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Research Article

Analytical Method Development And Validation For Estimation Of Bilastine In Pharmaceutical Formulationby Reverse Phase High Performance Liquid Chromatography

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ABSTRACT:
In this currentinvestigationeffort, an effort was made to build up anuncomplicated, speedy, truthfulas well as robust HPLC technique for the assessment of Bilastine in its tablet dosage form. Reverse phase high performance liquid chromatographic analysis was carried out on isocratic system. The column used for the investigation was Phenomenex C18 (250 mm× 4.6mm, 5µm) with ambient temperature. The optimized mobile phase was Methanol: Acetonitrile in the ratio of (20:80 %V/V). The detection was carried out at a wavelength of 245 nm using a flow rate of 1ml/min. The urbanizedtechnique was validated for validationconstraints like linearity, specificity, accuracy, precision as per ICH strategy. The %RSD for all constraints was well within the limits, which indicates the validity of the techniquein addition tothe assay results obtained are in reasonableconformity with the label claim of the marketed formulation. Thus, the conventionalscheme can be anticipated for repetitive investigation of this drug in laboratories and for superiority purposes.

Keywords: Bilastine, Acetonitrile, HPLC, Linearity.

INTRODUCTION:

Bilastine is a Phosphodiesterase 4 (PDE4) inhibitors chemically named as N-[2-[(1S)-1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-1,3-dioxoisoindol-4-yl] acetamide. It is used in the treatment of certain types of arthritis and skin conditions[1]. Literature survey revealed that few analytical techniques are available for estimation of Bilastine in pharmaceutical dosage form such as UV, HPLC. Keeping this objective in mind an attempt has been made to develop and validate the RP-HPLC method for the estimation of Bilastine in which the developed method would be a highly sensitivecost-effective method having good resolution and reproducible results [2].

MATERIALS AND METHODS:

Equipment

Chromatographic separation was conceded on WATERS HPLC system which is outfitted with the 515 dual head reciprocating pump & a 2489 UV Visible detector. The software used is Empower-2 software and column is Phenomenex C18 column of 250mm×4.6mm i.d, 5µm.

Materials and reagent

Bilastine drug was gifted by Aurobindo Pharmaceuticals, Hyderabad, Telangana, India. Acetonitrile, methanol, HPLC grade water, sodium hydroxide, Diammonium hydrogen orthophosphate and Hydrochloric acid were collected from local manufacturers.

Preparation of standard

solution:Standard stock arrangement was set up by gauging 25mg of Bilastineand moving in to 25 ml volumetric jar. At that point 25 ml weaken methanol was included and sonicated for 5 minutes to break down the medication. At that point the arrangement was weakened to check with methanol [6]. It was then separated through 0.45µm film channel, which gives the stock arrangement containing 1000µg/ml Bilastine.Standard arrangement was set up by moving in a 10 ml volumetric jar with a volume of 1 ml of standard stock arrangement and methanol separated through 0.45 separated layer channel; weaken the volume to provide a stock containing 100µg / ml Bilastine.

3.3.1

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Research Article

Design And Characterization Of Ethosomal Drug Delievry System Of Rilpivirine Hydrochloride

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ABSTRACT
Ethosomes are very effective since they enhance the penetration of drugs via skin to several times whose compound to the simple creams, elixirs and liposomal carriers. Hence, there is an absolute necessity to formulate ethosomes of the selected drugs, In the presant work ethosomal formulations of the selected drugs rilpivirine was prepared for obtaining the objective of improving skin permeability and bioavailability. The prepared formulations gave good percentage yield and size distribution. The maximum entrapment efficiency of Ethosomal vesicles as determined by ultracentrifugation was 75.3 % for Ethosomal formulation containing 20% ethanol (EF7) hence the best formulation of ethosomes of each respected drug were incorporated into carbopol based gel systems for controlled release. Results of entrapment efficiency also suggest that 2% phospholipids is optimalconcentration for entrapment efficiency and hence increased in concentration of phospholipids reduces the entrapment efficiency of vesicles. And the invitro studies proven that the formulations followed zero order release mechanisms. Compatability studies were performed for the materials selected and results are observed o be possitive. Stability studies indicated that the formulations were stable at low temperatures but can undergo rapid deformation at higher temperatures.

Keywords: Rilpivirine, Chitosan, Nanoparticles, HIV

INTRODUCTION
Transdermal drug delivery system (TDDS) showed promising result in comparison to oral drug delivery system as it eliminates gastrointestinal interferences and first pass metabolism of the drug but the main drawback of TDDS is it encounters the barrier properties of the Stratum Corneum i.e. only the lipophilic drugs having molecular weight < 500 Da can pass through it. To improve the permeation of drugs through the skin various mechanisms have been investigated, including use of chemical or physical enhancers, such as iontophoresis, sonophoresis, etc. Liposomes, niosomes, transferosomes and ethosomes also have been reported to enhance permeability of drug through the stratum corneum barrier. Permeation enhancers increase the permeability of the skin, so that the drugs can cross through the skin easily. Unlike classic liposomes, that are known mainly to deliver drugs to the outer layers of skin, ethosomes can enhance permeation through the stratum corneum barrier. Ethosomes permeate through the skin layers more rapidly and possess significantly higher transdermal flux in comparison to conventional liposomes.

Ethosomes are lipid vesicles containing phospholipids, alcohol (ethanol and isopropyl alcohol) in relatively high concentration and water. Ethosomes are soft vesicles made of phospholipids and ethanol (in higher quantity) and water

Ethosomes can entrap drug molecule with various physicochemical characteristics i.e. of hydrophilic, lipophilic, or amphiphilic. The size range of ethosomes may vary from tens of nanometers to microns (μ). In the presant work ethosomal formulations of the rilpivirine was prepared for obtaining the objective of improving skin permeability and bioavailability.

RILIPIVIRINE

EXPERIMENTAL METHODOLOGY:

Preparation of standard stock solution of Rilpivirine hydrochloride:
Standard stock solution of Rilpivirine hydrochloride (1 mg/mL) was prepared by transferring 10 mg of Rilpivirine hydrochloride into a 10 mL volumetric flask containing 4 mL of (8:2) methanol and water. It was then sonicated for 15 minutes and solution was diluted up to the volume by methanol and water. From these,

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STRATEGIES IN PHARMACEUTICAL MARKETING

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Keywords:

Pharmaceutical Products, Drug Promotion, Ethical standards

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ABSTRACT

The main objective of ethical criteria for medicinal drug promotion is to support and encourage the improvement of health care through the rational use of medicinal drugs.

WHO expanded its scope to people in all walks of life: governments; the pharmaceutical industry (manufacturers and distributors); the promotion industry (advertising agencies, market research organizations and the like); health personnel involved in the prescription, dispensing, supply and distribution of drugs; universities and other teaching institutions; professional associations; patients and consumer groups; and the professional and general media including publishers and editors of medical journals and related publication of the drug itself.According to WHO, Promotional materials for pharmaceutical products should be accurate, fair and objective and presented in such a way as to confirm not only to legal requirements but also to high ethical standards .

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Research Article

The Constantly Highly Expression of Limbal Stromal Cells Compared to the Bone Marrow Mesenchymal Stromal Cells, Adipose-Derived Mesenchymal Stromal Cells and Foreskin Fibroblasts

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Abstract

Limbal epithelial stem cells (LESC) have great potential in treating the blindness caused by corneal damage. LESC are maintained in stem cell niche called Palisade of Vogt. Limbal stromal (LS) cells are critical component of LESC niche and help in their self renewal. These cells resemble mesenchymal stromal/stem cells with multilineage differentiation potential. However little is known about their gene expression profile compared to MSC derived from various sources..

Keywords: limbal stromal cells; bone marrow mesenchymal stromal cells; adipose mesenchymal stem cells; gene expression profiling; microarray;limbal epithelial stem cells

Introduction

Human cornea on the front surface of eye is very critical for vision. The corneal transparency, continuous regeneration and functionality of corneal epithelium play an important role in refraction of light on to the retina. Corneal epithelium is regenerated by unique population of stem cells called limbal epithelial stem cells (LESC) that are located in the basal region of limbus. LESC differ from the corneal epithelium due to the lack of corneo-specific differentiation keratins (K3/K12) expression [1-3], connexin 43-mediated gap junction intercellular communication [4-6], p63 nuclear transcription factor [7,8], cell cycle duration [9], and label retaining property [10]. The limbalstroma provides a unique stem cell niche or microenvironment which is important for the modulation of stemness as it is heavily pigmented, highly innervated and vascularized. Clinically, destruction of LESC or the limbal stromal niche can lead to a pathological stage of LESC deficiency with severe loss of vision [11]. Chronic inflammation in the limbal deficient stroma is sufficient to cause detrimental damage to the conjunctivallimbalautograft transplanted to patients or experimental rabbits [12]. These findings suggest that the limbal stromal niche is critical in regulating the self-renewal and the fate of LESC. Although the mechanism remains elusive, modulation of epithelial proliferation, differentiation, proliferation and apoptosis by the limbalstroma has been reported to favor stemness [13]. Limbal stromal (LS) cells are very important component of limbal stromal niche that helps in self renewal of LESC. Recently, LS cells were shown to have multilineage differentiation potential [14-17]. In one of the studies, an ABCG2-expressing FACS sorted side population cells from limbalstroma were able to differentiate into chondrocytes and neurons following differentiation induction [14]. In other studies, multipotent cells were also found in corneal stroma [15] and limbalstroma [16-17]. Earlier, we have reported that an ex vivo expanded LS cells possess multipotent differentiation potential towards adipocytes, osteocytes and chondrocytes [18]. Other stromal cells such as mesenchymal stem/stromal cells (MSC) can also be isolated and expanded in vitro for tissue regeneration applications [19-22]. MSC were first identified from bone marrow aspirates [23,24] and subsequently in Wharton's jelly of human umbilical cords [25], adipose tissue [26], dental tissues [27,28] and skin [29]. Most of the stromal cells derived from various sources expressed the markers of MSCs such as CD44, CD73, CD90, CD105, STRO1 and do not express markers of hematopoietic lineage such as CD14, CD34, CD45 and HLA-DR [30].

In order to find out the specific molecular signature, cellular function and potential biomarkers of the LS cells, we compared the global gene expression profile including long non-coding RNA (lincRNA) of the expanded LS cells with the MSCs derived from bone marrow, adipose tissue and foreskin fibroblasts. In addition, we also evaluated the effects of two different culture conditions on the LS cells gene expression.

Methods

Establishment of limbal stromal cell culture

Corneoscleral rims from three cadaveric donors were obtained from post cornea graft transplantation with informed consent from the donor's relative. The rims were washed with phosphate buffer saline (PBS; Invitrogen Corporation, Carlsbad, CA) and then trimmed to remove the sclera. The limbal tissues were incubated at 37°C for 2 h with dispase (BD Biosciences, Mississauga, Canada) at a concentration of 5 mg/mL. The

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METHOD DEVELOPMENT AND VALIDATIONFOR ESTIMATION OF NATEGLINIDE IN TABLET DOSAGE FORM BY REVERSE PHASE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY

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ABSTRACT

An effortless, hasty, unambiguous, robust, exactas well as precise isocratic reverse phase high performance liquid chromatographic technique has been urbanizedin addition to validated for the assessment of Nateglinide in tablet dosage form. The chromatographic severance was accomplished on Phenomenex kinetex C_{18}(250mm×4.6mm i.d, 5µm) column by means of a mobile phase mixture containing methanol: buffer of pH 6.8: ACN in the proportion of 47:23:30 respectively at a flow rate of 1ml/min with injection volume of 20µl and recognition wavelength of 216 nm at ambient temperature. The retention time was established to be 4.823mins by way of a run time of 7mins. The linearity was obtained in the range of 20 to 300µg/ml with correlation coefficient of 0.9996. The mean entitlement recuperation at every level was established to be within the limits of 98% and 105%.The optimized method was used to assay the pharmaceutical dosage form and assay value was found to be 96.94%. The anticipated technique was validated as per ICH guidelines as well as applied for the investigation of Nateglinide in tablet dosage form.

Keywords: Nateglinide, Assay, RP-HPLC, Method development, Validation

INTRODUCTION:

Nateglinide is an amino acid derivative that induces an early insulin response to meals decreasing postprandial blood glucose levels. It is belonging to the meglitinide

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REVERSE PHASE HIGH PERFORMANCE LIQUID CHROMATOGRAPHIC METHOD DEVELOPMENT AND VALIDATION FOR ESTIMATION OF APREMILAST IN PHARMACEUTICAL FORMULATION

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ABSTRACT

In this current investigation effort, an effort was made to build up an uncomplicated, speedy, truthful as well as robust HPLC technique for the assessment of Apremilast in its tablet dosage form. Reverse phase high performance liquid chromatographic analysis was carried out on isocratic system. The column used for the investigation was Phenomenex C18 (250 mm× 4.6mm, 5µm) with ambient temperature. The optimized mobile phase was Methanol: Acetonitrile in the ratio of (20:80 %V/V). The detection was carried out at a wavelength of 230nm using a flow rate of 1ml/min. The urbanized technique was validated for validation constraints like linearity, specificity, accuracy, precision as per ICH strategy. The %RSD for all constraints was well within the limits, which indicates the validity of the technique in addition to the assay results obtained are in reasonable conformity with the label claim of the marketed formulation. Thus, the conventional scheme can be anticipated for repetitive investigation of this drug in laboratories and for superiority purposes.

Keywords: Apremilast, Acetonitrile, HPLC, Linearity

INTRODUCTION:

Apremilast is a Phosphodiesterase 4 (PDE4) inhibitors chemically named as N-[2-[(1S)-1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-1,3-dioxoisoindol-4-yl]acetamide. It is used in the treatment of certain types of

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Research Article Open Access

Design and Characterization of Mouth Dissolving Tablets of Zolmitriptan Using Novel Super Disintegrants

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ABSTRACT

The present study was carried out on Zolmitriptan Mouth dissolving tablets were prepared by direct compression method and different concentration super disintegrants like croscarmellose sodium, polyplasdone XL and Explotab were used in mouth dissolving tablets. A total of 9 formulations were prepared and evaluated for various pre and post compression parameters like angle of repose, bulk density, tapped density, carr's index, hausner's ratio, weight variation, hardness, friability, thickness, wetting time, water absorption ratio, drug content, *in vitro* disintegration time, *in vitro* drug release. The *in vitro* disintegration time of the optimized formulation (F4) of Zolmitriptan was found to be 7 sec. Release rate of drug was 97.54% within 10 minutes. FTIR studies showed good compatibility between drug and excipients.

Keywords: Zolmitriptan, croscarmellose sodium, polyplasdone XL, Explotab

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CONTENTS

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1. Introduction

The oral route of administration is considered as the most widely accepted route because of its convenience of self administration, compactness and easy manufacturing. But the most evident drawback of the commonly used oral dosage forms like tablets and capsules is difficulty in swallowing, leading to patients incompliance particularly in case of paediatric and geriatric patients, but it also applies to people who are ill in bed and to those active working patients who are busy or travelling, especially those who have no access to water. For these reasons, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Mouth disintegrating

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Formulation Development and *in vitro* Evaluation of Escitalopram Immediate Release Tablets

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Abstract
The aim of this study is to formulate and significantly improve the bioavailability and reduce the side effects of immediate release tablets Escitalopram. The precompression blends of Escitalopram were characterized with respect to angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio. The precompression blend of all the batches indicates good to fair flow ability and compressibility. Immediate release tablets were prepared with various polymers like PEG 6000, Croscarmellose sodium and Sodium-starch glycolate at different concentration ratios and were compressed into tablets. The formulated tablets were evaluated for various quality control parameters. The tablets were passed all tests. Among all the formulations F7 formulation containing, drug and Croscarmellose sodium showed good result that is 98.12 % in 45 min. Hence from the dissolution data it was evident that F7 formulation is the better formulation. By conducting further studies like *invitro* studies.

Keywords
Escitalopram, PEG 6000, Croscarmellose sodium and Sodium-starch glycolate, Immediate release.

*****

INTRODUCTION
Oral route is the most convenient and extensively used for drug administration. Oral administration is the most popular route for systemic effects due to its ease of ingestion, pain, avoidance, versatility and most importantly, patient compliance suitable for industrial production, improved stability and bioavailability. The concept of immediate release tablets emerged from the desire to provide patient with more conventional means of taking their medication when emergency treatment is required. Recently, immediate release tablets have gained prominence of being new drug delivery systems. The oral route of administration has so far received the maximum attention with respect to research on physiological and drug constraints as well as design and testing of product, Drug delivery systems (DDS) are a strategic tool for expanding markets/ indications, extending product life cycles and generating opportunities. Most immediate release tablets are intended to disintegrate in the stomach, where the pH is acidic. Several orally disintegrating tablet (ODT) technologies based on direct compression. In pharmaceutical formulation includes any formulation in which the rate of release of drug from the formulation is at least 70% (preferably 80%) of active ingredient within 4 hours, such as within 3 hours, preferably 2 hours, more

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DEVELOPMENT AND VALIDATION OF A RP-HPLC METHOD FOR ESTIMATION OF LAMOTRIGINE IN A TABLET DOSAGE FORM

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ABSTRACT

A simple, sensitive, and precise high performance liquid chromatographic method for the analysis of Lamotrigine has been developed and validated for the determination of compound in commercial pharmaceutical products. The compounds were well separated on BDS Hypersil C18 reverse phase column by the use of a mobile phase of mixed phosphate buffer and acetonitrile in a ratio of 40:60 v/v, at a flow rate of 1.0 ml/min with detection wavelength at 248nm. The method was validated in terms of linearity, precision, accuracy, and specificity, robustness and solution stability. The method does require only 10 minutes as runtime for analysis which prove the adoptability of the method for the routine quality control analysis of the drug.

Key words: Lamotrigine , RP-HPLC.

INTRODUCTION

Lamotrigine is chemically 6-(2,3- dichlorophenyl)-1,2,4-triazine-3,5-diamine1. Lamotrigine is an anticonvulsant drug used in the treatment of epilepsy and bipolar disorder2. For epilepsy it is used to treat partial seizures, primary and secondary tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome chemically unrelated to other anticonvulsants (due to Lamotrigine being a Phenyltriazine). Lamotrigine has relatively few side-effects and does not require blood monitoring in monotherapy.. Lamotrigine also acts as a mood stabilizer. Antiepileptic drug (AED) of the phenyltriazine Class.

MATERIAL AND METHODS

Wavelength selection: Since the detector selected was UV detector, UV scans Lamotrigine to determine the detection wavelength.

Procedure: Weigh accurately 100 mg of standard Lamotrigine and dissolve it in 100 ml of diluent to get a concentration of 1mg/ml. The prepared solutions was scanned in UV region of 200-400nm. The best possible wavelength were chosen as 248nm Lamotrigine by using UV spectrophotometer.

Preparation of analytical solutions

Preparation of mixed phosphate buffer solution: A weighed quantity of 1.1818 g of potassium dihydrogen-o- phosphate (KH_2PO_4) and 0.218 g of dipotassium hydrogen-ortho-phosphate (K_2HPO_4) taken in a 500ml volumetric flask. This is added with 500ml of HPLC water and mixed in an ultra sonicator. The solution pH is adjusted to pH - 3 with orthophosphoric acid.

Preparation of mobile phase: Mobile phase was prepared by mixing 400ml of mixed buffer solution with 600ml of acetonitrile (40:60 v/v) ratio.

Preparation of a standard Lamotrigine solution:

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A New Rp-Hplc Method Develop A New Rp-Hplc Method Development And Validation For Simultaneous Estimation Of Pyridoxine Hydrochloride And Doxylamine Succinate In Bulk Drug And Pharmaceutical Tablet Dosage Form.

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Abstract: *The Present work was to develop a simple, fast, accurate, precise, reproducible, reverse phase high performance liquid chromatographic method for simultaneous estimation of pyridoxine hydrochloride and doxylamine succinate in pharmaceutical tablet dosage form marketed as doxinate. Chromatographic separation was done using Inertsil ODS RP C18 column having dimension of 4.6×250mm having particle size of 5µm, with mobile phase consisting of phosphate buffer pH 3 ±0.02 pH adjusted with ortho phosphoric acid and acetonitril (50:50 %v/v), flow rate was adjusted to 1.0 ml/min and detection wavelength at 263nm. The retention times of pyridoxine hydrochloride and doxylamine succinate was found to be 2.35 and 4.80min. The Proposed method has been validated for accuracy, precision, linearity, range and robustness were within the acceptance limit according to ICH guidelines. Linearity for pyridoxine hydrochloride and doxylamine succinate was found in range of 25µg-150µg and correlation coefficient was found to be 0.999 and 0.999, %RSD for method precision was found to be 0.76, 0.82 and for system precision was 0.80 and 0.71 respectively, % mean recovery for pyridoxine hydrochloride and doxylamine succinate was found to be 99.18% to 99.48%. The method was found to be robust even by change in the mobile phase ±5% and in less flow condition. The developed method can be successfully employed for the routine analysis of pyridoxine hydrochloride and doxylamine succinate in API and Pharmaceutical dosage forms.*

Keywords: *Pyridoxine hydrochloride and Doxylamine succinate, RP-HPLC, Method development, Method validation.*

Date of Submission: 10-07-2017 Date of acceptance: 16-09-2017

I. Introduction

Pyridoxine hydrochloride is 3, 4-Pyridinedimethanol 5-hydroxy-6-methyl- hydrochloride and its chemical formula $C_8H_{11}NO_3 \cdot HCl$ Molecular weight : 205.64 Melting point : 214-215^{0}C.It is crystalline in nature and soluble in water and having pKa 5.0 and 9.0 and it's a vitamin nutritional supplement .Doxylamine Succinate is chemically : 1-(Isopropylamino)-3-(p-(2-methoxyethyl)phenoxy)- Ethananamine Chemical formula $C_{17}H_{22}N_2O \cdot C_4H_6O_4$Molecular weight : 388.4 pKa : 5.8 and 9.3.It is white or creamy powder and soluble in water and alcohol H1 Histamine receptor antagonist. Antihistaminic; sedative; hypnotic.There are several methods have been reported but only two methods were reported in Drug formulations .The aim of this present study is to develop a single method for the Pyridoxine HCl and Doxylamine succinate in a respective dosage form.

II. Experimental

Materials and Methods:

Selection of wavelength 10mg of doxylamine succinate and pyridoxine hydrochloride was dissolved in mobile phase. The solution was scanned from 200 -400 nm the spectrum was obtained. The overlay spectrum was used for selection of wavelength for doxylamine succinate and pyridoxine hydrochloride. The isobestic point was taken as detection wavelength and shown in Fig No 01.

Preparation of Potassium di hydrogen ortho phosphate (0.01N)

An accurately weighed quantity of 1.3609g of potassium di hydrogen ortho phosphate was dissolved in 1000ml of hplc water and sonicated for 10min for proper dissolution and adjusted to the pH 3 with Ortho phosporic acid. The resulting solution was filtered.

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Rp-Hplc Method Development And Validation Determination Of Simultaneous Estimation Of Olmesartan And Hydrochlorothiazide In A Combined Tablet Dosage Form

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Abstract: *A simple , precise and accurate RP-HPLC method was developed and validated for simultaneous estimation of Olmesartan and hydrochlorothiazide in tablet dosage form. Separation was achieved on a reversed-phase Symmetry C18 (4.6 x 150mm, 5µm, Make: XTerra) or equivalent using a mobile phase consisting of methanol / acetonitrile (pH 2.5, 65:35, v/v) at a flow rate of 0.8 ml per min and UV detection at 258 nm . The method was validated as per ICH guidelines for linearity , accuracy, precision and robustness. The developed method shows good linearity over the concentration range of 20-80 µg/mL (r^2=0.999) for both olmesartan and hydrochlorothiazide . The average percentage recoveries were in the range of 100.0-100.04% and 100.0-100.06% for olmesartan and hydrochlorothiazide, respectively . The limits of detection (LODs) were 0.04 µg/mL and 0.13 µg/mL for olmesartan and hydrochlorothiazide, and limits of quantification (LOQs) were 0.01 µg/mL and 0.05 µg/mL, respectively. Therefore, the proposed method can be applied for routine analysis of the bulk drugs as well as combined pharmaceutical dosage forms of olmesartan and hydrochlorothiazide.*

Keywords: *Olmesartan , Hydrochlorothiazide , Limits of quantification , limits of detection .*

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I. Introduction

Olmesartan is an antihypertensive agent, which belongs to the class of medications called angiotensin II receptor blockers . It is indicated for the treatment of high blood pressure and is marketed under the name Olmetec. Chemical formula is $C_{29}H_{30}N_6O_6$ and its Molecular mass 558.585 g/mol. Solubility is practically insoluble in water and sparingly soluble in methanol belongs to category Angiotensin II Type 1 Receptor Blockers Olmesartan is an ARB that selectively inhibits the binding of angiotensin II to AT1, which is found in many tissues such as vascular smooth muscle and the adrenal glands. Olmesartan is selective for AT1 and has a 12,500 times greater affinity for AT1 than the AT2 receptor. It reduces the reabsorption of electrolytes from the renal tubules. This results in increased excretion of water and electrolytes, including sodium, potassium, chloride, and magnesium. It has been used in the treatment of several disorders including edema, hypertension, diabetes insipidus, and hypoparathyroidism. IUPAC Name: 6-chloro-1,1-dioxo-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulfonamide Chemical formula: $C_7H_8ClN_3O_4S_2$ Solubility Slightly or very slightly soluble in water; sparingly soluble in alcohol; soluble in acetone; freely soluble in dimethylformamide; n-butylamine; and solutions of alkali hydroxides; insoluble in ether, chloroform, and dilute mineral acids.Category Antihypertensive Agents, Diuretics, Sodium Chloride Symporter Inhibitors Mechanism of action Hydrochlorothiazide, a thiazide diuretic, inhibits water reabsorption in the nephron by inhibiting the sodium-chloride symporter (SLC12A3) in the distal convoluted tubule, which is responsible for 5% of total sodium reabsorption. Normally, the sodium-chloride symporter transports sodium and chloride from the lumen into the epithelial cell lining the distal convoluted tubule. The energy for this is provided by a sodium gradient established by sodium-potassium ATPases on the basolateral membrane. Once sodium has entered the cell, it is transported out into the basolateral interstitium via the sodium-potassium ATPase, causing an increase in the osmolarity of the interstitium, thereby establishing an osmotic gradient for water reabsorption. By blocking the sodium-chloride symporter, hydrochlorothiazide effectively reduces the osmotic gradient and water reabsorption throughout the nephron.

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Research Article

METHOD DEVELOPMENT AND VALIDATION OF CAPTOPRIL BY USING RP-HPLC

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ABSTRACT

An isocratic reversed phase high-performance liquid chromatographic (RP-HPLC) method has been developed for the determination of captopril in API, dosage formulations and human serum. Chromatographic separation was achieved on SYMMETRY C18 150X4.6mm,3.7µm and columns using mobile phase, methanol: water (70:30 v/v) adjusted to pH 3.0 via phosphoric acid 85% having flow rate of 1.0 mL min -1 at ambient temperature with detector set at 272 nm. Calibration curves were linear over range of 5-25 µg mL -1 with a correlation coefficient ± 0.999. LOD and LOQ were in the ranges of 0.4-2.3 µg mL -1. Intra and inter-run precision and accuracy results were 98.0 to 102%.

KEYWORDS: *Captopril, Diuretics, RP-HPLC.*

INTRODUCTION

Captopril is a (2S)-1-[(2S)-2-methyl-3-sulfanylpropanoyl] pyrrolidine-2-carboxylic acid potent, competitive inhibitor of angiotensin-converting enzyme (ACE), the enzyme responsible for the conversion of angiotensin I (ATI) to angiotensin II (ATII). ATIIregulates blood pressure and is a key component of the renin-angiotensin-aldosterone system (RAAS) [1]. Captopril may be used in the treatment of hypertension Soluble in water (160 mg/ml) at 25 °C, sesame and corn oils (<1 mg/ml)at 25 °C, methanol (>100 mg/ml), ethanol (>100 mg/ml), isopropanol (>100 mg/ml), chloroform (>100 mg/ml), and dichloromethane (>100 mg/ml) [2-4]. ACE inhibitors bind to and inhibit the activity of both domains, but have much greater affinity for and inhibitory activity against the C-domain. Captopril, one of the few ACE inhibitors that is not a prodrug, competes with ATI for binding to ACE and inhibits and enzymatic proteolysis of ATI to ATII [5-8].

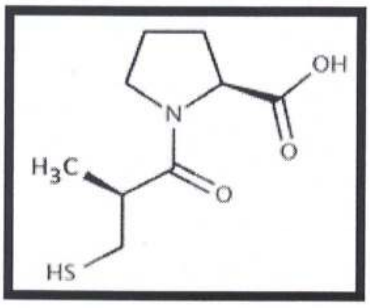

Fig. 1: Structure of Captopril

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MATERIALS AND METHODS

HPLC-auto sampler–UV detector separation module2695, PDA detector Empower-software version-2 Waters U.V double beam spectrometer UV 3000+U.V win software Lab India Digital weighing balance(sensitivity 5mg) ER 200A Ascoset pH meter AD 102U-ADWA Sonicator SE60US-Enertech.

Selection of wavelength:

10 mg of captopril was dissolved in mobile phase. The solution was scanned from 200-400 nm the spectrum was obtained .The overlay spectrum was used for selection of wavelength for captopril. The isobestic point was taken as detection wavelength.

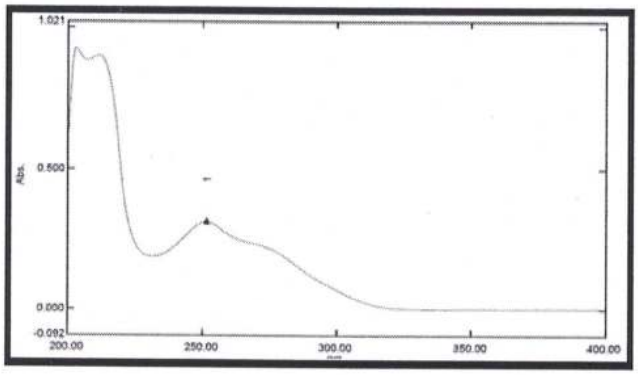

Fig. 2: Spectrum showing wavelength Captopril

Selection of diluent:

Selection of diluent is based on the solubility of the analyte Diluent selected: methanol : water(70: 30v/v) .

Selection of test concentration and injection volume:

Captopril label claimed 500mg and the test concentration selected is 10 ppm.

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DEVELOPMENT AND VALIDATION OF STABILITY INDICATING RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF ARTEROLANE MALEATE AND PIPIERAQUINE PHOSPHATE IN BULK AND TABLET DOSAGE FORM

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ARTICLE INFO

Key Words

Arterolane maleate , Piperaquine phosphate, Limits of quantification , limits of detection .

ABSTRACT

The drug of Arterolane maleate and Piperaquine phosphate were injected into the HPLC system and run in different solvent systems. From the overlaid spectra, 228 nm was selected as analytical wavelength for multi component analysis using HPLC method. The marketed solution was analyzed for the estimation of drug by proposed method. The system suitability parameters were evaluated from standard Chromatograms obtained, by calculating the % RSD of retention times, tailing factor, theoretical plates and peak areas from five replicate injections.Assay was performed in triplicate for various concentrations of Arterolane maleate and Piperaquine phosphate equivalent to 50, 100 and 150 % of the levels was injected into the HPLC system per the test procedure. The average % recovery of both Arterolane maleate and Piperaquine phosphate was calculated and the results were summarized. The accuracy studies were shown as % recovery for Arterolane maleate and Piperaquine phosphate at 50%, 100% and 150% the limits of % recovered Shown be in the range of 98-102% the results obtained for Arterolane maleate and Piperaquine phosphate were found to be within the limits. Hence the method was found to be accurate. In the System precision study, %RSD was found to be less than 2%. For Arterolane maleate and Piperaquine phosphate within limits .which indicates that the system has good reproducibility. Retention times were found to be 3.171min and 2.338min. for Arterolane maleate and Piperaquine phosphate respectively. Arterolane maleate shows linearity in the range of 0-180ppm Limit of detection (LOD) and Limit of quantification (LOQ) were estimated from the signal-to-noise ratio. The LOD values of Arterolane maleate and Piperaquine phosphate were found to be 0.087634, 0.722994 respectively. hence a new rp-HPLC method was developed and validated.

INTRODUCTION:

Arterolane maleate Chemicaly cis-Adamantane-2-spiro-3'-8'-[[[(2'- amino-2'-methylpropyl) amino] carbonyl] methyl]-1', 2', 4- trioxaspiro [4.5] decane hydrogen maleate and its molecular formula $C_{26}H_{40}N_2O_8$ belongs to category anti malarial and soluble in water and methanol and it is acting rapidly on blood schizonticide against all blood stages of P. falciparum without effect on liver stages and acts by inhibition of PfATP6, a sarcoplasmic endoplasmic reticulum calcium ATPase encoded by P. Falciparum. Piperaquine Phosphate

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Advance simultaneous determination of paracetamol, thiocolchicoside and aceclofenac in tablets by reverse phase high performance liquid chromatography

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ABSTRACT

Rapid and accurate high performance liquid chromatography method is described for simultaneous determination of paracetamol, thiocolchicoside and aceclofenac from the combination dosage form. The separation of three drugs was achieved on an Inertsil ODS (150 x 4.6 mm i.d.) with 5 µ particle size. The mobile phase consisted of buffer of pH 6.5 and acetonitrile in gradient elution system. The detection was carried out at wavelength 300 nm. The Inertsil ODS column showed the most favorable chromatographic parameters for analysis. The method was validated for system suitability, linearity, accuracy, precision, robustness and stability of sample solution. The linear ranges for paracetamol, thiocolchicoside and aceclofenac were 1250-3750 µg/ ml, 20-60 µg/ ml and 250-750 µg/ ml respectively. The method has been successfully used to assay of combined dosage form i.e. tablets containing 500 mg paracetamol, 8 mg of thiocolchicoside and 100 mg aceclofenac with good recoveries.

Key words: Paracetamol, Thiocolchicoside, Aceclofenac, HPLC.

INTRODUCTION

In this communication a new RP-HPLC method is developed for assay of paracetamol, thiocolchicoside and aceclofenac in combined dosage form.

Paracetamol is chemically N-(4-Hydroxyphenyl) acetamide. It is non steroidal anti-inflammatory, analgesic and anti-pyretic drug.

Thiocolchicoside is a semi synthetic derivative of naturally occurring compound of colchicoside from the seeds of various species of colchicum antumnale (autumn crocus, meadow saffron, Gloriosa upuba), chemically, N-[7(S)-3-(β-D-glucopyronosyloxy)- 1,2-dimethoxy – 10-(Methylsulfanyl)-9-oxo-5,6,7,9-tetrahydrobenzo-)[a]heptalen-7-yl]-(S)-acetamide. It is centrally acting muscles relaxant and it also show analgesic activity. It is used in treatment of muscular pain and gout.

Aceclofenac is chemically {[[2-[(2, 6-Dichlorophenyl) amino] phenyl] acetyl] oxy} Acetic acid. It is the non steroidal anti inflammatory, analgesic and anti-inflammatory drug. It is used as anti-inflammatory agent.

Nikhade R.D.[1] and others, Hapse S.A.[2] and others reported UV spectrophotometric methods and Dhaneshwar S.R.[3] and others reported HPLC method for assay of such combined dosage form. In this communication a new

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RESEARCH ARTICLE

Novel Spectrophotometric Method Development for the Estimation of Boceprevir in Bulk and in Pharmaceutical Formulations

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ABSTRACT:

A New, Simple, Rapid and economical extractive spectrophotometric methods were developed for the determination of Boceprevir (anti-retroviral drug). Boceprevir is a direct acting protease inhibitor for the treatment of hepatitis C. It also has two isomers in which the S isomer is more active than the R-isomer. The methods were based on the formation of color chromogens with Bromo cresol green, Bromo thymol blue, Bromo phenol blue and Methyl orange indicator. The extractive spectrophotometry was carried out with phthalate buffer and chloroform. The absorbances of the chromogens were measured at 410 nm and 415 nm against the corresponding reagent blank. The proposed methods have been successfully applied to the bulk drug. The method has been statistically evaluated and was found to be precise and accurate.

KEYWORDS: Anti-hepatitis, Anti-HIV, Chromogen, Boceprevir, Extractive spectrophotometry, Victerelis®.

INTRODUCTION:

Boceprevir (Victrelis™) is indicated for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients (18 years and older) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy [1-3]. Boceprevir has the following chemical name:(1R,5S)-N-[3-Amino-1- (cyclo butyl methyl)- 2,3dioxo propyl] -3-[2(S)-[[[(1,1-dimethyl ethyl) amino] carbonyl] amino]-3,3-dimethyl-1-oxobutyl] -6,6-dimethyl-3azabicyclo [3.1.0] hexan-2(S)-carboxamide[4-6]. The molecular formula is $C_{27}H_{45}N_5O_5$ and its molecular weight is 519.7. Boceprevir is manufactured as an approximately equal mixture of two diastereomers.

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Boceprevir is a white to off-white amorphous powder[7-9]. It is freely soluble in methanol, ethanol and isopropanol and slightly soluble in water. Victrelis ® 200 mg capsules are available as hard gelatin capsules for oral administration. Each capsule contains 200 mg of boceprevir and the following inactive ingredients: sodium lauryl sulfate, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, pre-gelatinized starch, and magnesium stearate. The red capsule cap consists of gelatin, titanium dioxide, D and C Yellow #10, FD and C Blue #1, and FD and C Red #40. The yellow capsule body contains gelatin, titanium dioxide, D and C Yellow #10, FD and C Red #40, and FD and C Yellow #6. The capsule is printed with red and yellow ink. The red ink contains shellac and red iron oxide, while the yellow ink consists of shellac, titanium dioxide, povidone and D and C Yellow #10 Aluminum Lake. Boceprevir is an inhibitor of the HCV NS3/4A protease that is necessary for the proteolytic cleavage of the HCV encoded polyprotein into mature forms of the NS4A, NS4B, NS5A and NS5B proteins. Boceprevir

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Formulation design and development of Orodispersible tablets of Levetiracetam

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ABSTRACT

Levetiracetam is a medication used to treat epilepsy. It is used for partial onset, myoclonic or tonic clonic Seizures. It works by decreasing abnormal excitement in the brain. The Current research work is aimed at developing a formulate and evaluate of an orodispersible tablet dosage form of Levetiracetam. The target of these new oral dissolving/disintegrating dosage forms have generally been pediatric, geriatric, bedridden and developmentally disabled patients and also patients with persistent nausea, who are in traveling, or who have little or no access to water are also good candidates for ODTs Direct Compression method was employed for blending of drug with polymers in the given ratio as a Nine formulations. The prepared powder blends were then compressed into tablets using the necessary Superdisintegrants (CP, SSG and CCS) and Excipients. The tablets were evaluated for Weight variation, thickness, hardness, friability, Drug Content and Disintegrating Time (Sec) were subjected to a 20 minutes *in vitro* drug release studies (USP dissolution rate test apparatus II, 50 rpm, 37^{0}C ±0.5^{0}C) using phosphate buffer, pH 6.8 as a dissolution medium (900ml). The amount of Levetiracetam released from the tablet formulations at different time intervals was estimated using a UV spectroscopy method. The formulations that showed a considerable retardation of the drug release are considered promising. Among the nine formulations, F5 formulation containing Drug to Sodium Starch Glycollate (SSG) and Cross Povidone (CP) is optimized based on its ability to till 10 minutes of *in-vitro* dissolution time, and its Cumulative % drug release of the 99.82±0.37% of dissolution study.

KEY WORDS: Levetiracetam, Orodispersible Tablets, Sodium Starch Glycollate, Cross Povidone.

1. INTRODUCTION:

The oral route of administration is the most preferred route due to its many advantages like ease of administration, accurate dosage, self-medication, pain avoidance, versatility and patient compliance. Tablets and capsules are the most popular dosage forms.[1-2]

Improved patient compliance has achieved enormous demand. Consequently demand for their technologies is also increasing many folds. To develop a chemical entity, a lot of money, hard work and time are required. So focus is rather being laid on the development of new drug delivery systems for already existing drugs, with enhanced efficacy and bioavailability, thus reducing the dose and dosing frequency to minimize the side effects.[3-4]

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2. MATERIALS AND METHODS:

2.1. Materials:

Levetiracetam was a gift sample from Aurobindo Pharma Ltd, Hyderabad, Cros povidone, Sodium Starch Glycolate, Croscarmellose Sodium was used and supplied by Yarrow chem. Products, Mumbai, Mannitol, Talc, Magnesium Stearate, and MCC was bought from Signet Chem.,Mumbai.

2.2. Methodology:

2.2.1. Preformulation Studies:

Standardization of Levetiracetam by UV-Visible spectrophotometry: Standard calibration of Levetiracetam in 6.8 Phosphate buffer: 100mg of Levetiracetam was accurately weighed and dissolved in 100ml of 6.8 phosphate buffer to obtain a concentration of 1000µg/ml. From the above 10ml was withdrawn and diluted to 100ml to obtain a concentration of 100µg/ml. From this stock solution aliquots of 0.5ml, 1ml, 1.5ml, 2ml and 2.5ml were diluted in 10ml volumetric flask with phosphate buffer to give concentrations in range of 5µg/ml to 25µg/ml respectively, absorbance was measured at 213 nm.

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Research Article

FORMULATION DESIGN, DEVELOPMENT AND EVALUATION OF GRDDS OF ETODOLAC BY USING NATURAL POLYMERS

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ABSTRACT

Etodolac is used to relieve pain from various conditions. It also reduces pain, swelling, and joint stiffness from arthritis. This medication is known as a non steroidal anti inflammatory drug (NSAID). Hence the current study was to intend a floating delivery system of Etodolac by using natural polymers by Direct Compression method. All the composition was evaluated for hardness, friability, disintegration time and dissolution. The tablets which are disintegrated were discarded. The tablets which were able to float were further evaluated. In this gastro retentive dosage form using Xanthan gum, Guar gum and Pectin was prepared to develop a prolonged release tablets, that could retain in the stomach for longer periods of time delivering drug to the site of action that is in the stomach. In-vitro dissolution studies of the formulations, it was concluded that the formulation F-3 which containing 150 mg of Xanthan gum, 85mg of $NaHCO_3$, 9 mg of Mg. stearate, 9mg of Talc and Quantity sufficient of micro crystalline cellulose is the optimized formulation. Among all the formulation F-3 is prepared with Xanthan gum in Drug: Polymer ratio of 1:0.5. F-3 exhibited 98.67±0.25% of drug release within 12 hours. As the result of this study it may fulfilled that the floating tablets using Xanthan gum is a natural polymer increases the GRT of the dissolution fluid in the stomach to deliver the drug in a persistent manner. The concept of formulating floating tablets of model drug offers a suitable and practical approach in serving preferred objectives of gastro retentive floating tablets.

Key words: *Etodolac, Floating Tablets, Natural Polymers.*

INTRODUCTION

Gastro retentive drug delivery is an approach to prolong gastric residence time, thereby targeting site-specific drug release in the upper gastrointestinal tract (GIT) for local or systemic effects. Gastro retentive dosage forms can remain in the gastric region for long periods and hence significantly prolong the gastric retention time (GRT) of drugs [1-3].

MATERIALS AND METHODS

Materials:

Etodolac obtained from Lupin Laboratories Ltd, Mumbai, Xanthan gum, Guar gum, Pectin was acquire from Signet Chem., Mumbai. Sodium Bicarbonate, Magnesium Stearate, Talc and MCC were used and provided by Yarrow chem. Products, Mumbai.

Methodology:

Standard curve for Etodolac pure drug:

Preparation of stock solution:

Standard stock solution of Etodolac was prepared by dissolving 10mg of Etodolac in 10ml of methanol which gives 1000µg/ml solution. Preparation of working solution From the above stock solution 1ml was transferred into 10ml volumetric flask and The volume made was up to mark with 0.1N Hcl to give 100µg/ml. from this 2ml was pippeted out into 10ml volumetric flask and made up to mark with 0.1N Hcl to give 20µg/ml Etodolac was scanned with UV is spectrophotometer in the range 200-400nm against methanol as blank and the wavelength corresponding to maximum absorbance was noted which is its max i.e.at 226nm (fig.1).

Preparation of calibration curve:

0.2 ml-1ml of 100µg/ml solution were diluted and the volume was made up to 10ml using methanol to produce 2-10µg/ml solutions respectively. The absorbance calibration curves were plotted by taking concentration on x-axis and absorbance on y-axis, which shows a straight line (fig.1). This straight line obeyed linearity in the concentration range of 2-10µg/ml. The correlation was found to be 0.999.

Fourier Transform infra-red (FTIR) spectroscopy:

FT-IR is a constructive analytical technique utilizes to check the chemical interaction between the drug and excipients used in the formulation.1-2 mg of solid fine powder of Etodolac and 200-300 mg of dry powder of KBr (IR grade) were taken in a mortar and mixed well with the help of a spatula. Spectrum measurement was carried out using KBr disk method in the wavelength region of 4000-400cm^{-1} by FTIR spectrophotometer. The IR spectrum of the physical mixture was compared with that of the pure drug to check any possible drug-excipient interaction [4,5].

Powder Flow properties: [6-9]

Bulk density (D_b):

It is the ratio of powder to bulk volume. The bulk density depends on particle size distribution, shape and cohesiveness of particles. Accurately weighed quantity of powder was carefully poured into graduated measuring cylinder through large funnel and volume was measured which is called initial bulk volume. Bulk density is expressed in gm/cc and is given by,

$$D_b = M / V_o$$

Where, D_b = Bulk density (gm/cc); M is the mass of powder (g)

V_o is the bulk volume of powder (cc)

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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF FELODIPINE IN BULK AND TABLET DOSAGE FORM BY USING RP-HPLC TECHNIQUES

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Abstract:

This paper describes the analytical method suitable for validation of Felodipine by reversed Phase High Performance Liquid Chromatography (RP-HPLC) method. The method utilized RP-HPLC (Water 2695 with PDA detector) model and a column ODS C18 (4.6 x 150mm, 5µm). The mobile phases were comprised with Acetonitrile and Water (80:20 V/V) at a flow rate of 1.0 ml/min. UV detection at 305 nm MTS were eluted with retention times of 3.155min. The method was continued and validated accordance with ICH guidelines. Validation revealed the method is rapid, specific, accurate, precise, reliable, and reproducible. Calibration curve plots were linear over the concentration ranges 15-75 µg/mL (R^2 = 0.9998). Limit of detection (LOD) was 0.19µg/ml and limit of quantification (LOQ) was 0.6µg/mL. The method showed good recoveries (98.9 - 100.4%). Statistical analysis was proves the method is suitable for the analysis of Felodipine as a bulk, in tablet dosage form without any interference from the excipients. It was also proved study for degradation kinetics. It may be extended for its estimation in plasma and other biological fluids.

Keywords: *Felodipine, RP-HPLC, Method Development and Validation.*

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Design and characterization of delavirdine ethosomal drug delivery to enhance the bioavailability via topical drug delivery

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Abstract---The increasing demand for efficient administration and delivery of pharmaceutical dosage forms possessing the attributes namely minimum side effects, improved patient compliance has resulted in the formulation of novel drug delivery system. Ethosomes are very effective since they enhance the penetration of drugs via skin to several times whose compound to the simple creams, elixirs and liposomal carriers. Hence, there is an absolute necessity to formulate ethosomes of the selected drugs, In the presant work ethosomal formulations of, delaviridine, was prepared for obtaining the objective of improving skin permeability and bioavailability. The prepared formulations gave good percentage yield and size distribution. The best formulation of ethosomes of each respected drug were incorporated into carbopol based gel systems for controlled release and the invitro studies proven that the formulations followed zero order release mechanisms. Compatability studies were performed for the materials selected and results are observed o be possitive. Stability studies indicated that the formulations were stable at low temperatures but can undergo rapid deformation at higher temperatures.

Keywords---delaviridine, ethosomes, drug delivery.

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Research Article

Analytical Method Development And Validation For Estimation Of Bilastine In Pharmaceutical Formulationby Reverse Phase High Performance Liquid Chromatography

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ABSTRACT:
In this currentinvestigationeffort, an effort was made to build up anuncomplicated, speedy, truthfulas well as robust HPLC technique for the assessment of Bilastine in its tablet dosage form. Reverse phase high performance liquid chromatographic analysis was carried out on isocratic system. The column used for the investigation was Phenomenex C18 (250 mm× 4.6mm, 5µm) with ambient temperature. The optimized mobile phase was Methanol: Acetonitrile in the ratio of (20:80 %V/V). The detection was carried out at a wavelength of 245 nm using a flow rate of 1ml/min. The urbanizedtechnique was validated for validationconstraints like linearity, specificity, accuracy, precision as per ICH strategy. The %RSD for all constraints was well within the limits, which indicates the validity of the techniquein addition tothe assay results obtained are in reasonableconformity with the label claim of the marketed formulation. Thus, the conventionalscheme can be anticipated for repetitive investigation of this drug in laboratories and for superiority purposes.

Keywords: Bilastine, Acetonitrile, HPLC, Linearity.

INTRODUCTION:

Bilastine is a Phosphodiesterase 4 (PDE4) inhibitors chemically named as N-[2-[(1S)-1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-1,3-dioxoisoindol-4-yl] acetamide. It is used in the treatment of certain types of arthritis and skin conditions[1]. Literature survey revealed that few analytical techniques are available for estimation of Bilastine in pharmaceutical dosage form such as UV, HPLC. Keeping this objective in mind an attempt has been made to develop and validate the RP-HPLC method for the estimation of Bilastine in which the developed method would be a highly sensitivecost-effective method having good resolution and reproducible results [2].

MATERIALS AND METHODS:

Equipment

Chromatographic separation was conceded on WATERS HPLC system which is outfitted with the 515 dual head reciprocating pump & a 2489 UV Visible detector. The software used is Empower-2 software and column is Phenomenex C18 column of 250mm×4.6mm i.d, 5µm.

Materials and reagent

Bilastine drug was gifted by Aurobindo Pharmaceuticals, Hyderabad, Telangana, India. Acetonitrile, methanol, HPLC grade water, sodium hydroxide, Diammonium hydrogen orthophosphate and Hydrochloric acid were collected from local manufacturers.

Preparation of standard solution:

Standard stock arrangement was set up by gauging 25mg of Bilastineand moving in to 25 ml volumetric jar. At that point 25 ml weaken methanol was included and sonicated for 5 minutes to break down the medication. At that point the arrangement was weakened to check with methanol [6]. It was then separated through 0.45µm film channel, which gives the stock arrangement containing 1000µg/ml Bilastine.Standard arrangement was set up by moving in a 10 ml volumetric jar with a volume of 1 ml of standard stock arrangement and methanol separated through 0.45 separated layer channel; weaken the volume to provide a stock containing 100µg / ml Bilastine.

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Review Article

Hyperthermia has Consistently Improved the Efficacy of Radiotherapy and Chemotherapy for Many Types of Cancers

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Abstract

Cancer stem-like cells (CSCs) are a subset of cancer cells that are resistant to conventional radiotherapy and chemotherapy. As such, CSCs have been recognized as playing a large role in tumor initiation and recurrence. Although hyperthermia is broadly used in cancer treatment either alone or in combination with radio- or chemo-therapy, its potential to target CSCs is not well understood. In this review, we discuss different types of hyperthermia and potential mechanisms of action in cancer treatment, particularly in regards to killing CSCs.

Keywords: hyperthermia; cancer Stem-like cells; chemotherapy; cytotoxic treatment; radiation; nanoparticle; ablation; LITT

Introduction

Despite advances in understanding the molecular changes underpinning cancer and improved technology and treatments, cancer remains a leading cause of death in America. The cancer stem-like cell (CSC) hypothesis posits that a subset of tumor cells have a high capacity for self-renewal, have the ability to differentiate into multiple lineages and can give rise to tumors [1-4]. These CSCs are highly malignant and can persist or proliferate in spite of cytotoxic treatment [1-4]. Therefore, these CSCs play a large role in tumor progression. Development of new treatment modalities that are able to target and kill CSCs may provide more durable cancer control [1-4].

Hyperthermia is a potent radiosensitizer that has been shown in numerous clinical trials to improve tumor control. Importantly, the efficacy of hyperthermia is seen across many cancer types, including breast cancer, prostate cancer, melanoma, sarcoma, rectal cancer, bladder cancer, esophageal cancer, cervical cancer and glioblastoma suggesting that it has broad clinical applicability [5–24]. Recently, combined hyperthermia and radiation has also been shown to improve pain palliation in patients with bone metastases compared to radiation alone [25]. Therefore, hyperthermia has widespread usage for patients with both locoregional disease and advanced cancers and can be used for patients with a variety of cancer types. The value of hyperthermia as a treatment has in fact been observed for centuries. Hippocrates, the father of modern medicine, is known to have said, "Those who cannot be cured by medicine can be cured by surgery. Those who cannot be cured by surgery can be cured by heat. Those who cannot be cured by heat, they are indeed incurable". Over the years, medicine and surgery have seen significant advances, and hyperthermia fell by the wayside. However, in modern times, hyperthermia is making a resurgence due to improved technology in delivering hyperthermia and in non-invasive thermometry techniques.

Hyperthermia is classified into two broad categories based on the target heating temperature. Thermal ablation refers to treatments with target temperatures above 50°C and mild temperature hyperthermia refers to treatments with temperatures between 39 and 43°C [26]. While thermal ablation largely kills tumor cells due to the direct cytotoxic effects of heat, mild temperature hyperthermia uses heat as an adjunct treatment to enhance the cytotoxic effects of radiation and chemotherapy [26–28]. The biologic effects of thermal therapy are dependent on time and temperature.

The mechanisms underlying the biologic effects are multi-factorial and impact the tumor population itself, the tumor microenvironment and immune system.

Methods for Administering Hyperthermia

Radio-frequency hyperthermia is the most widely used hyperthermia technique worldwide and is typically used for ablative heating [28–30]. To achieve heating, radio-frequency electrodes are passed into the tumor tissue under image guidance. A high-frequency alternating current is then passed through the electrodes to cause the rapid oscillation of ions in nearby cells, resulting in frictional heating [27,31]. The range of heating is limited to the millimeter range because it relies on heated tissue to conduct current to surrounding areas [32]. The short range of heating also limits the ability to heat tumors near blood vessels because the heat is dissipated too quickly [32,33].

Microwave hyperthermia is an alternate method of delivery that can overcome some of the limitations of radio-frequency hyperthermia. Microwave heating uses waves of higher frequency to kill cells. Unlike radio-frequency thermal therapy, microwave hyperthermia does not pass an electrical current through tissue, but rather creates an oscillating electromagnetic field that forces ions and dipoles to align with the field, causing them to rotate as the field oscillates [31,32,34]. This rotation causes friction that heats the tissue. Microwave hyperthermia presents several advantages compared to radio-frequency hyperthermia. While radio-frequency hyperthermia relies on ions inside tissue to conduct current, microwave hyperthermia creates an electric field, the effective range of which is larger without risking damage to tissue closer to the antenna or probe [32]. Microwave hyperthermia has a much higher effective range of up to 3 cm [32].

Laser interstitial thermal therapy (LITT) is a relatively new method of administering hyperthermia that uses a stereotactically placed laser probe to heat surrounding tissue with a low power (10–15 Watts) infrared laser (at Nd-YAG range) [35,36]. Heat essentially is produced after absorption of laser in the tissue and transferred up to 1.5–2 cm from the laser probe by conduction. To control the extent of thermal ablation, a specific sequence of MRI (MR-thermometry) is used to measure relative changes of temperature within the magnetic field. For deep seated lesions, including brain tumors, LITT is used in conjunction with MR-thermometry to give accurate thermal ablation of the target lesion [35,36].

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Research Article

Subcutaneous DL Technique Has Proven To Be an Adequate Host for Human Embryonic Stem Cells

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Abstract

Islet transplantation has become an important treatment modality for Type 1 Diabetes Mellitus (T1DM); nonetheless, the procedure may be limited by donor availability. An alternative has been the increasing use of cellular therapies derived from human Embryonic Stem Cells (hESC), showing very promising results in maturation, yield and ultimately, in insulin secretion in response to adequate stimuli. We recently developed a new technique for cellular transplantation under the skin. This manuscript evaluates the capabilities of the pre-vascularized Device-Less (DL) site to allow transplantation of Pancreatic Endoderm (PE) cells differentiated from hESC to treat diabetes mellitus. Fifty immunodeficient mice, n = 25 diabetic and n = 25 non-diabetic, were transplanted with PE cells. Animals were followed for 22 weeks and grafts were retrieved to evaluate engraftment and subsequent maturation. Diabetic mice showed slightly better engraftment (48% vs. 36%, $p = 0.19$) and secreted higher concentration of human C-peptide upon glucose stimulation (0.32 ± 0.15 ng/mL vs. 0.13 ± 0.09 ng/mL, $p = 0.30$), although differences were not significant. This maturation was not sufficient to successfully reverse diabetes. Monomorphic cystic changes were detected in 12% and 8%, respectively (diabetics vs. non-diabetics, $p = 0.32$) and all grafts seemed to be adequately contained by the surrounding collagen wall within the DL space. Our findings support the capabilities of the DL site to host PE cells and allow safe maturation as a new strategy to treat diabetes.

Keywords: islet Transplantation; embryonic stem cells; cell engraftment; cell maturation

Introduction

The recent advances in immunotherapy have allowed Islet Transplantation (IT) to become a mainstay treatment for Type 1 Diabetes Mellitus (T1DM). Today, the procedure is safer and long-term graft survival is comparable to that of pancreas transplant alone, with a reduced risk for complications [1,2]. Nonetheless, the IT procedure is limited by donor availability and usage. Significant variability is associated with this treatment modality and many factors may affect the successful utilization of a donated pancreas. In fact, the entire donation-transplant process depends upon many variables related to the donor clinical characteristics, the type of donation (living, brain death, cardiac death, etc.), the outcomes of islet isolation, and recipient characteristics. As a consequence, the process is not always efficient and like other transplant types, the demand may surpass the available donation pool.

An alternative to IT may be to use renewable sources for insulin secretion from proliferative stem cell populations. In particular, research using insulin-producing cells derived from human embryonic stem cells (hESC) has shown very promising results in maturation yield and ultimately, in insulin secretion in response to adequate stimuli [3-6]. The focus is now on optimizing the existing differentiation protocols to allow for a successful and stable diabetes reversal. However, finding the most efficient transplant site remains a dilemma given the infusion volume needed at the time of transplant and the potential need for graft retrieval in the event of tumor formation [7,8]. These reasons are a deterrent to use the conventional intra portal route for this transplantation modality.

Our group recently described a novel pre-vascularized Device-Less (DL) technique for cell transplantation in the subcutaneous space [9]. This approach was successful in reversing diabetes with mouse and human islets and is currently being used for other cell therapies.

We herein describe the use of the DL technique to safely allow engraftment and maturation of Pancreatic Endoderm (PE) cells derived from a hESC line in an experimental xeno-transplant model of diabetes.

Materials and Methods

Human Embryonic Stem Cells-derived Pancreatic Endoderm

Pancreatic Endoderm (PE) cells derived from a human embryonic cell line were kindly provided by Drs. M.C. Nostro and G. Keller at the McEwen Centre for Regenerative Medicine in Toronto. Their differentiation protocol uses a combination of cytokines and small molecules to simulate pancreatic development and produces multipotent pancreatic progenitor cells with the potential to differentiate into all pancreatic lineages [10,11]. At the time of transplant, cells were harvested and shipped overnight to Edmonton for immediate implantation.

Transplantation of PE cells

Immunodeficient 8-12 week B6.129S7-Rag1tm1Mom mice (Jackson Laboratory, Bar Harbor, ME, USA) were used for all experiments. Animals (n = 50) were housed under conventional conditions with access to food and water ad libitum and their care was in accordance with guidelines approved by the Canadian Council on Animal Care.

The DL space was created as previously reported by inserting a nylon catheter subcutaneously in the left lower abdomen and left for five weeks before transplant [9].Diabetes was chemically induced by intraperitoneally injecting 180 mg/kg of streptozotocin (STZ; Sigma-Aldrich, ON, Canada) in half of the recipients, one week prior to transplantation. Mice were considered diabetic after two consecutive blood glucose measurements ≥ 11.3 mmol/L (350 mg/dL).

Two groups of mice (diabetics and non-diabetics, n = 25/group) were transplanted with approximately 7×106 PE cells using the DL technique.

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RP-HPLC Method for The Simultaneous Estimation of Lumefantrine and Artemether in Pure Form and Tablet Dosage Form

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Abstract

A new, simple, accurate, precise and sensitive reverse phase high performance liquid chromatographic (RP-HPLC) method has been developed for the separation and quantification of Lumefantrine and Artemether in pure form and tablet dosage form. The determination was carried out using Symmetry C18 ODS (4.6mm×250mm, 5µm) particle size as a stationary phase and mobile phase comprised of Methanol: TEA Buffer (36:64v/v) and the pH of tri ethyl amine buffer adjusted to pH-4.2 using orthophosphoric acid. The flow rate was maintained at 1.0 ml/min and the eluent was monitored at 296nm.The retention time of Lumefantrine and Artemether were 2.249 min and 5.430min respectively. The method was validated in terms of linearity, precision, accuracy, specificity and robustness. The method was linear and for precision studies; RSD for RIS AND HPD were 0.02 and 0.04 respectively. The percentage recoveries for both drugs from their tablets were 100.2203 and 100.60% respectively. The method precision for the determination of assay was below 2.0 %RSD. The method is useful in the quality control of pharmaceutical formulations.

Keywords
Lumefantrine and Artemether, Method Development, Validation, Accuracy.

*****

INTRODUCTION

Lumefantrine is an antimalarial agent used to treat acute uncomplicated malaria. It is administered in combination with artemether for improved efficacy. This combination therapy exerts its effects against the erythrocytic stages of Plasmodium spp. and may be used to treat infections caused by P. falciparum and unidentified Plasmodium species, including infections acquired in chloroquine-resistant areas. Its chemical name is 2-(dibutylamino)-1-[(9Z)-2,7-dichloro-9-[(4-chlorophenyl) methylidene]-9H-fluoren-4-yl] ethan-1-ol and having molecular weight of 528.94 gm/mole. Lumefantrine is freely soluble in DMF, chloroform and ethyl acetate, soluble in dichloromethane, slightly soluble in ethanol and methanol, and insoluble in water. The exact mechanism by which lumefantrine exerts its antimalarial effect is unknown. However, available data suggest that lumefantrine inhibits the formation of β-hematin by forming a complex with hemin and inhibits nucleic acid and protein synthesis (Tripati K et al 2010, Suhas Sahebrao Khandave et al 2010, Arun R et al 2010, Srivasthava et al 2010).

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A New RP-HPLC Method for The Simultaneous Estimation of Cefpodoxime and Clavulanic Acid in It's Pure and Pharmaceutical Dosage Form as Per ICH Guidelines

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Abstract
A simple, specific, precise and accurate Stability indicating RP-HPLC method for simultaneous estimation of Cefpodoxime and Clavulanic Acid in its pure and pharmaceutical dosage form has been developed and validated as per ICH Guidelines. The separation was achieved by Phenomenex Gemini ODS C18 (4.6mm×250mm) 5µm column and Acetonitrile: Methanol: Water (55:25:20% v/v) used as mobile phase, at a flow rate of 1 ml/min. Detection was carried out at 229 nm. Retention time of Cefpodoxime and Clavulanic Acid were found to be 2.157 min and 3.631 min respectively. The method has been validated for linearity, accuracy, precision, robustness, LOD and LOQ. Linearity observed for Cefpodoxime 10 – 30µg/ml and for Clavulanic Acid 6 - 14µg/ml. Developed method was found to be accurate, precise and simple, specific for simultaneous estimation of Cefpodoxime and Clavulanic Acid in pure form and their Combined Pharmaceutical Dosage Form. The precision results are not more than 2%. The proposed method was successfully applied for the simultaneous estimation of both the drugs in commercial combined dosage form.

Keywords
Cefpodoxime and Clavulanic Acid, RP-HPLC, Validation, ICH Guidelines.

*****

INTRODUCTION
Cefpodoxime proxetil and Clavulanic acid are antibacterial drugs. Cefexime is chemically: (6R, 7R)-7-{[2-(2-amino-1,3-thiazol-4-yl)-2 carboxy methoxy imino) acetyl] amino}-3 (methoxy methyl)-8-oxo-5-thia- 1-azabicyclo [4.2.0] oct-2-ene-2-carboxylic acid. It is a III generation Cephalosporin antibiotic that acts by inhibiting cell wall synthesis. It has a molecular weight of 427.455 gMo/l. Cefpodoxime is soluble in organic solvents such as ethanol, methanol, DMSO and Acetonitrile. Cefpodoxime proxetil is a prodrug that is absorbed from the gastrointestinal tract. Cefpodoxime is active against a wide spectrum of Gram-positive and Gram-negative bacteria. Cefpodoxime is stable in the presence of beta-lactamase enzymes. As a result, many organism's

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Anthelmintic Activity of Some Medicinal Plants: A Short Review

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Abstract

Medicinal plants are one of the best natural sources of pharmacological activities with less side effects but possess less efficacy compared to synthetic medicines. Parasitic helminths cause huge health issues for mankind and livestock and major economic loss by declined livestock production. Many crude drugs were proved to possess anthelminthic activity in traditional systems and used by many ethnic groups throughout the world, are screened for anthelmintic activity by invitro and invivo screening models. This present review presents some medicinal plants which possess vermifuge and vermicidal activity proved scientifically by using preclinical screening methods and there is need for further investigation to develop a lead molecule for novel herbal products.

Keywords
Anthelminthic activity, medicinal plants, livestock, vermifuge and vermicidal

*****

INTRODUCTION

Helminthiasis is also called as worm infection and it is a macro parasitic disease occurs in mankind and animals. The helminths reside in the git of humans and animals, but they also burrow into different organs and causes different infections such as Liver (fasciolosis), Lung (paragonimiasis), Muscle (cysticercosis), Skin (strongyloidiasis), Lymph (filariasis), Eye (river blindness), Brain (paragonimiasis) respectively. Helminthiasis is transmitted by ingestion of contaminated food, contaminated water, mosquitoes and flies. It is more prevalent in tropical and subtropical areas including sub-Saharan Africa, central and East Asia and the Americas. In men, helminths Infections are more common than female. Helminthiasis is one of the causative factors for malnutrition, Iron deficiency anaemia, cognitive changes and increased susceptibility to tuberculosis, HIV and malaria. The second most prevalent parasitic disease of humans after malaria is Schistosomiasis due to poor management practices. Anthelmintic acts as vermifuges (stunning) or vermicides (killing). Stomach pain, nausea and vomiting, dizziness, spinning sensation, headache and temporary hair loss are the most common side effects of anthelmintic drugs. Now a days the availability of allopathic drugs is not sufficient for the treatment of helminthiasis of huge population and they developed resistance or not effective. There are no major side effects when ayurvedic drugs are used for treatment of helminthiasis and scientific evidence is required for use of plant products in Ayurveda.

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DEVELOPMENT OF NOVEL 1, 3, 4-OXADIAZOLE DERIVATIVES AS NEW ANTI-MICROBIAL AGENTS

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ABSTRACT

2-(arylideneamino)-4-(5-Aryl-1,3,4-Oxadiazol-2-yl) phenol (VII) derivatives were evaluated for antimicrobial activity by using cup and plate method. The synthesized compounds were characterized and evaluated for antibacterial activity against Bacillus subtilis Staphylococcus aureus, Escherichia coli and Proteus vulgaris and antifungal activity against Aspergillus niger, Curvularia lunata and Candida albicans by using Ampicillin sodium and Clotrimoxazole as a standard respectively. Among all the compounds, Compound VIId and Compound VIII were more effective against bacteria. Among the series Compound VIIp and Compound VIIi were exhibited more inhibition against fungal.

KEY WORDS

1,3,4-Oxadiazole, IR Spectrum, NMR Spectrum, Mass Spectrum, Antibacterial, Antifungal

INTRODUCTION:

The major drawback of current treatment of infectious diseases are challenging due to resistance to antimicrobial agents and their side effects. In order to overcome this situation, it is necessary to continue the search for new antibacterial agents. In recent scenario heterocycles plays a major role in drug synthesis. In that respect oxadiazole plays a significant role among other heterocycles. From the literature survey oxadiazole was found to be having diverse activity like antimicrobial (Banday MR, et al, 2010), anti-tumor (El-Hamouly et al, 2011), anti-convulsant (Tabatabai SA et al, 2013), anti-tuberculosis (Rajesh A et al, 2013), anti-oxidant (Nevena Mihailovic et al, 2017), anti-inflammatory (Ega Durga shivaprasad et al, 2013) etc. So, it was planned to synthesize a novel series of 1,3,4 oxadiazole derivatives and to check their activity as antimicrobial and antifungal agent.

MATERIALS AND METHODS

All melting points were taken in open capillaries on a veego VMP-1 apparatus and are uncorrected IR spectra were recorded as KBr pellets on a Perkin-Elmer FT IR 240-c spectrometer. The ^{1}H NMR spectra were recorded on Varian-Gemini 200 MHz spectrometer in DMSO-d6 using TMS as an internal standard and mass spectras were recorded on Schimadzu QP 5050A spectrometer.

Synthesis of methyl-4-hydroxy-3-nitrobenzoate (II)

To a solution of aluminium nitrate (40grms) in acetic acid- acetic anhydride (1:1) mixture (160ml), was added an appropriate phenol (I, 40grms) in small portions, while cooling and shaking occasionally. The reaction mixture was left at room temperature for 1.5 hours while shaking the contents intermittently to complete the nitration. The resulting brown solution was diluted to complete the nitration. The resulting brown solution was diluted with ice-cold water and acidified with concentrated Nitric acid to get a bulky, yellow precipitate. It was filtered washed with small quantity of

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Research Article **Open Access**

Design and Development of Modified Release Solid Oral Dosage Form (Entacapone)

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ABSTRACT

The present research work focuses on design and development of modified Release solid oral dosage form.entacapone: based on assessment of various parameters, in vitro drug dissolution profile and drug kinetics, hf14 was found to be optimized formulation.FT-IR & DSC studies revealed that there was no interaction between the drug and polymers used in the formulations. The drug release from hf14 was found to fit zero order of concentration independent and best fitted to higuchie model confirming to be diffusion assisted mechanism. Based on the mucoadhesive study, the optimized dosage form adhesive to gastro intestinal tract more than 12 hours. The marketed product released by first order kinetics by concentration dependent. In vivo bioavailability studies were conducted for optimized entacapone trilayer tablets and marketed product, the results were indicating that the optimized entacapone formulation was shown sustained release patterns where marketed product was shown immediate release

Keywords: Entacapone, modified drug release, trilayer

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CONTENTS

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1. Introduction

Requirement for the study: The need for the present investigation is to develop an Entacapone tablets and Tolcapone tablets controlled release formulation that releases the API release independent of its concentration. Entacapone marketed tablets found the release of drug in a controlled manner but the drug release is concentration dependent. Hence, the study was attempted with a plan to design Entacapone tri-layered matrix tablets and Tolcapone tri-layered matrix tablets by using Geo matrix technology that follows zero order kinetics i.e. Release of drug is independent of its concentration.

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STRATEGIES IN PHARMACEUTICAL MARKETING

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Keywords:

Pharmaceutical Products, Drug Promotion, Ethical standards

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ABSTRACT

The main objective of ethical criteria for medicinal drug promotion is to support and encourage the improvement of health care through the rational use of medicinal drugs.

WHO expanded its scope to people in all walks of life: governments; the pharmaceutical industry (manufacturers and distributors); the promotion industry (advertising agencies, market research organizations and the like); health personnel involved in the prescription, dispensing, supply and distribution of drugs; universities and other teaching institutions; professional associations; patients and consumer groups; and the professional and general media including publishers and editors of medical journals and related publication of the drug itself.According to WHO, Promotional materials for pharmaceutical products should be accurate, fair and objective and presented in such a way as to confirm not only to legal requirements but also to high ethical standards .

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Design And Characterization Of Zanamavir Ethosomal Drug Delivery System To Enhance The Bioavailability Via Topical Drug Delivery

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Abstract

The present study is to develop and evaluate an ethosomal gel formulation of Zanamavir. It aims to provide a topical treatment for many viral infections that affect the skin. Administration of medications topically having the facility of delivering a high concentration of the drug to the skin than would be possible with systemic therapy. Topical administration of drugs is better for local action and the efficiency of the topically administered drug is increased with liposome, proliposomes and ethosomes. Recently, it was found that ethosomal carriers were phospholipid vesicular systems having relatively high concentrations of alcohol enhances dermal and transdermal delivery of both lipophilic as well as hydrophilic molecules. Ethosomes were formulated using phospholipid, ethanol, polyethylene glycol and purified water by cold method. Ethosomes were evaluated for vesicle size, shape, optical microscopy, entrapment efficiency and in-vitro release study. **ZEF7** have better drug entrapment efficiency than the other formulation. The best formulation (**ZEF7**) was used to prepare gel by using carbopol 934 as a gelling agent. The ethosomes were entrapped in gel matrix of carbopol 980 in different concentration 0.5%, 1.00% and 1.5% w/w. FT-IR studies revealed no interaction between the drug and excipients. The formulated gel formulation was evaluated with parameter pH, viscosity, spreadability, in-vitro release test, washability, extrudability study and stability studies. The formulation **ZEF7** have better in-vitro drug release profile which contains carbopol 980 concentration 1.5 %w/w. The present work also focuses on making the formulation more pharmaceutically acceptable.

Keywords: Zanamavir, Ethosomal gel, Phospholipid, % Entrapment efficiency, Vesicle size

INTRODUCTION

In the past decades, topical delivery of drug by liposomal formulation have evoked considerable interest, it has been evident that traditional; liposomes are of little or no value as carrier for transdermal delivery of drug, because they do not deeply penetrate skin but remains confined to upper layer of the stratum corneum. To overcome problem of

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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF FELODIPINE IN BULK AND TABLET DOSAGE FORM BY USING RP-HPLC TECHNIQUES

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Abstract:

This paper describes the analytical method suitable for validation of Felodipine by reversed Phase High Performance Liquid Chromatography (RP-HPLC) method. The method utilized RP-HPLC (Water 2695 with PDA detector) model and a column ODS C18 (4.6 x 150mm, 5µm). The mobile phases were comprised with Acetonitrile and Water (80:20 V/V) at a flow rate of 1.0 ml/min. UV detection at 305 nm MTS were eluted with retention times of 3.155min. The method was continued and validated accordance with ICH guidelines. Validation revealed the method is rapid, specific, accurate, precise, reliable, and reproducible. Calibration curve plots were linear over the concentration ranges 15-75 µg/mL (R^2 = 0.9998). Limit of detection (LOD) was 0.19µg/ml and limit of quantification (LOQ) was 0.6µg/mL. The method showed good recoveries (98.9 - 100.4%). Statistical analysis was proves the method is suitable for the analysis of Felodipine as a bulk, in tablet dosage form without any interference from the excipients. It was also proved study for degradation kinetics. It may be extended for its estimation in plasma and other biological fluids.

Keywords: *Felodipine, RP-HPLC, Method Development and Validation.*

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EVALUATION OF ANTIHYPERLIPIDEMIC AND ANTIOXIDANT ACTIVITY OF *INULA RACEMOSA* ROOTS

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The potential of Inula racemosa roots on hyperlipidaemia and oxidative stress was investigated in diet induced hyperliperlipidaemia model, In vivo and In vitro antioxidant parameters. Hyperlipidemia is induced by mixing rat feed with cholesterol and saturated fats for 28 d. Serum was withdrawn on 7th, 14th, 21st and 28th d. Seperated serum was analysed for Cholesterol (CH), Triglycerides (TG), HDL, LDL, Glucose, Aspartate aminotranferase (AST), Alanine aminotransferase (ALT) and Bilirubin. On 28th d liver was isolated and analysed for In vivo and In vitro antioxidant parameters. Oral administration of Inula racemosa for 28 d resulted in significant ($P<0.05$) reduction of cholesterol, triglycerides, LDL, Glucose AST, ALT, Bilirubin and increase in HDL levels. The elicited effects were compared with standard drug, atorvostatin (10 mg/kg). The plant also displayed significantly ($P<0.01$) elevated Catalase and Glutathione levels and lowered LPO, NO and DPPH levels. The experimental results conferred significant ($P<0.01$) antihyperlipidemic activity of Inula racemosa in experimentally induced hyperlipidemia model and antioxidant activity. On the basis of present findings it can be concluded that Inula racemosa roots possess antihyperlipidaemic activity and antioxidant activity.

INTRODUCTION

Inula racemosa (*I. racemosa*) commonly known as pushkarmool belongs to the family Asteraceae. The plant is a shrub, with grooved stem bearing large leaves in racemose manner. Flowers are large, yellow in colour and produced in summer. Fruits are slender achenes with long pappus hairs. Roots are irregular, branched and possess a sweet odour with a bitter taste (Chopra *et al.* 1956a).

It is a traditional herb employed in Ayurvedic and Chinese system of medicines for

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Research Article

FORMULATION DESIGN AND DEVELOPMENT OF ZOLMITRIPTAN ODT

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ABSTRACT

Zolmitriptan is a Selective Serotonin receptor agonist. Used in the acute treatment of Migraine attacks with or without aura and headaches. The current research work is aimed at evolving a formulate and evaluate of a Rapid dispersible tablet dosage form of Zolmitriptan. Who have little or no access to water are also good candidates for orodispersible.Direct Compression technique was employ for combination of pure drug and excipients in the given ratio as an eight compositions. The primed powder blend was then compressed into tablets by the required Superdisintegrants (SSG, CCS and CP) and Polymers. The tablets be evaluate for hardness, thickness, weight variation, friability, Drug Content and Disintegrating Time (Sec) were subjected to a 7 minutes in-vitro drug release studies (USP dissolution rate test apparatus II, 50 rpm, 370C ±0.50C) using phosphate buffer, pH 6.8 as a dissolution medium (900ml). The quantity of Zolmitriptan released from the tablet compositions at dissimilar time intervals is predictable by means of a UV spectroscopy method. The compositions that showed a considerable retardation of the drug release are considered promising. Among the eight compositions, F5 formulation contains Drug to Croscaramellose Sodium (CCS) in ratio 1:2 is optimized based on its ability to till 5 mins of in-vitro dissolution time and its cumulative % drug release was found to be 99.24 %.

KEYWORDS: *Direct Compression technique, Zolmitriptan, Croscaramellose Sodium.*

INTRODUCTION

The faster the drug into solution, quicker the absorption and onset of clinical effect. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablets dosage form [1-4]. Fast dissolving tablets are those when put on tongue disintegrate instantaneously releasing the drug which dissolve or disperses in the saliva. The major advantage of the ODT formulation is that it combines the advantages of both liquid and conventional tablet formulations, and also offering advantages over both traditional dosage forms. It provides the convenience of a tablet formulation, and also allowing the ease of swallowing provided by the liquid formulation [5, 6].

MATERIALS AND METHODS

Zolmitriptan was a gift sample from Hetero Labs, Hyderabad, Magnesium Stearate, Microcrystalline Cellulose was used and supplied by Yarrow Chem Products, Mumbai. Sodium Starch Glycolate, Croscaramellose Sodium, Cros povidone, Mannitol was used and supplied by Signet chem, Mumbai, Aerosil was supplied by Loba chemicals, Yarrow Chem Products, Mumbai.

Methodology:

Standardization of Zolmitriptan by UV-Visible spectrophotometry:

Standard calibration of Zolmitriptan in 6.8 Phosphate buffer: 100mg of Zolmitriptan was accurately weighed and dissolved in100ml of 6.8 phosphate buffer to obtain a concentration of 1000µg/ml. From the above 10ml was withdrawn and diluted to 100ml to obtain a concentration of 100µg/ml. From this stock solution aliquots of 0.5ml, 1ml, 1.5ml, 2ml and 2.5ml were diluted in 10ml volumetric flask with phosphate buffer to give concentrations in range of 5µg/ml to 25µg/ml respectively, absorbance was measured at 224 nm.

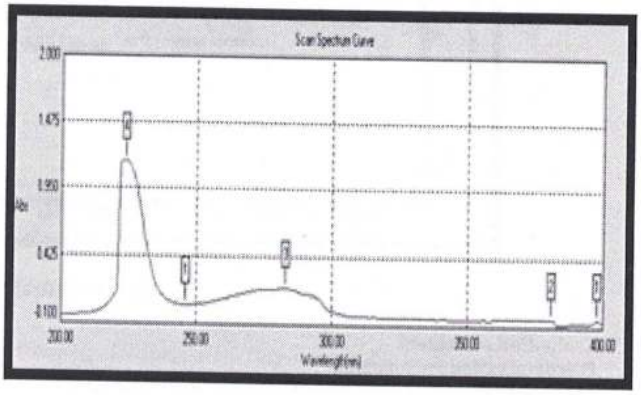

Fig. 1: λ_{max} of Zolmitriptan in pH 6.8 Phosphate buffer

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tapping is continued for 1250 times and tapped volume was noted. Tapping was continued until the difference between successive volumes is less than 2 % (in a bulk density apparatus). It is expressed in g/ml and is given by

$$Dt = M / Vt$$

Where, M is the mass of powder, Vt is the tapped volume of the powder

(C) Angle of Repose (θ): The friction forces in a loose powder can be measured by the angle of repose. It is an indicative of the flow properties of the powder. It is defined as maximum angle possible between the surface of the pile of powder and the horizontal plane.

$$\tan(\theta) = h / r$$
$$\theta = \tan^{-1}(h / r)$$

Where, θ is the angle of repose; h is the height in cms,r is the radius in cms.

The powder mixture was allowed to flow through the funnel fixed to a stand at definite height (h). The angle of repose was then calculated by measuring the height and radius of the heap of powder formed. Care was taken to see that the powder particals slip and roll over each other through the sides of the funnel.

(D) Carr's index (or) % compressibility: It indicates powder flow properties. It is expressed in percentage and is given by

$$I = Dt - Db / Dt \times 100$$

Where, Dt is the tapped density of the powder and Db is the bulk density of the powder.

(E) Hausner's ratio: Hausner's ratio is an indirect index of ease of powder flow. It is calculated by the following formula.

$$\text{Hausner's ratio} = Dt / Db$$

Where, Dt is the tapped density, Db is the bulk density.

Lower hausner's ratio (<1.25) indicates better flow properties than higher ones (>1.25) [10-12]

Post Compression Parameters:

Weight Variation Test: From each batch twenty tablets were selected at a random and average weight was determined. Then individual tablets were weighed and the individual weight was compared with an average weight, the variation in the weight was expressed in terms of % deviation.

Hardness and Friability Test: For each formulation the hardness was determined by using Monsanto hardness tester and Friability of the tablets was checked by using Roche Friabilator. This device subjects tablets to the combined effect of abrasion and shock by utilizing plastic chamber which revolves at 25 rpm dropping the tablets at a distance of 6 inches with an each revolution. Preweighed sample of tablets was placed in the friabilator, which was then operated for 100 revolutions. Tablets were dusted and reweighed and then % Friability was calculated.

Water Absorption Ratio and Wetting Time: A piece of tissue paper folded twice was placed in a small Petridish containing 6 ml of water. A tablet of known weight was put on the paper and the time required for complete wetting of tablet was measured. The wetted tablet was then weighed; water absorption ratio R was determined using t.

$$R = \frac{Wb - Wa}{Wb} \times 100$$

Where; Wb is weight of tablet before water absorption; Wa is weight of tablet after water absorption

Drug Content Uniformity Study:

Five tablets were weighed individually and powdered. The powder equivalent to 50 mg of Zolmitriptan was weighed and extracted in 6.8 phosphate buffer (100 ml) and the concentration of drug was determined by measuring absorbance at 224nm by spectrophotometer [13-15].

Table No. 2: Precompression Parameters

S. No	Formulation	Angle of repose	Bulk density	Tapped density	Carr's index
1	F1	25.25	0.41	0.52	14.27
2	F2	28.37	0.43	0.51	11.35
3	F3	25.35	0.44	0.53	15.39
4	F4	27.63	0.41	0.56	9.45
5	F5	29.73	0.49	0.54	8.26
6	F6	26.34	0.45	0.52	14.63
7	F7	30.75	0.42	0.55	12.53
8	F8	28.26	0.51	0.57	14.29

Preparation of tablets: Different tablets formulations were prepared by direct compression technique. All powders were passed through 60 mesh. Required quantities of pure drug and excipients were mixed thoroughly Magnesium stearate was added as lubricant. Aerosil was used as glidant. Micro crystalline cellulose was used as diluent. Finally the powder mix was subjected to compression after mixing uniformly in a polybag. Prior to compression, the blends were evaluated for several tests. In all formulations, the amount of the active ingredient is equivalent to 75 mg of Zolmitriptan.

Table No. 3: Composition of Zolmitriptan

S.No	Ingredient	F1	F2	F3	F4	F5	F6	F7	F8
1	Zolmitriptan	5	5	5	5	5	5	5	5
2	Sodium Starch Glycollate	7.5	12.5	17.5	-----	-----	-----	-----	-----
3	Cross Caramellose Sodium	-----	-----	-----	7.5	10	17.5	-----	-----
4	Cross Povidone	-----	-----	-----	-----	-----	-----	12.5	17.5
5	Microcrystalline Cellulose	QS	QS	QS	QS	QS	QS	QS	QS
6	Mannitol	5	5	5	5	5	5	5	5
7	Magnesium stearate	2	2	2	2	2	2	2	2
8	Aerosil	2	2	2	2	2	2	2	2
	Total weight (mg)	75	75	75	75	75	75	75	75

RESULTS AND DISCUSSION

Zolmitriptan have an UV absorbance of 224 nm. Solutions ranging from 5 to 25µg/ml were prepared using 6.8 Phosphate buffers separately, absorbance was measured for each solution at λmax of 224 nm using Labindia Double beam UV/ visible spectrophotometer and graph was plotted for absorbance vs. concentration of Zolmitriptan. Standard graph of Zolmitriptan in pH 6.8 Buffer at λ max 224 nm. The drug compatability studies were done by using FTIR and there is no interference to the drug and exipients. Precompression Parameters and post compression parameters were done and they were within the pharmacopoeial limits.

CONCLUSION

The orodispersible tablets of Zolmitriptan were prepared effectively by excipients in dissimilar ratios of through via Superdisintegrants. We can conclude Out of eight compositions using various Superdisintegrants akin to SSG, CCS and CP along with this composition F5 contains Cross Caramellose Sodium shows maximum drug release within 5 minutes of dissolution study. This formulation showed disintegration time of 21 seconds respectively. Thus based on Disintegration time and dissolution profiles, Formulations F5 is optimized to be the best among all the eight compositions.

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RESEARCH ARTICLE

Formulation Design, Development of Gastro Retentive Floating Tablets of Propranolol

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Abstract

Aim: The present research work was carried out by formulate and evaluate the gastro-retentive floating tablets of propranolol. **Materials and Methods:** Propranolol HCl is an antihypertensive agent. It is mainly used in the treatment of acute myocardial infarctions. Consequently, the current exploration was to design a gastro-retentive drug delivery system of propranolol using swelling polymer through wet granulation method. All the formulations were evaluated for weight variation, hardness, friability, drug content, and *in-vitro* dissolution. In this gastro-retentive dosage form using hydroxypropylmethylcellulose-K4M (HPMC-K4M) was prepared to develop a sustain release tablets, which could retain in the stomach for longer periods of time delivering the drug to the site of action that is in the stomach. **Statistical Analysis used:** Fourier-transform infrared signifying compatibility of the drug and polymers in the tablet composition. **Results:** Pre- and Post-compression parameters of all the formulations were within the pharmacopoeial limits and *in-vitro* drug release of F2 formulation was found to be 99.14% in 12 h. **Conclusion:** Dissolution studies of the composition, it was concluded that the formulation F2 which is containing 50 mg of HPMC-K4M, 25 mg of sodium bicarbonate, 25 mg of polyvinylpyrrolidone K30, 1.5 mg of magnesium stearate, and 1.5 mg of Talc is the best formulation. F2 possessed quick buoyancy lag time of 40 s and good total floating time of 12 h. As the consequence of this study, it may accomplish that the floating tablets using HPMC-K4M are a hydrophilic polymer increases the gross register tonnage of the dissolution fluid in the stomach to deliver the drug in a sustained manner.

Key words: Gastro retentive drug delivery system, hydroxypropylmethylcellulose-K4M, propranolol, wet granulation

INTRODUCTION

Gastric retention provides advantages, for instance, the delivery of drugs with narrow absorption windows in the small intestinal region. In addition, the longer residence time in the stomach could be advantageous for local action in the upper part of the small intestine. Furthermore, improved bioavailability is expected for drugs that are readily absorbed on release in the gastrointestinal tract. These drugs can be delivered ideally by slow release from the stomach.

Propranolol, a nonselective beta-adrenergic blocking agent, has been widely used in the treatment of hypertension, angina pectoris, and many other cardiovascular disorders. It is highly lipophilic and is almost completely absorbed after oral administration. Although, much of the drug is metabolized by the liver during its first passage through the portal circulation; on an average, only about 25% reaches the systemic circulation, its elimination half-life is also relatively short (about 2–6 h).[1-3]

MATERIALS AND METHODS

Propranolol, hydroxypropylmethylcellulose K4M (HPMC-K4M), HPMC K15 M, xanthan gum, sodium bicarbonate, magnesium stearate, talc, and microcrystalline cellulose.

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