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Fluconazole Ocuserts: Formulation and Evaluation

S.Venkateswara Rao[1]*, BCD. Tejaswi[2], A. Anusha[2] & K. Padmalatha[3]

[1,2]Department of Pharmaceutics, [3]Department of Pharmacology,
Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada–521108, India

Abstract

In the present study, it was aim to formulate ocuserts of Fluconazole and to evaluate both physicochemical parameters of *in vitro* release and *in vivo* permeation. Several polymeric systems used to fabricate ocular inserts for better ocular bioavailability and retention of drug for which gelling systems have shown advantages of convenient administration and increased contact time. Fluconazole ocular inserts were prepared by using Poly vinyl alcohol and Hydroxy propyl methyl celluloseas film forming polymers and Propylene glycol as plasticizer. Total six formulations were prepared by solvent casting technique and characterized thickness, weight variation, drug content, moisture loss, moisture absorption, folding endurance, surface pH, ocular irritation study, *in vitro* and *in vivo* release studies. The *in vitro* release studies were carried out by putting excised goat cornea between donor and receptor compartment of Franz diffusion cell. Formulation F5 shows a maximum cumulative percentage drug release of 69.02 % at the end of 2 hours through excised goat cornea. *In vivo* release profile indicated that drug release was less compared to *in vitro* release, and there was complete absence of eye irritation and redness of the rabbit eye. It can be concluded that Hydroxy Propyl methyl cellulose is a good film forming hydrophilic polymer and is a promising agent for ocular delivery.

Keywords: Film forming polymers, *In- vitro* drug release, Ocular inserts and Solvent casting technique

Introduction

Fluconazole, a synthetic antifungal agent, is a triazole derivative used in the treatment of a wide range of fungal infections and it belongs to class II of biopharmaceutical classification system (BCS) having low water solubility [1]. Fluconazole is a prescription drug indicated for the treatment and prophylaxis of fungal infections where other antifungals have failed or are not tolerated (e.g. due to adverse effects), including Candidiasis caused by susceptible strains of *Candida*, Tinea corporis, Tinea cruris or Tinea pedis, Onychomycosis and Cryptococcal meningitis [2]. Ocular therapy in the fungal infections would be significantly improves if the precorneal residence time of drugs could be increased [3]. Successful results have been obtained with inserts and collagen shields [4]. Several polymeric systems are investigated to fabricate ocular inserts for better ocular bioavailability and retention of drugs [5].

In the present study, it was aim to prepare and evaluate ocular films containing fluconazole along with film forming polymers namely; Poly vinyl alcohol and Hydroxy propyl methyl cellulose at different concentrations with better bioavailability and longer duration of action.

Materials

Fluconazole was procured from Hetero Drugs, Hyderabad. Polyvinyl Alcohol, Poly vinyl pyrolidine K30, HPMC K-100 and Propylene Glycol were purchased from S.D. Fine Chem. Ltd, Mumbai. All other chemicals were pharmaceutical grade and used without further modification.

Experimental Methods

Solubility Analysis

Pre-formulation solubility analysis was done, which included the selection of suitable solvent system to dissolve the drug as well as various excipients.

Melting Point Determination

Melting point determination of the obtained drug sample was done; as it is a first indication of purity of the sample. The presence of relatively small amount of impurity can be detected by lowering as well as widening in the melting point range.

Identification of Pure Drug

FTIR spectroscopy was used for identification of pure drug.

Determination of λ_{max}

An accurately weighed 10 mg of Fluconazole was transferred in a 100 ml volumetric flask. To the flask stimulated tear fluid was added in small proportion so as to dissolve fluconazole. The volume was made up to 100 ml with stimulated tear fluid (STF) pH 7.4 to get a concentration of 100µg/ml. 20 µg/ml solution of Fluconazole was prepared in dilution. The resulting solution was scanned in UV-Vis spectrophotometer from 400- 200 nm to determine the λ_{max}.

Construction of calibration curve

Weigh accurately 100 mg of Flucoazole& transfer into 100 ml volumetric flask & make up the final volume with pH 7.4 STF. From the stock solution different concentrations (1 - 10 µg/ml) were prepared by transferring suitable volume into the 10 ml volumetric flasks. Each concentration sample was taken & the absorption was measured at 260 nm by using UV spectrophotometer by using pH 7.4 STF as a blank. The graph was plotted by taking concentration versus absorption and the plot appeared as a straight line, the linearity was determined by using y= mx +c formula.

Compatibility studies

The compatibility of drug with the excipient used was studied by Fourier transform infrared (FTIR) spectroscopy. The FTIR spectrums of Fluconazole and Formulation (F-5) blend were studied by using FTIR spectrophotometer (Brukers) using the KBr disk method. The scanning range was 500 to 4000 cm−1, and the resolution was 1 cm−1. This spectral analysis was employed to check the compatibility of drugs with the polymers used.

Preparation of Ocuserts

The blank polymeric patches were prepared using PVA and HPMC alone by solvent casting technique [6]. Formulation of ocuserts was shown in Table 1. The polymeric drug reservoir films were prepared by dissolving 3, 4, and 5.0 % of PVA in 1/3rd volume of double distilled water. Along with this 300 mg of Fluconazole was separately dissolved in remaining amount of water and then it was poured to the polymeric solution. The solution was stirred using magnetic stirrer at 100 rpm. Then propylene glycol (6 % w/w) was incorporated to the above solution under same stirring conditions. After complete mixing the solution was cast in Petri dish (previously lubricated with Glycerin) using a ring of 5.0 cm diameter and with a funnel inverted on the surface (for uniform evaporation of solvent). The cast solution was allowed to evaporate by placing it inside a hot air oven maintained at 37 ± 2°C, 30 ± 0.5% of RH for 24 hours. After drying the medicated films of 1 cm^2 diameter each containing 15 mg of drug were cut using a stainless steel borer, which is previously sterilized. Similar procedure was carried out for the preparation of HPMC patches.

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FORMULATION AND EVALUATION OF FAST DISSOLVING ORAL FILM OF LEVOCITRAZINE DI HYDROCHLORIDE BY SOLVENT CASTING TECHNIQUE

Venkateswara Rao. S*, Rodhay. G, Padmalatha. K

Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada–521108,

***Corresponding Author E-mail:** venkateshsadhu@gmail.com

ARTICLE INFO

Key Words

Antihistaminic Agent, Film forming Polymers, Disintegrating Agent, Solvent Casting Method and *In-vitro* drug release.

ABSTRACT

Levocetirizine dihydrochloride is a class of third generation antihistaminic agent. It is an active enantiomer of cetirizine; its principal effects are mediated via selective inhibition of H1 receptor. Fast dissolving films have been played an important role in the current pharmaceutical research. They have convenience and ease of use over other dosage forms such as orally disintegrating tablets and immediate release tablets. In the present research, rapidly dissolving films of Levocetirizine dihydrochloride were developed using low viscosity grades of HPMC E-5LV & HPMC E-15LV as film forming polymers. To decrease the disintegration time of formulations crosspovidone was used as disintegrating agent. Levocetirizine dihydrochloride is moderately bitter drug, taste masking was achieved by use of sweeteners and flavours. The films of Levocetirizine dihydrochloride were prepared by solvent casting method using dichloromethane and methanol as solvents. The prepared films (F1 – F6) were evaluated for weight variation, thickness, drug content, folding endurance, surface pH, *in vitro* disintegration time and *in-vitro* drug release. Formulation F1 was considered optimum which contained drug and HPMC E5 in 1: 3 ratios. The *in vitro* disintegration time of the optimized formulation was found to be below 25 seconds respectively. The prepared films exhibited good integrity and thickness. *In vitro* dissolution studies were performed as per the FDA dissolution guidelines for about 10 minutes, the optimum formulation released complete drug within 10 minutes. FTIR studies showed no drug polymer interaction.

INTRODUCTION:

Oral route is the most preferred route for the delivery of the drugs till date as it bears various advantages over the other route of drug administration, but It is estimated that 25 % of the population finds it difficult to swallow tablets and capsules and therefore do not take their medication as prescribed by their doctors resulting in high incidence of non-compliance and ineffective therapy. Furthermore, 90% of the drugs administered through oral route are subjected to extensive first pass metabolism before reaching to the systemic circulation.

In spite of all the cones, the oral route of administration still remains to be the most popular means of drug administration due to its ease of administration, virtually pain free and patient compliance. A new oral dosage form is the oral thin films prepared using hydrophilic polymers which rapidly disintegrates and dissolves on tongue or the buccal cavity. The drug administered via oral mucosa gain access to the systemic circulation through a network of arteries and capillaries. The major artery supplying the blood to the oral cavity is the external

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DEVELOPMENT AND EVALUATION OF CHITOSAN BASED POLYMERIC NANOPARTICLES OF AN ANTI - ALZHEIMER'S DRUG MEMANTINE HYDROCHLORIDE

S. Venkateswara Rao[1*], K. Deepthi [1], M. Pradeep Kumar[2], K. Padmalatha[3]

[1,2]Department of Pharmaceutics, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada–521108, India

[3]Department of Pharmacology, Vasavi Institute of Pharmaceutical Sciences, Madhavaram-1 - 516247, Kadapa, India

***Corresponding author E-mail:** venkateshsadhu@gmail.com

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Alzheimer's disease, Polymeric nanoparticles and Ionotropic gelation

ABSTRACT

The aim of the study was to develop Memantine HCl loaded chitosan - sodium tripolyphosphate (STPP) nanoparticles using Ionic gelation method and evaluates their physicochemical properties and in-vitro release studies for possible targeted delivery to the brain. The objective was to fabricate polymeric nanoparticles for better controlled and targeting action of drug, which also overcome the problems associated with conventional formulations like multidose therapy, poor patient compliance and high cost. Memantine HCl loaded chitosan nanoparticles (F1 to F6) were prepared by Ionotropic gelation method. The formulated nanoparticles were evaluated for external morphological characters, determination of particle size analysis, zeta potential, drug content, entrapment efficiency and in-vitro release studies. The particle size varied from 148 to 317 nm and zeta potential was in negative and its value found to be - 46.4 mV. The drug content for the Memantine HCl loaded chitosan nanoparticles varied from 69.5 ± 7.2% to 87.9 ± 1.2%. The entrapment efficiencies were found to be minimum and maximum of 55.50 ± 2.4% and 86.30 ± 3.6%. The percentage yields of all formulations were in the range of 48.24 ± 1.24 to 86.13 ± 1.37%. In-vitro release of drug follows zero order and showed sustained release behaviour for a period of 24 hr. The optimized formulation contains 3:1 ratio of chitosan & STTP and demonstrated successful sustained release. Memantine HCl loaded chitosan nanoparticle is a potential new delivery system for treatment of Alzheimer's disease.

INTRODUCTION:

Neurodegenerative diseases represent a crucial and exponentially increasing challenge to the health care systems all over the world. Alzheimer's disease (AD) is the most common form of dementia and currently affects 35 million patients across the world which is expected to double in the next 20 years. Many hydrophilic drugs and neuropeptides fail to cross the blood–brain barrier (BBB). Consequently, the complete therapy for Alzheimer's disease (AD) can't be achieved. Many approaches have been

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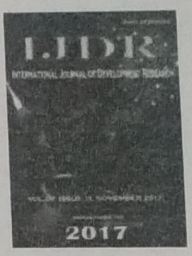

ORIGINAL RESEARCH ARTICLE

Open Access

COMPARATIVE IN VITRO STUDIES AND BIOEQUIVALENCE ASSESSMENT OF SOME COMMERCIALLY AVAILABLE METFORMIN HYDROCHLORIDE TABLETS IN VIJAYAWADA

[1,*]Venkateswara Rao, S., [1]Divya, K. and [2]Padmalatha, K.

[1]Department of Pharmaceutics, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada–521108, India

[2]Department of Pharmacology, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada–521108, India

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Metformin Hydrocloride Tablets,
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ABSTRACT

Metformin Hydrocloride tablets prescribed for treatment of non-insulin dependent diabetes mellitus (NIDDM). The aim of the study is to compare the differences in dissolution behavior and asses bioequivalence of some commercially available Metformin Hydrocloride tablets in Vijayawada. The objective is to find out potent generic brand and reduce the cost of treatment for diabetes mellitus with respect to its composition and manufacturer. Eight generic brands manufactured by different companies were evaluated for physicochemical properties, drug content, *in vitro* dissolution studies and compared with each other. The *in vitro* dissolution studies were performed in USP Dissolution Apparatus II using pH 6.8 phosphate buffer solution for 1 hr. The bioequivalence was assessed based on *In vitro* dissolution profile and f1 & f2 factors. *In vitro* dissolution of all the brands was satisfactory and the brand Obimet® shown highest dissolution of 94.49% within 1 hr. The f1 and f2 values were in the range of 2 – 8 and 74 – 93 respectively. It is evident that test products were bioequivalent to the reference product and the brand Obimet® could be used as a best generic substitute which reduce the dose and cost of treatment for diabetes mellitus.

Citation: Venkateswara Rao, S., Divya, K. and Padmalatha, K. 2017. Comparative in vitro studies and bioequivalence assessment of some commercially available metformin hydrochloride tablets in vijayawada". *International Journal of Development Research*, 9, (11), 16534-16540.

INTRODUCTION

Nowadays drug's cost increases due to the expensive branded drug and the cost can reduced by substituting cheaper generic drugs. The increase in production and consumption of generic drugs need bioequivalence for therapeutically equivalent to the branded drug. In order to find this, bioequivalent studies are conducted according to the Food and Drug Administration (FDA). Two different formulations of a same drug are bioequivalent when their rate of dissolution and absorption is same. Bioequivalence studies focus on the drug release from the formulation and subsequent absorption into the systemic circulation, which consist of both *in vivo* and *in vitro* studies (Demirturk E, 2006). According to USP Pharmacopeia, necessary *in vitro* tests are assay, content uniformity and dissolution studies. The *in vitro* dissolution used to predict the *in vivo* bioequivalence.

Therefore, *in vitro* tests can used to determine bioequivalence of products. The dissolution profile comparison is more precise than others to characterize the drug product. To compare dissolution profiles, two model independent fit factors, the difference factor (f1) and the similarity factor (f2) introduced by Moore and Flanner (1996) as mathematical indices, were used in this study. Metformin Hydrocloride is a biguanide, which used orally in hyperglycemic patients. Nowadays it is widely used in the management and control of non-insulin dependent diabetes mellitus (NIDDM). The oral bioavailability of metformin is 50 – 60% and biological half-life is 1.5 – 1.6 hr (http://www.rxlist.com/glumetza-drug.htm). It is freely soluble in water and has low permeability to cell membranes. Despite of widespread of NIDDM and extensive use of metformin (World Health Organization, 1998), there are no reports on the bioavailability and bioequivalence of the various brands of metformin Hydrocloride tablets in

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RESEARCH ARTICLE

FORMULATION AND EVALUATION OF OXICONAZOLE EMULGEL FOR TOPICAL DRUG DELIVERY

[1,*]Venkateswara Rao, S., [1]Vijaya Sri, P. and [2]Padmalatha, K.

[1]Department of Pharmaceutics, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada-521108, India

[2]Department of Pharmacology, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada-521108, India

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ABSTRACT

Emulgel is one of the emerging topical drug delivery system for the delivery of hydrophobic drugs which overcome various disadvantages of ointments and creams such as greasiness and phase inversion. The aim of present work was to develop and evaluate Oxiconazole emulgel with controlled release. The oxiconazole used in treatment of various fungal infections such as cutaneous and subcutaneous diseases like acne and psoriasis. Different formulations (F1-F4) of Oxiconazole emulgel was prepared by using carbopol 934 as gelling agent with varying concentrations of oily phase such as liquid paraffin and Tween-80 and Span-80 as a emulsifying agent. The prepared emulgels were evaluated for physical appearance, pH, drug content, *In-vitro* diffusion studies, microbiological assay and skin irritation test. By the *In-vitro* diffusion studies it was observed that formulation F1 showed 47.2% and marketed formulation (Oxistat cream) showed 42.1% of drug release after 10 hours and results concluded that the formulation F1 showed better releasing of drug than comparison with marketed cream.

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INTRODUCTION

Topical drug delivery system have been very useful for centuries for the treatment of local skin disorders without undergoing first pass metabolism and acid or enzymatic degradations. Emulgel is one of the interesting topical drug delivery system which drug is randomly distributed as oil micro droplets. The oxiconazole is broad spectrum antifungal used for the treatment of fungal diseases like tinea vermicular, athletes foot, jock itch etc. The aim of the work was to formulate Oxiconazole emulgel with sustained drug release in controlled manner and evaluate their characteristics.

MATERIALS

Oxiconazole Nitrate, Carbopol 934, Liquid Paraffin, Potassium Dihydrogen Phthalate and Sodium Hydroxide were procured from Research Lab Fine Chem Industries, Mumbai; Tri Ethanol Amine, Citric Acid and Dichloromethane were procured from Merch Specialities Pvt. Ltd, Mumbai; Span 80 from Qualikems Fine Chem Pvt. Ltd, Vadodara; All chemicals were pharmaceutical grade and used without further modification.

Corresponding author:* **Venkateswara Rao, S.,
Department of Pharmaceutics, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada-521108, India

METHODS

Standard Curve of Oxiconazole

The stock solution (1 mg/ml) was prepared by weighed accurately 50 mg of Oxiconazole nitrate and transferred to a 50 ml volumetric flask then makeup the final volume with methanol. Different concentrations (2, 4, 6, 8, and10µg/ml) of solutions were prepared from the stock and measure the absorbance at 427 nm by using UV-Visible spectrophotometer and reagent blank. Graphs were plotted taking concentration on X-axis and absorption on Y-axis to give linear curve and the method obeyed Beer's law.

Preparation of Oxiconazole Emulgel

The gel was prepared by dispersing Carbopol 934 in purified water with constant stirring and adjusted the pH to 6 to 6.5 using Tri Ethanol Amine (TEA) (Ramakanth Ambala and Sateesh Kumar Vemula, 2015; Ranga Priya *et al.*, 2012). The oil phase of the emulsion were prepared by dissolving Span 80 in light liquid paraffin while the aqueous phase was prepared by dissolving tween 80 in purified water. Methyl and Propyl paraben were dissolved in propylene glycol whereas drug was dissolved in ethanol and both solutions mixed with the aqueous phase.

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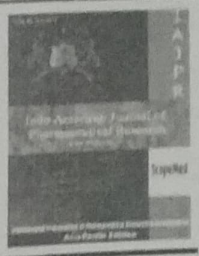

DEVELOPMENT AND VALIDATION OF NOVEL HYDROTROPIC SOLUBILIZATION METHOD FOR SPECTROPHOTOMETRIC DETERMINATION OF MYCOPHENOLATE MOFETIL

Venkateswara Rao. S*, Rodhay. G, Padmalatha. K

Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada, India.

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Spectrophotometric Analysis,
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ABSTRACT

The aim of present study was to develop and validate specific and accurate UV spectrophotometric method of Mycophenolate mofetil by using two different hydrotropic solubilizing agents. Objective was to perform solubility studies of Mycophenolate mofetil in the solutions containing urea (0.2 M) and sodium carbonate (0.2 M) as hydrotropic agents and find out the minimum hydrotropic concentration of urea and sodium carbonate for drug Mycophenolate mofetil. The linearity was observed in the concentration range of 10-30 µg/ml. The method was validated and found to be precise. Accuracy (percent recovery) for Mycophenolate mofetil was found to be 98.97-102.72. From the results it was concluded that urea as hydrotropic agent showed best aqueous solubility of Mycophenolate mofetil and all the validation parameters were found within the limits according to ICH guidelines. So that hydrotropic agent urea suitable solvent for increasing the solubility of Mycophenolate mofetil. The proposed method is new, simple, safe, eco-friendly, economic, accurate, cost-effective and can be successfully employed in routine analysis.

Corresponding author
Venkateswara Rao. S
Assoc. Professor,
Department of Pharmaceutics,
Vijaya Institute of Pharmaceutical Sciences for Women,
Enikepadu, Vijayawada – 521108.
venkateshsadhu@gmail.com

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RESEARCH ARTICLE

FORMULATION DEVELOPMENT AND *IN VITRO* EVALUATION OF GASTRORETENTIVE EFFERVESCENT FLOATING TABLETS OF DILTIAZEM USING VARIOUS POLYMERS

*[1]Pradeep Kumar, M., [1]Manjulam C., [2]Venkateswara Rao, S. [3]Swathi, P. and [4]Bhavani, B.

[1]Vasavi Institute of Pharmaceutical Sciences, Kadapa
[2]Vijaya Institute of Pharmaceutical Sciences for Women, Vijayawada
[3]AU College of Pharmaceutical Sciences, Visakhapatnam
[4]Vignan Institute of Pharmaceutical Technology, Visakhapatnam

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Diltiazem, Ethyl cellulose,
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ABSTRACT

In the present research work sustained release floating matrix formulation of diltiazem HCL by using various concentrations of polymer were developed. The formulation blend was subjected to various preformualation studies, flow properties and all the formulations were found to be good indicating that the powder blend has good flow properties. Among all the formulations F8 formulation was retarded the drug release up to desired time period i.e., 12 hours in the concentration of 60 mg. The dissolution data of optimized formulation was subjected to release kinetics; from the release kinetics data it was evident that the formulation followed higuchi release kinetics.

INTRODUCTION

Oral route of drug delivery was most utilized route of various pharmaceutical dosage forms, due to its ease of administration and patient compliance (Nayak, 2010 and Singh, 2011). The oral controlled drug delivery system was developed to allow a controlled rate of drug release over an extended period of time. This system, however, has a disadvantage of short gastric retention time, resulting in the incomplete release of drugs with narrow absorption window in the upper part of the gastrointestinal tract (Singh, 2011 and Singh, 2000). To overcome this drawback, gastroretentive drug delivery systems (GRDDS) were introduced (Singh, 2000). GRDDS are designed to retained in the stomach for a prolonged time and release their active ingredients and there by enable sustained and prolonged input of the drug to the upper part of the GIT (Singh, 2010; Singh, 2011; Singh, 2000; Arora, 2005 and Mayavanshi, 2008). To formulate a successful GRDDS, several techniques are currently used such as floating drug delivery system, low density system, raft systems incorporating alginate gel, bioadhesive or Mucoadhesive systems, high density systems, superporous hydrogel and magnetic system (Dehghan, 2009).

***Corresponding author:** **Pradeep Kumar,**
Vasavi Institute of Pharmaceutical Sciences, Kadapa

The floating system is the most used system as it is a simple and practical approach to increase the gastric retention time and to control the drug release (Nayak, 2010 and Singh, 2011). Floating drug delivery systems have a bulk density less than gastric fluid and so remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. While the system is floating on the gastric contents, the drug is released slowly at the desired rate from emptying rate for a prolonged period of time. While the system is floating on the gastric contents, the drug is released slowly at the desired rate from the system. After the release of drug, the residual system is emptied from the stomach. Thus, results in an increased gastric retention time and control of the fluctuation in plasma drug concentration (Mathur, 2010 and Shah, 2009). Diltiazem hydrochloride is a calcium channel blocker. It is widely prescribed for the treatment of hypertension and angina. Diltiazem hydrochloride undergoes extensive biotransformation results in bioavailability of 30% to 40% only. It has an elimination half-life of 3 to 4.5 h and has an absorption zone from the upper intestinal tract. Efficacy of the administered dose may get reduced due to incomplete drug release from the device above the absorption zone. The dosage is 30 mg, 4 times a day and increased as necessary up to 360 mg/day in divided doses (http://www.drugbank.ca and Hudson, 2014). Due to short half-life diltiazem hydrochloride require frequent administration. These disadvantages can

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RESEARCH ARTICLE

COMPARATIVE *IN VITRO* EVALUATION OF ACECLOFENAC AND PARACETAMOL COMBINATION TABLETS MARKETED IN ANDHRA PRADESH

[1,*]Venkateswara Rao, S., [1]Anitha, M. and [2]Padmalatha, K.

[1]Department of Pharmaceutics, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada, India

[2]Department of Pharmacology, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada, India

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In Vitro Dissolution Studies,
Bioequivalent and High Performance Liquid Chromatography.

ABSTRACT

Aceclofenac in combination with Paracetamol is now available in the market and indicated in pain, fever etc. These tablets manufactured and marketed by various multinational and local companies. In this study eight marketed brands of Aceclofenac & Paracetamol combination tablets have been evaluated using physicochemical properties and *in vitro* dissolution test with the object to assess bioequivalence and select a potent generic brand for reducing cost of the treatment. A simple high performance liquid chromatographic (HPLC) method was developed for the simultaneous determination of Aceclofenac & Paracetamol. The retention time of Aceclofenac & Paracetamol were found to be 4 ± 0.2 and 3 ± 0.2. The *in vitro* dissolution studies were performed in USP Dissolution Apparatus II using pH 6.8 phosphate buffer solutions separately for 45 minutes. The amount of Aceclofenac & Paracetamol released at different time intervals were estimated by HPLC method. *In vitro* dissolution of all the brands was satisfactory, the brand Spanac-p® showed higher drug release, respectively 79.32 % of Aceclofenac & 95.04 % Paracetamol within 45 minutes. The f1 and f2 values were in the range of 5 – 13 and 64 – 86 respectively. This suggests that release of Aceclofenac & Paracetamol from all brands were similar with reference. Therefore it is evident that test products were bioequivalent to the reference product and the brand Spanac-p ® could be used as a best generic substitute which reduce the dose and cost of the treatment.

INTRODUCTION

Paracetamol is one of the most popular over the counter drugs. It has analgesic and antipyretic properties with weak anti inflammatory activity and it is used in the symptomatic management of moderate pain and fever. It could also be used in the management of more severe pain like pain in cancer in combination with other drugs (Kalakuntla *et al.*, 2010). Aceclofenac, [(2-{2,6-dichlorophenyl)amino} phenylacetooxy acetic acid] is a non-steroidal anti-inflammatory drug (NSAID) indicated for the symptomatic treatment of pain and inflammation with a reduced side effect profile, especially gastro intestinal events that are frequently experienced with NSAID therapy. At present, beside paracetamol, a new paracetamol / aceclofenac formulation is designed to deliver faster dissolving and more quickly absorbed drug product.

***Corresponding author:* Venkateswara Rao, S.**
Department of Pharmaceutics, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada, India.

Paracetamol is often prescribed with aceclofenac for greater patient acceptability, increased potency, multiple activity, fewer side effects and quick relief (Liu *et al.*, 2011). Reducing pharmaceutical care cost with generic drugs while maintaining quality of health care is an important societal goal in developed and developing countries. Health care providers and policy makers also support the practice of prescribing low cost generic products principally for economic reasons. Generic drugs are less expensive than equivalent innovator brands because generic manufacturers do not have to conduct costly clinical trials to test the safety and effectiveness of a generic version of a drug that has been safely and effectively used for several years. It is therefore important that generics substitutes are analyzed for their physicochemical and biopharmaceutical equivalence, strength, quality, purity, and releasing profile of active ingredient in comparison to the innovator drug (S.M. Ashraful Islam *et al.*, 2011). The study was conducted to assess the comparative *in-vitro* quality control parameters through the evaluation of weight variation, hardness, friability, disintegration time and dissolution profile between the

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Phytochemical Composition of *Euphorbia Heterophylla* L.

Mamillapalli Vani*, S.K. Abdul Rahaman and A. Prameela Rani**

Department of Pharmacy, Jawaharlal Nehru Technological University, Kakinada, East Godavari (Dt.), Andhra Pradesh, India,**Department of Medicinal chemistry, Nirmala College of Pharmacy, Atmakur, Mangalagiri, Guntur (Dt.) A. P., India, Department of Pharmaceutics, Acharya Nagarjuna University, Nagarjuna Nagar, Guntur (Dt.), A.P. India**

E-mail : vanimamillapalli@yahoo.co.in

Corresponding Author
Mamillapalli Vani
Department of Pharmacy, Jawaharlal Nehru Technological University, Kakinada, East Godavari (dt.), Andhra Pradesh, India.
E-mail : vanimamillapalli@yahoo.co.in

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Abstract

The objective of the study was to screen the phytoconstituents present in the stem extracts of *Euphorbia heterophylla L.* by GC-MS. The stem powder of the plant was extracted using solvents hydroalcoholic mixture (50:50) and acetone. Column chromatography was carried out on the hydroalcoholic extract of the plant. Preliminary phytochemical screening showed the presence of alkaloids, glycosides, tannins, flavonoids, steroids, and saponins. GC-MS analysis of n-hexane: chloroform (9:1) fraction showed the presence of 23 phytochemical compounds. The study suggests that some compounds remained unexplored for pharmacological activities. Therefore an attempt should be made to isolate the individual components and study their pharmacological behavior which may prove as novel therapeutic agents.

Keywords: *Euphorbia heterophylla*, GC-MS, Column chromatography, pharmacological activities, alkaloids, glycosides, tannins, flavonoids and steroids

Introduction

Nature is the supreme combinatorial chemist and possibly has solutions to all ailments of humankind. Green plants constitute a repository of essential chemo-therapeutics as they are now-phytotoxic, more systemic and easily biodegradable (Chaman and Verma, 2006). A comprehensive knowledge of the phyto chemicals present in plant body is required to explore economic phytochemical agents for the synthesis of complex chemical substances and for ascertaining the importance of ethnomedicinal uses (Milne, 1993). GC-MS studies have been applied to the analysis of plant substances (Betz *et al.*, 1997).

Euphorbia heterophylla L. is a branched shrub belonging to the family Euphorbiaceae, widely distributed in South Asian countries. The plant was reported for activities like hepatoprotective activity (Augustine *et al.*, 2013), antidiabetic activity (Annapurna and Ketan Hardware, 2014), the effect of plant extraction kidney, liver and pancreatic functions was reported (Okolie Ngozi Paulinus *et al.*, 2015). The leaves were reported to contain quercetin (Falodun *et al.*, 2004), stigmasterol and 4-hydroxy benzoic acid (Abiodun Falodun *et al.*, 2008) diterpenoids were isolated the from roots (Rowan *et al.*, 2001). The medicinal usefulness of the plant motivates numerous chemical and pharma-cological studies. Traditional uses of the plant include, purgative, decoction of leaves in treating respiratory tract infections and asthma (Erden *et al.*, 1999). The present study focuses on exploiting the phytochemical constituents of stem extracts of *E. heterophylla* by GC-MS (Gas chromato- graphy-Mass spectrometry).

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PHYTOCHEMICAL CONSTITUENTS OF *GOMPHRENA SERRATA L*

VANI M*[1], RAHAMAN A SK[2] AND PRAMEELA RANI A[3]

[1]Department of Pharmacy, Research Scholar Jawaharlal Nehru Technological University, Kakinada, East Godavari District, A.P., India

Department of Pharmacognosy & Phytochemistry, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada, Pin: 521108, Krishna District, Andhra Pradesh, India

[2]Department of Medicinal Chemistry, Nirmala College of Pharmacy, Atmakur, Mangalagiri, Guntur (dt.), A.P., India

[3]Dept. of Pharmaceutics, Acharya Nagarjuna University, Nagarjuna Nagar, Guntur (Dt.). A.P., India

***Corresponding Author:: Mrs. Mamillapalli Vani; E Mail: vanimamillapalli@yahoo.co.in; Mob. No. 9704625782**

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ABSTRACT

The aim of the study was to screen the phytoconstituents present in the flower extracts of *Gomphrena serrata L.* and their further analysis by GC-MS. The flowers of the plant were extracted using solvents hydroalcoholic mixture (50:50) and acetone. Preliminary phytochemical screening showed the presence of alkaloids, glycosides, tannins, flavonoids, steroids, amino acids and proteins. Column chromatography was carried out on the acetone extract of the plant. GC-MS analysis of chloroform fraction showed the presence of 30 bioactive compounds. The study forms a basis for the biological characterization and importance of the compounds identified.

Keywords: *Gomphrena serrata*, GC-MS, bioactive compounds

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Mamillapalli Vani
(1). Research Scholar Jawaharlal Nehru Technological University, Kakinada, East Godavari District, Andhra Pradesh, India
(2). Department of Pharmacognosy & Phytochemistry, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada, Pin: 521108, Krishna District, Andhra Pradesh, India

SK Abdul Rahaman
Department of Medicinal Chemistry, Nirmala college of Pharmacy, Atmakur, Mangalagiri, Guntur (Dt.), Andhra Pradesh, India

Avula Prameela Rani
Department of Pharmaceutics, Acharya Nagarjuna University, Nagarjuna Nagar, Guntur (Dt.), Andhra Pradesh, India

Correspondence
Mamillapalli Vani
(1). Research Scholar Jawaharlal Nehru Technological University, Kakinada, East Godavari District, Andhra Pradesh, India
(2). Department of Pharmacognosy & Phytochemistry, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada, Pin: 521108, Krishna District, Andhra Pradesh, India

In vivo antiasthmatic studies & phytochemical characterization on the stem extracts of *Alternanthera sessilis* L. using Guinea pigs model

Mamillapalli Vani, SK Abdul Rahaman and Avula Prameela Rani

Abstract
The present investigation has been carried out to evaluate the antiasthmatic activity by *in vitro* and *in vivo* models *in* guinea pigs followed by phytochemical characterization using Gas chromatography Mass spectrum analysis of the hydroalcoholic and acetone extracts of the stem extracts of *Alternanthera sessilis*. In histamine and acetylcholine-induced bronchospasm studies acetone extracts of the plant have significantly increased PCT 10.52 and 11.36 by Tukey's test (**p<0.01), compared with control. Histamine and acetylcholine-induced ileum contraction studies also showed that the acetone extracts exhibited response was1.8 with 63.3% and 2.7 with 51% inhibition by Dunnett's test (p<*0.05). The results of GC-MS analysis depicted following phytoconstituents with major peak area namely 79.29% methoxy-bis (cyclopentadiene), 2.83% 5,10-dihexyl-5,10-dihydroindolo[3,2-b]indole-2,7-dicarbaldehyde and 1.84% 1,2-bis[3,4-dimethoxy benzyl]-1,2-bis (methoxymethyl) ethane respectively. The results of present study suggest the usage of plant extracts as antiasthmatic agents due to the phytochemicals reported through GC-MS.

Keywords: *Alternanthera sessilis*, asthma, bronchospasm, ileum contractions, GC-MS

1. Introduction
Asthma is a complex inflammatory disease. It causes airway narrowing associated with changes in the levels of eosinophils, mast cells, lymphocytes, cytokines and other inflammatory cell mediators [1]. Asthma patients have high levels of specific IgE that bind to receptors on mast cells and other inflammatory cell regulators [2]. The interaction between IgE antibody and antigen results in the activation of a series of inflammatory cellular reactions, including the release of mediators such as histamines, prostaglandins, and leukotrienes, which subsequently lead to contraction of airway smooth muscle and bronchoconstriction [3].The medicinal plant used for the treatment of asthma should have anti-inflammatory, immunomodulatory, antihistaminic, anticholinergic, smooth-muscle relaxant and antiallergic activities [4]. Current asthma therapy lacks satisfactory success due to adverse effect; hence patients are seeking complementary and alternative medicine to treat their asthma [4]. Asthma affects about 300 million people worldwide and it has been estimated that a further 100 million will be affected by 2025 [5]. *Alternanthera sessilis* is used as a vegetable in Asia, traditionally used in skin diseases, to cure wounds and as an antidote. The plant is reported for various pharmacological activities like haematinic [6], antioxidant [7], anti-inflammatory [8], hepatoprotective [9], antiulcer [10], antimicrobial [11], and wound healing [12]. It is reported to contain β- carotene [13], lupeol [14], α and β spinasterol [15], β-sitosterol, stigmasterol [16], and campesterol [13]. The literature survey indicates there are no reports available on antiasthmatic studies on *A.sessilis*. Therefore the present study was planned to conduct *in-vitro* and *in vivo* animal model studies for antiasthmatic activity and characterization of phytochemicals using Gas chromatography-mass spectrum (GC-MS) analysis.

2. Materials and Methods
2.1 Chemicals and Reagents
Histamine hydrochloride, acetylcholine, chlorpheniraminemaleate, atropine sulfate were purchased from Sigma- Aldrich chemical Co.

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Research article

ANTIHISTAMINIC AND ANTICHOLINERGIC STUDIES ON THE STEM EXTRACTS OF EUPHORBIA HETEROPHYLLA L.

*[1]Mamillapalli Vani, [2] Sk Abdul Rahaman and [3]Avula Prameela Rani

[1]Research Scholar Jawaharlal Nehru Technological University, Kakinada, East Godavari District, A.P., India.

Department of Pharmacognosy & Phytochemistry, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada, Pin: 521108, Krishna District, Andhra Pradesh, India.

[2]Department of Medicinal Chemistry, Nirmala College of Pharmacy, Atmakur, Mangalagiri, Guntur (dt.), A.P., India.

[3]Dept. of Pharmaceutics, Acharya Nagarjuna University, Nagarjuna Nagar, Guntur (Dt.). A.P., India.

ABSTRACT: The present investigation has been carried out to evaluate the *in vitro* and *in vivo* antihistaminic and anticholinergic activities for the stem extracts of *Euphorbia heterophylla L.* Preliminary phytochemical screening has been carried out on the hydroalcoholic and acetone extracts of the plant. The antihistaminic activity was studied *in vivo* by histamine-induced bronchospasm and *in vitro* by histamine-induced guinea pig ileum contractions. The anticholinergic activity was studied by acetylcholine-induced bronchospasm and *in vitro* by acetylcholine-induced guinea pig ileum contractions. Pre convulsion time and percentage inhibition of contractions were calculated. Preliminary phytochemical screening showed the presence of flavonoids, tannins, alkaloids, glycosides and steroids. In histamine-induced bronchospasm studies acetone extracts of the plant have significantly increased PCT 4.10 and in acetylcholine-induced bronchospasm studies it was 10.23 for hydroalcoholic extract by Tukey's test (*$p<0.05$), compared with control. In histamine-induced ileum contraction studies, the hydroalcoholic extract exhibited response 4.3 with 18.2% inhibition. In acetylcholine-induced ileum contraction studies, the hydroalcoholic extract showed 4.2 with 18.2% inhibition by Dunnett's test. ($p<*0.05$). The results of present study indicate that plant hydroalcoholic extract showed better anticholinergic activity. Therefore stem extracts of *Euphorbia heterophylla* can be used as antihistaminic and anticholinergic agents which suggest their usage for various therapeutic ailments such as asthma, liver damage, inflammation, and ulcer *etc.* The activity may be due to the phytochemicals which need to be further explored out.

Key words: *Euphorbia heterophylla*, bronchospasm, ileum contractions, therapeutic ailments, phytochemicals

*Corresponding author: Mamillapalli Vani, Dept. of Pharmacognosy & Phytochemistry, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada- 521108, Andhra Pradesh, India. vanimamillapalli@yahoo.co.in Mobile no. 9704625782

39. The Great Indian Novel: An Artifact of Cultural Significance

Vishnu Vandana Devi.V, Asst.Professor of English, Vijaya Institute of Technology for Women, Enikepadu, Vijayawada

The Great Indian Novel by Shashi Tharoor, a postcolonial novel raises some pertinent questions regarding the country's status during the Indian independence struggle, in the backdrop of the legendary text, *The Mahabharata*. The author's selection of the great epic to re-frame the history of India is a fact that reiterates the class and caste conflict. The novel accounts for the oppressed Indians in the hands of the British, and records the annexation of the princely state of Hastinapur to the British Raj. The British trying to introduce the new language, industries and other such social, economic and political reforms for the benefit of the Indians to enable them towards self-governance was a strategic policy of the British to leave their impression forever over the places they colonized. Tharoor's *The Great Indian Novel* enquires about the historical picture presented about India, due credits to the colonial rule. As a champion of peace and humanitarian values, Tharoor could easily interrogate the inequalities observed during *the Mahabharata* time as well as the oppression of the Indians by the British. A cultural study of *The Great Indian Novel* is to interpret the signs of culture as part of a power struggle. If we consider the *Mahabharata* as a cultural artifact, it generates various meanings to the Indian society. *"The Mahabharata has not only influenced the literature, art, sculpture and painting of India but it has also moulded the very character of the Indian people. Characters from the Great Epic... are still household words (which) stand for domestic or public virtues or vices...in India a philosophical or even political can hardly be found that has no reference to the thought of the Mahabharata."* (C.R.Deshpande, Transmission of the Mahabharata Tradition) Thus, the great epic reinforces certain ideologies and principles and it has become a part of a discourse, India. *The Great Indian Novel*, a political allegorical account based on *the Mahabharata*, satirizes the events, the characters of the great epic as to put forward the Indian independence struggle, questioning the common Indian's reverential attitude towards the legendary characters. It could be Bhishma or Gandhi, Tharoor leaves no stone unturned to throw light on the weaknesses of the two heroic personalities, thus shifting the readers' mind towards adopting a new, logical thinking. The character of Gandhi is questioned on the issues of principles and partition of the nation.

Ved Vyas, the narrator as he narrates his story, it slowly takes the form of the *song of Modern India*. The postcolonial work thus presents Vyasa as not only the narrator of the story, but also as a retired politician. As the Vyasa of the *Mahabharata,* the narrator here also is responsible for the creation and fortitude of the other characters also. He obeys his mother Sathyavathi's instructions and as a result we see the birth of Dhritarashtra, Pandu and Vidur. The age old practice of Niyoga is carried out with the support of the queen and the practice is held in great regard by all. Tharoor through his mock-epic questions the legitimacy of Ved Vyas in being used for Niyoga to continue the Kshatriya clan. As Satyavati bears him through her union with Parashar before her marriage to Shantanu, the authenticity of Ved Vyas being brought in for Niyoga, upon the refusal of Bhishma was criticized. When class system and caste system were practiced, it is quite surprising that adjustments and exceptions were allowed according to the convenience. Therefore, Satyavati is considered as *the embodiment of the driving force of womanhood, with motherly ambition blinding her vision at every turn,* by Dhanalakshmi Ayyer, author of *Satyavati: Blind Ambition*. The very process of identification, through which we project ourselves into our cultural identities, has become more open-ended, variable and problematic. This produces the post modern subject conceptualized as having no fixed, essential, or permanent identity. Identity becomes a 'moveable feast' formed and transformed continuously in relation to the ways we are represented or added in the cultural systems which surround us. --- (Hall, 1987)

The Great Indian Novel, therefore portrays the changing value system on par with the changing times and attitudes of people. For example, Ekalavya who is much-admired as an

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B. Sri Ram
Department of Science and Humanities, Acharya Nagarjuna University College of Engineering and Technology, Acharya Nagarjuna University, Guntur, Andhra Pradesh, India

V. Srinivas
[2]Department of Science and Humanities, Vijaya Institute of Pharmaceutical Sciences for Women, Vijayawada, Andhra Pradesh, India

R.R.L. Kantam
[3]Departments of Statistics, Acharya Nagarjuna University, Guntur, Andhra Pradesh, India

Correspondence
B Sri Ram
Department of Science and Humanities, Acharya Nagarjuna University College of Engineering and Technology, Acharya Nagarjuna University, Guntur, Andhra Pradesh, India

Extreme value control charts based on Rayleigh distribution

B Sri Ram, V Srinivas and RRL Kantam

Abstract
Variable control charts are based on subgroup statistics and variation in the values of the subgroups. In this paper extreme order statistic of the subgroup are considered to develop the control limits to decide upon the in control status of the process. Here, the quality characteristic is assumed to follow Rayleigh (Weibull with shape parameter 2) and gamma with shape parameter 2 distributions are considered. Relevant comparisons are presented with examples.

Keywords: Extreme value control chart, extreme order statistic, variable control charts.

Introduction

In order to monitor the variability in the quality control data by developing graphical procedures for subgroup statistics such as mean, range, standard deviation etc., the variable control charts are popularly used. Depending on the subgroup size and the sampling distribution of the subgroup statistics separate control chart constants and hence control limits would be constructed in practice. However some research works appeared in literature that deals with control charts for non-normally distributed process variates (Edgemen (1989), Kantam and SriRam (2001) [2] developed control charts for process variates which are non-normally distributed and the references therein). Control charts for individual observations in the case of normal process variates are developed and the principle was made use of to propose a procedure for comparison of multiple means known as Analysis of Means (OTT (1967). On similar lines the well known gamma and exponential distributions are assumed as models of process variate and the corresponding ANOM procedure along with control charts for individual observations are developed by SriRam (2004) [5]. Motivated from these aspects we extend the same principle to two probability models of Rayleigh distribution (Weibull with shape parameter 2) and gamma with shape parameter 2 developed alternative pairs of control limits for variable control charts and compare their appropriateness with that of existing pairs of limits in literature. The percentiles of extreme order statistics in samples from the models and their use in developing limits for variable control charts are presented in the section 2. In section 3, we compare our control limits with those existing in literature with examples.

Extreme Order Statistics Based Control Limits

If X is a process variate having a Rayleigh distribution (Weibull distribution with shape parameter 2) has the probability density function and distribution function given as

$$f(x) = \frac{x}{\sigma^2} e^{-x^2/2\sigma^2}; x \geq 0 \quad (2.1)$$

$$F(x) = 1 - e^{-x^2/2\sigma^2};\ for\ x \in [0, \infty) \quad (2.2)$$

In the standard form

$$f(z) = z.\ e^{-\frac{z^2}{2}};\ z \geq 0 \quad (2.3)$$

Research Article

Phytochemical and *In Vitro* Sun Protection Factor Evaluation of *Peltophorum Pterocarpum* Leaf Extracts

Vani Mamillapalli[1*], Padma Latha Khantamneni[2], Sindhu Koleti [1], Kathyayini Ghanta[1], Hanumantha Madhuri Yakkali[1], Krishna Madhuri Puli[1], Geethanjali Kolusu[1]

[1]Department of Pharmacognosy and Phyto Chemistry, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada, Krishna District, Andhra Pradesh, India.

[2]Department of Pharmacology, Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada, Krishna District, Andhra Pradesh, India.

***Corresponding author's E-mail:** vanimamillapalli@yahoo.co.in

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ABSTRACT

The medicinal plants are an important source of inexpensive and practical drugs for people throughout the world. Prolong exposure to UV radiation may initiate the production of reactive oxygen species, which causes oxidative injury and impairment of the antioxidant system. These injuries impair the metabolic pathways. Therefore the present study has been planned to evaluate *in vitro* flavonoid content and SPF of aqueous and ethanolic extracts of the *P. Pterocarpum*. The aqueous and ethanolic extracts were determined for flavonoid content, found to be 10mg/gm and 15mg/gm equivalent of quercetin. The cream and gel formulations were prepared for the extracts and tested for various parameters, further evaluated for Sun protection factor determination where the results were found to be 26.8, 34.7 and 9.70 for cream formulations followed by 15.6,16.8 and 100 for gel formulations of aqueous, ethanolic extracts compared to marketed product respectively. The ethanolic extract was more offering sun protection than aqueous extract and the responsible compounds were attributed to be flavonoids. Further phyto chemical screening is necessary to establish the phytochemical component responsible for the activity.

Keywords: *P. pterocarpum*, sunscreen, UV radiation.

INTRODUCTION

The medicinal plants are an important source of inexpensive and practical drugs for people throughout the world. The herbal products today symbolize safety in contrast to the synthetics that are regarded as unsafe to human and environment. In recent years, pharmaceutical companies have spent considerable time and money in developing therapeutics based upon natural products extracted from plants[1]. Sunlight composed of various wavelengths ranging from ultraviolet light through infrared to visible light. The solar spectrum radiation of the sun is divided into five regions: Ultraviolet C or UV-C (from 100 nm to 290 nm), Ultraviolet B or UV-B (from 290 nm to 320 nm), Ultraviolet A or UV-A (from 320 nm to 400 nm), visible (from 380 nm to 780 nm) and infrared (from 780 o nm t106 nm)[2]. In winter high proportion of UV- radiation is reflected than in summer[3, 4]. Prolong exposure to UV radiation may initiate the production of reactive oxygen species, which causes oxidative injury and impairment of the antioxidant system. These injuries impair the metabolic pathways of the skin, which lead to photoaging, erythema, edema, sunburn, lines, wrinkles, photosensitivity, immunosuppression, DNA damage as well as skin cancer in most severe conditions[5].

UVA radiation reaches the deeper layer of the epidermis and dermis, provokes the premature aging (photoaging), of the skin by causing damage to the elastic and collagen fibers of the connective tissue of the skin[6]. UVB is responsible for the skin damage due to sunburn and brings about acute inflammation (sunburn) and intensification of photo-aging[6]. The most biologically damaging radiation UV-C being the shorter wavelength has been filtered out by the ozone layer. Sunscreens and sunblocks are the two chemicals that absorb or block UV rays of sunlight. Therefore sunscreen compounds are generally incorporated in many cosmetic formulations such as creams, lotions, moisturizers and other skin care products [7]. The main purpose of sunscreen is to protect the skin against UV-A and UV-B rays (sunburn and photoaging), conserve the moisture content of skin and its own natural oils, which may be lost during the exposure of solar radiation[8]. They also help in absorbing the portion of erythema on the skin caused by radiation energy of the sun. The Sun Protection Factor (SPF) is a numerical rating system to indicate the degree of protection provided by a sun care product like sunscreen[9]. SPF is defined as the ratio of minimal erythema dose (MED) of solar radiation measured in the presence and in the absence of a sunscreen agent[10].The MED is defined as the lowest time interval or dosage of UV light irradiation sufficient to produce a minimal, perceptible erythema on the unprotected skin[11]. Most recently updated scientific method for evaluating the SPF of sunscreens has been developed by COLIPA (*The Comité de Liaison de la Parfumerie in Europe)* internationals.

The sunscreen should be capable of absorbing wavelength at the range of 280-450 nm, stable to withstand heat, light, and perspiration, should not be readily absorbed by the skin, protective, chemically inert, non-irritating, non-toxic[12]. There are several agents