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ORIGINAL ARTICLE

OPEN ACCESS

Development and Validation of Analytical Method for Estimation of Varenicline in Swab Samples

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ABSTRACT

The objective of the current study was to develop and validate simple and precise UV spectrophotometric method for estimation of Varenicline tartrate (VRC) in the swab samples to validate cleaning procedure. The swabbing procedure was optimized in order to obtain a suitable recovery from stainless steel surface using 100% sterile cotton swab stick. Detection wavelength selected was 237.60 nm. The proposed method was validated in terms of Linearity, precision, accuracy, limit of detection and limit of quantitation. Linearity was studied over concentration range of 2-10 µg / ml and correlation coefficient was found to be 0.9945 for regression line. A mean recovery obtained was 88.23 %.

Key words: Varenicline tartrate, Swab testing, spectrophotometric, cleaning validation.

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INTRODUCTION

Cleaning Validation is documented evidence that an approved cleaning procedure will provide equipment that is suitable for processing of pharmaceutical products or active pharmaceutical ingredients (APIs). For validation of cleaning procedure three methods of sampling that are considered to be acceptable, namely direct surface sampling (swab method), indirect sampling (use of rinse solutions) and placebo sampling. A combination of the first two methods is generally the most desirable, particularly in circumstances where accessibility of equipment parts can mitigate against direct surface sampling. In Swab method the suitability of the material to be used for sampling and of the sampling medium should be determined. The ability to recover samples accurately may be affected by the choice of sampling material. It is important to ensure that the sampling medium and solvent are satisfactory and can be readily used. Rinse samples allow sampling of a large surface area. In addition, inaccessible areas of equipment that cannot be routinely disassembled can be evaluated. However, consideration should be given to the solubility of the contaminant. A direct measurement of the product residue or contaminant in the relevant solvent should be made when rinse samples are used to validate the cleaning process. Placebo sampling method provides simulation of actual production of subsequent batches.

FDA has not published specific guidelines to set acceptance criteria or method for determining whether a cleaning process is validated because of wide variation in the equipment and process used throughout finished and bulk products. Therefore pharmaceutical companies are expected to establish acceptance criteria based on specific and logical rationale and these criteria should be practical, achievable and verifiable and scientifically sound. The analytical methods used to detect residuals or contaminants should be specific for the substance to be assayed and provide a sensitivity that reflects the level of cleanliness determined to be acceptable by the company. Important is to define the sensitivity of the analytical method in order to set their reasonable limits. The acceptance criteria vary with the varying products or drugs which are processed, equipments used for processing, the potency of the drug and toxicity levels.

Cleaning Validation Protocol is required to define how the cleaning process will be validated. It includes objective of the validation process, responsibilities for performing and approving the validation study, description of the equipment to be used, the interval between the end of production and the beginning of the cleaning procedure, the number of lots of the same product, which could be manufactured during a campaign before a full cleaning is done, detailed cleaning procedures to be used for each product, each manufacturing system or each piece of equipment, the number of cleaning cycles to be performed consecutively, any routine monitoring requirement, sampling procedures, including the rationale for why



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PHYTOCHEMICAL SCREENING OF *DIOSPYROS PEREGRINA*

(Gaertn.) Gurke

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ABSTRACT

Diospyros species are valuable traditional medicines of Chinese herbal medicine, Tibetan medicine, and Ayurvedic medicine. Extractive values and qualitative identification of phytochemicals constituents of Diospyros species was carried out. The phytochemical screening was carried out for the selected plant and results are hereby reported. The results will definitely be useful for further phytochemical research to be done on this plant.

Keywords: Diospyros, Ebenaceae, phytochemicals, fruits, extracts

INTRODUCTION

In recent times, the rapid development of multi resistant bacterial and fungal strains of clinically important pathogens fetches the interest of scientist to develop newer broad spectrum antimicrobial agents. The less availability and high cost of new generation antibiotics necessitates looking for the substances from alternative medicines with claimed antimicrobial activity. A number of herbs with significant antimicrobial activity have been reported in different traditional literatures. Now it is

aimed to explore scientifically the antimicrobial potential of three traditional plants and substantiate the folklore claims. *Diospyros peregrine* Gurke. (Ebenaceae) is a small middle sized tree of costal West Bengal. The fruits have ethnomedicinal significance for the treatment of diarrhoea, dysentery, cholera, ulcer of mouth and in wounds. The fruits contain triterpenes, alkanes, flavonoids and tannins [1, 2].

Extraction Processes:-

The process of separation active principle



RESEARCH ARTICLE

DEVELOPMENT AND VALIDATION OF Q- ABSORBANCE RATIO SPECTROPHOTOMETRIC METHOD SIMULTANEOUS ESTIMATION OF SIMVASTATIN AND LABETALOL HCL IN COMBINED DOSAGE FORM



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ABSTRACT : A simple, precise, accurate and economical methods without any extraction step' The solvent used was 0.25N sodium hydroxide. Two wavelengths 246.00nm (λ max of Labetalol HCl) and 243.48nm (Isoabsorptive point) were selected for estimation of Labetalol HCl and Simvastatin for Q-absorbance ratio method. The concentrations of a drugs were determined by a using ratio of Q absorbances at isoabsorptive points and at the λ -max of Labetalol HCl methods was a successfully applied to pharmaceuticals dosage forms.

Keywords : Labetalol HCl, Simvastatin, 0.25N sodium hydroxide.

INTRODUCTION : ^{5,6}

Simvastatin is 2,2-Dimethyl butanoic acid(1S,3R,7S, 8S,8aR)-1,2,3,7,8,8ahexahydro- 3,7- dimethyl-8-[2-[(2 R,4R)- tetrahydro-4-hydroxy-6 oxo2H pyran-2yl]ethyl]1-naphthalenyl ester Simvastatin belongs to a class of drugs called HMG-CoA reductase inhibitors commonly called statins that derived synthetically from fermentation products of *Aspergillus terreus*. All statins act by inhibiting HMG-CoA enzymes. A 3-hydroxy-3- methyl glutaryl reductase coenzyme, that decides the rate of the HMG-CoA reductase pathway, the metabolic pathway responsible for the endogenous production of cholesterol mainly used for the treatment of dyslipidemia and the prevention of cardiovascular diseases. Simvastatin is prodrug which is converted into its β - hydroxy which inhibits HMG CoA reductase (3-hydroxy-3-methyl glutaryl Coenzyme A) enzyme, responsible for catalysing the conversion of HMG CoA to mevalonate a rate limiting step in the synthesis of cholesterol in liver. Labetalol HCl is a selective α_1 and non-selective beta blocker used to treat a hypertension (high blood pressure). Chemically it is 2-hydroxy-5-[[1-hydroxy-2-(4 phenyl butane-2-yl) amino] ethyl] benzamide. It has a molecular formula $C_{19}H_{24}N_2O_3.Hcl$ and a molecular weight of 328.40g/mol.^[5,6]

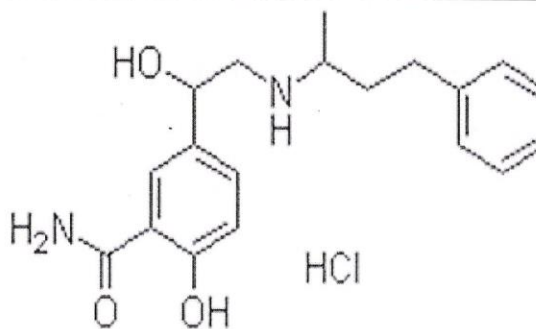


Fig 1: Chemical Structure of labetalol HCL

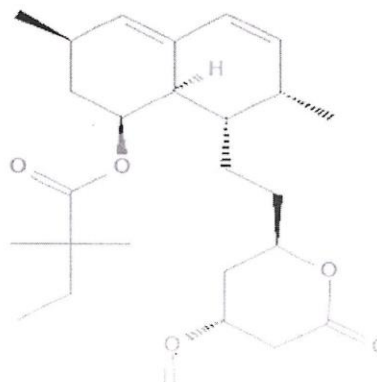


Fig 2: Chemical Structure of Simvastatin

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SHORT COMMUNICATION

Formulation and Evaluation of Herbal Hair Oil of *Murraya koenigii* Leaves Extract

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ABSTRACT

The present study was aimed to formulate the herbal hair oil for general purpose using various herbs for fewer side effects and have a better safety. The oil is prepared by using *Murraya koenigii*, *Azadirachta indica*, *Ocimum tenuiflorum*, *Hibiscus rosasinensis*, *Aloe barbadensis*, Coconut Oil. The formulated polyherbal hair oil was evaluated for the organoleptic properties, pH (6.4), acid value (1.90), saponification value (181), viscosity (32.40) and pH (6.4) and specific gravity (0.93). This oil used to treat common hair problems such as hair fall, alopecia, dandruff. The Formulated herbal hair oil having minimal or no side effects. The formulated hair oil provide good for hair growth, protection of hairs from dandruff, gives lustrous and shiny hairs.

Keywords: Cosmetics, hair oil, *Murraya koenigii*, Polyherbal hair oil

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INTRODUCTION

Hair is epidermal derivative increasing the overall elegance of the body. Hair fall, dandruff, lice, split ends, grey hair these are problems involved with hair faced by human. To avoid these, human takes many measures by applying many cosmetics. Hair oil is one used to solve all these problems. Herbal cosmetics are in high demand due to the increasing interest of human towards them because they have less side effect, easily available, more effective etc. Hair oil those which contains herbal drugs are called hair tonics, these formulated by herbal extracts in an oil base. Herbal hair oil not only moisturizes scalp but also reverse dry scalp and dry hair conditions. Antibacterial, antifungal and anti-inflammatory properties of *Murraya koenigii* leaves which fights against dandruff and infections of the scalp [1-3].

Hibiscus contains calcium, phosphorus, iron, copper, zinc, vitamin B1, riboflavin, niacin and vitamin C, which is used to stimulate thicker hair growth by strengthening the strands and prevents premature graying of hair. Hibiscus oil effectively revives the scalp and prevents it from turning dry. Hibiscus shows potential for cancer treatment and as a weight loss aid. Neem consist of several fatty acids such as linoleic acid, stearic acid, oleic acids that nourishes and revitalize rough hair to a smooth silky texture [4-6].

MATERIAL AND METHODS

Collection of plant part

For the preparation of herbal hair oil various plant materials were collected viz., *Murraya koenigii* leaves, leaves of *Azadirachta indica*, tulsi, Aloe vera and hibiscus were collected from botanical garden and coconut oil procured from local market.

Formulation of herbal hair oil

Herbs of all the crude drugs are collected and dried under shade. Drying under shade will retain the active constituents. Hence shade drying is preferred over artificial drying. Prepared powder of dried crude drugs by using mixer. Further on all these coarsely powdered drugs are passed through the mesh number 80 sieve. Thus obtained powders are blended together to get a uniform mixture. Now coconut oil is added



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Advances in Bioresearch

ORIGINAL ARTICLE

Formulation and Evaluation of Bilayer Tablet of Carbimazole as Immediate Release & Propranolol HCL as Sustained Release

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ABSTRACT

The objective is to formulate and evaluate the bilayer tablet containing carbimazole as immediate release and propranolol hcl as sustain release. Propranolol hcl is used complementary in therapy of hyperthyroidism. Propranolol & carbimazole used to treat hyperthyroid tremor and tachycardia. Propranolol HCl has been used in conjunction iodine to prepare mildly thyrotoxic patient for surgery but preferable to make the patient euthyroid with carbimazole. Bilayer tablet prepared in which one layer is of sustained release and another is of immediate release. Immediate release layer was formulated by wet granulation using sodium starch glycolate in 2-8 % and cross linked povidone in 2-5 %. Other ingredient used for formulation of immediate release was mannitol, talc and magnesium stearate. Sustain release layer of propranolol HCl was formulated by using ethyl cellulose as non- swellable polymer by direct compression method and other ingredients used are talc, magnesium stearate, starch and lactose. Various pre-formulation and studies such as identification test, melting point, compatibility study, solubility were checked. Also the micrometrics properties of powder blend such as bulk density tapped density, hausner's ratio, carr's index and angle of repose were evaluated. Post compression studies such as the hardness, weight variation, friability; drug content uniformity, thickness and in vitro drug release were performed. The result of the c5p1 batch was within limit and found to be as optimized batch. The drug release from the optimized batch was found 92.91 % for immediate layer within 1hr and 91.91% drug release of sustained release layer for 8hr. The optimized layers were selected to prepare the bilayer tablet. All the results were found within limit. The optimized batches are c5 of carbimazole and p1 of propranolol. The parameter selected for immediate release tablet was c5 (sodium starch glycolate) and p1 (ethyl cellulose) for optimized formulation. The principle behind drug release was diffusion and release kinetics by zero order.

Keywords: Bilayer Tablet, Carbimazole, Propranolol HCL, Sustained Release, Immediate Release, Ethyl Cellulose, Wet Granulation, Direct Compression.

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INTRODUCTION

The main aim behind this formulation is to overcome the disease and the clinical symptoms associated with it. Tablet is solid unit dosage form that has most patient acceptance among different dosage form. Tablet is used widely because these are easy to administer as compared to other dosage form. These are cheapest dosage form, stable, easy to dispense and deliver the accurate dose to the patient. Bilayer tablet is tablet containing two layers of different drugs that are incompatible or to enable development of different drug release profile such as immediate release and sustain release. Hyperthyroidism is condition related to thyroid gland. Thyroid gland produces T3 and T4 which controls how cell uses energy. Hyperthyroidism is condition when thyroid gland makes too much T3 and T4. This excess produced T3 and T4 causes tachycardia & tremor. The main advantage of combining two drugs is that Carbimazole against hyperthyroidism and Propranolol against Systolic hypertension [1]. Antithyroid action of Carbimazole is Carbimazole convert to methimazole [5]. Methimazole is the agent that reduces the uptake and concentration of inorganic iodine by thyroid it also reduces the formation of di-iodotyrosine and thyroxine. Propranolol HCL is used because the systolic hypertension is common



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ORIGINAL ARTICLE

Formulation And Evaluation of Sustained Release Mucoadhesive Tablet of Methyldopa

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ABSTRACT

An aim of the present study was formulation and evaluation of sustained release mucoadhesive tablets of methyldopa using mucoadhesive polymers to impart mucoadhesion. Methyldopa is a drug used in hypertension and also used in heart failure. Methyldopa is also used for hypertension in pregnancy. But the drug having half-life 1-2 hours and it given with a dose 250 mg 3 to 4 times a day and that favors development of sustained release formulation. The present study is for developing sustained released mucoadhesive tablet of methyldopa using carbopol and HPMC at various concentrations as release controlling polymers. There were total 9 batches formulated by direct compression method and evaluated by parameters such as precompression studies such as bulk density, tapped density, compressibility index, hausner's ratio, and post compression studies such as hardness, thickness, invitro drug release, swelling index etc. Among this MCH 3 batch was found to be optimized batch. This study includes that sustained release mucoadhesive tablets of methyldopa can provide a good mucoadhesion property and increase the bioavailability, improve the half life and reduce the dosing frequency of methyldopa.

Key Words: Mucoadhesion, sustained release, methyldopa, HPMC, carbopol, evaluation, matrix tablet, In vitro drug release, U.V. spectrophotometry.

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INTRODUCTION

Mucoadhesion describes the attractive forces between a biological material and mucous membrane [1]. Mucous membranes adhere to epithelial surfaces such as the gastrointestinal tract (GI-tract), the vagina, the lung, etc. They are generally hydrophilic as they contain many hydrogen macromolecules due to the large amount of water (approximately 95%) within its composition. However, mucin also contains glycoprotein that enable the formation of a gel-like substance [1]. Understanding the hydrophilic bonding and adhesion mechanisms of mucus to biological material is of most importance in order to produce the most efficient applications. For example, in drug delivery systems, the mucus layer must be penetrated in order to effectively transport micro or nano sized drug particles into the body [2]. Mucoadhesion involves various types of bonding mechanisms, and it is the interaction between each process that allows for the adhesive process such as wetting theory, adsorption theory, diffusion theory, electrostatic theory, and fracture theory [3]. Specific processes include mechanical interlocking, electrostatic, diffusion interpenetration, adsorption and fracture processes [4]. Methyldopa is an antihypertensive drug used in treatment of hypertension and heart failure. methyldopa belongs to a class of drugs called Alpha2 Agonists, Central-Acting. Methyldopa lower blood pressure by stimulating central inhibitory alpha-adrenergic receptors, false neurotransmission, and/or reduction of plasma renin activity. It works by relaxing the blood vessels so that blood can flow more easily through the body [5].

The short biological half-life of drug favors development of sustained release formulation. And also it given with a dose 250 mg 3 to 4 times a day, therefore it become necessary to formulate oral dosage form



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Advances in Bioresearch

ORIGINAL ARTICLE

Formulation and Evaluation Fast Dissolving Tablet of Nortriptyline HCl and Citalopram HBr for Treatment of Severe Depression

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ABSTRACT

The main aim is to combine nortriptyline HCl 50 mg with the citalopram HBr 40 mg by direct compression since combination of these two drugs showed significant superiority over citalopram alone in the treatment. Both drugs were undergoing extensive first pass hepatic metabolism, fdt formulation overcomes these problem. Excipients used in formulation are cross-povidone, sodium starch glycolate as superdisintegrant and mannitol, microcrystalline cellulose, magnesium stearate, talc as remaining excipient. Direct compression is used because it can formulate fdt with limited steps, cheap, high dose can be easily accommodate. Various precompression and postcompression studies were performed. Among 9 batches, nc8 batch was found to be the optimised batch with drug release, hardness, disintegration time, thickness, weight variation, friability, drug content, wetting time and water absorption ratio 92.21 %, 3.2 kg/cm², 76 sec, 3 mm, 199.9±1.68 mg, 0.69%, 97.21%, 20±0.9 sec, 113±0.9 respectively.

Keywords: fast dissolving tablet nortriptyline hcl, citalopram hbr, direct compression, sodium starch glycolate, cross-povidone.

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INTRODUCTION

Tablets are unit dosage form which contains one or more medicament with suitable excipient. Compared to other dosage forms tablets have relatively low manufacturing cost, packaging, more stability, temper resistance etc. The wide acceptance of tablet is due to ability of tablet to satisfy biopharmaceutical, marketing, production and patient requirements. Tablets offer advantages such as they are convenient dosage forms, they can be formulated to release the therapeutic agent to particular site within GI tract, less number of side effects, more accurate dosing, it is easier to mask the taste of bitter drugs, generally inexpensive. Tablet can be formulated with one or more therapeutic agent even if there are chemical or physical incompatibilities by using different approaches. A wide range of tablets can be formulated which offers range of release rates, duration, clinical effect. The chemical, physical and microbiological stability of tablets is superior to any other dosage forms.[1]

"A solid dosage form containing a medicinal substance or active ingredient which disintegrate rapidly usually within a matter of seconds when placed upon the tongue."The excipients used for formulation of FDT mostly contain at least one superdisintegrants. Permealising agent, bulking agent, sweetener or flavoring agent, lubricant.[2]

Nortriptyline HCl either inhibit the reuptake of the neurotransmitter such as serotonin at the β -receptors. It causes the more selective inhibition of the noradrenaline, which causes the symptomatic relieve from the depression. TCA does not cause inhibition of the monoamine oxidase nor do they affect the dopamine reuptake. As like other TCA antidepressants it has the effects on the histamine receptors 5-HT receptors in addition to other receptors.[11, 13]

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Advances in Bioresearch

ORIGINAL ARTICLE

UV Visible Spectrophotometry Method Development and Validation of Felodipine in Bulk Drug

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ABSTRACT

The objective of this study was to establish a validated method development for routine analysis of Felodipine in bulk drug samples. A simple, accurate, precise, and cost effective UV-visible spectrophotometric method was the estimation of Felodipine in its pure. The physicochemical characterization study of Felodipine was performed in UV-visible spectrophotometry, FT-IR and melting point techniques. The absorption maxima of the drug are found to be 362.20 nm in the solvent methanol. The concentration range 5-25 µg/ml was produced linear response with regression coefficient was 0.9965. Method validation parameters were performed as per the guideline of International Conference for Harmonization. The melting point was found to be 143° C in the standard range. The IR spectrum of Felodipine with potassium bromide was found the sharp and accurate peaks.

Key words: - Felodipine, λ_{max}, IR spectra, UV-visible spectrophotometer

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INTRODUCTION

UV Spectrophotometric in that method validation performed which is helps to validation of analytical method for a range of concentrations and that is the change in formulation or concentration do not require additional validation. Also analytical method development needed to understand the critical process parameters and which is minimize their influence on accuracy and precision.

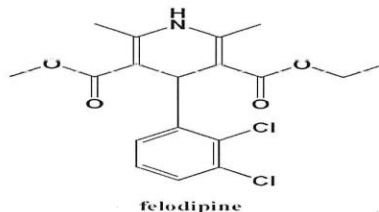


Fig. 1: Chemical structure of Felodipine

The IUPAC name of Felodipine is [(RS)-3-ethyl 5-methyl 4-(2, 3-dichlorophenyl)-2, 6-dimethyl-1, 4-dihydropyridine-3, 5-dicarboxylate]. Felodipine having molecular formula C₁₈H₁₉Cl₂NO₄ and their molecular weight is 284.3 g/mol [1]. The melting point of Felodipine is 141°C-145°C [8]. Felodipine is soluble in methanol. Felodipine is in class of calcium channel blocker. [10, 11, 12]

The Felodipine is used to treat myocardial infraction disease, stable angina, high blood pressure and heart failure [7]. Felodipine inhibits calcium ions from entering the slow channels of vascular smooth muscle and myocardium during depolarization. Felodipine is producing a relaxation of coronary vascular smooth muscle and coronary vasodilation [13].

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Advances in Bioresearch

ORIGINAL ARTICLE

Method Development and Validation of Pomalidomide Bulk Drug by Using UV Visible Spectrophotometer

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ABSTRACT

The aim of investigation was to develop a simple, accurate, precision and rapid UV visible spectrophotometric method for the determination of pomalidomide in its pure. Pomalidomide was estimated using UV-visible double beam spectrophotometer at the wavelength maxima are 217.40nm in 0.1N NaOH solvent. The drug was characterized by UV-visible spectrophotometry, Fourier transform infra-ray (FTIR) and melting point techniques. The analysis of pomalidomide was carried out by UV-visible method which was validated analytical parameters like precision, linearity, accuracy, limit of detection (LOD), limit of quantitation (LOQ) as per guidelines laid down by ICH. The melting point of pomalidomide was found to be 302.2°C. The FTIR spectra of pomalidomide with potassium bromide was found the sharp and accurate peak.

Key words: Pomalidomide, FTIR, UV-visible spectrophotometry

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INTRODUCTION

Method development is a process which proving the analytical method is use to measuring the concentration of bulk drug or active pharmaceutical ingredient in a dosage form. The method validation is process of provides a documented process demonstrating that the analytical procedure is suitable for its intended purpose, provides evidence of the method performance and ensure quality and reliability [1]. UV visible spectrophotometry is the one of the most frequently use technique in pharmaceutical analysis. It involves measuring the amount the visible radiation absorbs by a drug substance in solution. The basic principle of UV visible spectrophotometers is based on Beer-Lambert law [1].

The name of active pharmaceutical substance is pomalidomide. The category of pomalidomide is immunomodulation agent and also use in anti-myeloma tumouricidal activity. These drugs are soluble in 0.1 N NaOH and insoluble in water. Pomalidomide is chemically (RS)-4-amino-2-(2,6-dioxo-piperidin-3-yl)-isoindoline-1,3-dione [2-6]. Pomalidomide has a chiral carbon atom and exist as a racemic mixture of the R (+) and S (-) enantiomers.

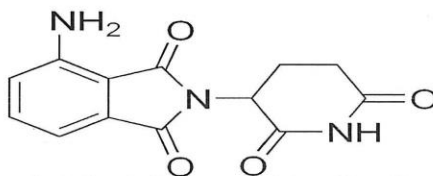


Fig.1 Chemical structure of Pomalidomide

Pomalidomide is a yellow solid powder. The molecular weight of pomalidomide is 273.24gm and molecular formula is C₁₃H₁₁N₃O₄. The pharmacokinetic of pomalidomide is maximum absorbed in a



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Advances in Bioresearch

ORIGINAL ARTICLE

Formulation and Evaluation of Sustained Release Mucoadhesive Oral Dosage Form Containing Clarithromycin Using Natural And Synthetic Polymer

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ABSTRACT

Formulation and Evaluation of mucoadhesive tablets of Clarithromycin using Guar gum as natural polymer and carbopol as synthetic polymer to impart mucoadhesion. Clarithromycin is a macrolide antibiotic used in treatment of peptic ulcer and works by stopping the growth of causing bacteria 'Helicobacter pylori'. The short biological half-life of drug favours development of sustained release formulation. And for this, guar gum and carbopol is used as sustained release mucoadhesive polymer and lactose, talc and magnesium stearate is used as remaining excipients. Direct compression method is used for the tablet formulation. Tablets were evaluated by various precompression and postcompression parameters such as, compatibility study, hardness, thickness, In vitro drug release, swelling index etc. Total 6 batches was formulated among this F6 batch was found to be the optimised batch with uniformity weight 349 mg, thickness 3.5, hardness 6.3, friability 0.52, drug content 98.99, drug release 84.48, swelling index 48.64, bioadhesion strength 33.2. This research includes that mucoadhesive tablets of clarithromycin can be a good way to bioadhesion properties and improve the bioavailability of clarithromycin.

Keywords: Clarithromycin, natural and synthetic mucoadhesive polymer, evaluation, matrix tablet, In vitro drug release.

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INTRODUCTION

Mucoadhesion describes the attractive forces between a biological material and mucous membrane [1]. Mucous membranes adhere to epithelial surfaces such as the gastrointestinal tract (GI-tract), the vagina, the lung, etc. They are generally hydrophilic as they contain many hydrogen macromolecules due to the large amount of water (approximately 95%) within its composition. However, mucin also contains glycoproteins that enable the formation of a gel-like substance [1]. Understanding the hydrophilic bonding and adhesion mechanisms of mucus to biological material is of most importance in order to produce the most efficient applications. For example, in drug delivery systems, the mucus layer must be penetrated in order to effectively transport micro or Nano sized drug particles into the body [2]. Mucoadhesion involves various types of bonding mechanisms, and it is the interaction between each process that allows for the adhesive process such as wetting theory, adsorption theory, diffusion theory, electrostatic theory, and fracture theory [3]. Specific processes include mechanical interlocking, electrostatic, diffusion interpenetration, adsorption and fracture processes [4]. Mucoadhesive tablets are the oral and most convenient dosage form. The present research was aimed to formulate and evaluate oral sustained release mucoadhesive matrix tablets of clarithromycin which is completely absorb by gastrointestinal tract. Clarithromycin is a macrolide antibiotic used in treatment of peptic ulcer and works by stopping the growth of causing bacteria 'Helicobacter pylori'. The short biological half-life of drug favors development of sustained release formulation [5].



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DEVELOPMENT AND VALIDATION OF CYCLOSERINE BY UV SPECTROPHOTOMETRIC METHOD

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ABSTRACT

Analytical method validation is a process which has been demonstrated to provide a high degree of assurance that uniform batches will be produced a result that meet the required specifications. It is a process to confirm that the analytical procedure used for a specific test is suitable for intended use and help to improve identity, safety, quality, purity and potency of the drug substance.

Cycloserine is an Antibiotic used to treat tuberculosis. The physiochemical characterization studies showed that Cycloserine is white to pale yellow crystalline powder, hygroscopic in nature and has melting point is 155 to 156 °C. Cycloserine is soluble in water, slightly soluble in methanol, propylene glycol .Develop a simple, precise and accurate UV Visible method for cycloserine drug. After considering the solubility water was selected as a solvent. Cycloserine showed maximum absorbance at 226.80 nm. In this method the linearity is observed between the range of 5-25 µg/ml. Precision, Robustness, Ruggedness parameter were studied. Also Limit of Detection (LOD) and Limit of Quantitation (LOQ) were validated. The method or all parameter were validated with the help of ICH guideline.

Keywords: Cycloserine, Spectrophotometric method, Validation

INTRODUCTION

Ultraviolet spectroscopy is a technique of the spectroscopy that uses light in the visible, UV (ultra violet), and NIR (Near

infrared Ranges). The Beer –Lambert Law states that the absorbance of a solution is directly proportional to the concentration of



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ORIGINAL ARTICLE

**Formulation and Evaluation of Bilayer Tablet Containing
Mefenamic acid As Sustained Release and Aloe Vera Gel Powder
as Immediate Release**

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ABSTRACT

The objective of present study is to formulate and evaluate Bilayer tablet containing Mefenamic acid as sustained release layer and aloe Vera is immediate release layer. Mefenamic acid is a NSAID it can causes ulceration in stomach by increasing ph of stomach but anta acid not given with mefenamic acid because anta acid decreases absorption of mefenamic acid. aloe vera gel powder have positive impact on this condition. Aloe vera gel powder has cyto-protective and healing properties it will help the sustained release layer of Mefenamic acid was formulated by using HPMC K15, HPMC K4 controlled release polymer. Immediate release layer of aloe vera gel powder was formulated by using various excipient such as croscopovidone, starch, talc, lactose etc. various pre-formulation parameter such as organoleptic characteristics was checked. Micro-meritics properties of both layer powder such as a bulk density, tapped density, hausners, ratio, carfsindex, angle of repose are performed. Post compression evaluation parameter was checked such as hardness, friability, weight variation, drug content uniformity, thickness, in vitro drug release of all batches was found in range of 95.38 to 93.56 within 8hr. Bilayer tablet of optimized batch of both layers (A3, M1). Optimized batch of both layer showed satisfactory result for different evaluation parameter. The optimized formula contain of immediate release layer A3 (croscopovidone) batch and sustained release layer of M1 (HPMC k4M) batch. The drug release mechanism was found to be zero order release found to be diffusion

Keywords: Bilayer tablet, Mefenamic acid, Aloe vera gel powder, HPMC K15, K4M, Immediate release, direct compression, Sustained release.

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INTRODUCTION

The purpose of any drug delivery system is to supply a therapeutic quantity of the drug to the proper site of action in the body to maintain the desired drug concentration. Oral rout is most suitable route of the administration dosage form. Tablet is a convenient dosage form acceptable by patients and medical practitioner. Bilayer tablet is suitable for sequential release of two drugs in single dosage form which one is immediate release and another is sustained release. [1]

Single dosage form containing two different category drugs. The benefit of combination therapy to reduce the number of the dosage form in prescription and maintain administrative cost as well as improving patient compliance. [2]

Mefenamic acid is an NSAID its mechanism of action by inhibiting the cyclooxygenase (COX). Mefenamic acid is used to treat Acute, moderate, severe Pain, Moderate Pain in dysmonoheral disease Mefenamic acid is rapidly and almost completely absorbed by oral route, 500 mg of single oral mefenamic acid absorbed extent of 30mcg/hr/ml Long term use of a Mefenamic acid can cause negative effect on gastric system in body it can cause gastric ulceration. Aloe vera with Mefenamic acid lower the side effect of Mefenamic acid it has cytoprotective, healing capacity. [4]



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ORIGINAL ARTICLE

OPEN ACCESS

Formulation and Evaluation of Polyherbal Tablets for Treatment of Upper Respiratory Tract Infection

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ABSTRACT

The present study is aimed at the formulation and evaluation of the polyherbal tablet for the treatment of upper respiratory tract infection. Following all the data and knowledge of polyherbal formulation of tablet for treatment of upper respiratory tract infection was prepared using ginger (*Zingiber officinale*), fennel (*Foeniculum vulgare*) & black pepper (*Piper nigrum*). Formulation of polyherbal tablet using these main therapeutically active medicinal drugs is important to meet better patient compliance. The present paper deals with formulation and evaluation of polyherbal tablet using dry extract of selected plants. The present communication also deals with evaluation using FTIR spectral studies showed that there is no interaction between excipients. In conclusion, formulation of polyherbal tablet is protected from upper respiratory infection. Our data confirmed that the selected formulation of polyherbal tablets has acceptable physicochemical features and may be considered as herbal medication for treatment of upper respiratory infection.

Key words: Polyherbal tablet, dry extract, respiratory tract infection.

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INTRODUCTION

Herbal medicines have existed world-wide and they were used in ancient Chinese, Greek, Egyptian and Indian medicine for various therapies purposes. In Ayurveda, single or multiple herbs (polyherbal) are used for the treatment. The Ayurvedic literature Sarangdhar Samhita highlighted the concept of polyherbalism to achieve greater therapeutic efficacy. The active phytochemical constituents of individual plants are insufficient to achieve the desirable therapeutic effects. When combining the multiple herbs in a particular ratio, it will give a better therapeutic effect and reduce the toxicity [1]. Ginger (*Zingiber officinale*) may have anti-inflammatory, antibacterial, antiviral, and other healthful properties. Some research indicates that enzymes in ginger can help the body break up and expel this gas, providing relief from any discomfort [2]. Fennel (*Foeniculum vulgare*) containing phytonutrients help clear sinuses. They make a great aid with bronchitis, congestion and cough as they have expectorant properties [3]. Black pepper (*Piper nigrum*) is particularly used to eradicate parasitic worms and as an appetizer. Black pepper is also used in treating coughs, colds, breathing and heart problems, colic, diabetes, anemia etc. The stomach ailments like dyspepsia, flatulence, constipation and diarrhoea are also treated with black pepper. Black pepper has been used in tooth powder for toothache, as well and an infusion of black pepper can work as a remedy for sore throat and hoarseness. It can also be chewed to reduce throat inflammation. [4]

MATERIAL AND METHODS

Materials:

The *Piper nigrum*, *Foeniculum vulgare* and *Zingiber officinale* were collected from local market of Pune, Maharashtra, India.

Method:

Powdered material was stored in air-tight container for further use, and preformulation study was done. The interaction studies were carried out to ascertain any kind of chemical interaction of drug with the excipients used in the preparation of tablet formulations. Fourier-transform infrared (FTIR) spectra were obtained by using an FTIR-Affinity-1 spectrophotometer (DRS-8000) SHIMADZU, Japan.



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**FORMULATION DEVELOPMENT AND EVALUATION OF IMMEDIATE
RELEASE TABLETS OF SYNTHETIC GLUCOCORTICOID USING VARIOUS
DISINTEGRANT AND THEIR EFFECT ON DISSOLUTION OF DRUG PRODUCT**

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ABSTRACT

The present study was aimed to formulate, develop and evaluate the immediate release tablet of synthetic glucocorticoid using various disintegrants and to observe the dissolution profile of drug product. The different disintegrant used like a partially gelatinized starch, sodium starch glycolate, crosscarmellose sodium in various concentration to achieve the drug release profile compare to RLD product. The super disintegrants like partially gelatinized starch, sodium starch glycolate, crosscarmellose sodium which shows different mechanism of action to disintegrate the tablet. So, for good dissolution profile as compare with RLD product we use various disintegrants at different concentration.

The generic tablet of dexamethasone 6mg was prepared by considering the approved reference product in Europe. The tablet was prepared by direct compression method. The excipient was used is based on the excipient which is used in reference listed product. Regarding a dissolution time we can prepare 6 optimized batches by OFAT drug design changing a concentration of disintegrant also a different disintegrants which shows the different dissolution profile and select the proper composition.

Keywords: Dexamethasone, synthetic glucocorticoids, disintegrants, dissolution profile

INTRODUCTION

The oral route of dose administration is most widely used due to ease of administration and most convenient route. Also, the oral route shows the more patient



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**AREA UNDER CURVE BY UV SPECTROPHOTOMETRIC METHOD FOR
DETERMINATION ACYCLOVIR IN BULK**

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ABSTRACT

The aim of present investigation is to establish simple, precise, and rapid Spectrophotometric method for the quantification of Acyclovir in Active Pharmaceutical Ingredient. In this, work is carried out to for estimation of Acyclovir bulk by utilizing an Area under Curve (AUC) method using UV – Visible Spectrophotometry. The study is designed to validate the developed methods as per ICH guidelines. For this purpose the wavelength range between 200-400 nm was selected. distilled water (50 ml water used for stock solution and serial dilution in 25 ml distilled water) was used as a solvent throughout the work. Linearity was obtained in concentration range 2 to 10 µg/ml ($r^2 = 0.999$) for the method. The developed method was found to be simple, linear, accurate, precise and highly sensitive and which can be used for routine quality control analysis for Spectrophotometric estimation of Active Pharmaceutical Ingredient.

Keyword: Acyclovir, linearity, AUC, spectrophotometer, distilled water

INTRODUCTION

A Acyclovir derivatives is USAN former BAN Antiviral Medication Acyclovir is structurally related to Acyclovir that is effective against many diseases. It is also called as (2-amino-9) Hydroxyethoxy)

Methyl 1,9 dihydro-6H-purine-6-onepurine nucleoside analogue) carbamic acid antiviral drugs ester. Pharmacologically Antiviral is a ZOVIRAX and ZOVIR. The principal mechanism of action of action for Antiviral



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**FORMULATION DEVELOPMENT AND EVALUATION OF IMMEDIATE
RELEASE TABLETS OF MUSCARINIC RECEPTOR ANTAGONIST USING
VARIOUS GRADES OF LACTOSE MONOHYDRATE AND API PSD TO STUDY
IMPACT ON FLOW PROPERTIES AND DISSOLUTION OF DRUG PRODUCT**

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ABSTRACT

Solifenacin succinate is a competitive muscarinic receptor antagonist. Solifenacin succinate is used to treat overactive bladder by relaxing the muscles in the bladder which improves the ability control the urination urge, urinary incontinence and increased urinary frequency in elderly patients. Solifenacin succinate belongs to the class of drug known as antispasmodics. Solifenacin succinate 10mg immediate release tablet formulation is prepared by direct compression strategy using the suitable excipients. During formulation development study, three different grades of lactose monohydrate and two lots of drug substances having different particle size distribution have been evaluated. Different grades of lactose monohydrate and PSD of drug substance ranging from $d_{90} - 40 \mu\text{m}$ to $110 \mu\text{m}$ have been evaluated to check the impact on flow ability of the blend and dissolution characteristics of drug product respectively. During formulation development study, pre-compression or lubricated blend parameters such as bulk density, tapped density, PSD by sieve analysis, compressibility index, Hausner's ratio etc. have been evaluated. Post-compression in-process parameters such as weight of tablet, tablet dimensions, hardness, friability, disintegration time etc. have also been evaluated. Dissolution profile all the test formulations was evaluated and compared with the dissolution profile of reference product. Based on formulation development studies conducted for development of oral; immediate release tablet formulation Solifenacin Succinate Tablets, 10 mg using direct compression strategy, SuperTab 14 SD a grade of lactose monohydrate and PSD of drug substance less than $40 \mu\text{m}$ has been finalized



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ORIGINAL ARTICLE

OPEN ACCESS

Method Development and Validation of Tofacitinib Bulk Drug By Using UV Visible Spectrophotometer

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ABSTRACT

Tofacitinib is a drug used for the treatment of rheumatoid arthritis. Tofacitinib is a janus kinase inhibitor (JAK). A sensitive, simple, rapid, accurate and economical UV spectrophotometric method has been developed for the method development and validation of tofacitinib. Tofacitinib was estimated using uv visible double beam spectrophotometer at the wavelength maxima are 286nm in water. The developed method obeyed beers law in a concentration range of 2-10 µg/ml with correlation coefficient (R^2) of 0.9978. The limit of detection was found to be 10.45 µg/ml and The limit of quantification was found to be 31.67 µg/ml.

Key words: Tofacitinib, analytical method validation, ICH guideline, Spectrophotometric

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INTRODUCTION

The name of active pharmaceutical ingredient is tofacitinib. The category of tofacitinib is janus kinase inhibitor, antineoplastic and immunomodulating agent and it is used in treatment of rheumatoid arthritis. Tofacitinib are soluble in water, DMSO[3,4,7].

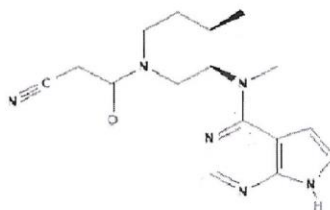


Fig. 1 Structure of Tofacitinib (Source: Google Images)

Tofacitinib is chemically 3-[(3R,4R)-4-methyl-3-[methyl (7H-pyrrolo[2,3-d]pyrimidin-4-yl)amino]piperidin-1-yl]-3-oxopropanenitrile. The molecular weight of tofacitinib is 312.37 g/mol and the molecular formula is $C_{16}H_{20}N_6O$. The half life is approximately 3 hrs.

Tofacitinib is a medication used to treat rheumatoid arthritis, ulcerative colitis, psoriasis arthritis, psoriasis. Tofacitinib is an inhibitor of the enzyme janus kinase 1 and janus kinase 3. Adverse effects include diarrhea, headache and high blood pressure.

Estimation of tofacitinib citrate by reported, however there was no method reported for tofacitinib by UV spectrophotometer for analytical method development and validation. It is robust, simple and accurate method and also economical analytical method.

MATERIAL AND METHODS

Experimental

Instrument and Material

Instruments- A double beam UV-1800 (Shimadzu) UV visible spectrophotometer. It consists of two similar, matched sample holder and it is made up of glass, quartz and silica. It is widely used for analytical



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ORIGINAL ARTICLE

OPEN ACCESS

Design, Formulation and Evaluation of Immediate Release Tablets Of Hydrochlorthiazide

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ABSTRACT

The aim is to formulate various formulations of immediate release tablet of Hydrochlorothiazide using different Superdisintegrants (Sodium Starch Glycolate, Croscarmellose, Crospovidone), Povidone K-30 and Magnesium stearate by wet granulation method. The pre-formulation study was carried out in order to establish, identity the compatibility Study between drug and excipients/polymers by FTIR spectroscopy, melting points, solubility, the result shown that the drug compatible to excipients without any significant changes in chemical nature of drug. Immediate release Hydrochlorothiazide was carried out by 3² factorial design varying concentration of Polymers and super disintegrants. The tablet was prepared separately using 8 station tablet compression machine and evaluated for their performance. The drug release zero order release pattern ($r^2 = 0.996$) and H6 formulation containing super disintegrant i.e. 33.3% sodium starch glycolate and 23.3 % cross carmellose sodium shows rapid disintegration (1.43min) of immediate release tablet, and in vitro drug release shows 91.28% drug release within 1 hr with Hixson drug release pattern ($r^2 = 0.994$).

Key words: Hydrochlorothiazide, immediate release tablets, superdisintegrants, design of experiment.

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INTRODUCTION

Oral route is one of the convenient and efficient routes of drug administration. It is effective to achieve the local and systemic effect of drug. Conventional dosage form is usually in the form of two or three daily doses, which can show the large fluctuations in the drug plasma concentration and cause side effects on the human body. These problems overcome by to develop innovative methods for drug delivery via the oral route. An immediate release dosage form allows a manufacturer to extend market exclusivity, while offering patients a convenient dosage form or dosage regimen. Immediate release tablets are those tablets which are designed to disintegrate and release their medication with no special rate, such as no special coatings and other techniques. Immediate release and fast dispersing drug delivery system may offer a solution to these problems. Recently immediate release tablets have started gaining popularity and acceptance as a drug delivery system, mainly because they are easy to administer, has quick onset of action is economical and lead to better patient compliance. They are also a tool for expanding markets, extending product life cycles and generating opportunities [1].

Hydrochlorothiazide is a diuretic under class thiazide diuretics. It acts by inhibiting the water reabsorption in the nephron by inhibiting the sodium chloride symporter in the distal convoluted tubule which is responsible for 5% total sodium reabsorption. Once sodium entered in cell via sodium potassium ATPase, causing increasing the osmolarity of interstitium, thereby establishing osmotic gradients for water reabsorption. HCTZ effectively reduce the osmotic gradient and water reabsorption throughout nephron [2].

When it is given orally the Bioavailability of the drug is 70% and peak plasma concentrations are reached 1-2 hours. The drug is widely distributed, reaching concentrations in the CSF that are 50% of those in the plasma and excreted by the kidneys partly by glomerular filtration and partly by tubular secretion. The plan of present research is to develop patient compliance and cost effective Hydrochlorothiazide immediate release tablets by wet granulation method. Thus eight different formulations were designed to obtain best optimized product by comparing with innovator.



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**APPLICATION OF QUALITY BY DESIGN APPROACH IN UV-VIS SPECTROSCOPY
METHOD DEVELOPMENT FOR SIMULTANEOUS ESTIMATION OF SAXAGLIPTIN
HCL AND METFORMIN HCL IN ACTIVE PHARMACEUTICAL INGREDIENT**

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ABSTRACT

A simple, accurate, precise and sensitive UV-Vis method has been developed for simultaneous estimation of Saxagliptin HCL and Metformin HCL in active pharmaceutical ingredient form by using quality by design (QbD) approach. A UV spectroscopic method was validated in terms of input variable effects on characteristics of UV spectrum were selected for critical parameters selection and parameters like linearity, accuracy, precision, robustness, ruggedness. The ICH guidelines Q8 to Q11 have discussed QbD implementation in API synthetic process and formulation development. Analytical QbD key tools are identification of critical quality attributes (CQA) with risk assessment, control strategy and Risk assessment, Analytical QbD method validation, continuous method monitoring (CMM) and continual improvement. The wavelength of 204.5nm and 232.5 nm are selected as absorbance maxima for Saxagliptin HCL and Metformin HCL respectively.

Keywords: Saxagliptin HCL, Metformin HCL, Quality by design, UV-Vis method

INTRODUCTION

Saxagliptin mainly used for the treatment of class of medications called dipeptidyl type 2 diabetes mellitus. Saxagliptin is in a peptidase-4 (DPP-4) inhibitors. Chemically



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ORIGINAL ARTICLE

OPEN ACCESS

Area Under Curve By UV Spectrophotometric Method For Determination Peliperidone In Bulk

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ABSTRACT

The aim of present investigation is to establish simple, precise, and rapid Spectrophotometric method for the quantification of Peliperidone in palmitate intramuscular injection. In this, work is carried out to for estimation of Peliperidone bulk by utilizing an Area under Curve (AUC) method using UV - Visible Spectrophotometry. The study is designed to validate the developed methods as per ICH guidelines. For this purpose the wavelength range between 400-800 nm was selected. Methanol and ethanol (50 ml methanol used for stock solution and serial dilution in 25 ml ethanol) was used as a solvent throughout the work. Linearity was obtained in concentration range 2 to 10 µg/ml ($r^2 = 0.950$) for the method. The developed method was found to be simple, linear, accurate, precise and highly sensitive and which can be used for routine quality control analysis for Spectrophotometric estimation of Active Pharmaceutical Ingredient.

Key words: Peliperidone, linearity, AUC, spectrophotometer, methanol, ethanol.

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INTRODUCTION

A peliperidone palmitate a new acting antipsychotic injection is Peliperidone is structurally related to schizophrenia that is effective against many diseases. It is also called as (9-(hydroxyrisperidone)-5HT(2A)-Peliperidone-5HT(2A)) [1] Pharmacologically citric acid Peliperidone is a schizophrenia. The principal mechanism of action of action for Peliperidone is by its inhibitory effect on antagonist at (alpha and beta which results in the adrenergic receptors H(1) receptors. [1] Peliperidone predominantly used in treatment of such antipsychotic that causes cysts in brain and janssen placebo. Peliperidone is practically insoluble in ethanol and sparingly soluble in methanol. Hence the analysis of Peliperidone is carried out in mixture of ethanol and methanol. The aim of this present work is to develop simple, precise and accurate Spectrophotometric method for the routine determination of Peliperidone in bulk. [2]

MATERIAL AND METHODS

Chemicals:

Peliperidone was obtained at collage sample of Vishal institute pharmaceuticals education and research ale, pune. Methanol, and ethanol was used as solvent throughout the experimentation.

Instrumentation:

A Shimadzu (Kyoto, Japan) model UV- 1800 double beam UV- Visible spectrophotometer attached with computer operated by software with UV probe 2.33. Spectral width of 2 nm, wavelength accuracy of 0.5 nm and pair of 1 cm matched quartz cells was used to measure absorbance of the resulting solutions. Digital Analytical balance, Mettler Toledo (Model JL 1503-C) was used for weighing purpose.

Experimental Work:

A) To check the solubility of Peliperidone:

Qualitative solubility analyses of drugs were done by dissolving 5 mg of Peliperidone in 5 ml solvent such as ethanol, methanol and ethanol. [3]

B) To identify the λ max of Peliperidone:

Weigh 10 mg of the pure drug (Peliperidone) and dissolve it in small portion of methanol and make up the volume up to 100 ml using methanol to obtained a standard stock solution of 100 µg/ml this solution is sonicate for 5 min to obtained clear solution. From above solution withdraw 0.5, 1, 1.5, 2, 2.5 ml and dilute with methanol to get standard solutions of concentrations: 2, 4, 6, 8 and 10 µg/ml. [4, 5] Spectrum peak details are shown in Figure No 2.



ज्ञानगंगा घरोघरी

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2020-2021




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Rp-Hplc Assay Method For Estimation Of Dimethyl Fumarate In Bulk And Capsules

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ABSTRACT:-

A simple, sensitive and accurate gradient reverse phase high performance liquid chromatography method was developed for determination of dimethyl fumarate in formulation . RP-HPLC method has been developed and validated to live dimethyl fumarate at wavelength (210nm) in order to assay. The retention time of dimethyl fumarate was found to be 3.3 ± 0.02 min. the worth of coefficient of correlation between peak area and concentration was found to be 0.9987. The mean percent recovery of dimethyl fumarate in capsules was found within the range of 99.65 to 101.64%. The results of forced degradation studies indicated that the drug was found to be stable in basic, oxidative and thermal conditions while degraded in acidic conditions. The mixture of buffer and ACN, in the ratio (70:30) used as a mobile phase .It are often conducted from results that the developed HPLC method is straightforward , accurate, precise and specific. Results of stress testing study revealed that the tactic is stability indicating. Thus, this method are often used for routine analysis of dimethyl fumarate capsules and check their stability.

Keywords : RP-HPLC, Method validation, Stability indicating assay method, Dimethyl fumarate, Simple and accurate method.

INTRODUCTION

Dimethyl fumarate is an anti-inflammatory drug, which is chemically trans-Butenedioic acid dimethyl ester [7]. The US FDA approved Tecfidera capsules (containing 240 mg of dimethyl fumarate) on March 27, 2013. This drug is indicated for the treatment of a patient with relapsing forms of multiple sclerosis [2]. Dimethyl fumarate isn't a politician drug in any Pharmacopoeia. Literature survey revealed that some methods have been reported for the determination of dimethyl fumarate by HPLC [3-6] and hyphenated techniques such as LC-MS [1], either alone or in combination. However, there's no stability indicating HPLC assay method was reported yet for estimation of dimethyl fumarate in capsules. This paper presents an easy stability indicating RP-HPLC assay method for estimation of dimethyl fumarate in bulk and capsules which will be utilized in stability testing.

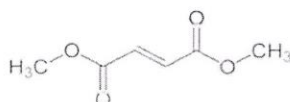


Fig. 1: Chemical structure of dimethyl fumarate

MATERIALS AND METHODS

Chemicals and reagents

Dimethyl Fumarate API was procured from gift sample in collage for research pourpose. Capsules (containing 240 mg of dimethyl fumarate) were obtained in market brand Tecfidera capsule of Biogen



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ORIGINAL ARTICLE

OPEN ACCESS

Area Under Curve UV Spectrophotometric Method for Determination of Sildenafil Citrate in Bulk

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ABSTRACT

To develop two simple UV spectroscopic methods for simultaneous estimation of Sildenafil citrate in bulk validates as per ICH guidelines. Method A involve Absorption maxima method which based on measurement of absorbance at λ_{max} of Sildenafil citrate 292.20 nm and Method B involves Area Under Curve (AUC) method which based on the measurement of AUC in the range of 277.0 – 304.00 nm. The developed method validated for Linearity, Precision, LOD and LOQ as per ICH guidelines. Both the methods were found to be linear within concentration range 5-25 $\mu\text{g/ml}$ for Sildenafil citrate.

Keywords: Sildenafil citrate API, phosphodiesterase type inhibitors, Area Under Curve Method, λ_{max} .

Received 18.04.2020

Revised 12.05.2020

Accepted 03.06.2020

INTRODUCTION

Sildenafil citrate is a potent and selective inhibitor of phosphodiesterase type 5 inhibitors. Chemically it is 5-[2-ethoxy-5-(4-methylpiperazin-1-yl)sulfonylphenyl]-1-methyl-3-propyl-6H-pyrazolo[4,3-d]pyrimidin-7-one. Sildenafil Citrate is the citrate salt of a pyrazolopyrimidinone derivative structurally related to zaprinast. Sildenafil selectively inhibits cyclic guanosine monophosphate (cGMP)-specific type 5 phosphodiesterase, resulting in vasodilation in the corpus cavernosum of the penis and penile erection (NCI04). Accordingly, the objective of this study was to develop and validate the simple spectrophotometric method for the estimation of Sildenafil citrate in bulk as per ICH guidelines. Drug was found to be freely soluble in methanol which was chosen for solvent proceeding studies. [1,2]. In the present study was to develop two simple UV spectroscopic methods for simultaneous estimation of Sildenafil citrate in bulk validates as per ICH guidelines.

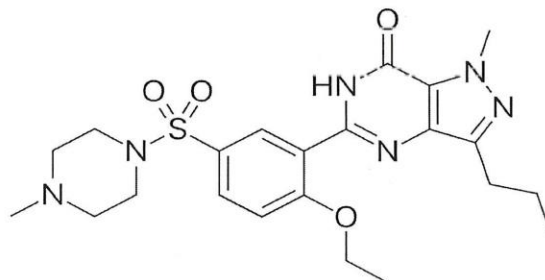


Figure 1: Chemical Structure of Sildenafil Citrate

MATERIAL AND METHODS

Chemicals

Sildenafil citrate was a gift sample from Flamingo Pharmaceutical, Taloja, Navi Mumbai, India. All chemicals and reagents used were of analytical reagent (AR) grade and purchased from Qualigens Fine Chemicals, Mumbai, India.

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ORIGINAL ARTICLE

OPEN ACCESS

Development and Validation of New Simple, Sensitive and Validated UV Spectrophotometric Method For The Simultaneous Estimation of Simvastatin and Labetalol

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ABSTRACT

A simple, precise and highly selective analytical method was developed for simultaneous estimation of Simvastatin and Labetalol in tablet formulation. Estimation was carried out by multicomponent mode of analysis at selected wavelength of 239 and 222.4 nm for Simvastatin and Labetalol respectively in 0.25 N NaOH. The method was validated in terms of linearity, accuracy (% Recovery), Precision (Interday, intraday, and reproducibility) and robustness. Methods were linear ($R^2 = 0.991 - 0.997$ for UV method) and accurate (% recovery was 98.3%-98.2%). The method was also obtained precise (% RSD < 2 %). The linearity was obtained in the concentration ranges of 2-10 µg/ml for Simvastatin and 2-10 µg/ml for labetalol. The method was validated as per international conference of Harmonization (ICH) guidelines.

KEYWORDS: Simvastatin, Labetalol, UV, ICH.

Received 13.04.2020

Revised 28.05.2020

Accepted 26.07.2020

INTRODUCTION

Simvastatin is chemically is 2,2-Dimethyl butanoic acid(1S,3R,7S,8S,8aR)-1,2,3,7,8,8ahexahydro- 3,7-dimethyl-8-[2-[(2R,4R)- tetrahydro-4- hydroxy-6 oxo2H pyran-2yl]ethyl]1-naphthalenyl ester used as a HMGCoA reductase inhibitors. Simvastatin belongs to a class of drugs called HMG-CoA reductase inhibitors commonly called statins that derived synthetically from fermentation products of *Aspergillus terreus*. All statins act by inhibiting 3-hydroxy-3-methylglutarylcoenzyme (HMG-CoA). A HMG-CoA reductase, the rate limiting enzyme of the HMG-CoA reductase pathway, the metabolic pathway responsible for the endogenous production of cholesterol mainly used for the treatment of dyslipidemia and the prevention of cardiovascular diseases. Simvastatin is prodrug which is converted into its β- hydroxy which inhibits HMG CoA reductase(3-hydroxy-3-methyl glutaryl Coenzyme A) enzyme, responsible for catalysing the conversion of HMG CoA to mevalonate at rate limiting step in the synthesis of cholesterol in liver.[2,3]

Labetalol HCl is a selective α₁ and non-selective β_{ad}renergic blocker used to treat high blood pressure. Chemically it is 2-hydroxy-5-[(1-hydroxy-2-(4 phenylbutane -2-yl) amino)ethyl]benzamide. It has amolecular formula of C₁₉H₂₄N₂O₃.Hcl and a molecular weight of 328.40g/mol.[2,3]

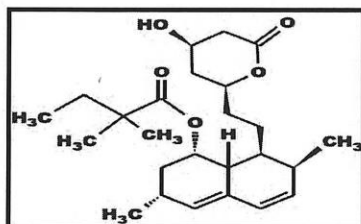


Fig.1 Chemical Structure of Simvastatin

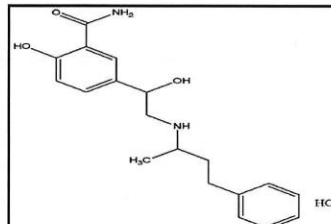


Fig.2 Chemical Structure of labetalol HCL



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ORIGINAL ARTICLE

OPEN ACCESS

Assay of Fusidic acid 1% w/w Viscous Eye Drops by HPLC

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ABSTRACT

A simple, precise and accurate method was developed and validated for analysis of Fusidic Acid 1% w/w Viscous eye drop formulation. An isocratic HPLC analysis was performed on Inertsil ODS column (4.6mm × 150 mm × 3.5 μ or equivalent). The compound was separated with the mixture of Methanol, Ortho-phosphoric acid and Acetonitrile as mobile phase, at flow of 1.5 mL/min. UV detection was performed at 235 nm using photo diode array detection. The retention time was found to be 19.5 min. The system suitability parameters such as theoretical plate count, tailing and percentage RSD between six standard injections were within the limit. The method was validated according to ICH guidelines. The developed method can be applicable for routine quantitative analysis.

Keywords: Fusidic acid, HPLC, Methanol, Ortho-phosphoric acid and Acetonitrile

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INTRODUCTION

Fusidic acid (FA) is a bacteriostatic antibiotic used in the treatment of primary and secondary skin infections caused by sensitive strains of *S. aureus*, Streptococci species, and *C. Minutissimum*. Fusidic acid is the steroidal antibiotic used to treat Gram positive infections. It acts by preventing the translocation of peptidyl tRNA. Fusidic acid₂ (2), chemically is 2-(16-acetyloxy-3,11-dihydroxy-4,8,10,14-tetramethyl-2,3,4,5,6,7,9,11,12,13,15,16-dodecahydro-1H-cyclopenta[a]phenanthren-17-ylidene)-6-methyl-hept-5-enoic acid. [1,2]

Fusidic acid is active in vitro against *Staphylococcus aureus*, most coagulase-positive staphylococci, Beta-hemolytic streptococci, *Corynebacterium* species, and most clostridium species. Fusidic acid has no known useful activity against enterococci or most Gram-negative bacteria (except *Neisseria*, *Moraxella*, *Legionella pneumophila*, and *Bacteroides fragilis*). Fusidic acid is active in vitro and clinically against *Mycobacterium leprae* but has only marginal activity against *Mycobacterium tuberculosis*. [3,4]

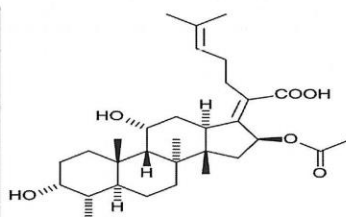


Figure1:- Chemical structure of fusidic acid

MATERIAL AND METHODS

Fusidic Acid standard:

Use the standard as such and use % potency on as is basis for calculations. Protect from light, preserve at a temperature of 2°C-8°C.



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ORIGINAL ARTICLE

OPEN ACCESS

Method Development and Validation of Saxagliptin Hydrochloride by RP-HPLC Method

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ABSTRACT

A sensitive, exact, rapid, avaricious and robust HPLC method was developed for the quantification of Saxagliptin Hydrochloride (SGH) with UV detector. In this method, a reversed-phase Grace C18 (250mm x 4.6ID, Particle size: 5 micron) column with a mobile phase of methanol: water (80:20; v/v) at 0.8ml/min flow rate was used to separate SGH with a detection of 212nm. The volume injected was 20 μ L. The retention time of SGH was obtained as 4.196 min. All necessary validation parameters and system suitability tests were carried out in details. The analytical curve was linear ($r^2 = 0.999$) over a wide concentration range (10 -50 μ g/ml). The system shows adequate accuracy with relative standard deviation less than 2.0%. The method showed good duplicability and recovery with % RSD less than 2%. So, the proposed system was found to be simple, specific, precise, accuracy, linear, and rugged. Hence it can be applied for practice analysis of Saxagliptin Hydrochloride (SGH) in bulk drug.

Keywords: RP-HPLC estimation, Method development, Validation, Saxagliptin HCl.

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Accepted 16.07.2020

INTRODUCTION

Analytical chemistry termed as science of determining the components of materials in terms of the elements or compound contained. The approach of this science are used to recognize the substances which may be present in a material and to determine the exact amounts of the identified substances. Analytical chemistry is important in nearly all aspects of chemistry. Analytical techniques proved in assuring and maintaining the quality of substance and are critical components of QA and QC.

Analytical method should be,

1. Most productive, economical and convenient,
2. As accurate and precise as required,
3. As simple as possible,
4. Most specific

Should be fully optimized before transfer for validation of its characteristics such as precision, accuracy, sensitivity etc.

According to USP, system suitability tests are integral part of chromatographic methods. These tests are used to verify that the reproducibility and resolution of the system are adequate for the analysis to be performed. framework such as plate count, symmetry factor, resolution and duplicability (%RSD retention time and area for 6 repetitions) are determined and compared against the specifications set for the method.

Now a day reversed-phase chromatography is the most commonly used disconnection method in HPLC due to its wide application range. It is approximate that over 65% (possibly up to 90%) of all HPLC disconnection are convey out in the reversed phase manner. The reasons for this incorporate the clarity, flexible, and scope of the reversed-phase method as it is able to hold compounds of a various duality and molecular mass.

Reversed phase chromatography has found both logic and preparative appeal in the district of biochemical detachment and clean. Molecules that possess some level of hydrophobic disposition can be separated by reversed phase chromatography with very good recovery and resolution. The separation



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ORIGINAL ARTICLE

OPEN ACCESS

Area Under Curve by UV Spectrophotometric Method for Determination of Ascorbic Acid in Bulk

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ABSTRACT

The aim of present work is to establish simple, precise, and rapid Spectrophotometric method for the quantification of Ascorbic acid in Active Pharmaceutical Ingredient. In this, work is carried out to for estimation of Ascorbic acid bulk by utilizing an Area under Curve (AUC) method using UV – Visible Spectrophotometry. The study is designed to validate the developed methods as per ICH guidelines. For this purpose the wavelength range between 200-400 nm was selected. Distilled water was used as a solvent throughout the work. Linearity was obtained in concentration range 2 to 10 µg/ml ($r^2 = 0.991$) for the method. The developed method was found to be simple, linear, accurate, precise and highly sensitive and which can be used for routine quality control analysis for Spectrophotometric estimation of Active Pharmaceutical Ingredient.

KEY WORDS: Ascorbic acid, AUC, distilled water, Spectrophotometer, linearity.

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Accepted 11.07.2020

INTRODUCTION

Ascorbic Acid also called as (vitamin C) is a freely water-soluble vitamin indicated for the prevention and treatment of scurvy, as ascorbic acid deficiency results in scurvy. Collagens like structures are primarily affected, and lesions produced in bones and blood vessels.[1] Administration of ascorbic acid completely reduced the symptoms of ascorbic acid (vitamin) deficiency. Ascorbic acid contains six carbon compound related to glucose nutraceutical compound. It is chemically described as (5R)-5-[(1S)-1,2-dihydroxyethyl]-3,4-dihydroxy-2,5-dihydrofuran-2-one. Ascorbic acid (Vitamin C) is an essential nutrient in human diets. And which is important to maintain connective tissue and bone. Its biologically active Vitamin C is considered an antioxidant. The aim of this present work is to develop simple, precise and accurate Spectrophotometric method for the routine determination of Ascorbic acid in bulk.[2]

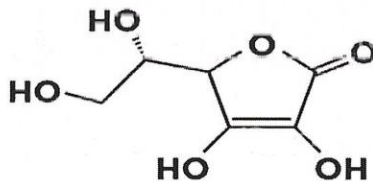


Fig No 1: Chemical Structure of Ascorbic acid

MATERIALS AND METHODS

Chemicals:

Ascorbic acid was obtained at collage sample of Vishal institute pharmaceuticals education and research ale, pune. Distilled water was used as solvent throughout the experimentation.



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ORIGINAL ARTICLE

OPEN ACCESS

A Development and Validation of By Using UV-Spectroscopic Methods for A Carbamazepine in Bulk Dosage Form

Shankar M. Dhobale*, Vikas D. Kedar, Suresh L. Jadhav, Salim G. Patel, Dushyant D. Gaikwad

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ABSTRACT

The Carbamazepine is sold under the name of anticonvulsant medication which is used for primary treatment of epilepsy and neuropathic pain. It is not effective for absence or myoclonic seizures. It is often considered to be one of the most vital drugs for the relief of pain associated with trigeminal neuralgia. Carbamazepine is related chemically to the tricyclic antidepressants. Aim of the Study was to develop and validate a simplified accurate, rapid, precise, reproducible and cost-effective Spectroscopic method for the quantitatively analysis estimation of carbamazepine in a pharmaceutical formulation.

Keywords: Carbamazepine, UV Spectrophotometry, Method development, Validation, Antiepileptic, Methanol.

Received 21.03.2020

Revised 06.05.2020

Accepted 29.07.2020

INTRODUCTION

The Carbamazepine, sold under the anticonvulsant medication used primary treatment of epilepsy and neuropathic pain. (fig.1) it is not effective for absence or myoclonic seizures. considered to be one of the most vital drugs for the relief of pain associated with trigeminal neuralgia [1-2] carbamazepine are related chemically to the tricyclic antidepressants. It is a derived of 5H-Dibenzo[b,f]azepine with a carbamoyl phosphate group of 5 positions this moiety is essential for potent antiseizure activity [3-4] it is white or almost white crystalline powder practically insoluble in the water freely soluble in methylene chloride sparingly soluble in acetone and alcohol practically insoluble ether. It shows polymorphism. carbamazepine is official in IP, BP, USP, etc [5-7] As per investigation of literature the UV spectrophotometric analytical method were developed on different wavelength for analysis of carbamazepine in plasma fluids human serum plasma and pharmaceutical tablet dosage form or bulk drug samples[8-11] the rationale of this work to develop a simple accurate rapid precise reproducible and cost-effective Spectrophotometric method for the direct quantitative determination of carbamazepine in this method for determination carbamazepine in bulk drug sample and tablet dosage form and validation as per international conference on Harmonization (ICH) guidelines [12].

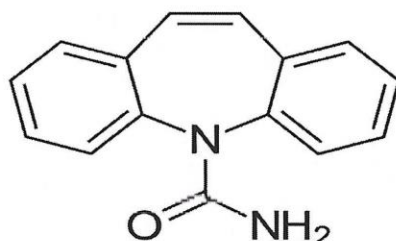


Fig.1: Chemical structure of Carbamazepine



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ORIGINAL ARTICLE

OPEN ACCESS

Area under Curve UV Spectrophotometric Method for Determination of Tadalafil In Bulk

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ABSTRACT

The aim of this work is to establish rapid, simple, precise and economical methods viz., area under curve were developed and validated for estimation of tadalafil in pharmaceutical dosage forms. Further, this study was designed to validate the developed methods as per ICH guidelines. The work was carried out to for estimation of Tadalafil in bulk pharmaceutical form by utilizing area under curve (AUC) method using UV-Visible Spectrophotometry. For this purpose the wavelength range 200-400 nm was selected. Methanol was used as a solvent throughout the work. Linearity was observed in concentration range 2-10 µm/ml ($r^2 = 0.9987$) for the method. The developed method was found to be simple, linear, precise, accurate and sensitive which can be used for routine quality control analysis for spectrophotometric estimation of Active Pharmaceutical Ingredient.

Keywords: Tadalafil, methanol, AUC method

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INTRODUCTION

Tadalafil is a Phosphodiesterase 5 inhibitor. Tadalafil is used to treat the male erectile dysfunction (impotence) and pulmonary arterial hypertension (PAH). Tadalafil is metabolized by CYP3A4 to a catechol metabolite. Tadalafil is a potent and selective inhibitor of cGMP specific phosphodiesterase type 5 (PDE5) which is responsible for degradation of cGMP in the corpus cavernosum. Tadalafil chemically, (2R,8R)-2-(2H-1,3-benzodioxol-5-yl)-6-methyl-3,6,17-triazatetracyclo[8.7.0.0.3,6.0.0]^{14, 18} heptadeca-1(10), 11,13,15-tetraene-4,7dione (Fig 1) Tadalafil is an annulated 2,5-diketopiperazine. It is also a 1,2,3,4-tetrahydro-β-carboline.

Accordingly, the objective of this study was to develop and validate the simple spectrophotometric method for the estimation of tadalafil in bulk as per ICH guidelines. Drug was found to be freely soluble in methanol which was chosen for solvent proceeding studies. [1,2]

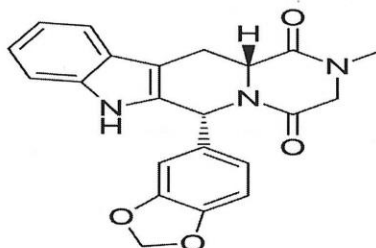


Figure 1: Chemical Structure of Tadalafil



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ORIGINAL ARTICLE

OPEN ACCESS

Simultaneous Estimation and Validation of Meclizine Hydrochloride and Caffeine in Bulk and Tablet Dosage Form By RP-HPLC

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ABSTRACT

A Simple, selective, rapid, sensitive and validated RP-HPLC (High Performance Liquid Chromatography) method has been developed for separation and analysis of meclizine hydrochloride and caffeine in bulk and in tablet dosage form. Separation was achieved on a reversed-phase Cosmosil C18, (250×4.6ID, 5μ) using a mobile phase Methanol: Water (65:35 v/v) at flow rate of 0.9 ml/min. The pH was adjusted to pH 3 by the addition ortho phosphoric acid (OPA). The samples were detected using a UV detector at 225 nm. The chromatographic conditions yield good separation between drugs with retention time (RT) 3.846 for meclizine hydrochloride and 5.825 for caffeine. Proposed method was validated according to ICH guidelines, which include linearity, precision, accuracy, robustness. The result obtained were within the acceptance criteria as per ICH guidelines.

Keywords: HPLC, meclizine hydrochloride, caffeine, Methanol, water, Reverse Phase Chromatography, Validation.

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INTRODUCTION

Analytical chemistry is the science of obtaining, processing, and communicating information about the composition and structure of matter. In other words, it is the art and science of determining what matter is and how much of it exists. Analytical chemistry plays an important role in nearly all aspect of chemistry for example agriculture, clinical, environmental, forensic, manufacturing, metallurgical, and pharmaceutical chemistry. The scientific approach which the analytical chemist applies consist of series of steps which includes understanding and defining the goal of analysis; nature of the sample; literature search; plan of action and execution.[1,2]

At present several analytical methods are available for analyzing analytes viz. spectroscopic and chromatographic. Spectroscopic method includes UV-visible, infrared, mass, NMR, absorbance spectroscopy while chromatographic methods include high performance liquid chromatography (HPLC), high-performance thin-layer chromatography (HPTLC), gas chromatography (GC), super-critical chromatography, gel permeation chromatography methods etc. Quality of manufactured drug in tablets, solution and emulsion form must be carefully controlled in pharmaceutical industry otherwise the drug can itself affect the therapeutic value. [3,4]

When completely unknown sample is presented to an analyst, the first requirement is usually to ascertain what substances are present in it. The solution of such problem lies within the provenance of Qualitative analysis. In both types of analysis the required information is obtain by measuring physical and chemical properties that are characteristically related to the components of interest. [5,6]

MATERIAL AND METHODS

Instrument Used:

HPLC: HPLC 3000 series P-3000-M reciprocating (UV Visible Detector)

Active Pharmaceutical Ingredients Used:

Meclizine hydrochloride



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ORIGINAL ARTICLE

OPEN ACCESS

Simultaneous Estimation Quantitation of Guggulsterone E & Z from Pharmaceutical Solid Dosage form by Using High Performance Liquid Chromatography

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ABSTRACT

Guggul is the oleo-gum-resin which is obtained from deep incisions at the basal part of stem bark of *Commiphora wightii* belonging to Burseraceae family. It is very popular ancient Ayurvedic medicine used to cure various diseases. In Ayurveda guggul is always purified prior to use in different formulations. This process is known as *sodhana*. Guggulsterone E and Z are the prime constituents of *Commiphora wightii*. This formulation contains extract of various crude drugs which is used in the following disease condition i.e Osteoarthritis, Rheumatoid arthritis, Gouty arthritis, Lumbago, Sciatica & Spondylosis. Guggulsterone (GS) (4,17 (20)-pregnadiene-3,16-dione) is a plant polyphenol (steroid). HPLC is preferred over other analytical method due to its several advantages such as reproducible, fast, simple method and many samples as well as standards can be tested simultaneously. It is cost-effective method. In this we used methanol acetonitrile and Orthophosphoric acid HPLC Grade solvents. Run time is 35 minutes. Column used is Inertsil – ODS-4 Column, 5 μ (4.6 X 250 mm). We used the tablet dosage form for the estimation and quantification of active components. Below method is validated as per ICH guidelines and results are acceptable and in the range. This method can be also used in the industry for the estimation of the Guggulsterone E & Z from the various dosage forms.

Key words: Guggulsterone E & Z, HPLC, estimation, quantification, Validation.

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INTRODUCTION

For the past few decades, compounds obtained from natural sources have been gaining importance because of their vast chemical diversity and activity many of them are being used as a medicine. Herbal-based medicines have traditional value in the curing of various diseases, and now it has become more popular due to its scientifically known pharmacological activity with fewer side effects [1]. Hence from last few years research activities regarding natural resources were increased. The WHO has taken a keen interest in the quality control of herbal medicine and recommends the use of High Performance Liquid Chromatography (HPLC) for the characterization and quality assurance of herbal medicines [2].

Commiphora genus has approximately 165 species. All species are very slow growing with small thorny, sturdy, highly branched small balsamiferous trees with a short trunk and thin papery bark [3]. *Commiphora wightii* (Arn.) Bhandari is one of the species which is widely cultivated in rocky tracts of the dry and semi-dry region of India, Pakistan, Bangladesh, In India, it is found in dry, rocky and sandy tracts of Rajasthan, Gujarat, Maharashtra, and Karnataka [4]. It is commonly known as "Guggul" or "Indian Bdellium" due to the presence of aromatic steroidal kenotic compounds like guggulsterone E&Z and its related guggulsterone I-IV. According to the Ayurvedic history, guggul is considered as a God gift. According to Vedas guggul is described as "Agni Sthana" and used for dhupa. Guggul was used externally as well as internally during the period of Charaka (1000 B.C.) and Sushruta (600 B.C.). Vagbhata (1700 A.D.) has described the use of guggul as a drug of choice for *medoroga* and *vatavikaras* [5].

In case of dry form when it is prepared in Tablet form the amount of Guggulsterone E & Z both isomers must have to find. The amount of guggulsterone E&Z depends upon the exposer of light, temperature, packaging, duration of storage, climatic conditions under which the plants are grown and the harvesting method. The hypolipidemic activity was found to be related guggulsterone E&Z (cis- and trans-4, 17(20)-



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ORIGINAL ARTICLE

OPEN ACCESS

UV-Spectrophotometric Method for Simultaneous Estimation of Simvastatin and Metformin in Bulk and Solid Dosage Form

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ABSTRACT

A simple, accurate, precise, sensitive, and highly selective ultra violet spectrometer method has been developed for the simultaneous estimation of simvastatin and Metformin in bulk and solid dosage form. The estimation of simvastatin was carried out at 239 nm while metformin was estimated at 239 nm. The developed method was validated for linearity range, precision, recovery studies and interference study for mixture, all these parameter showed the adaptability of the method for the method quality analysis of the drug in bulk and combination formulation.

Keywords: Simvastatin, Metformin, UV Spectrophotometric, Dosage form.

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INTRODUCTION

Simvastatin is chemically is 2,2-Dimethyl butanoic acid (1S,3R,7S,8S,8aR)-1,2,3,7,8,8ahexahydro- 3,7-dimethyl-8-[2-[(2R,4R)- tetrahydro-4-hydroxy-6 oxo2H pyran-2yl]ethyl]1-napthalenyl ester used as a HMGCoA reductase inhibitors. Simvastatin belongs to a class of drugs called HMG-CoA reductase inhibitors commonly called statins that derived synthetically from fermentation products of *Aspergillus terreus*. All statins act by inhibiting 3-hydroxy-3-methylglutarylcoenzyme (HMG-CoA). A HMG-CoA reductase, the rate limiting enzyme of the HMG-CoA reductase pathway, the metabolic pathway responsible for the endogenous production of cholesterol mainly used for the treatment of dyslipidemia and the prevention of cardiovascular diseases. Simvastatin is prodrug which is converted into its β -hydroxy which inhibits HMG CoA reductase (3 hydroxy 3 methyl glutarylCoenzyme A) enzyme, responsible for catalysing the conversion of HMG CoA to mevalonate a rate limiting step in the synthesis of cholesterol in liver.[9]

Metformin is a biguanide oral hypoglycemic used primarily for treating type 2 diabetes mellitus (T2D). It has molecular formula $C_4H_{11}N_5$ and molecular weight 135, chemically it is a 1,1-Dimethylbiguanide.[8]

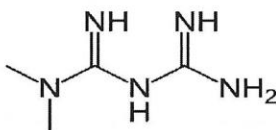


Figure1-Chemical structure of metformin



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ORIGINAL ARTICLE

OPEN ACCESS

**Development and Evaluation of Sustained Released Tablet
 Formulation Containing Fluphenazine HCl**

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ABSTRACT

The aim of the present work was to develop pharmaceutical dosage treatment of many patients with Dementia - related psychosis with at high risk of antipsychotic. Fluphenazine HCl drug to treat the psychotic Patient. drug to treat the high risk central nervous system disease simultaneous. In this formulation three batches are prepared by direct compression method preformulation parameter such as identification, solubility, melting point, compatibility studies and precompression parameter bulk density, tapped density, angle of repose, Hausner ratio, compressibility index and post compression parameter weight uniformity, hardness, drug content, thickness, in vitro drug release. In vitro drug release Fluphenazine HCl of all formulation B1, B2, B3 was carried out in 2hrs 0.1HCl and the 10 hrs in phosphate buffer pH dissolution media. Among all the formulation B3 was optimized as best formulation. B3 formulations B3 showed 85% for Fluphenazine hydrochloride maximum drug release at 12hrs.

Keywords: Sustained release tablet, Fluphenazine HCl.

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INTRODUCTION

Sustained-release oral delivery systems are designed to achieve therapeutically effective concentrations of drug in the systemic circulation over an extended period of time. Possible therapeutic benefits of properly designed SR dosage form include low cost, simple processing, improved efficacy, reduced adverse events, flexibility in terms of the range profiles attainable, increased convenience and patient compliance^[1].

Currently Fluphenazine hydrochloride available as separate tablet for the treatment of dementia-related psychosis. The formulation were prepared by granulation compression method. Single tablet containing only one drugs such as Fluphenazine Hcl release the compression typically done by using Lactose monohydrate and microcrystalline cellulose. The compatibility parameter preformulation study compression parameter and in vivo parameters were performed with pharmaceutical expectable^[2]. The aim of the present work was to develop pharmaceutical dosage treatment of many patients with Dementia - related psychosis with at high risk of antipsychotic.

MATERIAL AND METHODS

Materials

Fluphenazine HCl gifted sample (flamingo pharmaceutical) HPMCK4, (Thermosil fine chem), microcrystalline cellulose (research lab), magnesium stearate (Hilab chemicals) were sample is analytical grade^[3, 4].

Preparation of Tablet

The Fluphenazine hydrochloride were prepared by Granulation compression method using varying proportion of polymers either alone or combination. The ingredients were passed through 40 and 60 mesh sieve calculated amount of drug polymer (Lactose monohydrate, Starch 1500, Avicel PH 102, Super tab 14 SD microcrystalline Cellulose) was mixed thoroughly. Then it make a dry mix. Add purified water until wet granulation. Dry it. magnesium stearate was added as lubricant. The appropriate amount of the mixture was weighed and the compression machine(MAKE CREATE INDUSTRIES,MODEL-LP-8GMP).





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ORIGINAL ARTICLE

OPEN ACCESS

Area Under Curve UV- Spectrophotometric Method For Determination of Lurasidone HCl in Bulk

M. V. Gadhave*, S. R. Abhang, S. L. Jadhav, D. D. Gaikwad, S. M., Dhobale

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ABSTRACT

The simple, precise, and accurate UV-Spectrophotometric method has been developed and validated for the estimation of Lurasidone Hydrochloride in bulk. In that work was carried out for estimation of Lurasidone Hydrochloride in bulk by utilizing area under curve (AUC) method. For this purpose the wavelength range 200-400nm was selected. Methanol was used as solvent throughout the work. Linearity was observed in concentration range 5-25µg/ml for the method. The present method was found which can be used for routine quality control analysis for spectrophotometric estimation of Lurasidone Hydrochloride.

Keywords: Lurasidone Hydrochloride API, Area Under Curve Method, λ max.

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INTRODUCTION

Lurasidone is an atypical antipsychotic approved by the U.S. Food and Drug Administration (FDA) for treatment of Schizophrenia on October 28, 2010 [1]. Lurasidone Hydrochloride (3aR,4S,7R,7aS) - - ((1R,2R) -2 -[4 - (1,2 - benzisothiazol-3-yl) piperazin -1- ylmethyl] cyclohexylmethyl) hexahydro - 4, 7- methano -2H isoindole - 1,3 -dione hydrochloride (Fig.1) is a azapirone derivative antipsychotic used in the treatment of schizophrenia [2]. The efficacy of Lurasidone Hydrochloride in schizophrenia is mediated through a combination of central dopamine Type 2 (D2) and serotonin Type 2 (5HT2A) receptor antagonism and it gives Antipsychotic Activity. Lurasidone is metabolized in the liver via the enzyme CYP3A4 [3]. This means that its plasma concentrations may be increased when combined with CYP3A4 inhibitors like ketoconazole or grape fruit juice, possibly leading to more side effects. As with other Atypical Neuroleptics, Lurasidone should not be used in elderly patients because it puts them at an increased risk for a stroke or transient ischemic attack [3,4].

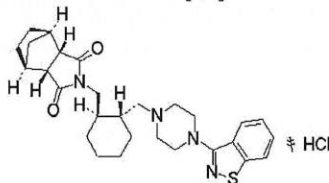


Figure 1: Chemical Structure of Lurasidone Hydrochloride

Literature search reveals following methods reported viz., simple spectrophotometric method for the estimation of Lurasidone in tablet dosage form [5,6], Simple RP-HPLC method for quantitative analysis of Lurasidone [7,8,9,10], LCMS method for quantification of Lurasidone in rat plasma and its application in pharmacokinetic studies [11] and Stability Indicating HPLC method for determination of Lurasidone in pharmaceutical dosage form [12]. To the best of our knowledge, no area under curve method has been reported for Lurasidone Hydrochloride. The present work describes a simple area under curve method of Lurasidone HCl.



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ORIGINAL ARTICLE

OPEN ACCESS

Area Under Curve UV Spectrophotometric Method for Determination of Sildenafil Citrate in Bulk

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ABSTRACT

To develop two simple UV spectroscopic methods for simultaneous estimation of Sildenafil citrate in bulk validates as per ICH guidelines. Method A involve Absorption maxima method which based on measurement of absorbance at λ_{max} of Sildenafil citrate 292.20 nm and Method B involves Area Under Curve (AUC) method which based on the measurement of AUC in the range of 277.0 – 304.00 nm. The developed method validated for Linearity, Precision, LOD and LOQ as per ICH guidelines. Both the methods were found to be linear within concentration range 5-25 $\mu\text{g/ml}$ for Sildenafil citrate.

Keywords: Sildenafil citrate API, phosphodiesterase type inhibitors, Area Under Curve Method, λ_{max} .

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INTRODUCTION

Sildenafil citrate is a potent and selective inhibitor of phosphodiesterase type 5 inhibitors. Chemically it is 5-[2-ethoxy-5-(4-methylpiperazin-1-yl)sulfonylphenyl]-1-methyl-3-propyl-6H-pyrazolo[4,3-d]pyrimidin-7-one. Sildenafil Citrate is the citrate salt of a pyrazolopyrimidinone derivative structurally related to zaprinast. Sildenafil selectively inhibits cyclic guanosine monophosphate (cGMP)-specific type 5 phosphodiesterase, resulting in vasodilation in the corpus cavernosum of the penis and penile erection. (NCI04). Accordingly, the objective of this study was to develop and validate the simple spectrophotometric method for the estimation of Sildenafil citrate in bulk as per ICH guidelines. Drug was found to be freely soluble in methanol which was chosen for solvent proceeding studies. [1,2]. In the present study was to develop two simple UV spectroscopic methods for simultaneous estimation of Sildenafil citrate in bulk validates as per ICH guidelines.

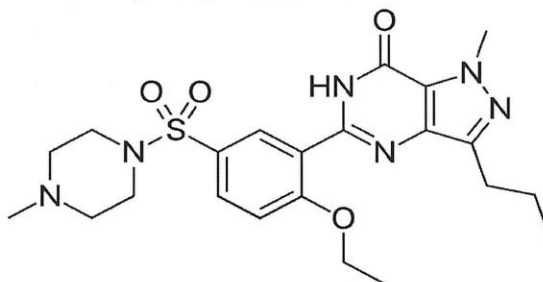


Figure 1: Chemical Structure of Sildenafil Citrate

MATERIAL AND METHODS

Chemicals

Sildenafil citrate was a gift sample from Flamingo Pharmaceutical, Taloja, Navi Mumbai, India. All chemicals and reagents used were of analytical reagent (AR) grade and purchased from Qualigens Fine Chemicals, Mumbai, India.



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ORIGINAL ARTICLE

OPEN ACCESS

Area Under Curve UV- Spectrophotometric Method for Determination of Cycloserine in Bulk

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ABSTRACT

The aim of this work is to establish simple, economical, and rapid spectrophotometric method for the quantification of cycloserine in Active Pharmaceutical Ingredient. Further, this study is designed to validate the developed methods as per ICH guidelines. The work was carried out to for estimation of cycloserine in bulk pharmaceutical form by utilizing area under curve (AUC) method using UV-Visible Spectrophotometry. For this purpose the wavelength range 200-400 nm was selected. 0.01N HCL was used as a solvent throughout the work. Linearity was observed in concentration range 5-25 µm/ml ($r^2 = 0.9962$) for the method. The developed method was found to be simple, linear, precise, accurate and sensitive which can be used for routine quality control analysis for spectrophotometric estimation of Active Pharmaceutical Ingredient.

Keywords: Cycloserine, 0.01N HCL, UV-Visible Spectrophotometry, Area Under Curve.

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INTRODUCTION

Cycloserine is a drug used as an antibiotic. It prevents tuberculosis bacteria from growing in your body. Cycloserine is also sometimes used to treat urinary tract and other types of infections that have not responded to other treatments. Cycloserine may also be used for purposes other than those listed medication guide. Chemically cycloserine is known as D-4-Amino-3-isoxazolidone as shown in Figure 1. Molecular formula is $C_3H_6N_2O_2$ and it is molecular weight 102.09 [1, 2]. Cycloserine which melting point on 147°C, it is white or pale yellow colour which is slightly hygroscopic in nature and degrade upon expose to humid atmosphere, So cycloserine should be kept in tightly closed container [3, 4]. A literature survey revealed a method such as UV- spectrophotometric method for the determination of cycloserine in bulk material [5, 6]. In this work two simple, economical, and rapid spectrophotometric methods have been established for the quantification of cycloserine in bulk material.

The developed methods were validated for accuracy, precision, ruggedness, and sensitivity. Accordingly, the objective of this study was to develop and validate the simple spectrophotometric method for the estimation of cycloserinehydrochloride in bulk and tablets as per ICH guidelines [7.] Drug was found to be freely soluble in 0.01N HCL which was chosen for solvent proceeding studies [8].

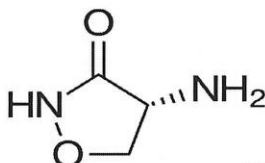


Figure 1: Chemical Structure of Cycloserine.



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ORIGINAL ARTICLE

OPEN ACCESS

**Design, Formulation and Evaluation of Osmotically Controlled
 Release Tablet of Simvastatin**

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ABSTRACT

The objective of present investigation is to Formulate and development of controlled release Simvastatin Tablet based on Osmotically Controlled Release technology to increase the residence time of drug to improve the therapeutic effect by increasing the bioavailability. Simvastatin is the lipid lowering agent which is used to decrease the bad cholesterol level. It is potent inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme, [HMG-CoA] reductase which catalyzes the conversion of HMG-CoA to Mevalonate, an early rate determining step in cholesterol biosynthesis. For the preparation of osmotic controlled release tablet sodium chloride, mannitol is used as the osmotic agent. Sodium Lauryl Sulphate is used as wetting agent and pvpk30 as a binder. Isopropyl alcohol is used as the solvent for wet granulation. For the coating of the tablet various concentration of coating solution are used in which cellulose acetate PEG400 are used. Sorbitol is used as pore forming agent. Pre-formulation study, Micromeritics properties of granules was performed and the result was found to be limit. The prepared tablets were subjected to post-compression parameters and the percentage release found to be 83.8%. S2c2 batch shows optimum batch. The dissolution data were subjected to various release kinetic model to recognize the mechanism of drug release. Finally it is concluded that s2c2 formulation shows optimum result as osmotic controlled release tablet by attaining zero order drug release for the effective treatment of hypercholesteremia.

KEYWORDS: Simvastatin, Osmotic release, controlled release, coating, semipermeable, tablet.

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INTRODUCTION

Oral route is one of the convenient and efficient routes of drug administration. It is effective to achieve the local and systemic effect of drug. Conventional dosage form is usually in the form of two or three daily doses, which can show large fluctuations in the drug plasma concentration and cause side effects on the human body. These problems are overcome by developing innovative methods for drug delivery via the oral route. Osmotically controlled drug delivery is the important approach to achieve the controlled release of drug to obtain sufficient bioavailability. Osmotically controlled oral drug delivery system is the one which utilizes osmotic pressure for controlled delivery of active agent. In which core tablet is coated with rate controlling polymer which acts as a semi-permeable membrane with a micro-orifice drilled on the surface through which drug is released for longer period. [1-12]. Simvastatin is the lipid lowering agent which is used to decrease the bad cholesterol level. It is potent inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme, [HMG-CoA] reductase which catalyzes the conversion of HMG-CoA to Mevalonate, an early rate determining step in cholesterol biosynthesis. [2] The primary uses of Simvastatin are to treat dyslipidemia and to prevent atherosclerosis-related complications such as stroke and heart attacks in those who are at high risk. Simvastatin reduced overall mortality in people with existing cardiovascular disease and high LDL cholesterol by 30% and reduced cardiovascular mortality by 42%. The risks of heart attack, stroke, or needing a coronary revascularization procedure were reduced by 37%, 28%, and 37%, respectively. [3] Absorption of Simvastatin is about 85% of an oral administration. However, because of Simvastatin undergoing extensive first-pass metabolism and hence bioavailability is low, it is about 5%. Both Simvastatin and its β -hydroxy acid metabolite are highly bound (approximately 95%) to human plasma proteins. Simvastatin can cross the blood-brain barrier. Route of elimination of an oral dose of ^{14}C -labeled Simvastatin in man, 13% of the dose was excreted in urine and 60% in feces. Peak plasma concentration





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ORIGINAL ARTICLE OPEN ACCESS

Formulation and Evaluation of Bilayer Tablet of Combination of Verapamil Hydrochloride and Ramipril for the Treatment of Hypertension by using Hydrophilic polymer

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ABSTRACT
The objective of present study is to develop a sustained release bilayer tablet of combination of verapamil hydrochloride and ramipril in the doses 50 mg and 10 mg respectively for to maintain constant levels of the drug for over 12 hrs. The both drugs possess antihypertensive effect; this combination is useful for severe cardiovascular disease such as angina pectoris, hypertension or congestive heart failure, heart attack, strokes, kidney problems. This bilayer tablet prepared by using superdisintegrant such as croscarmellose sodium which is for immediate release of ramipril and carbopol, xanthan gum, HPMC for sustained release layer of verapamil. All the formulations were possess preformulation parameters like solubility, compatibility (FTIR) study, melting point, precompression parameters such as angle of repose, bulk density, tapped density, Hausner's ratio and post compression parameters such as drug contained, friability, thickness, diameter were found to be within limits. In vitro studies of all formulated tablets were performed in acid buffer pH 1.2 for 30 min and phosphate buffer pH 6.8 for the remaining 12 hrs. The dissolution data were subjected to various release kinetic model to recognize the mechanism of drug release. The optimized formulation based on all the parameter R3 (cross carmellose sodium) is selected for immediate release layer and V3 (carbopol and HPMC) was selected for controlled release layer so it can be concluded that tablets were particularly suitable for sustained release action.
KEYWORDS: Verapamil HCl, Ramipril, Bilayer, Sustained release, Hydrophilic Polymer.

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INTRODUCTION
Oral route is the most frequently used route of drug administration and is the most convenient. Although solid-dose forms such as tablets and capsules have a high degree of drug stability in body and provide accurate dosage. Bilayer tablet is an innovative oral dosage form for continuous release of two drugs in

30°C Rain showers

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Research Article

Estimation of Nortriptyline hydrochloride in Bulk and Formulation by UV-Spectrophotometric Area Under Curve Method

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ABSTRACT

The simple, precise and accurate UV-Spectrophotometric method has been developed and validated for the estimation of nortriptyline hydrochloride in bulk and dosage form. In that work was carried out for estimation of nortriptyline hydrochloride in bulk and pharmaceutical dosage form by utilizing area under curve (AUC) method. For this purpose the wavelength range 200-400nm was selected. DMSO was used as solvent throughout the work. Linearity was observed in concentration range 5-25µg/ml ($R^2 = 0.996$) for the method. The present method was found which can be used for routine quality control analysis for spectrophotometric estimation of Nortriptyline hydrochloride in bulk and dosage form.

Keywords: Nortriptyline hydrochloride, Area under curve (AUC), DMSO, UV-Spectrophotometric.

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INTRODUCTION

Nortriptyline hydrochloride is 3 (10, 11 Dihydro 5H dibenzo [a, d] cyclohepten-5-ylidene propyl (methyl) amine hydrochloride were shown in Fig 1.

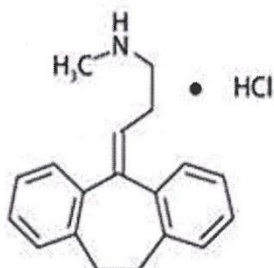


Figure 1: Chemical structure of Nortriptyline hydrochloride

Nortriptyline hydrochloride is an anti-depressant drug. It is a white or almost white powder and is sparingly soluble in water, sparingly soluble in ethanol (90%) and in methylene chloride¹. Nortriptyline hydrochloride was block the

reuptake of both nor adrenaline and serotonin into the pre synaptic terminals by binding to the transporters, viz. serotonin transporter (SERT) and norephidrin transporter (NET). The synaptic levels of this mono amine increased and there by prolong the action on the receptor. This Nortriptyline hydrochloride potentiates amine, neurotransmitter in the CNS^{2,3} Nortriptyline hydrochloride is the main active metabolite of Amitriptyline. It has been reported to have a longer plasma half-life than Amitriptyline. Nortriptyline hydrochloride is subject to extensive first-pass metabolism in the liver to 10-hydroxy Nortriptyline, which is active. Extensive literature survey revealed that only UV spectroscopy⁴⁻⁷ and PR-HPLC⁸⁻¹⁰ methods were reported for the estimation of Nortriptyline hydrochloride in combination with other drug but there is no method was reported for the estimation of area under curve of Nortriptyline hydrochloride in bulk and in formulation by UV-Spectrophotometry.

MATERIALS AND METHODS

1) Chemicals:

Nortriptyline hydrochloride standard drug substance was obtained as a gift sample from Alkem Laboratory, Mumbai. DMSO analytical reagent (AR) grade was used as solvent



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**Area under Curve UV Spectrophotometric Method for the
Determination of Chlorcyclizine Hydrochloride in Bulk.**

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ABSTRACT

The current work is carried out to for estimation of Chlorcyclizine Hydrochloride in bulk by utilizing area under curve (AUC) method using UV-Visible spectrophotometry. For this purpose the wavelength range 220-240nm was selected. Distilled water was used as a solvent throughout the work. Linearity was observed in concentration range 5-25µg/ml ($R^2=0.996$) for the method. The present method was found to be simple & linear which can be used for routine quality control analysis for spectrophotometric estimation of Chlorcyclizine Hydrochloride in bulk.

Keywords: Chlorcyclizine Hydrochloride, Area under curve, Antihistaminic, λ_{max} .

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HEB

**Phytochemical Analysis of Wound Healing
 Activity of the Leaves of Mundulea Sericea
 From Maharashtra**

JOHP

Kumbhar U. R., .Eknarayan R. A., Dharade S. Y., Deshmane J N., Babar R. B. Gadhave M.V. Jadhav S.L.

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ABSTRACT

The Mundulea sericea plant are the major source of drug comprising to different groups such as Wound healing activity, antioxidants, anti-insecticidal, anti-mycobacterial, antimicrobial and analgesic etc. To evaluate the phytochemical composition of Wound healing and the antioxidant activity of aqueous-methanolic (20:80) leaves extract of Mundulea sericea Willd. The composition of the non-polar extracts of the leaves, stem bark and twigs of Mundulea sericea (Fabaceae) were analyzed using IR, GC-MS. Eight, five and eleven components were identified from the leaves, twigs and stem bark extract, respectively. The phytochemicals screening was carried out standard experimental procedures in dry leaf powder of Mundulea sericea. This study scientifically validates the use of these plants in traditional medicines and the phytochemicals profile is helpful for standardization of indigenous drug.

Keywords: Mundulea sericea, Phytochemicals, Fabaceae and Wound healing activity.

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Zinjad et al

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Research Article

Solubility Enhancement of Azithromycin by Solid Dispersion Method by using Polymer PVP K 90

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ABSTRACT

Solubility is an important physicochemical factor affecting absorption of drug and its therapeutic effectiveness. In the solubility behavior of drugs remains one of the most exigent aspects in formulation development. Consequences of poor aqueous solubility would lead to failure in formulation development. Solubility enhancement leads to better absorption thus bioavailability improvement and Solid dispersions are investigated in many studies because they are highly versatile in their application. The poor solubility of drug substances in water and their low dissolution rate in aqueous G.I.T- fluid often leads to insufficient bioavailability. In the present investigation, an attempt was made to improve the solubility and dissolution rate of a poorly soluble drug, Azithromycin by solid dispersion method using PVP K 90 as carrier in 1:1, 1:2, 1:3, 1:4 and 1:5 ratios. Solid dispersion of Azithromycin was prepared by solvent evaporation method. In vitro release profiles of solid dispersions in phosphate buffer pH 6.8 were comparatively evaluated and also studied against pure Azithromycin. Faster dissolution was exhibited by PVP K 90 Solid dispersion containing 1:4 ratio. The prepared Solid dispersions were subjected for Assay, saturation solubility studies in distilled water and phosphate buffer pH 6.8.

Keywords: Azithromycin, PVP K 90, Solid dispersions, Methanol.

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Zinjad SS, Udmale DA, Suryawanshi AD, Jadhav SL, Gaikwad DD, Solubility Enhancement of Azithromycin by Solid Dispersion Method by using Polymer PVP K 90, Journal of Drug Delivery and Therapeutics. 2019; 9(3):121-124
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INTRODUCTION

Various techniques are used to enhance oral bioavailability of poorly water soluble drugs¹. These strategies may include the use of surfactants, cyclodextrins, Micronization², liquisolid techniques, Liposomes³, Ethosomes⁴, Dendrimers⁵, solid dispersions⁶ and permeation enhancers⁷.

Solid dispersions⁶:

Solid dispersions are investigated in many studies because they are highly versatile in their application. They can form the basis of products applied for various routes of administration and for various dosage forms, including the most popular oral dosage form.

Advantages of Solid Dispersions⁸:

- Solubility enhancement leads to better absorption thus bioavailability improvement.
- Better patient compliance in the form of solid dosage form.

- Need not to conduct clinical trials as in case of chemical approaches i.e. Prodrug, salt formation.
- Broad application.

- Ease of formulation and manufacture.

Disadvantages of Solid Dispersions:

- During processing (mechanical stress) or storage (temperature and humidity stress) the amorphous state may undergo crystallization.

- Moisture may increase drug mobility and promote drug crystallization.

- Phase separation, crystal growth or conversion from the amorphous to the crystalline state or from a metastable crystalline form to a more stable structure during storage.

- Poor scale-up for the purposes of manufacturing.

Mechanisms of increased solubility due to solid dispersion^{6,8}:

- Size reduction of drug.
- Solubilization effect of the carrier.

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Devhadrao et al

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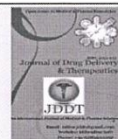
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Research Article

In-Vitro Anti-Fungal Activity and Phytochemical Screening of Stem Bark Extracts from *Ventilago denticulata*

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ABSTRACT

The objective of the present study was to assess the antifungal activity of pet. Ether extract, acetone extract, ethyl acetate, and ethanol bark extract of *Ventilago denticulata* (VD). The material was dried in shade made to a coarse powder and weighted quantity of the powder (1000 g) was subjected to hot percolation in a soxhlet apparatus using petroleum ether, ethyl acetate, acetone and ethanol, at a temperature range of 40-80°C. Phytochemical tests were done in presence of phytoconstituents like glycosides, alkaloids, tannins, steroids, flavonoids. The anti-fungal activity was carried out by using cup method using Sabraud's agar as medium. Plates were incubated at 25°C for 42hr and later observed for zones of inhibition. The effect of the extracts on fungal isolates was compared with Griseofluvin at a concentration of 10 mg/ml. The Ethyl acetate extract at low as well as high doses gives antifungal effect. Pet-ether extract, acetone extract and ethanolic extract did not produce any antifungal effect at both doses. Ethyl acetate extract shows zone of inhibition at low dose (T₁: 10 mg/ml) 10 mm and at high dose (T₂: 20 mg/ml) 16 mm.

Keyword: *Ventilago denticulata*, Anti-fungal, Griseofluvin.

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INTRODUCTION

Traditional medicines initially took the form of crude drugs such as tinctures, teas, poultices, powders, and other herbal formulations¹. The specific plants to be used and the methods of application for particular ailments were passed down through oral tradition. Plants with possible antimicrobial activity should be tested against some microbes to confirm the activity. The activity of plant extracts on bacteria and fungi has been studied by a very large number of researchers in different parts of the world^{2, 3}. As a result, antifungal therapy is playing a greater role in health care and the screening of traditional plants in search of novel antifungal is now more frequently performed⁴. The selection of crude plant extracts for screening programs has the potential of being more successful in initial steps than the screening of pure compounds isolated from natural products⁵. Fungal diseases represent a critical problem to health and they are one of the main causes of morbidity and mortality worldwide⁶. Human infections, particularly those involving the skin and mucosal surfaces, constitute a serious problem, especially in tropical and subtropical developing countries⁷.

In humans, fungal infections range from superficial to deeply invasive or disseminated, and have increased dramatically in recent years. The treatment of mycoses has lagged behind bacterial chemotherapy and fewer antifungal than antibacterial substances are available. Therefore, a search for new antifungal drugs is extremely necessary⁸. During the past several years, there has been an increasing incidence of fungal infections due to a growth in immune compromised population such as organ transplant recipients, cancer and HIV/AIDS patients^{9, 10}. This fact coupled with the resistance to antibiotics and with the toxicity. Pathogenic fungi, dermatophytes, have the ability to invade keratinized tissues of animals and humans and cause a disease, dermatophytosis, which is the commonest human contagious fungal disease^{11, 12}. *Trichophyton rubrum* (T. rubrum) is the most prevalent pathogenic fungus worldwide and it represents 80% of clinical isolates¹³. Due to the increasing development of drug resistance in human pathogens as well as the appearance of undesirable effect of certain antimicrobial agents, there is a need to search for new antifungal agent without toxicity and side effect. Plant extracts or plant-derived compounds are likely to provide a

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Analytical Method Development of Saxagliptin HCl by RP-HPLC

Sanchay S Zinjad
S G Patel
D D Gaikwad
S L Jadhav

DOI <https://doi.org/10.22270/jddt.v9i4.3040>

ABSTRACT

Reversed-phase chromatography is the mainly used in chromatographic mode, it is used to separate neutral molecules in solution based on their hydrophobicity. This technique is the reverse of normal-phase chromatography in the intelligence that it involves the employ of a polar mobile phase and a non-polar stationary phase. A sensitive, accurate, rapid, cost effective and robust HPLC method was developed for the quantification of Saxagliptin Hydrochloride (SGH) with UV detector. In this method, a reversed-phase Grace C18 (250mm x 4.6ID, Particle size: 5 micron) column with a mobile phase of methanol: water (80:20; v/v) at 0.8ml/min flow rate was used to separate SGH with a detection of 212nm. The volume injected was 20 µL. The retention time of SGH was obtained as 4.196 min. Hence it can be applied for routine analysis of Saxagliptin Hydrochloride (SGH) in bulk drug.

Keywords: Saxagliptin Hydrochloride (SGH), RP-HPLC, Assay, Method validation.

ABSTRACT
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Open Access

Research Article

Estimation of Metformin Hydrochloride in Bulk and Formulation by UV - Spectroscopic Area Under Curve Method

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ABSTRACT

The current work is carried out for estimation of Metformin Hydrochloride by using area under curve (AUC) method using UV-visible spectrophotometer. For this purpose the wavelength range 221-241 nm was selected. Distilled water was used as a solvent throughout the work. Linearity was observed in concentration range 5-25 µg/ml ($R^2 = 0.994$) for the method. The present method was found to be simple and linear which can be used for routine quality control analysis for spectrophotometric estimation of Metformin hydrochloride in bulk.

Keywords: Metformin Hydrochloride, Area under curve, Antidiabetic, λ_{max} .

Article Info: Received 24 March 2019; Review Completed 30 April 2019; Accepted 02 May 2019; Available online 15 May 2019



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<http://dx.doi.org/10.22270/jddt.v9i3.2632>

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INTRODUCTION

Metformin hydrochloride is a hypoglycemic agent used in the treatment of non-insulin dependent diabetes mellitus. It acts as an antidiabetic agent by decreasing the uptake of glucose which enhance the glycemic control by increasing insulin sensitivity. Limitation associated with it is that, it does not show any response to dietary modification. It is basically a synthetic entity and chemically it is N,N-dimethylimidodicarbonimidic diamide hydrochloride (1,1-dimethyl biguanide hydrochloride). Generally used in combination with sulfonylureas, thiazolidinedione or other hypoglycemic agents or it can be used alone.¹⁻³

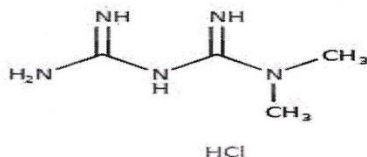


Figure 1: Chemical structure of Metformin HCL

MATERIAL AND METHOD

Chemicals:

Metformin hydrochloride was a gift sample from Flamingo Pharmaceutical, Taluja, Navi Mumbai, India. Metformin Hydrochloride Sustained Release Tablet 500 mg (Exermet 500) Cipla. All chemicals and reagents were of analytical (AR) grade.

Instrumentation:

A Shimadzu (Kyoto, Japan) UV-1800 double beam UV- Visible spectrophotometer attached with computer operated software UV probe 2.33 with spectral width of 2 nm, wavelength accuracy.

METHOD:

Area Under Curve Method:

The Area method is applicable where there is no sharp peak or when broad spectra are obtained. It involves the calculation of integrated value of absorbance with respect to the wavelength between two selected wavelengths λ_1 and λ_2 . Area calculation processing item calculates the area bound by the curve and the horizontal axis is selected by entering the wavelength range over which area has to be calculated. This wavelength range is selected on the basis of repeated observation so as to get the linearity between area curve and concentration. The above mentioned spectrums were

AREA UNDER CURVE UV SPECTROPHOTOMETRIC METHOD FOR DETERMINATION OF VALSARTAN IN BULK.

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ABSTRACT:- The simple, precise and accurate UV Spectrophotometric method has been developed and validated for the estimation of valsartan (VAL) in bulk. In that work is carried out to for estimation of Valsartan bulk by utilizing Area Under Curve (AUC) method using UV – Visible Spectrophotometry. For this purpose the wavelength range 200-400 nm was selected. Methanol was used as solvent throughout the work. Linearity was observed in concentration range 5-25 µm/ml ($R^2 = 0.996$) for the method. The present method was found which can be used for routine quality control analysis for spectrophotometric estimation of Valsartan in bulk.

Keywords: Valsartan, AUC, Methanol, UV Spectrophotometric.

INTRODUCTION:

Valsartan is a non - peptide, orally active and specific angiotensin II receptor blocker acting on the AT1 receptor subtype. The Valsartan is chemically described as (Figure 1) ^[1] N-(1-Oxo pentyl)-N- [Z(1H-Tetrazol-5yl)(1,1'biphenyl) 4-yl methyl]L-valine. Valsartan is used for treatment of hypertension, can be used alone or in combination with other antihypertensive drugs for treatment of high blood pressure. It is not official in any of the pharmacopoeia. The pharmacokinetics properties of valsartan have been investigated in healthy volunteers after oral administration of the sample. The aim of this work is to develop simple, accurate, precise spectrophotometric method for the routine determination of valsartan in bulk. [2, 3, 4, 5]

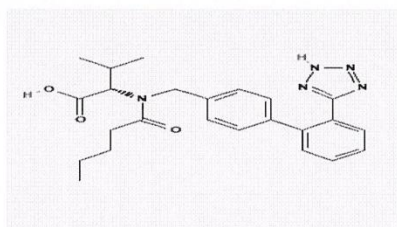


Figure 1: Chemical Structure of Valsartan.

MATERIALS AND METHODS:

Chemicals:

Valsartan was obtained at gift sample from alembic pharmaceuticals, Vadodara. Methanol analytical reagent (AR) grade was used as solvent throughout the experimentation. A pharmaceutical preparation was purchased from local pharmacy.

Instrumentation:

A Shimadzu (Kyoto, Japan) model UV- 1800 double beam UV- Visible spectrophotometer attached with computer operated software UV probe 2.33 with spectral width of 2 nm, wavelength accuracy of 0.5 nm and pair of 1 cm matched quartz cells was used to measure absorbance of the resulting solutions. Analytical balance of make Mettler Toledo (Model JL 1503- C) was used for weighing purpose.



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Research Article

Formulation and in-vitro evaluation of theophylline sustained release tablet

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ABSTRACT

The aim of present study was to prepare sustained release tablet of Theophylline so as to prolong its elimination time and at the same time to keep cost of the formulation minimum. In this study ethyl cellulose and Eudragit are used in the formulation to sustain the release of Theophylline. Ethyl cellulose and Eudragit are added at the granulation step to form a sustained release coating around each granule. Different batches were designed one after another on trial and error basis to get the optimum drug release upto 12 hours.

Keywords: Theophylline, ethyl cellulose, Eudragit, sustained release, coating, tablet.

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INTRODUCTION

For decades acute disease and chronic illness is being clinically treated through delivery of drugs to patients in the form of tablets, capsules, pills, creams, liquids, ointments, aerosols, injectables and suppositories. To maintain the concentration of an administered drug within therapeutically effective range, it is required to take drug dosage several times and this result in fluctuations in plasma drug concentration¹. This can be overcome by formulation of sustained release dosage form which gives drug release in an amount sufficient to maintain therapeutic drug level over extended period of time. As a result sustained release formulations are preferred for drugs which are administered orally and have high dosing frequency^{2,3}.

Theophylline has long been used as a treatment for diseases, including bronchial asthma. However, as its therapeutic concentration range is narrow, and its absorption is prone to the effects of meals, the dosing management of the drug has been difficult. The drug release rate is difficult to control in a sustained release tablets. Moreover, as they are manufactured by a complicated process, the drug release rate is likely to vary among lots, and advanced processing is needed to ensure consistent quality. Drug absorption from a conventional matrix tablet is influenced heavily by its transition rate in the GI tract, and accordingly, the bioavailability of conventional matrix tablet varies widely. It is the purpose of this study to develop a new dosage form

that overcomes these biological and technological problems^{4,5,6}.

In this study sustained release granules of theophylline were prepared, using granulation method. Unlike film coating, no expensive instrument was used.

MATERIALS & METHODS

Materials: Theophylline anhydrous, Ethyl Cellulose, Eudragit L100, Polyvinyl Pyrrolidone(K-30), Magnesium Stearate, Talc, Isopropyl Alcohol, Dichloromethane, Acetone.

Preparation of sustained release tablet of Theophylline anhydrous:

Sustained release tablets of Theophylline were prepared by wet granulation method. Different quantities of different polymers (Table 1) were dissolved in respective solvents and the resulting solution was added slowly to 20# passed Theophylline blend in Kenwood granulator. In present study ethyl cellulose was added at the granulation step in solubilized form. This results in application of ethyl cellulose at molecular level to form water insoluble coat around granule. The resulting granules were dried in Rapidrier at 30-40°C till LOD becomes below 2.5%. Dried granules were passed through 20# and mixed with magnesium Stearate and talc. Tablets were prepared from these granules using 16 station rotary tablets compression machine.

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Research Article

Simultaneous estimation of simvastatin and labetalol in bulk and solid dosage form

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ABSTRACT

A simple, accurate, precise, sensitive, and highly selective ultra violet spectrometer method has been developed for the simultaneous estimation of simvastatin and labetalol in bulk and solid dosage form. The estimation of simvastatin was carried out at 239 nm while labetalol was estimated at 222.4 nm. The developed method was validated for linearity range, precision, recovery studies and interference study for mixture, all these parameter showed the adaptability of the method for the method quality analysis of the drug in bulk and combination formulation.

Keywords: Simvastatin, Labetalol, UV Spectrophotometric, Dosage form.

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INTRODUCTION

Simvastatin is chemically is 2,2-Dimethyl butanoic acid (1S,3R,7S,8S,8aR)-1,2,3,7,8,8ahexahydro- 3,7- dimethyl-8-[2-[(2R,4R)- tetrahydro-4-hydroxy-6 oxo2H pyran-2yl]ethyl]1 naphthalenyl ester used as a HMGCoA reductase inhibitors. Simvastatin belongs to a class of drugs called HMG-CoA reductase inhibitors commonly called statins that derived synthetically from fermentation products of *Aspergillus terreus*. All statins act by inhibiting 3-hydroxy-3-methylglutarylcoenzyme (HMG-CoA) A HMG-CoA reductase, the rate limiting enzyme of the HMG-CoA reductase pathway, the metabolic pathway responsible for the endogenous production of cholesterol mainly used for the

treatment of dyslipidemia and the prevention of cardiovascular diseases. Simvastatin is prodrug which is converted into its β - hydroxy which inhibits HMG CoA reductase (3-hydroxy-3-methyl glutarylCoenzyme A) enzyme, responsible for catalysing the conversion of HMG CoA to mevalonate a rate limiting step in the synthesis of cholesterol in liver.⁷

Labetalol HCl is a selective α_1 and non-selective β adrenergic blocker used to treat high blood pressure. Chemically it is 2-hydroxy-5-[[1-hydroxy-2-(4 phenyl butane-2-yl) amino] ethyl]benzamide. It has a molecular formula of C₁₉H₂₄N₂O₃.HCl and a molecular weight of 328.40g/mol.⁸

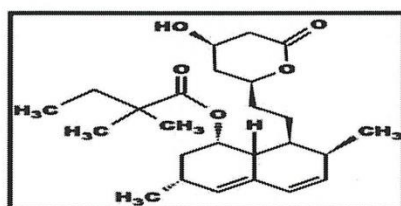


Figure 1 Chemical Structure of Simvastatin

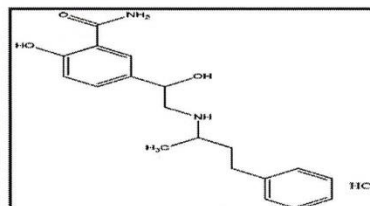


Figure 2 Chemical Structure of labetalol HCl



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Research Article

Design and Characterisation of Bi-layer Tablets Containing Simvastatin as Sustained Release and Labetalol HCl as Immediate Release

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ABSTRACT

The objective of present investigation is to design and characterise sustained release Simvastatin and immediate release of Labetalol HCl, a bi-layer tablet. The combination therapy of Simvastatin and Labetalol HCl can be useful in severe cardiovascular disease such as hypertension, angina pectoris, congestive heart failure which may occur along with increasing cholesterol level in the blood, while this combination remain preferable choice to the patient as compared to single dosage form. The bi-layer tablet is suitable for sequential release of two drugs in combination which are compatible with each other. Objective of present investigation is to prepare bi-layer tablet in which one layer is sustained while another one is immediate release. For the preparation of bi-layer tablet, different super disintegrants like cross carmellose cellulose, micro crystalline cellulose is used for immediate release and HPMC and Carbapol as controlled release polymer. The pre-formulation parameter such as solubility, melting point, compatibility study (FTIR) were studied. Pre-compression parameter such as angle of repose, bulk density, tapped density, hausner's ratio and compressibility index were studied. The tablets were evaluated by physical and chemical parameters such as weight uniformity, hardness, thickness, diameter, friability, drug content, disintegration time and in-vitro drug release. The dissolution data were subjected to various release kinetic model to recognize the mechanism of drug release.

Keyword: sustained release tablet, bi-layer tablet, Simvastatin, Labetalol HCl.

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1. INTRODUCTION

Oral route is most convenient route for administration of dosage form. Tablet is the convenient oral dosage form and acceptable by patients and physicians. Bi-layer tablet is suitable for sequential release of two drugs in which one is immediate release and another is sustained release. Sustained release drug delivery is the important approaches to achieve the controlled release of drug to obtained sufficient bioavailability. Hypertension and hypercholesterolemia frequently coexist and may require concomitant drug treatment.^{1,2}

Simvastatin is the lipid lowering agent which is used to decrease the bad cholesterol level. It is potent inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme, [HMG-CoA] reductase which catalyzes the conversion of HMG-CoA to Mevalonate, an early rate determining step in cholesterol biosynthesis. Absorption of Simvastatin is about 85% of an oral administration. However because of Simvastatin is undergo extensive first pass metabolism and hence bioavailability is low is about 5%. peak plasma concentration found to be 1.3-2.4 hours after administration. So sustained release drug

delivery system is suitable for Simvastatin.³ Labetalol HCl is a third generation selective alpha-1-adrenergic agonist and non selective beta-adrenergic antagonist with vasodilatory and antihypertensive properties. Labetalol competitively bind to alpha-1-adrenergic receptor in vascular smooth muscle, thereby inhibiting the adrenergic stimulation of endothelial cell function and vasoconstriction and peripheral blood vessels. The result is a decrease in resting and exercise heart rate cardiac output and both systolic and diastolic blood pressure thereby resulting vasodilation and hence reduce the hypertension. Labetalol is completely absorbed (100%) from gastrointestinal tract. The half-life of Labetalol HCl is approximately 4-6 hrs.⁴

The combination therapy of Simvastatin and Labetalol HCl may be useful and effective in serious cardiovascular disease such as hypertension, angina pectoris, congestive heart failure which may occur along with increasing cholesterol level in the blood, while this combination remain preferable choice to the patient as compared to single dosage form. The statin combine with antihypertensive drugs may improve the B.P. control in patients having obesity and hypertension.²

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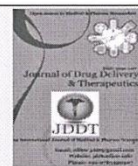
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Research Article

Formulation and *In-vitro* evaluation of sustained release matrix tablet of Metformin hydrochloride

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ABSTRACT

The low bioavailability and short half-life of Metformin hydrochloride (MH) make the development of sustained-release forms desirable. Present work involves preparation and optimization of sustained release matrix tablet of MH by direct compression method using HPMC K 100 and ethyl cellulose as a matrix forming polymer. Avicel was added as a direct compaction vehicle to improve the compaction behavior of Metformin which otherwise exhibits poor compaction behavior which again is further increased by its relatively high dose. Hydrophilic matrix of HPMC alone resulted in initial burst of Metformin release, however when combined with ethyl cellulose drug release was slowed down and thereafter it became optimal at particular concentration of polymers.

Keywords: Metformin, HPMC, Ethyl cellulose, sustained release, matrix, tablet.

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INTRODUCTION

In recent years, hydrophilic matrices are becoming popular in controlling the release of soluble drugs from solid dosage forms. These systems appear to be one of the most attractive approaches from an economic as well as from the process development points of view. The use of mixtures of polymers represents a potential way of achieving required release properties. Mixtures of different nonionic cellulose ethers have been used to give different viscous efficiencies¹.

The most widely used polymer for hydrophilic matrices is hydroxypropyl methylcellulose (HPMC). This polymer is considered among the water-soluble polymers. Ethyl cellulose (EC) is considered as a water insoluble polymer due to the hydrophobic substituents (ethyl-). This polymer has been used mainly to form films for the manufacture of oral extended release dosage forms like granules, pellets, microcapsules and film tablets. A second polymer like hydroxypropyl cellulose has been admixed to change the release properties by providing hydrated channels for drug release. Mixtures of different proportions of polymers with different permeation characteristics could provide a wide range of release rates of a drug by changing the diffusivity of the drug through a polymer barrier^{2,3}.

Metformin hydrochloride is the first line drug of choice for the treatment of type II diabetes, especially, in overweight and obese people. Metformin helps to improve

hyperglycemia primarily by suppressing glucose production by the liver (hepatic gluconeogenesis). The conventional form of Metformin tablets have been found to have many side effects such as gastrointestinal upset, including diarrhea, cramps, nausea & vomiting. In order to reduce the above mentioned side effects and to enhance patient compliances, sustained release formulation of Metformin was developed. Numerous studies have been reported in literature investigating the HPMC matrices to control the release of variety of drug^{4,5}.

In present study an attempt has been made, to formulate the Sustained release matrix tablets of Metformin Hydrochloride and tested for controlled delivery of drug using hydrophilic matrix polymer HPMC in combination with hydrophobic ethyl cellulose, resulting in reduction in the dosing frequency of Metformin and there by its dose related side effects.

MATERIALS & METHODS

Materials: Metformin hydrochloride, HPMC, Ethyl Cellulose, Avicel (Microcrystalline cellulose), Magnesium Stearate, Talc.

Preparation of sustained release tablet of Metformin hydrochloride:

Sustained release matrix tablets containing 500 mg Metformin hydrochloride were prepared by a direct compression method. All ingredients except talc and magnesium stearate were passed through 60 mesh and



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Suryawanshi et al

Journal of Drug Delivery & Therapeutics. 2019; 9(3):168-170



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Research Article

Estimation of Labetalol Hydrochloride in bulk and formulation by UV-Spectrophotometric Area Under Curve.

Akshada D. Suryawanshi*, Shankar M. Dhobale, Suchita R. Abhang, Salim G. Patel

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ABSTRACT

The current work was carried out for estimation of labetalol hydrochloride in bulk and pharmaceutical dosage form by utilizing area under curve method (AUC) method. For this purpose the wavelength range 200-400 nm was selected. Distilled Water was used as a solvent throughout the work. The linearity was observed in concentration range 5-25 µg/ml ($r^2=0.9788$) for the method. The present was found which can be used for routine quality control analysis for spectrophotometric estimation of labetalol hydrochloride in bulk and dosage form.

Keywords: Labetalol hydrochloride, Area under curve (AUC), Distilled Water, UV Spectrophotometric.

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INTRODUCTION

Labetalol is used with or without other medications to treat high blood pressure (hypertension). Labetalol Hydrochloride is the hydrochloride form of labetalol, a third generation selective α_1 -adrenergic antagonist and non-selective β -adrenergic antagonist with vasodilatory and antihypertensive properties. Labetalol competitively binds to α_1 -adrenergic receptors in vascular smooth muscle, thereby inhibiting the adrenergic stimulation of endothelial cell function and vasoconstriction in peripheral blood vessels. This agent also binds to β -receptors in the bronchial and vascular smooth muscle, resulting in a decrease in adrenergic stimulation. The result is a decrease in resting and exercise heart rates, cardiac output, and in both systolic and diastolic blood pressure, thereby resulting in vasodilation, and negative chronotropic and inotropic cardiac effects. Chemically is 2-hydroxy-5-[1-hydroxy-2-(4-phenylbutan-2-ylamino)ethyl]benzamide;hydrochloride.^{1,2}

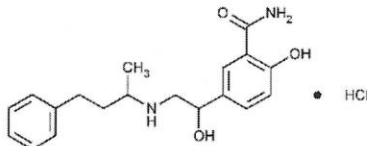


Figure 1 :Chemical Structure of labetalol hydrochloride.

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MATERIALS AND METHOD

1.Chemicals : Labetalol hydrochloride was a gift sample from Flamingo Pharmaceutical, Taloja, Navi Mumbai, India. Labetalol Hydrochloride 100 mg MACLEODS. All chemicals and reagents were of analytical (AR) grade.

2.Instrumentation:

A Shimadzu (Kyoto, Japan) model UV - 1800 double beam UV - Visible spectrophotometer attached with computer operated software UV probe 2.33 with spectral width of 2 nm, wavelength accuracy of 0.5 nm and pair of 1 cm matched quartz cells was used to measure absorbance of the resulting solutions. Analytical balance and matter Toledo (Model JL1503-C).

3.METHOD:

A) UV-Spectroscopy Methods:

a)Area under curve method :

The AUC (area under curve) method is applicable where there is no sharp peak or when broad spectra are obtained. It involves the calculation of integrated value of absorbance with respect to the wavelength between the two selected wavelengths λ_1 and λ_2 . Area calculation processing item calculates the area bound by the curve and the horizontal axis. The horizontal axis is selected by entering the wavelength range over which area has to be calculated. This wavelength range is selected on the basis of repeated



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Research Article

Extraction, Characterization and Evaluation of Okara Mucilage

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ABSTRACT

Mucilage is the thick, gluey substances produced by nearly all plant and some microorganisms. Okra mucilage is extracted from the plant of the *malvaceae* [*A. esculantus*]. Which is originally from Egypt, but it also in cropped in southern Asia elsewhere for nutritional purposes. Their use as potential reinforcement in polymer composites requires the understanding of their microstructure and mechanical properties. This work investigates the extraction methods, solubility behavior, TLC, loss on drying, ash value, FTIR spectra, surface tension, organoleptic properties. Extracted mucilage is soluble in warm water while insoluble in organic solvents. This can shows that it safely used in dosage form without causing any adverse effect.

Keywords: Okara Mucilage, Pharmaceutical Excipients, Controlled-Release Formulation

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INTRODUCTION

Mucilages are most commonly used adjuvant in pharmaceutical preparations. Plant mucilages are pharmaceutically important polysaccharide with wide range of applications such as thickening gelling agent, binding, disintegrating, suspending, and emulsifying, stabilizing and gelling agents. They have been also used as matrices for sustained and controlled release drugs. Naturally available mucilages are preferred to synthetic materials due to their non toxicity low cost, emollient and non irritating nature. Acacia, tragacanth, gum ghati, gum karaya are popular examples of plant mucilages. As a present paper deals with isolation, phytochemical screening and evaluation of binding properties of *Hibiscus esculentus* mucilage's. As a dose formulators essential to develop cost-effective and less tedious procedures for preparation of sustained release formulations on the industrial scale. The most commonly used method for fabricating drugs in a controlled-release formulation is by incorporating them into a matrix containing a hydrophilic rate controlling natural polymer¹.

Now a day many research are going on for the use of natural occurring biocompatible polymeric material in designing of pharmaceuticals dosage form for oral controlled release administration .most of the natural gums are biodegradable and nontoxic, which hydrate and swell contact with aqueous media, so these have been used for the preparation of

dosage form. Polysaccharide obtains forms plants has been shown to be useful for the construction of drug delivery systems². Regular research is going on in field of use of natural occurring biocompatible polymeric material in designing of dosage form for oral controlled release administration. Natural gums are biodegradable and nontoxic, which hydrate and swell on contact which aqueous media, and these have been for the preparation of dosage form³.

Natural are playing an important role as pharmaceutical excipients. These are easily available biodegradable and having economic. Biocompatibility of these natural polymers promotes their use as in pharmaceutical formulations. Present work used granulation compression technique to prepare tablets. In present study diclofenac sodium a non-steroidal anti-inflammatory drug is selected as model drug [NSAID] with analgesic and antipyretic properties⁴. Diclofenac sodium is used treatment is used in treatment of pain, dysmenorrhea, ocular inflammation, osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, and actinic keratosis.

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Research Article

Enhancement of solubility and dissolution rate of saxagliptine hydrochloride by solid dispersion technique

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ABSTRACT

Saxagliptine hydrochloride, PEG, polaxamer-407, ethyl cellulose were prepared to study the dissolution of sparingly water soluble Saxagliptine hydrochloride drug. Solid dispersion of Saxagliptine hydrochloride were prepared using different ratios of PEG 6000 & Polaxamer-407. Some of the practical aspects to be considered for the preparation of solid dispersion such as selection of polymers, methods of preparation, solubility of drug and dissolution study of drug in solid dispersion are also discussed. The present research provides a there is increase in solubility of Saxagliptine hydrochloride and also solid dispersion complex of drug was giving better dissolution profile as compared to other solid dispersions this improve bioavailability. FT-IR, shows the compatibility of drug & carrier.

Keywords- solid dispersion, solubility enhancement, dissolution rate

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INTRODUCTION^(1,11)

Solid dispersions can be defined as molecular or amorphous mixtures of poorly water soluble drugs in hydrophilic carriers in which the polymer properties play an important role in the drug dissolution profile. It has been estimated that 40% of new chemical entities being discovered are poorly water-soluble. With recent advances in screening methods for identifying potential drug candidates, an increasing number of poorly water-soluble drugs have been identified as potential therapeutic agents. Unfortunately, these drugs have poor bioavailability due to their poor solubility. This has limited the commercial potential of these drugs. The solid dispersion technique is one of the most efficacious to improve the bioavailability of drugs with low water solubility. Among the important factors increasing the solubility of drugs in solid dispersions, particle size reduction, reduced agglomeration, improved wettability and solubility, or dispersion of the drug as micro-fine crystals, amorphous materials or in a molecular form must be mentioned. These formulations offer many advantages over others and the most relevant are the lower cost of the adjuvants and the feasible industrial application.

Solid dispersion in an inert carrier or matrix of solid state prepared mainly by the melting (or fusion) and solvent evaporation methods. The melting method involves heating a physical mixture of an active agent and a carrier until melted,

followed by rapidly solidifying under vigorous mixing, resulting in super saturation of the drug by instantaneous solidification. On the other hand, the solvent evaporation method involves dissolving a physical mixture of two or more chemicals in a common solvent, followed by evaporation of the solvent. The proper selection of solvent and its removal rate are crucial in determining the quality of the final dispersion. The release mechanism of drug from a variety of solid dispersions depends on the physical properties of carriers as well as drug substances and preparation methods.

MATERIALS AND METHODS

Materials

Saxagliptine was received from NEXA lab, All other materials used were of pharmaceutical or analytical grade.

Preparation of solid dispersion by solvent evaporation method⁽¹⁾:

Required amount of Saxagliptine hydrochloride was dissolved in 20 ml of acetone. Accurately weighed carrier corresponding to different drug: carrier ratio by weight was dispersed in drug solution. Then the solvent was allowed to evaporate completely. The resulting solid mass was then pulverized in a mortar to get dry free-flowing powder. The powder was passed through a #40 mesh sieve. The resulting mass was transferred to desiccators containing silica

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Research Article

Area Under Curve UV Spectrophotometric Method for Determination of an Opioid Analgesic in Bulk

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ABSTRACT

The aim of this work is to establish rapid, simple, precise and economical methods viz., area under curve were developed and validated for estimation of tramadol hydrochloride in pharmaceutical dosage forms. Further, this study is designed to validate the developed methods as per ICH guidelines. The work was carried out to for estimation of Tramadol in bulk pharmaceutical form by utilizing area under curve (AUC) method using UV-Visible Spectrophotometry. For this purpose the wavelength range 200-400 nm was selected. Distilled water was used as a solvent throughout the work. Linearity was observed in concentration range 5-25 µg/ml ($r^2 = 0.9992$) for the method. The developed method was found to be simple, linear, precise, accurate and sensitive which can be used for routine quality control analysis for spectrophotometric estimation of Active Pharmaceutical Ingredient.

Keywords: Tramadol HCL, Distilled water

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INTRODUCTION

Tramadol hydrochloride is a centrally acting synthetic opioid analgesic binding to specific opioid Receptors. It is a non-selective, pure opioid agonist at μ , delta and kappa opioid receptors with a higher affinity for μ receptors. Tramadol chemically, (1R,2R)-2-((dimethyl-amino)methyl)-1-(3-methoxyphenyl) cyclohexanol hydrochloride (Fig. 1), is a typical opioid which is a centrally acting analgesic used for treating moderate to severe pain. Tramadol Hydrochloride can be estimated by UV spectrophotometry¹⁻⁸, RP-UPLC [9-12] and GC-MS⁹ alone or in combination with other drugs. Accordingly, the objective of this study was to develop and validate the simple spectrophotometric method for the estimation of tramadol hydrochloride in bulk and tablets as per ICH guidelines. Drug was found to be freely soluble in water which was chosen for solvent proceeding studies.

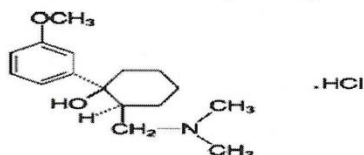


Figure 1: Chemical Structure of Tramadol Hydrochloride.

MATERIALS AND METHODS

Chemicals

Tramadol hydrochloride was a gift sample from Flamingo Pharmaceutical, Talaja, Navi Mumbai, India. All chemicals and reagents used were of analytical reagent (AR) grade and purchased from Qualigens Fine Chemicals, Mumbai, India.

Instrumentation

Shimadzu (Kyoto, Japan) model UV- 1800 double beam UV-Visible spectrophotometer attached with computer operated software UV probe 2.33 with spectral width of 2 nm, wavelength accuracy of 0.5 nm and pair of 1 cm matched quartz cells was used to measure absorbance of the resulting solutions. Analytical balance of make Mettler Toledo (Model JL 1503- C) was used for weighing purpose.

METHOD

Experimental Work

A) To check the solubility of Tramadol Hydrochloride

25 mg of Tramadol was weighed and solubility of this sample was checked in 25 ml distilled water, methanol, ethanol.



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Research Article

Estimation of Metformin Hydrochloride in Bulk and Formulation by UV - Spectroscopic Area Under Curve Method

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ABSTRACT

The current work is carried out for estimation of Metformin Hydrochloride by using area under curve (AUC) method using UV-visible spectrophotometer. For this purpose the wavelength range 221-241 nm was selected. Distilled water was used as a solvent throughout the work. Linearity was observed in concentration range 5-25 µg/ml ($R^2 = 0.994$) for the method. The present method was found to be simple and linear which can be used for routine quality control analysis for spectrophotometric estimation of Metformin hydrochloride in bulk.

Keywords: Metformin Hydrochloride, Area under curve, Antidiabetic, λ_{max} .

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INTRODUCTION

Metformin hydrochloride is a hypoglycemic agent used in the treatment of non-insulin dependent diabetes mellitus. It acts as an antidiabetic agent by decreasing the uptake of glucose which enhance the glycemic control by increasing insuline sensitivity. Limitation associated with it is that, it does not show any response to dietary modification. It is basically a synthetic entity and chemically it is N,N-dimethylimido dicarbonimidic diamide hydrochloride (1,1-dimethyl biguanide hydrochloride). Generally used in combination with sulfonylureas, thiazolidinedione or other hypoglycemic agents or it can be used alone.¹⁻³

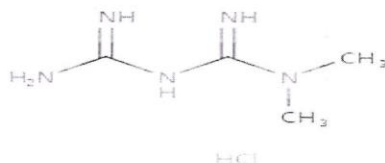


Figure 1: Chemical structure of Metformin HCL

MATERIAL AND METHOD

Chemicals:

Metformin hydrochloride was a gift sample from Flamingo Pharmaceutical, Talaja, Navi Mumbai, India. Metformin Hydrochloride Sustained Release Tablet 500 mg (Exermet 500) Cipla. All chemicals and reagents were of analytical (AR) grade.

Instrumentation:

A Shimadzu (Kyoto, Japan) UV-1800 double beam UV- Visible spectrophotometer attached with computer operated software UV probe 2.33 with spectral width of 2 nm, wavelength accuracy.

METHOD:

Area Under Curve Method:

The Area method is applicable where there is no sharp peak or when broad spectra are obtained. It involves the calculation of integrated value of absorbance with respect to the wavelength between two selected wavelengths λ_1 and λ_2 . Area calculation processing item calculates the area bound by the curve and the horizontal axis is selected by entering the wavelength range over which area has to be calculated. This wavelength range is selected on the basis of repeated observation so as to get the linearity between area curve and concentration. The above mentioned spectrums were



Estimation of Pazufloxacin Mesylate in bulk and formulation by UV-Spectrophotometric area under Curve Method

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ABSTRACT

The current work is carried out to for estimation of Pazufloxacin mesylate in bulk and pharmaceutical dosage form by utilizing area under curve (AUC) method. For this purpose the wavelength range 229-260nm was selected. Distilled water was used as a solvent throughout the work. Linearity was observed in concentration range 2-12µg/ml ($r^2 = 0.999$) for the method. Recovery studies for area under curve were found to be 99.32%. The method developed was validated for linearity, precision, accuracy, LOD, and LOQ as per ICH guidelines.^[1] The present method was found to be simple, linear, precise, accurate and sensitive which can be used for routine quality control analysis for spectrophotometric estimation of Pazufloxacin mesylate in bulk and dosage form.

Keywords: Pazufloxacin mesylate, Area under curve (AUC), and ICH guidelines.

INTRODUCTION

Pazufloxacin mesylate is a newer broad-spectrum fluoroquinolone antibiotic. Chemically is (3R)-10-(1-aminocyclopropyl)-9-fluoro-2,3-dihydro-3-methyl-7-oxo-7H-pyrido[1,2,3-de]1,4-benzoxazine-6-carboxylic acid methanesulfonate (Fig. 1) [2]. The potent broad-spectrum activity of the molecule is due to the presence of the aminoacyl group at C10, imparting against gram negative and gram positive bacteria including a variety of resistant strains and anaerobic bacteria.





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Research Article

An Overview: Analytical Methods of Estimation of Azoles as Antifungal Agents

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ABSTRACT

One of the important aspects of the drug discovery process is analytical method development and validation. To ensure quality & safety of the drug development of analytical method is done which will provide accurate & precise data. Method can be developed by using various instruments but due to speed and accuracy generally reverse phase high performance liquid chromatography is preferred by researchers. In this review we discuss various kind analytical methods available for estimation of azoles but in literature survey but mainly RP-HPLC & UV method is used.

KEYWORDS: Azoles, RP-HPLC, Analytical methods.

INTRODUCTION

The fungal kingdom mainly involves yeast, moulds, rusts etc. The fungal infection caused by invasion of micro organism in epithelial tissue. Over all kind of fungal agents some are not harmful but some are pathogenic to humans. These pathogenic fungi after entry in human body may cause mild to severe infection. This antifungal agent selectively eliminates fungal micro organism from without or with minimal toxicity to host. They are classified on the basis of pharmacophore or according to mechanism. The classification which we have is according to pharmacophore^{1, 2}

Classification²-

- 1) Polyenes - Nystatine
- Amphotericin B
- 2) Imidazoles - Miconazole
- Clotrimazole
- Ketoconazole
- 3) Triazoles - Fluconazole
- Itraconazole
- Voriconazole

- oxiconazole
- 4) Allylamines - Nifitfine
- Terbinafine
- Butenafine
- 5) β -3-glucan inhibitor- Caspofungin
- Micafungin
- Anidulafungin
- 6) Other- Griseofulvin
- flucytosine
- Tolnaftate

Azoles primarily inhibit the fungal cytochrome P450 3A Enzyme lanosterol 14-alpha-demethylase which leads to prevention of conversion of lanosterol to ergosterol, these leads to depletion of ergosterol and accumulation of sterol precursors. Due to ergosterol depletion the integrity and function of fungal cell membrane is disrupted, leads to cell lysis.^{2, 3, 4}. Generally the analytical method development and validation is important for the newly introduced drug or drug combination to check and ensure the quality standards of the drugs and drug formulations, because such



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Shinde et al

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Research Article

Analytical method development and validation of assay test of pravastatin sodium tablets

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ABSTRACT

A simple, accurate, precise and stability indicating Ultra performance liquid chromatographic method for determination of pravastatin sodium in tablet dosage form. The separation was carried on Acquity UPLC ® HSS C₁₈, 2.1 × 100mm, 1.8µm ID column, with mobile phase comprising of mixture of pH 5.5 buffer: methanol in the ratio of 30 : 70 v/v, as the mobile phase at a flow rate 0.2 ml/min and the detection was carried out using UV-visible detector at 238nm. The method was validated by evaluation of different parameters such as accuracy, precision, linearity, ruggedness, robustness, filter equivalency, solution stability. The retention time were found to be 1.5 min. Calibration curves were linear with correlation coefficient (r²) 0.999. The Percent assay of Pravastatin sodium tablet was found to be 98.4%. The developed methods were validated as per the ICH guidelines.

Keywords: Pravastatin sodium (PVS), UPLC, Method Validation.

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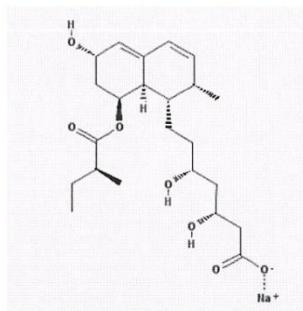
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INTRODUCTION

Chromatography is a non-destructive procedure for resolving a multi-component mixture of trace, minor, or major constituents into its individual fractions. UPLC refers to Ultra Performance Liquid Chromatography.¹⁻⁵ It improves in three areas: chromatographic resolution, speed and sensitivity analysis. It uses fine particles and saves time and reduces solvent consumption. UPLC comes from HPLC. HPLC has been the evolution of the packing materials used to effect the separation. An underlying principle of HPLC dictates that as column packing particle size decreases, efficiency and thus resolution also increases. As particle size decreases to less than 2.5µm, there is a significant gain in efficiency and it's doesn't diminish at increased linear velocities or flow rates according to the common Van Demeter equation. By using smaller particles, speed and peak capacity (number of peaks resolved per unit time) can be extended to new limits which is known as Ultra Performance.⁶

Drug Profile:

Name: Pravastatin Sodium



Structure of Pravastatin sodium

Chemical Name : sodium (3R,5R)-3,5-dihydroxy-7-
[(1R,2S,6S,8R,8aR)-6-hydroxy 2-methyl-8-
[[[(2S)-2-methylbutanoyl]oxy]-1,2,6,7,8,8a-hexahydronaphthalen-1-yl]-heptanoic acid

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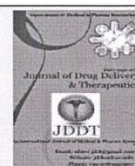
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Research Article

Design and Characterisation of Bi-layer Tablets Containing Simvastatin as Sustained Release and Labetalol HCl as Immediate Release

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ABSTRACT

The objective of present investigation is to design and characterise sustained release Simvastatin and immediate release of Labetalol HCl, a bi-layer tablet. The combination therapy of Simvastatin and Labetalol HCl can be useful in severe cardiovascular disease such as hypertension, angina pectoris, congestive heart failure which may occur along with increasing cholesterol level in the blood, while this combination remain preferable choice to the patient as compared to single dosage form. The bi-layer tablet is suitable for sequential release of two drugs in combination which are compatible with each other. Objective of present investigation is to prepare bi-layer tablet in which one layer is sustained while another one is immediate release. For the preparation of bi-layer tablet, different super disintegrants like cross carmellose cellulose, micro crystalline cellulose is used for immediate release and HPMC and Carbapol as controlled release polymer. The pre-formulation parameter such as solubility, melting point, compatibility study (FTIR) were studied. Pre-compression parameter such as angle of repose, bulk density, tapped density, hausner's ratio and compressibility index were studied. The tablets were evaluated by physical and chemical parameters such as weight uniformity, hardness, thickness, diameter, friability, drug content, disintegration time and in-vitro drug release. The dissolution data were subjected to various release kinetic model to recognize the mechanism of drug release.

Keyword: sustained release tablet, bi-layer tablet, Simvastatin, Labetalol HCl.

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1. INTRODUCTION

Oral route is most convenient route for administration of dosage form. Tablet is the convenient oral dosage form and acceptable by patients and physicians. Bi-layer tablet is suitable for sequential release of two drugs in which one is immediate release and another is sustained release. Sustained release drug delivery is the important approaches to achieve the controlled release of drug to obtained sufficient bioavailability. Hypertension and hypercholesterolemia frequently coexist and may require concomitant drug treatment.^{1,2}

Simvastatin is the lipid lowering agent which is used to decrease the bad cholesterol level. It is potent inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme, [HMG-CoA] reductase which catalyzes the conversion of HMG-CoA to Mevalonate, an early rate determining step in cholesterol biosynthesis. Absorption of Simvastatin is about 85% of an oral administration. However because of Simvastatin is undergo extensive first pass metabolism and hence bioavailability is low is about 5%. peak plasma concentration found to be 1.3-2.4 hours after administration. So sustained release drug

delivery system is suitable for Simvastatin.³ Labetalol HCl is a third generation selective alpha-1-adrenergic agonist and non selective beta-adrenergic antagonist with vasodilatory and antihypertensive properties. Labetalol competitively bind to alpha-1-adrenergic receptor in vascular smooth muscle, thereby inhibiting the adrenergic stimulation of endothelial cell function and vasoconstriction and peripheral blood vessels. The result is a decrease in resting and exercise heart rate cardiac output and both systolic and diastolic blood pressure thereby resulting vasodilation and hence reduce the hypertension. Labetalol is completely absorbed (100%) from gastrointestinal tract. The half-life of Labetalol HCl is approximately 4-6 hrs.⁴

The combination therapy of Simvastatin and Labetalol HCl may be useful and effective in serious cardiovascular disease such as hypertension, angina pectoris, congestive heart failure which may occur along with increasing cholesterol level in the blood, while this combination remain preferable choice to the patient as compared to single dosage form. The statin combine with antihypertensive drugs may improve the B.P. control in patients having obesity and hypertension.²



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Research Article

Pharmacognostical and Phytophysicochemical investigations of *Trigonella foenum - graecum* Linn

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ABSTRACT

Fenugreek (*Trigonella foenum-graecum* L.), plant is distributed throughout the world and which belongs to the family Fabaceae. The fenugreek seed contains active constituents such as Carbohydrates, Proteins, Alkaloids, Flavonoids, Free amino acids, Saponins, Glycosides, Vitamins, Minerals, Mucilage, Fixed Oils & Volatile Oils etc. It has been commonly used as a traditional food and medicine. Fenugreek is known to have hypoglycemic, and hypocholesterolaemic effects, Anti-inflammatory effects. Fenugreek has potential for curing diseases and also as a source for preparing raw materials of pharmaceutical industry like in steroidal hormones. This review gives view mainly on the Morphological evaluation, Microscopic evaluation, Physicochemical evaluation, Fluorescence Analysis and Phytochemical evaluation.

Keywords: *Trigonella Foenum-graecum* L., Seeds, Fabaceae, Saponins.

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Introduction

Herbal drug technology is used for converting botanicals materials into medicines, where standardization and quality control with proper integration of modern scientific techniques and traditional knowledge is important. Methods of standardization should take into consideration all aspects that contribute to the quality of the herbal drugs, namely correct identity of the sample, organoleptic evaluation, pharmacognostic evaluation, volatile matter, quantitative evaluation (ash values, extractive values), phytochemical evaluation, test for the presence of xenobiotics, microbial load testing, toxicity testing and biological activity. The phytochemical profile is of special significance since it has a direct bearing on the activity of the herbal drugs¹.

With these objectives in consideration, the raw materials were evaluated on the basis of pharmacognostical, physicochemical and phytochemical parameters.

Fenugreek (*Trigonella Foenum-graecum* Linn) is an annual herb indigenous to the countries bordering on the eastern shores of the Mediterranean and largely cultivated in India, Egypt, and Morocco. The name fenugreek comes from foenum-graecum, meaning Greek hay, as the plant was traditionally used to scent inferior hay. The name of the genus, *Trigonella*, is derived from the old Greek name,

denoting 'three-angled', probably referring to the triangular shape of the flowers. The first recorded use of fenugreek is described on an ancient Egyptian papyrus dated to 1500 B.C. Fenugreek seed is commonly used in cooking. Fenugreek has strong flavor and aroma. The plants leaves and seeds are widely consumed in Indo-Pak subcontinent as well as in other oriental countries as a spice in food preparations, and as an ingredient in traditional medicine. A wide range of uses were found for fenugreek in ancient times. Medicinally it was used for the treatment of wounds, abscesses, arthritis, bronchitis, ulcer and digestive problems. Traditional Chinese herbalists used it for kidney problems and conditions affecting the male reproductive tract. Fenugreek was, and remains, a food and a spice commonly eaten in many parts of the world.

The chemical components of fenugreek seeds include a large carbohydrate fraction (mucilaginous fiber, galactomannan); 20-30% proteins high in tryptophan and lysine; pyridine-type alkaloids; flavonoids ; free amino acids (4-hydroxyisoleucine, arginine, lysine, histidine); saponins; glycosides; vitamins, minerals, (28%) mucilage, (22 %) proteins, 5 % of a stronger-smelling, bitter fixed oil. volatile oils. Bitterness is mainly due to the oil, steroidal saponins and alkaloids.



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FORMULATION AND EVALUATION OF TOOTHPASTE CONTAINING COMBINATION OF ALOE AND SODIUM CHLORIDE

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Keywords:

Toothpaste, *Aloe vera*,
Sodium Chloride, Antimicrobial
activity, Future scope, etc

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ABSTRACT: The formulation and evaluation of toothpaste contain *Aloe vera* along with the combination of sodium chloride. *Aloe vera* shows a number of uses either internally or externally, and the number of uses also increases as the research going on. In this formulation, we tried to find out the antimicrobial activity of *Aloe vera* in toothpaste formulation, for the said purpose we use *S. aureus* culture. After designing the batches in software Design Expert® 10, the batches were formulated and evaluated. At the end of work, we found that the prepared toothpaste shows considerable zone of inhibition which concludes its antimicrobial activity. The formulation also shows sufficient foaming power for its cleansing action. The observed results were found to significant concerning the chosen cubic model in software Design Expert® 10. Thus from the collected results, we concluded that the toothpaste containing a combination of *Aloe* and sodium chloride possesses antimicrobial activity, but for its practical use its necessary to determine its effect on oral cavities and probable side effects after its long term use of its oral application as its future scope. The present work provides hint for those who prefer herbal formulations.

INTRODUCTION: To promote the attractiveness and to maintain the health of teeth the formulation is used called as toothpaste¹. For cleaning the teeth, toothpaste are widely used preparations². This primary function of cleaning is carried out with the help of a toothbrush. The objective behind the use of tooth paste is its ability to deliver preventive and therapeutically active agents such as fluoride, metal salts and pyrophosphate. These agents may be useful for calcium inhibition also reduce the growth of plaque and to treat dentine hypersensitivity along with dental hygiene.

Along with refreshing breath, removal of food particles, reduction of superficial plaque or stain, polishing of tooth surface is the function of toothpaste or dentifrices. Some therapeutic and cosmetic functions may be desired such as whitening, bleaching, desensitizing, inhibition of plaque formation and protection against periodontal problems.

Active pharmaceutical ingredients, abrasives, humectants, detergents, binders, sweeteners, preservatives and antioxidants, and flavors are the most commonly used ingredients of toothpaste^{1,2}. There is a number of materials, and their combinations were used in the formulation of toothpaste but they might damage teeth and gums. Hence, nowadays there is a need for safe, effective and well-formulated dentifrices³. To achieve this, present work deals with formulation and evaluation of toothpaste containing aloe and sodium chloride

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DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR ESTIMATION OF SIMVASTATIN IN SWAB SAMPLES

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ABSTRACT: Cross contamination is one of the major problems focused in manufacturing of drugs utilizing common facility which leads to inferior quality of final product and cause considerable loss to the company. The objective of the current study was to develop and validate simple and precise UV spectrophotometric method for estimation of simvastatin in the swab samples to validate cleaning procedure. The swabbing procedure was optimized in order to obtain a suitable recovery from stainless steel surface using 100% sterile cotton swab stick. Detection wavelength selected was 237.8 nm. The proposed method was validated in terms of Linearity, precision, accuracy, limit of detection and limit of quantitation. Linearity was studied over concentration range of 0.5 - 3 µg / ml and correlation coefficient was found to be 0.9973 for regression line. A mean recovery obtained was 88.23 %.

Keywords: simvastatin, Swab testing, spectrophotometric, cleaning validation.

Introduction:
Cleaning Validation is documented evidence that an approved cleaning procedure will provide equipment that is suitable for

procedure so that the analytical monitoring may be omitted or reduced to a minimum in the routine phase. Cleaning validation has become a regulatory requirement now. 1963 GMP regulations (part 133.4) states that manufacturing equipments must be maintained in clean and orderly manner, all processing equipment should be specifically designed to facilitate cleanliness and permit visual inspection and whenever possible, the equipment should be made of smooth surfaces of nonreactive materials. Critical areas (i.e., those hardest to clean) should be identified, particularly in large systems that employ semi-automatic or fully automatic CIP systems.[1,2,6,9,12]

EXPERIMENTAL:
A) Reagent and Chemicals:
Simvastatin working standard was obtained as the gift sample from Flemigo pharmaceutical. All other reagents used were of analytical grade. Methanol (AR grade) was used as solvent for swab testing. The sample solution was passed through Whatman filter paper. Swab sampling was done by using 100% cotton sterile swab.



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Bangar et al

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Open Access

Research Article

Formulation and evaluation of Vasaka granules for asthma

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ABSTRACT

Asthma is a chronic disease of bronchi which usually requires continuous medical care. Approaches for drug formulation that easy to administer especially for chronic diseases can form valuable therapy. Adhatoda vasica is a plant believed to have several therapeutic effects including antiasthmatic properties. It is the leaves, which are of great importance for asthma. Adhatoda vasica leaves belonging to family Acanthaceae, it is found mainly in India. It is also called as vasaka. Vasaka herb is used for treating cold cough and asthma. It is a well-known ayurvedic medicine for expectorant and helps to ease out the phlegm. Vasaka leaves contain quinazoline alkaloids such as vasicinone, vasicine, vasicinol, vasicol granules can be used for the treatment of asthma as they offer advantages such as faster disintegration and dissolution as compared to tablet capsules.¹

Keywords: vasicinone, vasicine, vasicol, Acanthaceae, Adhatoda

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1. INTRODUCTION

Asthma is thought to be caused by a combination of genetic and environmental factors. Diagnosis is usually based on the pattern of symptoms, response to therapy over time, and spirometry. There is no cure for asthma. Symptoms can be prevented by avoiding triggers, such as allergens and irritants, and by the use of inhaled corticosteroids. Asthma attacks all age groups but often starts in childhood. Asthma is a chronic disease characterized by recurrent attacks of breathlessness and wheezing, which vary in severity and frequency from person to person.^{1,2,3}

Bronchodilators are recommended for short-term relief of symptoms. In those with occasional attacks, no other medication is needed. If mild persistent disease is present (more than two attacks a week), low-dose inhaled corticosteroids or alternatively, a leukotriene antagonist or a mast cell stabilizer by mouth is recommended. During an asthma attack, the lining of the bronchial tubes swells, causing the airways to narrow and reducing flow of air into and out of the lungs.



Figure 1: Vasaka leaves

The medicinal herb expands the airways and provides great relief to the bronchitis patients. The active chemical constituents present in vasaka leaves are quinazoline, vasicinone, vasicine, vasicinol, vasicol, vasicnine, adhatodine and 6-hydroxyl vasicine¹ as they offer advantages such as faster disintegration and dissolution as compared to tablets and capsules, palatable as compared to syrups and decoctions, greater acceptability in pediatrics

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Microwave assisted synthesis and biological evaluation of tetrahydropyrimidine derivatives

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ABSTRACT

Twelve [6- (2-methoxy-phenyl)-2-oxo-4-phenyl / substituted phenyl-1, 2,3, 4- tetrahydropyrimidine-5-yl] acetic acid derivatives have been synthesized in a two-step reaction. In the first step benzene or substituted benzene react with succinic anhydride in presence of aluminum trichloride (Friedel Craft reaction) to obtain 4- (substituted phenyl)-4-oxo- butanoic acid. Second step involves synthesis of [6-(2-methoxy-phenyl)-2-oxo-4-phenyl/substituted phenyl-1,2,3,4-tetrahydro pyrimidine -5-yl] acetic acid by reaction between 4-(substituted phenyl)-4-oxo- butanoic acid, urea and substituted aldehydes (Biginelli reaction). Their structures are confirmed by IR, ¹H NMR, T.L.C. of synthesized compounds performed in chloroform: ethanol (3:1) solvent system. The anti-inflammatory activity of all compounds has been recorded on the basis of reference standard Indomethacin. All the compounds showed tendency to cause a fall in oedema and showed anti-inflammatory activity. The anti-inflammatory data shows that use of anisole in first step plays important role in the activity. Anti-inflammatory activity of all compounds was taken by Carrageenan induced rat paw oedema as described by Winter et al. on albino rats.

Keywords: Pyrimidine, Anti-inflammatory activity, aryl alkanoic acid, NSAID's.





Formulation and Evaluation of Luliconazole Emulgel for Topical Drug Delivery

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ABSTRACT

The aim of the present study was to develop an emulgel formulation of Luliconazole using carbopol 934 as a gelling agent. The Luliconazole has anti-Fungal activity. It acts by inhibiting lanosterol demethylase, which is major component of fungus cell wall. Emulgel has emerged as a promising drug delivery system for the delivery of hydrophobic drugs. The prepared emulgel were also evaluated for their physical properties, pH, drug content and rheological properties. *Candida albicans* was used as a model fungus to evaluate the antifungal activity of the prepared formulations. Stability studies revealed no significant differences in formulation.

It was concluded that Luliconazole emulgel formulation (F3) prepared by using Carbapol 934 as gelling agent, emulsifying agent in its high level and liquid paraffin in its low level was the choice of formula, since it showed the highest drug release and antifungal activity.

Keywords: Emulgel, Luliconazole, Topical drug delivery.

INTRODUCTION

Topical formulations apply a wide spectrum of preparations both cosmetic and dermatological, to healthy or diseased skin [1]. These formulations range in consistency from solid through semisolid to liquids. When gels and emulsions are used in a combined form, the dosage forms are referred to emulgel. [2, 3] As the name suggests they are the combination of emulsion



Microwave assisted synthesis and biological evaluation of tetrahydropyrimidine derivatives

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ABSTRACT

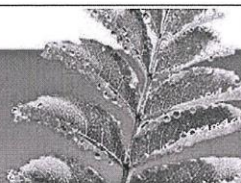
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Keywords: Pyrimidine, Anti-inflammatory activity, aryl alkanoic acid, NSAID's.





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Isolation and standardization of gingerol from ginger rhizome by using TLC, HPLC, and identification tests

Dr. Gaikwad DD, Shinde Sachin K, Kawade Ashwini V, Dr. Jadhav SJ and Dr. Gadhave MV

Abstract

Many drugs commonly used today are herbal origin. About 25% of prescription drug in the US contains atleast one active ingredient derived from plant material. Herbal medicine is the oldest form of healthcare known to mankind. Herbs has been used by all cultures throughout history. Herbal medicine are also in great demand in developed world for primary healthcare because of their efficacy, safety and lesser side effects. The aim of present study is to isolate and standardize gingerol obtained from *Zingiber officinale* rhizome. *Zingiber officinale* rhizomes were extracted with ethanol (95%) by simple maceration process. This extract was studied phytochemically and gingerol is isolated by using TLC and HPLC technique. The isolated compound was found to be oleoresins. Gingerol constituents responsible to reduce effects such as emesis and nausea.

Keywords: Herbal medicine, *Zingiber officinale*, gingerol, emesis, nausea

1. Introduction

Zingiber officinale belonging to family Zingiberaceae is an ancient Indian medicine used in several disorders. *Zingiber officinale* commonly called as 'Adrak' in Hindi and Urdu, 'Sunthi' in Marathi. It has various vernacular names such as Ginger, Srngaveram, Adrak, Sunthi. *Zingiber officinale* is possibly native to India and China. It is now widely grown as a commercial crop in south and Southeast Asia, tropical Africa (especially Sierra Leone and Nigeria), Latin America, the Caribbean (especially Jamaica) and Australia. Ginger has a distinctive thickened, branched rhizome (underground stem) which sometimes looks somewhat like a swollen hand. The rhizome has a brown corky outer layer (usually removed before use) and a pale yellow centre with a spicy lemon-like scent. Shoots (pseudostems), up to 1.2 m tall, arise annually from buds on the rhizome. Ginger is a well-known tropical herbs whose root is used in both Traditional Chinese Medicine and Western Herbal Medicine. It has a long history of medicinal used dating back 2500 years in China and India for conditions such as headaches, nausea, rheumatism, and colds, has been used since ancient times for a variety of condition, including fevers, and digestive problems, and as an appetite stimulant.

2. Materials and Methods

2.1 Chemical and Reagents

FTIR Spectrophotometer (Perkin elmers), UV Spectrophotometer (SHIMADZU 1800), HPLC Waters 1650, all chemicals and solvents used were of A.R. Grade and IPA was obtained from Alkem Labs. Ltd. Mumbai.

2.2 Plant material

The ginger rhizome were purchased from local market of Pune. The material were cleaned & dried under shade & then placed in oven at 20-40 °C. The dried rhizomes were weighed and stored in desicator.

2.3 Isolation of gingerol from ginger

Dry ginger was crushed to a coarse powder and extracted with 95% ethanol by simple maceration process. Solvent was evaporated by distillation to obtain thick pasty mass. The thick pasty mass was suspended in water. The Ginger resin precipitates in water which was removed by filtration and the residue obtained was dried under vacuum.

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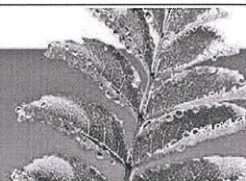
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Design and optimization of *In-situ* floating gel containing ondansetron hydrochloride dihydrate using 3² factorial design

Shelke Gajanan, Dhobale Shankar, Jadhav Suresh and Gaikwad Dushyant

Abstract

The aim of the present study was to develop an *in-situ* floating gel of Ondansetron HCl dihydrate. The Ondansetron HCl dihydrate has low gastro intestinal Transit time that result in low absorption of drug. Floating *in-situ* gel is most suitable form to achieve greater absorption of drug. *In-situ* gel floats on the gastric fluid for sufficient time and also increases the gastric transit time. An *in-situ* floating gel prepared by using various excipients like sodium alginate, calcium carbonate, sodium citrate, D-mannitol, methyl paraben, propyl paraben. The compatibility study was performed by using FT-IR. Formulations were optimized by using 3²-factorial designs. Concentration of Sodium Alginate and calcium carbonate were selected as independent variables whereas floating lag time and drug release after 8 hrs (Q₈) were selected as dependent variables. The prepared formulations were evaluated for viscosity, floating lag time, duration of floating, *in-vitro* gelation and *in-vitro* drug release. All formulations showed floating within 60 s and had total floating time 24 hrs. The concentration of Sodium Alginate and calcium carbonate had significant influence on floating lag time, cumulative percentage drug release in 8 hrs. Among different formulae tested, formulation A5 showed optimum floating lag time (38sec) and drug release after 8 hrs (98.56%). Therefore, floating *in-situ* gelling of Ondansetron HCl dihydrate containing Sodium Alginate as a gelling polymer to sustain the drug release for 8 hrs. All the formulations showed good pourability.

Keywords: Floating *in-situ* gelling system, Ondansetron HCl dehydrate (OSD), oral drug delivery, sustained release, sodium alginate

1. Introduction

Ondansetron hydrochloride is a 1,2,3,9-tetrahydro-9-methyl-(2-methyl-1H-imidazol-1-yl)methyl-4H-carbazol-4-one, monohydrochloride [1]. Ondansetron hydrochloride is a short acting drug for the management of nausea and vomiting. Chemotherapeutic agents and radiotherapy cause release of 5HT in the small intestine initiating the vomiting reflex by activating vagal afferents via 5HT₃ receptor. It blocks the initiation of these reflexes [2-3]. It has a short biological half-life of 3.1h.

Powder dosage form was traditionally used dosage form. Tablet taken by oral route which through GI tract reaches in stomach and intestine simultaneously, then it shows pharmacological action. Tablet is a most popular dosage form, but tablet also having limitation like it is difficult to administration in small children, unconscious patient and dose dumping [4]. The main limitation regarding tablet dosage form is gastro intestinal Transit time (6 to 8 hrs). Some drug having specific absorption site, they absorb only at that site. Even the gastro intestinal transit time if smaller, the drug has less time for absorption and when it misses the absorption window, further there is no any absorption site.

When we increase the residential time of tablet remain intact in stomach for more period and result in more absorption of drug. This can be achieve by various means, out of which preparation of floating *in-situ* gel is most suitable form, as it can be float on the gastric fluid for sufficient time and also increases the gastric transit time [5].

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Research Article

Formulation and Evaluation of Colon Targeted Drug Delivery of Mesalamine

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ABSTRACT

In this study, we report pectin–Chitosan compression coated core tablets of Mesalamine for colonic delivery. Each 150 mg core tablet contained Mesalamine and was compression coated using 100% pectin 1:1, 10 pectin:1 Chitosan, or 10 pectin :2 Chitosan, at coat weights as 400mg. Drug dissolution or system erosion or degradation studies were carried out in pH 1.2, 6.8,7.4 phosphate buffers using a pectinolytic enzyme. The system was designed based on the gastrointestinal transit time concept, under the assumption of colon arrival times of 6 h. It was found that pectin alone was not sufficient to protect the core tablets and Chitosan addition was required to control the solubility of pectin. The optimum Chitosan concentration was 1 and such system would protect the cores up to 6 h and after that under the influence of pectinase the system would degrade faster and delivering 5-ASA to the colon. The pectin–Chitosan (10:1) envelope was found to be a promising drug delivery system for those drugs to be delivered to the colon.

Keywords: Colonic delivery, 5-Aminosalicylic acid, Pectin, Chitosan, Compression coating, Pectinase.

INTRODUCTION

Delivery of a drug to a specific organ or tissue i.e. spatial placement and controlling the rate of drug delivery to the specific sites i.e. temporal delivery are the two main aspects of the drug delivery systems¹. Now a day the colon has recently become accepted as an increasingly important site for drug delivery. Colon specific diseases are often inefficiently managed by oral therapy, colon specific drug delivery systems, which can deliver drugs to the lower gastrointestinal tract without releasing them in the upper GI-tract, can be expected to increase the quality of life for patients suffering from colon specific diseases. Treatment might be more effective if the drug substances were targeted directly on the site of action in the colon. The concentration of drug reaching the colon depends on formulation factors, the extent of retrograde spreading and the retention time². Number of serious diseases of the colon might be capable of being treated more effectively if drugs were targeted on the colon. Therefore, it appears that targeted drug delivery with an appropriate release pattern could be crucial in providing effective therapy for these chronic diseases. In addition to providing more effective therapy of colon related diseases, colon specific delivery has the potential to address important unmet therapeutic needs including oral delivery of macromolecular drugs³. In the past two decades, the pharmaceutical scientists are extensively investigated in the area of colonic region for targeted drug delivery system Local action in the treatment of ulcerative colitis and Systemic absorption of protein and peptide drugs.

MATERIAL AND METHODS

Equipments used

Method

Micronization of Mesalamine

Micronization Parameters (Spiral Air jet mill)

Air pressure – 8 bar

Grinding Pressure – 4 kg/cm²

Ventury pressure – 1 kg/cm²

Preparation of 5-ASA core tablets

Weigh mesalamine, Sodium starch glycolate, MCC (Avicel PH 101) & pass through sieve no. 40. PVP (K 30) solution in water was prepared for granulation purpose. Wet granules were prepared & sieved through 18 no sieve and dried overnight at 40°C to obtain LOD up to 2% moisture content then granules pass through sieve no 20. After adding 4% magnesium stearate as a lubricant & talc as glidant lubricated granules compressed using a laboratory size multi station tablet press (Emtech) with 8 mm flat faced punches. Tablet quality control tests such as weight variation, crushing strength, friability, thickness, and dissolution were performed on the core tablets.

Compression Coating of Core Tablets⁴⁻⁷

Core tablets were first dedusted then placed in 12 mm die cavity of a laboratory multi press. Depending on the design 100%pectin, pectin: Chitosan (5:1), pectin: Chitosan (10:1) combinations were used for the outer shell compression the coat weights were 400 mg. Tablet quality control tests such as weight variation, crushin strength, friability, thickness, dissolution & erosion rates in different media were carried out.

Evaluation of Pre-compressed granules of Mesalamine

Angle of repose

In this method weighed 20 gm of granule, allowed to flow



ESTIMATION OF KETOROLAC TROMETHAMINE IN PHARMACEUTICAL FORMULATION BY SPECTROPHOTOMETRIC METHOD.

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ABSTRACT

The simple, accurate and precise spectrophotometric method Area Under Curve(AUC) Was established for the estimation of the Ketorolac Tromethamine in Pharmaceutical dosage form. The area under two points of the spectra is directly proportional to the concentration of the component. The area selected for the estimation of the Ketorolac Tromethamine is between 313.20-333.60nm. The method characterize the regression coefficient ($R^2=0.9992$) at concentration range 5-25 μ g/ml. Estimation of the drug was found up to 100% representing the accuracy of the method. The validation of

projected methods was carried out as per the USP guidelines. The developed method can be successfully useful in routine work for the estimation of the Ketorolac Tromethamine in its Pharmaceutical dosage forms.

KEYWORDS: Ketorolac Tromethamine, AUC, Spectrophotometric method.

INTRODUCTION

The Ketorolac Tromethamine is used as the NSAID agent as an anti-inflammatory agent in the treatment of Rheumatoid Arthritis. Chemically it is 1,3-dihydroxy-2-(hydroxyl methyl)propane-2-aminium 5-benzoyl 2-3 dihydro-1H pyroline 1-carboxylate. It is available in white to off white crystalline powder which belongs to BCS-II. Ketorolac Tromethamine is structurally related to the Indomethacin and used for its Analgesic Activity.

The aim of present work is to establish the simple spectrophotometric method AUC for the Routine Estimation of the Ketorolac Tromethamine. The structure of Ketorolac Tromethamine is shown in figure:





Throat et al

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Open Access

Research Article

Formulation and evaluation of Lornoxicam loaded Lyotropic liquid crystalline gel

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ABSTRACT

GIT irritation is prominent limitation with the use of Non-steroidal anti-inflammatory drugs (NSAID's). There is rising interest in designing formulations which will deliver the drug at the site of action as topical gels, to avoid GIT irritation and other systemic side effects. Liquid Crystal phase has emerged as a novel material for the preparation of topical drug delivery system. In present study the attempt is made to prepare Lornoxicam loaded lyotropic liquid crystalline gel using glycerol monooleate. Glycerol monooleate is biocompatible, bioadhesive, penetration enhancer and sustain release agent. It also promotes ceramide extraction and enhancement of lipid fluidity in the stratum corneum region of the skin. Five formulation of lornoxicam were prepared and evaluated for parameters like drug content, viscosity, spreadability, Extrudability *In-vitro* drug release along with *in vivo* study. *In-Vitro* and *Ex-Vivo* drug release kinetics showed that there was 72.85% and 77.98% drug release within 48 hrs. Skin irritation test suggested that prepared formulation was safe for human use. *In-Vivo* evaluation of this formulation was done by carrageenan induced rat paw edema anti-inflammatory model.

Keywords: Lornoxicam, GMO, Lyotropic liquid crystal, Anti-Inflammatory, Topical drug delivery

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INTRODUCTION:

NSAIDs are the best choice to be administered through Topical drug delivery system in the management of diseases like, Osteoarthritis, rheumatoid Arthritis, and similar inflammatory disorders.^[1]

Oral administration of NSAID shows side effects like Nausea, Vomiting, Heartburn, Gastric Ulceration, Epigastria. These drawbacks can be overcome by developing sustained release non-steroidal anti-inflammatory topical gel which is able to provide constant drug concentration at the site of administration. Hence attempt is to formulate a Liquid Crystalline gel (LCG) of Lornoxicam. Glycerol monooleate is used to formulate the LCG. ⁽²⁾ GMO is a mixture of the glycerides of oleic acid and other fatty acids, consisting mainly of the monooleate. GMO offer various Advantages like ⁽³⁾ Biocompatibility, Bioadhesiveness, Penetration Enhancer, Non Toxic, Non Irritant. Pluronic F 127 is used as a stabilizer. The prepared gel is having enhanced moisturizing ability. Moisture content of liquid crystalline system is retained for a long time. It promoted the ceramide

extraction and enhancement of lipid fluidity in the stratum corneum region of the skin. ⁽⁴⁾ These gels are appropriate candidates for sustained release because the drug diffusion is reduced by a factor of 10 to 1000. ⁽⁵⁾ Clinical evidence indicates that topical gel is a safe and effective treatment option for use in the management of skin related disease. ⁽⁶⁾

Topical Drug Delivery System :

Topical drug administration is a localized drug delivery system anywhere in the body through ophthalmic, rectal, vaginal and skin as topical routes. ⁽⁷⁾

this avoids first pass effect, GIT irritation, with increased patient compliance and ease of application ⁽⁸⁾. ⁽⁹⁾ The only major disadvantage associated is that it may cause allergic reaction to the skin, skin irritation, dermatitis⁽¹⁰⁾

MATERIALS & METHODS :

Materials:

Drug Lornoxicam was obtained as a gift sample from Macleods pharmaceuticals, Andheri, Campul Glyceryl



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Research Article

Formulation and Evaluation of the Sustained Release Tablet of Ketorolac Tromethamine Using Natural Polymer as an Extended Releasing Agent

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Available Online: 25th August, 2017

ABSTRACT

Sustained release tablets of Ketorolac Tromethamine were formulated using Aloe vera Gel Powder as extended drug releasing agent. The tablets were evaluated for preformulation studies like angle of repose, bulk density, compressibility index and physical characteristics like hardness, weight variation, friability and drug content. *In-vitro* release of drug was carried out in phosphate buffer solution pH 6.8 for twelve hours. All the physical characters of the formulated tablet were found within the acceptable limit. The tablet with Aloe Vera gel powder in Batch-F3 exhibited greater drug release than other batches. It is proved from the dissolution profile of Ketorolac Tromethamine, that Aloe Vera gel powder possess the drug release retarding ability.

keywords: Ketorolac Tromethamine, Aloe Vera Gel Powder, Sustained release tablets, release retarding ability.

INTRODUCTION

Drug products designed to reduce the frequency of dosing by altering the rate of drug absorption. Regular research aroundis, that the use of natural biocompatible polymer while formulating the dosage form for oral sustained release administration. The advantages of natural plant based excipients include low cost, natural origin, free from side effects, biocompatible, bioacceptable, renewable source; environmental friendly processing, local availability, better patient tolerance as well as patient acceptance. The Ketorolac Tromethamine is the NSAID belongs to BCS-I that exhibit the analgesic activity, used in treatment of rheumatoid arthritis. It gives upto the approximately 100% absorption upon oral administration. But the half life of the drug is 2.5hrs which requires frequent administration of drug to maintain the required therapeutic level in body. Hence it is required to be formulated in sustained release dosage form. This study mainly aimed for oral controlled delivery system of highly water soluble drug i.e. Ketorolac Tromethamine using Aloe Vera gel powder as extended drug releasing agent. The genus Aloe belongs to the family, Liliaceae and includes the species *Aloevera barbadensis miller*, commercially known as *Aloe vera*. Chemical analysis has shown that the Aloe vera gel powder contains amino acids, minerals, vitamins, enzymes, proteins, polysaccharides and biological stimulators.

MATERIAL AND METHOD

Material

The Ketorolac Tromethamine was obtained as gift sample from Divis Pharmaceuticals Pvt.Ltd. India. And the

Aloevera Gel powder was gifted from Maple Biotech Pvt.Ltd Bhosari, Pune. All other excipients and chemicals used were of analytical reagent grade.

Method

Preparation of sustained release tablet of ketorolac tromethamine using natural polymer (aloe vera gel powder)

The direct compression method was used for the formulating the sustained release tablet of the ketorolac tromethamine using the natural polymer aloevera gel powder.

The Ketorolac Tromethamine, Aloevera gel powder, lactose were mixed and passed through the 40# sieve. Afterward magnesium stearate and talc was added and mixed to it. Final mixture was compressed on the multistation rotary tablet compression machine.

Evaluation parameters

Phytochemical studies

Aloe vera gel powder was subjected to preliminary tests to confirm the nature of the obtained powder. The tests

Table 1: Formula for the formulation of the sustained release tablet using aloevera gel powder.

Ingredient (mg)	F1	F2	F3
Ketorolac	20	20	20
Tromethamine			
Aloevera Gel Powder	40	60	80
Magnesium stearate	2	2	2
Talc	4	4	4
Lactose	84	64	44
Total	150	150	150



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Research Article

Formulation and Evaluation of Colon Targeted Drug Delivery of Mesalamine

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Available Online: 25th January, 2017

ABSTRACT

In this study, we report pectin–Chitosan compression coated core tablets of Mesalamine for colonic delivery. Each 150 mg core tablet contained Mesalamine and was compression coated using 100% pectin 1:1, 10 pectin:1 Chitosan, or 10 pectin :2 Chitosan, at coat weights as 400mg. Drug dissolution or system erosion or degradation studies were carried out in pH 1.2, 6.8,7.4 phosphate buffers using a pectinolytic enzyme. The system was designed based on the gastrointestinal transit time concept, under the assumption of colon arrival times of 6 h. It was found that pectin alone was not sufficient to protect the core tablets and Chitosan addition was required to control the solubility of pectin. The optimum Chitosan concentration was 1 and such system would protect the cores up to 6 h and after that under the influence of pectinase the system would degrade faster and delivering 5-ASA to the colon. The pectin– Chitosan (10:1) envelope was found to be a promising drug delivery system for those drugs to be delivered to the colon.

Keywords: Colonic delivery, 5-Aminosalicylic acid, Pectin, Chitosan, Compression coating, Pectinase.

INTRODUCTION

Delivery of a drug to a specific organ or tissue i.e. spatial placement and controlling the rate of drug delivery to the specific sites i.e. temporal delivery are the two main aspects of the drug delivery systems¹. Now a day the colon has recently become accepted as an increasingly important site for drug delivery. Colon specific diseases are often inefficiently managed by oral therapy, colon specific drug delivery systems, which can deliver drugs to the lower gastrointestinal tract without releasing them in the upper GI-tract, can be expected to increase the quality of life for patients suffering from colon specific diseases. Treatment might be more effective if the drug substances were targeted directly on the site of action in the colon. The concentration of drug reaching the colon depends on formulation factors, the extent of retrograde spreading and the retention time². Number of serious diseases of the colon might be capable of being treated more effectively if drugs were targeted on the colon. Therefore, it appears that targeted drug delivery with an appropriate release pattern could be crucial in providing effective therapy for these chronic diseases. In addition to providing more effective therapy of colon related diseases, colon specific delivery has the potential to address important unmet therapeutic needs including oral delivery of macromolecular drugs³. In the past two decades, the pharmaceutical scientists are extensively investigated in the area of colonic region for targeted drug delivery system Local action in the treatment of ulcerative colitis and Systemic absorption of protein and peptide drugs.

MATERIAL AND METHODS

Equipments used

Method

Micronization of Mesalamine

Micronization Parameters (Spiral Air jet mill)

Air pressure – 8 bar

Grinding Pressure – 4 kg/cm²

Ventury pressure – 1 kg/cm²

Preparation of 5-ASA core tablets

Weigh mesalamine, Sodium starch glycolate, MCC (Avicel PH 101) & pass through sieve no. 40. PVP (K 30) solution in water was prepared for granulation purpose. Wet granules were prepared & sieved through 18 no sieve and dried overnight at 40°C to obtain LOD up to 2% moisture content then granules pass through sieve no 20. After adding 4% magnesium stearate as a lubricant & talc as glidant lubricated granules compressed using a laboratory size multi station tablet press (Emtech) with 8 mm flat faced punches. Tablet quality control tests such as weight variation, crushing strength, friability, thickness, and dissolution were performed on the core tablets.

Compression Coating of Core Tablets⁴⁻⁷

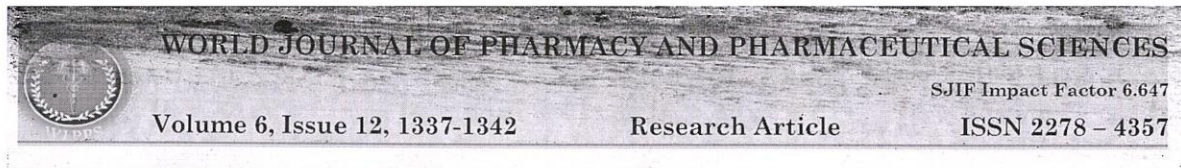
Core tablets were first dedusted then placed in 12 mm die cavity of a laboratory multi press. Depending on the design 100%pectin, pectin: Chitosan (5:1), pectin: Chitosan (10:1) combinations were used for the outer shell compression the coat weights were 400 mg. Tablet quality control tests such as weight variation, crushing strength, friability, thickness, dissolution & erosion rates in different media were carried out.

Evaluation of Pre-compressed granules of Mesalamine

Angle of repose

In this method weighed 20 gm of granule, allowed to flow

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**FORMULATION AND EVALUATION OF A POLYHERBAL FACE
GEL FOR DAILY USE**

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ABSTRACT

Herbal formulations have growing demand in the world market. Face wash prepared by herbal ingredient are better than the synthetic ingredient to avoid side effects. The present work deals with the development and evaluation of the polyherbal face gel containing three extract of Neem leaves, Hibiscus flower, Aloe vera and three oils Peppermint, Cinnamon oil, Lemon oil and Camphor. The plant have been reported in the literature having good antimicrobial, anti- oxidant, antiseptic, anti- inflammatory activity. Acne is the common disorder. It is mainly caused by the oil glands. Face and neck are the areas more prone to the acne. The above properties of plant which are necessary to keep the skin, smooth and attractive. Various formulations batches i.e. F1 and F2 were prepared using gelling agent like Carbapol 940 in varied concentration. Gel was prepared and evaluated for its

Spreadability, consistency, PH and the result were found to be satisfactory.

KEY WORDS: Polyherbal Face Gel, Daily use, Anti-bacterial, Cleansing agent.

INTRODUCTION

Acne is an extremely common disorder of skin that affects virtually all individuals. About 85% of the teenagers face this problem today. The incidence of acne peaks at teenage, but substantial no. of men and women between 20-30 years of age are also affected by the disorder. Skin is major part of body. The disorder occurring due to changes in hormones such as androgens, corticosteroids.



**PHARMACOGNOSTIC, PHYTOCHEMICAL, PHYSICOCHEMICAL
AND TLC PROFILE STUDY OF LEAVES *BOUGAINVILLEA GLABRA*
*CHOISY (NYCTAGINACEAE)***

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ABSTRACT

This paper deals with the detailed study of pharmacognostic, phytochemical, physicochemical and TLC profile study of leaves *Bougainvillea glabra Choisy*. These leaves were collected, dried in a shed, made a powder by grinding and powdered leaves were subjected to alcohol extraction by Soxhlet extraction method. The extract then subjected for chemical tests to investigate chemical profile of *Bougainvillea glabra*. Work comprises of collection, identification, microscopically, morphologically, phytochemical evaluation of leaves of plant and TS. Shows presence of epidermis, vascular bundles, trichomes (uniseriate, multicellular, bulbous) and stomata actinomyces type. Extraction is carried out by using Soxhlet extraction technique. Alcoholic extract of leaf shows presence of alkaloids, carbohydrates, flavonoids, tannins & saponins. Physicochemical analysis was carried out on these leaves, which include parameters such

as water soluble ash, acid insoluble ash, sulphated ash of plant were determined. TLC profiling of plant extract in different solvent system was performed & different R_f values are obtained.

KEYWORDS: *Bougainvillea glabra Choisy*, Microscopical study, TLC, Physicochemical screening.



ज्ञानगंगा घरोघरी

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PHARMACOGNOSTIC, PHYTOCHEMICAL, PHYSICO-CHEMICAL AND TLC PROFILE STUDY OF LEAVES THESPIA POPULNEA
SOLEX.CORREA. (MALVACEAE)

August 2021

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Abstract and Figures

Thespesia Populnea

Morphology of Leaves of... Staining / Diagnosis/... Physico-Chemical/Phytochemicals constant of leav... of Extracts of...

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**PHARMACOGNOSTIC, PHYTOCHEMICAL, PHYSICOCHEMICAL
AND DETAIL MICROSCOPICAL EVALUATION OF *CAPPARIS*
ZEYLANICA LINN. LEAVES**

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ABSTRACT

Capparis Zeylanica Linn. Commonly known as Indian caper is an important medicinal plant. The present study attempt to evaluate the Pharmacognostic, phytochemical, physicochemical and detail microscopical evaluation parameters of *Capparis zeylanica* Linn. leaves belong to family *Caparadaceae* is a climbing shrub found in through out India. The plant is used in folk medicine to treat rheumatism, abdominal ulcers and hernia, swelling, itching, hepatitis, liver tonic, insect poisoning and anti-inflammatory, analgesic, antioxidant, antipyretic and antimicrobial. But there is less work reported on *Capparis zeylanica* Linn. leaves. Physicochemical parameters, preliminary characterization and phytochemical analysis were carried out. There finding will be useful to words establishing quality control parameters for the standardization of the plant material.

KEYWORDS: *Capparis zeylanica* Linn., Phytochemical screening, Microscopical study.

INTRODUCTION

Capparis zeylanica Linn. (Capparaceae) is a many branched thorny, sub-scandent climbing shrub. Plants are 2-3 m in height, armed with 3-6mm long recurved thorns, branched, leaves are elliptic or broadly lanceolate, base rounded, apex mucronate; flower profuse, pinkish white, later turning pink, berries are globular or elliposide, 3-4 cm in diameter, and seeds are globase, embedded in white pulp. It is grows in moist habitat. The plant distributed through out the major parts of India, Bangladesh and some parts of Pakistan.^[1] *Capparis zeylanica*



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Pharmacognostic, phytochemical, physicochemical and TLC profile study Mace (Aril) of *Myristica malabarica* Lamk. (Myristicaceae)

Seema Yuvraj Mendhekar*, Chetana Dilip Balsaraf, Mayuri Sharad Bangar, S.L. Jadhav, D.D. Gaikwad

ABSTRACT

The plant *Myristica malabarica* Lamk. is traditionally used as a medicine and spices in food. It is belonging to family *Myristicaceae*. The plant is native to India and endangered trees are mostly found in western ghat. Extracted with various solvents by successive soxhlet hot extraction process with increasing order of polarity on phytochemical investigation. The extract has shown alkaloids, saponin, tannin and flavones glycosides. It has important medicinal uses like Ayurvedic Medicines. It is traditionally used as anticancer, anti-inflammatory, anti-Oxidant, Sedative hypnotics, Antimicrobial, Antifertility, Hepatoprotective and cytotoxicity. The chemical constituents such as Malabaricones, Malabaricanol, Isoflavones are isolated. *Myristica* Fragrans also known as fragrant Nutmeg or true Nutmeg. The present study i.e. Pharmacognostic, Phytochemical, Physicochemical and TLC Profile Study of Mace (Aril) Of *Myristica malabarica* Lamk. is helpful in the characterization of the crude drug. Physicochemical and phyto-chemical analysis of mace confirm the quality and purity of plant and its identification. The information collected is useful for further pharmacological and therapeutical evaluation of mace (Aril) Of *Myristica malabarica* Lamk. and anthology of quality control of crude drug.

Keywords: *Myristica* fragrans, Malabaricone, Malabaricanol, Phytochemical screening, Microscopical study, TLC.

INTRODUCTION

Myristica malabarica is commonly called as Malabar nutmeg or Jatiphala. *Myristica malabarica* seed and seed aril is used as spice in Indian foods. They enhance the taste and aromatic flavor of the food. Recent scientific studies proved their biological activity according to their traditional claim. They are now known to possess Gastroprotective, anticancer, antioxidant, antifungal, anthelmintic. Plant have played a significant role in maintaining human health & improving the quality of human life for thousands of years & have served humans well as valuable components of medicines. Herbal Medicine is based on the premise that plant contain natural substances that can promote health. Malabar Nutmeg is a tree about 25 m tall. Bark is greenish-black, smooth; blaze reddish. Branches are horizontal, branchlets round, hairless. Red sap oozes from cut end of bark. Alternately arranged leaves, 9.5-22 x 3.7-10 cm, are elliptic or elliptic-oblong, tip pointed, base narrow or flat, margin entire, glossy above, hairless and glaucous beneath, leathery. Leaf-stalks are 1.0-1.5 cm long. Midrib is raised above, secondary nerves 8-14 pairs. Flowers are unisexual, urn-shaped, and white. Male flowers are numerous, smaller than female flowers, borne in cymes in leaf axils. Female flowers are borne in 5-6 flowered umbels. Capsule is 5-7.5 x 1.8-3.5, oblong, velvety, with one oblong seed. Aril covering the seed yellow and stringy. Malabar Nutmeg is endemic to the Western Ghats - South and Central Sahyadris [1-2].

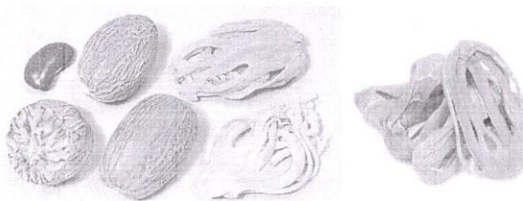


Figure 1: Mace (Aril) of *Myristica malabarica* Lamk.

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Research Article

PHARMACOGNOSTIC, PHYTOCHEMICAL, PHYSICOCHEMICAL AND DETAIL MICROSCOPICAL EVALUATION OF LEAVES *ABUTILON INDICUM*

(*L.*) SWEET SSP. *INDICUM* FAMILY (*MALVACEAE*)

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ABSTRACT

Abutilon indicum (L.) Sweet ssp. *Indicum* Family (Malvaceae) popularly known as *Atibala* is used as one of the most important drug in traditional system of medicine to treat various ailments. The present study deals with pharmacognostic, phytochemical, physicochemical and detail microscopical evaluation of leaves of *Abutilon indicum*. *Abutilon indicum* may be attributed to the successful conversion of botanical folklore medicines to modern wonder drugs and to amend the health condition for people and also to used in pharmaceuticals and nutraceuticals merchandise of commercial significance. Ethnic people use the ethnobotanical important plant species of *Abutilon indicum*. So there is necessary to study some phytochemical analysis and biological activities of this plant. Phytochemical screening should be carried out by using pure extract of various plant species of *Abutilon indicum*. Purification and toxicological studies should be carried out with a view of sourcing Antimicrobial agents for drug development. The propose work of present research is to focus on poisonous effect of *Abutilon indicum* in the form of powder of leaves and prepare the crude extract.

Keywords: *Abutilon indicum* (L.) Sweet ssp. *Indicum*, Malvaceae, *Atibala*, Pharmacognostic.

INTRODUCTION

Indian Mallow is an erect velvety-pubescent shrub with circular-ovate or heart-shaped leaves with coarsely crenate-serrate margins. The plant can reach up to 1-2 m. The leaves are alternately arranged, and have long stalks and have velvety, soft, pale hairs on them. Orange-yellow flowers, 2-3 cm across, occur solitary in axils, on long stalks, 4-7 cm. Orange-yellow petals are triangular-obovate, 1 cm long or slightly more, staminal-tube hairy with stellate hairs. Fruit is quite interesting - it is circular in shape, consisting of 11-20 radiating hairy carpels, brown when dry; each carpel flattened, somewhat boatshaped. Seeds are kidney-shaped. The plant is a weed commonly found on disturbed land. Flowering: September-April. The leaves contain mucilage, tannin, amino acids, glucose, fructose, galactose, gallic acid sesquiterpene alkaloids, flavonoids, sterols,

triterpenoids, saponins, cardiac glycosides and asparagin (11.5 %). Asparagin has diuretic activities. Mucilage present in the plant protects the mucous membrane, urinary system and helps in gastro-intestinal inflammations, lesions and ulcers. Mucilage is diuretic and demulcent (relieve irritation of the mucous membranes in the mouth by forming a protective film). It reduces acidity. annin is astringent and stops bleeding on topical application and diarrhea on oral use. Roots contain fatty acids (linoleic, oleic, stearic, palmitic, lauric, myristic, caprylic, capric etc.). Flowers contain seven flavonoid compounds including quercetin and its glycosides. A chemical compound, β -sitosterol, which has been identified as the active ingredient in many medicinal plants, is present in *A. indicum* and a petroleum ether extract provided larvicidal properties against the mosquito larvae *Culex quinquefasciatus*.



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DEVELOPMENT AND EVALUATION OF CREAM CONTAIN GREEN TEA EXTRACT, ALOE GEL AND VITAMIN E: AS SKIN TONER

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Abstract:
The purposes of the present research work was to development and evaluate herbal vanishing cream. This vanishing cream Contain Green Tea Extract, Aloe Gel and Vitamin E: As Skin Toner. Herbal creams offer several advantages over other creams. The majority of existing creams which has prepared from drugs of synthetic origin and give extra fairness to face, but it has several side effects such as itching or several allergic reactions. Herbal creams do not have any of these side effects, without side effects it gives the nourishment to skin. Method carried out to prepare herbal cream was very simple. Firstly, oil phase was prepared, the mixture of stearic acid (17%), potassium hydroxide (0.5%), sodium carbonate (0.5%) were melted at 70°C. Secondly aqueous phase was prepared, mixture of alcoholic extract of crude drugs, including Glycerin (6%), perfume (0.3%), water (71%) heated at 70°C. Then aqueous phase was added into the oil phase at 70°C with continuous stirring. Now, once the transfer was completed it was allowed to come at room temperature all the while being stirred. Perfume was added at last just before the finished product was transferred to suitable container. The above prepared herbal cream was evaluated. The physical parameters such as pH, homogeneity by visual and by touch, appearance (color), rubout spread ability, wetness, washability, consistency. Patch test, irritancy test accelerated stability studies, type of smear, emolliency were determined.

Key Words: Vanishing cream, Evaluation, Green tea, Vitamin E, Aloe gel

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