Original Article

Formulation Development and Evaluation of Gastro Retentive Bio Adhesive Drug Delivery System for Moxifloxacin. HCl

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ABSTRACT

Objective: The purpose of present research work is to develop gastro retentive formulation for Moxifloxacin using various drug release modifiers. Moxifloxacin, novel synthetic fluoro quinolone, antibacterial agent. **Methods:** SR granules were prepared by gastro retentive tablets of Moxifloxacin. HCl were prepared using variable amounts of HPMCK100M, *Lannea coromandelica* gum (LCG) by moist granulation technique. Totally 10 SR granule formulations were prepared and subjected to precompression analysis and drug release profiles. Based on the results screening of concentrations for polymers and are used for Tablet formulations. Six tablet formulations were designed and are evaluated for various pharmacopoeial tests. Drug release profiles of formulation trails subjected to kinetic modeling. a,b,r were determined. **Results:** The results reveals that retention time decreases with decreased viscosity of polymer. F16 prepared with LCG was found to have highest swelling property. High bioadhesive strength of the formulation is likely to increase its GI residence time. *Lannea coromandelica* gum powder needs to explored as a sustain release material at commercial scale.

Key words: Moxifloxacin. HCl, Gastroretentive, Bio adhesion, HPMCK100M, Lannea coromandelica gum, Swelling Study.

INTRODUCTION

Numerous factors shows impact on effectiveness of oral delivery practice such as gastric emptying process, GI transit time, Drug release pattern from Formulation and Absorption site for drug.[1-3] The design of oral controlled Drug delivery systems (DDS) is targeted to obtain predictable and improved *in-vivo* availability. Gastric transit time in humans, influences absorption of drugs, can result inappropriate drug release from formulation leading to diminished clinical response. Gastric transit time is a dynamic process and ability to sustain the release of drug at predictive rate, which retain in the acidic environment for a longer period of time than prompt release formulations.

Several difficulties were present in front of researchers for developing controlled release systems for better absorption, improved bioavailability.[4] The controlled gastric retention of solid dosage forms may be achieved by the mechanisms of muco adhesion, flotation, sedimentation (High density), expansion, modified shape systems, or by the simultaneous administration of pharmacological agents that delay gastric emptying.[4-6]

Bioadhesive delivery systems produce many more benefits over other oral modified release systems by virtue of gastro retentivity, localization by targeting drug product at a specific site. It also proven that bioadhesive systems, they provide intimate contact between absorptive

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Original Article

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Statistical design, formulation, and evaluation of gastroretentive floating tablets for moxifloxacin using natural and semisynthetic polymers

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ABSTRACT

Purpose: The objective of the current study is to develop gastroretentive formulation for moxifloxacin using various drug release modifiers, moxifloxacin, novel synthetic fluoroquinolone, and antibacterial agent. **Materials and Methods:** Floating tablets of moxifloxacin.HCl were prepared using variable amounts of hydroxypropyl methylcellulose (HPMC) K100M and *lannea coromandelica* gum (LCG) with effervescent mixtures as per 3^2 factorial designs by direct compression technique. Amount of release modifiers required to obtain the prolonged release of drug was chosen as independent variables, X_1 and X_2, respectively, whereas time taken for 10%, 50%, 75%, and 90% of drug release were chosen as dependent variables. **Results and Discussion:** Nine formulations were developed and are checked for pharmacopeial tests. Results show that all the factorial batches were lie within the standard limits. Dissolution parameters of all formulations were subjected to kinetic fitting; various statistical parameters were determined. Polynomial equations were developed and verified for dependent variables. **Conclusion:** Formulation (F_5) containing 50 mg of HPMCK100M and 50 mg of LCG is the best formulation showing similarity f_2 = 71.733 and f_1 = 4.272 with the marketed product (AVELOX). Formulation F_5 follows Higuchi's kinetics, Non-Fickian Diffusion, and first-order kinetics (n = 1.098).

Keywords: 3^2 factorial design, first-order kinetics, gastroretentive, hydroxypropyl methylcellulose K100M, lannea coromandelica gum, moxifloxacin, non-Fickian diffusion mechanism

INTRODUCTION

The effective oral drug delivery practice depends on numerous factors such as gastric emptying process, gastrointestinal (GI) transit time, release of drug from dosage form, and absorption site for the drug.[1-3] The design of oral controlled drug delivery systems (DDS) is aimed to obtain desirable and enhanced bioavailability. Gastric emptying is a dynamic process and gastroretentivity of dosage form results improved clinical response.

Numerous factors show the impact on the effectiveness of oral delivery practice such as gastric emptying process, GI transit time, drug release pattern from the formulation and absorption site for the drug. The design of oral controlled DDS is targeted to obtain predictable and improved *in vivo* availability. Gastric transit time in humans, influences absorption of drugs, can result inappropriate drug release from formulation leading to diminished clinical response. Gastric transit time is a dynamic process and ability to sustain the release of drug at a predictive rate, which retains in the acidic environment for a longer period of time than prompt release formulations.

Several difficulties were present in front of researchers for designing controlled release systems for better absorption, improved bioavailability.[4] The controlled gastric retention of solid dosage forms was obtained by numerous mechanisms such as flotation, bioadhesion, high density (sedimentation), modified shape systems, expansion, or by simultaneous administration of pharmacological agents that delay gastric emptying.[5,6]

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Research Article

A NEW VALIDATED STABILITY INDICATING RP-HPLC METHOD FOR THE QUANTIFICATION OF ALLOPURINOL AND LESINURAD IN BULK AND PHARMACEUTICAL FORMULATIONS

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ABSTRACT

The objective of this study was to develop and validate a method for simultaneous quantitative analysis of Allopurinol and Lesinurad in bulk drug and pharmaceutical formulations. An isocratic HPLC analysis method using a reverse phase Waters spherisorb ODS1 C18 column (250 mm x 4.6 mm, 5µ) and a simple mobile phase without buffer was developed, optimized, and fully validated. Analyses were carried out at a flow rate of 0.9 mL/min at 50°C and monitored at 246 nm. This HPLC method exhibited good linearity, accuracy, and selectivity. The recovery (accuracy) of both Allopurinol and Lesinurad from all matrices was greater than 98%. The Allopurinol and Lesinuradpeak detected in the samples of a forced degradation study and no interference of excepients or the degradation products formed during stress study. The method was rugged with good intra- and interday precision and sensitive. This stability indicating HPLC method was selective, accurate, and precise for the simultaneous analysis of Allopurinol and Lesinurad in pharmaceutical formulations.

Keywords: Allopurinol, Lesinurad, HPLC analysis, Method development, Stress degradation

1. INTRODUCTION

Allopurinol is a xanthine oxidase inhibitor specially used for the treatment of gout caused by high levels of uric acid in the body [1]. It is also used to prevent specific types of kidney stones and for high uric acid levels that can occur with chemotherapy [2].Allopurinol inhibits xanthine oxidase which is the enzyme that responsible for converting hypoxanthine to xanthine and xanthine to uric acid [3]. Stomach upset, nausea, diarrhea, or drowsiness are the possible side effects with the use of allopurinol.

Lesinurad is a non-nucleoside reverse transcriptase inhibitor and a novel uric acid transporter 1 inhibitor prescribed for the treatment of hyperuricemia associated with gout [4, 5]. It is prescribed for the patients that are not achieved target serum uric acid levels with xanthine oxidase inhibitor like allopurinol, oxypurinol and tisopurine [6]. Lesinurad works by inhibiting urate anion transporter (URAT1) which is responsible for uric acid reabsorption in proximal tubule which leads to the increase of urate excretion in urine and reduce the concentration in plasma [7].

Kidney problems such as lower back pain, painful or difficult urination, nausea, vomiting, change in the amount of urine are the possible side effects associated with the use of Lesinurad.

Allopurinol and Lesinurad are the combined medication used for the treatment of gout. In literature only two HPLC assay methods were reported for the simultaneous analysis of Allopurinol and Lesinurad [8, 9]. One Ultra-performance hydrophilic interaction liquid chromatography coupled with tandem mass spectrometry method was reported for the analysis of Allopurinol and Lesinurad in combination with oxypurinol in rat plasma [10]. Very few methods reported for the analysis of Lesinurad in single dosage formusing UV spectrophotometry [11] or in combination with alphalipoicacid [12] and oxipurinol [13] using HPLC. One HPLC method for the analysis of Lesinurad in formulations [14] and one UHPLC-MS/MS method for the analysis of Lesinurad in rat plasma [15] were reported. As the literature survey confirms that there is no stability indicating HPLC method reported for the

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Original Article

Formulation Development and Evaluation of Gastro Retentive Floating Drug Delivery System for Novel Fluoroquinolone using Natural and Semisynthetic Polymers

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Abstract

The purpose of present research work is to develop gastro retentive formulation for Moxifloxacin using various release retardants. Moxifloxacin, that is a novel synthetic fluoro quinolone, is an iantibacterial agent. Floating tablets of Moxifloxacin. HCl were prepared using variable amounts of HPMCK4M, HPMCK15M and HPMCK100M with effervescent mixtures by direct compression technique. Totally 9 formulations were designed, prepared and are evaluated for various pharmacopoeial tests like uniformity of weight, thickness, Hardness, friability, floating lag time, Total floating time. Drug release profiles of formulation trails subjected to kinetic modeling. Parameters like correlation coefficient(r), slope (b), intercept (a) were determined. The results reveal that floating lag time decreases with decreased viscosity of polymer composites. According to SUPAC guidelines formulation (F_4) containing 12.5% HPMCK15M was found to be most identical formulation (similarity factor f_2= 70.997, dissimilarity factor f_1= 6.007 to marketed product (AVELOX). Trail F_4 drug release found to be first order kinetics, Non-Fickian Diffusion Anomalous Transport. (n= 1.065).

Keywords: Moxifloxacin. HCl, Gastroretentive, Floating Lag Time, HPMCK15M, Anomalous transport, First order kinetics.

1. Introduction

The effective oral drug delivery practice depends on numerous factors like gastric emptying process, GI transit time, release of drug from dosage form and absorption site for drug [1-3]. The design of oral controlled drug delivery systems (DDS) is aimed to obtain desirable and enhanced bioavailability. Gastric emptying is a dynamic process and gastro retentivity of dosage form results improved clinical response.

Several difficulties were present in front of researchers (Formulation Scientist) for designing controlled release systems for better

DRUG DISCOVERY

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Assessment of Antidepressant Profile of Methanolic extract of *Areca catechu* using Mice as an experimental Model

Alhasan Sabah Mansour[1], Prasada Rao Manchineni[2], Raghavendra Kumar Gunda[3]✉

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ABSTRACT

Purpose: The purpose of present investigation to assess the anti-depressa activity of methanolic extract of *Areca catechu* using Mice model. *Methods:* T methanolic extract was prepared using cold extraction process with the he of continuous hot percolator apparatus. The final extract was evaluated preliminary phytochemical analysis, acute toxicological studies (Mice Mode Anti-depressant assessment was carried out as per the standard methods forced swimming test, tail suspension test, 5-HT induced head twitches mice, clonidine induced aggression, L-dopa induced hyper activity a aggressive behavior test. *Results:* Results reveals that extract possess go antidepressant potential. By observing significant change in the immobili (reduced immobility) for both forced swimming test as well tail suspensi test it confirms the antidepressant effect for *Areca catechu* methanolic extra *Conclusion:* Methanolic extract of Areca catechu having potent antidepressant profile. Further continuing research is needed to determi constituents, those having antidepressant activity for the safe and effective u in human welfare.

Keywords: Methanolic extract, *areca catechu*, mice, immobility, tail suspensio test, forced swimming.

1. INTRODUCTION

Among all neurological disorders Depression is considered to be mo affective one compared to other disorders of the same class. A wide range categories were seen from a mild to severe kinds of depression, sometim transformed to hallucinations; cases were reported earlier (Porter et al., 200 Depression shows typical characteristics by observing loss of appeti (anorexia), disturbance in sleep and behavior as well energy (fatigu (Frasure et al., 2006). It was globally recognized as life threatening ailmer There is no restriction to age , it was experienced by all ages of patients fro pediatrics to geriatrics (Anderson et al., 1998) Form the literature; it came know the major categories of depression referred as unipolar and bipol

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Original Research Article
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Effect of combination polymers of natural and semi synthetic origin on the drug release of Flavoxate. HCl

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Abstract:

The objective of current work is to study the effects of combination of macromolecules (polymers) of natural (*Lannea coromandelica* gum) and semi synthetic (HPMCK100M) origin on the drug release of Flavoxate.HCl from the Gastro retentive floating formulation.Flavoxate.HCl, an antispasmodic agent,Mainly used for treating urinary incontinence andurgency of urination.Floating tablets of Flavoxate.HClwere prepared using variable composition of HPMCK100M, *Lannea coromandelica* gum (LCG) with effervescent mixturesby direct compression technique.9 formulations weremade and evaluated for quality control parameters. the obtained results showthat all formulations pass the compendial limits. Data obtained from the dissolution study fitted well to kinetic modeling andkinetic parameters were determined.$GRFX_5$composed of 40mgof HPMCK100M &40mg of LCG, is the best formulation showing similarity f_2=84.66, f_1=4.29with the marketed product (**URISPAS**). Formulation $GRFX_5$follow first order, whereas release mechanism found to be nonfickian type (n= 0.77).

Keywords: Flavoxate.HCl; gastro retentive; HPMCK100M; *Lannea coromandelica* gum; Non-Fickian Diffusion.

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1. Introduction

Gastric emptying is a dynamic process and gastro retentivity of dosage forms results in improved clinical response [1].

Effectiveness of oral delivery practice was influenced by certain factors such as gastric emptying process, GI transit time, Drug release pattern from theformulation and Absorption site of drug.Gastric transit time in humans influences absorption of drugs, thatcan result in inappropriate drug release from formulation leading to diminished clinical response. Gastric transit time is a dynamic process and ability to sustain the release of drug at predictive rate, which retain in the acidic environment for a longer period of time than prompt release formulations.

The controlled gastric retention of solid dosage forms was obtained by numerous mechanisms such as flotation, bioadhesion, High density (sedimentation), modified shape systems, expansion, or by simultaneous administration of pharmacological agents that delay gastric emptying [2-6].

Floating Drug Delivery Systems (FDDS) have a bulk density that is less than gastric fluids and thus remain buoyant in gastric environment for prolonged period of time, without affecting the gastric emptying rate. Dosage form stayed in stomach due to flotation mechanism,

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Effect of combination polymers of natural and semi synthetic origin on the drug release of Flavoxate. HCl

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Abstract:

The objective of current work is to study the effects of combination of macromolecules (polymers) of natural (*Lannea coromandelica* gum) and semi synthetic (HPMCK100M) origin on the drug release of Flavoxate.HCl from the Gastro retentive floating formulation.Flavoxate.HCl, an antispasmodic agent,Mainly used for treating urinary incontinence andurgency of urination.Floating tablets of Flavoxate.HClwere prepared using variable composition of HPMCK100M, *Lannea coromandelica* gum (LCG) with effervescent mixturesby direct compression technique.9 formulations weremade and evaluated for quality control parameters. the obtained results showthat all formulations pass the compendial limits. Data obtained from the dissolution study fitted well to kinetic modeling andkinetic parameters were determined.GRFX$_5$composed of 40mgof HPMCK100M &40mg of LCG, is the best formulation showing similarity f_2=84.66, f_1=4.29with the marketed product (**URISPAS**). Formulation GRFX$_5$follow first order, whereas release mechanism found to be nonfickian type (n= 0.77).

Keywords: Flavoxate.HCl; gastro retentive; HPMCK100M; *Lannea coromandelica* gum; Non-Fickian Diffusion.

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1. Introduction

Gastric emptying is a dynamic process and gastro retentivity of dosage forms results in improved clinical response [1].

Effectiveness of oral delivery practice was influenced by certain factors such as gastric emptying process, GI transit time, Drug release pattern from theformulation and Absorption site of drug.Gastric transit time in humans influences absorption of drugs, thatcan result in inappropriate drug release from formulation leading to diminished clinical response. Gastric transit time is a dynamic process and ability to sustain the release of drug at predictive rate, which retain in the acidic environment for a longer period of time than prompt release formulations.

The controlled gastric retention of solid dosage forms was obtained by numerous mechanisms such as flotation, bioadhesion, High density (sedimentation), modified shape systems, expansion, or by simultaneous administration of pharmacological agents that delay gastric emptying [2-6].

Floating Drug Delivery Systems (FDDS) have a bulk density that is less than gastric fluids and thus remain buoyant in gastric environment for prolonged period of time, without affecting the gastric emptying rate. Dosage form stayed in stomach due to flotation mechanism,

Research Article

A study on pain assessment and management in post-operative patients

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ABSTRACT

Introduction: Pain is subjective in nature. It can express different manners by the patient (or) Individuals. The role of diagnostic pain procedures is considered very important. It can be classified into acute pain (i.e.; short-lived pain)and chronic pain (i.e.; pain that lasts for months). It shows the effect on the socio-economic status of the patients. Poor pain management is likely to persist until pain management practices became consistent with guidelines developed from the best available scientific evidence. **Aim:** The main aim of the present study was to find out the pain assessment importance during pain management. **Materials and Methods:** This study was a prospective observational multi-center study. **Results:** The study was conducted from July 2021 to December 2021 in various hospitals in and around the Guntur district. A total of 563 patients participated in the current study out of 290 were males and the remaining were females. At the 4-h visual analog scale (VAS) evaluated that, moderate pain was found to be 39.25% of the total population and severe pain as 19.89%. The study results were monitored and continued for 24 h. Only 5.5% of patients were consumed strong opioids during the first 24 h as postoperative analgesics. **Conclusion:** Pain assessment plays a major role in the management of chronic and acute pain. If the assessment was done we can improve the pharmaceutical care and improved socio-economic status of the patients.

Keywords: Pain assessment, pain, rational, scientific evidence, subjective

Introduction

Pain is the fifth vital sign. Pain that is assessed at regular intervals and treated with the same zeal as abnormalities in other vital signs has a much better chance of being treated effectively. The care of patients with pain is challenging and requires a systematic approach to assessment and treatment. In the past two decades, it has been seen that there is a gradual shift in focus toward pain control and pain management, independent of the cause of the pain. Pain increases morbidity and mortality.[1,2]

The different type's scales are as follows[3,4]

a. Facial scale
b. Numerical rating scale
c. FLACC scale
d. CRISE scale
e. COMFORT scale
f. Mc Gill Pain scale
g. Color Anlog scale
h. Mankoski pain scale
i. Brief pain inventory
j. Visual analogue scale (VAS).

The characteristics and factors to consider a complete pain assessment are the intensity, timing, location, quality, personal meaning aggravating and alleviating factors, and pain behavior. Physiologic processes of pain including the activity of neurotransmitters are operative at multiple sites along the structural pathway to aid in conveying the signal. This process is referred to as nociception. Nociceptive process begins at the peripheral level. When damage occurs, biochemical agents that initiate or sensitize the nociceptive response are released. These agents include potassium, substance (P), bradykinin, and prostaglandin. The initial injury provokes a series of physiologic events. The sensory experience of pain depends on the interaction between the nervous system and the

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Research Article

DEVELOPMENT AND VALIDATION OF A STABILITY INDICATING RP-HPLC METHOD FOR THE SIMULTANEOUS ESTIMATION OF HALOBETASOL AND TAZAROTENE IN BULK AND PHARMACEUTICAL FORMULATIONS

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ABSTRACT

The objective of the present study is to develop simple RP-HPLC method for the simultaneous determination of Halobetasol and Tazarotene without prior separation. In this method, Luna C_{18} (250 mm×4.6 mm, 5µm) column was used. The mobile phase used was methanol and 0.1 M sodium perchlorate in the ratio of 87:13 (v/v) at pH 5.8, at flow rate of 1 ml/min. UV detection was monitored at 231 nm. Calibration graphs were established in the range of 4.5 to 27µg/mL for Tazarotene and 1 to 6µg/mL for Halobetasol. The retention time for Halobetasol and Tazarotene was found to be 3.4 min and 2.6 min, respectively. The intraday and interday precision expressed as percent relative standard deviation, were below 2%. The mean recovery of paracetamol and lornoxicam was found to be in the acceptable range. Hence it can be concluded that the validated HPLC method was found to be rapid, precise and accurate and can be readily utilized for analysis of Halobetasol and Tazarotene in bulk and in pharmaceutical formulations.

Keywords: Halobetasol, Tazarotene, HPLC method, Forced Degradation, lotion formulation.

1. INTRODUCTION

Halobetasol is an ultra potent corticosteroid having anti-inflammatory and antiproliferative effects. It is prescribed for the treatment of eczema, dermatitis, rash and psoriasis [1]. It reduces the itching, redness and swelling that occur in these types of conditions. Burning, stinging, itching, dryness or redness are the possible side effects associated with the use of Halobetasol. Halobetasol diffuses across cell membranes and interact with cytoplasmic corticosteroid receptors located in both the dermal and intradermal cells, thereby activating gene expression of anti-inflammatory proteins mediated via the corticosteroid receptor response element [2-3]. Stretch marks, skin discoloration, excessive hair growth and hair bumps are the possible side effects associated with the use of Halobetasol.

Tazarotene is a third-generation retinoid drug belongs to acetylenic class and is prescribed for the treatment of psoriasis, acne, and photodamaged skin (photodamage) [4]. In animals and humans, Tazarotene rapidly de-esterified in to its active carboxylic acid derivate which binds to retinoic acid receptors and modify gene expression [5]. Sensitivity to sunlight, dry skin, itchiness and redness are the major side effects associated with the use for Tazarotene.

Halobetasol and Tazarotene are the combined medication available in lotion formulation and is used for the treatment of plaque psoriasis in adults [6]. The literature survey for the analysis of Halobetasol and Tazarotene confirms that there is only one HPLC method reported for the simultaneous estimation of Halobetasol and Tazarotene [7]. One HPLC [8] and One UV spectrophotometric [9] method reported for the estimation of Halobetasol in combination with other drugs. One HPLC method [10] is reported for the estimation of Tazarotene and its related impurities. Hence, the present work aimed to develop a simple, precise accurate HPLC method for the simultaneous estimation of Halobetasol and Tazarotene in pharmaceutical formulations. The molecular structure of Halobetasol and Tazarotene was given in fig. 1.

2. MATERIAL AND METHODS

2.1. Instrumentation

The separation and quantification of Tazarotene and Halobetasol was carried in waters spherisorb ODS1 C18

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