Progressive Education Society's, Modern college of Pharmacy (For Ladies) Moshi, Pune.

Collaborative Research Publications

Year	Collaborative research Publications with other institutes
AY2023	CRP2023001. Dr. Ashim K. Sen and Dr. Dhanya B. Sen of Department of Pharmacy, Sumandeep Vidyapeeth Deemed to be University, Vadodra 391760.
	CRP202302. Dr. Rahul H. Khiste of Marathwada Mitra Mandal's, College of Pharmacy, Thergaon, Pune 411033.
	CRP202303. Dr. Vishnu P. Chaudhari, Department of Quality Assurance, School of Pharmacy, MIT World Peace University, Pune, Maharashtra.
	CRP202304. Pratibha Milind Chaudhari, Paul Johnson & Antoine Al-Achi, Campbell University College of Pharmacy and Health Sciences, PO Box 1090, Buies Creek, NC, 27506, USA.
	CRP202305. Vishnu P. Chaudhari, Department of Qulaity Assurance, School of Pharmacy, MIT World Peace University, Pune, Maharashtra.
AY2022	CRP202201 Dr. Archana M. Karnik, SCES,s Indira cllege of Pharmacy, Pune and Mr. Santaji U. Nalwade of Analytical development department, Callidus Research LabPvt. Ltd Pune 410501.
	CRP202202. Dr. Archana M. Karnik, SCES,s Indira cllege of Pharmacy, Pune.
	CRP202203. Dr. Vishnu P. Chaudhari, Department of Qulaity Assurance, School of Pharmacy, MIT World Peace University, Pune, Maharashtra.
	CRP202204. Dr. Archana M. Karnik, SCES,s Indira cllege of Pharmacy, Pune.
	CRP202205. Dr. Vishnu P. Chaudhari, Department of Qulaity Assurance, School of Pharmacy, MIT World Peace University, Pune, Maharashtra.
AY2021	CRP202101. Dr. Rahul H. Khiste of Marathwada Mitra Mandal's, College of Pharmacy, Thergaon, Pune 411033.
	CRP202102. Dr. Archana M. Karnik, SCES,s Indira cllege of Pharmacy, Pune.
	CRP202103. Dr. Archana M. Karnik, SCES,s Indira cllege of Pharmacy, Pune.
	CRP202104. Dr. Rahul H. Khiste of Marathwada Mitra Mandal's, College of Pharmacy, Thergaon, Pune 411033.
	CRP202105. Dr. Ujjwala Y. Kandekar of JSPM's, Rajashri Shahu college of Pharmacy and Research, Tathwade, Pune, Maharashtra 411033.
	CRP202106. Dr. Ujjwala Y. Kandekar of JSPM's, Rajashri Shahu college of Pharmacy and Research, Tathwade, Pune, Maharashtra 411033.
AY2020	CRP202001. Mr. S. P. Jalakam of Bioanalytical Research Development, Synapse Lab Pvt Ltd., Pune, Maharashtra, India.
	CRP202002. Dr. Archana M. Karnik, SCES,s Indira cllege of Pharmacy, Pune.
	CRP202003. Dr. Ashim K. Sen and Dr. Dhanya B. Sen of Department of Pharmacy, Sumandeep Vidyapeeth Deemed to be University, Vadodra 391760.
AY2019	CRP201901. Ms. Singh P., faculty of Alard college of Pharmacy, Alard Hinjewadi, Pune, Maharashtra, India.
	CRP201902. Dr. Vishnu P. Chaudhari, Department of Qulaity Assurance, School of Pharmacy, MIT World Peace University, Pune, Maharashtra.
	CRP201903. Dr. Rahul H. Khiste of Marathwada Mitra Mandal's, College of Pharmacy, Thergaon, Pune 411033.
AY2018	CRP201801. Ms. Sarika R. Jadhav, faculty of Rasiklal M. Dharwal College of Pharmacy, Chinchwad Station, Pune-411019.

Progressive Education Society's, Modern college of Pharmacy (For Ladies) Moshi, Pune.

Collaborative Research Publication 2023

CRP202301. Collaborative research Publication of our Faculty Dr. Nilesh S. Kulkarni and Manojkumar K. Munde with Dr. Ashim K. Sen and Dr. Dhanya B. Sen of Department of Pharmacy, Sumandeep Vidyapeeth Deemed to be University, Vadodra 391CRP202301760.

A NOVEL VALIDATED STABILITY INDICATING METHOD FOR QUANTIFICATION OF EMPAGLIFLOZIN IN BULK AND MARKETED FORMULATION BY HPTLC APPLYING EXPERIMENTAL DESIGN APPROACH

Manojkumar K. Munde[a,b]*, Nilesh S. Kulkarni[b], Ashim K. Sen[a] and Dhanya B. Sen[a]

(Received 12 June 2021) (Accepted 12 April 2023)

ABSTRACT

For the purpose of analyzing empagliflozin, a stability indicating high performance thin layer chromatographic method was developed. This method was optimized using design of experiment. In order to optimize the process, independent variables such as the proportion of isopropyl alcohol in the mobile phase, the duration of time that the chamber was saturated and the distance of mobile phase travelled were considered. On an aluminum plate that had previously been coated with silica gel, development was carried out with the assistance of twin trough glass chambers in ascending lines. The findings from these studies led to the selection of a mobile phase that had a composition of ammonium acetate (2 %), triethylamine and isopropyl alcohol in the ratio of 4:1:5 (V/V/V), and this mobile phase was utilized in the process of method development using central composite design approach. The saturation time was established at 10 minutes, and the ultraviolet detection was performed at a wavelength of 237 nm. The value 0.82 was discovered to be the retention factor (R_f) for empagliflozin. The method was linear, precise and accurate over the entire concentration range examined (100-600 ng band^{-1}), along with correlation coefficient value of 0.992. The proposed method is quick and selective, and a straightforward method of sample preparation and analysis for empagliflozin in its bulk and commercially available dosage forms. The stability of the drug was tested under a variety of different stress conditions in accordance with ICH guidelines, and the results obtained from the force degradations indicate that the developed method is appropriate for stability studies.

Keywords: Empagliflozin, method development, validation, DoE, HPTLC, Forced degradation study

INTRODUCTION

Empagliflozin (EN) is a drug that is used to treat type 2 diabetes and is an inhibitor of the sodium glucose cotransporter-2 (SGLT-2). SGLT-2 inhibitors, also known as gliflozins, are recently developed anti-hyperglycemic medications. EN reduces blood sugar levels by preventing the kidneys from reabsorbing glucose. EN (Fig. 1) is 1-chloro-4-(glucopyranos-1-yl)-2-(4-(tetrahydrofuran-3-yloxy) benzyl) benzene, according to its chemical structure[1,2]. The review of literature for EN with its analytical method should include the following procedures for pharmaceutical dosage form, either alone or in combination with metformin hydrochloride/linagliptin. Thorough review of the literature revealed numerous high performance liquid chromatography (HPLC)[3–17], high performance thin layer chromatography (HPTLC)[18–19] and spectrophotometry[20–23] methods for the analysis of EN. A high performance thin layer chromatography (HPTLC) method has been developed for estimating EN in formulations using the central composite design (CCD) approach. The method that has been suggested will prove useful for the quantification of EN in bulk as well as for marketed dosage form. Using a CCD strategy, the proposed work aimed to develop a high performance thin layer chromatography (HPTLC) analytical method that could indicate stability.

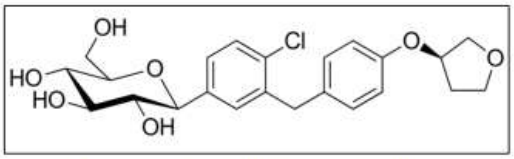

Fig. 1: Chemical structure of empagliflozin (EN)

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Back to Index

CRP202302. Collaborative research Publication of of our Faculty Dr. Nilesh S. Kulkarni with Dr. Rahul H. Khiste of Marathwada Mitra Mandal's, College of Pharmacy, Thergaon, Pune 411033.

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REVIEW ARTICLE

A Review on recent approaches for the use of different Analytical Techniques to Analyze some Calcium Channel Blockers and their Combinations with other Antihypertensive Drugs

Saylee Ganorkar[1], Nilesh Kulkarni[2] and Rahul Khiste[1,*]

[1]*Department of Pharmaceutical Chemistry, Marathwada Mitra mandal's College of Pharmacy, Thergaon, Pune 411033, Maharashtra, India*
[2]*Department of Pharmaceutics, Progressive Education Society's PES Modern College of Pharmacy (For Ladies), Moshi, Pune 412105, Maharashtra, India*

Abstract:

Background:

Diabetes, high cholesterol, and high blood pressure all considerably raise the risk of cardiovascular disease. When all three of these characteristics occur at once, a metabolic problem is postulated. A combination of antihypertensive, hypolipidemic, and anti-diabetic medications is frequently utilised to treat cardiovascular diseases. While statins (fluvastatin, simvastatin, *etc.*) are used to lower cholesterol levels, calcium channel blockers (*e.g.* amlodipine, efonidipine, and azelnidipine, *etc.*) are used to target the smooth muscles of the heart. Diuretics (*e.g.* chlortalidone, hydrochlorothiazide, *etc.*) and angiotensin II receptor antagonist (blockers) are also used to manage high blood pressure.

Objective:

The study aimed to review liquid chromatography and related high-performance (HPLC) techniques that have been developed and used for evaluating the above drugs, together with an overview of the research work published in various scientific and drugs-linked journals.

Results:

A basic critical investigation of the detailed published information has been completed and the current status of HPLC and related techniques as a percent measure of calcium channel blockers has been examined.

Conclusion:

This survey has explored several matrices, including pharmacological products and organic samples, as well as methods for examining direct calcium blockers in them. It also discusses the current state of calcium channel blocker stability investigations. Additionally, it offers scientific approaches for the concurrent estimate of angiotensin II receptor antagonism, diuretics, statins, and beta-blockers with calcium channel blockers.

Keywords: HPLC, Azelnidipine, Efonidipine, Cilnidipine, Calcium channel blockers (CCBs), Diabetes.

Article History	Received: February 22, 2023	Revised: August 21, 2023	Accepted: August 30, 2023

1. INTRODUCTION

Hypertension is a regular, ongoing, age-related problem, which frequently involves weakening cardiovascular and renal entanglements. Pulse is normally noted in blend with other cardiovascular factors. Hypertension is associated with other cardiovascular factors, for example, stomach weight, dyslipidemia, diabetes, hyperinsulinemia, and hyperuricemia, which are typical fundamental reasons. Hypertension progressively depends on computerized procedures of circulatory strain estimation. Antihypertensive medication treatment decreases the complications of hypertension. Historically, doctors have prescribed calcium channel blockers to manage hypertension and prevent angina. A common therapy option for hypertension is a group of medications known as dihydropyridine calcium channel blockers, which also include amlodipine, felodipine, and lacidipine.

Dihydropyridine calcium channel blockers (CCBs) act by loosening up vascular smooth muscle, widening veins and thus diminishing fringe obstruction. Benzothiazepines (such as

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DOI: 10.2174/012210299X250401231010114247, 2023, *1*, e2210299X250401

Back to Index

CRP202303.Collaborative research Publication of of our Faculty Dr. Vijaya S. Vichare with Dr. Vishnu P. Chaudhari, Department of Qulaity Assurance, School of Pharmacy, MIT World Peace University, Pune, Maharashtra.

Original Article

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Molecular Docking Studies of Selected Phytoconstituents from Some Indigenous Medicinal Plants against Different Targets of Severe Acute Respiratory Syndrome Coronavirus 2

Vijaya Sachin Vichare, Snehal H. Sutar, Manasi Pratap Rokade, Shashikant N. Dhole, Vishnu P. Choudhari[1]

Abstract

BACKGROUND: COVID-19 is a transmissible disease and propagated through a new strain severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) since December 2019 emerged from Wuhan, China, and this infection has widespread globally that causes to declare public health emergency in the whole world by the WHO. In this article, an attempt was made to recognize natural phytoconstituents from various indigenous medicinal plants, in order to utilize as a source against COVID-19 infections by virtue of molecular docking. The main focus of the study was molecular docking analysis of forty phytoconstituents from plants such as *Tinospora cordifolia*, *Zingiber officinale*, *Azadirachta indica*, *Withania somnifera*, *Glycyrrhiza glabra*, and *Ocimum tenuiflorum* with four different targets of SARS-CoV-2.

AIM AND OBJECTIVE: The aim of the study is to determine binding affinity of phytoconstitutents against different targets of SARS CoV2.

MATERIALS AND METHODS: Molecular docking was performed using VLifeMDS® (version: 4.6. 08032021) and AutoDockTools.

RESULTS: Among forty phytoconstituents based on binding affinity, berberine and vicenin 2 showed the highest potential toward 3-chymotrypsin-like protease enzyme of SARS-CoV-2. Licorice and tinosporide had the potential to bind with the angiotensin-converting enzyme-2 of SARS-CoV-2. Rosmarinic acid also has a binding affinity toward papain-like protease (PLpro) enzyme of SARS-CoV-2. It has been also seen that isoorientin has ability to bind to RNA-dependent RNA polymerase of SARS-CoV-2.

CONCLUSION: Based on docking scores, the phytoconstituents from *T. cordifolia*, *Z. officinale*, *A. Indica*, *W. somnifera*, *G. glabra*, and *O. tenuiflorum* showed a good potential for binding to selected targets of SARS-CoV-2, and the antiviral activity of these plants can be scientifically supported by docking studies.

Keywords:
COVID-19, molecular docking, phytoconstituents, severe acute respiratory syndrome coronavirus 2

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Introduction

The new public health pandemic COVID-19 is threatening to the world with the outbreak of novel coronavirus resulting in more than 4.5 million deaths worldwide.[1] It has been declared as a public health emergency by the WHO.[2] In December 2019, a new virus has been

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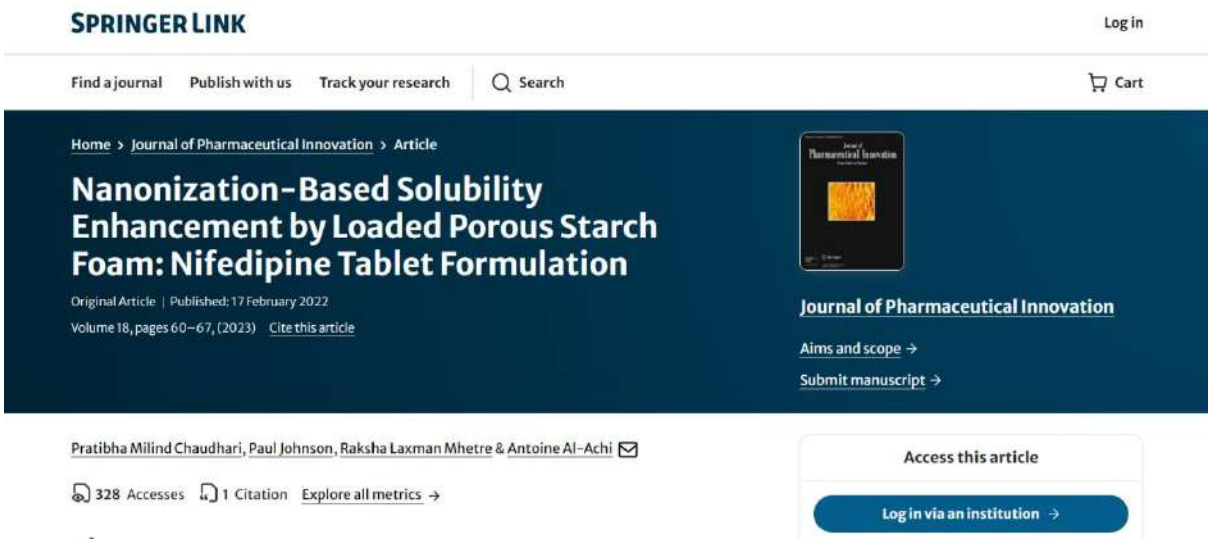
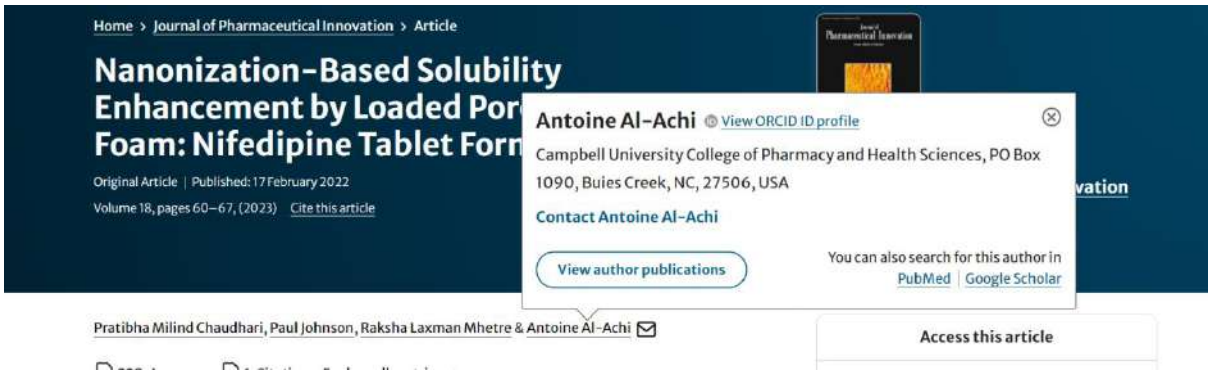
Back to Index

Progressive Education Society's, Modern college of Pharmacy (For Ladies) Moshi, Pune.

CRP202304 Collaborative research Publication of our Faculty Dr. Raksha L.Mhetre with Pratibha Milind Chaudhari, Paul Johnson & Antoine Al-Achi, Campbell University College of Pharmacy and Health Sciences, PO Box 1090, Buies Creek, NC, 27506, USA.

Nanonization-Based Solubility Enhancement by Loaded Porous Starch Foam: Nifedipine Tablet Formulation | Journal of Pharmaceutical Innovation (springer.com)





Back to Index

Progressive Education Society's, Modern college of Pharmacy (For Ladies) Moshi, Pune.

CRP202305. Collaborative research Publication of of our Faculty Dr. Vijaya S. Vichare with Dr. Vishnu P. Chaudhari, Department of Qulaity Assurance, School of Pharmacy, MIT World Peace University, Pune, Maharashtra.

Identification of Oxidative Degradation Products of Dapsone in Presence of Adapalene by RP-HPLC–MS | Chromatographia (springer.com)

Back to Index

Progressive Education Society's, Modern college of Pharmacy (For Ladies) Moshi, Pune.

Collaborative research Publication 2022

CRP202201 Collaborative research Publication of our Faculty Dr. Vrushali S. Tambe with Dr. Archana M. Karnik, SCES,s Indira cllege of Pharmacy, Pune and Mr. Santaji U. Nalwade of Analytical development department, Callidus Research Lab Pvt. Ltd Pune 410501.

Back to Index

CRP202202 Collaborative research Publication of our Faculty Dr. Vrushali S. Tambe with Dr. Archana M. Karnik, SCES,s Indira cllege of Pharmacy, Pune.

Knowledge, Attitude & Practices Study on Hand Hygiene among the Children Aged 12-17 Years.

Received: 16 August 2022, **Revised:** 19 September 2022, **Accepted:** 24 October 2022

Keywords: COVID-19, India, pandemic, lockdown, hand hygiene'

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ABSTRACT

Introduction: The COVID-19 pandemic has demonstrated that good hand hygiene practices are crucial in controlling infections. Handwashing is one of the ways through which children can be kept safe from infections.

Objective: The primary objective of the research study was to determine the hand hygiene knowledge, attitude, and practices (KAP) of the respondents aged 12-17 years of the Maharashtra region. The study focused on comparing gender to understand who had a better knowledge regarding hand hygiene and comparing their attitudes.(1)

Method: A randomized survey was conducted among children aged 12 to 17 years old. A total of 108 respondents participated in the research study. A well-defined questionnaire determined respondents' KAP regarding hand hygiene. Statistical methods like the Chi-square test and Pearson Correlation test were performed to assess respondents' knowledge, attitude, and practices.

Results: Respondents had adequate hand hygiene knowledge, and COVID-19 has positively impacted respondents' attitude toward hand hygiene (P-value 0.30945509). However, respondents had a misconception regarding proper hand hygiene steps and practices. When correlating knowledge and practice, Pearson Correlation gave a value of -0.8842, indicating the correlation between Knowledge and Practices followed by the respondents was negative.

Conclusion: There was an adequate amount of knowledge about hand hygiene among respondents. The Chi-square analysis also indicated that girls' knowledge, attitude, and practices were better than boys. However, there was still a need to increase respondents' understanding of proper hand hygiene practices and procedures. On the positive side, COVID-19 has made respondents more aware of their hand hygiene practice.

Back to Index

CRP202203 Collaborative research Publication of of our Faculty Dr. Vijaya S. Vichare with Dr. Vishnu P. Chaudhari, Department of Qulaity Assurance, School of Pharmacy, MIT World Peace University, Pune, Maharashtra.

[Back to Index]

CRP202204 Collaborative research Publication of our Faculty Dr. Vrushali S. Tambe with Dr. Archana M. Karnik, SCES,s Indira cllege of Pharmacy, Pune.

Research Paper

Development and Validation of Liquid Chromatography Method for Simultaneous Estimation of Miconazole and Clobetasol and Characterization of Hydrolytic Degradation Products using Liquid Chromatography with Tandem Mass Spectrometry

ARCHANA KARNIK*, VRUSHALI TAMBE[1], B. S. KUCHEKAR[2]

Department of Pharmaceutical Chemistry, Shree Chanakya Education Society's Indira College of Pharmacy, Pune, Maharashtra 411033, [1]Department of Pharmaceutical Chemistry, Progressive Education Society's Modern College of Pharmacy, Pune, Maharashtra 412105, [2]Department of Pharmaceutical Chemistry, MAEER's Maharashtra Institute of Pharmacy, Pune, Maharashtra 411038, India

A reverse phase high performance liquid chromatography method was developed to estimate miconazole nitrate and clobetasol propionate simultaneously from a cream formulation. The developed method was validated as per International council for harmonisation guidelines. The proposed method was effectively applied for the characterization of degradation products formed under hydrolytic stressed conditions. The major degradants formed by hydrolysis of both the analytes were separated, identified and characterized. Both drugs were found susceptible to acid and base hydrolytic conditions while were stable under neutral hydrolysis. The liquid chromatography with tandem mass spectrometry studies were further carried out on stressed samples that provided the accurate masses of drug and their degradation products. The mass spectral data and fragmentation patterns were further explored to characterize the degradants and assign structures to them. Total nine degradants were characterized and the degradation pathways for both the drugs were proposed.

Key words: Miconazole nitrate, clobetasol propionate, degradation products, high performance liquid chromatography, liquid chromatography with tandem mass spectrometry, validation

The antifungal agent, Miconazole nitrate (MIC) is used to treat topical fungal infection because of its effective action against dermatophytes and *Candida albicans*. Clobetasol propionate (CLO), a super potent class I corticosteroid with anti-inflammatory, vaso-constrictive and anti-pruritic activity is a drug of choice to treat skin disorders like dermatoses, psoriasis and seborrhoea. The combination of CLO and MIC is used in various skin diseases like inflammatory skin conditions, itching, yeast infection of vagina and vulva and other conditions due to their synergistic effect[1].

An extensive literature indicates, High Performance Liquid Chromatography (HPLC) is widely used for estimation of MIC and CLO either alone[2-6] or in combination with another drugs[7-11] from formulation or biological fluid[12]. CLO is estimated using certain Ultraviolet (UV) spectrometry methods[13,14]. Few chromatographic methods based research articles on stability studies for the estimation of MIC alone[15,16] and in combination of MIC or CLO with another drug[17-20] have been reported. There also exist reports on simultaneous estimation of titled analytes in bulk sample and formulation by HPLC[21,22], High Performance Thin Layer Chromatography (HPTLC)[23] and UV spectrophotometry[24]. Thus, numerous methods have been published in the literature to estimate MIC and CLO in bulk, drug product as well as in bio samples. But, so far, there exists no report on the development

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Back to Index

Progressive Education Society's, Modern college of Pharmacy (For Ladies) Moshi, Pune.

CRP202205 Collaborative research Publication of of our Faculty Dr. Vijaya S. Vichare with Dr. Vishnu P. Chaudhari, Department of Qulaity Assurance, School of Pharmacy, MIT World Peace University, Pune, Maharashtra.

Advances in Pharmacology and Pharmacy 10(3): 173-180, 2022 http://www.hrpub.org
DOI: 10.13189/app.2022.100303

Characterization of Oxidative Degradation Product of Canagliflozin by LC-MS/MS

Vijaya Vichare[1,*], Vishnu Choudhari[2], Vrushali Tambe[1], Shashikant Dhole[1]

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[2]School of Pharmacy, MIT World Peace University, Pune, Maharashtra, India

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(b): Vijaya Vichare, Vishnu Choudhari, Vrushali Tambe, Shashikant Dhole (2022). Characterization of Oxidative Degradation Product of Canagliflozin by LC-MS/MS. Advances in Pharmacology and Pharmacy, 10(3), 173 - 180. DOI: 10.13189/app.2022.100303.

Abstract Prior knowledge of chemical stability of drugs directs path for right selection of dosage form, excipients, storage conditions and packaging material. Literature survey revealed that, there are analytical methods reported for quantification and stability indication of Canagliflozin in bulk and formulation. But there is not much information available about the degradation products generated under different stability conditions. With this background, characterization of oxidative degradation product of Canagliflozin was successfully carried out by Liquid Chromatography-Mass Spectrometry (LC-MS/MS) studies. Degradation product was generated by forced degradation, according to International Conference on Harmonization (ICH) guidelines. Degradation product was separated from Canagliflozin by validated reverse phase (RP)-HPLC method using C18 column and Acetonitrile: Water pH 3.0 adjusted with 0.1% formic acid (70: 30, v/v) as mobile phase at a flow rate of 1mL/min. The developed RP-HPLC method was validated for different parameters as per ICH guidelines. The method was found to be linear in a range of 25-225 µg/mL. The developed method was found to be specific, accurate, precise, sensitive and robust. The marketed tablet formulation was analyzed by the developed method and the percent drug content was found to be 100.09 ± 1.96 % w/w. Separated degradation product was characterized by LC-MS/MS studies. From LC-MS/MS data probable structure of the degradation product was interpreted and the mechanism of degradation was proposed. The probable structure of degradation product was proposed as2-(4-Fluorophenyl)-5-({2-methyl -5-[3,4,5-trihydroxy-6-(hydroxymethyl)oxan-2-yl]phenyl} methyl) thiophene-1-one. The mechanism of degradation was proposed by S-oxidation of thiophene ring to form thiophene oxide. This information will help synthetic chemists to design a synthesis scheme for the oxidative degradation product, which can be used as a reference standard for impurity profiling. It is also suggested to protect CN from oxidative conditions for improved stability.

Keywords Canagliflozin, RP-HPLC Method, Oxidative Degradation, LC-MS/MS, Characterization

1. Introduction

Canagliflozin (CN) is a selective SGLT2 inhibitor approved by FDA for the treatment of type 2 Diabetes Mellitus [1]. 90% of glucose is reabsorbed by kidney through SGLT2. Inhibition of SGLT2 inhibits renal reabsorption of glucose and helps in maintenance of blood glucose levels in diabetes mellitus patients [2]. CN is chemically,2-{3-[5-(4-fluoro-phenyl)-thiophen-2-ylmethy l]-4-methyl-phenyl}-6hydroxymethyltetrahydro-pyran-3,4 ,5-triol [3] (Figure 1). It is not official in IP, BP and USP.

Back to Index

Progressive Education Society's, Modern college of Pharmacy (For Ladies) Moshi, Pune.

Collaborative research Publication 2021

CRP202101 Collaborative research Publication of our Faculty Dr. Nilesh S. Kulkarni with Dr. Rahul H. Khiste of Marathwada Mitra Mandal's, College of Pharmacy, Thergaon, Pune 411033.

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REVIEW ARTICLE

A Review on Applications of Hydroxy Propyl Methyl Cellulose and Natural polymers for the development of modified release drug delivery systems

Rahul Khiste[1]*, Nilkanth Bhapkar[1], Nilesh Kulkarni[2]
[1]Department Department of Pharmaceutical Chemistry, Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune-411033, Maharashtra, India.
[2]Department of Pharmaceutics, PES Modern College of Pharmacy (For Ladies), Moshi, Pune- 421 105, Maharashtra, India.
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ABSTRACT:
This review summarizes applications of Hydroxy Propyl Methyl Cellulose along with Natural polymers for the development of modified release drug delivery systems. The HPMC was available in variety of grades which show different applications in drug delivery. The various grades of HPMC utilized for the variety of action e.g. Coating agent, Adhesion promoter, Targeted release of drug etc. The modified release drug delivery system one of the highly researched field in pharmacy. Even though it is researched and various modified release formulations available in market. The developing more safer approach for drug release is still area of research, which contain easier routes, safer excipients, highly specific target selective materials. Natural polymer show very less side effects as well as it achieves the desired release of drug, so they are the choice of majority of formulations. e.g. Guar gum, Chitosan and Xanthan gum used in various drug delivery systems. Guar gum Cefapodoxime proxetil floating tablet prepared Guar gum, Xanthan gum ophthalmic preparation. Chitosan used in waste water treatment and various biomedical fields like tissue engineering, buccal drug delivery, anticancer treatment etc. Pollulan nanocrystals were studied for the anticancer drug delivery. The review solely based on HPMC-Natural polymer application in Modified release of drug. The various grades of HPMC utilized for the variety of action.

KEYWORDS: HPMC, Natural polymer, Chitosan, Guar gum, Xanthan gum etc.

INTRODUCTION:
The oral solid unit dosage form, it is the most preferred route for administration of dosage form due to its patient compliance, ease of administration, optimal amount of drug is delivered, But still it need to be improved a lot (controlling the release, drug delivery at desired site, shielding of drug from biological fluid of body, avoiding the multiple dosing are some of the aspects expected to improve)[1,2], To meet that various modifications are made in conventional drug delivery system which is known as modified drug delivery system or modified release drug delivery system. A modified release drug delivery addresses, delayed release, extended release, and oral drug delivery system as well as system which are changed in order to achieve modified release effect.

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Definition by USP - A modified-release dosage form is defined "as one for which the drug release characteristics of time course and/or location are chosen to accomplish therapeutic objectives which are not obtainable by conventional dosage forms. A modified release drug delivery address both[3].

Following must be considered for modified release dosage form:

- Small dose
- Short half-life (Long half-life drugs already have the desired kinetics)
- Wide Therapeutic Window
- Absorbed through the GI
- Modest to rapid absorption
- Highly stable in the GI

Advantages:[3,4]

1. Reduce dosing frequency
2. Improve patient compliance

Back to Index

Progressive Education Society's, Modern college of Pharmacy (For Ladies) Moshi, Pune.

CRP202102 Collaborative research Publication of our Faculty Dr. Vrushali S. Tambe with Dr. Archana M. Karnik, SCES,s Indira cllege of Pharmacy, Pune.

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A VALIDATED STABILITY-INDICATING RP-LC METHOD FOR PROPYLTHIOURACIL WITH LC-MS STUDIES OF FORCED DEGRADATION PRODUCTS AND SIMULTANEOUS ESTIMATION OF ITS IMPURITY

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Keywords:

Propylthiouracil, Thiourea, Impurity, Stability Indicating, LC-MS

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ABSTRACT: A simple, precise, accurate, sensitive and robust stability-indicating HPLC method for simultaneous estimation of propylthiouracil and its impurity thiourea has been proposed. The separation was achieved on a C_{18} column (4.6 mm × 150 mm, particle size 5.0 µm) maintained at 45 °C with a mobile phase composed of water: methanol: acetonitrile (50:35:15 v/v/v) with 0.1% acetic acid and detection wavelength was 241 nm. In statistical analysis, the linear response in the range of 30 - 300 µg/ml for propylthiouracil and 0.3 - 30 µg/ml for thiourea with a correlation coefficient greater than 0.99 was obtained. In forced degradation studies, PTU was found to degrade under basic hydrolysis, oxidative and photo stress while found resistant to acid/neutral hydrolysis and thermal degradation. The probable structures of six major degradants generated under stress conditions were identified by LC-MS studies and the most likely degradation pathway was proposed from mass spectral data. The information presented herein could be very useful for the impurity profiling of drugs as well as can be employed to check the drug product quality during stability studies.

INTRODUCTION: Propylthiouracil (PTU) belongs to anti-thyroid drugs class called thion-amides, commonly used to treat hyperthyroidism, thyrotoxicosis and hyperthyroidism associated with pregnancy. It is a potent inhibitor of thyroid peroxidase enzyme and impairs the oxidation and organic binding of thyroid iodide thus blocks thyroid hormone synthesis [1]. PTU is cited in various Pharmacopoeia to have contaminated by impurity; thiourea (TU). Therefore, it was thought worth determining this impurity to ensure safety, efficacy and quality of the final formulation [2, 3].

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Detailed literature indicated different methods *viz*; HPLC [3], titrimetry [2], potentiometry [2, 3] are available for quantification of PTU in bulk and formulation. Simultaneous estimation methods *viz*; voltammetry [4] and UPLC-MS/MS [5] with other anti-thyroid drugs are also reported in the literature.

Official TLC method to detect impurity; TU is a semi-quantitative method and lacks stability-indicating potential [2]. Two stability-indicating HPLC methods have been reported in the literature; one is applicable to bulk drug [6] and other is to tablet assay [7]. The reported stability-indicating method is applicable for assay but is not applicable to its impurity; TU. These methods do not involve the identification of degradation products and are not suitable for LC-MS studies. Other reported methods include the study of the effect of temperature on stability of extemporaneously

Back to Index

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CRP202103 Collaborative research Publication of our Faculty Dr. Vrushali S. Tambe with Dr. Archana M. Karnik, SCES,s Indira cllege of Pharmacy, Pune.

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Plant Phyto-constituents as Antibiotic Adjuvants: A Systematic Review and Bibliometric Analysis

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Review Article

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ABSTRACT

The advent of antibiotics in the 19th century has significantly reduced the morbidity and mortality of infectious diseases. However, irrational use of antibiotics in humans as well as in animals has driven the 21st century to the rapid emergence of MultiDrug Resistance Bacteria (MRB). Moreover, the dissemination of COVID-19 pandemic has paved the way for MRB, typically due to increased use of antibiotics to avoid secondary infections.

The fast pace progression of bacterial resistance for the antibiotics and their combinations is making the management of MRB infections tough and increasing the cost of the treatment as well. However, use of Efflux Pump Inhibitors (EPI) as adjuvant for antibiotics has shown a ray of hope by retaining the susceptibility of the antibiotics and thereby reducing the burden of immediate requirement of new antibiotics for MRB. Accordingly, the present paper is aimed to scrutinize the predominant literature depicting the plant Phyto-constituents as an EPI and adjuvant for antibiotics in the management of MRB infections.

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Back to Index

Progressive Education Society's, Modern college of Pharmacy (For Ladies) Moshi, Pune.

CRP202104 Collaborative research Publication of our Faculty Dr. Nilesh S. Kulkarni with Dr. Rahul H. Khiste of Marathwada Mitra Mandal's, College of Pharmacy, Thergaon, Pune 411033.

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Development and Evaluation of Floating Microspheres of Sumatriptan Succinate using Ethyl Cellulose and Mucilage Extracted from *Vigna Mungo*

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This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Aim: The present investigation is to formulate and evaluate gastroretentive floating microspheres for sumatriptan succinate. Gastric retention is widely used approach to retain dosage form in stomach and to enhance absorption of drugs.
Methods: The gastroretentive floating microspheres was prepared by two different techniques as solvent evaporation and W/O/W multiple emulsion technique. Ethyl cellulose, HPMC K4M polymer and mucilage extracted from *Vigna Mungo* in various proportions were used for formulation of microspheres. Combination of ethyl acetate and acetone in different proportion was used as organic phase and the microspheres were characterized for particle size, shape, morphology, percentage yield, entrapment efficiency, drug loading, *In-Vitro* Floating/Buoyancy study, In-vitro Floating/Buoyancy study and release kinetics.
Results: The average particle size of all batches was found in the range 100 to 210 µm and the entrapment efficiency of all formulations was found in the range of 17.46 % to 59.28 %.Total

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Back to Index

Progressive Education Society's, Modern college of Pharmacy (For Ladies) Moshi, Pune.

CRP202105 Collaborative research Publication of our Faculty Dr. Vijaya Vichare with Dr. Ujjwala Y. Kandekar of JSPM's, Rajashri Shahu college of Pharmacy and Research, Tathwade, Pune, Maharashtra 411033.

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Production and Analysis of Lip Balm using Herbal Resources

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This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Lip care products are an integral part of a day-to-day lifestyle. These impart the colour and protect the lips from the external environment. The major function of lip balm is to protect and moisturize the lips. A variety of lip care products are available in the market. The main concern with this product is that these contain synthetic colourant and flavouring agents that may have adverse effects such as darkening of lips. Besides, these may contain heavy metals that adversely affect various body organs. The current research work deals with preparation lip balm by using maximum possible natural ingredients and evaluation of the formulation. Various natural ingredients used were beetroot extract, Cocoa powder, Almond oil and Vitamin E. The physicochemical properties such as colour, odour, consistency, spreadability, melting point, pH and stability were studied. It was found that the formulation possesses red colour due to the addition of beetroot pigments, it had a typical flavour of cocoa powder, uniform in consistency and good spreadability. The melting point and pH of formulation were found to be 58-60°C ± 0.62 and 6.9 ± 0.25 respectively. The stability study indicated that formulation is stable at room temperature and refrigeration temperature. It can be concluded that lip balm formulation was successfully prepared by using these natural additives and better alternatives to synthetic excipients.

Keywords: Lip balm; natural ingredients; beetroot; cocoa powder; almond oil.

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Back to Index

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CRP202106 Collaborative research Publication of our Faculty Dr. Rohini R. Pujari with Dr. Ujjwala Y. Kandekar of JSPM's, Rajashri Shahu college of Pharmacy and Research, Tathwade, Pune, Maharashtra 411033.

Original Article

Exploration of Elephant Foot Yam (*Amorphophallus paeoniifolius*) Starch: An Alternative Natural Disintegrant for Pharmaceutical Application

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ABSTRACT

Aim and Objectives: The aim of the current study is to isolate the starch from elephant foot yam (*Amorphophallus paeonifolius*) and investigate its potential as a disintegrant in tablet formulation as compare to standard corn starch. The objective of the study is to explore the applications of natural resources and develop an alternative to commercially available starches. **Materials and Methods:** Starch was isolated by a simple method, evaluated for phytochemical and physico-chemical properties. Tablets were prepared by wet granulation by varying concentrations of elephant foot yam or corn starch in the range of 2.5%, 5%, 7.5% and 10%. Further granules were evaluated for flow properties and tablets were evaluated for post-compression parameters. **Results:** It was found that the pH of the isolated starch sample was found to be neutral; it exhibited good swelling capacity and fair flow properties. P-XRD pattern showed a C-type diffraction pattern, SEM studies indicated that starch granules had a smooth surface. Granules possessed good flow properties and tablets complied with standard limits of weight variation. Hardness and friability were found in the range of 4.11-4.69 kg/cm^2 and 0.11-0.50% respectively. The wetting time was found in the range of 7 to 35 sec for elephant foot yam starch and 16-49 sec for corn starch. Disintegration time for elephant foot yam starch was found to be 28 to 84 sec and for corn starch, it was 40 to 90 sec. **Conclusion:** Formulations containing elephant foot yam starch showed a similar dissolution profile as that of corn starch. Stability studies were performed on F4 batch and it was found stable for three months.

Key words: Elephant foot yam, Corn starch, Disintegrant, Fast Disintegrating tablet, Disintegration time, Wetting time.

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INTRODUCTION

Excipients are a critical and integral part of pharmaceutical dosage forms and are used for various purposes along with active ingredients.[1] Excipients play a vital role to ease the manufacturing process of various dosage forms, modify physical properties of dosage form, improve patient compliance by imparting color and flavor, acts as a carrier for insoluble drug, modify the release pattern in case of fast disintegrating and prolong release dosage forms, improve stability and bioavailability of drug etc.[2] Stable and efficacious product can be obtained by addition of appropriately stable and compatible excipients in precise quantities in the formulation. Excipients range from simple to complex substances that can be challenging to characterize. Inappropriate use of excipient might lead to mild to severe toxic effects. It is a critical task of a formulator to select appropriate excipients to develop an efficacious and stable dosage form as per the requirements. Hence the development of the excipients is one of the key research areas in pharmaceuticals. Starch is an immortal excipient!!! It is the major storage polysaccharide of higher plants found in the form of discrete granules.

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Back to Index

Progressive Education Society's, Modern college of Pharmacy (For Ladies) Moshi, Pune.

Collaborative research Publication 2020

CRP202001 Collaborative research Publication of our Faculty Dr. Vrushali S. Tambe with Mr. S. P. Jalakam of Bioanalytical Research Development, Synapse Lab Pvt Ltd., Pune, Maharashtra, India.

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DIRECT CHIRAL HPLC-MS/MS METHOD FOR DETERMINATION OF R-LACOSAMIDE IN HUMAN PLASMA

S. P. Jalakam,[1] V. S. Tambe,[2,*] M. N. Deodhar,[3] V. Prakya,[4] J. Waghmode,[1] and P. Pawar[1]

Original article submitted November 15, 2017.

R-Lacosamide (RLC) is a new approved antiepileptic drug for adjunctive use and monotherapy for partial-onset seizures in some countries. RLC use in other epilepsies and diseases is under study. Research is also going on the activities exhibited by the S-enantiomer (SLC). Taking into consideration further perspectives, the development of direct chiral method that can selectively estimate R-isomer in the presence of S-isomer from human plasma is needed. Plasma samples were spiked with RLC, deuterated internal standard, and SLC. Deuterated RLC as the internal standard enabled us to precisely measure the concentration of RLC by minimizing variations associated with the extraction, ionization, and separation. Target compounds were recovered by liquid-liquid extraction from human plasma using methyl *tert*-butyl ether. The percentage recovery was found to be 68%.The isomers were resolved completely using DIACEL-IC3 column in the reverse phase mode. The retention times of R- and S-isomers were found to be 6.20 ± 0.5 and 8.00 ± 0.5 min, respectively. The proposed method was found to be linear in a concentration range from 1.00×10^2 to 1.50×10^4 ng/mL. Direct chiral HPLC tandem mass spectrometric method that can quantify R-lacosamide in the presence of S-isomer from human plasma without any carry-over and matrix effects was successfully developed. This method is very simple, fast, economic, sensitive, and validated as per EMA guidelines.

Keywords: lacosamide; HPLC-MS/MS; direct chiral bioanalysis; blood plasma, liquid-liquid extraction.

1. INTRODUCTION

R-Lacosamide (RLC), formerly harkoseride, is the latest antiepileptic drug (AED) approved by the FDA for adjunctive use and monotherapy for partial-onset seizures. The R-enantiomer of this 2-acetamido-N-benzyl-3-methoxypropionamide possesses anticonvulsant and antinociceptive properties. The mechanism of RLC action is not yet fully understood [1]. It has been suggested to cause slow inactivation of sodium channels, which is an endogenous mechanism thereby reducing the ectopic hyperactivityof neurons. RLC binds to the collapsin response mediator protein-2 (CRMP-2) and modulates its function *in vitro*. It has favourable pharmacokinetics and safety profiles in comparison to all other approved AEDs.

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RLC displays a favorable interaction profile with currently prescribed AEDs and other commonly used medications. The effect of carbamazepine-induced liver enzyme induction on RLC metabolism has not yet been studied [2]. Although some preclinical studies suggested that RLC could be potentially effective against generalized onset seizures, there was no human study yet to establish RLC as a broad spectrum AED. RLC may expand treatment options for patients with partial epilepsy and may provide significant benefit to patients with refractory seizures [3]. It is also undergoing clinical evaluation for the monotherapy treatment of diabetic neuropathic pain, fibromyalgia, and migraine prophylaxis [4]. Also, the S-enantiomers (SLC) showed promising effect to reduce postoperative and neuropathic pain by inhibiting CRMP-2 phosphorylation by targeting specific sensory neuron populations [5]. In order to evaluate the activity, toxicity, absorption, distribution, metabolism, and excretion properties of the individual enantiomers, and any potential for chiral inversion caused by the biotransformation process, chiral bioanalytical assays are necessary for individual enantiomers and/or their metabolites *in vivo*.

Some achiral methods were reported for the analysis of lacosamide in formulations and plasma [6 – 9]. Only two

Back to Index

Progressive Education Society's, Modern college of Pharmacy (For Ladies) Moshi, Pune.

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Research Article

HPTLC Method Development for the Simultaneous Estimation of Ketorolac Tromethamine and Tramadol Hydrochloride from a Formulation

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Abstract

Objective: The study was aimed to develop simple, specific, accurate HPTLC method for simultaneous determination of the Ketorolac Tromethamine and Tramadol HCl in pharmaceutical dosage form.

Material and Method: A rapid, selective and simple high performance thin layer chromatographic method was developed and validated for their simultaneous estimation in a mixture. Well resolved peaks were observed for both the drugs on aluminium sheet with silica gel 60 F_{254} as the stationary phase. The solvent system consisted of ethyl acetate: methanol: 25% ammonia solution [8.5: 1.5: 0.5 v/v/v]. The λmax were observed at 282nm and 271nm for Ketorolac Tromethamine and Tramadol HCl respectively. Spectrodensitometric scanning-integration was performed at a wavelength of 282 nm.

Results: This system was found to give compact spots for both Ketorolac [Rf value of 0.08 ± 0.01] and Tramadol [Rf value of 0.52 ± 0.02]. The polynomial regression data for the calibration plots showed good linear relationship in the concentration range of 200-700 ng/band for ketorolac [r^2 =0.999] and 500-1750 ng/band for Tramadol [r^2 = 0.995]. The LOD and LOQ were found to be 0.3912 ng/band and 1.7930 ng/band for Ketorolac and 4.6370 ng/band and 7.7551 ng/band for Tramadol, respectively. The peak purity of both drugs was found to be always more than 0.995 proving the specificity of the method.

Conclusion: The method was validated for linearity, LOD, LOQ, specificity, accuracy and precision as per ICH guidelines. The proposed method has demonstrated to have a potential use in simultaneous analysis of Ketorolac tromethamine and Tramadol hydrochloride from a tablet formulation.

Keywords: Ketorolac Tromethamine; Tramadol Hydrochloride; HPTLC Method; Simultaneous Estimation

Abbreviations

KETO: Ketorolac Tromethamine; TRAM: Tramadol Hydrochloride

Introduction

Two drugs are used in this study are Ketorolac Tromethamine [KETO, Figure 1a, NSAID] and Tramadol Hydrochloride [TRAM, Figure 1b, Opioid analgesic]. The combination of KETO/TRAM is a rational therapy for pain by different mechanisms of action. Ketorolac is a carboxylic acid derivative mainly used for its analgesic activity. Tramadol is a centrally acting analgesic used to produce pain relief. The combination of ketorolac and tramadol analgesic efficacy is higher than each of its component individually and has a faster onset of action. Literature revealed analytical methods viz. HPLC [1-8], UPLC [9], HPTLC [10-13] and Spectrophotometric techniques [14-19] for analysis of individual drugs as well as in combinations with other drugs. But no single HPTLC method has been reported for the simultaneous estimation of KETO and TRAM in a formulation.

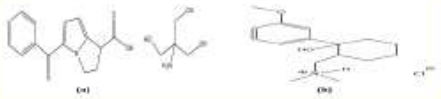

Figure 1: (a) Structure of Ketorolac Tromethamine. (b) Structure of Tramadol hydrochloride.

HPTLC is a reliable, fast and accurate for quantitative drug analysis. Moreover, many samples can be run simultaneously using a small quantity of mobile phase, thus minimizing analysis time and cost per analysis. So here an attempt has been made to develop simple, accurate, sensitive, rapid, economic and specific HPTLC method for simultaneous estimation of KETO and TRAM from a formulation.

Citation: Vrushali S Tambe., *et al.* "HPTLC Method Development for the Simultaneous Estimation of Ketorolac Tromethamine and Tramadol Hydrochloride from a Formulation". *Acta Scientific Pharmaceutical Sciences* 4.1 (2020): 84-88.

Back to Index

Progressive Education Society's, Modern college of Pharmacy (For Ladies) Moshi, Pune.

CRP202003 Collaborative research Publication of our Faculty Dr. Nilesh S. Kulkarni and Manojkumar K. Munde with Dr. Ashim K. Sen and Dr. Dhanya B. Sen of Department of Pharmacy, Sumandeep Vidyapeeth Deemed to be University, Vadodra 391760.

Original Article

A Novel Validated Stability Indicating Analytical Method for Simultaneous Quantification of Metformin Hydrochloride and Empagliflozin in Bulk and Marketed Formulation by HPTLC using Box-Wilson Experimental Design Approach

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ABSTRACT

Background: A novel stability indicating analytical method was developed and validated by High Performance Thin Layer Chromatography (HPTLC) using Design of experiment approach. The proposed method is useful for quantification of Metformin hydrochloride and Empagliflozin in bulk and its dosage forms simultaneously. Design of experiment approach was applied for optimization of chromatographic conditions. **Materials and Methods:** For optimization process independent variables were used as Isopropyl alcohol proportion in mobile phase, saturation time of chamber and distance travelled by mobile phase. Experiments were carried out on silica gel pre-coated plate using mobile phase as 2 % Ammonium acetate: Isopropyl alcohol: Triethylamine (4:6:0.1 v/v/v). Direct evaluation of chromatograms were done by TLC scanner with reflectance/absorbance mode set at 242 nm. Method was validated as per ICH Q2 (R1) requirements. **Results:** Correlation coefficients for calibration curves were found to be 0.985 and 0.988, the calibration curve is in concentration range of 5000-30000 ng band^{-1} and 125–750 ng band^{-1} for Metformin hydrochloride and Empagliflozin respectively. The method showed % recovery between 99.05 to 102.54 % for Metformin hydrochloride and 99.20 to 101.50 % for Empagliflozin. The method has a prospective to determine Metformin hydrochloride and Empagliflozin simultaneously. The Metformin hydrochloride and Empagliflozin were subjected to forced degradation studies like hydrolysis, oxidation, thermolysis and photo-degradation. **Conclusion:** Proposed method has capacity to separate the Metformin hydrochloride and Empagliflozin in its degradation products. Hence one can apply this method effectively for routine analysis and during stability study as per regulatory requirements.

Key words: Method development, Validation, HPTLC, Stability studies, DoE.

INTRODUCTION

Chemically Empagliflozin, 1-chloro-4-(glucopyranos-1-yl)-2-(4-(tetrahydrofuran-3-yloxybenzyl) benzene, [Figure 1 (a)] is an orally available competitive inhibitor of Sodium-glucose Co-transporter-2 (SGLT2) with anti-hyperglycemic activity. Empagliflozin function by inhibiting SGLT-2 present in proximal tubules in the kidneys. Empagliflozin reduces renal reabsorption of glucose leads to increase in urinary excretion of glucose and act as a antidiabetic agent for treatment of type-2 diabetes.[1] Metformin [Figure 1 (b)] is anti-hyperglycemic agent acts by inhibition of hepatic glucose output and therefore, the liver is most likely the principle site of Metformin function.[2] Chemically Metformin is 1-carbamimidamido-N,N-

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Back to Index

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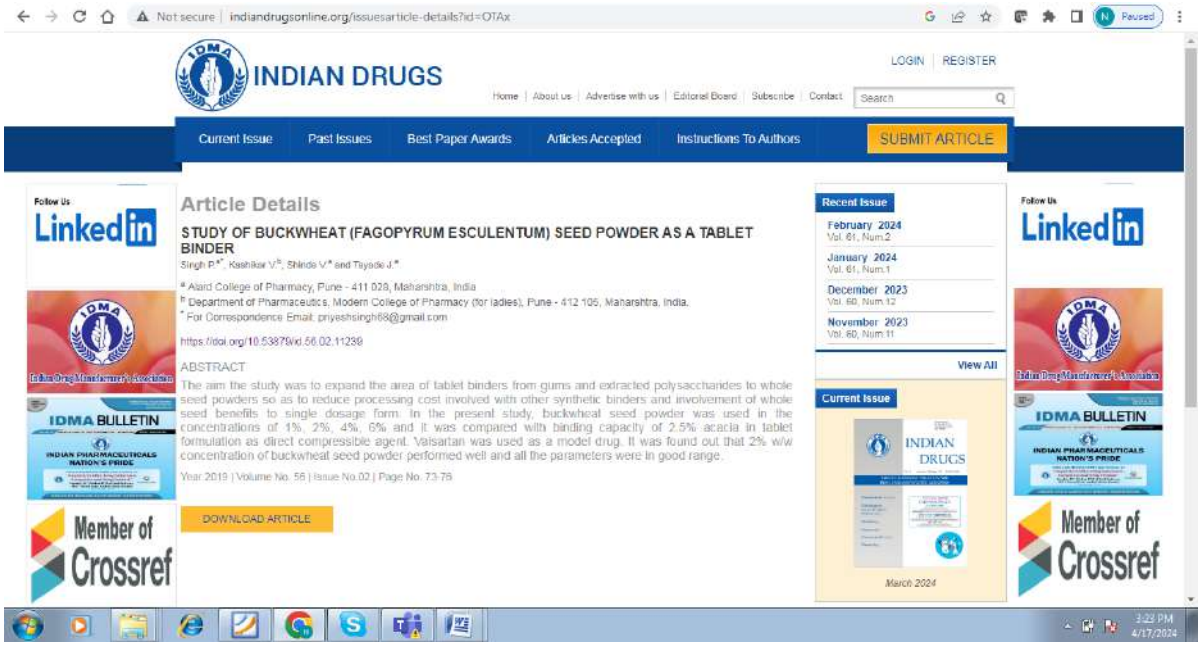

Back to Index

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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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Back to Index

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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]

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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.

Back to Index

Progressive Education Society's, Modern college of Pharmacy (For Ladies) Moshi, Pune.

Collaborative research Publication 2018

CRP201801 Collaborative research Publication of Mr. Hemant P. Alhat with Ms. Sarika R. Jadhav, faculty of Rasiklal M. Dharwal College of Pharmacy ,60/61, Acharya AnandRushiji Marg, Opposite to Finolex Company Telco Road, Chinchwad Station, Pune-411019.

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Research Article

ANALYTICAL METHODS DEVELOPMENT & VALIDATION FOR SIMULTANEOUS ESTIMATION OF LOPINAVIR & RITONAVIR IN PHARMACEUTICAL FORMULATION BY SIMULTANEOUS EQUATION METHOD USING UV SPECTROPHOTOMETRY

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ABSTRACT

The present work deals with the simultaneous estimation of Lopinavir and Ritonavir in bulk and pharmaceutical dosage form using the UV method. Shimadzu UV system was used for analysis. The solvent selected for analysis was acetonitrile: water (30:70v/v). The wavelength of Lopinavir and Ritonavir were found 257.5 nm and 240.0 nm respectively. The Linearity for simultaneous equation method was studied by plotting a graph Conc. Vs. absorbance, Linearity was observed in the concentration range 80-180µg/ml for Lopinavir and 10-60 µg/ml of Ritonavir Coefficient of correlation (R^2) was found to be 0.997 and 0.998 for Lopinavir and Ritonavir respectively. The LOD was found to be 2.379µg/ml and 0.66 µg/ml for Lopinavir and Ritonavir respectively. LOQ was found to be 7.21µg/ml and 2 µg/ml for Lopinavir and Ritonavir respectively. The developed method was employed for the analysis of marketing formulation. The amount of drug obtained was in accordance with label claim. The recovery studies were carried out at three levels, i.e.80 %, 100% and 120% by the standard addition method. The precision of the proposed method was also established. The method was found to be accurate and precise.

Keywords: Lopinavir, Ritonavir, Simultaneous Equation Method, UV Spectrophotometer, Validation.

INTRODUCTION

Lopinavir and Ritonavir are antiretroviral drugs from a protease inhibitor class. The drugs have been proved to be effective in anti-HIV treatment. Chemically Lopinavir is (2S)-N-[(2S,4S,5S) -5-[2- (2,6dimethylphenox acetamido] -4-hydroxy-1,6-iphenylhexan-2-yl] -3-methyl-2-(2-oxo-1,3-diazinan-1-yl) butanamide and its empirical formula is $C_{37}H_{48}N_4O_5$ with a molecular weight of 628.80 (Figure 1 A) [1-3] and Ritonavir (5s, 8s, 10s,11s)-10-hydroxy-2-methyl-5-(1-methylethyl) -1-[2-(1-methylethyl)-4-thiazolyl]-3,6-dioxo-8,11-is (phenylmethyl) -2,4,7,12-etraazatidecan-13-oic acid 5-thiazolyl methyl ester of molecular formula $C_{37}H_{48}N_6O_5S_2$ and its molecular weight is 720.95 (Figure 1 B) [1-3]. Ritonavir is the most potent protease inhibitor, it has an ability to inhibit CYP-450 and efflux pump-P-glycoprotein as a result the potential for severe drug interaction is quite great because of strong CYP-450 the inhibiting effect of ritonavir. The drug has found value when used in fixed dosage form combination with other Pharmaceutical Ingredients to block their metabolism and acts as a booster for these drugs. In these cases, ritonavir is used in a sub therapeutic dose, but boosts the effectiveness of the co administered drug. [4-7]

Literature survey of lopinavir and ritonavir either single or in combination with ritonavir shows that several methods based on UV- spectrophotometry, HPLC and HPTLC were developed and validated. However, there are few UV- spectrophotometric method for simultaneous determination are available which are costly and time consuming. The present method was validated as per ICH guideline.

MATERIALS AND METHODS [8-17]

Instrument

An UV –visible double beam spectrophotometer of make JASCO, model V-530 with a pair of 1cm matched quartz cell, spectral bandwidth of 2cm and Shimadzu balance, AUX-220 were used for experimental purpose.

Chemicals

Acetonitrile-AR, Distilled water

Method

The stock solutions were prepared as follows-

Preparation of stock solution of Lopinavir

An accurately weighed 100 mg of Lopinavir was transferred to 100ml volumetric flask. Dissolved and made up to the volume with a mixture of acetonitrile: water (30:70v/v) which is previously prepared and sonicated for 10min., obtain the concentration of 1000µg/ml. Stock solution was sonicated for 15 min and filtered it. From this stock solution pipette out 0.8ml, 1ml,1.2ml, 1.4ml, 1.6ml in 10ml volumetric flasks and made the volume with a mixture of Acetonitrile : water (30:70v/v) to get final concentration range 80-160µg/ml.

Back to Index