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 the last five years

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1. Tailoring the properties of chitosan by grafting with 2-mercaptobenzoic acid to improve mucoadhesion: in silico studies, synthesis and characterization

Prog Biomater. 2022 Dec;11(4):397-408. doi: 10.1007/s40204-022-00201-x. Epub 2022 Oct 7.

Tailoring the properties of chitosan by grafting with 2-mercaptobenzoic acid to improve mucoadhesion: in silico studies, synthesis and characterization

Tejinder K Marwaha [1], Ashwini Madgulkar [2], Mangesh Bhalekar [2], Kalyani Asgaonkar [3], Rajesh Gachche [4], Pallavi Shewale [4]

Affiliations

PMID: 36205916 PMCID: PMC9626691 DOI: 10.1007/s40204-022-00201-x
Free PMC article

Abstract

Mucoadhesive polymers improve oral bioavailability of drugs by prolonging the duration of adhesion of drugs with mucosa. Various methods could be employed to address the problems of mucoadhesive polymers like weak adhesion forces. Chemical modification of polymers, such as the addition of a thiol group or thiolation, is another way for improving the polymers' mucoadhesive properties that is studied in present research work. A novel thiomer of chitosan was prepared by attaching 2-mercaptobenzoic acid, a hydrophobic ligand onto it. The docking of thiomer and chitosan with mucin structure showed higher binding energy for former. The prepared thiomer was subjected to X-ray diffraction and DSC which established reduction in crystallinity and formation of a new compound through changes in glass transition, melting point and change in diffraction pattern. The NMR studies established conjugation of 2-mercapto benzoic acid to chitosan. The increased mucoadhesion in thiomer behaviour (2-3 fold) was confirmed through mucus glycoprotein assay as well as through texture analysis. The permeation enhancing the property of thiomer was established by demonstrating the permeation of phenol red across thiomer treated intestinal membrane. An in vitro cell toxicity assay was done to establish toxicity of chitosan and thiolated chitosan. Finally, the reduced water uptake of thiomer over chitosan proved that the increase in mucoadhesion is not contributed by swelling. Thus, a thiomer with improved mucoadhesion and enhanced permeation properties was prepared and characterized. Hence, all these properties render the newly synthesized polymer a better alternative to chitosan as an excipient for mucoadhesive drug delivery systems.

Keywords: Chitosan; Docking; Mucin; Mucoadhesion; Thiomer.

Figures

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2. Pastillation with amorphous synthetic polymers: a key to solubility enhancement of poorly soluble drugs

7/20/23, 10:39 AM Pastillation with Amorphous Synthetic Polymers: A Key to Solubility Enhancement of Poorly Soluble Drugs - Pharmacophore

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Pastillation with Amorphous Synthetic Polymers: A Key to Solubility Enhancement of Poorly Soluble Drugs

Download PDF

Ashish Guha, Mangesh Bhalekar, Ashwini Madgulkar, Ankita Ingale

Abstract

Solubility has always been a challenge for the pharmaceutical fraternity owing to the dependency of bioavailability on the same. The objective of the current work was to improve the aqueous solubility of a BCS class II anti-retroviral drug, ritonavir, by using melt technology via the Pastillation technique. EUDRAGIT® EPO was chosen as representative of amorphous high molecular weight synthetic functional polymers. Ritonavir with EUDRAGIT® EPO and other plasticization aid was processed using the melt technique to fabricate ritonavir-loaded pastilles by using an in-house Pastillation device. The ratio of the ingredients was studied using the DOE approach where the quantities of drug, polymer, and plasticizer were studied as independent variables, and dissolution time and processability were studied as responses. The optimized pastilles were further subjected to physicochemical analysis, morphological characterization, in-vitro drug release, and in-vivo pharmacokinetic studies in Wistar rats. It was observed that the optimized pastilles had excellent processability, good physical properties, and an improved dissolution rate compared to the marketed tablets. The improved dissolution was supported by the DSC and XRD data which showed the amorphous conversion of the drug, thus improving solubility in the aqueous medium. In-vivo pharmacokinetic evaluation in rats resulted in an improved bioavailability of the drug from the pastilles compared to the marketed tablets. It is believed that a simple and economic technique such as Pastillation can be efficiently used with high molecular weight synthetic functional polymers to improve the drug solubility thereby improving the bioavailability of the drug, which is a major problem in the pharmaceutical industry.

Cite this article

Vancouver

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APA

Guha, A., Bhalekar, M., Madgulkar, A., & Ingale, A. (2022). Pastillation with Amorphous Synthetic Polymers: A Key to Solubility Enhancement of Poorly Soluble Drugs. *Pharmacophore, 13*(6), 70-76. https://doi.org/10.51847/3bKBG2fm1T

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3. Quality by Design Enabled Development and Optimization of the Nanoparticulate System of Cabazitaxel

International Journal of Pharmaceutical Sciences and Drug Research
ISSN: 0975-248X | DOI Prefix: 10.25004 | CODEN (USA): IJPSPP

QUALITY BY DESIGN ENABLED DEVELOPMENT AND OPTIMIZATION OF THE NANOPARTICULATE SYSTEM OF CABAZITAXEL

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DOI https://doi.org/10.25004/IJPSDR.2022.140115

ABSTRACT

Cabazitaxel (CTX), a novel taxane derivative, has proven effective in many solid tumors. It is also approved in many countries for multiple uses in solid tumors. The current marketed formulation lacks the tumor-targeting ability, and its uneven distribution in the body causes toxicity to normal tissues. Further, it is a surfactant (polysorbate 80) based micellar formulation composed of ethanol as a co-solvent to improve the solubility of CTX, which causes severe and life-threatening side effects. Hence, to avoid the problem associated with this conventional CTX formulation, the nanoparticulate drug delivery system of CTX was developed by employing the Quality by Design (QbD) approach. The CTX nanoparticulate system was developed by employing a bottom-up followed by a top-down approach. The size reduction was obtained by High-Pressure Homogenizer (HPH). The formulation optimization was done using QbD approach. Design of experiments (DoE) was used to understand the effect of various formulation and process variables on a dependent variable like particle size distribution.
The stabilizer concentration, concentration of solubilizer, HPH pressure, and passes were selected as independent factors while particle size distribution was selected as a dependent factor for evaluation. The nanoparticulate system was developed using PEG-400 as solubilizing agents, while Soya Phosphatidylcholine (SPC) was used as a surface stabilizer. Response surface plots revealed a decrease in particle size with increasing concentration of SPC and PEG 400. Similarly, a decrease in particle size with increased HPH passes and pressure was found. The optimum concentrations of SPC and PEG 400 were found to be 20% and 2.5%,

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4. Wound Healing Dressing System for Diabetic Wounds Based on Curcumin and Syringic Acid. International Journal of pharmaceutical Investigation

Int. J. Pharm. Investigation, 2022; 12(1) : 82-86 Original Article

Wound Healing Dressing System for Diabetic Wounds Based on Curcumin and Syringic Acid

Rahul Padalkar*, Ashwini Madgulkar, Rohit Kharade
Department of Pharmaceutics, AISSMS College of Pharmacy, Pune, Maharashtra, INDIA.

ABSTRACT

Background: This work is based on the development of a wound healing dressing system for diabetic wounds using curcumin and syringic acid. A diabetic wound differs from a normal wound in respect to many pathophysiological changes. Therefore multiple issues like hemostasis, inflammation, cell proliferation and tissue remodeling need to be considered while selecting actives. A combination of curcumin, syringic acid and *Aloe vera* can address such aspects of pathophysiological changes in diabetic wound healing. **Materials and Methods:** Initially curcumin and syringic acid were mixed with *Aloe vera* juice. Carbopol 934 was used as a gelling agent for this mixture. This gel was loaded into sterilized polyurethane foam. The prepared dressing system was evaluated for *in vitro* and *in vivo* performance. **Results:** The dressing system showed excellent folding endurance. *Ex vivo* antibacterial activity was found to be excellent against *Staphylococcus aureus* and *Escherichia coli*. The zone of inhibition of developed foam dressing was found 25 ± 5 mm for *Staphylococcus aureus* and 20 ± 3 mm for *Escherichia coli*. *In vitro* diffusion was found to be 88.40% and 84.65 % for curcumin and syringic acid respectively. Diabetes induced rats were used for evaluating *in vivo* wound healing activity and complete wound healing was observed at the end of 14 days. **Conclusion:** Polyurethane foam dressing system based on curcumin, syringic acid and *Aloe vera* can show promising wound healing in diabetes conditions.

Key words: Polyurethane foam dressing, Curcumin, Syringic acid, *Aloe vera* gel, Diabetic wound.

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DOI: 10.5530/ijpi.2022.1.15

INTRODUCTION

Skin is the largest organ of the human body. It performs different functions like forming a protective barrier to the external environment, preventing external noxious agents such as bacteria and viruses and maintaining the internal environment through the regulation of water and electrolyte balance. Skin also plays a role in thermoregulation.[1] A wound is a disruption of the physiological arrangement of skin cells. It also disturbs the normal function of the skin like connecting and protecting underlying tissues and organs. A wound is classified as an acute and chronic wound.[1] The normal wound healing process occurs through phases like hemostasis, inflammation, cell proliferation and tissue remodeling.[2]

Diabetic wounds begin as acute wounds, but the healing process is interrupted and trapped in different phases of wound healing. Thus acute wound fails to repair and becomes more chronic. In diabetic patients, the wound healing process is affected by hyperglycemia, chronic inflammation, micro and macro-circulatory dysfunction, hypoxia, autonomic and sensory neuropathy and impaired neuropeptide signaling.[3] In diabetes, a prolonged inflammatory response after the injury is one of the reasons for delayed wound closure.[3]

The current work describes the development of a polyurethane foam-based dressing system using curcumin, syringic acid and *Aloe vera* gel. The foam dressing absorbs exudates from the wound, provides moisture to the wound helping in the epithelialization.[4] Curcumin, syringic acid and *Aloe vera* have a diabetic wound healing potential.[5,6] The combination of curcumin, syringic acid and *Aloe vera* gives synergistic action in diabetic wound healing. This study suggests that developed foam dressing is a promising treatment for non-healing diabetic wounds.

MATERIALS AND METHODS

Drugs and Chemicals

Polyurethane foam (Bombay Rexine, Pune), Curcumin (Loba Chemie), Syringic acid (P C Chemicals), *Aloe vera* leaves (Institutional botanical garden), Carbopol 934 (Loba Chemie), Sodium benzoate (Loba Chemie), Sodium metabisulphite (Loba Chemie), Glycerin (Loba Chemie), Triethanolamine (Loba Chemie), Alloxan monohydrate (Loba Chemie).

Animals

Adult male Wistar rats, weighing from 250-280 g were procured from the Central Animal House of Institute. The research proposal was approved by The Institutional Animal Ethical Committee (IAEC). *In vivo* study was carried out by following CPCSEA guidelines for the use and care of experimental animals.

Characterization of Polyurethane foam Density

The dimension (length, width and thickness) of foams were measured using a vernier caliper in mm. The foams were weighed. The density of six samples of foam was calculated and the average density was reported as g/cm^3.[47]

Formulation and Development of Dressing System

Fresh *Aloe vera* leaves were collected from the institutional botanical garden and washed. *Aloe vera* pulp was collected and homogenized. The obtained *Aloe vera* juice was filtered through a muslin cloth and observed against a white background to see any particulate matter.[8] *Aloe vera* gel formulation was prepared with different concentrations of carbopol 934. Carbopol was soaked overnight in water and stirred

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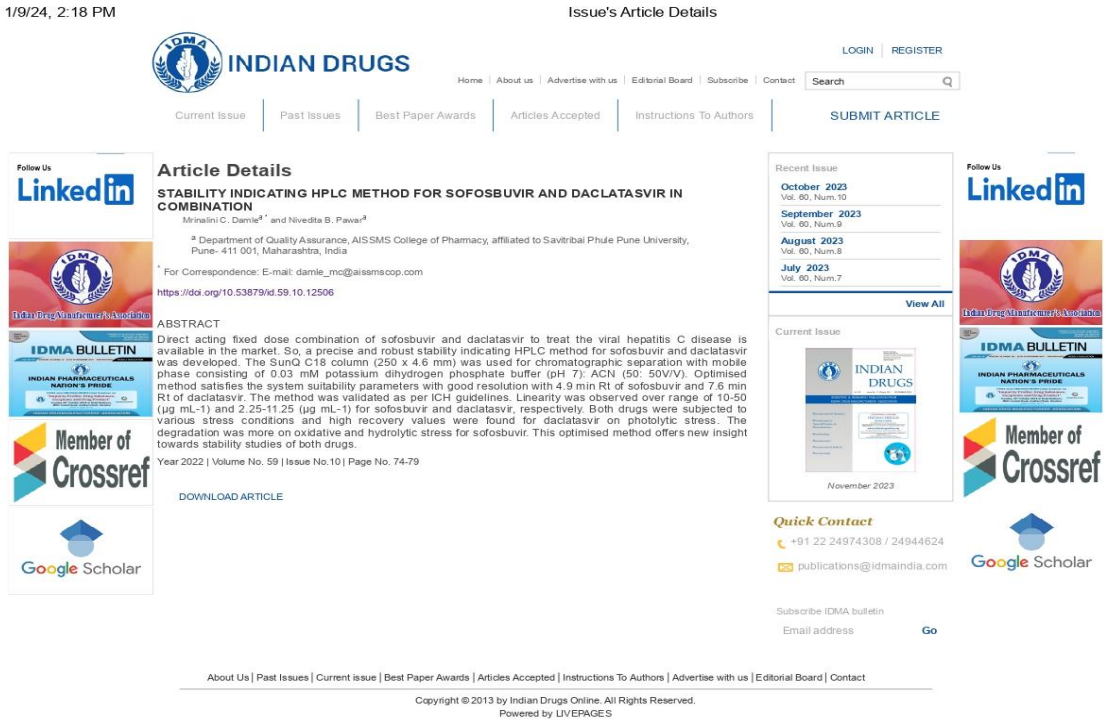
5. Stability indicating HPLC method for Sofosbuvir and Daclatasvir in combination



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STABILITY INDICATING HPLC METHOD FOR SOFOSBUVIR AND DACLATASVIR IN COMBINATION

Mrinalini C. Damle[a,*] and Nivedita B. Pawar[a]

[a] Department of Quality Assurance, AISSMS College of Pharmacy, affiliated to Savitribai Phule Pune University, Pune- 411 001, Maharashtra, India

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https://doi.org/10.53879/id.59.10.12506

ABSTRACT

Direct acting fixed dose combination of sofosbuvir and daclatasvir to treat the viral hepatitis C disease is available in the market. So, a precise and robust stability indicating HPLC method for sofosbuvir and daclatasvir was developed. The SunQ C18 column (250 x 4.6 mm) was used for chromatographic separation with mobile phase consisting of 0.03 mM potassium dihydrogen phosphate buffer (pH 7): ACN (50: 50V/V). Optimised method satisfies the system suitability parameters with good resolution with 4.9 min Rt of sofosbuvir and 7.6 min Rt of daclatasvir. The method was validated as per ICH guidelines. Linearity was observed over range of 10-50 (µg mL-1) and 2.25-11.25 (µg mL-1) for sofosbuvir and daclatasvir, respectively. Both drugs were subjected to various stress conditions and high recovery values were found for daclatasvir on photolytic stress. The degradation was more on oxidative and hydrolytic stress for sofosbuvir. This optimised method offers new insight towards stability studies of both drugs.

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6. Stability indicating HPTLC method for active principle Psoralen and its application to accelerated stability testing of marketed formulation

Indian Journal of Traditional Knowledge (IJTK)

DOI: 10.56042/ijtk.v21i4.33055

Stability indicating HPTLC method for active principle psoralen and its application to accelerated stability testing of marketed formulation

Damle, Mrinalini ; sheth, Sayali Rajendra

Abstract

Psoralen is a phytoconstituent found in the plant. Psoralea corylifolia also known as Bawchi/Bakuchi in India. A stability indicating HPTLC method for estimation of psoralen has been developed. The effects of accelerated conditions on the psoralen content from marketed formulation (seed powder) was studied. The powder of dried seeds and standard psoralen were applied to silica gel 60 F254 aluminium-supported precoated TLC plates using optimised mobile phase containing toluene: ethyl acetate 9: 1 (v/v). Densitometric scanning was conducted at λmax= 246 nm. A compact peak for psoralen (Rf= 0.62±0.03) was observed with linearity ranging from 40 ng-200 ng/band with good correlation coefficient of r2= 0.991. The standard marker was subjected to degradation studies as per ICH Q1A (R2) guidelines and found susceptible to degradation in all conditions like hydrolysis, photolytic, oxidation and thermal. The marketed formulation (seed powder) was exposed to accelerated conditions for 3 months. The method was found to be reproducible, selective and reliable for estimation of stability of standard psoralen in marketed formulations.

Keyword(s)

Bawchi; HPTLC; Psoralen; Seed powder; Stability

Refbacks

There are currently no refbacks.

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7. Development and validation of dissolution method for Linagliptin tablets

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Vol 15, Issue 8, 2022

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Research Article

DEVELOPMENT AND VALIDATION OF DISSOLUTION METHOD FOR LINAGLIPTIN TABLETS

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Received: 09 May 2022, Revised and Accepted: 20 June 2022

ABSTRACT

Objective: Linagliptin is used to treat type-2 diabetes. It is available singly as 5 mg tablet. Since there is no official dissolution method in Indian pharmacopeia, there is a need to develop a method for testing dissolution of linagliptin immediate release tablet.

Methods: For establishing dissolution method, various media, volume of media, and speed of rotation were tried. Quantification of dissolution samples was carried out using HPTLC and UV method. TLC plate pre-coated with silica gel 60 F_{254} was used as stationary phase and mobile phase employed for the development of TLC plates was methanol: toluene in a ratio of 7:3 v/v. The mobile phase was allowed to travel a distance of 70 mm and saturation time set was 20 min. Detection wavelength set was 294 nm.

Results: The most suitable condition for dissolution of linagliptin tablet was found to be dissolution apparatus type II (paddle) using 900 ml 0.1 N HCl as medium at speed of 75 rpm. The optimized chromatographic condition resulted in compact band at Rf value of 0.76±0.02.

Conclusion: Both the chromatographic and spectroscopic methods which were used for quantification were found to be linear with r^2 value of 0.9929 and 0.9918, respectively, accurate, precise, and robust.

Keywords: HPTLC, UV spectrophotometry, Dissolution, Method development, Validation, Linagliptin.

 DOI: http://dx.doi.org/10.22159/ajpcr.2022v15i8.45145. Journal homepage: https://innovareacademics.in/journals/index.php/ajpcr

INTRODUCTION

Linagliptin is used in the treatment of non-insulin-dependent diabetes mellitus. It is a member of class "gliptins" which are orally active DPP-4 inhibitors that are dipeptidyl peptidase-4 inhibitors [1]. Linagliptin chemically is 8-[(3R)-3-aminopiperidin-1-yl]-7-but-2-ynyl-3-methyl-1-[(4-methylquinazolin-2-yl) methyl] purine-2,6-dione [2]. It is yellowish to white solid substance which is very slightly soluble in water, isopropanol, acetone, soluble in methanol, and sparingly soluble in ethanol. Structurally, it is (Fig. 1); The recommended dose for linagliptin is 5 mg once daily [3]. It is available as tablet dosage form with label claim of 5 mg per tablet.

The best way of assessing therapeutic efficacy of drug is *in vivo* determination of bioavailability which is done when a new formulation is introduced into market. However, to monitor batch to batch consistency, this method becomes costly, tedious, and time consuming; hence, *in vitro* dissolution test emerged as best quality control tool to quantitatively assure about biological availability of drug from its formulation [4]. *In vitro* test is useful in guiding formulation and development, monitor manufacturing process, assessing quality of batch, and may be useful to predict *in vivo* performance in terms of bioavailability. Dissolution test is also used to identify bioavailability problems and to assess the need for further bioequivalence (BE) studies relative to scale-up and post-approval changes (SUPAC) [5].

The literature survey revealed that there is one paper of dissolution method of linagliptin using HPLC and UV [6]. To the best of our knowledge, there is no report of dissolution method of linagliptin using HPTLC and UV comparison. Keeping in mind, high-throughput advantage of HPTLC, it was considered worthwhile to develop HPTLC method for quantification of linagliptin in dissolution test. The developed method was validated as per International Council for Harmonization (ICH) guidelines [7], based on parameters such as specificity, linearity, precision, accuracy, and robustness.

METHODS

Instruments

Dissolution samples were analyzed using Camag HPTLC system (winCATS 1.4.2) and Shimadzu UV 1780 UV-Visible spectrophotometer, Japan, and other equipment used were Shimadzu AY 120 Analytical Balance, Japan, Electrolab DI 08L Dissolution apparatus USP (type II) and Labtronics LT 11 Auto Digital pH meter.

Chemicals and reagents

Linagliptin reference standard was obtained as gift sample. The chemicals used were methanol and water of HPLC grade and toluene of AR grade. Methanol was purchased from Merck Lifesciences, Pvt. Ltd., Mumbai, India, and toluene was purchased from Loba Chemie, Pvt. Ltd., Mumbai, India. For dissolution purpose, marketed tablets of label claim 5 mg were purchased from local pharmacy.

Phosphate buffer of pH 4.5, citrate buffer of pH 3, and 0.1 N HCl were prepared freshly as per IP [8].

Chromatographic conditions

The quantification of dissolution samples was performed on Merck TLC plate pre-coated with silica gel 60 F_{254}. Samples were applied on plate in the form of 6 mm band using 100 µl sample syringe with the help of semiautomatic Linomat applicator IV. 20×10 twin trough chamber was used

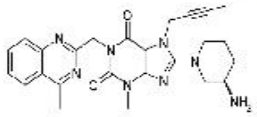

Fig. 1: Chemical structure of linagliptin

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8. Bioanalytical method for estimation of Teriflunomide in human plasma

International Journal of Pharmacy and Pharmaceutical Sciences

Print ISSN: 2656-0097 | Online ISSN: 0975-1491 Vol 14, Issue 9 2022

Original Article

BIOANALYTICAL METHOD FOR ESTIMATION OF TERIFLUNOMIDE IN HUMAN PLASMA

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Received: 26 May 2022, Revised and Accepted: 06 Jul 2022

ABSTRACT

Objective: Teriflunomide is used for the treatment of multiple sclerosis and is available in 7 mg and 14 mg tablets. This study aimed to develop and validate a simple and economical HPTLC method for the estimation of Teriflunomide in human plasma.

Methods: HPTLC method was developed using toluene: ethyl acetate: acetic acid as the mobile phase and the stationary phase was a TLC plate precoated with silica gel 60 F_{254}. The detection wavelength set was 294 nm. The sample preparation involved a simple protein precipitation technique with Acetonitrile as a precipitating protein agent; the internal standard selected was Rilpivirine. The validation was carried out as per bio-analytical method guidelines.

Results: The Rf value for Teriflunomide was found to be 0.46±0.04. The linearity range was observed from 10-60 µg/ml with a regression coefficient value of 0.9819. The developed method was validated for various parameters like specificity, linearity, accuracy, precision, recovery, and stability.

Conclusion: The developed method is simple, specific, accurate, and economical for the estimation of Teriflunomide in human plasma.

Keywords: Teriflunomide, HPTLC, Protein precipitation, Rilpivirine, Bioanalytical

DOI: https://dx.doi.org/10.22159/ijpps.2022v14i9.45151. Journal homepage: https://innovareacademics.in/journals/index.php/ijpps.

INTRODUCTION

Teriflunomideis the active metabolite of Leflunomide which is a pyrimidine synthesis inhibitor used for the treatment of relapsing forms of multiple sclerosis. Also, it has anti-inflammatory and immunomodulatory properties. Chemicallyit is (Z)-2-cyano-3-hydroxy-N-[4-(trifluoromethyl) phenyl] but-2-enamide [1].

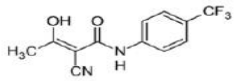

Fig. 1: Chemical structure of Teriflunomide

Teriflunomide selectively and reversibly inhibits dihydro-orotate dehydrogenase, which is a key enzyme in the pyrimidine synthesis pathway. As Teriflunomide inhibits this enzyme leads to a reduction in the proliferation of activated T and B lymphocytes without causing cell death [2]. The oral bioavailability of Teriflunomide is 100%, with peak plasma levels achieved within 1-2 h of intake and Cmax ranging from 19-45µg/ml. Teriflunomide has a mean plasma half-life of 10-18 d [3].

The literature survey revealed that there are many papers [4-12] on the bioanalytical method of Teriflunomide using LC-MS/MS, LC-UV, and UPLC. But there is no paper reported on the bioanalytical method for Teriflunomide using HPTLC. Bioanalytical methods involve the determination of analytes of interest in various biological matrix-like plasma, serum, urine, etc [13]. Some of the advantages of HPTL Conclude, a short analysis time, cost-efficient analysis, prior treatments for solvents like filtration and degassing can be evaded, and a fresh stationary phase and mobile phase are used for analysis which helps to prevent carryover.

MATERIALS AND METHODS

Chemicals and reagents

Teriflunomide was obtained as a gift sample from Natco Pharmaceuticals, Hyderabad, India. Rilpivirine was received as a gift sample from Mylan laboratories, Hyderabad, and was used as an internal standard. Methanol and ethyl acetate was of HPLC grade purchased from Merck Lifesciences, Pvt. Ltd., Mumbai, and toluene and acetic acid used were of AR grade purchased from Loba Chemie, Pvt. Ltd., Mumbai, India. Pooled plasma was obtained as a gift sample from Sassoon hospital, blood bank Pune, India.

Instrumentation

Camag HPTLC system with win CATS software version 1.4.2, Shimadzu UV 1780 UV-Visible spectrophotometer, Japan, Shimadzu AY 120 Analytical balance, Japan, Remi Cyclo-mixer and Remi Centrifuge R-302.

Experimental

Chromatographic conditions

HPTLC method

The chromatographic resolution was performed on a Merck TLC plate precoated with silica gel 60 F_{254} using a Camag Linomat V sample applicator. Samples were applied on the plate in the form 6 mm band using a Camag 100 µl sample syringe. 20×10 twin trough chamber was used for ascending development with mobile phase toluene: ethyl acetate: acetic acid (6.5:3:0.5v/v/v). Saturation time was set at 20 min; the plate was allowed to develop up to70 mm of distance. Densitometric scanning was performed on a Camag TLC scanner III at 294 nm for all developments operated by Win cat's software version 1.4.2. Deuterium and tungsten lamps were used as the radiation source.

Method development

Selection of mobile phase

The mobile phase first tried was toluene: ethyl acetate: glacial acetic acid in the ratio of 7.5:2:0.5 v/v/v [14]. To obtain well-resolved peaks of internal standard and Teriflunomide, the mobile phase was optimized to toluene: ethyl acetate: glacial acetic acid in the ratio of 6.5:3:0.5 v/v/v.

Selection of internal standard

Based on the λmax of the drug, various internal standards like Ivabradine hydrochloride, Mifepristone, Nebivolol, Rilpivirine, and

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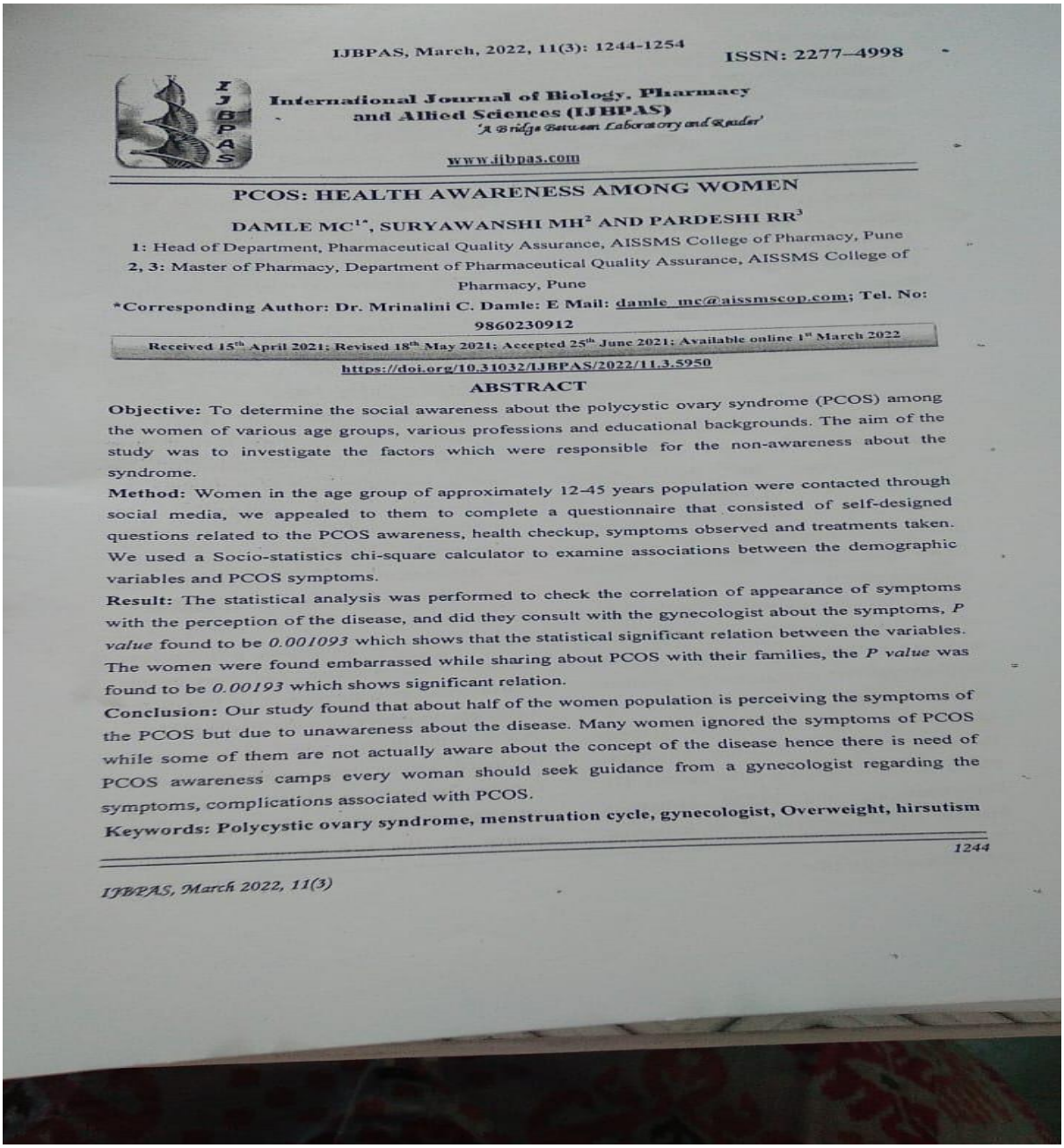
9. PCOS: Health awareness among women



IJBPAS, March, 2022, 11(3): 1244-1254 ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)
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PCOS: HEALTH AWARENESS AMONG WOMEN

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Received 15th April 2021; Revised 18th May 2021; Accepted 25th June 2021; Available online 1st March 2022
https://doi.org/10.31032/IJBPAS/2022/11.3.5950

ABSTRACT

Objective: To determine the social awareness about the polycystic ovary syndrome (PCOS) among the women of various age groups, various professions and educational backgrounds. The aim of the study was to investigate the factors which were responsible for the non-awareness about the syndrome.

Method: Women in the age group of approximately 12-45 years population were contacted through social media, we appealed to them to complete a questionnaire that consisted of self-designed questions related to the PCOS awareness, health checkup, symptoms observed and treatments taken. We used a Socio-statistics chi-square calculator to examine associations between the demographic variables and PCOS symptoms.

Result: The statistical analysis was performed to check the correlation of appearance of symptoms with the perception of the disease, and did they consult with the gynecologist about the symptoms, *P value* found to be *0.001093* which shows that the statistical significant relation between the variables. The women were found embarrassed while sharing about PCOS with their families, the *P value* was found to be *0.00193* which shows significant relation.

Conclusion: Our study found that about half of the women population is perceiving the symptoms of the PCOS but due to unawareness about the disease. Many women ignored the symptoms of PCOS while some of them are not actually aware about the concept of the disease hence there is need of PCOS awareness camps every woman should seek guidance from a gynecologist regarding the symptoms, complications associated with PCOS.

Keywords: Polycystic ovary syndrome, menstruation cycle, gynecologist, Overweight, hirsutism

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10. Stability indicating HPTLC method for Bedaquiline Fumarate

Research Journal of Pharmacy and Technology

(Home.aspx)

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0974-3618 (Print)

Stability Indicating HPTLC Method for Bedaquiline Fumarate (AbstractView.aspx?PID=2022-15-9-22) (https://scholar.google.co.in/scholar?q=Stability Indicating HPTLC Method for Bedaquiline Fumarate)

Author(s): M. C. Damle (search.aspx?key=M. C. Damle), O. A. Shinde (search.aspx?key=O. A. Shinde)

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DOI: 10.52711/0974-360X.2022.00662 (https://doi.org/10.52711/0974-360X.2022.00662) (https://scholar.google.co.in/scholar?q=10.52711/0974-360X.2022.00662)

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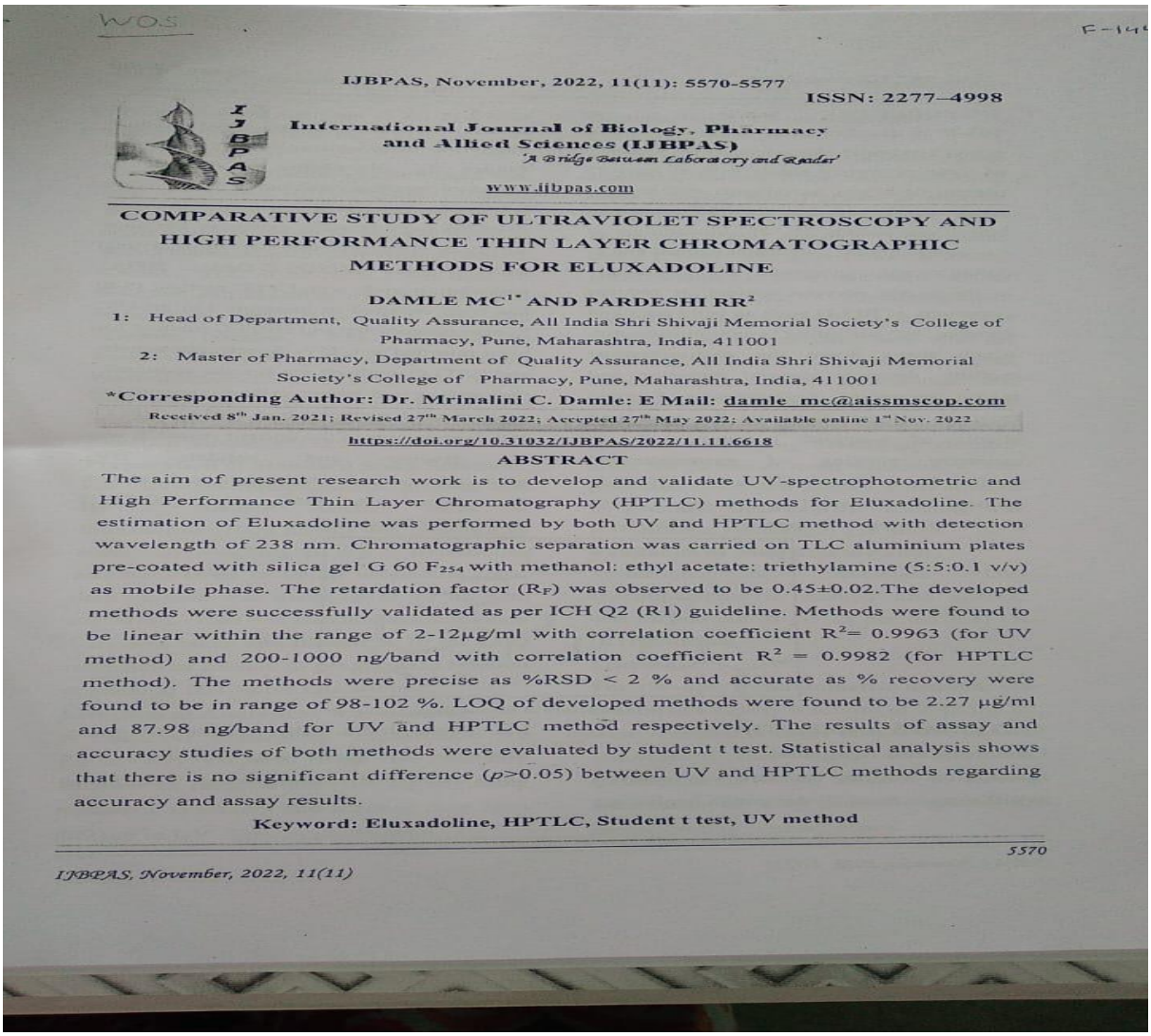
11. Comparative study of Ultraviolet spectroscopy and High Performance Thin Layer Chromatographic method for eluxadoline



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COMPARATIVE STUDY OF ULTRAVIOLET SPECTROSCOPY AND HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHIC METHODS FOR ELUXADOLINE

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https://doi.org/10.31032/IJBPAS/2022/11.11.6618

ABSTRACT

The aim of present research work is to develop and validate UV-spectrophotometric and High Performance Thin Layer Chromatography (HPTLC) methods for Eluxadoline. The estimation of Eluxadoline was performed by both UV and HPTLC method with detection wavelength of 238 nm. Chromatographic separation was carried on TLC aluminium plates pre-coated with silica gel G 60 F_{254} with methanol: ethyl acetate: triethylamine (5:5:0.1 v/v) as mobile phase. The retardation factor (R_F) was observed to be 0.45±0.02.The developed methods were successfully validated as per ICH Q2 (R1) guideline. Methods were found to be linear within the range of 2-12µg/ml with correlation coefficient R^2= 0.9963 (for UV method) and 200-1000 ng/band with correlation coefficient R^2 = 0.9982 (for HPTLC method). The methods were precise as %RSD < 2 % and accurate as % recovery were found to be in range of 98-102 %. LOQ of developed methods were found to be 2.27 µg/ml and 87.98 ng/band for UV and HPTLC method respectively. The results of assay and accuracy studies of both methods were evaluated by student t test. Statistical analysis shows that there is no significant difference (p>0.05) between UV and HPTLC methods regarding accuracy and assay results.

Keyword: Eluxadoline, HPTLC, Student t test, UV method

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12. Kinetic study of hydrolytic degradation of Rivaroxaban by HPTLC

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Kinetic Study of Hydrolytic degradation of Rivaroxaban by HPTLC (AbstractView.aspx?PID=2022-15-12-21) (https://scholar.google.co.in/scholar?q=Kinetic Study of Hydrolytic degradation of Rivaroxaban by HPTLC)

Author(s): M. C. Damle (search.aspx?key=M. C. Damle), A. D. Chandan (search.aspx?key=A. D. Chandan)

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DOI: 10.52711/0974-360X.2022.00927 (https://doi.org/10.52711/0974-360X.2022.00927) (https://scholar.google.co.in/scholar?q=10.52711/0974-360X.2022.00927)

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13. Development And Validation Of Stability Indicating HPTLC Method For Determination Of Iguratimod In Bulk And Pharmaceutical Dosage Form

International Journal of Pharmacy and Pharmaceutical Sciences

Print ISSN: 2656-0097 | Online ISSN: 0975-1491

Int J Pharm Pharm Sci, Vol 14, Issue 11, 31-36 Original Article

DEVELOPMENT AND VALIDATION OF STABILITY INDICATING HPTLC METHOD FOR DETERMINATION OF IGURATIMOD IN BULK AND PHARMACEUTICAL DOSAGE FORM

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Received: 30 Jun 2022, Revised and Accepted: 14 Sep 2022

ABSTRACT

Objective: The objective of the work was to develop and validate stability indicating HPTLC method for the estimation of Iguratimod.

Methods: The method employed HPTLC aluminium pre-covered silica gel 60 GF_{254} plates (10 cm × 10 cm with 250 µm layer thickness) as stationary phase while the solvent system was n-Hexane: Ethyl Acetate (5:5 v/v) with densitometric scanning at 256 nm. Sample was applied as a band of 8 mm width using Camag 100 µl sample syringe (Hamilton, Switzerland) using a linomat 5 applicator (Camag, Switzerland). Migration distance was 80 mm. Further the sample was subjected for stress conditions under acid and base hydrolysis, oxidation, thermal, neutral and photolytic conditions. Method validation done according to ICH Q2 (R1) guidelines.

Results: Retention factor (Rf) of the drug was 0.41±0.02. The linearity of the method was found to be within the concentration range of 200-1200 ng/band with R^2= 0.983. Limit of detection and limit of quantification were found to be 34.69 and 105.12 ng/band respectively. The % mean recovery was found to be 100.38±0.83. Stress results showed that there is degradation in acid and base conditions but two degradant peaks were observed only under alkaline stress condition

Conclusion: The developed method found to be accurate, simple and precise. Method is successfully employed for quantification of the drug under various stress conditions.

Keywords: High-performance thin layer chromatography, Iguratimod, Method validation, Stress degradation

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14. A Rational Approach to Anticancer Drug Design; 2D, 3D QSAR, Molecular Docking and Prediction of ADME Properties Using In Silico Studies of Thymidine Phosphorylase Inhibitors

A Rational Approach to Anticancer Drug Design: 2D and 3D- QSAR, Molecular Docking and Prediction of ADME Properties using Silico Studies of Thymidine Phosphorylase Inhibitors

Authors: Raut, Vaibhav V.; Bhandari, Shashikant V.; Patil, Shital M.; Sarkate, Aniket P.
Source: Letters in Drug Design & Discovery, Volume 20, Number 2, 2023, pp. 153-166(14)
Publisher: Bentham Science Publishers
DOI: https://doi.org/10.2174/1570180819666220215115633

Abstract | References | Citations | Supplementary Data

Background: Cancer is the most prevalent disease seen nowadays. Thymidine phosphorylase (TP) is an angiogenic enzyme that is overexpressed in many solid tumors. Over the years, Thymidine phosphorylase has emerged as a novel target for anticancer drug development as an inhibitor.

Objective: To design novel oxadiazole-isatin pharmacophore-containing molecules and explore their structural requirements related to the anticancer activity.

Methods: Pharmacophore optimisation was carried out for oxadiazole-isatin hybrid molecules using molecular modeling studies (2D and 3D QSAR). Further, the new chemical entities were designed using the combilib tool of V life software. To have a better understanding of the binding interactions, the newly designed molecules were docked. To achieve a drug-like pharmacokinetic profile, molecules were also tested for ADME prediction.

Results: Two-Dimensional Quantitative Structure-Activity Relationship (2D-QSAR) model was generated using the multiple regression method with $r^2 = 0.84$ and $q^2 = 0.76$. Three-Dimensional Quantitative Structure-Activity Relationship (3D-QSAR) model was obtained by simulated annealing k nearest near (SA kNN) method with $q^2 = 0.8099$. Molecular docking studies showed promising results. Compound 5 was found to be with the best dock score and the best fit to the active site pocket of the thymidylate phosphorylase enzyme. The compounds have notable absorption, distribution, metabolism, and excretion (ADME) properties that can be predicted to assure a drug-like pharmacokinetic profile.

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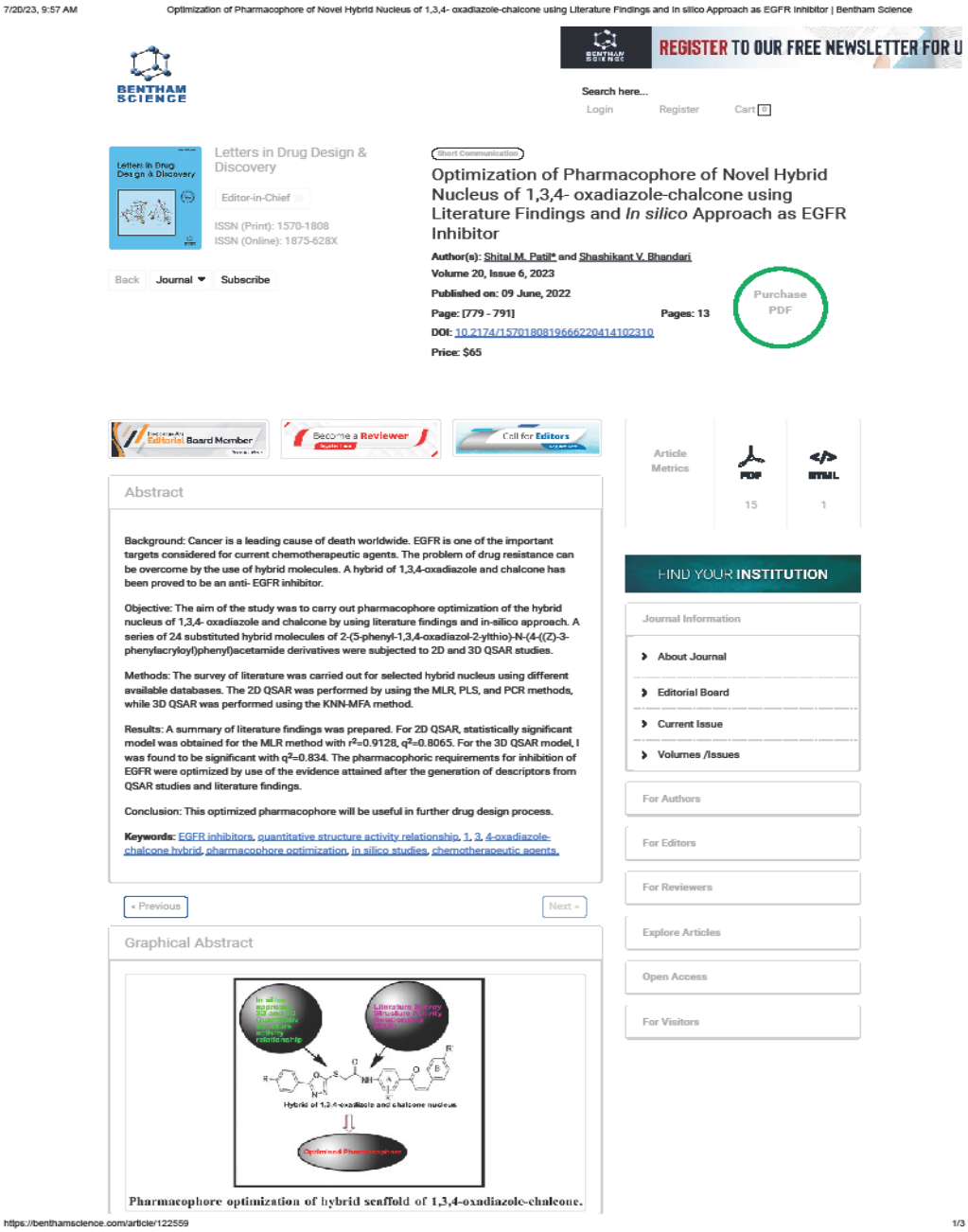
15. Optimization of Pharmacophore of novel hybrid nucleus of 1,3,4-oxadiazole-chalcone using literature findings and in-silico approach as EGFR Inhibitor



7/20/23, 9:57 AM Optimization of Pharmacophore of Novel Hybrid Nucleus of 1,3,4- oxadiazole-chalcone using Literature Findings and In silico Approach as EGFR Inhibitor | Bentham Science

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Short Communication

Optimization of Pharmacophore of Novel Hybrid Nucleus of 1,3,4- oxadiazole-chalcone using Literature Findings and *In silico* Approach as EGFR Inhibitor

Author(s): Shital M. Patil* and Shashikant V. Bhandari
Volume 20, Issue 6, 2023
Published on: 09 June, 2022
Page: [779 - 791] Pages: 13
DOI: 10.2174/1570180819666220414102310
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Abstract

Background: Cancer is a leading cause of death worldwide. EGFR is one of the important targets considered for current chemotherapeutic agents. The problem of drug resistance can be overcome by the use of hybrid molecules. A hybrid of 1,3,4-oxadiazole and chalcone has been proved to be an anti- EGFR inhibitor.

Objective: The aim of the study was to carry out pharmacophore optimization of the hybrid nucleus of 1,3,4- oxadiazole and chalcone by using literature findings and in-silico approach. A series of 24 substituted hybrid molecules of 2-(5-phenyl-1,3,4-oxadiazol-2-ylthio)-N-(4-((Z)-3-phenylacryloyl)phenyl)acetamide derivatives were subjected to 2D and 3D QSAR studies.

Methods: The survey of literature was carried out for selected hybrid nucleus using different available databases. The 2D QSAR was performed by using the MLR, PLS, and PCR methods, while 3D QSAR was performed using the KNN-MFA method.

Results: A summary of literature findings was prepared. For 2D QSAR, statistically significant model was obtained for the MLR method with r^2=0.9128, q^2=0.8065. For the 3D QSAR model, I was found to be significant with q^2=0.834. The pharmacophoric requirements for inhibition of EGFR were optimized by use of the evidence attained after the generation of descriptors from QSAR studies and literature findings.

Conclusion: This optimized pharmacophore will be useful in further drug design process.

Keywords: EGFR inhibitors, quantitative structure activity relationship, 1, 3, 4-oxadiazole-chalcone hybrid, pharmacophore optimization, in silico studies, chemotherapeutic agents.

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Graphical Abstract

Pharmacophore optimization of hybrid scaffold of 1,3,4-oxadiazole-chalcone.

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16. Convenient Microwave Assisted Chlorosulfonic Acid-Catalyzed Synthesis of some Quinazolinones from 2-Phenylindole

Published: 13 April 2022

Convenient Microwave-Assisted Chlorosulfonic Acid-Catalyzed Synthesis of Some Quinazolinones from 2-Phenylindole

A. P. Sarkate, P. P. Sarode, S. V. Bhandari, K. S. Karnik, I. S. Narula, B. D. Kale, V. S. Jambhorkar & A. P. Rajhans

Russian Journal of Organic Chemistry **58**, 428–432 (2022)

Abstract

A new convenient method has been developed for the synthesis of quinazolinones from 2-phenyl-1*H*-indole and substituted amines under catalysis by chlorosulfonic acid. The target quinazolinones were synthesized through a coupling reaction of 2-phenyl-1*H*-indole and different amines using chlorosulfonic acid and hydrogen peroxide in DMSO on heating at 100°C, as well as under microwave irradiation at 80°C. The microwave-assisted synthesis provided excellent yields in 8 min compared to 4–5 h under conventional heating. The developed method is

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17. Design, Synthesis, Molecular Docking and Antioxidant Evaluation of Benzimidazole-1,3,4 oxadiazole Derivatives

ScienceDirect

Journal of Molecular Structure
Volume 1276, 15 March 2023, 134747

Design, Synthesis, Molecular Docking and Antioxidant Evaluation of Benzimidazole-1,3,4 oxadiazole Derivatives

Shashikant V. Bhandari [a], Om G. Nagras [a], Pranali V. Kuthe [a], Aniket P. Sarkate [b], Kaustubh S. Waghamare [a], Dattatraya N. Pansare [c], Somdatta Y. Chaudhari [d], Shivraj N. Mawale [a], Mrunal C. Bahvate [a]

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https://doi.org/10.1016/j.molstruc.2022.134747
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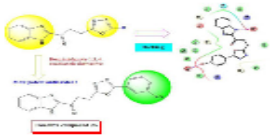
Abstract

In this research, we synthesised novel benzimidazole-1,3,4 oxadiazole derivatives and studied their antioxidant properties using the DPPH Radical Scavenging Assay. A significant class of substances with a broad range of biological activities is the 1,3,4-benzimidazole family. Furthermore, enabling for various biological activities are the five-membered heterocyclic moieties. Thus, a number of benzimidazole derivatives have been created, there in vitro antioxidant activity has been evaluated, and they have been characterized by FTIR and ^{1}H NMR spectral studies. Compounds **1A, 2A** and **3A** have the highest G-score i.e., - 7.575 kcal/mol, -6.932 kcal/mol, -6.911 kcal/mol, as compared to standards propyl gallate and Ascorbic acid, which had glide scores of -4.757 kcal/mol and -4.50 kcal/mol respectively. The benzimidazole-1,3,4 oxadiazole containing compounds that were created demonstrated impressive antioxidant activity. When compared to the reference standard, ascorbic acid, (IC_{50}-11.51±0.31 µg/ml) Compound 2A demonstrated the strongest antioxidant activity with an IC_{50} value (53.00±1.31 µg/ml) respectively.

Graphical Abstract



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Introduction

Antioxidants are one of the body's many defences against oxidative/nitrosative damage [1]. Being a highly reactive atom, oxygen may mix with other elements to create "free radicals," which are potentially dangerous molecules. Free radicals, which may damage nucleic acids, proteins, carbohydrates, and lipids, are molecules or molecular fragments having one or more unpaired electrons in atomic or molecular orbitals [2]. Early ageing, carcinogenesis, atherosclerosis, cardiovascular disease, moderate cognitive impairment, diabetes mellitus, ischemia, Alzheimer's disease, Parkinson's disease, liver injury, inflammation, skin damages, and arthritis are just a few of the disorders that can result from this [3], [4], [5], [6], [7], [8], [9], [10], [11]. Regular bodily processes result in the production of free radicals and other reactive oxygen species (ROS).

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18. Exploration of novel Pyridine-Pyrimidine Hybrid Phosphonate Derivatives as Aurora Kinase Inhibitors

Bioorganic & Medicinal Chemistry Letters
Volume 67, 1 July 2022, 128747

Explorations of novel pyridine-pyrimidine hybrid phosphonate derivatives as aurora kinase inhibitors

Shailee V. Tiwari [a], Aniket P. Sarkate [b], Deepak K. Lokwani [c], Dattatraya N. Pansare [d], Surendra G. Gattani [e], Sameer S. Shaikh [a], Shirish P. Jain [c], Shashikant V. Bhandari [f]

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Highlights

- A series of novel pyridine-pyrimidine hybrid phosphonate derivatives were synthesized and characterized by spectral methods.
- *In vitro* Enzyme assay and molecular docking study helped to predict the target enzyme.
- Compounds 4f, 4j and 4o had shown good potential to inhibit Aurora kinase.
- Compounds 4f, 4j and 4o exhibited relatively no cytotoxicity to normal LO2 cells.

Abstract

For developing novel therapeutic agents with good anticancer activities, a series of novel pyridine-pyrimidine hybrid phosphonate derivatives 4(a–q) were synthesized by the Kabachnik-Fields method using CAN as catalyst. The compound 4o exhibited the most potent anticancer activity with an IC_{50} value of 13.62 μM, 17.49 μM, 5.81 μM, 1.59 μM and 2.11 μM against selected cancer cell lines A549, Hep-G2, HeLa, MCF-7, and HL-60, respectively. Compound 4o displayed seven times more selectivity towards Hep-G2 cancer cell lines compared to the human normal hepatocyte cell line LO2 (IC_{50} value 95.33 μM). Structure-Activity Relationship (SAR) studies were conducted on the variation in the aromatic ring (five-membered heterocyclic ring, six-membered heterocyclic ring) and the variation of substituents on the phenyl ring (electron donating groups, electron withdrawing groups). Furthermore, the mechanism of anticancer activity was clarified by further explorations in bioactivity by using in vitro aurora kinase inhibitory activity and molecular docking studies. The results showed that the compound **4o** at IC_{50} concentration demonstrated distinctive morphological changes such as cell detachment, cell wall deformation, cell shrinkage and reduced number of viable cells in cancer cell lines. Compound 4o induced early apoptosis and late apoptosis of 27.7% and 6.1% respectively.

Graphical abstract

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19. In Search of HIV Entry Inhibitors Using Molecular Docking, ADME, and Toxicity Studies of Some Thiazolidinone-Pyrazine Derivatives Against CXCR4 Co-receptor

FULL TEXT LINKS
Bentham Science Full-Text Article

Curr HIV Res. 2022 Aug 12;20(2):152-162. doi: 10.2174/1570162X20666220214123331.

In Search of HIV Entry Inhibitors Using Molecular Docking, ADME, and Toxicity Studies of Some Thiazolidinone–Pyrazine Derivatives Against CXCR4 Co–receptor

Shital M Patil [1], Kalyani D Asgaonkar [1], Bhairavi Bakhle [1], Kshitija Abhang [1], Ayush Khater [1], Muskan Singh [1], Trupti S Chitre [1]

Affiliations
PMID: 35156573 DOI: 10.2174/1570162X20666220214123331

Abstract

Background: Entry inhibitors prevent the binding of human immunodeficiency virus protein to the chemokine receptor CXCR4 and are used along with conventional anti-HIV therapy. They aid in restoring immunity and can prevent the development of HIV-TB co-infection.

Aims: In the present study, various thiazolidinone-pyrazine derivatives earlier studied for NNRT inhibition activity were gauged for their entry inhibitor potential.

Objective: The objective of the study is to perform molecular docking, ADME, toxicity studies of some thiazolidinone-pyrazine derivatives as entry inhibitors targeting CXCR4 co-receptors.

Methods: In-silico docking studies were performed using AutoDock Vina software and compounds were further studied for ADME and toxicity using SwissADME and pkCSM software, respectively.

Results: Taking into consideration the docking results, pharmacokinetic behaviour and toxicity profile, four molecules (compounds 1, 9, 11, and 16) have shown potential as entry inhibitors.

Conclusion: These compounds have shown potential as both NNRTI and entry inhibitors and hence can be used in management of immune compromised diseases like TB-HIV coinfection.

Keywords: Anti-HIV; AutoDock Vina; CXCR4; SwissADME; docking; entry inhibitors; pkCSM; thiazolidinone-pyrazine.

Related information

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20. Progress in Biomaterials, Tailoring the properties of chitosan by grafting with 2-mercaptobenzoic acid to improve mucoadhesion: in silico studies, synthesis and characterization

Prog Biomater. 2022 Dec;11(4):397-408. doi: 10.1007/s40204-022-00201-x. Epub 2022 Oct 7.

Tailoring the properties of chitosan by grafting with 2-mercaptobenzoic acid to improve mucoadhesion: in silico studies, synthesis and characterization

Tejinder K Marwaha [1], Ashwini Madgulkar [2], Mangesh Bhalekar [2], Kalyani Asgaonkar [3], Rajesh Gachche [4], Pallavi Shewale [4]

Affiliations

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Free PMC article

Abstract

Mucoadhesive polymers improve oral bioavailability of drugs by prolonging the duration of adhesion of drugs with mucosa. Various methods could be employed to address the problems of mucoadhesive polymers like weak adhesion forces. Chemical modification of polymers, such as the addition of a thiol group or thiolation, is another way for improving the polymers' mucoadhesive properties that is studied in present research work. A novel thiomer of chitosan was prepared by attaching 2-mercaptobenzoic acid, a hydrophobic ligand onto it. The docking of thiomer and chitosan with mucin structure showed higher binding energy for former. The prepared thiomer was subjected to X-ray diffraction and DSC which established reduction in crystallinity and formation of a new compound through changes in glass transition, melting point and change in diffraction pattern. The NMR studies established conjugation of 2-mercapto benzoic acid to chitosan. The increased mucoadhesion in thiomer behaviour (2-3 fold) was confirmed through mucus glycoprotein assay as well as through texture analysis. The permeation enhancing the property of thiomer was established by demonstrating the permeation of phenol red across thiomer treated intestinal membrane. An in vitro cell toxicity assay was done to establish toxicity of chitosan and thiolated chitosan. Finally, the reduced water uptake of thiomer over chitosan proved that the increase in mucoadhesion is not contributed by swelling. Thus, a thiomer with improved mucoadhesion and enhanced permeation properties was prepared and characterized. Hence, all these properties render the newly synthesized polymer a better alternative to chitosan as an excipient for mucoadhesive drug delivery systems.

Keywords: Chitosan; Docking; Mucin; Mucoadhesion; Thiomer.

Figures

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21. Diverse Synthetic Approaches and Biological Activities of Lucrative Pyrimidine-Triazine Hybrid Derivatives: A Review

Review Curr Org Synth. 2023;20(7):734-757. doi: 10.2174/1570179419666220920093734.

Diverse Synthetic Approaches and Biological Activities of Lucrative Pyrimidine- Triazine Hybrid Derivatives: A Review

Kalyani Asgaonkar [1], Shital Patil [1], Kunal Pradhan [1], Sushruti Tanksali [1], Jidnyasa Jain [1]

Affiliations

PMID: 36125826 DOI: 10.2174/1570179419666220920093734

Abstract

Pyrimidine and Triazine are rewarding pharmacophores as seen from their presence in different naturally and synthetically occurring drug molecules. Hybridization is a functional concept used in drug design. This updated review encompasses various synthetic procedures that have been used to prepare molecular hybrids of Pyrimidine and Triazine, detailed structureactivity relationship, and molecular docking studies with patents granted. The most potent and promising hybrid compounds have also been identified. The study has revealed the synthetic feasibility of Pyrimidine-Triazine hybrids along with a plethora of potent biological activities such as anticonvulsant, antiviral, anti-inflammatory, analgesics, etc. This paper highlights the importance of coupling Pyrimidine and Triazine to provide better insight for medicinal chemists to further explore the hybrid for a significant therapeutic effect.

Keywords: Molecular hybridization; biological activity; pharmacophores; pyrimidine; synthesis; triazine.

Related information

PubChem Compound (MeSH Keyword)

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22. Development of optimized pyrimido-thiazole scaffold derivatives as anticancer and multitargeting tyrosine kinase inhibitors using computational studies

Journal of the Indian Chemical Society 100 (2023) 100803

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Development of optimized pyrimido-thiazole scaffold derivatives as anticancer and multitargeting tyrosine kinase inhibitors using computational studies

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ARTICLE INFO

Keywords:
Tyrosine kinase inhibitors
Anti-cancer
Combilib
ADMET
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Pyrimidine
Thiazoles

ABSTRACT

Cancer is one of the frontier causes of leading death ratesglobally and one of the most researched domains. Despite many drugs available in the market currently, their effectiveness towards resistance, randomly mutating cancer targets, and side effects initiate the necessity of developing target selective and effective anti-cancer drugs.This study aimed to develop a congeneric series of fused pyrimidine and thiazole-containing hybrid series and evaluate its anticancer potential using in-silico tools. Molecular modeling strategies were used to develop various derivatives of fused thiazole-pyrimidines as anticancer agents for target-based drug discovery. Strategically, based on Structural Activity Relationship (SAR), of the synthesized or studied compounds, a combinatorial library was generated using the lead grow tool to develop a possible combination of various derivatives. Using Swiss ADME and Osiris; the ADMETproperties were predicted and screened molecules were docked using Auto-dock vina and Swiss Dockto obtain possible interactions with 5 listed targets of Tyrosine Kinase Inhibitors (TKI's) namely BCR-ABL kinase (PDB- 2GQG), c-ABL Kinase (PDB-3PYY), EGFR(PDB-1M17), VEGFR(PDB- 4ASD), and BRAF inhibitors (PDB- 2FB8). SAR of the pyrimido-thiazole molecules was derived from the literature survey and substitutions that enhance the anticancer activity were incorporated into the Combilib to generate a library of 221 compounds. This library of compounds was subjected to a Lipinski Filter. About 45 compounds were screened and tested for their drug-likeliness parameters. The 24 compounds that qualified with good absorption, drug-likeliness, and ADME were tested for their toxicity for developing relatively safe drugs with low side effects. These molecules were docked intofivedifferent PDB's and their binding affinity scores along with prominent interactions were noted. Compound 33 has shown comparable binding affinity and key interactions with all the five PDB's and thus can be used as a lead for further investigations. These studies have helped to optimize the relationship between fused pyrimidine and thiazoles as anticancer Tyrosine Kinase Inhibitors.

1. Introduction

Being one of the leading causes of death, cancer is a complex, adaptable, and heterogenous product of genetic modifications that interrupt cells' normal function and behavior [1,2]. Despite significant advances in the treatment, mutations, severe side effects and resistance to drugs are some of the challenges before the researchers [3]. According to WHO, cancer accounts for about 10 million deaths in 2020 of which breast cancer, colon, rectal, prostate, skin and stomach cancer were found to have the largest effect [4].Targeted cancer therapies are a solution to cancers of wide genera which refers to designing new drugs that could interfere with a specific target protein or enzyme [5,6].

Tyrosine kinases (TKI's)are one of the rapidly explored classes of molecular targeted therapies involving various types of cancers out of which some of the most important classes are the Abelson Murein Leukemia Virus (ABL), proto-oncogene tyrosine protein kinase sarcoma (SCR), platelet-derived growth factor, vascular endothelial growth factor receptor (VEGFR) and epidermal growth factor receptor (EGFR) families [7,8].

The current curve of drug discovery shows that ABL- Kinase, Abl-c kinase, EGFR, VEGFR and Serine-Threonine Protein Kinase B-Raf (BRAF)are some of the key oncogenic drug targets. The prominent targets along with the standard drugs of the class are listed below (Fig. 1).

ABL-a kinases are to date one of the most successful targets explored for the treatment of chronic myeloid cancers to solid tumors like breast

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23. Malnutrition: A detailed examination of government programs and nutritional reports

Science, Technology and Development ISSN : 0950-0707

Malnutrition: a detailed examination of government programs and nutritional reports

Aparna A. Lakare, Dr. Sachin V. Tembhurne, Preetam P. Palkar, Nikhil A. Potdar ,Onkar A. Dindore*

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Sangamwadi, Shivajinagar, Pune, Maharashtra -411001.

Abstract:According to the World Health Organization (WHO), malnutrition is defined as deficiencies, excesses, or imbalances in a person's energy and/or nutrient consumption. It is commonly understood that maternal, baby, and child nutrition all play important roles in a kid's normal growth and development, as well as his or her eventual socioeconomic level. According to reports from the National Health and Family Survey, the United Nations International Children's Emergency Fund, and the World Health Organization, malnutrition rates among teenage girls, pregnant and lactating mothers, and children are disturbingly high in India, according to reports from the National Health and Family Survey, the United Nations International Children's Emergency Fund, and the World Health Organization. The nutritional condition of mothers, breastfeeding behaviour, women's education, and cleanliness are all factors that contribute to malnutrition in the country.Children are affected in a variety of ways, including stunting, childhood sickness, and growth retardation. Despite the fact that India has theoretically decreased malnutrition over the previous decade and has various government programmes in place, there is still a need for efficient application of information gathered from research to combat undernutrition, which impedes the country's socio-economic growth. These findings might be valuable for other developing countries attempting to reduce child malnutrition in their own countries.

Keywords: Malnutrition, Nutrient intake, Government Programs, Nutrition, India, Children, Public health

I. INTRODUCTION

Malnutrition in children is a public health problem in many developing countries. Mainly because malnourished children require more intense care from their parents and are less physically and intellectually productive as adults. Being malnourished is also a violation of a child's human rights. Lessons from the causes, and from government initiatives to manage and reduce child malnutrition in emerging economies, such as India, should be useful for other such countries wishing to diminish child malnutrition at home and to improve public intervention strategies.

In the South Asian region, India is one of the fastest growing countries economically, educationally, and technologically. Despite economic progress, India has failed to combat malnutrition that adversely affects the country's socio-economic progress. More than one-third of the world's malnourished children are in India. Half of the world's malnourished children reside in 3 countries: Bangladesh, India, and Pakistan. [1]

The prevalence of malnourished children in India is nearly double that in Sub-Saharan Africa and affects the mortality rate, productivity, and economic growth. Each year, nearly half of children in India are malnourished and almost a million children die before reaching one month of age. In India, 43% of children under 5 years are underweight and 48% are stunted, due to severe malnutrition (3 out of every 10 children are stunted) [2].

Based on comparison of data from the Fourth National Family Health Survey (NFHS-4) and the Third National Family Health Survey (NFHS-3) in the National Nutrition Strategy report of National Institution for Transforming India (NITI), Aayog reports a decline of underweight prevalence in children under 5 years in all states and Union Territories (except Delhi), although absolute levels remain high [3]. According to the research, around 1.5 million women and children died in 2010 from malnutrition-related causes [4]. According to the Partnerships and Opportunities to Strengthen and Harmonize Actions for Nutrition in India (POSHAN), low birth weight, malnutrition, and iron deficiency kill 309,300 new-borns on their first day, 876,200 babies in their first month, and 1.6 million babies before their fifth birthday and). Around 22% of new-borns are underweight, 42% of toddlers (0–5 years) are underweight, and 79% of children (6–35 months) are iron deficient. [5]

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24. Malnutrition related diabetes mellitus (MRDM): current status

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Malnutrition Modulated Diabetes mellitus: current status

AGEING/AGING | BIOCHEMICAL PHARMACOLOGY | CLINICAL PHARMACOLOGY | ENDOCRINE PHARMACOLOGY | METABOLOMICS | OBESITY/METABOLIC SYNDROME

Preetam Palkar, Aparna Lakare, Nikhil Potdar, Onkar Dindore, Dr. Sachin V. Tembhurne

Abstract

Malnutrition related diabetes mellitus (MRDM) is rare type of diabetes which is associated with long term malnutrition .It is classified in 2 subgroups by the American Diabetes Association as Fibrocalcific or fibrocalculous pancreatic diabetes (FCPD) and Protein-deficient pancreatic diabetes (PDPD)/protein-deficient diabetes mellitus (PDDM). This review summarises about the diagnosis criteria , prevalence and pathophysiology of FCPD and PDDM. Various clinical studies have been carried out to understand the impact of malnutrition on the glucose homeostasis. Different animal models have been developed to study the pathophysiological aspects of MRDM. This review also focuses on the management of diabetes in terms of Medical nutrition treatment (MNT) , pain management, exocrine management, diabetes management and ayurvedic management . Keywords:- Malnutrition related Diabetes mellitus (MRDM), Fibrocalcific or fibrocalculous pancreatic diabetes (FCPD), protein-deficient diabetes mellitus (PDDM), diagnosis criteria of MRDM, management of MRDM.

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25. Pharmacotechnical Evaluation by SeDeM Expert System to Develop Orodispersible Tablets

AAPS PharmSciTech. 2022 May 9;23(5):133. doi: 10.1208/s12249-022-02285-x.

Pharmacotechnical Evaluation by SeDeM Expert System to Develop Orodispersible Tablets

Monica R P Rao [1], Sharwari Sapate [2], Ashwini Sonawane [2]

Affiliations

PMID: 35534652 DOI: 10.1208/s12249-022-02285-x

Abstract

Sediment delivery model (SeDeM) system is innovative tool to correlate micromeritic properties of powders with compressibility. It involves computation of indices which facilitate direct compressibility of solids and enable corrective measures through particle engineering. Study had multiple objectives, viz, (i) to enhance solubility of BCS class II, nevirapine using solid dispersions; (ii) SeDeM analyses of excipients and solid dispersions to analyze direct compressibility; and (iii) prepare orodispersible tablets (ODT). Solid dispersions were prepared by solvent evaporation. Superdisintegrants and solid dispersions were analyzed for primary indices of dimension, compressibility, flowability, stability, and disgregability derived from micromeritic properties. Radar diagrams were constructed to provide visual clues to deficient properties for direct compressibility. ODTs were prepared using excipients which passed criteria for direct compressibility and evaluated for tablet properties. Solid dispersions with Eudragit S100 revealed 6 to 10 fold increase in solubility in various dissolution media including biorelevant media in comparison with plain drug. Solubility was found to be pH dependent. SeDeM analyses facilitated identification of superdisintegrants and excipients with unfavorable compressibility. Radar diagrams provided a clear pictorial evidence of lacunae in powder properties. Based on SeDeM results, tablets were formulated by direct compression using crosspovidone, croscarmellose sodium, and mannitol. All batches showed 40% release in first minute in simulated salivary fluid.

Keywords: SeDeM; antiretrovirals; micromeritics; nevirapine; orodispersible; superdisintegrants.

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26. Artemether and Lumefantrine Loaded Self-nanoemulsifying drug Delivery System for Enhancement of Bioavailability

Original Article

Artemether and Lumefantrine Loaded Self-nanoemulsifying drug Delivery System for Enhancement of Bioavailability

Rao Monica Raghavendra Prasad*, Pardeshi Amol A

Department of Pharmaceutics, AISSMS College of Pharmacy, Pune, Maharashtra, INDIA.

ABSTRACT

Introduction: This study involves development and evaluation of bioavailability of oral self-nanoemulsifying drug delivery system of BCS class II and IV drugs, Artemether and Lumefantrine (AL), respectively. This fixed combination is used for treatment of drug resistant malaria. Self nanoemulsifying drug delivery system (SNEDDS) was developed due to lipophilicity of both drugs. Pseudo ternary phase diagrams were derived based on solubility of drugs in oils and surfactants for identifying self-nanoemulsifying region. **Materials and Methods:** Propylene glycol dicaprylate caprate, Cremophor EL, Tween 80 (1:1) and Transcutol HP were selected as oil and surfactants. Pseudo ternary plots were constructed based on solubility of AL in oils and surfactants to identify composition of formulations. They were evaluated for self-emulsification time, percent transmittance, cloud point, thermodynamic stability and *in vitro* release. Globule size analysis was done using Malvern Zeta sizer. Pharmacokinetic parameters like area under curve (AUC), C_{max} and T_{max} were evaluated using Wistar rats. **Results and Discussion:** All formulations displayed globule size between 27-32 nm while percent transmittance was between 90-99%. Cloud point above 37°C was indicative of integrity of self-nanoemulsifying properties *in vivo*. Cumulative percent release in 1 hr in 0.1 N HCl was in range of 75 to 100 %. A two-fold enhancement in bioavailability was observed with SNEDDS as compared to plain drugs. AUC_{0-5h} were increased by 2 times for artemether and 1.71 times for lumefantrine compared to plain drug suspensions. This proved the prospective use of SNEDDS to improve dissolution and oral bioavailability for poorly water-soluble antimalarial drugs.

Key words: Artemether, Lumefantrine, Low oral bioavailability, Self-nanoemulsifying drug delivery system, *In vitro* dissolution.

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www.ijper.org

INTRODUCTION

Nearly 30% of the world's population is affected by parasitic infections especially third world countries.[1] Amongst various parasitic infections, malaria is the most life-threatening disease. In 2019, more than 229 million people were affected by malaria and 409,000 deaths. An estimated 94% of deaths in 2019 were in the African Region.[2] Existing chemotherapy for malaria includes limited number of clinically effective antimalarial agents. Although treatment for malaria has been successful, the clinical utility of many antimalarial agents is hampered due to poor oral bioavailability and emergence of resistant parasite strains. Paradoxically, since the infection is majorly prevalent in third world countries the economic benefits to pharmaceutical companies is insignificant to drive research for the development of new anti-malarial agents. This scenario has enforced combined use of current antimalarial agents to reduce drug resistance of parasite strain. Adopting smart formulation technologies to maximize or optimize the therapeutic potential of combination drugs is hence the need of the hour.[3]

Combination of Artemether (ART) and Lumefantrine (LUM) was first registered in 1992 in Peoples Republic of China

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18.	A survey based approach to determine the momentous role played by the community pharmacy during Covid 19 pandemic	Kalyani D Asgaonkar Shital M Patil Kshitija Abhang Ayush Khater	.Journal of Emerging Technologies and Innovative Research,2021,8(5), c338	2021	View Article	55
19.	Effect of diabetes mellitus on micronutrient levels and their maintenance with help of plant based naturally occurring foods	Dr. Sachin S. Tembhurne,Anirudha A. Chaskar, Anup S. Deshmukh, Gautam S. Gundecha , Kamlesh B	**PENSEE.** VOLUME 51. 1206, 2021	2021	View Article	56
20.	Oral contraceptives – its adverse effects and other health risks	Dr.Sachin V. Tembhurne, Anup S. Deshmukh, Anirudha A. Chaskar , Gautam S. Gundecha , Kamlesh B. Patil	**PENSEE.** VOLUME 51. 1206, 2021	2021	View Article	57
21.	Folic acid and micronutrients supplements from natural origin and food components: a systematic review	Gautam S. Gundecha,Dr. Sachin V Tembhurne , Anirudha A. Chaskar , Anup S. Deshmukh , Kamlesh B. Patil	**PENSEE.** VOLUME 51 327,2021	2021	View Article	58

Sr. No.	Title of the Paper	Name of the Author	Title of the Journal	Year of publication	Go to article	Page No.
22.	Development and Evaluation of Nutritious Supplementary Food Product in Phenyl Hydrazine Induced Anaemia in Wistar Rats.	Dipali Hanamghar, Shivani Salokhe, Sachin Tembhurne, Swati Kolhe	Journal of Drug Delivery & Therapeutics. 2021; 11(1):68-7	2021	View Article	59
23.	Natural Blue Pigment Color Gel for Foods, beverages and Pharmaceuticals	Amruta Avalaskar*, Shivam Jaiswal, Vipul Fegade, Vinod Gaikwad	Journal of Emerging Technologies and Innovative Research January 2021, Volume 8, Issue 1 2021	2021	View Article	60
24.	Self-Assembling Dioscorea bulbifera loaded mixed micelles: Formulation optimization, in-vitro cytotoxicity and in-vivo pharmacokinetics	Sagar Trivedia,* Shubhangi Thool b, Kamlesh Wadher c, Mangesh Bhalekar b, Priyanka Bire	Journal of Drug Delivery Science and Technology, Volume 65, October 2021, 102722	2021	View Article	61

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1. **Brain Targeted Delivery of Rizatriptan using Glutathione Conjugated Liposomes through Transmucosal Nasal Route**

Brain Targeted Delivery of Rizatriptan using Glutathione Conjugated Liposomes through Transmucosal Nasal Route.

- **Source:** International Journal of Pharmaceutical Investigation . Jul-Sep2021, Vol. 10 Issue 3, p344-350. 7p.
- **Author(s):** Padalkar, Rahul Ravindra; Madgulkar, Ashwini Raghavendra; Bhalekar, Mangesh Ramesh
- **Abstract:** Objectives: The objective of this work was to enhance the bioavailability of rizatriptan for brain targeted drug delivery through glutathione conjugated liposomes. Methods: Cholesterol glutathione conjugate was synthesized used as a rigidizing agent for liposomes. Liposomes with free cholesterol were also prepared for comparison. 9 batches each were prepared for glutathione conjugated liposomes and non-conjugated liposomes. All formulations were administered to rats. Results: For optimum non-conjugated liposomes batch particle size, drug release and entrapment efficiency were found to be 181nm, 90.2% and 88.1% respectively whereas the same values for glutathione conjugated batch were 194 nm, 84.9% and 86.4% respectively. Zeta potential was between 5 to 19. Polydispersity index was below 0.5. Scanning electron microscopy revealed slightly different shapes for both types of liposomes. These two types of rizatriptan liposomes and marketed oral tablet were administrated to rats to study plasma and brain levels. The t_{max} for liposomes was faster (1 hr) as compared to the oral tablet. C_{max} and AUC values for oral tablet, non-conjugated liposomes and conjugated liposomes were found to be 150.19 ng/ml and 223.99 ng.hr/ml; 320.55 ng/ml and 426.6 ng.hr/ml; 410.12 ng/ml and 543.49 respectively. Maximum brain levels were achieved by glutathione conjugated liposomes over other liposomes and oral delivery (C_{max} 310.46, 135.42 and 79.16 ng.ml respectively; AUC 786.94, 229.55 and 118.11 ng.hr/ml respectively). Drug targeting efficiency for conjugated liposomes was about 5 times higher. Conclusion: The study concluded that glutathione conjugated liposomes of rizatriptan administered by nasal transmucosal route can offer a promising approach to enhance targeted delivery to brain and bioavailability.
-

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2. *In situ* Nasal Gel of Granisetron for Enhancement of Bioavailability over Oral Delivery: Formulations, Optimization, and *In vivo* Evaluation

International Journal of Pharmaceutical Sciences and Drug Research 2020;12(5):544-553

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International Journal of Pharmaceutical Sciences and Drug Research

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Research Article

In situ Nasal Gel of Granisetron for Enhancement of Bioavailability over Oral Delivery: Formulation, Optimization, and *In vivo* Evaluation

Rahul Padalkar*, Ashwini Madgulkar

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Box-Behnken design, Fulvic acid, Granisetron, *In situ* nasal gel, Poloxamer PF 127, Transmucosal.

DOI:
10.25004/IJPSDR.2020.120517

ABSTRACT

The objective of the present work was the formulation, optimization, and *in vivo* evaluation of *in situ* nasal gel of granisetron (GRA) that shows liquid to gel transformation at nasal temperature (32–34°C) and maximum drug release after 4 hours; shows bioavailability enhancement over oral delivery. Formulations were prepared using poloxamer PF 127 as gel-forming polymer, carbopol as a mucoadhesive agent, and fulvic acid as a penetration enhancer. A Box-Behnken design was used to prepare the experimental batches and Design Expert software for optimization of the formulation. *Ex vivo* evaluations were carried out on sheep nasal mucosa and for *in vivo* evaluation, rabbits were used. It was observed that optimized formulation showed gelation temperature near 33°C and drug release of 96% after 4 hours. Fulvic acid was evaluated as a penetration enhancer in this work and showed significant enhancement of drug diffusion across the nasal mucosal membrane. *Ex vivo* histological evaluation of nasal mucosa treated with optimized formulation showed no significant destructive effects. *In vivo* evaluations showed that the plasma level profile of prepared *in situ* nasal gel was enhanced significantly over oral delivery. The findings suggested that nasal route nasal transmucosal delivery of GRA can result in enhancement of its bioavailability over the oral route.

INTRODUCTION

The GRA is a potent 5-HT3 receptor antagonist, widely prescribed for the prevention and treatment of chemotherapy-induced nausea and vomiting. Although GRA is rapidly absorbed from the gastrointestinal tract, it is subjected to extensive first-pass metabolism. The oral bioavailability of GRA is about 41 to 60%. In healthy volunteers, a half-life of about 3 to 4 hours is reported.[1,2] Therefore, current GRA treatment generally involves an oral dose of 1 to 2 mg within 1-hour before the start of chemotherapy treatment, then 2 mg daily in 1 to 2 divided doses up to 4 days. Also, a single 3 mg IV dose of GRA can be administered, repeated if necessary with a maximum daily dose of 9 mg.[1,3] Although GRA is effective when given orally, it has got many limitations. Once vomiting has started, particularly if it is moderate or severe, the oral route clearly cannot be used and some alternative is needed. The most common parenteral alternatives to the oral route are injectables. The limitations of these dosage forms include pain and the need for a skilled person for administration because of their invasive nature. In order to improve patient acceptance, there is a need to design a dosage form that offers the advantages of injectables, like the rapid onset of action, improved bioavailability, and simultaneously it should allow self-administration and be non-invasive.

The transmucosal route is being explored as a non-invasive alternative to injectable parenteral routes.[4,5] The mucous membrane is present at various sites, like the nasal cavity, buccal cavity, git, rectum, vagina, eyes, etc.

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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3. Nanosuspension coated multiparticulates for controlled delivery of albendazole

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Research Articles

Nanosuspension coated multiparticulates for controlled delivery of albendazole

Monica R. P. Rao, Rohit Vidyadhar Godbole, Sameer G. Borate, Sanskar Mahajan & Tejal Gangwal

Pages 367-376 | Received 10 Feb 2020, Accepted 12 Jan 2021, Accepted author version posted online: 25 Jan 2021, Published online: 15 Mar 2021

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Abstract

Objective

Improving solubility and bioavailability of albendazole (ALB).

Significance

ALB is a broad-spectrum anthelminthic BCS class II drug with aqueous solubility of solubility of 4.1 mg/l at 25 °C and oral bioavailability of <5%.

https://www.tandfonline.com/doi/abs/10.1080/03639045.2021.1879830 1/4

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4. Self-nanoemulsifying Drug Delivery System of Cilnidipine

Original Article

Self-nanoemulsifying Drug Delivery System of Cilnidipine

Monica Raghavendra Prasad Rao*, Sayali Kulkarni, Ashwini Sonawane, Sayali Sugaonkar

Department of Pharmaceutics, AISSMS College of Pharmacy, Pune, Maharashtra, INDIA.

ABSTRACT

Aim: Self-nanoemulsifying Drug Delivery Systems (SNEDDS) are physically stable, isotropic mixtures of oil, surfactant and co-surfactant. The turbulence generated by peristaltic movements of the GIT causes formation of oil-in-water (o/w) nano-emulsions upon dilution. The objective of this study was to improve solubility and oral bioavailability of Cilnidipine by formulating liquid-SNEDDS. **Materials and methods:** Capmul PG8 NF, Cremophor RH40, and Transcutol HP were selected as oil, surfactant, and co-surfactant. Ternary phase diagrams were constructed to evaluate the nanoemulsification region. A 3^2 factorial design was employed to optimize L-SNEDDS with droplet size and drug release as responses. SNEDDS of CLN was evaluated for droplet size, self-emulsification time, *in vitro* drug release, *ex-vivo* permeation, pharmacokinetics and tissue distribution studies and stability studies. The optimized L-SNEDDS was converted into solid form using β-cyclodextrin nanosponges as adsorbents and evaluated in terms of micromerities, drug content, scanning electron microscopy and powder X-ray diffraction. **Results:** The optimized batch exhibited droplet size of 23.70 nm, and *in vitro* drug release of 95.24 % in 60 min.The *in-vivo* studies revealed nearly 5.53 folds increase in $AUC_{0-\infty}$ of optimized batch of liquid SNEDDS compared to CLN which can be credited to increase in solubility and dissolution rate. **Conclusion:** *In vivo* studies revealed improved pharmacokinetic properties which were attributed to greater surface area and lymphatic absorption leading to circumvention of hepatic first pass metabolism.

Key words: Cilnidipine, 3^2 factorial designs, Nanosponges, solid SNEDDS, Oral bioavailability.

INTRODUCTION

The number of new chemical entities with prolonged receptor binding characteristics, higher therapeutic efficacy but minimal aqueous solubility is expanding. This leads to reduced membrane permeability and poor and erratic bioavailability.[1] Various approaches to overcome these challenges include salt formation,[2] micronizatio,[3] solid dispersions,[4] complexation with cyclodextrins,[5] self-emulsifying formulations,[6] and liposomes.[7]

Lipid-based drug delivery systems represent a diverse group of formulations which include several classes of excipients (e.g.triglyceride oils, mixed glycerides, lipophilic surfactants, hydrophilic surfactants and water-soluble co-solvents).[8] Pouton *et al.*[9] suggested a lipid formulation classification system (LFCS) based on *in-vivo* fate of components of formulation. The physico-chemical properties of the drug play a key role to select the best LFCS. Type III formulations comprising mixture of hydrophilic surfactants and/or hydrophobic surfactants/ solvents are most effective for hydrophobic drugs such as lacidipine,[10] efavirenz,[11] docetaxol,[12] atorvastatin.[13] This type gives rise to self-emulsifying drug delivery systems which have greater acceptability as they have a plethora of advantages which include thermodynamically stable formulations with improved bioavailability and circumvention of first pass metabolism.[14]

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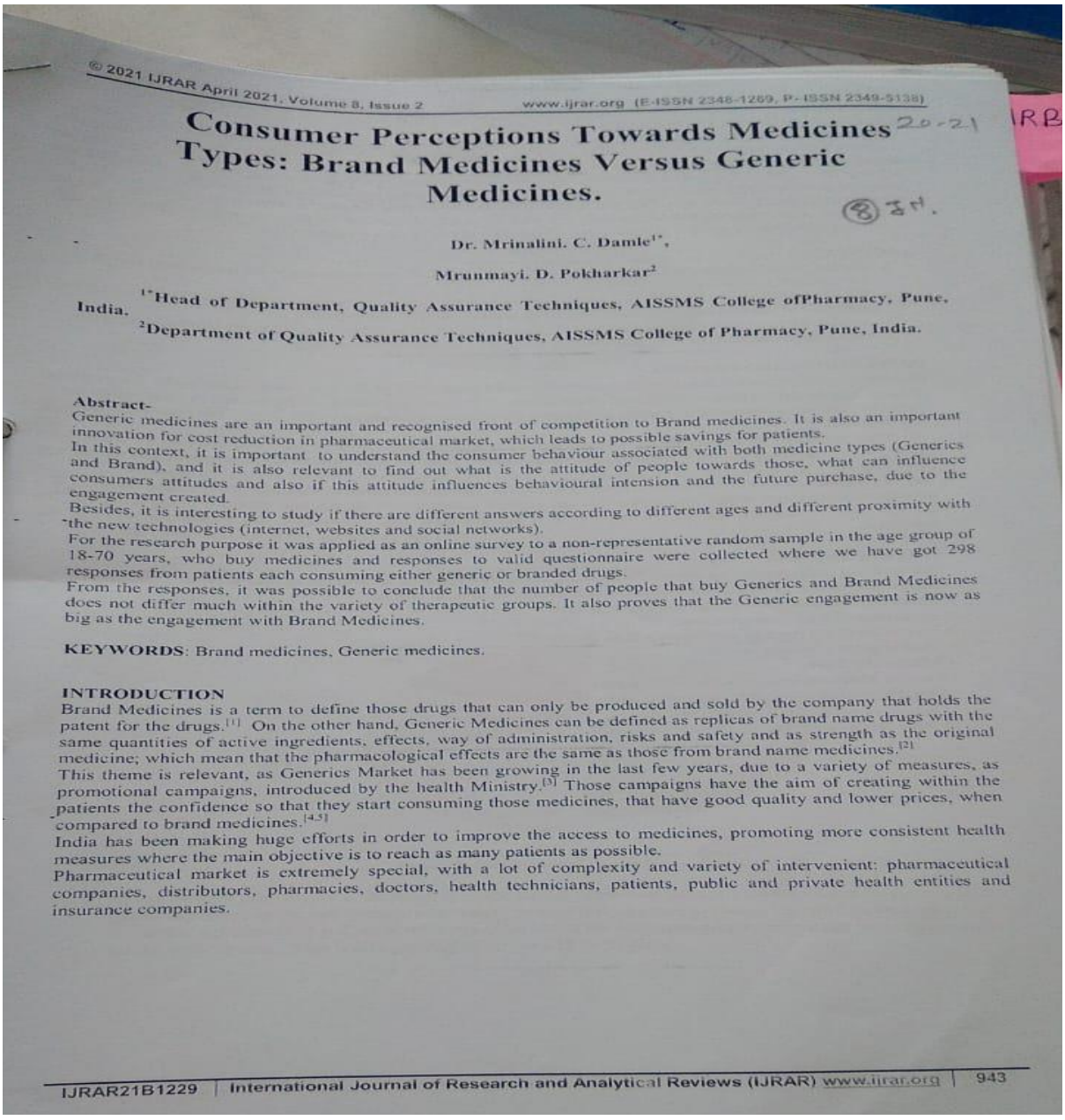
5. Consumer Perceptions Towards Medicines Types: Brand medicines Versus Generic medicines



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Consumer Perceptions Towards Medicines Types: Brand Medicines Versus Generic Medicines.

Dr. Mrinalini. C. Damle[1*],

Mrunmayi. D. Pokharkar[2]

[1*]Head of Department, Quality Assurance Techniques, AISSMS College ofPharmacy, Pune, India.

[2]Department of Quality Assurance Techniques, AISSMS College of Pharmacy, Pune, India.

Abstract-

Generic medicines are an important and recognised front of competition to Brand medicines. It is also an important innovation for cost reduction in pharmaceutical market, which leads to possible savings for patients.

In this context, it is important to understand the consumer behaviour associated with both medicine types (Generics and Brand), and it is also relevant to find out what is the attitude of people towards those, what can influence consumers attitudes and also if this attitude influences behavioural intension and the future purchase, due to the engagement created.

Besides, it is interesting to study if there are different answers according to different ages and different proximity with the new technologies (internet, websites and social networks).

For the research purpose it was applied as an online survey to a non-representative random sample in the age group of 18-70 years, who buy medicines and responses to valid questionnaire were collected where we have got 298 responses from patients each consuming either generic or branded drugs.

From the responses, it was possible to conclude that the number of people that buy Generics and Brand Medicines does not differ much within the variety of therapeutic groups. It also proves that the Generic engagement is now as big as the engagement with Brand Medicines.

KEYWORDS: Brand medicines, Generic medicines.

INTRODUCTION

Brand Medicines is a term to define those drugs that can only be produced and sold by the company that holds the patent for the drugs.[1] On the other hand, Generic Medicines can be defined as replicas of brand name drugs with the same quantities of active ingredients, effects, way of administration, risks and safety and as strength as the original medicine; which mean that the pharmacological effects are the same as those from brand name medicines.[2]

This theme is relevant, as Generics Market has been growing in the last few years, due to a variety of measures, as promotional campaigns, introduced by the health Ministry.[3] Those campaigns have the aim of creating within the patients the confidence so that they start consuming those medicines, that have good quality and lower prices, when compared to brand medicines.[4,5]

India has been making huge efforts in order to improve the access to medicines, promoting more consistent health measures where the main objective is to reach as many patients as possible.

Pharmaceutical market is extremely special, with a lot of complexity and variety of intervenient: pharmaceutical companies, distributors, pharmacies, doctors, health technicians, patients, public and private health entities and insurance companies.

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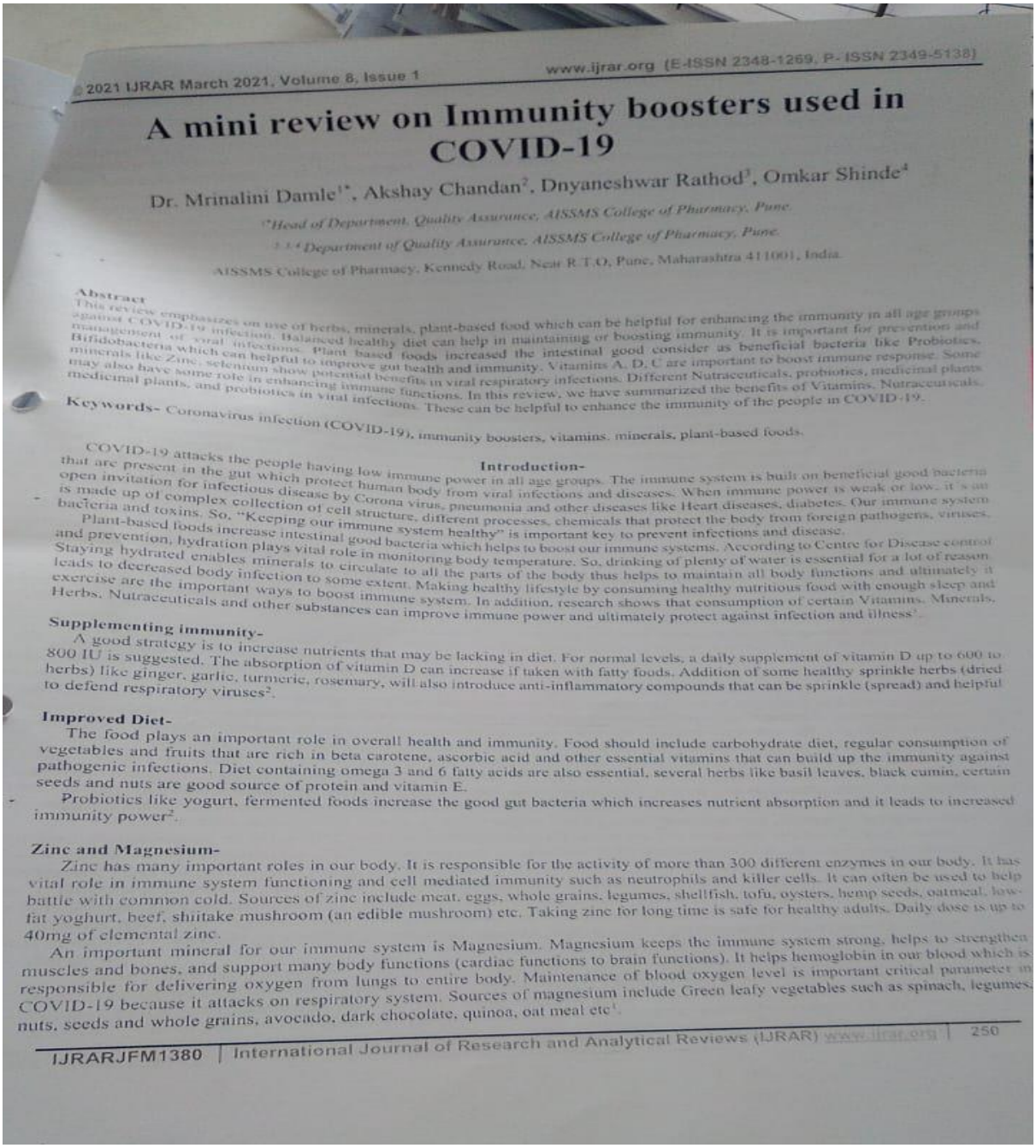
6. A Mini Review on Immunity Boosters used in Covid-19



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A mini review on Immunity boosters used in COVID-19

Dr. Mrinalini Damle[1*], Akshay Chandan[2], Dnyaneshwar Rathod[3], Omkar Shinde[4]

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Abstract

This review emphasizes on use of herbs, minerals, plant-based food which can be helpful for enhancing the immunity in all age groups against COVID-19 infection. Balanced healthy diet can help in maintaining or boosting immunity. It is important for prevention and management of viral infections. Plant based foods increased the intestinal good consider as beneficial bacteria like Probiotics, Bifidobacteria which can helpful to improve gut health and immunity. Vitamins A, D, C are important to boost immune response. Some minerals like Zinc, selenium show potential benefits in viral respiratory infections. Different Nutraceuticals, probiotics, medicinal plants may also have some role in enhancing immune functions. In this review, we have summarized the benefits of Vitamins, Nutraceuticals, medicinal plants, and probiotics in viral infections. These can be helpful to enhance the immunity of the people in COVID-19.

Keywords- Coronavirus infection (COVID-19), immunity boosters, vitamins, minerals, plant-based foods.

Introduction-

COVID-19 attacks the people having low immune power in all age groups. The immune system is built on beneficial good bacteria that are present in the gut which protect human body from viral infections and diseases. When immune power is weak or low, it's an open invitation for infectious disease by Corona virus, pneumonia and other diseases like Heart diseases, diabetes. Our immune system is made up of complex collection of cell structure, different processes, chemicals that protect the body from foreign pathogens, viruses, bacteria and toxins. So, "Keeping our immune system healthy" is important key to prevent infections and disease.

Plant-based foods increase intestinal good bacteria which helps to boost our immune systems. According to Centre for Disease control and prevention, hydration plays vital role in monitoring body temperature. So, drinking of plenty of water is essential for a lot of reason. Staying hydrated enables minerals to circulate to all the parts of the body thus helps to maintain all body functions and ultimately it leads to decreased body infection to some extent. Making healthy lifestyle by consuming healthy nutritious food with enough sleep and exercise are the important ways to boost immune system. In addition, research shows that consumption of certain Vitamins, Minerals, Herbs, Nutraceuticals and other substances can improve immune power and ultimately protect against infection and illness[1].

Supplementing immunity-

A good strategy is to increase nutrients that may be lacking in diet. For normal levels, a daily supplement of vitamin D up to 600 to 800 IU is suggested. The absorption of vitamin D can increase if taken with fatty foods. Addition of some healthy sprinkle herbs (dried herbs) like ginger, garlic, turmeric, rosemary, will also introduce anti-inflammatory compounds that can be sprinkle (spread) and helpful to defend respiratory viruses[2].

Improved Diet-

The food plays an important role in overall health and immunity. Food should include carbohydrate diet, regular consumption of vegetables and fruits that are rich in beta carotene, ascorbic acid and other essential vitamins that can build up the immunity against pathogenic infections. Diet containing omega 3 and 6 fatty acids are also essential, several herbs like basil leaves, black cumin, certain seeds and nuts are good source of protein and vitamin E.

Probiotics like yogurt, fermented foods increase the good gut bacteria which increases nutrient absorption and it leads to increased immunity power[2].

Zinc and Magnesium-

Zinc has many important roles in our body. It is responsible for the activity of more than 300 different enzymes in our body. It has vital role in immune system functioning and cell mediated immunity such as neutrophils and killer cells. It can often be used to help battle with common cold. Sources of zinc include meat, eggs, whole grains, legumes, shellfish, tofu, oysters, hemp seeds, oatmeal, low-fat yoghurt, beef, shiitake mushroom (an edible mushroom) etc. Taking zinc for long time is safe for healthy adults. Daily dose is up to 40mg of elemental zinc.

An important mineral for our immune system is Magnesium. Magnesium keeps the immune system strong, helps to strengthen muscles and bones, and support many body functions (cardiac functions to brain functions). It helps hemoglobin in our blood which is responsible for delivering oxygen from lungs to entire body. Maintenance of blood oxygen level is important critical parameter in COVID-19 because it attacks on respiratory system. Sources of magnesium include Green leafy vegetables such as spinach, legumes, nuts, seeds and whole grains, avocado, dark chocolate, quinoa, oat meal etc[1].

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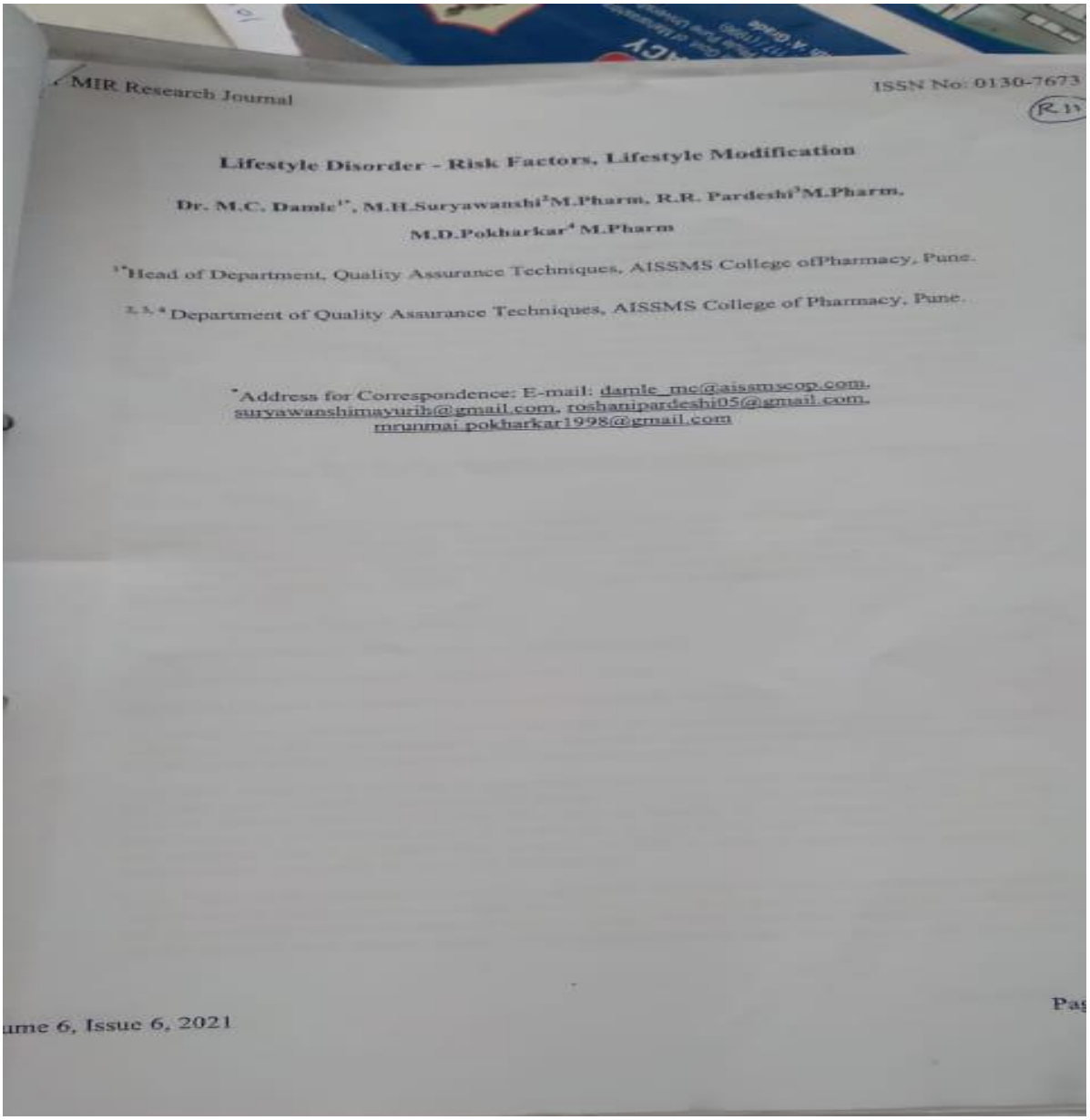
7. Lifestyle Disorder – Risk Factors, Lifestyle Modification



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Lifestyle Disorder - Risk Factors, Lifestyle Modification

Dr. M.C. Damle[1*], M.H.Suryawanshi[2]M.Pharm, R.R. Pardeshi[3]M.Pharm, M.D.Pokharkar[4] M.Pharm

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8. Fingerprinting analysis and Marker compounds in quality assessment of Phytopharmaceuticals

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Home FINGERPRINTING ANALYSIS AND MARKER COMPOUNDS IN QUALITY ASSESSMENT OF PHYTOPHARMACEUTICALS

FINGERPRINTING ANALYSIS AND MARKER COMPOUNDS IN QUALITY ASSESSMENT OF PHYTOPHARMACEUTICALS

Abstract

Since decades, human beings have been utilizing plants to fulfill their food, medicine, and shelter needs. In the modern era plants, plant-derived products are developed as medicine and drug containing phytoconstituents by combining traditional knowledge and modern technologies. The presence of these phytoconstituents is needed to validate qualitatively and quantitatively to serve the purpose of the development of 'phytopharmaceutical'. To achieve this, explicit plant species, the exact amount of phytoconstituents to show efficacy is required, *i.e.*, quality control of the drug is crucial. Hence, this review focuses on different quality control attributes of herbal material and related products to develop as a 'pharmaceutical drug'. Considering marker compounds and fingerprint analysis as the main characteristic features for maintaining the quality of herbal drugs, this review has been designed. Using these features, falsification is detected in crude drugs, extracts, and final products with the application of different spectroscopic, chromatographic techniques. Thus, this review has quoted the use of reliable, efficient analytical tools through recapitulation of different case studies of adulteration detection of plant material, determination of phytoconstituents present in extracts, and formulations using chromatographic and spectroscopic methods to provide a quality assessment.

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Authors: Suvarna Jarande* and Mrinalini Damle

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9. Spectrophotometric Determination of Carbimazole and Its Major Impurity, Degradation Product and Metabolite: Methimazole

Published: 26 December 2021

Spectrophotometric Determination of Carbimazole and Its Major Impurity, Degradation Product and Metabolite: Methimazole

S. S. Kurdaikar, A. Fernandes, S. V. Gandhi, P. Pattewar & A. A. Mahajan

Optics and Spectroscopy **129**, 948–957 (2021)

Abstract

The present research work was carried out in order to develop simple, accurate and precise UV spectrophotometric methods having comparable sensitivity as that of sophisticated chromatographic techniques. Two methods were developed namely first derivative spectrophotometry and ratio spectra derivative spectrophotometry for accurate determination of specified impurity methimazole (imp A) in presence of drug carbimazole. First derivative spectrophotometric method involves recording of zero order spectra of both the drugs

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10. Comparison of Chemometric assisted UV Spectrophotometric and RP-HPLC Method for the simultaneous determination of Ofloxacin and Tinidazole in their combined dosage form

Author(s): Santosh V. Gandhi (search.aspx?key=Santosh V. Gandhi), Deepak Patil (search.aspx?key=Deepak Patil), Atul A. Baravkar (search.aspx?key=Atul A. Baravkar)

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(https://scholar.google.co.in/scholar?q=10.52711/0974-360X.2021.00993)

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Published In: Volume - 14, Issue - 11, Year - 2021 (Issues.aspx?VID=14&IID=11)

ABSTRACT:
In present work, chemometric-assisted UV spectrophotometric methods as well as RP-HPLC method were developed for the simultaneous estimation of Ofloxacin and Tinidazole in their combined pharmaceutical dosage form. The two chemometric methods i.e. principle component regression (PCR) and partial least square regression (PLS) were successfully applied to quantify each drug in mixture using UV absorption spectra in range of 280 to 320nm at ?? of 0.5nm. Chemometric model development was done using 24 binary mixture solutions and 12 solutions were used for validation of model. The chemometric-assisted analysis does not require any prior separation step. In addition, RP-HPLC method was also developed using THERMOSIL C18 column with a mobile phase consisting ofAcetonitrile: Phosphate Buffer (85:15% v/v), flow rate of 1 ml/min and quantification was achieved using UV detector at 300 nm. The methods were successfully applied for the simultaneous determination of these drugs in synthetic mixture. The results obtained for analysis by PCR and PLS methods were compared with RP-HPLC method and a good agreement was found.

Keywords: Chemometric () PCR () PLS () HPLC () Ofloxacin () Tinidazole. ()

Cite this article:
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11. 2D, 3D QSAR and molecular docking studies of Pyrazolyl-thiazolinone derivatives as EGFR inhibitors

ISSN: 2455-2631 October 2022 IJSDR | Volume 7 Issue 10

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Abstract :
Background: Cancer is a leading cause of death worldwide. Pyrazoles, thiazoles and fused thiazoles have been reported to possess many biological activities including anticancer activity.
Aims and Objectives: To study 2D and 3D QSAR followed by Molecular Docking studies to generate new chemical entities (NCE's) containing pyrazolyl-thiazolinone as pharmacophore for anticancer activity.
Materials and methods: In the presented studies we have reported the results of QSAR studies for the 36 derivatives of pyrazolyl-thiazolinone synthesized by Ke-Ming Qiu et.al. 2D and 3D QSAR studies were done by using V Life software. The NCE's were designed by using Lead grow tool in V Life Software and screened by Lipinski screen. The designed compounds having the Lipinski score 5 were subjected to molecular docking studies with EGFR Kinase enzyme by using Schrodinger software.
Result and Discussion: The r^2 and q^2 for the 2D QSAR and 3D QSAR was found to be 0.781 and 0.709 respectively. By performing docking studies, we established that most of the molecules showed the good binding energy and the docking score. Molecule 1 and 3 have the highest dock score with good binding energy.
Conclusion: The molecule 1 and 3 are the significant molecules developed from the results of QSAR and molecular docking studies and they have potential to act as anticancer agent.

Keywords - pyrazolyl-thiazolinone, Antitumor, 2D-3D QSAR, Docking.

I. INTRODUCTION –

Cancer is a leading cause of death worldwide, accounting for nearly 10 million deaths in 2020. (WHO report 2020) [1]. Various pyrazole derivatives have been reported to have a broad spectrum of biological activities such as antiviral/antitumor [2,3], antibacterial [4,5], anti-inflammatory [6], analgesic [7], fungistatic [8], and anti-hyperglycaemic activity [9]. Similarly, Thiazolinone have also exhibited a wide spectrum of biological activities such as anti-inflammatory, antimicrobial, antiproliferative, antiviral, anticonvulsant, antifungal, and antibacterial [10,11,12].
Both theses scaffold together as a hybrid have been reported to possess EGFR and HER-2 kinase inhibitory activity [13]. QSAR is a powerful tool for drug design. It gives the idea about the relationship of chemical structure and biological activity [14,15]. In present study we have attempted to optimize the Pyrazole- Thiazolinone pharmacophore for anticancer activity by two dimensional (2D) and three-dimensional Quantitative structure activity relationship (3D QSAR). New compounds were designed by using Combilib tool in V-Life software and were screened by Lipinski filter. The compounds having the Lipinski score of 5 were subjected to the molecular docking process by using the Schrodinger software.

II. MATERIAL AND METHODS –

2.1 MATERIALS -

All the molecular modelling studies (2D, 3D QSAR and Lead grow) were carried out by using the software V life MDS (V Life MDS 4.4). The molecular docking studies were carried out by using the Schrodinger Software. [16,17,15] The structure of all the compounds were sketched by using Chem Draw Ultra 8.0 software. The 3D optimization and energy minimization step were performed by using the Chem Draw 3D Ultra 8.0 software.

DATA SET –

Data set of 36 derivatives of pyrazolyl-thiazolinone with antitumor activity reported by Ke-Ming Qiu et.al was used for QSAR studies. Biological activity is expressed in terms of minimum inhibitory concentration (MIC) was converted into pMIC [pMIC = -log(MIC)] [13]
For development of QSAR model, entire data set was divided into training set (to generate the regression models) and test set (to evaluate the predictive ability of these models). The test compounds were selected manually based on structural diversity and distribution of their antitumor activity. Uni-Column statistics for training set and test set were generated to check correctness of selection criteria for training and test set molecules. The antitumor activities expressed as pMIC values were used as dependent variables in the QSAR analyses while the molecular descriptors served as the independent variables. [16,17].

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12. One pot synthesis, in silico study and evaluation of some novel flavonoids as potent topoisomerase II inhibitors

ScienceDirect

Bioorganic & Medicinal Chemistry Letters
Volume 40, 15 May 2021, 127916

One pot synthesis, in silico study and evaluation of some novel flavonoids as potent topoisomerase II inhibitors

Aniket P. Sarkate [a], Vidya S. Dofe [b], Shailee V. Tiwari [c], Deepak K. Lokwani [d], Kshipra S. Karnik [a], Darshana D. Kamble [a], Mujahed H.S.H. Ansari [a], Suneel Dodamani [e], Sunil S. Jalalpure [e f], Jaiprakash N. Sangshetti [g], Rajaram Azad [h], Prasad V.L.S. Burra [i], Shashikant V. Bhandari [j]

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Highlights:

- One pot method was employed for the synthesis of novel flavonoid derivatives.
- Seven synthesized compounds demonstrated an antiproliferative effect comparable to that of doxorubicin.
- Two synthesized compounds exhibited robust inhibition of enzyme topoisomerase-II.

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13. Comprehensive Review on Versatile Nature of curcumin and its Pharmacological Activities

IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Comprehensive Review on Versatile Nature of Curcumin and it's Pharmacological Activities

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Abstract

Many natural medicinal plants have been utilised to cure a range of disorders since ancient times and are regarded as a possible source of phytochemicals for the creation of new medications. One of these is curcumin, a bioactive molecule that is easily available, affordable, and harmless. It is a vital, naturally occurring, highly lipophilic and phenolic chemical. Curcumin (diferuloylmethane), a low-molecular-weight chemical derived from the roots of Curcuma longa L. (family Zingiberaceae), is mostly used as a curry spice, flavouring agent, insect repellant, food colouring agent, traditional medication, and cosmetic component. Curcumin is a tautomeric molecule that exists in organic solvents as an enolic form and in water as a keto form. Though inconclusive, epidemiological findings show that turmeric intake may lessen the incidence of some malignancies and provide other beneficial biological benefits in people. Turmeric's biological benefits have been linked to its ingredient curcumin, which has been extensively researched for its anti-inflammatory, anti-ulcer, anti-diabetic, anti-viral, antioxidant, wound healing, and anti-cancer properties. Curcumin is a low-toxicity nutraceutical that has been utilised successfully in a variety of medical ailments, as discussed in this article.

Keywords

Curcumin, pharmacological activities, turmeric, structure activity relationship, molecular targets

I. Introduction

Since ancient times, humans have used herbs and plants to heal a variety of ailments[1,2]. Plants have been utilised for numerous reasons throughout human history, and evidence supporting the use of herbal medicine continues to grow. Traditional and indigenous medicines are currently receiving a lot of interest from researchers all around the world because of their great therapeutic potential and lack of known or reported negative effects. Curcumin is a well-known, lucrative, and vital traditional plant ingredient. Curcumin (diferuloylmethane), a polyphenolic molecule isolated from the rhizomes of Curcuma longa L. and related species, is the natural yellow colour in the roots of turmeric (family Zingiberaceae). Curcumin's chemical name is 1,7-bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-3,5-dione, and it is water insoluble. Curcumin is fragrant, having a faint orange and ginger scent, yet it has a bitter taste[3]. It accounts for around 4% of the drug's dry weight[4]. Maceration, microwave treatment, digestion, infusion, and Soxhlet extraction procedures have all been utilised to extract curcumin from turmeric. When all of the published techniques are compared, Soxhlet extraction comes out on top. Curcumin may be extracted in huge quantities with less solvent, saving time, money, and energy[5].

Turmeric has a carbohydrate content of 69.4 %, 13.1 % water, 6.3 % protein, 5.1 % fat, and 3.5 % minerals[6,7]. Turmeric fractions are known as curcuminoids. Curcuminoids make up commercial curcumin, which contains

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14. A review: Discovering 1,3,4-oxadiazole and chalcone nucleus for Cytotoxicity/ EGFR Inhibitory Anticancer Activity

Review Mini Rev Med Chem. 2022;22(5):805-820. doi: 10.2174/1389557521666210902160644.

A Review: Discovering 1,3,4-oxadiazole and Chalcone Nucleus for Cytotoxicity / EGFR Inhibitory Anticancer Activity

Shital Patil [1], Shashikant Bhandari [1]

Affiliations

PMID: 34477516 DOI: 10.2174/1389557521666210902160644

Abstract

Introduction: Cancer is reported to be one of the most life-threatening diseases. Major limitations of currently used anticancer agents are drug resistance, very small therapeutic index, and severe, multiple side effects.

Objective: The current scenario necessitates developing new anticancer agents, acting on novel targets for effectively controlling cancer. The epidermal growth factor receptor is one such target, which is being explored for 1,3,4-oxadiazole and chalcone nuclei.

Methods: Findings of different researchers working on these scaffolds have been reviewed and analyzed, and the outcomes were summarized. This review focuses on Structure-Activity Relationship studies (SARs) and computational studies of various 1,3,4-oxadiazole and chalcone hybrids/ derivatives reported as cytotoxic/EGFR-TK inhibitory anticancer activity.

Result and conclusion: 1,3,4-oxadiazole and chalcone hybrids/derivatives with varied substitutions are found to be effective pharmacophores in obtaining potent anticancer activity. Having done a thorough literature survey, we conclude that this review will surely provide firm and better insights to the researchers to design and develop potent hybrids/derivatives that inhibit EGFR.

Keywords: 1,3,4-oxadiazole; EGFR-TK inhibitors; cancer; chalcone; cytotoxic anticancer activity; hybrids.

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15. Synthesis, Docking and Antitubercular Activity of Ttriazole- Thiadiazole Hybride

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SYNTHESIS, DOCKING AND ANTITUBERCULER ACTIVITY OF TRIAZOLE-THIADIAZOLE HYBRIDE

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Associate Professor[1, 8, 9,] Student [2, 3, 4,5,6,7]

Department of Pharmaceutical Chemistry,

All India Shri Shivaji Memorial Society's College of Pharmacy, Kennedy Road, Near R.T.O., Pune-411001, M.S., India.

Abstract: Aim of the present work was to synthesize some triazole and thiadiazole derivatives and evaluate them for their Anti-tubercular activity. Six triazole-thiadiazole hybrid derivatives were synthesized, subjected to docking studies and evaluated for their anti-tubercular activity using XTT Reduction Menadione Assay Protocol. The compounds , **5E** viz.,3-(3-nitrophenyl)-[1,2,4]triazolo[3,4-b][1,3,4]thiadiazol-6(5H)-thione and **5F**, 3-(2,4-dichlorophenyl)-[1,2,4]triazolo[3,4-b][1,3,4]thiadiazol-6(5H)-thione have shown better activity as compared to other derivatives. The 5E has shown better docking score as compared to the standard used. Hybrids of triazole and thiadiazole thus can be further explored.

***Index Terms*:** Antitubercular, Triazole- Thiadiazole Hybrid, DNA gyrase, XTT Assay, Molecular Docking

I. INTRODUCTION:

Tuberculosis (TB) is a leading cause of death worldwide from a single infectious agent called, *Mycobacterium tuberculosis* (MTB). Predominantly it infects lungs (pulmonary TB) but can also infect any other part of body (extra-pulmonary TB); if left untreated it destroys the body tissue by chronic inflammation and may culminate in death. About one third of the world's population is infected with MTB that causes TB. On an average 5–10% of these carriers become sick or infectious at some time during their life. [1-2]

Literature survey has revealed that derivatives of 1, 2, 4- triazole and 1,3,4- thiadiazole possesses broad spectrum of activities either alone or in hybrid scaffold. [3-26] In view of the promising anti-tubercular [27-41] activity of thiadiazole and 1,2,4-triazole derivatives we have designed 1,3,4-thiadiazole-1,2,4-triazole hybrids by incorporation of these two molecular entities in to a single framework. Further docking studies were performed on MTB DNA gyrase (PDB code: 2XCT) and studies of the minimum energy docked poses of these compounds revealed that they could fit into the binding pocket of DNA gyrase. [42]

II. MATERIAL AND METHODS

Synthetic study

All chemicals and solvents were purchased from Sigma Aldrich and Merck, respectively. Melting points (mp) were determined by a Veego VMP-D apparatus and are uncorrected. Infrared (IR) spectra were recorded using KBr on a Varian-160 FTIR spectrometer using Diffuse Reflectance Attachment. ^{1}H NMR spectra were measured on Jeol JNM ECX-400 P 0and Bruker Advance II-400 spectrometers in $CDCl_3$/ DMSO with TMS as internal standard. Mass Spectra were measured on a Jeol JMS-700 or Thermo Scientific Q-Exactive, Accela 1250 pump. Analytical thin-layer chromatography (TLC) was carried out on Merck's precoated silica-gel plates 60 F_{254} and spots were visualized by irradiation with UV light (254 nm) .

Step 1: Synthesis of Substituted benzoic esters from Substituted Benzoic acids (2A-2F):

Carboxylic acid (0.1 mole) was dissolved in 30 ml of dried ethanol or methanol in a dry RBF. To this, 0.1 mol of conc. H_2SO_4 was added drop wise with mechanical stirrer. The reaction mixture was refluxed for 7-8 hrs at 50-60^{0}c. Mixture was then allowed to cool and pH was neutralised by 10% Sodium Bicarbonate ($NaHCO_3$) solution to obtain the product. Reaction was monitored using TLC with mobile phase: n-Hexane: Ethyl Acetate (8:2) [43]

Step 2: Synthesis of Substituted benzohydrazide from Substituted benzoester(3A-3F):

To a solution of ester (1 mmol, 1 equiv.), 99% hydrazine hydrate (3 mmol, 3.0 equiv.) was added drop-wise. The reaction mixture was refluxed for 5 hrs at 50^{0}c; after completion of the reaction, a solid product was formed, and the excess solvent was removed under reduced pressure. Reaction was monitored using TLC with mobile phase: Methanol: Chloroform (1:10) [44]

Step 3: Synthesis of 4-amino-5-Substituted-4H-1,2,4-triazole-3-thiol from Substituted benzohydrazide(4A-4F):

To the solution of Potassium hydroxide (1.5 mmol, 1.5 equiv.) and absolute ethanol (25ml); substituted hydrazides (1 mmol, 1 equiv.), and carbon disulphide (1.5 mmol, 1.5 equiv.) was added drop-wise and mixture was refluxed for about 10 hrs. After completion of the reaction, the solvent was evaporated under reduced pressure to obtain the intermediate. To the crude product 99% Hydrazine Hydrate (25

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16. *In silico* Studies, Synthesis and Antitubercular Activity of Some Novel Quinoline – Azitidinone Derivatives

Curr Comput Aided Drug Des. 2021;17(1):134-143. doi: 10.2174/1573409916666200129095952.

In silico Studies, Synthesis and Antitubercular Activity of Some Novel Quinoline - Azitidinone Derivatives

Trupti S Chitre [1], Kalyani D Asgaonkar [1], Amrut B Vikhe [1], Shital M Patil [1], Dinesh R Garud [2], Vijay M Khedkar [3], Dhiman Sarkar [4], Laxman U Nawale [4], Amar Yeware [4]

Affiliations

PMID: 31995017 DOI: 10.2174/1573409916666200129095952

Abstract

Background: Diarylquinolines like Bedaquiline have shown promising antitubercular activity by their action of Mycobacterial ATPase.

Objective: The structural features necessary for a good antitubercular activity for a series of quinoline derivatives were explored through computational chemistry tools like QSAR and combinatorial library generation. In the current study, 3-Chloro-4-(2-mercaptoquinoline-3-yl)-1- substitutedphenylazitidin-2-one derivatives have been designed and synthesized based on molecular modeling studies as anti-tubercular agents.

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17. A comprehensive overview of synthetic methods of Oxadiazole Thiadiazole and Triazole

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Title

A COMPREHENSIVE OVERVIEW OF THE SYNTHETIC METHODS OF OXADIAZOLE, THIADIAZOLE AND TRIAZOLE

Authors

Shruti Suryawanshi
Sheetal Parse
Pooja Wagh
Nagasawjanya Dongari
Trupti Chitre,Kalyani Asgaonkar

Abstract

Many drugs are producing resistance to the various diseases. So, there is an urgent need to synthesize the new chemical entities with potent biological activity. This review may help the medicinal chemist to develop the new chemical entities with Oxadiazole, Thiadiazole and Triazole as the heterocyclic nucleus with higher efficiency and less side effects. This review gives the information about the synthetic routes of the Oxadiazole, Thiadiazole and triazole.

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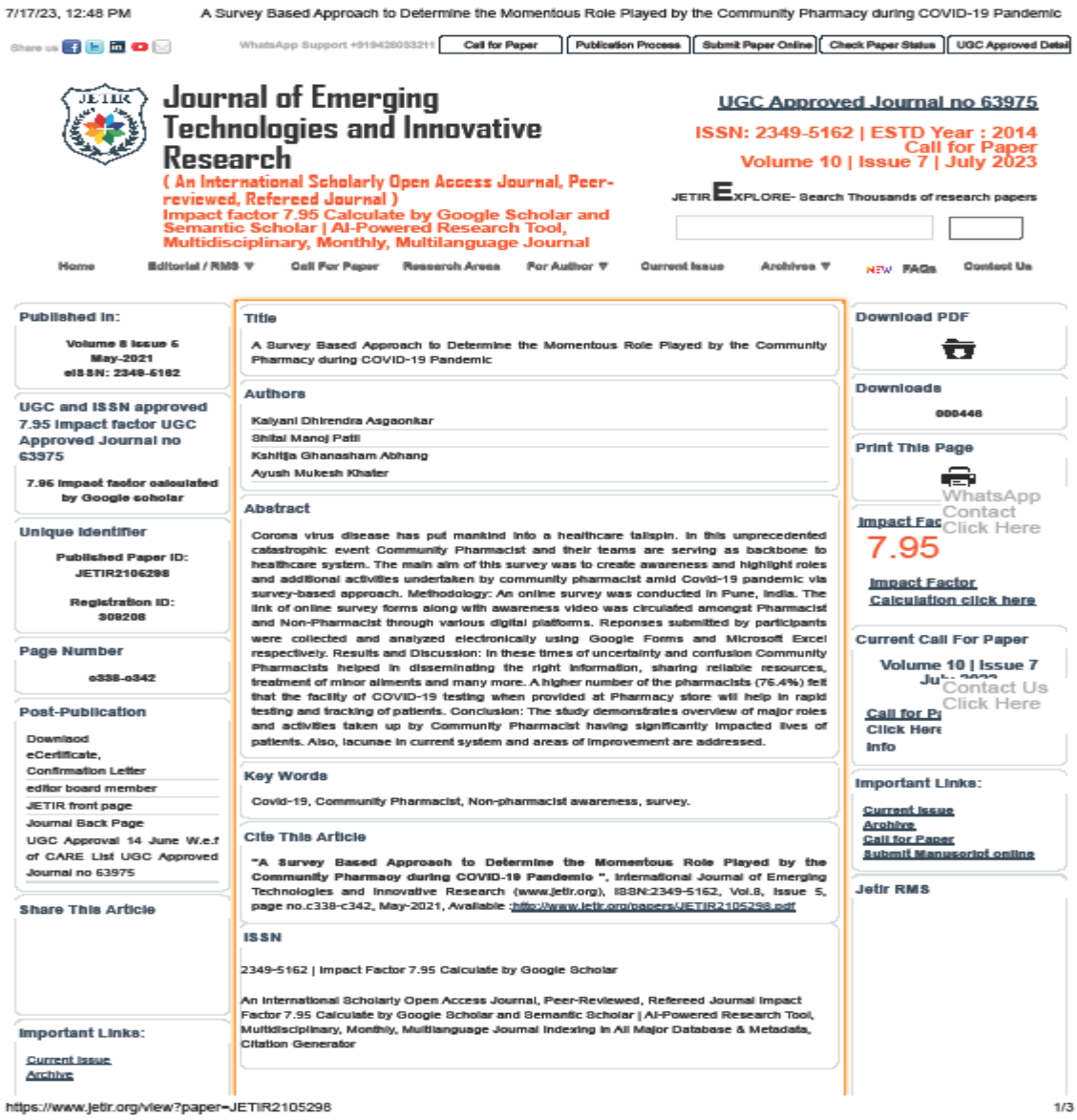
18. A survey based approach to determine the momentous role played by the community pharmacy during COVID-19 Pandemic



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Title

A Survey Based Approach to Determine the Momentous Role Played by the Community Pharmacy during COVID-19 Pandemic

Authors

Kalyani Dhirendra Asgaonkar
Shital Manoj Patil
Kshitija Ghanasham Abhang
Ayush Mukesh Khaire

Abstract

Corona virus disease has put mankind into a healthcare tailspin. In this unprecedented catastrophic event Community Pharmacist and their teams are serving as backbone to healthcare system. The main aim of this survey was to create awareness and highlight roles and additional activities undertaken by community pharmacist amid Covid-19 pandemic via survey-based approach. Methodology: An online survey was conducted in Pune, India. The link of online survey forms along with awareness video was circulated amongst Pharmacist and Non-Pharmacist through various digital platforms. Reponses submitted by participants were collected and analyzed electronically using Google Forms and Microsoft Excel respectively. Results and Discussion: In these times of uncertainty and confusion Community Pharmacists helped in disseminating the right information, sharing reliable resources, treatment of minor ailments and many more. A higher number of the pharmacists (76.4%) felt that the facility of COVID-19 testing when provided at Pharmacy store will help in rapid testing and tracking of patients. Conclusion: The study demonstrates overview of major roles and activities taken up by Community Pharmacist having significantly impacted lives of patients. Also, lacunae in current system and areas of improvement are addressed.

Key Words

Covid-19, Community Pharmacist, Non-pharmacist awareness, survey.

Cite This Article

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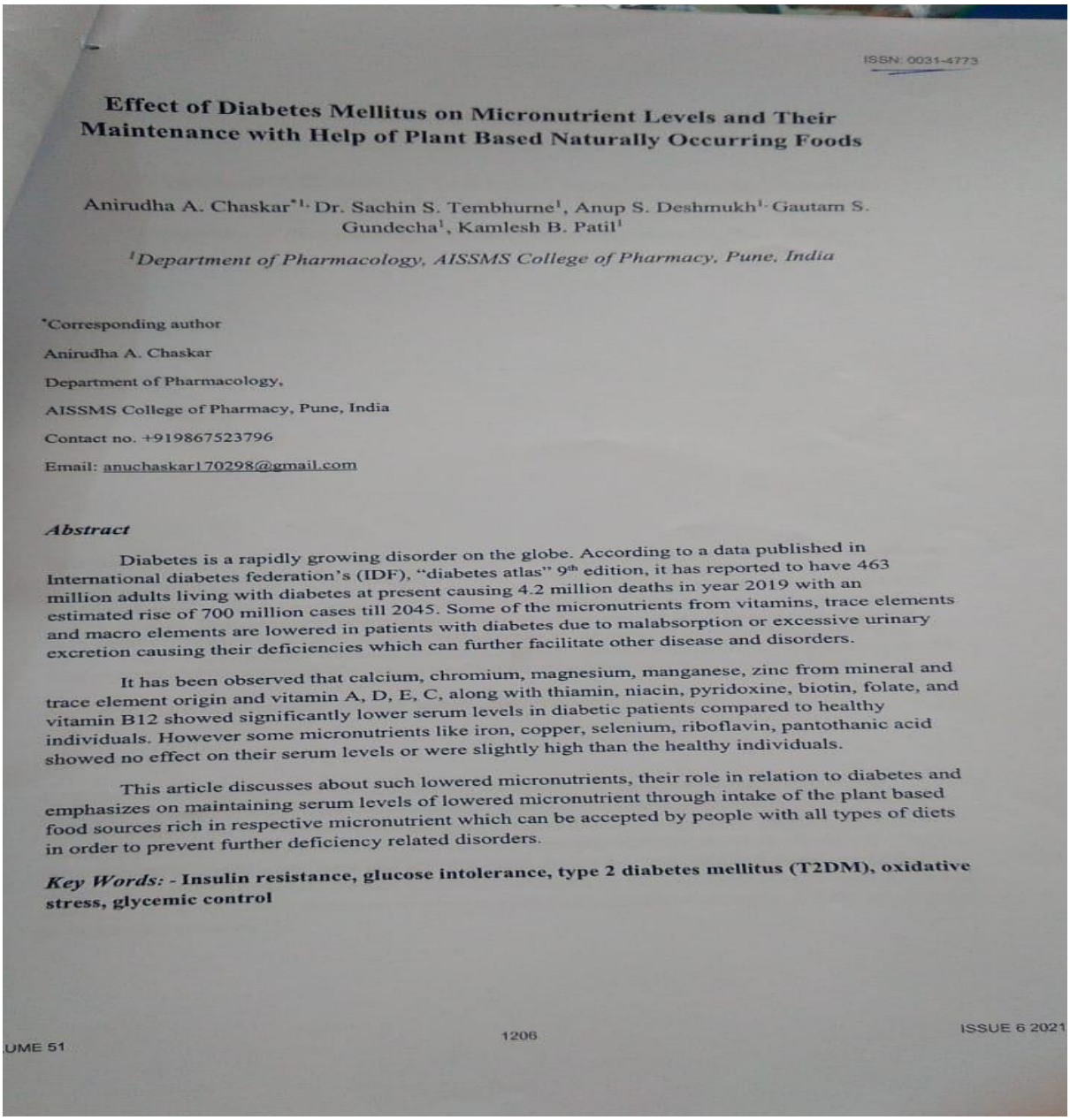
19. Effect of diabetes mellitus on micronutrient levels and their maintenance with help of plant based naturally occurring foods



ISSN: 0031-4773

Effect of Diabetes Mellitus on Micronutrient Levels and Their Maintenance with Help of Plant Based Naturally Occurring Foods

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Abstract

Diabetes is a rapidly growing disorder on the globe. According to a data published in International diabetes federation's (IDF), "diabetes atlas" 9th edition, it has reported to have 463 million adults living with diabetes at present causing 4.2 million deaths in year 2019 with an estimated rise of 700 million cases till 2045. Some of the micronutrients from vitamins, trace elements and macro elements are lowered in patients with diabetes due to malabsorption or excessive urinary excretion causing their deficiencies which can further facilitate other disease and disorders.

It has been observed that calcium, chromium, magnesium, manganese, zinc from mineral and trace element origin and vitamin A, D, E, C, along with thiamin, niacin, pyridoxine, biotin, folate, and vitamin B12 showed significantly lower serum levels in diabetic patients compared to healthy individuals. However some micronutrients like iron, copper, selenium, riboflavin, pantothanic acid showed no effect on their serum levels or were slightly high than the healthy individuals.

This article discusses about such lowered micronutrients, their role in relation to diabetes and emphasizes on maintaining serum levels of lowered micronutrient through intake of the plant based food sources rich in respective micronutrient which can be accepted by people with all types of diets in order to prevent further deficiency related disorders.

Key Words: **- Insulin resistance, glucose intolerance, type 2 diabetes mellitus (T2DM), oxidative stress, glycemic control**

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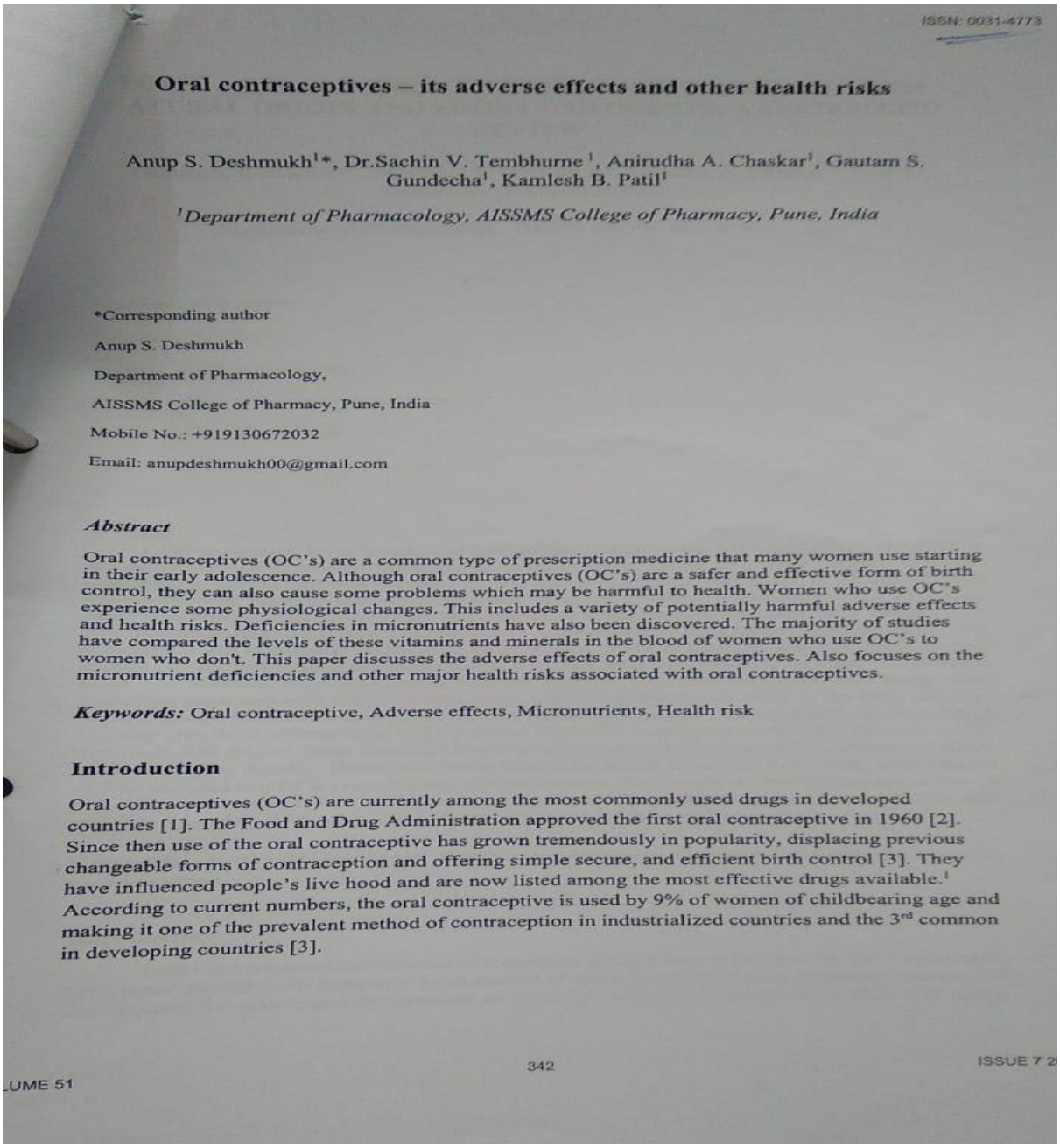
20. Oral contraceptives – its adverse effects and other health risks



ISSN: 0031-4773

Oral contraceptives – its adverse effects and other health risks

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Abstract

Oral contraceptives (OC's) are a common type of prescription medicine that many women use starting in their early adolescence. Although oral contraceptives (OC's) are a safer and effective form of birth control, they can also cause some problems which may be harmful to health. Women who use OC's experience some physiological changes. This includes a variety of potentially harmful adverse effects and health risks. Deficiencies in micronutrients have also been discovered. The majority of studies have compared the levels of these vitamins and minerals in the blood of women who use OC's to women who don't. This paper discusses the adverse effects of oral contraceptives. Also focuses on the micronutrient deficiencies and other major health risks associated with oral contraceptives.

Keywords: Oral contraceptive, Adverse effects, Micronutrients, Health risk

Introduction

Oral contraceptives (OC's) are currently among the most commonly used drugs in developed countries [1]. The Food and Drug Administration approved the first oral contraceptive in 1960 [2]. Since then use of the oral contraceptive has grown tremendously in popularity, displacing previous changeable forms of contraception and offering simple secure, and efficient birth control [3]. They have influenced people's live hood and are now listed among the most effective drugs available.[1] According to current numbers, the oral contraceptive is used by 9% of women of childbearing age and making it one of the prevalent method of contraception in industrialized countries and the 3rd common in developing countries [3].

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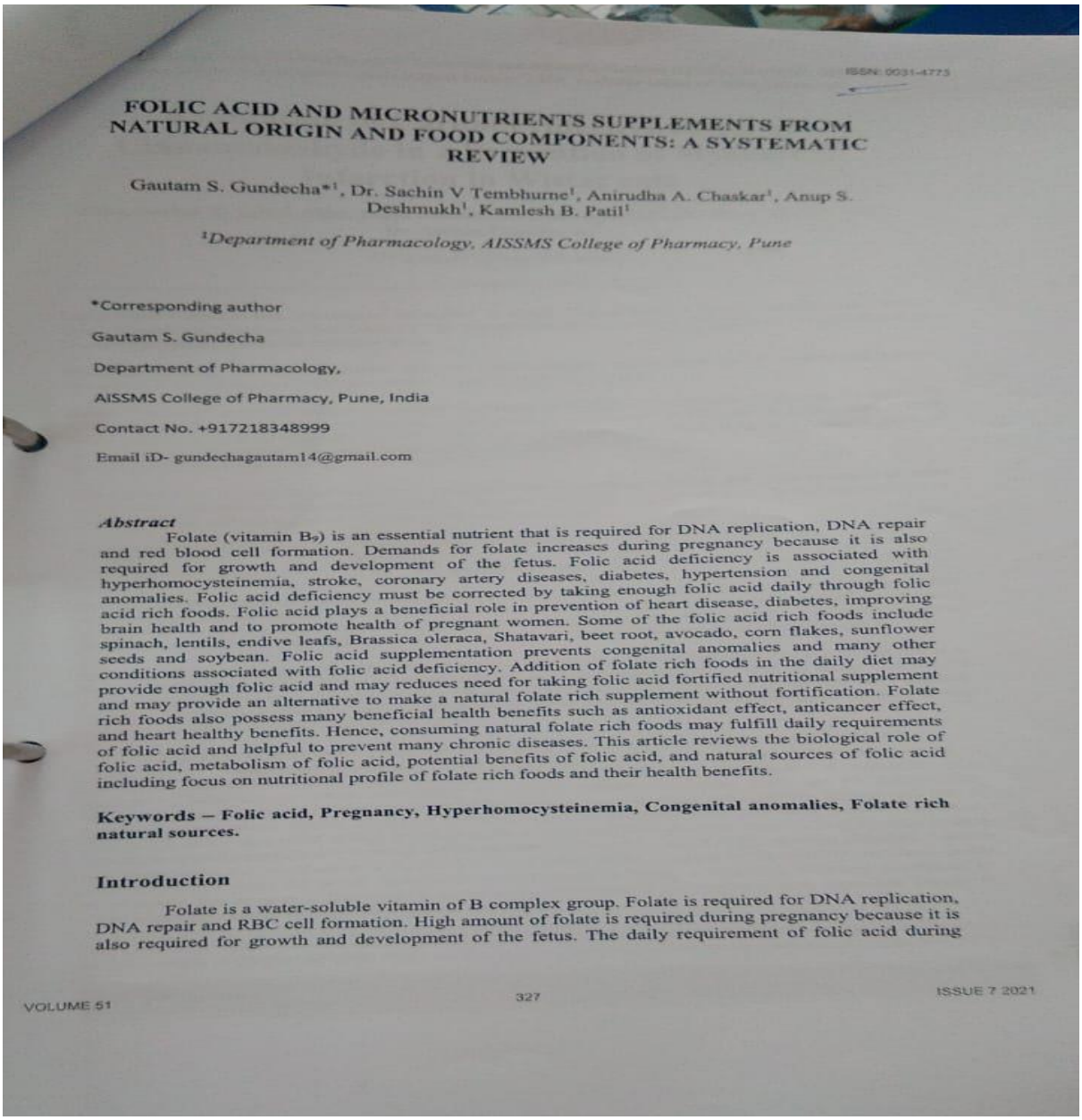
21. Folic acid and micronutrients supplements from natural origin and food components: a systematic review



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FOLIC ACID AND MICRONUTRIENTS SUPPLEMENTS FROM NATURAL ORIGIN AND FOOD COMPONENTS: A SYSTEMATIC REVIEW

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Abstract

Folate (vitamin B_9) is an essential nutrient that is required for DNA replication, DNA repair and red blood cell formation. Demands for folate increases during pregnancy because it is also required for growth and development of the fetus. Folic acid deficiency is associated with hyperhomocysteinemia, stroke, coronary artery diseases, diabetes, hypertension and congenital anomalies. Folic acid deficiency must be corrected by taking enough folic acid daily through folic acid rich foods. Folic acid plays a beneficial role in prevention of heart disease, diabetes, improving brain health and to promote health of pregnant women. Some of the folic acid rich foods include spinach, lentils, endive leafs, Brassica oleraca, Shatavari, beet root, avocado, corn flakes, sunflower seeds and soybean. Folic acid supplementation prevents congenital anomalies and many other conditions associated with folic acid deficiency. Addition of folate rich foods in the daily diet may provide enough folic acid and may reduces need for taking folic acid fortified nutritional supplement and may provide an alternative to make a natural folate rich supplement without fortification. Folate rich foods also possess many beneficial health benefits such as antioxidant effect, anticancer effect, and heart healthy benefits. Hence, consuming natural folate rich foods may fulfill daily requirements of folic acid and helpful to prevent many chronic diseases. This article reviews the biological role of folic acid, metabolism of folic acid, potential benefits of folic acid, and natural sources of folic acid including focus on nutritional profile of folate rich foods and their health benefits.

Keywords – Folic acid, Pregnancy, Hyperhomocysteinemia, Congenital anomalies, Folate rich natural sources.

Introduction

Folate is a water-soluble vitamin of B complex group. Folate is required for DNA replication, DNA repair and RBC cell formation. High amount of folate is required during pregnancy because it is also required for growth and development of the fetus. The daily requirement of folic acid during

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22. Development and Evaluation of Nutritious Supplementary Food Product in Phenyl Hydrazine Induced Anaemia in Wistar Rats

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Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

Open Access Full Text Article

Research Article

Development and Evaluation of Nutritious Supplementary Food Product in Phenyl Hydrazine Induced Anaemia in Wistar Rats

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Abstract

Objective- Nutritional deficiency anemia mainly results from a lack of iron, but it also associated due to lack of folate/vitamin B12 and low vitamin C intake. From various studies this is found anemia in people is due to poor eating habits, such as not eating enough fruits and legumes such as beans and peas. Proper nutritional supplementation may be useful in such condition. The aim of the present work was to select a suitable iron rich food material, and prepared a suitable dosage form for management of anaemic condition and to evaluate anti-anaemic potential of nutritious supplementary food. **Method**- Anemia was induced by phenyl-hydrazine. Animals were treated with nutritious supplementary food throughout the study for 30 days. The haemoglobin concentration was determined after 30 days. **Results**- Nutritious supplementary food was found to be rich in folic acid, ascorbic acid, and iron. Following the induction of anaemia, the haemoglobin concentration decreased by 30%. Administration of standard hematinic preparation and nutritious supplementary food 2gm/day in divided dose resulted in significant increase ($P \leq 0.05$) in haemoglobin concentration when compared to the untreated phenyl hydrazine-induced anaemic rats. **Conclusion**- Nutritious supplementary food effectively raised the level of haemoglobin. Vitamin and minerals found in nutritious supplementary food are most likely active ingredients responsible for its hematinic effects.

Keywords- Anaemia, nutrition, nutritional anaemia, iron, phenyl hydrazine

INTRODUCTION

Anaemia is a condition in which the blood does not have enough healthy Red Blood Cells. Anaemia results from a lack of RBC/ dysfunctional RBC in the body. This leads to reduce oxygen flow to the body's organs[1,2]. Anaemia affects over 30% of the world's population, according to the World Health Organization (WHO). According to global data April 2018, India has the highest prevalence of anaemia and this even higher among Indian women with around 50% of women. It is often more common in pregnant women and children [3,4,21].

Nutritional anaemia is an important nutritional problem affecting large population groups in most developing countries. Nutrition deficiency anaemia is common issue that can happen if the body does not absorb enough of certain nutrients. It can results from an imbalanced diet or certain health condition. Iron, folate or vitamin B12 these nutrients can cause the nutrition deficiency anemia and low vitamin C intake can contribute to it. Nutrition deficiencies can lead to a low red blood cell count, low of haemoglobin in these cells, or red blood cells that do not function as they should. Iron deficiency can delay the development of unborn babies [5, 6,17].

From various studies this is found anaemia in people is due to poor eating habits, such as not eating enough fruits and legumes such as beans and peas. So these nutrients are important for maintaining the wellbeing of human[7,15,22].

Dr. Stephen Defelice coined the term "Nutraceutical" from "Nutrition" and "Pharmaceutical" in 1989. Nutraceutical is a broad term that is used to describe any product obtained from food sources. Nutraceutical product is a food supplement and it provides medical benefits to human beings. Nutraceutical provides medical benefits such as it helps in improving health, delay the aging process, prevent chronic diseases, increase life expectancy, therefore nutraceutical known as medicinally / nutritionally functional food [8,18]. When food is being cooked/prepared using "scientific intelligence" with or without knowledge of how or why it is being used, the food is called "functional food". Thus functional food provides the body with the required amount of vitamins, fats, proteins, carbohydrates, etc., needed for its healthy survival. When functional food aids in the prevention and /or treatment of disease(s) and /or disorders other than anaemia, it is called a nutraceutical [8,19].

In the present innovation, composition of nutritious supplementary food contains kidney beans, soybeans, corn flakes, oats, tomato powder, beetroot powder. The composite nutraceutical preparation tested for presence of iron and folic acid. These food materials are rich source of iron, folic acid, vitamins such as vitamin C. vitamin B12, and minerals.

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23. Natural Blue Pigment Color Gel for Foods, beverages and Pharmaceuticals

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Natural Blue Pigment Color Gel for Foods, beverages and Pharmaceuticals

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ABSTRACT:

Colorants are mainly used to impart a distinctive appearance to the pharmaceutical dosage forms. There are many types of pharmaceutical formulations which need to be coloured such as tablets, tablets coatings, capsules (hard gelatine, soft gelatine), liquid orals, tooth pastes, ointments and salves etc. The purpose of colouring varies with different formulations. Colouring may be required to increase the aesthetic appearance or to prolong the stability or to produce standard preparations or for identification of a particular formulation. So current study involves the preparation of blue colour gel which can be used in dairy products, beverage, food, and pharmaceuticals. *Clitoria ternatea* has an antioxidant property, prevent greying of hair and medicinal use etc. Parabens were used as a preservative because blue colour is sensitive to light, with added antioxidants and stored in amber colour container in cool place.

Keywords: *Clitoria ternatea*, blue color, antioxidant, medicinal use.

INTRODUCTION:

Color is a major component in food, beverages and pharmaceuticals. It has many applications in confectioneries and coatings for other food products. Vitamins and food supplements in tablet form and potential application in the cosmetics industry. At present, the demand for natural dyes is increasing due to increased awareness on therapeutic and medicinal properties and their benefits among public and also because of the recognized toxic effects of synthetic colors. Natural dyes are those derived from naturally dyes, plant-based pigments have medicinal values so are mostly preferred. The natural colors like orange, red, yellow, green and blue which commonly used as colorants in Pharmaceuticals, Beverages and Foods.

FD & C Designation	Name	Color	Molecular Formula
Blue No.1	Brilliant blue FCF	Blue	$C_{37}H_{34}N_2Na_2O_9S_3$
Blue No.2	Indigotin	Indigo	$C_{16}H_8N_2Na_2O_8S_2$
Green No.3	Fast green FCF	Turquoise	$C_{37}H_{34}N_2Na_2O_{10}S_3$
Red No. 3	Erythrosine	Pink	$C_{20}H_6I_4Na_2O_5$
Red No.40	Allura Red AC	Red	$C_{18}H_{14}N_2Na_2O_8S_2$

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24. Self-Assembling Dioscorea bulbifera loaded mixed micelles: Formulation optimization, in-vitro cytotoxicity and in-vivo pharmacokinetics

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Self-Assembling *Dioscorea bulbifera* loaded mixed micelles: Formulation optimization, *in-vitro* cytotoxicity and *in-vivo* pharmacokinetics

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Keywords:
Dioscorea bulbifera
Pluronic F-127
Soluplus
Mixed micelles
Cytotoxic activity

ABSTRACT

Dioscorea bulbifera (DB)is one among the traditionally used medicinal plant which has been reported to have anticancer property and capable of inducing apoptosis of tumors, but the poor water solubility restricts its pharmacological application. The study aims at improving the aqueous solubility of *Dioscorea bulbifera* and enhancing the bioavailability by formulating Pluronic F-127 and Soluplus® incorporated polymeric mixed micelles (PL–SO–MMs). Micelles were prepared by thin film dispersion method, using 3^2 factorial design-response surface methodology with Particle size (nm) and entrapment efficiency (EE%)as indicators. Transmission electron microscopy (TEM)images revealed that prepared Mixed Micelles were nano-spherical and having average particle size of 61.45 ± 0.4 nm and zeta potential in range of −18.11 ± 1.2 mV to −21.70 ± 0.9 mV and with acritical micelle concentration (CMC) of 0.821 ± 0.002 % w/v. The cell toxicity assays of DB loaded Polymeric mixed micelles was performed on MCF7 and MDAMB-231 showed higher cell toxicity compared with free DB. The IC_{50} values of DB and DB loaded PL–SO–MMs on MCF7 and MDAMB-231 were 8.92μg/ml,12μg/ml and 3.07 μg/ml, 8.1 μg/ml respectively. In conclusion, the Mixed Micelles (PL–SO–MMs) developed in the present study were proven as promising drug delivery system for *Dioscorea bulbifera*.

1. Introduction

Applications of nanoparticles in drug delivery are escalating with advancement in technology and of various nanocarriers being researched till date, among which micellar systems are found to be promising drug delivery system. This nano-sized drug delivery system provides increased solubility and stability of the hydrophobic drug and in-vivo advantages versus the free drug. The stability of the mixed micelles depends on copolymers self-aggregation tendency. The critical micelle concentration (CMC) of the amphiphilic polymers is influenced by the hydrophilic-lipophilic balance (HLB) of the polymer [1,2]. Nanocarriers are a very important constituent of novel drug formulation as they protect and stabilize sensitive agents and increase bioavailability with fewer side effects.

Mixed micelles is a novel nano delivery system made up of a combination of two or more amphiphilic block copolymers presents several advantages such as, selective Targeting, improving drug-loading capacities, greater stability, protection of drug against oxidation and premature drug degradation and importantly, reduction in side effects [3,4].Poorly water-soluble drugs can be easily entrapped into the hydrophobic inner core and the core is surrounded by a hydrophilic outer shell that can self-assembled into polymeric micelles in an aqueous solution [5]. The degradation rate and the drug release rate can be adjusted by varying the ratio of a hydrophilic and lipophilic polymer [6]. Mixed micelles can self-assemble with two or more similar structures and performance block copolymers. Mixed micelles can provide multiple functionality micelles by constituent copolymers.

Soluplus® (SO) a graft copolymer consisting of polyethylene glycol (PEG), polyvinyl caprolactam, and polyvinyl acetate shows an excellent self-assembling micelle forming property. The block polymer shows enhanced micellar property because of its amphiphilic character, ultimately leading to formation of micelle in various aqueous mediums and increasing the bioavailability of drug by enabling the solubilisation of poorly water-soluble drugs [7]. Pluronic F-127 known as Poloxamers are also among the class of block copolymers, structurally consisting of poly (ethylene oxide) (PEO) and poly (propylene oxide) (PPO), possessing amphiphilic characteristics and various association and adsorption properties. Particularly, this polymer improves the aqueous

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28.	Preclinical evaluation of hydroalcoholic extract of sesbania sesban leaves on antiulcer activity by pylorus ligation induced gastric ulcer on experimental rats.	Rutuja D. Vibhute*, Swati U. Kolhe and Sachin V. Tembhurne	European Journal of Biomedical and Pharmaceutical Sciences. 2020, 7(12), 226-230	2020	View Article	96
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1. Self-microemulsifying drug delivery system (SMEDDS) of curcumin attenuates depression in olfactory bulbectomized rats

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Research article

Self-microemulsifying drug delivery system (SMEDDS) of curcumin attenuates depression in olfactory bulbectomized rats

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Pharmacology
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Depression
Curcumin
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SMEDDS

ABSTRACT

Background: Current therapies for depression remain limited and plagued by various side effects. Problems associated with curcumin administration include poor aqueous solubility and bioavailability issues. Hence to overcome these, curcumin self micro emulsifying drug delivery system (SMEDDS) which will result in a nanosize emulsion droplets when administered *in vivo* were formulated in the present study.
Methods: Depression was induced by bilateral olfactory bulbectomy and the animals were randomized into 8 groups as normal, control [(vehicle 10 ml/kg, p.o., (per oral)], pure curcumin (10, 20, 40 mg/kg, p.o.), and curcumin SMEDDS (10, 20, 40 mg/kg, p.o). After 14 days of respective treatment, behavioral parameters such as open field test (OFT), ambulation counts and passive avoidance response (PAR) were evaluated. At the end of experiments, blood was withdrawn from r.o.p (retro orbital plexus) for serum cortisol estimation.
Results: In OFT, increased central area frequency, peripheral area frequency, central area duration and decreased rearing and grooming were recorded with an increased ambulation counts. In PAR, significant reduction in number of trials and step down from platform was observed in the animals treated with test drug. Serum cortisol level was also found to be decreased in the test groups.
Conclusion: Behavioral and biochemical estimations in the present study revealed the improved brain permeability and further increase in biological activity of curcumin SMEDDS.

1. Introduction

The term psychiatric illness (or mental illness) encompasses a broad range of medical conditions affecting thinking, feeling, mood, ability to relate to others and daily functioning within society. Such conditions include schizophrenia, psychosis, depression, bipolar affective disorder, anxiety disorders (e.g. panic disorder, obsessive-compulsive disorder and post-traumatic stress disorder) and disorders relating to substance abuse [1]. As per WHO, major depression represents the most common mental health problem worldwide with an estimated 322 million people, equivalent to 4.4% of the world's population [2]. Most common clinical manifestation includes feeling of intense sadness, worthlessness or excessive guilt. Symptomatically, a significant increase or decrease in appetite, loss of interest or pleasure and in worsening conditions, suicidal ideation or suicidal attempts [3]. The clinical manifestation of different types of depression may be diverse but all these types of depression ultimately affect mood or thoughts [4, 5]. Selective Serotonin Reuptake Inhibitors (SSRIs') are the mainstay for the management of depression [6, 7]. But existing drug therapies are linked with adverse effects like anorexia, decreased libido, activation and aggravation of psychosis, serotonin syndrome, cheese reaction etc. [8]. Hence, plant derived products are increasingly being sought out as an option to avert the adverse effects with an existing therapy. St John's Wort (*Hypericum perforatum L.*) is a drug from natural origin which is now accepted as the classified antidepressant drug [9, 10].

Turmeric is most widely used as flavoring and coloring agent in various Indian dishes. It has a wide biological and pharmacological profile as it is reported to possess anti-oxidant, anti-inflammatory and anti-carcinogenic properties [11, 12]. It also possess hypocholesterolemic, antibacterial, wound healing, antispasmodic, anticoagulant, antitumor and hepatoprotective activities [13]. Curcumin from *Curcuma longa L.* has also been reported for its potent antidepressant activity [14, 15, 16]. Curcumin is an inhibitor of monoamine oxidase (MAO) enzyme and also modulates the levels of norepinephrine, dopamine, and

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2. Molecular docking, synthesis, and characterization of chitosan-graft-2-mercaptobenzoic acid derivative as potential drug carrier

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ARTICLE

Applied Polymer SCIENCE WILEY

Molecular docking, synthesis, and characterization of chitosan-graft-2-mercaptobenzoic acid derivative as potential drug carrier

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Abstract

Chitosan is a hydrophilic polymer with prominent mucoadhesive properties. However, it forms weak hydrogen bonds with mucin thus limiting its mucoadhesion and exhibit reduced bioavailability due to its short retention time in the body. The aim of the present study was to synthesize and characterize novel thiolated chitosan with improved functional property. A unique approach of using molecular docking to select ligand to chemically modify chitosan has been employed in the present research. A set of ligands were screened virtually using docking analysis and 2-mercapto benzoic acid showed the lowest glide score of −4.31 Kcal/Mol thus displayed better binding interaction with chitosan. Based on the docking results, the best-fit ligand was selected for wet lab synthesis. 2-Mercapto benzoic acid was covalently attached to chitosan via formation of an amide bond and the reaction was mediated by carbodiimide and *N*-hydroxysuccinimide. The synthesized polymer was in turn evaluated for zeta potential, Fourier transformed infrared, differential scanning calorimetry, molecular weight that confirmed conjugation of chitosan with the thiol ligand. The prepared thiomer was further subjected to mucoadhesion studies and displayed better mucoadhesion properties as compared to unmodified chitosan. Thus, the potential of the novel thiomer can be further explored as an excipient for drug delivery system with an emphasis on mucoadhesion.

KEYWORDS
adhesives, biomaterials, grafting, polysaccharides, theory and modeling

1 | INTRODUCTION

Chitosan is a natural biodegradable, biocompatible, and nontoxic polysaccharide exhibiting mucoadhesive properties.[1,2] Synthetic alteration of chitosan gives another approach to growing new subordinates having promising biological activities and physiochemical properties. Various derivatives of chitosan are prepared by chemical modification without changing the overall effects of chitosan. The prominently modified chitosans are quarternized chitosan, N-alkyl chitosan, carboxy alkyl chitosan, acyl chitosan, thiolated chitosan, and sulfated chitosan.[3] The chemical modification of chitosan by thiolation is mainly aimed at improving its mucoadhesive

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3. Brain Targeted Delivery of Rizatriptan using Glutathione Conjugated Liposomes through Transmucosal Nasal Route

Int. J. Pharm. Investigation, 2020;10(3):344-350 *Original Article*

Brain Targeted Delivery of Rizatriptan using Glutathione Conjugated Liposomes through Transmucosal Nasal Route

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ABSTRACT

Objectives: The objective of this work was to enhance the bioavailability of rizatriptan for brain targeted drug delivery through glutathione conjugated liposomes. **Methods:** Cholesterol glutathione conjugate was synthesized used as a rigidizing agent for liposomes. Liposomes with free cholesterol were also prepared for comparison. 9 batches each were prepared for glutathione conjugated liposomes and non-conjugated liposomes. All formulations were administered to rats. **Results:** For optimum non-conjugated liposomes batch particle size, drug release and entrapment efficiency were found to be 181nm, 90.2% and 88.1% respectively whereas the same values for glutathione conjugated batch were 194 nm, 84.9% and 86.4% respectively. Zeta potential was between 5 to 19. Polydispersity index was below 0.5. Scanning electron microscopy revealed slightly different shapes for both types of liposomes. These two types of rizatriptan liposomes and marketed oral tablet were administrated to rats to study plasma and brain levels. The t_{max} for liposomes was faster (1 hr) as compared to the oral tablet. C_{max} and AUC values for oral tablet, non-conjugated liposomes and conjugated liposomes were found to be 150.19 ng/ml and 223.99 ng.hr/ml; 320.55 ng/ml and 426.6 ng.hr/ml; 410.12 ng/ml and 543.49 respectively. Maximum brain levels were achieved by glutathione conjugated liposomes over other liposomes and oral delivery (C_{max} 310.46, 135.42 and 79.16 ng.ml respectively; AUC 786.94, 229.55 and 118.11 ng.hr/ml respectively). Drug targeting efficiency for conjugated liposomes was about 5 times higher. **Conclusion:** The study concluded that glutathione conjugated liposomes of rizatriptan administered by nasal transmucosal route can offer a promising approach to enhance targeted delivery to brain and bioavailability.

Key words: Glutathione, Liposomes, Migraine, Rizatriptan, Brain targeted drug delivery, *in-vivo* evaluation.

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INTRODUCTION

Rizatriptan is commonly used for the treatment of migraine headache. It acts through one or more of the following mechanisms: it stimulates the presynaptic 5-HT1D receptors and inhibits both dural vasodilation and inflammation; inhibition of trigeminal nuclei cell excitability in the brainstem and vasoconstriction of vessels. Although oral absorption of rizatriptan is about 90%, it has a bioavailability of only 45 to 47% due to extensive hepatic first pass metabolism.[1] The major enzyme that metabolizes rizatriptan in monoamino oxidase A. The metabolites produced are pharmacologically inactive.

Nasal transmucosal drug delivery offers a promising approach for systemic delivery due to numerous advantages like non-invasive nature, faster drug permeation across the mucus membrane etc.[2] The nasal route is also beneficial because of its preferential delivery to the brain via olfactory pathway without encountering the blood brain barrier.[3] The aforementioned challenges faced in the oral therapy of rizatriptan can be overcome with nasal administration.

Liposomes are vesicles found to be effective in crossing various body membranes.[4] The basic structure of liposomes is a bi-layer lipid vesicle with an inside aqueous compartment. High lipid content present in liposomes makes them suitable for targeting the drug across the highly lipophilic blood brain barrier.[5] BBB contains tight junctions of highly specialized brain endothelial cells and epithelial structure of the fully differentiated neurovascular system.

Cholesterol is an integral part of liposomes as it gives rigidity to liposomal walls. It provides thermal and physical stability to liposomes. Cholesterol is also a potential candidate for conjugation with peptides which are intended for targeting the drug specifically to certain organs in the body. Glutathione is proposed to be an excellent agent for selective targeting to the brain. Conjugation of cholesterol with glutathione would assert that liposomal surface would bear the glutathione moiety. As cholesterol is present in the membrane of liposomes, the conjugated moieties would protrude outwards and insides of the liposomes. The mere addition of glutathione during the preparation of liposomes would not be sufficient for successful targeting of liposomes as these targeting ligands should be present on the surface of liposomes.

Furthermore, the distribution of drugs and transport across BBB can be enhanced by targeting the drug selectively to the brain. For targeting the drug to brain glutathione was proposed as a targeting ligand in the present work. GSH is present in high amounts in the body. GSH is a natural antioxidant, found at high levels in the brain, with an excellent safety profile; only the BBB possesses GSH transporters that actively carry GSH to the brain against a gradient concentration.[6,7] It does not require the modification of the active components, thereby avoiding the need for extensive preclinical tests and clinical trials before regulatory agencies approval, can carry various classes of molecules, has low costs and straightforward manufacturing.

Attributing to all these advantages, the liposomal drug delivery system containing GSH as the ligand was used to target delivery of rizatriptan to brain.

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4. In situ Nasal Gel of Granisetron for Enhancement of Bioavailability over Oral Delivery: Formulation, Optimization, and In vivo Evaluation

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Research Article

In situ Nasal Gel of Granisetron for Enhancement of Bioavailability over Oral Delivery: Formulation, Optimization, and *In vivo* Evaluation

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ABSTRACT

The objective of the present work was the formulation, optimization, and *in vivo* evaluation of *in situ* nasal gel of granisetron (GRA) that shows liquid to gel transformation at nasal temperature (32–34°C) and maximum drug release after 4 hours; shows bioavailability enhancement over oral delivery. Formulations were prepared using poloxamer PF 127 as gel-forming polymer, carbopol as a mucoadhesive agent, and fulvic acid as a penetration enhancer. A Box-Behnken design was used to prepare the experimental batches and Design Expert software for optimization of the formulation. *Ex vivo* evaluations were carried out on sheep nasal mucosa and for *in vivo* evaluation, rabbits were used. It was observed that optimized formulation showed gelation temperature near 33°C and drug release of 96% after 4 hours. Fulvic acid was evaluated as a penetration enhancer in this work and showed significant enhancement of drug diffusion across the nasal mucosal membrane. *Ex vivo* histological evaluation of nasal mucosa treated with optimized formulation showed no significant destructive effects. *In vivo* evaluations showed that the plasma level profile of prepared *in situ* nasal gel was enhanced significantly over oral delivery. The findings suggested that nasal route nasal transmucosal delivery of GRA can result in enhancement of its bioavailability over the oral route.

INTRODUCTION

The GRA is a potent 5-HT3 receptor antagonist, widely prescribed for the prevention and treatment of chemotherapy-induced nausea and vomiting. Although GRA is rapidly absorbed from the gastrointestinal tract, it is subjected to extensive first-pass metabolism. The oral bioavailability of GRA is about 41 to 60%. In healthy volunteers, a half-life of about 3 to 4 hours is reported.[1,2] Therefore, current GRA treatment generally involves an oral dose of 1 to 2 mg within 1-hour before the start of chemotherapy treatment, then 2 mg daily in 1 to 2 divided doses up to 4 days. Also, a single 3 mg IV dose of GRA can be administered, repeated if necessary with a maximum daily dose of 9 mg.[1,3] Although GRA is effective when given orally, it has got many limitations. Once vomiting has started, particularly if it is moderate or severe, the oral route clearly cannot be used and some alternative is needed. The most common parenteral alternatives to the oral route are injectables. The limitations of these dosage forms include pain and the need for a skilled person for administration because of their invasive nature. In order to improve patient acceptance, there is a need to design a dosage form that offers the advantages of injectables, like the rapid onset of action, improved bioavailability, and simultaneously it should allow self-administration and be non-invasive.

The transmucosal route is being explored as a non-invasive alternative to injectable parenteral routes.[4,5] The mucous membrane is present at various sites, like the nasal cavity, buccal cavity, git, rectum, vagina, eyes, etc.

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5. Exploring Recent Advances in Nanotherapeutics

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Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

Open Access Review Article

Exploring Recent Advances in Nanotherapeutics

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ABSTRACT

Nanotechnology is a rapidly expanding field, encompassing the development of materials in a size range of 5-200 nanometers (nm). The applications of nanotechnology to drug delivery opened the floodgates to create novel therapeutics and diagnostics which have changed the landscape of pharmaceutical and biotechnological industries. Advances in nanotechnology are being utilized in medicine for therapeutic drug delivery and treatment of various diseases and disorders. The biodegradable nanoparticle/nanocarriers, in which drug is dissolved and entrapped are specially designed to absorb the drug and to protect it against chemical and enzymatic degradation. The important role to design these nanostructures as a delivery system is to release pharmacologically active molecules for site-specific action with an accurate dose. In recent times, several biodegradable polymeric nanostructures have been developed with an innate capacity to target specific organs/tissue to deliver the drug. Nanoparticulate drug delivery systems use polymers or lipids as carriers for drugs. Newer polymers engineered to achieve temporal and spatial drug delivery form the mainstay of these systems. In nanotechnology, being tiny molecules of immunotherapeutic have many advantages over biological drugs regarding complexity, tissue penetration, manufacturing cost, stability and shelf life, which is one of dominating therapy in the current research field. The present review gives details about the recent developments of nanostructure drug delivery systems and their applications.

Keywords: liposomes, polymeric micelles, gold nanoparticles, superparamagnetic nanoparticles, solid lipid nanoparticles, aptamers, quantum dots.

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INTRODUCTION

Nanotechnology is a dynamic and multi-disciplinary field, encompassing a plethora of generically distinct spheres such as nanoelectronics, information technology, biotechnology and cellular and molecular biology. In the last two decades, we have seen its profound impact on drug delivery, diagnostics, nutraceuticals and production of biomaterial[1].The development of various novel material processes and phenomena in the nanoscale and the advances in theoretical as well as experimental techniques for research have spawned the development of innovative nanosystems and nanostructured materials[2].The applications of nanotechnology to drug delivery opened the floodgates to create novel therapeutics and diagnostics which have changed the landscape of pharmaceutical and biotechnological industries. Various nanotechnology platforms, either in the form of developmental or clinical stages are being investigated to achieve effective and safer targeted therapeutics for a wide gamut of clinical application[3]. In nanotechnology, being tiny molecules of immunotherapeutic have many advantages over biological drugs regarding complexity, tissue penetration, manufacturing cost, stability and shelf life, which is one of dominating therapy in the current research field[4].

Nanoparticulate drug delivery systems use polymers or lipids as carriers for drugs. Newer polymers engineered to achieve temporal and spatial drug delivery form the mainstay of these systems. Craparo E et al (2008) described the preparation of PEGylated nanoparticles of acryloylated polyaspartamide polymers using rivastigmine as a model drug and their physicochemical and *in vitro* biological characterization[5]. The nanosystems were evaluated for cytotoxicity and their ability to circumvent the macrophage system. Doxorubicin nanoparticles of poly (butyl cyanoacrylate) exhibited efficient brain-targeting in intracranial glioblastoma in rats. Proteins are biodegradable, biocompatible, and versatile and the presence of several synthetic functional groups in protein molecules are potential sites for covalent or non-covalent bonding of drugs. This is exemplified by paclitaxel-loaded albumin nanoparticles which are used for the treatment of metastatic cancer[6].

Kreuter J et al (2007) have described the delivery of apolipoprotein A-I and apolipoprotein B-100 to the brain by

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6. Stability indicating HPTLC method for Sofosbuvir and Daclatasvir in combination

Article

Stability Indicating HPTLC Method for Sofosbuvir and Daclatasvir in Combination

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Authors:

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Abstract

Direct acting antiviral agents represent the major advance in treatment of hepatitis C virus (HCV) infection. Daclatasvir with sofosbuvir that are co-administrated once per day oral dose has been reported to achieve a high rate of virological response in patients with HCV genotype 1, 2 or 3. So, the basic objective of a research involved development and validation of stability indicating HPTLC Method for simultaneous estimation of Sofosbuvir and Daclatasvir available in market in the form of combination tablet. Samples were applied on HPTLC aluminium plates precoated with silica gel 60 F254 (250µm thickness). Mobile phase consists of ethyl acetate: isopropanol in the ratio 9:1v/v. A good resolution was observed between peaks of both the drugs. The retention factor for Sofosbuvir is about 0.51 ±0.02. And for Daclatasvir is about 0.30 ± 0.02. Deuterium lamp as a source of radiation at the wavelength of 260 and 318 nm for analysis of Sofosbuvir and Daclatasvir, respectively. The proposed method was validated according to ICH guidelines and the results were acceptable for linearity and range, accuracy, precision, robustness, detection limit and quantitation limit. The calibration curves were linear over a wide range of 200-1000 ng/band (r2= 0.991) for Sofosbuvir and 45-225 ng/band (r2=0.990) for Daclatasvir. The limit of detection was found to be 21.17 ng/band and 4.38 ng/band for SOF and DAC and limit of quantitation was 64.18 ng/band and 13.28 ng/band for SOF and DAC respectively. During stress degradation study, it was observed that the Daclatasvir is degraded less in thermal and photolytic condition but more in basic hydrolysis condition. Sofosbuvir was found to be sensitive to all stress conditions except the fluorescent light. The suggested method was successfully applied for analysis of both drugs and excellent recovery results were obtained. Being simple, fast, robust, and economic, the method could be applied to the quality control and routine stability monitoring of Sofosbuvir and Daclatasvir.

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7. Validated Stability indicating HPTLC method for Protocatechuic Acid

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VALIDATED STABILITY INDICATING HPTLC METHOD FOR PROTOCATECHUIC ACID

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Keywords:

Protocatechuic acid, Stress degradation, HPTLC

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Abstract: Protocatechuic acid (PCA) is a type of widely distributed naturally occurring phenolic acid, commonly found in bran, grain, brown rice, fruits such as plums, gooseberries, grapes and also in onion peels. A new, simple, precise, accurate and sensitive stability-indicating HPTLC method for Protocatechuic acid was successfully developed. This method is based on HPTLC separation followed by UV detection at 258 nm. The HPTLC method is used to determine the presence and quantify the protocatechuic acid in onion peel extract. The separation was carried out on Merck TLC aluminum sheets precoated with silica gel 60F254 using Toluene: Ethyl Acetate: Formic acid (6:6:1.2 v/v/v) as a mobile phase and scanning was done by using TLC Scanner III. Protocatechuic acid gave well defined and sharp peak at R_f 0.52 ± 0.03 at 258 nm. The calibration curve was linear in range 100-500 ng/band. Protocatechuic acid was subjected to stress conditions like hydrolysis under acidic, basic and neutral conditions, oxidation, heat, and photolysis.

INTRODUCTION: Protocatechuic acid (PCA) is a type of naturally occurring phenolic acid. PCA is chemically 3, 4-dihydroxybenzoic acid. PCA has structural similarity with gallic acid, caffeic acid and vanillic acid which are well-known antioxidant compounds. The chemical formula is C7H6O4, and molar mass is 154.12 g/mol. It is freely soluble in methanol and sparingly soluble in water, insoluble in benzene [1, 2]. Protocatechuic acid has many pharmacological activities such as anti-bacterial, anti-inflammatory, hepatoprotective, anti-cancer, anti-diabetic, anti-oxidant, anti-ulcer, anti-mutagenic, analgesic, *etc* [3-10].

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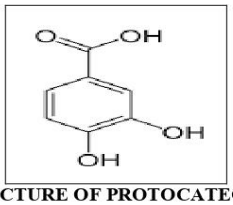

FIG. 1: STRUCTURE OF PROTOCATECHUIC ACID

As per literature search there is no stability-indicating method reported for determination of protocatechuic acid in onion peel by HPLC and HPTLC. Development of SIM is based on systematic exposure of API to various stress conditions. Systematic optimization trials are required to arrive at combination of "concentration of stress reagent and duration of exposure," to obtain degradation preferably in the 10-20% range. Typical degradation conditions involve hydrolysis under different pH conditions, photolysis, oxidation and thermal studies [12 - 13].

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8. Validated stability indicating HPTLC method for Sofosbuvir and Velpatasvir

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Research Article

Stability Indicating HPTLC Method for Sofosbuvir and Velpatasvir in Combination

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ABSTRACT

The discovery of new direct-acting antiviral drugs gave rise to a leap forward in the treatment of hepatitis C viral (HCV) infections. For the first time since 1998, the Food and Drug Administration (FDA) approved interferon-free oral treatment paradigms. Among the new treatment regimens, the combinations of Sofosbuvir (SOF) and Velpatasvir (VEL) became ideal treatment regimens for being potent, highly tolerated, and used once daily. Hence accurate, precise, selective, and sensitive stability-indicating method for simultaneous estimation of SOR and VEL by high-performance Thin layer chromatography has been developed and validated. Chromatographic separation was achieved on TLC plates coated with silica gel 60 F_{254} as a stationary phase. Ethyl acetate: isopropyl alcohol (9:1 v/v) was used as a mobile phase. Densitometric scanning was carried out at 260 and 302 nm for SOF and VEL, respectively. The method was successfully validated as per the ICH Guideline. The linear concentration range was 100-2000 ng/band (r^2 = 0.991) and 100-500 ng/band (r^2 = 0.991) for SOF and VEL respectively. The LoD was 25.16 ng/band and 9.96 ng/band for SOF and VEL, LoQ were 76.25 ng/band and 30.19 ng/band for SOF and VEL. The method could be applied to the quality control and routine analysis of SOF and VEL in their pure forms and pharmaceutical formulations.

INTRODUCTION

Hepatitis C is a liver disease caused by the HCV. The fixed drug combination consists of sofosbuvir (SOF) (400 mg) and Velpatasvir (VEL) (100 mg), used in the treatment of hepatitis C. This is a new direct-acting antiviral drug combination, which is approved by United States Food and Drug Administration in June 2016. The combination of SOR and VEL became the ideal treatment regimen for being most potent, highly tolerated. This direct-acting antiviral was approved for the treatment of adults with chronic hepatitis C with or without compensated cirrhosis, and in combination with ribavirin for decompensated cirrhosis, for all 6 genotypes.

The IUPAC name of SOR is Isopropyl (2*S*)-2-[[[(2*R*,3*R*,4*R*,5*R*)-5-(2,4-dioxopyrimidin-1-yl)-4-fluoro-3-hydroxy-4-methyl-tetrahydrofuran-2-yl]-methoxy-phenoxy-phosphoryl]-amino]-propanoate. It is inhibitor of the HCV NS5B ribonucleic acid (RNA) dependent RNA polymerase, which undergoes intracellular metabolism to form uridine analogue triphosphate and inhibits the viral replication by incorporating into HCV RNA and acts as a chain terminator.

VEL chemically is methyl((S)-1-((S)-2-(5-(6-(2((S)-1-((methoxycarbonyl)-L-valyl)pyrrolidin-2-yl)-1H-imidazol-4-yl)naphthalen-2-yl)-1H-benzo[d]imidazol-2-yl) pyrrolidin-1-yl)-3-methyl-1-oxobutan-2-yl)carbamate is an inhibitor of HCV NS5A protein, which blocks the action of the protein and inhibits the viral replication.

The main objective of the current work was to develop and validate the stability-indicating high-performance thin layer chromatography (HPTLC) method for the

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9. Stability indicating HPTLC method for analysis of Teriflunomide

Stability Indicating HPTLC Method for Analysis of Teriflunomide

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Abstract | Cite | References | Authors Details

Abstract

Teriflunomide is an immunosuppressive agent that inhibits or prevents activity of immune system. Teriflunomide is not official until to date in IP, USP, and BP. Many studies have reported the HPLC, UPLC, LC/MS methods for estimation of teriflunomide. The current work is intended towards the development of a stability indicating method by high-performance thin layer chromatographic (HPTLC) method coupled with a densitometer for the estimation of Teriflunomide. The chromatographic development was performed on aluminium plates coated with silica gel 60 F254 using toluene: ethyl acetate: glacial acetic acid as the mobile phase. Densitometric scanning was achieved at theabsorbance maxima 294 nm. Teriflunomide was subjected to hydrolysis under different pH conditions, oxidation, thermal and photolytic stress conditions. A well-separated band was observed with Rf value 0.46 ± 0.01. The calibration curve plotted in the concentration range 100-500 ng/band exhibited an excellent linear relationship with the R2 value of 0.997. The method was found to comply with all the validation parameters as per the ICH guidelines Q2 (R1). This stability indicating method ensures short run time compared to other reported analytical methods. This validated method can be used by quality control laboratories for monitoring the stability of teriflunomide.

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10. Development and Validation of Stability Indicating HPTLC method for Determination of Indapamide and Amlodipine Besylate

WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES
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DEVELOPMENT AND VALIDATION OF STABILITY INDICATING HPTLC METHOD FOR DETERMINATION OF INDAPAMIDE AND AMLODIPINE BESYLATE

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ABSTRACT

A new simple, accurate, precise and sensitive stability- indicating high performance thin layer chromatographic (HPTLC) method was developed and validated for simultaneous estimation of Indapamide and Amlodipine besylate in bulk and in tablet dosage form. The chromatographic development was carried out on precoated silica gel 60 F_{254} aluminium plates using mixture of Chloroform: Glacial acetic acid: Methanol (8.5: 1: 0.5 v/v) as mobile phase and densitometric evaluation of bands at 241 nm using Camag TLC Scanner-3 with win CAT 1.4.3 version software. The R_f value of Indapamide and Amlodipine besylate were found to be 0.69 ± 0.02 and 0.29 ± 0.02, respectively. The method was validated with respect to linearity, accuracy, precision and robustness. The calibration curve was found to be linear over a range of 100 - 1000 ng/ band for Indapamide and 500 – 3000 ng/ band for Amlodipine Besylate. The drugs were subjected to stress condition of hydrolysis (acid, base, neutral), oxidation, photolysis and thermal degradation.

KEYWORDS: Indapamide, Amlodipine besylate, HPTLC, Stability.

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11. Development and Validation of Stability Indicating HPTLC Method for Estimation of Ledipasvir

WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES
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DEVELOPMENT AND VALIDATION OF STABILITY INDICATING HPTLC METHOD FOR ESTIMATION OF LEDIPASVIR

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ABSTRACT

The present work describes development and validation of a new simple, accurate, precise and selective stability-indicating high performance thin layer chromatographic (HPTLC) method for determination of Ledipasvir as bulk drug and in synthetic mixture. As stability testing is major step with the development of new drug formulation, stress degradation studies were carried as per ICH guidelines. Chromatographic resolution of Ledipasvir and its degradation products was achieved by using precoated, silica gel 60 F-254 aluminium plates as stationary phase and Ethyl acetate: Methanol (9.5:0.5, v/v) as mobile phase. Densitometric scanning was carried out at 334 nm. The retention factor was found to be 0.31 ± 0.02. The developed method was validated with reference to linearity, accuracy, precision, limit of detection, limit of quantitation and robustness as per ICH guidelines. Results found to be linear within the concentration range of 200-1200 ng/band. Ledipasvir was mainly found susceptible to acid, alkali hydrolysis as well as oxidation. The developed method has been successfully applied for the estimation of drug in synthetic mixture.

KEYWORDS: Ledipasvir, HPTLC, Stability indicating, forced degradation, Method Development and Validation.

INTRODUCTION

Ledipasvir (LPV),chemically methyl N[(2S)-1-[(6S)-6-[5-[9,9-difluoro-7-[2[(1S,2S,4R) -3 -[(2S) -2(methoxycarbonylamino)-3methylbutanoyl]-3-azabicyclo[2.2.1]heptan-2-yl]-3H benzimidazol-5-yl]fluoren-2-yl]-1H-Imidazol-2yl]-5-azaspiro[2.4]heptan-5-yl]-3-methyl-1oxobutan-2yl]carbamate[1] (Figure 1) is an orally available inhibitor of the hepatitis C virus

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12. Development and Validation of UV Spectrophotometric Methods for Estimation of Terbuataline Sulphate and Bromhexine HCl in Combined Dosage Form

WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES
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DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRIC METHODS FOR ESTIMATION OF TERBUATALINE SULPHATE AND BROMHEXINE HCl IN COMBINED DOSAGE FORM

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ABSTRACT

A simple, accurate and precise spectrophotometric methods has been developed for simultaneous determination of Terbutaline sulphate and Bromhexine HCl in bulk and in combined pharmaceutical dosage form. The methods developed were area under curve method and first derivative spectroscopy method using methanol as solvent. Regression analysis of beers plot showed good correlation range of 5-30 µg/ml for Terbutaline sulphate as well as for Bromhexine HCl. Proposed methods have been extensively validated as per ICH guidelines. There was no significant difference between the performance of the proposed methods regarding the mean values and standard deviations. Methods can be used for routine determination of these two drugs in combined dosage form.

KEYWORDS: UV-Spectrophotometry, Terbutaline sulphate, Bromhexine HCl, Validation.

INTRODUCTION

Terbutaline Sulphate is chemically 5-[2-(tert-butylamino)-1-hydroxyethyl]benzene-1,3-diol;sulfuric Acid. It is the sulfate salt form of terbutaline, an ethanolamine derivative with bronchodilating and tocolytic properties. Terbutaline sulfate selectively binds to and activates beta-2 adrenergic receptors, leading to intracellular adenyl cyclase activation via a trimeric G protein and subsequent increase in cyclic cAMP production. Increased cAMP levels result in relaxation of bronchial and vascular smooth muscle mediated through the activation of protein kinase A (PKA), which phosphorylates proteins in control of muscle tone. cAMP also

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13. Development and Validation of UV Spectrophotometric Methods for Estimation of Cefuroxime Axetil and Linezolid in Combined Dosage Form

WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES
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DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRIC METHODS FOR ESTIMATION OF CEFUROXIME AXETIL AND LINEZOLID IN COMBINED DOSAGE FORM

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ABSTRACT

The present work deals with simple spectrophotometric method development for simultaneous estimation of Cefuroxime axetil and Linezolid in bulk and in two component tablet formulation. The methods developed were first derivative spectroscopy method and area under curve method. Methanol was used as solvent throughout the analysis. Regression analysis of beers plot showed good correlation in the range of 5-30 µg/ml for Cefuroxime as well as for Linezolid. The recovery studies confirmed accuracy of proposed method and low values of standard deviation confirmed precision of method. The method is validated as per ICH guidelines. The proposed method was successfully applied for determination of these drugs in formulation.

KEYWORDS: UV-Spectrophotometry, Cefuroxime, Linezolid, Validation.

INTRODUCTION

Cefuroxime Axetil is chemically (1 RS)-1-(acetyloxy)ethyl(6R,7R)-3[(carbamoyloxy)methyl]-7[[(Z)-2-(furan2-yl)-2-(methoxyimino)acethyl]amino]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate.[1] Cefuroxime is official in Indian pharmacopoeia and United States of Pharmacopoeia.[2] It is the first oral beta-lactam to combine high intrinsic activity with stability to beta–lactamase enzymes from most gram-positive and gram-negative organism and Cefuroxime exerts its bactericidal effect against a range of gram-positive and gram-negative bacteria by inhibiting the synthesis of bacterial cell wall.[3] Linezolid is synthetic antibiotic. It is N-[[(5S)-3-(3-fluoro-4-morpholin-4-ylphenyl)-

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14. Development of Validated Stability-indicating RP-HPLC Method for Determination of Novel Directly Acting Antiviral agent and Characterization of its Degradants by LC–ESI–MS

Original Article

Development of Validated Stability-indicating RP-HPLC Method for Determination of Novel Directly Acting Antiviral agent and Characterization of its Degradants by LC–ESI–MS

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ABSTRACT

Aim: The current study was performed to develop and validate stability indicating high performance liquid chromatography method (RP-HPLC) for determination of ledipasvir (LPR); to identify and characterize its major degradants by liquid chromatographic–tandem mass spectrometric method (LC-ESI-MS). **Materials and Methods:** The method was developed using reverse phase gradient elution and validated for standard ICH parameters. The optimized mobile phase comprised of acetonitrile:water with 0.2 % formic acid (70:30% v/v) at 1 ml/min flow rate with satisfactory retention time (tR), theoretical plates and good resolution of LPR and its degradants. Further, forced degradation under acid, base, thermal, photolytic and oxidative stress conditions was studied as per ICH guidelines. LC-ESI-MS with time of flight analyser was used to characterize the degradants. The degradation pathways for major degradants were proposed. **Results:** The developed method had retention time of 6 mins. The RSD for system was found to be less than 2% whereas mean recovery was obtained 97.2 – 102.5%. Linearity range of 5-30 μg/ml with 0.998 regression coefficient (R^2) was observed. Detection and quantification limits were obtained as 0.010 μg/mL and 0.032 μg/mL, respectively. LPR was stable in photolytic and thermal environments whereas degraded in acid, base and oxidative states. LC–ESI–MS was used effectively for characterization and structural elucidation of degradants. **Conclusion:** The results indicated that validated RP-HPLC technique can be employed for routine analysis of LPR in bulk and dosage formulas and also would be capable of separating degradants from analyte peak.

Key words: RP-HPLC, LC-ESI-MS, Ledipasvir, Stability indicating ICH method, Validation, Degradation pathway.

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INTRODUCTION

Viral hepatitis has become a serious public health concern as it affects more than 3% of world population. Out of this more than 1% of the population is infected by hepatitis C virus (HCV).[1,2] The prevalence of HCV infection doubled between 2010-2014 and till date. Annually almost 1.75 million infections are reported worldwide for HCV infection.[3] If HCV infection remains untreated; can progress to cirrhosis, fibrosis and hepatocellular carcinoma.[4] Such long-term problems are fatal, lethal and a reason for 96% of the deaths owing to viral hepatitis. The people infected with HCV are unaware about the infection, as they don't receive the well identified symptoms till complications emerge. The people may be infected for a period greater than 30 years before they develop clinical symptoms.

Till the development of directly acting antivirals (DAA), ribavirin in combination with the PEGlyated interferon was the only option available for the treatment. Nonetheless, it has been accompanied

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15. Formulation, optimization and evaluation of gastro retentive novel floating in-situ gelling system of *Phyllanthus niruri*

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Research Article
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FORMULATION, OPTIMIZATION AND EVALUATION OF GASTRO RETENTIVE NOVEL FLOATING IN-SITU GELLING SYSTEM OF PHYLLANTHUS NIRURI

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ABSTRACT
The oral liquid dosage forms are more prone to low bioavailability because of their quick transit from the stomach. Producing sustained release formulation of an oral liquid dosage form could be successfully augmented through a strategy of liquid in-situ gelling system. There are many advantages of in situ forming polymeric delivery systems viz. ease of administration and reduced frequency of administration, improved patient compliance and comfort. In-situ forming polymeric formulation is in sol form before administration in the body, but once administered undergoes in-situ gelation. The objective of this study was to develop a novel in-situ gel system of *Phyllanthus niruri* for treatment of peptic ulcer. The delivery system consists of varying concentrations of sodium alginate and calcium carbonate. The system was subjected to various in vitro study. In vitro drug release studies were conducted in 0.1 N HCl. The finalised formulation (F7) contained sodium alginate (0.5 % w/v), calcium carbonate (1.5 % w/v) which showed drug release of 90.7 %. The floating lag time was found to be less than 1 min and system was found to be floating throughout the drug release time of 12 h. The gelation occurred immediately after addition in acidic medium. The optimized cream showed maximum drug release and floating gel was found to give good results.

KEYWORDS: *Phyllanthus niruri*, Corilagin, Floating in situ gel, Gastroprotective, Optimization.

INTRODUCTION

In situ gel forming drug delivery systems are in principle capable of releasing drug molecule in a sustained manner affording relatively constant plasma profiles. These hydrogels are liquid at room temperature but undergo gelation when in contact with body fluids or change in pH. These have a characteristic property of temperature dependent, pH dependent and cation induced gelation. Compared to conventional controlled release formulations, in situ forming drug delivery systems possess potential advantages like simple manufacturing processes and ease of administration.[1,2]

Gastric ulcers are common pathologies that affect a significant number of people around the world. The increased incidence of gastric ulcers is associated with aggressive factors against the gastric mucosa such as ethanol exposure, stress, smoking, nutritional deficiencies and frequent ingestion of non-steroidal anti-inflammatory drugs. Although many conventional drugs are available to treat ulcers, most of these drugs have adverse reactions when used over long term. Moreover, short residence time of drug leads to incomplete eradication of gastric ulcer as there is insufficient concentration of the drug in the gastric mucous layer or epithelial cell surface. The instability of the drug in the low pH of gastric fluid can also be a reason for it. Therefore, it is necessary to design drug delivery systems that not only alleviate the shortcomings of conventional delivery system but also deliver the drug into the epithelial cells.[3-5]

Different therapeutic strategies have been studied for complete eradication of the gastric ulcer. One way to improve the efficacy in eradicating the gastric ulcer is to deliver the drug locally in the stomach. Better stability and longer residence time (gastro retentive system) will allow more of the drug to contact the gastric mucus layer. Many approaches have been reported in the literature for the formulation of gastro retentive systems. Bioadhesive systems may result in irritation of the mucous layer due to high localized concentration of the drug. In addition, single-unit systems such as tablets or capsules may exhibit the all-or none emptying phenomenon leading to variability in bioavailability. Floating in-situ gel (FIG) formulations present a novel and interesting approach to obtain gastro retentive sustained release of drugs and FIG has been developed for several drugs. This system would have the advantage of ease of administration, as being a liquid and also be more patient compliant.[6-9]

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16. Stability indicating RP-HPLC method development and validation for determination of Didanosine in tablet dosage form.

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STABILITY INDICATING RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR DETERMINATION OF DIDANOSINE IN TABLET DOSAGE FORM

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ABSTRACT

The present work describes development and validation of a new simple, accurate, precise and selective stability-indicating reverse phase high performance liquid chromatography (RP-HPLC) method for determination of Didanosine as bulk drug and in tablet dosage form. As stability testing is key step in new drug as well as formulation development, stress degradation studies were performed according to ICH guidelines. Chromatographic resolution of Didanosine and its degradation products was accomplished by use of Jasco HPLC system equipped with Grace C_{18} column (150 x 4.6 mm i.d.) as stationary phase and mixture comprising of Acetonitrile: Methanol (85: 15, v/v) the pH was adjusted to 8 with triethylamine as optimum mobile phase. Densitometric detection was carried out at 250 nm. The retention time was found to be 2.58 ± 0.04 min. The developed method was validated with respect to linearity, accuracy, precision, limit of detection, limit of quantitation and robustness as per ICH guidelines. Results were linear in the range of 5-30 µg mL^{-1}. The developed method has been successfully applied for the estimation of drug in tablet dosage form.

KEYWORDS: Didanosine, RP-HPLC, Forced degradation, Tablet dosage form.

INTRODUCTION

Didanosine, chemically, 9-[(2R,5S)-5-(hydroxymethyl)oxolan-2-yl]-1H-purin-6-one is reverse-transcriptase inhibitor used to treat Human immunodeficiency virus infection and acquired immune deficiency syndrome and used in combination with other medications as part of highly active antiretroviral therapy (HAART).[1]

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17. Validated stability indicating RP-HPLC method development for determination of ebastine in tablet dosage form

WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
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VALIDATED STABILITY INDICATING RP-HPLC METHOD DEVELOPMENT FOR DETERMINATION OF EBASTINE IN TABLET DOSAGE FORM

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ABSTRACT

A new simple, accurate, precise and selective stability-indicating reverse phase high performance liquid chromatography (RP-HPLC) method for determination of Ebastine as bulk drug and in tablet dosage form has been developed and validated. The drug was exposed to hydrolytic, oxidative, thermal and photolytic stress conditions to check the stability nature of drug. Chromatographic resolution of Ebastine and its degradation products was accomplished by use of Jasco HPLC system equipped with HiQSil C_{18} column (150 x 4.6 mm i.d.) using Potassium dihydrogen o-phosphate buffer: Acetonitrile (30: 70, v/v) as mobile phase. Densitometric detection was carried out at 253 nm. The retention time was found to be 3.12 ± 0.02 min. The developed method was validated with respect to linearity, accuracy, precision, limit of detection, limit of quantitation and robustness as per ICH guidelines. Results were linear in the range of 5-30 µg mL^{-1}. The developed method has been successfully applied for the estimation of drug in tablet dosage form.

KEYWORDS: Ebastine, RP-HPLC, Forced degradation, Tablet dosage form, Validation.

INTRODUCTION

Ebastine, chemically, 4-tert-butyl-4[4-(diphenylmethoxy) piperidino] butyrophenone, is a second-generation H1 receptor antagonist with long duration of action and is used mainly for allergic rhinitis and chronic idiopathic urticaria.[1]

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18. Validated stability-indicating RP-HPLCmethod development for simultaneous determination of amlodipine besylate and rosuvastatin calcium in combined tablet dosage form

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VALIDATED STABILITY-INDICATING RP-HPLC METHOD DEVELOPMENT FOR SIMULTANEOUS DETERMINATION OF AMLODIPINE BESYLATE AND ROSUVASTATIN CALCIUM IN COMBINED TABLET DOSAGE FORM

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ABSTRACT
A new simple, accurate, precise and selective stability-indicating reverse phase high performance liquid chromatographic (RP-HPLC) method has been developed and validated for simultaneous estimation of Amlodepine besylate and Rosuvastatin calcium in combined tablet dosage form. An isocratic, reverse phase HPLC method was developed on Jasco HPLC system equipped with Grace C_{18} column (150 x 4.6 mm i.d.) using acetonitrile: 50mM sodium acetate (pH adjusted to 3.1 with ortho phosphoric acid) (60: 40, v/v) as mobile phase and detection was carried out at 250 nm. Both the drugs were subjected to stress condition of hydrolysis (acid, base), oxidation, photolysis and thermal degradation. Results were linear in the range of 10-50 µg mL^{-1} for both the drugs. The retention times for Amlodepine besylate and Rosuvastatin calcium were 3.6 min and 6.1 min, repectively.

KEYWORDS: RP-HPLC, Amlodipine besylate, Rosuvastatin calcium, Forced degradation.

INTRODUCTION

Amlodipine Besylate, chemically, 3-*O*-ethyl 5-*O*-methyl 2-(2-aminoethoxymethyl)-4-(2-chlorophenyl)-6-methyl-1, 4-dihydropyridine-3, 5-dicarboxylate is used as antihypertensive and antianginal drug.[1] Rosuvastatin calcium is the calcium salt form of rosuvastatin with antilipidemic activity and chemically is calcium (*E*, 3R, 5S)-7-[4-(4-fluorophenyl)-2-[methyl (methylsulfonyl) amino]-6-propan-2-ylpyrimidin-5-yl]-3, 5 dihydroxyhept-6-enoate.[2]

Extensive literature survey revealed that different analytical methods such as spectrophotometry,[3] high performance liquid chromatography (HPLC)[4-9] and high performance thin layer chromatography (HPTLC)[10] has been reported for the determination of amlodipine besylate either as single drug or in combination with other drugs. Analytical methods reported for rosuvastatin calcium includes spectrophotometry,[11] high performance liquid chromatography (HPLC)[12-16] either as single drug or in combination with other drugs.

To best of our knowledge, no reports were found in literature for simultaneous determination of Amlodipine besylate and Rosuvastatin calcium in combined tablet formulation by stability indicating RP-HPLC method. Therefore, the present study is aimed at development of suitable stability indicating RP-HPLC method for this combination by degrading the drugs below different stress conditions such as hydrolysis, oxidation, thermal and photolytic stress which is suggested by ICH guidelines.[17,18]

MATERIALS AND METHODS

Chemical and reagents

Working standards Amlodipine besylate and Rosuvastatin calcium were obtained as gift samples from Pfizer Ltd., Thane (Mumbai, India). The pharmaceutical tablet dosage form containing 10 mg of Amlodipine besylate and 10 mg of rosuvastatin calcium was procured from local pharmacy. Acetonitrile (HPLC grade) and AR grade sodium acetate were obtained from Merck specialties Pvt. Ltd. (Mumbai, India).

Instrumentation and chromatographic conditions

JASCO HPLC system equipped with pump (Model PU 2080 Plus), Rheodyne sample injector of 20 µL capacity, PDA detector (MD 2010) operated with Borwin- PDA software (version 1.5). Grace C18 column with dimension 150 x 4.6 mm was utilized. Flow rate of 1 mL min^{-1} was maintained and detection was monitored at 250 nm.

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19. Designing of Thiazolidin-4-one Pharmacophore using QSAR Studies for Anti-HIV Activity

Original Article

Designing of Thiazolidin-4-one Pharmacophore using QSAR Studies for Anti-HIV Activity

Trupti Sameer Chitre*, Shital Manoj Patil, Anagha Govindrao Sujalegaonkar, Kalyani Dhirendra Asgaonkar

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ABSTRACT

Background and Aim: In an effort of drug development in the area of HIV, present work deals with development of 2D and 3D QSAR of thiazolidinone derivatives against HIV-RT activity as a powerful method for elucidation the relationships between structure and activity. **Materials and Methods:** 2D QSAR and 3D QSAR were performed using MLR and SA kNN method respectively. Models which had higher predictability were generated as indicated from their statistical parameters. **Results and Discussion:** Best models generated showed correlation coefficient r^2 = 0.9256 and q^2 =0.8623 for 2D QSAR and q^2 =0.8444 for 3D QSAR. The models indicated the requirement of electro topological, electrostatic and steric descriptors which would significantly contribute to HIV-RT inhibitory activity. Further a few compounds were designed using the outcome of QSAR studies.

Key words: Non-nucleoside Reverse Transcriptase, Human Immunodeficiency Virus-1, QSAR, Thiazolidin-4-one, Combilib.

INTRODUCTION

Development of newer molecules against HIV drug resistant strains is the need of the hour due to rapid emergence of drug resistance strains which are limiting the performance of existing drugs in treatment of HIV.[1] Non-nucleoside reverse transcriptase inhibitors (NNRTIs) have played a significant role in management of HIV infection especially with excellent potency of second generation NNRTIs against wild and various mutant strains of HIV-1. They also provide diversity in chemical structures providing a wider opportunity for drug development.[2-4] Thiazolidin-4-one derivatives have gained importance for drug development because of its wide array of biological activities, including Anti tubercular and Anti-HIV.[5] Several thiazolidin-4-one derivatives have been studied and have shown promising activity at micromolar concentrations against reverse transcriptase with less cytotoxicity.[1,6-9] Quantitative structure activity relationship (QSAR) is an important chemometric method of analysis for rational drug design of new anti-HIV drugs. It reveals the relationship between chemical structures and their biological activity. In continuation of our efforts in computational studies QSAR studies were carried out to predict the desired properties of compounds for a series of thiazolidinone derivatives.[10,11]

In the present study we have performed 2D QSAR with multiple linear regression (MLR) and 3D QSAR using simulated annealing k Nearest Neighbor (SA kNN) method.[12-16] Compounds were designed using Combilib tool and were screened with Lipinski filter to study their drug like pharmacokinetics.

RESULTS AND DISCUSSION

2D QSAR study

The results of unicolumn statistics indicated that the test set molecules were within the activity range of the training set. The mean

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20. A comprehensive overview of synthetic methods of Oxadiazole Thiadiazole and Triazole

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A COMPREHENSIVE OVERVIEW OF THE SYNTHETIC METHODS OF OXADIAZOLE, THIADIAZOLE AND TRIAZOLE.

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Abstract - Many drugs are producing resistance to the various diseases. So, there is an urgent need to synthesize the new chemical entities with potent biological activity. This review may help the medicinal chemist to develop the new chemical entities with Oxadiazole, Thiadiazole and Triazole as the heterocyclic nucleus with higher efficiency and less side effects. This review gives the information about the synthetic routes of the Oxadiazole, Thiadiazole and triazole.

Index Terms - **Oxadiazole, Thiadiazole, Triazole, Synthesis.**

I. INTRODUCTION

It is observed that the five membered heterocyclic rings such as Oxadiazole, Thiadiazole and Triazole give variety of biological activities. [1] [2].

Oxadiazoles are 5-membered heterocyclic fragment compounds consisting of 1 oxygen atom, 2 nitrogen atoms and 2 carbon atoms.[3] Depending on the position of the nitrogen with inside the ring, numerous isomers exist together with 1,2,4-; 1,2,5-; 1,2,3; and 1,3,4-oxadiazole (Figure 1) [4] Various pharmacological activities such as Antibacterial [5], Anti-Fungal [6], Anticonvulsant [7], Anticancer [8], Antitubercular [9], Antimicrobial [10] as well as Analgesic [11] have been reported for this scaffold.

Fig 1 – Isomers of Oxadiazole

Thiadiazole is a five membered ring system containing two nitrogen atoms, one sulphur, two carbon atoms in ring system. [12, 13] Thiadiazole is found in four forms 1,2,4thiadiazole,1,2,3 thiadiazole,1,2,5 thiadiazole and 1,3,4 thiadiazole. (Figure 2) [14] Various pharmacological activities such a [15]. Anti-diabetic [16], antimicrobial [17], anticancer [18], antitumor [19], anti-inflammatory [20], antitubercular [21]as well as antiviral [22] have been reported for this scaffold.

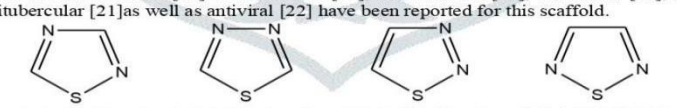

Fig. 2 – Isomers of Thiadiazole.

Triazole is one of the classes of organic heterocyclic compounds containing a five membered structure composed of three nitrogen atoms and two carbon atoms. Two isomers of Triazole are present these are as follows (figure 3):

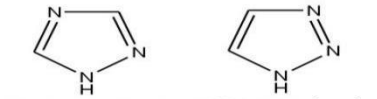

Fig. 3 – Isomers of Triazole.

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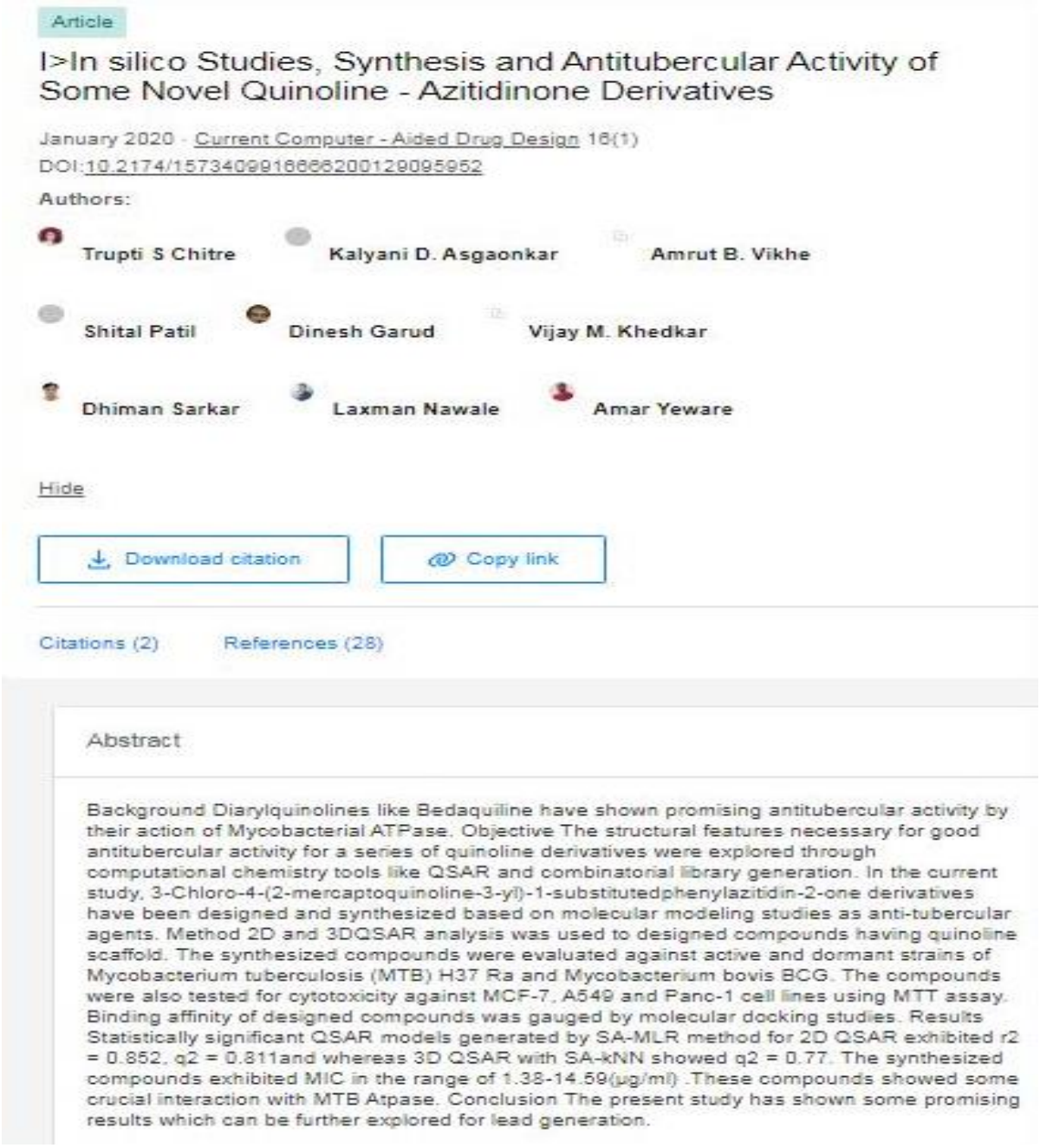
21. In silico Studies, Synthesis and Antitubercular Activity of Some Novel Quinoline - Azitidinone Derivatives



Article

I>In silico Studies, Synthesis and Antitubercular Activity of Some Novel Quinoline - Azitidinone Derivatives

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Citations (2) References (28)

Abstract

Background Diarylquinolines like Bedaquiline have shown promising antitubercular activity by their action of Mycobacterial ATPase. Objective The structural features necessary for good antitubercular activity for a series of quinoline derivatives were explored through computational chemistry tools like QSAR and combinatorial library generation. In the current study, 3-Chloro-4-(2-mercaptoquinoline-3-yl)-1-substitutedphenylazitidin-2-one derivatives have been designed and synthesized based on molecular modeling studies as anti-tubercular agents. Method 2D and 3DQSAR analysis was used to designed compounds having quinoline scaffold. The synthesized compounds were evaluated against active and dormant strains of Mycobacterium tuberculosis (MTB) H37 Ra and Mycobacterium bovis BCG. The compounds were also tested for cytotoxicity against MCF-7, A549 and Panc-1 cell lines using MTT assay. Binding affinity of designed compounds was gauged by molecular docking studies. Results Statistically significant QSAR models generated by SA-MLR method for 2D QSAR exhibited r2 = 0.852, q2 = 0.811and whereas 3D QSAR with SA-kNN showed q2 = 0.77. The synthesized compounds exhibited MIC in the range of 1.38-14.59(µg/ml) .These compounds showed some crucial interaction with MTB Atpase. Conclusion The present study has shown some promising results which can be further explored for lead generation.

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22. Pharmacological evaluation of clove oil emulsion on propylthiouracil induced hypothyroidism in wistar rats

Research Article

Pharmacological evaluation of clove oil emulsion on propylthiouracil induced hypothyroidism in wistar rats

Harshada Lanjekar*, Swati Kolhe, Sachin Tembhurne

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Received: 3July 2020 Revised: 22 August 2020 Accepted: 26 August 2020

Abstract

Objective: The present work was carried out to evaluate the effect of clove oil for enhancing thyroid function. **Material and methods:** Wistar rats received propylthiouracil at a dose 0.3mg/kg/bw (orally) daily for 21 days as pretreatment for induction of hypothyroidism and after induction treated with clove oil emulsion at dose 100, 200 and 300 mg/kg (orally) daily for 21 days. All animals were observed throughout the whole experiments and note down body weight of each animal once in week. Blood samples were taken before and after treatment and hormonal level assay was performed. Histopathological analysis was also assessed. **Results and conclusion:** Significantly increase value of T3, T4 and compared with control, standard and test value. Histopathological changes were observed with few vacuolation. It was concluded that clove oil emulsion plays vital role on propylthiouracil (PTU) induced hypothyroidism by enhancing thyroid functions in experimental wistar rats.

Keywords: Propylthiouracil (PTU), clove oil, emulsion, hypothyroidism

Introduction

Human body is made up of five basic elements (PANCHMAHABHOOT). These elements revolve around the normal functioning of the body (Physiology), Occurrences of disease (Pathology), Action of drugs on various parts of body (Pharmacokinetics). Imbalance between them complications can be occurred. So, any disorders can be raised by imbalance between these 5 elements and by balancing these elements these problems can be cured (Holloway et al., 2004).

Endocrine System is one of the largest systems in human body; it is controlled by Pituitary Gland. It produces various hormones which are secreted directly into blood stream & these are chemical signaling molecules (Larsen et al., 1973). Thyroid gland is part of endocrine system. It is most important hormonal gland which produces thyroid hormones and it plays major role to regulate various body functions like metabolism, growth, development, temperature digestive functions etc. Now a day's thyroid disorders are growing rapidly (Pantos et al., 2003). It becomes serious health issue. It is a general term representing several different diseases involving thyroid hormones and the thyroid gland (Abrams and Larsen, 1973).

In India 42 Million people have thyroid disorders like hypothyroidism and it is most common thyroid disorders. The prevalence of thyroid dysfunctions varies by age, sex, and geographically through variations in dietary iodine intake. Thyroid disorders are more common in women than men, and in older adults compared with younger age groups (Greer, 1968). Abnormal thyroid function has important ramification on health outcomes mostly seen in older adults including cardiovascular disease, myocardial infarction, bone health, mental health. Many factors affect normal level of thyroid hormones which leads to complications in thyroid functions. It arises due to excessive thyroid hormones productions or not enough (Shahi et al., 2018).

Complications are hypothyroidism, hyperthyroidism, goiter, hashimoto's disease, Graves' disease etc. Iodine deficiency & autoimmune inflammation is one of the most common causes of thyroid disorders. Treatments of thyroid complications depend upon its symptoms and severity (White, 2015). Hormonal replacement therapy is most commonly used long term treatment. Many modern medicinal therapies and medicines are available for the treatment of this disease but in these cases re-occurrence rate is high. Side effects like nausea, vomiting, hair loss, weight loss, bone pain, diarrhea or sometimes severe side effects seen (Claire et al, 2004), So, traditional herbal remedies regarded as safe and cost

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23. Twenty eight days repeated dose oral toxicity study of hydro-alcoholic extract of Helicteres isora dried fruits in experimental wistar rats

TWENTY EIGHT DAYS REPEATED DOSE ORAL TOXICITY STUDY OF HYDRO-ALCOHOLIC EXTRACT OF HELICTERES ISORA DRIED FRUITS IN EXPERIMENTAL WISTAR RATS.

- **Source:** Journal of Advanced Scientific Research . 2020 Supplement, Vol. 11, p183-193. 11p.

- **Author(s):** Murudkar, Prajakta H.; Kolhe, Swati U.; Tembhurne, Sachin V.

- **Abstract:** The aim of this study was to evaluate the 28 days repeated dose oral toxicity or subacute oral toxicity study of hydroalcoholic extract of Helicteres isora (HAEHI) dried fruits in male and female experimental wistar rats. This toxicity study was carried out at 200mg/kg, 500mg/kg and 1000mg/kg of doses of hydroalcoholic extract of Helicteres isora dried fruits. During the study period of 28 days all the animals were observed weekly for changes in body weight, food consumption, water consumption, behavior changes, any sign of morbidity and mortality. After 28 days of study period, all the animals were humanly sacrificed by using cervical dislocation technique and were examined for changes in their relative organ weight, biochemical and hematological parameters and also observed for histopathological changes. The results of the present study indicated that there is increase in food consumption as well as elevated body weight at 1000mg/kg doses in both male and female wistar rats. The results of biochemical tests and hematological tests show significant changes in some parameters at higher dose of HAEHI. In the histopathology, animals treated with extract at 1000mg/kg body weight showed minimal tubular degeneration in kidney of both male and female wistar rats; however, liver, heart and lungs did not show any toxicity at any of the doses when compared with control group animals. From results, our study concludes that repeated administration of hydroalcoholic extract of H. isora dried fruits for 28 days increases the food consumption along with body weight and indicates its role as dietary supplement. The hydroalcoholic extract of Helicteres isora dried fruits was found to be safe in 28 days repeated dose toxicity study. While at higher doses it shows minor significant alteration in histopathology, biochemical and hematological parameters.

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24. Protective effect of hydro-alcoholic extract of dried fruits of Helicteres isora in dextran sulfate sodium (dss) induced ulcerative colitis in experimental wistar rats

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Research Article

Protective Effect of Hydroalcoholic Extract of Dried Fruits of *Helicteres isora* in Dextran Sulfate Sodium Induced Ulcerative Colitis in Experimental Wistar Rats

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ABSTRACT

Ulcerative colitis (UC) is the most common form of inflammatory bowel disease (IBD), which mainly affects colon. The treatment of UC depends upon severity of the diseases. The aim of the present study was to determine the effect of hydroalcoholic extract of dried fruits of *Helicteres isora* (HI) in dextran sulfate sodium (DSS) induced UC in experimental Wistar rats. In this study, Wistar rats of either sex were divided into five experimental groups, where control group received only distilled water. Group 2 was negative control group, which received 4% DSS from drinking water between 15th and 21st days. Group 3 received low dose of hydroalcoholic extract of *H. isora* at a dose 100 mg/kg orally, along with 4% DSS from drinking water between 15th and 21st days. Group 4 received high dose of hydroalcoholic extract of *H. isora* at a dose 200 mg/kg orally along with 4% DSS from drinking water between 15th and 21st days. In group 5, sulfasalazine was used as a standard drug at a dose of 100 mg/kg orally along with 4% DSS from drinking water between 15th and 21st days. Twenty four hours after treatment, animals were sacrificed, and further macroscopical, biochemical, and histopathological evaluation was done, and all the results were compared with control at $p < 0.05$ significant value.

INTRODUCTION

The UC is an inflammatory bowel disease, which is an idiopathic, chronic inflammatory disorder of the colonic mucosa. UC starts initially in the rectum and then extends proximally in a continuous manner into the entire colon UC shows symptoms, like abdominal pain, diarrhea, and hematochezia.[1,2] UC can be acute or severe, which needs timely recognition, evaluation, and intervention for its management.[3] There are various which lead to the pathogenesis of UC, such as, genetic factors, intestinal microbiota, host immune system disorders, and various other environmental factors.[4]

In current study, UC in experimental rats was induced by DSS. The induction of UC by using DSS is one of themost widely used experimental model which causes epithelial damage. Administration of DSS to experimental rats in a drinking water causes human UC-like pathologies in which it causes toxicity to the epithelial cells of the colon which further cause disturbances in the mucosal barrier function.[5] There are several types of medications which are used for the treatment of colitis by controlling inflammation or reduce symptoms of colitis. Herbal medicine or traditional medicines includes an extensive range of practices, as well as, therapies. Herbal drugs are safer than synthetic drug, and therefore, preferred widely to treat various ailments. Some potential benefits of herbal drugs that their acceptance rate by the patient is high, they have good efficacy, relatively safe, and have low cost.[6]

In present study hydroalcoholic extract of *H. isora* dried fruit was used. *H. isora* L. (Malvaceae), is one of

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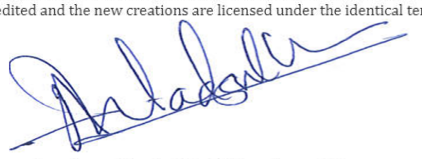
Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



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25. Protective effect of hydro-alcoholic extract of dried fruits of Helicteres isora in acetic acid induced ulcerative colitis in experimental rats

PROTECTIVE EFFECT OF HYDRO-ALCOHOLIC EXTRACT OF DRIED FRUITS OF HELICTERES ISORA IN ACETIC ACID INDUCED ULCERATIVE COLITIS IN EXPERIMENTAL RATS

Published Jul 31, 2020

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Abstract

Ulcerative colitis is an inflammatory bowel disease which causes inflammation and ulceration in the lining of large intestine i.e., colon. The aim of the present work was to study the effect of Hydro-alcoholic extract of dried fruits of Helicteres isora in acetic acid induced ulcerative colitis in experimental rats. In current study wistar rats were randomly divided in to five experimental groups. The control group received only saline by transrectal route. In second group i.e., negative control group experimental animals received only 2ml of 3% acetic acid for 14 days. Third group and fourth group received low dose (100mg/kg) and High dose (200mg/kg) of hydroalcoholic extract of Helicteres isora dried fruits respectively by oral route along with 2ml of 3% acetic acid for 14 days. Fifth group received prednisolone along with 2ml 3% acetic acid for 14 days. After treatment period rats of all groups were sacrificed on day 15th and their distal colonic segments were dissect out, cut and assessed for macroscopic examination. The activity was evaluated in terms of lipid peroxidation, superoxide dimutase (SOD) levels and Catalase (CAT) levels. The results of present study indicate significant results of lipid peroxidation, superoxide dimutase and catalse concentrations. The present study also shows significant results of C-reactive protein levels and histopathology of the colon thus study concludes that hydroalcoholic extract of Helicteres isora dried fruits have protective effect in acetic acid induced ulcerative colitis.

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26. In Vitro Antioxidant Activity and Acute Oral Toxicity Study of Polyherbal Formulation (Alangium Salviifolium &ClitoriaTerntea) in Mice

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In Vitro Antioxidant Activity and Acute Oral Toxicity Study of Polyherbal Formulation (Alangium Salviifolium & Clitoria Terntea) in Mice

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ABSTRACT

***Alangiumsalvifolium* and *Clitoriatrentea* are the medicinal plants which are reported that they can be used to treat brain related disorders for their nootropic activity. *Alangiumsalvifolium* (Linn. F) Wang. is a little deciduous tree or bush, which develop in the wild all through the hotter regions of the India. It has a place with the family *Alangiaceae*. It is utilized as diuretic, astringent, sharp, anthelminthic, laxative, emetic, against protozoal, hypoglycemic movement, hostile to diabetic and for anti-ulcer action. *Clitoriaternatea*, ordinarily known as Shankpushpi, is generally utilized in the conventional Indian Ayurvedic medication as a mind tonic and is accepted to advance memory and insight. The purpose of this study was to test the in-vitro antioxidant activity and acute oral toxicity of the extracts of the seeds obtained from these both plants. Acute oral toxicity study of ethanolic extract of the seeds obtained from *Alangiumsalvifolium* and *Clitoriaterntea* was performed. The extract was prepared in the ratio of 1:1 of both plant seeds powder. Acute toxicity studies were adopted from OECD guidelines 423. The animals were orally administered a single dose of 250, 500, 1000 and 2000 mg/kg body weight. Indications of mortality and toxicity were noted after 1hr, 4hr, and 24hr of administration of the extract for 14 days. The highest dose administered was (2000mg/kg body weight).**

Keywords: *Alangium Salvifolium, Clitoriatrentea*, Acute Oral Toxicity, Polyherbal formulation, mice.

INTRODUCTION

Over past few years, the study of plants as alternative medicine, or more commonly known as herbal remedies, has grown enormously around the world. There is a lot of evidence that shows medicinal plants have great potential for curing various diseases and medical disorders. A large and increasing number of patients in the world use medicinal plants and herbs for health purpose. In this way, logical examination of their restorative potential, organic properties, and wellbeing will be helpful in settling on insightful choices about their utilization. There are several noteworthy medications and organically dynamic mixes created from the conventional therapeutic plants. Medicinal plants contain various complex chemical substances of different compositions, which give such plant their preventive and curative properties. These complex chemical substances act by modulating the functions of various body systems. They are grouped as glycosides, alkaloids, corticosteroids, essential oils, tannins, etc. and provide therapeutic effect in many neurological disorders.

Alangiumsalvifolium is deciduous shrub or a tree, up to 10m in height with a maximum girth of 1.2m with rough light brown bark. Branch lets grey or purple-brown, often with strong spines up to 1.2 cm. long, pubescent or glabrous. Leaves alternate up to 15cm x 5cm simple, oblong and lanceolate. The flowers are White or cream, fragrant, 1.2-3.0cm long, axillary fascicles from the axils of fallen leaves, seeds are Stamens 10–32, 5–14 mm long; having ovary inferior, 1 to 2 celled, style 8.5–27.5 mm long, their stigma is conical or head-shaped, and is slightly lobed. The fruits are ellipsoidal when young and become purplish red globular when ripen. The wood is valued for musical instruments and furniture in India. It is likewise utilized in working as pillars, for ground surface, furnishings, bureau work, decorating, cutting, bobbins, axles, transports, rice pestles, device handles, strolling sticks, gunstocks and handicraft articles in Asia. The twigs are used for brushing the teeth in India. The stems are used for spears in Kenya. The different parts of this plant are also used for wide range of diseases. The root is used for diarrhea, paralysis, piles, vomiting and is useful for external application in acute case of rheumatism, leprosy and inflammation. Seeds are used in hemorrhages, leprosy, skin disease and arthritic. Leaves are used in diabetes. The bark shows antitubercular activity. Root bark used as antidote for several poisons. The fruits obtained from this plant are sweet, cooling and laxative and utilized as a poultice for the treatment of burning sensation and also used in hemorrhagic conditions.

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27. Subacute toxicity study of the ethanolic extract of Mesua ferrea (L.) flowers in rats

DRUG AND CHEMICAL TOXICOLOGY
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RESEARCH ARTICLE

Subacute toxicity study of the ethanolic extract of *Mesua ferrea* (L.) flowers in rats

Pallavi Shirsat[a], Ziyaurrahman A. R.[b], Rama Kashikar[a], Manjushree Athavale[a], Tejas Athavale[a], Pritam Taware[a], Tina Saldanha[a], Swati Kolhe[a] and Sachin Tembhurne[a]

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ABSTRACT

Mesua ferrea Linn. is used traditionally in India and South East Asian countries as an antiseptic, antidote and a brain tonic. Recent pharmacological studies on the plant have highlighted *M. ferrea* to be a rich source of secondary metabolites, with proven therapeutic applications. Since the toxicity of a plant following repeated exposure is of higher clinical significance, the present investigation was conducted to establish the subacute toxicity profile of the ethanolic extract of *Mesua ferrea* flowers (MFE). The study was conducted in accordance with the OECD Guideline 407, wherein MFE was administered orally to groups of male and female rats ($n = 5$/group/sex) at the doses of 100, 500 and 1000 mg/kg, over a period of 28 days. Repeated administration of MFE had no adverse effect on the growth rate and hematological parameters of the animals. There were no changes in the biochemical parameters, except for a slight decrease in the CHOL (total cholesterol) levels, and an increase in the levels of AST (aspartate aminotransferase) and ALT (alanine aminotransferase), at the highest dose. The latter corroborated with the histopathological findings exhibiting mild lymphocytic infiltration and hepatocyte degeneration observed in the liver tissues of both sexes. According to the study, the no-observed-adverse-effect level (NOAEL) of *M. ferrea* in the 28-day repeated dose toxicity study in rats was 500 mg/kg. Though the overall effects of the extract at the highest dose did not translate into any serious complications, its effect on hepatic function needs to be established over a longer period of study.

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KEYWORDS
Subacute oral toxicity; wistar rats; herbal extract; *Mesua ferrea*; toxicological profile

Introduction

The use of traditional, complementary and alternative medicine has increased on a global scale in the last decade, with about 80% of the population in developing countries relying on plant remedies for their healthcare (Ezeja *et al.* 2014). Several pharmacological studies have been conducted on various medicinal plants based on their traditional uses in alternative medicine. However, very few plants have been thoroughly evaluated for their possible toxic effects (Bello *et al.* 2016). Mensah *et al.* 2019 have reported of instances wherein a few plants have proven to be toxic when given in a single dose or at repeated dose. Therefore, it is imperative that toxicological assessments of plant extracts are conducted to establish their safety for further therapeutic applications.

Mesua ferrea (Calophyllaceae) is a perennial tree which is indigenous to parts of India, Sri Lanka, southern Nepal, Burma, Thailand and New Guinea (Lim 2014). Different species of *M. ferrea* are traditionally used in these countries as a cure for various diseases such as asthma, cough, fever, itchiness, nausea, dyspepsia and renal disease (Asif *et al.* 2017). In the Indian system of medicine, the plant, commonly known as *Nagakesara*, is used as a brain tonic, diaphoretic and stimulant. The plant is also traditionally used for its antiemetic, anthelminthic, aphrodisiac and diuretic effects, and as an antidote (Anandakumar *et al.* 1986). *Nagakesara* is also an ingredient of ayurvedic formulations such as *Brahma Rasayan* and *Chyawanprash*, which are used to boost immunity (Chahar *et al.* 2012).

There have been validated reports on bioactivities of the plant which are of pharmacological significance, including its antioxidant activity (Makchuchit *et al.* 2010), analgesic activity (Hassan *et al.* 2006), anti-cancer activity (Nordin *et al.* 2004), antiarthritic activity (Jalalpure *et al.* 2011), antivenom activity (Uawonggul *et al.* 2006), to name a few. A number of phytochemical investigations conducted on various parts of the plant revealed the presence of secondary metabolites such as xanthones, biflavones, coumarins, cyclohexadione derivatives and an essential oil (Verotta *et al.* 2004).

There have been studies which have evaluated the acute toxicological profile of the flowers and stamens, both intraperitoneally (Tiwari *et al.* 2012, Tiwari and Nandy 2012) and orally (Udayabhanu *et al.* 2014, Barbade and Datar 2015) inferring that the LD_{50} of MFE was estimated to be higher than 2000 mg/kg after a single dose administration. However, a single dose toxicity study is not sufficient to establish a complete safety profile. Lack of toxic effects upon acute

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28. Preclinical evaluation of hydroalcoholic extract of sesbania sesban leaves on antiulcer activity by pylorus ligation induced gastric ulcer on experimental rats

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PRECLINICAL EVALUATION OF HYDROALCOHOLIC EXTRACT OF SESBANIA SESBAN LEAVES ON ANTIULCER ACTIVITY BY PYLORUS LIGATION INDUCED GASTRIC ULCER ON EXPERIMENTAL RATS

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Article Received on 27/09/2020 **Article Revised on 17/10/2020** **Article Accepted on 07/11/2020**

ABSTRACT
Ulcer is developed in the inner lining of the stomach i.e. gastric ulcer or the small intestine i. duodenal ulcer. Both the ulcers are called as peptic ulcers also. 10% of world population is affected by this type of ulcers. The study was designed for the investigation of the antiulcer activity of hydro-alcoholic extract of *Sesbania sesban* leaves (Fabiaceae) in experimental rats in different doses. The animals were selected as the waight of the animal 150-250gm. After selection animal (n=6) each group contain six animals, they were treated with extract of *Sesbania sesban* (100 and 200 mg/kg) and omeprazole (20mg/kg) orally. While the control animals were given with normal water. The treatments were given for 15days consequently.

KEYWORDS: *Sesbania sesban* linn, Pylorus ligation induced, gastric ulcer, ulcerated area.

INTRODUCTION

Gastric ulcer, one of the most widespread, is believed to be due to an imbalance between aggressive and protective factors.[1] Ulcer is a major disease of gastrointestinal system which affects 10% of the world population with different aetiologies. Chronic alcohol intake, excessive stress, smoking, usage of non-steroidal anti-inflammatory drugs and H. pylori bacterial infection these are the main causes of peptic ulcer which hare characterized by inflammation, abdominal pain and mucosal bleeding in patient.[2,3] All over the world the significant morbidity is due to the Peptic ulcer disease and its complications, representing a major burden for health care resources.[4] Even if potent anti-ulcer drugs are available there, there is a need to search the new alternatives just because most of them produce several toxicities.[5] For the first line of primary health care 80% of the world population depends on the medicines which are derived from the plant.[6] Treatment of peptic ulcers by drugs is targeted at either counteracting aggressive factors (acid, pepsin, active oxidants, platelet aggravating factor "PAF", leukotrienes, endothelins, bile or exogenous factors including NSAIDs) or stimulating the mucosal defences (mucus, bicarbonate, normal blood flow, prostaglandins(PG), nitric oxide).[7] The goals of treating peptic ulcer disease are to relieve pain, heal the ulcer and prevent ulcer recurrence. Currently there is no cost-effective treatment that meets all these goals.

2. MATERIALS AND METHODS

Plant material

The leaves of *Sesbania sesban* (S.sesban) were collected from georai, district of Beed, Maharashtra and authenticated by M/s. shamantak enterprises, pune. Certificate of Aunthentification number of *Sesbania sesban* is SE/AC/ 2019/05.

2.2 Preparation of extract

The leaves of S. sesban were collected from the mature plants, shade dried and powdered (80mesh). The powdered leaves (2000g) was defatted with petroleum ether and later extracted (soxhlet) using 90% ethanol and water. The hydro alcoholic extract was prepared and used for the antiulcer activity.

2.3 Chemicals and Reagents

Acetic acid (AR), Thiobarbituric acid (AR), sodium dodecyl sulphate (SDS) (AR), NAOH (AR), HCL(AR), N-butanol (AR), pyridine (AR), DPPH (AR), Triss HCL buffer (AR), Ethanol (AR), Ketamine Hydrochloride Injection (Celtiss Therapeutics pvt ltd Hyderabad), Xylazine Hydrochloride Injection (Indian Immunological Ltd., Hyderabad), Omeprazole tablets, Anesthetic Ether-I.P. (Nandkrishna chemicals PVT LTD, Nardana, Dist-Dhule).

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29. 28 Days Repeated Dose Oral Toxicity Study Of Hydroalcoholic Extract Of Sesbania Sesban Leaves In Experimental Rats

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28 DAYS REPEATED DOSE ORAL TOXICITY STUDY OF HYDROALCOHOLIC EXTACT OF SESBANIA SESBAN LEAVES IN EXPERIMENTAL RATS

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ABSTRACT
Natural medication is the hotspot for the inquiry of numerous novel helpful mixes in agricultural nations. Prior to utilized as medication, drugs from plant cause must be guaranteed safe. The study is aimed at evaluating the possible toxicity in 28-day subacute oral toxicity of hydroalcoholic extract *Sesbania sesban (S.sesban)* in male and female Wistar rats. The 28-day subacute poisonousness study was directed to recognize the no-watched unfriendly impact level (NOAEL). In this investigation, a sum of 48 rodents were isolated into the control, low dose (200 mg/kg), medium dose (500 mg/kg) and high dose (1000 mg/kg) gatherings. The HAESS was given daily from day 1 until day 28. At the last day of the study, the animals were humanely sacrificed and assessed for the effect extract of Sesbania sesban leaves on body weight and relative organ weights and hematological, biochemical and histopathological parameters.

KEYWORDS: subacute oral toxicity Sesbania sesban, biochemical analysis, hematological parameters, histopathology.

INTRODUCTION

Herbal medicine is the source for the search of many novel therapeutic compounds in developing countries. Before used as medicine, drugs from plant origin must be ensured safe.[1] Plant-derived medicines are used in all civilizations and cultures and, hence, plants have always played a key role in health care systems worldwide. In most developing countries, the indigenous methods of home grown treatment are an aspect of the way of life and the prevailing strategy for recuperating treatment. These remedies, with impressive degree of adequacy, are socially acknowledged, financially reasonable and, generally, are the main accessible source. This raises concerns about the potential toxic effect resulting from chronic use of such medicinal plants. Consequently, assessing the toxicological impacts of any therapeutic plant extricate expected to be utilized clinically or preclinically, is a significant aspect of its appraisal of possible poisonous impacts.[2] Recently, increasing interest in herbal medicines is the belief that because these medicines are natural and have been traditionally used, they are safe and harmless. Sesbania sesban Linn. consist of dried bark of the plant Sesbania Sesban Linn. (Fabaceae) is found all through the fields of India and generally called as Jayanti (SANS) and Shevri (MAR).[3] The plant is inreached with full of medicinal uses. According to ethno medicinal claims the poultice of leaves of Sesban Linn. Advances festering of bubbles and abscesses and retention of provocative rheumatic swellings. Juice of new leaves is credited with Anthelmintic properties.[4] However, no studies on the toxicity of S. sesban leaves have been described in the literature. In this way, in the current examination, we intended to research the toxicity (oral subacute) of S. sesban leaves so as to expand the trust in their security to people to treat different illnesses.

MATERIALS AND METHODS

Collection and Identification of Plant Material

The part of plant S sesban is leaves were collected from georai, district of Beed, Maharashtra and authenticated by M/s. shamantak enterprises, pune. Certificate of Aunthentification number of Sesbania sesban is SE/AC/ 2019/05.

Preparation of Plant Extract

The leaves of S. sesban were collected from the mature plants, shade dried and powdered (80mesh). The powdered leaves (2000g) was defatted with petroleum ether and later extracted (soxhlet) using 90% ethanol and water. The hydroalcoholic extract was concentrated in a rotary flash evaporator at a temperature not exceeding 50° C to get a solid residue. Different concentration (200mg/kg and 400 mg/kg p.o.) of hydroalcoholic extract of leaves of S. sesban was given according to body weight of animals.

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30. 28 Days repeated oral toxicity study of Rosmarinus officinalis in Wistar Rats

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Journal of Drug Delivery and Therapeutics

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Open Access Research Article

28 Days repeated oral toxicity study of *Rosmarinus officinalis* in Wistar Rats

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Abstract

Rosmarinus officinalis has long been used as a traditional oriental medicine. It is traditionally used as antioxidants as well as essential oil. Rosmarinus officinalis mainly contains the phenolic compounds which is responsible for the antioxidant property. In the present study, 28-day subacute oral dose toxicity studies of hydroalcoholic extracts of the plant of Rosmarinus officinalis were performed in Wistar rats. The repeated oral toxicity study was carried out to detect the no-observed adverse effect level (NOAEL). In this study, a total of 48 rats were classified into the control, low dose (300 mg/kg), medium dose (500 mg/kg) and high dose (1000 mg/kg) treatment groups. The extract was administered daily from day 1 until day 28. At the end of the study, the animals were humanely sacrificed and assessed for the effect extract of Rosmarinus officinalis plant on body weight and relative organ weights, biochemical, haematological and histopathological parameters. The biochemical parameters for the assessment of kidney and liver injuries were carried out. Results of haematological and biochemistry results showed no changes in the control and treated groups. In the histopathology, evaluation of kidney tissues in all treated groups showed no significant ($p > 0.05$) lesions. The results conclude that hydro-alcoholic extract of leaves Rosmarinus officinalis was found to be safe at highest dose level of 1000mg/kg for 28 days of oral administration.

Keywords: *Repeated toxicity study, Rosmarinus officinalis, biochemical analysis, histopathological study*

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INTRODUCTION:

Medical developments have supported work that explores the creation and innovative use of medicinal plants due to their biological properties and availability at regional and around the world. A variety of natural materials are commonly used as raw materials for treatments, fitness-conscious meals and home remedies [1,2]. Herbal extracts are believed to be more secure than chemical products. Therefore, toxicity studies of natural substances do not usually receive as much attention as studies of chemical products. However, a few natural substances are probably poisonous and can be dangerous to human health. Furthermore, issues concerning the actual safety of natural substances are constantly being discussed[3-4]. Therefore, systematic safety studies are also vital for compounds which can be herbal-based drug treatments or practical health ingredients.

The extract of the rosemary *(Rosmarinus officinalis)* contains phenolic acids (2 to 3% rosmarinic, chlorogenic, and caffeic acids), phenolic diterpenoid bitter substances (up to 4.6% carnosic acid, carnosol, rosmaridiphenol, and rosmanol), triterpenoid acids (oleanolic and ursolic acids), flavonoids (apigenin, luteolin, nepetin, and nepitrin), 1.2 to 2.5% volatile oils (15 to 50% 1,8-cineole, 15 to 25% -pinene, 12 to 24% -terpineol, 10 to 25% camphor, 5 to 10% camphene, 1 to 6% borneol, 1 to 5% bornyl acetate), and tannins [5,6,7,8]. Although phenolic diterpenes, carnosic acid, carnosol, rosmanol, and epi- and iso-rosmanol are antioxidant compounds in rosemary leaves. These extracts have been used in the treatment of arthritis, kidney damage due to diabetes, mental tiredness, fibromyalgia, gum disease (gingivitis), hypotension, opioid withdrawal etc. For the therapeutics purpose, the plant extract need to administer daily for several days and there may be safety concern for its repeated use. So in the present investigation our study was undertaken to evaluate safety profile (qualitative and quantitative examinations) of hydro-alcoholic extract of the rosemary in terms of 28 days repeated oral administration in wistar rats.

MATERIAL AND METHODS:

Plant Material:

The plant samples were collected (September 2019) in the city of Pune, state of Maharashtra, India. The plant was

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31. Evaluation of Anti-Anaphylactic Activity of methanolic extract of Momordica charantia in Experimental Animals

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Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

Open Access Research Article

Evaluation of Anti-Anaphylactic Activity of methanolic extract of *Momordica charantia* in Experimental Animals

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ABSTRACT

Anaphylaxis is a syndrome that can be fatal, which is seen due to systemic release of inflammatory mediators. Antigen and Antibody reaction is usually a trigger in the body to go into anaphylactic shock. In this study, anaphylaxis induced by egg albumin in the rats. The efficiency of MC (*Momordica charantia*) against anaphylaxis was evaluated. The standard drug used was Dexamethasone. The MC extract is given in doses 100 and 200 mg/kg p.o.

Results: The MC extract was found to be effective ($p<0.01$) inhibitor of egg albumin induced anaphylactic reaction.

Conclusion: From this study, we can conclude that *Momordica charantia* fruits have good anti-anaphylactic activity.

Keywords: Anaphylaxis, Momordica charantia, Egg albumin, Passive paw anaphylaxis, Dexamethasone.

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http://dx.doi.org/10.22270/jddt.v10i5-s.4506

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INTRODUCTION:

Anaphylaxis is a fatal syndrome, which can be caused by sudden influx of inflammatory mediators in systemic circulation. The inflammatory mediators involved are histamine, heparin, nitric oxide produced from the activity of IFN- γ and TNF- α, etc [1]. The triggers for anaphylaxis can be a number of things, including foods like nuts, fish, wheat, etc and some drugs like Penicillin and even venom of some insects [2].

Anaphylaxis can trigger or can be the cause of many disorders like asthma, inflammation, pain, rhinitis, etc. It is a type of Type I hypersensitivity and in the mechanism involved in this is, when an antigen binds to the complex of CD4 and Th2 cells specific to the antigen. This in turn stimulates the release of B cells which leads to production of IgE antibodies leading release of inflammatory mediators. Thus, the treatment of anaphylaxis is important to consider [3].

Momordica charantia, also called bitter squash or Karela, is annual climber, from the family of Cucurbitaceae [4]. There have been claims since the ancient times for its medicinal value and as a vegetable for consumption and its therapeutic characteristics like, anti microbial, antiinflammatory, anti diabetic, asthma, cough, etc [5]. It also is used for its activity as anti- pyretic, hepatoprotective, wound healing activity, etc [6].

In this study, an effort was made to determine the anti anaphylactic activity of MC (Momordica charantia) in experimental rats.

MATERIALS AND METHODS:

1.1 Plant Materials: Momordica charantia fruits were purchased from a market in Pune, Maharashtra. The fruits were then sliced thinly and dried. The slices were then grinded to form powder. The powder was then allowed to soak for three days in 80% methanol. The product, finally, was obtained by using Soxhalet apparatus [7, 8, 9].

1.2 Animals: Animals were obtained from the Animal House of AISSMS College of Pharmacy, Pune. Wistar rats weighing 180-200 gm were chosen for the study. The animals were kept in a group of 5 and were provided with water and the standard feed ad libitum. They were housed in the 12-12 hour light-dark cycle and in the temperature of 24 + 1°C. These animals were selected in a randomized manner for this experiment. The

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32. Evaluation of mast cell stabilization activity of Momordica charantia in rats

EVALUATION OF MAST CELL STABILIZATION ACTIVITY OF MOMORDICA CHARANTIA IN RATS.

- **Source:** Journal of Advanced Scientific Research . 2020 Supplement, Vol. 11, p339-341. 3p.

- **Author(s):** Deshpande, S. D.; Salokhe, S. S.; Kolhe, S. U.; Tembhurne, S. V.

- **Abstract:** Mast cells have a major role in our immune system and they are also important targets in many inflammatory diseases. On degranulation, mast cells releases histamine and thereby produces inflammatory reaction and this makes it an important target in disease like asthma. The purpose of present investigation was to evaluate the potential of Momordica charantia (MC) on mast cell stabilization, as a parameter in management of asthma. In experimental animal the mast cell degranulation was induced by clonidine and the test extract was administered at doses of 100 and 200mg/kg (p.o.) and the standard used was ketotifen fumarate (1 mg/kg p.o). The result of study demonstrated that, extract of Momordica charantia significantly decreases the degranulation of mast cells indicating the protective effect. From this study it concludes that extract of Momordica charantia possess mast cell stabilizing effect.

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33. Formulation And Evaluation Of Antiemetic H. spicatum Lozenges

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FORMULATION AND EVALUATION OF ANTIEMETIC *H. spicatum* LOZENGES

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ABSTRACT

Hedychium spicatum also called as Kapoorkachri or Shati is a rhizomatous, fragrant leafy herb with robust stem belonging to Zingiberaceae. Rhizomes have strong aromatic odour and bitter camphoraceous taste. *Hedychium spicatum* is traditionally used for its stimulant, carminative, stomachic and expectorant properties. Shati rhizomes have mention in Ayurvedic text for its use in Hairloss, Digestion and Respiratory problems, Cleansing Teeth, Cardiac Health , Headache, Joint pain and Hiccups. Rhizomes are usually used in the form of powder or formulated in syrups or tablets. Rhizome is reported to contain sitosterol and its glucosides, P-methoxy cinnamic acid ethyl ester, furanoid diterpene-hedychenone and 7- hydroxy hedychenone and essential oil contains Cineole, terpinene, limonene, phellandrene, p-cymene, linalool and terpeneol which contribute to its activity. Paediatric patients have low patient compliance towards drug formulations like tablets because of unpalatable taste . On the other hand, children can easily accept and swallow sweet lozenge with additive flavour. In order to provide better patient compliance we have formulated lozenges using shati rhizome extract specially for paediatric patients. Aim of this study involves design, preparation and evaluation of medicated lozenges. Methodology includes extraction of drug with cold maceration method using aqueous : ethanolic extract (1:1) proportion .Lozenge base was made with Sugar and corn syrup followed by addition of drug extract. Ginger juice was added as natural flavour and for additive antiemetic and antitussive property .Lozenges were made by casting method where in the resultant hot mix was poured in moulds. This lozenges are evaluated by pharmaceutical methods like moisture content, friability test, disintegration test which complies with IP.

Keywords: *Hedychium spicatum,* antiemetic, paediatric, Ayurvedic text.

INTRODUCTION

Emesis is defined as action or process of vomiting, by virtue of which contents of stomach are thrown out via the mouth. Emesis is precipitated by several factors such as psychosocial stressors related to accomplishments and family, fiasco in context of expectation of parents, eating pathology, lack of exercise, medication and food poisoning. In addition to above precursors, emesis is also precipitated by sensory stimuli such as bad odour, ghastly sight, severe pain, fear and recall of an obnoxious event.

Emesis is prevalent among all age groups including paediatrics and geriatrics. Synthetic drugs for emesis have been used for its treatment. This is suitable for adults but often result in potential side effects and masking of underlying condition in children. Furthermore, rationale of designing a dosage form which is compatible to paediatrics is crucial. A low patient acceptance is seen for tablets and capsules due to large size, poor taste. Intravenous route is never preferred for paediatrics due to pain attributed with it.

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1. Development of Hot Melt Coating Technique for Taste Masking of Chloroquine Phosphate Tablets

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Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

Open Access Research Article

Development of Hot Melt Coating Technique for Taste Masking of Chloroquine Phosphate Tablets

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ABSTRACT

In the present study to mask the unpleasant taste of chloroquine phosphate, hot melt coating technique was used as a taste masking tool. Hot melt coating is a solvent free technology grants rapid, additionally economical coating process with reduced risk of dissolving drug during process and provide uniform application rate of coating agent. Precirol ATO 5 was used as hot melt coating material for taste masking. Tablets were prepared by wet granulation method and coated using hot melt coating technique. Coated tablets exhibited good uniformity of drug content. Amount of drug release from all batches were evaluated. Taste evaluation of hot melt coated tablets was done by using electronic tongue.PrecirolATO5 was found to be a better taste masking agent when used by hot melt coating technique.

Keywords: Precirol ATO 5, Hot melt coating, taste masking.

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INTRODUCTION

Coating is one of the effective techniquefor taste masking of solid dosage forms.Traditionally sugar coating and various polymers were used to this end.Having some disadvantages i.e. it require longer processing time, use of organic solvents,and when aqueous solvent used there is a risk ofbacteriological contamination and toxicity as compared to Hot Melt Coating.

An innovative approach, hot melt coating has been reported in order to mask the poor taste of many API's. In HMC technique, the coating material is applied on the substrate, in a molten state, and no solvent is needed[1], it can reduce coating time (no need for drying/evaporation step), production costs, safety measurements, solvent recovery and disposal processes [2].

HMC is carried out to coat capsules, granules, pellets,spherules and tablets. The coatings, which contain a lipid and an emulsifier, which facilitate the production of coated immediate-release products with a neutral taste [3,4], production of sustained release tablets , pellets , used in controlling the stability and release properties of the dosage form , used for enteric coating , preparation of orally disintegrating tasted masked granules, and tablets .

Taste, odour and texture form important consideration in development of oral dosage forms, they ensure better patient compliance and good product quality. Taste masking of bitter drugs has achieved the importance as the most of the drugs are administered orally[5].Various methods are used for taste masking of unpleasant drugs that include flavour's and sweeteners[6,7],inhibiting bitterness [8,9], numing of taste buds [10,11], prodrug, formation of different salts [12,13], complexation approaches, microencapsulation ,multiple emulsion[14], using viscosity modifiers [15],vehicles and liposomes coating of drug particle[16] thereby, minimizing the interaction between drug and the taste bud .

The objective of this study is to evaluate effectivenessof hot Melt coating technique as an approach of taste masking by coating. Precirol ATO 5 was used as a HMC material for taste masking of chloroquinephosphate tablets. The bitterness masking of tablets were evaluated using electronic tongue and tablets were found to have taste protected.

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2. Nanoparticulate of fenofibrate for solubility enhancement: Ex -Vivo evaluation

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Nanoparticulates of Fenofibrate for Solubility Enhancement: *Ex-Vivo* Evaluation

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ABSTRACT

The aim of present research work was to formulate and evaluate nanosuspension of fenofibrate which is categorized as BCS class II agent. With an intention to increase solubility and dissolution rate of fenofibrate nanosuspension were prepared by high pressure homogenization method, a top down technique. Using poloxamer 188 and Tween 80 as a stabilizer. Formulation scheme was developed by Box Behnken Design. Formulation factor which affect the particle size includes Concentration of surfactant and processing parameters includes Homogenization pressure and Homogenization cycles. In this study practically water insoluble fenofibrate was nanosized and surfactant was added for their stabilizing effect. *In vitro* dissolution study showed that the increase in the release rate of fenofibrate from nanoparticles as compared to pure drug. Scanning electron microscopy study showed that the spherical morphology of nanoparticles. Particle size distribution, zeta potential, crystal form of formulated nanosuspension were studied by using particle size analyzer, and X-ray powder diffraction, *Ex-vivo* study for calculating absorption rate. The result showed that the drug dissolution rate in nanosuspension formulation is depends upon the crystal form, solubility, procedure involved, and stabilizer used.

Keywords: Solubility, Dissolution, high pressure homogenization, lyophilization, nanosuspension.

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INTRODUCTION

Solubility is the most important parameter for a drug to show good bioavailability and hence therapeutic effect[1, 2]. More than 40% of new drug entities are poorly water soluble which frequently create problems in formulating them into conventional dosage forms and result in poor bioavailability[3].

Fenofibrate is a antihyperlipidemic belonging to BCS class II, it is practically insoluble in water (0.3µg/ml at 37°C) and has high lipophilicity (logP 5.3), thus it is evident that the rate limiting step for the absorption of fenofibrate from gastrointestinal tract is the dissolution[4, 5]. The solubility / dissolution of drugs can be improved using various conventional techniques such as micronization, precipitation technology, Salt formation and others like liposome, microemulsion, solid dispersion, and inclusion complexation with cyclodextrin. Various approaches have been reported for solubility improvement of fenofibrate[6, 7, 8]. Nanotechnology can be used to solve the problems associated with these conventional approaches for solubility and bioavailability enhancement. Nanoparticulates offer an efficient method as reduction in particle radius coupled with high energy surfaces contribute to improve saturation solubility[9, 10].

The nanoparticulates of fenofibrate have been reported by methods such as melt emulsification and precipitation[11, 12].

Present work describes the formulation and optimization of nanosuspension of fenofibrate by using a high pressure homogenizer. The formulation and process parameters surfactant concentration, homogenization pressure and homogenization cycle are optimized using Box Behnken Design to obtain lowest particle size[13]. The nanoparticles were evaluated for DSC, PXRD and SEM analysis. These nanoparticles were incorporated into the tablet formulation and subjected to *invitro* dissolution and *exvivo* absorption studies.

MATERIALS AND METHODS

Materials

Fenofibrate was obtained from Medley pharmaceutical Ltd, Research centre, poloxamer 188 (Lutrol F68) was given from

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3. Formulation and Evaluation Transdermal Patch of Hesperidin

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Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

Open Access Research Article

Formulation and Evaluation Transdermal Patch of Hesperidin

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ABSTRACT

The aim of the present study is to formulate and evaluate the transdermal patch of Hesperidin. In the present study, transdermal patch of Hesperidin were prepared by using HPMC E 5, Eudragit S 100 as a polymer, Dibutyl phthalate as a plasticizer and glycerin as a lubricant. Nine batches (F1-F9) were prepared by solvent evaporation method using methanol and chloroform in ratio 1:1 as a solvent. The prepared transdermal patches were evaluated on the basis of different parameters like weight, thickness, folding endurance, percent moisture content, drug content , in vitro drug release study. To confirm the optimised batch, the data were computed in design expert software. And it was concluded that the prepared formulation F5 batch showed highest percent of drug release.

Keywords: Transdermal drug delivery, Design expert, HPTLC, Hesperidin.

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INTRODUCTION

Transdermal delivery system allows delivery of drug into the systemic circulation via skin layers at a controlled rate. These systems are easy to apply and remove. This approach of drug delivery is more pertinent in case of chronic disorders which require long-term dosing to maintain therapeutic drug concentration [1-2]. The transdermal route of drug delivery has gained popularity because large number of drugs can be delivered by this route to treat various diseases. Transdermal patches were first developed in the 1970s and the first was approved by the FDA in 1979 for the treatment of motion sickness [3].

Hesperidin is the major flavanone glycoside in sweet orange and lemon obtained as an abundant product of Citrus cultivation. Hesperidin has antioxidant, anti-inflammatory, cholesterol-lowering properties. It is known to reduce permeability and fragility of capillary walls. The bioavailable formulations of this bioflavonoid may prove to be an effective treatment for many blood vessel disorders like haemorrhoid, varicose veins, venous stasis etc. In all these diseases proper therapeutic treatment is not widely available. As a result patient suffers until the disease aggravates to the level of surgery. For improving therapeutic efficacy of hesperidin it is required to identify the problems associated with its bioavailability in order to develop various formulations which can prove to be effective to treat various symptoms of venous diseases at early stage[4-7]. Hesperidin is reported to be unstable at gastric pH where it undergoes hydrolysis into aglycone hesperidin and enzymatic degradation. Hesperidin has a lower bioavailability by its traditional oral route (tablet, film coated tablet) and its gastric absorption is greatly affected by food intake and high acidic pH in the GI track[8]

MATERIAL

Extract of citrus peel, HPMC, Eudragit S 100, Dibutyl phthalate, Glycerin, Potassium dihydrogen orthophosphate, Sodium hydroxide.

METHOD[9-10]

In the present study patch of Hesperidin were prepared by using solvent evaporation technique and evaluated for various parameters. Transdermal patch of hesperidin were prepared by using HPMC E5 and Eudragit as a polymer, Dibutyl phthalate as a plasticizer, glycerin as a lubricant, Chloroform:Methanol as a solvent. Composition of formulation decided as per 3^2 factorial design. Concentrations of HPMC E5 and Eudragit S-100 taken as independent variables at three levels code as (-1,0,+1) respectively (Table 2). Composition of all formulations as per factorial design shown (Table no-3). Polymer HPMC E5 and Eudragit S 100 were mixed in a solvent mixture of

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4. Demonstration of Lymphatic Uptake of (6)-Gingerol Solid Lipid Nanoparticles

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Journal of Drug Delivery and Therapeutics

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Demonstration of Lymphatic Uptake of (6)-Gingerol Solid Lipid Nanoparticles

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ABSTRACT

(6)-Gingerol, a disease modifying anti-rheumatoid drug (DMARD) agent in the treatment of Rheumatoid Arthritis is a potent inhibitor of COX-1, COX-2 activity, inhibits PGE2 production. It also inhibits the production of TNF-α by blocking the cell associated conversion of TNF precursor to mature proteins thus, halting the proliferation of synovitis. (6)-Gingerol undergo extensive phase I metabolism & underlies low systemic exposure. The aim of the present study was to overcome these limitations and formulate and evaluate Ginger extract Solid Lipid Nanoparticles to improve bioavailability by enabling lymphatic uptake. (6)-Gingerol Solid Lipid Nanoparticles were prepared by melt emulsification-homogenization method and the particle size, Zeta potential PDI and % entrapment efficiency was optimized using Box Behnken design. The optimized SLN were found to be 237nm in size, bearing -25.3mv zeta potential, 0.350 PDI and entrapment efficiency of 91.33%. *Ex vivo* endocytic uptake studies (everted intestine method) revealed involvement of endocytic pathways in the uptake of Solid Lipid Nanoparticles from intestine. Thus underlining the utility of SLN for enhancement of uptake of (6)-Gingerol.

Keywords: (6)-Gingerol; Stearic acid; Solid lipid nanoparticles; High pressure homogenization; Lymphatic uptake; Rheumatoid arthritis.

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ABBREVIATIONS: DMARD- Disease Modifying Anti-Rheumatoid Drug, SLN-Solid ipid nanoparticles, EE -Entrapment efficiency.

1. INTRODUCTION

The traditional approach to treatment of rheumatoid arthritis (RA) is a combination of disease modifying anti rheumatoid drugs (DMARDs) and NSAIDs [1]. Various agents such as chloroquine, 5fluoro uracil, sulfasalazine have been reported to have disease modifying properties[1,2,3]. However the toxicity of some of these agents leads us to look to phytochemicals which have DMARD like action, there are many medicinal plant extracts that have been shown to be effective in treating RA, e.g. aloe vera, ashwagandha, ginger, piperine [4]. One such compound (6)-Gingerol($C_{17}H_{26}O_4$) is homologous phenolic ketones found in fresh ginger rhizome (Zingiber officinale Rosco) belonging to the family Zingiberaceae [8].

(6)-Gingerol inhibits the production of TNF-α by blocking the cell associated conversion of TNF Precursor to mature proteins thus halting the proliferation of synovitis. Gingerol is a potent inhibitor of COX-1, COX-2 activity and inhibits PGE2 production thus decrease proliferation of inflammation and disease condition. (6)-Gingerol is given orally in a dose of 120mg//kg/day. The low solubility of (6)-Gingerol has led to its poor oral absorption and fast metabolism has hindered the clinical applications of the drug [5,6]. Currently, gingerols are available as soft capsule formulation. It has been suggested that new therapeutic approaches should be directed at overcoming the issues relating to effective delivery, potential off-target effects, safety, toxicity, large-scale production costs, and tissue specificity [5,6].

To overcome these limitations, (6)-Gingerol has been formulated as SMEDDS and proliposomes which has resulted in improved bioavailability by 5-fold in vivo compared with free drug [5,6]. Solid Lipid Nanoparticles (SLN) are colloidal drug carriers and have particle size ranging from 50nm to 1000nm which have ability to enter lymphatic circulation when administered orally through Peyer's patch [9,10,11].

Hence formulation of (6)-Gingerol as lipid nanoparticles may be able to improve bioavailability by entry of particles through lymphatic route and also may allow the accumulation of SLN at inflamed site by passive diffusion [12].

The present work attempts to incorporate ginger extract in SLN by using principal of design of experiment (DOE) and demonstrate its lymphatic uptake by ex vivo everted rat gut sac model.

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5. Formulation and evaluation of chewable tablets of pomegranate peel extract

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Journal of Drug Delivery and Therapeutics

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Formulation and Evaluation of Chewable Tablets of Pomegranate Peel Extract

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ABSTRACT

Nowadays, dental caries is one of major oral disease caused due to facultatively anaerobic, gram-positive *Streptococcus mutans*. Pomegranate peel powder extract is known to have activity against *Streptococcusmutans*. The ethanolic extract of pomegranate peel powder was tested against streptococcus mutans (MTCC 497t). The Minimum inhibitory concentrations was found to be 6.24 mg/ml. Chewable tablet containing 10x MIC of the pomegranate peel powder was tested by cup plate method for its antibacterial activity against Streptococcus mutans. The study concludes that pomegranate peel extract is a natural antibacterial source can be used in formulating chewable tablet which are better than chemical formulations specially mouth washes as stay-in-mouth time of these chewable tablet are extended ensuring good antibacterial activity with good organoleptic properties.

Keywords: Dental caries, Chewable tablet, Pomegranate peel, *Streptococcus mutans*.

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INTRODUCTION:

Dental caries is one of the major oral diseases caused primarily by *streptococcus mutans*.It is of great concern to dentists as it affects all age groups causing loss of tooth structure, moderate to severe pain, swelling and infection[1-2]. The organism, in presence of fermentable carbohydrates produces acid which induces demineralization of tooth structure. Dental caries have conventional treatment with antibiotics and Fluoride, Acetaminophen, Ibuprofen.Traditional medicine offers a good alternative to synthetic chemical substances,large number antibacterial compounds have been isolated from plant species. Natural ingredients such as clove oil, aloe vera, turmeric, sesame, cranberry, meswak, sesame, red clover are also used for the dental caries treatment.Pomegranate peels extract has been reported to exhibit high level of antibacterial activity[3-4]. The extract also hasother medicinal activities like antioxidant,antidiarrheal,antifungal[5-6].Chemical constitutents present in pomegranate are Punicalagin, gallic acid, ellagic acid, Punic acid .The objective of this study is to develop an effective formulation containing pomegranate peel extract and evaluation of invitro antibacterial activity[7-8]of the same,under accelerated storage conditions for 3 months

MATERIAL AND METHOD:

Plant Material and Extraction:

Pomegranates (*Punicagranatum*) were personally picked from farm. The sample was authenticated by Botanical Survey of India. The peel was manually removed, sun-dried and powdered. Powder was extracted with a Soxhlet extractor using ethanol for 36 hours[6]. Ethanolic extract thus prepared was then concentrated on electric water bath. Then semisolid (sticky) extract was obtained.

The material used for the preparation of tablets were:Xylitol (Research lab fine chem industries, Mumbai),Talc(Zimlaborateies, kalmeshwar, Nagpur), Lactose Monohydrate (LOBA Chemicals, Mumbai), Polyvinylpyrrolidone (ANA Lab fine chemicals, Mumbai), Mannitol (ANA Lab fine chemicals, Mumbai), Magnesium sterate (Loba chemicals, Mumbai)

Triple stability chamber (Make -Thermolab) was used for stability testing.

Formulation of Chewable Tablets of Pomegranate Peel extract:

Chewable tablets containingPomegranate peel extract were formulated as shown in table no.1

The extract was mixed with xylitol, mannitol, lactose and the powder so obtained was moistened with aqueous solution of PVP K 30. The material obtained was granulated through sieve number 18 and dried to constant weight at room temperature. The dried granules were passed through sieve

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6. Formulation of Coffee bean extract (Cholinergic acid) Solid lipid nonoparticle for lymphatic uptake on oral administration

Available online on 15.07.2019 at http://jddtonline.info

Journal of Drug Delivery and Therapeutics

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Formulation of Coffee Bean Extract (Chlorogenic Acid) Solid Lipid Nanoparticles for Lymphatic Uptake on Oral Administration

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ABSTRACT

Coffee bean extract (Chlorogenic Acid), Disease Modifying Anti-Rheumatoid Drug (DMARD) agent in the treatment of Rheumatoid Arthritis is believed to inhibit the production of TNF-α by blocking the cell associated conversion of TNF Precursor to mature proteins this, halting the proliferation of synovitis.CGA inhibit the proliferation of the fibroblast-like synoviocyte cell line (RSC-364), stimulated by interleukin (IL)-6, through inducing apoptosis. CGA inhibit the inflammatory proliferation of RSC-364 cells mediated by IL-6 through inducing apoptosis. CGA was also able to suppress the expression levels of key molecules in the JAK/STAT and NF-κB signaling pathways, and inhibit the activation of these signaling pathways in the inflammatory response through IL-6-mediated signaling, thereby resulting in the inhibition of the inflammatory proliferation of synoviocytes. The aim of the present study was to formulate and evaluate coffee bean extract (chlorogenic acid) solid lipid nanoparticles using a positive charge on it by means of enabling lymphatic uptake. Coffee bean extract (chlorogenic acid) solid lipid nanoparticles were prepared by melt emulsification-high pressure homogenization method and the particle size, PDI and % entrapment efficiency was found to be 210nm, 0.455 and 91.18% .ex vivo endocytic uptake studies revealed engrossment of endocytic pathways in the uptake of solid lipid nanoparticles from intestine.

Keywords: Coffee bean extract (Chlorogenic Acid), Glyceryl monostearate, Solid Lipid Nanoparticles, Lymphatic Uptake

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Abbreviations: CGA-ChlorogenicAcid, GMS-Glyceryl monostearate, DMARD- Disease Modifying Anti-Rheumatoid Drug, SLN-Solid Lipid Nanoparticles.

1. INTRODUCTION

Coffee bean extract (Chlorogenic Acid), has been reported to serve as Disease Modifying Anti-Rheumatoid Drug (DMARD). Chlorogenic acid given orally in a dose of 40mg/Kg is reported to inhibit the production of TNF-α by blocking the cell associated conversion of TNF Precursor to mature proteins thus halting the proliferation of synovitis [1,2].

Solid lipid nanoparticles (SLN) are colloidal drug carriers and have particle size ranging from 50 nm to 1000 nm and its advantages include biocompatibility, stability and protects drug against chemical degradation[5]. SLN are reported to have ability to enter lymphatic circulation when administered orally through Peyer's patch[6,7].the factors such as particle size, zeta potential on particles are known to affect the uptake[6]

The present work attempts to formulate chlorogenic acid in solid lipid nanoparticulate carrier by using principal of design of experiment (DOE) and demonstrate its lymphatic uptake by *ex vivo* everted rat gut sac model.

2. MATERIAL AND METHODS:

2.1. Materials

Coffee bean extract was purchased from shamantak enterprises (pune, india). Glyceryl mono stearate (analab fine chemicals),chlorogenic acid (sigma aldrich) purchased locally. All the other chemicals and reagents were of analytical grade and procured from local sources.

2.2 Methods

2.2.1 Characterization of Coffee bean extract:

2.2.1.1 Standard calibration curve of chlorogenic acid by UV-Visible spectrophotometry

Solution of chlorogenic acid were prepared in concentration range of 5 to 30µg/ml in ethanol. The absorbance of resulting solutions was measured at 324 nm using double beam UV-Visible Spectrophotometer (LABINDIA UV 3000) against ethanol as blank [10].

2.2.1.2 Selection of lipid using solubility parameter:[11,12]

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7. Molecular docking in formulation and development

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Review Article

Molecular Docking in Formulation and Development

Author(s): Tejinder Kaur*, Ashwini Madgulkar, Mangesh Bhalekar and Kalyani Asgaonkar

Volume 16, Issue 1, 2019
Page: [30 - 39] **Pages:** 10
DOI: 10.2174/1570163815666180219112421
Price: $65

Abstract

Background: In pharmaceutical research drug discovery and development process is timeconsuming and expensive. In many cases, it produces incompetent results due to the failure of in vitro and in vivo conventional approaches. Before any new drug is placed in the market it must undergo rigorous testing to get FDA approval. Due to the several limitations imposed by the drug discovery process, in recent times in silico approaches are widely applied in this field. The purpose of this review is to highlight the current molecular docking strategies used in drug discovery and to explore various advances in the field.

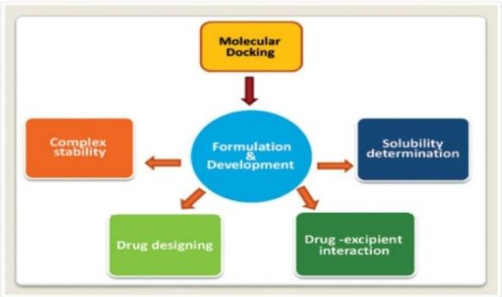
Methods: In this review we have compiled database after an extensive literature search on docking studies which has found its applications relevant to the field of formulation and development. The papers retrieved were further screened to appraise the quality of work. In depth strategic analysis was carried out to confirm the credibility of the findings.

Results: The papers included in this review highlight the promising role of docking studies to overcome the challenges in formulation and development by emphasizing it's applications to predict drug excipient interactions which in turn assist to increase protein stability; to determine enzyme peptide interactions which maybe further used in drug development studies; to determine the most stable drug inclusion complex; to analyze structure at molecular level that ascertain an increase in solubility, dissolution and in turn the bioavailability of the drug; to design a dosage form that amplify the drug discovery and development process.

Conclusion: This review summarizes recent findings of critical role played by molecular docking in the process of drug discovery and development. The application of docking approach will assist to design a dosage form in the most cost effective and time saving manner.

Keywords: Molecular modelling, drug discovery, molecular docking, formulation and development, pharmaceutical research, molecular modeling.

Graphical Abstract



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8. Formulation and evaluation of alfuzosin hydrochloride extended release tablets

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Formulation and evaluation of alfuzosin hydrochloride extended release tablets

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ABSTRACT

Purpose The aim of the study was to design extended release tablets capable of producing a 20 h extended release profile there by eliminating the use of immediate release tablets which require a frequent administration of three tablets containing 2.5 mg of alfuzosin hydrochloride of the daily dose. The present study deals with the formulation of Alfuzosin Hydrochloride extended release tablets. Benign prostatic hyperplasia is a noncancerous prostate problem in which the normal elements of the prostate gland grow in size and number, requires an alpha-adrenergic blocker which is having optimum therapeutic window concentration for a prolonged duration. With the above characteristics, Alfuzosin Hydrochloride was selected as an active therapeutic agent. Methods. Alfuzosin HCl extended release matrix tablets were prepared by direct compression method by employing hydrophilic polymer HPMC K 100 M and Crosslinked Xyloglucan (XG). The crosslinked XG was prepared by crosslinking of natural polysaccharide that is XG with crosslinking agent Sodium Trimetaphosphate (STMP). Simplex centroid design was applied for the optimization process. The prepared tablets were evaluated for various physicochemical parameters by official procedures. The in-vitro release study of matrix tablets was carried out in 0.01N HCl for 24 hours. Results. The tablets exhibited acceptable physicochemical characteristics and extended drug release pattern was observed for about 20h. Analysis of drug release data from the matrix system indicated that the drug release follows zero order kinetics by anomalous (non-fickian) diffusion. Conclusion. The crosslinked XG along with HPMC K 100M and DCP showed the potential for prolonged delivery of Alfuzosin over a 20 h period and therefore may be a suitable candidate for use in sustained release drug delivery system.

Keywords— *Immediate release, Alfuzosin, Crosslinked, Xyloglucan, Sodium trimetaphosphate*

1. INTRODUCTION

Hydrophilic gums have been used as matrix former in several sustain release delivery systems (Sumathi and Ray 2002). Xyloglucan (XG is natural polysaccharide obtained from seeds of Tamarindus indica, also known as tamarind seed polysaccharide. Crosslinking is the process of joining two or more molecules by covalent bond linkage through a chemical treatment. It reduces the hydrophilicity of the gums thereby decreasing the diffusion of the drug from the matrix rendering it to be used as a release retardant (Albhar et al 2012). Various cross linking agents have been reported in literature to reduce the drug release from tablets and microspheres (Sumathi and Ray 2002) The different crosslinkers such as glutaraldehyde have been reported but all these have toxicity, Sodium Tri Metaphosphate (STMP) is a biocompatible cross linker used widely in food and pharmaceuticals (Reddy et al 2012).

Hydrophilic gums have been used as matrix former in several sustain release delivery systems (1). Xyloglucan (XG is natural polysaccharide obtained from seeds of Tamarindus indica, also known as tamarind seed polysaccharide. Crosslinking is the process of joining two or more molecules by covalent bond linkage through a chemical treatment. It reduces the hydrophilicity of the gums thereby decreasing the diffusion of the drug from the matrix rendering it to be used as a release retardant (2). Various cross-linking agents have been reported in the literature to reduce the drug release from tablets and microspheres (1) the different crosslinkers such as gluteraldehyde have been reported but all these have toxicity, Sodium Tri Metaphosphate (STMP) is a biocompatible cross linker used widely in food and pharmaceuticals (3).

Alfuzosin HCl is a selective antagonist of post-synaptic alpha -adrenoreceptors, which are located in the prostate, bladder base, bladder neck, prostatic capsule and prostatic urethra. Alfuzosin is indicated for the treatment of benign prostatic hyperplasia.

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9. Scientific Coformer Screening, Preparation and Evaluation of Fenofibrate Tartaric acid Cocrystal

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Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

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Scientific Coformer Screening, Preparation and Evaluation of Fenofibrate Tartaric Acid Cocrystal

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ABSTRACT

Objective: This present study aims to screen pharmaceutical cocrystal of Fenofibrate and coformers. Further the preparation and evaluation of fenofibrate-coformer cocrystal and *In-Vitro* drug release and *Ex-Vivo* Permeation study was done. **Material and Methods:** The coformers for Fenofibrate were screened using molecular docking. The cocrystals produced were characterized using Differential Scanning Calorimetry (DSC), X-ray diffraction (XRPD) study and Infrared spectroscopy. **Results:** Cocrystal of Fenofibrate with tartaric acid was successfully prepared. The cocrystals displayed enhanced dissolution rate by 2.36 fold, similarly the *ex-vivo* drug uptake through everted chicken intestine model was improved by 4.38 fold. The formation of cocrystals of fenofibrate with tartaric acid was evaluated by DSC, IR and XRPD.

Conclusion: The fenofibrate - tartaric acid cocrystal exhibited increased % drug release and permeation compared to fenofibrate. This study confirms that selection of proper coformer is very vital step in preparation of stable, superior cocrystal. Based upon above study and results it revealed that cocrystallization offers a valuable way to improve the physicochemical properties of the API.

Keywords: Pharmaceutical Cocrystal, Fenofibrate , Coformer, Molecular docking.

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INTRODUCTION

Pharmaceutical cocrystallization is a reliable method to modify and improve physical and chemical properties of drugs such as solubility, stability, dissolution rate, hygroscopicity and compressibility without changing their pharmacological activity.[1] Pharmaceutical cocrystals offer an alternative to chemical modification of the drug substance as well as established salt, solvate, amorphous, inclusion complexes and polymorphic drug forms all of which have restrictions in their utility. Formation of cocrystal depends on the functional groups between API and coformer, to allow for the occurrence of hydrogen bonds or other forms of solid interaction.[2] Cocrystals consist of two or more neutral molecular components in a crystal lattice with defined stoichiometry. These are homogeneous phases, which are solids at room temperature and are held together by weak interactions, mainly hydrogen bonding.

Capability of forming non-covalent interactions especially hydrogen bonds with an APIs forms the basis of coformer selection. Various approaches to coformer selection were supramolecular synthon approach, Hansen solubility parameter, pKa based, lattice energy calculation, hydrogen bond propensity and Molecular docking.[3]

Fenofibrate is a extensively used as hypolipidemic drug. This drug is used mostly in lipid regulation as it decreases low-density lipoprotein (LDL) and very-low density lipoprotein (VLDL) levels, and increases high density lipoprotein (HDL) level. Solubility and permeability are the fundamental parameters controlling the rate and extent of drug absorption. Fenofibrate is a BCS class II drug with low solubility and high permeability. Various reported methods to improve dissolution of fenofibrate are micronization, nanonization, salt formation, incorporation of surface active agent, solid dispersion, polymorphism and cocyrstal synthesis. [4,5,6,7]

The aim of the study was to improve dissolution of Fenofibrate using cocrystal formation. The study involved *in silico* screening of coformers, preparation and *in-vitro, ex-vivo* evaluation of Fenofibrate cocrystals. The anti-solvent addition method was used to form cocrystals with tartaric acid. The cocrystals were characterized by IR spectroscopy, DSC and XRPD.

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10. Study of Polymeric Mixed Micelle System of Sulphasalazine for Improvement of Oral Bioavailability

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Study of Polymeric Mixed Micelle System of Sulphasalazine for Improvement of Oral Bioavailability

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ABSTRACT

Sulfasalazine (SSZ) has been recommended for rheumatoid arthritis, ulcerative colitis, and Crohn's disease. However, low aqueous solubility and reduced bioavailability obstruct its clinical application. The aim of this study was to formulate a mixed micelles (MM) system composed of two biocompatible copolymers Soluplus and Pluronic F127 to improve the solubility and oral bioavailability of insoluble drug SSZ. SSZ-MM was prepared by an ethanol solvent evaporation method and optimized using 32 factorial designs with respect to quantity of polymers. The average size, zeta potential and entrapment efficiency of the optimized formulation were found to be 59.12 nm, -16.4 mV and 62.04% respectively. The SSZ-MM showed sustained release up to 24 h in in-vitro release study. Ex-vivo endocytic uptake studies revealed involvement of endocytic pathways in the uptake of mixed micelles from the intestine. The in-vivo oral bioavailability study in Wistar rats showed 2.19 folds higher AUC of SSZ-MM than free SSZ, indicating the mixed micelles of Soluplus and Pluronic F127 is a feasible drug delivery system to promote insoluble drug oral absorption in the gastrointestinal tract.

Keywords: Sulfasalazine, Bioavailability, Absorption, Factorial design, Micelles, Pharmacokinetics.

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11. Multiparticulate drug delivery system for gastro intestinal tuberculosis

International Journal of Pharmaceutical Sciences and Drug Research 2019; 11(5): 210-220

RESEARCH ARTICLE

ISSN: 0975-248X
CODEN (USA): IJPSPP

Multiparticulate Drug Delivery System for Gastrointestinal Tuberculosis

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ABSTRACT

Drug solubility poses numerous challenges in design of formulations for drugs with poor aqueous solubility. Ethionamide is an antitubercular drug belonging to biopharmaceutical classification system class II drug having less aqueous solubility. Nanosuspensions were prepared by using various solvents such as methanol, ethanol, acetone and chloroform and it was prepared using anti-solvent precipitation technique by using probe sonication. Various stabilizers such as tocopherolpolythytlene glycol succinate, polyvinylpyrrolidone and tween 80 singly or in combination were studied. A 3^2 factorial design was employed to study the effect of independent variables, concentration of stabilizers and stirring speed on particle size and cumulative percent drug release. The particle size of the optimized batch was 97.54 ± 8.47 nm with polydispersity index of 0.36 and zeta potential -10.1 ± 2.3 mV. The cumulative percent drug release of optimized batch was found to be 95.01 ± 1.16% in 60 min. Optimized batch was ultracentrifuged and evaluated for saturation solubility studies, stability and powder X-ray Diffraction studies. Optimized nanosuspension was loaded on Espheres by spraying in a coating pan and then coating of Eudragit controlled release polymers. The coated Espheres were evaluated for drug content, friability, scanning electron microscopy, *ex-vivo* permeation studies and drug release kinetics studies. The friability value for primary coated sphere was found to be 0.8 ± 0.12% and for secondary was 1% and the best fit model was found to be Korsmeyer-Peppas model which is indicative of diffusion controlled release. *Ex vivo* diffusion studies revealed a moderate increase in permeability.

Keywords: Solubility enhancement, Ethionamide, Nanosuspension, Coating, Multiparticulate system, Drug release kinetics.

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INTRODUCTION

Solubility is the property of substance in which solute molecules get dissolved in the different solvent to form a homogeneous solution. Particle size, polymorph, nature of solute and solvent are various factors that affect solubility. Drugs with poor water solubility (BCS class II) give some problems related to low solubility and low absorption. Different strategies to overcome

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12. Formulation and development of gastroretentive drug delivery system of efavirenz.

International Journal of Pharmaceutical Sciences and Drug Research 2019; 11(5): 231-240

RESEARCH ARTICLE

ISSN: 0975-248X
CODEN (USA): IJPSPP

Formulation and Development of Gastroretentive Drug Delivery System of Efavirenz

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ABSTRACT

Efavirenz, a non-nucleotide reverse transcriptase inhibitor is an important drug for treating patients with Human Immunodeficiency Virus infections. It belongs to BCS class II have low solubility and poor intrinsic dissolution rate. It is highly basic (pKa 10.2) which makes it suitable candidate for floating dosage form for continuous delivery in stomach.The study was aimed to improve the solubility by solid dispersion technique.Saturation solubility study and drug content were evaluated for solid dispersion preparation. Saturation solubility shows 8 fold increases in 0.1 N HCL compared to plain drug and drug content was found to be between 95%-102%. Further effervescent floating gastroretentive drug delivery system was prepared by 3^2 full factorial design with independent variables i.e., concentration of HPMC K100 as matrix forming agent and citric acid as gas generating agent. Lag time, floating time, percent drug release were studied as responses. The optimized batch exhibited floating lag time of 40 sec and the *in vitro* release studies showed 89.5% drug release in 9 h and tablet remained floating for greater than 8 h. The study thus demonstrated that solubility is increased by solid dispersion technique and floating delivery systems may increase solubility and bioavailability of Efavirenz.

Keywords: Efavirenz, GRDDS, Solid dispersion (SD), Solvent evaporation method, Solubility enhancement, Percent drug release.

DOI: 10.25004/IJPSDR.2019.110513 **Int. J. Pharm. Sci. Drug Res. 2019; 11(5): 231-240**

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INTRODUCTION

Controlled drug delivery systems are recognized as important pharmaceutical systems that have made major inroads in dosage form design. Drugs which have short half-lives are absorbed in gastrointestinal tract (GIT) without any difficulty and also eliminated from the systemic circulation. [1] To obtain desired therapeutic effect, repeated dosing of the drugs is essential. Oral controlled release formulations enable this limitation to be overcome by slow release of the drug in the GIT and maintain sufficient plasma drug concentration for required time span. [2] Gastric retention devices are intended to prolong the gastric residence time of oral controlled release dosage forms. This results in increased residence time and hence absorption of drugs that act locally. Drugs that have

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13. Formulation and Evaluation of Mucoadhesive Clotrimazole vaginal tablet using liquisolid technology

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Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

Open Access Research Article

Formulation and Evaluation of Mucoadhesive Clotrimazole Vaginal Tablet Using Liquisolid Technology

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ABSTRACT

Liquisolid technology is very effective technique for improving the solubility and dissolution properties of poorly water soluble drug formulations like Clotrimazole. Clotrimazole is a BCS Class II, antifungal drug used for treatment for *Vaginal Candidiasis.* In this liquisolid technique the drug soluble in non volatile solvents and then it converted into free flowing, non adherent powder, which can be compressed into tablet. Here N-methyle-2-pyrrolidone and propylene glycol is used in the ratio of 1:1 as a solvent. Neusilin US2 and Aerosil 200 used as Coating and Carrier material respectively. For mucoadhesion on vaginal wall Sodium carboxymethyle cellulose used as a mucoadhesive agent. Mucoadhesive tablets were prepared using direct compression technique. Magnesium Stearate used as a glidant. Mucoadhesive liquisolid tablets were evaluated as precompression evalutions and post compression evaluations. Future tablets were evaluated as *In vitro* and *Ex vivo* evaluations. The optimized batch showed that *In vitro* release in simulated vaginal fluid pH 4.5 in 6 hr was 99%. *Ex vivo* diffusion studies of optimized batch showed 80% of drug diffusion in 6 hr. Mucoadhesive strength showed high mucoadhesion of optimized batch that is 36 gm. From this study it was concluded that liquisolid technology is an effective technique to improve solubility and dissolution properties of poorly water soluble drug formulations like Clotrimazole.

Keywords: Liquisolid Tablets, Clotrimazole, Non volatile solvents

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INTRODUCTION

Vaginal candidiasis is a fungal infection which is also called as *candida vaginitis*. It develops in mucosa that usually causes a watery, white, cottage cheese-like vaginal discharge [1]. Many conventional formulations are prepared for treatment of vaginal candidiasis like oral and vaginal tablets. Vaginal drug delivery has many advantages as compared to oral drug delivery like bypassing the first pass metabolism and local drug delivery. For many years imidazole derivatives have been used as drugs of choice for treating this infection. Clotrimazole (CTZ) is BCS class II drug which has prominent antifungal action. It works to kill individual *Candida* or fungal cells by altering the permeability of the fungal cell wall. It binds to phospholipids in the cell membrane and inhibits the biosynthesis of ergosterol and other sterols required for cell membrane production. This leads to the cell's death via loss of intracellular elements [2]. CTZ is available in various formulations like tablets, creams, gels for local treatment. However, a major problem with these formulations is low residence time [3].

Liquisolid technology is used to enhance solubility and dissolution of drug. In liquisolid technique the drug is dissolved in a suitable solvent and the liquid medication is loaded on solid carrier and coating material. A flowable, compressible powder is obtained by addition of suitable excipients like disintegrants, glidants and lubricants. Liquisolid compacts are prepared by direct compression or slugging method. It is cost effective technique and easy for industrial production [4]. Generally water insoluble or poorly water soluble drugs are dissolved in non volatile organic solvents like propylene glycol (PG), polyethylene glycols 400 (PEG 400), N-methyle-2-Pyrrilidone (NMP) etc. These solvents are then loaded on various ratios of carrier and coating materials till a flowable, compressible powder is obtained.

The aim of this study was to enhance solubility and dissolution rate of CTZ by liquisolid technique and formulation of mucoadhesive CTZ vaginal tablet using suitable mucoadhesive agent. A 3^2 factorial design was employed for formulation designs of batches. Carrier/coating material and mucoadhesive agent were the two independent factors selected and percent drug diffusion and mucoadhesive strength were selected as responses. Liquid Load Factor (L_f) was calculated for various carrier/coating ratios for selection of suitable

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14. Design of transdermal patch of ketoprofen by full factorial design for treatment of rheumatoid arthritis

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Design of transdermal patch of ketoprofen by full factorial design for treatment of rheumatoid arthritis

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ABSTRACT

Oral therapy of NSAIDs for treatment of rheumatoid arthritis causes gastric irritation and ulceration. In the present study transdermal patch of ketoprofen was developed using hydroxyl propyl methyl cellulose E5 and Eudragit S100. Patches were prepared by solvent evaporation method. Optimization was carried out by 3^2 factorial design with polymer concentration (HPMC E5) and plasticizer concentration (propylene glycol) as independent variables. Patches were evaluated for folding endurance, surface pH, drug content, percent moisture content, water uptake and swelling studies. E*x vivo* permeation studies of optimized patch was performed using Franz diffusion cell while bioadhesion force and tensile strength were measured by using texture analyzer. Hydrophilic nature, swelling ability and wettability of polymer and plasticizer were responsible for increase in flux and bioadhesion with increase in their concentrations in the factorial batches. Swelling index of all formulations was in the range of 17.3 ±1.2 to 65.29 ±4.78 up to 3h. Flux obtained from all batches was in the range of 3.37±0.23 to 5.43±0.13µg/h/cm². Anti-inflammatory studies using carrageenan-induced rat paw edema showed greater paw swelling reduction in case of ketoprofen patch. Cumulative percent drug permeation of optimized patch through nylon 66, Wistar rat skin and cadaver skin was found to be 92.3% >86.28 %>63.42% in 8h, while flux order was 6.073> 5.442 > 2.219 µg/h/cm² respectively. The study concludes that transdermal patch of ketoprofen will be more efficacious with absence of gastric irritation observed in oral formulations.

Keywords: Ketoprofen, Bioadhesion, HPMC E5, Flux, Backing membrane

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INTRODUCTION

Rheumatoid arthritis (RA) is a chronic, progressive inflammatory disease of the joints characterized by synovial proliferation and inflammatory and immunological processes. These mechanisms lead to irreversible degradative and erosive changes in the articular cartilage and juxta articular bone. RA affects multiple joints, most commonly small joints of the hands, feet and cervical spine, but larger joints like the shoulder and knee can also be involved[1,2].

Non-Steroidal Anti-Inflammatory Drug (NSAID) and steroids are used to reduce inflammation thereby decreasing pain and improving function. Disease-Modifying Antirheumatic Drugs (DMARDs) are required to inhibit the underlying immune process and prevent long-term damage[1,3]. NSAIDS lead to gastrointestinal side effects such as dyspepsia to gastric bleeding[4]. The acidic character of NSAIDS may lead to local irritation, and lesions on the gastrointestinal mucosa are known as NSAIDS gastropathy[5].

Ketoprofen (KTF) is a propionic acid derivative which causes inhibition of Cyclooxygenase-2 (COX-2), an enzyme involved in prostaglandin synthesis via the arachidonic acid pathway. This results in decreased levels of prostaglandin that mediate pain, fever and inflammation. KTF is a non-specific cyclooxygenase inhibitor and inhibition of COX-1 is responsible for its side effects, such as GI upset and ulceration[6]. Currently available marketed dosage form of KTF are enteric coated and extended release tablets, topical gel, liquid spray, suppositories, extended release capsules and formulation based on transfer some technology for direct application on the skin has been developed[7].

Transdermal therapeutic systems are defined as, discrete dosage forms which, applied to the intact skin, deliver the drugs at a controlled rate to the systemic circulation via skin and this delivery system offers an advantageous alternative to conventional delivery system such as injections or oral delivery[8,9]. Transdermal drug delivery system (TDDS) offers many advantages such as reduced side effects, less frequent administration to produce the desired constant plasma concentration associated with improved patient compliance,

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15. Formulation Development of Sustained Release Epidural Injection of Analgesic Drug

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Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

Open Access Research Article

Formulation Development of Sustained Release Epidural Injection of Analgesic Drug

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ABSTRACT

The objective of this work was to formulate and evaluate sustained release epidural injection of analgesic drug diclofenac sodium used in chronic lower back pain. The formulation composed of a thermosensitive polymer Pluronic F127 (20%) and sustained release copolymers HPMC K100M (1%) and HPMC K4M (0.5%) optimized using 3^2 factorial design. The formulation was found to be clear, colorless, sterile, syringeable through 18gauge, forming a stable gel at 37°C with a gel strength of 9.67g/cm. The drug release was found to be 98.13% in 72 hrs. The formulation was found to be stable at refrigerator temperature of 5°C for a month. Thus, a stable parenteral formulation was developed that can be an appropriate and convenient approach for patients requiring frequent parenteral administration, reducing recurrence of dosage and ultimately expanding patient comfort and satisfaction in case of chronic ailments.

Keywords: Diclofenac Sodium, in situ gel, Pluronic F127, Epidural, lower back pain.

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INTRODUCTION

The lower back supports the weight of the upper body and provides mobility for everyday motions such as bending and twisting. Muscles in the low back are responsible for flexing and rotating the hips while walking, as well as supporting the spinal column. Nerves in the low back supply sensation and power the muscles in the pelvis, legs, and feet. Most acute low back pain results from injury to the muscles, ligaments, joints, or discs. The body also reacts to injury by mobilizing an inflammatory healing response. While inflammation sounds minor, it can cause severe pain.

Symptoms of lower back pain are usually described by type of onset and duration i.e. Acute pain comes on suddenly and lasts for a few days or weeks, and is considered a normal response of the body to injury or tissue damage, Subacute low back pain is usually mechanical in nature (such as a muscle strain or joint pain) but is prolonged and Chronic back pain which is defined as lower back pain that lasts over 3 months, this type of pain is usually severe, does not respond to initial treatments, and requires a thorough medical workup to determine the exact source of the pain. It is also possible for low back pain to develop with no definitive cause. When this happens, the primary focus is on treating the symptoms rather than the cause of the symptoms and the patient's overall health.[1]

Various treatments are available for low back pain such as physical therapy, surgeries, and medications. The medications includes topical such as Aspercreme, Ben-Gay, Oral medications (NSAIDs, Narcotics, Muscle relaxants, steroids, etc) and injections. Epidural steroid injections are common treatment option for many forms of low back pain, however the effects of the injection tend to be temporary, so it need to be used in combination with comprehensive rehabilitation program, providing relief from pain for one week up to one year.[2]

The rationale behind injecting drug into the epidural space adjacent to the spinal nerve is that it will combat the inflammatory response and thus reduce pain. The inflammation can lead to direct neuronal activity, as well as swelling and mechanical compression of the nerve within the intervertebral foramen so to facilitate earlier pain relief and return to full function, for rapid effects of medication on cerebrospinal tissues or meninges, medication can be administered into the epidural space of the spinal cord. This technique avoids absorptive problems otherwise presented by the blood–brain barrier. So far, to our knowledge, for general clinical epidural use there is only one slow-release liposome product of morphine available on market (DepoDur®).[3,4]

Diclofenac is non-steroidal anti-inflammatory drug (NSAID), indicated in the relief of all grades of pain and inflammation associated with a wide range of conditions, including arthritic conditions, acute musculo-skeletal disorders and

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16. Evaluation of Pharmacokinetic Studies and Analgesic Activity of Sustained Release Epidural Injection of Analgesic Drug on Wistar Rat

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Evaluation of Pharmacokinetic Studies and Analgesic Activity of Sustained Release Epidural Injection of Analgesic Drug on Wistar Rat

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Abstract: The purpose of this work was to carry out the pharmacokinetic studies and analgesic activity of the developed sustained release in situ gel forming epidural injection of an analgesic drug Diclofenac sodium for the treatment of low back pain. The formulation was prepared using pluronic F 127 as a thermosensitive polymer and HPMC K100 M, HPMC K4 M as release retardant copolymers that gelled at 37°C i.e. body temperature and showed a sustained release of 98.13% over a period of 3 days. In-vivo studies involved the pharmacokinetic and analgesic activity studies of the SR formulation and its comparison with marketed immediate release injection. The Cmax of sustained release and immediate release formulation were found to be 13.21µg/ml and 10.14µg/ml respectively, AUC0-∞ was found to be 933.53µg.hr/ml and 52.47µg.hr/ml respectively. These parameters achieved by the sustained release formulation was found be longer than that of immediate release formulation. The analgesic activity was determined by studying writhing reflex that showed significant decrease in pain as compared with immediate release injection which required frequent administration. Thus, the formulation showed the effectiveness of its use in animals as a sustained drug delivery system that could effectively be employed in clinical studies.

Index Terms- **Pharmacokinetic Studies, Analgesic Activity, In-Situ Forming Gel, Epidural Injection.**

I. INTRODUCTION

Diclofenac is non-steroidal anti-inflammatory analgesic drug (NSAID) with potent cyclo-oxygenase inhibition activity indicated in the relief of all grades of pain and inflammation associated with a wide range of conditions, including low back pain, arthritic conditions, acute musculo-skeletal disorders and other painful conditions resulting from trauma. The dosage of diclofenac injection is 25 mg per ml, not to exceed 150 mg per day.

Diclofenac Sodium is well-absorbed after oral administration with extensive hepatic metabolism. It exhibits a terminal half life of 1–2 hr. Cmax is reached at approximately 4 hours. Diclofenac is associated with serious dose-dependent gastrointestinal, cardiovascular, and renal adverse effects. The gastrointestinal toxicity of Diclofenac through oral administration can be avoided by injecting drug directly at the target site. The in situ forming gel formulation is developed to provide prolong drug release, increase residence time and bioavailability, reduction in frequent dosing and patient compliance.[1,2,3,4]

The analgesic activity of analgesic or anti-inflammatory agents is evaluated using writhing reflex induced by acetic acid. Writhing reflex is described as stretching, extension of the hind legs and abdominal contractions. Any writhing reflex is regarded as a positive reaction.[5,6]

The present work was focused on pharmacokinetic evaluation and analgesic activity of the developed sustained release insitu gel forming epidural injection of an analgesic drug Diclofenac sodium for the treatment of low back pain over a 3 days period in order to reduce the frequency of administration and to improve patient compliance.

II. MATERIALS AND METHODS

1. Materials:

Diclofenac Sodium was obtained as a gift sample from Emcure Pharmaceuticals Pune. PluronicF127 was provided by Ana lab fine chemical, Mumbai. Hydroxy propyl methyl cellulose K100M, K4M (HPMC K100M, HPMC K4M) was provided by Chemica-biochemic-reagents, Otto chemie,Pvt.Ltd. Methanol, Acetonitrile HPLC grade, Diethyl ether was provided by SD fine chem., Mumbai.

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17. Evaluation of hepatoprotective activity of hydroalcoholic extract of Onion peels containing Protocatechuic acid

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Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

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Evaluation of Hepatoprotective Activity of Hydroalcoholic Extract of Onion Peels Containing Protocatechuic Acid

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ABSTRACT

India is the second largest country for cultivation of onion. 19.90% of onion is cultivated in India. Onion that is Allium cepa family Amaryllidaceae used in daily diet for taste. Onions also have number of medicinal properties, such as hepatoprotection, anticancer, antifungal, antioxidant, antiulcer, anti-agging, anti-inflammatory, anticancer etc.[1-2] The dried scales or peels of onion also have the same medicinal constituents with same activity as raw onions. The onion peels contains flavonoids, such as anthocyanins, flavones (qurcertin and its derivatives), ferulic, Gallic, protocatechuic acids, sulphur, vitamins etc. In the present study determination of protocatechuic acid in onion peels extract has been performed using HPTLC. HPTLC separation was carried out on Merck TLC aluminium sheets precoated with silica gel $60F_{254}$ using Toluene: Ethyl acetate: Formic acid (6: 6: 1.2 v/v/v) as mobile phase.[3-11] Quantitative analysis was carried out in the absorbance mode at 258 nm. Hydroalcoholic extract was tested for hepatoprotective activity in wistar rats (either sex) by using CCl_4 as hepatotoxicity inducing agent and Silamyrin as standard. Hydroalcoholic extract shows hepatoprotective activity as indicated by decrease in the level of SGOT, SGPT, total protein, billirubin an which hepatotoxicity was induced by CCl_4 intraperitonial injection route to animal, from the result it may be concluded that onion peels extract may be used for hepatoprotective activity.

Keywords: Onion peel extract, Protocatechuic acid, HPTLC, hepatoprotection.

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INTRODUCTION

There is an increasing interest in herbal remedies because of their effectiveness, less side effects in clinical experiments and relatively low cost. Protocatechuic acid (PCA) is widely distributed and present in most edible plants used in medicine. It is also a very common compound present in human diet, present in bran and brown rice (Oryza sativa L.) and onion (Allium cepa L.). Onion peels are the external part of onion bulb and having several folds, it is thin, light weight, strong often translucent paper. Onion peel contains numbers of phytoconstituent such as sulphur, qurcertin, protocatechuic acid, calcium, flavonoids, phenolic acid, etc[1,5].

PCA has been reported to possess antioxidant, antibacterial, anticancer, antiulcer, ant diabetic, ant ageing, antifibrotic, antiviral, anti-inflammatory, analgesic, antiatherosclerotic, cardio protective, hepatoprotective, neurological and nephroprotective activities. As per literature search there is no method for determination of protocatechuic acid in onion peel extract and evaluation of hepatoprotective activity in rats[6-9].

Liver is one of the largest organs in the human body and chief site for intense metabolism and excretion. Liver diseases are one of the major health problems in the world. These are caused by toxic chemicals, autoimmune disorders, infections and excess consumption of alcohol. The hepatotoxic chemicals can induce lipid peroxidation and oxidative damages. It is involved in almost all the biochemical pathways to growth, fight against the disease, nutrient supply, energy provision and reproduction.[10-14]

The hydroalcoholic extract of onion peels contains PCA as active constituent. There are many literature record indicating hepatoprotective activity of PCA. Despite of there is no report available on action of onion peel extract. For that reason the present study changed into undertaken to

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18. Development of analytical method to monitor dissolution of Bepotastine Besilate tablet

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Open Access Research Article

Development of Analytical Method to Monitor Dissolution of Bepotastine Besilate Tablet

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ABSTRACT

Bepotastine Besilate is an anti-histaminic drug and it is marketed as tablet of strength 10mg. In this study an attempt is made to monitor the dissolution of Bepotastine Besilate tablet. Dissolution study was done for marketed sample using phosphate buffer 6.8, phosphate buffer 4.5 and 0.1 N HCl as dissolution media. Samples were analysed using UV spectrophotometer, HPLC and HPTLC. Detection wavelength selected was 226nm. A chromatographic separation is achieved on a C18 column with a mobile phase consisting of acetonitrile, water with isocratic elution with flow rate 1ml/min. Solvents used for development in HPTLC were chloroform and methanol. Percentage release of bepotastine besilate was calculated by extrapolation of calibration curve. The results of three analytical methods were compared by applying One-Way ANOVA.

Keywords: Bepotastine Besilate, Dissolution, UV, HPLC, HPTLC

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INTRODUCTION

Bepotastine is a second-generation nonsedating antihistamine. It possesses a dual mode of action as it also stabilizes mast cell function and suppresses migration of eosinophils into the inflamed tissues[1]. Its molecular formula is $C_{21}H_{25}ClN_2O_3$. Chemically it is benzenesulfonic acid;4-[4-[(S)-(4-chlorophenyl)- pyridin-2-ylmethoxy]piperidin-1-yl]butanoic acid as shown in fig.1.

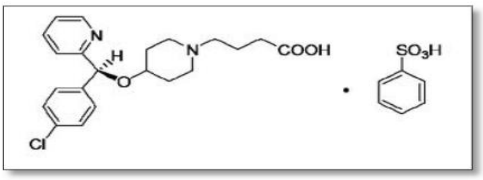

Fig 1: Structure of Bepotastine Besilate

Molecular weight is 547.063 g/mol[2]. It is soluble in Acetonitrile and methanol. It was approved in Japan for use in the treatment of allergic rhinitis and urticaria/pruritus. It is available as ophthalmic solution and oral tablet. It is a direct H1 receptor antagonist that inhibits the release of histamine from mast cells. Literature survey revealed the estimation of Bepotastine by several techniques such as simultaneous estimation RP-HPLC techniques[3,4], Stability indicating method by HPTLC[5], development of alternative salt i.e. Bepotastine salicylate[6], comparison of branded and generic[7].

MATERIAL AND METHOD

All AR grade chemicals and reagents i.e. Methanol, Chloroform, Acetone, Hydrochloric acid(HCL), Sodium hydroxide (NaOH), Potassium Dihydrogen Phosphate (KH_2PO_4) were purchased from LOBA CHEMIE PVT. LTD., Mumbai.

Selection of Wavelength

Standard stock solution of 1,000ug/ml was prepared by using ACN. Further dilution was carried out to make solution of 10µg/ml and was scanned over 200 to 400nm in UV-Spectrophotometer. Wavelength 226nm showed considerable absorbance hence it was selected as analytical wavelength. UV spectrum is given as

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19. Formulation and evaluation of chewable tablets of Pomegranate peel extract

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Open Access Research Article

Formulation and Evaluation of Chewable Tablets of Pomegranate Peel Extract

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ABSTRACT

Nowadays, dental caries is one of major oral disease caused due to facultatively anaerobic, gram-positive *Streptococcus mutans*. Pomegranate peel powder extract is known to have activity against *Streptococcusmutans*. The ethanolic extract of pomegranate peel powder was tested against streptococcus mutans (MTCC 497t). The Minimum inhibitory concentrations was found to be 6.24 mg/ml. Chewable tablet containing 10x MIC of the pomegranate peel powder was tested by cup plate method for its antibacterial activity against Streptococcus mutans. The study concludes that pomegranate peel extract is a natural antibacterial source can be used in formulating chewable tablet which are better than chemical formulations specially mouth washes as stay-in-mouth time of these chewable tablet are extended ensuring good antibacterial activity with good organoleptic properties.

Keywords: Dental caries, Chewable tablet, Pomegranate peel, *Streptococcus mutans*.

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INTRODUCTION:

Dental caries is one of the major oral diseases caused primarily by *streptococcus mutans*.It is of great concern to dentists as it affects all age groups causing loss of tooth structure, moderate to severe pain, swelling and infection[1-2]. The organism, in presence of fermentable carbohydrates produces acid which induces demineralization of tooth structure. Dental caries have conventional treatment with antibiotics and Fluoride, Acetaminophen, Ibuprofen.Traditional medicine offers a good alternative to synthetic chemical substances,large number antibacterial compounds have been isolated from plant species. Natural ingredients such as clove oil, aloe vera, turmeric, sesame, cranberry, meswak, sesame, red clover are also used for the dental caries treatment.Pomegranate peels extract has been reported to exhibit high level of antibacterial activity[3-4]. The extract also hasother medicinal activities like antioxidant,antidiarrheal,antifungal[5-6].Chemical constitutents present in pomegranate are Punicalagin, gallic acid, ellagic acid, Punic acid .The objective of this study is to develop an effective formulation containing pomegranate peel extract and evaluation of invitro antibacterial activity[7-8]of the same,under accelerated storage conditions for 3 months

MATERIAL AND METHOD:

Plant Material and Extraction:

Pomegranates (*Punicagranatum*) were personally picked from farm. The sample was authenticated by Botanical Survey of India. The peel was manually removed, sun-dried and powdered. Powder was extracted with a Soxhlet extractor using ethanol for 36 hours[6]. Ethanolic extract thus prepared was then concentrated on electric water bath. Then semisolid (sticky) extract was obtained.

The material used for the preparation of tablets were:Xylitol (Research lab fine chem industries, Mumbai),Talc(Zimlaborateies, kalmeshwar, Nagpur), Lactose Monohydrate (LOBA Chemicals, Mumbai), Polyvinylpyrrolidone (ANA Lab fine chemicals, Mumbai), Mannitol (ANA Lab fine chemicals, Mumbai), Magnesium sterate (Loba chemicals, Mumbai)

Triple stability chamber (Make -Thermolab) was used for stability testing.

Formulation of Chewable Tablets of Pomegranate Peel extract:

Chewable tablets containingPomegranate peel extract were formulated as shown in table no.1

The extract was mixed with xylitol, mannitol, lactose and the powder so obtained was moistened with aqueous solution of PVP K 30. The material obtained was granulated through sieve number 18 and dried to constant weight at room temperature. The dried granules were passed through sieve

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20. Stability indicating HPTLC method for Hepseridin

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UGC Approved Journal

Stability Indicating HPTLC Method for Hesperidin

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Abstract
A stability indicating assay method was developed and validated according to the ICH guidelines for estimation of Hesperidin using HPTLC. **Objective**-Hesperidin is flavonoid with anti-inflammatory, anti-oxidant properties. The objective was stability-indicating method development and validation for Hesperidin by HPTLC. **Method** – HPTLC method was developed and validated using Mobile phase consisting of Ethyl acetate: Methanol: Water (7:2:2 v/v/v) and detected at wavelength 283 nm. Various forced degradation conditions were used to check degradation of drug. **Results** - The method showed a good linear relationship (r^2= 0.9855) in the concentration range 200-1000 ng/band. It was found to be linear, accurate, precise and specific. **Conclusion**–The proposed HPTLC method for Hesperidin can be applied for quality control as well as for stability testing of Hesperidin. The developed method was validated as per ICH guideline Q2(R1).

Keywords
Hesperidin, HPTLC, Stability indicating. ICH guidelines.

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INTRODUCTION
Chemically, Hesperidin is (2S)-5-hydroxy-2-(3hydroxy-4-methoxyphenyl)-7-[(2S,3R,4S,5S,6R)-3,4,5trihydroxy-6-{[(2R,3R,4R,5R,6S)-3,4,5-trihydroxy-6methyloxan-2-yl]oxymethyl}oxan-2-yl]oxy-2,3dihydrochromen-4-one[1]. Hesperidin is a flavonoid. Highest concentrations are found in citrus fruit peels. For instance, peels from tangerines contain hesperidin the equivalent of 5-10 % of their dry mass [2]. Hesperidin plays a protective role against fungal and other microbial infections in plants. These flavonoids have been detected in human plasma after orange and grapefruit diets. Decades of research revealed its many therapeutic applications in prevention and treatment of many human disorders. Hesperidin shows different activities such anti-inflammatory, anti-oxidant, anti-carcinogenic, cardiovascular, anti-diabetic, anti-allergic, etc. It is used clinically for the treatment of Rheumatoid Arthritis [3]. The objective was development of stability indicating method for Hesperidin by HPTLC. The method was validated as per ICH Q2(R1) guidelines. The stability indicating assays are important to determine the shelf life of the products. It also helps to determine the storage conditions by knowing the process of degradation. Literature survey reveals that, there are some reported quantitative estimation methods [4-8] and stability indicating methods reported for Hesperidin

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21. Stability indicating HPTLC method for determination of Mesalamine

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Stability Indicating HPTLC Method for Determination of Mesalamine

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Abstract
Mesalamine is an anti-inflammatory agent used for treating ulcerative colitis and mild to moderate Crohn's disease. It is used clinically for the treatment of conditions such as diarrhea, rectal bleeding and stomach pain. It belongs to class of drugs known as amino salicylates. It is available in the market as granules, tablets, capsule, rectal suspensions, enema and suppositories in different strengths. A simple, rapid validated stability indicating HPTLC method for Mesalamine has been successfully developed. This method is based on HPTLC separation followed by UV detection at227nm. The separation was carried on Merck TLC aluminium sheets pre-coated with Silica Gel $60F_{254}$ using Ethyl acetate: Methanol: Ammonia as a Mobile Phase. Mesalamine gave well defined and sharp peak at R_f0.40± 0.02. Calibration curve was linear in range 250-1250ng/band. Stress degradation was carried out as per ICH Q1A(R2). The study included hydrolysis at different pH, oxidation, thermal and photolytic stress conditions. This method can be applied to determination of stability of Mesalamine. The suitability of this HPTLC method for quantitative determination of Mesalamine was proved by validation in accordance with requirements of ICH guidelines Q2A(R1).

Keywords
Mesalamine, Stability-Indicating HPTLC, Validation.

*****

INTRODUCTION:
Chemically, Mesalamine is 5-aminosalicyclic acid which is an anti-inflammatory agent, more specifically classified as amino salicylates in NSAID drugs [1]. It is used clinically for the treatment of ulcerative colitis, diarrhea, rectal bleeding, and stomach pain [2-3]. It is available in the market as granules, tablets, capsule, rectal suspensions, Enema, suppositories in different strengths. It is official in IP/USP/ BP. [4-6]. There are number of UV method [7], HPLC methods [8-12], UPLC methods [13-14], and HPTLC method [15-16], reported for estimation of Mesalamine. There are four stability-indicating methods reported in literature so far; two by HPLC & two by HPTLC technique. The results of stress degradation studies reported in these, vary a lot. Hence, the main objective of my research work was to confirm the stress degradation study results. Stress degradation studies were carried out as per ICH Q1A(R2) guidelines [17] and ICH Q1B guidelines [18] method was validated as per ICH Q2(R1) guidelines [19].

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22. Stability indicating chromatographic method for estimation of Methimazole

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Stability Indicating Chromatographic Method for Estimation of Methimazole

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Abstract
A stability indicating high performance thin layer chromatography (HPTLC) method was developed and validated for determination of anti-thyroid drug, Methimazole. HPTLC separation was carried out on Merck TLC aluminium sheets precoated with silica gel $60F_{254}$ using mobile phase as Chloroform: Acetone. Methimazole gave sharp peak at Rf 0.44 ±0.03 at 252nm. Calibration curve was linear in range 200-600ng/band for methimazole. Stress degradation study was carried out according to ICH guidelines Q1A (R2) and the method was validated as per ICH guideline.

Keywords
Methimazole, HPTLC, stability, validation.

*****

INTRODUCTION
Methimazole is used to treat hyperthyroidism, a condition that occurs when the thyroid gland produces too much thyroid hormone. It directly interferes with thyroid synthesis by preventing iodine and peroxidase from combining with thyroglobulin to form thyroxine (T4) and triiodothyronine (T3). This action decreases thyroid hormone production[https://en.wikipedia.org/wiki/Thiamazole]. Methimazole is chemically 3-methyl-1-imidazole-2-thione. It is a white, crystalline substance that is freely soluble in water. It is metabolite of carbimazole[https://www.drugbank.ca/drugs/DB00763]. Several analytical methods have been reported for the analysis of carbimazole and methimazole such as HPLC method for methimazole in human plasma, urine and fish homogenates [1-6], HPLC and HPTLC method for carbimazole [7 & 8], stability indicating method for carbimazole by HPTLC [9]. Literature survey revealed that no stability indicating HPTLC method is reported for determination of methimazole in bulk drug and tablet dosage form. The main objective of the proposed work was to develop a simple, accurate, precise and sensitive HPTLC method for the estimation of methimazole in bulk drug and tablet. The method was further optimized and validated in accordance with guidelines suggested by ICH guidelines (International Council for Harmonization). Structure of methimazole is given as Fig 1.

MATERIAL AND METHODS
All chemicals and reagents that is Methanol, Chloroform, Acetone, Hydrochloric acid(HCL), Hydrogen peroxide solution 6% w/v (H_2O_2), Sodium hydroxide (NaOH) were purchased from LOBA CHEMIE PVT. LTD., Mumbai.
CHROMATOGRAPHIC CONDITION

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23. Validated Stability indicating HPTLC method for Protocatechuic Acid

IJPSR (2020), Volume 11, Issue 1 **(Research Article)**

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VALIDATED STABILITY INDICATING HPTLC METHOD FOR PROTOCATECHUIC ACID

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Keywords:

Protocatechuic acid, Stress degradation, HPTLC

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Abstract: Protocatechuic acid (PCA) is a type of widely distributed naturally occurring phenolic acid, commonly found in bran, grain, brown rice, fruits such as plums, gooseberries, grapes and also in onion peels. A new, simple, precise, accurate and sensitive stability-indicating HPTLC method for Protocatechuic acid was successfully developed. This method is based on HPTLC separation followed by UV detection at 258 nm. The HPTLC method is used to determine the presence and quantify the protocatechuic acid in onion peel extract. The separation was carried out on Merck TLC aluminum sheets precoated with silica gel 60F254 using Toluene: Ethyl Acetate: Formic acid (6:6:1.2 v/v/v) as a mobile phase and scanning was done by using TLC Scanner III. Protocatechuic acid gave well defined and sharp peak at R_f 0.52 ± 0.03 at 258 nm. The calibration curve was linear in range 100-500 ng/band. Protocatechuic acid was subjected to stress conditions like hydrolysis under acidic, basic and neutral conditions, oxidation, heat, and photolysis.

INTRODUCTION: Protocatechuic acid (PCA) is a type of naturally occurring phenolic acid. PCA is chemically 3, 4-dihydroxybenzoic acid. PCA has structural similarity with gallic acid, caffeic acid and vanillic acid which are well-known antioxidant compounds. The chemical formula is C7H6O4, and molar mass is 154.12 g/mol. It is freely soluble in methanol and sparingly soluble in water, insoluble in benzene [1, 2]. Protocatechuic acid has many pharmacological activities such as anti-bacterial, anti-inflammatory, hepatoprotective, anti-cancer, anti-diabetic, anti-oxidant, anti-ulcer, anti-mutagenic, analgesic, *etc* [3-10].

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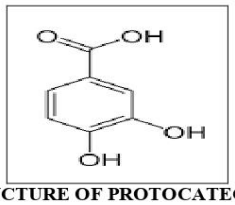

FIG. 1: STRUCTURE OF PROTOCATECHUIC ACID

As per literature search there is no stability-indicating method reported for determination of protocatechuic acid in onion peel by HPLC and HPTLC. Development of SIM is based on systematic exposure of API to various stress conditions. Systematic optimization trials are required to arrive at combination of "concentration of stress reagent and duration of exposure," to obtain degradation preferably in the 10-20% range. Typical degradation conditions involve hydrolysis under different pH conditions, photolysis, oxidation and thermal studies [12 - 13].

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24. Validated stability indicating HPTLC method for Sofosbuvir and Velpatasvir

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Research Article

Stability Indicating HPTLC Method for Sofosbuvir and Velpatasvir in Combination

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ABSTRACT

The discovery of new direct-acting antiviral drugs gave rise to a leap forward in the treatment of hepatitis C viral (HCV) infections. For the first time since 1998, the Food and Drug Administration (FDA) approved interferon-free oral treatment paradigms. Among the new treatment regimens, the combinations of Sofosbuvir (SOF) and Velpatasvir (VEL) became ideal treatment regimens for being potent, highly tolerated, and used once daily. Hence accurate, precise, selective, and sensitive stability-indicating method for simultaneous estimation of SOR and VEL by high-performance Thin layer chromatography has been developed and validated. Chromatographic separation was achieved on TLC plates coated with silica gel 60 F_{254} as a stationary phase. Ethyl acetate: isopropyl alcohol (9:1 v/v) was used as a mobile phase. Densitometric scanning was carried out at 260 and 302 nm for SOF and VEL, respectively. The method was successfully validated as per the ICH Guideline. The linear concentration range was 100-2000 ng/band (r^2 = 0.991) and 100-500 ng/band (r^2 = 0.991) for SOF and VEL respectively. The LoD was 25.16 ng/band and 9.96 ng/band for SOF and VEL, LoQ were 76.25 ng/band and 30.19 ng/band for SOF and VEL. The method could be applied to the quality control and routine analysis of SOF and VEL in their pure forms and pharmaceutical formulations.

INTRODUCTION

Hepatitis C is a liver disease caused by the HCV. The fixed drug combination consists of sofosbuvir (SOF) (400 mg) and Velpatasvir (VEL) (100 mg), used in the treatment of hepatitis C. This is a new direct-acting antiviral drug combination, which is approved by United States Food and Drug Administration in June 2016. The combination of SOR and VEL became the ideal treatment regimen for being most potent, highly tolerated. This direct-acting antiviral was approved for the treatment of adults with chronic hepatitis C with or without compensated cirrhosis, and in combination with ribavirin for decompensated cirrhosis, for all 6 genotypes.

The IUPAC name of SOR is Isopropyl (2*S*)-2-[[[(2*R*,3*R*,4*R*,5*R*)-5-(2,4-dioxopyrimidin-1-yl)-4-fluoro-3-hydroxy-4-methyl-tetrahydrofuran-2-yl]-methoxy-phenoxy-phosphoryl]-amino]-propanoate. It is inhibitor of the HCV NS5B ribonucleic acid (RNA) dependent RNA polymerase, which undergoes intracellular metabolism to form uridine analogue triphosphate and inhibits the viral replication by incorporating into HCV RNA and acts as a chain terminator.

VEL chemically is methyl((S)-1-((S)-2-(5-(6-(2((S)-1-((methoxycarbonyl)-L-valyl)pyrrolidin-2-yl)-1H-imidazol-4-yl)naphthalen-2-yl)-1H-benzo[d]imidazol-2-yl) pyrrolidin-1-yl)-3-methyl-1-oxobutan-2-yl)carbamate is an inhibitor of HCV NS5A protein, which blocks the action of the protein and inhibits the viral replication.

The main objective of the current work was to develop and validate the stability-indicating high-performance thin layer chromatography (HPTLC) method for the

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25. Stability indicating HPTLC method for analysis of Teriflunomide

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Stability Indicating HPTLC Method for Analysis of Teriflunomide

Abstract

Teriflunomide is an immunosuppressive agent that inhibits or prevents activity of immune system. Teriflunomide is not official until to date in IP, USP, and BP. Many studies have reported the HPLC, UPLC, LC/MS, but no work is intended towards the development of a stability indicating method by high-performance thin layer chromatographic (HPTLC) method coupled with a densitometer for the estimation of Teriflunomide. The chromatographic development was performed on aluminium plates coated with silica gel 60 F254 using toluene: ethyl acetate: glacial acetic acid as the mobile phase. Densitometric scanning was achieved at theabsorbance maxima 294 nm. Teriflunomide was subjected to hydrolysis under different pH conditions, oxidation, thermal and photolytic stress conditions. A well-separated band was observed with Rf value 0.46 ± 0.01. The calibration curve plotted in the concentration range 100-500 ng/band exhibited an excellent linear relationship with the R2 value of 0.997. The method was found to comply with all the validation parameters as per the ICH guidelines Q2 (R1).

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26. Method Development, Validation and Comparative Study of Generic And Branded Formulations of Linezolid in Tablet Dosage Form

METHOD DEVELOPMENT, VALIDATION AND COMPARATIVE STUDY OF GENERIC AND BRANDED FORMULATIONS OF LINEZOLID IN TABLET DOSAGE FORM

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ABSTRACT:

UV Spectrometric and HPLC methods were developed and validated for estimation of Linezolid in tablet dosage form. Developed methods were applied for comparative study of generic vs branded formulations of Linezolid. The main objective is to compare and evaluate the price and quality of branded and generic formulations of Linezolid 600 mg tablet. Linezolid in methanol shows maximum absorbance at 258 nm. The data of linear regression analysis indicated a good linear relationship over the concentration range of 5-30 µg/ml with a correlation coefficient (R^2) 0.998 by both UV- Spectroscopy and HPLC. The evaluation parameters like weight variation, hardness of the tablet, friability, thickness, disintegration test, drug content uniformity and in vitro release studies were performed as prescribed in Indian Pharmacopeia 2010.

Keywords: Branded, Generic, Quantitative and Qualitative Determination, Ultraviolet spectroscopy, HPLC, Comparative studies.

INTRODUCTION:

Introducing generic products from multiple sources into health care systems exist in many countries in an approach aiming to improving the overall healthcare system. The use of generic drugs is steadily increasing internationally as a result of economic pressure on drug budgets. Generic drugs provide the opportunity for major savings in healthcare expenditure since they are usually substantially lower in price than the innovator brands.[1] However, this has been accompanied by a variety of problems, the most critical of which is the widespread distribution of substandard products. Product selection of the same active ingredients from several generic products available in the market is very important step during the course of therapy and cause several concerns to a healthcare practitioner. Therapeutic equivalence must be ensured by ascertaining the biopharmaceutical equivalency of such drug products. Drug products that are therapeutically and chemically equivalent must have the same strength, quality, purity and content uniformity, and disintegration and dissolution rates. The need to ensure that the generic and branded drug products are pharmaceutically and therapeutically equivalent cannot be overemphasized.

Linezolid is the first member of a new class of antibiotics, the oxazolidinones. It is an important therapeutic option for the treatment of infections caused by multiresistant Gram-positive bacteria. Linezolid is active against vancomycin-resistant *Enterococci*, methicillin-resistant *Staphylococcus aureus* (MRSA)and glycopeptide-intermediate *S. aureus*.[2] Fewer methods

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27. Development and Validation of Stability Indicating UV Spectroscopic Method for Estimation of Dapsone

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Research Article | Pharmaceutical Sciences | Open Access | MCI Approved
UGC Approved Journal

Development and Validation of Stability Indicating UV Spectroscopic Method for Estimation of Dapsone

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Abstract

A stability-indicating UV Spectrophotometric method has been developed for analysis of the Dapsone in the presence of the degradation products and is validated as per ICH Q2 R1 guidelines. Dapsone in methanol shows maximum absorbance at 295 nm. The data of linear regression analysis indicated a good linear relationship over the range of 2-20 μgml^{-1} concentrations with a correlation coefficient (R^2) of 0.984. The LOD and LOQ were found to be 0.066 $\mu g\ ml^{-1}$ and 1.200 $\mu g\ ml^{-1}$, respectively. Percentage assay of Dapsone tablets was found to be in the range of 98.36 - 101.49 %. Dapsone was subjected to different stress testing conditions. Degradation of Dapsone was mainly found in alkaline and acidic condition. The developed method was found to be simple, accurate and precise for analysis of Dapsone and can be adopted for routine analysis of drug in bulk and pharmaceutical dosage form.

Keywords

Dapsone, Method development, Stability indicating method, Ultraviolet spectroscopy, Validation.

*****

INTRODUCTION:

Dapsone (DAP) chemically bis (4-aminophenyl) sulphone[1],is an antibiotic commonly used in combination with rifampicin and Clofazimine the treatment of leprosy. It is a second-line medication for the treatment and prevention of pneumocystis pneumonia and for the prevention of toxoplasmosis in those who have poor immune function. Additionally, it has been used for acne, dermatitis herpetiformis and various other skin conditions [2]. Literature survey reveals that few analytical methods have been reported for the estimation of Dapsone in pharmaceutical dosage form including UV-Vis spectroscopy [3,4], high performance liquid chromatography (HPLC) [2,4-9], TLC [5], LC-MS/MS [10] and HPTLC [11].Present work describes a simple, stability indicating UV spectroscopic method and validation for the determination of Dapsone in bulk and tablet dosage form according to ICH guidelines.

MATERIALS AND METHODS

Reagents and chemicals

Dapsone Tablets I.P labeled to contain Dapsone 100 mg was procured from local market. Methanol (AR grade), was purchased from S.D. Fine Chemical Laboratories, Mumbai. Hydrochloric acid (HCl), acetic acid (CH_3COOH), hydrogen peroxide (H_2O_2), and sodium hydroxide (NaOH); all AR grade were purchased from Loba Chemie Pvt. Ltd., Mumbai.

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28. Method development, validation and comparative study of generic Vs. branded generic formulations of amoxicillin trihydrate in capsule dosage form

Available online on 15.06.2019 at http://jddtonline.info

Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

Open Access Research Article

Method development, validation and comparative study of generic Vs. branded generic formulations of amoxicillin trihydrate in capsule dosage form

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ABSTRACT

The present work relates to development and validation of simple, precise and sensitive UV spectrometric and high-performance thin layer chromatographic (HPTLC) method for the analysis of Amoxicillin Trihydrate in Capsule dosage form. Method were developed and applied for comparative study of generic vs branded generic formulations of Amoxicillin Trihydrate. Amoxicillin Trihydrate in methanol shows maximum absorbance at 229 nm and the data of linear regression analysis indicated a good linear relationship over the concentration range of 5-30 µg/ml with a correlation coefficient (R^2) 0.998 by UV- Spectroscopy and the concentration range of 2000-12000 ng/band with a correlation coefficient (R^2) 0.997 by HPTLC. The main objective was to compare and evaluate the price and quality of branded generic and generic formulations of Amoxicillin Trihydrate 250 mg Capsule. The evaluation parameters like content of active ingredients, content uniformity test, mass variation, disintegration test, and in vitro release studies were performed as described in Indian Pharmacopeia 2010.

Keywords: Branded Generic, Generic, Quantitative and Qualitative Determination, Ultraviolet Spectroscopy, HPTLC, Comparative Studies.

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INTRODUCTION

Analytical chemistry spreads its application in many allied areas. Especially in the pharmaceutical industry; quality of the manufactured drugs in tablets, solutions, suspension or other dosage form must be carefully controlled. Slight variation in composition or in the purity of drug itself can affect therapeutic value. Therefore, there is constant need to develop newer and better methods for pharmaceutical analysis. The main objective of this study is to carry comparative study and evaluate the price and quality for certain drugs for their IPQC tests and dissolution studies in Branded Vs Generic solid dosage forms. As there is belief that due to its cheaper cost and non-popularity generic medicines are of poor quality. The marketing cost is also saved, government takes responsibility to decide the price of medicines and due to competition between manufacturers the cost of generic medicines is less compare to branded ones. In case of branded medicines, the time and its development cost need to be paid more for the original company that's why the branded medicines are costlier than the generic medicines [1,2]. The generic and branded generic formulation of the drug should have same strength, quality and physicochemical properties [3]. We need to ensure that both formulations are pharmaceutically and therapeutically same.

Amoxicillin is [[2S [2α,5α,6β, (S*)]]-6-[[Amino(4-hydroxyphenyl) acetyl] amino]-3, 3-dimethyl-7-oxo-4-thia-1-azabicyclo [3.2.0] heptane-2-carboxilic acid].)1) is an oral semi-synthetic penicillin structurally related to ampicillin. Amoxicillin is β -lactam antibiotic that belong to the group of penicillin. It is semi-synthetic, broad spectrum, acid stable, orally absorbed antibiotics that inhibit bacterial cell, it is normally used for the treatment of common bacterial infection [4].

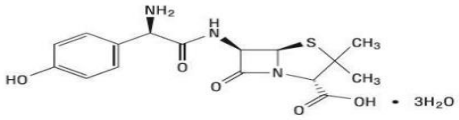

Fig I: Chemical structure of Amoxicillin Trihydrate

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29. HPLC Method Development and Validation for Estimation of Chlorthalidone in Tablet Dosage Form

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Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

Open Access Research Article

HPLC Method Development and Validation for Estimation of Chlorthalidone in Tablet Dosage Form

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ABSTRACT

The present work relates to development and validation of simple, precise and rapid high-performance liquid chromatographic (HPLC) method for the analysis of Chlorthalidone in tablet dosage form. Method was developed for qualitative and quantitative estimation of Chlorthalidone in tablet dosage form. The chromatographic separation was achieved by using mobile phase 20 mM potassium dihydrogen orthophosphate buffer pH 4.0: methanol (30:70 %v/v) on HiQ Sil C_8 (4.6 mm*250 mm* 5µm) column. The mobile phase was pumped at a flow rate of 1.0 ml/min and the eluent was monitored at 230 nm. Retention time was 3.334±0.042 min. Linearity was observed in the concentration range of 5-30 µg/ml with a correlation coefficient (R^2) of 0.9915. All the parameters were validated as per ICH guidelines and found to be suitable for routine analysis of drug in pharmaceutical dosage form.

Keywords: Chlorthalidone, Quantitative and Qualitative estimation, HPLC.

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Gandhi SV, Sanklecha AP, HPLC Method Development and Validation for Estimation of Chlorthalidone in Tablet Dosage Form, Journal of Drug Delivery and Therapeutics. 2019; 9(4):53-56 http://dx.doi.org/10.22270/jddt.v9i4.3127

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INTRODUCTION

Chlorthalidone is a long acting thiazide-like diuretic of the sulfamoylbenzamide class that is devoid of the benzothiadiazine structure. Chlorthalidone directly inhibits sodium and chloride reabsorption on the luminal membrane of the early segment in the distal convoluted tubule (DCT) in the kidney. This leads to an increase in sodium, chloride, bicarbonate, and potassium secretion resulting in the excretion of water. In addition, this agent, like other thiazide diuretics, decreases calcium and uric acid secretion. In addition, this agent inhibits many carbonic anhydrase (CA) isoenzymes.Chlorthalidone is considered first-line therapy for management of uncomplicated hypertension as there is strong evidence from meta-analyses that thiazide diuretics such as Chlorthalidone reduce the risk of stroke, myocardial infarction, heart failure, and cardiovascular all-cause mortality in patients with hypertension. Chlorthalidone is used in the treatment of high blood pressure, edema and congestive heart failure [1-2]. Chlorthalidone is chemically described as 2-chloro-5-(2, 3-dihydro-1-hydroxy-3-oxo-1H-isoindol-1-yl) benzenesulfonamide [3].

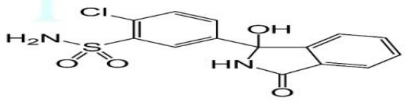

Figure I: Chemical structure of Chlorthalidone

Literature review indicated that few UV spectrophotometric [4-6], HPLC [7-10] methods was reported for estimation of drug as individual or in combination with other drugs.

literature survey reveals that the data of reported HPLC methods is incomplete hence based on these observations we have developed HPLC method and validated as per International Conference on Harmonization Guidelines[12] for estimation of Chlorthalidone.

MATERIALS AND METHODS

Reagents and chemicals

Chlorthalidone tablets I.P labeled to contain Chlorthalidone 6.50 mg were purchased from local market. Methanol (AR grade), Methanol (HPLC grade), potassium dihydrogen phosphate, ortho-phosphoric acid, HPLC Grade water was used in study.

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30. Development and Validation of UV Spectroscopic Method for Estimation of Baricitinib

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Development and Validation of UV Spectroscopic Method for Estimation of Baricitinib.

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ABSTRACT

A simple, sensitive and reproducible spectrophotometric method for the analysis of Baricitinib in pure form and in its dosage form has been developed. Baricitinib is a synthetic antineoplastic and immunomodulating drug. Baricitinib is a selective and reversible Janus kinase 1 (JAK1) and 2 (JAK2) inhibitor. Janus kinases belong to the tyrosine protein kinase family and play an important role in the proinflammatory pathway signalling that is frequently over-activated in autoimmune disorders such as rheumatoid arthritis. Developed method obeyed beer's law in a concentration range of 10-60 µg/ml with a correlation coefficient (R^2) of 0.993. Quantification was carried out at 250 nm. Percentage assay of Baricitinib was found to be close to 100 %. The results of analysis have been validated statistically and recovery studies confirmed the accuracy of the proposed method.

Keywords: Spectrophotometric method, Baricitinib, Antineoplastic, immunomodulating, Beer's law.

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INTRODUCTION:

Baricitinib is chemically, 2-[1-(ethanesulfonyl)-3-(4-{7H-pyrrolo[2,3-d]pyrimidin-4-yl}-1H-pyrazol-1-yl)azetidin-3-yl]acetonitrile. It is used for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs as monotherapy or in combination with methotrexate. Upon administration, baricitinib binds to JAK1/2, which inhibits JAK1/2 activation and leads to the inhibition of the JAK-signal transducers and activators of transcription (STAT) signaling pathway. This decreases the production of inflammatory cytokines and may prevent an inflammatory response. In addition, baricitinib may induce apoptosis and reduce proliferation of JAK1/2-expressing tumor cells. JAK kinases are intracellular enzymes involved in cytokine signaling, inflammation, immune function and hematopoiesis; they are also upregulated and mutated in various tumor cell types. In February 2017, Baricitinib was approved for use in the EU as a second-line oral therapy for moderate to severe active rheumatoid arthritis in adults, either alone or in combination with methotrexate. It is marketed under the trade name Olumiant. [1-3]. The structure of Baricitinib is given in Fig 1.

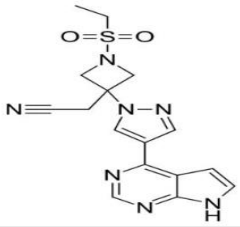

Fig 1: Structure of Baricitinib

As per the literature survey the data shows that simultaneous quantification of Baricitinib and Methotrexate in rat plasma by LC-MS/MS is reported [4]. No spectroscopic method has been reported for estimation of baricitinib in bulk or dosage form. The present manuscript describes simple and sensitive spectroscopic procedure for the determination of baricitinib in accordance with International Conference on Harmonisation Guidelines.[5]

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31. Development and Validation of Stability Indicating HPTLC Method for Estimation of Dapsone

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DEVELOPMENT AND VALIDATION OF STABILITY INDICATING HPTLC METHOD FOR ESTIMATION OF DAPSONE

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ABSTRACT
A simple, precise and sensitive stability indicating high performance thin layer chromatographic (HPTLC) method has been developed and validated for the analysis of Dapsone in bulk and in tablet dosage form. The separation was performed on pre-coated silica gel 60 GF_{254} plates using Toluene: Ethyl acetate (5:5 v/v) as mobile phase. The retention factor (R_f) was found to be 0.38. The detection of band was carried out at 295 nm.The drug was subjected to different stress conditions like acid, base hydrolysis, oxidation, thermal degradation and photolysis. The method was successfully validated according to ICH Q_2 (R1) guidelines. The linear regression analysis data for the calibration plot showed good linear relationship with R^2 =0.9534 in the range of 200-1200 ng $band^{-1}$. The method found to be accurate as results of the recovery studies are close to the 100 %. The developed method can be adopted for routine analysis of Dapsone in bulk and pharmaceutical dosage form.

KEYWORDS: High performance thin layer chromatography (HPTLC), Dapsone, method validation, stability indicating method.

INTRODUCTION
Dapsone (DAP) chemically bis (4-aminophenyl) sulphone,[1] is an antibiotic commonly used in combination with rifampicin and Clofazimine the treatment of leprosy. It is a second-line medication for the treatment and prevention of pneumocystis pneumonia and for the prevention of toxoplasmosis in those who have poor immune function. Additionally, it has been used for acne, dermatitis herpetiformis and various other skin conditions.[2] Literature survey reveals that few analytical methods have been reported for the estimation of Dapsone in pharmaceutical dosage form including UV-Vis spectroscopy[3,4] high performance liquid chromatography (HPLC),[2,4,9] TLC[5] and LC-MS/MS.[10] Literature search reveals no reports related to stability indicating HPTLC method for Dapsone. Thus present work describes a simple, stability indicating HPTLC method and validation for the determination of Dapsone in bulk and tablet dosage form according to ICH guidelines.

MATERIALS AND METHODS
Reagents and chemicals
Dapsone Tablets I.P labeled to contain Dapsone 100 mg was procured from local market. Methanol (AR grade), ethyl acetate (AR grade), toluene (AR grade) were purchased from S.D. Fine Chemical Laboratories, Mumbai. Hydrochloric acid (HCl), acetic acid (CH_3COOH), hydrogen peroxide (H_2O_2), and sodium hydroxide (NaOH); all AR grade were purchased from Loba Chemie Pvt. Ltd., Mumbai.

Chromatographic conditions
Chromatographic separation of drug was performed on aluminum plates precoated with silica gel 60 F_{254} (10 cm × 10 cm with 250 µm layer thickness). Sample was applied on the plate as a band of 5 mm width using Camag 100 µl sample syringe (Hamilton, Switzerland) with a linomat 5 applicator (Camag, Switzerland). The mobile phase was composed of Toluene: Ethyl acetate (5:5 v/v). 10 cm × 10 cm Camag twin trough glass chamber was used for linear ascending development of TLC plate under 15 min saturation conditions and 10 ml of mobile phase was used per run. Migration distance was 80 mm. Densitometric scanning was carried out using Camag TLC scanner at 295 nm, operated by win CATS software (version 1.4.3), slit dimensions were 4.00 × 0.45 mm and Deuterium lamp was used as a radiation source.

Selection of detection wavelength
From the standard stock solution (1000 µg ml^{-1}) further dilutions were made using methanol and scanned over the range of 200-400 nm and the spectra was obtained. It was observed that the drug showed considerable

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32. Study of Forced Degradation Behaviour of a Novel Proteasome-Inhibiting Anticancer Drug by LC-MS and Development of a Validated Stability-Indicating Assay Method

Agarwal and Gandhi, IJPSR, 2019; Vol. 10(3): 1186-1193. E-ISSN: 0975-8232; P-ISSN: 2320-5148

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STUDY OF FORCED DEGRADATION BEHAVIOUR OF A NOVEL PROTEASOME-INHIBITING ANTICANCER DRUG BY LC-MS AND DEVELOPMENT OF A VALIDATED STABILITY-INDICATING ASSAY METHOD

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Keywords:

Carfilzomib, Stress degradation, Stability indicating assay method, LC-MS, Degradation pathway

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ABSTRACT: In the present study, comprehensive stress testing of Carfilzomib, a newly approved proteasome-inhibiting anticancer drug was carried out according to ICH guideline Q1A (R2). The drug was subjected to acid (0.1N HCl), neutral and alkaline (0.1N NaOH) hydrolytic conditions at 70 ºC, as well as to oxidative decomposition at room temperature. Photolysis was carried out in 0.1N HCl, water and 0.1N NaOH at 40 ºC. LC-PDA and LC-MS investigated the products formed under different stress conditions. The LC-PDA method that could separate all degradation products formed under various stress conditions involved a C18 column and a mobile phase comprising of ACN and phosphate buffer (pH 3). The flow rate and detection wavelengths were 1 ml/min and 220 nm, respectively. The developed method was found to be precise, accurate, specific and selective. It was suitably modified for LC-MS studies by replacing phosphate buffer with water, where pH was adjusted to 3.0 with formic acid. The drug showed instability in the solution state (under acidic, neutral, alkaline and oxidative stress conditions), but was relatively stable in the solid-state, except the formation of minor products under accelerated conditions. Primarily, maximum degradation products were formed in acid conditions, though the same were also produced variably under other stress conditions. LC-MS fragmentation studies characterized the products. Based on the results, a complete degradation pathway for the drug could be proposed. LC-ESI-MS/MS characterized the major stress degradation product, and its fragmentation pathway was proposed.

INTRODUCTION: Stability testing is nowadays the key procedural component in the pharmaceutical development program for a new drug as well as new formulation.

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Drugs undergo physicochemical degradation upon storage. Pharmaceutical companies perform forced-degradation studies (stress testing) during pre-formulation to help in the selection of compounds and excipients for further development, to facilitate in salt selection or formulation optimization, and to produce samples for developing stability-indicating analytical methods.

Thus, stability testing of a drug under various temperature and humidity conditions is indispensable during the drug development process.

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33. Non nucleoside Reverse Transcriptase Inhibitors, Molecular Docking Studies and Antitubercular Activity of Thiazolidin-4-one Derivatives

Non Nucleoside Reverse Transcriptase Inhibitors, Molecular Docking Studies and Antitubercular Activity of Thiazolidin-4-one Derivatives

Authors: Chitre, Trupti S.; Patil, Shital M.; Sujalegaonkar, Anagha G.; Asgaonkar, Kalyani D.; Khedkar, Vijay M.; Garud, Dinesh R.; Jha, Prakash C.; Gaikwad, Sharddha Y.; Kulkarni, Smita S.; Choudhari, Amit; Sarkar, Dhiman

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DOI: https://doi.org/10.2174/1573409915666181221102903

Abstract | References | Citations | Supplementary Data

Background: Management of Co-existence of Acquired immunodeficiency syndrome and Tuberculosis has become a global challenge due to the emergence of resistant strains and pill burden.

Objective: Hence the aim of the present work was to design and evaluate compounds for their dual activity on HIV-1 and Tuberculosis (TB).

Methods: A series of seven, novel Thiazolidin-4-one derivatives were synthesized and evaluated for their anti-HIV and anti-tubercular activity along with Molecular docking studies. All the seven compounds displayed promising activity against the replication of HIV-1 in cell-based assays. The four most active compounds were further evaluated against X4 tropic HIV-1UG070 and R5 tropic HIV-1VB59 primary isolates. The binding affinity of all the designed compounds for HIV-RT and Mycobacterium tuberculosis Enol Reductase (MTB InhA) was gauged by molecular docking studies which revealed crucial thermodynamic interactions governing their binding.

Results: The CC50 values for the test compounds were in the range of, 15.08-34.9 µg/ml, while the IC50 values were in the range of 16.1-27.13(UG070; X4) and 12.03-23.64 (VB59; R5) µg/ml. The control drug Nevirapine (NVP) exhibited CC50 value of 77.13 µg/ml and IC50 value of 0.03 µg/ml. Amongst all these compounds, compound number 3 showed significant activity with a TI value of 2.167 and 2.678 against the HIV-1 X4 and the R5 tropic virus respectively. In anti-mycobacterial screening, the compounds proved effective in inhibiting the growth of

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34. Chemoprotective Effect Of Buchanania Lanzan Seeds Extract On Toxicity Of Cisplatin Induced Nephrotoxicity In Rats

ejbps, 2019, Volume 6, Issue 7, 263-267. **Research Article** **SJIF Impact Factor 4.918**

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CHEMOPROTECTIVE EFFECT OF *BUCHANANIA LANZAN* SEEDS EXTRACT ON TOXICITY OF CISPLATIN INDUCED NEPHROTOXICITY IN RATS

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ABSTRACT
The clinical use of cisplatin is highly restricted, because of nephrotoxicity. The study objective was to investigate the protective effects of *Buchanania lanzan* on cisplatin induced nephrotoxicity. Wistar rats were assigned into 7groups weighing 220–250 g, were included in the study. The control group received distilled water for 21 days. The second group of animals injected only with cisplatin (6mg/kg i.p) on day 17 to 21. Third and fourth group of animals administered with extract of *Buchanania lanzan* (200 and 400 mg/kg p.o.) and injected with Cisplatin on day 17 to 21. Fifth and sixth group of animals only injected with extract of *Buchanania lanzan* (200 and 400mg/kg p.o.) and seventh group of animals injected with standard Mesna for 21 days respectively and injected with cisplatin (6mg/kg i.p) on day 17 to 21.On day 22, the rats were decapitated, and blood and hepatic tissues were taken. The results indicated significant changes in serum urea and creatinine concentration in cisplatin group compared with control group. *Buchanania lanzan* was observed to have a protective effect on cisplatin induced Kidney toxicity.

KEYWORDS: *Buchanania lanzan* spreng seed, Cisplatin, Mesna, Nephroprotectivity.

INTRODUCTION

Cisplatin is one of the important anti-neoplastic drugs that is useful in the treatment of many tumours including head, ovary, testis and lungs malignancies. Therapeutic effects of cisplatin are associated with severe side effect, mainly nephrotoxicity and neurotoxicity. The major restriction to use a high dose of cisplatin is its strong side effects in the kidney and gastrointestinal tract. Original pathways of cisplatin transport in renal cells are active transport, although cisplatin enters the cells through passive diffusion as well. The organic cation transporter 2 is the major transporter for cisplatin uptake in proximal tubular cells. Cisplatin also induces the production of free radicals and activates the mitogen-activated protein kinase (MAPK) intracellular signalling pathways. In the presence of cisplatin, reactive oxygen species (ROS) are generated in cells via the xanthine-xanthine oxidase system, mitochondria, and NADPH oxidase.[1]

There is an increasing interest in herbal remedies because of their effectiveness, less side effects in clinical experiments and relatively low cost. Buchanania lanzan spreng. (*B. lanzan*) belongs to the Family Anacardiaceous, is commonly known as 'Chaar' in India.[2] In ayurvedic medicine various part this plant used as astringent, depurative, constipating, brain tonic, cardio tonic and for glandular swelling. The Phytoconstituents reported in seeds of this plant are flavonoids, sterols, tannins, quercetin, glycosides, Triterpenoid, Saponins, carbohydrates, phenolic compounds. The reported pharmacological activity of *B. Lanzan* is Anti-inflammatory and analgesic activity, Antioxidant Activity, Antidiabetic and antihyperlipidemic, Antiulcer, Antidiarrheal, Wound healing activity, Memory booster, Antivenom and Diuretic activity.[3] Based on the reported findings for the presence of flavonoids and antioxidant property, the present study was undertaken to evaluate the effects of ethanolic extract of Buchanania lanzan seed in cisplatin induced nephrotoxicity.

MATERIAL AND METHODS

Collection and Identification of plant Materials

Buchanania lanzan seed were collected from the surrounding area of rural Pune during August-September 2018. The plant was identified and authenticated by M/s. Shamantak Enterprises. Dr. Gautam, Botanist, Pune, India.

Preparation of Plant Extract

A weighed quantity (50g) of the air-dried powdered seeds of *B. lanzan* was drawn and then it was extracted with 90% ethanol in a Soxhlet extractor. The hydroalcoholic extract was concentrated in a rotary flash

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35. Evaluation of Hepatoprotective Activity of Hydroalcoholic Extract of Onion Peels Containing Protocatechuic Acid

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Journal of Drug Delivery and Therapeutics

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Evaluation of Hepatoprotective Activity of Hydroalcoholic Extract of Onion Peels Containing Protocatechuic Acid

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ABSTRACT

India is the second largest country for cultivation of onion. 19.90% of onion is cultivated in India. Onion that is Allium cepa family Amaryllidaceae used in daily diet for taste. Onions also have number of medicinal properties, such as hepatoprotection, anticancer, antifungal, antioxidant, antiulcer, anti-agging, anti-inflammatory, anticancer etc[1-2] The dried scales or peels of onion also have the same medicinal constituents with same activity as raw onions. The onion peels contains flavonoids, such as anthocyanins, flavones (qurcertin and its derivatives), ferulic, Gallic, protocatechuic acids, sulphur, vitamins etc. In the present study determination of protocatechuic acid in onion peels extract has been performed using HPTLC. HPTLC separation was carried out on Merck TLC aluminium sheets precoated with silica gel $60F_{254}$ using Toluene: Ethyl acetate: Formic acid (6: 6: 1.2 v/v/v) as mobile phase.[3-11] Quantitative analysis was carried out in the absorbance mode at 258 nm. Hydroalcoholic extract was tested for hepatoprotective activity in wistar rats (either sex) by using CCl_4 as hepatotoxicity inducing agent and Silamyrin as standard. Hydroalcoholic extract shows hepatoprotective activity as indicated by decrease in the level of SGOT, SGPT, total protein, billirubin an which hepatotoxicity was induced by CCl_4 intraperitonial injection route to animal, from the result it may be concluded that onion peels extract may be used for hepatoprotective activity.

Keywords: Onion peel extract, Protocatechuic acid, HPTLC, hepatoprotection.

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INTRODUCTION

There is an increasing interest in herbal remedies because of their effectiveness, less side effects in clinical experiments and relatively low cost. Protocatechuic acid (PCA) is widely distributed and present in most edible plants used in medicine. It is also a very common compound present in human diet, present in bran and brown rice (Oryza sativa L.) and onion (Allium cepa L.). Onion peels are the external part of onion bulb and having several folds, it is thin, light weight, strong often translucent paper. Onion peel contains numbers of phytoconstituent such as sulphur, qurcertin, protocatechuic acid, calcium, flavonoids, phenolic acid, etc[1,5].

PCA has been reported to possess antioxidant, antibacterial, anticancer, antiulcer, ant diabetic, ant ageing, antifibrotic, antiviral, anti-inflammatory, analgesic, antiatherosclerotic, cardio protective, hepatoprotective, neurological and nephroprotective activities. As per literature search there is no method for determination of protocatechuic acid in onion peel extract and evaluation of hepatoprotective activity in rats[6-9].

Liver is one of the largest organs in the human body and chief site for intense metabolism and excretion. Liver diseases are one of the major health problems in the world. These are caused by toxic chemicals, autoimmune disorders, infections and excess consumption of alcohol. The hepatotoxic chemicals can induce lipid peroxidation and oxidative damages. It is involved in almost all the biochemical pathways to growth, fight against the disease, nutrient supply, energy provision and reproduction.[10-14]

The hydroalcoholic extract of onion peels contains PCA as active constituent. There are many literature record indicating hepatoprotective activity of PCA. Despite of there is no report available on action of onion peel extract. For that reason the present study changed into undertaken to

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36. Antiobesity, antihyperlipidemic and antidiabetic agents of proto-catechuic acid in high fatty diet along with alloxan induced diabetes

Rajguru et al., IJPSR, 2019; Vol. 10(4): 1741-1746. E-ISSN: 0975-8232; P-ISSN: 2320-5148

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ANTIOBESITY, ANTIHYPERLIPIDEMIC AND ANTIDIABETIC AGENTS OF PROTO-CATECHUIC ACID IN HIGH FATTY DIET ALONG WITH ALLOXAN INDUCED DIABETES

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Keywords:

Obesity, High fatty diet, Alloxan, Protocatechuic acid, Diabetes

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ABSTRACT: Aim: The present investigation was carried out by evaluating the effect of protocatechuic acid (PCA) on a high-fat diet (HFD) along with a low dose of alloxan-induced hyperglycemia in male Wistar rats. **Methods:** In the present study, administration of high fatty diet (HFD) for 45 days along with low dose of alloxan (80 mg/kg) in rats on 30 days produced significant high fatty diet in the, body weight, low density lipoproteins (LDL), triglycerides (TG) and blood glucose levels while decreases the high density lipoprotein (HDL) and serum insulin level. Protocatechuic acid (PCA) was started to administered at a dose of 50, 100, 200 mg/kg (orally) on day 45 of HFD administration and continue further 45 days. Glibenclamide was used as reference standard. **Results:** Results of PCA shows a significant decreased in body weight, blood glucose level after 45 days of treatment in diabetic animals. Result also indicated to increase in serum insulin level. The result of lipid profile indicated to normalize after 45 days treatment with PCA in diabetic rats. All the results are compared with reference standard glibenclamide. **Conclusion:** From this result, it concludes that PCA decreases the body weight, blood glucose level dose-dependently indicated antidiabetic and antiobesity activity. Antidiabetic activity of PCA is associated with increased in the level of serum insulin.

INTRODUCTION: Obesity is a metabolic disease of pandemic proportions mainly arising from positive energy balance, a consequence of sedentary lifestyle, conditioned by environmental and genetic factors. Obesity is characterized by the accumulation of excess fat in adipose tissues and results in various life upcoming complications such as cardiovascular diseases, Type 2 diabetes, and cancer [1].

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The modern lifestyle of increased intake of high-calorie cafeteria fast food associated with decreased energy expenditure also contributes to the current rising prevalence of obesity and type 2 diabetes [1, 2].

Insulin resistance plays a primary role in the development of Type 2 diabetes and is a characteristic feature of other health disorders including obesity, dyslipidemia, hypertension, and cardiovascular disease [3]. It is widely known that an elevation in circulating free fatty acid (FFA) levels impairs insulin action and leads to insulin resistance in animals and human [4]. This may represent a physiologic mechanism of insulin resistance because elevated FFA levels are generally observed in most human insulin resistance states [5].

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37. Chemoprotective Effect of Buchanania Lanzan Seed Extract On Toxicity of 5-Flurouracil Induced Hepatotoxicity in Rats

CHEMOPROTECTIVE EFFECT OF *BUCHANANIA LANZAN* SEED EXTRACT ON TOXICITY OF 5- FLUROURACIL INDUCED HEPATOTOXICITY IN RATS.

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Abstract: Objective-5-fluorouracil-induced (5-FU), an anticarcinogenic agent, is reported to have side-effects that include hepatotoxicity. The study objective was to investigate the protective effects of *Buchanania lanzan* on 5-FU-induced hepatotoxicity. Material and Methods- Male Wistar rats were assigned to seven groups. Weighing 220–250 g, were included in the study. The animals were housed under adequate moisture and light conditions, at a suitable room temperature, and were provided with sufficient water and food until the day of the experiment. The control group received distilled water for 21 days. The second group of animals injected only with 5-FU (20 mg/kg i.p) on day 17 to 21. Third, fourth group of animals administered with extract of *Buchanania lanzan* (200 and 400 mg/kg p.o.) and injected with 5-FU on day 17 to 21. Fifth and Sixth group of animals only injected with extract of *Buchanania lanzan* (200 and 400mg/kg p.o.) and seventh group of animals injected with standard Silymarin for 21 days respectively and injected with 5-FU (20 mg/kg i.p) on day 17 to 21. On day 22, the rats were decapitated, and blood and hepatic tissues were taken. *Buchanania lanzan* was observed to have a protective effect on 5-FU induced Liver toxicity. Results of histopathological examination also revealed multifocal moderate hepatocellular vacuolation (macro vesicular) in 5-FU treated rats while prior treatment with Buchnania lanzan for 21 days showed focal mild hepatocellular vacuolation in liver. Conclusion-In this study it was determined that the *Buchaniana lanzan* have protective effects on 5-FU-induced liver toxicity.

Index Terms **– *Buchanania lanzan* spreng seed, Aqueous ethanolic extract, 5-Flurouracil, Silymarin, Hepatoprotective, Histopathology.**

1.0 INTRODUCTION

5-fluorouracil (5-FU), a fluorinated pyrimidine, is classified as an antimetabolic agent and influences the synthesis of DNA and RNA in normal and tumor cells. The majority of 5-FU is abolished through liver metabolism and only a small portion is removed from the body via kidney excretion. 5-FU is widely used in chemotherapy for various cancers (Longley *et al*, 2003). As a fluoropyrimidine antimetabolite agent, it plays an important role in the treatment of colon, breast, gastrointestinal, head, neck, and pancreatic cancer. In addition, it has hepatotoxic effects, with increased aspartate aminotransferase (AST), lactate dehydrogenase (LDH) and alkaline phosphatase (ALP) activity in tissue (Volkan, 2017; and Ray, et al, 2007).

Liver is one of the largest organs in the human body and chief site for intense metabolism and excretion. Liver diseases are one of the major health problems in the world. These are caused by toxic chemicals, autoimmune disorders, infections and excess consumption of alcohol. The hepatotoxic chemicals can induce lipid peroxidation and oxidative damages. It is involved in almost all the biochemical pathways to growth, fight against the disease, nutrient supply, energy provision and reproduction. (DeLeve et al, 1995 and Farrel, 1998).

Buchanania lanzan spreng (locally called as Chironji), a member of family Anacardiaceae is a commercially useful tree species found in several areas of India. The plant has well-known traditional uses and its seeds are used as expectorant and tonic. The oil extracted from kernels is applied on skin diseases and also to remove spots and blemishes from the face. The root is used as expectorant, in biliousness and also for curing blood diseases. The juice of the leaves is digestive, expectorant, aphrodisiac and purgative. The rhizome of *B. lanzan* finds an important place in indigenous medicine as an expectorant, diuretic and carminatives. It is also found to have anticancer, antihypertensive, larvicidal and anti-diabetic activities. (Achuthan et al, 1997; and Choochote et al 1999). It is a commercially useful tropical plant. Chironji tree is a medium evergreen deciduous tree, growing 50 ft. tall. It bears fruits each containing a single seed, which is a popular edible nut, known as chironji. It is common in India mostly in eroded lands. It has tickly leathery leaves which are broadly oblong, with blunt tip and rounded base (Dai et al 2002; and Kumar et al, 2007). Silymarin was used as reference standard.

1.0 MATERIALS AND METHODS

2.1 Collection and Identification of Plant Material:

Buchanania lanzan seeds were collected from the surrounding area of rural Pune during September 2018. The plant was identified and authenticated by M/s. Shamantak Enterprises, Dr. Gautam, Botanist, Pune, India.

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38. Anti-Anxiety and Antidepressant Activity of Ethanolic Extract of Dalbergia Sissoo for Anxiety and Depression in Ovariectomized Rats

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Journal of Drug Delivery and Therapeutics

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Anti-Anxiety and Antidepressant Activity of Ethanolic Extract of *Dalbergia Sissoo* for Anxiety and Depression in Ovariectomized Rats

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ABSTRACT

There are studies showing the effects of long-term ovarian hormones withdrawal and post-menopause on animal behavior. Ovarian hormones play a critical role is modulating anxiety and depressive symptoms in female. Thus, this current study evaluated the anxiety and depression of long-term ovariectomy (OVX) in adult rats subjected to the light and dark chamber and forced swimming tests. In this study, we tested the effect of hydroalcoholic extract of *Dalbergia sissoo* on female anxiety and depression in long-term postsurgical bilateral ovariectomized female rats. 6-month old female Wistar rats were used and distributed in 5 groups; diestrus rats, ovariectomized (OVX) groups with 60 days, OVX treated with standard β Estradiol (0.1mg/kg/s.c), OVX treated hydroalcoholic extract of *Dalbergia sissoo* (200 & 400 mg/kg). All treatments were given for further 28 days after post-surgical period (60 days) in ovariectomized female rats. They were evaluated on the 28th day in the light and dark chamber and forced swim test apparatus. The treatment of the hydroalcoholic extract of *Dalbergia sissoo* (200 and 400 mg/kg) in the OVX rats shows significant increase in the time spent in the light chamber and the immobility time was significantly decrease in the extracted treated groups as compared to the OVX group. Anxiety-like and depressive-like behaviors were observed in rats which were influenced by post-menopause or ovarian hormone withdrawal. Results suggested that 28 days of treatment with hydroalcoholic extract of *Dalbergia sissoo* is able to lower the anxiety levels and depression in estrogen deficient females.

Keywords: *Dalbergia sissoo*, Post menopause, Anxiety, Depression, Light dark box, Forced swim test.

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INTRODUCTION

Depression and anxiety are among the most cited psychological symptoms related to the absence of ovarian hormones that are observed in postmenopausal women [1, 2]. In human, menopause causes depletion of estrogens, whereas in experimental animals OVX is a common method to deplete animals of their gonadal hormones. In females the absence of the ovaries induces a drastic decrease of circulating estrogens [1]. Women carry a greater burden of affective and anxiety disorders than do men, with the lifetime prevalence of depression in women at about 21% compared with 13% in men [4]. During the perimenopausal/ menopausal period, which occurs at approximately 45-55 years of age, women often suffer from mood disorders such as depression, altered emotionality, and malaise [5, 6, 7]. Depressive symptoms develop during natural and surgical menopause, and estrogen replacement therapy has been used as a beneficial treatment for many years [8]. Relatively high levels of depression and anxiety have been reported in women post physiological or after surgical induction of menopause in comparison with premenopausal intact women [1, 9].

Okada et al. (1997) demonstrated that ovariectomized rats showed significantly prolonged immobility as compared to sham-operated rats 14 days after ovariectomy [10]. Therefore, it is conceivable that the prolongation of immobility following ovariectomy might be a useful tool for experimentally investigating menopausal depression and for evaluating the efficacy of potential treatments [11].

Studies have demonstrated that 17β-estradiol, a primary estrogen produced by the ovaries, decrease anxiety- related behavior and produce antidepressant-like effects in animal models. In fact, proestrus rats, which have high physiological 17β-estradiol levels, have decreased anxiety-like behavior across a variety of tasks and decreased mobility time in the forced swim test compared to female rats in diestrus phases, which have lowering 17β-estradiol levels [12, 13, 14]. Furthermore, the administration of 17β-estradiol regimen in

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39. Preclinical evaluation of ethanolic extract of Dalbergia sissoo for female sexual dysfunction in experimental rats

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PRECLINICAL EVALUATION OF ETHANOLIC EXTRACT OF *DALBERGIA SISSOO* FOR FEMALE SEXUAL DYSFUNCTION IN EXPERIMENTAL RATS.

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Abstract: In this study, we tested the effect of hydroalcoholic extract of *Dalbergia sissoo* on female sexual dysfunction (FSD) in 30 days postsurgical bilateral ovariectomized female rats. 3-month old female Wistar rats were used and distributed in 5 groups, ovariectomized (Ovx) groups with 30 days, Ovx treated hydroalcoholic extract of *Dalbergia sissoo* (200 & 400 mg/kg), Ovx treated with standard β Estradiol (0.1mg/kg/s.c) and estrous control rats. All treatments were given for further 28 days after post-surgical period (30 days) in ovariectomized female rats. They were evaluated on the 14th day and on 28th day in the copulatory arena with the sexually experienced male rats and for serum estrogen levels. After 28 days of treatment, histopathology of uterus and vagina were quantified. The treatment of the hydroalcoholic extract of *Dalbergia sissoo* (200 and 400 mg/kg) in the Ovx rats shows significance increase in the sexual activity, lordosis, serum estrogen level and histology results. All the results of *Dalbergia sissoo* are comparable with standard β Estradiol. Results suggest that 28 days of treatment with hydroalcoholic extract of *Dalbergia sissoo* is able to increase the sexual function in estrogen deficient females, serum estrogen levels and decreased atrophy of vaginal epithelium and uterus.

***Index Terms - Dalbergia sissoo*, Post menopause, Copulatory arena, Serum estrogen level, Histopathology, Atrophy.**

1.0 INTRODUCTION

Estradiol is a predominant female sex hormone in women that helps maintain the integrity of vaginal mucosal epithelium and promotes lubrication. Estrogen plays a major role in regulating sexual function and nitric oxide synthesis in the vagina and clitoris (Rupesh, 2007). It also has vasoprotective and vasodilator effects on the vagina. After menopause, vaginal lubrication and sexual desire and frequency decrease, which may result in vaginismus (Sarrel, 1998)]. Adjustment in estradiol levels results in vaginal wall smooth muscles atrophy and can increased vaginal canal acidity, eventually leading to discomfort and stress (Berman and Goldstein, 2001). Estrogen replacement therapy in postmenopausal women has been shown to improve vaginal lubrication and sexual desire. Female sexual dysfunction (FSD) is considered as a significant age-related, progressive and highly prevalent problem that affects a substantial number of women (Renata *et al*, 2010). Women are commonly more affected by sexual dysfunction than men, with one study reporting that 43% of women experienced sexual problems as compared to only 31% of men (Laumann *et al*, 1999).

Loss of interest in sexual activity may occur due to a medial or psychiatric condition, abrupt change in internal hormonal milieu such as major depressive disorder and the initiation of menopause (Lopez *et al*, 2007). A drop-in libido at menopause can be due in part to physical changes, including vaginal dryness or atrophy that can further lead to vaginal pain or irritation, fatigue, sleep disturbances, hot flashes, night sweats, and general health concerns (Rioux *et al*, 2000).

In Indian traditional system of medicine, many herbs have been claimed for its effect on libido in females. However, among these herbs, very few have been scientifically documented so far. Despite the increasing handiness of effective typical medical treatments, plant derived and seasoning remedies still give a preferred different for men and ladies seeking to enhance their sex life due to their effects which is associated with comparatively lesser side effects (Rowland and Tai, 2003).

Dalbergia sissoo (DS), popularly known as shisham in India, is an erect deciduous tree. *D. sissoo* is widely available throughout the Indian subcontinent. Various pharmacological properties of *D. sissoo*, including stimulation of new cell growth and tissue regeneration, have been reported. Phytopharmacological evaluation program aimed at finding an effective alternative therapy for postmenopausal osteoporosis, we recently reported that several phytoestrogens, particularly methoxy isoflavones, were present in the crude extract made from the leaves of *D. sissoo* and exhibited in vitro bone-forming activity (Bijauliya *et al*, 2017). Comprehensive investigation of *D. sissoo* reported to contain estrogenic flavonoids and some sterols with estrogenic activity. The reported results of phytochemical analysis indicated to the presence of flavonoids in *Dalbergia sissoo* (Dixit *et al*, 2012). Thus, the objective of the present study was to evaluate the effect of hydro alcoholic extract of *Dalbergia sissoo* on copulatory behaviors in bilateral ovariectomized induced post-menopausal female rats.

2.0 MATERIALS AND METHODS

2.1 Collection and Identification of Plant Material:

D. sissoo leaves were collected from the surrounding area of rural Pune during September 2018. The plant was identified and authenticated by M/s. Shamantak Enterprises, Dr. Gautam, Botanist, Pune, India.

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40. Evaluation of subacute oral toxicity induced by ethanolic extract of Dalbergia sissoo leaves in experimental rats

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EVALUATION OF SUBACUTE ORAL TOXICITY INDUCED BY ETHANOLIC EXTRACT OF *DALBERGIA SISSOO* LEAVES IN EXPERIMENTAL RATS

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ABSTRACT
Herbal medicine is the source for the search of many novel therapeutic compounds in developing countries. Before used as medicine, drugs from plant origin must be ensured safe. The study is aimed at evaluating the possible toxicity in 28-day subacute oral toxicity of ethanolic extract *Dalbergia sissoo* (*D. sissoo*) in male and female Wistar rats. The 28-day subacute toxicity study was conducted to detect the no-observed adverse effect level (NOAEL). In this study, a total of 48 rats were divided into the control, low dose (200 mg/kg), medium dose (500 mg/kg) and high dose (1000 mg/kg) groups. The extract was administered daily from day 1 until day 28. At the end of the study, the animals were humanely sacrificed and assessed for the effect extract of *Dalbergia sissoo* leaves on body weight and relative organ weights and hematological, biochemical and histopathological parameters. The hematological and serum biochemical parameters for the assessment of kidney and liver injuries were carried out. Results of hematological and serum biochemistry results showed no changes in the control and treated groups. In the histopathology, evaluation of kidney tissues in all treated groups showed no significant ($p > 0.05$) lesions.

KEYWORDS: subacute oral toxicity, *Dalbergia sissoo,* biochemical analysis, hematological parameters, histopathology.

INTRODUCTION

Herbal medicine is the source for the search of many novel therapeutic compounds in developing countries. Before used as medicine, drugs from plant origin must be ensured safe.[1] Plant-derived medicines are used in all civilizations and cultures and, hence, plants have always played a key role in health care systems worldwide. In most developing countries, the indigenous modes of herbal treatment are a part of the culture and the dominant method of healing therapy. These remedies, with considerable extent of effectiveness, are socially accepted, economically viable and, mostly, are the only available source. This raises concerns about the potential toxic effect resulting from chronic use of such medicinal plants. Therefore, evaluating the toxicological effects of any medicinal plant extract intended to be used clinically or preclinically, is a crucial part of its assessment of potential toxic effects.[2] Recently, increasing interest in herbal medicines is the belief that because these medicines are natural and have been traditionally used, they are safe and harmless. Nevertheless, their natural origin is not a guarantee of safety, as concerning the risks associated with the use of herbal products have noted. Hence, scientific information regarding the safety of this plant for use as an alternative medicine is vary important before it is further developed into a new medicinal herbal therapy.[3]

Dalbergia sissoo, popularly known as shisham in India, is an erect deciduous tree. *D. sissoo* is widely available throughout the Indian subcontinent. Various pharmacological properties of *D. sissoo*, including stimulation of new cell growth and tissue regeneration, have been reported. In Indian medicinal practice, the leaf juice of *D. sissoo* is prescribed for eye ailments. In our phytopharmacological evaluation program aimed at finding an effective alternative therapy for postmenopausal osteoporosis, we recently reported that several phytoestrogens, particularly methoxy isoflavones, were present in the crude extract made from the leaves of *D. sissoo* and exhibited in vitro bone-forming activity.[4] Comprehensive investigation of *D. sissoo* reported to contain estrogenic flavonoids and some sterols with estrogenic activity. The reported results of phytochemical analysis indicated to the presence of flavonoids in Dalbergia sissoo.[5]

However, no studies on the toxicity of *D. sissoo* leaves have been described in the literature. Therefore, in the present investigation, we aimed to investigate the

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41. Aphrodisiac activity of hydro-alcoholic extract of Celosea argentea dried seeds in male rats.

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Aphrodisiac activity of hydro-alcoholic extract of *Celosea argentea* dried seeds in male rats

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ABSTRACT

Objective: The study was aimed at to investigate the aphrodisiac activity of hydro-alcoholic extract of *Celosea argentea* dried seeds (Amaranthacea) in male albino rats in different doses. **Material and methods:** The animals were selected in the present investigation on the basis of their performance in the Copulatory arena and runway apparatus. After selection animal (n=6), they were treated with extract of Celosea argentea (200 and 400 mg/kg) and sildenafil citrate (5mg/kg) orally. While the control animals were given with normal water. All the treatments were given for 21days. Sexual motivation and mating behavior parameters in male rats were monitored on 11th and 21st day of treatment pairing with receptive females. After termination of drug treatment the parameter such as sexual motivation, mating behavior, serum testosterone level, histological examination of testes, relative organ weight and body weight percent were evaluated. **Result:** The hydro-alcoholic extract of *celosia argentea* seeds showed a significant increase in mating behavior, serum testosterone levels, testes- body weight ratio as compared to vehicle control, while at the dose of 400mg/kg of *Celosea argentea* seeds extract assume closer resemblance of above parameters with the standard used. **Conclusion**: The results of the study strongly suggest that the seed extract of Celosia argentea have good aphrodisiac activity.

Keywords: Aphodisiac, *Celosea argentea*, sexual motivation, mating behavior, Serum testosterone level

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Cite this article as:

Yadav N, Kolhe S, Tembhurne S, Aphrodisiac activity of hydro-alcoholic extract of *Celosea argentea* dried seeds in male rats, Journal of Drug Delivery and Therapeutics. 2019; 9(3-s):296-302 http://dx.doi.org/10.22270/jddt.v9i3-s.3011

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1. INTRODUCTION

An agent (food or drug) that arouses sexual desire is called Aphrodisiac. Aphrodite is derived from Greek goddness of sexual, love and beauty[1]. Erectile dysfunction (ED) has been one of the most common complaints among men with sexual health issue[2]. Erectile dysfunction has been identified as the persistent inability to attain and maintain penile erection sufficient for satisfactory sexual performance[3]. The prevalence rate of ED in Asia ranged widely from 2% to 88%[4]. Today, Drug therapy mainly focuses on phosphodiesterase type 5 inhibitors which increase the levels of cGMP in the cavernosal vasculature leading to facilitation and prolongation of penile erection[5]. WHO estimates that up to 80% of people still rely mainly on traditional remedies[6].

In Indian system of medicine, several plants are claimed to possess aphrodisiac potential[7,8]. *Celosia argentea* is medicinal important plant, belong to family amaranthanceae. In India, it is found to be grown as a weed of bajara fields. It is an herbaceous erect and branching plant[9]. Seeds of Celosia *argentea* are called 'semen celosiae'. According to traditional Chinese medicinal system, seeds are reputed for purging hepatic pathogenic fire to improve eyesight and it is also used for hepatoprotection, anti-diarrhea, anti-diabetics, antioxidant etc[10].

Based on the literature finding and its claim in Indian system of medicine[11]. Our study was undertaken to evaluate aphrodisiac properties of the Celosia argentea seeds extract on the male rat.

2. MATERIAL AND METHOD

2.1 Plant material

The seeds of *Celosia argentea* (CA) were collected from vita, district of sangli, Maharashtra and authenticated by M/s. shamantak enterprises, pune. Certificate of Aunthentification number of Celosia argentea is SE/AC/ 2018/04.

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42. Evaluation Of Subacute Oral Toxicity Study Induced By Ethanolic Extract Of Sesbania Grandiflora Flower Extract In Experimental Rats

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EVALUATION OF SUBACUTE ORAL TOXICITY STUDY INDUCED BY ETHANOLIC EXTRACT OF SESBANIA GRANDIFLORA FLOWER EXTRACT IN EXPERIMENTAL RATS.

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Abstract:-

The objective of this study to evaluate the sub-acute toxicity of the ethanolic extract of sesbania grandiflora flower [family- Fabaceae] in wistar rat. Herbal medicine is the source for the search of many novel therapeutic compounds in developing countries. Before used as medicine, drugs from plant origin must be ensured safe. The study is aimed at evaluating the possible toxicity in 28-day sub-acute oral toxicity of ethanolic extract *Sesbania grandi*flora flower extract) in male and female Wistar rats. The 28-day sub-acute toxicity study was conducted to detect the no-observed adverse effect level . In this study, a total of 48 rats were divided into the control, low dose (200 mg/kg), medium dose (500 mg/kg) and high dose (1000 mg/kg) groups. The extract was administered daily from day 28. At the end of the study, the animals were sacrificed and assessed for the effect extract of *Sesbania Grandiflora* flower extract on body weight and relative organ weights and hematological, biochemical and histopathological parameters. The hematological and serum biochemical parameters for the assessment of kidney and liver injuries were carried out. Results of hematological and serum biochemistry results showed no changes in the control and treated groups. In the histopathology, evaluation of kidney tissues in all treated groups showed no significant ($p > 0.05$) lesions.

KEYWORDS: sub-acute oral toxicity, Sesbania grandiflora, biochemical analysis, hematological parameters, histopathology.

INTRODUCTION

Advanced in medical technology have encouraged studies examining the development and novel use of biological resources. A number of natural substances are widely used as raw materials of medicine, health function foods and home remedies. . These remedies, with considerable extent of effectiveness, are socially accepted, economically viable and, mostly, are the only available source. This raises concerns about the potential toxic effect resulting from chronic use of such medicinal plants. Therefore, evaluating the toxicological effects of any medicinal plant extract intended to be used clinically or preclinically, is a crucial part of its assessment of potential toxic effects.[1] Recently, increasing interest in herbal medicines is the belief that because these medicines are natural and have been traditionally used, they are safe and harmless. Nevertheless, their natural origin is not a guarantee of safety, as concerning the risks associated with the use of herbal products have noted. Hence, scientific information regarding the safety of this plant for use as

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43. Preclinical evaluation of Sesbanian grandiflora flower extract for antihyperlipidimic and antiobesity activity on experimental rats

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Journal of Drug Delivery and Therapeutics

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Preclinical evaluation of *Sesbanian grandiflora* flower extract for antihyperlipidimic and antiobesity activity on experimental rats

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ABSTRACT

Obesity is a chronic disorder of global prevalence and associated with morbidity and mortality. So the attention is being focused on the investigation of plant based drug used in the traditional medicine for the treatement of obesity .The present study is undertaken to evaluate the anti- hyperlipidimic and anti-obesity activity of *Sesbania grandiflora* flower extract in High Fatty Diet induced Obesity in rats. Female wistar rat weighing 150-200 g were divided into different groups i.e. normal control, Negative control [Hfd control], orlistat [STD control], extract of sesbania grandiflora flower contain 200mg/kg and 400mg/kg group. .Obesity was assessed by measuring biochemical parameters such as glucose, triglyceride, serum cholesterol, HDL [High Density Lipoprotein], LDL [Low Density Lipoprotein] level. The results of the present investigation demonstrated that, the extract of sesbania grandiflora flower at 200mg/kg and 400 mg/kg shows significant protective effects on biochemical parameters such as body weight, BMI, obesity index, and adiposity index respectively as compared to HFD [High Fatty Diet] control group. Similarly, serum glucose, triglyceride, total cholesterol HDL, LDL was found to be attenuated as compare to HFD control group. The ethanolic extract of sesbania grandiflora flower exhibit significant anti-hyperlipidemia and anti- obesity activity in High fatty diet induced in obese rat.

Keywords: HFD [High fatty diet], sesbania grandiflora flower extract, anti- obesity, Anti –Hyperlipidimic Activity.

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INTRODUCTION

Obesity is the condition in which fat accumulates the body, which exhibits adverse effect on health and life expectance. According to the WHO, obesity is one of the five leading causes of death all around the world. It is chronic disorder caused by genetic and environmental factors.[1] It characterized by high cholesterol level indicated by increase in level of fatty acid; alteration in metabolism; insulin resistence;lethargy ,stone in gall bladder , hypertension, breathing deficiency; cancer , liver disorder arthritis. Overweight and obesity are the most common nutritional disorders in developed countries. Individuals having BMI between 25 and 30/ kg/m^2 are defined as obese [2]. Obesity accompanied by hyperlipidemia which is indicated by abnormally high concentration of lipid in blood. Nowadays [3,4] , change in human lifestyle and high energy diet have been increased the incidence of obesity and even have become risk factor to the population. There are several pharmacological substances available as antiobesity drugs, however they have several hazardous effect and hence natural products have been used for treating obesity in many Asian countries.[5] The potential of natural products for the treatement of obesity is still largly unexplored and can be excellent for the safe and effective development of antiobesity drug.[6]

Currently the drug available in the market for treatement of obesity can be divided into two measure classes one being orlistat which reduces the fat absorption of [7,8] pancreatic lipase and second is subutramine which is an appetite suppresment. The synthetic drug having high cost, and it show the potentially hazardous side effect, So the need of natural products against the obesity is under exploration [9] which may be an alternative strategy for developing effective, safe antiobesity drug. The antiobesity effect of natural products from more diverse source. Sesbania grandiflora scientifically reported to wound healing activity, Antimicrobial activity, Antioxidant, Antiulcer Activity[10]. .posses; there is also reported paper for its hypolipidemic

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44. Neuropharmacological Evaluation of Sesbania sesban Using Experimental Animals

WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
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NEUROPHARMACOLOGICAL EVALUATION OF *SESBANIA SESBAN* USING EXPERIMENTAL ANIMALS

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ABSTRACT

The extension of the expectancy of life and ageing of populations on a global level in recent times are expected to cause a huge rise in the occurrence of many chronic, progressive, non-communicable conditions inclusive of neurological disorders. This has stimulated the use of a variety of medicinal plants containing numerous chemical constituents to provide therapeutic effects similar to those drugs obtained from other sources, with lesser or no side effects. The current study includes the use of ethanolic extract of *Sesbania sesban* which are evaluated for their neuropharmacological activities.The different types of animals models used for neuropharmacological evaluation consisted of elevated plus maze test, radial arm maze test and conditioned place preference chamber test. The estimation of dopamine in rat brains was also carried out using UV-visible spectroscopy. The extract was found to possess anxiolytic, partially nootropic and non-addictive properties from the results obtained.

KEYWORDS: Conditioned place preference, dopamine, elevated plus maze, neuropharmacological, radial arm maze.

INTRODUCTION

The increasing capacity of modern medicine to prevent death has also increased the frequency and severity of impairment attributable to neurological disorders. This has led to the rise of the issue of restoring or creating a quality of life acceptable for people who suffer from the sequelae of neurological/mental/psychiatric disorders. [World Health Organization; 2006; Neurological Disorders: Public Health Challenges].[1]

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45. Taste Evaluation by Electronic Tongue and Bioavailability Enhancement of Efavirenz

AAPS PharmSciTech (2019) 20:56
DOI: 10.1208/s12249-018-1277-8

Research Article

Taste Evaluation by Electronic Tongue and Bioavailability Enhancement of Efavirenz

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Received 20 July 2018; accepted 7 December 2018

Abstract. Self-nanoemulsifying drug delivery systems (SNEDDS) are isotropic and thermodynamically stable mixtures of oil, surfactant, co-surfactant, and drug which emulsify spontaneously on contact with aqueous phase under mild agitation. Efavirenz used for treatment of acquired immune deficiency syndrome, is poorly water soluble and bitter tasting drug resulting in "burning mouth syndrome (BMS)." The objective of this study was to improve solubility and oral bioavailability by formulating liquid-SNEDDS and to mask bitter taste and minimize BMS. Capmul PG8 NF, Cremophor RH40, and Transcutol HP were selected as oil, surfactant, and co-surfactant. Ternary phase diagrams were constructed to evaluate the nanoemulsification region. A 3^2 factorial design was employed to optimize L-SNEDDS with droplet size and drug release as responses. Optimized batch was subjected to evaluation of taste by human panel method and electronic tongue, cloud point determination, phase separation, *in vivo* and stability studies. The optimized batch exhibited droplet size of 21.53 nm, polydispersibility index 0.155, and *in vitro* drug release of 92.26% in 60 min. The *in vivo* studies revealed 4.5 times enhancement in oral bioavailability. Taste evaluation indicated reduced the intensity and shortened duration of BMS. The formulation was stable at 40°C ± 75% RH after 3 months. Comparison between standard bitter drug and efavirenz in SNEDDS formulation using e-tongue by principal component analysis revealed significant differences in discrimination index, computed by multivariate data analysis. This study demonstrated that L-SNEDDS may be an alternative approach to improve solubility and oral bioavailability and for masking the bitterness of efavirenz.

KEY WORDS: burning mouth syndrome; efavirenz; electronic tongue; oral bioavailability; SNEDDS.

INTRODUCTION

Taste is a key parameter in designing of oral dosage forms (1). Administration of oral formulations having bitter tasting drugs is a challenge for pediatric and geriatric patients. Bitter taste affects patient compliance leading to incomplete therapy and increased health care cost (2,3). Several methods have been investigated for improving bitter taste of drugs like addition of flavors and sweeteners (4) for ibuprofen and complexation (5) for benexate HCl. Other methods include lipid-based self-emulsifying drug delivery system (SMEDDS and SNEDDS) (6) for paracetamol and ion exchange resins (IERs) (7,8) for norfloxacin.

There are various methods to evaluate taste masking efficiency such as "human panel method" (9), measurement of frog flavor nerve responses, (10) "electronic tongue (e-Tongue)" (11), and spectrophotometric technique (12). The cost, time, and safety issues related to human panel method makes it a challenging method (13). Biomimetic taste assessment using multichannel sensory (e-Tongue) is based on principle of cyclic voltammetry wherein potential is applied to working electrode and current generated due to redox reaction in the solution is measured (14). The e-tongue is capable of analyzing and classifying flavors of multicomponent mixtures and is used widely in food analysis and in pharmaceutical industry (15).

Human immunodeficiency virus (HIV) has infected about 40 million people globally (16). Efavirenz (EFV) is a first-choice non-nucleoside reverse transcriptase inhibitor (NNRTI) recommended by the World Health Organization (WHO). EFV is (S)-6-chloro-4 (cyclopropylethynyl)-1, 4-dihydro-4-(trifluoromethyl)-2H-3, 1-benzoxazin-2-one. It is crystalline powder, non-hygroscopic, bitter in taste. It is strongly basic (pKa 10.2) and lipophilic (log P 5.4) (17). It has poor aqueous solubility (4 μg/mL), low rate of dissolution (0.037 mg/cm^2/min), high protein-binding, and poor oral bioavailability (40–50%). EFV is available as tablets, capsules, and oral solution (18).

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46. Comparative Docking Studies: A Drug Design Tool for Some Pyrazine-Thiazolidinone Based Derivatives for Anti-HIV Activity

Curr Comput Aided Drug Des. 2019;15(3):252-258. doi: 10.2174/1573409915666181219125944.

Comparative Docking Studies: A Drug Design Tool for Some Pyrazine– Thiazolidinone Based Derivatives for Anti–HIV Activity

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PMID: 30569873 DOI: 10.2174/1573409915666181219125944

Abstract

Background: Acquired immunodeficiency Syndrome (AIDS) is caused by Human immunodeficiency virus type 1 (HIV-1). Pyrazine and Thiazolidinone pharmacophore has diverse biological activities including anti HIV activity.

Aims and objectives: To study binding behavior of Pyrazine- thiazolidinone derivatives on four different crystal structures of HIV- 1RT.These molecules which were already reported as anti-TB were investigated for dual activity as Anti-HIV and Anti-TB.

Materials and methods: In the present study we describe a comparative docking study of twentythree derivatives of N-(4-oxo-2 substituted thiazolidin-3-yl) pyrazine-2-carbohydrazide. Binding pattern of these derivatives was gauged by molecular docking studies on four different receptors bearing PDB code 1ZD1, 1RT2, 1FKP and 1FK9 of HIV-RT enzyme using V. Life MDS software Genetic algorithm docking method.

Result and discussion: The studies revealed hydrogen bonds, hydrophobic interaction and pi-pi interactions playing significant role in binding of the molecules to the enzyme.

Conclusion: Most of the molecules have shown good dock score and binding energy with anti-HIV receptors but Molecules 13 and 14 have potential to act as anti-tubercular and Anti HIV and hence can be further explored for dual activity.

Keywords: Docking; HIV-RT; NNRTI; anti-HIV; pyrazine; thiazolidinone..

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1. Improvement of Oral Bioavailability of Lopinavir Without Co-administration of Ritonavir Using Microspheres of Thiolated Xyloglucan

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Research Article

Improvement of Oral Bioavailability of Lopinavir Without Co-administration of Ritonavir Using Microspheres of Thiolated Xyloglucan

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Received 18 July 2016; accepted 11 June 2017

Abstract. Lopinavir is a BCS Class IV drug exhibiting poor bioavailability due to P-gp efflux and limited permeation. The aim of this research was to formulate and characterize microspheres of lopinavir using thiolated xyloglucan (TH-MPs) as carrier to improve its oral bioavailability without co-administration of ritonavir. Thiomeric microspheres were prepared by ionotropic gelation between alginic acid and calcium ions. Interaction studies were performed using Fourier transform infrared spectroscopy (FT-IR). The thiomeric microspheres were characterized for its entrapment efficiency, T_{80}, surface morphology, and mucoadhesion employing *in vitro* wash off test. The microspheres were optimized by 3^2 factorial design. The optimized thiomeric microsphere formulation revealed 93.12% entrapment efficiency, time for 80% drug release (T_{80}) of 358.1 min, and 88% mucoadhesion after 1 h. The permeation of lopinavir from microspheres was enhanced 3.15 times as determined by *ex vivo* study using everted chick intestine and increased relative bioavailability over 3.22-fold over combination of lopinavir and ritonavir as determined by *in vivo* study in rat model.

KEY WORDS: thiolated xyloglucan; microspheres; permeation; bioavailability.

INTRODUCTION

The BCS class III and IV drugs mainly suffer from poor bioavailability issues due to decrease in permeation along with PgP efflux and presystemic metabolism [1, 2]. Lopinavir is an advanced protease inhibitor (PI) antiretroviral belonging to BCS Class IV which is derived from ritonavir [3, 4]. Lopinavir and ritonavir are peptidomimetic antiretroviral (ARV) agents; together they curb the human immunodeficiency virus (HIV) protease enzyme from the hacking of Gag-Pol polyprotein that outrages infantile and non-infectious viral fragments [5, 6].

Lopinavir, if administered alone, suffers from impaired oral bioavailability due to low aqueous solubility (0.01 mg/ml), solubility limited dissolution, and higher P-glycoprotein efflux [7, 8]. Ritonavir being a substrate for CYP3A4 hepatic microsomal isoenzyme protects lopinavir, and its co-administration leads to improvement of pharmacokinetic properties of lopinavir and hence better activity against HIV-1 protease, although the co-administration of lopinavir and ritonavir has been reported to cause irritation, tenderness, and distress to GIT mucosa on oral administration [9].

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Due to the reasons mentioned above, lopinavir becomes a poor candidate for drug development [10]. This can be overcome by use of thiolated polymers which can enhance intestinal permeation and inhibit PgP efflux [11].

Tamarind seed xyloglucan is a natural polysaccharides composed of glucose, xylose, and galactose units in ratio 2.8:2.25:1 and is isolated from seeds of *Tamarindus indica* Linn. [12, 13]. The thiolation of xyloglucan with thiol-containing residues has been reported to increase mucoadhesion by formation of disulfide bonds between thiomer and cysteine-rich subdomains of mucus glycoprotein [14]. Thiolated polymers are also reported to inhibit CYP-mediated presystemic metabolism and PgP efflux and increase transmucosal permeation [11].

Microspheres offer advantages like enhanced drug bioavailability because of high surface-to-volume ratio and an intimate contact with mucous layer at the site of absorption [15]. The use of thiolated xyloglucan as carrier can help to overcome the poor bioavailability of drugs such as lopinavir.

Some of the reported attempts to improve bioavailability of lopinavir are based on nanoparticulate drug delivery [9, 16–18]. Nanoparticulates are difficult to manufacture and involve a lot of energy input. Hence, the present work attempts a simple approach of formulation of lopinavir microspheres using sodium alginate and xyloglucan cysteamine thiomer as carrier; the use of thiomer provides stronger mucoadhesion, increase intestinal permeability, and

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2. Investigation of cyclodextrin-based Nanosponges for solubility and bioavailability enhancement of Rilpivirine

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Research Article

Investigation of Cyclodextrin-Based Nanosponges for Solubility and Bioavailability Enhancement of Rilpivirine

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Received 14 December 2017; accepted 11 May 2018; published online 4 June 2018

Abstract. Rilpivrine is BCS class II drug used for treatment of HIV infection. The drug has low aqueous solubility (0.0166 mg/ml) and dissolution rate leading to low bioavailability (32%). Aim of this work was to enhance solubility and dissolution of rilpivirine using beta-cyclodextrin-based nanosponges. These nanosponges are biocompatible nanoporous particles having high loading capacity to form supramolecular inclusion and non-inclusion complexes with hydrophilic and lipophilic drugs for solubility enhancement. Beta-cyclodextrin was crosslinked with carbonyl diimidazole and pyromellitic dianhydride to prepare nanosponges. The nanosponges were loaded with rilpivirine by solvent evaporation method. Binary and ternary complexes of drug with β-CD, HP-β-CD, nanosponges, and tocopherol polyethylene glycol succinate were prepared and characterized by phase solubility, saturation solubility in different media, *in vitro* dissolution, and *in vivo* pharmacokinetics. Spectral analysis by Fourier transform infrared spectroscopy, powder X-ray diffraction, and differential scanning calorimetry was performed. Results obtained from spectral characterization confirmed inclusion complexation. Phase solubility studies indicated stable complex formation. Saturation solubility was found to be 10–13-folds higher with ternary complexes in distilled water and 12–14-fold higher in 0.1 N HCl. Solubility enhancement was evident in biorelevant media. Molecular modeling studies revealed possible mode of entrapment of rilpivirine within β-CD cavities. A 3-fold increase in dissolution with ternary complexes was observed. Animal studies revealed nearly 2-fold increase in oral bioavailability of rilpivirine. It was inferred that electronic interactions, hydrogen bonding, and van der Waals forces are involved in the supramolecular interactions.

KEY WORDS: bioavailability; nanosponges; beta-cyclodextrin; inclusion complex; rilpivirine.

INTRODUCTION

One of the major route of drug delivery is the oral route, especially for the treatment of many chronic diseases. High lipophilicity of 50% of the drugs, however, is a major deterrent for oral delivery. Biopharmaceutical classification system class II and IV drugs are a challenge to formulators, as their poor bioavailability is primarily caused by poor water solubility resulting in low drug absorption [1, 2]. To overcome these problems, various strategies have been adopted such as inclusion complexation, drug micronization, prodrug formation, and solid dispersions. Lipid-based drug delivery systems such as self-nanoemulsifying [3, 4] and self-microemulsifying drug delivery system (SNEDDS and SMEDDS) have also seen a surge in interest among formulators for their role in enhancing solubility and bioavailability [5].

Nanosponges (NS) are nanostructured carriers which have been prepared by reacting cyclodextrin with cross-linkers like diphenyl carbonate, pyromellitic dianhydride (PMDA), carbonyl diimidazole (CDI), and hexamethylene diisocynate [6, 7]. Beta cyclodextrin (β-CD)-based nanosponges (NS) are biocompatible and nanoporous carriers having the capability of forming supramolecular inclusion complexes as well as non-inclusion complexes with both hydrophilic and lipophilic drugs [8, 9]. The toxicological studies of the NS have proven them to be safe for use in pharmaceutical products. Shende et al. reported the toxicological safety of NS on the basis of acute and repeat dose toxicity studies on rats [10]. Extensive preclinical safety/toxicity assessments, *in vitro* cell line toxicity (evaluated on MCF-7, HT-29, Vero, HCPC-I cell lines), and hemolytic activity assessment have also been performed on NS [11].

Drug loading can be improved by varying the cyclodextrin (CD) and crosslinker ratio and to obtain a customized release profile. NS may be synthesized by either melt or

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3. Development of controlled release formulation of palonosetron hydrochloride using novel parenteral drug delivery system

INTERNATIONAL RESEARCH JOURNAL OF PHARMACY
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Research Article

DEVELOPMENT OF CONTROLLED RELEASE FORMULATION OF PALONOSETRON HYDROCHLORIDE USING NOVEL PARENTERAL DRUG DELIVERY SYSTEM

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ABSTRACT

The purpose of this study was to formulate and evaluate Parenteral Controlled Release Formulation of an antiemetic drug using the technology of in situ forming gel, based on temperature change mechanism in order to reduce the frequency of dosing and increase patient compliance in the long term treatment of Chemotherapy induced nausea and vomiting. Formulation was optimized, prepared, filled aseptically, sterilized and evaluated for prerequisites of Parenterals and other parameters like gelation temperature, gel strength, viscosity, drug content, in vitro and in vivo studies and stability studies. It was prepared using cold method and optimized by 3^3 factorial design, comprising of drug, Pluronic F127, HPMC K 100M ,PEG 400,was found to be clear, colorless, isotonic, sterile, pH as 6.2-6.5, viscosity of 1400cps, syringeable through 21 gauze needle, forming a stable in-situ gel at body temperature having gel strength of 16.47gm/cm showing a controlled release of 96.0 % in Simulated Body fluid at 120hrs following Korsmeyer –peppas model .The in vivo pharmacokinetics showed increase in t_{max} and AUC. Histopathological analysis showed no signs of inflammation or necrosis or any other cellular changes. The sterile formulation packed in amber colored ampoule was found to stable with most suitable storage condition at the refrigerator temperature. Thus, a biocompatible, stable parenteral formulation was developed which can be an alternative and convenient approach to the patients that require frequent parenteral administration, reducing the frequency of dosing and ultimately increasing patient compliance and comfort.

Keywords: Palonosetron HCL, In situ gel, Pluronic F127, Gel strength

INTRODUCTION

Palonosetron hydrochloride an antiemetic and antinauseant agent is a serotonin (5- hydroxytryptamine or 5-HT) receptor antagonist is which exerts its effect by interacting with the 5-HT3 receptors as an antagonist used in chemotherapy induced nausea and vomiting. A single dose of 250 µg is the lowest effective dose in preventing acute nausea and vomiting induced by highly emetogenic chemotherapy given 30 minutes prior to start of Chemotherapy. The drug has to be repeatedly administered as a single day injection for 5 days over the course of Chemotherapy and also further to prevent the nausea and vomiting incidences associated.[1-3]

Frequent injections leads to patient discomfort, pain and patient noncompliance. These problems can be overcome by administrating, controlled release drug delivery systems which can reduce total number of injections throughout the effective treatment and improve patient compliance. Parenteral controlled release drug delivery systems include novel technology as *in situ* forming implants which use smart polymers that release the drug in controlled manner by undergoing sol-gel transition once administered due to stimuli like, temperature change.[4-7]

Thus the overall aim was to formulate a parenteral controlled drug delivery of Palonosetron Hydrochloride using the technology of *in situ* forming implant based on temperature change stimuli as a once a day injection to be administered at the start of chemotherapy to achieve a release over a 5 day time period with an aim to improve patient compliance and reduce dosing frequency in chemotherapy induced nausea and vomiting.

MATERIALS AND METHOD

Palonosetron HCL was obtained as a gift sample from Emcure Pharmaceuticals Pune. PluronicF127 was provided by Ana lab fine chemical, Mumbai. Hydroxy propyl methyl cellulose K 100 M (HPMC K 100M) was provided by Chemica-biochemic-reagents, Otto chemie, Pvt. Ltd.

OPTIMIZATION

A response surface statistical experimental design was used to optimize the effect of different independent factors on response. The responses were investigated using a Box–Behnken statistical experimental design using Design-expert software® 9.0.4 (Stat-Ease, Inc., USA)

This design was based on a 3^3factorial design, three replicates of the central run, leading to13sets of experiments, enabling each experimental response to be optimized. Different batches were prepared with different independent variables at different levels and responses. The criterion for selection of optimum formulations was based on the gelation at body temperature and highest gel strength to remain stable for prolonged period of time i.e. for 5 days.

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4. Formulation development of sustained release intra-articular injection of analgesic drug

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Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

Open Access Research Article

FORMULATION DEVELOPMENT OF SUSTAINED RELEASE INTRA-ARTICULAR INJECTION OF ANALGESIC DRUG

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ABSTRACT

The purpose of this study was to formulate and evaluate Parenteral Intraarticular Sustained-Release Formulation of an analgesic drug using the technology of in situ forming gel, based on temperature change mechanism in order to reduce the frequency of dosing and increase patient compliance in the treatment of knee pain. The formulation was optimized, prepared, filled aseptically, sterilized and evaluated for prerequisites of parenteral and other parameters like gelation temperature, gel strength, viscosity, drug content, in vitro and in vivo studies and stability studies. It was prepared using cold method and optimized by 32 factorial design, comprising of drug, Pluronic F127, HPMC K 100M and HPMC K4M was found to be clear, colorless, isotonic, sterile, pH as 6.8-7, viscosity of 1800 cps, syringeable through 18 gauze needle, forming a stable in-situ gel at knee joint temperature having gel strength of 43.80 gm/cm showing a drug release of 95.88 % in phosphate buffer pH 7.4 at 120hrs. The sterile formulation packed in transparent ampoule was found to the stable with most suitable storage condition at the refrigerator temperature. Thus a biocompatible, stable parenteral formulation was developed which can be an alternative and convenient approach to the patients that require frequent parenteral administration, reducing the frequency of dosing and ultimately increasing patient compliance and comfort.

Keywords: Tramadol HCL, In situ gel, Pluronic F127, intra-articular

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INTRODUCTION

Analgesics are common medications used for moderate and severe pain given by a variety of different routes of administration which are effective for both nociceptive and neuropathic pain symptoms. Tramadol is a widely used analgesic that acts as a μ-opioid receptor agonist, altering the perception and response to pain, centrally and peripherally which are used in moderate to severe pain, available as immediate-release/orally disintegrating tablets (400 mg/day), extended-release tablets (300 mg/day). It is widely used in case of knee pain either as in oral dosage forms or in injections forms (100mg/day).[1]

One of the treatments for knee pain involves the intraarticular injections which are an attractive treatment for knee pain. An intraarticular route has been underestimated in the past years in the treatment of joint-related disorders, and reliance on the systemic routes of administration prevailed instead. It involves the injection of medications like non-steroidal anti-inflammatory drugs (NSAIDS), hyaluronic acid and corticosteroids into a joint space, usually to reduce inflammation, pain and increasing function. These conventional treatments suffer from the drawbacks of fast drug leakage in joint cavity, provide only short-term pain relief, quick release and frequent dosing or multiple injections are needed. These drawbacks can be overcome with sustained drug delivery systems. Development of new sustained release injectable formulation has received considerable attention due to many advantages of these systems such as localized and site-specific action, prolonged delivery period, decreased drug dosages, reduction of side effects and improved patient comfort and compliance over the

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5. Pharmacokinetic In Vivo Evaluation of In-Situ Gel Forming Injectable Drug Delivery System of Analgesic Drug

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Pharmacokinetic *In Vivo* Evaluation of In-Situ Gel Forming Injectable Drug Delivery System of Analgesic Drug

IJPPR
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HUMAN

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Keywords: Pluronic F127, pharmacokinetics, histopathology, radio imaging, in-situ, intraarticular.

ABSTRACT

The aim of this work was to study the *In vivo* pharmacokinetic analysis of the developed sustained release intraarticular injection of an analgesic drug Tramadol HCl for the treatment of knee pain. The formulation was developed using pluronic F 127 as a thermosensitive gelling agent and HPMC K100M, HPMC K4M as a release retardant polymers in order to achieve a prolonged release over a period of 5 days so as to reduce the frequency of administration and to improve patient compliance and target the dosage form at the knee joint. *In vivo* pharmacokinetic analysis involved administration of sustained release formulation in rats at the knee joint and analysis for various pharmacokinetic parameters of the SR formulation and its comparison with available immediate release injection, *in vivo* gel formation studies, histopathological and radio imaging studies. The *in vitro* drug release was found to be 95.40% in phosphate buffer pH 7.4 at 32°C over a period of 5 days. Pharmacokinetic studies shows the C_{max} of sustained release formulation and immediate release as 491.74µg/ml and 127.98µg/ml respectively. The $AUC_{0-\infty}$of sustained release formulation and immediate release was found to be 12579.10µg.hr/ml and 1699.40µg.hr/ml respectively. The *in vivo* gel formation studies confirms the immediate formation of in situ gel and the histological studies shows the formulation to be biocompatible with no abnormality detected at the site of injection. The X-ray studies confirmed the formation of gel in knee joint and maintaining its stability over a period of 120hrs. Thus, the formulation demonstrated the feasibility of its use in animals as a sustained drug delivery system which could be potentially applied in clinical studies.

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6. Validated stability indicating method for *Karanjin* using HPTLC and HPLC

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Validated stability indicating method for *Karanjin* using HPTLC and HPLC

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Abstract
Karanjin is an active marker present in Karanja seed. Seed powder is valued for Anti-Plasmodia activity, Anti-Inflammatory activity, Anti-ulcer Activity, Hypoglycemic and Hypolipidemic Activity, Antiviral Activity, Ant diabetic activity, renal protective activity. The present study was aimed to develop and validate stability indicating method for karanjin by HPLC and HPTLC. The development was done using TLC plates precoated with silica gel $60F_{254}$. Toluene-Ethyl acetate (8:2 v/v) were used as mobile phase and scanning was done by using TLC Scanner III. The developed HPLC method involved use of RP-C18 (150 × 4.6 mm) column. The detection done at 260 nm using PDA detector having mobile phase Methanol: ACN: Water (70:15:15 v/v/v). The flow rate was kept as 1 mL/min. The linearity range 80-400 ng/band was set for HPTLC and for HPLC 10-50 µg/ml. Stress degradation studies were carried out for karanjin as per the ICH guidelines. The characterisation of stress sample were done using LCMS.

Keywords: *Pongamia pinnata*, HPTLC, HPLC, LCMS, forced degradation studies, validation

Introduction
Karanja consists of dried root bark, leaf, root, seeds and stem bark of *Pongamia pinnata* (Linn.) Merr. Syn. P. glabra Vent. (Fam. Fabaceae), a glabrous tree [1]. A semi evergreen glabrous tree with up to 18 m or more in height. Different parts of Karanja plant Bark, Leaves, Flowers, Fruits, and Seeds are used. Pulp of seed has an application in leprosy. Commonly used in Bronchitis and whooping cough. Other Uses are keloid tumors, hypertension, skin ailments and rheumatic arthritis. Seed powder valued for Anti-Plasmodia activity, Anti-Inflammatory activity, Anti-ulcer Activity, Hypoglycemic and Hypolipidemic Activity, Antiviral Activity, Antidiabetic activity, renal protective activity. *Pongamia pinnata* also used as Bio fuel [2, 3]. Since there are number of pharmacological activities reported of karanjin and one HPTLC method are reported according to literature survey, karanjin is selected for further study [4, 5].

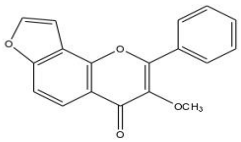

Fig 1: Structure of karanjin

In the field of pharmaceutical industry HPLC and HPTLC is playing important role for the resolution of drugs. The development of the method for the quantitative analysis of compound. A rapid simple reproducible stability-indicating HPTLC method was developed and validated. So far to our knowledge there was no stability indicating method has been reported using HPTLC OR HPLC for karanjin.

Materials and Methods [6, 7]
Collection of Plant material
The whole plant *Pongamia pinnata* was collected from Medicinal garden, AISSMS College of pharmacy pune and authenticated from Botanical survey of India, Pune. The authentication no. BSI/WRC/IDEN.CER./2016. Plant seeds were collected and powdered using a mixer grinder and stored in air tight container. Marker karanjin was procured from M/S Yucca Enterprises.

Chemicals
The reagents used for present study are as follows Methanol, Acetonitrile, Toluene, Ethyl

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7. Determination of Iguratimod in human plasma by HPLC method

WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.074
Volume 7, Issue 14, 404-413. Review Article ISSN 2277– 7105

DETERMINATION OF IGURATIMOD IN HUMAN PLASMA BY HPLC METHOD

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ABSTRACT

A simple bioanalytical HPLC method for estimation of Iguratimod in human plasma has been developed and validated. Extracted sample was eluted using HiQ Sil C_{18} column. The optimized mobile phase was ACN: WATER adjust the pH-3 with glacial acetic acid (40:60v/v) at flow rate 1 ml/min. In this method Rosuvastatin is used as internal standared. Iguratimod and Rosuvastatin eluted at retention time 9.033 and 11.925min. Calibration curve was linear in range of 1-7ug/ml. The method was validated according to MHLW (Japan) guidelines(2013). The data of linear regression analysis indicated a good linear relationship over the range of 1-7 ug/ml with correlation coefficient value of 0.9551. The proposed method can be applied for estimation of Iguratimod in human plasma in pharmacokinetic studies.

KEYWORDS: Iguratimod and Rosuvastatin.

INTRODUCTION

Iguratimod is antirheumatic. It is used for treatment of rheumatoied arthritis and it is developed by Toyama chemical company. Iguratimod is approved in Japan. Iguratimod also inhibits the production of inflammatory cytokines in cultured human synovial cell and human monocytic leukemia cell. It reduces immunoglobuline production by acting directly in B lymphocytes in both mice and humans. There are some methods reported for estimation of Iguratimod from human plasma.[1,2,3]

Iguratimod molecular formula is $C_{17}H_{14}N_2O_6S$. Its chemical name is N-[7-(methanesulfonamido)-4-oxo-6-phenoxychromen-3yl]formamide as shown in fig.1.

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8. Stability indicating RP-HPLC method for estimation of Tenofovir Disoproxil Fumarate

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Research Article | Biological Sciences | Open Access | MCI Approved| ज्ञान-विज्ञान विमुक्तये
|UGC Approved Journal |

STABILITY INDICATING RP-HPLC METHOD FOR ESTIMATION OF TENOFOVIR DISOPROXIL FUMARATE

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ABSTRACT

A stability indicating assay method was developed and validated according to the ICH guidelines for estimation of Tenofovir Disoproxil Fumarate. HiQSil C18 HPLC column was used. Mobile phase consisting of potassium di hydrogen ortho phosphate buffer of pH -3 : Acetonitrile (70:30 v/v) at a wavelength of 260 nm. Drug was subjected to forced hydrolytic, oxidative, photolytic and thermal degradation conditions. Degradation was observed for Tenofovir Disoproxil Fumarate in hydrolytic conditions.

KEY WORDS

Tenofovir Disoproxil Fumarate, Stress degradation, Validation, Stability Indicating.

INTRODUCTION

Tenofovir Disoproxil Fumarate (TDF) chemically is 9-[(R)-2[[bis[[(isopropoxycarbonyl)Oxy] methoxy] phosphinyl] methoxy] propyl] adenine fumarate [1]. A nucleotide reverse transcriptase inhibitor (NtRTI), the ester prodrug of tenofovir which is hydrolyzed to tenofovir intracellularly and phosphorylated to the active metabolite, tenofovir diphosphate. Tenofovir is a nucleotide analogue of deoxyadenosine monophosphate, with activity against HIV-1, HIV-2 and Hepatitis B virus (HBV). Literature survey revealed that there are number of stability indicating HPLC methods [2-7] reported but the results of stress degradation do not match, hence it was thought necessary to confirm the same by developing Stability Indicating HPLC method.

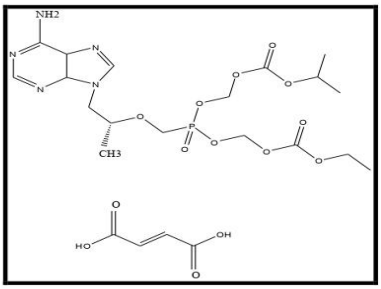

Fig 1: Chemical structure of Tenofovir Disoproxil Fumarate

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9. Stability indicating HPTLC method for simultaneous estimation of Brimonidine Tartrate and Timolol Maleate

INTERNATIONAL JOURNAL OF RESEARCH CULTURE SOCIETY ISSN: 2456-6683 Volume - 2, Issue - 7, July– 2018
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Stability Indicating HPTLC Method For The Simultaneous Estimation Of Brimonidine Tartrate And Timolol Maleate

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Abstract: *A new, simple, precise, accurate and sensitive High Performance Thin Layer Chromatographic method has been developed for the estimation of Brimonidine Tartrate and Timolol Maleate in combination. The determination was made at 281 nm for Brimonidine Tartrate &Timolol Maleate. Chloroform: Methanol: Ammonia in ratio of (9: 0.2: 0.1) v/v/v was the optimized mobile phase for estimation of combination. The validation of method was carried out as per ICH Guidelines.*

Key Words: *Brimonidine & Timolol, HPTLC, Stability indicating.*

1. INTRODUCTION:

Brimonidine Tartrate is chemically [5- bromo-6(2-imidazolidinylideneamino) quinoxaline L-tartrate]&Timolol Maleate [(S)-1-[(1,1-dimethylethyl)amino]-3-[[4-(4-morphonlinyl)-1,2,5- thiadiazol -3-yl]oxy]-2-propanol,(Z)-2-butenedioate] (1). Timolol Maleate and Brimonidine Tartrate are used separately and in combination for the treatment of Glaucoma (2). Timolol Maleate blocks both β-1 and β-2 adrenergic receptors, reduces intraocular pressure by reducing aqueous humor production or possibly outflow; reduces blood pressure by blocking adrenergic receptors and decreasing sympathetic outflow, produces a negative chronotropic and inotropic activity through an unknown mechanism. Brimonidine Tartrate is an alpha adrenergic receptor agonist. It has a peak ocular hypotensive effect occurring at two hours post-dosing. Fluorophotometric studies in animals and humans suggest that brimonidine tartrate has a dual mechanism of action by reducing aqueous humor production and increasing uveoscleral outflow. Number of chromatographic methods like HPTLC (3) and HPLC (4,5,6) methods are reported. Literature survey reveals that spectrophotometric methods like Simultaneous Equation Method (7), Absorbance Ratio Method (8) & Area Under Curve (9) are reported. But no stability indicating HPTLC method was reported for estimation of Brimonidine Tartrate & Timolol Maleate.

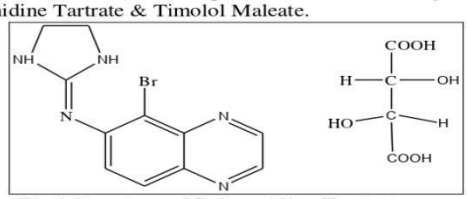

Fig.1 Structure of Brimonidine Tartrate

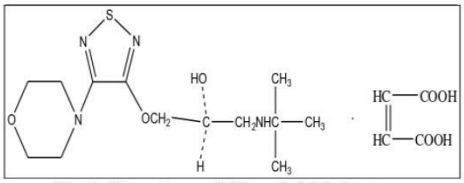

Fig.2 Structure of Timolol Maleate

2. MATERIAL AND METHODS :

Instruments

HPTLC

Camag Linomat 5 (Semiautomatic Spotting device)
Camag Twin trough chamber (10 x10 cm)
Camag TLC Scanner-3
Camag WINCATS Software (version 1.4.3.6336)
Hamilton Syringe (100 µl)
All weighing were done on electronic analytical balance. (Shimadzu AY 120)

Chemicals and Reagents:

Timolol Maleate and Brimonidine Tartrate working standards were obtained from Micro Labs pvt. Ltd., India. , Distilled water. Chloroform, Methanol & Ammonia were purchased from LOBA Chemie (Mumbai).

Selection of a Mobile Phase:

Chloroform: Methanol: Ammonia (30%) (9:0.2:0.1 v/v/v) was selected as a mobile phase for Brimonidine Tartrate & Timolol Maleate.

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10. Development and validation of Stability indicating HPLC method for the estimation of Canagliflozin

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DEVELOPMENT AND VALIDATION OF A STABILITY-INDICATING HPLC METHOD FOR THE ESTIMATION OF CANAGLIFLOZIN

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Abstract:
The objective of the study was to develop and validate a simple, specific, precise and accurate HPLC method for the estimation of Canagliflozin in bulk and tablet dosage form. Chromatographic separation was achieved by using Acetonitrile: Water (pH adjusted to 4.5 using 0.1% v/v Ortho -phosphoric acid) as mobile phase in a ratio of 50:50 v/v. Chromatographic separation was achieved using Neosphere C18 column (150×4.6mm i.d. 3.5µm) at 1ml/min as flow rate. The detection was carried out at 291nm using PDA detector. The retention time was observed to be 4.7 ±0.05min. This drug was subjected to various stress degradation conditions as per ICH Q1A (R2). Linearity was found to be in the concentration range of 10-50µg/ml with R^2 =0.996 .The suitability of this HPLC method for quantitative estimation of Canagliflozin was proved by validation as per ICH Q2A(R1) guidelines and can be used for the routine analysis of Canagliflozin in bulk and tablet dosage form.

Keywords– Canagliflozin, HPLC, stress degradation, Stability indicating.

I. INTRODUCTION

Canagliflozin is an anti-diabetic agent used to improve glycemic control in people with type-2diabetes. [1] Chemically it is (2S,3R,4R,5S,6R)-2-(3-{[5-(4-fluorophenyl)thiophen-2-yl]methyl}-4-methylphenyl)-6-(hydroxymethyl)oxane-3,4,5-triol with molecular formula $C_{24}H_{25}FO_5S$. It is white to off-white solid, soluble in organic solvents like methanol, acetonitrile but insoluble in aqueous media. [2] Canagliflozin is an inhibitor of subtype 2 sodium-glucose transport proteins (SGLT2) which is responsible for at least 90% of renal glucose re-absorption. Canagliflozin is effective in reducing blood glucose levels and has lowered blood glucose levels more significantly than DPP-4 inhibitors in clinical trials. The anti-diabetic drug causes the body to pass out glucose from the blood via the urine, which means that calories in the glucose are excreted. This action helps support weight loss when the drug is used in combination with a healthy diet and regular physical activity. It was developed by Mitsubishi Tanabe Pharma and is marketed under license by Janssen, a division of Johnson & Johnson.[3] As per the literature survey it is revealed that the drug has been estimated by Modified HPLC Quantification Analytical Technique for Canagliflozin and Metformin Hydrochloride in Bulk and Tablets.[4] RP-HPLC Method Development and Validation for the Determination of Canagliflozin in Human Plasma. [5] Development and validation of a Stability-Indicating High Performance Thin Layer Chromatography analysis has been reported for the estimation in bulk and pharmaceutical dosage form. (Ishpreet Kaur et al., 2015). [6] Development and Validation of a Stability- Indicating Reverse Phase HPLC-PDA Method for Determination of Canagliflozin in Bulk and Pharmaceutical Dosage Form. [7] SIM RP-HPLC Method for Estimation of Canagliflozin in Dosage Form .[8] Thus, there are only three stability indicating High Performance Liquid Chromatography analysis has been reported for the estimation of Canagliflozin in bulk and pharmaceutical dosage forms. ICH conditions for photostability has not been used and it has been reported that the drug is prone to photolysis in one paper whereas it has also been reported that the drug is prone to alkaline degradation and is photostable in other reference [6][7][8] Though, the photostability results and ICH Conditions has not been used in the reported literature , therefore, the aim of the present work is to develop and validate a simple, stability indicating

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11. Development and validation of Stability indicating HPTLC method for the determination of Paliperidone Palmitate as bulk drug

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DEVELOPMENT AND VALIDATION OF STABILITY INDICATING HPTLC METHOD FOR DETERMINATION OF PALIPERIDONE PALMITATE AS BULK DRUG

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Abstract:

A simple, economical and precise thin-layer chromatography method has been developed for determination of Paliperidone palmitate. The method was validated as per International Conference on Harmonization (ICH) guidelines. Aluminium TLC plates precoated with silica gel $60F_{254}$ were used as the stationary phase and chloroform: methanol 3:7 (v/v) as mobile phase. A compact band (Rf 0.54 ± 0.03) was obtained for Paliperidone palmitate. Densitometric analysis was performed in the absorbance mode at 236 nm. The calibration curve was found to be linear in the concentration range of 500-2500 ng/band. The limits of detection and quantitation were found to be 47.70ng/band and 144.56ng/band respectively. Paliperidone palmitatae was subjected to stress conditions like hydrolysis under acidic, basic and neutral conditions, oxidation, heat and photolysis.

Keywords: Paliperidone Palmitate, HPTLC, Stability indicating method

INTRODUCTION

Paliperidone is the primary active metabolite of the older antipsychotic risperidone. While its specific mechanism of action is unknown, it is believed that Paliperidone and Risperidone act via similar if not the same pathways. It has been proposed that the drug's therapeutic activity in schizophrenia is mediated through a combination of central dopamine type 2 (D2) and serotonin type 2 (5HT2A) receptors and H1 histaminergic receptors, which may explain some of the other effects of the drug. Paliperidone chemically described as 3-[2-[4-(6-fluoro-1,2benzisoxazol-3yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-9-hydroxy-2-ethyl-4*H*-pyrido[1,2-a]pyrimidin-4-one(Fig. I)[1].

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12. Development and validation of Stability indicating High Performance Thin Layer Chromatographic (HPTLC) method for the estimation of Acotiamide Hydrochloride Hydrate

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DEVELOPMENT & VALIDATION OF A STABILITY- INDICATING HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHIC (HPTLC) METHOD FOR THE ESTIMATION OF ACOTIAMIDE HYDROCHLORIDE HYDRATE

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ABSTRACT
The objective of the study was to develop & validate a simple, specific, rapid, precise and accurate HPTLC method for the estimation of Acotiamide Hydrochloride. The HPTLC separation was carried out on Merck TLC aluminium sheets Precoated with Silica gel $60F_{254}$ using mobile phase as Chloroform : methanol(6:4v/v) and it was validated as per ICH Q2 (R1) guidelines. Forced degradation study was carried out under different stress conditions. The analysis of the spots was performed at 332nm. A linear data over the range of 200-1000ng/band with a good correlation coefficient of 0.996 unfolds linear relationship between area and concentration in calibration curve. Stress degradation study of Acotiamide Hydrochloride was done according to ICH guidelines Q1A (R2) and the proposed method can be used for the routine analysis of Acotiamide Hydrochloride in bulk and pharmaceutical dosage form.

KEYWORDS: Acotiamide Hydrochloride Hydrate, HPTLC, ICH guidelines, forced degradation studies.

INTRODUCTION

Acotiamide Hydrochloride Hydrate is an anti emetic agent, chemically N-[2-[di(propan-2-yl)amino]ethyl]-2-[(2-hydroxy-4,5-dimethoxybenzoyl)amino]-1,3-thiazole-4-carboxmide; trihydrate; hydrochloride. Acotiamide Hydrochloride Hydrate is the hydrochloride salt form of acotiamide, which is a prokinetic agent having gastrointestinal (GI) motility-enhancing activity.[1] Although, the exact mechanism by which acotiamide exerts its effect has yet to be fully elucidated, this agent appears to inhibit acetylcholinesterase (AchE), which is an enzyme responsible for the breakdown of acetylcholine (Ach). Increased Ach concentrations lead to an improvement of gastric emptying and GI motility and eventually to a reduction of dyspepsia symptoms. Acetylcholine release via acting as an antagonist on the M1 and M2 muscarinic receptors in the enteric nervous system and inhibiting acetylcholinesterase activity. Acotiamide has been approved in Japan in March 2013 and launched in Japan in June 2013, making it the world's first approved treatment for Functional Dyspepsia in patients.[2]

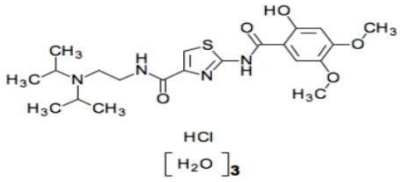

Fig. 1: Structure of Acotiamide Hydrochloride Hydrate.

Acotiamide Hydrochloride Hydrate is not official in IP/BP/USP. Literature survey reveals that few analytical methods have been reported viz., the determination of Acotiamide Hydrochloride Hydrate in Rat plasma by

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13. Development and validation of stability indicating HPLC method for determination of Acotiamide Hydrochloride

Damle and Harne, IJPSR, 2018; Vol. 9(10): 4410-4415. E-ISSN: 0975-8232; P-ISSN: 2320-5148

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INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

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DEVELOPMENT AND VALIDATIONOF OF STABILITY INDICATING HPLC METHOD FOR DETERMINATION OF ACOTIAMIDE HYROCHLORIDE

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Keywords:

Acotiamide hydrochloride, Stability indicating, HPLC, Validation, ICH guideline

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ABSTRACT: A simple and rapid stability indicating HPLC method for acotiamide hydrochloride was developed and validated. The stationary phase used was thermo gold cyno (250 × 4.6 mm) 5 µ with a mobile phase consisting of mixture of acetonitrile and 10 mM KH_2PO_4 in water in the ratio of 80:20 v/v at a flow rate of 0.8ml/min. Detection was carried at 284 nm. The retention time observed was 8.1 ± 0.2 min. The column was maintained at ambient temperature and 20 µl of solutions were injected. The eluted compound was detected by using PDA detector. The linear regression analysis data for calibration plot show good relationship with coefficient of regression value, r^2=0.99 in the concentration range 10-50 µg/ml. The stress degradation studies were performed as per ICH guidelines. Acotiamide hydrochloride degraded with acid/base hydrolysis, thermal, oxidation and photolytic stress. The method was validated as per ICH Q2A (R1) guideline with respect to linearity, accuracy, precision, specificity and robustness. This method can be used for monitoring the stability of acotiamide hydrochloride.

INTRODUCTION: Acotiamide hydrochloride is a new prokinetic drug that is used to treat functional dyspepsia (FD). Extensive literature review reveals that Acotiamide is a drug approved in Japan for the treatment of postprandial fullness, upper abdominal bloating, and early satiation due to functional dyspepsia [1]. It acts as an acetyl cholinesterase inhibitor. Functional dyspepsia (FD) is a highly prevalent condition characterized by symptoms suggested to be of gastro duodenal origin, in the absence of an organic cause that is likely to explain the symptoms. It is generally assumed that FD is heterogeneous condition, which consists of different entities and may require specific management or treatment approaches.

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However, it has proven difficult to identify reliably subgroups of clinically meaningful importance. Functional dyspepsia is treated by two major categories of drugs; acid inhibitors such as H_2-receptor antagonists and proton pump inhibitors (PPIs), and prokinetic drugs which accelerate disturbed GI motility with modifying altered visceral sensitivity [2]. Eradication of *H. pylori* and psychotropic agents such as anxiolytics and antidepressants were added as other options for FD treatment.

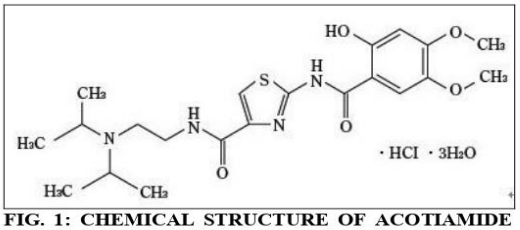

FIG. 1: CHEMICAL STRUCTURE OF ACOTIAMIDE HYDROCHLORIDE

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14. Validated Stability indicating methods for Thymoquinone using HPLC and HPTLC

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IJPBS™ | Volume 8 | Issue 4 | OCT-DEC | 2018 | 01-06
Research Article | Pharmaceutical Sciences | Open Access | MCI Approved| ज्ञान-विज्ञान विमुक्तये
|UGC Approved Journal |

VALIDATED STABILITY INDICATING METHODS FOR *THYMOQUINONE* USING HPLC AND HPTLC

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ABSTRACT

A stability indicating assay method was developed and validated according to the ICH guidelines for estimation of Thymoquinone using HPLC & HPTLC. HiQSil C18 column was used with Acetonitrile as mobile phase. Wavelength selected was 253 nm. HPTLC analysis was done using precoated silica plates. Toluene was used as mobile phase & detection wavelength was 253 nm. Drug was subjected to forced degradation studies. Validation was carried according to ICH guidelines.

KEY WORDS

Thymoquinone, HPLC, HPTLC, Stability indicating.

INTRODUCTION

Among various medicinal plants, *Nigella sativa* (*N. sativa*) (Family Ranunculaceae) is emerging as a miracle herb with a rich historical and religious background since many researches revealed its wide spectrum of pharmacological potential. *N. sativa* is commonly known as black seed. *N. sativa* is native to Southern Europe, North Africa and Southwest Asia and it is cultivated in many countries in the world like Middle Eastern Mediterranean region, South Europe, India, Pakistan, Syria, Turkey, Saudi Arabia (1). Thymoquinone chemically is 2-Isopropyl-5-methyl-1,4-benzoquinone. It is very important constituent in *Nigella sativa* seeds (2). Besides being used as a spice and a condiment, *N.S.* seeds have been used for medicinal purposes in many Middle Eastern and Far Eastern countries for more than two thousand years. It is very popular in various traditional systems of medicine like Unani and Tibb, Ayurveda and Siddha. Seeds and oil have a long history of folklore usage in various systems of medicines and food. The seeds of *N. sativa* have been widely used in the treatment of different diseases and ailments. In Islamic literature, it is considered as one of the greatest forms of healing medicine. It has been recommended for using on regular basis in Tibb-e-Nabwi (Prophetic Medicine). It has been widely used as antihypertensive, liver tonic, diuretic, digestive, anti-diarrheal, appetite stimulant, analgesics and in skin disorders. Literature survey reveals that certain pharmacological studies (3,4) have been reported on *Nigella sativa* (5-7). But no stability indicating HPLC & HPTLC methods are reported for marker Thymoquinone.

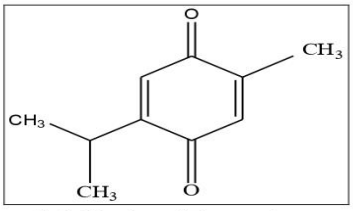

Fig 1. Structure of Thymoquinone

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15. Absorption correction Method for simultaneous estimation of Domperidone and Ilaprazole by UV spectrometry

J Pharm Sci Bioscientific Res. 2018. 8 (3):144-147 ISSN NO. 2271-3681

JOURNAL OF PHARMACEUTICAL SCIENCE AND BIOSCIENTIFIC RESEARCH (JPSBR)

(An International Peer Reviewed Pharmaceutical Journal that Encourages Innovation and Creativities)

Absorption Correction Method for Simultaneous Estimation Domperidone and Ilaprazole by UV Spectrometry

M.C. Damle[1]*, P. Uttekar[1], V. Rathore[1], P. Gavali[1], S. Bhobe[1].

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Damle M. C., Uttekar P., Rathore V., Gavali P., Bhobe S. Absorption Correction Method for Simultaneous Estimation Domperidone and Ilaprazole by UV Spectrometry **J Pharm Sci Bioscientific Res**. 2018. 8(3):144-147

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(www.jpsbr.org)

ABSTRACT:

Domperidone and Ilaprazole are drugs used in the treatment of gastro-oesophageal reflux. They are also given in combination. The current work describes a simple UV spectrophotometric method for estimation of these two in combination. It is based on the principle of Absorbance correction for interference. The choice of 285nm and 320 nm is based on the fact that Ilaprazole shows practically negligible absorbance at 320 nm whereas both these drugs absorb significantly at 285 nm. The method is economical, fast and has been checked for linearity, accuracy, precision, LOD, and LOQ.

KEY WORDS: Domperidone, Ilaprazole, Absorbance corrected method, Validation.

INTRODUCTION:

Domperidone, a drug used in the treatment of gastro-oesophageal reflux disease, is chemically 5-Chloro-1-(1- [3-(2- oxo- 2,3- dihydro -1H –benzo d] imidazol -1-yl)propyl]piperidin-4-yl)-1H-benzo[d]imidazol-2(3H)-one[(1)]. It increases gastrointestinal peristalsis resulting in increase in transit of food through stomach. It is used in relieving nausea and vomiting. Its molecular formula is $C_{22}H_{2}ClN_{5}O_{2}$. Ilaprazole, a proton pump inhibitor (PPI) is used in the treatment of dyspepsia, peptic ulcer disease (PUD), gastro-oesophageal reflux disease (GORD/GERD) and duodenal ulcer. Ilaprazole[(2)] chemically is 2-[(RS)-[(4-methoxy-3-methylpyridin-2-yl)methyl]sulfinyl]-5-(1H-pyrrol-1-yl)-1H-benzimidazole. Its molecular formula is $C_{19}H_{18}N_{4}O_{2}S$.

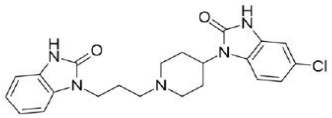

Figure 1 Structure of Domperidone

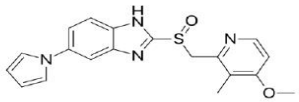

Figure 2 Structure of Ilaprazole

A thorough literature search revealed that there are number of HPLC methods[(3-4)], stability indicating chromatographic[(5-9)] and a UV spectro photometric [(10)] method reported for determination of Domperidone and Ilaprazole in combination. When UV spectrum of these two was overlapped, it was observed that Ilaprazole has considerable absorbance at 285 nm as well as 320 nm whereas Domperidone has appreciable absorbance at 285 nm but negligible absorbance at 320 nm. This suggests that absorbance correction method may be applicable to this combination[(11)].

MATERIALS AND METHODS

Apparatus:

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16. An in-vitro study of antioxidant capacity and radical scavenging effect of Spinacea Olaracea leaf extract

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Knowledge to Innovation

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Research Article

AN *IN VITRO* STUDY OF ANTIOXIDANT CAPACITY AND RADICAL SCAVENGING EFFECT OF *SPINACIA OLERACEA* LEAF EXTRACT

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Received: 20 June 2018, Revised and Accepted: 16 July 2018

ABSTRACT

Objective: The study was carried out to evaluate the preliminary phytochemical screening and antioxidant activity of ethanolic extract of *Spinacia oleracea* (SO).

Methods: The leaves of SO were shade dried, and the extract was prepared using solvent ethanol by Soxhlet extraction method. The preliminary phytochemical screening was carried out on the leaf extract of the plant. The total phenolic content and total flavonoids were estimated using Folin-Ciocalteu's and aluminum chloride reagents, respectively. Antioxidant activities were studied using 1,1-diphenyl-2-picrylhydrazyl, nitric oxide, hydrogen radical, lipid peroxidation, and phosphomolybdenum radical scavenging assays.

Results: The preliminary phytochemical analysis revealed the presence of bioactive constituents such as phenols, alkaloids, flavonoids, saponins, and glycosides. As SO is a rich source of different bioactive component, it contains a considerable amount of flavonoids and phenols. The different antioxidant assays proved that spinach is one of the best antioxidants with its ability to scavenge different radicals that generate oxidative stress.

Conclusion: The observed activity may be associated with bioactive components such as phenols and flavonoids present in the leaf extracts and could have greater importance as nootropic plant in oxidative stress-related degenerative diseases such as Alzheimer and dementia.

Keywords: *Spinacia oleracea*, Antioxidant activity, 1,1-Diphenyl-2-picrylhydrazyl, Saponins, Flavonoids, Phenols, Anti-Alzheimer activity.

 DOI: http://dx.doi.org/10.22159/ajpcr.2018.v11i11.28021

INTRODUCTION

The oldest form of health care known to humanity is the use of herbs as medicine. It has been used in all cultures throughout the history. In ancient time, tribal people methodically collected information on herbs and developed well-defined herbal pharmacopeias. There is physical evidence of the use of herbal remedies. In the 20th century, much of the pharmacopeia of scientific medicine was derived from the herbal knowledge of the native people. Plants or part of a plant that has been converted into phyto-pharmaceuticals using simple processes involving harvesting, drying, and storage is known as "herbal drug." In addition to the definition, it also includes other crude products derived from plants, which no longer show any organic structure, such as essential oils, fatty oils, resins, and gums [1,2].

The substances that neutralize free radicals or their actions are known as "antioxidants." Every cell is having adequate protective mechanisms to fight against any harmful effects of free radicals such as glutathione peroxidase, glutathione reductase, thioredoxin, thiols, and disulfide bonding. These are buffering systems in every cell. Vitamin E and C, carotenoids, flavonoids, and related polyphenols are essential nutrient which is responsible for preventing the propagation of free radical reactions in all cell membranes in the human body. Nowadays, the demand for natural drug products which produces antioxidants is increasing day by day.

"Oxidative stress" is a concept that defines the relationship between free radical and a disease. The generation of prooxidants in the form of reactive oxygen species and reactive nitrogen species which are present in healthy human body when gets exposed to adverse physicochemical, environmental, or pathological agents such as atmospheric pollutants, cigarette smoking, ultraviolet rays, radiation, toxic chemicals, and overnutrition the favorable conditions for prooxidants occurs by shifting the delicate balance between prooxidants and antioxidative mechanism in body which further results in the formation of "oxidative stress."

Natural compounds which are derived from dietary sources provide a large number of antioxidants. Tea is also rich sources of antioxidants. Catechin is one of the most active constituents present in it which acts as a potent antioxidant. Apart from the dietary sources, a number of Indian medicinal plants are also a rich source of antioxidants. [3,4] Superoxide dismutase, catalase, glutathione peroxidase, or non-enzymatic compounds, such as uric acid, bilirubin, albumin, and metallothioneins, are the enzymes but known for their endogenous antioxidant activity. Exogenous antioxidants came into existence when the endogenous factors were not able to control oxidative stress causing agents. Examples of exogenous antioxidants are Vitamin E, Vitamin C, β-carotene, Vitamin E, flavonoids, mineral Se, Vitamin D, and Vitamin K_3 [5].

Plants are one of the most important sources of medicines. The medicinal plants are rich in secondary metabolites (which are potential sources of drugs) and essential oils of therapeutic importance. The important advantages claimed for the therapeutic uses of medicinal plants in various ailments are their safety besides being economical, effective, and their easy availability. *Spinacia oleracea* Linn. (SO) is a plant having medicinal property native to central and southwestern Asia. It is cultivated for the sake of its succulent leaves and was introduced in Europe in the 15th century. It is the favorite food among Indians in the winter season [6].

SO is plant known as spinach is one of the rich sources of nutrients. It is widely cultivated all over the world having different pharmacological activities. Therefore, the aim of the present study is to determine different phytoconstituents of SO and its *in vitro* antioxidant activity to correlate its medicinal or pharmacological activity due to the presence of abundant phytoconstituents [7].

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17. Development and Validation of Stability Indicating HPTLC Method for Estimation of Amiodarone Hydrochloride

WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.074
Volume 7, Issue 5, 1001-1013. Research Article ISSN 2277– 7105

DEVELOPMENT AND VALIDATION OF STABILITY INDICATING HPTLC METHOD FOR ESTIMATION OF AMIODARONE HYDROCHLORIDE

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ABSTRACT

A simple, sensitive and accurate stability indicating high performance thin layer chromatographic (HPTLC) method has been developed and validated for the estimation of Amiodarone hydrochloride in bulk and in pharmaceutical dosage form. The separation was performed on pre-coated silica gel 60 GF_{254} aluminum plates using Ethyl acetate: Methanol (9:1 v/v) as mobile phase. The retention factor (R_f) for drug was found to be 0.48 ± 2.05. The detection of band was carried out at 242 nm. The drug was subjected to different stress conditions like acid, base, neutral hydrolysis, oxidation, thermal degradation and photolysis. The method was successfully validated according to ICH Q2 (R1) guidelines. The data of linear regression analysis indicated a good linear relationship over the concentration range of 200-1200ng/band with correlation coefficient (R^2) 0.9976. The accuracy of the method was established based on the recovery studies. The developed method was found to be simple, sensitive, selective, accurate and repeatable for analysis of Amiodarone hydrochloride and can be adopted for routine analysis of drug in bulk and in pharmaceutical dosage form.

KEYWORDS: High performance thin layer chromatography (HPTLC), Amiodarone hydrochloride, Stability indicating, Validation.

INTRODUCTION

Amiodarone hydrochloride is a class III anti-arrhythmic agent and one of the most powerful drug used in the treatment of ventricular and supraventricular tachycardia. Amiodarone hydrochloride is a benzofuran derivative, chemically it is 2-butylbenzofuran-3-yl-4-(2-

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18. Simultaneous Estimation of Levofloxacin and Cefpodoxime Proxetil inTablet Formulation by Ratio Spectra Derivative Spectroscopy

INTERNATIONAL JOURNAL OF RESEARCH CULTURE SOCIETY ISSN: 2456-6683 Volume - 2, Issue - 5, May – 2018
Monthly, Peer-Reviewed, Refereed, Indexed Journal Impact Factor: 3.449 Publication Date: 31/05/2018

Simultaneous Estimation of Levofloxacin and Cefpodoxime Proxetil in Tablet Formulation by Ratio Spectra Derivative Spectroscopy

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Abstract: *A simple, sensitive, rapid, accurate and precise method for simultaneous determination of Levofloxacin and Cefpodoxime Proxetil in combined tablet dosage form has been developed. The method is based on ratio spectra derivative spectrophotometry. The amplitudes 250 nm and 267 nm in first derivative of the ratio spectra were selected to determine Levofloxacin and Cefpodoxime Proxetil respectively in combined formulation. The developed method was showing linearity in concentration range of 4-24 µg/ml for Levofloxacin and Cefpodoxime Proxetil with the correlation coefficient (R^2) 0.999 and 0.998, respectively. Results of analysis were validated statistically and by recovery studies. The percent relative standard deviation (% RSD) of inter-day and intra-day precision studies were found to be within limits of not more than 2 % indicating that the present method is precise as per ICH guidelines Q2 (R1). The developed method can be used for routine estimation of Levofloxacin and Cefpodoxime Proxetil in bulk and pharmaceutical dosage form.*

Key Words: *Levofloxacin, Cefpodoxime Proxetil, Ratio Derivative Spectroscopy*

1. INTRODUCTION:

1.1. Levofloxacin (LEVO) is having its IUPAC name as (3S)-9-fluoro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-2,3-dihydro-7H-[1,4]oxazino[2,3,4-ij]quinoline-6-carboxylic acid. LEVO is a broad spectrum antibiotic of fluoroquinolone class of drug having greater activity towards gram positive bacteria and lesser activity toward gram-negative bacteria. It is also knows as respiratory quinolone. It inhibits bacterial type II topoisomerases, DNA gyrase and topoisomerase IV. [1]

1.2. Cefpodoxime proxetil (CP) is an oral third generation cephalosporin antibiotic used to treat a variety of bacterial infections. Its IUPAC name is 1-propan-2-yloxycarbonyloxyethyl (6R, 7R)-7-[[(2z)-2-(2-amino-1,3-thiazol-4-yl)-2-methoxyiminoacetyl]amino]-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-caboxyate.
Cefpodoxime proxetil is indicated for the treatment of mild to moderate infections caused by susceptible strains of the designated microorganisms. [2-4]

Literature survey reveals few UV spectrometric methods reported like absorption ratio method [5-7], simultaneous equation method [5] and absorption correction method [8]. An RP-HPLC method for determination of LEVO and CP with other drugs is also reported in literature.[9, 10] To the best of our knowledge no Ratio Spectra Derivative Spectroscopy method has been reported for estimation of Levofloxacin and Cefpodoxime Proxetil in combination. The present work describes a Ratio spectra derivative spectroscopy method in bulk and pharmaceutical dosage form (MACPOD LX) according to the International conference on harmonization (ICH) guidelines Q2 R (1).[11]. The structure of LEVO (a) and CP (b) is shown in figure 1 and its overlapped in spectra is shown in figure 2.

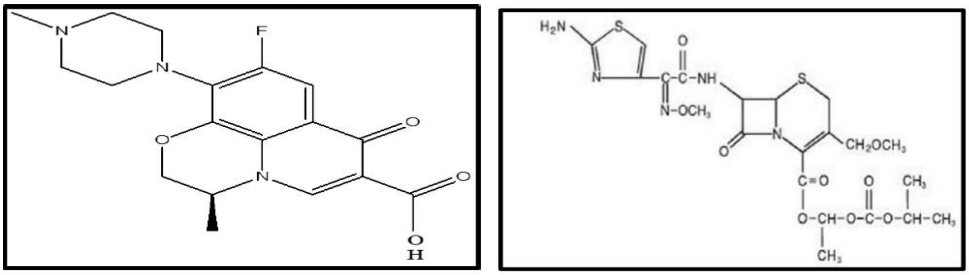

Figure 1. Structure of (a) Levofloxacin and (b) Cefpodoxime Proxetil

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19. Simultaneous Estimation of Nitazoxanide and Ofloxacin in Tablet Formulation by Ratio Spectra Derivative Spectroscopy

International Journal of Research in Pharmacy and Pharmaceutical Sciences

International Journal of Research in Pharmacy and Pharmaceutical Sciences
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Impact Factor: RJIF 5.22
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Volume 3; Issue 3; May 2018; Page No. 28-31

Simultaneous estimation of nitazoxanide and ofloxacin in tablet formulation by ratio spectra derivative spectroscopy

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Abstract
A simple, sensitive, rapid, accurate and precise method for simultaneous determination of Nitazoxanide and Ofloxacin in combined tablet dosage form has been developed. The method is based on ratio spectra derivative spectrophotometry. The amplitudes 269 nm and 236.5 nm in first derivative of the ratio spectra were selected to determine Nitazoxanide and Ofloxacin respectively in combined formulation. The developed method was showing linearity in concentration range of 5-30 µg/ml for Nitazoxanide and 2-12 µg/ml for Ofloxacin with correlation coefficient (R^2) 0.999 and 0.996; respectively. The percent assay was found to be 99.12 % and 100.69 % for Nitazoxanide and Ofloxacin, respectively. The method showed good linearity, precision and reproducibility. Results of analysis were validated statistically and by recovery studies.

Keywords: nitazoxanide, ofloxacin, ratio spectra derivative spectroscopy, simultaneous determination

Introduction
Nitazoxanide [NTZ] chemically N-(5-nitro-2-thiazolyl) salicylamide acetate [Fig. 1 (a)] is a synthetic nitrothiazole benzamide derivative. It is a broad spectrum antiprotozoal. It is indicated for amebiasis, helminthiasis, giardiasis, etc[1].
Ofloxacin [OFX] is 9-fluoro-2, 3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl) -7-oxo-7H-pyrido [1, 2, 3-de] [1, 4] benzoxazine-6-carboxylic acid [Fig. 1 (b)]. It is a synthetic antibiotic of the fluoroquinolone drug class considered to be a second-generation fluoroquinolone. It is used to treat certain infections including bronchitis, pneumonia and infections of the skin, bladder, urinary tract, reproductive organs, and prostate [2, 3].
Few methods are reported for quantitative determination of NTZ and OFX in single and in combination such as UV Spectrometry [3-5] and RP-HPLC [6-9].
Extensive literature survey revealed that no method available for simultaneous estimation of Nitazoxanide and Ofloxacin in combined dosage form by ratio spectra derivative spectroscopy. Aim of present work was to develop simple, economical, reproducible and rapid method for simultaneous estimation of binary drug formulation.

Theoretical aspects [10-11].
The method is based on dividing the spectrum for a mixture in to the standard spectra for each of the analyte and deriving the quotient to obtain a spectrum that is independent of the analyte concentration used as a divisor. The use of standardized spectra as a divisor minimizes the experimental error and background noise. An accurate choice of standard divisors and working wavelengths is the fundamental for several reasons. Easy measurement on separate peaks, higher values of the analyte signals and no need to work at zero crossing point (some time co-existing compounds have no maximum or minimum at these wavelengths) are advantages for ratio derivative spectrophotometry. Also the presence of a lot of minima and maxima in ratio spectra derivative data is another advantage, since these wavelengths give an opportunity for the determination of these compounds in presence of other active compound and excipients that possibly interfere with the assay. The method basically is dividing the absorption spectrum for a mixture in to the standardized spectra for each of the analytes. Derivatization of the obtained spectra gives derivative spectra that are independent of analyte concentration used as a divisor.

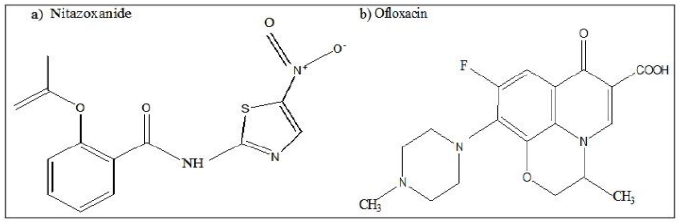

Fig 1: Structure of a) Nitazoxanide (NTZ) and b) Ofloxacin (OFX)

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20. Formulation and Evaluation of Phytoconstituents Cream for the Treatment of Varicose Veins

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SJIF Impact Factor 8.074
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FORMULATION AND EVALUATION OF PHYTOCONSTITUENTS CREAM FOR THE TREATMENT OF VARICOSE VEINS

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ABSTRACT

Phytoconstituents rutin and quercetin are used to assist the treatment of venous disorder like varicose veins and hemorroids, which reduces the capillary permeability and boost the integrity of vessels. There are certain limitations to the use of these phytoconstituents in the pharmaceutical formulations because of their physical properties like limited aqueous solubility, poor bioavailability and high oral dose. Therefore in the present research work cream of rutin and quercetin were developed for improving solubility and bioavailability using topical route.A mixture of rutin and quercetin was formulated in o/w cream. The cream was optimized to achieve good spreadability and highest drug diffusion using a two factor glyceryl caprylate (GC) and triethanolamine (TEA) three level (spreadability, viscosity and drug diffusion) factorial design. The cream was then characterized for physicochemical parameters. *In-vitro* diffusion and *ex-vivo* permeation studies were performed to estimate the diffusion of the drugs from the prepared formulation.It was observed from *ex-vivo* permeation studies that the flux for optimized cream was found to be 0.1898 and 0.3481mg/hr/cm^{2}respectively as compared to the saturated solution of pure rutin (0.1035mg/hr/cm^2) and quercetin (0.1264mg/hr/cm^2).The formulation was optimized and had viscosity 8190Cps, spreadability 56.4g and *in-vitro* drug diffusion flux as 0.2053 mg/hr/cm^2 for rutin and 0.1621mg/hr/cm^2 for quercetin respectively. Thus, it can be concluded that the components are contributing to providethe phytoconstituents at the site of action by topical cream optimized for the spreadability, viscosity and drug diffusion which control the release and entry of actives through skin barrier.

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21. RP-HPLC Method for Simultaneous Estimation of Cefixime Trihydrate and Cloxacillin Sodium from Bulk and Tablet Dosage Form

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RP-HPLC Method for Simultaneous Estimation of Cefixime Trihydrate and Cloxacillin Sodium from Bulk and Tablet Dosage Form

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HUMAN

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Keywords: Cefixime trihydrate and Cloxacillin; RP-HPLC; Method Validation

ABSTRACT

A simple and effective RP-HPLC method has been developed for the estimation of cefixime and cloxacillin in combination on C8 HiQsil column using phosphate buffer pH(3): Acetonitrile, (70:30 v/v) as mobile phase at flow rate of 1ml/min. Detection carried at 225 nm. Retention time found to be 2.120 for cefixime and 6.017 for cloxacillin. The linear dynamic ranges were 2-12 µg/ml (r^2>0.999) for Cefixime Trihydrate and 5-30µg/ml (r^2>0.995) for Cloxacillin sodium, respectively. The mean % recovery was found to be 100.314 % for Cefixime trihydrate and 100.830 % for Cloxacillin Sodium. The method was quantitatively evaluated in terms of linearity, precision, accuracy (recovery), selectivity and robustness in accordance with ICH guidelines. The obtained results show the proposed RP-HPLC method is simple, rapid, precise, accurate and cost-effective which is useful for the routine determination of Cefixime trihydrate and Cloxacillin sodium in bulk drug and in its tablet dosage form.

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22. Development and Validation of Stability Indicating HPLC Method for Estimation of Dapsone

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Original Article

Development and Validation of Stability Indicating HPLC Method for Estimation of Dapsone

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ABSTRACT

Objective: The aim of the present study was to develop a validated stability indicating reverse phase high performance liquid chromatography (RP-HPLC) method for estimation of Dapsone. **Experimental approach:** An isocratic, RP-HPLC method was developed using neosphere C_{18} (150 x 4.6 mm, 3.5 µm) column using 10 mM ammonium acetate buffer (pH 3) and methanol (60:40 v/v) as mobile phase at flow rate of 1 ml/min at detection wavelength of 295 nm. **Findings and discussion:** The retention time (RT) of drug was 4.3 ± 0.328 min. The method was validated with respect to linearity, precision, accuracy and robustness. The data of linear regression analysis indicated a good linear relationship over the range of 2-12 µg/ml concentrations with a correlation coefficient (R^2) of 0.997. Dapsone was subjected to different stress testing conditions.

Conclusion: The developed method was found to be simple, sensitive, selective, accurate, and precise for analysis of Dapsone and can be adopted for routine analysis of drug in bulk and pharmaceutical dosage form.

Keywords: High performance liquid chromatography (HPLC), Dapsone, Stability indicating, Validation.

1. INTRODUCTION

Dapsone (DAP) chemically bis (4-aminophenyl) sulphone is an antibiotic commonly used in combination with rifampicin and clofazimine for the treatment of leprosy[1]. It is a second-line medication for the treatment and prevention of pneumocystis pneumonia and for the prevention of toxoplasmosis in those who have poor immune function. Additionally, it has been used for acne, dermatitis herpetiformis and various other skin conditions[2]. Literature survey reveals that few analytical methods have been reported for the estimation of Dapsone in pharmaceutical

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23. Formulation and Evaluation of Phytoconstituents Emulgel for the Treatment of Varicose Veins

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EJPMR

FORMULATION AND EVALUATION OF PHYTOCONSTITUENTS EMULGEL FOR THE TREATMENT OF VARICOSE VEINS

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Article Received on 14/05/2018 **Article Revised on 04/06/2018** **Article Accepted on 24/06/2018**

ABSTRACT
The aim of the present research work was to investigate the potential of emulgel in enhancing the topical delivery of phytocontituents rutin and quercetin. Emulgel formulations of phytoconstituents were prepared using gelling agent Carbopol 934. The influence of the gelling agent, the concentration of the oil phase and emulsifying agent on the drug diffusion from the prepared emulgel was investigated using a 3^2 factorial design. The factors chosen were the concentration of glyceryl caprylate (GC) and the ratio of surfactants as Span 80: tween 80. The prepared formulations were evaluated for viscosity, spreadability, drug diffusion, globule diameter, drug content and skin irritancy test. The optimized batch showed acceptable globule diameter (218.6 nm), spreadability (41.9 g), viscosity (7850 cps), drug content for rutin and quercetin (98.8% and 101.8%) and pH (6.7). The *in-vitro* drug diffusion and *ex-vivo* permeation were found to be higher for optimized formulation as compared to the saturated solutions of pure drugs. The result of studied emulgel reveled that the invitro flux value of optimized batchwas found 0.2316 mg/hr/cm^2 (rutin) and 0.2457mg/hr/cm^2 (quercetin) respectively. It was observed from ex-vivo permeation studies that the flux for optimized emulgel was found to be 0.5367 and 0.5297 mg/hr/cm^2 respectively as compared to the saturated solutions of rutin (0.1035mg/hr/cm^2) and quercetin (0.1264mg/hr/cm^2). While result of skin irritation test shows no edema and erythema on the skin of the rabbits. In general conclusion, it was suggested that the emulgel formulation succeed the drug release for sustained drug delivery in a controlled manner in comparison.

KEYWORDS: Rutin, Quercetin, Emulgel, Varicose veins, Exvivo permeation.

INTRODUCTION

Varicose Veins is a disease of veins leadingtothe backward flow and turbulence in the circulation of the blood.[1] The veins get perverted, become enlarged due to a condition called edema. It involves a genetic predisposition, incompetent valves, weakened vascular walls, and increased intravenous pressure. A heavy, achy feeling, itching or burning and worsening with prolonged standing are all symptoms of varicose veins.[2] It is thought to be due to reasons like menopause, obesity, standing for long period of time, pregnancy etc.[3] Prominent treatment strategies are external laser treatment, injection sclerotherapy, endovenous interventions and surgery.[4] Choice of therapy is affected by symptoms, patient preference, cost, potential for iatrogenic complications and available medical resources. Different traditional and alternative therapy for treating varicose veins, we have identified phytoconstituents like rutin and quercetin which are reported to have good effect on the veins helping them in better functioning. Rutin through its free radical activity is able protect these walls and it inhibit the PAF (platelet activating factor) and thromboxane A2 thus diminishing capillary permeability.[5,6] Quercetin dramatically stabilize small blood vessels relating to the veins, helping reduce fluid retention and specifically boost integrity of vessels.[7] Presently these phytoconstituents are administered orally in suppliments form with very high doses and which show poor bioavailability.

Therefore present study attempts to formulate these phytoconstituents as topical novel emulgel form which is patient friendly using principles of formulation design and design of experiment strategy to get a formulation with desired performance attributes.

MATERIALS AND METHOD

Materials

Rutin was acquired from Loba Chemie Pvt. Ltd., (Mumbai, India) and Quercetin was obtained from Green Heaven India Pvt. Ltd., (Nagpur, India). All other ingredients used in the formulation of cream were purchased from local market and were of extra pure grade.

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24. Development And Validation of Stability Indicating HPTLC Method For Estimation of Terizidone

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Development And Validation of Stability Indicating HPTLC Method For Estimation of Terizidone

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[2]Reserch candidate, Dept of Quality Assurance Techniques
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Abstract- *A simple, sensitive and accurate stability indicating HPTLC method has been developed and validated for estimation of Terizidone in bulk and pharmaceutical dosage form. The chromatograph was developed by spotting drug on precoated silica gel 60 F_{254} aluminum plates using n-Hexane: Chloroform (5:5 v/v) as mobile phase. The retention factor (R_f) was found to be 0.25 ± 1.5. The detection of band was carried at 264 nm. The drug was subjected to different stress conditions like acid, base, neutral hydrolysis, oxidation, thermal degradation and photolysis. The method was successfully validated according to ICH guidelines Q2 (R1). The data of linear regression analysis indicated a good linear relationship over the concentration range of 200-1200 ng/band with correlation coefficient 0.94. The method found to be accurate as results of the recovery studies are close to 100 %. The developed method was found to be simple, sensitive, selective, accurate and repeatable and can be adopted for routine analysis of drug in bulk and pharmaceutical dosage form.*

Keywords- High performance thin layer chromatography (HPTLC), Terizidone, Stability indicating, Validation.

I. INTRODUCTION

Terizidone will be further abbreviated as TERI. TERI IUPAC name is 4-[(E)-({4-[(1E)-[(3-oxo-methylidene)amino]-1,2-oxazolidin-3-one.TERI is not official in any pharmacopoeia [1]. It has an antibiotic activity against mycobacterium tuberculosis and *M. avium* for the treatment of tuberculosis, i.e. pulmonary and extra pulmonary [2]. This drug comes under second line drugs that means it is used only when first line drugs are not able to show expected results [3]. Literature survey reveals methods reported are area under curve, first order derivative spectrophotometry [4], simple UV spectrophotometric method [5] and stability indicating HPLC for estimation of TERI [6]. To the best of our knowledge no stability indicating HPTLC method has been reported for estimation of TERI. The present work describes a stability indicating HPTLC method in bulk and pharmaceutical dosage form (Tericox) according to the International conference on harmonization (ICH) guidelines [7-8]. The chemical structure of TERI is given in Fig no.1

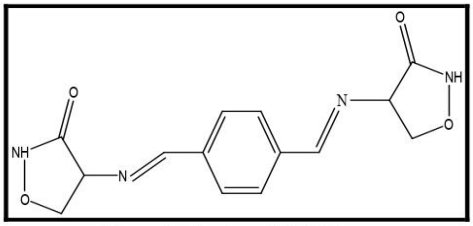

Fig no. 1-Structure of Terizidone

II. MATERIALS AND METHODS

Reagents and chemicals

The marketed formulation Tericox labeled to contain TERI 250 mg was procured form local market. Methanol (AR grade), n- Hexane (AR grade), Chloroform (AR grade), DMSO (AR grade), were purchased from S. D. Fine Chemical Laboratories, Mumbai. Hydrochloric acid (HCl), hydrogen peroxide (H_2O_2) and sodium hydroxide (NaOH) were purchased from LOBA Chemie, Mumbai. All chemicals were of analytical grade and used as received.

Chromatographic condition:

Chromatographic separation of drug was performed on aluminum plates precoated with silica gel 60 F_{254}, (10 cm × 10 cm with 250 µm layer thickness). Sample was applied on the plate as a band of 4 mm width using Camag 100 µl sample syringe (Hamilton, Switzerland) with a Linomat 5 applicator (Camag, Switzerland). The mobile phase was composed of n-Hexane: Chloroform (5:5 v/v). 10 cm × 10 cm CAMAG twin trough glass chamber was used for linear ascending development of TLC plate under 10 min saturation conditions

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25. Development and validation of stability indicating UV spectroscopic method for estimation of sofosbuvir

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Research Article | Pharmaceutical Sciences | Open Access | MCI Approved| ज्ञान-विज्ञान विमुक्तये
|UGC Approved Journal |

DEVELOPMENT AND VALIDATION OF STABILITY INDICATING UV SPECTROSCOPIC METHOD FOR ESTIMATION OF SOFOSBUVIR

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ABSTRACT

A stability-indicating UV Spectrophotometric method has been developed for analysis of the drug in the presence of the degradation products and is validated as per ICH Q2 R1 guidelines. Sofosbuvir in water shows maximum absorbance at 260.5 nm. The data of linear regression analysis indicated a good linear relationship over the range of 10-100 µg/ml concentrations with a correlation coefficient (R^2) of 0.9984. The LOD and LOQ were found to be 0.269 µg/ml and 0.814 µg/ml respectively. A recovery of Sofosbuvir in tablet formulation was observed in the range of 99.524-101.208 %. Percentage assay of Sofosbuvir tablets was found to be in the range of 99.812-101.740 %. Sofosbuvir was subjected to different stress testing conditions. Degradation of Sofosbuvir was mainly found in alkaline condition. The developed method was found to be simple, accurate and precise for analysis of Sofosbuvir and can be adopted for routine analysis of drug in bulk and pharmaceutical dosage form.

KEY WORDS

Method development, Sofosbuvir, Stability indicating method, Ultraviolet spectroscopy, Validation.

INTRODUCTION:

Sofosbuvir is a direct acting pyrimidine nucleotide analog representing the first NS5B HCV polymerase inhibitor. The drug is approved by the US FDA and the European Medicines Agency and has become commercially available for the treatment of Hepatitis C in the US in late 2013 and in several European countries in early 2014. Sofosbuvir is used in the treatment of chronic HCV genotype 1, 2, 3, or 4 infections in adults, including those with hepato cellular carcinoma awaiting liver transplantation and those with HIV co-infection. Limited data is available for treatment of chronic HCV infection caused by genotype 5 or 6. Chemically it is (S)-Isopropyl 2- ((S) - (((2R,3R,4R,5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)-4-fluoro-3-hydroxy-4-methyltetra hydrofuran-2-yl) methoxy) -(phenoxy) phosphoryl amino) propanoate. [1] (www.drugbank.ca/drugs/DB08934).

Literature survey reveals that several analytical methods have been reported for the estimation of Sofosbuvir in pharmaceutical dosage form including spectroscopic methods[2-4] and high performance liquid chromatography (HPLC) in single as well as in combination with other drugs,[5-7] high performance thin layer chromatography,[8] ultra-high performance liquid chromatography[9-10] and in biological fluids by RP-HPLC.[11] Although few reports are available on stability indicating HPLC methods in single as well as in combination with other drugs,[12-16] stability indicating HPTLC methods[17] but no method is available on stability indicating UV spectroscopy hence we have tried to develop stability indicating UV spectroscopic method for estimation of Sofosbuvir in bulk and pharmaceutical dosage form. The present work describes a simple stability indicating UV spectroscopic method for the determination of Sofosbuvir in bulk and pharmaceutical dosage form (MyHep™-400mg) according to the

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26. Chemometric–Assisted UV Spectrophotometric Method for Determination of Cefixime Trihydrate and Cloxacillin Sodium in Pharmaceutical Dosage Form

Asian J. Research Chem. 11(4): July–August 2018

ISSN 0974-4169 (Print)
0974-4150 (Online)

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RESEARCH ARTICLE

Chemometric–Assisted UV Spectrophotometric Method for Determination of Cefixime Trihydrate and Cloxacillin Sodium in Pharmaceutical Dosage Form

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ABSTRACT:
UV spectrophotometry is the simple, precise and accurate method of analysis. Chemometrics are set of statistically improved and verified multicomponent methods for analysis. These methods of analysis were developed using Principle Component Regression (PCR) and Partial Least Square (PLS) to apply and study new technique in project work. The spectra of both drugs were recorded at concentrations within their linear ranges at 2.0-12.0 µg/ml for Cefixime and 5.0-30.0 µg/ml for Cloxacillin. The spectra were recorded in the 220 nm-260 nm wavelength range at wavelength interval of 0.5 nm. International Conference on Harmonization Q2 (R1) (ICH) guidelines were followed to validate the method. The proposed method can be used as alternative analytical tool in quality control of these drugs.

KEYWORDS: Chemometrics UV-assisted Studies, Cefixime trihydrate, Cloxacillin Sodium, PCR, PLS.

1. INTRODUCTION:[1]

Cefixime (CFX) is chemically 8-[[2-(2-Amino-1, 3-thiazol-4-yl)-2- (carboxy-methoxy-imino) acetyl] amino]-4-ethenyl-7-oxo-2-thia-6-azabicyclo [4.2.0] oct-4-ene-5-carboxylic acid. It is an oral third generation cephalosporin antibiotic which used to treat a number of bacterial infections[1]. Cloxacillin(CLOXA) is chemically (2S,5R,6R)-6-[3-(2-chlorophenyl)5-methyl-1,2-oxazole-4-4-thia-1-azabicyclo[3.2.0]heptanes-2-carboxylic acid which act like β-lactamase resistant penicillin antibiotic with antibacterial activity[2, 3]. The structures are presented in Fig. 1. Few methods have been reported for quantitative determination of drugs CFX and CLOXA in single or combination such as UV and RP-HPLC and HPTLC [4-18].

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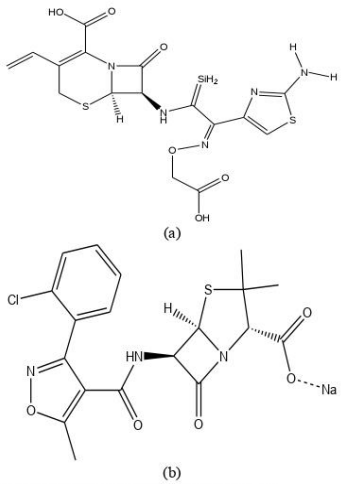

(a)

(b)

Fig. 1: Structure of a) Cefixime and b) Cloxacillin

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27. Potential of RP-HPLC-DAD-MS for the Qualitative and Quantitative Analysis of Dapagliflozin in Tablets and Degradants

POTENTIAL OF RP-HPLC-DAD-MS FOR THE QUALITATIVE AND QUANTITATIVE ANALYSIS OF DAPAGLIFLOZIN IN TABLETS AND DEGRADANTS

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(Received 07 July 2018) (Accepted 01 August 2018)

ABSTRACT

Dapagliflozin is a new drug of the gliflozin class which inhibits subtype 2 of the sodium-glucose transport proteins (SGLT2). It is a recent drug in the market and the generic market may soon get flooded with it. Therefore, newer methods are required to control dapagliflozin in pharmaceuticals. In the present study, a new method based on RPHPLC coupled to DAD and MS was developed to validate the analysis of dapagliflozin in tablet dosage form. A wavelength of 222 nm was selected to perform a cost-effective quantification and the method showed adequate linearity, with an R^2 value of 0.9998, and acceptable values of accuracy (75%–102%) and precision (residual standard deviation < 5%). The detection and quantification limits were 1.16 µg/mL and 0.53 µg/mL, respectively. Furthermore, the use of high-resolution MS enabled us to ensure the specificity, check impurities and better sensitivity. Therefore, this methodology promises to be suitable not only for the routine analysis of dapagliflozin in pharmaceutical dosage forms, but also for potential degradants.

Keywords: Dapagliflozin, Mass spectrometry, RP-HPLC, Tablets, Diode-Array-Detection (DAD)

INTRODUCTION

Dapagliflozin is a drug of the gliflozin class and it can be used to treat type 2 diabetes[1-4]. Dapagliflozin inhibits subtype 2 of the sodium-glucose transport proteins (SGLT2) which are responsible for at least 90% of the glucose reabsorption in the kidney. Blocking this transporter mechanism causes blood glucose to be eliminated through the urine[5-7]. Dapagliflozin is chemically (2*S*, 3*R*, 4*R*, 5*S*, 6*R*)-2-[4-chloro-3-[(4- ethoxyphenyl) methyl] phenyl)-6-(hydroxymethyl) oxane-3, 4, 5-triol. The molecular formula is $C_{21}H_{25}ClO_6$. The molecular weight is 408.873 g/mol. The structure of dapagliflozin was shown in Fig. 1. Dapagliflozin[8] is soluble in organic solvents such as ethanol, DMSO, and dimethyl formamide, which should be purged with an inert gas. It is also soluble in methanol and dichloromethane. The objective of the research work was to develop and validate a simple and accurate reverse phase chromatographic method to estimate amount of drug in dosage form. The developed method can be applied successfully to estimate the amount of dapagliflozin in tablet dosage form. Liquid chromatography (LC) coupled to UV detection has been applied to determine dapagliflozin in pharmaceutical

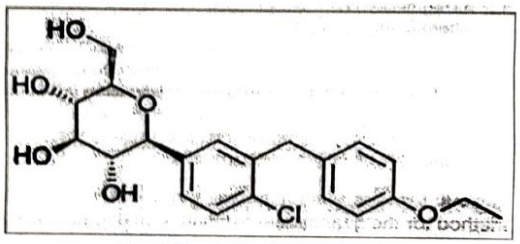

Fig. 1 Structure of Dapagliflozin

preparations[9-11]. In these studies, reversed phase (RP) liquid chromatography using silica-based C_{18} columns is the most common mode. HPLC methods are reported for apagliflozin in its combined dosage form[12-13].

No pharmaceutical approaches are addressed to identify impurities and degradation products in dapagliflozin.

Therefore, in the present study, a fast and simple RP- HPLC-DAD methodology for the determination of dapagliflozin in tablets was developed and validated. This study was also supported by the use of MS to perform the qualitative analysis of this compound in both positive and negative ionization modes, ensure the specificity and

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28. RP-HPLC Method for Simultaneous Estimation of Nitazoxanide and Ofloxacin from Bulk and Tablet Dosage Form

ORIGINAL RESEARCH

RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF NITAZOXANIDE AND OFLOXACIN FROM BULK AND TABLET DOSAGE FORM.

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ABSTRACT:
A simple reverse phase liquid chromatographic method has been developed and subsequently validated for simultaneous determination of Nitazoxanide and Ofloxacin in tablet dosage form. The separation was carried out using a mobile phase containing acetonitrile, methanol and 0.4 M citric acid, (60:30:10, v/v/v). The column used was Thermo C_{18} (4.6mm*250 mm, 5 µ) with flow rate of 1 mL / min using UV detection at 300 nm. The retention time of Nitazoxanide and ofloxacin was 3.071 min and 12.47 min, respectively. The described method was linear over a concentration range of 5-30 µg/mL (r^2>0.999) for Nitazoxanide and 2-12 µg/mL (r^2>0.998) for Ofloxacin. The mean % recovery was found to be 99.96 % for Nitazoxanide and 101.05 % for Ofloxacin. The limit of detection (LOD) for Nitazoxanide and Ofloxacin were found to be 0.3788 and 0.0929 µg/mL, respectively. Whereas the limit of quantification (LOQ) for Nitazoxanide and Ofloxacin was 1.1479 µg/mL and 0.2816 µg/mL, respectively. The results of the study showed that the proposed RP-HPLC method is simple, rapid, precise, accurate and cost effective which is useful for the routine determination of Nitazoxanide and Ofloxacin bulk drug and in its tablet dosage form.

KEYWORDS: Nitazoxanide; Ofloxacin; RP-HPLC; Method Validation.

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29. Neuroprotective effect of Sesbania Sesban on Scopolamine induced amnesia in wistar rats: Behavioral and biochemical study

Research Article

Neuroprotective effect of *Sesbania sesban* on Scopolamine induced amnesia in wistar rats: Behavioral and biochemical study

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Abstract

Objective: The present work was carried out to evaluate the effects of hydroalcoholic extract of *Sesbania sesban* (HAESS) on cognitive impaired rats. **Materials and methods:** In wistar rat's amnesia was induced by subcutaneous administration of scopolamine butyl bromide (1mg/kg). Nootropic activity evaluated in terms of Spatial memory using T maze spontaneous alternation task. **Results and conclusion:** HAESS (400mg/kg) have shown significant level improvement in scopolamine-induced deficit with respect to recognition in spatial memory. The observed results suggest that hydroalcoholic extract of aerial parts of *Sesbania sesban* improves cognitive performance with respect to spatial memory processes.

Keywords: Acetylcholinesterase, antioxidant, amnesia, T-maze, Scopolamine

Introduction

Alzheimer's disease (AD) is a progressive neurodegenerative disorder with loss of memory as one of the earliest symptoms. The pathological causes of this disease are numerous senile plaques composed of beta-amyloid (Ab) peptide, aberrant oxidative and inflammatory processes, neurotransmitter disturbances and cell loss in the affected brain regions, particularly in the areas that are important for learning and memory including the hippocampus and the prefrontal cortex (Villemagne and Burnham, 2013). Impairment of cholinergic neuronal system is consistently associated with memory loss and severity of Alzheimer's disease. It has been shown that selective and excessive loss of cholinergic neurons, deprived acetylcholine (Ach) levels, reduced numbers of cholinergic receptors in the brain cause the blockade of central Ach muscarinic receptors leads to disruption of learning and memory function in rodents, nonhuman primates and humans (Ishola et al., 2013). Scopolamine, A muscarinic receptorantagonist, interferes with a cholinergic neuronal system which ultimately affects the process of memory and learning functioning. Increased availability of ACh released into the neuronal synaptic cleft has been used as a means of enhancing cholinergic function in an AD. This prolongation may be achieved by preventing or decreasing ACh hydrolysis by acetylcholinesterase inhibition (AChE). AChE inhibitors, including Piracetam, Tacrine, Memantine, and Galantamine, are well-accepted pharmacological therapies for an AD, But, these drugs have some limitations, such as short half-lives and severe side effects (e.g. Bradycardia, convulsions hepatotoxicityare most frequent and important side effect of these medications). Recent studies evaluated that AD is associated with inflammatory processes. Reactive oxygen species (ROS) are capable to damage cellular components and acts as a secondary messenger in process of inflammation. Use antioxidants may be useful in the treatment of Alzheimer's disease (AD).

Sesbania sesban (L.) Merr. commonly known as Jayanti, Jait, Shewari belongs to the family Fabaceae. It is a short-lived shrub or small tree up to 8 m tall, commonly grown as a shade plant for young seedlings grown during the hot season and as a windbreak for sugarcane. The plant belongs to the genus Sesbania and is common throughout Africa and in Asian countries(Gomase et al., 2012).

In present investigation our aim was to assess theNeuroprotective activity of HAESS in Scopolamine induced Amnesia in Rats Using T-maze alternation score task and Biochemical Oxidative Parameters (Andriambeloson et al., 2014).

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30. Effect of Dalbergia Sissoo on lipid profile and oxidative stress in ovariectomized rats

Research Article

Effect of *Dalbergia sissoo* on lipid profile and oxidative stress in ovariectomized rats

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Abstract

Objective: In this study, we tested the effect of hydroalcoholic extract of *Dalbergia sissoo* on oxidative stress, lipid profile in 90 days postsurgical bilateral ovariectomized female rats. **Material and Methods:** 3-month old female Wistar rats were used and distributed in 6 groups: intact groups with 90 days, ovariectomized groups with 90 days, ovariectomized (Ovx) treated hydroalcoholic extract of *Dalbergia sissoo* (200, 350 and 500mg/kg p.o.), ovariectomized treated with standard β Estradiol (0.1mg/kg/s.c). All the treatments were given for further 90 days after post-surgical period (90 days) in ovariectomized female rats. After 90 days of treatments serum estrogen level, level of thiobarbituric acid reactive substances and lipid profile were quantified. **Results:** The treatment of the hydroalcoholic extract of *Dalbergia sissoo* (200, 350 and 500mg/kg) in the Ovx rats shows significant increase in the serum estrogen level, normalization of lipid profile, decreased in the thiobarbituric acid reactive substances. All the results of *Dalbergia sissoo* are comparable with standard β Estradiol. **Conclusion:** Our results suggest that 90 days of treatment with hydroalcoholic extract of *Dalbergia sissoo* is able to increase the estrogen level thereby normalized the lipid profile and oxidative stress in ovariectomized rats.

Keywords: *Dalbergia sissoo*, ovariectomized, estrogen, lipid profile, oxidative stress

Introduction

Ovarian hormone decline after menopause is linked to many pathophysiological reactions. Dyslipidaemia is often seen in postmenopausal women and is characterized by an overall shift toward a more atherogenic lipid profile (Juliana et al., 2011; Rachon et al., 2008). Its incidence increases after menopause due to decreased oestrogen level, since oestrogens are involved in cholesterol metabolism by lowering LDL and increasing HDL concentrations in plasma (Juliana et al., 2011; El-Swefy et al., 2002). It is well known that oestrogens, acting as free radical scavengers, break the free radical chain formation produced from membrane oxidation processes and hence inhibit lipid and protein oxidation (Juliana et al., 2011; Akçay et al., 2000). Estrogens have antioxidant properties and can inhibit lipid peroxidation in vitro (Saeedeh et al., 2013; Arteaga et al., 2003). After menopause, the incidence of cardiovascular disease increases (Saeedeh et al., 2013; Castelao et al., 2008). As antioxidants, isoflavones exert protective effects against cardiovascular disease by decreasing plasma concentrations of thiobarbituric acid reactive substances, which are biomarkers of lipid oxidation, and by increasing the resistance of LDL (Saeedeh et al., 2013; Young et al., 2007; Tsai et al., 1999; Wiseman et al., 2000; Omani et al., 2005). Recently, several animal studies demonstrated that a combined treatment of exercise and an Isoflavone-supplemented diet is more effective against bone loss and fat gain than either treatment alone in estrogen-deficient animals (Wu et al., 2003; Wu et al., 2001; Wu et al., 2004).

Recently, certain plant-derived natural products, mostly phytoestrogens (Isoflavone, lignans, coumestanes, stilbenes, flavonoids) and many more novel estrogen-like compounds in plants has been reported. Although, a number of papers are published on effect of natural products on menopause related osteoporosis, but there is paucity of literature on the accompanying direct effect on other parameters such as lipid profile and oxidative stress in ovariectomized animals with estrogen deficit (Abdullah et al., 2015).

Comprehensive investigation of *Dalbergia sissoo* reported to contain estrogenic flavonoids and some sterols with estrogenic activity. The reported results of phytochemical

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31. Self-nanoemulsifying Drug Delivery System of Mebendazole for Treatment of Lymphatic Filariasis

Research Paper

Self-nanoemulsifying Drug Delivery System of Mebendazole for Treatment of Lymphatic Filariasis

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Lipid-based self-nanoemulsifying drug delivery system was explored to improve the oral bioavailability and target specificity of mebendazole for treatment of lymphatic worm infestations. Ternary phase diagrams were constructed to select suitable oil-surfactant mixture. Liquid self-nanoemulsifying drug delivery system consisting of Capmul MCM L8, Chromophore RH40 and tocopherol polyethylene glycol succinates a pre-concentrate was systematically optimized using 32 full factorial designs. β-cyclodextrin-based nanosponges were used to prepare solid self-nanoemulsifying drug delivery system. Characterization of liquid self-nanoemulsifying drug delivery system was carried out using percent transmission, globule size, zeta potential, polydispersity index and drug content. Globule size in the range of 50-90 nm and zeta potential of –5 to –12 mV was obtained, which co-related well with percent transmission. Powder X-ray diffraction, differential scanning calorimetry and scanning electron microscope of solid self-nanoemulsifying drug delivery system indicated the presence of mebendazole as a molecular dispersion. *Ex vivo* studies showed nearly five-fold increase in the flux. *In vivo* studies showed two-fold increase in bioavailability. Significant enhancement in drug dissolution and saturation solubility from solid self-nanoemulsifying drug delivery system resulted in an increase in the bioavailability. Besides this, greater surface area, improved release, P-gp modulation potential of excipients and lymphatic bypass via Peyer's patches protected drug from hepatic first pass metabolism all of which would contribute to the observed improved bioavailability. Lymphatic transport of drug could achieve target specificity in lymphatic filariasis.

Key words: Mebendazole, Capmul MCM L8, TPGS, Cremophor RH40, β-CD nanosponge

More than 127 million people are infested by lymphatic filariasis, a mosquito-borne disease and about 1.2 billion people are at risk of the disease in 70 countries. It is most common in Africa and Asia. Lymphatic filariasis is caused by parasites, *Wuchereria bancrofti*, *Brugia malayi* and *Bruga timori*. These infest the lymph channels and disrupt the flow of the lymph leading to lymph oedema[1]. The chronic phase is marked by lymph varices (dilation of vessels), lymph scrotum, hydrocele, chyluria and elephantiasis[2]. Another form of systemic infestation is caused by the larva form of *Necator americanus*, which penetrates human skin and travels through the blood vessels to reach the pulmonary alveoli and travels up the trachea. Once it enters in lymph nodes, the larvae starts entering the blood, lungs and intestines. The therapy for these and other similar conditions comprises benzimidazoles, specifically albendazole and pyrantel pamoate[3].

Self-nanoemulsifying drug delivery system (SNEDDS) is a novel drug delivery system with numerous advantages including ease of production, improvement of drug solubility and oral bioavailability. SNEDDS are preconcentrates composed of isotropic mixtures of oils, surfactants and co-surfactants, which spontaneously form fine oil in water (o/w) emulsion *in situ* upon contact through aqueous medium with a globule size in the range of 20-200 nm[4]. Various other potential features of SNEDDS in improving oral bioavailability of lipophilic drugs consists of simplifying transcellular and paracellular absorption, decreasing cytochrome-P450 metabolism in the gut enterocytes, stimulating lymphatic transport via Peyer's patches and protecting drug from hepatic first pass metabolism[5]. The major drawbacks of liquid-

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32. Liposomal drug Delivery for stability and Bioavailability Enhancement of Efavirenz

Research Paper

Liposomal Drug Delivery for Solubility and Bioavailability Enhancement of Efavirenz

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To overcome the limited solubility and low bioavailability of efavirenz a liposomal drug delivery system was formulated using thin film hydration technique. Optimal ratios of total lipid blend:drug, soya lecithin:cholesterol and polyethylene glycol 400 concentration were determined using Box-Behnken design with vesicle size and entrapment efficiency as responses. The optimized liposomal dispersions were characterized by vesicle size, entrapment efficiency, transmission electron microscopy, *in vitro* drug release and *in vivo* pharmacokinetics. The vesicle size was found to be in range of 694.5-1200.0 nm and entrapment efficiency was above 80 %. Statistical studies revealed that vesicle size and entrapment efficiency increased with increase in total lipid blend:drug and polyethylene glycol 400 concentration. Transmission electron microscopy showed that unilamellar and multi-lamellar vesicles were formed. Optimized liposomal dispersion was solidified using nanosponges. Solid liposomes were characterized by micromeritics, differential scanning calorimetry, Fourier-transform infrared spectroscopy and bioavailability. As compared to plain drug a 10-fold increase in percent release was observed in 6 h in liposomal preparation. *In vivo* pharmacokinetic studies revealed that bioavailability increases 2 folds as compared to plain drug. Lipid-based drug delivery like liposomes are taken up through lymphatic pathway. Since the human immunodeficiency virus settles in lymphoid organs, lymphatic drug delivery can be advantageous in the treatment of acquired immune deficiency syndrome. Thus, the pharmacokinetic studies demonstrated that efavirenz-loaded liposomes could significantly upgrade the solubility and oral bioavailability of efavirenz and improve the therapeutic efficacy.

Key words: Bioavailability, solubility, liposome, nanosponges, efavirenz

Solubility, dissolution and gastrointestinal permeability are fundamental parameters that control rate and extent of drug absorption and its bioavailability. Therefore, development of novel drug delivery systems are essential as a large number of new chemical drug entities have poor solubility or permeability. Solubility and bioavailability significantly influence attainment of desired concentration of drug in systemic circulation for generating a pharmacological action[1].

The human immunodeficiency virus (HIV) causes one of the deadliest diseases of modern times, acquired immune deficiency syndrome (AIDS) affecting around 40 million people globally. HIV is a retrovirus of the lentivirus family, which fundamentally destroys CD_4^+ T cells a key segment of the immune system. Since 1996, the highly active antiretroviral treatment (HAART) has saved about 2.9 million lives[2]. Three main classes of antiretroviral (ART) drugs i.e. non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors, HIV integrase inhibitors are proposed in HAART regimens These include nevirapine, efavirenz (EFA), etravirine, rilpivirine, saquinavir, indinavir, ritonavir, raltegravir, elvitegravir, and dolutegravir.

Various drug delivery systems are used to deliver the HIV drugs in a controlled and targeted manner thereby increasing the drug bioavailability and residence time at target sites with a significant improvement in quality of life of HIV patients. These drugs are cost effective with less dose dumping problems. However, the ARTs have low oral bioavailability and cytochrome P450 (CYP)-mediated metabolism[3]. The methodologies, which are used to overcome these drawbacks include chemical

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