CRITERIA III

Key Indicator 3.3 - Research Publication and Awards

3.3.1 Number of research papers published per teacher in the Journals notified on UGC CARE list during 2019

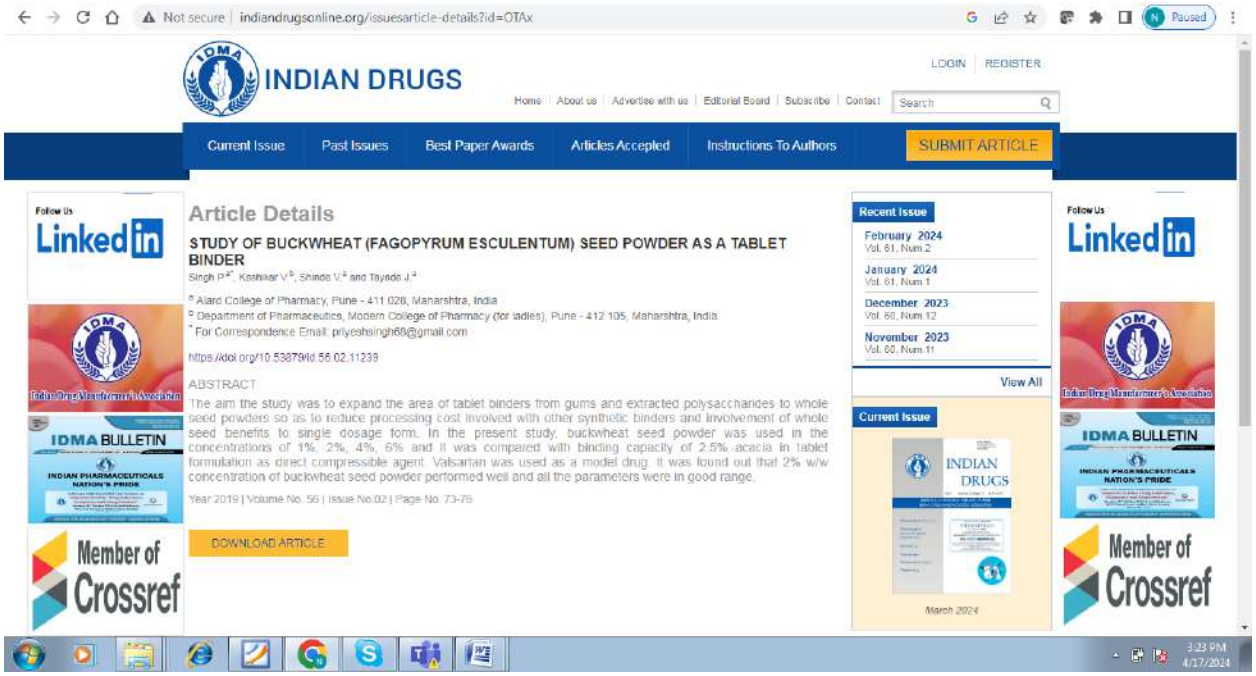
Research Publication 2019

PES Modern college of Pharmacy (For Ladies), Moshi, Pune 412105.

RESEARCH PUBLICATION 2019

Year	Sr. No.	Name of Faculty	Title of the Paper	Name of Journal	Year, Vol, Page No, Issue	ISSN No.
2019	1	Dr. V.S. Kashikar	Study of buckwheat (*Fagopyrumesculentum*) seed powder as a tablet binder	Indian Drugs	Vol. 2019, Issue 56 (02), 73-77	**0019-462X**
2019	2	Ms. V. S. Vichare	Development and validation of UV-visible spectroscopic methods for simultaneous extimation of canagliflozin and metformin in pharmaceutical formulation	Asian Journal of Research in Chemistry	Vol. 2019, Issue 12 (1), 16-20.	ISSN 0974-4150(Online)
2019	3	Dr. V. S. Kashikar	Development and validation of spectroscopic estimation by area under curve method of eperisone hydrochloride with aceclofenac	World Journal of Pharmacy and Pharmaceutical Sciences	Vol 8, Issue 7, 949-956, 2019.	ISSN: 2278-4357
2019	4	Dr. V. S. Kashikar	Development and validation of chromatographic estimation and forced degradation study of eperisone hydrochloride & ibuprofen	World Journal of Pharmacy and Pharmaceutical Sciences	Vol 8, Issue 7, 957-973, 2019.	ISSN: 2278-4357
2019	5	Dr. Prof. S. N. Dhole,	Multiparticulate floating drug delivery system of anagliptin: design and optimization for its efficacy in management of metabolic syndrome	International Journal of Applied Pharmaceutics	2019, 11(4), 171-181	0975-7058
2019	6	Dr. Prof. S. N. Dhole,	Lipid-based floating multiparticulate delivery system for bioavailability enhancement of berberine hydrochloride	Journal of Applied Pharmaceutical Science	2019, 9(11)	2231-3354
2019	7	Dr. Ms. S. D. More	Review on Nano Flare: A Novel Diagnostic Probe	Current Trends in Pharmacy and Pharmaceutical Chemistry	2019, 24 (3), 24-30	2582-5062
2019	8	Dr. Ms. S. D. More, Dr. Ms. M.C. Upadhye	Formulation and Evaluation of Diclofenac Aqua Gel	American Journals of Pharmacy & Health Research	2019, 7 (7), 1-6	2321-3647
2019	9	Ms. V. S. Vichare	Study of intrinsic stability of mometasonefuroate in presence of salicylic acid by HPTLC and characterization, cytotoxicity testing of major degradation product of mometasonefuroate	Current Pharmaceutical Analysis	2019,15, 592-603	1875-676X
2019	10	Dr. Mr. N.S. Kulkarni, Dr. Prof. S.N. Dhole	A Review on Hydrotropic Solubilization for Poorly Water-Soluble Drugs: Analytical application and Formulation development.	Research Journal of Pharmacy and Technology.	2019, 12 (7), 3157-3163.	0974-3618

2019	11	Dr. Mr. N.S. Kulkarni, Dr. Prof. S.N. Dhole	Characterization of Self-Microemulsifying Dosage Form: Special Emphasis on Zeta Potential Measurement	International Journal of Pharmaceutical & Biological Archives	2019, 10 (3), 172-179.	09763333
2019	12	Dr. Mr. N.S. Kulkarni	Simultaneous Equation and Area Under the Curve Spectrophotometric Methods for Estimation of Ranolazine Hydrochloride Presence of its Base-induced Degradation Product: A Comparative Study	International Journal of Pharmaceutical & Biological Archives	2019, 10 (3), 202-206.	09763333
2019	13	Ujjwala Y. Kandekar, RohiniPujari	Exploration of MucoadhesiveMicroparticlesby using Linumusitatissimum Mucilage	Latin American Journal of Pharmacy	38 (12): 2463-72 (2019)	2362-3853
2019	14	Ms. M.H. Tapkir	Lique Solid Compact Drug Delivery System: A Review	World Journal of Pharmacy and Pharmaceutical Sciences	2019,8(10), 329-345	2278-4357
2019	15	Ms. M.H. Tapkir	Nasal Drug Delivery: A Promising Approach for Brain Targeting	World Journal of Pharmacy and Pharmaceutical Sciences	2019,8(10), 477-491	2278-4357



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RESEARCHARTICLE

Development and Validation of UV-Visible Spectroscopic Methods for Simultaneous Estimation of Canagliflozin and Metformin in Pharmaceutical Formulation

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ABSTRACT:
Two simple, accurate, precise and rapid UV-Visible spectroscopic methods have been developed and validated for simultaneous estimation of Canagliflozin (Cana) and Metformin HCl (Met) in pharmaceutical formulation. Method A was Absorbance correction UV spectroscopy while method B was First order derivative spectroscopy. Method A was based on measurement of absorbances at wavelengths 233 nm (λ max of Met) and 291 nm (λ max of Cana). In case of Method B, from the first order derivative overlain spectra wavelengths 243 nm (Zero absorbance of Cana) and 318 nm (Zero absorbance of Met) were selected for analysis. Analysis of marketed formulation was done by both the methods. The percentage drug contents were found to be 98.48 ± 0.83 and 100.76 ± 1.29 for Cana and Met respectively by method A. Similarly, by method B the percentage drug contents were found to be 97.94 ± 0.96 and 97.22 ± 1.15 for Cana and Met respectively. Both the developed methods were validated as per ICH guidelines Q2 (R1) for linearity, range, accuracy and precision. Linearity of both the methods was found to be in a range of 0.75 – 4.5 µg/ml and 2.5 – 15 µg/ml for Cana and Met respectively. The accuracy of the methods was determined by recovery studies. The % of drugs recovered was found to be close 100, indicating accuracy of the method. Precision of the methods was estimated by repeatability and intermediate precision studies. The % RSD values were found to be less than 2, proving methods were precise. Therefore, the developed methods could be effectively used for routine quality control analysis in industry for simultaneous analysis of Cana and Met in pharmaceutical formulation.

KEYWORDS: UV-Visible spectroscopy, Derivative spectroscopy, Canagliflozin, Metformin, method development, validation.

1. INTRODUCTION:

Canagliflozin (Cana) is a selective Sodium-Glucose Co-transporter 2 (SGLT2) inhibitor used for the management of type 2 Diabetes Mellitus. Chemically it is (2S,3R,4R,5S,6R)- 2-{3-[5-(4-fluoro-phenyl)-thiophen-2-ylmethyl]-4-methyl-phenyl}-6 hydroxymethyltetrahydro-pyran-3,4,5-triol (Figure 1)[1]. It is not official in IP-2014, BP-2008 and USP-2011.

Metformin HCl (Met) is chemically *N, N*-dimethyldiguanide used in the treatment of type 2 diabetes. It suppresses hepatic gluconeogenesis and

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DEVELOPMENT AND VALIDATION OF SPECTROSCOPIC ESTIMATION BY AREA UNDER CURVE METHOD OF EPERISONE HYDROCHLORIDE WITH ACECLOFENAC

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ABSTRACT

A simple, sensitive, rapid and reproducible UV method has been developed and validated for simultaneous determination of Eperisone Hydrochloride (EPE) and Aceclofenac Sodium (ACE) in bulk and in Laboratory mixture. RP - HPLC methods has been developed and validated for simultaneous determination of Eperisone Hydrochloride (EPE) and Ibuprofen (IBU) in bulk and in Laboratory mixture. For development of UV method for EPE and ACE methanol was used as a solvent and detection wavelengths were found to be at 255 nm and 277 nm respectively. The method was found to be linear in concentration range 2-10 µg/mL for both drugs. The method was validated as per ICH guidelines. The Recovery study, precision and repeatability results showed % RSD less than 2%. The method is found to be robust & rugged.

KEYWORDS: Eperisone hydrochloride, Aceclofenac, Simultaneous equation method, Q – ration analysis, Area under curve method, UV.

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WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES
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DEVELOPMENT AND VALIDATION OF CHROMATOGRAPHIC ESTIMATION AND FORCED DEGRADATION STUDY OF EPERISONE HYDROCHLORIDE & IBUPROFEN

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ABSTRACT

A simple, sensitive, rapid and reproducible RP - HPLC methods has been developed and validated for simultaneous determination of Eperisone Hydrochloride (EPE) and Ibuprofen (IBU) in bulk and in Laboratory mixture. The RP - HPLC analysis was performed on the Phenomenex Luna 5µ C8 (5µm, 250mm × 4.6mm) column, at ambient temperature using Methanol: 0.1% ortho-phosphoric acid (70:30) as mobile phase. The flow rate was adjusted to 1.0 mL/min. The detection was carried out at 265 nm. Linearity was found to be in concentration range 2-10 µg/mL for both drugs (i.e. EPE & IBU) with coefficient of correlation 0.998 and 0.997. Accuracy, intermediate precision, Repeatability result showed % RSD less than 2%. The method is found to be rugged and robust.

KEYWORDS: Eperisone hydrochloride, Ibuprofen, HPLC, Forced degradation.

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Original Article

MULTIPARTICULATE FLOATING DRUG DELIVERY SYSTEM OF ANAGLIPTIN: DESIGN AND OPTIMIZATION FOR ITS EFFICACY IN MANAGEMENT OF METABOLIC SYNDROME

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ABSTRACT

Objective: The present research aims to design and optimize gastroretentive floating pellets of anagliptin (a dipeptidyl peptidase-4 inhibitor), so as to reduce P-Glycoprotein (PGP)–mediated efflux in the intestine hence to improve oral bioavailability.

Methods: The drug-containing core pellets were prepared by extrusion and spheronization process followed by subsequent coating with three successive layers i.e. Eudragit RS 100, sodium bicarbonate ($NaHCO_3$): hydroxypropyl methylcellulose E5LV (HPMC E5LV) and Eudragit RL 100 using fluidized bed processor. A 3 level 3 factor box-behnken design was adopted to investigate the effect of Eudragit RS 100, $NaHCO_3$: HPMC E5LVand Eudragit RL 100 on floating lag time and drug release at 10 h. Desirability function under numerical optimization technique was used to identify the optimum formulation.

Results: The study reveals the significant effect of the amount of $NaHCO_3$ and coating level of polymers on floating lag time and drug release. The optimum system could float within 4 min and exhibited more than 85% drug release in 10 h. The pharmacokinetic study conducted in male Wistar rats indicated 2.51 fold increase in relative bioavailability of optimized formulation compare to anagliptin drug. Formulated anagliptin pellets were evaluated in cafeteria diet-induced metabolic syndrome model in male Wistar rats. Anagliptin floating pellets treatment compared to cafeteria diet group significantly inhibited increase in body weight (238.79±2.52 g vs. 277.98±3.69 g, $P<0.001$), calorie intake (2283.99 kcal vs. 3086.05 kcal, $P<0.05$) and serum levels of total cholesterol (95.19±0.61 mg/dl vs. 110.04±1.31 mg/dl, $P<0.01$), triglycerides (96.12±1.25 mg/dl vs. 105.99±1.29 mg/dl, $P<0.01$) while high-density lipoproteins levels were improved (42.15±0.92 mg/dl vs. 30.92±0.77 mg/dl, $P<0.01$) indicated its hypophagic and anti-hyperlipidemic effects.

Conclusion: The gastroretentive floating pellets of anagliptin was obtained and could be a promising technique to deliver anagliptin with improved bioavailability in the management of the metabolic syndrome.

Keywords: Anagliptin, Metabolic syndrome, Floating drug delivery system, Pellets and Spheronization

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INTRODUCTION

The urbanization and sedentary lifestyles of 21st century leads to increase the prevalence of metabolic syndrome and is becoming a major public health concern. Metabolic syndrome includes the number of chronic disease such as insulin resistance, obesity, dyslipidemia, cardio-metabolic risk and hypertension [1]. Patient compliance becomes an issue in the management of metabolic syndrome, due to the use of multiple drugs and risk of enhanced drug-drug interactions [2]. Identifying drug candidates exhibiting polypharmacology could be one of the strategies favourable to deal with multifactorial diseases [3]. Anagliptin a dipeptidyl peptidase 4 (DPP4) inhibitor, besides their glucose-lowering activity, is a promising drug candidate for management of multifactorial diseases constituting metabolic disorders [4]. However, systemic bioavailability of anagliptin is limited by PGP mediated efflux in the intestine [5]. PGP, a plasma membrane-bound ATP-dependent efflux transporter, is a well-recognized factor that can influence drug pharmacokinetics [6]. In addition, anagliptin has a shorter biological half-life of 3-4 h. It is needed to improve the oral bioavailability of anagliptin to be effectively used in many clinical applications. The conventional controlled-release technologies are not suitable for the delivery of PGP substrates because they carry a significant part of the drug to distal regions of the gastrointestinal tract (GIT). On the other hand, continuous delivery to the proximal part of the GIT, as provided by gastroretentive dosage forms, might be useful for these drugs [7-9]. Various approaches have been reported to retain the formulation in the upper part of GIT such as swelling systems, high-density systems, magnetic systems, mucoadhesive systems and floating systems [10]. Among all the gastroretentive systems, due to minimum effect on GIT motility, floating drug delivery systems (FDDS) are considered suitable and preferable [11-13]. These systems are particularly useful for drugs having absorption in upper GIT, drugs which are unstable in the intestine and exhibits poor solubility in intestinal pH [14]. FDDS are low density system which allows them to remain buoyant over gastric content for prolonged period of time [15]. Based upon the mechanism of buoyancy effervescent systems are the widely employed technique used in the development of FDDS. In the effervescent systems, carbon dioxide gas liberation occurs upon contact with gastric fluid due to neutralization reaction which lowers the density and allows the system to remain buoyant [16]. A wide range of single unit and multiparticulate FDDS were designed and developed, the multiparticulate FDDS were preferred over single unit system due to reduce inter and intra subject variabilities in drug absorption and lower possibility of dose dumping [17-19]. Designing sustained release multiparticulate drug delivery system of anagliptin with prolonged residence time in the stomach using FDDS approach can significantly improve the overall bioavailability.

In the present investigation, a floating multiparticulate drug delivery system of anagliptin based on effervescent technique was developed. The drug-containing core pellets were prepared using extrusion and spheronization process. The drug-loaded pellets were coated with three successive layers, internal coat of Eudragit RS 100 as release retardant followed by effervescent layer coat ($NaHCO_3$: HPMC E5LV); and top coat of Eudragit RL 100 as a gas entrapped polymeric membrane. The effect of the amount of effervescent agent and coating level of polymeric membrane on floating ability and drug release properties were studied and optimized using response surface methodology.

MATERIALS AND METHODS

Materials

Anagliptin was obtained as gift sample from Wockhardt Limited, Aurangabad, India. Eudragit RL 100 and Eudragit RS 100 were provided by Evonik Pharma, Mumbai, India. Sodium bicarbonate, Hydroxypropyl

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Lipid-based floating multiparticulate delivery system for bioavailability enhancement of berberine hydrochloride

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Key words:
Berberine hydrochloride, gelucire, solid dispersion, lipid floating multiparticulate, gastroretentive.

ABSTRACT

The objective of the present investigation was to design and optimize lipid-based floating multiparticulate of Berberine hydrochloride (BERH), so as to increase its solubility and to reduce P-Glycoprotein mediated efflux in the intestine, hence to improve oral bioavailability. Solid dispersions were prepared using hydrophilic carriers gelucire 44/14 and gelucire 50/13 in different ratio. The prepared solid dispersion of BERH was further formulated into sustain release gastroretentive floating pellets using hydrophobic lipid carrier gelucire 43/01 as release retardant, sodium bicarbonate ($NaHCO_3$) and hydroxylpropyl methyl cellulose K4M (HPMC K4M) as gas former and matrix polymer, respectively. The effect of amount of gelucire 43/01 and $NaHCO_3$: HPMC K4M were studied and optimized using a 3-level, 2-factor, factorial design. Solid dispersion of BERH compared to pure drug showed 4-fold enhancement in aqueous solubility. The optimum system could float for more than 8 hours and showed 88.46% drug release in 8 hours. The pharmacokinetic study conducted in male Wistar rats indicated 2.32-fold increase in relative bioavailability of optimized formulation compare to the marketed tablet. The lipid-based floating pellets of BERH were obtained and could be an applicable choice to deliver BERH with improved bioavailability in effective use for various clinical applications.

INTRODUCTION

Berberine hydrochloride (BERH), a quaternary isoquinoline alkaloid, presents in various plants of Berberis species which are commonly found in the Eastern hemisphere (Kosalec *et al*., 2009). It has been historically used as an anti-diarrheal agent in Ayurvedic and Chinese medicine (Chang, 1959). In the past few years, numerous studies have demonstrated the potential therapeutic applications of BERH including anti-diabetic, anti-hyperlipidemic, anti-obesity, anti-arrhythmic, and anti-cancer (Gao *et al*., 2013; Jantova *et al*., 2003; Kettmann *et al*., 2004; Kong *et al*., 2004; Lee *et al*., 2006; Sanchez, 1996; Shen *et al*., 2014; Tsai and Tsai, 2004). However, the systemic bioavailability of BERH is very low due to its poor water solubility and dissolution rate which limits its clinical use (Tan *et al*., 2011). BERH is also a P-glycoprotein substrate (P-gp) results into active efflux from the intestine (Maeng *et al*., 2002; Pan *et al*., 2002; Zhang *et al*., 2013). In addition, BERH has a shorter biological halflife of 2–2.5 h (Alolga *et al*., 2016). Hence, it is necessary to improve the solubility and bioavailability of BERH so that it can be effectively used in many clinical applications.

In recent years, some studies have explored the use of P-gp inhibitors, permeation enhancers and lipid-based delivery systems to enhance the oral bioavailability of BERH (Fan *et al*., 2013; Ke *et al*., 2015; Khayam *et al*., 2018; Sailor *et al*., 2015; Wei *et al*., 2011; Zhu *et al*., 2013). However, P-gp inhibitors possess their own pharmacological effects and might leads to toxic effects while use of permeation enhancers suffers with the drawback of compromised integrity of intestinal mucosa (Davis, 2005). Among the lipid-based systems, self-microemulsifying systems, solid lipid nanoparticle and liposomes of BERH were developed showed significant enhancement in bioavailability but faces the problems of either low drug loading capacity or poor long term stability (Sailor *et al*., 2015). Solid dispersion technique is one of the areas that have been

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Review Article

Review On Nano Flare: A Novel Diagnostic Probe.

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ABSTRACT

It is important these days to develop the new methods which will provide early detection of cancer to reduce metastatic risk before the existence of secondary tumors. Clinical treatments administered after metastatic tumor diagnosis are not effective. If the cancer is detected at early stage then available therapies can be administered and patient prognoses can be improved. Amongst all the therapies available, Nano flare is a novel diagnostic probe which offer a new method for detecting cancer biomarkers using live cells. This technique is based on the nanotechnology. These probes are based on spherical nucleic acid and are composed of gold nanoparticle core and densely packed with highly oriented oligonucleotide shells; these sequences are complementary to specific mRNA targets and are hybridized to fluorophore labeled reporter strands. When target mRNA binds to capture strand, reporter strand gets displaced and shows fluorescence which can be detected by using any fluorescence detection platform. Nano flares hold promise for the early detection of cancer markers in living cells.

KEYWORDS: Nano flare, Smart flare, Merck Millipore, Spherical Nucleic Acid, Nanoparticles, Diagnostic probes.

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Research Article
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Formulation and Comparative Evaluation of Diclofenac Aqua Gel by Using Various Polymers

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ABSTRACT

Aqua gel is a polymeric gel formulated by using crosslinking agent to form a network of crosslinked polymer chains. It is a hydrophilic structure with capability of holding water in their three-dimensional networks. Formulation and comparative evaluation of Diclofenac aqua gel by using various polymers have been carried out to check efficient concentration of various polymers as well as to choose an appropriate polymer. Diclofenac has chosen as an active pharmaceutical ingredient which have tendency to cause acidity or GI irritation when comes in contact with GI fluid. Avoidance of such side effect is one of the motives of this research. Administration of Diclofenac trans dermally will avoid to get contact with GI fluid as well as avoid GI irritation. In this research various concentration of polymer has been taken to compare between polymer concentration as well as various polymer efficiency.

Keywords: Aqua gel, Hydrogel, topical gel, Diclofenac gel, hydrophilic gel.

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RESEARCH ARTICLE

Study of Intrinsic Stability of Mometasone Furoate in Presence of Salicylic Acid by HPTLC and Characterization, Cytotoxicity Testing of Major Degradation Product of Mometasone Furoate

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Abstract: ***Background:*** A successful attempt has been done to develop and validate a simple stability indicating HPTLC method for the estimation of Mometasone furoate (MF) and its degradation product in the presence of Salicylic acid (SA). The degradation product was isolated, characterized and tested for cytotoxicity.

Introduction: Mometasone furoate (MF) is chemically 9,21-Dichloro-17α-[(2-furanylcarbonyl) oxy]-11β-hydroxy-16-α-methylpregna-1,4-diene-3,20-dione, a high potency glucocorticoid. Salicylic acid (SA) has antiseptic, antifungal and keratolytic properties. Combination of MF and SA is available in the market as an ointment and is used for the treatment of skin inflammation, skin diseases, acne, skin redness and other conditions. Till now, there is no scientific documentation on HPTLC method for simultaneous estimation of MF and SA in the topical formulation; stress testing of drugs and determination of degradation products.

Methods: Combination of Toluene: Ethyl Acetate: Methanol: Ammonia (6.4:1.5:2.0:0.1) was selected as the mobile phase. Detection was done by UV absorbance mode at wavelength 250 nm. Topical formulation containing MF and SA was analyzed by the developed method. The developed method was validated as per ICH guidelines. The standard drugs were subjected to stress testing like hydrolysis, oxidative, thermal and photolytic degradation.

Results: Good separation with R_f values 0.61 ± 0.02 (MF) and 0.21 ± 0.02 (SA) was achieved by optimized chromatographic conditions. The % drug content was found to be 97.41±1.15 and 99.43 ± 0.73 for MF and SA, respectively in a topical formulation. From the results of validation parameters, the developed method was found to be specific, accurate, precise, sensitive and robust. After stress testing, SA was found to be stable under different stress conditions. Whereas, MF was found to be base sensitive and single degradation product was observed and isolated by preparative TLC. It was characterized by LC-MS and LC-MS/MS studies. Isolated degradation product was subjected to cytotoxicity testing on A549 and SiHa cell lines.

Conclusion: A simple stability indicating HPTLC method was developed and validated for the estimation of MF and its degradation product in presence of SA. Probable structure of degradation product of MF and probable pathway of degradation was interpreted. Results of cytotoxicity testing showed that the degradation product was more cytotoxic as compared to MF against both the cell lines.

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1. INTRODUCTION

Mometasone furoate (MF) (Fig. **1**) is chemically 9,21-Dichloro-17α-[(2-furanylcarbonyl) oxy]-11β-hydroxy-16-α-methylpregna-1,4-diene-3,20-dione, a high potency glucocorticoid. It has anti-inflammatory, immuno-suppressive, vasoconstrictive and antiproliferative actions. It is used in the treatment of rhinitis and skin diseases like eczema, dermatitis, psoriasis etc. It is also used to prevent asthmatic attacks [1, 2]. It is official in IP-2014, BP-2008 and USP-2011 [3-5].

Salicylic acid (SA) (Fig. **2**) has antiseptic, antifungal and keratolytic properties. It is used in the treatment of skin conditions like acne, dandruff, warts, corns and psoriasis [1, 2]. It is official in IP-2014, BP-2008 and USP-2011 [3-5].

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REVIEW ARTICLE

A Review on Hydrotropic Solubilization for Poorly Water Soluble Drugs: Analytical Application and Formulation Development

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ABSTRACT:
Solubilisation of poorly soluble drugs is encountered as a challenge in screening studies of new chemical entities as well as its formulation development is obstacle. A number of methodologies can be adapted to improve solubility of poor water soluble drug and its bioavailability. Hydrotropes possess the ability to increase the solubility of sparingly soluble and poorly soluble drugs in water. It is a molecular phenomenon, adding a second solute (i.e. hydrotrope) helps to increase the aqueous solubility of poorly soluble drug. The presence of a excess quantity of one solute enhances the solubility of another solute. Various organic solvents are used for the development of analytical methods for poorly water soluble drugs. The major drawback of such solvents is cost, toxicity and environmental hazards. To overcome these issues less costly hydrotropic agents have gain wide application for the development of analytical methods for routine analysis of marketed dosage form and developed dosage forms. The mixed hydrotropy approach suggests the minimum amount of the hydrotropic agents as a blend of two or more agents. Such blends results in lesser quantity as that of single hydrotropic agents. Similarly the hydrotropic agents are now days widely used to develop dosage forms as solid dispersion, mouth dissolving tablets, injections to improve therapeutic effectiveness and bioavailability for poorly water soluble drugs.

KEYWORDS: Solubility, Hydrotropy, Mixed Hydrotrophy, dosage form.

INTRODUCTION:
Solubilisation of poorly soluble drugs is encountered as a challenge in screening studies of new chemical entities as well as its formulation development is obstacle. A number of methodologies can be adapted to improve solubility of poor water soluble drug and its bioavailability. Orally administered drugs undergo complete absorption only drug shows excellent solubility in gastric environment and ultimately shows better bioavailability if drug belong to BCS class II. Bioavailability is dependent on several factors, aqueous drug solubility and drug permeability across the biological membranes.

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For BCS class III drugs permeability is the rate limiting step for the absorption and has limited bioavailability. Solubilized drug molecules only can be absorbed by the cellular membranes to subsequently reach the site of drug action (vascular system for instance). The drug must be present in the form of an aqueous solution at the site of absorption. Therefore drug solubility and its oral bioavailability remains one of most challenging aspects of drug development process. The solubility issue may lead to poor in vivo and in vitro characteristics and difficult to achieve predictable and reproducible in vivo/in vitro correlations because of solubility issues. There are numerous approaches available in literature to enhance the solubility of poorly water soluble drugs. The techniques are selected on the basis of certain aspects such as physicochemical properties of drug, excipients to be used and type of dosage form need to be developed. The generally used techniques for solubilisation of drug include chemical modification, pH adjustment, solid dispersion, complexation, co-solvency, micellar

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RESEARCH ARTICLE

Characterization of Self-Microemulsifying Dosage Form: Special Emphasis on Zeta Potential Measurement

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ABSTRACT

The emulsion is a disperse system which is thermodynamically unstable. To improve the stability of the disperse system microemulsion or nanoemulsion was prepared to improve thermodynamic stability. Zeta potential is a physical property which is exhibited by any particle in suspension/emulsion, i.e., in colloidal dispersion. It can be used to optimize the formulations of suspensions and emulsions. Zeta potential is the measure of overall charges acquired by particles in a particular medium and is considered as one of the benchmarks of stability of the colloidal system. As a rule of thumb, suspensions/dispersed system with zeta potential above 30 mV (absolute value) are physically stable. Suspensions with a potential above 60 mV show excellent stability. Suspensions below 20 mV are of limited stability; below 5 mV they undergo pronounced aggregation if the system is stabilized by the electrostatic mechanism. If the values are low for visually stable emulsions, it could be attributed to steric repulsion between approaching molecules, i.e., system is sterically stabilized. Such sterically stabilized colloidal systems though they have low zeta potential values are found to be stable during storage. Tween is well accepted steric stabilizer for colloidal systems. Stability of such a visually stable emulsion or microemulsions should be carried out under accelerated or long-term stability conditions to confirm the globule size and zeta potential on aging.

Keywords: SMEDDS, surfactants, zeta potential

INTRODUCTION

The emulsion is a disperse system which is thermodynamically unstable. To improve the stability of the disperse system microemulsion or nanoemulsion was prepared to improve thermodynamic stability.

FORMULATION OF SELF-MICROEMULSIFYING DRUG DELIVERY SYSTEM (SMEDDS)

SMEDDS is defined as mixtures of oils (natural/synthetic), surfactants (solid/liquid) or alternatively, and cosolvents/cosurfactants that have a capacity to form fine oil-in-water (o/w) microemulsions on dilution followed by agitation in gastrointestinal fluid (*in vivo*) or when added to the dissolution medium (*in vitro*). The appearance of SMEDDS formulations is transparent or bluish tinge, with particle size in the range of 1–200 nm on dilution. As emulsions are metastable and thermodynamically unstable dispersed forms, SMEDDS is physically and thermodynamically stable formulations that are easy to manufacture.[1-3]

ORAL ABSORPTION AND BIOAVAILABILITY OF POORLY WATER SOLUBLE DRUG BY SMEDDS

Bioavailability enhancing property has been associated with a number of *in vivo* properties of lipid formulation including:

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RESEARCH ARTICLE

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

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ABSTRACT

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

Keywords: Base degradation, ranolazine hydrochloride, spectrophotometric methods

INTRODUCTION

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

Experimental

Instruments

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

Software

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

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Exploration of Mucoadhesive Microparticles by using *Linum usitatissimum* Mucilage

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***SUMMARY*. Era has arisen to circumvent the application of conventional oral dosage forms and explore these novel drug delivery approaches to gain better benefits. Present investigation was carried out in the view to develop and characterize the mucoadhesive polymeric microparticles of mucilage obtained from natural resource *i.e. Linum usitatissimum* in order to prolong the release and overcome the drawbacks such as shorter half life and gastrointestinal irritation of dexibuprofen. *L. usitatissimum* mucilage was isolated and combined with sodium alginate for its fabrication into microparticles. Various batches were formulated and characterized, the results of FITR and DSC studies revealed the compatibility between drug and polymers. Apart from this, percent mucoadhesion was found to be in the range of 50-85%, whereas particle size was found in the range of 830-865 μm. Optimized formulation was successful in releasing the drug for the prolonged time period of 12 h. Overall study indicated that natural mucilage can be efficiently utilized to retard the drug release and minimize the side effects of the drug, so as to get maximum utilization of the therapeutic dose.**

RESUMEN. Ha surgido una era para eludir la aplicación de formas de dosificación oral convencionales y explorar estos nuevos enfoques de administración de medicamentos para obtener mejores beneficios. La presente investigación se llevó a cabo para desarrollar y caracterizar las micropartículas poliméricas mucoadhesivas de mucílago obtenidas del recurso natural *Linum usitatissimum* para prolongar la liberación y superar los inconvenientes, como la vida media más corta y la irritación gastrointestinal del dexibuprofeno. El mucílago de *L. usitatissimum* se aisló y se combinó con alginato de sodio para su fabricación en micropartículas. Se formularon y caracterizaron varios lotes y los resultados de los estudios FITR y DSC revelaron la compatibilidad entre el fármaco y los polímeros. Aparte de esto, se encontró que el porcentaje de mucoadhesión estaba en el rango de 50-85%, mientras que el tamaño de partícula se encontró en el rango de 830-865 μm. La formulación optimizada tuvo éxito en la liberación del fármaco durante el período de tiempo prolongado de 12 h. El estudio general indicó que el mucílago natural se puede utilizar de manera eficiente para retrasar la liberación del fármaco y minimizar los efectos secundarios del mismo, a fin de obtener la máxima utilización de la dosis terapéutica.

KEY WORDS: dexibuprofen, *Linum usitatissimum*, mucoadhesive, sodium alginate

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LIQUE SOLID COMPACT DRUG DELIVERY SYSTEM: A REVIEW

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ABSTRACT

Drugs which are orally administered possess the solubility is one of the major problem, because of the drugs with the low aq. solubility, such drugs get slowly dissolve and leads to low bioavailability. So, it is the biggest provocation in front of the scientists to improve the solubility of such drugs. Nearly about 40-50% of the drugs shows this problem. SEDDS is novel approach for improving the solubility of the lipophilic drug. The special feature of this delivery system is its ability to self-emulsify, that is their propensity to form oil-in-water emulsion on gentle agitation when diluted with aq. phase present outside the gastrointestinal tract. SEDDS possess low cost including easily available excipients such as natural oils or synthetic oil, surfactant, co-surfactant/ co-solvent. The major advantage of SEDDS is that it avoid the first pass effect and get absorbed by the lymphatic pathways. In this review we present a report on the formulation characterization, different dosage forms and application of SEDDS with examples of currently available marketed preparations.

KEYWORDS: Self emulsifying drug delivery, Bioavailability and Solubility enhancement.

INTRODUCTION[1]

Due to low aq. Solubility of drug, low oral bioavailability is seen and it is a major concern for formulation scientists. So, It is major part of study for the pharmaceutical scientists to convert those molecules into such a formulation that will show the desired bioavailability after oral administration. There are various strategies used in formulation development that can be use to improve the bioavailability of poorly soluble drug, it can be done by increasing the dissolution rate or by keeping the drug in solution and maintaining the drug in solution in intestinal lumen. SEDDS is an isotropic mixture of oil, surfactant, solvents, co-solvents/

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NASAL DRUG DELIVERY: A PROMISING APPROACH FOR BRAIN TARGETING

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ABSTRACT

The delivery of potential therapeutic moieties to brain is restricted by the Blood Brain Barrier. Approximately 1.5 billion people undergoing from disorder of CNS, these disorders needed to be cured by proper drug delivery to brain. Recently CNS disorders, such as Alzheimer's disease, Parkinson's disease, Huntington's disease, depression, anxiety, seizures, epilepsy, migraine, etc can be effectively treated by intranasal drug delivery to brain and CNS. Intranasal route of delivery facilitates direct delivery of drug to the brain without systemic absorption, thus enhancing the efficacy and decreasing the side effects of neurotherapeutics. The olfactory and the trigeminal neural pathways enable direct targeting drug to the brain by passing the BBB, this has gained an important consideration for delivery of wide range of therapeutic moieties to brain. This short review aims to known basically the barriers for nasal drug delivery, crucial factors for nasal formulations and some advantages and disadvantages of intranasal drug delivery system.

KEYWORDS: Intranasal drug delivery, Blood Brain Barrier, bioavailability, olfactory and trigeminal pathways.

INTRODUCTION[1,2,3]

The delivery of drug to the brain still remains problematic because of poor bioavailability due to the impervious nature of the endothelial membrane separating the central intestinal fluid and the systemic circulation from blood (termed as Blood Brain Barrier-BBB). The absorption and permeation of drug for desired therapeutic action in brain is restricted by the blood brain barrier (BBB). Thus the nasal route facilitates direct targeting the brain via olfactory and trigeminal neural pathway by passing the BBB. Intranasal brain targeting drug

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