Article

An Overview of Compulsory Licensing in Pharmaceuticals

Pooja Aggarwal, Dr. Bayya Subba Rao*, Dr. M. Ravi Kumar
Faculty, Geethanjali College of Pharmacy, Cheeryala, Keesara, Hyderabad, Telangana.

Abstract

Members of World Trade Organisation are obliged for TRIPS and it directs in fulfilling the minimum criteria of infrastructure upgrade or vest new intellectual property legislations. TRIPS indicate an independent decision at the discretion of the country to issue compulsory licenses while simultaneous monitoring of anti-competitive licensing practices. Compulsory licensing is a provision that contradicts patents issued and an attempt is made in bringing awareness.

Keywords: Compulsory licensing, Pharmaceuticals, SWOT

Introduction

TRIPS agreement was a founding agreement when countries became members of World Trade Organisation (WTO) in 1995. At the fourth Ministerial Conference (2001) of WTO, the Doha Declaration on the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Public health was adopted[1]. TRIPS agreement comprises of seven parts with seventy three articles as guidelines for implementation and enforcement in the member countries. The agreement insists on national treatment, vest new or upgrade already existing legislations. While emphasizing the exclusivity provisions, TRIPS insists on institutional arrangements, protection of undisclosed information (trade secret/data exclusivity) with respect to local needs, role of judicial, custom authorities, conditions for civil/criminal proceedings, role of TRIPS council, co-ordination of WIPO and WTO etc. The current article is to emphasize the role of compulsory licensing.

Conditions for Compulsory Licensing:

For a better understanding, all possible conditions for opting compulsory licensing were categorized to the following options:

Option 1: An invention that was patented and is not worked, with high price not reachable to common man.

Option 2: An invention that was patented and is not manufactured within the country (or imported).

Option 3: An invention that was patented and the innovator is unable to fulfill the market demands.

Option 4: An invention that was patented and the product is required under national emergency/calamities/disease outbreak conditions, for the sake of public on non-commercial grounds.

Under such circumstances, after three years from date of grant, a third party can approach a patent office (especially for options 1, 2, 3) for grant of compulsory license provided the third party approached the patentee requesting for a patent licensing and failed.

Hence, a compulsory licensing mechanism is either initiated by the Government authority or by a third party. It is necessary to realize that a compulsory licensing mechanism is only for the country needs (local needs) but, certain circumstances may provide an option for manufacturing in one country and exporting into another country. In either of the conditions, it is necessary the compulsory license holder has to pay a proportional of royalty with respect to the business made. It is necessary that the compulsory license holder has to submit the amount of drug/drug product manufactured, amount for local needs and for export needs, total sale of product to the government authority and where ever needed to the patent holder.

Provision of License of Right

The concept of license of right comes into picture when the patentee wishes to lose right for exclusivity in return, the government waivers the maintenance fee. It is obvious that a patentee who has ample business over rides maintains exclusivity rights.

Case Studies where Compulsory/Voluntary Licensing issued:

For the national and international levels, several compulsory/voluntary licenses[2] were granted by various governments for local needs. Some of the countries include Argentina (Oseltamivir for Tamiflu), Brazil (Atazanavir, Efavirenz, Indinavir, Nelfinar, Lopinavir + Ritonavir, Tenofovir for HIV/AIDS), Canada (Ciprofloxacin for Anthrax), Ecuador (Lopinavir + Ritonavir for HIV/AIDS), Egypt (Sildenafil for NCD), Ghana (ARVs for HIV/AIDS), India (Imatinib Mesylate for Cancer), Indonesia (Lamivudine and Nevirapine for HIV/AIDS), Malaysia (Didanosine, Zidovudine, Lamivudine + Zidovudine for HIV/AIDS), Mozambique (Lamivudine, Stavudine, Nevirapine for HIV/AIDS), Rwanda (Lamivudine + Nevirapine + Zidovudine for HIV/AIDS), South Africa (Nivirapine, Lamivudine, Zidovudine, Stavudine, Didanosine, Efavirenz, Indinavir, Abacavir for HIV/AIDS), Taiwan (Ostamivir for Avian Flu/Pandemic Flu), Thailand (Efavirenz for HIV/AIDS; Lopinavir + Ritonavir, Clopidogrel for HIV/AIDS, CVS; Imatinib Mesylate for Cancer; Letrozole, Docetaxel, Erlotinib for Cancer), United States (Ciprofloxacin for Anthrax), Zambia (Lamivudine, Stavudine, Nevirapine for HIV/AIDS) and Zimbabwe (ARVs for HIV/AIDS).

The conditions clearly indicate critical life threatening diseases like cancer, HIV/AIDS to communicable diseases (national emergency conditions) like Flu, Anthrax to the local demands such as use of Sildenafil.

The cases clearly indicate for drugs that are expensive and not reachable to common man, lack of in house manufacturing facilities, unable to fulfill market demands, national emergency conditions, disease outbreaks, market demands etc.

In India, M/s. Natco Pharma Limited, Hyderabad has received the first ever compulsory licensing for indigenous needs upon fulfilling valid reasons. Indian patent office, has maintained strong grounds while granting compulsory licensing and rejected several applications on valid reasons.

Lead resources for initiating Compulsory Licensing Mechanism:

It is necessary to monitor the patents granted by various country patent offices and their working status. For instance, Indian Patent Office is releasing notices to the patent holders to update the working status of the granted patents. Such information usually provides an opportunity

*E-mail: drbayyasubbarao@yahoo.com

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Quality of Life of Patients with Renal Calculi: An Observational Research

R. Ranjith Kumar, Samiha Shah Khan, Md. Mohasin Pasha, Sreenivas Pasula, Bolay Bhattacharya*

Geethanjali College of Pharmacy, Hyderabad-501301, India

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Corresponding Author:
E-mail : balay.ju@gmail.com
Mob.: +919703268291

Abstract

Kidney stones are responsible for about 3.66 million medical consults each year with treatment costing about $2 billion annually in medical bills. The main objective of the study was to analyze the quality of life of patients by existing renal calculi. The study would be focused on providing better therapeutic, cost-effective and safe treatment in renal calculi patients. The study was conducted in a urology department of Tulasi Multi-Super Speciality Hospitals (300 bedded hospital), ECIL 'X' Road, Hyderabad, India. This study was conducted on 60 patients to study the quality of life of patients with renal calculi for the duration of 6 months. We collected information from patients from 10-80 years of age. For our logical and rational observational study, divided the patient in different age groups, male-female, alcoholic-nonalcoholic, working-nonworking, vegetarian-nonvegetarian, married-unmarried etc. Through our observational study we can reach to a logical conclusion that smoking, alcoholism etc. adversely affects the quality of life of patients of renal calculi. Moreover, vegetarian diet may also indirectly help to improve the quality life of the patients with renal caliculi. Finally, it was found that, if the patient leads hygienic and disciplined life quality of such patients will be somewhat better. If situation permits and open surgery can be avoided by using medicines, modern approach of therapy or modern better surgery, quality of life of patients with renal caliculi will be somewhat better.

1 Introduction

The kidneys are a pair of bean shaped, red-brown organ, whose function is to dispose of the waste matter produced by the normal functioning of the body and to keep the salts and water of the body in the correct balance.

Each kidney is joined with the ureter, the tubes that conduct urine to the bladder. At the centre on one side of each kidney is an indentation known as the renal hilus, the exit point for the ureter and the location where nerves, blood and lymphatic vessels enter and exit. Enclosing each kidney is a protective membrane, the renal capsule.

Surrounding each capsule is a cushion of fatty tissue and a layer of connective tissue, which attaches kidney to the back of the wall of the abdomen. An adrenal gland sits on top of each kidney.

Each kidney has an outer layer – the cortex, an inner layer – the medulla, and a pelvis, a hollow inner structure that joins with the ureters. The renal medulla contains between 8 and 18 renal pyramids with a striped appearance. The pyramids are positioned with their tips, the renal papillae, facing towards the renal hilus and their bases aligned with the edge of the renal cortex. The cortex continues in between each pyramid creating areas known as renal columns.

The functional units of the kidneys are microscopic structures called nephrons, of which there are estimated to be 1.2 million in each kidney. Each nephron has a renal corpuscle, which lies in the renal cortex, and a renal tubule which runs through a renal pyramid. The renal corpuscle is comprised of an extensive ball shaped capillary network called the glomerulus surrounded by a double walled cup of epithelial tissue- the glomerular or Bowman's capsule. Together, these structures filter the blood,

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PREPARATION AND EVALUATION OF BETAMETHASONE DIPROPIONATE CREAM: MULTI EMULSION A NOVEL APPROACH

RESEARCH ARTICLE

S. S. RAJU[1], T. MANGILAL[1], I. BISWAL[2], B. SWATHI[2], A. DINDA*[2]

[1]Geethanjali Collage of Pharmacy, Hyderabad, Telangana - 501301, India.

[2]Gyan Jyothi College of Pharmacy, Hyderabad, Telangana - 500098, India.

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ABSTRACT

Betamethasone dipropionate cream was prepared by using multiple emulsion technique. Cream was characterized for determination of pH, drug content uniformity, viscosity, spreadibility, tube extrudability, stability studies, in-vitro drug release, infrared spectral analysis, primary skin irritation test on laboratory experimental animals. The pH of formulations was found to be 6.1-6.3. Viscosity was determined by Brookefield viscometer and the non-newtonian flow was observed. The cream when applied to skin was able to spread easily on surface. The cream was extruded easily from the tube. The stability studies was carried out for a period of one month and analyzed for physical appearance, rheological properties which were found to be effective. From the IR spectral analysis, it was found that there is no major shifting of peaks confirming no drug excipient interactions. A skin irritation study for the prepared cream was done on animals which showed non-irritant effect on skin. From the study it may be revealed that betamethasone dipropionate multiple emulsion cream formulation should be useful for treatment of skin psoriasis, can be easily washed by water with increased patient compliance.

Key words: *Cream, Betamethasone, psoriasis, in-vitro drug release.*

INTRODUCTION

Discovery of a new chemical entity that exerts pharmacological effects for curing or treating diseases or relieving symptoms is only the first step in the drug developmental process. Topical semisolid dosage forms are normally presented in the form of creams, gels, ointments and pastes [1]. They contain one or more active ingredients dissolved or uniformly dispersed in a suitable base and any suitable excipients such as emulsifiers, viscosity increasing agents, anti-microbial agents, antioxidants, or stabilizing agents. Creams are homogeneous, semi-solid preparations consisting of opaque emulsion systems [2]. Their consistency and rheological properties depend on the type of emulsion, either water-in-oil (w/o) or oil-in-water (o/w) and on the nature of the solids in the internal phase [3]. Creams are intended for the application to the skin or certain mucous membranes for protective, therapeutic, or prophylactic purposes, especially where an occlusive effect is not necessary. For enhanced penetration of topical drugs, occlusion of skin is the prime criterion [4]. This requirement can be achieved easily by the incorporation of large quantities of fats and oils, especially liquid and semisolid paraffin. In the present study a cream containing betamethasone dipropionate for treatment of skin psoriasis was prepared by multi emulsion method to obtain a high degree of occlusivity with smooth, flexible films and easily washable cream.

MATERIALS AND METHODS

Materials:

Betamethasone Dipropionate was received as a gift from GVK Pharmaceuticals, Hyderabad, Borax (BDH labs, England), Acetone (BDH Labs, England), Bees Wax (Kukdong oils and chemicals, Korea), Liquid Paraffin (Kukdong oil and chemicals, Korea), De-ionized water (Medilines Diagnostic division).

Corresponding Author: A. Dinda*[2]
[2]Gyan Jyothi College of Pharmacy, Hyderabad, Telangana - 500098, India.

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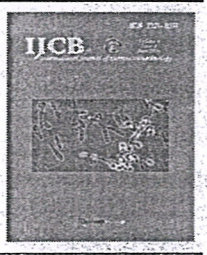

Prevalence of Dermatophytes and other Keratinophilic Fungi from soil of playgrounds and public parks of Hyderabad, India.

Kalyani Jatoth[1]*, T Mangilal[2] and Sunil Junapudi[3]

[1]Department of Microbiology, Chandralabs, IDA prasanthi nagar,kukatpally, Hyderabad Telangana, India.
[2]Department of Pharmacy, UCT, Osmania University, Hyderabad, Telangana, India.
[3]Department of Pharmaceutical Chemistry, Geethanjali college of Pharmacy, cherryal, keesara, Ranga Reddy District, Telangan, India.

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Keratinophilic fungi, Dermatophytes, Hyderabad soils, *Chrysosporium indicum*, hair baiting technique.

ABSTRACT

Dermatophytes, related keratinophilic fungi were isolated from isolated from different locations in Hyderabad (Public parks, playgrounds, Zoological park- in and around animal and Bird enclosures). These samples were screened by using hair baiting techniques for isolation. Out of a total 60 samples, 52 (86%) were positive for growth of keratinophilic fungi. Eleven genera and 19 species were isolated and identified, of which *Chrysosporium indicum* (33.33 %) the most predominant species was isolated followed by *C.tropicum* (28.33%), *Aspergillus flavus* (25%), *Microsporum gypseum* (16.6%) and *Trichophyton terrestre* (11.6%). Garden soils, followed by playground soils were found to be the most suitable for fungal growth. Some of the other fungi isolated were C.zonatum , Alternaria alternata, Aspergillus niger, Aspergillus terreus, Fusarium moniliforme,F.solani ,Aphanoascus fulvescens etc. To our knowledge, this appears to be the first report concerning the isolation of keratinolytic fungi *M. canis* and *Trichophyton terrestre* from soils of Hyderabad by hair baiting technique.

Introduction

Keratinophilic fungi are significant economically and play important function in natural degradation of keratinous substrates. Soils that are rich in keratinous materials are the majority conducive for the growth and occurrence of keratinophilic fungi. Their sharing is changeable with the environment and depends on different factors, such as human and or animal presence. Keratinous substances which are important natural material, happening in nature mainly in the form of hairs, wools, feathers, horns, hooves, nails, skin and other cornified appendages constitutes natural baits for these fungi (Khanam and Jain , 2002). More than a few researchers have studied soil mycoflora with value to keratinophilic fungi in the past few decades (Al-Musallam 1988; Augt, 1995; Caglar, 2006; Deshmukh, 2008; Garg, 1985; Min, 2011; Ulfig, 1995). Keratinophilic fungi include a variety of filamentous fungi, mainly comprising hyphomycetes and several other taxonomic groups. Hyphomycetes include dermatophytes and a great variety of non dermatophytic filamentous fungi (Mukesh and Sharma, 2010).The majority of dermatophytes can live saprophytically and every keratinophilic fungi can be considered as a potential pathogen. Dermatophytes cause human and animal mycoses and thus have drawn the attention of medical and veterinary epidemiologists (Marcella and Mercantini, 1986). Keratinolytic fungi are a group of microorganisms that are able to decompose keratin remains in environment and are pathogenic to humans and animals. These fungi exist in communities together with keratinophilic fungi that have weaker affinity to keratin and utilize chiefly the products of its decomposition (Dominik and Majchrowicz, 1964). based on their occurrence in natural habitat, kertainophilic fungi are divided into three categories: Anthropophilic, when human beings are the natural hosts. Zoophilic, when a variety of animals act as natural hosts. Geophilic, when the soil is the natural habitat (Ali-Shtayeh, 1989; Neetu, 2011; Piontelli, 1990; Vollekova, 1992).

Hence it will be significant to analyze and identify the mycoflora of school playgrounds, public parks and Zoo in order to evaluate the presence of keratinophilic fungi and dermatophytes in these environments. This paper, reports on the prevalence of keratinophilic fungi and its related dermatophytes in the soils of Hyderabad, India. This would help us know, the distribution and occurrence of dermatophytes and other keratinophilic fungi; it will also through light on the risk of human dermatophytosis in these regions.

*Corresponding author.
Email address: telavathe@gmail.com
Mobile: +918897724262

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STUDY OF QUALITY OF LIFE OF PATIENTS WITH RENAL CALCULI

SURYAWANSHI HARINATH
National Institute of Pharmaceutical Education and Research NIPER-Kolkata, West Bengal, India

Dr. TEELAVATH MANGILAL
University College of Technology, Osmania University, Hyderabad, Telangana, India
Email ID: teelavath@gmail.com

Abstract

Kidney stones are responsible for about 3.66 million medical consults each year with treatment costing about $2 billion annually in medical bills. The main objective of the study was to analyze the quality of life of patients by existing renal calculi. The study would be focused on providing better therapeutic, cost-effective and safe treatment in renal calculi patients. The study was conducted in a urology department of Medcity Multi-Super Speciality Hospitals (400 bedded hospital), Medchal, Hyderabad, India. This study was conducted on 80 patients to study the quality of life of patients with renal calculi for the duration of 5 months and collected information from patients from 20-80 years of age. Divided the patient in different age groups, male-female, alcoholic-non alcoholic, working-nonworking, vegetarian-non vegetarian, married-unmarried and concluded that smoking, alcoholism etc. adversely affects the quality of life of patients of renal calculi. Moreover, vegetarian diet may also indirectly help to improve the quality life of the patients with renal calculi. Finally, it was found that, if the patient leads hygienic and disciplined life quality of such patients will be somewhat better.

Keywords: *Renal calculi, Red brown organ, ureter, urinary bladder and renal hilus.*

Introduction

The kidneys are a pair of bean shaped, red brown organ, whose function is to dispose of the waste matter produced by the normal functioning of the body and to keep the salts and water of the body in the correct balance. The kidneys are located at the back of the abdomen, one on each side of the spine, at the level of the lowest ribs. Because of the position of the liver, the right kidney is located slightly lower than the left. Each kidney is joined with the ureter, the tubes that conduct urine to the bladder. At the centre on one side of each kidney is an indentation known as the renal hilus, the exit point for the ureter and the location where nerves, blood and lymphatic vessels enter and exit. Enclosing each kidney is a protective membrane, the renal capsule. Surrounding each capsule is a cushion of fatty tissue and a layer of connective tissue which attaches kidney to the back of the wall of the abdomen. An adrenal gland sits on top of each kidney[1].

The bladder muscle (detrusor muscle) is capable of distending to accept urine without increasing the pressure inside; this means that large volumes can be collected (700-1000 ml) without high-pressure damage to the renal system. When urine is passed, the urethral sphincter at the base of the bladder relaxes, the detrusor contracts, and urine is voided via the urethra[2].

Structure of the Kidney

Each kidney has an outer layer – the cortex, an inner layer – the medulla, and a pelvis, a hollow inner structure that joins with the ureters. The renal medulla contains between 8 and 18 renal pyramids with a striped appearance. The pyramids are positioned with their tips, the renal papillae, facing towards the renal hilus and their bases aligned with the edge of the renal cortex. The cortex continues in between each pyramid creating areas known as renal columns[3].

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Research Article

Evolution of Anti-Inflammatory Activity of Aqueous Methanolic Extract of *Basella alba* on Wistar Alibino Rats

Naidu Narapusetty *[1], Konda Ravi kumar [2], R. SivaKumar [3], L. Ramachandra reddy [3], Ch. M.M. Prasada Rao[3], Gondu Eswara Rao[4], Fredipaul Chlukoti[5]

*1. Department of Pharmacology, Bellamkonda Institute of Technology & Sciences, Podili, India.
2. Department of Pharmaceutical Chemistry, Hindu college of Pharmacy, Amaravathi road, Guntur, India.
3. Department of Pharmacogonosy & Phytochemistry, QIS College of Pharmacy, ongole-523272, India.
4. Department of Pharmaceutical Chemistry, Vignan Pharmacy College, Vadlamudi, Guntur Dt. - 522213, India.
5. Department of Pharmacy, Monroe College, New Rochelle, Newyork-10801, United States of America.

***Corresponding author's E-mail:** narapusetty.naidu@gmail.com

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ABSTRACT

The present study is carried out to investigate the anti-inflammatory potential of aqueous Methanolic extract of *Basella alba* (BA). Anti-inflammatory activity was evaluated by using Egg Albumin, Turpentine Oil & Formaldehyde as phlogistic agents. The animals were treated with doses 250mg/kg and 500mg/kg of extract and Diclofenac Sodium at a dose of 10mg/kg is used as a standard drug. The BA showed a significant anti-inflammatory activity in a dose dependent manner in all the models when compared with the standard treatment. The extract (500mg/kg) exhibited maximum anti-inflammatory activity i.e., 46.26%, 44.34%, 46.38% (P<0.001) like standard Diclofenac 47.03%, 46.54%, 48.55% in Egg albumin, Turpentine oil and Formaldehyde induced methods respectively. Based on the above results, we conclude that the BA has significant anti-inflammatory activity and might prove efficacious for further design and development of agents with significant biological activity.

Keywords: *Basella alba*, anti-inflammatory activity, phlogistic agents.

INTRODUCTION

Herbal therapy is also known as herbalism, which play a major role in treatment of so many diseases in so many countries & in traditions[1]. Inflammation is a complex process, which is frequently associated with pain and involves occurrences such as: the increase of vascular permeability, increase of protein denaturation and membrane alteration. When tissue cells become injured they release kinins, prostroglandins and histamine[2]. Rheumatoid arthritis a ravaging disease is a major public health burden in about 1% of the population worldwide. As the currently used drugs are associated with severe side effects, the urge to develop new chemical entities with potent biological activity from natural sources with lesser side effects has become mandatory. Traditional medicine using plant extracts continue to provide health coverage for over 80% of the world's population especially in developing countries[3]. Many medicinal plants have been investigated for novel drugs or templates for the development of new therapeutic agents[4]. Various species from the *Genus alba* have been reported to possess anti-inflammatory activity.

The childhood arthritis is the fifth most common chronic disease of the childhood and the most common of the paediatric rheumatic disease, affecting as many people in America. Despite of the use of the conventional methods in pain management, persistent pain continuous to be predominant problem in children.[5] The aim of the present study was to identify the identify the anti-inflammatory activity of the plant extract in animal models and to identify the better molecule which useful to human use.

Basella alba (Telugu: *bachhali*; Family: *Basellaceae*) is a vine spinach, leaves are thick, rugose, succulent and green to purple colour. Basella Alba is advantageous for treating Ulcers and Abscesses, Rheumatic pain and Swellings[6]. Medicinal plants contain numerous biologically active compounds such as carbohydrates, proteins, enzymes, fats and oils, vitamins, alkaloids, quinines, terpenoids, flavonoids, carotenoids, sterols, simple phenolic glycosides, tannins, saponins, polyphenols etc. Basellaalba contains Vitamin A, Vitamin E, Vitamin K, flavonoids, saponins and β- Carotene. The plant is reported to treat against laxative, rubefacient, skin diseases, burns, ulcers, diarrhoea, diuretic[7] and cancer. The present study was under taken to evaluate anti-inflammatory activities of aqueous Methanolic leaf extract of *Basellaalba.*

MATERIALS AND METHODS

Collection of Plant Material & Extraction

The leaves of Malabar spinach were collected from surrounding villages of Kakinada A.P. The plant authentication was done by Dr. A. Srinivasa Rao, Dept. of Botany, P.R Degree College, Kakinada, East Godavari District, Andhra Pradesh, India & the voucher was preserved. The plant material was thoroughly cleaned, shade dried at room temp. for 23 days & then pulverized to a coarse powder and shifted. 80% Methanol was added to coarsely powered (2kg) plant material & extracted by

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DOCKING, SYNTHESIS AND EVALUATION OF ANTIOXIDANT ACTIVITY OF 9-(PIPERAZIN-1-YL) ACRIDINE DERIVATIVES FROM 2-[(4-METHYL-2-NITROPHENYL) AMINO]BENZOIC ACID

R. Sivakumar*, Ch. M. M. Prasada Rao and K. Durga Prasad

Department of Pharmaceutical Chemistry, QIS College of Pharmacy, Vengamukkapalem, Pondur Road, Prakasam Dt, AP 523 272.

***Corresponding Author: R. Sivakumar**

Department of Pharmaceutical Chemistry, QIS College of Pharmacy, Vengamukkapalem, Pondur Road, Prakasam Dt, AP 523 272.

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ABSTRACT

A series of nitrogen-containing heterocyclic compounds such as substituted 9-(piperazin-1-yl) acridine derivatives were synthesized by [(4-Methyl-2-nitrophenyl) amino] benzoic acid, phosphorus oxychloride, piperazine, dichloro methane evaluated for their antioxidant activity by DPPH method. Among the screened compounds, electron rich acridine exhibited significant antioxidant activities. The *in vitro*. Molecular docking results shows that the compound CP-05(*2-methyl -4-nitro-9-[(4-benzyl) piperazin-1-yl] acridine*) shows siginificant anti oxidant activity than compare with the standard compound α-Tocopherol. In all the synthesized compounds, CP-05 shows best binding energy and IC 50 value -9.27 Kcal/mol and 155.03 nano molar concentration respectively. The compound CP-05 shows molecular interactions like H-Bonds ASN10; ASN59; GLY60 and Pi-Bonds at ASP27; ASN59; PRO89; ALA92; PRO187. The ADME results of the compounds obeys Lipinski rule of five and the compounds shows the low Mutagenic and no toxicity shows on Tumerogenic, Effect on Reproductive system, Eye Irritant.

KEYWORDS: acridine derivatives, phosphorus oxychloride, anti oxidant activity, DPPH method, Molecular docking.

INTRODUCTION

The cytochrome P450 (CYP) enzymes are heme-thiolate enzymes involved in the metabolism of a large number of exogenous molecules (natural products, drugs, and environmental carcinogens) and endogenous compounds such as hormones. The human CYPs are encoded by 57 genes[1] and are classified into four classes. The Class I and Class II CYPs (majority of the CYPs) are versatile monooxygenases catalyzing a large number of reactions such as conversion of alkenes to epoxides, alkanes to alcohols, arenes to phenols, and oxidation of sulfides. CYP enzymes belonging to the 1, 2 and 3 CYP families have been found in healthy and cancerous hepatic tissues.[2,3] The metabolism of carcinogens, pro-carcinogens, and chemotherapeutics by CYPs gives them an indisputable role in the cancer prevention and treatment strategies. CYPs 1B1 and 2W1 are indeed expressed specifically in tumors.[4–9] Numerous studies have implicated a role for CYPs in tumor formation and development.[4,5,10–14] Inhibition of CYPs is a widely pursued area of research for the treatment and prevention of cancer.[15,16] The CYP enzymes can be targeted by small molecules as delineated in three strategies: (1) inhibit the enzyme through competitive inhibitors; (2) inhibit the enzyme through mechanism-based inhibitors that result in the modification of the enzyme; and (3) design prodrugs that are activated by the CYPs. Intense effort is ongoing by many research groups to find specific and potent CYP inhibitors for the individual members of the CYP superfamily. Understanding the key structural features of the inhibitors responsible for their inhibition potency has been essential for CYP inhibitor design and development. Computational methods such as docking studies, and quantitative structure activity studies (QSAR) have been extensively employed toward this end as outlined in various review articles.[17–24]

Nitrogen containing heterocyclic compounds especially acridine compounds are indispensable structural subunit in many polycyclic natural products[25] and various medicinal leads.[26] Differently substituted acridine moieties are known to show antiedema, anti-inflammatory[27], antibacterial[28], analgesic[29], anticancer[30-31], activities and COX-2/LOX inhibitor. In the view of the facts mentioned above, free radical scavenged antioxidant activity of substituted imidazole is considered relevant. Highly reactive free radicals and oxygen species are present in biological systems from a wide variety of sources such the regular metabolism or external sources.[32,33] The action of free radicals is counteracted by free radicals endogenous or exogenous or synthetic route. Reactive oxygen species (ROS) such

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Nine - Piperazinyl Acridine Derivatives - A Novel Class of Antibacterial Agents

Sivakumar. R[1]* and Kasthuribai. N[2]

1Department of Pharmaceutical Chemistry, QIS College of Pharmacy, Ongole, Prakasam District -523 272, Andhra Pradesh, India.

2Pharmacognosy Division, Interdisciplinary Institute of Indian System of Medicine (IISM), SRM University, Kattankulathur 603 203, Tamil Nadu, India.

*Correspondence to : rsiva.chemist@gmail.com

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ABSTRACT

A novel series of 9-piperazinyl acridine derivatives were synthesised and characterised by IR, 1H NMR. 9-chloroacridine, 9-piperazin-1-yl acridine and their substituted compounds with varied substitutions were evaluated for in vitro antibacterial activity by measuring the minimum inhibitory concentration, all the derivatives exhibited significant to moderate antibacterial activity. This introductory research on 9-piperazinyl acridine derivatives, paves way for advanced mechanism antibacterial studies.

Key words: N-Phenylanthranilic acid, 9-piperazinyl acridine, antibacterial activity, benzyl derivatives, minimum inhibitory concentration

INTRODUCTION

Momentous attempt continues to be dedicated to the research, development and trade of novel antibacterial agents. Increasing problem of drug resistance by the existing class of pharmaceutical has imposed an urge in the exploring of novel chemical classes as anti-bacterial agents. Though novel target based inhibitory chemical classes have emerged, they failed in the clinical trials, due to lack of knowledge in the structural activity relationship of the drug[1]. Synthesis of acridine and their derivatives has attracted substantial attention from organic and medicinal analysts for countless years, since most of the natural sources have been proclaimed to acquire this heterocyclic nucleus[2]. Acridine is an alkaloid from anthracene. Commonly, known by the names of dibenzopyridine, 2,3,5,6-dibenzopyridine and 10 azaanthracene. Salts of acridine exhibits blue fluorescence[3].

In the present arena, enormous increase in drug resistance for bacterial infections has attracted the consideration towards acridine and its derivatives for novel therapeutic leads. During the last 20–30 years a large number of derivatives belonging to the general class of aniline acridine have been prepared and evaluated extensively as anti-malarial[4,5], anti-inflammatory [6], antimicrobial [7] and anticancer [8,9,10] and antibacterial agents [11,12].

Inspired by the wide range of versatile chemotherapeutic activities of acridine, a significant amount of research activity has been directed toward this class in recent years. Hence the present work describes methods for the synthesis of novel substituted acridine derivatives as antibacterial agents. Characterization of the synthesized compounds was carried out using Infrared spectroscopy and NMR interpretations. Anti-bacterial potential has been studied based on the minimum inhibitory concentration in accordance with the standard drug.

2. Experiment

All chemicals used were of reagent grade and purified as per need of the reaction. Progress of the reaction was monitored by TLC using hexane:ethylacetate (7:3)

Research Article

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Preparation of Bosentan extended release matrix tablets with different viscosity grades of Ethylcellulose polymers

[1] Narender K*, [1] Narayana Raju P and [2] Shivakumar R.

Malla Reddy Institute of Pharmaceutical Sciences, Maisammaguda, Secunderabad, Telangana, India.

QIS College of Pharmacy, Vengamukkaplem,Ongole, Prakasam District, Andhra Pradesh, India.

* Corresponding Author: E-Mail: narenderreddy.karra@gmail.com

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ABSTRACT

In the present study oral extended release matrix tablets of Bosentan were formulated, characterized and evaluated for in vitro dissolution. The matrix tablets were prepared using different viscosity grades of Ethyl cellulose such as EC N 7, EC N 50, and EC N 100 as the release rate retardant polymers. The tablets were characterized for physical properties, in vitro dissolution, accelerated stability (40°C ± 2°C and 75 ± 5% RH) testing. In vitro studies revealed that the release rate decreased with increase in polymer concentration, polymer viscosity. The drug release from the matrix tablets followed diffusion mechanism. Comparable correlation of in vitro drug release was observed in the initial and accelerated stability samples of Bosentan matrix tablets prepared with Ethyl cellulose. DSC and FT-IR spectra of initial and stability samples showed good drug-excipient compatibility in the formulations. The developed extended release matrix tablets of Bosentan were stable up to 6 months. The release of the matrix tablets for prolonged periods of time employing Ethyl cellulose as drug rate retarding polymers could be advantageous than conventional Bosentan tablets. The study could be extended for bioavailability studies in clinical subjects.

Keywords: Bosentan, Ethyl Cellulose, Controlled release, Matrix tablets, Stability.

1. INTRODUCTION

Sustained release dosage forms are designed to complement the pharmaceutical activity of the medicament in order to achieve better selectivity and longer duration of action. Sustained release preparations are helpful to reduce the dosage frequency and side effects of drugs and improve patient's convenience. Sustained release matrix tablet is relatively easy to fabricate by incorporating drug molecules in slowly disintegrating or inert porous materials. The most commonly used method of modulating the drug release is to include it in a matrix system [1,2].

Bosentan is a dual endothelin receptor antagonist used in the treatment of pulmonary artery hypertension (PAH) to decrease the rate of clinical worsening in patients with WHO Class III or IV symptoms and to improve exercise ability. Endothelin-1 (ET-1) is a neurohormone and its effects are mediated by binding to ETA and ETB receptors present in the endothelium and vascular smooth muscle. Patients with pulmonary arterial hypertension have elevated levels of ET-1 concentrations in plasma and lung tissue. Bosentan acts as a specific and competitive antagonist of endothelin receptor types ETA and ETB. Bosentan has higher affinity for ETA receptors than for ETB receptors. Route of elimination of Bosentan is by biliary excretion followed by metabolism in the liver. The drug has half life of 5 hours and hence required to administer frequently to maintain the constant plasma concentration. [3-5].

2. MATERIALS METHODS

2.1. Materials

Bosentan was used as active ingredient. Different grades of Ethyl cellulose like EC N 7, EC N 50 and EC N 100 were used as the polymers obtained from DOW chemical company. The other ingredients used were microcrystalline cellulose, magnesium stearate, aerosol were obtained as gift samples from Lupin Laboratories. All reagents used were of analytical grade.

Influence of Pharmaceutical Imports into India-An Overview

Dr. Bayya Subba Rao

Abstract: *For a drug product to be imported or marketed in Indian territory, it is mandatory to have a prior permission from Drugs Controller General of India, Government of India. Schedule D, Y of Drugs and Cosmetic Act, 1940 puts forth the import legislation and its implementation is being monitored by DCGI and CDSCO of Health Ministry, Government of India. The current article is to analyse countries from which drug products are imported into India.*

Introduction

Drugs are imported into a country under circumstances where a country does not have manufacturing facilities, lack of technologies within the facilities, a innovator's patented product not manufactured within the country, competitive cheaper price, selected personal use of medicines, for conducting clinical trials, inherent with dangerous technologies, multiple step synthesis, Indian companies acquiring foreign facilities, establishing facilities in foreign countries, contract manufacturing, carbon count, drug product patented in India and cannot be manufactured in India, a foreign subsidiary company directly importing instead manufacturing, manufacturing within India with prior permission for conducting clinical trials, drug distributors, certain circumstances where a drug is not available for an orphan disease and is being imported, semi-synthetic drugs (involve with both synthetic and biotechnology processes), bi-lateral agreements, parallel imports, compulsory licensing etc. When a comparison of India's exports, imports and net total are observed, a positive balance towards exports was reported[1]. For the FY 2011, India's import of Medicinal and Pharmaceutical Products was US $ 2375.61 million.

Even though Foreign Direct Investment (FDI) exists in India since long time, current "Make in India" and "Startup" policies are promising indigenous manufacturing. It can also be assumed that under the said policies, some room is provided preventing hindering of manufacturing within India especially relating to innovator's patented products. The current article is aimed to identify the countries, drug products imported.

History

India is a rich source of natural herbs and since ages, Ayurveda system of medicine prevailed. As time passed, to meet market demands cultivation was initiated. Simultaneously, allopath system of medicine entered into India and the system dominated due to faster cure of ailments. At one stage, due to import of drugs, it is believed that drug prices in India were the highest amongst the countries in the World. To meet the demands, several foreign country pharmaceutical manufacturers established facilities in India and along with some indigenous companies, manufacturing was initiated in India. Drugs and Cosmetic Act-1940, The Pharmacy Act-1948 and The Patents Act-1970 are some of the legislations that brought establishment of regulatory bodies, monitoring of drugs, establishment of pharmaceutical education system and availability of cheaper drugs by implementation of process patent system within India. Currently, several legislations are updated, newly drafted/implemented. Indian Pharmaceutical Industry (IPI) had undergone a four phase infrastructure change to meet from local needs to international needs of pharmaceutical products. For instance, India is not within the ICH region but, Indian Pharmaceutical Industry is producing pharmaceutical products to meet the standards set forth for the region.

Methodology

All the available official data from DCGI/CDSCO was compiled and the data was made uniform. After treating multiple renewals as one, the data was subjected to removal of duplicates with

Professor, Department of Pharmaceutical Management & Regulatory Affairs, Geethanjali College of Pharmacy, Cheeryala, Keesara, Hyderabad, Telangana., **Email: drbayyasubbarao@yahoo.com.**

Article

An Overview of Compulsory Licensing in Pharmaceuticals

Pooja Aggarwal, Dr. Bayya Subba Rao*, Dr. M. Ravi Kumar
Faculty, Geethanjali College of Pharmacy, Cheeryala, Keesara, Hyderabad, Telangana.

Abstract

Members of World Trade Organisation are obliged for TRIPS and it directs in fulfilling the minimum criteria of infrastructure upgrade or vest new intellectual property legislations. TRIPS indicate an independent decision at the discretion of the country to issue compulsory licenses while simultaneous monitoring of anti-competitive licensing practices. Compulsory licensing is a provision that contradicts patents issued and an attempt is made in bringing awareness.

Keywords: Compulsory licensing, Pharmaceuticals, SWOT

Introduction

TRIPS agreement was a founding agreement when countries became members of World Trade Organisation (WTO) in 1995. At the fourth Ministerial Conference (2001) of WTO, the Doha Declaration on the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Public health was adopted[1]. TRIPS agreement comprises of seven parts with seventy three articles as guidelines for implementation and enforcement in the member countries. The agreement insists on national treatment, vest new or upgrade already existing legislations. While emphasizing the exclusivity provisions, TRIPS insists on institutional arrangements, protection of undisclosed information (trade secret/data exclusivity) with respect to local needs, role of judicial, custom authorities, conditions for civil/criminal proceedings, role of TRIPS council, co-ordination of WIPO and WTO etc. The current article is to emphasize the role of compulsory licensing.

Conditions for Compulsory Licensing:

For a better understanding, all possible conditions for opting compulsory licensing were categorized to the following options:

Option 1: An invention that was patented and is not worked, with high price not reachable to common man.

Option 2: An invention that was patented and is not manufactured within the country (or imported).

Option 3: An invention that was patented and the innovator is unable to fulfill the market demands.

Option 4: An invention that was patented and the product is required under national emergency/calamities/disease outbreak conditions, for the sake of public on non-commercial grounds.

Under such circumstances, after three years from date of grant, a third party can approach a patent office (especially for options 1, 2, 3) for grant of compulsory license provided the third party approached the patentee requesting for a patent licensing and failed.

Hence, a compulsory licensing mechanism is either initiated by the Government authority or by a third party. It is necessary to realize that a compulsory licensing mechanism is only for the country needs (local needs) but, certain circumstances may provide an option for manufacturing in one country and exporting into another country. In either of the conditions, it is necessary the compulsory license holder has to pay a proportional of royalty with respect to the business made. It is necessary that the compulsory license holder has to submit the amount of drug/drug product manufactured, amount for local needs and for export needs, total sale of product to the government authority and where ever needed to the patent holder.

Provision of License of Right

The concept of license of right comes into picture when the patentee wishes to lose right for exclusivity in return, the government waivers the maintenance fee. It is obvious that a patentee who has ample business over rides maintains exclusivity rights.

Case Studies where Compulsory/Voluntary Licensing issued:

For the national and international levels, several compulsory/voluntary licenses[2] were granted by various governments for local needs. Some of the countries include Argentina (Oseltamivir for Tamiflu), Brazil (Atazanavir, Efavirenz, Indinavir, Nelfinar, Lopinavir + Ritonavir, Tenofovir for HIV/AIDS), Canada (Ciprofloxacin for Anthrax), Ecuador (Lopinavir + Ritonavir for HIV/AIDS), Egypt (Sildenafil for NCD), Ghana (ARVs for HIV/AIDS), India (Imatinib Mesylate for Cancer), Indonesia (Lamivudine and Nevirapine for HIV/AIDS), Malaysia (Didanosine, Zidovudine, Lamivudine + Zidovudine for HIV/AIDS), Mozambique (Lamivudine, Stavudine, Nevirapine for HIV/AIDS), Rwanda (Lamivudine + Nevirapine + Zidovudine for HIV/AIDS), South Africa (Nivirapine, Lamivudine, Zidovudine, Stavudine, Didanosine, Efavirenz, Indinavir, Abacavir for HIV/AIDS), Taiwan (Ostamivir for Avian Flu/Pandemic Flu), Thailand (Efavirenz for HIV/AIDS; Lopinavir + Ritonavir, Clopidogrel for HIV/AIDS, CVS; Imatinib Mesylate for Cancer; Letrozole, Docetaxel, Erlotinib for Cancer), United States (Ciprofloxacin for Anthrax), Zambia (Lamivudine, Stavudine, Nevirapine for HIV/AIDS) and Zimbabwe (ARVs for HIV/AIDS).

The conditions clearly indicate critical life threatening diseases like cancer, HIV/AIDS to communicable diseases (national emergency conditions) like Flu, Anthrax to the local demands such as use of Sildenafil.

The cases clearly indicate for drugs that are expensive and not reachable to common man, lack of in house manufacturing facilities, unable to fulfill market demands, national emergency conditions, disease outbreaks, market demands etc.

In India, M/s. Natco Pharma Limited, Hyderabad has received the first ever compulsory licensing for indigenous needs upon fulfilling valid reasons. Indian patent office, has maintained strong grounds while granting compulsory licensing and rejected several applications on valid reasons.

Lead resources for initiating Compulsory Licensing Mechanism:

It is necessary to monitor the patents granted by various country patent offices and their working status. For instance, Indian Patent Office is releasing notices to the patent holders to update the working status of the granted patents. Such information usually provides an opportunity

*E-mail: drbayyasubbarao@yahoo.com

Article

An Analysis of Para IV Certifications of USFDA

A. Nagarani, M. Swathi, Dr. Bayya Subba Rao*
*Professor, Geethanjali College of Pharmacy, Cheeryal, Keesara, Hyderabad, Telangana State, India

Abstract:

Para IV certification filing at USFDA, for approval of generic or tentative needs through back ground of formulation technology knowledge, innovator's patented technologies and its drawbacks. A para IV challenge makes the entry of the generic or tentative drug product into the market before patent expiry. Such filings are usually made by high end generic industries. The current study is an analysis of various Para-IV filings at USFDA.

Introduction

Hatch-Waxman Act, commonly called as Drug Price Control and Patent Term Restoration Act, is a balance mechanism among the innovator, generic and the end user of medicines. The Act provides a provision of early entry of generic (or tentative) by filing a drug product application, claiming for challenging of the innovator's active patents[1]. The difference among ANDA and Tentative are identical and similar drug products respectively.

Filing a para IV certification indicates that the generic manufacturer is challenging his drug product technology with patented technology claiming as non-infringement. Usually, a para IV challenger claims the patented technology is invalid, obvious, mere commercial exploitation, guilty on disclosure of best mode, double patenting, limited use, lack of novelty etc. Unlike in India, the most critical aspect with US patent system is the exclusivity claim for a specific clinical condition use.

Methodology

Compiled and available Para IV certifications of USFDA was reprocessed and correlated with orange book for interpretations.

The most critical part in the analysis is not with relating to which product, which innovator company and which patent, but the applicant who has filed the challenge for the patent. Such information needs a thorough review from US court database, PACER. However, an attempt is made from US court of appeals database which has free access.

Analysis of Paragraph IV Certifications

Over all Certifications

A total of 1082 para IV certifications were submitted since 2001, taking into consideration as such the official data[2]. Among these, after fine tuning the data with respect to drug name, dosage form, innovator and the brand name of drug product, and after removal of 47 certifications due to ANDA withdrawal/exclusivity relinquished a final total of 832 certifications was observed.

Para IV Certifications (Year Wise)

Analysis, Table 1, indicates year wise number of certifications made at USFDA. Among the total 1082, the lowest (1) is observed in the year 2001 and the highest (97) is observed in the year 2008 with respect to the available data. It is necessary to understand that several drug products having different strengths being claimed for para IV certification.

Table 1: Year Wise Submission of Application with Para IV Certification (as on 22nd September, 2016)

Year	No. of Drug Products	Year	No. of Drug Products
2001	1	2011	63
2004	47	2012	60
2005	56	2013	59
2006	55	2014	55
2007	84	2015	62
2008	97	2016	19
2009	96	Prior 2009	3
2010	78	No data	247
		Total	1082

Para IV Certification (Type Wise)

A para IV certification filed by a generic applicant at USFDA is with respect to innovator's NDA or ANDA application. Analysis, Table 2, indicates that majority (1049, 97 %) of the para IV certification filings are with respect to NDA filings of the innovator.

Table 2: No. of Para IV Certifications w.r.t Innovator's Application Type (as 22nd Sep, 2016)

Innovator's Application Type	No. of Para IV filings
ANDA	6
NDA	1049
No Data	27
Total	1082

Time duration to file para IV Certification

In order to find out the duration taken by the generic applicant to file a para IV certification w.r.t innovator's drug product approval date, a compilation of USFDA para IV data and orange book data was made. From the compiled data, among the available dates, a difference of date of submission of para IV certification from date of approval of innovator's drug product was calculated. It has been observed that para IV certification filing ranges from [Minimum (14 days) to Maximum (28 years)], but on an average it has been observed that 5 ± 4.5 years to file a certification.

*E-mail: drbayyasubbarao@yahoo.com

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Role of Normal Error Curve in Pharmaceuticals

N.P. Sneha, K. Venu, R. Manohar, B. Gayathri & Dr. Bayya Subba Rao*

Abstract: *When a drug regulatory authority asks for statistics in a pharmaceutical manufacturing industry, it is not the previous batches data of the various attributes of a drug product indicating pharmacopoeial compliance but it is the establishment of statistical methods and ensuring the sample drawn from a batch is statistically significant with quality attributes for the entire batch. The current article is an attempt in establishing statistics at the root level limiting to production levels.*

Introduction:

Statistics are a compilation of numerical data of an attribute and analyzing for its significance. In majority of the circumstances, an attribute (parameter) with respect to a population falls under either binomial, poisson, normal, student t, F or Chi-square distribution (trend or curve) when plotted on a graph sheet. In several circumstances, the type of distribution depends on the sample size drawn from a population. If the sample size is large, the usual distribution is the normal, also called as Gaussian or the Normal error distribution/curve (Figure 1). For instance, during the tablet punching process, some of the tablets have very less hardness (brittle) and some of the tablets have very high hardness due to ware and tare of the machine during punching. When a sample of 1000 tablets (say) were checked for hardness, they have a trend of normal error curve for a large sample and a student t-curve for a small sample. Figure 1 illustrates a normal distribution where in the curve features with a central bell shape with either sides with tails. Similar to normal, a student t curve is observed with a difference of elongated two tails and slightly flattened at the bell.

Irrespective of a commodity, statistics are helping to ensure that a product available in the market is of standard quality based on the test conducted on a sample drawn from the population (say a batch of the product manufactured). Role of a statistical analysis is to ensure that a sample tested and its quality judged is whether significant or not with respect to the entire population/ batch. This means that, if several samples drawn from the same population do they fulfill the quality which is ensured by only one test conducted on a sample drawn from the population.

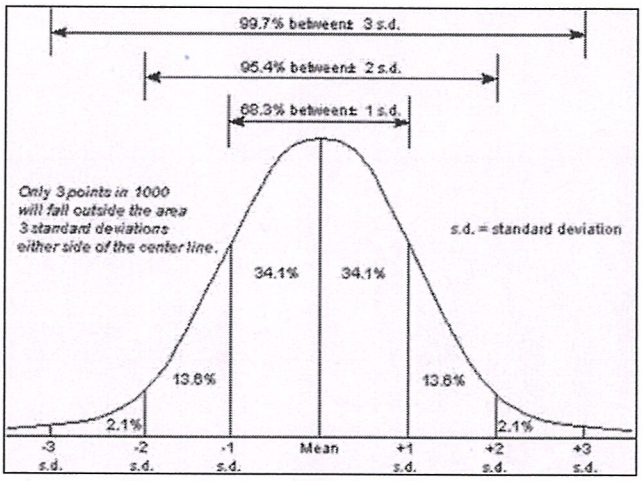

Figure-1

In pharmaceuticals, samples are drawn and analyzed for pharmacopoeial compliance. It is observed that pharmacopoeial parameters are statistical conclusions, but all pharmaceutical industries does not establish distribution curves for products and this can be further strengthened by drawing sample by statistical calculation and analyzing various pharmacopoeial parameters by statistical methods and drawing conclusion statistically. It is assumed that high end industries follow statistics and the current article is aimed for those industries who wish to initiate.

A question arises, whether is it possible to initiate? The answer is yes. This is because industries maintain quality data of past batches or an industry can freshly start with the current batch that is being manufactured. In case data is collected from past records, the data is called as retrospective data where as

Geethanjali College of Pharmacy, Cheeryal, Hyderabad, Telangana State., **Email: drbayyasubbarao@yahoo.com**

A Study on Identification of Attributes in Pharmaceuticals for Resolving the Issue of Zero-Defect

M. Swathi, A. Nagarani & Dr. Bayya Subba Rao*

Abstract: *As the word indicates occurrence of no defect in a product is called as zero-defect. Six sigma is an administrative strategy to minimize defective products while maintaining good communicative work atmosphere. Six sigma is a statistical model in which up to 3.4 defects in a million are considered acceptable. Disciplines other than pharmaceuticals especially the automobiles, food industry were found in succeeding the effect. The current article is to the international perspective, emphasizing pharmaceutical products and the reason behind various drug products were being recalled, with drawn from market upon notification by drug regulatory authority or voluntarily by the pharmaceutical company.*

Introduction

Pharmaceutical industries in the World are striving to release quality products into the market. Pharmaceutical industries maintain various nationally, globally accepted procedures and on day to day ensure through quality and assurance departments that products meet the standards and release the products into the market. It is believed that machinery of the pharmaceutical industry originated from food industry. Several high end technologies are making availability of products in the market with minimal defects in the products. In several cases, laser technologies, magnetic field, metal detectors are withdrawing defect products during the process from the batch and making the batch comply with the standards set forth.

In pharmaceuticals, drug products that proved pharmacopoeial standards are approved and released into the market. In such a case, the possibilities of errors have to be reviewed in the current context. In a broad sense, an error may be human, machine, intentional or un-intentional keeping apart the concept of counterfeit drugs (desperate intentional) from discussion. Systematic errors are found to occur either too high or too low and lack in accuracy and are believed to be not amenable to statistical treatment. Whereas the other non-systematic (or random errors) are found to occur sometimes larger or sometimes smaller and are believed to lack in precision and are believed suitable for statistical treatment. In a pharmaceutical industry, right from inception of the industry, especially high end industries, protocols such as installation, operational, performance, statistical validations are established for stable, repeatable manufacturing to achieve quality. Upon ensuring all the validation protocols periodically, only then a product is made available in the market. In such circumstances, how a defect product is seen in the market is the current point of question? This can be interpreted with several assumptions which have to be ensured with the industry in practical reality. In pharmaceuticals, statistics are being applied and this indicates that errors are occurring on random. Even though several precautions are taken, several product recalls, product withdrawals from the markets are witnessed. In the current article, a few drug regulatory authority databases were selected on random and an emphasis is made on various dosage forms and their causes of withdrawal, recall from market.

Observations from Drug Regulatory Authority Databases:

The databases clearly indicate that products either voluntarily, upon intimating by authority, upon receiving complaints of an incident were withdrawn from market. Industries voluntarily withdraw, recall products where there is a suspicion or have identified an accidental mistake in the manufacturing process. The following are some of the observations made and led to withdrawal of the product from the market:

Labeling errors, printing errors on labels/cartons, label mix up, label lacking Rx/warning symbol, tablet chipping, tablet breakages, discolourations, coloured spots on the tablets,

*Professor, Geethanjali College of Pharmacy, Cheeryal, Keesara, Hyderabad, Telangana State.

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PHYTOCHEMICAL STUDIES AND QUALITATIVE ANALYSIS BY TLC OF MURRAYA KOENIGII BARK EXTRACT

N. Anjaneyulu*[1], Tejasri Alla[2], Swetha Naram Reddy [2], A. Sai Ravali[1], Gopigari Nikitha[1], P.V. Srividhya[1] R. Sai Vinay[1]

[1]. Department of Pharmaceutical Analysis, Geethanjali College of Pharmacy, Cheryal (V), Keesara, Medchal Dist. Telangana, India.

[2]. Department of Pharmaceutical Chemistry, Anurag Group of Institutions, School of Pharmacy, Ghatkesar, Medchal, Telangana, India.

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Abstract:

Murraya koenigii is a medium size, ever green plant which has been utilized as a source of food, medicine, and other agricultural purposes in different communities. Thus, the preliminary phytochemical analysis and TLC separation was done using methanol, n-hexane, and ethyl acetate(1:3:1), as solvent system while iodine vapour as spotting agent. The phytochemical screening of diethyl ether extracts of bark revealed the presence of carbohydrates , anthraquinones glycosides ,saponins flavanoids, and alkaloids, while chloroform extracts of bark revealed carbohydrates, tannins, saponins, and alkaloids, while acetone extracts of bark revealed the presence of carbohydrates, anthraquinones glycosides, flavanoids and alkaloids,while ethanol extracts of bark revealed the presence of carbohydrates, tannins, anthraquinones glycosides,s aponins, flavanoids and alkaloids.TLC separation showed (3) spots each of Diethyl Ether, Chloroform, Acetone, Ethanol from bark extracts. From our findings, it can be concluded that Murraya Koenigii contains some significant phytochemicals that can exhibit desired therapeutic activities such as Antioxidant, Anti-Microbial, Anti-Fungal, Anti-Diabetic, Anti-Ulcer and Cosmetic use. However, there is a need to conduct further Pharmaceutical Analysis on test extracts in order to establish these biomedical applications.

Keywords: *Thin Layer Chromatography, Murraya koenigii Bark, Phytochemical screening.*

Corresponding Author:
Dr. N.Anjaneyulu, M.Pharm, Ph.D
Department of Pharmaceutical Analysis
Geethanjali College of Pharmacy,
Cheryal (V) Keesara (M) RR Dist,
Telangana, 501301
9959967431
dranji27@gmail.com
anjipharmcy@gmail.com

QR code

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STUDY OF THE CNS ACTIVITIES OF *MIMOSA PUDICA Linn.* IN ANIMAL MODEL

R. Naga Kishore*[1], A.Teja Sri[2], N.Anjaneyulu[1], Ch.Ramanikanth[1], A.Divya[1], K.Sainath[1] and L.Saneela Suri[1]

[1]Department of Pharmacology, Geethanjali College of pharmacy, Keesara, Medchal, Telangana, India.

[2]Department of Pharmaceutical Chemistry, Anurag Group of Institutions, School of Pharmacy, Ghatkesar, Medchal, Telangana, India.

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Abstract

*The present study was undertaken to evaluate the effects of CNS of Mimosa Pudica Linn. **Mimosa pudica** is a creeping annual or perennial herb of the pea family Fabaceae often grown for its curiosity value: the compound leaves fold inward and droop when touched or shaken, defending themselves from harm, and re-open a few minutes later. aqueous leaf extract of Mimosa Pudica suspended in water in presence of 3%v/v Tween-80 solution were administered orally. All the drugs were administered i.p for experimental purpose. Adult albino mice (25-30gms) of either sex were used for the study. The animals were divided into three groups containing of 6 animals of each group-1 received normal saline, group-2 received standard drug and group-3 received test drug aqueous extract of Plant extract (MP) maintained in a well-ventilated room with 12:12 hour light/dark cycle in polypropylene cages. Locomotor activity results showed that plant extract treated mice exhibited significant result when compared with that of standard in improvement of locomotor performance. Elevated Plus Maze is used to evaluate psychomotor performance and emotional aspects of rodents. Results showed that plant extract treated nice exhibited significant increase in the number of open arm entries. The number of arm entries, but decreases in time spent in closed arm reflects anxiolytic property. Rota rod test, the difference in the fall of time from the rotating rod between the vehicle and extract treated groups were taken as an index of muscle relaxation. Test drug showed significant decrease in the locomotory score and fall of time of the mice from the rotating rod. From the above observations we can conclude that aqoues extract of Mimosa pudica possesses significant CNS activities at both the dose level which is comparable with the standard.*

Keywords: *Mimosa Pudica, Actophotometer, Rotarod*

Corresponding Author:
R. Naga Kishore,
Department of Pharmacology,
Geethanjali College of pharmacy,
Keesara, Medchal, Telangana, India.
Email: r24kishore@gmail.com
Mobile number: +91 9908307838

QR code

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STUDY OF THE CNS ACTIVITIES OF *MIMOSA PUDICA Linn.* IN ANIMAL MODEL

R. Naga Kishore*[1], A.Teja Sri[2], N.Anjaneyulu[1], Ch.Ramanikanth[1], A.Divya[1], K.Sainath[1] and L.Saneela Suri[1]

[1]Department of Pharmacology, Geethanjali College of pharmacy, Keesara, Medchal, Telangana, India.

[2]Department of Pharmaceutical Chemistry, Anurag Group of Institutions, School of Pharmacy, Ghatkesar, Medchal, Telangana, India.

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Abstract

The present study was undertaken to evaluate the effects of CNS of Mimosa Pudica Linn. Mimosa pudica is a creeping annual or perennial herb of the pea family Fabaceae often grown for its curiosity value: the compound leaves fold inward and droop when touched or shaken, defending themselves from harm, and re-open a few minutes later. aqueous leaf extract of Mimosa Pudica suspended in water in presence of 3%v/v Tween-80 solution were administered orally. All the drugs were administered i.p for experimental purpose. Adult albino mice (25-30gms) of either sex were used for the study. The animals were divided into three groups containing of 6 animals of each group-1 received normal saline, group-2 received standard drug and group-3 received test drug aqueous extract of Plant extract (MP) maintained in a well-ventilated room with 12:12 hour light/dark cycle in polypropylene cages. Locomotor activity results showed that plant extract treated mice exhibited significant result when compared with that of standard in improvement of locomotor performance. Elevated Plus Maze is used to evaluate psychomotor performance and emotional aspects of rodents. Results showed that plant extract treated mice exhibited significant increase in the number of open arm entries. The number of arm entries, but decreases in time spent in closed arm reflects anxiolytic property. Rota rod test, the difference in the fall of time from the rotating rod between the vehicle and extract treated groups were taken as an index of muscle relaxation. Test drug showed significant decrease in the locomotory score and fall of time of the mice from the rotating rod. From the above observations we can conclude that aqoues extract of Mimosa pudica possesses significant CNS activities at both the dose level which is comparable with the standard.

Keywords: *Mimosa Pudica, Actophotometer, Rotarod*

Corresponding Author:
R. Naga Kishore,
Department of Pharmacology,
Geethanjali College of pharmacy,
Keesara, Medchal, Telangana, India.
Email: r24kishore@gmail.com
Mobile number: +91 9908307838

QR code

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Review Article

ROLE OF NANOBIOTECHNOLOGY IN PHARMACY AND MEDICINE: A REVIEW

Neeraja Podichety [1]*, Fatima Benazir [2], Parthasarathy Tigulla [3], Sudhakar Muvvala [4]
[1]Department of Pharmacy, University College of Technology, Osmania University, Hyderabad, Telangana, India
[2]Geethanjali College of Pharmacy, Cheeryal, Hyderabad, Telangana, India
[3]Department of Chemistry, Osmania University, Hyderabad, Telangana, India
[4]Department of pharmaceutics, Mallareddy College of Pharmacy, Maisammaguda, Secunderabad, Telangana, India
*Corresponding Author Email: neerajapodichety@gmail.com

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ABSTRACT

Nanobiotechnology is a term, which describes the combination of the two different worlds of engineering and molecular biology. It is a fusion of the following words: "nano" meaning very small, "bio" meaning living, and "technology" meaning use of tools. Tools and devices designed in nanobiotechnology applications are dependent directly on the current nanotechnology principles. In this review, the applications of nano biotechnology in various areas such as drug delivery, gene therapy, tissue engineering, molecular diagnostics and food safety are summarized. The multidisciplinary area of Nanobiotechnology has a powerful impact in various disciplines of scientific fields. It provides opportunities to develop new materials and techniques that improve the ability for developing quick, sensitive and reliable analytical techniques.

Key words: Nanobiotechnolgy, nanoparticles, nanobiology, nanomedicine, drug delivery and biotechnology

INTRODUCTION

Nanobiotechnology, a unique merger of nanotechnology and biotechnology is defined as the design, development and application of nanomaterials & devices to deal with functional processes of biological agents like microorganisms[1]. The field of nanobiotechnology is expected to have exponential growth and development in the future.

By this methodology, atom or molecule level devices can be constructed by incorporation of biological systems. Hence nanobiotechnology eases various aspects of biological sciences with the help of nanotechnology and information technology into biological problems. This technology has the potential to eliminate boundaries between different branches of sciences providing newer challenges and giving new directions in the field of research & diagnostics, education in the coming future[2].

Historical developments in the field of nanobiotechnology

The nanotechnological concepts were discussed for the first time in 1959 by physicist Richard Feynman during his talk "There's Plenty of Room at the Bottom". In this he described the different possible methods of synthesis by directly manipulating atoms. In 1974, Norio Taniguchi used the term "nanotechnology". With the invention of the scanning tunneling microscope in the year 1981, the visibility of individual atoms and bonds was clear. This has given the basics for manipulating individual atoms in the year 1989.

Harry Kroto, Richard Smalley, and Robert Curl, discovered Fullerenes in 1985 and received a Nobel Prize in Chemistry in 1996 for his work. Initially the term nanotechnology was used regarding subsequent work related to graphene tubes (also known as bucky tubes or carbon nanotubes) which has essential applications in designing nanoscale devices[3].

The National Nanotechnology Initiative (NNI) defines nanotechnology as research and development at the atomic level, molecular level, or macromolecular levels in the range of sub-100 nm for creating structures, devices, and systems that have novelty in their functional properties. At the nanoscale, manipulation of atoms was possible to create efficient materials with tailored parameters. By giving the inherent nanoscale properties to the biological tissues, it was evident that nanotechnology could be applied to the life sciences successfully. This has given rise to the term "nanobiotechnology", a unique fusion of biotechnology and nanotechnology[4].

Relation between nanobiotechnology and bionanotechnology

Nanobiotechnology, bionanotechnology, and nanobiology are the terms referring to the intersection of nanotechnology and biology. Nanobiotechnology uses advances in nanotechnology to improve biotechnology, and bionanotechnology aims to take advantage of natural/biomimetic approaches to create devices and tools of size in nanometers. Hence, both the technologies are co-related but complementary to each other[5]. Relation between nanobiotechnology and bionanotechnology is shown in Figure 1.

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Original Article

EVALUATION OF DIFFERENT CULTURE MEDIA FOR ENHANCED PRODUCTION OF *PSEUDOMONAS AERUGINOSA* (MTCC NO 2453) BIOMASS AND ITS PROTEINS

P. NEERAJA[a*], T. PARTHASARATHY[b], M. SUDHAKAR[c]

Department of Pharmacy, University College of Technology, Osmania University, Hyderabad, Telangana 500007, India, Department of Chemistry, Osmania University, Hyderabad, Telangana 500007, India, Department of pharmaceutics, Malla Reddy College of Pharmacy, Maisammaguda, Secunderabad, Telangana 500014, India
Email: neerajapodichety@gmail.com

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ABSTRACT

Objective: Microorganisms, especially bacteria and its proteins have proven to be potential anti-cancer agents as they selectively attack the tumor cells or tumor micro-environments. The extract of *Pseudomonas aeruginosa* found to contain proteins that have shown promising anticancer activity. In this work, it was attempted to increase the biomass and trigger the total protein fraction of *Pseudomonas aeruginosa* (MTCC 2453).

Methods: The organism was cultivated in three different such as Luria-Bertani (LB) broth, minimal medium9 (M9), super broth medium (SB) and asparagine-proline (AP) broth. Asparagine proline broth was selected as it has shown high cell growth rate. The media was further optimized by the addition of $NaHCO_3$ and copper sulphate to trigger the protein production. Optimized Aspergine proline broth has achieved highest cell biomass. After the shake flask culture, the overnight grown culture in optimized AP medium was further grown in a 5 L bioreactor by fed-batch cultivation to achieve higher cell densities.

Results: The highest protein production was achieved at 40 ° C. Highest biomass and protein content was observed at pH 8 while lowest biomass was produced at pH 2. A gradual increase in biomass content observed from 12 h towards to 48 h.

Conclusion: High biomass and proteins content and of *Pseudomonas aeruginosa* (MTCC 2453) can be produced in optimized asparagine-proline broth. Further the extract is purified to produce novel anti-cancer proteins.

Keywords: *Pseudomonas aeruginosa,* Anticancer activity, Bacterial proteins, Optimized media, Biomass and asparagine-proline broth

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INTRODUCTION

Today, cancer treatment is facing difficulties with secondary effects caused by standard therapies and affected by tumor cell resistance. There is no effective drug or vaccine exists to prevent cancer initiation, drug resistance and toxicity. Bacterial proteins are studied as one of the potential strategies to treat cancer.

Live, attenuated bacteria have shown the ability to act as anticancer agents [1]. But sometimes they may cause infections and cross contamination reactions. Bacterial proteins have been extensively studied as anticancer agents [2]. These proteins found to act on tumor cells specifically and cause tumor regression through growth inhibition; cell cycle arrest and apoptosis induction [3]. Protein from *Pseudomonas aeruginosa, Streptococcus pneumoniae, Corynebacterium diphtheria* and *enterococcus* sp. has exhibited prominent anti-cancer activity against human cell lines [4]. *Bacillus thuringiensis* found to contain a new anticancer protein [5].

Clostridium novyi demonstrated significant anti-tumor effects. *C. novyi* has also been investigated in conjunction with radiotherapy, radioimmunotherapy, and further chemotherapy in experimental tumor models. Protein such as *Pseudomonas* exotoxin, diphtheria toxin, and ricin may be useful in cancer therapy [8, 9].

The crude extract derived from *Pseudomonas* sp. isolated from soil in Greenland has shown promising antimicrobial and anticancer properties [10].

The extract of *Pseudomonas aeruginosa* found to contain proteins such as azurin that have shown promising anticancer activity. The cell growth and protein production by *Pseudomonas* is influenced by carbon, nitrogen sources and growth factors.

Pseudomonas aeruginosa contains largest genomes. This bacterium adapts to diverse ecological environments, ranging from water and soil to human bodies. *P. aeruginosa* possesses more complicated metabolic and protein sorting pathways than Gram-negative bacteria with smaller genome sizes. It contains genes involved in the expression of various proteins especially redox type which can act as prominent anti-cancer agents [11]. Unlike anticancer drugs that target a specific step in the cancer progression pathway, bacterial proteins target multiple steps in the cancer progression pathways, thereby interfering in cancer growth both *in vitro* and *in vivo*. Hence, in this work an effort was made to increase the biomass and total protein content of *Pseudomonas aeruginosa* extract by using different culture media and growth conditions.

MATERIALS AND METHODS

Materials

Bacterial strains (*Pseudomonas aeruginosa* MTCC 2453 collected from Microbial Type Culture Collection, Chandigarh, India), Components of culture medium for the cultivation of bacterial strains such as yeast extracts, peptone, potassium phosphate, sodium hydrogen phosphate, copper sulfate, potassium nitrate, sodium dodecyl sulfate, etc. Luria-Bertani (LB) broth, minimal medium9 (M9), super broth medium (SB), and asparagine-proline (AP) broth are used for the study.

Optimization of media

Pseudomonas aeruginosa (MTCC 2453) collected from MTCC, Chandigarh, India and cultivated in three different types of media. The media such as Luria-Bertani (LB) broth, minimal medium9 (M9), super broth medium (SB) and asparagine-proline (AP) broth were used for the study.

Preparation of inoculum and shake flask culture

The organisms were inoculated in 50 ml of LB medium in 250 ml Erlenmeyer flasks to prepare seed culture. It was incubated 37 °C for

Kalyani Jatoth, T Mangilal and Sunil Junapudi, Prevalence of Dermatophytes and other Keratinophilic Fungi from soil of playgrounds and public parks of Hyderabad, India. J.Curr.Biotechnol., 2016, 4(6):1-5.

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Prevalence of Dermatophytes and other Keratinophilic Fungi from soil of playgrounds and public parks of Hyderabad, India.

Kalyani Jatoth[1]*, T Mangilal[2] and Sunil Junapudi[3]

[1]Department of Microbiology, Chandralabs, IDA prasanthi nagar,kukatpally, Hyderabad Telangana, India.
[2]Department of Pharmacy, UCT, Osmania University, Hyderabad, Telangana, India.
[3]Department of Pharmaceutical Chemistry, Geethanjali college of Pharmacy, cherryal, keesara, Ranga Reddy District, Telangan, India.

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Key words:
Keratinophilic fungi, Dermatophytes, Hyderabad soils, *Chrysosporium indicum*, hair baiting technique.

ABSTRACT

Dermatophytes, related keratinophilic fungi were isolated from isolated from different locations in Hyderabad (Public parks, playgrounds, Zoological park- in and around animal and Bird enclosures). These samples were screened by using hair baiting techniques for isolation. Out of a total 60 samples, 52 (86%) were positive for growth of keratinophilic fungi. Eleven genera and 19 species were isolated and identified, of which *Chrysosporium indicum* (33.33 %) the most predominant species was isolated followed by *C.tropicum* (28.33%), *Aspergillus flavus* (25%), *Microsporum gypseum* (16.6%) and *Trichophyton terrestre* (11.6%). Garden soils, followed by playground soils were found to be the most suitable for fungal growth. Some of the other fungi isolated were C.zonatum , Alternaria alternata, Aspergillus niger, Aspergillus terreus, Fusarium moniliforme,F.solani ,Aphanoascus fulvescens etc. To our knowledge, this appears to be the first report concerning the isolation of keratinolytic fungi *M. canis* and *Trichophyton terrestre* from soils of Hyderabad by hair baiting technique.

Introduction

Keratinophilic fungi are significant economically and play important function in natural degradation of keratinous substrates. Soils that are rich in keratinous materials are the majority conducive for the growth and occurrence of keratinophilic fungi. Their sharing is changeable with the environment and depends on different factors, such as human and or animal presence. Keratinous substances which are important natural material, happening in nature mainly in the form of hairs, wools, feathers, horns, hooves, nails, skin and other cornified appendages constitutes natural baits for these fungi (Khanam and Jain , 2002). More than a few researchers have studied soil mycoflora with value to keratinophilic fungi in the past few decades (Al-Musallam 1988; Augt, 1995; Caglar, 2006; Deshmukh, 2008; Garg, 1985; Min, 2011; Ulfig, 1995). Keratinophilic fungi include a variety of filamentous fungi, mainly comprising hyphomycetes and several other taxonomic groups. Hyphomycetes include dermatophytes and a great variety of non dermatophytic filamentous fungi (Mukesh and Sharma, 2010).The majority of dermatophytes can live saprophytically and every keratinophilic fungi can be considered as a potential pathogen. Dermatophytes cause human and animal mycoses and thus have drawn the attention of medical and veterinary epidemiologists (Marcella and Mercantini, 1986). Keratinolytic fungi are a group of microorganisms that are able to decompose keratin remains in environment and are pathogenic to humans and animals. These fungi exist in communities together with keratinophilic fungi that have weaker affinity to keratin and utilize chiefly the products of its decomposition (Dominik and Majchrowicz, 1964). based on their occurrence in natural habitat, kertainophilic fungi are divided into three categories: Anthropophilic, when human beings are the natural hosts. Zoophilic, when a variety of animals act as natural hosts. Geophilic, when the soil is the natural habitat (Ali-Shtayeh, 1989; Neetu, 2011; Piontelli, 1990; Vollekova, 1992).

Hence it will be significant to analyze and identify the mycoflora of school playgrounds, public parks and Zoo in order to evaluate the presence of keratinophilic fungi and dermatophytes in these environments. This paper, reports on the prevalence of keratinophilic fungi and its related dermatophytes in the soils of Hyderabad, India. This would help us know, the distribution and occurrence of dermatophytes and other keratinophilic fungi; it will also through light on the risk of human dermatophytosis in these regions.

*Corresponding author.
Email address: telavathe@gmail.com
Mobile: +918897724262

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REVIEW ARTICLE

inventi | Spreading Knowledge

Talinum cuneifolium (vahl.) Willd (Portulaceae): Overview

Junapudi Sunil[1*, 2], Yasodha Krishna Janapati[3], Pallaval Veera Bramhachari[4]

Abstract: The Portulacaceae family is commonly used by many ethnic communities as traditional medicine all through the world. The maximum number of plants of the family is used in Indian traditional medicine. The ethnopharmacologial studies of this family indicate that plants of the family have antidiabetic, antibacterial, antifungal and antioxidant properties. Few reviews have been published yet, providing information regarding medicinal plants of the family and their biomedical properties. All published reviews have focused either on particular taxa or a few species. The present review is focused on the traditional medicinal uses of the plant, phytochemical properties and pharmacological studies of *Talinum cuneifolium (vahl.) Willd.* A study of the literature revealed significant traditional medicinal importance of the family. The most important property of plants of the family is antidiabetic activity and is shown by the large number of plant species studied. The reviews provide a ground for future research in *Talinum cuneifolium (vahl.) Willd.*

INTRODUCTION

The genus Talinum consists of approximately 500 species across the world. The family is cosmopolitan and it has 19 genera and more centered in South Africa and America. [1] *Talinum Cuneifolium (vahl.) Willd* native species growing in deciduous forests of Tirumala region. *Talinum Cuneifolium (vahl.) Willd* is a genus of shrubs comprising about 50 species. *Talinum Cuneifolium (vahl.) Willd* is a plant used in traditional medicine for the treatment of diabetic disorders and mouth ulcers by the tribals of Chittor district, Andhra Pradesh, India. [2] It is Perennial, suffrutescent, shrubby plant distributed from Rajasthan, India south wards in to the peninsular region; also found in Nepal. It is cultivated in Africa and, like spinach, is used as a vegetable. It is also said to be used as an aphrodisiac. [3] The leaf powder of *Talinum Cuneifolium (vahl.) Willd* mixed with leaf powder of *Gymnema sylvestre* is taken one spoon full in milk twice a day for 30 days was used in the treatment of diabetes mellitus. [4] The leaves of *Talinum Cuneifolium (vahl.) Willd* was used in stomach ache. The leaves part of *Talinum Cuneifolium (vahl.) Willd* used as a part of traditional medicine for the treatment of malaria in Uganda the leaves of *Talinum Cuneifolium (vahl.) Willd* was used in the treatment of mouth ulcers. Previous chemical studies on this species reported that leaves contain scopoletin, phytoconstitutents like tannins, phosphates, urea and various minerals with a larger amount of magnesium were identified from leaves of *Talinum Cuneifolium (vahl.) Willd.* [5]

Talinum Cuneifolium (vahl.) Willd. (Protulacaceae) is locally used as medicinal plants in Assam. Leaves and roots are used for treatment of diabetes, mouth ulcer, as aphrodisiac, in cough, gastritis, pulmonary tuberculosis, diarrhoea and stomachic. [6] The plant is rich in vitamin A and mineral content [7] and endowed with wide range of pharmacological activities. [8] The preliminary phytochemical analysis of this plant was carried out by various researchers from various parts of India. [9-11]

For the present review, information regarding medicinal of plants was gathered via searching books and scientific databases including Pub Med, Elsevier, GoogleScholar, Springer, etc.

TAXONOMY

Talinum Cuneifolium (vahl.) Willd. Synonyms were *Talinum portulacifolium* (forsk.) Asch. and Schwe.; Orygia *portulacifolia* forsk.; *Portulaca cuneifolia* Vahl.; Talinum indicum Wt. and Arn. [2, 18]

Erect herbs, Leaves alternate, 10 x 3.5 cm, obovate, cuneate, membraneous, emarginate at apex; leaf base decurrent to the petiole; petiole to 1.5 cm. Panicle terminal, to 15 cm; flowers pink; bracts lanceolate, 6 mm; pedicels to 1.5 cm; sepals 2, 6 mm, lanceolate; petals 5, I x 0.6 cm, (obovate; stamens many, filaments unequal, connate at the base; ovary 3-celled, globose, 2 mm, style 6 mm, stigma 3 fid. Capsule 6 mm across, globose. Flowering and fruiting June –December. [2, 18]

PHYTOCHEMISTRY

Talinum Cuneifolium (vahl.) Willd were subjected to preliminary phytochemical screening for the detection of various phytochemical constituents such as carbohydrates, proteins, amino acids, steroids, tannins, flavonoids, alkaloids, saponins, mucilage and glycosides. [12, 17]

PHARMACOLOGICAL ACTIVITIES OF *TALINUM CUNEIFOLIUM (VAHL.) WILLD*

Antibacterial and Antifungal Properties

Savithramma *et al.*, [8] antimicrobial efficacy of the plant was evaluated against three bacteria and two fungal species by disc diffusion method. Preliminary phytochemical screening was carried out among hexane, ethylacetate, methanolic extracts of leaf and root tuber for different potent chemicals. The leaf methanolic extract of *T. cuneifolium* showed maximum effect on the growth of Proteus (25.8 mm) followed by Bacillus (24.62 mm) and *E. coli* (19.42 mm). The tuberous methanolic extract of *T. cuneifolium* showed maximum effect on growth of Proteus

[1]Department of Pharmacy, Jawaharlal Nehru Technological University, Kakinada-533003, Andhra Pradesh, India.
E-mail: sunilpharma49@gmail.com
*Corresponding author

[2]Geethanjali College of Pharmacy, Cherryal, Keesara-501301, Ranga Reddy District, Telangana, India.

[3]Department of Pharmaceutical Chemistry, CHS, Mekelle University, Mekelle, Ethiopia.

[4]Department of Biotechnology, Krishna University, Machilipatnam-521001, Krishna District, Andhra Pradesh, India.

RESEARCH ARTICLE

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Hepatoprotective Activity of *Holostemma ada Kodien* Shcult, Extract against Acetaminophen Induced Hepatic Damage in Rats

Junapudi Sunil[1*, 2], Janapati Yasodha Krishna[3], Pallaval Veera Bramhachari[4]

Abstract: *Holostemma ada Kodien* Shcult has been traditionally used in Indian medicine as a result of its curative results of hepatitis, gonorrhea and diabetes, it is probably not proof-founded. However folklore has given us many powerful therapies, based on plant sources. So claims which can be made for the protective efficacy of *Holostemma ada Kodien* Shcult (family: Asclepiadaceae) to treat hepatic diseases. The present study focused on investigating the role of alcoholic extract of *Holostemma ada Kodien* Shcult. It appreciably prevented the increased in serum Aspartate amino transferase (AST), Alanine amino transferase (ALT), alkaline phosphatase (ALP) and total serum bilirubin (SB) level in acute liver damage by Acetaminophen and elevated the activities of lipid peroxidation (LPO) and glutathione (GSH) in the liver. Histopathological observation of the liver used to be additionally performed to further support the evidence from the biochemical analysis. The observation that these significant protective effect against acute hepatotoxicity induced by acetaminophen of *Holostemma ada Kodien* Shcult.

INTRODUCTION

Holostemma ada-kodien shcult (Syn: *Holostemma annulare*) belongs to Asclepiadaceae family. [1-3] It is also called as Jivanti, Arkapushpi, Kshira, Dodi and Suryavalli. It is widely distributed in the Tropical rain forests in India. [4] The plant is used for maintaining vigor, strength and vitality. [5] The terpenoid sugars present in the root tubers of the plant are used as medicinal properties. [6] The plant diversity is thinly distributed in India, W. Peninsula, Ceylon and China. In India it is found in tropical Himalayas, Burma and Andhra Pradesh (AP). This species is distributed throughout the plains of AP on open hill areas, including waste lands and on the fences of Sri Venkateswara University campus in Tirupati, Tirumala and Talakona. [7] Traditionally the plant is used as an alternative, astringent to the bowels; cures ulcers, diseases of the blood, worms, [8] itching, leucoderma; useful in gonorrhea. [9, 10] Roots are used for diabetes, [11, 12] cough, gonorrhea, as tonic and stomachic, Aphrodisiac Agent. [13] Though some of the plants are reputed in the indigenous systems of medicine for their activities, [14] it requires scientific evaluation.

Acetaminophen (AMP) (N-acetyl-p-aminophenol, Paracetamol) is usually used as an analgesic and antipyretic drug. [15] Extensive make use of AMP for therapeutic functions leads to severe hepatic damage. Toxic doses of AMP could reason changes in the morphology and function of liver mitochondria. [16] Formation of N-acetyl-p-benzoquinone imine (NAPQI) is the responsible for liver injury through depletion of glutathione (GSH) even as it binds to cellular proteins. [17] AMP induced hepatotoxicity is known to involve liver cytochrome P_{450} (CYPs) together CYP2E1, CYP3A4 and CYP1A2 and it also inhibits the mitochondrial oxidative phosphorylation, reduction of adenosine triphosphate (ATP) and produces selective mitochondrial oxidant stress. [18] Cellular necrosis of the liver cells raises the lipid peroxidation and depletion of glutathione (GSH) besides elevating the serum biochemical marker levels. [15]

The present study exceptionally focused on investigating the function of alcoholic extracts from *Holostemma ada-kodien* shcult (AEHA) against acetaminophen-induced hepatic injury of rats. To evaluate the hepatoprotective effect of AEHA in the *in-vivo* study, the serum levels of different marker enzymes regarding hepatic integrity, such as Alanine Amino Transferase (ALT), Aspartate Amino Transferase (AST), Alkaline Phosphatase (ALP), Total Serum Bilirubin (SB) were determined. And also estimation of Glutathione (GSH) and Lipid Peroxidation (LPO) was determined in the form of Malondialdehyde (MDA) protein on the cellular degree in the liver. Furthermore, histological reviews had been carried out to prove the effectiveness of AEHA in a preventive and healing function against Acetaminophen-induced toxicity of liver histopathology in rats.

MATERIALS AND METHODS

Chemicals

Acetaminophen (Paracetamol) 500 mg tablets obtained from Nirmal Prime, Mumbai, India. Silymarin was purchased from Micro Labs, Tamilnadu, India. Moreover, saline was once bought from the nearby provider GSN Pharmaceutical Private Limited, Hyderabad, Telangana and India. The following biochemical parameters of AST, ALT, ALP and Bilirubin were estimated through specifications kits obtained from Span Diagnostics, Surat, India. Rat's feed was once supplied from Mahaveer Endeavors, Madipally and Hyderabad, India. Other chemicals and reagents for this investigation had been of diagnostic grade.

Plant Materials

Holostemma ada Kodien Shcult plant material was collected from Tirumala hills in the month of December from Chitoor

[1]Department of Pharmacy, Jawaharlal Nehru Technological University, Kakinada-533003, Andhra Pradesh, India.
E-mail: suniljunapudi@gmail.com
*Corresponding author

[2]Department of Pharmaceutical Chemistry, Geethanjali College of Pharmacy, Cheeryal, Keesara, Ranga Reddy District- 501301, Telangana, India.

[3]Department of Pharmaceutical Chemistry, CHS, Mekelle University, Mekelle, Ethiopia.

[4]Department of Biotechnology, Krishna University, Machilipatnam, Krishna District-521001, Andhra Pradesh, India.

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Review Article

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Neeraja Podichety [1]*, Fatima Benazir [2], Parthasarathy Tigulla [3], Sudhakar Muvvala [4]
[1]Department of Pharmacy, University College of Technology, Osmania University, Hyderabad, Telangana, India
[2]Geethanjali College of Pharmacy, Cheeryal, Hyderabad, Telangana, India
[3]Department of Chemistry, Osmania University, Hyderabad, Telangana, India
[4]Department of pharmaceutics, Mallareddy College of Pharmacy, Maisammaguda, Secunderabad, Telangana, India
*Corresponding Author Email: neerajapodichety@gmail.com

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ABSTRACT

Nanobiotechnology is a term, which describes the combination of the two different worlds of engineering and molecular biology. It is a fusion of the following words: "nano" meaning very small, "bio" meaning living, and "technology" meaning use of tools. Tools and devices designed in nanobiotechnology applications are dependent directly on the current nanotechnology principles. In this review, the applications of nano biotechnology in various areas such as drug delivery, gene therapy, tissue engineering, molecular diagnostics and food safety are summarized. The multidisciplinary area of Nanobiotechnology has a powerful impact in various disciplines of scientific fields. It provides opportunities to develop new materials and techniques that improve the ability for developing quick, sensitive and reliable analytical techniques.

Key words: Nanobiotechnolgy, nanoparticles, nanobiology, nanomedicine, drug delivery and biotechnology

INTRODUCTION

Nanobiotechnology, a unique merger of nanotechnology and biotechnology is defined as the design, development and application of nanomaterials & devices to deal with functional processes of biological agents like microorganisms[1]. The field of nanobiotechnology is expected to have exponential growth and development in the future.

By this methodology, atom or molecule level devices can be constructed by incorporation of biological systems. Hence nanobiotechnology eases various aspects of biological sciences with the help of nanotechnology and information technology into biological problems. This technology has the potential to eliminate boundaries between different branches of sciences providing newer challenges and giving new directions in the field of research & diagnostics, education in the coming future[2].

Historical developments in the field of nanobiotechnology

The nanotechnological concepts were discussed for the first time in 1959 by physicist Richard Feynman during his talk "There's Plenty of Room at the Bottom". In this he described the different possible methods of synthesis by directly manipulating atoms. In 1974, Norio Taniguchi used the term "nanotechnology". With the invention of the scanning tunneling microscope in the year 1981, the visibility of individual atoms and bonds was clear. This has given the basics for manipulating individual atoms in the year 1989.

Harry Kroto, Richard Smalley, and Robert Curl, discovered Fullerenes in 1985 and received a Nobel Prize in Chemistry in 1996 for his work. Initially the term nanotechnology was used regarding subsequent work related to graphene tubes (also known as bucky tubes or carbon nanotubes) which has essential applications in designing nanoscale devices[3].

The National Nanotechnology Initiative (NNI) defines nanotechnology as research and development at the atomic level, molecular level, or macromolecular levels in the range of sub-100 nm for creating structures, devices, and systems that have novelty in their functional properties. At the nanoscale, manipulation of atoms was possible to create efficient materials with tailored parameters. By giving the inherent nanoscale properties to the biological tissues, it was evident that nanotechnology could be applied to the life sciences successfully. This has given rise to the term "nanobiotechnology", a unique fusion of biotechnology and nanotechnology[4].

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Article

An Overview of Compulsory Licensing in Pharmaceuticals

Pooja Aggarwal, Dr. Bayya Subba Rao*, Dr. M. Ravi Kumar
Faculty, Geethanjali College of Pharmacy, Cheeryala, Keesara, Hyderabad, Telangana.

Abstract

Members of World Trade Organisation are obliged for TRIPS and it directs in fulfilling the minimum criteria of infrastructure upgrade or vest new intellectual property legislations. TRIPS indicate an independent decision at the discretion of the country to issue compulsory licenses while simultaneous monitoring of anti-competitive licensing practices. Compulsory licensing is a provision that contradicts patents issued and an attempt is made in bringing awareness.

Keywords: Compulsory licensing, Pharmaceuticals, SWOT

Introduction

TRIPS agreement was a founding agreement when countries became members of World Trade Organisation (WTO) in 1995. At the fourth Ministerial Conference (2001) of WTO, the Doha Declaration on the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Public health was adopted[1]. TRIPS agreement comprises of seven parts with seventy three articles as guidelines for implementation and enforcement in the member countries. The agreement insists on national treatment, vest new or upgrade already existing legislations. While emphasizing the exclusivity provisions, TRIPS insists on institutional arrangements, protection of undisclosed information (trade secret/data exclusivity) with respect to local needs, role of judicial, custom authorities, conditions for civil/criminal proceedings, role of TRIPS council, co-ordination of WIPO and WTO etc. The current article is to emphasize the role of compulsory licensing.

Conditions for Compulsory Licensing:

For a better understanding, all possible conditions for opting compulsory licensing were categorized to the following options:

Option 1: An invention that was patented and is not worked, with high price not reachable to common man.

Option 2: An invention that was patented and is not manufactured within the country (or imported).

Option 3: An invention that was patented and the innovator is unable to fulfill the market demands.

Option 4: An invention that was patented and the product is required under national emergency/calamities/disease outbreak conditions, for the sake of public on non-commercial grounds.

Under such circumstances, after three years from date of grant, a third party can approach a patent office (especially for options 1, 2, 3) for grant of compulsory license provided the third party approached the patentee requesting for a patent licensing and failed.

Hence, a compulsory licensing mechanism is either initiated by the Government authority or by a third party. It is necessary to realize that a compulsory licensing mechanism is only for the country needs (local needs) but, certain circumstances may provide an option for manufacturing in one country and exporting into another country. In either of the conditions, it is necessary the compulsory license holder has to pay a proportional of royalty with respect to the business made. It is necessary that the compulsory license holder has to submit the amount of drug/drug product manufactured, amount for local needs and for export needs, total sale of product to the government authority and where ever needed to the patent holder.

Provision of License of Right

The concept of license of right comes into picture when the patentee wishes to lose right for exclusivity in return, the government waivers the maintenance fee. It is obvious that a patentee who has ample business over rides maintains exclusivity rights.

Case Studies where Compulsory/Voluntary Licensing issued:

For the national and international levels, several compulsory/voluntary licenses[2] were granted by various governments for local needs. Some of the countries include Argentina (Oseltamivir for Tamiflu), Brazil (Atazanavir, Efavirenz, Indinavir, Nelfinar, Lopinavir + Ritonavir, Tenofovir for HIV/AIDS), Canada (Ciprofloxacin for Anthrax), Ecuador (Lopinavir + Ritonavir for HIV/AIDS), Egypt (Sildenafil for NCD), Ghana (ARVs for HIV/AIDS), India (Imatinib Mesylate for Cancer), Indonesia (Lamivudine and Nevirapine for HIV/AIDS), Malaysia (Didanosine, Zidovudine, Lamivudine + Zidovudine for HIV/AIDS), Mozambique (Lamivudine, Stavudine, Nevirapine for HIV/AIDS), Rwanda (Lamivudine + Nevirapine + Zidovudine for HIV/AIDS), South Africa (Nivirapine, Lamivudine, Zidovudine, Stavudine, Didanosine, Efavirenz, Indinavir, Abacavir for HIV/AIDS), Taiwan (Ostamivir for Avian Flu/Pandemic Flu), Thailand (Efavirenz for HIV/AIDS; Lopinavir + Ritonavir, Clopidogrel for HIV/AIDS, CVS; Imatinib Mesylate for Cancer; Letrozole, Docetaxel, Erlotinib for Cancer), United States (Ciprofloxacin for Anthrax), Zambia (Lamivudine, Stavudine, Nevirapine for HIV/AIDS) and Zimbabwe (ARVs for HIV/AIDS).

The conditions clearly indicate critical life threatening diseases like cancer, HIV/AIDS to communicable diseases (national emergency conditions) like Flu, Anthrax to the local demands such as use of Sildenafil.

The cases clearly indicate for drugs that are expensive and not reachable to common man, lack of in house manufacturing facilities, unable to fulfill market demands, national emergency conditions, disease outbreaks, market demands etc.

In India, M/s. Natco Pharma Limited, Hyderabad has received the first ever compulsory licensing for indigenous needs upon fulfilling valid reasons. Indian patent office, has maintained strong grounds while granting compulsory licensing and rejected several applications on valid reasons.

Lead resources for initiating Compulsory Licensing Mechanism:

It is necessary to monitor the patents granted by various country patent offices and their working status. For instance, Indian Patent Office is releasing notices to the patent holders to update the working status of the granted patents. Such information usually provides an opportunity

*E-mail: drbayyasubbarao@yahoo.com

REGULATIONS GOVERNING CLINICAL TRIALS IN INDIA, EUROPE AND USA- A COMPARATIVE STUDY

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REVIEW ARTICLE

Agarwal Pooja*, Priyanka B

Faculty in Dept. of Pharmaceutical Management and Regulatory Affairs, Geethanjali College of Pharmacy, Cheeryal(V), Keesara (M), Medchal Dist., Hyderabad, Telangana, India 501 301

Corresponding Author's E-mail: p_agarwal89@yahoo.co.in

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ABSTRACT

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Isolation And Charaecterisation of Compounds Produced By Bacillus Starins From Soil And Determination of Antiinflammatory Activity

E. Sam Jeeva Kumar[1*], Dr.M Ravi Kumar[2], T. Vimal Kannan[3], P.Venkata Ramana[4] , S. Parveen[4] S.Md.Yaseen Shahzadi[5], S. Susmitha[5]

1- Research Scholar, JNTUH, Hyderabad.
2- Principal, Githanjali collage of pharmacy, Hyderabad.
3,4,& 5- Department of pharmacy practice PRRM Collage of pharmacy Kadapa.
Address for correspondence:
E. Sam Jeeva kumar
Associate professor
P.Rami reddy memorial college of pharmacy
Utukur,Kadapa. pin: 516003
Corresponding Author: E. Sam Jeeva Kumar

Abstract: *The soil is considered as the region of earth crest was geology and biology meat. There are two category of soil namely mineral soil which contains solid matter in the region and organic solid which contain rich amount of organic matter. Bacillus are rod shaped bacteria which consist of two genera namely aerobic bacilli an aerobic bacilli. Bacillus organism produce a wide range products like antibiotic, enzymes and insecticides. The soil is collected from the mountain region of south India primary and secondary screening were done. The resulted organism were subjected to fermentation by LG medium. The form the product was subjected to analytic characterization. Also the test for anti inflammatory activity was carried out. The morphological and biochemical characterization were done for the organism. A rod shape bacteria was seen on viewing through a light microscope. The submerged fermentation and solid state fermentation produce aezulene, pergenenediol and ethyl iso allocholate. The compound showed excellent anti inflammatory activity. Economically this compound showed useful results of anti inflammatory activity.*

Keywords: *Soil, bacillus strains, anti inflammatory activity.*

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I. Introduction

Soil as been defined as the region as earth's crest were geology and biology meet. From a functional view point the soil may be considered as the land surface of the earth which provide the substration for plant and animal life. The characteristics of the soil environment varry with the locale and climate. Soil differ in depth, physical properties, chemical composition and organisams. Generally there are two types of soil namely Mineral soil, in which the solid matter present is inorganic &Organic solids those which have very little inorganic matter. Fertile soil consist of root system of higher plants & many animal form like rodents, insets,& worms. It also contains a large numbers of microorganisam. The differences in the compositions of soil along with their differences physical characteristics and agricultural practices by which there are cultivated results in a large differences in the microbial populations both in total numbers and kinds. The condition present in the soil influence the growth of microorganism in the laboratory. The condition which the microbes need for the growth with reference to the soil are

1. Amount & type of nutrients.
2. Available moisture.
3. Degree of Aeration.
4. Temperature.
5. pH.
6. Practice and occurrences which contribute large number of micro organisms in the soilThe existence of roots & extensiveness of root systems in the soil also influnce the number and kinds of microorganism present in the soil.

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R. Ranjith Kumar, Samiha Shah Khan, Md. Mohasin Pasha, Sreenivas Pasula, Bolay Bhattacharya*

Geethanjali College of Pharmacy, Hyderabad-501301, India

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Corresponding Author:
E-mail : balay.ju@gmail.com
Mob.: +919703268291

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1 Introduction

The kidneys are a pair of bean shaped, red-brown organ, whose function is to dispose of the waste matter produced by the normal functioning of the body and to keep the salts and water of the body in the correct balance.

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Surrounding each capsule is a cushion of fatty tissue and a layer of connective tissue, which attaches kidney to the back of the wall of the abdomen. An adrenal gland sits on top of each kidney.

Each kidney has an outer layer – the cortex, an inner layer – the medulla, and a pelvis, a hollow inner structure that joins with the ureters. The renal medulla contains between 8 and 18 renal pyramids with a striped appearance. The pyramids are positioned with their tips, the renal papillae, facing towards the renal hilus and their bases aligned with the edge of the renal cortex. The cortex continues in between each pyramid creating areas known as renal columns.

The functional units of the kidneys are microscopic structures called nephrons, of which there are estimated to be 1.2 million in each kidney. Each nephron has a renal corpuscle, which lies in the renal cortex, and a renal tubule which runs through a renal pyramid. The renal corpuscle is comprised of an extensive ball shaped capillary network called the glomerulus surrounded by a double walled cup of epithelial tissue- the glomerular or Bowman's capsule. Together, these structures filter the blood,

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Safilguda, Hyderabad..

India.

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Corresponding Author:
E-mail : balay.ju@gmail.com
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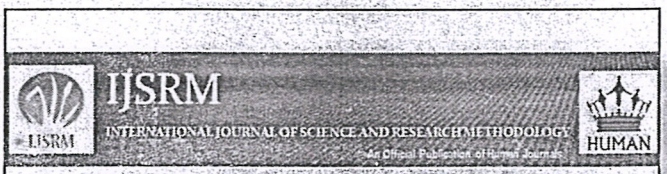

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INCIDENCE OF ADVERSE DRUG REACTIONS AND DRUG INTERACTIONS OF ORAL HYPOGLYCEMIC AGENTS IN TYPE 2 DIABETIC PATIENTS AT GUWAHATHI MEDICAL COLLEGE HOSPITAL

Jyothirmayee Vattem*, Mangala Lahkar, Dipti Sharma

Department of Pharmacy Practice, NIPER – Guwahathi, Guwahathi – 781032, Assam, India.

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

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Polypharmacy

ABSTRACT

To determine the incidence of adverse drug reactions and drug interactions due to oral hypoglycemic agents in patients suffering from type 2 diabetes. **Methodology**: Prior to the conduction of study, approval from institutional human ethics committee was obtained. The cross sectional, observational study was carried out in Guwahathi medical college hospital. Data collection was done over a period of five months through a pre-formulated case report form. Patients fulfilling all the inclusion criteria were selected randomly and interviewed for any objective and subjective evidence of ADR. For validation of ADR all the reactions were discussed and confirmed by practicing physician. **Results**: A total of 250 patients were included in the study and the data was tabulated in excel sheets and analyzed with appropriate statistical methods. The incidence rate of ADR was found to be 21.2% of which hypoglycemia is the predominant ADR. A combination of Glimepiride and Metformin caused more ADR than any other drug. Of all the ADR 30.2% are probable and 69.8% are possible. 10.4% ADR can be preventable accounting for DI. Of the 26 interactions 57.7% interactions were probable. All interactions were moderate in severity. A significant association was found between incidence of ADR and age, gender and polypharmacy. **Conclusion**: Improvement in patient-physician interaction time or the intervention of clinical pharmacist in educating patients about the disease and management of ADR will improve patient outcome.

1. INTRODUCTION

Diabetes is the most prevailing disorder and India is the diabetic capital of world[1]. Due to change in life style, number of patients with diabetes is increasing day by day and hence the use of drugs to treat this condition. Oral hypoglycemic agents are used to treat type 2 diabetes and most important ones are Sulfonylureas, Thiazolidinediones and Biguanides. The use of drugs is always associated with adverse effects. The International Conference on Harmonization defines an adverse drug reaction as "A response to a drug which is noxious and Unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function"[2]. Drug Interactions also cause ADR. When the effect of one drug is altered by co-administration of another drug or food or presence of disease then the phenomenon is called as drug interaction (DI). Type 2 Diabetes is also called as adult onset diabetes and mostly associated with diseases like hypertension, renal diseases and cardiovascular diseases that necessitate polypharmacy, which in turn leads to drug interactions. The unwanted effects caused by a drug may lead to prolonged hospital stay, increased health care costs and indirect

HEB JOHP

A STUDY ON PATIENT SATISFACTION IN THE OUTPATIENT DEPARTMENT OF GAUHATI MEDICAL COLLEGE HOSPITAL

Jyothirmayee Vattem, Swapna Kakoty

Department of Pharmacy Practice, National Institute of Pharmaceutical Education and Research-Guwahati, Narakasur Hills, Assam, India. 781032.
Associate Professor, Department of community medicine, Gauhati Medical College, Guwahati, Kamrup, Assam, India.

Address for Correspondence: editorjohp@gmail.com

ABSTRACT

Objective: To determine the level of satisfaction, in patients attending the outpatient department of tertiary hospital, Guwahati. **Material and Methods:** The data was collected from the outpatient department of Guwahati Medical College and Hospital through pre-structured questionnaires. This method was approved by Institutional Ethical Committee. **Results:** Average waiting time for consultation was 33.7 min and 83.3% patients opinioned that the waiting room was comfortable. Sanitation of waiting room (85%) and staff behavior (71.7%) can be improved. Average consultation time was found to be 12.3 min and overall satisfaction towards doctor-patient interaction was 88.3%. Average waiting time at the Pharmacy was 8.1 min and satisfaction regarding the availability of drugs was miserable (10%). Affordability was found to be 66.7%. Overall satisfaction towards hospital was found to be good (80%). **Conclusion:** The study indicated the different areas where patient satisfaction can be improved. Lack of drug availability and long waiting time constituted main dissatisfactory reasons. Sanitation and staff behavior can be improved to increase the quality of health care services.

Key words: Patient satisfaction, Survey, Tertiary hospital.

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