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Available online at: http://www.iajps.com *Review Article*

CURRENT STATUS AND FUTURE PROSPECTS OF TRANSFERSOMAL DRUG DELIVERY

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Abstract:
Vesicular systems have gained immense importance in the last few years as a means for sustained and efficient drug delivery. This article was designed to review all aspects of a novel class of vesicles, transfersomes. Transfersomes (elastic or ultraflexible liposomes) were a new class of lipid vesicles introduced. Transfersomes overcome the skin barrier by opening extracellular pathways between cells in the organ and then deforming to fit into such passages. In the process, Transfersomes undergo a series of stress-dependent adjustments of the local carrier composition to minimize the resistance of motion through the otherwise confining channel. It exists as an ultra-deformable complex having a hydrated core surrounded by a complex layer of lipid. The carrier aggregate is composed of at least one amphipathic molecule (like phospholipids) which when added to aqueous systems self-assemble into a bilayer of lipid which eventually closes into a lipid vesicle and one bilayer softening agent which is generally a surfactant which is responsible for the flexibility of the vesicle. Transfersomes provide the primary advantage of higher entrapment efficiency along with a depot formation which releases the contents slowly. The characterisation of transfersomes is similar to that of other vesicles like liposomes, niosomes and micelles. Transfersomes can be used for delivery of insulin, corticosteroids, proteins and peptides, interferons, anti-cancer drugs, anaesthetics, NSAIDs and herbal drugs.

Keywords: *Transfersomes, Transdermal, Skin barrier, Corticosteroids, Carrier aggregate.*

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A REVIEW: PULSATILE DRUG DELIVERY SYSTEM

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ABSTRACT

In the recent times the focus is more on the development of effective drug delivery systems rather than the development of new drug molecules. Pulsatile drug delivery ensures a right dose at right time at right place. It shows a sigmoid drug release with a lag time. After the lag time the drug is released rapidly and completely at a certain time or place. Pulsatile drug delivery delivers the drug at a particular time which is needed for the diseases which exhibit circadian rhythm and for the drugs which show high first pass metabolism, gastric irritation or for local effect. Several diseases such as asthma, cardiovascular diseases, peptic ulcers which follow the circadian rhythm can be treated by Pulsatile drug delivery. It has many advantages like decreased dose, minimum side effects and increased patient compliance. There are many systems like single unit, multiple unit and stimuli induced systems. Several Pulsatile drug delivery technologies are discussed in the article.

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REGULATION OF HERBAL MEDICINES IN INDIA, EUROPEAN UNION AND CHINA

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Herbal medicines have long been used for the treatment of multiple diseases in various health systems such as Ayurveda, Unani, Siddha and Homeopathy. The use of herbal medicines and supplements have grown tremendously over the past three decades, with atleast 80 per cent of people worldwide dependent on them for some portion of primary healthcare. Herbal medicinal products have recently become increasingly important and are commonly used in the prevention of various disorders. A commercial herbal medicinal product should comply with the regulatory requirements of quality, safety and efficacy. The World Health Organization has stated that each country should have a system to regulate herbal medicines in their territory. This article gives a brief overview of herbal medicines, market share value and regulations of herbal medicines in India, China and the European countries.

A. Introduction:

Herbal medicines are plant-derived products or formulations with therapeutic or other health benefits that contain either one or more raw or refined ingredients of plant. In some cultures, they may be materials of inorganic or animal origin. Herbal medicine means any herbal product that contains parts of the plant other than the plant mate as active ingredients, in aerial or underground.[1] The importance of some herbs with their medicinal values is given in *Table 1*.

In India, herbs are used in Ayurveda, Siddha, Unani and Homeopathic system of medicines and the data is depicted in *Figure 1*. These are popular in India due to abundance of plants due to their varied agro-climatic zones. In India, there are around 45,000 plant species, of which 15,000-20,000 plants have proven medicinal value.[2]

In European Union (EU), millions of people are using herbal medicines. The European Directive, which came into force in 2004, aims to protect public health by allowing Member States to use a reliable and unique set of information in the evaluation of herbal medicines. In 2004, Directive 2004/24/EC introduced a simplified registration procedure for Traditional Herbal Medicinal Products (THMP).[3]

The use of herbal medicine can be found in China at the beginning of written history, i.e. around 200 B.C. appearing the first known record. In China, herbal medicines, also known as Traditional Chinese Medicines (TCM), mean the medicines used to prevent and treat diseases by describing their effects and using under Chinese traditional theories of medicine.[4] TCM is a significant example of how ancient and accumulated knowledge in today's healthcare is applied in a holistic approach, as it has more than 3,000 years of history. The Devine Farmer's Classic of Herbalism was published in China around 2000 years ago and is the world's oldest documented herbal text, although the accumulated and preserved herbal knowledge has evolved *into vario*.

Herbal medicines are classified into four types such as: *Category 1:* Indigenous herbal medicines, *Category 2:* Herbal medicines in the system, *Category 3:* Herbal medicines modified, and *Category 4:* Herbal medicinal products imported.[6] The market share of herbal medicines in China, India and the European countries is shown in *Figure 2*.

B. Market Share Value and Regulations of Herbal Medicines in India:

Throughout India, there is a lot of folk knowledge about traditional use of herbal medicines among ordinary people. Because most practitioners formulate and dispense their own recipes, it is difficult to quantify the market size of

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Review Article

Comparability Pathway for the Approval of Similar Biologics with Respect to Reference Biologics in Europe and Brazil

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ABSTRACT

The regulatory environment for biologics is continuously evolving, because they are ensuring the targeted therapies for many dreadful diseases. But the high cost of biologics has made the European Union to go for the biosimilar development for the first time after the expiration of patents. The strict requirements by the European Medicines Agency (EMA) guaranteed the highest quality standards. These biosimilars are complex in nature and difficult to characterize because they are extracted from the living sources and requires modern biotechnological methods that differ widely from the conventional drugs. The biosimilarity will be assessed based on the comparability studies where there should not be any traces of clinical differences in terms of quality, safety and efficacy. While the Brazil focused mainly on reducing the cost of biosimilar which are essential in treating many rare and specific diseases which lead to the PPD concept for the sake of the public health care system. Two regulatory pathways are emerged for the biosimilars in Brazil in which the molecules that were licensed through the comparability pathway are only considered as biosimilars. The present article summarizes the development process, regulatory perspectives of biosimilars and related issues that may occur due to interchangeability, extrapolation and International non-proprietary names in EMA, ANVISA and also mentioned about the benefits and purpose of Brazil National Health Surveillance Agency (ANVISA) Partnership for productive development (PPD) concept.

Key words: Biologics, biosimilars, EMA, ANVISA, comparability, International non-proprietary name Partnership for productive development.

INTRODUCTION

A Biologic is a large protein based therapeutic (monoclonal antibodies and recombinant proteins) which will be made by using a unique cell lines and is more complex in structure and in functioning. These are produced using the proprietary cell banks optimized for manufacturing. The molecular size of the biologics is 1,000 times more than that of the chemical drugs and has highly complex structures including protein folding. Biologics plays an important role in terms of active therapy. There are several issues associated with the development and manufacturing processes of complex large molecular biologics as opposed to small molecule drugs. The treatment with biologics is expensive and it places a substantial financial burden on the health care system. In addition, these high costs restrict the availability and accessibility of such drugs to only those who can afford them. Some countries, such as Australia, have responded to these high costs by restricting the administration of the biologics to only indication that receive reimbursement through their pharmaceutical benefits scheme. Nevertheless, problems such as formulary inclusions, drug availability and patient out of pocket

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A REVIEW ON CHRONOPHARMACEUTICAL DRUG DELIVERY SYSTEM TO SYNCHRONIZE WITH CIRCADIAN RHYTHM DISEASES

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ABSTRACT

It is secret that living beings, including plants, livestock, fungi and cyanobacteria, undergoes a biological and inner process called circadian rhythm that controls the sleep-wake period and repeats about every 24 hours. This cycle is coordinated by the suprachiasmatic nucleus and controls about all body features, including related to drug delivery systems. The major aim is it should match with the circadian clock of the body indicating that these drug delivery systems deliver the right dose at a specific time at a particular site in order to accomplish this different techniques, such as time-controlled, pulsed, and programmed drug delivery systems which have been created and widely studied leading to chrono pharmaceutical drug delivery so that synchronization of this drug implementation with circadian rhythms leads to enhanced disease management and a higher patient therapeutic outcome. This review article tries to explain the function of circadian rhythms in different diseases and their states such as asthma, cardiovascular disease, arthritis, and cancer in a concise way. It also discusses the different oral drug delivery techniques introduced and their results in chronotherapeutic disease therapy.

Keywords: Circadian rhythm, chronopharmaceutical drug delivery system, chronotherapeutic diseases, Pulsed drug delivery systems, Cardiovascular Diseases, Chronotherapy

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Open Access Research Article

Formulation, Characterization and Antihelminthic Activity Testing of Nitazoxanide Superporous Hydrogel Tablets

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ABSTRACT

In the pharmaceutical field controlled release products have the ability to maintain desired medicament concentration or a longer period of time. Certain drugs are relatively insoluble in water and have high dose requirements that render unsuitable formulation difficulties in sustained release formulations. Nitazoxanide which is a high dose water insoluble antiprotozoal drug was formulated with the aim. To modulate gastro-retentive dosage form based on the superporous hydrogel composites. Foaming technique was used in the preparation of SPH composites. The superporous hydrogels were extremely sensitive to pH of swelling media and good porosity. Superporous hydrogels tablets of nitazoxanide showed good pre-compressional and post-compressional properties. Formulation X is the best formulation containing chitosan, polyvinyl alcohol, formaldehyde, exhibited good swelling ratio. The compatibility studies were performed by Fourier Transform Infrared (FT-IR) Spectroscopic Studies, Differential Scanning Calorimetry Studies (DSC). All formulations were evaluated for stability, drug content, and kinetic drug release & *in-vitro* drug release profile. It was concluded that the proposed gastro-retention drug delivery provides a different supply of nitazoxanide directly to the stomach.

Keywords: Nitazoxanide, Anti protozoal, foaming technique, Chitosan

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INTRODUCTION

Hydrogels are hydrophilic, cross linked polymers which are able to absorb large amounts of water and remain water in soluble all though slow swelling is beneficial their arises situations where a fast swelling polymer is more desirable therefore a new generation of hydrogels[1]. Which swell and absorb water rapidly has been developed and is termed as superporous hydrogels which swell to an extent of uniform and equilibrium size in a short span of time. The synthesis involves either cross linking of monomers using multifunctional cross linking agent usually by polymerization and gas blowing technique or copolymerization by using chemical compounds/ irradiation[2]. For drug delivery applications conventional hydrogels is limited due to slow swelling kinetics. Improvement of swelling rate is possible by making hydrogel porous or superporous. The word superporous means the pore structure of the hydrogel is open and connected. In this way the water will be absorbed into the hydrogel structure by means of diffusion and capillary actions. The draw back here is the more porous the structure is the weaker the hydrogel structure so to improve mechanical properties foaming and gelation process are used to improve compressive strength, elasticity[3].

Nitazoxanide is an antihelminthic and antiprotozoal agent having broad spectrum of activity. It is chemically 2-acetyloxy (N-(5-nitro-2thiazolyl) benzamide. Nitazoxanide is a light yellow crystalline powder which is insoluble in water and poorly soluble in ethanol. It belongs to BCS class II drug in biopharmaceutical classification system i.e. low solubility and high permeability. It is used for treating diarrhea caused

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Research Article

Development and Preclinical Testing of Nasal Aerosol for the Delivery of Novel Spray Dried Polyherbal Formulation to Treat Alzheimer's Disease

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ABSTRACT

Alzheimer's disease (AD) is an irreversible, progressive brain disorder that slowly destroys memory and thinking skills and eventually the ability to carry out the simplest tasks. The present investigation was undertaken to evaluate anti-alzheimer's activity of novel herbal aerosol spray formulation containing pure extracts of *Curcuma longa, Commiphora wightii and Withania somnifera*.Pressurized aerosol packs containing polyherbal spray dried dispersions in the concentration range of 0.5, 1 and 2% w/v dispersed in 10/90, 20/80, 30/70/ 40/60, 50/50) propellant blends of HFA-134a were developed in 3 in 1 aerosol filling machine and evaluated. Behavioural studies were performed in male wistar rats and histopathological studies were performed. The preparations were also assessed for AChE inhibitory activity. Results with P values < 0.05 were considered statistically significant. Chitosan exhibited compatibility with the polyherbal extracts in FT-IR studies. DSC thermogram revealed an endothermic peak of 65°C with chitosan. Spray dried poly herbal extracts exhibited a spherical morphology particle size distribution of 5-50µm with a practical yield of 20-30%. Aerosol formulations exhibited a particle size range below 10µm. average weight per actuation of canister was 7-8mg with a total 210 deliveries per pack. Zeta potential of the formulations was ±0.997. HPTLC fingerprinting showed band ranges at 256 and 366nm. The optimized aerosol spray in behavioral tests exhibited 10mg/kg and 20mg/kg intranasally reversed the scopolamine induced amnesia. Histopathological findings showed decreased Ach activity in male albino wistar rats. Percentage inhibition of formulation and standaed on AChE activity shoed an IC_{50} of 62% for 10mg/kg aerosol spray and 72% with 20mg/kg aerosol spray dosing.

Keywords: alzhiemer's disease; herbal; spray dried chitosan; aerosol; nasal spray;

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INTRODUCTION

Alzheimer's disease is a neurodegenerative disorder of uncertain cause and pathogenesis. It mostly affects the elderly. [1] In mild cases it results in forgetfulness and as the disease progresses it affects both short- and long-term memory. It is commonest cause of dementia in elderly, responsible for approximately 60-80 % of cases. It has significant effect on quality of life. Currently available treatments can modulate the disease course and ameliorate some symptoms but no proven effective therapeutic cure for Alzheimer has been identified to date. Traditional medicinal system in India particularly Ayurveda mentions neuroprotective actions of plant drugs like *Brahmi, Shankhapushpi, Amla, Guduchi, Tulsi, Ashwagandha* and *Haritaki*, which can help in improving the treatment armamentarium for Alzheimer's disease.[2-3] The understanding of Alzheimer's disease neurobiology is improving now and the search for better treatment options is still on. This provides an opportunity for more research on integrated approach using existing therapies, traditional and alternative medicines with newer treatments and potential candidates for management of Alzheimer's disease. [9] Based on other existing evidence, it was depicted that oxidative stress has a considerably important role to play in this process. The hippocampal network, which is the main part of the brain has such a prominent role in long-term memory and spatial navigation, and it is also one of the strikingly first regions of the brain that can meticulously show damages, memory problems and disorientation in AD patients. Novel drug delivery systems has opened new areas for research in herbal drugs. In order to improve stability, studies are mostly dedicated to solid forms of polymeric systems. An interesting approach is spray drying technique. spray drying technique is widely used in pharmaceutical field since it allows the preparation of dry powders with specific characteristics such as particle size and shape. In addition, formulation process including encapsulation, complex formation and even polymerization can be accomplished in a single step. [8]. Use of natural

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FORMULATION AND EVALUATION OF MULTI HERBAL FACE WASH GEL

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ABSTRACT

Background: In the present scenario, natural remedies are more acceptable when compared to the synthetic remedies because of their safety with fewer side effects. The present research work has been undertaken with the aim to formulate and evaluate of multi herbal face wash gel.

Materials and methods: Herbal face wash containing Tulasi (*Ocimum sanctum* Linn. belonging to the family Lamiaceae), Tamalapaku (Piper betel L. belonging to the family Piperaceae), Aloevera (*Aloe barbadensis* Mill. belonging to the family Asphodelaceae), Green tea (*Camellia sinensis* (L) Kuntze, belonging to the family Theaceae), Lemon (*Citrus limon* L. belonging to the family Rutaceae) and Turmeric (*Curcuma longa* L. belonging to the family Zingiberaceae).

Results: It has been reported in literature that these plants have good antimicrobial, anti-inflammatory, anti-bacterial, anti-fungal, anti-acne, anti-ageing, dirt absorbent and anti-oxidant activities. Various formulations were prepared i.e. F1 to F4 using herbal extract in different concentrations and evaluated for certain parameters like colour, consistency, viscosity, spreadability, extrudability, washability, foam ability, grittiness, skin irritancy, pH and stability conditions.

Conclusion: Results showed that F4 formulation was found to be optimum for all evaluation parameters.

Keywords: Piperaceae, *Camellia sinensis*, Extrudability, Asphodelaceae, Zingiberaceae, Skin irritancy

International Journal of Research in Pharmaceutical sciences and Technology

Formulation and *In-vitro* evaluation of ciprofloxacin HCl floating matrix tablets

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ABSTRACT

Oral drug delivery is the most widely utilized route of administration among all the routes that have been explored for systemic delivery of drugs via pharmaceutical products of different dosage form. Oral route is considered most natural, uncomplicated, convenient and safe due to its ease of administration, patient acceptance and cost-effective manufacturing process. Gastroretentive drug delivery system was developed in pharmacy field and drug retention for a prolonged time has been achieved. The goal of this study was to formulate and *in-vitro* evaluate Ciprofloxacin HCl controlled release matrix floating tablets. Ciprofloxacin HCl floating matrix tablets were prepared by wet granulation method using two polymers such as HPMC K100M (hydrophilic polymer) and HPMC K15M. All the Evaluation parameters were within the acceptable limits. FTIR spectral analysis showed that there was no interaction between the drug and polymers. *In-vitro* dissolution study was carried out using USP dissolution test apparatus (paddle type) at 50 rpm. The test was carried out at 37 ± 0.5 0C in 900ml of the 0.1 N HCl buffer as the medium for eight hours. HPMC K100M shows a prolonged release when compared to HPMC K15M. These findings indicated that HPMC K100M can be used to develop novel gastroretentive controlled release drug delivery systems with the double advantage of controlled drug release at GIT pH. On comparing the major criteria in evaluation such as preformulation and in vitro drug release characteristics, the formulation F8 was selected as the best formulation, as it showed the drug content as 99±0.4% and swelling index ratio was 107.14, and *in-vitro* drug released 61.31±0.65% up to 8 hours. Results indicated that controlled Ciprofloxacin HCl release was directly proportional to the concentration of HPMC K100M and the release of drug followed non-Fickian diffusion. Based on all the above evaluation parameters it was concluded that the formulation batch F8 was found to be best formulation among the formulations F1 to F8 were prepared.

Keywords: Ciprofloxacin HCl, HPMC K100M, *In-vitro* drug delivery, Gastroretentive drug delivery.

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INTRODUCTION

Oral drug delivery is the most widely utilized route of administration among all the routes that have been explored for systemic delivery of drugs via pharmaceutical products of different dosage form. Oral route is considered most natural, uncomplicated, convenient and safe due to its ease of administration, patient acceptance and cost-effective manufacturing process [1].

Pharmaceutical products designed for oral delivery are mainly conventional drug delivery systems, which are designed for immediate release of drug for rapid absorption. These immediate release dosage forms have some limitations such as [2, 3].

Sustained release (SR) - gastroretentive dosage forms (GRDF) enable prolonged and continuous input of the drug to stomach and upper parts of the gastrointestinal (GI) tract. These systems are designed to be retained in the stomach for longer period of time and hence significantly prolong the gastric residence time of drugs. Therefore, different approaches have been proposed to retain the dosage form in the stomach including bioadhesive systems, swelling and expanding systems, floating systems and delayed gastric emptying devices [4, 5, 6].

Among these, the floating dosage form has been used most commonly. This technology is suitable for drugs with an absorption window in the stomach or in the

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MICROSPHERES FOR CONTROLLED RELEASE DRUG DELIVERY: AN OVERVIEW ON PREPARATION METHODS AND CHARACTERISATION

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ABSTRACT

Microspheres are the multiparticulate drug delivery systems which are manufactured to acquire prolonged or controlled drug delivery, which can enhance bioavailability, stability and also the drug can be delivered at a predetermined rate. Some of the difficulties of conventional therapy can be controlled by an effectively designed controlled drug delivery system and the therapeutic efficacy of a given drug is enhanced. Vast attention has been attained by this microspheric drug delivery system because of its prolonged release and also its wide range of application in drug targeting to the particular site in order to maximize the concentration of drug in a particular tissue or organ of the body that surpass the drug's therapeutic efficacy, toxicity can be reduced and improves the patient compliance and patient comfort. Various approaches have been developed to deliver a drug to particular site in a sustained controlled release manner. Among them, one of the approaches is utilizing microspheres as drug carriers. Microspheres were used not only for prolonged release, but the anticancer drugs to the tumour also can be targeted. They consist of a drug which is centrally placed and a unique polymeric membrane that is biodegradable in nature is used to enclose it. The present review is anxious about the microspheres as novel drug delivery system. The main aim of the present study is to review various features of microspheres, methods used for preparation and various applications as targeted or controlled drug delivery system.

Keywords: Microspheres, conventional, targeted, applications, controlled release

International Journal of Research in Pharmaceutical sciences and Technology

Formulation and evaluation of lansoprazole loaded enteric coated microspheres

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ABSTRACT

The research focuses on the development of multiparticulate delivery system for acid-labile Lansoprazole to prevent its degradation in the acidic environment of the stomach and enhance its bioavailability via intestinal absorption. This problem can be solved by enteric coating. In this project, cellulose acetate phthalate a polymer usually utilized for gastrointestinal film coating of tablets, was used to prepare enteric microspheres of lansoprazole with solvent evaporation technique in various formulations such as F1, F2, F3, F4, F5 with drug: polymer ratios of 1:1, 1:2, 1:3, 1:4, 1:5 respectively. FTIR study indicated compatibility between drug and polymer. Increase in concentration of polymer increased spheriocity and mean diameter of the microspheres. The drug entrapment efficiency was in the range of 72.23% to 88.64%. SEM revealed that microspheres were found spherical and porous. In-vitro study proves that drug release slowly increases as the pH of the medium increased and prevents degradation of drug in acidic pH. In-vitro drug release was found to be 92.80%, 94.55%, 92.72%, 96.34%, 98.65% in all 5 formulations. All 5 formulations showed gastric resistance around 80-90%. So it is concluded that the developed enteric coated microspheres of Lansoprazole prevented drug release in the stomach which would lead to significant improvement in its bioavailability through enhanced intestinal absorption.

Keywords: Microencapsulation, Solvent evaporation, Microspheres, CAP, Lansoprazole.

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Rubatosis Publications

INTRODUCTION

Oral drug delivery route is perhaps the preferred way to take medicines. Though, their short circulation half- life and limited absorption through a specified intestine segment restricts several other drugs' therapeutic effects[1]. Currently, no drug delivery system is ideally conductive to achieving all the ambitious goals, but genuine efforts have been made to accomplish them via novel drug delivery approaches. A number of new drug delivery technologies have developed that include different paths of implementation to ensure managed and targeted delivery of drugs[3]. The focused drug delivery method was designed to try to concentrate the drug in the tissues of interest while increasing the overall concentration of the drug in the other tissues. The drug is therefore placed on the target site. Therefore, the drug does not affect the surrounding tissues[2]. Microspheres were tiny spherical bodies with just a diameter of 1 to 1000 in the μm range[4]. Micro particles from different natural and synthetic components can be produced. It is possible to alter the drug behaviour *in vivo* by mixing the drug with a carrier molecule. The carrier's activity drastically alters clearance kinetics, tissue distribution, metabolism i.e., kinetics and cellular interaction of the drug. Using these improvements in the action of pharmacodynamics will result in increased therapeutic output. A wide range of materials namely immunoglobulin serum proteins, liposomes, microspheres, microcapsules, nanoparticles and even cells like erythrocytes were also used as drug carriers[5]. Oral microspheres were used to support the release of drugs and to reducing or eliminating discomfort of the gastrointestinal tract. Moreover, multiparticulate delivery systems in the gastrointestinal tract distributed more evenly. This tends to result in a much more reproducible uptake of the drug and lessens local irritation better than single unit dosage forms along with no disintegrating polymer tablets. It is also possible to avoid excessive intestinal accumulation of the

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A comprehensive overview on nanofiber technology and their advancements in the field of pharmaceuticals

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ABSTRACT

Nanotechnology is a growing technology that has been marked as the most vital scientific and commercial venture across the world with great benefits. Globally many researchers are involved in the development of newer types of nanomaterials through modifications of various fabrication techniques. Nanofibers have been an emerging trend in the field of nanomaterials due to its unique physicochemical characteristics. Properties such as high surface area and high porosity absorbance ratio with the interconnected fibrous networks makes nanofibers unique. The current review explores the present status and upcoming advancements in the field of nanofiber technology. The article is focused on the various preparation techniques and applications in medicine, tissue engineering and regenerative medicine and pharmaceuticals. Despite the advancements, the limitations and future prospects in the area of nanofiber technology have been highlighted.

Keywords: Nanofibers, electrospinning process, phase separation technique, pharmaceuticals, bioengineering.

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INTRODUCTION

The advancements in the field of drug discovery augmented from the middle of 19th century. The world of nanomaterials embraces for their outstanding physicochemical characteristics. Nanomaterials include quantum dots, nanorods, nano tubes, nano wires, nano fibers and one-dimensional nanosheets. Amongst all, nanofibers stand apart due to their impending applications. Nanofibers have been fabricated from various materials such as natural and synthetic polymers; carbon based, semi-conducting and composite nanomaterials[1]. Nanofibers are defined as fibers with diameters less than 50-500 nm. National Science Foundation (NSF) defines nanofibers as having at least one dimension of 100 nm or less. The objective of nanofiber drug delivery system is to deliver a defined amount of drug proficiently, specifically for a defined period of time. Many techniques have been reported till date for the fabrication of nanofibrous scaffolds including electrospinning, self-assembly and phase separation techniques. Out of all, electrospinning is a relatively simple and robust production method. Electrospinning has become a widely used and reliable method since it allows the production of different alignment scaffolds of ultra-fine fibers, in the range of nano to microscale in diameter, from a variety of natural and synthetic polymers.

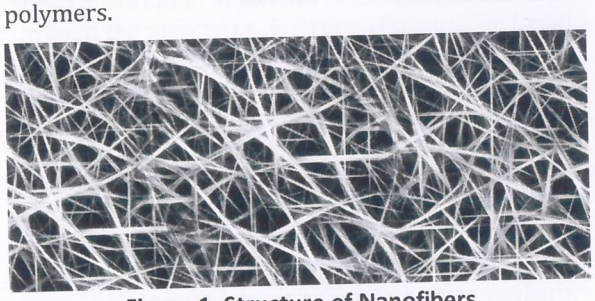

Figure 1: Structure of Nanofibers

Electron microscopic view of a nanofiber Advantages

Now-a-days, nanofibers are emerging as a means for various drug delivery systems for the treatment of diseases in the healthcare systems. The nanofibers demonstrate the significance and suitability of them as drug carriers. The smaller size and surface area to volume ratio of nanofibers is the winsome property

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FORMULATION AND EVALUATION OF NIOSOMAL BASED HERBAL SUNSCREEN SPRAY

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ABSTRACT

Background: In the current paradigm, herbal remedies are more appropriate than synthetic ones due to their protection and less harmful impacts. The present research work has been undertaken with the aim to formulate and evaluate niosomal based herbal sunscreen spray.

Materials and methods: Essential oils (carrot seed oil, blue berry seed oil) having good SPF. Aloe vera (Aloe barbadensis Mill. belonging to the family Asphodelaceae), Cholesterol, Tween80, Alcohol, Glycerine, Water. Niosomes were prepared by coacervation method.

Results: It has been identified that carrot seed oil, blue berry seed oil have good SPFs. The combination of both the essential oils is having SPF higher than the individual formulations. 3 formulations are made F1, F2, F3. Carrot seed oil was incorporated as a UV protecting agent in F1 and SPF was found to be 27.78; blue berry seed oil was incorporated as UV protectant in F2 and SPF was found to be 21.65 and F3 is the combination of both carrot seed oil and blue berry seed oil where the SPF was found to be 28.90.

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

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

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

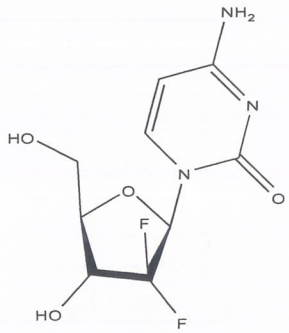
Date of Submission: 08-01-2020 Date of Acceptance: 23-01-2020

I. Introduction:

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

GEMCITABINE

Structure:



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

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Method Development and Validation of Efavirenz by UV Spectrophotometer

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Abstract: *The developed method for Efavirenz determined in tablet was found to be simple, sensitive, precise, selective, rapid and economic. Efavirenz exhibited maximum absorption at 291nm and obeyed Beer's law in the concentration range of 10-50µg/ml, showed linear regression y=0.181x+1.071 with correlation coefficient (r^2) of 0.999. Recoveries obtained do not differ significantly from 100% showed that there was no interference from the common excipients used in tablet formulation indicating accuracy and reliability of the method. The proposed method can be used for drug analysis in routine quality control & method proves to be more economical than the other standard methods. The developed and validated UV spectrophotometry method is rapid, simple, accurate, sensitive and specific. This method was validated as per ICH guidelines and results of accuracy, precision, ruggedness, was in the limit. There was no any interference of excipients in the recovery study. The method was also successfully used in quantitative estimation and analysis of Efavirenz from formulation.*

Key Words: *Efavirenz, Accuracy, Spectrophotometer, Quality Control.*

Date of Submission: 17-01-2020 Date of Acceptance: 05-02-2020

I. Introduction

Efavirenz, a non-nucleotide reverse transcriptase inhibitor is used in highly active human immune deficiency virus type1. It is a white crystalline powder. Efavirenz is also used in combination with other antiretroviral agents as part of an expanded post exposure prophylaxisregimen to reduce the risk of HIV infection.The usual adult dose of Efavirenz is 600mg once a day. Efavirenz inhibits the activity of viral RNA-directed DNA polymerase. Antiviral activity of efavirenz is dependent on intracellular conversion to the active phosphorylated form. Thus, reverse transcriptase inhibitors are virustatic and do not eliminate HIV from the body.Even though human DNA polymeraseis less susceptible to the pharmacologic effects of triphosphorylated efavirenz,this action may never account for some of the drug toxicity.

The UV- Spectrophotometric method for the simultaneous determination of Efavirenz and combination of few drugs were carried out with acetonitrile: water (50:50, v/v) solvent system. Linearity was observed over a range of 1-20µg/mL for Efavirenz, 1-10µg/mL . In another method a quantitative estimation of Efavirenz in bulk and tablets was described, in methanol: water (80:20, v/v), Efavirenz exhibits an absorption maximum at 245 nm and method obeys Beer's law.

EXPERIMENTAL SECTION

METHOD DEVELOPMENT

The develop simple, sensitive, accurate, precise, reproducible, rugged, and robust and relatively inexpensive analytical method (UV- Spectrophotometric) for the analysis of Efavirenz.

Instrument used UV-Visible spectrophotometer

DRUG PROFILE

DRUG NAME : Efavirenz

IUPAC NAME : (S)-6-Chloro-4-(cyclopropylethynyl) -1,4-dihydro-4-(trifluoromethyl)-2H-3,1-benzoxazin-2-one

COMPARISON OF GENERIC DRUG APPLICATION AND APPROVAL PROCESS IN INDIA, USA AND EUROPE

Bhargavi M., Lakshmi Prasanthi Nori and Rama Rao Nadendla

Generic drug registration is a very strenuous and complicated process in many countries. It varies from country to country based on their regulations. This study deals with the differences in registration requirements for generics in European Union (EU), United States of America (USA) and India. Generic drugs in EU are approved under the Marketing Authorization Application (MAA); in USA, they are approved under the Abbreviated New Drug Application (ANDA); whereas in India, it is under the filing of ANDA. Bio-Availability (BA) and Bio-Equivalence (BE) study data is critical in the generic drug approval process as Clinical Trials (CTs) can be omitted.

This study also deals with few comparisons of generic drug registration requirements in these three countries. Understanding the differences in registration process will get a substantial impact on the success of its multicountry submission strategy. Therefore, this article provides the strategy in advance which could make a smooth review process without any significant delays or failures.

Introduction:

A generic drug product is one that is comparable to a patented drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. All approved products, both innovator and generic are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal & *invitro*) and clinical (human) trial data to establish safety and effectiveness.[1] Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e. performs in the same manner as the innovator drug). One way scientists demonstrate BE is to measure the time it takes a generic drug to reach the bloodstream in 24 to 36 healthy volunteers. This gives them the rate of absorption, or BA, of the generic drug, which they can then compare to that of the innovator drug. The generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug.

Using BE as the basis for approving generic copies of drug products was established by the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This Act expedites the availability of less costly generic drugs by permitting FDA to approve applications to market generic versions of brand-name drugs without conducting costly and duplicative CTs. At the same time, the brand-name companies can apply for upto five additional years longer patent protection for the new medicines they developed to make up for the time lost while their products were going through FDA's approval process. Brand-name drugs are subject to the same BE tests as generics upon reformulation.

Objectives of ANDA:

- To reduce the price of the drug.
- To reduce the time of development of the drug.[2]
- To provide or make available a good quality product.
- To increase BA in comparison to reference listed drug.

Generic Drug:

According to India, a generic drug is a pharmaceutical drug which has the same chemical substance as developed originally and patented innovative drug. Generic drugs are allowed for sales after patent(s) on original drug

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SIMULTANEOUS ESTIMATION OF METFORMIN HYDROCHLORIDE AND GLICLAZIDE IN BULK AND TABLET DOSAGE FORM BY RP-HPLC METHOD

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Abstract:

A simple, precise, rapid, selective, and economic reversed phase high-performance liquid chromatography (RP-HPLC) method has been established for the simultaneous analysis of Lamivudine and Tenofovir Disoproxil Fumarate in Bulk and Pharmaceutical dosage form on a Phenomenex C_{18} (250×4.6mm i.d) chromatographic column equilibrated with mobile phase containing methanol, acetonitrile & Phosphate buffer (2.954g of potassium dihydrogen orthophosphate in 1000 ml water). Experimental conditions such as pH of mobile phase, organic phase ratio, flow rate, selection of wavelength, etc. were critically studied and the optimum conditions were selected. Efficient chromatographic separation was achieved with mobile phase containing combination of methanol, acetonitrile & phosphate buffer pH 5.0 in ratio of 55:10:35 v/v and mixture was adjusted to pH 5.0 at flow rate of 1.5 ml/min and eluent was monitored at 257 nm. The sample was injected using a 20 µl fixed loop, and the total run time was 5 min. The retention time for Lamivudine and Tenofovir Disoproxil Fumarate were 1.037 min and 2.123 min respectively. The method was linear in the range of 10-50 µg/ml and for both Lamivudine and Tenofovir Disoproxil Fumarate. The proposed method was successfully applied to the analysis of Lamivudine & Tenofovir Disoproxil Fumarate in their Bulk and Pharmaceutical dosage form without interference from other additives. The developed method was validated according to ICH guidelines. Linearity, regression value, recovery, % RSD of method precision, LOD, LOQ values were found within the limits and the method was found to be satisfactory. This validated HPLC procedure is economic, sensitive, user-friendly & less time consuming than other chromatographic procedures.

***Key words**: RP-HPLC, Lamivudine, Tenofovir Disoproxil Fumarate, validation, chromatography.*

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DEVELOPMENT AND VALIDATION OF STABILITY INDICATING RP-HPLC METHOD FOR THE ESTIMATION OF METOLAZONE IN BULK AND PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

A stability indicating reverse phase high performance liquid chromatographic method has been developed and validated for estimation of Metolazone in its bulk and formulation. Method development was carried out on Hypersil BDS C18 column, (150×4.6mm, particle size 5µ). The chromatographic separation was achieved using a mobile phase containing acetonitrile and HPLC water in the ratio of 50:50 v/v at flow rate of 0.7 ml/min using detection at 236 nm. Linearity was performed from 1-10 µg/ml with correlation coefficient of 0.999. The LOD and LOQ for the method were found to be 0.1µg/ml and 0.3µg/ml respectively. The statistical analysis shows that the method was found to be accurate, reliable, simple and reproducible. The

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METHOD DEVELOPMENT AND VALIDATION OF RELATED IMPURITIES FOR ASSAY OF OLMESARTAN MEDOXOMIL AND HYDROCHLORTHIAZIDE IN SOLID ORAL TABLETS BY RP-HPLC

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ABSTRACT

The purpose of this work is to develop an accurate and precise HPLC method for the determination of Hydrochlorothiazide and Olmesartan Medoxomil in solid dosage form. Separation of the drug was achieved on an inertsil ODS 3V 150x4.5 column using a mobile phase consisting of 0.01M pH 3.0 phosphate buffer and acetonitrile by using a gradient programmer. The flow rate was 1.2ml/min and the detection wavelength was 262nm. The linearity was observed in the range of 15-90p-pm for Hydrochlorothiazide and 24-144ppm for Olmesartan Medoxomil with a correlation coefficient of 0.999 and 0.999 respectively. The impurities of Hydrochlorthiazide and Olmesartan Medoxomil were optimized and separated. The proposed method was validated for its linearity, accuracy, precision and robustness. This method can be employed for routine control analysis of Hydrochlorothiazide and Olmesartan Medoxomil in solid dosage form by RP-HPLC.

Keywords: Hydrochlorothiazide, Olmesartan Medoxomil, impurity profiling, dosage form RP-HPLC, validation

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BIO ANALYTICAL METHOD DEVELOPMENT AND VALIADTION FOR THE QUANITIFICATION OF CYTARABINE IN RAT PLASMA BY USING HPTLC

Supriya.Palaparthi*, Syed Afrin, M.Siva Prasad,Rama rao.N
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Keywords
Cytarabine,
HPTLC aetron.

ABSTRACT

It is a simple, sensitive, rapid and economic chromatographic method has been developed for the determination of cytarabine in rat plasma using standard API. This analytical technique used for development was high performance thin layer chromatography. HPTLC aetron with already coated silica gel plates 60 F_{254} (10X10 cm) at 250 nm thickness was used as stationary phase. the mobile phase used consisted of 2-butanone :acetone :water (65:20:15 % v/v/v)[4] the plasma sample were extracted by protein precipitation with methanol concentration ranges of 1000,2000,3000,4000,5000 ng/ml respectively ,were used mixed plasma for the calibration curves .the stability of cytarabine in plasma were confirmed during three freeze-thaw cycles (-20 ℃) on a bench for 24 hrs and post preparattively for 48 hrs.this method was validated statistically and proved suitable for the determination of cytarabine in rat plasma.

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International Journal of Lifescience and Pharma Research

Research Article

Pharmaceutical analysis for Novel drug formulation

Quantification of Atazanavir and Ritonavir in Human Plasma Samples by Rp-Hplc Include Method of Detection in the Title, Eg: Using Pda Detection

Abhinandana.Patchala*[1, 2] and Ramarao Nadendla[2]

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Abstract: A fixed oral dose combination of Atazanavir and Ritonavir is currently used for the treatment of patients with HIV infections. A selective and novel bio-analytical technique was designed to evaluate Atazanavir and Ritonavir by mass spectroscopic investigation in plasma matrices. The method was chromatographed with Agilent TC-C18, 4.6 x 75 mm, 3.5 µm, 80 Å column, 5mM ammonium acetate: acetonitrile (20:80 v/v) mobile phase was used for Chromatographic separation. UV detector was used to detect the Atazanavir and Ritonavir at 235 nm. For extraction of the analyte and internal standard, Liquid-liquid extraction was employed .This method is validated over a linear concentration range of 50.0 – 10000.0 ng/ml for Atazanavir and Ritonavir with a correlation coefficient (r) of = 0.9997 and both drugs were stable in plasma samples.

Keywords: HPLC; Atazanavir, Ritonavir, Human plasma; Bio analytical

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QUANTIFICATION AND VALIDATION OF AMLODIPINE BESYLATE, OLMESARTAN MEDOXOMIL AND HYDROCHLOROTHIAZIDE BY RP-HPLC IN MARKETED DOSAGE FORM

Abhinandana Patchala [*1] and Ramarao Nadendla [2]

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Chalapathi Institute of Pharmaceutical Sciences [2], Lam, Guntur - 522034, Andhra Pradesh, India.

Keywords:

Amlodipine, Hydrochlorothiazide, Olmesartan medoxomil, RP-HPLC, Validation

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ABSTRACT: The endeavor of the present work is to develop a simple, economical, efficient, novel green analytical method for the estimation of Amlodipine besylate, Olmesartan medoxomil and Hydrochlorothiazide in pharmaceutical formulation. Quantification was carried out using an Inertsil CN-3.5 µm (4.6 ×250 mm) column, where the mobile phase consisting of 10 mm Phosphate buffer (pH 3.0) and Acetonitrile (40:60). The flow rate was 1.0 mL/min and the effluent was monitored at 262 nm. The observed linearity was in the range of 5-25 µg/ml for Amlodipine (AMLO), Hydrochlorothiazide (HCTZ) and Olmesartan medoxomil (OLME) with a correlation coefficient of 0.997, 0.999 and 0.999 respectively. The proposed method was validated as per ICH guidelines in terms of linearity, accuracy, precision, robustness, and specificity, the limit of detection and limit of quantification. The method has been applied to Amlodipine, Hydrochlorothiazide and Olmesartan formulation without the interference of excipients of the formulation.

INTRODUCTION:

Amlodipine Besylate: Amlodipine Besylate (2-[(2-Aminoethoxy) methyl]- 4- (2-chlorophenyl)-1, 4-dihydro-6-methyl-3, 5-pyridinedicarboxylic acid 3-ethyl 5-methyl ester benzene sulfonate). Amlodipine is an L-type calcium channel blocker, which decreases the contraction of action and myosin fibers in the cardiac tissue by decreasing the supply of calcium ions. This results in a significant decrease in blood pressure [1, 4-8]. The chemical structure was shown in **Fig. 1**.

QUICK RESPONSE CODE

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DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.11(5).2350-55

Formula: $C_{26}H_{31}ClN_2O_8S$

Chemical Structures of Drugs:

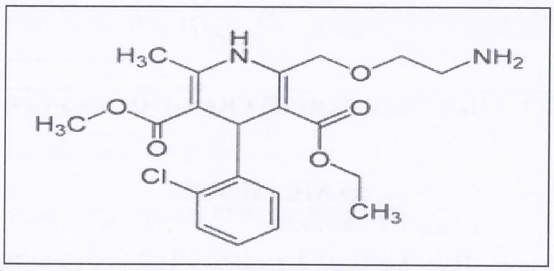

FIG. 1: CHEMICAL STRUCTURE OF AMLODIPINE BESYLATE

Hydrochlorothiazide: Hydrochlorothiazide (6-chloro- 1, 1- dioxo- 3, 4- dihydro- 2H- 1, 2, 4-benzothiadiazine-7-sulfonamide) is a thiazide-type diuretic, which causes an increased elimination of fluid in the urine, thereby decreasing the blood

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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF BICALUTAMIDE IN TABLETS BY RP- HPLC AND QUALITATIVE ANALYSIS OF CEFAZOLIN SODIUM BY DIFFERENT ANALYTICAL TECHNIQUES

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ABSTRACT

An isocratic reverse phase liquid chromatography (RP-HPLC) method has been developed and subsequently validated for the determination of Bicalutamide in pharmaceutical formulation. In this method Shimadzu technologies Phenomenex (250×4.6mm; particle size 5µm) column with mobile phase consisting of 0.5g of sodium dihydrogen phosphate buffer (pH adjusted to 2.9 with ortho phosphoric acid) and acetonitrile in ratio of 70:30 v/v was used. The detection wavelength is 271nm, flow rate 1.0 ml/min and the retention time was 9.302 min. The linearity was found in the range of 50µg/ml to 250µg/ml and shows a correlation coefficient of 0.998. Cefazolin sodium exhibits antibiotic activity. Analysis of cefazolin sodium was done by different analytical techniques like UV, HPLC. In UV the

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RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF TRAMADOL HYDROCHLORIDE AND DICLOFENAC IN BULK DRUGS AND PHARMACEUTICAL DOSAGE FORMS

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Abstract:

The aim of the present work was to develop and validate a simple, efficient, economical method for the analysis of Tramadol and Diclofenac in pharmaceutical dosage forms by Rp-HPLC.A hypersil C_{18} reverse phase column (4.6 × 200,5µm) with mobile phase containing 10mm phosphate buffer (pH-4.5): Acetonitrile(30:70v/v) is used and eluents monitored at 270nm.The Retention time of Tramadol and Diclofenac was 2.34 and 4.57 respectively.

The validated characteristics, included, specificity, Linearity, LOD, LOQ, Precision, Accuracy, Robustness, Validation acceptance criteria were met in all cases. The percent recoveries ranged between 95% and 105%. The RSD was found to be less than 2. The method could be successfully used for the analysis of Tramadol and Diclofenac in bulk and Pharmaceutical dosage forms.

Key Words: *Rp-HPLC, Method development, Tramadol, Diclofenac, Validation.*

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QR code

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Research Article | Pharmaceutical Sciences | Open Access | MCI Approved

Recapitulation of Modernize Medical Devices and Market-Oriented Economies in United Kingdom

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Received: 12 Oct 2019 / Accepted: 18 Nov 2019 / Published online: 01 Jan 2020
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Abstract
The purpose of this study is to illuminate the importance of medical devices, regulatory requirements for the registration of medical device manufacturers in U.K. The controversy for companies developing and producing medical device is to update on the regulatory requirement and implement them in the process. Medicines and devices are regulated under European Union (EU) law, the regulatory regimens are very different, and some have argued that features of the pharmaceutical regime should be applied to medical devices in the current review of the medical device directives. The UK medical device market is third largest in Europe; the medical device trade is import-led, as most domestically manufactured products are exported to other markets. But two of these countries had different regulations to maintain the quality of medical devices marketing in their countries. The review will give a brief statement of the main points of regulatory requirements and registration of medical devices.

Keywords
Medical device, Regulations, Registrations, Approval.

*****

INTRODUCTION:

MEDICAL DEVICES

The term "medical device" means any instrument, apparatus, implement, machine, appliance, implant, and reagent for in vitro use, software , material or their similar or related articles, intended by the manufacturer to be used , alone or in combination , for human beings , for more of the specific medical purposes. The global medical device industry has experienced significant growth over the last five years and is expected to continue, reaching approximately US $ 302 billion in 2017 with a CAGR of 6.1% during next six years (2011-2017).these new segments are expected to improve the prospects for the market [1].

GLOBAL HARMONIZATION TASK FORCE (GHTF)

The Global Harmonization Task force (GHTF) was founded in 1993 by the governments and industry representatives of Australia, Canada, Japan, the European Union, and the United States of America. The purpose of GHTF is to encourage a convergence in standards and regulatory practices related to the safety, performance and quality of medical devices. WHO collaboration with the GHTF could facilitate access for developing countries (both those importing and those wishing to manufacture) to:

- Information on the major regulatory system for medical device
- Device approvals and health technology assessment from highly regulated markets
- Adoption of a single medical device nomenclature
- Innovative technology advances

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International Journal of Lifescience and Pharma Research

Research Article

Pharmaceutical analysis for Novel drug formulation

A Simultaneous Estimation of Clotrimazole and Its Impurities

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Abstract: A simple, efficient and reproducible method for the simultaneous determination of Clotrimazole and its Impurities (Imidazole and (2-chlorophenyl) phenyl methanone (2-chlorobenzophenone)) has been developed using reversed phase high performance liquid chromatography. The separation was carried out using a mobile phase consisting of Potassium dihydrogen phosphate buffer (pH 7.2): Acetonitrile (25:75 %v/v). Column used was SHIMADZU C_{18} (4.6x250 mm, 5 µm) with a flow rate of 0.8 ml/min and the column temperature was maintained at 40 °C. The detection wavelength used was at 220 nm. The retention time of Clotrimazole, Imidazole and 2-chlorophenyl phenyl methanone (2-chlorobenzophenone)was 8.12, 7.56 and 3.02 min respectively. Linearity of Clotrimazole and its Impurity are in range of 0.013-0.076 mg/mL. For System Suitability % RSD was found to be 1.60 for Clotrimazole, 1.29 for Imp-D, 1.15 for Imp-E..The Mean% Recoveries were found to be within the range of 98-102 %.Analytical parameters were calculated and a statistical evaluation was included.

Keywords: Clotrimazole; Imidazole; 2-chlorophenyl phenyl methanone (2-chlorobenzophenone); HPLC; Simultaneous; estimation; Impurity.

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Review Article

Thiazolidinediones (TZDs) as a Versatile Scaffold in Medicinal Chemistry Biological Importance: A Review

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ABSTRACT

Thiazolidinediones are a versatile scaffold of linking various classes of organic compounds with only one of its kind structural feature of hydrogen bonding donor and the hydrogen bonding acceptor region. Thiazolidinedione is an important heterocyclic ring system, is a derivative of thiazolidine ring which came into existence for its role as a ligand of Peroxisome proliferator activated receptor. A wide-ranging number of researches have led to determination of its huge biological profile with wide range of therapeutic applications. Thiazolidine-2, 4-dione is an outstanding heterocyclic moiety in the field of drug discovery, which provides various opportunities in exploring this moiety as an antidiabetic agent. In this review, an effort has been made to summarize the research work of various synthetic strategies for Thiazolidinedione derivatives as well as their biological significance.

Keywords: Thiazolidinedione, PPAR-gamma, antidiabetic activity.

INTRODUCTION

Historical aspects of Thiazolidinediones

Thiazolidinediones (TZDs) were first reported as insulin-sensitizing drugs in the early 1980s by the pharmaceutical company Takeda, but their mechanism remained a mystery until the mid-1990s, when they were found to be ligands for the nuclear receptor transcription factor PPARγ. PPARγ is expressed at high levels in adipose tissue, where it functions as a master regulator of adipocyte differentiation, and at much lower levels in other tissues. The simplest model for TZD function involves PPARγ agonism in adipose tissue.

Thiazolidinediones (TZDs), or "glitazones," were first introduced for the treatment of type 2 diabetes in 1996, when troglitazone was approved by the Food and Drug Administration. Since the introduction of this unique class of compounds, many clinicians have embraced their use, whereas others have debated the role of insulin-sensitizing therapy for the management of type 2 diabetes.

Before the introduction of glitazones, conventional management of type 2 diabetes involved stepwise addition of medical nutrition therapy, sulfonylureas, and metformin. Despite broader use of early drug therapy, many patients do not achieve adequate blood glucose control. Even in those who do achieve treatment targets, a gradual deterioration in blood glucose control is often seen. These observations have prompted clinicians to use newer therapies, such as the glitazones, and have increased the use of early combination therapy to achieve glycemic targets.

Glitazones uniquely target insulin resistance-a core physiologic defect in those with type 2 diabetes and by so doing significantly improve glucose control. Glitazones improve insulin action in muscle, adipose, and hepatic tissue by acting as agonists of peroxisome proliferator–activated receptor-γ (PPAR-γ) nuclear receptors. Activation of PPAR-γ results in a myriad of both metabolic and vascular effects by up regulating and down regulating expression of numerous genes, including genes known to regulate lipid and glucose metabolism, vascular function, thrombotic function, and the inflammatory response. Glitazones increase nonoxidative glucose disposal, increase triglyceride synthesis, and improve free fatty acid (FFA) metabolism. Glitazones also lower blood pressure, improve lipid metabolism (raising HDL cholesterol, reducing triglyceride levels, and increasing concentrations of large, buoyant LDL particles), and improve vascular reactivity and rheologic abnormalities common to type 2 diabetes and insulin resistance.

Glitazones' unique effects suggest that these compounds may have significant advantages over other commonly used glucose-lowering therapies. The potential of several of these advantages are outlined below and establish both the clinical benefit of glitazone therapy and the clinical potential of these and other insulin-sensitizing therapies.

Diabetes Mellitus (DM) is an endocrine disorder resulting from an inadequate production or impaired use of insulin. Uncontrolled diabetes leads to chronic hyperglycemia (too much sugar in the blood). DM is a chronic disease for which there is no single cause. DM is often a secondary diagnosis to other disorders. Each year approximately 65,000 people are diagnosed with diabetes. The American Diabetes

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Rp-hplc method development and validation for simultaneous estimation of lopinavir and ritonavir in bulk and tablet dosage form

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Abstract: **A simple, Accurate, precise method was developed for the simultaneous estimation of the ritonavir and lopinavir in bulk and tablet dosage form. Chromatogram was run through schimadzu C_{18} (250 x 4.6 mm, 5µ).Mobile phase containing Acetonitrile: phosphate Buffer taken in the ratio 60:40v/v was pumped through column at a flow rate of 1.2 ml/min. Buffer used in this method was 0.1% OPA buffer. Optimized wavelength selected was 226 nm. Retention time of ritonavir and lopinavir were found to be 6.428min and 7.325 min. %RSD of the ritonavir and lopinavir were and found to be 0.7 and 0.8 respectively. %Recovery was obtained as 100.16% and 98.96% for ritonavir and lopinavir. LOD, LOQ values obtained from regression equations of ritonavir and lopinavir were 4.08, 3.49 and 12.3, 10.5 respectively.Regression equation of ritonavir is y =13739x+11111, and y = 3713x+3510 of lopinavir.Retention times were decreased and run time was decreased, so the method developed was simple and economical that can be adopted in regular quality control test in Industries.**

Keywords: **Ritonavir, lopinavir, Method development, RP-HPLC**

INTRODUCTION

Genotype 1a/b and 4 treatment-naïve patients with or without cirrhosis.. Ritonavir is an HIV protease inhibitor that interferes with the reproductive cycle of HIV. Although it was initially developed as an independent antiviral agent, it has been shown to possess advantageous properties in combination regimens with low-dose ritonavir and other protease inhibitors. It is now more commonly used as a booster of other protease inhibitors and is available in both liquid formulation and as capsules.

While ritonavir is not an active antiviral agent against hepatitis C virus (HCV) infection, it is added in combination therapies indicated for treatment of HCV infections as a booster. Ritonavir is a potent CYP3A inhibitor that increases peak and trough plasma drug concentrations of other protease inhibitors such as Paritaprevir and overall drug exposure. American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) guidelines recommend ritonavir-boosted combination therapies as a first-line therapy for HIV(Fig.1)

Lopinavir is an antiretroviral belonging to the *protease inhibitor* class. It is marketed by Abbott as Kaletra, a co-formulation with a sub-therapeutic dose of ritonavir, as a component of combination therapy to treat HIV/AIDS.(Fig.2)

From the literature review i found that more usage of buffer and I found 2-3 methods.But there are less 1-2 methods for assay determination of ritonavir and lopinavir in bulk and tablet dosage forms.

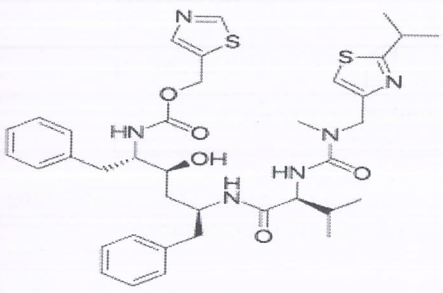

Figure 1 Ritonavir structure

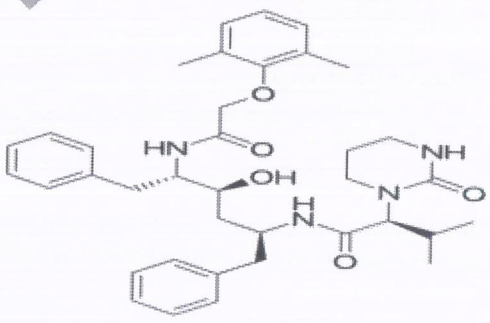

Figure 2 Lopinavir structure

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Formulation and Evaluation of Pantoprazole Sodium Microspheres

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Date of Submission: 15-11-2020 Date of Acceptance:04-12-2020

ABSTRACT: Microspheres are typically free flow powders consisting of proteins or synthetic polymers which are biodegradable in nature and ideally having a particle size less than 200 µm. An attempt was made to prepare floating microspheres of pantoprazole using polymers of PVP and HPMC by coacervaton technique. It was concluded that the drug release from the floating microspheres was controlled by the polymer. The nature of the polymers and their concentration influenced the physical and floating behaviour of the prepared microspheres. In vitro release data obtained from buoyant microspheres showed good buoyancy and prolonged drug release for formulations.

KEYWORDS Microspheres, Controlled released, HPMC, PVP , Pantoprazole.

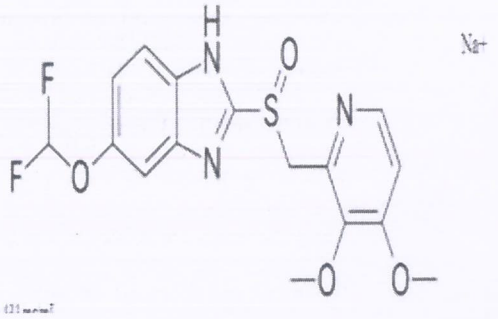
I. INTRODUCTION

Drug delivery systems (DDS) that can precisely control the release rates or target drug to a specific body site have had an enormous impact on the health care system. The last two decades there has been a remarkable improvement in the field of novel drug delivery systems. Carrier technology offers an intelligent approach for drug delivery by coupling the drug to a carrier particle such as microspheres, nanoparticles, liposomes, etc. which modulates the release and absorption characteristics of the drug. Microspheres constitute an important part of these particulate DDS by virtue of their small size and efficient carrier characteristics.

Ion gelation technique is one of the several methods that is used for production of microspheres. Although this way may not be the main method, but it is the simplest one that several variables can affect the outcome, as well.[1]

Sustained release microspheres may be produced by several methods utilizing emulsion system (oil-in-water, oil-in-oil, water-in-oil-in-water), as well as by spray drying. The common emulsion system used oil-in-water (o/w), with microspheres being produced by the emulsion solvent evaporation method. This relatively simple method enables the entrapment of a wide range of hydrophobic drugs.[2]

Pantoprazole is used to treat certain stomach and esophagus problems (such as acid reflux). It works by decreasing the amount of acid your stomach makes. This medication relieves symptoms such as heartburn, difficulty swallowing, and persistent cough. It helps heal acid damage to the stomach and esophagus, helps prevent ulcers, and may help prevent cancer of the esophagus. Pantoprazole belongs to a class of drugs known as proton pump inhibitors (PPIs).



Appearance: White to off white ampholytic crystalline powder.
Solubility: freely soluble in water and Slightly soluble in phosphate buffer at PH 7.4. Water Solubility : 0.431 mg/mL
Molecular Formula : $C_{16}H_{14}F_2N_3NaO_4S$
Molecular Weight : 423.367 g/mol
Iupac Name : Sodium;5-(difluoromethoxy)-2-[(3,4-dimethoxypyridin-2 yl)methylsulfinyl]benzimidazole-1-ide;hydrate
Storage: Store Pantoprazole at 20^0- 25^0C (68^0 - 77^0 F); excursions permitted to 15^0 - 30^0C (59^0 – 86^0 F)
Category: Proton Pump Inhibitor (PPI)
Melting point: 139-140°C
Log P: 2.18
Bioavailability: 77%
Half life: 1-2 hr

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International Journal of Drug Regulatory Affairs

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Review Article

Drug Registration requirements for Pharmaceuticals in Emerging markets

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Abstract

Registration of pharmaceutical drug products in emerging market is maximum worrying task. Although the requirements are harmonized in regulated international locations by way of CTD (Common technical document) submitting, yet others have considerable diversity in necessities. International conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) has brought regulatory authorities and pharmaceutical industries of US, Japan and Europe collectively for various factors of drug registration. But there is no such harmonized guideline for rising marketplace besides Association of Southeast Asian Nations (ASEAN) and Gulf Co-operation Council (GCC) where harmonization exists in clusters with their mutual situation. Quality, Safety and Efficacy information has significance importance in dossier registration. Pharmaceutical Industries has to conform with regulatory requirement in Emerging market and for betterment of public Health and protection. The business importance of markets is increasing globally. It is important for pharmaceutical enterprise to address the regulatory necessities for betterment of public and to ensure their place in the marketplace. The review additionally explains a short approximately extraordinary regulatory requirement for Registration of drug product in Emerging market and comparative data for registration of dossier software in Emerging marketplace.

Keywords: Dossier Registration, Emerging Markets, GCC, ASEAN, Common technical document (CTD), WHO, Harmonization, Drug Product

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1. Introduction

Drug Regulatory Affairs is one of the evolving and developing department with least impacted through the acquisition and merger, and also in the duration of recession. Global harmonization has brought steady method in regulatory submission. Asia is predicted to overtake Europe in pharmaceutical marketplace within the next decade and sales are driven by using increase in key rising markets. E.g., China is deemed to be the second biggest pharmaceutical` marketplace after the USA.

Emerging markets

The term "rising marketplace economy" was first utilized in 1981 by "Antoine W.VanAgtmael" of the International Finance Corporation of the World Bank. Emerging markets are economies of countries that are within the process of becoming a developed country. And normally are transferring closer to blended or unfastened markets. Emerging marketplace economies often have decrease according to capita income than developed countries, and frequently have liquidity in fairness markets, are instituting regulatory bodies and exchanges with notice speedy boom. (1) According to the Morgan Stanley Capital International Emerging Market Index, 24 developing international locations qualify as emerging markets. The index follows the market caps of the groups at the countries' stock markets as given in Table 1. (2) More than 85 % population lives in the emerging market and so the real financial boom has come from these markets. This promotes many MNC's switched to those rising international locations particularly in China, India, Russia, Korea and Mexico. The growing presence is more and more moving beyond the usage of CRO's and marketing of properly mounted merchandise to include early-degree studies and generation geared toward specific medical needs of patients in those areas. (3)

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CONTRIBUTION TO THE PHYTOCHEMICAL AND PHARMACOLOGICAL STUDIES OF TRADITIONAL PLANT *TABERNAEMONTANA DIVARICATA* IN THE TREATMENT OF INFLAMMATION AND UROLITHIASIS

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ABSTRACT

This study determined the phytochemical screening, acute toxicity studies, anti-inflammatory and anti urolithiatic of the aqueous and methanolic extracts of *Tabernaemontana divaricata* (carnation of India) belonging to the family *Apocynaceae*. Natural products which are of plant origin are found to be very useful and contain active constituents that cure or prevent many diseases. These natural products are believed to be safer when compared with synthetic drugs as they are less toxic with minimal side effects. *Tabernaemontana divaricata* (TD) is a shrub or small tree, usually glabrous, found in Konkan/Kanara regions of India and Bangladesh. The crude aqueous (AETD) and methanolic (METD) extracts of *Tabernaemontana divaricata* were tested for acute toxicity, anti-

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BIOLOGICAL EVALUATION OF SELECTED PHYTOCHEMICALS FOR THEIR ANTI-ACNE PROPERTIES BY CHEMICAL INDUCED ACNE VULGARIS IN RODENTS

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ABSTRACT

The present work is to screen the selected phytochemicals for alleviate chemical induced acne in mice. The treatment for acne with synthetic drugs have various drawbacks, usage may lead to development of resistant towards these drugs. Hence plants derived compounds are required to overcome the above drawbacks and treat the acne. Present study was aimed to evaluate anti acne potential of selected phytochemicals on the primary clinical lesion, microcomedone, which are the precise, almost all other acne lesions by applying topically on skin. Animals of either sex were collected from the animal house of Chalapathi Institute of Pharmaceutical sciences were randomized into 10 groups consisting of five animals/ group. Benzalkonium chloride used for inducing acne. The test compounds (2% geraniol, 2% hesperidine 2% ellagic acid and 2%liquorice) showed that decreased the inflammation in mice ear. On the10th day there was a significant decrease ($p<0.0001$) in inflammation (0.66±0.1503, 0.32±0.0734, 0.32±0.0734) with respective to the disease control. The test compounds at 2% showed significant reduction in the overall damage caused by acne induced by chemical contact and reduced the proliferation of inflammatory cell into the ear region.

Keywords: Acne, Benzalkonium chloride, Ellagic acid, Hesperidine, and Geraniol

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Quality Assesment of Selected Commercial Brand of Chilli Powder in Andhrapradesh Region

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ABSTRACT: Analysed quality parameters of different commercial brand red chilli powders (*Capsicum annuum L)* collected from Guntur Mirchi yard, Guntur, Andhra Pradesh. The quality parameters of moisture content, pH, total ash content, acid soluble ash content, ascorbic acid content, minerals (sodium, potassium, calcium), capsaicin content and ASTA colour value were assessed which are directly related to quality, processing technique, storage condition, packaging of chilli powder. In different varieties of chilli powders moisture content, ash content and ASTA colour values differ significantly between 1.6 to 8.6%, 3.6 to 7.3% and to 76.45 ASTA.

Capsaicin content was estimated by colorimetric method and R^2 shows 0.9978, which shows developed method was linear. In addition, a minimum of 1 mcg/mL capsaicinoids can be detected and developed method can efficiently analyze a great quantity of samples in a short time.

Based on the capsaicin content and colour value of different red chilli powders provides useful information for buyers of chilli exporters and industrial applications.

KEYWORDS: *Capsicum annuum L.*, Capsaicin, Ash value, ASTA colour value.

I. INTRODUCTION

Chilli (*Capsicum annuum* L.) is an important vegetable cum spice crop grown in almost all parts of tropical and subtropical regions of the world. It belongs to the family Solanaceae and originated from South and Central America where it was domesticated around 7000 BC. The genus *Capsicum* includes 30 species, five of which are cultivated *Capsicum annuum* L., *C. Frutescens* L., *C. Chinense* Jacq, *C. pubescens*

R. & P. and *C. Baccatum* L. (Bosland and Votava, 2000; Wang and Bosland, 2006 and Ince *et al.*, 2010) [1-6].

Capsicum annuum is cultivated either for pungent fruited genotypes called chilli (synonyms: hot pepper, American pepper, chile, azi, cayenne, paprika *etc.*) or non-pungent fruited genotypes called sweet pepper (synonyms: Capsicum, paprika, bell pepper, Shimla mirch). Chilli has many culinary advantages. It comprises numerous chemicals including steam-volatile oils, fatty oils, capsaicinoids, carotenoids, vitamins, proteins, fibres and mineral elements (Bosland and Votava, 2000). *Capsicum* fruits may serve as a source of natural bactericidal agents to be used in food and medicinal systems [7-10].

Perez-Galvez *et al*., 2004; Manjula *et al*., 2011 and Sharanakumar *et al*., 201

In India chilli occupies an area of 7.50 lakh hectares with an annual production of 11.67 lakh tones (2009). Andhra Pradesh, Maharashtra, Karnataka and Tamil Nadu are major chilli growing states in India which together contributes about 75 per cent of the total cultivated area (Rajesh Kumar *et al*., 2011). Karnataka stands second in area (1.234 lakh hectares) and production (1.419 lakh tones), while in productivity it ranks eighth in position with an average yield of 1150 kgs of dry chilli per hectare. The important chilli growing districts in Karnataka are Haveri, Dharwad, Gadag, Koppal, Belgaum, Bellary and Raichur of which Haveri and Dharwad districts themselves make up 72 and 60 per cent of total area and production, respectively (http://horticulture.kar.nic.in). In recent years, there has been a great demand for increasing the diversity in chilli for within both culinary and ornamental purposes [14-17].

Though India is the leading producer, the average yield of chilli is very low (1.11 t/ha dry chilli) as compared to developed countries like USA, China, South Korea, Taiwan etc, where the average yield ranges from 3 - 4 t/ha. Low productivity in chilli is mainly attributed to lack, of high yielding, pest and disease resistant varieties or hybrids. Only about 2.60 percent chilli area is under hybrids in India, while in the countries like Korea and Taiwan more than 90 percent area is covered by hybrids [18-20].

Capsicum has been cultivated over centuries, producing both pungent and sweet fruits. *Capsicum annuum* L. is characterized by a wide variety of fruit size, shape and with different capscaicnoid content. Despite the importance of this plant as spice and its medicinal uses, research on its genetic variability and

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Editorial

A Simple Method for Animal Dose Calculation in Preclinical Research

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In preclinical research, the experimental animals are dosed according to their body weight. The selection of doses is usually decided based on acute oral toxicity studies. In most cases, at least three doses of a test compound will be used to demonstrate the dose-dependent effect. If the preclinical research is based on clinical findings, the human dose is converted into corresponding animal dose using this formula:

Animal dose (mg/kg) = Human dose (mg/kg) × Human (Km)/Animal (Km)

The correction factor (Km) = Body weight (kg)/Body surface area (m^2)

Km for Human = 60/1.6 →37; Rat= 0.15/0.025 → 6; Mouse= 0.02/0.007 → 3

For example, Human dose of telmisartan = 0.67 mg/kg

The rat dose of telmisartan is calculated as 0.67 × 37/6 = 4.13 mg/kg

The mouse dose of telmisartan is calculated as 0.67 × 37/3 = 8.26 mg/kg

Next, it is important to determine the volume of injection according to the body weight of animals. Calculating the volume of injection for each animal is time consuming and there is a chance of error. To overcome this issue, the following tips can be useful.

For rats

In case of drug stock solution for a test compound which is sparingly soluble in water that intended to be administered at a dose of 100 mg/kg, i.p., the concentration of drug solution could be used as follows.

For example, if the dose of rats is 100 mg/kg, a stock solution of 100 mg/ml has to be prepared.

If the dose is 200 mg/kg, prepare a stock solution of 200 mg/ml and so on.

1. This compound is sparingly soluble in water. Therefore, the test compound should be prepared as suspension using suspending agents like sodium carboxymethylcellulose (CMC), acacia and tragacanth. Use of organic solvents that commonly used in *in vitro* studies is not recommended in *in vivo* animal studies.

2. This drug solution should be prepared sterile due to its parenteral route of administration. A suspension of 0.5% w/v of CMC in sterile water for injection or in normal saline could be used for drug stock solution preparation.

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RESEARCH ARTICLE

Synergistic Effect of Leaf Extracts of *Ficus Hispida* and *Psidium Guajava* for Anti-Diabetic Activity on Wistar Rats

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ABSTRACT:

Ficus hispida (tropical fig tree) is a moderate sized tree which is commonly known as devil fig, traditionally used in the ailment of pain, inflammation, and neurological disorders. *Psidium guajava* (Guava/peru)is a well-known tropical tree and also used as a folk herbal tea used to treat diabetes and leaves were used as astringent, anodyne, febrifuge, antispasmodic, tonic, in wounds, cholera, lactagouge, diarrhoea, vomiting and variety of diseases like diarrhoea, dysentery, hypertension, gastroenteritis, diabetes, cough, oral ulcers etc., The aim of the present study is set out to evaluate the anti-diabetic activity of ethanolic leaf extracts of *ficus hispida* and *psidium guajava* on streptozocin induced diabetized rats. The leaf extracts at a dose of 100mg/kg were screened for their blood glucose lowering effectamong streptozocin induced diabetized rats and the blood samples were collected through the tail vein from which blood glucose levels were determinedat 0h, 1h, 2h and 4hafter administration of test samples. Both the leaf extracts of *ficus hispida* and *psidium guajava* produced significant ($p \leq 0.01$) decrease in the blood glucose levels. The ethanolic extract of leaves of *ficus hispida* and *psidiumguava* produced synergistic effect when compared with standard by showing an effective response on diabetic rats. These plants supported the folk fore claim of anti-diabetic activity. Further investigations are needed for the proper identification and isolation of these bioactive compounds to produce safer drugs for treatment of harmful diseases.

KEYWORDS: *Ficus hispida*, *psidiumguajava*, wistar rats, streptozocin, lactagouge, folkfore.

INTRODUCTION:

Diabetes is a disorder characterised by chronic hyperglycemia, glycosuria, hyperlipidaemia, negative nitrogen balance together with biochemical alterations of glucose and lipid metabolism. Liver is an Insulin dependent tissue, plays a pivotal role in glucose and lipid homeostasis which get adversely affected during diabetes[1]. Many traditional plants are used in the treatment of the diabetes but only few plants has received scrutiny. According to WHO, 8.7% population was suffering with diabetes as a growing challenge of age group 20-70 years in India.

There are four main types of diabetes. They are

Type 1. Insulin dependent diabetes mellitus or juvenile onset diabetes mellitus
Type 2. Noninsulin dependent diabetes mellitus or mature onset diabetes mellitus
Type 3. Alzheimer's disease from resistant insulin
Type 4. Gestational diabetes

Ficus hispida (tropical fig tree)is a moderate sized tree which is commonly known as devil fig, traditionally used in the ailment of pain, inflammation, and neurological disorders[2]. *Ficus hispida* is documented to possess anti-diarrheal activity[3], anti ulcerogenicactivity[4], cardio protective[5], sedative, anti-convulsant[6], neuroprotective, antineoplastic[7], anti-inflammatory[8], antipyrectic, hepatoprotective effects[9] and anti-oxidant activity[10]. The presence of phytoconstituents like tannins such as hispidine, β-sitosterol, lupeol, β-amyrin and bergapten have been reported[11].

HERBALISING THE FUTURE: A PERSPECTIVE ON HERBAL SHAMPOO

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Abstract: Herbal formulations have growing demand in the market due to their availability, low cost and few or no side effects. Shampoos are the cosmetic preparations, which are used for promotion of hair growth and to remove the dirt or oil present on the scalp. Cosmeceuticals are the cosmetics in which one or more ingredients of pharmacological activity are present. The herbal shampoos are meant for cosmetic property as well as possess anti dandruff activity. The present work is aimed to prepare and evaluate the effective herbal shampoo which promote hair growth and reduces dandruff. Various herbal ingredients are used in this study and evaluated for its morphological characters, pH, viscosity, surface tension, total soli content, anti-microbial activity, dirt stability, foam stability and wetting property. All these parameters were found to be satisfactory and the formulation is effective against dandruff.

IndexTerms - Cosmeceuticals, herbal shampoo, herbal ingredients, evaluation

I.INTRODUCTION

A shampoo is formulation of a surface active materials in the form like liquid,solid (or) powder which when used based on specific conditions they can remove surface grease,dirt and skin debris from the hair shaft and scalp without adversely affecting the user [1]. They can cleanse, modifying the texture, changing of the colour ,giving life to stressed hair, providing nourishment to the hair and giving healthy look to the hair. Shampoos are available as Powder Shampoo, Liquid Shampoo, Lotion Shampoo, Cream Shampoo, Jelly Shampoo, Aerosol Shampoo, Specialized Shampoo which are meant for conditioning, anti-bacterial and two-layer shampoo.

Herbal shampoo: Herbal shampoos are the cosmetic preparations meant for cleansing the hair and scalp. It can help the hair to improvise their quality of moisture, shine, growth, silkiness,thickening, strengthening of hair. It is also helpful for prevention of dandruff, promoting hair growth by nourishing the hair. The most desirable quality of this herbal shampoo is it should not cause any side effects.The active ingredients include,

Amla : It helps for growth and nourishment, shine and allowing natural texture,oils of the hair.It should prevent hair loss. It has fatty acids, which can remove dryness and dandruff

Lemon grass oil: It should impactfragrance and pH of herbal shampoo

Ashwagandha: It is an ancient medicinal herb.It may help to reduce stress and anxiety and improves scalp blood circulation.

Brahmi: It has good strengthening property and helpful for hair follicle strengthening property.It provides proper nutrients to the hair follicles thus invigorating the hair growth.

JRP Journal of Research in Pharmacy

Research Article

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Morinda citrifolia Linn. (Noni) fruit extract attenuates ethanol seeking behavior in mouse runway paradigm

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ABSTRACT: In this study, we used methanolic extract of *Morinda citrifolia* Linn. fruit (MMC) in order to find its effect against ethanol seeking behavior in a modified mouse runway paradigm. During conditioning/acquisition animals were treated with accelerated doses of ethanol (0.5-4 g/kg, i.p.) for 5 days (Day 1- Day 5). Then, ethanol seeking behavior was assessed on Day 6 (postconditioning test). Ethanol seeking behavior was confirmed in ethanol control group in which the run time to reach the target box was significantly decreased. The test drug MMC (1, 3, and 5 g/kg, p.o.) caused a significant reversal of the ethanol seeking behavior by increasing the run time to reach the goal box as seen with the reference drug acamprosate (ACAM; 300 mg/kg, p.o.) in mice. After postconditioning test, non-rewarded abolishment assays were performed for a period of five days (Day 7 –Day 11). After 5 days of abolishment (abstinence), a priming dose of ethanol (the highest dose at 1/5th portion applied in control (i.e. 0.8 g/kg, i.p.)) in house cage significantly reinstated the ethanol-seeking behavior. Interestingly, MMC at a higher dose (5 g/kg, p.o.) showed significant halt on ethanol-induced reinstatement in mice as shown with the reference drug ACAM (300 mg/kg, p.o.). The outcome of this study reveals that MMC alleviated ethanol seeking behaviour in modified mouse runway paradigm and it could be effectively used to treat alcohol dependence.

KEYWORDS: Alcohol dependence; acamprosate; *Morinda citrifolia* Linn; mouse runway paradigm; self-administration.

1. INTRODUCTION

The motivational effects of numerous consummatory reinforcers including food, water and drugs of abuse have been extensively studied using a test on alley running performance in rodents [1]. Traditional runway models of operant drug reward have been restricted by systematization aspects related to the requirement to ensure medicament delivery to the animal over heavy distances beside intervening with the runway behavior of rats [2]. Ideally, one would want a system with precise motivational and confounding factors that should not affect animal behavior. Recently, we developed a novel runway model of drug self-administration using mice without compromising a great active long-term analysis of runway efficient performance for drug reward [3].

Morinda citrifolia Linn. (Noni) has been utilized as diet source, medicine, and fabric dyes by Polynesian people [4]. Traditionally, *M. citrifolia* has been widely used as prophylaxis and treatment of many CNS disorders such as anxiety, depression, psychosis and drug dependence. In earlier study by our research group, MMC was reported for anxiolytic and antidepressant-like activity [5] anti-psychotic-like activity [6] and anticraving effect in opposition to heroin, ethanol and methamphetamine dependence using conditioned place preference test in rats and mice [7-10]. The current investigation was designed to test the activity of MMC against ethanol seeking behavior in mice by employing modified runway paradigm of self-administration of drug.

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EVALUATION OF CARDIOPROTECTIVE ACTIVITY OF SAPONINS (*SAPINDUS MUKOROSSI*) ON WISTAR RATS

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ABSTRACT

Sapindus mukorossi Linn belongs to the family Sapindaceae. The fruit is valued for the saponins (10.1%) present in the pericarp and constitutes up to 56.5% of the drupe known for inhibiting tumour cell growth and traditionally fruit of *Sapindus mukorossi* is used for epilepsy, chlorosis (Iron deficiency anaemia) and excessive salivation. In the present study an attempt was made to isolate saponins from *Sapindus mukorossi* and to evaluate the cardioprotective potential of isolated saponins against isoproterenol induced cardio toxicity in wistar rats. The pericarp of *Sapindus mukorossi* is powdered, extracted with water and was subjected for phytochemical screening. The saponins (200mg/kg) exhibited significant cardio protective effect against Isoproterenol (2 mg/Kg, i.p.) induced myocardial damage by

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Original Article

Evaluation of anti-psoriatic activity of selected phytochemicals on UV-induced psoriasis in mouse tail model

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ABSTRACT

Objectives: To evaluate anti-psoriatic activity of Phytochemicals on UV-Induced psoriasis in mouse tail model.

Materials and Methods: Anti-psoriatic activity of selected phytochemicals on UV-Induced psoriasis in mouse tail model. The animals were dividing into 05 groups and each group contain 5 animals. Disease control group did not receive any treatment only exposure to UV-light, vehicle control treated with simple ointment, standard group treated with salicylic acid (1%w/w) ointment, remaining group are treated 1% and 2% selective phytochemical at two concentrations of ointment to topically on the tail skin. And the data were analysed using *one way ANOVA* followed by *two-way ANOVA* (Dunnett's multiple comparisons test).

Results: There was significant decrease in epidermal thickness ($P < 0.05$) as compared with control group. In 2% phytoconstituents has shown a significant reduction in the total epidermal thickness 8.4****±0.748, 7.6**±0.6781 and 8*±0.8366 in geraniol, glycyrrhizic acid and ellagic acid treated group, when compare to the disease induced animal, there was no lesion of Munro's microabscess, capillary loop dilation along with elongation of rete ridges in the section of skin of rats. Psoriasis Severity Index was reduced in test treated groups as compared with that of disease control group. It was slowly reduced to 2nd week, totally (55-70%) reduction in PSI is observed at the time of third week of treatment period.

Conclusion: The result of the study showed that the 2% of geraniol, ellagic acid, glycyrrhizicacid and hesperidin, exhibited significant activity on UV-induced psoriasis in rodents. The study implies that selected phytoconstituents are a promising research for further investigations to prove its anti-psoriatic activity.

Keywords: Psoriasis, UV-Ray, Hesperidin, Ellagic acid and geraniol

INTRODUCTION

Psoriasis is a common inflammatory condition of human skin characterised by focal to coalescing raised cutaneous plaques with consistent scaling and variable erythema. Typical histologic features of psoriasis include epidermal hyperplasia (acanthosis) with elongated rete ridges, a less discrete epidermal granular layer (hypogranulosis), parakeratosis and leucocytic infiltration of the dermis and epidermis.[1] It is a chronic inflammatory disease of the skin characterised by epidermal hyperplasia, dermal angiogenesis, infiltration of activated T cells and increased cytokine levels.[2] An increase in mitotic activity in the stratum basale, abnormal keratinisation and elongation of

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ORIGINAL ARTICLE

Methanolic Extract of *Mitragyna speciosa* Korth Leaf Exhibits Place Preference Only at Higher Doses in Mice

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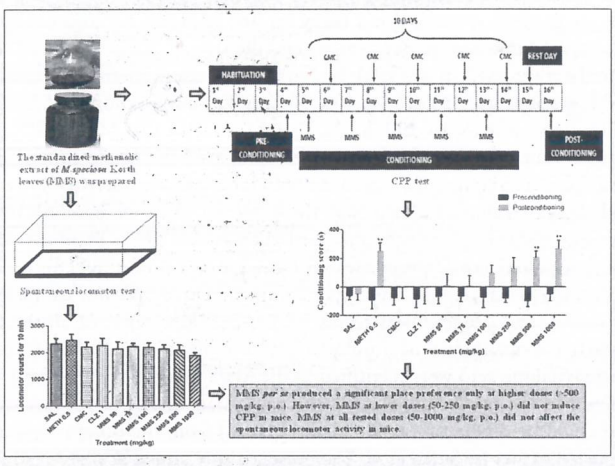
ABSTRACT

Background: *Mitragyna speciosa* Korth possesses a wide range of therapeutic benefits, despite having abuse liability. **Objectives:** The purpose of this research was to investigate the reinforcing properties of *M. speciosa* Korth leaf extract obtained via methanol extraction using mouse conditioned place preference (CPP) test. **Materials and Methods:** In CPP study, following baseline preference test (preconditioning score), the mice were subjected to conditioning trials at varying doses of methanolic extract of *M. speciosa* (MMS, 50, 75, 100, 250, 500, and 1000 mg/kg, p.o.) or reference drugs methamphetamine (0.5 mg/kg, intraperitoneally [i.p.]) and clozapine (1 mg/kg, p.o.) or vehicle controls (1% w/v sodium carboxy methyl cellulose [10 mL/kg, p.o.] and saline [10 mL/kg, i.p.]) followed by a preference test performed under drug-free state (postconditioning score). In addition, the effect of all tested drugs on the spontaneous locomotor activity was assessed. **Results:** The CPP study results revealed that MMS *per se* produced a significant place preference only at higher doses (>500 mg/kg, p.o.). Nevertheless, MMS at lower doses (50–250 mg/kg, p.o.) did not induce CPP in mice. In addition, MMS at all tested doses (50–1000 mg/kg, p.o.) did not affect the spontaneous locomotor activity in mice. **Conclusion:** MMS *per se* exhibits reinforcing properties at only an increased dose of >500 mg/kg, and therefore, it is best to administer at lower doses (<250 mg/kg) for the potential therapeutic benefits in preclinical studies.

Key words: Clozapine, conditioned place preference, drugs abuse, methamphetamine, *Mitragyna speciosa*

SUMMARY

- The methanolic extract of *Mitragyna speciosa* (MMS) leaf showed a place preference in conditioned place preference test only at higher doses (>500 mg/kg) in mice, which was comparable to the reference drug methamphetamine (0.5 mg/kg). However, MMS did not display place preference at lower doses (<250 mg/kg) in mice. The study results suggest that MMS could have addictive potential at higher doses, and it should be used only at lower doses (<250 mg/kg) for any therapeutic investigations in preclinical research.



Abbreviations Used: MMS: Methanolic extract of *Mitragyna speciosa*; METH: methamphetamine; CLZ: clozapine; CMC: carboxy methyl cellulose; SAL: saline; CPP: conditioned place preference.

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INTRODUCTION

The application of cannabis, coca, and opium poppy in hospitals and medical surgeries was dated back to few centuries ago. Morphine obtained from the opium poppy drips in hospitals served as a potent pain killer; cocaine obtained from *Erythroxylon coca* plant served as an anesthetic agent in certain medical surgeries; and cannabinoids obtained from the cannabis plant are used for the treatment of chemotherapy-induced nausea and vomiting and epileptic seizures.[1-4] Although these plants were proved to be beneficial in all aspects mentioned above, the addictive and fatality potentials of these plants are undeniable. Appropriate use of these drugs in terms of dose, dosage forms, and duration of the treatment makes them beneficial rather than harmful. *Mitragyna speciosa* is one such plant that possesses vast therapeutic benefits with addictive potential. Identifying the nonaddictive dose of *M. speciosa* leaf extract is crucial in novel drug discovery for various ailments.

M. speciosa is a tropical tree mostly found in Thailand and Northern Malaysia, which has been used conventional for therapeutic and recreational purposes. *M. speciosa* is known as "Kratom, Thang, Thom, and Kakuam" in Thailand and "Ketum or Biak-biak" in Malaysia, and it has been reported for many pharmacological activities such as analgesic, antidiarrheal, antipyretic, local anesthetic, and antipsychotic activities.[5,6] Boyer *et al.* reported that *M. speciosa* acts as an opioid agonist and exhibits a strong analgesic (pain-relieving) effect, which is often used in place of powerful prescription of opioids.[7] Besides, it is evident that

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Research Article

A COMPARATIVE STUDY ON INHALATION TOXICOLOGY BETWEEN AIR FRESHENERS OF SYNTHETIC AND NATURAL ORIGIN

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ABSTRACT

The main objective of this research is to design and formulate natural air freshener gel and evaluate the inhalational toxicity by comparing it with synthetic air freshener gel. The natural air freshener was prepared using natural gelatin and sandalwood oil as essential oil and the synthetic air freshener was prepared by using carbopol-940, Propylene glycol (10 % w/w), Ethanol (3% of total volume), triethanolamine as chemical composition and sandalwood as essential oil. The animals were acquired as per the CPCSEA guidelines, divided into groups and undergone with chronic exposure of prepared gels for 2 months. The animals were sacrificed, and the tissues were sent for histopathological studies. As per the results obtained from histopathology, it is observed that the animal groups which were allowed for the chronic inhalation of natural air freshener are safer when compared with the synthetic air freshener. The alveolar walls of the lungs became thicker and destroyed at some places for the animal group that was treated with synthetic air freshener and very less thick in case of natural ones. In case of liver, the normal polygonal shape of hepatocytes was distorted, their nuclei were enlarged, tissue was also damaged due to the appearance of blood streaks among the hepatocytes in synthetic treated group and the similar effects in natural are very less. In case of cerebral cortex of brain of mice, vacuolation was found in some areas due to damage and degeneration of neuronal cell body in synthetic treated group and these are very less in natural treated groups.

Keywords: Air freshener, triethanolamine, sandalwood oil, carbopol – 940, propylene glycol.

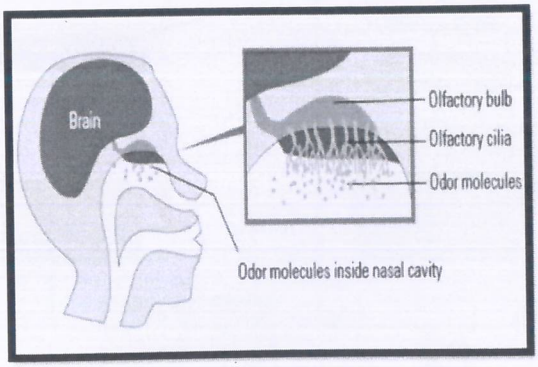
INTRODUCTION

Many things in this world change according to the trend. Now due to the impact of globalization, everyone has the opportunity to access what the other person is able to, since every industry is reaching global standards. So, if there is any bright thing about the product and people start to use it, it is acceptable. Suppose if there is a dark shade of the product which is found very later, after the widespread of it, then it is difficult to eradicate it. In this current scenario, where perfumery merged with various other industries like disinfectants, clothing and air fresheners especially, to enhance the fragrance and solubilize various fragrant ingredients, lot of harmful chemicals are being used, since they are available at cheaper range. Though they might not show immediate adverse reactions, they even can cause cancer on long term exposure.

Here, we chose to observe if there are any clear differences between natural ingredients-based air freshener and synthetic air freshener in terms of safety and efficiency.

To begin with the mechanism of the reception activity of olfactory bulb, it is shown with a diagrammatic representation:

External View



The odor molecules give an impulse from olfactory cilia to olfactory bulb and then brain.

https://eschooltoday.com/science/the-five-senses/the-sense-of-taste.html

Figure 1: Physiology of Olfaction (External)

Thalla *et al. The Egyptian Journal of Bronchology* (2020) 14:46
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RESEARCH Open Access

A prospective observational study on acute exacerbation of chronic obstructive pulmonary disease in pulmonology department of tertiary care hospital

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Abstract

Background: Chronic obstructive pulmonary disease (COPD) is a common, preventable, and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gasses. An acute exacerbation of COPD refers to a flare up or episode where a person breathing becomes worse than normal. An acute exacerbation of COPD refers to a flare up or episode where a person breathing becomes worse than normal. Acute exacerbation in COPD (AECOPD) is frequent in the course of the illness and is the most common reason for medical visits, hospital admissions, and mortality among these patients. Exacerbations of COPD are associated with increased morbidity and mortality. To assess the exposure and severity of acute exacerbations of COPD with COPD Assessment Test (CAT Scale) and mMRC (modified Medical Research Council) Dyspnea scale. Study design was a hospital-based prospective observational study. Study site was conducted at Pulmonology Department of Government General Hospital, Vijayawada.

Results: The total patients were 197. Out of which, 119 were from In-patient Department (IPD) and 78 were from Out-patient Department (OPD). In this study, males were 167 (85%), among which, IPD were 97 (49%), OPD were 70 (36%), and females were 30 (15%), among which, IPD were 22 (11%), OPD were 8 (4%).

Conclusion: The morbidity and mortality of COPD have been increased in recent years. This study concludes that there is a relation between risk of acute exacerbations in COPD with habitual history and occupational history. Increase in exposure to occupational hazards, smoking habit leads to an increase in risk of acute exacerbations in COPD patients. The level of severity was more in smokers and the patients who had biomass, organic dust, and mineral exposure. When severity was observed, group D severity is more observed in population according to CAT scale and mMRC dyspnea scale.

Keywords: Pulmonology, Out-patients, In-patients, Department, Acute exacerbations, Chronic, COPD, Fever, Chest tightness, Shortness of breath, CAT, MMRC

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Review

Protective effect of mangiferin on memory impairment: A systematic review

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Natural product

ABSTRACT

Memory impairment (MI) is one of the predominant criteria generally used to identify schizophrenia, dementia and amnesia that are associated with neurodegenerative disorders by evaluating patient's cognitive symptoms. To date, there is no available treatment that can completely mitigate MI. Currently, there is a trend in recent investigations towards symptomatic therapy approaches using a variety of natural compounds. Mangiferin is one of them that have been investigated extensively. Mangiferin is a naturally occurring potent glucoxilxanthone and is mainly isolated from the *Mangifera indica* (Mango) plant. This review is aimed at providing a comprehensive overview on the efficacy of mangiferin on MI, based on *in-vivo* animal studies. After screening through articles identified from Scopus and PubMed based on the inclusion and exclusion criteria, a total of 11 articles between 2009 and 2019 were included. The minimum and maximum dose of mangiferin were 10 and 200 mg/kg respectively and administered over the period of 12–154 days. The results of 11 articles showed that mangiferin effectively improved spatial recognition, episodic aversive events, short- and long-term memories primarily occurring via its antioxidant and anti-inflammatory effects. The outcomes of the review revealed that mangiferin improves memory and cognitive impairment in different animal models, indicating that it has potential preventive and therapeutic roles in MI.

Contents

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Research Article

A Case Control Study on Factors Influencing Suicide Attempts

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ABSTRACT

Aim: We aim to study psychosocial, socio-demographic and personality related factors associated with suicide attempts. **Methods:** From 1st September 2018 to 28th February 2019, we conducted a hospital-based case control study in Department of Psychiatry, Government General Hospital, Guntur, India. One hundred forty-five cases and one hundred forty five age and sex matched controls were selected for study. Eysenck Personality Questionnaire, Modified kuppuswamy scale, Presumptive Stressful Life Event Scale, Suicide Intent Scale were used. Statistical analysis was done using computerized software. **Results:** Majority (n=69, 47.58%) of the suicide attempters were between 21-30 years of age. The number of suicide attempters are more in rural areas than in urban areas and it is statistically significant with an Odds Ratio 2.39. The risk of suicide attempts is more in people who are uneducated (OR – 1.51). It was observed that being an alcoholic will increases the risk of suicide attempt (OR-1.73). The average of PSLES score of individuals is more in case group (166.8) than control group (111.386). Having a family history of suicide attempts will increases the risk of suicide attempt (OR -2.28). **Conclusion:** Residing in rural areas, alcoholism, having no support from family members and having more stress full life events emerged as predominant risk factors for attempting suicide.

Key words: Suicide attempt, Socio-demographic factors, Personality traits, Stressful life events, Suicide intent, Psychiatric illnesses.

INTRODUCTION

Suicide can be defined as death caused by self-directed injurious behaviour with an intent to die as a result of the behaviour whereas Suicide attempt is a non-fatal, self-directed, behaviour with an intent to die as a result of the behaviour; might not result in injury.[1] Suicide attempt may occur up to 20 times more frequently than completed suicide. Suicide attempt is mostly associated with adverse long-term situations like psychiatric and medical comorbidity, hospitalization, repeated suicide attempts, poverty, chronic stress and stigma.[2] India's contribution to global suicides increased about 11.3% from 1990 to 2016. India comprised about 17.8% of world population but accounted for 36.6% of suicides among women and 24.3% among men in 2016.[3] A total number of 6226 suicides were reported in Andhra Pradesh in the year 2015 among them 1916 that is 30% of the suicides were due to illness which is the 3rd highest percentage share in all India average of suicides due to illness. Rate of suicides in Andhra Pradesh during the year 2105 is 12.1 per one lakh population.[4] Suicidal behaviour has a large number of hidden (under) causes. The factors that place people at risk for suicide are complex and interact with one another. Identifying these factors and understanding their roles in suicidal behaviour are central to prevent suicides.[5] People with a diagnosed mental health condition are shown to be at a higher risk of attempting and completing suicide,[6] with more than 90% of suicides and suicide attempts having been found to be associated with a psychiatric disorder. Across the globe, the highest rates of suicide were associated with depressive disorders across the globe.[7] In order to clearly understood the role of

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Available online at: http://www.iajps.com *Research Article*

PERIORBITAL EDEMA AND OPTIC DISC EDEMA SECONDARY TO USAGE OF IMATINIB MESYLATE IN CHRONIC MYELOID LEUKEMIA PATIENT

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Abstract:

Chronic myeloid leukemia is a myeloproliferative disorder. Imatinib mesylate (Gleevec®) is a first line pharmacologic treatment for all phases of chronic myeloid leukemia and for advanced gastrointestinal stromal tumors (GISTs). Imatinib mesylate is generally well tolerated. Well-known ocular side effects for Imatinib are periorbital edema, epiphora, conjunctival hemorrhage, blepharoconjunctivitis, visus alterations and ocular dryness and also optic disc edema is the rare ocular event associated with Imatinib use. Here we reported a case of 58-year-old Caucasian male was diagnosed with Chronic Myeloid Leukemia (CML) and he is treating with Imatinib for 7 years. Patient was presented with moderate periorbital edema along with optic disc edema and these ocular events can be self reducible in our case after suspension of Imatinib for 1 week without any treatment. Prompt consultation with an ophthalmologist can lead to early detection, proper diagnosis and appropriate therapeutic measures.

Keywords: *Chronic myeloid leukemia, Imatinib mesylate, optic disc edema, periorbital edema.*

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Impact of Clinical Pharmacist in Evaluating Drug–Drug Interactions in Outpatients of a Tertiary Care Hospital: An Observational Study

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Abstract

Background: In patients receiving multi-drug therapy, drug–drug interactions (DDIs) are of extensive concern. The term drug–drug interaction is used when the effect of one drug is altered by the concomitant use of another drug. Aim: To analyze the impact of clinical pharmacist in evaluating drug–drug interactions in outpatients of a tertiary care hospital in various departments in a tertiary care hospital. Objectives: To assess the prevalence of drug–drug interactions and severity of DDIs. Material and Methods: This study was a cross-sectional, observational study conducted for a period of 6 months from July 2019 to December 2019. The medications in the patient profile forms were then entered into the Excel sheet. The DDIs were classified based on the number of drug interactions, number of prescriptions, severity, mechanism of actions and different variables related to Drug Interaction were also determined. Results: From 126 patients, 69% males were more prone to DDIs than females that are 30.9%. Majority of the patients belongs >65 years of age (34.9%). A total of 126 prescriptions were analyzed of which 550 prescriptions had DDIs. Most of the DDIs were pharmacodynamic (50.7%) followed by pharmacokinetic (30.9%) and unknown (18.2%). A severity assessment showed that majority of the DDIs were moderate (27.7%) followed by major (20.6%), minor (41.2%) unknown (10.3%). Based on the different variables, comorbid conditions and total number of drugs prescribed were statistically significant with DDIs. Conclusion: The chances of occurrence of drug–drug interactions are more prevalent in the current hospital settings. Our study helped to understand the most prone age group, common mechanisms and severity and different variables that affect the patient's disease condition.

Keywords: *Drug–drug interactions (DDIs), multidrug therapy, prevalence, clinical pharmacist, cross-sectional*

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INTRODUCTION

Background

Drug–drug interactions (DDIs) can take place when two or more medications are administered simultaneously, where one medication increases or decreases the effectiveness and activity of the second drug. When drug–drug interactions occur, there are possible outcomes, one drug may increase the effects of the other, one drug may reduce the effects of the other and the combination may produce a new response which is not seen

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Case Report

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WJPMR

SPIRONOLACTONE INDUCED GYNECOMASTIA- A CASE REPORT

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ABSTRACT

Gynecomastia is proliferation male breast tissue due to an imbalance in estrogen and androgen action. Though it is rare it causes anxiety, embarrassment and physical discomfort in the affected male. This case report is of a 69-year-old male patient who presented with the symptom of painful swelling in his both breasts. He is suffering from hypothyroidism, type 1 diabetes mellitus and myocardial infarction from past few years and using Eltroxin, Atorvastatin, Aspirin, Clopidogrel, Glimipride and Metformin. He was also diagnosed with clinically controlled Congestive Cardiac Failure (CCF) for which he was prescribed Lasilactone (Furosemide 20mg and Spironolactone 50mg) and developed enlargement of his breast after 9 months of treatment and diagnosed by the physician as bilateral gynecomastia. The physician withdrawn Lasilactone and added Furosemide 40mg. but the poor prognosis of his pedal edema caused by his CCF made the patient to take Lasilactone and the symptoms of gynecomastia recurred again. Diagnosing drug induced gynecomastia and discontinuing the drug causing it will prevent the need of surgery for gynecomastia.

KEYWORDS: Spironolactone, Gynecomastia, Case report.

INTRODUCTION

Benign proliferation of male breast glandular tissue due to imbalance between estrogen action relative to androgen action at the breast tissue level appears to be the main etiology of gynecomastia.[1] Asymptomatic gynecomastia is more common in healthy adult male with a prevalence of 32-65% and the prevalence of symptomatic gynecomastia is lower.[2] Though there may be several endocrine etiologies which will affect hormonal balance for gynecomastia. Its association with drugs is not fragile.[3] Gynecomastia coexists with many pathological conditions, including chronic liver disease, which is of unquestionable epidemiological importance for the Polish population. Another common trigger for gynecomastia -inducing mechanisms may be drugs, affecting the hormonal balance.[2] Drug-induced gynecomastia is common and might account for a quarter of all cases, including those among children.[3] The drugs that can cause gynecomastia are listed in Table 1. Although the mechanisms by which many medications induce gynecomastia are not yet understood, some mechanisms are clear.[4] This is a case report of 69year old male who developed spironolactone induced gynecomastia.

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ASSESSMENT OF QUALITY OF LIFE IN BREAST CANCER PATIENTS: A RETROSPECTIVE COHORT STUDY

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Abstract:

In India the Breast cancer is the most common type of cancer in women. The patients with breast cancer were facing many problems neither by the disease nor by the treatment side effects. So that measuring quality of life in patients with breast cancer is important for assessing the treatment outcomes. Thus in our study we analysed the impact of treatment on quality of life of women with breast cancer. The purpose of present study is to assess the quality of life in breast cancer patients to manage their treatment and to prevent further progression of disease.

Key words: *Quality of life, Breast cancer, pain, EORTC QLQ BR 45, FACT B.*

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REVIEW ARTICLE

inventi | Spreading Knowledge

The Novel Coronavirus (COVID-19) - A Short Review

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Abstract: Coronavirus disease is an infectious viral disease emerged in 2019 which is caused by novel corona virus. Corona viruses are a large group of viruses. Research has shown that the virus is transmitted through birds and mammals in earlier days. Recent evidence shows that humans being are vulnerable to infection and transmission of the virus. On March 11th 2020, the WHO declared the novel coronavirus outbreak as a global pandemic viral infection. The clinical symptoms of COVID-19 include fever, which is the most common symptom, cough, fatigue, malaise and shortness of breath. Due to its high transmission capability day by day the incidence of corona increasing, this may be coupled with morbidity and mortality. The diagnosis tests include RT-PCR and antibody testing is most widely used to detect corona virus in collected sample specimens. As of now there is no proper treatment and vaccination for corona virus the only option is to maintaining some preventive strategies like wearing masks, hand hygiene and social distancing.

INTRODUCTION

Coronavirus disease (COVID-19) is a viral infectious disease caused by a virus named SARS-CoV-2 (Severe Acute Respiratory Syndrome corona virus 2). The first isolation of corona virus was years back to 1937. Researchers found a corona virus was responsible for an infectious bronchitis virus in birds. The first evidence of human corona viruses was found by scientist in the 1960s, in the noses of people with the common cold. Various forms of human corona viruses include 229E, NL63, OC43 and HKU1. The name "coronavirus" comes from the crown-like projections on their surfaces. "Corona" in Latin means "halo" or "crown." In recent years authorities first identified the virus in Wuhan, China in the year 2019. Since then, the virus has spread to nearly every country in the world. The World Health Organization (WHO) declares this pandemic is a Health emergency. [1]

STRUCTURE OF CORONAVIRUS

Coronaviruses belong to the family *Coronaviridae* in the order *Nidovirales.* They can be classified into four genera: *Alphacoronavirus, Betacoronavirus, Gammacoronavirus* and *Deltacoronavirus.* Among them, alpha- and betacoronaviruses infect mammals, gammacoronaviruses infect avian species and deltacoronaviruses infect both mammalian and avian species. Representative alphacoronaviruses include human coronavirus NL63 (HCo V-NL63). Representative betacoronaviruses include SARS-CoV, MERS-CoV. Coronaviruses are large, enveloped, positive-stranded RNA viruses. They have the largest genome among all RNA viruses, typically ranging from 27 to 32 kb. The genome is packed inside a helical capsid formed by the nucleocapsid protein (N) and further surrounded by an envelope. Associated with the viral envelope are at least three structural proteins: The membrane protein (M) and the envelope protein (E) are involved in virus assembly, whereas the spike protein (S) mediates virus entry into host cells. The coronavirus spike contains three segments: a large ectodomain, a single-pass transmembrane anchor and a short intracellular tail. [2]

TRANSMISSION OF VIRUS

Person-to-Person Transmission

Experts believe the virus that causes COVID-19 spreads mainly from person to person. There are several ways this can happen:

1. **Droplets:** When an infected person coughs, sneezes, or talks, droplets with the virus fly into the air from their nose or mouth. Anyone who is within 6 feet of that person can breathe those droplets into their lungs.
2. **Airborne transmission:** Research shows that the virus can live in the air for up to 3 hours. When you breathe air that has the virus floating in it, it gets into your lungs.
3. **Surface transmission:** Another way to catch the new coronavirus is when you touch surfaces that someone who has the virus has coughed or sneezed on. You may touch a countertop or doorknob that's contaminated and then touch your nose, mouth, or eyes. The virus can live on surfaces like plastic and stainless steel for 2 to 3 days. To stop it, clean and disinfect all counters, knobs and other surfaces you and your family touch several times a day.
4. **Fecal-oral:** Studies also suggest that virus particles can be found in infected people's poop. But experts aren't sure whether the infection can spread through contact with an infected person's stool. If that person uses the bathroom and doesn't wash their hands, they could infect things and people that they touch.

The virus most often spreads through people who have symptoms. But it may be possible to pass it on without showing any signs. Some people who don't know they've been infected can give it to others. This is called asymptomatic spread. You can also pass it on before you notice any signs of infection, called presymptomatic spread.

Community Spread

Sometimes, a person can trace how they got the virus because they know that they've been in contact with someone who's sick. In other cases, the cause is unknown. Community spread is when someone gets the virus without any known contact with a sick person. [3]

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EJPMR

AWARENESS ON NOVEL CORONAVIRUS (COVID-19) AMONG HEALTH CARE PROVIDERS IN SOUTHERN PART OF INDIA

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ABSTRACT

Background: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). World Health Organization (WHO) formally named the disease as "COVID-19" and declared it as health emergency due to its continues spread globally. It has become a major cause of concern for health care professionals all over the world. **Aim/objectives:** Aim and objective of the study to assess the awareness regarding COVID-19 among health care providers in southern part of India. **Materials and methods:** A cross sectional online based survey conducted during the month of April due to strict lockdown effect. A designed and validated questionnaire was administered to participants through online mode. Data was collected and tabulated. Knowledge score was calculated among health care providers. **Results:** A total of 1422 sample were responded to online questionnaire. The respond rate of participants to survey questionnaire was about 96.5%. Regarding profession of subjects most of the subjects were pharmacy back ground which were 36% of B.Pharmacy, 12.4% of Pharm.D and 19.4% of M.Pharmacy graduates. Doctors, nurses, pharmacists and other healthcare professionals were few with 5.6%, 5.0%, 6.1% and 14.9% respectively. Regarding symptoms, transmission of virus and preventive methods most of the health care providers (HCP) have adequate knowledge with percentage of 96% 76% and 93% respectively. Participants have altered knowledge about history of corona isolation (48%), facts about spread (74%), structure of virus (95%), diagnosis (62%), common disinfectant usage in India (74%), incubation period (89%), family of virus (84%) and latin name of virus (56%). **Conclusion:** The knowledge score of individuals was calculated and categorized into low knowledge (1%), moderate knowledge (39%) and high knowledge (60%). Overall results of the study shows that almost more than half of the health care providers have adequate knowledge regarding COVID-19 transmission, symptoms, preventive measures but moderate knowledge regarding history and few diagnosis techniques of corona virus. Additional education intervention and campaigns are required for health care providers to avail them with the knowledge regarding all aspects of COVID-19.

KEYWORDS: Corona virus, Knowledge, Health care providers, Awareness, Southern India.

INTRODUCTION

Coronavirus disease is an infectious disease emerged in 2019 which is caused by novel corona virus. Coronaviruses are a large group of viruses. Research has shown that the virus is transmitted through birds and mammals in earlier days. Recent evidence shows that humans being are vulnerable to infection and transmission of the virus.[1] World Health Organization (WHO) formally named the disease as "COVID-19". It was firstly identified in late December 2019 in Wuhan, Republic of China, and then had spread globally.[2] Present epidemiological data reported that on January 13th 2020, the first lab-confirmed "COVID-19" was found in Thailand globally and within the month of January only, the other "COVID-19" cases from Wuhan were spread to Japan and Republic of Korea.[3] On March 11th 2020, the WHO declared the novel coronavirus outbreak as a global pandemic viral infection as the number of cases of COVID-19 outside China has increased 13-fold, and the number of affected countries became tripled. After declaring the COVID-19 is pandemic, on 13th March, there were 118 infected countries.[4] By the middle of May month total conformed cases were around 4.44 millions, recovered cases 1.59 millions, deceased ones were 302 thousand.

Previously, the severe acute respiratory syndrome-coronavirus (SARS-CoV) and the Middle East respiratory syndrome-coronavirus (MERS-CoV) have been known to affect humans. Outbreaks of respiratory

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Original Research Article

Knowledge, attitude and practice among health care professionals regarding COVID-19 and barriers faced by health care professionals in South India

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ABSTRACT

Background: Corona virus disease or SARS-CoV-2 is the rapidly emerging pandemic in the present world. It has become a major concern for the front liners (health care professionals) globally. Aim of the study to assess the knowledge, attitude and practice among health care professionals regarding COVID-19 and barriers faced by HCP's during practicing in south India.

Methods: A cross sectional online survey was conducted during the month of May. The questionnaire was designed and validated and it was administered among participants. The statistical significance was calculated for collected data.

Results: Total 658 subjects were responded. Gender distribution, females (64%) and males (36%). The questions included about profession, geographical distribution, age, source of information. Out of 658 samples, 418 (63.49%) with good knowledge and 240 (36.51%) with poor knowledge. Regarding attitude findings showed only few have positive attitude. Regarding practice 74.9% have good practice and 25.1% have poor practicing. By calculated the Chi-square test gives the statistical significance $p<0.0001$ at 95% CI. Logistic regression analysis was done using gender versus knowledge ($p<0.0001$), age versus knowledge ($p<0.0001$) and area of residence versus knowledge ($p<0.438$) hence. Whereas gender versus practice ($p<0.0001$), age versus practice ($p<0.402$) and area of residence versus practice ($p<0.0001$) at 95% CI.

Conclusions: In the present pandemic situation HCP's were the front liners so, they must have proper knowledge, attitude and practicing skills. Our results showed positive outcome still the awareness should be created by conducting educational campaigns, journal clubs and continuous professionals programs for more positive outcome.

Keywords: Attitude, Corona virus, Health care professionals, Knowledge, Practice, Southern India

INTRODUCTION

Coronavirus disease 2019 also known as COVID-19 is a rapidly emerging pandemic caused by a novel human coronavirus which is SARS-CoV-2. COVID-19 was first reported in Wuhan, China at December 2019 among patients with viral pneumonia symptoms.[1] It spread globally, resulting in the ongoing 2019-20 corona virus pandemic. On March 11th 2020, the WHO declared the novel coronavirus outbreak as a global pandemic viral infection as the number of cases of COVID-19 outside China has increased within number of countries throughout the world.[2] Recent epidemiology of COVID-19, at the beginning of June month total conformed cases were around 6.8 million and deceased ones were 397 thousand. Where as in India total conformed cases were around 257 thousand, recovered cases 124 thousand and deceased ones were around 7135 persons. As of now 180

Research Article

Assessment of Diabetes Risk And Nutritional Status: A Cross Sectional Epidemiological Study on Students of Graduation and Under Graduation From Guntur

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ABSTRACT

Background: This epidemiological study is to assess the diabetes risk and nutritional status and stating their association among healthy students of graduation and under graduation in between age 18 to 24 years. **Objectives:** To predict and assess the diabetes risk, nutritional status and assess the association between diabetes and nutritional status. **Methods:** The study was designed to be a cross-sectional study. It was conducted in students of graduation and under graduation in Guntur District, Andhra Pradesh over one month from 1st October to 1st November which includes 57 students. Students are enrolled based on Inclusion and exclusion criteria. Specially designed data collection form used to obtain the data required for the study. **Results:** In our study we collected data from 57 students out of the 31 (54.38%) were males and 26 (45.21%) were females. Diabetes risk assessed by using IDRS, AUSDRISK tool, nutritional status by Using MNA-SF and shown that malnutrition having impact on diabetes risk. **Conclusion:** We came to a temporary conclusion that most of the students have moderate to low risk of diabetes mellitus. Students who are at risk of malnourishment and malnourished having moderate to high risk of diabetes mellitus.

Key words: Diabetes risk, Nutritional status, IDRS, AUSDRISK, MNA-SF, Students.

INTRODUCTION

Asia is the hub of greater than 60% among the world's diabetic population. India occupies the highest prevalence of diabetes among Asia According to the International diabetes federation 11% of individuals with prediabetes develop Type 2 diabetes mellitus every year.[1] The young-onset of diabetes is more common nowadays. Most of the diagnosed young with a family history of diabetes and obesity and a sedentary lifestyle.[2] A well balanced and fulfilled diet is essential for growth and development in adolescence. Malnutrition among young in India is under-reported.[3] malnutrition is adjustable and thus adequate interventions and strategies should be developed and implemented. Our paper aims at assessing diabetes risk by using IDRS, AUDRA'S and screening of nutritional status by using MNA-SF[4] in the age group between 18 years to 24 years and to check whether there is any relation between nutritional status[5] and diabetes risk.[6]

MATERIALS AND METHODS

The study was designed to be a cross-sectional study. It was conducted in students of graduation and under graduation in Guntur district, Andhra Pradesh. This study was conducted over one month from 1st October to 1st November. Sample size was estimated assuming that 50% of students would have moderate to high risk score. Sample size was estimated using the formula 4pq/L, where prevalence (p) = 50%, q = 50%, relative error (L) = 26% of prevalence and estimated sample size came out to be 57. Students were enrolled in the study based on Inclusion and Exclusion criteria. All healthy human male and female students, age

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Original Article

Risk of Developing T2DM among Students of Graduation and Undergraduation Courses in Andhra Pradesh: An Evaluation using Indian Diabetes Risk Score (IDRS)

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ABSTRACT

Background: Diabetes Mellitus is a major public and clinical health concern. It is a basic knowledge thatT2DM causes a serious decline in normal Quality of Life, where late identification in later ages is the major challenge. The main motive of this study was to evaluate a pre-existing multivariate risk factors for the development of Type 2 Diabetes Mellitus in youth. **Objectives:** To predict and assess the risk and risk factors for Type 2 Diabetes Mellitus. **Methods:** The study was designed to be a cross-sectional epidemiological study. It was conducted in the students of graduation and under graduation courses in Guntur District, Andhra Pradesh over 6 months from 1st September 2019 to 1st February 2020 which includes 2524 students with a response rate of 92.5%. Students are enrolled based on Inclusion and exclusion criteria. Specially designed data collection form used to obtain the data required for the study. **Results:** In our study we have collected data from 2524 students where, 1088 students (34.50%) were males and 1435 (65.49%) were females. Diabetes risk was assessed using validated tool, Indian Diabetes Risk Score. **Conclusion:** We came to a conclusion that most of the students have moderate to low risk of diabetes mellitus, with significantly contributing risk factors like family history, low PA.

Key words: Andhra Pradesh, Diabetes risk, Family history, IDRS, India, Students, Youth.

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is one of the most widely recognized chronic disorders that represent a genuine social and monetary issue at present in numerous nations regardless of the degree of improvement.[1] As expressed by the International Diabetes Federation (IDF), around 415 million grown-ups between the ages of 20 to 79 years had T2DM in 2015.[2] Diabetes mellitus was so normal among all age groups that were currently being analyzed in teenagers, kids and even in more youthful population as of late Incidence is a lot of hard to gauge than prevalence. T2DM is the most settled type of DM, which represents 90% to 95% of every single diabetic patient and is relied upon to increment to 439 million by 2030.[3] In the event that any of the individuals in your family have diabetes, you may have a hereditary composition to the circumstance. The risk factors for the hereditary appearance including raising BP, obesity, physical activity, decline in the admission of protein diet, increment in midriff boundary may have an energetic opportunity to get T2DM. This incessant(chronic) condition as a metabolic issue results from the tissue resistance to insulin as a result of low physical movement level and robustness, which are regular of individuals in their mature age, yet now it is ordinarily found in youths, youngsters and more youthful grown-ups than more established individuals.[4]

Indian Diabetes Risk Score

The Indian Diabetes Risk Score (IDRS) was conceived by the Madras Diabetes Research Foundation. It is a powerful diabetes screening tool which includes family history, abdomen obesity, age and physical activity of the person. Consequently, individual with high risk of developing diabetes mellitus in near future can be distinguished and methodical counseling and further interventions can be applied so as to lessen diabetes related complications.[5] The current study was done to assess and spread the awareness with respect to risk for type 2 diabetes mellitus utilizing IDRS of MITS College, Gwalior having age group 18-25 yrs. Risk Interpretation was done as high, moderate and low risk if their IDRS score is ≥60, 30-50 and <30 respectively.[5]

MATERIAL AND METHODS

This is an epidemiological cross-sectional observational study carried out in different graduation and post-graduation colleges located in and around Guntur district, Andhra Pradesh. It covers a total population of 2523 students pursuing

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PCN98
ASSESSMENT OF QUALITY OF LIFE IN PATIENTS WITH METASTATIC BREAST CANCER AND ITS PHARMACEUTICAL MANAGEMENT IN TERTIARY CARE HOSPITAL: A PROSPECTIVE OBSERVATIONAL STUDY

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Objectives: To assess QOL in patients with metastatic breast canc er and its pharmaceutical management, To assess the QOL in patients with metastatic breast cancer,To emphasize the pharmaceutical care in improving QOL. ***Methods:*** The data was collected in the designed data collection form. After the necessary data was collected Assessment of quality of life was performed by using self-designed and validated questionnaire (which was taken from European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer {EORTC QLQ-BR23} and Functional Assessment of Cancer Therapy-Breast Cancer {FACT-B}) was used to assess the quality of life in metastatic breast cancer patients which consists of 30 closed ended questions. ***Results:*** Based on the results obtained our study revealed that 16 (30.76%) of the 52 subjects the first distant metastasis was to bone. Of the 18 subjects whose first metastasis was to the viscera, the organ most often involved was the liver (n=9 ; 17.30%) followed by lung (n=6 ; 11.53%) and brain (n=3 ;5.77%) .These findings were in concordance with study done by Linda Vona-Davis et al., (2014) conducted a study on "Breast Cancer Pathology, Receptor Status, and Patterns of Metastasis in a Rural Appalachian Population[6]" and 9 out of 52 subjects were diagnosed with recurrence(17.30%) . remaining 9 subjects were diagnosed with multiple site metastasis i.e., out of 9 (17.30%) 3 subjects were diagnosed with lung, bone (5.77%) and bone, recurrence(n=1 ;1.92%), liver, recurrence (n=1; 1.92%),liver, brain (n=1 ;1.92 %),liver,lung (n=1 ; 1.92%) bone, liver (n=1;1.92%) lung,bone, liver (n=1 ; 1.92%). ***Conclusions:*** Our study concludes that Pharmaceutical care and Psychosocial support and the provided patient information leaflet which was mainly focused on healthy diet plays a vital role in improving adherence to the therapy there by enhancing the QOL of patients with metastatic breast cancer being treated with Bisphosphonates or chemotherapy and hormonal therapy.

PCN99
WHAT IS THE IMPACT OF CHEMOTHERAPY INDUCED PERIPHERAL NEUROPATHY ON INDIVIDUALS AND THE COMMUNITY?

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Objectives: Chemotherapy induced peripheral neuropathy [CIPN]) is a major side effect of chemotherapy treatment that impacts on patients' quality of life (QoL). The impact of CIPN for patients and the community has historically been underestimated. Patient-centred care requires an understanding of the impact of CIPN. This paper reports the results of research which investigated quality of life, employment and health costs of CIPN. ***Methods:*** Cross-sectional and longitudinal data were collected from 566 patients who were exposed to neuropathy inducing chemotherapy treatment. Self-reported information on CIPN, QoL (AQoL 8D), presentism and absenteeism was linked to administrative data on medical services and pharmaceutical scripts. ***Results:*** Increasing severity of peripheral neuropathy is associated with a substantial decrease in QoL (0.12, p=0.02) and an increased probability of missing and/or postponing work. CIPN also affected concentration and the pace of work for those who remained at work. The impact of CIPN on non-employment activities was lower. Compared to those not reporting CIPN patients with CIPN had higher total medical service costs per quarter when not receiving chemotherapy ($1507 vs. $1121, p<0.001). However, pharmaceutical costs decreased for those with CIPN relative to those without it because CIPN patients received less chemotherapy. An increasing severity of CIPN was associated with an increased need for carers. ***Conclusions:*** It is important that those who develop CIPN, their families, carers as well as decision makers are aware of the potential impact on their lives of this adverse event. Information regarding the full impact of CIPN, including on the receipt of chemotherapy, QoL and productivity can assist in the design and delivery of cost-effective patient-centred strategies designed to avoid or mitigate the consequences.

Cancer - Real World Data & Information Systems

PCN100
THE ECONOMIC BURDEN OF GASTRIC CANCER MORTALITY IN BRAZIL/LATAM

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Objectives: There are geographic and ethnic differences in the incidence of gastric cancer around the world as well as with its trends for each population over time. The incidence patterns observed among immigrants change according to where they live. Our goal is to analyze the economic burden of gastric cancer mortality in Brazil/ LATAM, among Asian and Non-Asian set. ***Methods:*** In Brazil, gastric cancer mortality is 2,2 times higher in Asian descendent than in Non-Asian with a male predominance. Monthly income between US$ 500 and 1.500 (rate 1:4, USD: R$). This research was carried out through an observational, descriptive and cross-sectional study with quantitative approach. Statistical analysis was performed using Pearson's chi-square with relative risk, Pearson's chi-square for trend, Fischer's exact test, and standard deviation / variance. Plus pharmacoeconomic model as economic adapted comparisons . ***Results:*** From 2006 to 2016 there were 14,878 deaths from gastric cancer in Brazil, of which 13,326 among the general population (white, brown, black and indigenous) and 1,552 in the Brazilian Asian population. Therefore, among Asian descendent population the economic losses were from 776,000 to 2,328,000 USD,and Non-Asian pop = 6,663,000 to 19,989,000 USD . It means that in the worse and better scenario the losses will be 3,90 % higher in comparison with 8,58% expect without mortality epidemiology data. ***Conclusions:*** The economic burden of gastric cancer mortality in Brazil/ LATAM is directly linked to Asian & Non-Asian incidence / prevalence. In Brazil gastric cancer mortality is 2,2 times higher in Asian descendent than in Non-Asian. The losses data of 3,90 % higher in comparison with 8,58 % expect without mortality epidemiology data need to be studied.

PCN101
HEALTHCARE RESOURCE UTILIZATION, COSTS, AND CLINICAL OUTCOMES IN PATIENTS WITH TRIPLE-NEGATIVE BREAST CANCER IN NORTHERN THAILAND: A REAL WORLD EVIDENCE USING ELECTRONIC HEALTH RECORDS

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Objectives: Evidence on clinical outcomes and healthcare resource utilization (HRU) among triple-negative breast cancer (TNBC) patients in Thailand has been very limited. Therefore, this study aims to evaluate health outcomes, prognostic factors, and HRU using electronic health records (EHR) among Thai TNBC patients. ***Methods:*** About 143,053 EHR during 2005-2018 were retrospectively obtained from a tertiary hospital. Data included patient's characteristics, diagnosis, laboratory test, medication used, healthcare cost, length of stay, and clinical outcomes. All costs were adjusted to the 2018 value and converted to US dollars ($) using an exchange rate of 30.35 Thai baht. Non-parametric tests were applied to compare healthcare costs between TNBC and non-TNBC groups. ***Results:*** Among 5,712 breast cancer patients, about 0.68% were diagnosed with TNBC and 60.1% were metastatic TNBC. The median age at diagnosis of TNBC patients was 51.7 (interquartile range, 44.9-60.7) years and a median follow-up time was 144.9 months. Median survival time of TNBC cohort was 12.4 (95%CI 8.1-21.3) months and there was no significant prognostic factor on this outcome. For outpatient visit of TNBC group, mean annual number of visits (SD), annual treatment cost, and lifetime cost were 4.6 (5.2) times, $2,478 ($7,376), and $4,191 ($10,750), respectively. For inpatient visit of TNBC group, mean annual number of visits, length of stay, annual treatment cost, and lifetime cost were 2.3 (2.1) times, 7.0 (8.2) days, $2,481 ($2,366), and $3,125 ($2,960), respectively. Mean lifetime cost of TNBC group ($4,191) was significantly lower than non-TNBC group ($23,085), which drug costs accounted for 76% and 87%, respectively. ***Conclusions:*** This study highlights the poor outcome and the high burden of TNBC patients in Thailand. Compared to non-TNBC group, a lower lifetime cost in TNBC group might result from the lower drug expenditure. Strategies to improve efficiency of TNBC treatments and clinical outcomes should be further explored.

PCN104
TREATMENT PATTERNS AND HEALTH RESOURCE UTILIZATION IN PATIENTS WITH HR+/HER2- LOCALLY ADVANCED OR METASTATIC BREAST CANCER IN REAL WORLD SETTING IN TAIWAN

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Objectives: To understand current treatment patterns and health care resource utilization (HRU) of women with locally advanced and metastatic breast cancer (ABC) in Taiwan overall and within patients meeting the MONARCH 3 (NCT02246621) clinical trial criteria (postmenopausal women with no prior systemic therapy in the advanced setting). ***Methods:*** A chart review was conducted in 118 patients: women ≥ 18 years old with hormone receptor positive (HR+)/human epidermal growth receptor-negative (HER2-) ABC diagnosed between 2015 and 2017. Anonymized data on patient characteristics, treatment pathways and HRU was abstracted. Descriptive