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**3.1.2 Additional Information**

**Research Publications by utilizing seed money**



## A Validated high Performance Liquid Chromatographic Method for the Quantification of Favipiravir by PDA Detector

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**Abstract:** Favipiravir is an antiviral agent showing activity for the treatment of various life threatening viruses such as Ebola virus, Lassa virus and also recent virus for COVID-19. It is a pyrazine carboxamide derivative with activity against RNA viruses which targets RNA-dependent RNA polymerase enzymes which are necessary for the transcription and replication of viral genomes. The lack of research work and no compendial methods available for the estimation of this drug influenced the current research investigation to give a simple, sensitive, rapid, precise, accurate and robust isocratic high performance liquid chromatographic and UV Spectroscopic method for the determination and quantification of Favipiravir. The elution was done by using SHIMADZU Prominence-i, LC-2030 C system equipped with Shim-Pack GIST C18 (250X 4.6 mm, 5µm) column with a mobile phase mixture of 10 mM potassium dihydrogen ortho phosphate buffer (pH 4.0) and acetonitrile in the ratio of 90:10 v/v at a flow rate of 1.0 ml/min. The ultraviolet detection was done at the wavelength of 315 nm by maintaining column temperature at 30°. The total run time was 8.0 min. Calibration plot showed best regression over the concentration range of 10-60 µg/ml of Favipiravir standard solutions. The LOD and LOQ was found to be 0.18 µg/ml and 0.53 µg/ml, respectively. The accuracy of the proposed method was determined by performing recovery studies and was found to be between 99.47-100.80%. The repeatability testing for both sample and standard solutions was found as %RSD<2.0% which is within the acceptable limits showing that the method is precise as well. The proposed method was successfully applied for the marketed formulations of Favipiravir tablets. In addition the main features of the proposed method are economic and eco-friendly with less retention time around 4.622 min.

**Keywords:** Favipiravir, Antiviral, HPLC, UV, method development, Validation

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*Principal*  
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## **Anti- Parkinsonian Drug Estimation by RP-HPLC**

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### **Authors' contributions**

*This work was carried out in collaboration between both authors. Author RRN designed the study, wrote the protocol and managed the analyses of the study. Author PA made the literature searches and performed the statistical analysis. Both authors read and approved the final manuscript.*

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**Original Research Article**

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### **ABSTRACT**

**Aim:** The main aim of the current study is to give best and simple method for the estimation of antiparkinsonian drugs named Carbidopa, levodopa and entacapone.

**Study Design:** Simultaneous estimation of Carbidopa, levodopa and entacapone was performed by using Quadrapumped (SHIMADZU Prominace-i, LC-2030C) RP-HPLC equipped with PDA detector.

**Place and Duration of Study:** Chalapathi Drug Testing Laboratory, Chalapathi Institute Of Pharmaceutical Sciences, Lam, Guntur-522034, Andhra Pradesh, India during the period of August 2019 to February 2020.

**Methodology:** The assets of the study can determined as the process of qualification and quantification was done on SHIMADZU Prominace-i, LC-2030C system equipped with Phenomenex ODS (150 x 4.6 mm, 5µm) column and mobile phase was optimized using combination of acetonitrile and 0.1% ortho phosphoric acid in the ration of 50:50 v/v at a flow rate 1.0 ml/min. The wavelength was set as 270nm at ambient temperature by injecting 20µl of solution and the run time was fixed for 5 min.

**Results:** Calibration plot shown best regression over the concentration range of 5-160 µg/ml of Carbidopa, Levodopa and Entacapone standard solutions. The LOD and LOQ were found to be 0.85 and 2.54 µg/ml for Entacapone, 0.24 and 0.71 µg/ml for Levodopa, 0.14 and 0.43 µg/ml for Carbidopa respectively. The accuracy of the proposed method was determined by performing recovery studies and was found to be between 98-102%. The repeatability testing for both sample

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2016

## Assessment of Efficacy and Safety of Newly Formulated Natural Sun Protective Cream

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**Abstract:** This research aims to formulate and evaluate the photo protective activity of an cream containing oil in water emulsion with different natural oils in varying proportions. The formulation is evaluated for its physical, chemical, microbiological and organoleptic properties for 28 days. The formulation was stable, white preparation with no recognisable irritancy when tested. SPF was determined to be 59.7 that can give both UV A and UV B protection. Aerobic microbial count was within the limit and there was no presence of Pseudomonas and yeast cells in the formulation. The newly formulated sunscreen cream was proved to exhibit a number of promising properties and attributes that might open new opportunities for the development of more efficient, safe, and cost-effective skin-care products.

**Keywords:** Ultraviolet light; sunprotection; sunscreen; SPF; UV A and B protection.

### I. Introduction

The skin is the body's first line of defense for external exposure. The signs of ageing skin are most visible in the skin. Although, ageing skin is not a threat of a person, it can have a detrimental effect on the psychology of a person<sup>[1]</sup>. Every year, about one million people are diagnosed with skin cancer and about 10,000 die from malignant melanoma<sup>[2]</sup>. Most skin cancer occurs on the areas of the body that are most frequently exposed to the sun, such as the face, neck, head and back of the hands<sup>[3]</sup>.

The harmful effects of solar radiation are caused predominantly by the ultraviolet (UV) region of the electromagnetic spectrum, which can be divided into UV A (400 to 320 nm), UV B (320 to 290 nm) and UV C (290 to 200 nm)<sup>[4]</sup>. UV C radiation is filtered out by the atmosphere before reaching earth. UV B radiation is not completely filtered out by the ozone layer and is responsible for the damage due to sunburn and pyrimidine dimers<sup>[5]</sup>. UVA radiation reaches the deeper layers of the epidermis and dermis and provokes the premature ageing of the skin and is responsible for the generation of free radicals. UV B radiation is involved in 65% damage of all skin<sup>[6]</sup>. Exposure to ultraviolet radiation has pronounced acute and chronic effects on the skin. People are conscious of the possible dangers of photo ageing, sunburn and skin cancer, occurring as a result of sun overexposure<sup>[7]</sup>.

To prevent these harmful sun effects, body creams and lotions with added sunprotectants that scatters or reflects radiation were prepared<sup>[8]</sup>. Most of the sunscreens are applied topically on skin surface which leads to penetration of the ingredients into deeper layers of skin which leads to toxic effects many of which are not desirable<sup>[9,10]</sup>. Hence this work aims at developing sunprotecting cream by using naturally available sunprotectants which will cause no irritation and also gives nourishment to the skin.

### II. Materials And Methods

#### Chemicals required

The cream is formulated using olive oil, almond oil, carrot seed oil, avocado oil, beeswax, vitamin-E, lemon grass oil, glycerin and distilled water. All the chemicals are high grade purchased from Merk and HighMedia and compatible with skin.

#### Preparation

The cream was prepared by using the procedure mentioned in the literature with slight modification<sup>[11,12,13]</sup>. Five different formulations were prepared and tested for SPF. The formulation with good stability was reported in this paper. Cream base was prepared using measured quantity of oil components and adding them into aqueous components. The oil components contain emulsifier (cetostearyl alcohol and sodium lauryl sulphate in 9:1 proportions). The composition of oil and aqueous phase are mentioned in table 1. Both aqueous and oil phases were heated in a water bath maintained at 80°C for aqueous phase and 70°C for oil phase and stirred the components regularly to distribute the heat. Both the phases are mixed together by pouring the oil phase into the aqueous phase with vigorous stirring for 1-2 minutes to allow the formation of emulsion. The





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## Research Article

# Pharmacological evaluation of ellagic acid for the treatment of common dermatological disorders in Wistar rats

0-73

J. Naga Lakshmi\*, T. Vandana, K. Sahithi, A. Narendra Babu

### ABSTRACT

**Aim:** The objective of the study is mainly to perform pharmacological evaluation of ellagic acid for the treatment of common dermatological disorders in Wistar rats. **Materials and Methods:** (a) For psoriasis control group, rats were treated with the vehicle (water) alone. For disease control group, psoriasis was induced to the rats, did not receive any treatment. For standard group, psoriasis was induced to the rats and treated with salicylic acid at the dose level of 0.1% by applying on to the upper surface of the tail. For the first test group, psoriasis was induced to the rats and treatment was performed once daily by the topical administration for 16 days 0.5% of the ellagic acid. For the second test group, psoriasis was induced to the rats and treatment was performed once daily by the topical administration for 16 days 1.0% of the ellagic acid. (b) For dermatitis control group, dermatitis was induced to the rats, did not receive any treatment. For low-dose test group, dermatitis was induced to the rats and treatment was performed once daily by oral administration 25 mg/day ellagic acid. For high-dose test group, dermatitis was induced to the rats and treatment was performed once daily by oral administration 50 mg/day ellagic acid. **Results:** Psoriasis was induced by repeated application of ultraviolet (UV)-light on rat tail, and ellagic acid of concentrations 0.5% and 1% had shown same effects in reducing tail thickness as that of the standard drug salicylic acid had shown. Dermatitis was also induced by UV-light ellagic acid of concentrations 0.5% and 1% had shown more effect in reducing tail weight and epidermal thickness when compared to the standard drug salicylic acid. **Conclusion:** Histopathological study of ellagic acid does not showed significant effect when compared with standard drug for treating psoriasis, but ellagic acid was proved to be effective for treating dermatitis.

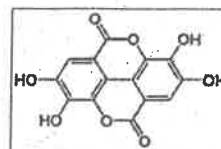
**KEY WORDS:** Dermatitis, Ellagic acid, Epidermal thickness, Psoriasis, Salicylic acid, Tail weight

## INTRODUCTION

The term tannin refers to the use of tannins in tanning animal hides into leather; however, the term is widely applied to any large polyphenolic compound containing sufficient hydroxyls and other suitable groups (such as carboxyls) to form strong complexes with proteins and other macromolecules.<sup>[1,2]</sup> Tannins are secondary metabolites of plants, nonnitrogenous, and phenolic in nature. They have a property to precipitate gelatin and heavy metals. Tannins are astringent, bitter plant polyphenols that either bind and precipitate or shrink proteins. The astringency from the tannins is that which causes the dry and puckery feeling in the mouth following the consumption of red wine, strong tea, or an unripened fruit. Tannins are

found as shapeless yellowish or light brown masses such as powder, flakes, or sponge.<sup>[3,4]</sup>

Ellagic acid is a polyphenol, found in certain fruits and nuts including grapes, strawberries, raspberries, pomegranate, *Morinda citrifolia*, *Terminalia chebula*, and walnut. This phenol is one of the most promising chemopreventive agents.<sup>[5,6]</sup> Medical findings in Europe shows that ellagic acid may reduce the incidence of birth defects promote wound healing, reduce chemically induced liver fibrosis and may help in the fight against heart disease. It also has antibacterial, antiviral, and antioxidant properties.<sup>[7,8]</sup>



Psoriasis is a chronic inflammatory disease affecting the skin, nails, and joint. Between 0.6% and 4.8% of

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## A SURVEY ON RISK ASSESSMENT AMONG DIABETIC POPULATIONS IN GUNTUR REGION OF ANDHRA PRADESH

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### ARTICLE INFO

### ABSTRACT

#### Key Words

Diabetes mellitus,  
Retrospective study,  
Diabetic education,  
Obesity



Diabetes mellitus (DM) has evolved as a major public health concern worldwide, as its prevalence is increasing exponentially. Therefore, finding an effective way to identify individuals at risk of developing diabetes is necessary. The objective of this study is to review the problems and risk limitations facing by the existing diabetic population to assess the need for further development in their drug therapy and life style. Obesity and diabetes are major causes of morbidity and mortality as evidences from several studies indicates that these obesity and weight gain are associated with an increased risk of diabetes. There is however considerable new knowledge regarding the etiology of different forms of diabetes as well as more information on different blood glucose values for the complications of diabetes. Along with these, many other factors like age, sex, life style, physical exercise, family history, diabetic education, drug therapy and follow up etc., plays a major role in the risks and other limitations in diabetic patients. Predictions, risk assessment and risk profiling are among the various decision support techniques that this survey increasingly rely on to provide early diagnose in patients with elevated risks and to slow down the rapid increase in prevalence of chronic diseases.

### INTRODUCTION:

The recent studies estimates by the International Diabetes Federation (IDF) showed that the number of adults affected by the disease in 2011 was 366 million which was projected to increase to 552 million by 2030. Nearly 80% of the affected people live in middle- and low-income countries. Type 2 diabetes mellitus, which constitutes more than 95% of all the diabetic populations, has an insidious onset with a long, latent, asymptomatic phase. Among the top 10

Countries/territories with the largest number of diabetic adults, five are in Asia. China tops the list with 90.0 million followed by India which has 61.3 million persons affected by diabetes. The numbers are estimated to rise to 129.7 million and 101.2 million, respectively by 2030. Predictions, risk assessment and risk profiling are among the various decision support techniques that this survey increasingly rely on to provide early diagnose in patients with elevated risks and to slow down the rapid increase in prevalence of chronic diseases.







Research article

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## Phytochemical studies and anti-ulcer activity of *Limonia acidissima* linn. leaf in treating ethanol induced ulcer Albino rats

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### ABSTRACT

#### Keywords:

*Limonia acidissima*,  
Ethanol, Gastric ulcer,  
Ranitidine

#### Article Info:

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The preliminary phytochemical analysis of *Limonia acidissima* plant leaf, showed the presence of alkaloids, flavonoids, steroids, saponins, glycosides, phenols, gum and mucilage, fixed oils and fats, resins and tannins. The objective of the present investigation is to elucidate the anti-ulcer activity of ethanolic leaf extract of *Limonia acidissima* in ethanol induced GIT damage in albino rats. The lyophilized extract was given by oral gavages (200mg/kg and 400mg/kg) before administering ethanol at 1ml/kg. Pre-treatment with extract significantly decreased the ulcerated area. The volume and acidity of the gastric juice decreased in the pre-treated rats. In conclusion, *L. acidissima* was able to decrease the acidity and increase the mucosal defense in the gastric areas, there by justifying its use as an anti-ulcerogenic agent.

### 1. INTRODUCTION

Ulcer is a common disorder of the gastrointestinal system, which causes much discomfort in patients, disrupting their daily routines and causes mental agony. Peptic ulcer disease can be characterized by inflamed lesions or excavations of the mucosa and tissue that protect the gastrointestinal tract. A peptic ulcer is a sore in the lining of stomach or duodenum, the first part of small intestine. If peptic ulcers are found in the stomach, they are called gastric ulcers. If they are found in the duodenum, they are called duodenum ulcers. Gastric ulcers are also associated with considerable morbidity related to chronic epigastric pain, nausea, vomiting, and anemia. Rarely, an ulcer can lead to a gastric or duodenal perforation. This is extremely painful and requires immediate surgery. Recently, *Helicobacter pylori* have been implicated in the antral gastritis, peptic ulcer, gastric malignancy and the non-ulcer dyspepsia. With the increasing use of non-steroidal anti-inflammatory drugs and alcohol consumption.

Ethanol induced gastric ulceration (EIGU) in rats is considered to be a reliable tool to study the pathogenesis of acute gastric mucosal ulceration. The gastric sub-mucosal micro vascular disturbance

resulting in local ischemia is an important early reaction following the use of ethanol. The endogenous mediators for the early vascular damage of the gastric mucosa include: nitric oxide, leukotrienes, histamine, adenosine, TNF $\alpha$  and endothelins. The release of endothelins plays a role not only in the pathogenesis of EIGU but also in the process of ulcer healing.

*Limonia acidissima* is one of the medicinally important plants belonging to Rutaceae, commonly known as wood apple. *Limonia*, confined to India, Pakistan, Sri Lanka and Southeast Asia. It is also known as wood apple, elephant-apple, monkey fruit, curd fruit, kathbel and kaitha. This plant is given as a medicine for the treatment of various disorders. *L. acidissima* is a deciduous, slow-growing, erect tree with a few upward-reaching branches bending outwards near the summit where they are subdivided into slender branchlets drooping at the tips.

**Chemical Constituents:** Major chemical constituents present in the ethanolic extract of leaves of *L. acidissima* are Acidissimin and Acidissiminol. Various parts of wood apple have been used against various ailments in ethnomedicine. Juice of young leaves is mixed with milk and sugar candy given as remedy for biliousness and intensive troubles of children.



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## Analytical Method Development and Validation of Gemcitabine in Tablets by HPLC by Different Analytical Techniques

Syed. Afrin, P. Prachet, Shaik.Munwar, Rama Rao. Nadendla

Department of Pharmaceutical Analysis, Chalapathi institute of Pharmaceutical Sciences, Chalapathi nagar, Lam, Guntur-522034, Guntur district, Andhra Pradesh, India

**Abstract:** An isocratic reverse phase liquid chromatography (RP-HPLC) method has been developed and subsequently validate for the determination of Gemcitabine in pharmaceutical formulation. In this method, Agilent TC C18 (250\*4.6mm ; ) particle size 5µm column with mobile phase consisting of Acetonitrile and water in ratio of 50:50 v/v was used. The detection wavelength is 270nm and the flow rate 1.0mL/ min. The linearity was found in the range of 80µg/ml and shows a correlation coefficient of 0.9992. The method precision for the determination of assay was below 2.0% RSD. The developed method was validating by determining specificity, accuracy, precision and linearity. The developed method is simple, fast, accurate and precise hence can be applied for the routine quality control analysis of Gemcitabine in pure and pharmaceutical formulation.

**Key words:** HPLC, Gemcitabine, Agilent TC C18, correlation coefficient and Acetonitrile.

Date of Submission: 08-01-2020

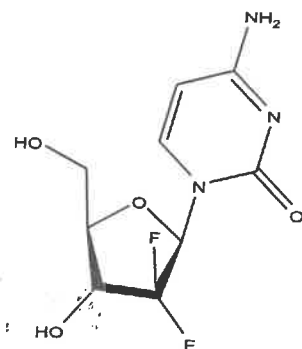
Date of Acceptance: 23-01-2020

### I. Introduction:

Gemcitabine is deoxy cytidine analogue having (antineoplastic or cytotoxic) activity. It is broad spectrum Antimetabolite used in treatment of various forms of cancer such as pancreatic adenocarcinoma, ovarian, cancer small cell lung. Cancer, bladder cancer. It acts by inhibition of thymidilate kinase and DNA synthesis. It is a prodrug and converted to its active metabolites. Following influx through the cell membrane via nucleoside transporters, gemcitabine undergoes complex intra cellular conversion to the nucleotides gemcitabine diphosphate (dfdCDP) and triphosphate (dfdCTP) responsible for its cytotoxic actions. The cytotoxic activity of gemcitabine may be the result of several actions on DNA synthesis. dfdCTP completes with deoxycytidine triphosphate (dCTP) is an inhibition of DNA polymerase. dfdCDP is a potent inhibition of ribonucleoside reductase resulting in depletion of deoxyribonucleoside pools necessary for DNA synthesis and by potentiating the effects of dfdCTP. DfdCTP is incorporated into DNA and the incorporation of one or more nucleotide leads to DNA stand termination. This extra nucleotide may be important in hiding the dfdCTP from DNA repair enzymes, as incorporation if dfdCTP into DNA appears to be resistant to the normal mechanisms of DNA repair. Gemcitabine HCl is soluble in water, slightly soluble in methanol, and practically insoluble in ethanol and polar organic solvents.

Structure:

GEMCITABINE



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**Chemical name:** 4-amino-1-(2-deoxy-2, 2- difluoro-β-D -erythro -pentofuranosyl) pyrimidin-2(1H)-one .  
**Molecular weight:** 269.198g/mol.





# Simultaneous Estimation of Daclatasvir and Sofosbuvir in Tablet Dosage form by Reverse Phase High-Performance Liquid Chromatography

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## Abstract

A simple, rapid reversed-phase high performance liquid chromatographic method had been developed and validated for estimation of Daclatasvir and Sofosbuvir in tablet dosage form. The estimation was carried out on Inertsil ODS-C<sub>18</sub> column (250 x 4.6 mm, 5 $\mu$ ) column with a mixture of Acetonitrile: Methanol: 0.1% Triethylamine buffer (pH-3.0) 25:35:40 (v/v/v) as mobile phase. UV detection was performed at 250 nm. The method was validated for linearity, accuracy, precision, specificity and sensitivity as per ICH norms. The developed and validated method was successfully used for the quantitative analysis of commercially available dosage form. The retention time was 2.09 and 3.50 min for Daclatasvir and Sofosbuvir respectively and total run time was 6.0min at a flow rate of 1.0 mL/ min. The calibration curve was linear over the concentration range of 5.0-25.0  $\mu$ g/ mL for Daclatasvir and 2.0-10.0  $\mu$ g/ mL for Sofosbuvir. The LOD and LOQ values were found to be 0.313 and 0.948  $\mu$ g/ mL for Daclatasvir and 0.021 and 0.065  $\mu$ g/mL for Sofosbuvir, respectively. The high percentage of recovery and low percentage coefficient of variance confirm the suitability of the method for the simultaneous estimation of Daclatasvir and Sofosbuvir in tablet dosage form.

**Keywords:** Sofosbuvir, Daclatasvir; RP- HPLC; Validation, Chromatography

## INTRODUCTION

Hepatitis C is a comprehensive liver disease produced by the hepatitis C virus (HCV) and can increase liver cirrhosis, liver failure, liver cancer and liver transplantation. The standard treatment for HCV is pegylated-interferon (Peg-IFN) and ribavirin (RBV) whoever these agents caused side effects such as bacterial infections, anemia, hematological toxicity, and neutropenia and anorectal symptoms.

Telaprevir and boceprevir were the first generation direct-acting protease inhibitors that developed and approved for the treatment of genotype I chronic hepatitis C However, they have to be co-administered with interferon and ribavirin therefore they were associated with their common side effects so their effectiveness were limited [1-2].

Second-generation direct-acting antiviral drugs were developed and aimed to have a high pangenotypic activity with fewer undesirable side effects. These drugs include daclatasvir and sofosbuvir. Both medicines have effective antiviral activity and genotypic coverage [3-5].

Daclatasvir, Methyl [(2S)-1-[(2S)-2-[4-(4'-{2-[(2S)-1-[(2S)-2-[(methoxycarbonyl) amino]-3-methylbutanoyl]-2-pyrrolidinyl]-1H-imidazol-4-yl]-4-biphenyl)-1H-imidazol-2-yl]-1-pyrrolidinyl]-3-methyl-1-oxo-2-butanyl] carbamate, is a nucleotide analogue NS5A polymerase inhibitor [6].

Sofosbuvir, (S)-Isopropyl 2-((S)-(((2R,3R,4R,5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-2-yl)-4-fluoro-3-hydroxy-4-methyltetrahydrofuran-2-yl)methoxy) (phenoxy) phosphorylamino) propanoate, is a nucleotide analogue HCV NS5B polymerase inhibitor that is used in the treatment of chronic hepatitis C genotypes 1,2,3 or 4 [21]. The sofosbuvir and daclatasvir combination is associated with a high rate of SVR4 in difficult-to-treat patients

infected with genotype 1 or 4. Combination with ribavirin increases the SVR rate in cirrhotic and treatment experienced patients with no additive effect of extension of treatment from 12 to 24 weeks. Since patient compliance is an important point in the treatment so taking the two drugs in one tablet will be a better choice. On another hand, the combined therapy is economically reduced the cost of the treatment and this will give a chance for many companies to formulate the three drugs in one tablet sooner. Additionally, the co-administered drugs might affect each other and there is no sufficient information about drug-drug interaction and thus the establishment of separation method is of great importance [31].

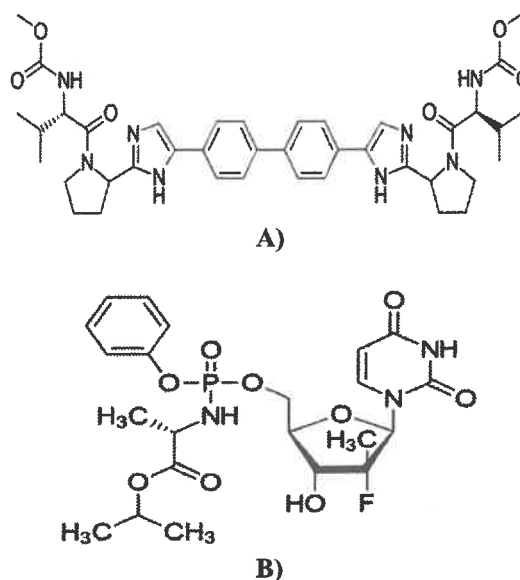


Fig.1: Chemical Structures of A) Daclatasvir B) Sofosbuvir



# Design and Development of Gastroretentive Tablets of *Coccinia grandis* leaf extract for treating *Helicobacter pylori* infection

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## Abstract

**Aim:** To design and develop a gastroretentive herbal formulation of *Coccinia grandis* for the treatment of *Helicobacter pylori* infection. **Material and Methods:** *C. grandis* extract was obtained by soxhlation process with ethanol as the menstrum. The herbal gastroretentive tablets containing 200 mg of *C. grandis* ethanolic extract were prepared by direct compression method using effervescent technique. HPMC K4M, HPMC K100M, Carbopol and guar gum were used as retarding polymers at various concentrations. Sodium bicarbonate was used at 20%w/w as gas generating agent and Avicel at 35%w/w as diluent. FTIR and DSC methods were employed to investigate the drug-excipient interactions. The formulated tablets were evaluated for various quality control parameters. **Results and Discussion:** The FTIR and DSC study revealed that there was no interaction between the extract and the excipients. All the formulated tablets were within the quality control limits. The kinetic studies specified that the release of extract from the gastroretentive tablets was by erosion-controlled diffusion mechanism. **Conclusion:** The formulation having the combination of gum with HPMC K15M exhibited minimum floating lag time and good release pattern which followed first-order kinetics.

**Key words:** *Coccinia grandis*, gastroretentive, *Helicobacter pylori*, herbal extract, resistance

## INTRODUCTION

Warren and Marshall identified *Helicobacter pylori*, a Gram-negative bacterium, which is one of the most chronic pathogens in humans.<sup>[1]</sup> The World Health Organization categorized *H. pylori* as Class 1 carcinogen.<sup>[2]</sup> About 50% of the world population are infected with *H. pylori* and occurrence is more in developing countries than in developed countries.<sup>[3]</sup> *H. pylori* infection persists throughout life as an asymptomatic condition. However, their presence in the stomach can cause chronic gastric inflammation and leads to severe gastric diseases such as peptic ulcer to tissue lymphoma. The abolition offers the most direct approach to reduce the gastric and peptic ulcer prevalence in high-risk population. The humans may have more than one strain of *H. pylori* and many strains are resistant to commonly used antibiotics. The international guidelines for treating the patients diagnosed with *H. pylori* infection are by triple therapy. It consists of proton pump inhibitor (PPI), clarithromycin, and amoxicillin for 7-14 days. The cure rate observed was less due to *H. pylori* resistance to clarithromycin. Hence,

second-line therapy was proposed, comprising a PPI with two or three antibiotics such as amoxicillin, clarithromycin, metronidazole, and tetracycline. The *H. pylori* organism exhibiting biofilm formation by that showing the drug resistance.<sup>[4,5]</sup> Hence, there is a vast need to find out new and efficient treatment techniques against *H. pylori* infection. Plants exhibit a wide range of pharmaceutical action similar to modern medicine. This is due to their secondary metabolites; they have the ability to overcome the resisting antibiotic monotherapy. Biofilms are communities of microbes attached on the surface. *H. pylori* form biofilms on the surface of gastric mucosa and showing resistance.<sup>[6]</sup> Hence, antibiofilm formers are required for eradication of *H. pylori*. The residence of *H. pylori* is in the stomach region. Hence, the formulations which showing more residence time in the stomach are suitable to eradicate the *H. pylori*.<sup>[7]</sup>

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## FORMULATION AND EVALUATION OF FLOATING GEL BEADS OF LORATADINE

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### Keywords:

Floating,  
Gel beads, Loratadine,  
Ionic gelation, Zero-order release

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**ABSTRACT:** A floating controlled drug delivery system of loratadine was formulated to enhance the retention time in the stomach and to modify the release characteristics of loratadine. Loratadine loaded floating gel beads were prepared by ionic gelation technique using different polymers such as HPMC K4M, HPMC K15M, and carbopol 934P in different proportions and sodium bicarbonate as the gas forming agent. FT-IR spectra revealed that there was no significant interaction of loratadine with the carriers and other excipients. The prepared beads were evaluated for particle size analysis, bulk density, tapped density, compressibility index, hausner's ratio, the angle of repose, swelling index, drug entrapment efficiency, % yield, % buoyancy of loratadine floating beads, *in-vitro* drug release studies, kinetic modeling of drug release and stability studies. Results of the *in-vitro* drug release study indicated sustained release of loratadine for up to 12 h. The drug release kinetics of optimized formulation F7 was best fitted with the zero order and Peppas model with  $n > 0.45$ .

**INTRODUCTION:** The oral route is increasingly being used for the delivery of therapeutic agents because the low cost of the therapy and ease of administration lead to high levels of patient compliance. More than 50% of the drug delivery systems available in the market are oral drug delivery systems<sup>1</sup>. A major drawback in oral controlled drug delivery is that not all drug candidates are absorbed uniformly throughout the GIT. Some drugs are absorbed only in a particular portion of GIT or are absorbed to a different extent in various segments of GIT.

An absorption window exists because of physiological, physicochemical or biochemical factors. Recent scientific and patent literature reveals increased interest in novel dosage forms that can be retained in the stomach for a prolonged and predictable period.

One of the most feasible approaches is to control the gastric residence time using gastro-retentive dosage forms (GRDDS) that can provide newer therapeutic options. GRDDS can improve the controlled delivery of drugs by continuously releasing the drug for a prolonged period before it reaches its absorption site, thus ensuring its optimal bioavailability<sup>2</sup>. Loratadine is an antihistamine that reduces the effects of natural chemical histamine in the body. Histamine can produce symptoms of sneezing, itching, watery eyes, and runny nose. Loratadine is absorbed in the proximal part of the

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### Formulation and Optimization of Zolmitriptan Oral Fast Dissolving Films

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**Abstract :** The present research work deals with development and optimization of oral fast dissolving films of zolmitriptan to improve bioavailability and patient compliance. It is anti-migraine drug which has oral bioavailability of 45% due to hepatic firstpass metabolism. Oral fast dissolving films of zolmitriptan were prepared by solvent casting method using HPMC E-5 as a film forming polymer, propylene glycol as a plasticizer, sodium starch glycolate as a superdisintegrant and aspartame is added as sweetener. The prepared film characterised by FTIR showed no incompatibility between drug and polymer. A 2<sup>3</sup> factorial design is employed for the optimization of formulation considering concentration of polymer, plasticizer and superdisintegrant as independent variables with drug release, disintegration time, folding endurance as dependent variables. The formulations F1-F8 are made by varying the levels of independent variables and evaluated for disintegration time, dissolution rate and folding endurance. The results are treated by DesignExpert software to optimise the oral fast dissolving film. The optimised film is analysed by X-ray diffraction shows crystalline to amorphous transformation of drug and DSC thermogram shows a broad peak further confirms the amorphous nature of drug. It was found that enhancing the polymer and plasticizer concentrations shows negative effect on disintegration time and drug release. But when the concentration of superdisintegrant was increased it had a positive effect on drug release and disintegration time. From the results obtained the optimized formulation was prepared with 4% of HPMC E5, 1.5% of propylene glycol and 4% of sodium starch glycolate showed disintegration time 10 sec, drug release 93.15% and folding endurance of 260 times.

**Key words :** Zolmitriptan, Hydroxyl Propyl Methyl Cellulose, Propylene glycol, Sodium starch glycolate, Aspartame.

#### Introduction:

Fast dissolving films are most advanced form of solid oral dosage form due to its flexibility. It improve efficacy of active pharmaceutical ingredient (API) by dissolving in the short time in oral cavity after the contact with less amount of saliva as compared to mouth dissolving tablet.<sup>[1]</sup> The oral cavity covers the cheek, lips, tongue, hard palate and soft palate. The lining of the oral cavity is referred to as the oral mucosa.<sup>[2]</sup> The delivery

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## SCREENING OF BIOACTIVE PHYTOCHEMICALS FOR THEIR ANTI-ALLERGIC ACTIVITY ON GUINEA PIGS AGAINST NON-IMMUNOLOGICAL CONTACT URTICARIA

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### Keywords:

Urticaria, Hesperidin, Ellagic acid, Benzoic acid and Geraniol

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**ABSTRACT:** Pharmacological screening of selective phytochemicals for common skin allergic disorder, which is defined by the occurrence of itchy and even painful wheals, angioedema or erythema (Urticaria). The main cause of allergic reactions is chemicals, certain foods, insect stings, which often lead to the cause of histamine release, then the tiny blood vessels (capillaries) leak fluid. For induction of urticaria (BA & CA) were selected; they cause the NICU on animal skin whenever they contact the skin. Healthy adult guinea pigs weighing 300-400 gm, were selected for the present study, totally 5 groups each contains five guinea pigs. Those groups were considered as group-1 (Disease control), group-2 (standard), group-3 (Vehicle control), group-4 (test-1) and group 5 (test-2). Parameters such as ear thickness, redness, itching, swelling and time taken for reducing swelling was recorded. Topical application of Benzoic acid and Cinnamon acid to all groups, those animals produced signs of urticaria, which is characterized by redness, itching, swelling. A dose dependent increase in ear thickness was observed in disease control. Topical treatment of phytochemicals reduces redness on guinea pig ears, ear thickness; it is significant reduced with 1% w/w ointment treated group ( $0.27 \pm 0.01^{****}$ ,  $0.318 \pm 0.015^{****}$ ,  $0.266 \pm 0.015^{****}$ ) when compared with the disease control group. 2% w/w ointment treated group also produced the significant effect with high reduction of ear thickness which is similar to that of standard group ( $0.19 \pm 0.008^{****}$ ,  $0.214 \pm 0.009^{****}$ ,  $0.154 \pm 0.014^{****}$ ). Ear thickness  $^{****}P < 0.001$  vs. disease control. Based on the results, it was concluded that selected phytochemicals are suitable for treating NICU without complications.

**INTRODUCTION:** The skin is the largest organ of our body, accounting for about 15% of total body weight. It is continuous with the mucous membranes lining the body surface.

It is a complex organ; an average square inch of skin consists of 650 sweat glands, 20 blood vessels, and more than 1000 nerve endings <sup>1</sup>. Urticaria is a skin rash triggered by a reaction to food, medicine, or other irritants. It is the dermal edema resulting from vascular dilation and leakage of fluid into the skin in response to molecules released from mast cells. The major preformed mediator histamine produces a prototypic, short-lived urticarial <sup>2</sup>. Acute Urticaria is most often a benign self-limited skin disease.

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# A VALIDATED HIGH PERFORMANCE LIQUID CHROMATOGRAPHIC METHOD FOR THE QUANTIFICATION OF FAVIPIRAVIR BY PDA DETECTOR

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## ABSTRACT

Favipiravir is an antiviral drug showing activity for the treatment of various life threatening viruses such as Ebola virus, Lassa virus and also recently for COVID-19. It is a pyrazine carboxamide derivative with activity against RNA viruses which targets RNA-dependent RNA polymerase enzymes which are necessary for the transcription and replication of viral genomes. The lack research work and no compendial methods available for the estimation of this drug influenced for the current research investigation to give a simple, sensitive, rapid, precise, accurate and robust isocratic high performance liquid chromatographic and UV Spectroscopic method for the determination and quantification of Favipiravir. The elution was done by using SHIMADZU Prominence-i, LC-2030 C system equipped with Shim-Pack GIST C18 (250X 4.6 mm, 5 $\mu$ m) column with a mobile phase mixture of 10 mM potassium dihydrogen ortho phosphate buffer (pH 4.0) and acetonitrile in the ratio of 90:10 v/v at a flow rate of 1.0 ml/min. The ultra violet detection was done at the wavelength of 315 nm by maintaining column temperature at 30°. The total run time was 8.0 min. Calibration plot shown best regression over the concentration range of 10-60  $\mu$ g/ml of Favipiravir standard solutions. The LOD and LOQ was found to be 0.18  $\mu$ g/ml and 0.53  $\mu$ g/ml, respectively. The accuracy of the proposed method was determined by performing recovery studies and was found to be between 99.47-100.80%. The repeatability testing for both sample and standard solutions was found as %RSD<2.0% which is within the acceptable limits showing that the method is precise as well. The proposed method was successfully applied for the marketed formulations of Favipiravir tablets. In addition the main features of proposed method are economic and eco-friendly with less retention time around 4.622 min.

**KEYWORDS:** Favipiravir, Antiviral, HPLC, UV, method development, Validation

