

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Original Article

PRESCRIPTION ANALYSIS OF HYPERTENSIVE PATIENTS AND AWARENESS AMONG PHYSICIAN REGARDING ANTIHYPERTENSIVE DRUG

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ABSTRACT

Objective: This study was conducted to analyze prescriptions of the hypertensive patient and to determine the awareness of physicians regarding antihypertensive drugs.

Methods: Prepare a questionnaire by the pilot study on five physicians. Review and finalized the questionnaire after discussion with pharmacologist. The answers were seek for awareness. Moreover the prescription of 30 patients was collected from the same physician who has undertaken the awareness regarding Antihypertensive Drugs. Study was conducted during Oct-2019 to Dec 2019.

Results: Average 83% awareness was found in the physician regarding antihypertensive drugs. Lack of awareness regarding diabetes and in ulcer patients was observed. Highest drug is given i.e. β blockers in antihypertensive patients. To determine the irrationality in the prescription of hypertensive patients.

Conclusion: To determine the FDC's given to hypertensive patients. To determine the type of antihypertensive drugs given to patients.

Keywords: Rational use of Drugs, Survey on antihypertensive use, Awareness, Knowledge regarding combination drug use hypertensive patient

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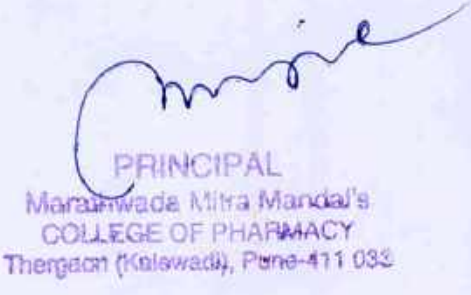
INTRODUCTION

Hypertension is a cardiac chronic medical condition result in increasing systemic arterial blood pressure. Hypertension means blood pressure is more than 140/90 mm of Hg [1]. Symptoms: headache, sleepiness, coma, confusion. If any person suffer from high blood pressure, but certain factors can seriously aggravate hypertension and increase the risk of complications [2]. Such as a tendency in the family to suffer hypertension, obesity, smoking, diabetes type 1 or type 2, kidney diseases, excessive salt intake, lack of exercise, certain medicines, such as steroids [3]. Antihypertensive agents are classified into Angiotensin-II receptor antagonists, β-blockers, α-blockers, Calcium-channel blockers and Diuretics, Drug Interaction of Antihypertensive Drugs: 1. ACE inhibitors: a. ACE inhibitor+Alpha blocker: Acute hypotension, dizziness, fatigue or sweating develop, and to remain lying down until symptoms abate. b. ACE inhibitor+Clonidine: ACE inhibitors may potentiate the antihypertensive effects of clonidine, and this can be clinically useful. 2. Beta-blockers: Examples are Cardio selective β1 blocker (Atenolol)+Antacid: Reduced cardioselective β1 blocker absorption b. Cardio selective β1 blocker (Atenolol)+antiarrhythmic: Increased cardiac adverse effect. Alpha-blocker: a. Alpha blocker+ACE inhibitor: 3. Calcium channel blocker: a. Bepridil+Quinolones: Increased risk of cardiac arrhythmias 4. Diuretics: If possible avoid beta-blockers especially in the presence of marked LVF (left ventricular failure) [4]. β blockers that block β2 receptors and cause shortness of breath in asthmatics. As with other drugs that may use for treating high blood pressure, sexual dysfunction may be observed in patients. β blockers influence blood glucose level and mask the symptoms of hypoglycemia in patients with diabete [5]. Hypertension is associated with increased risk of stroke, myocardial infarction, atrial fibrillation, heart failure, peripheral vascular disease, and renal disease. Regarding changes in diet, a low sodium diet is beneficial for the patient with hypertension. The level hypertension can be treated on a number of features including a current blood pressure of patients, sodium or potassium balance, detection and omission of environmental toxic substances, changes in end or target organs for treatment, major factors for heart diseases and the age at diagnosis of prehypertension or at major risk for hypertension. Nowadays, lifestyle changes are also an important factor to lower blood pressure, before the initiation of prescription drug therapy [6]. In Antihypertensive the goal of treatment is to reduce blood pressure so that you have a lower risk of complications. Classification of Antihypertensive and their mechanism of action: 1. Diuretics-Sympatholytic (Sympathetic Depressants) 1) Beta-Adrenergic Blockers (Beta Blockers): Atenolol (Tenormin), Metoprolol (Lopressor) Beta-1 cardioselective Nadolol (Corgard), Propranolol (Inderal)-Nonselective Beta-1, Beta2 2) Centrally Acting Sympatholytics Agents or Adrenergic Blockers: Clonidine Hydrochloride, Methyldopa 3) Alpha-Adrenergic Blockers: Prazosin HCL 4) Adrenergic Neuron Blockers (Peripherally acting sympatholytics): Reserpine (Serpasil) and guanethidine (Ismelin) 5) Alpha-1 and Beta-1 Adrenergic blockers: Carteolol (Cartrol), Labetalol (Trandate). Direct-Acting Arteriolar Vasodilators-potent: Hydralazine (Apresoline)-Angiotensin Antagonists-Angiotensin-Converting Enzyme Inhibitors (ACE inhibitors) Captopril (Capoten), Enalapril (Vasotec), Lisinopril (Zestril) Angiotensin II receptor Antagonists (Blockers)-A-II Blockers: Losartan (Cozaar) Calcium Channel Blockers: Verapamil (Calan), Nifedipine (Procardia), Diltiazem (Cardizem [7].

Alpha blockers+Beta blockers: The risk of first-dose hypotension with prazosin (resulting in dizziness or even fainting) is higher if the patient is already taking a beta-blocker. This is likely to be true of other alpha-blockers, particularly alfuzosin, bunazosin and terazosin. In a small study, tamsulosin did not have any clinically relevant effects on blood pressure that was already well controlled by atenolol. Alpha-blockers and beta-blockers may be combined for an additional lowering of blood pressure in patients with hypertension. It is recommended that those already taking beta-blockers should have the dose reduced to a maintenance dose and begin with a low-dose of an alpha-blocker, with the first dose taken just before going to bed. They should also be warned about the possibility of postural hypotension and how to manage it (i.e. lay down, raise the legs, and get up slowly when recovered). Similarly, when adding a beta®. Adrenergic neuron blocker: Amfetamines+Guanethidine: When hypertensive patients taking guanethidine were given single doses of dexamfetamine or metamfetamine, the hypotensive effects of the guanethidine were completely abolished, and in some instances, the blood pressures rose higher than before treatment with the guanethidine. Direct acting



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Original Article

AWARENESS, KNOWLEDGE AND ATTITUDE ABOUT DENGUE AMONG SOCIETY

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ABSTRACT

Objective: The survey about dengue was carried out to gather the information about dengue fever, create awareness among the people. To determined the index of knowledge, attitude and awareness among the surveyed population about dengue.

Methods: The questionnaire was prepared under the guidance of a pharmacologist. Pilot study was conducted among ten nos. of the population prior actual study. Questionnaire was revised and finalized according to an input of the pilot study. This questionnaire presented to the hundred peoples of different age group. Method involves face to face interview and seeking answers for different questions. Responses were recorded for further analysis and interpretation. Responses were sorted and analyzed. Different questions were categorized into the domain of awareness, knowledge and attitude. Data was presented in the form of graphs.

Results: Percentage of awareness, knowledge and attitude found to be 59, 44, 52 respectively. It is observed that three parameters are almost in the range of fifty percent. Precautions plays vital role in prevention of Dengue.

Conclusion: it is concluded that there is scope for improvement for creating awareness, knowledge and attitude among the surveyed population as representative of the general population. This may help to overcome the risk of this communicable and deadly disease.

Keywords: Awareness, Dengue among

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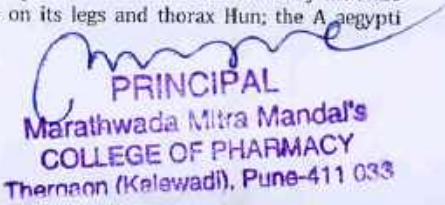
INTRODUCTION

Dengue fever, also called as break-bone fever, is a mosquito-borne infection that causes a severe flu-like illness. There are four types of viruses that can cause dengue fever, all of which spread by a certain type of mosquito. Dengue can vary from mild to severe and severe forms include dengue shock syndrome and dengue hemorrhagic fever (DHF). According to the WHO 2.5 billion people, or two-fifths of the world's population, are now at risk from dengue. The disease is now endemic in over 100 numbers of countries. Dengue hemorrhagic fever is leading cause of serious illness and death among children in the number of Asian countries. In 2007, there were over 890,000 numbers of reported cases of dengue in the Americas, of which 26,000 cases were DHF. Dengue infection rates among the people who have not been previously exposed to the virus are commonly 40% to 50% during epidemics but may sometimes reach 80% to 90%. Now a day's approximately half-a-million people with DHF are hospitalized each year, of which many are children. About 2.5% of these patients die. DHF fatality reads may exceed 20% if untreated. If there is access to medical care with health care professionals are trained in treating DHF, the death rate may be less than 1%. A symptom is something the patient feels or/and reports, while a sign is something that other people, including the doctor, detects. A headache an example of a symptom, while a rash may be an example of a sign [1-3]. Causes of Dengue-There are four Dengue viruses that cause Dengue fever, all of which are spread by a species of mosquito known as the *Aedes aegypti* mosquito, and rarely by the *Aedes albopictus* mosquito. *Aedes aegypti* was originated in an African country, but nowadays is found in all tropical areas around the world and prospers in and close to areas of the human population. High-risk regions for dengue fever are South America, Central America, the Caribbean and tropical Asia; specifically-northern Argentina, northern Australia, the entirety of Bangladesh, Barbados, Bolivia, Brazil, Cambodia, Dominican Republic, Costa Rica, Guatemala, Guyana, Honduras, India, Indonesia, Jamaica, Laos, Mexico, Malaysia, Micronesia, Pakistan, Panama, Paraguay, Puerto Rico, Philippines, Samoa, Singapore, Sri Lanka, Taiwan, Suriname, Thailand, Trinidad, Venezuela and Vietnam, and increasingly in southern China [4-6]. Diagnosis of Dengue fever:- Assess the symptoms-the doctor will take into account all your symptoms to properly diagnose whether you have dengue. Some tests ordered to determine whether it is dengue infection or other. Blood sample-this sample can be tested in a laboratory in a number of ways to find signs of the dengue virus. If virus is found diagnosis is straightforward; if this fails there are other blood tests which identify antibodies, antigens and nucleic acids and including ELISA (enzyme-linked immunosorbent assay), HI assay (hemagglutination inhibition assay) and RT-PCR (reverse transcriptase-polymerase chain reaction), Assess your medical history-The doctor will need to know travel history and medical history of the patient, if it involves mosquito exposure [7-9]. Milder forms of dengue treatment methods are: Prevent dehydration-high fever and vomiting it can dehydrate the body of patient. Make sure drink clean water rather than tap water. Rehydration salts also help replace fluids and minerals. Painkillers-this can help lower fever and pain. As some non-steroidal anti-inflammatory drugs, such as aspirin or ibuprofen, can increase the risk of internal bleeding, patients are advised to use Paracetamol instead. For More severe forms of dengue fever: Intravenous fluid supplementation (IV drip)-in some harsher cases of dengue the patient is unable to take fluids via the mouth) and will need to receive an IV drip. Blood transfusion-a blood transfusion recommended for patients with severe dehydration. Hospital care-it is important that patients treated by medical professionals, this way you can be properly monitored (e. g. blood pressure, fluid levels) in case your symptoms worsen. If the patient is cared for by physicians and nurses experienced with the effects and complications of hemorrhagic fever, lives can be saved [10]. The best method of prevention is to avoid being bitten by mosquitoes. Clothing-your chances of being bitten are reduced if you expose as little skin as possible. Mosquito repellants-be sure to use one with at least 10% concentration of DEET, avoid using DEET on young children. Use mosquito traps or nets-studies have shown that the risk of being bitten by mosquitoes is considerably reduced if you use a mosquito net when you go to sleep. Smell-Avoid wearing scented soaps and perfumes. Windows-use structural barriers, such as window screens or netting. Camping-if you are camping, treat clothes, shoes and camping gear with permethrin [11]. Dengue viruses are transmitted by the bite of an infected Aedes (subgenus Stegomyia) mosquito Virus. It can be identified by the scale patterns or white bands on its legs and thorax Hun; the A. aegypti



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FORMULATION AND EVALUATION OF CONTROLLED POROSITY OSMOTIC TABLET OF VERAPAMIL HYDROCHLORIDE

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Keywords:

Osmotic System, Controlled porosity osmotic tablet, Pore formers, Wicking agent

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ABSTRACT: Verapamil hydrochloride is a water-soluble drug, so it is suitable to develop controlled porosity osmotic pump. As Verapamil HCl is a short-acting drug, so developed formulation provides the advantages of controlled release formulations. The developed formulation provides advantages of less steps of manufacturing procedure, no need for laser drilling, and economical, all of which made the procedure easily amenable to mass production using conventional tablet machines. Verapamil HCl 120 mg core formulations were prepared coated with film former (cellulose acetate): pore former (sorbitol). The effect of different formulation variables, namely, membrane weight gain, and amount of pore former in the membrane, were studied. Verapamil HCl release was inversely proportional to the membrane weight (coating thickness) but directly related to the initial amount of pore former (sorbitol) in the membrane. Drug release from the developed formulations was independent of pH but dependent on the osmotic pressure of the release medium. Verapamil HCl release from the developed formulation follows zero-order. The drug release from formulation was proved as dependent on osmotic pressure only. Results of SEM studies showed the formation of pores in the membrane after coming in contact with aqueous dissolution fluid from where the drug release occurred. The manufacturing procedure was found to be reproducible, and formulations were stable after three months of accelerated stability studies.

INTRODUCTION: For many decades, conventional dosage forms, which are of prompt releasing nature, are used for the treatment of acute and chronic diseases. The conventional dosage forms provide no control over the release of the drug. Recently, several technical advancements have been made. These have resulted in the development of new techniques in drug delivery. These techniques are capable of controlling the rate of drug delivery, sustaining the duration of therapeutic activity and/or targeting the delivery of the drug to tissue.

It is advantageous to deliver some drugs with a short half-life and which are to be given frequently for chronic ailments in the form of controlled release formulations. The majority of existing oral controlled release systems are matrix-based, and their principle drug release mechanism is based on drug diffusion through the matrix system. The diffusion is altered by the pH of the medium, the presence of food, hydrodynamic conditions, and the body's other physiological factors, all of which can cause difficulty in controlling the drug release rate

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

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Keywords:

Chlorthalidone, Amlodipine, RP-HPLC, ICH Guidelines, Regression coefficient

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ABSTRACT: The RP-HPLC stability-indicating assay method has been developed and validated for the estimation of the amlodipine and chlorthalidone in bulk and combined dosage form. The method was optimized by using the mobile phase as a mixture of 0.1% formic acid: methanol: acetonitrile in the ratio of (50:5:45 v/v) at pH 3 was adjusted with orthophosphoric acid. The method was carried out on the Octadecylsilane C18 column (5 µm, 25 cm × 4.6 mm) using a flow rate of 1.0 ml per min. The method was scanned at λ_{max} 266 nm for both the drugs using a PDA detector. The retention time was found to be at 6.32 min and 5.32 min for AML and CHL respectively. The calibration curve determined at respective retention time is found to be 2.5-7.5 µg/ml and 06-18 µg/ml with a regression coefficient of 0.9990 and 0.9940 for AML and CHL respectively. The developed and validated method is reliable, simple, precise and accurate and easy to apply in the laboratories.

INTRODUCTION: Amlodipine besylate is a second-generation calcium channel blocker that is used in the therapy of hypertension and angina pectoris. Chemically, it is 3-O-ethyl 5-O-methyl 2-(2- aminoethoxymethyl)- 4- (2- chlorophenyl)- 6-methyl-1,4-dihydropyridine-3,5-dicarboxylate [1, 2] **Fig. 1**. Chlorthalidone is a long acting thiazide-like diuretic of the sulfamoylbenzamide class that is devoid of the benzothiadiazine structure.

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Chlorthalidone directly inhibits sodium and chloride reabsorption on the luminal membrane of the early segment in the distal convoluted tubule (DCT) in the kidney. This leads to an increase in sodium, chloride, bicarbonate, and potassium secretion resulting in the excretion of water. In addition, this agent, like other thiazide diuretics, decreases calcium and uric acid secretion. Chemically it is (RS) 2-chloro-5-(1-hydroxy-3-oxo-2, 3- dihydro- 1, hisoindol- 1- yl) benzene- 1-sulfonamide [3, 4] **Fig. 2**.

A literature survey for amlodipine and chlorthalidone was done. It showed that the estimation of Amlodipine individually and in combined dosage forms with other APIs like metoprolol [5], telmisartan [6], valsartan [7], hydrochlorthiazide [8], losartan [9], olmesartan [10] and

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A State-of-the-art Review on Applications of Different Analytical Techniques for Some ACE Inhibitors

Sandip D. Firke, Komal R. Bhoi, Kiran R. Patil, Shubham D. Jayswal, Avinash R. Tekade & Shailesh S. Chalikwar

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Review Article

A Review on Solid Dispersion and Carriers Used Therein for Solubility Enhancement of Poorly Water Soluble Drugs

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Abstract

A large number of hydrophilic and hydrophobic carriers in pharmaceutical excipients are available today which are used for formulation of solid dispersions. Depending on nature of carriers the immediate release solid dispersions and/or controlled release solid dispersions can be formulated. Initially crystalline carriers were used which are transformed into amorphous solid dispersions with enhanced properties. The carriers used previously were mostly synthetic one. Recent trend towards the use of natural carriers have replaced the use of synthetic carriers. This review is the overview of various synthetic, natural, semisynthetic, modified natural hydrophilic carriers used for formulation of solid dispersions.

Introduction

Absorption of drug and its therapeutic effectiveness get affected by solubility which is a significant physicochemical factor. Poor aqueous solubility can leads to failure in formulation development process. The main reason behind inadequate bioavailability of drug is its low dissolution rate and low solubility in aqueous medium.[1] A large number of hydrophilic carriers are explored today which have shown significant results for solubility enhancement. Nowadays, most of the drug substances were innovated but the venture to improve the solubility and dissolution of hydrophobic drug substances remain one of the trickiest tasks in drug development. Dissolution of drug in aqueous medium like gastric fluid is important to get better absorption and bioavailability for orally administered drug. Therefore, to progress bioavailability of poorly water soluble compounds like biopharmaceutical classification system class II and IV drugs, polymer matrix of various origin can be used. Various solubility enhancement methods have been introduced to triumph over this problem.[1] There are several techniques for solubility enhancement which can be categorized into physical modification, chemical modifications for the drug substance, and other techniques[2] which are listed in Table 1.

One of the most promising and efficient techniques for solubility enhancement is solid dispersion formulation. According to Chiou and Riegelman, solid dispersion systems can be defined as 'the dispersion of one or more active ingredients in an inert carrier or matrix at solid state prepared by the melting [fusion], solvent, or melting-solvent method'. The drug is hydrophobic in nature whereas matrix is hydrophilic. Solid dispersion can be classified as simple eutectic mixtures, solid solutions, glass solutions and glass suspensions, amorphous precipitation in a crystalline carrier, compound or complex formations.[3] However, several modifications have been done in classification systems by various researchers which will be discussed in the following.

Classification of solid dispersions

On the basis of recent advancement in solid dispersion, they can be classified as:

First generation solid dispersion

The solid dispersions which could be prepared by using crystalline carriers are categorized as the first generation solid dispersions.[6] Examples of used crystalline carriers are urea and sugars.[7] In this type, thermodynamically stable crystalline solid dispersion get formed which releases the drug slowly.[6] The dissolution rate is faster in case of amorphous solid dispersions (ASDs) as compared

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Bird's eye view on aquasome: Formulation and application

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ABSTRACT

Aquasomes are globe shaped (60–300 nm), three layered, self-assembled nanoparticulate drug delivery system. They contain an innermost solid nanocrystalline core coated with polyhydroxyl oligomer onto which biochemically active drug molecules are adsorbed. They are designed to accomplish successful delivery of bioactive agents as well to protect the conformational integrity. Its elevated degree of surface exposure is used in targeting bio-active molecules to specific sites. They can be used as a RBC substitutes, carrier for delivery of viral antigen and as a targeted system for intracellular gene therapy. The current review provides a bird eye view of the aquasome as a promising tool for drug delivery. It describes all the aspects of aquasomes including its composition, mechanism of formation, methods of preparation, its characterization and therapeutic applications as a drug delivery system. This review also furnishes useful information about aquasomes and how it shields and preserves the delicate biological molecules, its conformational integrity which makes it an attractive carrier system for drug delivery.

1. Introduction

In 1974, Dr. Gregory Gregoriadis was the first to propose the potential application of nanoparticulate systems as drug carrier and proposed liposomes as nanoparticulate drug delivery system [1,2]. Now a day, nanoparticulate systems are ideal choice for drug delivery. Because, the drug may be adsorbed, covalently linked on the nano carrier system or encapsulated inside the nanocarrirer systems [3–7]. Aquasome is emerging as one such alternative and ideal choice for drug delivery.

In 1995, aquasome was first developed by Nir Kossovsky [8–10]. The word 'aquasome' is derived from two words i.e. 'aqua' means water and 'somes' means body and hence, known as 'bodies of water.' These are self-assembled structures generally comprised of central solid nanocrystalline core that is coated with polyhydroxy oligomer onto which biochemically active molecules are adsorbed (Fig. 1). Aquasome is a successful carrier system for bioactive molecules like peptides, proteins, hormones, antigens and genes to target the sites. Because, it maintains conformational integrity as well as it exhibits the high degree of surface exposure. Solid core provide structural stability while, carbohydrate coating shields the molecule against dehydration. The fragile biomolecules can be preserved and protected by aquasomes due to its water like properties.

In recent advancements, aquasomes of ceramic have been designed with a coating of carbohydrates onto which peptide drug molecules are adsorbed [11,12]. The aquasomes made up of ceramic are stabilized by carbohydrates and by using methods like co-polymerization, diffusion or adsorption; the pharmacologically active molecules are incorporated on to the carbohydrate surfaces of preformed nanoparticles [13]. In this, carbohydrate plays an important role and acts like a natural stabilizer [14]. The glassy molecular layer produced by the sugar coating adsorbs the small molecules or therapeutic proteins without modification in three-dimensional conformations [15,16]. The three layered structures of aquasomes are self-assembled by non-covalent bonds and explored the main advantage that there is no interaction between drug and carriers unlike the other nanoparticulate carrier systems. Due to oligosaccharide coating, drug molecule remains stable in water like environment [17–19]. The principal of self-assembly of macromolecule is governed by three physiochemical processes.

1.1. Interaction between charged groups

The interactivity between charged groups eases the self-assembling of macromolecules in the aqueous environment which also plays a key role in stabilizing the tertiary structures of the proteins [20,21]. For the first phase of self-assembly, it is necessary that the long range interactivity of constituent subunit starts at intermolecular distance of around 15 nm but, with the hydrophobic structures, long range forces may extend up to 25 nm [9]. The innate chemical groups or adsorbed ions from the biological environment confer a charge polarity to most

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RJPT

RESEARCH ARTICLE

Development and Validation of Novel Analytical Method for Empagliflozin and Metformin Hydrochloride in Bulk and Pharmaceutical Dosage Form by Four Different Simultaneous Estimation Approaches using UV Spectroscopy

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ABSTRACT:

Four new UV spectrophotometric methods namely simultaneous equation, absorbance ratio, area under curve and first derivative (zero crossing) spectroscopic methods were developed and validated for simultaneous estimation Empagliflozin and Metformin hydrochloride in bulk and tablet formulation. In simultaneous equation method, absorbance was measured at 224 and 232 nm for both the drugs. Empagliflozin and Metformin hydrochloride was estimated using 224 and 232 nm in absorbance ratio method. In Area under curve method both drugs were estimated at 224 and 232 nm respectively. First derivative (zero crossing) method was based on the transformation of UV spectra in to first derivative spectra followed by measurement of first derivative signal at 224 and 232 nm for Empagliflozin and Metformin hydrochloride, respectively using 2 nm as wavelength interval (Δλ) and 1 as scaling factor. Methods were found to be simple, fast, highly sensitive, cost effective and hence can be useful for simultaneous estimation of Empagliflozin and Metformin hydrochloride in commercial tablet formulation for routine quality control analysis.

KEYWORDS: Simultaneous equation, absorbance ratio, area under curve method, first derivative (zero crossing) spectroscopic methods, tablet formulation.

INTRODUCTION:

Empagliflozin (EN) chemically,(1-chloro-4-[b-D-glucopyranos-1-yl]-2-[4-([S]-tetrahydrofuran-3-yl-oxy) benzyl]-benzene is an orally administered selective sodium glucose cotransporter-2 (SGLT-2) inhibitor, which lowers blood glucose in people with type 2 diabetes by blocking the reabsorption of glucose in the kidneys and promoting excretion of excess glucose in the urine. Empagliflozine have the potential to reduce cardiovascular risk in patients with type 2 diabetes[1,2].

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In patients with type 2 diabetes and hyperglycaemia a higher amount of glucose is filtered and reabsorbed. Empagliflozin improves glycaemic control in patients with type 2 diabetes by reducing renal glucose reabsorption. The content of glucose moiety removed by renal excretion, through this glucuretic mechanism is dependent on blood glucose concentration and GFR. Inhibition of SGLT2 in patients with type 2 diabetes and hyperglycaemia leads to excess glucose excretion in the urine[3-5]. Metformin hydrochloride (MET) is given orally in the treatment of type 2 diabetes mellitus and is the drug of choice in overweight patients. They do not stimulate insulin release but require that some insulin be present in order to exert their antidiabetic effect. Possible mechanism of action includes the delay in the

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Paroxetine Hydrochloride Proliposomes: For Enhanced Delivery by Oral Route

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Keywords: Proliposomes, Paroxetine hydrochloride, Bioavailability

ABSTRACT

One of the major contributors to suicide mortality and disability globally is Major Depressive Disorder (MDD). The administration of antidepressants was considered to be the most significant treatment option. Paroxetine hydrochloride, a highly potent antidepressant is a widely used and approved drug for treating MDD. The present systematic study focused to investigate the advantages of proliposomes for improved oral delivery of paroxetine hydrochloride to overcome the disadvantages with existing oral formulations. Paroxetine hydrochloride loaded proliposomes were prepared using stearic acid (SA), cholesterol (CHOL) and hydrogenated soy phosphatidylcholine (HSPC) in different ratios by film deposition method and the optimized formulations were characterized for zeta potential, entrapment efficiency, and micromeritics. Further a dissolution study and in vitro drug release study carried out provide an insight on the stability and enhanced dissolution of paroxetine hydrochloride from proliposomes formulation. The solid-state characterization (DSC, SEM, and PXRD) studies unravel the transformation of paroxetine hydrochloride to molecular state or amorphous from the native crystalline form. Based on the overall results proliposomes are a suitable carrier for improving the solubility of Paroxetine Hydrochloride.

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Review Article

A REVIEW ON CARBON NANOTUBES: DEVELOPMENT, PURIFICATION AND APPROACHES

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ABSTRACT

Carbon nanotubes are one of the remarkable inventions and have gained increasing attention due to their unique properties like chemical functionalities, high aspect ratios, nano sizes, light weight, good conducting and tensile properties. They are used to carry proteins and in anticancer therapy as carriers for drugs like doxorubicin, camptothecin, carboplatin, cisplatin, paclitaxel, Platinum (II), and Platinum (IV), and genes including plasmid DNA, small-interfering RNA, oligonucleotides, and RNA/DNA aptamers. They are used in nanotechnology, nanomedicine, transistors, actuators, sensors, membranes, and capacitors. Carbon nanotubes can be single or multi walled and can be produced by various methods like the laser ablation method, chemical vaporize deposition, sol gel method and arc-discharge method. These can also be used as mediators for photo thermal and photodynamic therapy to destroy cancer cells. The toxicity of Carbon nanotubes is summarized and it will become strongest tools in biomedical field and cancer therapy.

Keywords: Carbon nanotubes, Synthesis, Cancer, Therapy.

INTRODUCTION

Nanotechnology is the manipulation of matter, including the synthesis, assembly, control and measurement on the atom and molecular level. It has been used in number of various fields such as electronics, mechanics, chemistry, and biology, biomedical fields for detection, diagnosis, imaging, and therapy. It also provides innovative and promising alternatives to conventional strategies to detect tumors[1]. Among this, Carbon nanotubes (CNTs) have earned exhaustive attention and interest during past twenty years due to their exclusive mechanical properties along with electrical and thermal conductivity. By functionalizing their surfaces with wide group or biochemical species paves the way for numerous therapeutic and drug delivery applications[2-4].

The goal of this paper is to give an overview of the potential impact, on the Carbon nanotubes that can have various approaches, where these can be used as nanocarriers to transport anticancer drugs, genes, and proteins for chemotherapy; they are also used in bio sensing and for cancer diagnosis and therapy[5].

Table 1- Types of Carbon nanotubes

SWCNTs	MWCNTs
A single-walled carbon nanotubes (SWCNTs) can be considered to be formed by the rolling of a single layer of graphite (called a graphene layer) into a seamless cylinder (long wrapped graphene sheets)	Multi-walled carbon nanotubes (MWCNTs) can be considered as a collection of concentric SWCNTs (consist of multiple layers of graphite rolled in on themselves to form a tube shape) with different diameters.
SWCNTs have a diameter of close to 1 nm.	The interlayer distance in MWCNTs is close to the distance between graphene layers in graphite, approximately 3.3 A°.
SWCNTs are a very important variety of Carbon nanotubes because they exhibit important electric properties that are not shared by the MWCNT variants.	The special case of MWCNTs (double-walled carbon nanotubes DWCNTs) must be emphasized here because they combine very similar morphology and properties as compared to SWCNT.

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ORIGINAL ARTICLE

Extended Hildebrand Solubility Approach: Prediction and Correlation of the Solubility of Itraconazole in Triacetin: Water Mixtures at 298.15°K

Genişletilmiş Hildebrand Çözünürlük Yaklaşımı: 298,15°K'da İtrakonazolün Triasetin: Su Karışımlarında Çözünürlüğünün Belirlenmesi ve Korelasyonu

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ABSTRACT

Objectives: The aim of the study is to explore the suitability of an empirical approach for the extended Hildebrand solubility approach (EHSA) to predict and correlate the solubility of the crystalline drug itraconazole (ITRA) in triacetin: water mixtures.

Materials and Methods: The physicochemical properties of ITRA like fusion enthalpy, solubility parameter, and ideal mole fraction solubility were estimated. The solubilities of ITRA in mixed solvent blends comprising triacetin: water were determined at 298.15°K. Theoretical solubilities were back calculated using a polynomial regression equation of the interaction energy parameter *W* as a function of the solubility parameter (δ_1) of the solvent mixture. Similarly, the solubilities were predicted by direct method based on the use of logarithmic experimental solubilities ($logX_2$) against the solubility parameter (δ_1) of the solvent mixture. The predictive capabilities of both EHSA and the direct method were compared using mean percent deviations.

Results: The solubility of ITRA was increased in all the triacetin: water blends and was highest in the blend in which the solubility parameter of ITRA equaled that of the solvent mixture. The prediction capacities of the direct method (mean % deviation was -1.89%) were better than those of EHSA (mean % deviation was 9.76%) in the fifth order polynomial.

Conclusion: The results indicated that the solubility of any crystalline solute can be adequately predicted and correlated with the mere knowledge of physicochemical properties and EHSA. The information could be of help in process and formulation development.

Key words: Itraconazole, extended Hildebrand solubility approach, interaction energy, solubility parameter, prediction, correlation of solubilities

ÖZ

Amaç: Triasetin: su karışımlarında kristal formdaki itrakonazol (ITRA)'nın çözünürlüğünün genişletilmiş Hildebrand çözünürlük yaklaşımı (EHSA) için uygunluğunun deneysel bir yaklaşımla tahmin ve korele edilmesi bu araştırmanın amacıdır.

Gereç ve Yöntemler: ITRA'nın füzyon entalpisi, Hildebrand çözünürlük yaklaşımı çözünürlük parametresi ve ideal mol oranı gibi fizikokimyasal özellikleri tahmin edilmiştir. ITRA'nın triastin: sudan oluşan karışım halindeki çözeltilerdeki çözünürlükleri 298,15°K'da belirlenmiştir. Teorik çözünürlükleri çözelti karışımındaki çözünürlük parametresi (δ_1)'nin bir fonksiyonu olarak etkileşim enerji parametresi W kullanılarak polinominal regresyon denklemi ile hesaplanmıştır.

Bulgular: Tüm triasetin: su karışımlarında ITRA'nın çözünürlüğü atmıştır ve çözünürlüğün en yüksek olduğu karışım ITRA'nın çözünürlük parametresinin çözelti karışımınınkine eşit olduğu karışımdır. Doğrudan yöntemin tahmin kapasitesi (ortalama % sapması -%1,89) beşinci polinominal sırada EHSA'dan (ortalama % sapması %9,76) daha iyi bulunmuştur.

Sonuç: Bu sonuçlar çözünen kristalin çözünürlüğünün tek başına fizikokimyasal özellikler ve EHSA bilgileriyle yeterince ögörülebileceğini ve ilişkilendirilebileceğini göstermiştir. Bu bilgi süreç ve formülasyon geliştirmede yardımcı olabilir.

Anahtar kelimeler: İtrakonazol, genişletilmiş Hildebrand çözünürlük yaklaşımı, etkileşim enerjisi, çözünürlük parametresi, tahmin, çözünürlüklerin korelasyonu

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Original Article

Development of Validated Stability-indicating RP-HPLC Method for Determination of Novel Directly Acting Antiviral agent and Characterization of its Degradants by LC–ESI–MS

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ABSTRACT

Aim: The current study was performed to develop and validate stability indicating high performance liquid chromatography method (RP-HPLC) for determination of ledipasvir (LPR); to identify and characterize its major degradants by liquid chromatographic–tandem mass spectrometric method (LC-ESI-MS). **Materials and Methods:** The method was developed using reverse phase gradient elution and validated for standard ICH parameters. The optimized mobile phase comprised of acetonitrile:water with 0.2 % formic acid (70:30% v/v) at 1 ml/min flow rate with satisfactory retention time (tR), theoretical plates and good resolution of LPR and its degradants. Further, forced degradation under acid, base, thermal, photolytic and oxidative stress conditions was studied as per ICH guidelines. LC-ESI-MS with time of flight analyser was used to characterize the degradants. The degradation pathways for major degradants were proposed. **Results:** The developed method had retention time of 6 mins. The RSD for system was found to be less than 2% whereas mean recovery was obtained 97.2 – 102.5%. Linearity range of 5-30 µg/ml with 0.998 regression coefficient (R^2) was observed. Detection and quantification limits were obtained as 0.010 µg/mL and 0.032 µg/mL, respectively. LPR was stable in photolytic and thermal environments whereas degraded in acid, base and oxidative states. LC-ESI-MS was used effectively for characterization and structural elucidation of degradants. **Conclusion:** The results indicated that validated RP-HPLC technique can be employed for routine analysis of LPR in bulk and dosage formulas and also would be capable of separating degradants from analyte peak.

Key words: RP-HPLC, LC-ESI-MS, Ledipasvir, Stability indicating ICH method, Validation, Degradation pathway.

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INTRODUCTION

Viral hepatitis has become a serious public health concern as it affects more than 3% of world population. Out of this more than 1% of the population is infected by hepatitis C virus (HCV).[1,2] The prevalence of HCV infection doubled between 2010-2014 and till date. Annually almost 1.75 million infections are reported worldwide for HCV infection.[3] If HCV infection remains untreated; can progress to cirrhosis, fibrosis and hepatocellular carcinoma.[4] Such long-term problems are fatal, lethal and a reason for 96% of the deaths owing to viral hepatitis. The people infected with HCV are unaware about the infection, as they don't receive the well identified symptoms till complications emerge. The people may be infected for a period greater than 30 years before they develop clinical symptoms.

Till the development of directly acting antivirals (DAA), ribavirin in combination with the PEGlyated interferon was the only option available for the treatment. Nonetheless, it has been accompanied

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RESEARCH ARTICLE

Development, Characterization and Optimization of Mucoadhesive Tablet for Buccal Delivery of Domperidone

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Abstract: ***Background and Objective***: Upon oral administration domeperidone is rapidly absorbed, but subjected to the first pass effect which lowers systemic bioavailability to 15%. Mucoadhesive tablet can remain attached to buccal mucosa and becomes capable of bypassing hepatic first-pass metabolism to improve absorption directly into systemic circulation. The present research work was carried with an aim to develop, evaluate and optimize mucoadhesive tablet containing domperidone (DOME) for buccal delivery using different bio-adhesive polymeric combinations.

Methods: The buccal tablets were formulated by wet granulation method using isopropyl alcohol. The preliminary formulations were prepared using combinations of HPMC K4, HPMC K15, HPMC K100, HPMC E5 as mucoadhesive polymers. 3^2 full factorial design was applied to determine the effect of independent variables like concentration of mucoadhesive polymers (HPMC K15 and HPMC K100) over dependent variables like mucoadhesive properties (swelling index, bioadhesive strength and *in vitro* drug release). The prepared mucoadhesive tablets were evaluated for their tablet properties and mucoadhesive properties. The interactions between drug and polymers were studied by Fourier Transform Infrared Spectroscopy (FTIR) and Differential Scanning Calorimetry (DSC).

Results: All formulations of factorial design showed satisfactory physicochemical, mechanical and bioadhesive characteristics. The formulation F9 exhibited maximum cumulative drug release, mucoadhesive strength and swelling index.

Conclusion: The developed buccal tablet of domperidone might prove alternative to bypass the hepatic first pass metabolism and to avoid degradation which in turn may result in reducing the frequency of administration. Thus, mucoadhesive tablet of domeperidone may become viable alternative overcoming the side effects; achieving greater therapeutic effectiveness and improving the patient compliance.

Keywords: Domperidone, mucoadhesive buccal tablet, mucoadhesive strength, drug release kinetics, experimental design.

1. INTRODUCTION

Mucoadhesive delivery of drugs is considered as one of the alternative route to the oral administration, particularly for the drugs that undergo hepatic first-pass metabolism. Problems associated with oral route such as extensive hepatic first pass effect and degradation of drugs in gastro intestinal tract (GIT) can be overcome by delivery of these drugs through the buccal route [1]. This buccal delivery allows numerous benefits like easy accessibility, direct entry into the systemic circulation after absorption, avoidance of hepatic first-pass effect, no enzymatic degradation, ease of administration, feasibility of termination of delivery as and when required [2]. Numerous attempts have been made to develop various mucoadhesive dosage forms like tablets [3], films [4], ointments [5], gels [6], patches [7], disks [8], and strips [9]. The ideal buccal drug delivery systems should have strong mucoadhesive properties. It should also give the release of drug in a controlled and predictable manner, to get the desired therapeutic response [10]. To achieve this, strong mucoadhesive contact needs to be established between dosage form and buccal mucosa. Thus, the foremost step in the development of buccal drug delivery systems is the selection of adhesive polymer system. Many bioadhesive polymers either alone or in combinations have been evaluated for the development of buccal delivery systems.

The Hydroxyl Propyl Methyl Cellulose (HPMC) is the most hydrophilic and bioadhesive polymer due to its higher hydration and swellability. The overall performance depends upon the design of the system. The difference in the chain length and substitutions in the different HPMC grades imparts the different degrees of mucoadhesivity and release

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ORIGINAL ARTICLE

Enhancement of Dissolution of Fenofibrate Using Complexation with Hydroxy Propyl β-Cyclodextrin

Hidroksi Propil β-Siklodekstrin ile Kompleksasyon Kullanılarak Fenofibratın Çözünmesinin Arttırılması

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ABSTRACT

Objectives: The aim of the present study was to enhance the dissolution rate of fenofibrate using complexation with hydroxy propyl β-cyclodextrin (HPβCD).

Materials and Methods: The phase solubility behavior of fenofibrate was studied in various concentrations of (HPβCD) aq. solution at 37°C. The solubility of fenofibrate increased with an increase in the amount of HPβCD aq. solution. Gibbs free energy $(\Delta G^{\circ})_{tr}$ values were all negative. Complexes of fenofibrate with HPβCD were prepared in 1:1 ratio by kneading and coprecipitation. These complexes were evaluated by dissolution studies, fourier transform infrared (FTIR) spectroscopy, and differential scanning calorimetry (DSC) studies.

Results: The complexation of fenofibrate with HPβCD exhibited an enhanced dissolution rate. The mean dissolution time of fenofibrate decreased significantly upon complexation. FTIR studies showed the formation of intermolecular hydrogen bonding between fenofibrate and HPβCD. DSC studies indicated a loss in crystalline state of fenofibrate in complexes.

Conclusion: Complexation with HPβCD can be used as a useful tool for the enhancement of dissolution of fenofibrate.

Key words: Fenofibrate, hydroxy propyl β-cyclodextrin, solubility, Gibbs free energy, dissolution rate

ÖZ

Amaç: Bu çalışmanın amacı, hidroksi propil β-siklodekstrin (HPβCD) ile kompleksasyon kullanarak fenofibratın çözünme hızını arttırmaktı.

Gereç ve Yöntemler: Fenofibratın faz çözünürlük davranışları (HPβCD) çeşitli konsantrasyonlardaki sulu çözeltisinde, 37°C'de çalışıldı. Fenofibratın çözünürlüğü, artan miktarda HPβCD'nin sulu çözeltisi ile arttı. Gibbs serbest enerji $(\Delta G^{\circ})_{tr}$ değerlerinin hepsi negatifti. HPβCD ile fenofibrat kompleksleri, 1:1 oranında yoğurma ve kopresipitasyon ile hazırlandı. Bu kompleksler, çözünme çalışmaları, fourier dönüşümü kızılötesi spektroskopisi (FTIR) ve diferansiyel tarama kalorimetrisi (DSC) çalışmaları ile değerlendirildi.

Bulgular: Fenofibratın HPβCD ile kompleksasyonu, gelişmiş bir çözünme hızı sergiledi. Fenofibratın ortalama çözünme süresi, kompleksasyon üzerine önemli ölçüde azaldı. FTIR çalışmaları fenofibrat ve HPβCD arasında moleküller arası hidrojen bağlanmasının oluşumunu göstermiştir. DSC çalışmaları komplekslerde kristalin fenofibrat durumunda bir kayıp olduğunu gösterdi.

Sonuç: HPβCD ile kompleksasyon, fenofibratın çözünmesinin arttırılması için yararlı bir araç olarak kullanılabilir.

Anahtar kelimeler: Fenofibrat, hidroksi propil β-siklodekstrin, çözünürlük, Gibbs serbest enerjisi, çözünme hızı

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Theranostics Brain,Spine & Neural Disord

Transnasal Delivery of Fluoxetine HCL to Brain for Treating Depression

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Abstract

The objective of this study is to formulate a mucoadhesive microemulsion containing Fluoxetine HCl as antidepressant and Cedar oil as penetration enhancer. Water titration method was used to formulate the microemulsion using two different ratios of selected surfactant and cosurfactant (Tween 80 and Propylene Glycol). The prepared microemulsion showed mean globule size of 303.84nm. The prepared microemulsion is non-irritant for nasal mucosa which was confirmed by ciliotoxicity study using sheep nasal mucosa. It is clearly evident from *ex vivo* diffusion study that mucoadhesive microemulsion can deliver drug for longer time, the initial release was burst release in the first hour followed by sustained for next three hours, and increased diffusion will definitely help in reducing dose related side effects associated with the Fluoxetine HCl. Thus, present study concluded that the prepared microemulsion containing Fluoxetine HCl have potential to deliver the drug efficiently to the brain by nasal administration.

Keywords: Transnasal delivery; Depression; Fluoxetine Hcl; Brain

Introduction

A common mental disorder termed as depression that limits psychosocial functioning and diminishes quality of life [1,2] It is different from emotional responses to daily life challenges and mood fluctuations also. It can lead to suicide if it is severe, according to WHO about 8 lakh peoples die due to suicide every year which is the second leading cause of death in age group of 15-29 years. Not all the peoples get effective treatments that are available for depression; barriers include lack of resources, lack of trained health-care providers, and social stigma associated with mental disorders. Another barrier to effective care is inaccurate assessment. Sometimes, people who are depressed are often not correctly diagnosed, and others who do not have the disorder are too often misdiagnosed and prescribed with antidepressants [1]. Major Risk factors includes Personal or family history of depression, Major life changes, trauma, or stress and Certain physical illnesses and medications.

Signs and Symptoms [2-4]

If anyone is suffering through the following signs and symptoms most of the day or for at least two weeks he/she might be depressed: Persistent sad, anxious, or "empty" mood, Feelings of hopelessness, or pessimism, Irritability, Feelings of guilt, worthlessness, or helplessness , Loss of interest or pleasure in hobbies and activities, Decreased energy or fatigue, Moving or talking more slowly, Feeling restless or having trouble sitting still, Difficulty concentrating, remembering, or making decisions, Difficulty sleeping, early-morning awakening, or oversleeping, Appetite and/or weight changes, Thoughts of death or suicide, or suicide attempts, Aches or pains, headaches, cramps, or digestive problems without a clear physical cause and/or that do not ease even with treatment.

Types [1,3]

It might be mild, moderate, or severe depending on number and severity of symptoms of depressive episodes.

a) Recurrent/ Persistent Depressive Disorder: This involves repeated depressive episodes.

b) Postpartum Depression: Women may suffer through postpartum depression i.e. experiences full-blown major depression during pregnancy or after delivery.

c) Psychotic Depression: When a person has severe depression plus some form of psychosis that may be the psychotic depression, such as having disturbed false fixed beliefs (delusions) or hearing or seeing upsetting things that others cannot hear or see (hallucinations). The psychotic symptoms typically have a depressive "theme," such as delusions of guilt, poverty, or illness.

d) Seasonal Affective Disorder: It is characterized by the onset of depression during the winter months, when there is

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RESEARCH ARTICLE

Simultaneous Equation and Area Under the Curve Spectrophotometric Methods for Estimation of Ranolazine Hydrochloride Presence of its Base-induced Degradation Product: A Comparative Study

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ABSTRACT

Two simple spectrophotometric methods were developed and validated for the determination of ranolazine hydrochloride in the presence of its base-induced degradation product, namely simultaneous equation method using two wavelengths of 272 and 249 nm method (A) and area under the curve method using two wavelength ranges of 267–277 nm and 244–254 nm method (B). The accuracy, precision, and linearity ranges of the planned methods were firm. The methods were validated and the specificity was assessed by analyzing synthetic mixtures containing the drug and it's degradant. The two methods were useful for the determination of the cited drug in its pharmaceutical preparation and the obtained results were statistically compared with those of a reported method. The comparison shows that there is no important difference between the proposed methods and the reported method about both accuracy and precision.

Keywords: Base degradation, ranolazine hydrochloride, spectrophotometric methods

INTRODUCTION

Ranolazine hydrochloride (RS)–N-(2,6-dimethylphenyl)-2-[4-[2-hydroxy-3-(2-methoxyphenoxy)-propyl]piperazin-1-yl] acetamide [Figure 1] is an antianginal class. Ranolazine HCl is available as tablet dosage form 1 to 2. Ranolazine is not official in pharmacopoeia. A few methods in literature were reported for the determination of ranolazine HCl by ultraviolet (UV)-visible spectroscopy, high-performance liquid chromatography (HPLC), and high-performance thin-layer chromatography method.[1-3] Although these techniques are sufficiently sensitive, they use expensive instrument and time consuming. The present UV method is a simple method and does not include complicated solvent system development as required for liquid chromatography.[4,5] Therefore, this study aimed to develop and validate simple, rapid, accurate and specific, fast, low cost, and selective methods for routine quality control analysis of pharmaceutical product containing ranolazine HCl. UV spectrophotometry is an easy to use and robust method for the quantification of drugs in formulation when there is no interference from excipients.[6]

Experimental

Instruments

SHIMADZU UV-1800 PC dual-beam UV-visible spectrophotometer was used.

Software

UV-Probe personal spectroscopy software version 2.1 (SHIMADZU) was used.

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Research Article

Synthesis, Characterization and Biological Screening of Substituted Indoledihydro-pyrimidine derivatives.

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ABSTRACT

A series of Schiff bases of N-Substituted-4-(1H-indol-3-yl)-6-methyl-2-oxo-1,2,3,4-tetrahydropyrimidone-5-carbohydrazide U(1-5) were synthesized as per the scheme reported. Structures of synthesized compounds were confirmed by spectral study such as FT-IR, ^{1}H-NMR, Mass and Elemental analysis. The synthesized compounds were subjected to antibacterial evaluation. The structure of synthesized derivatives correlated and it has been observed that electron donating groups like hydroxyl U-4, attached to the phenyl ring increases antibacterial activity. The compound U-5, have shown excellent activity against *E. coli* compared with standard drug ciprofloxacin.

KEYWORDS

Indole, Biginelli reaction, antibacterial activity, MIC determination.

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A MODERN APPROACH IN ANTICANCER THERAPY USING ADEPT: AN OVERVIEW

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ABSTRACT

Anticancer drugs selectivity is improved by strategy called Antibody-directed enzyme prodrug therapy. It is a two-step process which benefits over radioimmunoconjugate, chemo-toxin etc. The main functions of Antibody-directed enzyme prodrug therapy are prodrug activation by enzyme and targets cancer cells by the conjugates and selectivity characteristics of prodrug/drugs/enzymes are reviewed. Generation of cytotoxic agents at tumor sites by antibody vectored enzyme from non-toxic pro-drugs. The traditional approach improves the properties of prodrugs which include solubility, permeability, stability, distribution etc. but this therapy improves selectivity. The activation of prodrugs is mainly governed by enzymes that are at higher amounts in tumors, which leads to selective antitumor activity.

KEYWORDS

ADEPT, Targeting, Enzymes, Prodrug, Antibody-enzyme conjugates and Tumor therapy.

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INTRODUCTON

The main causes of death that account for about 13% of mortality rate is cancer[1]. Traditional cancer treatment includes chemotherapy, radiotherapy and surgery which have drawbacks, as it affects the normal cells in the body and also epithelial and intestinal cells. The aim of ADEPT is to kill the cancerous cells without affecting the normal cells and one of those approach is ADEPT (antibody directed enzyme linked prodrug therapy) which is a two-step process[2,3]. Conventional pro-drugs aim at improving aqueous solubility, stability, absorption and permeability along with reduction in unacceptable taste, pain, irritation, metabolism and

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Research Article

RP-HPLC and UV-Spectrophotometric Methods Development and Validation for Simultaneous Estimation of Teneligliptin and Metformin in Fixed Dose Combination.

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ABSTRACT

The reliable, economical, sensitive and reproducible RP-HPLC and UV- Spectrophotometric methods were developed and validated for the simultaneous estimation of Teneligliptin (TEN) and Metformin (MET) in combined dosage form. In the RP-HPLC method the mobile phase used was 50mM potassium dihydrogen orthophosphate (KH_2PO_4) buffer: Methanol (40:60) at P^H 3.0 and flow rate was 1.0 ml per min. The method was scanned at λmax 250 nm for both the drugs. The linearity range for MET and TEN was found to be 200 - 600 µg/ml and 1 - 30 µg/ml with regression correlation coefficient (R^2) 0.9996 and 0.9991 respectively. The retention time for Metformin and Teneligliptin was found to be 10.3 min and 21.56 min respectively. The UV-Spectrophotometric simultaneous equation and Absorption Ratio methods were developed and validated in which the λmax for Metformin and Teneligliptin was found to be 232 nm and 243 nm, the Isoabsorbtive point was found to be 249 nm. The linearity for both the drugs was found to be 5-30 µg/ml and regression coefficient equation was 0.9896 and 0.9988 for MET and TEN respectively. The developed methods of RP-HPLC and UV-Spectrophotometry were validated as per ICH guidelines.

KEYWORDS

Teneligliptin (TEN), Metformin (MET), Correlation equation; RP-HPLC, UV-Spectrophotometry, ICH Guidelines.

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DEVELOPMENT AND VALIDATION OF A HPLC ANALYTICAL METHOD FOR DETERMINATION OF ELLAGIC ACID IN *EPILOBIUM ANGUSTIFOLIUM* EXTRACT

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Keywords:

Canadian willow herb extract, HPLC, Validation, Quality control

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ABSTRACT: Development of quality assessment parameters for natural products is a prominence necessity to justify their acceptability and activity. Establishment of authentic and reliable analytical methods which profile the quantitative phytochemical composition of marker constituents in multicomponent composition like extract is a challenging task. A simple, rapid, precise, and reliable HPLC method was developed for the separation and estimation of ellagic acid from *Epilobium angustifolium* (Canadian willow herb) extract. The estimation was carried out using Sunfire C18 column, 5µ (4.6 × 250 mm); mobile phase consisting of 0.1% orthophosphoric acid and acetonitrile; the flow rate of 1 mL/min and ultraviolet detection at 280 nm with a properly resolved having run time of 35 min. The method was validated as a final verification of method development concerning precision, linearity, accuracy, ruggedness, and robustness. The correlation coefficient (r^2) > 0.999, a method is considered to be linear as the correlation coefficient was found to be within acceptance criteria. The % RSD of peak area response due to ellagic acid in five replicate injections of standard solution was to be less than 2.0%, and system suitability parameters were passed. The % Average recovery of ellagic acid in Canadian willow Extract observed within the acceptance criterion of 98 - 102% indicates the accuracy of the method. The present validation proves that the HPLC-method is suitable for the determination of assay of ellagic acid from Canadian willow herb, extract at prescribed conditions.

INTRODUCTION: Plant species represent a great source of biologically active compounds whose effects on heritable material are mostly unknown. Investigation of medicinal plants is valuable on two levels: as a measure of safety for the continued use of medicinal plants and as a source of potential chemotherapeutic drugs.

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Due to widespread use in pharmacy and non-traditional medicine of extracts of medicinal plants, it could be necessary to investigate more on their safety [1]. The chromatographic or spectroscopic fingerprint profiles serve as guidelines to the phytochemical profile of the drug in ensuring the quality, while quantification of the marker compound/s would serve as an additional parameter in assessing the quality of the sample.

More recently a concept of multiple fingerprints construction and multidimensional fingerprinting have gained much attention, a large amount of chromatographic and spectroscopic signals enable more comprehensive data analysis [2].

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QUALITY ASSESSMENT OF VRANROPAN TAILA: AN AYURVEDIC SIDDHA TAILA FOR WOUND HEALING AND ANTI-MARK PROPERTY

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Keywords:

Ayurvedic formulation, Rancidity, Vranropantaila

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ABSTRACT: Standardization can create trust and confidence in the products and increase market relevance. It is an essential requirement for the open exchange of information; without it, the network will simply not work. The practitioner, as well as the consumer, now seeks assurance from the manufacturer about the quality, safety, and efficacy of a readymade Herbal supplement or Ayurvedic formulations. An average person's diet, lifestyle and other social habits, all who play important roles in disease and treatment, are completely different today. Hence, the earlier recommendations for herbs for specific disease states may not hold today unless validated in today's times. Phenotypic changes in plant species. Hence, the original pharmacological claims of these formulations need to be revalidated. Pharmaceutical research is aimed at meeting the medical needs of the population for whom appropriate therapeutic remedies are not available or at those that are available are unsafe for prophylactic use for various disorders. While meeting medical needs, research also has to ensure that the market needs for such exist. Vranropantaila is a Siddha taila used in Ayurveda for wound healing as well as anti-mark property. It contains sixteen Herbal and mineral origin ingredients in it. It is prepared by special procedure mention in Ayurveda. But because of polyherbal formulation, it becomes difficult to standardize it. The present study is mainly aimed to standardize "Vranaropantaila" in terms of identity, purity, safety, and efficacy.

INTRODUCTION: Traditional systems of medicine (TSM) / complementary and alternative systems of medicines (CAM) have been used throughout the world for centuries. One such important system is Ayurveda - the holistic system of medicine from India still used extensively, in developed and developing countries [1]. Ayurvedic knowledge and practical database can provide new functional leads to reduce time, money and toxicity - three main obstacles in drug development. These records are particularly valuable since from ancient times people are using it for effective treatment.

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One of the characteristics of traditional preparations is that all the herbal medicines either presenting as a single herb or a group of herbs in composite formulae, which are extracted with boiling water during the decoction process [2]. This may be the main reason why quality control of traditional oriental drugs is more difficult than that of the western drug. Efforts are underway to establish pharmaco-epidemiological evidence base concerning safety and efficacy for the practice of Ayurvedic medicines [3].

Nowadays for rationalize the utility of positive and judicious use of traditional formulation; it becomes a prime need to standardize it by various quality control parameters. A concept of the golden triangle which comprises of Ayurveda, modern medicine and science will be helpful to search for new, safe and cheap with better efficiency of

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STUDY OF FORCED DEGRADATION BEHAVIOUR OF A NOVEL PROTEASOME-INHIBITING ANTICANCER DRUG BY LC-MS AND DEVELOPMENT OF A VALIDATED STABILITY-INDICATING ASSAY METHOD

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Keywords:

Carfilzomib, Stress degradation, Stability indicating assay method, LC-MS, Degradation pathway

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ABSTRACT: In the present study, comprehensive stress testing of Carfilzomib, a newly approved proteasome-inhibiting anticancer drug was carried out according to ICH guideline Q1A (R2). The drug was subjected to acid (0.1N HCl), neutral and alkaline (0.1N NaOH) hydrolytic conditions at 70 °C, as well as to oxidative decomposition at room temperature. Photolysis was carried out in 0.1N HCl, water and 0.1N NaOH at 40 °C. LC-PDA and LC-MS investigated the products formed under different stress conditions. The LC-PDA method that could separate all degradation products formed under various stress conditions involved a C18 column and a mobile phase comprising of ACN and phosphate buffer (pH 3). The flow rate and detection wavelengths were 1 ml/min and 220 nm, respectively. The developed method was found to be precise, accurate, specific and selective. It was suitably modified for LC-MS studies by replacing phosphate buffer with water, where pH was adjusted to 3.0 with formic acid. The drug showed instability in the solution state (under acidic, neutral, alkaline and oxidative stress conditions), but was relatively stable in the solid-state, except the formation of minor products under accelerated conditions. Primarily, maximum degradation products were formed in acid conditions, though the same were also produced variably under other stress conditions. LC-MS fragmentation studies characterized the products. Based on the results, a complete degradation pathway for the drug could be proposed. LC-ESI-MS/MS characterized the major stress degradation product, and its fragmentation pathway was proposed.

INTRODUCTION: Stability testing is nowadays the key procedural component in the pharmaceutical development program for a new drug as well as new formulation.

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Drugs undergo physicochemical degradation upon storage. Pharmaceutical companies perform forced-degradation studies (stress testing) during pre-formulation to help in the selection of compounds and excipients for further development, to facilitate in salt selection or formulation optimization, and to produce samples for developing stability-indicating analytical methods.

Thus, stability testing of a drug under various temperature and humidity conditions is indispensable during the drug development process

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Solubilization and determination of solution thermodynamic properties of itraconazole in different solvents at different temperatures

Sachin K. Jagdale & Rajesh B. Nawale

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ORIGINAL ARTICLE

Estimation and Correlation of Solubility of Practically Insoluble Drug Itraconazole in 1,4-Butanediol + Water Mixtures Using Extended Hildebrand Solubility Approach

Sachin K. Jagdale[1] · Rajesh B. Nawale[2]

Abstract

Purpose Extended Hildebrand solubility approach (EHSA) was applied to estimate and correlate the solubilities of itraconazole in 1,4-butanediol + water mixtures at 298.15 K.

Methods Experimental solubilities and properties like entropy of fusion and ideal mole fraction solubilities were determined. EHSA was applied to estimate interaction parameter W to understand the solute solvent interaction. Theoretical solubilities were calculated by using W as a function of solubility parameter of solvent blend (δ_1) and by direct method using logarithmic experimental solubilities ($\log X_2$) against solubility parameter of solvent mixture (δ_1). Prediction capacities of EHSA and direct method were compared using mean percent deviations obtained while comparing theoretical solubilities with experimental ones.

Results Itraconazole solubility was increased in all the proportions of solvent mixtures and was found to be highest at 0.9 mass fraction of 1,4-butanediol where solubility parameter of drug matched with solvent mixture. Prediction capacity of EHSA was found to be better with regular polynomial equation of order 5 with mean deviation of − 1.69%.

Conclusions Using EHSA, the solubility of any solute can be adequately predicted with the knowledge of few physicochemical properties.

Keywords Itraconazole · 1,4-Butanediol + water solvent mixture · Solute solvent interactions · Extended Hildebrand solubility approach · Solubility parameter

Introduction

Triazole antifungal agents are commonly preferred against broad spectrum of fungal infections caused by different species [1, 2]. Itraconazole (Fig. 1) is a classic example of this category and more commonly recommended for oral [3, 4], topical [5], and intravenous [6] as well as ocular applications [7] to treat several fungal infections. According to the biopharmaceutics classification system (BCS), it is classified as BCS class II drug owing to its practically insoluble characteristics [8]. Such physicochemical properties restrict the applications of itraconazole. Also, its behavior in aqueous and aqueous miscible solvents is not fully understood until date. Under the purview of these facts, cosolvency could be regarded as one of the best techniques to overcome the solubility issues in pharmaceutical sciences for process and product development [9–11]. It is notable that the knowledge about drug's behavior in solution form is useful for purification, crystallization, preformulation, and dosage form developments. Due to such reasons, estimation of drug solubilities in all the probable cosolvent mixtures is valuable to generate the comprehensive physico-chemical data about the industrially important solution forms of the drug.

It is well known that various empirical models have been developed for the correlation and prediction of solubility. These models are capable of predicting the solubility of any solute in neat as well as in solvent blends by the correlation of various physicochemical properties [12–14]. In literature, such models have been used for variety of pharmaceutical applications like formulation design and development [15, 16], prediction of drug activity [17], purification and

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RJPT

RESEARCH ARTICLE

Phytochemical and Pharmacognostical Evaluation of Milky Mangrove *Excoecaria agallocha* Linn

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ABSTRACT:

Background: *Excoecaria agallocha* Linn. (Euphorbiaceae) is a small mangrove tree that grows widely in the tidal forests and coastal areas of India. Milky Mangrove is known to have antihyperglycemic, antimicrobial, anti-inflammatory and many other bioactivities. **Aim:** The present work aims to perform a comprehensive phytochemical and pharmacognostical study of *Excoecaria agallocha* Linn. **Materials and Methods:** The Pharmacognostical studies on *Excoecaria agallocha* including parameters such as morphological evaluation, microscopical evaluation, leaf constants, physicochemical parameters, Thin layer chromatography (TLC) and phytochemical studies were established. **Result and Conclusion:** Mean ash values (%) were 16.00 (total), 2.75 (acid insoluble), and 13.35 (water soluble). Loss on drying was 0.20%. Microscopy reveals dorsiventral leaf and presence of diacytic stomata in the leaf sample. Quantitative microscopical features such as Stomatal Index, Vein islet number, vein termination number and palisade ratio was determined. The report of TLC indicates presence of Alkaloids and flavonoids. Phytochemical study revealed the presence of alkaloids, steroids, flavonoids, terpenes, tannins and phenolic compounds. **Conclusion:** The results of the study can serve as a valuable resource of pharmacognostic and phytochemical information. Further work is needed to isolate, characterize, and quantify active constituents present in the leaves of *Excoecaria agallocha* Linn. by sophisticated techniques.

KEYWORDS: *Excoecaria agallocha* Linn., Pharmacognostic evaluation, Phytochemical evaluation, Thin Layer Chromatography.

INTRODUCTION:

Recent widespread interest in plant-derived drugs reflects its recognition of the validity of many traditional claims regarding the values of natural products in health care. For quality control of traditional medicines, phytochemical investigations are mainly applied. Thus, it makes a great significance to investigate chemical constituents and study pharmacological activity on this plant for its medicinal uses, which will be very useful in the field of medicine as new emerging drug. According to the WHO, medicinal plants are the best sources to obtain a variety of new herbal drug[1].

Excoecaria agallocha Linn is a small mangrove tree that grows widely in the tidal region forests and swamps. This plant found in the countries of temperate and tropical Asia, Australasia and South-Western Pacific[2]. Mangrove forests are among the world's most productive ecosystems. They enrich coastal waters, yield commercial forest products, protect coastlines, and support coastal fisheries. However, mangroves exist under conditions of high salinity, extreme tides, strong winds, high temperatures and muddy, anaerobic soils. There may be no other group of plants with such highly developed morphological, biological, ecological and physiological adaptations to extreme conditions. Mangrove forests are still quite unfamiliar to a vast population due to their limited distribution. However, the people inhabiting areas near mangrove forests heavily depend on these forests to meet their needs including their healthcare. During the early stage of human civilization, mangrove forests drew very little or no attention. This is to some extent because of the difficulty to access these areas. As the population continued to grow, people had to find new and unexplored sources

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Review Article

A Review on Phytopharmacopial Potential of *Epilobium angustifolium*

Prasad Kadam[1]*, Manohar Patil[2], Kavita Yadav[1]

ABSTRACT

Nature has been a source of medicinal agents for thousands of years, and an impressive number of modern drugs have been isolated from natural sources which are based on their use in traditional medicine. *Epilobium angustifolium* L. is a perennial herbaceous plant that belongs to the *Onagraceae* family. It exhibits various therapeutic properties like anticancer, antibacterial, anti-inflammatory, antioxidant, and anti-aging properties. *Epilobium angustifolium* L. contains polyphenols and secondary metabolites like oenothein B. Information was collected via Medline, PubMed, and Science Direct. Also some data have been collected from scientific journals, books, and reports. This review gives the current information on the chemical composition, traditional uses, and documented biological activities of *Epilobium angustifolium* L. These studies reveal that *Epilobium angustifolium* L. is a source of medicinally active compounds and have various pharmacological effects. These studies will be helpful to create interest toward *Epilobium angustifolium* L. and may be useful in developing a new direction for further research. *Epilobium angustifolium* L. is a medicinally important plant belongs to Onagraceae family. Extract from the plant is used in the treatment of many diseases for its anti-tumor, antimicrobial, anti-inflammatory, antioxidant, anti-ulcer and many other properties. The medicinal properties of fireweed have been attributed to its high content in polyphenols and more particularly to the most abundant of its secondary metabolites: Oenothein B.

Key words: *Epilobium angustifolium L.*, Oenothein B Pharmacological effects, Herbaceous, Biological activities.

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INTRODUCTION

Epilobium angustifolium is a remedial plant that belongs to the Onagraceae family, which contains more than 200 different species. It is called "fireweed" in North America, "rosebay willow-herb" in Great Britain and "maitohorsma" in Finland.[1] Within *Epilobium* species, *E.angustifolium* is one of the well-known medicinal plants which is used worldwide in customary medicine. Extracts obtained from rosebay willow-herb shows a variety of pharmacological effects.[2] *Epilobium* taxa has both *in vitro* and *in vivo* studies to show many therapeutic properties, including anti-inflammatory, antiandrogenic, antiproliferative, antimicrobial, Antinociceptive, and antioxidanteffects.[3] *Epilobium angustifolium* is widely used in non-traditional medicine to treat gastrointestinal disorders, mucous membrane lesions, such as mouth ulcers, wounds healing, skin sores, swelling.[4] In the last few decades there has been a growing interest in phytochemical composition of various parts of Epilobium plants.Ellagitannins is the major bioactive compounds present in Epilobium plants. Some ellagitannins present in the plant exhibit immune modulatory activity. The main biologically active component in Epilobium taxa is Oenothein B (a dimeric macrocyclic ellagitannin) which is present in high concentrations in Epilobiumspecies. Earlier studies on Oenothein B has been revealed significant antioxidant, antitumor, antibacterial, and antiviral activities.[5]

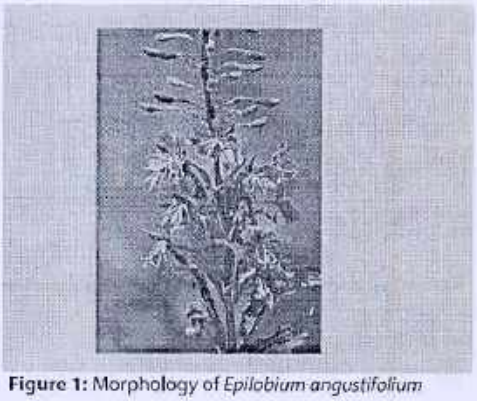

Figure 1: Morphology of *Epilobium angustifolium*

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RESEARCH ARTICLE

Nanostructured cubosomes in an *in situ* nasal gel system: an alternative approach for the controlled delivery of donepezil HCl to brain

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ABSTRACT

The purpose of this research was to develop cubosomal mucoadhesive *in situ* nasal gel to enhance the donepezil HCl delivery to the brain. Glycerol mono-oleate (GMO) and surfactant poloxamer 407 were used to prepare cubosomes. The developed formulations were characterized for particle size (PS), poly dispersity index (PDI), zeta potential (ZP), entrapment efficiency (EE), transmission electron microscopy (TEM), *in vitro* drug release and *in vivo* bio-distribution study in blood and brain tissue. Central composite design was used for the optimization purpose and the selected formulation (containing GMO 2 g and poloxamer 1.5%) was prepared in presence of gellan gum and konjac gum as gelling agent and mucoadhesive agent respectively. The optimal cubosomal dispersion and optimal cubosomal mucoadhesive in situ nasal gel were subjected to *in vivo* bio-distribution studies in rat model. It showed significantly higher transnasal permeation and better distribution to the brain, when compared to the drug solution. Thus, the formulated cubosomal mucoadhesive *in situ* gel could be considered as a promising carrier for brain targeting of CNS acting drugs through the transnasal route.

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Donepezil HCl; intranasal delivery; cubosomes; mucoadhesion; *in situ* gel; bio-distribution; brain targeting

1. Introduction

The incidence of central nervous system (CNS) diseases for example Alzheimer's, Parkinson's and Huntington's are expected to increase significantly in the twenty-first century (Sharma *et al.* 2014). Alzheimer's disease (AD) is characterized by synaptic loss and degeneration of cholinergic neurons in the cortex and other areas of the brain, which result in deficits in cholinergic transmission and acetylcholine (ACh) level. Cholinesterase inhibitors (ChEIs) catalyse the breakdown of AChE in synaptic cleft, thus enhancing ACh level to moderate AD (Yang *et al.* 2013) Alzheimer's disease (AD) is clinically characterized by progressive loss of memory, impaired judgment, altered decision making, apraxia resulting in complete brain failure and death (Muntimadugu *et al.* 2016). The global prevalence of Alzheimer's disease (AD) is approximately 25 million (Shadab *et al.* 2014). Thus, there is an increasing need of novel brain drug carriers for macromolecular drugs for the treatment of CNS disorder like AD.

Developing drug delivery system for CNS targeting is challenging task due to the presence of blood–brain barrier (Devkar *et al.* 2014). Numerous successful studies focusing on the nasal pathway for CNS drug delivery has been reported previously (Horvát *et al.* 2009). The blood–brain barrier (BBB) provides protection for the brain but hinders the treatment and diagnosis of neurological diseases because the drugs must cross the BBB to reach the lesions. The non-invasive nose-to-brain delivery has advantages over other routes of administration like circumventing first pass metabolism and blood brain barrier (BBB) thus providing a promising route for CNS targeting. The unique anatomic and physiologic properties of the olfactory region and trigeminal nerve provide both extracellular and intracellular pathways into the CNS that bypass the BBB (Serralheiro *et al.* 2015, Meng and Bi-Botti 2010). Thus, centrally acting drugs can be administered more effectively via nasal route using various carriers.

Numerous carriers such as liposomes, microspheres, nanoparticles are promising approaches to target CNS (Devkar *et al.* 2014) overcoming the problems of stability, low drug encapsulation, and residual solvent (Lehr 2000). Colloidal carrier system protects compound of interest in the nasal cavity from the degrading environment and promote their transport beyond nasal mucosa (Abdelrahman *et al.* 2015). Recently, researchers have considered cubosomes as a potential drug delivery system for CNS targeting in order to treat CNS disorders efficiently. Cubosomes (Cubs) are nanostructured liquid particles which are crystalline in nature consisting of bi-continuous lipid bilayers having the capacity to incorporate drugs of different physicochemical properties (Horvát *et al.* 2009, Morsi *et al.* 2014, Milak and Andreas 2015).

With the recent developments in the technology, experience and expertise in the area of nano-pharmaceuticals, cubosome-based systems are being actively pursued as potential alternatives to non-common systems such as liposomes and niosomes (Rarokar *et al.* 2016). Cubosomes are made up of a binary system of mono-olein and water, where

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Abstract

FORMULATION AND EVALUATION OF ATENOLOL AND HYDROCHLOROTHIAZIDE BILAYERED TABLET

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ABSTRACT

The aim of present study is to develop a bilayered tablet for management of Hypertension using Hydrochlorothiazide and Atenolol. The bilayered tablets gives biphasic drug release like loading dose of HCTZ and maintenance dose of Atenolol. The bilayered tablets are prepared using croscarmellose sodium as superdisinugrant for immediate released layer and different viscosity grades of hydrophilic polymers for sustained released layer, prepared tablets are evaluated for their physic-chemical properties. In this study, formulation (A6) made up from 10% CCS, and formulation (B6) made up from intragranulation techniques and 30mg blend of polymers releases the total drug content at the end of the 60 minutes and 12 hrs respectively. The release data obtained from the dissolution study of bilayered tablets are analyzed with respect to zero order, first order, Higuchi, Korsmeyer-Peppas models and release kinetic is fitted to Korsmeyer-peppas equation. The mechanism of drug release was regarded as anomalous diffusion of drug from matrix. The optimized formulation fulfilled many requirements such as easy to fabricate and high patient compliance.

Keywords: Bilayered tablets, Hydrochlorothiazide, Atenolol, CCS, Hydrophilic polymers.

[Full Text Article]

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DESIGN, DEVELOPMENT AND CHARACTERIZATION OF SELF MICRO EMULSIFYING DRUG DELIVERY SYSTEM FOR ACECLOFENAC

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Keywords:

Aceclofenac, SMEDDS, Phase Diagram, Dissolution rate

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ABSTRACT: Self-microemulsifying drug delivery system (SMEDDS) of Aceclofenac (ACE) was aimed at overcoming the problems of poor solubility. ACE is practically insoluble in water as a result it shows erratic oral absorption and affects the bioavailability. The formulation strategy included selection of oil phase based on saturated solubility studies and surfactant and co-surfactant screening on the basis of their emulsification ability. Ternary phase diagrams were constructed to identify the self-emulsifying region. Labrafac PG 8 (20%) as oil, Tween 80 (60%) as surfactant and Polyethylene glycol 400 (20%) as co-surfactant were concluded to be optimized components. The prepared SMEDDS was characterized through its droplet size, zeta potential, emulsification time and rheological determination. The optimized formulation exhibited 98.14 ± 0.34% *in vitro* drug releases, which was significantly higher than that of the drug solution. The study confirmed the potential of ACE SMEDDS for oral administration. It was concluded that the SMEDDS formulation approach can be used to improve solubility and dissolution of poorly water-soluble drugs such as ACE.

INTRODUCTION: Approximately, one third of the drugs emerging from drug discovery programs are poorly water soluble, presenting several problems when the pharmaceutical scientist developing formulations of such active pharmaceutical ingredients (API). Conventional oral dosage forms for poorly water soluble drugs present the drug in a solid form to the gastrointestinal tract which means the drug has to dissolve in the GI fluids before it can be absorbed. Thus, their rate and extent of absorption is largely dependent on the rate of dissolution. The formulation technique plays an important role in overcoming this short coming of poorly water soluble drugs.

According to the Biopharmaceutical Classification System (BCS), two classes of drugs show poor aqueous solubility namely BCS II and BCS IV. BCS II drugs possess poor aqueous solubility but have good permeation properties. BCS class IV drugs are poorly water soluble and poorly permeable. Developing a formulation for a class IV drug is nearly impossible unless the dose necessary is very small. Most of the times, such drugs are withdrawn at its lead optimization stage of drug discovery and reworked to improve its physicochemical properties.

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Quality assessment of *Syzygium aromaticum*: A pharmacognostic and phytochemical approach

Kavita N Yadav, Prasad V Kadam, Chandrashekhar L Bhingare and Manohar J Patil

Abstract
Since from ancient time human beings are taking help of plants as a medicine, although most of these applications are anarchic. The worldwide herbal resources have a great potential as drug and are of great commercial importance. This use of herbal product has also given rise to various forms of abuse and adulteration of the products leading to patient's dissatisfaction and in some instances fatal consequences. They are very often obtained and processed without any scientific evaluation and launched onto the market without any safety and toxicology studies. There is a need to development of good quality assurance and standardization of herbal medicines and products. On that basis, an attempt was made on well-known herbal drug *Syzygium aromaticum* flower buds by evaluation of pharmacognostic, phytochemical and toxicological parameters like heavy metals, aflatoxins, total microbial load and pesticide residues.

Keywords: Pharmacognostic evaluation, *Syzygium aromaticum*, standardization, quality control

Introduction

Majority of the users trust on herbal medicines for health care because the other treatment options available are costly and they are often thought to be more associated with serious side effects. Medicinal plants are defined as a group of plants that possess some distinct properties that qualify them as articles of drugs and therapeutic agents. Medicinal plants contain some organic compounds having definite physiological action on the human body and these bioactive substances include tannins, alkaloids, carbohydrates, terpenoids, steroids and flavonoids [1]. These Chemical constituents having therapeutic activity found in high concentrations in plants determine their considerable role in the prevention of various degenerative diseases. Most of the medicines today are obtained from natural sources or semi synthetic derivatives of natural products used in the traditional and alternative systems of medicine. Spices play a very important role as a medicine in healthcare system. Spices like clove, black pepper, turmeric, nutmeg and cinnamon have been used for centuries as food preservatives, taste modifier and as medicinal plants mainly due to its antioxidant and antimicrobial activities [2]. Nowadays, many reports confirm the antibacterial, antifungal, antiviral and anticarcinogenic properties of spice plants. Clove in particular has attracted the attention due to its active use in food & pharmaceutical industry standing out among the other spices. Essential oil compounds are fat soluble thus possess the ability to permeate the membranes of the skin before being captured by the microcirculation and drained into the systemic circulation which reaches all targets organs [3]. Clove (*Syzygium aromaticum*) is one of the most commonly used spices in Indian kitchens. Cloves are the aromatic dried flower buds of a tree *Syzygium aromaticum*, native to the Maluku islands in Indonesia and used as a spice in cookeries all over the world [4]. Clove oil has germicidal properties and is frequently used in the dental care due to its germicidal properties. It has been shown to be a potent chemo preventive agent, used by the traditional Ayurvedic healers of India since prehistoric times to treat respiratory and digestive ailments [5].

Whole and ground cloves are used to enhance the flavor of meat and rice dishes and used widely in curry powders and masalas. They are highly valued in medicine as a carminative and stimulant and are said to be a natural anthelmintic [6]. Oil of clove is used extensively for flavoring all kinds of food products, such as meats, sausages, baked goods, confectionery, candies, table sauces, pickles, etc. It is used in medicine for its antibacterial, antiseptic and antibiotic properties [7, 8]. It has also been successfully used for asthma and various allergic disorders by oral administration. Sesquiterpenes, found in clove were also investigated as potential anti-carcinogenic agents. The oil has many industrial applications and is used extensively in perfumes, soaps and as a clearing agent in histological work.

POTENTIAL OF RP-HPLC-DAD-MS FOR THE QUALITATIVE AND QUANTITATIVE ANALYSIS OF DAPAGLIFLOZIN IN TABLETS AND DEGRADANTS

Agarwal B.[a*] and Gandhi S.[b]

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ABSTRACT

Dapagliflozin is a new drug of the gliflozin class which inhibits subtype 2 of the sodium-glucose transport proteins (SGLT2). It is a recent drug in the market and the generic market may soon get flooded with it. Therefore, newer methods are required to control dapagliflozin in pharmaceuticals. In the present study, a new method based on RPHPLC coupled to DAD and MS was developed to validate the analysis of dapagliflozin in tablet dosage form. A wavelength of 222 nm was selected to perform a cost-effective quantification and the method showed adequate linearity, with an R^2 value of 0.9998, and acceptable values of accuracy (75%–102%) and precision (residual standard deviation < 5%). The detection and quantification limits were 1.16 µg/mL and 0.53 µg/mL, respectively. Furthermore, the use of high-resolution MS enabled us to ensure the specificity, check impurities and better sensitivity. Therefore, this methodology promises to be suitable not only for the routine analysis of dapagliflozin in pharmaceutical dosage forms, but also for potential degradants.

Keywords: Dapagliflozin, Mass spectrometry, RP-HPLC, Tablets, Diode-Array-Detection (DAD)

INTRODUCTION

Dapagliflozin is a drug of the gliflozin class and it can be used to treat type 2 diabetes[1-4]. Dapagliflozin inhibits subtype 2 of the sodium-glucose transport proteins (SGLT2) which are responsible for at least 90% of the glucose reabsorption in the kidney. Blocking this transporter mechanism causes blood glucose to be eliminated through the urine[5-7]. Dapagliflozin is chemically (2*S*, 3*R*, 4*R*, 5*S*, 6*R*)-2-{4-chloro-3-[(4- ethoxyphenyl) methyl] phenyl}-6-(hydroxymethyl) oxane-3, 4, 5-triol. The molecular formula is $C_{21}H_{25}ClO_6$. The molecular weight is 408.873 g/mol. The structure of dapagliflozin was shown in Fig. 1. Dapagliflozin[8] is soluble in organic solvents such as ethanol, DMSO, and dimethyl formamide, which should be purged with an inert gas. It is also soluble in methanol and dichloromethane. The objective of the research work was to develop and validate a simple and accurate reverse phase chromatographic method to estimate amount of drug in dosage form. The developed method can be applied successfully to estimate the amount of dapagliflozin in tablet dosage form. Liquid chromatography (LC) coupled to UV detection has been applied to determine dapagliflozin in pharmaceutical

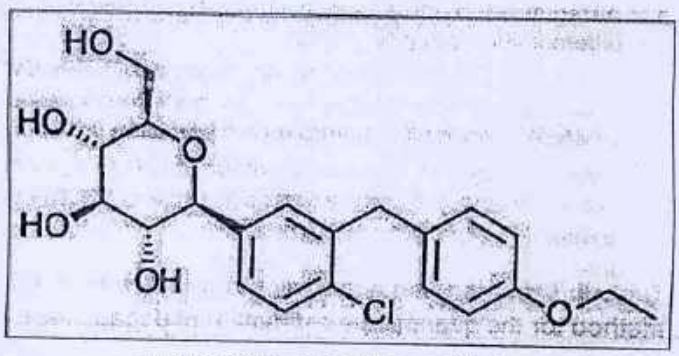

Fig. 1 Structure of Dapagliflozin

preparations[9-11]. In these studies, reversed phase (RP) liquid chromatography using silica-based C_{18} columns is the most common mode. HPLC methods are reported for apagliflozin in its combined dosage form[12-13].

No pharmaceutical approaches are addressed to identify impurities and degradation products in dapagliflozin.

Therefore, in the present study, a fast and simple RP- HPLC-DAD methodology for the determination of dapagliflozin in tablets was developed and validated. This study was also supported by the use of MS to perform the qualitative analysis of this compound in both positive and negative ionization modes, ensure the specificity and

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DESIGN OF EXPERIMENT IN THE BIO-ANALYTICAL DETERMINATION OF QUETIAPINE FUMARATE IN HUMAN PLASMA BY A RP-HPLC METHOD

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Keywords:

Design of Experiment, RP-HPLC, Quetiapine fumarate, Validation, human plasma, extraction

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ABSTRACT: A new, simple, sensitive, accurate and precise RP-HPLC method was developed for the estimation of quetiapine fumarate in human plasma. Full factorial design was used for the optimization of an extraction method. The main effect of volume of deproteinating agent, speed of centrifugation, time of centrifugation and temperature of centrifugation was found to be significant at $P<0.0001$ on all the responses. After deproteinization, the drug was analyzed on a C18 (150 x 4.6mm, 5 µm) column using UV detector. The mobile phase consisting acetonitrile and phosphate buffer (pH 3) in the ratio of 50:50 (v/v) at a flow rate of 1.0 ml/min. The standard calibration curve was constructed in the concentration range of 5 µg/ml to 30 µg/ml and linearity was found to be 0.999. Irbesartan was used as the internal standard. The retention time of quetiapine fumarate and the internal standard was found to be 5.42 and 2.89 min, respectively. No interference peak was perceived. The high performance liquid chromatography method was successfully demonstrated as rapid and sensitive method which can be used as an alternative for the analysis of quetiapine fumarate in plasma samples.

INTRODUCTION: Quetiapine fumarate (QTF) is an atypical antipsychotic agent indicated for the treatment of schizophrenia and for the treatment of acute manic episodes associated with bipolar disorder. It is a selective monoaminergic antagonist [1]. However, this effect is mediated through antagonism of dopamine type 2 (D_2) and serotonin type 2 ($5HT_2$) receptors. QTF is a dibenzothiazepine derivative and is chemically 2, (2-[2-(4-Dibenzo [*b,f*] [1,4]thiazepin-11-yl-1-piperazinyl) ethoxy] ethanol) fumarate.

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QTF belongs to the same family as clozapine and olanzapine, which are classified as a typical anti-psychotic and do not cause major extrapyramidal side effects. The generic name is Seroquel. It is white or almost white powder, moderately soluble in water and soluble in methanol and 0.1 N HCl.

It is available in tablets form in dosage level of 25 mg, 50 mg, 100 mg, 200 mg, 300 mg and 400 mg. Maximum daily dosages is 800 mg in adults. This drug is rapidly absorbed after oral administration with peak plasma concentration attained within 1.50 hrs. Bioavailability of tablet formulation is 100% relative to an oral solution, which may be marginally affected by food. Plasma protein binding of QTF is 83 %. The drug is extensively metabolites, principally through CYP3A4. The drug is having half-life period of approximately 6 hours.

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Standardization and quantification of curcumin from *Curcuma longa* extract using UV visible spectroscopy and HPLC

Prasad V Kadam, Kavita N Yadav, Chandrashekhar L Bhingare and Manohar J Patil

Abstract
Curcuma longa (Turmeric) is used successfully in Ayurvedic formulations from ancient times. It is a rich source of bioactive phytoconstituents like curcuminoids, turmerone and many more. Curcuminoids is the group of chief dynamic components and has number of medicinal uses such as anti-inflammatory, anti – HIV, antitumour, antiviral, anticancer, antifungal and antiparasitic. Different analytical methods have been developed in recent year for the quality control analysis of curcuminoids in *Curcuma longa* extract including HPLC, HPTLC and UV-Visible Spectrophotometry. While the primary component curcumin from curcuminoids is still lacking for its analytical method development along with validation. Therefore, in the present study, a simple UV visible and HPLC method was developed and validated according to international conference harmonization (ICH) guidelines for the quantitative estimation of curcumin in *Curcuma longa* extract.

Keywords: Curcuminoids, curcumin, *curcuma longa,* HPLC, UV visible spectroscopy

Introduction
Natural plant products have been used for several medical treatments in humans [1]. Natural plant products are suitable for treating a wide range of infections and diseases. Plants of Zingiberaceae family have been frequently and widely used in traditional systems of medicine [2]. Turmeric (*Curcuma longa* Linn) is a member of the Zingiberaceae family and is cultivated in tropical and subtropical regions around the world and it is originates from India, Southeast Asia and Indonesia [3]. India is the largest producer of turmeric in the world (93.7% of total world production) and is cultivated in 150,000 hectares in India [4].For traditional Ayurvedics, turmeric plant was an excellent natural antiseptic, disinfectant and analgesic, while at the same time the plant has been often used to aid digestion, to improve intestinal flora, and to treat skin irritations [5]. Medicinally, it possess strong antimicrobial, anti-inflammatory, anti-tumour and immunological activities [2]. The pharmacological activity of turmeric has been attributed mainly to curcuminoids consists of curcumin (CUR) and two related compounds demethoxy Curcumin (DMC) and bisdemethoxycurcumin (BDMC) [3]. The curcuminoids are polyphenols and are responsible for the yellow color of turmeric.[6] Herbal product studies cannot be considered scientifically valid if the product tested was not authenticated and characterized. Standardization of herbal drugs is usually based on one or more known and accepted active biochemical compound. Many a times where the active biochemical compound is not known, a characteristic compound is used as a "marker," which signifies the presence of the other biochemical compounds that give the herb its therapeutic properties [7].
Different analytical methods have been developed in recent year for the quality control analysis of curcuminoids in *Curcuma longa* extract including; HPLC, HPTLC and UV-Visible Spectrophotometry. While UV-spectrophotometric and HPLC methods are more suitable methods to quantify the curcumin in *Curcuma longa* extract. Therefore, in the present study, a simple UV and HPLC method was developed and validated according to international conference harmonization (ICH) guidelines for the quantitative estimation of curcumin in *Curcuma longa* extract.

Material and Methods
Material
Preparation of standard solution of Curcumin for UV Visible Spectroscopy
Curcuma longa (curcuminoids 95%) extract has been procured

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Evaluation of anticonvulsant activity of the ethanolic extracts from leaves of *Excoecaria agallocha*

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ABSTRACT

Ethnopharmacological relevance: *Excoecaria agallocha* is popularly known as 'Thillai' plant in the tamil language of the South India. Its uses are mentioned on the temple inscription of the Chidambaram Temple, Chidambaram, India which dates back to 2nd Century CE.
Aim: To investigate the anticonvulsant activity of ethanolic extract of leaves mangrove plant *Excoecaria agallocha*.
Material and methods: The ethanolic leaf extract of *Excoecaria agallocha* (100, 200 and 40 mg/kg) was evaluated in Swiss albino mice and male wistar rats were used for the study. Two different study models were employed; Maximal electroshock and Lithium-Pilocarpine convulsion method. The ethanolic extract was also subjected to acute toxicity study and phytochemical evaluation.
Results: The ethanolic extract of leaves of *Excoecaria agallocha* was found to be safe in toxicity studies when compared to the standard drugs. It has LD_{50} of 2.12 g/kg of oral dose and 3.12 mg/kg of intraperitoneal dose. This extract (100–400 mg/kg) produced a significant ($P < 0.01$) dose dependent delay in onset of seizures in the MES model on oral administration which is comparable to Phenytoin (20 mg/kg i.p). This extract (100–400 mg/kg) produced a significant ($P < 0.01$) dose dependent reduction in intensity of seizures in the Lithium-Pilocarpine epilepsy model which was comparable to the standard drug diazepam (10 mg/kg).
Conclusion: The results obtained from this study and finding suggests for the use of *Excoecaria agallocha* for the management of convulsions and justifies its use in traditional medicine.

1. Introduction

Epilepsy has been recorded throughout ancient history, and was considered as a spiritual condition [1]. the word epilepsy is itself derived from as Latin term meaning to seize, possess or afflict [2]. It is a group of neurological diseases mostly with unknown reasons, some patients may develop epilepsy due to infection in brain such as meningitis, viral encephalitis, birth defects, stroke, injury or tumours in brain and brain stem [3,4]. It is a chronic disorder characterised by recurrent seizures due to decreased resistance of excitatory neurons to fire and down regulation of inhibitory neurons. This occurs in a particular region known as 'seizure focus' and the excessive, abnormal neuronal firing results in to a wave of depolarization which is termed as paroxysmal deploring shift [5]. Epilepsy is incurable but modern medicine can help control most cases of seizures but several conditions such as nonresponsive cases need to opt for surgery, neurostimulation or lifestyle changes [6,7]. This situation can also be improved with the help of traditional and local medicines obtained from the natural flora of the region. A proper identification of medicinal properties and their scientific evaluation provides with much superior relief then the contemporary practice of medicine.

Excoecaria agallocha Linn (Euphorbiaceae) is an mangrove tree that occurs alongside swamps in India, Bangladesh, Australia [8]. It is a small tree growing up to a height of 15 m consisting of male and female flower separately with capsular fruit. This tree finds description in prehistoric Hindu traditional literature, the Purana and considered revered in religious practice [9]. It is commonly known as blinding tree, in local languages it is known as tillai, geva, surrund, komatti, geon. All part of this tree has been used for various medicinal properties. Leaves, wood, stem, bark and roots

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HERBAL REMEDY FOR WOUND MANAGEMENT: A REVIEW

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Keywords:

Wounds,
Wound healing,
Indian medicinal plants,
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ABSTRACT: Since from prehistoric times the practice of herbal medicine has existed as the primary form of medicine. India is one of leading bio-diversity center with presence of over 50, 000 different plant species. Many plants are unexplored though they were used from ancient times in traditional system of medicine. At the same time several plants activity was proven scientifically and its resurgence as herbal medicines was started in the past few years. Many countries have included herbal products, in their national health programs and national health schemes, as an important alternative for treatment of various diseases. In day to day life people came across accidental wounding and management of wound is a complicated process. Wound healing is a complex and dynamic process of restoring damaged tissue that involves a series of independent and overlapping stages. Many plants have potential to heal the wounds owing to vast array of medicinal compounds they can synthesize. In most of the countries, a great number of plants are used by tribal and folklore for the treatment of wounds and burns. These natural agents induce healing and recovery of the lost tissue by several mechanisms. These phytomedicine are not only cheap and affordable but are also harmless. The presence of wide range of life-sustaining constituents in plants has insisted scientists to examine these plants with a view to define potential wound healing properties. The current article provides a glance on plants identified from various ethno botanical surveys and folklore medicinal survey possessing wound healing activity and their formulations.

INTRODUCTION: Since from ancient time man has taken help of nature in the treatment and prevention of many diseases. The medicinal preparations derived from nature, were either in the simple form of plant parts or in the more complex form of crude extracts, mixtures, *etc*. Herbal products are fast becoming a part of the integrative healthcare systems of the developed nations, known as complementary and alternative systems of medicine.

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In this era of advanced technology, herbal medicines still flourish and are finding exceptional acceptance in both the developing and the developed countries due to their natural origin and lesser side effects. In ancient literature we got a reference, that plants are a rich source of a variety of chemicals, with nutritive and therapeutics properties. Herbs may be used directly as decoction or extracts and they may be used in the production of medications. In India, about 2000 drugs have been used to cure human diseases. Out of them only $1/10^{th}$ are of animal and mineral origin; rest are of plant origin. The plants have healing properties due the presence of several complex chemical substances of different compositions *e.g.* secondary metabolites (Tannins, alkaloids, flavonoids, glyacosides, *etc*.).

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STABILITY –INDICATING DENSITOMETRIC METHOD FOR SIMULTANEOUS DETERMINATION OF DONEPEZIL HYDROCHLORIDE AND CURCUMIN IN *INSITU* NASAL GEL

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Abstract:

A stability indicating high performance thin layer chromatography (HPTLC) method was developed and validated for determination of Donepezil hydrochloride and curcumin in in situ nasal gel. Study was performed on pre-coated silica gel HPTLC plates using toluene: methanol: glacial acetic acid (8: 2: 0.1 v/v/v) as the mobile phase. A TLC scanner set at 254 nm was used for direct evaluation of the chromatograms in the reflectance/absorbance mode. Method was validated according to ICH guidelines. The correlation coefficients of calibration curves were found to be 0.994 and 0.988 in the concentration range of 300–1800 and 120–720 ng band^{-1} for donepezil hydrochloride and curcumin, respectively. The method had an accuracy of 100.6 % for donepezil hydrochloride and 99.08% for curcumin. The method had the potential to determine these drugs simultaneously from dosage forms without any interference of the excipients. Donepezil hydrochloride and curcumin were also subjected to acid, base, oxidation, heat and photo-degradation studies. The degradation products obtained were well resolved from the pure drugs with significantly different R_f values. As the method could effectively separate the drugs from its degradation products, it can be used for stability-indicating analysis.

Keywords: *High-performance thin-layer chromatography, Donepezil hydrochloride and Curcumin, Stability-indicating method*

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Research Article
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Atorvastatin Loaded Microsponges based Emu Oil Emulgel for Faster Wound Healing

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Abstract

A micro sponge delivery system is patented, highly cross-linked, porous and polymeric in nature. Polymeric system consisting of porous microspheres that can entrap wide range of actives and then release them onto the skin over a time and in response to trigger. The fundamental appeal of the micro sponge technology overcome the problems of greasiness, stickiness associated with the conventional formulations in releasing active ingredients over an extended period of time that often result in lack of patient compliance. When applied to the skin, the MDS releases its active ingredient on a time mode and also in response to other stimuli (rubbing, temperature, pH, etc). Delivery system comprised of a polymeric bead having network of pores with an active ingredient held within was developed to provide controlled release of the active ingredients

Introduction

Micro sponge formulations have higher payload (50 to 60%), still free flowing and can be cost effective [1-3]. Microsponge scan be prepared by Emulsion solvent diffusion method and Suspension polymerization method.

Eudragits polymers are preferred to control the release of drug in formulation of microsponges by quasi emulsion solvent diffusion method. It is a copolymer of ethyl acrylate, methyl methacrylate, and a low content of Methacrylic acid ester with quaternary ammonium groups. As the polymer contains the ammonium salt groups, its permeability is pH independent [4]; Wound is defined as disruption of cellular, anatomical and functional continuity of a living tissue, produced by physical, chemical, thermal, microbial or immunological insult to the tissue [5]. A wound is colonized when growth and death of bacteria in the wound is balanced by the host. If the host is not able to keep the bacterial growth in balance, the wound will enter the infection phase (Bacterial load in excess of $10^{[5]}$). Symptoms for an infected wound are erythema, edema, warmth, pain and exudate. Infections of chronic wounds are often polybacterial with *Staphylococcus aureus* and anaerobs being the most common in chronic wound [6].

Wound healing is the interaction of a complex cascade of cellular and biochemical actions leading to the restoration of structural and functional integrity with regain of strength of injured tissues [5]. The healing of a wound is achieved by way of the integrated phases of haemostasis, inflammation, proliferation and remodeling. These phases must occur in the proper sequence and time period, without interference and at optimalintensity, in order for a wound to heal normally [7].

However, medical therapies for wound care are limited; therefore, development of new treatment modalities to improve wound healing in diabetic patients is an essential and emerging field of investigation [8]. Numerous conservative methods, such as honey as a dressing solution [9], topical antimicrobial therapies total contact casting [10], wound dressings [11] for the treatment of diabetic wounds have been reported in the literature. Herbal therapies were also reported [12]. In this study, a well-known agent. Atorvastatin is used for the treatment of wounds. It is reported that statins may be useful in the treatment of diabetic foot ulceration (DFU) [13]. Statins are widely used for the treatment of hyperlipidaemia, has been shown to prevent cardiovascular events in patients with diabetes. In addition to preventing macrovascular diseases, statins may also be able to retard the progression of microvascular complications of diabetes [14]. Statin drugs directly enhance the ability of endothelial nitric oxide synthase to generate nitric oxide in endothelial cells independent of lipid-lowering effects [15,16]. In animal studies, the use of statins on the vascular system, such as the coronary artery, cerebral artery, small mesenteric artery, aorta, and corpus cavernosum, was shown to result in vascular relaxation by up regulating nitric oxide synthase [16-18] Indeed,

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Original Article

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Influence of Unani polyherbal formulation on learning and memory retention in mice

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Unani polyherbal formulation; Learning and memory; Memory impairment; Nootropic.

ABSTRACT

The drug discovery should not be always limited to discovery of a single molecule and current belief one disease one drug approach may be untenable in the future and that rationally designed polyherbal formulations could also be investigated as an alternative in multi-target therapies and prophylaxis. Considering this the Influence of Unani Polyherbal Formulation (UPF) was investigated for its nootropic activity. To investigate nootropic activity of the UPF various experimental paradigms of learning and memory were used including transfer latency (TL) on elevated plus-maze, spatial memory evaluation using radial arm maze, passive avoidance response (PAS) and object recognition test. Mice were devided in four groups viz control i.e vehicle treated, UPF 200 mg/kg, UPF 400 mg/kg and piracetam 150 mg/kg as standard. The investigation reported that UPF 200 and 400 mg/kg significantly reduced the TL on 2nd and 9th day and significantly increased the step down latency in the PAS at acquisition and retention test. In Radial arm maze task UPF 200 and 400 mg/kg showed significant decrease in the days to make the mice learned and latency to find food in reference as well as working memory. UPF also attenuated scopolamine induced memory deficit. Furthermore the UPF 200 and 400 mg/kg increased discrimination index in the object recognition test indicating nootropic activity. To conclude UPF showed significant facilitatory effect on aversively motivated learning and memory in mice, spatial learning and memory and improvement of memory in absence of cognitive deficit.

1. INTRODUCTION

The nootropic drugs belong to the class of psychotropic agents with selective facilitatory effect on intellectual performance, learning and memory[1]. Dementia is a mental disorder characterized by loss of intellectual ability sufficiently severe as to interfere with one's occupational or social activities. Dementia is of several types and it invariably involves impairment of memory. The most common cause of dementia is Alzheimer's disease, which is a progressive neurodegenerative disorder associated with loss of neurons in distinct brain areas. The central cholinergic pathways play a prominent role in learning and memory processes[2]. Centrally acting antimuscarinic drugs

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SYNTHESIS AND EVALUATION OF SOME NOVEL BENZIMIDAZOLE AND QUINOLONE DERIVATIVES FOR THEIR ANTIFUNGAL AND ANTIDIABETIC ACTIVITY

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ABSTRACT

A series of novel benzimidazole and Quinolone derivatives have been synthesized and evaluated for antifungal and antidiabetic activity. The newly synthesized compounds have been characterized by IR, ^{1}H-NMR and elemental analyses. All the compounds have been found to promising antifungal activity when compared with standard drug Griseofulvin. All the compounds were screened for *in-vitro* anti-diabetic activity by α-glucosidase inhibitory action by different concentration like 150 µg/ml, 200 µg/ml by inhibition of α- glucosidase method. Acarbose was used as standard drug.

KEYWORDS: antifungal activity, antidiabetic activity, elemental analyses, Acarbose Griseofulvin, α-Glucosidase.

INTRODUCTION

Microbial infections have become more dreadful and dangerous so the search of new antibiotics and antibacterials is a continuous process in drug discovery. Fungal infections are termed mycoses which affect skin, nails, scalp, mucous membranes, deeper tissues and organs. The commonest systemic fungal infections are candidiasis, blastomycosis, histoplasmosis, coccidiomycosis and paracoccidiomycosis. Older people, diabetics, pregnant women and burn wound victims are all more prone to fungal infections.[1, 2]

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SOLUBILITY ENHANCEMENT OF POORLY WATER SOLUBLE DRUG USING NATURAL CARRIER

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ABSTRACT

Atorvastatin calcium is a synthetic lipid-lowering agent. Atorvastatin (ATR) is an inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase. This enzyme catalyzes the conversion of HMG-CoA to mevalonate, an early and rate-limiting step in cholesterol biosynthesis. According to the biopharmaceutical classification, ATR comes under Class II (low solubility and high permeability). Because of the limited aqueous solubility, it exhibits dissolution rate limited oral absorption. The objective of this investigation was to improve the solubility of the poorly water soluble drug atorvastatin, using solid dispersion (SD) techniques, with Aegel marmelos Gum (AMG) as a hydrophilic carrier. The effect of two variables related to solid dispersions preparation (drug to carrier ratio and method of preparation) were investigated. All the SDs prepared by Microwave induced fusion and Lyophilisation techniques showed remarkable increase in the solubility compared to the pure ATR.The solubility analysis demonstrated highest increase in the solubility of drug observed with ATR-AMG ratio 1:1 by lyophilisation technique. During In Vitro study result obtained that the SD prepared using the Lyohilisation method containing 1:1 ATR-AMG ratio displays faster dissolution rates compared with those prepared using the other that is 98.8±0.09% drug release within 90 min. The SD was characterized using DSC and XRD technique.

Keywords: Atorvastatin Calcium, Lyophilisation, Microwave, Solid Dispersion

INTRODUCTION

In recent years, the formulation of poorly soluble compounds presented interesting challenges for formulation scientists in the pharmaceutical industry. Up to 40% of new chemical entities discovered by the pharmaceutical industry are poorly soluble or lipophilic compounds, which lead to poor oral bioavailability The enhancement of oral bioavailability of poorly water soluble drugs remains one of the most challenging aspects of drug development. Atorvastatin (ATR) is a synthetic lipid-lowering agent.[1-3] Atorvastatin is an inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase. This enzyme catalyzes the conversion of HMG-CoA to mevalonate, an early and rate-limiting step in cholesterol biosynthesis. According to the biopharmaceutical classification, ATR comes under Class II (low solubility and high permeability). Because of the limited aqueous solubility, it exhibits dissolution rate limited oral absorption.[10, 11, 12] Solid dispersion (SD) techniques have been used to enhance the dissolution and oral bioavailability of many poorly water soluble drugs.[4, 5] To overcome the solubility problem, many authors formulated solid dispersions using number of various polymers and methods. In spite of tremendous research activity on solid dispersions since 1961, their commercial application is limited. Only a few products have been marketed so far.[6, 7, 8, 9] One aspect of solid dispersion technology on which most workers in the field would agree is that the number of marketed products arising from this approach has been disappointing. Research for alternative carriers has been increasing to suit for the industrial applications as well as to reduce the production cost and toxic effects. Recently, many natural polymers have been evaluated for their uses in formulation of solid dispersion. Cost effective pharmaceutical excipients are always desirable.[13,14] Pharmaceutical excipients developed from natural

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RESEARCH ARTICLE

Full Factorial Design for Optimization, Development, Validation of RPHPLC Method and Stability-Indicating Method for Tamsulosin and Dutastaride

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ABSTRACT:
High performance liquid chromatographic method was optimized developed and validated as per the ICH guidelines. Full factorial design was used to optimize the effect of variable factors. Full factorial design was used during forced degradation experiments and the factors/combination of factors which were most likely to affect degradation under various conditions was identified and was optimized further. In this study the methanol: water in the 80:20 ratios were used as mobile phase for the analysis. Drugs were exposed to acid, alkali and oxidation effect by hydrogen peroxide, dry heat, wet heat and photolytic conditions. The retention time values of tamsulosin and dutastaride were found to be 1.9min and 7.94 min respectively. Percent recovery in terms of accuracy was found in the range of 96.7–102.9%. Drugs were found to be stable under wet heat, dry heat and photolytic conditions, but substantial degradation was observed under acid, alkali and oxidative conditions. The method was found to be simple and fast by making use of experimental design.

KEYWORDS: HPLC, Dutastaride, Tamsulosin, Stability indicating method Full factorial Design.

INTRODUCTION:

The method for the analysis of drug in the formulation should be robust, sensitive and precise; hence, in this method design of experiment has been applied to study the effect of factors individually and in combination also. Design of experiment (DOE) is based upon the principles of experimental design, mathematical equations or models and outcomes of the factors. This research article focuses on the optimization, development and validation of a new analytical method with DOE[1,2].

Forced degradation/stress testing, defined as the stability testing of drug substance and drug product under conditions exceeding those used for accelerated testing. From a drug development and regulatory perspective, forced degradation studies provide data for the identification of possible degradation products, prediction of degradation pathway, validation of stability-indicating analytical procedures, identification of conditions in which the drug is less stable, the choice of packing material and selection of storage conditions. Although the regulatory guidance documents define the concept of stress testing, they do not provide detailed information about a stress testing strategy. The experimental conditions to conduct stress testing are described in a general way and the exact stress conditions to be applied are not described. Researchers have suggested that degradation can be achieved by exposing the drug, for extended periods of time, to

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EFFECT OF HYDROALCOHOLIC EXTRACT OF DRIED FRUITS OF *TRAPA NATANS* L ON ANIMAL MODELS OF COGNITIVE DYSFUNCTION

Ambikar D. B.* and Vyawahare N. S.

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ABSTRACT

In the traditional system of medicine, the dried fruits of *Trapa natans L var bispinosa* (TB) have been employed clinically for their nutritional and medicinal property like nervine tonic. The effect of hydroalcoholic extract of fruits of *Trapa natans L var bispinosa* was investigated for its nootropic activity using various experimental paradigms of learning and memory, viz. transfer latency (TL) on elevated plus-maze, passive avoidance response (PAS), scopolamine induced amnesia (SIA) and brain acetylcholineestrase activity in albino mice. The investigation reported that TB 500 mg/kg significantly reduced the TL on 2nd and 9th day while TB 250 mg/kg was found effective on 9th day. TB 250 and 500 mg/kg significantly increased the step down latency in the PAS at acquisition and retention test. The extract also significantly attenuated the amnesic effects of scopolamine on the TL and SDL. The brain AchE levels were not altered with the pretreatment TB. In present investigation TB extract showed significant facilitatory effect on aversively motivated learning and memory in mice. Moreover it attenuates the scopolamine induced memory disruption in mice.

Keywords: Cholinergic modulation, Learning and memory, Nootropic, *Trapa bispinosa.*

INTRODUCTION

Trapa natans L var bispinosa (TB), a floating aquatic herb is one of the medicinal plants that has been used as a nerve tonic from time immemorial. The acrid juice is used for diarrhea and dysentery. The fruits are used as intestinal astringent, aphrodisiac, anti-inflammatory, antileprotic, in urinary discharges, fractures, sore throat, bronchitis and anemia[1,2]. TB is has been reported to have hepatoprotective activity[3], free radical scavenging activity[4], antimicrobial activity, antitumor activity and antioxidant activity[5,6]. TB is possesses significant facilitatory effect on aversively motivated learning and memory in mice[7]. TB also reported to reverse D-galactose induced ageing changes to some extent which could resulted due to oxidative damage[8]. Moreover, TB fruit is also claimed as nerve tonic and is useful in nervous debility[1] Keeping these facts in mind, the present investigation was undertaken to investigate the nootropic activity of hydroalcoholic extract of fruits of TB.

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MATERIALS AND METHODS

Plant material

The plant material (dry fruits of *Trapa bispinosa*), collected from Maihar region of Madhya Pradesh, India was authenticated by botanical survey of India, Pune (voucher specimen number-BSI/WC/Tech/2008-976). The hydroalcoholic extract of dried fruits was prepared at approved laboratory of Green Chem, Bangalore, India using following procedure.

Preparation of extract

Dried fruits were extracted with 50% mixture of hydroalcohol and concentrated. The concentrated mass was washed several times with petroleum ether to remove the resinous matter. Then, the mass was diluted with mixture of hydroalcohol (75 + 25), filtered and concentrated, dried to get the powdered form of the extract[9] (yield: 0.25 %).

Chemicals and drugs

Acetylthiocholine iodide (SD Fine Chemical), 5, 5-dithiobisnitrobenzoic acid (Loba Chemicals) were used. Piracetam syrup and scopolamine injection was purchased from the local market.

Animals

Swiss male albino mice (18 - 22 g), obtained from animal house of AISSMS COP, Pune and certified as healthy by a veterinary physician, were used. These mice

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RESEARCH ARTICLE

BENTHAM SCIENCE

Development and Evaluation of Naproxen Sodium Gel Using *Piper cubeba* for Enhanced Transdermal Drug Delivery and Therapeutic Facilitation

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Abstract: ***Background:*** The absorption of drug through skin avoids many side effects of oral route like gastric irritation, nausea, systemic toxicity etc and thus improves patient compliance. Naproxen sodium (NPRS) is one of the potent NSAID agents.

Objective: The present study was aimed to develop and evaluate the gel formulation containing NPRS for transdermal drug delivery reducing the side effects and improving patient compliance. The patents on topical delivery of NSAIDS (US 9012402 B1, US 9072659 B2, US 20150258196 A1) and patents indicating use of herbal penetration enhancers (US 20100273746A1, WO 2005009510 A2, US 6004969 A) helped in selecting the drug, excipients.

Method: Current protocol employs various extracts of *Piper cubeba* fruit to evaluate its role in absorption of NPRS. Various batches containing 1% NPRS and varying concentrations of synthetic permeation enhancers or the extracts were formulated in carbopol gel. Gel was evaluated for parameters like organoleptic parameters, pH, viscosity and spreadability. An *ex-vivo* percutaneous absorption of NPRS from gel was investigated and compared with best performing synthetic enhancer, transcutol P (TP).

Result: The batch containing 2% n-hexane extract (NHE) of *Piper cubeba* showed higher permeation than TP and Chloroform (CE), Methanolic (ME) and aqueous (AE) extracts as well. It showed improved % cumulative release (85.09%) and flux (278.61μg/cm^{2}h), as compared to TP and other extracts. Histopathology indicated the formulation safer as compared to that with synthetic enhancer.

Conclusion: It suggests *P. cubeba* as effective and safer tool for transdermal delivery and acts as therapeutic facilitator for naproxen. GC-MS analysis indicates lignans & terpenes in NHE to which this permeation enhancement activity may be attributed.

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1. INTRODUCTION

Drug delivery *via* dermal route has many advantages over intravenous and oral routes of administration. But human skin, in particular the stratum corneum, is designed to be a formidable barrier to the passage of molecules either from inside to out or *vice versa*. Thus skin limits topical and transdermal bioavailability thereby affecting the drug penetration. Hence skin penetration enhancement techniques have been developed to improve bioavailability and increase the range of drugs for which topical and transdermal delivery is a viable option [1, 2]. Many approaches have been employed to mitigate stratum corneum permeability like drug selection, prodrugs and ion-pairs, supersaturated drug solutions, eutectic systems, complexation, liposomes *etc.* [3]. One of the most common and long standing approaches is that of sorption promoters, also known as penetration enhancers which penetrate into skin to reversibly decrease the barrier resistance [2].

Currently, one can witness great resurgence of using alternative treatments and the increasing use of natural products, especially those obtained from herbs due to several reasons like adverse or toxic effects shown by most of the synthetic drugs and excipients. Hence there is always need to knock new sources for safer and better options of medication and excipients for various routes of administration. There is a great interest and medical need for the improvement or modification of therapeutic effect of a large number of drugs which are used chronically, are expensive, toxic or are poorly bioavailable [4].

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SHORT NOTE

ANTICONVULSANT ACTIVITY OF LAMOTRIGINE POLYMERIC MICELLE AND SAFRANAL NIOSOMAL FORMULATION AGAINST STRYCHNINE-INDUCED CONVULSION

ABSTRACT

Lamotrigine is currently available as a tablet which is administered 2-3 times per day as divided doses of 25-600 mg. Oral liquid formulations with additional sustained release properties are always preferred for pediatric, geriatric even dysphagic patients, due to their ease of administration and patient compliance even at the time of epileptic attack. Hence, polymeric micelle formulation of lamotrigine and safranal niosomal nasal formulation were studied. Polymeric micelles containing lamotrigine were prepared by direct dissolution technique using block copolymer (Pluronic L81, Pluronic F68) in combination (1:1) ratio. Niosomes containing safranal were prepared by modified ether injection technique using non-ionic surfactants (Span 80 and Tween 20 & 80), Gelucire 44/50, Pluronic F-127 and cholesterol at different ratios. In this test, strychnine (4 mg/kg) was injected to the animal subcutaneously (s.c.) beneath the loose folds of neck skin. Fifteen minutes post administration of lamotrigine and safranal administration by intravenous route. Animals were observed for 10 min for occurrence and onset on various seizures. Latencies were noted in seconds. The present study is to evaluate anticonvulsant activity of lamotrigine (LTG) polymeric micellar formulation and safranal niosomal formulation on strychnine induced convulsions in mice. Vehicle failed to protect the mice from generalized clonic-tonic convulsions induced by strychinine. Lamotrigine significantly delay the onset of myoclonic, clonic and tonic extensor by all three routes i.e. nasal, intravenous and oral as compared to vehicle group. Effect of lamotrigine by nasal route is similar to the effect by intravenous route. Lamotrigine by nasal and intravenous route have shown more effect when given by oral route. Lamotrigine and safranal significantly delay the onset of myoclonic, clonic and tonic extensor by I.V. route as compared to vehicle group.

Keywords: Lamotrigine, Safranal, polymeric micelle, niosomal, strychnine.

INTRODUCTION

Lamotrigine has a broad spectrum in antiepileptic activity[1-5]. The drug is currently available as a tablet which is administered 2-3 times per day as divided doses of 25-600 mg[6]. In the present investigation mixed micelles made of hydrophobic Pluronic L81 and hydrophilic Pluronic F68 were investigated and have several advantages over other conventional systems.

This study focuses on the anti-convulsant activity of safranal[10]. Safranal also has antioxidant properties[12].

MATERIALS AND METHODS

Safranal, Pluronics (Pluronics F68, Pluronic L81 and Pluronic F-127) were purchased from Sigma-Aldrich. Lamotrigine was a gift sample from Kopran Pharmaceuticals Mumbai. Tween 80 & 20 Span 80, Gelucire, methanol and chloroform were purchased from S.D.Fine Chemicals, Mumbai. Cholesterol was purchased from Loba Chemicals, Mumbai.

Lamotrigine containing suspension was prepared by first adding 0.2% of carboxymethyl cellulose to distilled water. Polymeric micelles containing lamotrigine were prepared by direct dissolution technique using block copolymer (Pluronic L81, Pluronic F68) in combination (1:1) ratio. Niosomes containing safranal were prepared by modified ether injection technique using non-ionic surfactants (Span 80 and Tween 20 & 80), Gelucire 44/50, Pluronic F-127 and cholesterol at different ratios.

Animals

The use of animals for the present study was approved by Institutional Animal Ethical Committee, (IAEC), Marathwada Mitra Mandal's College of Pharmacy, Pune, India. The experiments were conducted on adult albino mice (body weight 25±5 g). The mice were housed in cages with free access to food and water ad libitum. They were kept under standardized laboratory conditions (a 12-h light-dark cycle and a temperature of 21 ± 1°C). The experimental groups, each consisting of eight animals, were chosen using a randomization.

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Research Article
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EVALUATION OF WOUND HEALING POTENTIAL OF VARIOUS WOUND HEALING CREAMS IN FRESH, DIABETIC AND BURN WOUND MODELS

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ABSTRACT

Introduction: The present study was designed to investigate comparative efficacy of various wound healing creams WHCs (F1 to F7) with placebo cream and marketed formulations (Mupirocin cream, Silver Sulfadiazine Cream and Jatyadi oil) using excision, incision and burn wound models in normal and diabetic rats. **Materials and Methods:** In-vivo excision, incision and burn wound models in normal and diabetic rats were used in order to assess comparative efficacy of various wound healing creams WHCs (F1 to F7) with marketed formulations. In case of the excision and burn wound models, wound contraction and period of epithelization were studied. Histopathological study was conducted in order to assess fibroblast proliferation, collagen formation, angiogenesis and epithelialization of wound. In incision wound model, tensile strength of wound was evaluated. **Result:** WHC [Formulation No. 4 (F-4)] showed significantly better wound healing activity than placebo cream, other various WHCs, Mupirocin Cream, Silver Sulfadiazine Cream and Jatyadi Oil. F-4 also showed complete epithelization and good collagen deposition as compared to Placebo Cream, other various WHCs, Mupirocin Cream, Silver Sulfadiazine Cream and Jatyadi Oil. **Conclusion:** F-4 showed statistically significant better wound healing activity in excision, incision and burn wound models in normal and diabetic rats as compared to placebo cream, other various WHCs, Mupirocin Cream, Silver Sulfadiazine Cream and Jatyadi Oil.

KEYWORDS: Burn wound model, Excision Model, Incision Model, Wound healing potential, diabetic wound healing model, Silver Sulfadiazine Cream, Jatyadi Oil.

INTRODUCTION

Wound is defined as a loss or breaking of cellular and anatomic or functional continuity of living tissues[1] and Wound healing involves platelet aggregation, blood clotting, formation of fibrin, an inflammatory response to injury, angiogenesis and re-epithelization.[2-4] This complex cascade of event starts from the moment of injury and continues for varying periods of time depending on the severity of wounding. Normal wound healing contains four highly integrated and overlapping phases of cellular and biochemical activities including hemostasis, inflammation, proliferation and maturation or remodeling.[5] In spite of tremendous advances in pharmaceutical drug industry, the availability of drugs capable of stimulating the process of wound repair is still limited.[6,7] Only 1–3% of the drugs listed in Western pharmacopoeias are intended for use on wounds; on the other hand, at least one-third of herbal remedies are applied as wound healing agents.[7,8] Many traditional practitioners across the world have valuable information of many plants for treating wounds and burns. The presence of bioactive constituents in plants has urged researchers to screen medicinal plants with a view to determine potential wound healing activities and isolate chemical entities associated with wound healing.[9] Wound healing process is promoted efficiently by the use of traditional remedies which are mainly based on plant sources. These remedies have been shown to affect one or more stages of the wound healing process. In this context, traditional medicines can provide a vast source for the discovery of original drug leads.[10-12]

There is need for new cost-effective therapies with better efficacy for wound healing. Medicinal plants are important sources of new chemical substances that have beneficial therapeutic effect.[13] Taking in to consideration the need of today's world, Ari Healthcare Pvt. Ltd. has conceptualized and developed the wound healing cream (WHC). Based on the traditional documents on Indian medicine, various new wound

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RESEARCH ARTICLE

Phytochemical and Toxicological Evaluation of *Acorus calamus* and *Argyreia speciosa Leaves Extract*

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ABSTRACT:

In present study *Acorus calamus* and *Argyreia speciosa* were collected, their authentications were performed. These two plants were extracted by three different solvents. Extracts of these plants were subjected to different phytochemical analysis. Acute toxicity studies of these plant extracts were performed to determine their safety. Phytochemical Investigation were carried out by performing various tests viz. test for detection of carbohydrate, alkaloid, proteins, volatile oils, flavonoids, saponins, phenols, resins, tannins, amino acid, steroids, triterpenoids, anthraquinones and coumarines. Acute oral toxicity was performed using OECD 420 guidelines. Groups of female rats are dosed in a stepwise procedure using the fixed doses of 5, 50, 300 and 2000 mg/kg. No toxic symptoms or mortality were observed in any animals, which lived up to 14 days after the administration of all extract of AC and AS upto the level of 2000 mg/kg body weight

KEYWORDS: *Acorus calamus, Argyreia speciosa*, Phytochemical, Toxicological

INTRODUCTION:

Incidences of central nervous system (CNS) diseases are increasing day by day. Among them, epilepsy has now become the most serious brain disorder. A number of synthetic antiepileptic drugs are available in practice but their clinical utility is restricted due to various limitation viz. teratogenicity, drug interactions and memory deficit. *Acorus calamus* and *Argyreia speciosa* are Indian medicinal plants. Epilepsy and memory deficit are closely related and generally occurs simultaneously. Also, there are always chances that one disorder may follow other. Through literature survey was performed.

It was found that root part of *Acorus calamus* and *Argyreia speciosa* have been evaluated for treating some CNS system disorders. Leaves part of these plants have not been evaluated for its CNS activity [1] In present study *Acorus calamus* and *Argyreia speciosa* were collected, their authentications were performed. Through literature survey was performed. It was found that root part of *Acorus calamus* and *Argyreia speciosa* were studied for few central nervous system (CNS) diseases. Leaves part of the plants were not screen for its different CNS activities. Moreover, their CNS activity in combination and in tablet formulation have not been determined. These two plants were extracted by three different solvents. Extracts of these plants were subjected to different phytochemical analysis. Acute toxicity studies of these plant extracts were performed to determine their safety.

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DEVELOPMENT AND VALIDATION OF HPLC METHOD FOR THE ESTIMATION OF IRBESARTAN

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Irbesartan,
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ABSTRACT

A simple, specific, accurate and precise reverse phase high performance liquid chromatographic method was developed and validated for the estimation of Irbesartan. AMicrosorb-MV 100-5 C-18 (250 x 4.6mm, 5 µm) column using UV detector with mobile phase containing methanol, 0.02% Formic acid (70:30, v/v) was used. The flow rate was 1.0 ml/min and detection was carried out at 234 nm. The retention time for Irbesartan was 8.18 min. The method was validated for linearity, accuracy, precision, limit of detection, limit of quantification and robustness. The results of all the validation parameters were well within their acceptance values.The proposed method was successfully applied for the quantitative determination of Irbesartan.

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VALIDATED HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF ISOTRETINOIN AND ERYTHROMYCIN IN BULK DRUG FORM

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ABSTRACT

A simple, rapid, accurate, specific and sensitive reverse phase-HPLC method has been developed and validated for the estimation of Isotretinoin(ISO) and Erythromycin(ERY) in bulk drug and pharmaceutical dosage form. The chromatographic separation was performed on C18 Column using a mobile phase of Methanol & Phosphate Buffer pH6 (60:40 v/v), at a flow rate of 1ml/min at an ambient temperature with the detection wavelength at 231nm. The retention times of ISO & ERY were 1.69min and 2.8min respectively. The linearity was performed in the concentration range of 10-60µg/ml for ISO and 100-600µg/ml for ERY with a correlation coefficient of 0.995 and 0.994 for ISO & ERY respectively. The proposed method was then validated for different parameters as per the ICH guidelines. The method was validated for linearity, accuracy, precision, limit of detection, limit of quantification and robustness. The results of all the validation parameters were well within their acceptance values. The proposed method was successfully applied for the quantitative determination of Isotretinoin and Erythromycin. Thus the developed method was successfully employed for routine quality control analysis in the bulk dosage forms.

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A NOVEL SYNTHESIS ROUTE TO INDOLOPYRIDOQUINAZOLINE ALKALOID ANALOGUES FROM CONDENSED PYRIMIDINE SCAFFOLDS

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Indolopyridoquinazoline,
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ABSTRACT

Development of new, elegant synthetic routes to bioactive quinazolinocarboline alkaloids Rutaecarpine, Euxylophoricine and their analogues is a challenging task of current interest. The present work focuses on a novel synthetic approach to Indolopyridoquinazoline and it's derivatives. The pentacyclic compounds were synthesized efficiently by using various condensed 2-chloromethyl pyrimidine scaffolds as important heterocyclic building blocks. This approach has been extended to the synthesis and diversification of compounds based on cyclization of a variety of nitriles with *o*-aminoesters of benzene, dimethoxybenzene under acidic conditions for pyrimidine scaffolds. Starting from condensed pyrimidine scaffolds, we have demonstrated an elegant five step practical synthesis of bioactive natural Indolopyridoquinazoline alkaloid analogues. This novel synthetic approach is amenable for the generation of library of bioactive Indolopyridoquinazoline analogues.

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ORIGINAL ARTICLE

Synthesis, characterization and evaluation of the suppression of insulin resistance in Type-II diabetes mellitus animals by treatment with metal complex

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KEYWORDS

Thespesia populnea;
Vanadium complex;
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Abstract The present study is characterized toward thespesone isolation from *Thespesia populnea* (Malvaceae). Subsequently it was modified and characterized to study its effect on diabetes related symptoms. The complex is administered to diabetes induced mice with the doses of 5, 10 and 20 mg/kg, p.o. and the effect of complex on the level of body weight, lipid profile and blood glucose was studied after 22 days. The results have indicated that diabetic mice show a significant ($p < 0.01$) decrease in the level of serum triglyceride, plasma glucose and increase in body weight. Hence the present investigation reveals that newly synthesized complex is useful in the management of Type-II diabetes mellitus because of its ability to reduce insulin resistance.

1. Introduction

Diabetes is the most common disease as far as metabolic disorder is concerned, its incidence in the year 2010 was 210 million and by 2025 it is proposed to increase to 300 million (Patel et al., 2013). Diabetes mellitus is divided into two types, Type-I and Type-II. Type-II diabetes, however, is also called non-insulin dependent diabetes mellitus, it develops on the root of impaired insulin secretion or increased insulin resistance (Kuriya et al., 2003). The use of synthetic drugs might be connected with unnecessary side effects, including hypoglycemia and cell death, which are effective in increasing insulin secretion (Georgino et al., 2006). Hence, there is an increased scope to develop more safe, effective and cheap methods for its treatment. It is a body's condition where tissues turn resistant to insulin, which results in an evident reduction of glucose metabolism in response to insulin. Recent studies also suggest that insulin resistance results from complex interactions between genetic and environmental factors and is associated with common diseases such as Type-II diabetes, hypertension, obesity and coronary artery disease

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RESEARCH ARTICLE

Conception and Evaluation of Extended Release Multiparticulate System of Milnacipran Hydrochloride

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ABSTRACT:

Milnacipran HCl is a selective norepinephrine and serotonin reuptake inhibitor well used drug for the treatment of depression and fibromyalgia. Milnacipran HCl belongs to biopharmaceutical class I having short elimination half-life. Milnacipran HCl recommended immediate release [IR] dose 50mg twice a day associated with frequent dosing which cause side effects, lack of patient compliance and discontinuation of therapy. To overcome such problems, the aim of the present study was to design novel once a day extended release multiparticulate system of Milnacipran HCl using Fluidized bed processor with coating technique. To achieve the goal, drug solution layering was done on seal coated #25 – 30 non pareil sugar spheres followed by release controlling polymer coating of Ethyl cellulose and Hydroxypropyl methyl Cellulose in the ratio 90:10 respectively. In vitro dissolution study of 10, 12, and 14% release controlling polymer coated pellets was carried in distilled water using USP type II dissolution apparatus with sinkers. Ratio of hydrophobic to hydrophilic polymer and level of coating have highest effect on drug release. Milnacipran HCl release extended for longer duration as percent of release controlling polymer coating increased. The release kinetics was explored and explained with zero order, first order, Higuchi and Korsmeyer equations. The drug release from pellets has no significant effect of pH of dissolution medium.

KEYWORDS: Milnacipran HCl, Extended release pellets, Ethyl Cellulose, Hydroxypropyl methyl Cellulose

INTRODUCTION:

Milnacipran HCl has been approved since 1997 for treatment of depression and also approved in January 2009 for treatment of fibromyalgia. Milnacipran HCl is commercially available as immediate release (IR) formulations in the form of tablets and capsules with dose of 12.5-100 mg.[1] U.S. Patent No. 6,602,911 to paillard states "for administration orally, the compounds may be formulated as a sustained release preparation".[3] However, patent does not describe diminishing locally and/or centrally mediated side effects.

Patent describes a prolonged release formulation of Milnacipran HCl with dosages ranging from 60-240 mg, in which 10-55% of the total dose is released within two hours between 40 and 75% in 4 hours, 70 and 90% in 8 hours and 80 and 100% of the dose released in 12 hours. Gautam Singhvi et al., worked on design and characterization of cost effective hydrophilic matrix tablets of Milnacipran HCl using Hydroxypropyl methylcellulose (HPMC).[4] Literature revealed that multi granules extended Release [ER] formulations are better in release control than conventional matrix of single granules.[5] It is also reported that a combination of hydrophilic and hydrophobic polymers in a matrix can better control the drug release than alone hydrophilic polymer for prolong time.[6] Hydrophobic polymers not only act as water repellent surface, but also provide

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The isolation, Characterization and Preclinical Studies of Metal Complex of Thespesia populnea for the Potential Peroxisome Proliferator-activated Receptors-γ Agonist Activity.

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Author information

Abstract

BACKGROUND: Diabetes mellitus is an international public health problem since ancient days. The condition is predominantly more severe in developing countries like India where, life is more sedentary due to the even changing lifestyles in this fast-paced global scenario. Thespesia populnea is widely used in the ayurvedic system of medicine for treatment of diabetes mellitus in India for years. The aim of this work is to explore the anti-diabetic activity of the isolated compound.

MATERIALS AND METHODS: The sesquiterpene isolated from hexane fraction of bark of T. populnea modified synthetically then identified by using analytical techniques such as electron paramagnetic resonance spectra for confirmation and the anti-diabetic activity was evaluated by anti-hyperglycemic, hypoglycemic potential.

RESULT: In the present work, we have studied the anti-hyperglycemic and hypoglycemic activity of the vanadium complex in glucose loaded and normal animals were shown significantly decreased in plasma blood glucose level. The results derived from preclinical studies confirm the potential of new sesquiterpene.

CONCLUSION: The findings could provide evidence regarding the anti-diabetic potential of T. populnea by lowering blood glucose level.

SUMMARY: Thespesia populnea is widely used in the ayurvedic system of medicine for treatment of diabetes in India. Present study aimed to explore the anti diabetic potential of isolated compound. Isolation of sesquiterpene from hexane fraction of bark of Thespesia populnea and modified synthetically then authenticated by using analytical techniques such as electron paramagnetic resonance spectra for confirmation. The modified complex was further assessed for its anti diabetic property in glucose loaded rats. Vanadium complex demonstrated significant reduction in plasma blood glucose level in glucose loaded animals. The results derived from preclinical studies confirm the potential of new sesquiterpene. The

Free Radical Scavenging and Cytotoxic Potential of *Celosia argentea*

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ABSTRACT

Introduction: Oxidative stress due to reactive oxygen species often leads to pathogenesis of chronic diseases such as cancer. Research states that a diet rich in polyphenols renders many health benefits by scavenging such harmful reactive species. *Celosia argentea* (Amaranthaceae), a common weed in India has been reported as a potential source of cheap, natural antioxidants due to its phenolic abundance. In this research work efforts were made to identify and screen the phenolic rich fractions of *Celosia argentea* for their antioxidant and anticancer potential. Materials and Methods: Various solvent fractions with increasing polarity were subjected to total phenolic content, followed by antioxidant assays- DPPH, ABTS and anti proliferative assays- Brine shrimp Bioassay, Antimitotic and MTT assays. Results: IC_{50} value of methanolic fraction for DPPH assay was statistically significant (26.25; ***P<0.001) when compared with ascorbic acid (12.50; ***P<0.001). Also TEAC values for methanolic fraction and BHT (standard) for ABTS assay were similar (2.1; ***P<0.001) Methanolicfraction at 400 µg/ml exhibited strong cytotoxicity (9.0 ± 0.81; ***P<0.001) against brine shrimps comparable to Methotrexate at 50 µg/ml(10; ***P<0.001) and significantly reduced mitotic index from 96.8 to 38.0 (***P<0.001) which was further confirmed by MTT assay where IC_{50} value of methanolic fraction for SiHa and MCF-7 cells was found to be 28 µg/ml with no cytotoxicity to normal cells proving its anticancer potential. Conclusion: This research proves antioxidant and anticancer potential of phenolic rich fraction of *Celosia argentea* and suggests it to be useful in cancer management as antiproliferative, chemo preventive and in cancer chemotherapy induced immune suppression and oxidative stress.

Key words: Antioxidant, Brine shrimp, Mitotic index, MTT, Phenolics.

INTRODUCTION

Imbalanced metabolism and excess reactive oxygen species (ROS) generation end into development of oxidative stress leading to range of disorders such as cancer, diabetes, atherosclerosis, cardiovascular diseases, Alzheimer's, Parkinson's disease, aging and many other neural disorders. Toxicity of free radicals contributes to proteins and DNA injury, inflammation, tissue damage and subsequent cellular apoptosis. Antioxidants are now being looked upon as persuasive therapeutic as they have capability to combat by neutralizing free radicals.[1]

As the natural antioxidant defense mechanism becomes inefficient, dietary intake of antioxidant is important to replenish and regenerate antioxidants that are responsible for removal of free radicals, scavenging ROS or their precursors, and binding metal ions needed for catalysis of ROS generation.[2] Synthetic antioxidants like BHT and BHA have their accompanied unavoidable side effects like radio sensitization, toxicity of other chemicals, mutagenicity, and tumor formation from chemical carcinogens.[3] Hence, there is a need to explore the nature and screen the medicinal plants as potent antioxidants. It is found that dietary polyphenols obtained from various herbs, spices, fruits and vegetables are found to possess anticancer effects via

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Research Article

Immunomodulatory profile of *Celosia argentia*-Activity of Isolated compounds I and II

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ABSTRACT:

Immunostimulation and immunosuppression both need to be tackled in order to regulate the normal immunological functioning.Immunomodulators not only boost immunity, but normalize it.Being safe,effective and pocket friendly,plant based immunomodulators can provide as alternatives or adjuvants to conventional drugs. The aerial parts of *Celosia argentea Linn*, a common weed found in Maharashtra are reported to be rich in flavonoids that are believed to play a significant role in body's defense mechanism.Hence the present study explores the effectivity of the compound I-Luteolin7-0 glycoside and compound II–1-(4-hydroxy-2-methoxybenzofuran-5-yl)-3-phenylpropane-1,3-dione obtained from the aerial parts of *Celosia argentea Linn*.Fresh whole plants of *Celosia argentea Linn*.were collected from Bhor, district-Pune, Maharashtra and dried in the shade at room temperature. The herbarium of the plant specimen was deposited and authenticated at Botanical Survey of India, Pune.Proximate analysis was done andPhysicochemical constants such as moisture content, ash value, extractive value and foreign organic matter were studied using standard methods. When both the isolated compounds I and II were tested for in vivo immunomodulatory activity using Mice Paw Sensitivity test, Phagocytic Index and HA Titre parameters, it was found that Compound I exhibited impressive immunomodulatory activity (***p<0.001) followed by compound II (**p<0.01), for all the three assays. Immunosuppressive state is involved in the etiology as well as pathophysiology of many neoplastic, inflammatory and autoimmune diseases. Thus, the present research work suggests that compounds I and II of aerial parts have a significant potential for immunoregulation and may be administered as alternativesor adjuvants to therapies requiring immunomodulation, , especially when the host defense mechanism has to be activated under the condition of impaired immune response in degenerative diseases.

Keywords:*Celosia argentea Linn*, Immunomodulator, Compound I, Compound II, Flavonoid

INTRODUCTION:

Immunomodulator is a substance that alters the immune response by augmenting or reducing the ability of the immune system. The substances showing such property are called as Immunomodulatory agents.Modulator given to someone with a healthy immune system will have

Research Article

Quantitative Determination of Rosuvastatin Calcium and Niacin Individually and Combined Tablet Dosage Form by Using UV-VIS Spectrophotometer

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ABSTRACT

Two simple, specific, accurate and economical UV-Spectrophotometric methods were developed and validated for quantitative determination of Rosuvastatin and niacin in combined tablet dosage form. Method I is based on the simultaneous equation and method II is based on the absorbance ratio method. The solvent used to develop the method was Double distilled water. The absorbance maxima were found to be at 241and 262nm in water for the Rosuvastatin and niacin respectively. Beer's law is obeyed in the concentration range 5-40µg/ml with correlation coefficient within range of 0.998 for both the drugs. The accuracy of the method was checked by recovery experiment performed at three different levels i.e., 50%, 100% and 150%.The % recovery was found to be 98-105% for Rosuvastatin and niacin respectively. The low values of % R.S.D are indicative of the accuracy and reproducibility of the method. The % R.S.D value less than 2 indicate that the method is precise. The above method was a rapid and cost-effective quality-control tool for routine analysis of pharmaceutical dosage form.

Keywords: Simultaneous equation method, absorbance ratio method, Rosuvastatin and niacin

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INTRODUCTION

Rosuvastatin (statin) HMG-CoA reductase inhibitor [1]. and niacin (nicotinic acid) are used, in the primary and secondary prevention of coronary heart disease, carotid artery disease and other atherosclerotic vascular diseases. In US guidelines, the lowering of low-density lipoprotein cholesterol (LDL-C) is the primary goal of lipid-modifying therapy in patients with atherosclerotic disease and those at risk for atherosclerotic disease due to dyslipidaemia. However, in patients with primary hyperlipidemia [2] and atherogenic dyslipidaemia [3] and (i.e. those with high triglyceride levels, low high-density lipoprotein cholesterol [HDL-C] levels and small dense LDL particles), LDL-C levels may underestimate the cardiovascular risk. Therefore, the US guidelines recommend lowering both LDL-C and non- HDL-C in patients with hypertriglyceridemia.

In available lipid-modifying drugs, statins are the most effective for lowering plasma LDL-C and are considered the cornerstone of treatment for dyslipidaemia and hyperlipidemias [4].

Niacin at pharmacological doses, displays wide-ranging lipid-modifying activity, reducing levels of all atherogenic lipid and lipoprotein subclasses, including total cholesterol, LDL-C, non- HDL-C, triglycerides, apolipoprotein B, and lipoprotein(a), and also significantly increasing levels of HDL-C and apolipoprotein A. Furthermore, the combination of two lipid-lowering agents in one formulation may potentially improve patient compliance. Niacin is also used in the treatment of hyperlipidemia because it reduces very low density lipoprotein (VLDL), a precursor of low density lipoprotein (LDL) or "bad" cholesterol, secretion from the liver and inhibits cholesterol synthesis [4,5].

Literature survey revealed that numerous methods have been reported for estimation of Rosuvastatin and Niacin in

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Piper Betle: A Promising Tool for Drug Permeation Enhancement of Naproxen Sodium Transdermal Gel Formulation

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S.K. Patwardhan

Abstract: The main objective of present investigation was to study the influence of *Piper betle* on the permeation of Naproxen sodium gel when applied on skin. This route avoids the side effects of NSAIDS on oral administration like irritation of the gastrointestinal tract, and systemic toxicity and improves the patient compliance and therapeutic efficacy. The leaves of *P. betle* were subjected to maceration using successive solvent extraction with solvents like n-hexane, chloroform, methanol and water. All four extracts were screened for preliminary phytochemical tests. The carbopol gel formulations containing Naproxen sodium (1% w/w) and selected concentrations (1% / 2% w/w) of synthetic penetrations enhancers or four herbal extracts were prepared as various batches. These formulations were subjected to characterization tests of colour, pH, viscosity, spreadability. Formulations were subjected to *ex-vivo* permeation of the drug across rat skin using Franz diffusion cell. The permeation using herbal extracts was compared with synthetic penetration enhancer, Transcutol P(TP). The formulation containing 2% w/w of N- hexane extract (NHE) showed better % cumulative release (47.97%) and flux (157.072 $\mu g/cm^2 h$), as compared to synthetic enhancer transcutol P (43.11% CR and flux as 141.15 $\mu g/cm^2 h$) and other extracts. Histopathology shows focal stripping of stratum corneum and normal adnexal structure in both these formulations (containing NHE & TP). But mild degeneration of epidermis and dermis was seen along with hemorrhage in skin treated with formulation containing TP. The results suggest that *Piper betle* may be safer and better option for increasing the skin permeability of Naproxen sodium as compared to synthetic penetration enhancers.

Keywords: Anti-inflammatory activity, naproxen sodium, *Piper betle*, penetration enhancer, therapeutic enhancer; transdermal permeation.

INTRODUCTION

Most of the synthetic drugs and exciepients/ additives show adverse or toxic effects. Hence there is always need to tap new sources for safer and better options of medication in oral, parenteral as well as topical route. Currently, one can witness great resurgence of using alternative treatments and the increasing use of natural products, especially those obtained from herbs due to several reasons. There is a great interest and medical need for the improvement or modification of therapeutic effect of a large number of drugs which are

(a) frequently consumed by the people and showing some side effects on chronic use

(b) poorly bioavailable

(c) toxic and expensive.

(d) prone to undesired effect due to drug interaction [1].

The transdermal gel formulation offers many advantages over oral route of administration. Gel is composed of small amount of solids dispersed in relatively large amount of liquid, yet they posses more solid-like than liquid-like character. Penetration through skin is a complex process, with a variety of barriers to cross. Penetration

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Research Article

Development and Validation of RP-HPLC Method for the Estimation of Rosuvastatin Calcium and Niacin in Combined Tablet Dosage Form

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ABSTRACT

A simple, specific, accurate and precise reverse phase high performance liquid chromatographic method was developed and validated for the estimation of Rosuvastatin and Niacin individually and combined tablet dosage form. An Inertsil ODS C-18, 5µm column having 15cm x 4.6mm internal diameter in isocratic mode with mobile phase containing potassium (dihydrogen) orthophosphate buffer: acetonitrile (50:50v/v) was used. The flow rate was 1.0 ml/min and effluents were monitored at 254 nm. The retention time for Rosuvastatin and Niacin was 1.58 and 4.84-5.5 min. The method was validated for linearity, accuracy, precision, specificity, limit of detection, limit of quantification and robustness. Limit of detection and limit of quantification were found in ng and recovery of Rosuvastatin and Niacin from tablet formulation was found 98-105 %. The accuracy of the method was checked by recovery experiment performed at three different levels i.e., 50%, 100% and 150%.The % recovery was found to be 98-105% for Rosuvastatin and niacin respectively. The low values of % R.S.D are indicative of the accuracy and reproducibility of the method. The % R.S.D value less than 2 indicate that the method is precise. The proposed method was successfully applied for the quantitative determination of Rosuvastatin and Niacin in tablet formulation.

Keywords: Rosuvastatin and Niacin, HPLC, Linearity, Validation, Combined dosage form

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INTRODUCTION

Rosuvastatin HMG-CoA reductase inhibitor (statin) and Niacin (nicotinic acid) are used, along with therapeutic life-style changes, in the primary and secondary prevention of coronary heart disease, carotid artery disease and other atherosclerotic vascular diseases. In US guidelines, the lowering of low-density lipoprotein cholesterol (LDL-C) is the primary goal of lipid-modifying therapy in patients with atherosclerotic disease and those at risk for atherosclerotic disease due to dyslipidemia. However, in patients with atherogenic dyslipidemia (i.e. those with high triglyceride levels, low high-density lipoprotein cholesterol [HDL-C] levels and small dense LDL particles), LDL-C levels may underestimate the cardiovascular risk. Therefore, the US guidelines recommend lowering both LDL-C and non-HDL-C in patients with hypertriglyceridemia.

Of the available lipid-modifying drugs, statins are the most effective for lowering plasma LDL-C and are considered the cornerstone of treatment for dyslipidemia. At pharmacologic doses, niacin displays wide-ranging lipid-modifying activity, reducing levels of all atherogenic lipid and lipoprotein subclasses, including total cholesterol, VLDL-C [1],LDL-C, non- HDL-C, triglycerides, apolipoprotein B, and lipoprotein(a), and also significantly increasing levels of HDL-C and apolipoprotein A. Furthermore, the combination of two lipid-lowering agents in one formulation may potentially improve patient compliance [2].

Literature survey revealed that numerous methods have been reported for estimation of Rosuvastatin and Niacin in pharmaceutical formulations individually or