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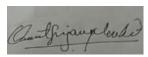
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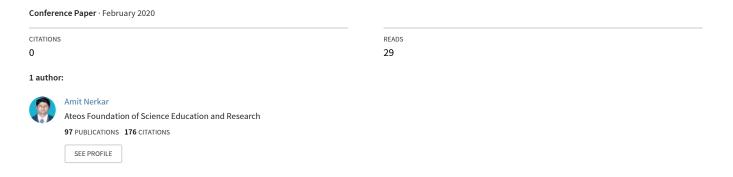


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Proceedings of Savitribai Phule Pune University sponsored Two Days National Conference on "Pharmaceutical Validation" Held on 22nd and 23rd Feb 2020





Proceedings of Savitribai Phule Pune University sponsored **Two Days National Conference** on "Pharmaceutical Validation" Held on 22nd and 23rd Feb 2020 At PES's Modern College of Pharmacy (For Ladies), Moshi, Pune, M.S., India

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BY



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A1

First-Aid and its Applications in Emergency

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First aid is the primary treatment given to a person which mitigates pain, provides comfort and reduces trauma for a temporary duration of time. An emergency can occur at any time and at any place. Lack of first aid awareness might result into severe situations that could have been circumvented. Thus it is crucial for a person to be familiar with basic first aid techniques and their use cases. A layperson who is aware of essential first aid techniques and present on the scenecan minimize the ill effects and trauma experienced by an individual. First aid treatments can vary depending on the type of the circumstances. Appropriate first aid treatment given at the right time can significantly alter the outcomes and save the lives of many people. Theaim of this article is to review the objectives of first aid and its applications. It imparts knowledge regarding different first aid treatments such as cardiopulmonary resuscitation (CPR), free airways, minimizing external bleeding, etc. that can be carried out indiverse scenarios. Providing first aid can help alleviate an individual's suffering, stabilize his condition as well as increase his chances of survival in case of emergencies.

Keywords: Trauma, first aid, Cardiopulmonary Resuscitation.

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A2

Review on Xeroderma Pigmentosum

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Xeroderma pigmentosum, which is commonly known as XP, is an inherited condition characterized by an extreme sensitivity to ultraviolet (UV) rays from sunlight. This condition mostly affects the eyes and areas of skin exposed to the sun. Some affected individuals also have problems involving the nervous system. The signs of xeroderma pigmentosum usually appear in infancy or early childhood. Many affected children develop a severe sunburn after spending just a few minutes in the sun. The sunburn causes redness and blistering that can last for weeks. Other affected children do not get sunburned with minimal sun exposure, but instead tan normally. By age 2, almost all children with xeroderma pigmentosum develop freckling of the skin in sun-exposed areas (such as the face, arms, and lips); this type of freckling rarely occurs in young children without the disorder. In affected individuals, exposure to sunlight often causes dry skin (xeroderma) and changes in skin coloring (pigmentation). This combination of features gives the condition its name, xeroderma pigmentosum. People with xeroderma pigmentosum have a greatly increased risk of developing skin cancer. Without sun protection, about half of children with this condition develop their first skin cancer by age 10. Most people with xeroderma pigmentosum develop multiple skin cancers during their lifetime. These cancers occur most often on the face, lips, and eyelids. Cancer can also develop on the scalp, in the eyes, and on the tip of the tongue.

Keywords: Xeroderma pigmentosum, skin cancer, freckling.

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A3

Method Development and Validation of Clotrimazole Containing Ear Drops

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Aim of the the study was to validate analytical method of Clotrimazole containing ear drop by using HPLC by using modified wavelength. A rapid and precise high performance liquid chromatographic method has been validate of a in clotrimazole containing ear drop .chromatography was carried out on phenomena C18 column (4.6*250 mm *5 mm) column using mobile phase acetonitrile and diaamonium hydrogen phosphate (buffer) (60:40) as the mobile phase at a flow rate of 1 ml/min, the detection was carried out at 210 nm which gives more precise impurities in ear drop. The method is validated for linearity, accuracy, precision, repeatability, robustness, impurity study.

Keywords: Clotrimazole, buffer, robustness, accuracy.

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Α4

Toxoplasma Gondii: A Review

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In 1908 in Pasture Institute of Tunis Charles Nicolle and Louis Manceaux discovered a protozoan organism in the tissue of rodent. The first case of Toxoplasmosis found in 1940 in Peru in 22 years old person. The Toxoplasma Gondii have sexually and asexual type of reproduction in host. Therefore the primary host for transmission of Toxoplasma Gondii was cats. The Toxoplasma Gondii shows sexual reproduction only in cat's intestine. The protozoa have three types of growth stages, tachyozoits, merozoites and bradyzoits. The host shows immune response by stimulating interleukin and interferon. The toxoplasma gondii effect on survival instincts of the host. The infected host shows symptoms like fever, muscle pain fatigue, vomiting, headache. In some cases the infected host could suffer from severe trauma or it can cause death. The transmission of Toxoplasma Gondii to animals and humans by food, ingested water, soil, vegetables or anything which are contaminated with oocytes of Toxoplasma Gondii. It can be transmitted from blood transfusion or organ transplant and mother to fetus. The treatment for infection of Toxoplasma Gondii is done by using antibiotics.

Keywords: Tachyozoits, survival instincts, organ transplant

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A5

Optimization of Microemulsion Based Gel of Quinolone Antibiotics

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The aim of the present investigation was to develop, design and optimize microemulsion based gel formulation for topical delivery. The purpose of the formulation was to enhance the solubility and increase the bioavailability of drug by topical route, thus avoiding first pass metabolism of drug, and topical delivery avoid the antibiotic resistance. Pseudo ternary phase diagrams were constructed for microemulsion formulations composed of Oleic acid as oil, Tween 80 as surfactant and Propylene glycol as co-surfactant respectively. The physicochemical properties of the microemulsion were investigated. Microemulsion was incorporated into optimized gel of Carbapol 934 P and Sepineo P 600 by 3² Factorial Design. Optimized batch (F1) of the microemulgel was homogenous, white and clear and was viewed under inverted microscope to study globule shape and size between 1.43-2.54µm. The zeta potential of emulsion batch F1 was found to be -11.3 mv which showed good stability of emulsion. In vitro and ex vivo drug permeation of gel was also investigated and F1 shows highest drug release of 94.8 and 82.1% respectively. In microbiological assay the % inhibition of Microemulgel (17.5% inhibition) which is higher than that of marketed ointment is. Thus, the prepared microemulgel will act as depot of drug which releases drug in controlled manner and an effective antibacterial topical preparation in future.

Keyword: co-surfactant, drug release, microemulgel

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A 6

Stability-Indicating HPLC Method for Simultaneous Determination of Lisinopril Anhydrate and S-Amlodipine Besylate in Pharmaceutical Dosage Form

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A stability indicating high performance liquid chromatography (HPLC) method was developed and validated for determination of Lisinopril Anhydrate (Lisino) and S-Amlodipine Besylate (S-Amlo) in combined dosage form used for treatment hypertension. The separation was carried out using Kromasil C8 column and mobile phase consisting of mixture of 0.02 M potassium dihydrogen phosphate solution and methanol (70:30 %v/v) at a flow rate of 1ml/min with UV detection carried out at 218 nm. Stability indicating studies were conducted under the ICH guidelines Q1A R2 and validated as per guidelines of ICH Q2. The linearity was found in the range of 5-50 μ g/mL. The drug was subjected to degradation in alkaline, acidic, oxidative, heat and photolytic conditions. The degradation products obtained were well resolved from the pure drugs. As the method could effectively separate the drugs from its degradation products, it can be used as a stability-indicating assay.

Keywords: Kromasil C8 column, degradation, UV detection

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A7

Study of Ameliorating Effect of Flavanoid Rich Fraction of *Punica Granatum* in Diabetic Neuropathy in Experimental Animals

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Different parts of *Punica granatum* Linn. (Punicaceae) are traditionally used for diabetes mellitus in the Indian system of medicine. However, there is paucity of information regarding its role in diabetic neuropathy. The present study investigates the neuroprotective potential of ethyl acetate fraction of *P. granatum* (EAPG) leaves in streptozotocin (STZ)-induced diabetic neuropathy in experimental animals. Experimental diabetic neuropathy was induced in Wistar rats by single intraperitoneal injection of STZ (65mg/kg) dissolved in ice cold citrophosphate buffer (pH4.3). After induction rats were divided into six groups and administered with three dose levels of EAPG, i.e. 50, 100, and 200mg/kg for 28days. Fasting blood glucose, lipid profile, oxidative stress parameters (SOD, GSH, CAT & MDA levels)&behavioural parameters (FST, TST, & memory deficit study) were assessed at the end of the treatment period. All above parameters were normalized in treatment group as compared to disease control. The results of our study thus prove the neuroprotective effect of EAPG in diabetic neuropathy by ameliorating oxidative stress and disturbed glucose homeostasis in experimental animals.

Keywords: diabetes mellitus, neuropathy, homeostasis

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A8

Icthyosis: An Update

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Ichthyoses refers to group of skin disorders also called as disorders of keratinization or cornification (DOK), constitutes a heterogeneous group of skin diseases associated by the common clinical feature of abnormal barrier function, causing a default compensatory pathway of hyperproliferation, resulting into generalized or localized scaling of skin. Other clinical manifestations include generalized erythroderma, xerosis, palmoplantar and hypohydrosis keratoderma infections. Dependent on pathophysiology, mode of inheritance and clinical features, icthyosis was firstly classified at Ichthyosis Consensus Conference, 2009 into two forms: nonsyndromic forms having clinical features limited to the skin and syndromic forms including involvement of additional organ systems. This review mainly gives the details about the definition, types, etiology, epidemiology, prevalence rate, pathophysiology, immunology, clinical features, diagnosis and treatment of icthyosis.

Keywords: icthyosis, pathophysiology, epidemiology

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A 09

Development of Targeted Delivery System of Rifampicin

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Tuberculosis (TB) is a major cause of death worldwide as it is a highly communicable disease. Every year eight million peoples suffer from active tuberculosis and approximately two million deaths. The treatment for TB includes administration of multidrug combination of anti-tuberculosis drugs. Six months multidrug therapy effectively treats drug-sensitive TB. Before completion of treatment course, patient discontinuing course is high and which leads to multidrug-resistant and extensively drug-resistant TB. To increase the patient compliance, targeted drug delivery system of anti-Tb drug is beneficial as it may reduce the dose of a drug. Rifampicin (RIF) is a semi synthetic derivative of rifamycin B used in treatment of tuberculosis. In the present work an attempt was made to develop Hyaluronic acid coated chitosan nanoparticles of rifampicin. As Hyaluronic acid interacts with CD44 receptors present on the macrophage where mycobacterium tuberculosis resides. Chitosan nanoparticles were prepared by using vanillin as a cross linker and then prepared chitosan nanoparticles were interacted with Hyaluronic acid. Effect of concentration of hyaluronic acid on particle size and entrapment efficiency was studied. Optimised nanoparticles were characterised by Fourier Transform Infrared Spectroscopy (FTIR), Differential Scanning Calorimetry (DSC), scanning electron microscopy and macrophage uptake study. Particle size and entrapment efficiency (of rifampicin) of hyaluronic acid coated nanoparticles was found to be higher as compared to chitosan nanoparticles. FTIR and DSC study revealed the formation of nanoparticles. Macrophage uptake study indicates that % phagocytosis of Hyaluronic acid coated chitosan nanoparticle swas higher as compared to uncoated chitosan nanoparticles.

Keywords: multidrug therapy, Hyaluronic acid, nanoparticles

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A10

Amorphophallus paeoniifolius Starch: As Novel Alternative Disintegrant for Pharmaceutical Application

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Oral drug delivery system has always been the most prevalent route of administration and continuous efforts are made to improve the drug delivery by this route. The purpose of the current research work was to isolate and study the physicochemical properties of the Amorphophallus paeoniifolius starch and further compare its disintegration ability with the maize starch. Starch was isolated from Amorphophallus paeoniifoliu by aqueous extraction method and possesses characteristic that are typical of starches. It was further evaluated for presence of other foreign matter and phytoconstituents. Results showed that isolated sample was free from foreign organic matter and total ash value was found to be 0.1%. P-XRD study indicates amorphous nature of starch and SEM images reveals smooth nature of particles. Tablets were prepared by wet granulation method by varying concentration in the range of 2.5 to 10% w/w for both the starches. Pre and post-compression parameters were studied and were found within the pharmacopoeial limits. Disintegration tests showed that disintegration time decreases with increasing concentration of both the starches. At 10% w/w concentration, disintegration time was found to be lowest hence it was selected as optimized formulation and stability studies were performed and it was found to be stable. Determination of disintegration efficiency indicates that Amorphophallus paeoniifolius starch exhibit disintegrating potential.

Nanoparticles

Keywords: phytoconstituents, wet granulation, optimized formulation

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A11

A Novel Formulation Approach of Enhancing Efficacy of Marketed Poly-Herbal Composition Indicated for Treatment of Rheumatoid Arthritis

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Commercially available polyherbal oil that is indicated for local application for relieving typical symptoms of rheumatoid arthritis has been formulated as organogels after forming oil loaded nanosponges. The objective of the work was to reduce irritation, enhance efficacy and to prolong the delivery of medicated oil. The sponges were prepared by emulsion –solvent diffusion technique using polymer and co-polymer combination of ethyl cellulose and polyvinyl alcohol and dichloromethane as cross-linking agent. The F4 formulation of nanosponge was found to be superior in terms of contents, particle size, and entrapment efficiency of medicated oil. Moreover, it possessed greater stability with no gross changes in any of its physical, physic-chemical and functional characteristics. The *in vivo* studies were carried out in Wistar rat model of rheumatoid arthritis and effects of the treatment on levels of serum copper, CRP, RA factor, CAT, LPO, NO were estimated. The model revealed high potency of the organogels for control of symptoms of Rheumatoid Arthritis.

Keywords: efficacy, nanosponges, rheumatoid arthritis

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A12

A Review on Analytical Method Development and Validation for Antidiabetic Drugs by UV, HPLC and HPTLC

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SGLT-2 are the newly developed class of antidiabetic medicine also called as gliflozins. Empagliflozin, Dapagliflozin, Canagliflozin are the SGLT-2 class inhibitor. Which are used to treatment of type II diabetes mellitus. Drug required the analytical procedures along with pharmacokinetics and pharmacodynamic parameters and stability study of the drug are required. In this review we compiled different published analytical method for the development and determination of the empagliflozin. It shows the pharmacological parameters of various SGLT-2 inhibitors which include the protein binding, Tmax, T1/2, and bioavailability of various SGLT-2 inhibitors. It shows the analytical method development and validation of Empagliflozin, Canagliflozin and Dapaglilozin alone with its combination of other drug by using UV, HPLC, HPTLC method.

Keywords: SGLT-2 inhibitors, Tmax, empagliflozin

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A13

Stability-Indicating RP-HPLC Method for Simultaneous Estimation of Ketoconazole and Hydrocortisone acetate in Topical Dosage Formulation

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Hydrocortisone Acetate is the synthetic acetate salt form of hydrocortisone, a corticosteroid with anti-inflammatory and immunosuppressive properties. Hydrocortisone acetate initially binds to the cytoplasmic glucocorticoid receptor; then the receptor-ligand complex is translocated to the nucleus where it initiates the transcription of genes encoding for anti-inflammatory mediators, such as cytokines and lipocortins. Lipocortins inhibit phospholipase A2, thereby blocking the release of arachidonic acid from membrane phospholipids and preventing the synthesis of prostaglandins and leukotrienes.

Ketoconazole is an imidazole that impairs the synthesis of ergosterol by inhibiting fungal cyt P450 enzymes. Ergosterol is a vital component of fungal cell membranes.

The separation was achieved by using column C18 (250 mm \times 4.6 mm, 5.0 μ) using water: methanol pH adjusted to 2.5 with orthophosphoric acid in the ratio of 30:70%v/v as eluent. Mobile phase flow rate was 0.6 ml/min and data integrationwas achieved at 250 nm.

The results of the various validation studies showed that the HPLC method is fast, specific, accurate, reproducible, possessed significant linearity and precision. The drug was found to bestable under all the stress conditions.

Keywords: Immunosuppressive, Lipocortins, Validation

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A14

Bio Analytical Method Guidelines as per US FDA and ICH: A Perspective Study in Bio Analytical Method Development and Validation

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Bioanalysis is related to the analysis of analytes (drugs, metabolites, biomarkers) in biological samples and it involves several steps from sample collection to sample analysis and data reporting. Validation of any analytical method helps to achieve reliable results that are necessary for proper decisions on drug dosing and patient safety. In the case of bioanalytical methods, validation additionally covers steps of pharmacokinetic and toxicological studies — such as sample collection, handling, shipment, storage, and preparation. Attention was drawn to the difference of both the newest FDA Guidance and the ICH Guideline on bioanalytical method validation; and aimed to point out advantages of both documents from the laboratory perspective.

Bio analytical method was developed for estimation of fluvastatin, with RP-HPLC, using RP - C_{18} column equipped with UV detector. The mobile phase [acetonitrile: acetate buffer pH 4.0 (pH adjusted with acetic acid)] was pumped at a flow rate of 0.8 ml/min in the ratio of 60:40 % v/v and the eluents were monitored at 245 nm.

The drug was shown linear response in all conc ranges in plasma. The drug was estimated from the plasma; and any interference of the plasma and matrix effect was not observed during the development of simple isocratic RP - HPLC bio analytical method with UV detection.

The method can be applied for relative bioavailability and bioequivalence study of the drug or/and dosage form; and the method is free from separation techniques like solid phase extraction or liquid-liquid extraction.

Keywords: Bioanalytical, Fluvastatin, Plasma and matrix effect

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A16

Herbal Medications: Potential Candidate in the Treatment of Allergy

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Allergies are hypersensitive responses mediated by the immune system to a foreign substance entering the body. It is one of the most widespread diseases in the modern world with diverse manifestations such as asthma, allergic rhinitis, atopic dermatitis, and food allergy. Statistically, each in three people suffers from an active allergy at any given point of time and approximately three out of four develop allergic reactions throughout their life span. Hence, effective and safe treatment of allergic diseases is of utmost importance and can become a challenge for specialists.

The commonly used allopathic drugs for allergies are steroids, anti-histamine, topical corticosteroids, decongestants, mast cell stabilizers, anticholinergics, and leukotriene receptor antagonists. However, due to the adverse effects such as sedation, dry mouth, immunosuppressive reactions, drowsiness etc. of the allopathic drugs; in recent years, the use of herbal medications for anti-allergic activities has risen drastically. A variety of components purified from medicinal herbs have been found to exert the immune-modulatory effects. The effectiveness and safety of use have been one of the most contributing factors for the use of herbal medications in the treatment of allergy. A wide range of formulations and herbs can be used against allergic reactions in humans. Phytochemicals such as flavonoids, polysaccharides, lactones, alkaloids, diterpenoids and glycosides, present in several plants, have been reported to be responsible for the immunomodulatory properties.

The present review will give insight about wide plant-derived compounds and herbal formulations which have exhibited an immunomodulatory effect and has been used for allergic treatments.

Keywords: Immunomodulatory, Diterpenoids, Atopic dermatitis, Allopathic drugs

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A17

Green Tea: Potential Health Benefits

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Green tea, which is produced from the leaves of the *Camellia sinensis* plant, is one of the most popular beverages consuming worldwide. Numerous health benefits associated with this herbal drink promotion of cardio vascular health, prevention of cancer (due to antioxidant property), prevention of skin disorders (antibacterial), promote immune system, anti-inflammatory action, useful in maintenance of cholesterol and weight management etc. which proved by scientific evidences by scientists. The main objective of this review paper is to clarify the health benefits/ side effects and responsible chemical constituents with its action. This review covers classification of Green tea, details about manufacturing process, chemical components with its pharmacological action, comparison of green tea with white tea, adulteration and its identification tests. Present article focus on an International standard for tea, function of tea board, ISO recommendation for green tea, various manufacturing plant in India. .This review is done to spread cognizance among general population about the benefits of green tea.

Keywords: Skin disorders, Adulteration, Cancer

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A18

General Characterization and Proteome Analysis of Snake Venom Toxins

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Snake venoms are complex mixtures of organic and inorganic compounds, many of which display biological activity. Also snake venoms are an extremely rich source of pharmacologically active proteins with a considerable clinical and medical potential. It has been demonstrated that antisera raised against whole venom or a single purified venom protein from one species of snake will react with proteins in the venom of other species. The structural and functional elucidation of snake venoms components may contribute to a better understanding of the mechanism of action of these proteins during envenomation and their potential pharmacological and therapeutic applications. The latest achievements in the determination of snake venom proteome, based primarily on the development of new strategies and techniques. Detailed knowledge of the venom toxin composition and biological properties of the protein constituents should provide the scaffold for the design of new more effective drugs for the treatment of the haemostatic system and heart disorders, inflammation, cancer and consequences of snake bites, as well as new tools for clinical diagnostic and assays of haemostatic parameters.

Keywords: Antisera, Scaffold, Haemostatic Parameters

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A19

Pharmaceutical Process Validation Aspects

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Process validation plays a key role in the pharmaceutical manufacturing process as it offers a high degree of confidence and proof that the process being carried out yields the standardized results, that is; it meets the necessary requirements that have been correctly conducted. Process validation is an integral part of quality assurance and therefore its goal is to ensure that the quality required is achieved Validation of the different steps used in the pharmaceutical product manufacturing is known as process validation. Process validation is collecting and analyzing the different data collected alongside the documentation throughout the design and manufacture of a product. Validation strengthens procedures but also ensures whether the method is properly developed and thus decreases the risk of errors. The main purpose of this work is to provide an outline and general overview of Pharmaceutical Drug process validation.

Keywords: Manufacturing, Risk, Quality assurance

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A20

Risk of Complications in Obese Patients

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Obesity is a medical condition in which excess of body fat accumulation to an extent that it may have negative effect. Such as in type 2 diabetes, where there occurs a resistant to insulin secreted, due to accumulation of fat. Due to obesity the HDL level reduces which leads to heart disease. Also the obesity causes cancer by promoting chronic lower level inflammation which causing damage to DNA and other health problems. The people are generally considered as an obese when their body mass index is more than or equal to 25kg/sq.m. The measurement of body mass index is obtained by dividing person's weight by the square of person's height in meter square. Obesity is a cause of all chronic diseases which leads to increase in death rate. Considering the body mass index the obesity is thus treated as –if BMI IS LESS THAN 28 it can be treated by controlling diet and physical exercise , if it is in between 28 to 35 then pharmacological treatment is preferred. If it is exceed than 35 or 40 then the bariatric surgery is recommended.

Keywords: Obesity, Inflammation, Body mass index, Bariatric surgery

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A24

Evaluation of Various Marketed Hair Conditioner

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Hair conditioner is a hair care product used to improve the feel, appearance and manageability of hair its main purpose to reduce the friction between strands of hair to allow easier brushing or combing, which might otherwise cause damage to the scalp. The evaluation is helpful to have technical measurements of product performance that provide guidence to the formulation chemist, while also potentially being useful in product marketing. Of course, these instrument-based evaluations contain no information about the aesthetics of formulations, which are considered to be atleast equal in consumer importance. As such, surface lubrication represents the primary function of conditionning products, with improve manageability through grooming becoming an additional benefit. The ideal pH of hair conditioners for occuring the seal of cuticle and provide shine to the hair is 4.0. The work is aim to evaluate marketed brands (Dove, Loreal, TRESemme, Pantene, Sunsilk) for Colour, PH, wetting action, surface tension.

Keywords: Brushing, Performance, Aesthetics

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A25

Mask for Viral Infections, Energy Boosting and Stress Relief

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There is a well-known phrase "prevention is always better than cure", mouths masks are one of the most commonly used preventive measure for various viral infection as mouth mask help limit the spread of germs while talking, sneezing, coughing, and protecting the other people from all type of respiratory viral infection this masks can be made more effective by incorporating various medication in them. Also various types of masks can be prepared for relaxing body and mind and also for reducing stress and fatigue by using various mixture of essential oil in them .This mask can be used as a self-medication and can be made available in cheaper cost. Instead of using cotton mask, it is preferable to use surgical mask as a supporting medium for this formulation. It is easy and comfortable to use for individual of any age group and also easily disposable.

Keyword: Preventive measure, Stress and fatigue, Disposable

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A26

Investigation of Antivenom Activity of Tamarindus Indica Seed Extract

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Snake envenomation is common in tropical and subtropical regions of the world. Snakebites represent a public health hazard that leads to high morbidity and mortality in the Indian subcontinent. Snakebite is an occupational hazard for the rural agriculturist. Among the poisonous snakes of India, Vipera russelli and common cobra are one of the most common causes of snakebite. Antivenom is currently the only available antidote for treating snakebite universally. Antivenins are commonly used to treat the snakebites; however, they are limited in their efficacy in the neutralization of local tissue damage. In the recent years, there has been growing interest in alternative therapies and therapeutic use of natural products, especially which are derived from plants. Lethality, inhibition of phospholipase A2 enzyme, neutralization of hemorrhagic action, neutralization of procoagulant activity and protease inhibition are tested for the antivenom efficacy of plant extract. Plant extracts represent an extremely rich source of pharmacologically active compounds and possess more than one biochemical/pharmacological property. Interaction of such compounds with the toxins/enzymes leads to the neutralization/inhibition of their activities. Tamarind (Tamarindus indica) belongs to the family Leguminosae and grows abundantly all over India. Tamarind seed extract inhibited the PLA2, protease, hyaluronidase, L-amino acid oxidase and 5-nucleotidase enzyme activities of venom in a dose dependent manner.

Keyword: Hazard, Antidote, Neutralization, Procoagulant activity

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A27

Quality By Design (QBD) Approach in Pharmaceuticals

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Traditional approach of formulating a new drug product is an exhaustive task and involves a number of resources like man, money, time and experimental efforts, using this Quality by Design (QbD) approach one can get the pharmaceutical product of desired (best) quality with minimizing above resources as well as knowing the influence of one factor over the desired associated process. Hence aim of this review is the understanding of QbD approach to design product and manufacturing process to get desired pharmaceutical product. QbD follows the concepts of ICH guidelines (Q8, Q9 & Q10) which are essential for processing a pharmaceutical process. This review emphasis various aspects of keynotes of QbD like ascertaining drug product quality profile, priorizing input variables for optimization, modelization & validation of QbD methodology and in the last QbD validation, scale up and production as well as software used for QbD. Hence QbD approach not only useful in facilitating comprehension of the products or process but also useful to attain an excellent and economical product which follow federal compliance.

Keyword: Optimization, Modelization, Scale up

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A28

Structural evidence of differential forms of Nanocrystals and its effect on solubilization of a model drug by Response Surface Methodology

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Introduction: Nanocrystals are tiny particle with a size of about a virus, which can be filled with a wide variety of drugs and can circulate around the body until they encounter the specific target site and stick on the surface and begin to release the drug in a controlled and predictable manner. Objectives: The present study was carried out to utilize the practicability of polymeric nanoparticles as an alternative carrier for targeting Rasagiline mesylate (RM), for improving poor oral bioavailability. Methodology:RMloaded nanocrystalswith different polymerswere developed by precipitation techniquewithresponse surface methodology (RSM)was evaluated for various physicochemical parameters and in vitro drug release. Results and Discussion:Infra-red (IR) studies revealed that there was no interaction between the drug and polymer. In DSC, endothermic peak was observed which indicated substantial crystalline change of drug due to nanosizing. XRD of formulation confirmed that formation of amorphous product which might lead to enhanced solubility of the drug. From the RSM it was observed that best optimized formulation was F6 which showed i.eEntrapment efficiency 83.7%, Particle size 246 nm. The particle size analysis revealed that 90% of the particles had a particle size around 240 nm which perfectly matched with the SEM (Average by scale 242 nm) had almost round and uniform shape and an average particle size of 246 nm was observed in TEM which was porous and spherical in nature. The value of zeta potential indicates the more retention time for nanocrystalsand stability. Conclusion: It is thus concluded that controlled drug delivery via the polymer based systems hasbeen proposed to be conquest both in present and in future; as having copious prospective advantages for scientific as wellas economic reasons.

Keywords: Solubility, Particle size, zeta potential, Bioavailability

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A 29

Hylocereus polyrhizus (Dragon Fruit) - An overview

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Pitaya (Hylocereus spp.) or dragon fruit is originated principally from the tropical and subtropical forest regions of Latin Americas, including North, Central and South America. It is a perennial, epiphytic climbing cactus with triangular, fleshy, and jointed green stems. The red pitaya is a rich source of nutrients and minerals i.e., vitamin B1, vitamin B2, vitamin B3 and vitamin C, protein, fat, carbohydrate, crude fiber, flavonoid, thiamin, niacin, pyridoxine, kobalamin, phenolic, betacyanins, polyphenol, and carotene. Red pitaya fruit is rich in phytoalbumins which exhibit high antioxidant activities. Thus, the probiotic properties and high antioxidant uses of the red pitaya fruit have been reported. Dragon fruit is used to flavor and color juices and alcoholic beverages, such as "Dragon's Blood Punch" and the "Dragotini". The flowers can be eaten or steeped as tea. The red and purple colors of Hylocereus fruits are due to betacyanins, a family of pigments that includes betanin, the same substance that gives beets, Swiss chard, and amaranth their red color. A 100 gram amount of pitaya contains 60 calories, 82% carbohydrates, 4% protein, and 11% of the Daily Value each for vitamin C and calcium. Dragon fruit helps in improving platelet count in dengue patients because of its antioxidant properties. It has been also reported to possess several pharmacological activities too. This review gives us an idea about the pharmacognostical and pharmacological profile and several traditional uses of Dragon fruit. **Keyword:** Probiotic, Phytoalbumins, Antioxidant

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A30

Comprehensive Study on Standardization Parameters of Indigenous Medicinal Plants

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Pharmacognosy is considered as study of medicine derived from natural sources, mainly from plant. It basically deals with standardization, authentication and study of natural drug. Pharmacognostic studies ensures plant identify, lays down standardization parameter which will and help prevent adlterations. The present study will be helpful for conformation of the identity, finding quality and purity and detection of presence of adulterants by various parameters like morphological, microscopical, physicochemical, chemical and biological observations. Muntingia calabura. Is an important medicinal plant as the leaves can be used for preparing herbal tea for various health benefits.. Also traditional medicinal uses have been reported for the leaves including tretment for headaches, prostate problems, gastric ulcers, bark is sused as antiseptic, flowers are important as antiseptic, reducing swelling, antispasmodic and fruits have reported to be useful in respiratory problems and antidiarrheic.

As per records, comparitive pharmacognostical work on such potential drug is not mentioned, the present work was taken up to produce the pharmacognostical standards. The study deals with the pharmacognostical examinations including morphological, microscopical and phytochemical characters. Physicochemical constants of leaves, bark and fruits of *Muntingia calabura* were also determined which include determination of leaf constants, ash value, foaming index, swelling index, moisture content and extractive value, foreign organic matter, crude fiber content etc as per official guidelines. This study will be helpful for setting of the monograph and standards of *Muntingia calabura*.

Keyword: Conformation, Potential drug, Antidiarrheic

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A31

Formulation and Evaluation of Topical Delivery System of Herbal Anti-Inflammatory Active

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Inflammation is a response of a living tissue because of injury, microbial infections, physical factors, chemical substances, tissue necrosis and hypersensitive reactions. The primary aim of the present research work was to explore topical delivery of ficusrascemosaleaves ethanolic extract as an alternative for the treatment. Literature review suggests that oral administration of Ficusrascemosa leaf extract is having anti-inflammatory activity. However, when herbal extracts are taken orally, there may cause digestive trouble, systemic adverse effects or side effects as it contains various chemical constituents. To avoid these problems, extract may be applied at the site of action. In the present research an attempt has been made to determine anti-inflammatory activity of ethanolic extract of ficusrascomosa leaf (2.5% and 5%) after application of it at the site of inflammation. The selected strength of an ethanolic leaf extract was formulated in transdermal patch. Transdermal patches were prepared by applying 32 factorial designs. Concentration of HPMC and PVP were selected as independent variables. Tensile strength and t₅₀ were selected as two response as dependent variable. As viscosity of polymer (grades of polymer) increases, tensile strength and t₅₀ increases. Transdermal patch (HPMCK4M 5% and PVP 1.5%) having high tensile strength (0.67Kg/cm^2) and less $t_{50}(195.6 \text{ min})$ was selected as the optimized formulation. Significant difference in % inhibition of paw oedema by marketed formulation and patch containing 5% Ficus Rascemosa extracts was found. Optimized transdermal patch was subjected to stability study no appreciable changes were found for the tested parameters.

Keyword: Topical delivery, 3² factorial designs, Optimized formulation

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A32

Structure Based Drug Design

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Structure-based drug design is the design and optimization of chemical structure with the goal of identifying a compound suitable for clinical testing. The drug is most commonly an organic small molecule that activates or inhibits the function of a biomolecule such as a protein, which in turn results in a therapeutic benefit to the patient. Drug design that relies on the knowledge of the three-dimensional structure of the biomolecular target is known as structure-based drug design. Drug discovery has evolved through various stages into more rational and evidence-based drug designing. Compared to conventional methods which were time consuming and less logical, new drug designing based on structure is rational, evidence based, faster and more scientific in nature. In the era of modern medicine, where newer insights into molecular level of disease processes are available, it is very essential that drug designing be based on molecular mechanism of pathologic processes. Structure-based drug designing has made tremendous contributions in the field of cancer chemotherapy, drug resistant infections, neurological diseases, to mention a few.Computational structure-based drug designing opens the door to novel treatments in modern medicine.

Keyword: Optimization, Biomolecular target, Cancer chemotherapy

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A33

A Review on Analytical Method Development and Validation for Antiretroviral Drugs

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Efavirenz, Atazanavir, Nevirapine, Doravirine, Rilpivirine belongs to the class of antiretroviral drugs under Nonnucleoside reverse transcriptase inhibitor class. Antiretroviral drugs are the medications used for infection of retroviruses mainly HIV. They function as a chain-terminator during the extension of DNA chain during reverse transcription process. different classes of antiretroviral drug act at different stages of the HIV life cycle. In this review we complied different analytical method for the development and determination of the Efavirenz, Atazanavir, Nevirapine. It shows the pharmacological parameters of various Antiretroviral drugs alsoIt shows the analytical method development and validation of Efavirenz, Atazanavir, Nevirapine, Doravirine, Rilpivirine alone with its combination of other drug by using HPLC method.

Keyword: Analytical method, Chain-terminator, Rilpivirine

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A35

Doehlert Design- A Methodology for Analytical Method Development and Validation

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An analytical chemistry involves various Techniques and methodologies applicable for qualitative, quantitative and structural information of drug substances. QbD is one of the methodologies for analytical method development and Validation. QbD means that product and process performance characteristics are scientifically designed to meet specific objectives, not merely empirically derived from performance of test batches. In a QbD approach, the impact and interactions between critical method variables are understood using a Design of Experiments approach. Doehlert Design is symmetrical second order experimental design widely used in analytical chemistry for analytical method development and validation. In this review we studied various applications of Doehlert Design in analytical Chemistry. Applications of the Doehlert design in analytical chemistry are increasing in recent years, mainly because of its advantageous characteristics in relation to other designs. **Keywords**: Quality by Design, Design of Experiments, Doehlert Design

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A36

Water Never Becomes Stale

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Water is essential for life,now a days we are facing scarcity of Water. Water supplied by municipalities is purified by sedimentation, filtration and chlorination. In every house water is collected daily, storedand used for drinking and cooking purposes. Usually remaining water is thrown out because in our society people believe that stored water becomes stale. So attempt is made in present work to find out microbial quality ofwater stored for 7 days. Microbial quality of stored water is tested by two methods- 1) Plate count method: where number of microorganisms in water were measured as colony forming unit per ml of water. 2) Turbidity method: where number of microorganismsin water were expressed as absorbance by using liquid medium. Municipality water has 1 ppm residual chlorine levels which protect water from microbial multiplication. Number of microorganisms in water does not increase if stored in clean and closed container. It was observed that there is no increase in number of microorganisms in water on storage. Our experiment proves that microbial quality of water does not deteriorate during storage, so drinking water should not thrown out. Drinking water stored properly can be used even after 7 days and is safe microbiologically.

Keywords: Turbidity method, Sedimentation, Deteriorate

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A37

A Review on Comparative Analysis of Phenolic, Flavonoid Content and Antioxidant Potential of Endogenous Medicinal Plant

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Medicinal plants are considered as rich sources of ingredients which can be used in drug development either pharmacopeial, non pharmacopeial or synthetic drug. Phenolic acids and flavonoids plays a significant role in plants, their impact mainly as antioxidant, on human health have been of great interest in recent years. Flavonoids are powerful antioxidants with anti inflammatory and immune system benefits. While phenols are used for anticancer activity. The given investigation describes the phytochemical analysis, phenolic content, flavonoid content and in vitro antioxidant activity of given endogenous plant. The phenolic and flavonoid content was estimated by spectrophotometric method and antioxidant property of aqueous and alcoholic extracts was estimated by % Hydrogen Peroxide activity Scavenging activity.

Keywords: Anticancer activity, Phytochemical analysis, Spectrophotometric

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A 38

Inherent Stability Testing of Anti-Acne Drug Combination by Different Validated Chromatographic Methods

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Understanding of inherent stability of drugs helps in proper formulation development. This information also guides regarding selection of appropriate storage conditions, packaging material and shelf life. Stress testing and development of stability indicating methods is the way for understanding the inherent chemical stability of a drug. In stress testing, drugs are subjected to undergo degradation under harsher conditions than accelerated stability studies. The ICH recommended stress testing conditions involve hydrolysis (acid, base, neutral), effect of temperature (with 10°C increments above accelerated stability studies), humidity, oxidation and photolysis on a drug substance. Such a stress testing generates likely degradation products. Identification of DPs helps in establishing degradation pathways and validating the stability indicating property of analytical procedures used. Therefore, a stability indicating RP-HPLC method was developed and validated for an anti-acne drug combination. The major DP was isolated and structure was predicted by LC-MS studies.

Keywords: Shelf life, Stress testing, Degradation, Anti-acne drug

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A39 Pharmaceutical Validation: A Mandatory Perspective

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It has always been known that the processes involved in pharmaceutical production impact significantly on the quality of the products The processes include raw material and equipment inspections as well as in-process controls. Process controls are mandatory in good manufacturing practice (GMP). The purpose is to monitor the on-line and off-line performance of the manufacturing process, and hence, validate it. Thus validation is an integral part of quality assurance. Quality is the primordial intention to any industry and its products manufactured. Multiple views on obtaining quality is the current interest in the pharmaceutical industry.

Method validation is an important part of analytical chemistry to confirm that the method employed for a specific test is suitable for its intended use. As such, it is an essential requirement for any package of information submitted to regulatory agencies in support of new product marketing or clinical trial applications. Currently, there is no single source or final guideline on analytical method validation that helps analysts to perform validation in a systematic manner. Therefore, industry depends on the analyst's knowledge and experience to develop simple and efficient methods of analysis.

The concept of validation has expanded through the years to embrace a wide range of activities from analytical methods used for quality control drug substances and drug products to computerized systems for clinical trials, labeling, or process control. Validation is founded on but not prescribed by regulatory requirements and is best views as an important & integral part of cGMP.

Keywords: Equipment, Quality assurance, Quality control

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A 40

In-vitro fertilization- An important tool of assisted reproductive technology

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In-vitro fertilization popularly known as IVF technology is one of the most successful forms of assisted reproductive technologies that are available today to assist couples who are finding it difficult to have children. It is a simple process in which the egg of a woman is fertilised with a sperm in a medically controlled laboratory under artificial conditions (literally in a glass). The fertilised embryo is then transferred into the uterus for growth. There is a systemic method for carrying out this process in numerous hospitals all over the world. The term In-vitro, from Latin word meaning in glass is used, because early biological experiments involving cultivation of tissues outside the living organism, from which they came, were carried out in glass containers such as beakers, test tubes or Petri-dishes. Today, the term in vitro is used to refer to any biological procedure that is performed outside the organism it would normally be occurring in, to distinguish it from an in vivo procedure, where the tissue remains inside the living organism within which it is normally found. This review gives us idea about all the aspects of in vitro fertilisation

Keywords: Technologies, Cultivation, Fertilisation

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A42

RP-HPLC Bioanalytical Method For Quantification Of Cilnidipine In Human Plasma

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A RP-HPLC method for quantitative estimation of Cilnidipine in human plasma was developed and validated. The chromatographic separation was performed on CYBERLABTM, USA RP-HPLC system equipped with C18 column (NeoSphere 250 mm X 4.6 mm with 5 micron pore size) using a mobile phase acetonitrile:water (70:30v/v) with a flow rate of 1mL per minute. The method was validated over concentration range 100-2000 ng/mlwith coefficient of correlation value (R^2) 0.999. The recovery was found to be 92.95 -103.60%. Limit of detection and limit of quantification was found to be 0.0002 ng/ml and 0.0007ng/ml respectively. This simple, selective and precise bioanalytical method was further successfully applied for pharmacokinetic study of nanoparticulate drug delivery system.

Keywords: Cilnidipine, Bioanalytical, Nanoparticulate

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A43

Development And Validation Of UV/VIS Method For Quantification Of Telmisartan In Dosage Form

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A simple, rapid, accurate and economic UV/VIS method for estimation of telmisartan in nanoparticulate drug delivery system was developed and validated. Telmisartan has showed wavelength of maxima at 296 nm. The method was validated over concentration range 4 -24 $\mu g/ml$ with coefficient of correlation value (R²) 0.9993.The mean recovery was found to be 100.39%. This value was within acceptable limits with a low % RSD.The results of intra-day and inter-day precision were indicated that the assay method was reproducible within the same day and between days.Limit of detection and limit of quantification was found to be 0.355 $\mu g/ml$ and 1.08 $\mu g/ml$ respectively. The developed method was found to be reproducible for routine analysis of telmisartan in dosage form.

Keywords: Nanoparticulate, Precision, Limit of quantification

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A 44 Research Work on Cleaning Validation Using Lab Made Disinfectant

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A Quality management system necessitates forethought into the number of variables that must be managed in *corrective action*, *preventative action*(CAPA) approach. *Cleaning validation* is the process of assuring that cleaning procedure effectively removes the residue from manufacturing equipment / facilities below a predetermined level. *Disinfectant* is a chemical liquid that destroys bacteriaensuring that contamination is *controlled* in cleanrooms, on & in equipment, and in relation to personnel isan important step in maintaining *microbial control* of production process & a focus on the structure in which pharmaceutical product are prepared. A well thought out cleaning, disinfection & decontamination program for the pharmaceutical manufacturing environment is one of the fundamental components of successful operation.

Keywords: Microbial control, Decontamination, Equipment

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A 45

Thermal and X-Ray crystalographic study in development of formulation stage Pratiksha Bhojane*, Divya Chavan, Kajal Khilari, Om Bagade, Saroja Survase, Ankita Chaudhari

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Thermal techniques and X ray crystallography are useful techniques that have been successfully applied in the pharmaceutical industry to reveal important information regarding the physicochemical properties of drug and excipient molecules such as polymorphism, stability, purity, formulation compatibility among others and used to determine the arrangement of atoms of a crystalline solid in three dimensional spaces respectively. In pharmaceutical industries drug excipient physicochemical characterization is a systematic approach towards design of therapeutically active and stable dosage forms. For high resolution were used to get an insight on solid state properties of the drug and evaluate drug-excipient compatibility this analytical techniques are mainly used. This article contains considerations and interpretation of the graphical data obtained from these techniques.

Keywords: Polymorphism, Excipient, Systematic approach

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A 46

Formulation and *in vitro* characterization of Multi grain nutritious cookies for Diabetes Mellitus

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Introduction: Diabetes mellitus (DM) is group of metabolic disorder. Diabetes is due to either the pancreas not producing enough insulin, or the cells of body not responding properly to the insulin produced. Most of the people consumes cookies during breakfast and get energy, so we are formulating the cookies using different plants on the basis of palatability for diabetic patients. Objective: To improves fat and fiber content. Methodology: Grinding and blending method is used to formulate the cookies with different compositions of ingredients such as roasted black gram, juice of bitter guard, mango leaves, plum seeds etc. Result and Discussion: All ingredients were weighed as per formula and passed through the sieves after grinding with definite shape and size. Micromeritics study was observed at initially. Formulations were characterized by using some test like moisture content, ash value, fat content, carbohydrate content, protein content etc. Conclusion: On the basis of formulated data, it was found that our herbal cookies have high amount of proteins, fibers, carbohydrates preferably for the diabetic patients as compared to marketed products. Thus, the scale up of nutritious cookies can be possible with low cost and high efficiency.

Keywords: Micromeritics, Grinding and blending, Fibers

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A 47 Dry Powder Inhaler: An Exploitation of Emerging Technique

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Introduction: A Dry Powder Inhaler (DPI) is a device that delivers medication to the lungs in the form of dry powder. The study is set up with an intended to examine about the technical, physiological, and efficacy aspects of the novel pulmonary route of drug targeting and different delivery devices such as metered dose inhalers (MDI), dry powder inhalers (DPI), nebulizers. DPIs is efficient and environmentally friendly way of delivering drug to the lungs. DPIs is alternative to pMDI that delivers medications to the lungs in the form of dry powder. DPI are formulated using foue types of formulation strategies such as; Carrier free, Drug carrier, Drug additive, Drug carrier additive. Pharmaceutical powders once in a while spherical, and shape components are dimensionless measures of the deviation from sphericity. Particle size of API must be present in size range about 1-10 micrometer which also guarantee that the patients gets the same dose every time at different air flow rate. Conclusion: The study of DPI improves aerosol drug delivery system. It carries high dose capacity & high patient compatibility.

Keywords: Sphericity, Strategies, Pulmonary route, Nebulizers

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A 48

Fabrication and statistical optimization of Carbamazepine loaded Nanocomposite beads

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Introduction:Nanocompositesbeads can be defined as multiphase materials, where one or more of the phases have at least one dimension less than 100 nm. Nanocomposites have a wide range of applications in drug delivery. **Objective:** To enhance the dissolution rate as well solubility poorely water soluble drug. Methodology:Carbamazepine loadedNanocomposite beads with different polymer were prepared by using sol gel transition method by factorial design was evaluated for various physicochemical parameters and in vitro drug release. Result and discussion: The FTIR study showed that there was no chemical interaction between the drug and polymer thus it governs the compatability. Furthermore, the drug was stable in all the formulation. The experiment result indicated that combined with surfactant, were evaluated as stabilizer to control the particle size and enhance nanoparticles.Conclusion: CBZ NCs stability of drug beads significantimprovement in the dissolution rate. This method is quite better for easy scale up and transformation in to the desire dosage form with minimum time.

Keywords: Particle size, Physicochemical parameters, Polymer

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A 49

An Abridgment on challenges & Tools in Pharmaceutical Process Validation *Choudhary Kanchan, Gadkar Aarti, Harshada Puranik

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Procedure validation is setting up recorded proof which gives a high level of confirmation that a specific process such as the assembling of pharmaceutical dosage structures will reliably deliver an item meeting its foreordained details and quality attributes. The reason of process validation is to guarantee differed inputs lead to reliable and top notch yields. All Bio producers take a stab at operational greatness, administrative consistence, and new improvements of patient treatments. Pharmaceutical pioneers and bio process validation specialists are attempting to expand on strategies by disposing of dangers, guaranteeing sterility, and examining item quality at each stage. Presently, the industry is creating methods that include a proceeding with confirmation way to deal with improvementin bio process products. Bio makers make progress toward operational greatness, administrative consistence, and new improvements of patient treatments. Many emerging challenges for stage 2 PPQ are to be studied. Procedure validation is a noteworthy program in pharmaceutical industry. Herewe explore emerging challenges and tools for process validation. The reception of science and hazard based ways to deal with process validation carries with it a need to exhibit improved procedure understanding, control methodology and procedure vigor. The customary apparatus sets like inferential measurements applied to little example populaces utilized for process validation discovered are insufficient and progressively new methods e.g. prescient models, consistent information are required to successfully address these issues. The optimization of a processes and newer tools used for maximum efficiency, while maintaining quality standards, is a consequence of validation is of prime importance. Hence to Optimize is "To prepare highly efficient, perfect with higher utility". The optimization should result in a product that meets quality requirements at the economical rates.

Keywords: Quality standards, Science and hazard, Emerging challenges

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A 50

Design, Development and Evaluation of Antimalerial Drug Loaded Solid Lipid Nanoparticles

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The drug used in study is considered as the basis in the treatment of *Plasmodium falciparum* malaria due to their high potency and rapid action. However, it has short half-life, low solubility, and poor oral bioavailability. Its efficacy is hampered by poor aqueous solubility and stability resulting in low oral bioavailability, hence it is necessary to formulate sustained release lipid particulate dosage form of these drugs. The main objective of the current study was to design and develop SLN's. Solid lipid nanoparticles were prepared by solvent injection followed by probe sonication method. Cetyl palmitate was used as lipid and Tween80 as a surfactant. Batches were prepared by varying the concentration of the lipid and the surfactant. SLN of drug were optimized by using 32 factorial designs. Batch was selected on the basis of entrapment efficiency, size, stability and consistency. It was concluded that formulation F5 showed good entrapment efficiency and a drug release of optimized batch was 83.4% and 97.5%. Design expert software also showed batch F5 as optimized batch. The solid lipid nanoparticles were evaluated for particle size analysis, drug entrapment efficiency, zeta potential and in vitro drug release study. The final batch was evaluated for drug content, pH, in-vitro diffusion and ex-vivo study. Zetasizer study of SLN batch revealed formation of nanoparticles of approximately size 278.1 nm. Thus, it can be concluded that prepared SLN had improved solubility, controlled release and the oral delivery of the same would add to its benefit in treatment of malarial infection.

Keywords: Efficiency, Nanoparticles, Zeta potential, Controlled release

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Formulation and Evaluation of Colloid Based Emulgel for Topical Drug Delivery

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Present work was carried out with the grail of formulating gellified emulsion of colloid having antibacterial agent. Transdermal route of administration of drug is effective route of administration. Purpose of present investigation was to develop colloidal emulgel, which have emerged as a promising drug delivery system for the delivery of hydrophobic drugs. Formulation deals with use of Carbapol 940, sodium CMC and HPMC were used as a gelling agent. Colloidal sol showed good antibacterial property which when used in the formulation can provide better activity on skin. Olive oil and Oleic acid were used as penetration enhancers. The emulsion was prepared and it was incorporated in gel base. The formulations were evaluated for physical properties, pH, drug content and rheological properties, spreading coefficient studies, skin irritation studies, anti-bacterial activity. Formulations showed comparable increase in antibacterial activity as compared to pure drug having antibacterial property. Colloidal emulgels has expanded both in cosmetics and in pharmaceutical preparation. So, it can be concluded that topical emulgel of colloids have shown better anti-bacterial activity. This concept will also be helpful in formulating many other formulations for oral and topical routes.

Keywords: Antibacterial, Penetration Enhancers, Transdermal,

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A Review On In Vivo And In Vitro Testing Of Antiallergic Formulations Sonal A. Konde, Mayuri M. More, V. S. Tambe

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Allergic diseases have great impact on the quality of life of both people and domestic animals. Allergy is one of the most important safety problems. In this topic, we reviewed common food allergy cell models including mast cells, basophil granulocyte and basophil as well as the animal models of mouse, rat, cat and zebra fish. For allergic conjunctivitis, the animal model used is guinea pig model of ovalbumin (OA). Dogs are also very useful species to improve our understanding on the mechanism involved in people's allergies and a natural model to study eczema. Large animals like sheep and horse are also used for screening of allergy. The purpose of the current topic is to review allergic diseases across species and to focus on how these diseases compare to the counterpart in people.

Keywords: Eczema, Ovalbumin, Basophil granulocyte

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Review on Development of Nanosponges

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Nanosponges are the recent advances in nanotechnology. Nanosponges are the tiny sponges with a size of about a virus with an average diameter below 1 um. NSs are prepared with melt method, solvent diffusion method, solvent method, ultrasound assisted method and sonication. NSs are the target site specific drug delivery which has less side effects. It improves solubility of poorly soluble drug, posses higher drug loading capacities compared to other nanocarriers. Nanosponges have particle size less than 500 nm, melting pointless than 250 C of drug, pH varies from 1 to 11 for Nanosponges. Nanosponges has wide applications such as topical delivery of drug, for cancer drug therapy, for protein delivery and also as chemical sensors.

Keywords: Diffusion, Loading capacities, Nanocarriers, Chemical sensors

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A review on Pulsatile drug delivery system

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Traditionally drug release pattern is either immediate or extended type. The PDDS is the important drug delivery system where disease having predictable cyclic rhythm, ex-arthritis ,peptic ulcer, hypertension , asthma, cardiovascular disease, Diabetes mellitus .The main advantages of PDDS is that release of drug at right time, at right site of action ,at right amount. There are different methodologies for PDDS is single unit system and multiple unit system — in that included capsular system,pulsatile delivery by osmosis, pulsatile delivery by erosion of membrane, delivery by rupture of membrane. This system is develop to deliver drug according chronopharmacological behavior of disease. The system is beneficial to drug having high first pass effect or having high risk of toxicity or side effects. These system is also helpful for patient to improve affectivity or reduce dosing frequency.

Keywords: Chronopharmacological, Methodologies, Erosion

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Development and validation of stability-indicating high-performance thin layer chromatography method for bergapten

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Bergapten, a phytoconstituent has many therapeutic activities such as antimicrobial, anti-inflammatory, anticancer, antioxidant, anticonvulsant, and osteoporosis activities. Owing to increased demand of standardization of herbal drugs and their formulations, it is essential to know degradation pathways for bergapten, which would give direction about its formulation development, packaging and storage conditions. A simple, precise, accurate and rapid stability-indicating High-Performance Thin Layer Chromatography (HPTLC) method was developed for bergapten. For development of chromatograms, toluene: dichloromethane: ethyl acetate (7:2:1 v/v/v) was used as mobile phase. The densitometric scanning was performed at 318 nm. The method was found linear over from 25 to 400ng/band with correlation coefficient 0.998. The developed HPTLC mod was validated as per ICH guidelines. Validated HPTLC method was used to reveal the degradation products of bergapten after it was subjected to forced degradation. The proposed method would be able to selectively analyze bergapten and its degradation products in drug substance and its formulation.

Keywords: Phytoconstituent, Osteoporosis, Chromatograms, Degradation products

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The cow dung is considered very sacred in Indian philosophy, it says that Gomay Vaste Laxmi i.e. Goddess of Wealth resides in cow dung. Cow dung is basically the rejects of herbivorous matter. The chemical based Tooth powders available in the market contain some harmful and poisonous chemicals, which are likely to cause threat to human health. An attempt has been made to prepare a 100% herbal product, based on traditional practices and rural wisdom. It is effective and cheaper than presently chemical based Tooth powder. Since it is totally herbal, it has no side effects on human health. The main aim of this product development is to provide employment to the rural youth and economic gains to farmers. This study deals with selection and Characterization of ingredients and evaluation of antimicrobial activity of Tooth Powder. Studies conducted about the comparison with the existing Marketed tooth powder. Cow dung tooth powder is very useful in case of tooth decay, sensitiveness for hot and cold water, swelling of gums, mouth pain, ulcers over tongue, sore throat, deterioration of taste, tonsillitis, hoarse throat, it is very beneficial for bad smell of mouth, pyorrhea.

Keywords: Tooth decay, Swelling of gums, Tonsillitis

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Formulation and evaluation of topical delivery system for the treatment of Cheilitis.

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The aim of the study is to formulate and evaluate the topical delievery system for the treatment of cheilitis using Curcuma longa and Pterocarpus santalinus. Cheilitis is a inflammation of lips.these inflammation may include perioral skin(skin around the mouth), the vermilion border, and/or labial mucosa.curcumin is one of the ingredient found in the spice turmeric. Topical curcumin to be effective in a number of condition associated particularly with skin injury and inflammation. Topical preparations of curcumin can be more easily formulated to increase penetration of hydrophobic curccumin to skin.Ptrocarpus santalinus belongs to the family fabaceae commonly known as red sandal wood. Various pharmacological activities of this plant has been shown by the researches such as; heartwood is rubbed with water, honey, gheeand oil applied as collyrium to alleviate defects of vision; treats skin diseases bone fracture, leprosy, spider poisoning, scorpionsting, hiccup, ulcer, general deability. In this study we formulated organogel and hydrogel of curcumin and ptrocarpus santalinus and effect was observed on female Sprague Dawley rats weighing from 120-140gm. From this study we observed reduction in thickening of epidermis, stratum corneum and infiltration of inflammatory cells however no presence of edema and hemorrhage and increased number of sebaceous glands.

Keywords: Skin diseases, Curccumin, Organogel

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Preformulation: Strengthen the foundation for formulation and development

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Abstract: The preformulation is the first step in the rational development of a dosage form of a drug substance alone and when combined with excipients. **Objective:** The main objective of this study to generate useful information to the formulator to design an optimum drug delivery system. Preformulation studies strengthen the scientific foundation of the guidance, provide regulatory relief and conserve resources in the drug development and evaluation process, improve public safety standards, enhance product quality, facilitate the implementation of new technologies, and facilitate policy development and regulatory decision making. **Conclusion:** Preformulation studies give directions for development of formulation in choice of drug form, excipients, composition, physical structure, helps in adjustment of pharmacokinetic and biopharmaceutical properties, support for process development of drug substance support and useful data for development of analytical methods.

Keywords: Technologies, Regulatory, Pharmacokinetic

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Formulation, development and statistical optimization of Losartan Potassium loaded Microsponges drug delivery system

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Introduction: Microsponge are tiny, spherical, uniform and micropous polymeric beads. The size of microparticles are in the range of 5-300μ. The purpose of this work was to develop a prolonged microsponge drug delivery system containing Losartan potassium. Methods: Losartan potassium-loaded, Eudragit-based microsponges were prepared using a quasiemulsion solvent diffusion method by factorial design. The compatibility of the drug with formulation components was established by differential scanning calorimetry (DSC) and Fourier transform infra-red (FTIR). Process parameter like calibration curve that can be used to check linearity and wavelength of drug. Results: The results of compatibility tests showed that no chemical interaction or changes takes place during preparation of the formulations. furthermore, the drug was stable in all the formulations. In increase in drug: polymer ratio (X1) resulted in a reduction in the release rate of the drug from the microsponges. Entrapment efficiency was found to be around 90-95%. Wherein SEM image showed that the particles are found to be around spherical in shape. **Conclusion:** This study presents an approach for the modification of microsponges for prolonged drug release of losartan potassium. The compressibility of microsponges can be applied to achieve effective local action since microsponges may be taken up by macrophages present in colon.

Keywords: Factorial design, Release rate, Local action

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A 60

Consequences Of Errors In Validation

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Validation is independent procedure that is used for checking that a product, service, or system meets requirements and specifications and that fulfills its required purpose. Many times we have studied and seen what validation exactly is and how necessary it is to maintain and regulate the quality of required product; but here via case studies we are discussing about the consequences which affects the health of the society if validation goes wrong. Here we have studied the cases, out of which one is of MiniMed 600 Series insulin pump [Model 630G (MMT-1715) and Model 670G (MMT-1780)] which recalled due to a missing or broken retainer ring which helps to lock the insulin cartridge into place in the pump's reservoir compartment. If the cartridge is not locked firmly into place, under or over delivery of insulin may occur, this could result in hypoglycemia or hyperglycemia. Severe hyperglycemia can result in a loss of consciousness, seizure, and death. In this way we have studied the cases which clearly give us an idea about worst effects of errors in validation.

Keywords: Specifications, Regulate, Insulin cartridge

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Study of different approaches of tablet coating and its impact in development stage

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Introduction: Tablet coating is the key step involved in the manufacturing of tablets having controlled release, delayed release profiles. The tablet coating have number of advantages like masking odor, taste, color of the drug, providing physical and chemical protection to drug, Protecting drug from the gastric environment. Solid dosage forms are coated for a number of reasons the most important of which is controlling the release profiles and bioavailability of the active ingredient. Objective: To study the different types of coating approaches for different types of tablets and focus on recent trends in tablet coating focuses on overcoming disadvantage of solvent based coating. Methodology: Three primary components of tablet coating are tablet properties, coating process and coating composition. Tablets are usually coated in horizontal rotating pan with coating solution is either directly poured or sprayed on to them. The amount of coating on the surface of a tablet is critical to the effectiveness of the oral dosage form. Tablets are usually coated in horizontal rotating pans with the coating sprayed onto the free surface of the tablet bed. Tablets must have a coating mass that lies within a prescribed range with very little inter-and intra-tablet coating variability. Conclusion: This study concerns with the different coating process, equipments involved, coated tablets evaluation and specialized coating techniques.

Keywords: Active ingredient, Key step, Release profiles

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A 62 Ayurveda, Diabetes mellitus and Antidiabetic formulations

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Diabetes is fastest growing disease worldwide,and India cases are increasing as alarming rate mainly due to day to day life style. It is a type of metabolic disorder, which leads to dysfunction glucose metabolism and its concentration in blood increases. Indian system of medicine, *Ayurveda* describes diabetes as *madhumeha*. There are many methods reported in Ayurveda to deal with the diabetes; which are preventive or curative. Conventional medicaments for diabetes mellitus also have for its minimal side effects. Plants in Ayurveda which have antidiabetic activityrestore the function of the β cell in pancreas as well as restore the action of insulin. In present review Ayurvedic perspective of the disease is discussed. The chemistry and pharmacology of major plant material in formulations for diabetes have been correlated with modern findings. There is a need to look upon the preventive and curative methods and formulations used for the treatment of diabetes in traditional system of medicine worldwide. Their exploration and correlation with modern finding is also required. Emphasis is also on the herbal formulations; their processing methods and usage in the traditional system of medicine.

Keywords: Madhumeha, Preventive, Herbal formulations

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Pharmaceutical Process Validation: An Important tool towards Product Quality, Safety, Efficacy

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Quality is always an imperative prerequisite when we consider any pharmaceutical product. Therefore, drugs and its intermediates must be manufactured to the highest quality levels. End-product testing by itself does not guarantee the quality of the product. Quality assurance techniques must be used to build the quality into the product at everystep and not just tested for at the end. In pharmaceutical industry 2019, Process Validation performs this task to build the quality into the product because according to ISO 9000:2000, it had proven to be an important tool for quality management of pharmaceuticals. Validation is one of the important steps in achieving and maintaining the quality of the final product. If each step of production process is validated we can assure that the final product is of the best quality. Validation of the individual steps of the processes is called the process validation. Different dosage forms have different validation protocols. Process Validation is one of the important steps in achieving and maintaining the quality of final product. It gives a higher degree of assurance. Through this study focuses on process validation and drug quality as well as various approaches to process validation. Also special emphasis is given on Statutory and regulatory requirements for process validation as well as types of process validation, validation protocol and report. First and foremost, it is important to design processes that ensure product quality, safety and efficacy. Today's software systems can help validate pharmaceutical manufacturing and steer the most appropriate design of processes in the right way. These systems can deliver clear documentation; provide version control for the multitude of systems in use and backup to ensure all risks are mitigated.

Keywords: Pharmaceutical industry, Degree of assurance, Software systems

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A 65 Cleaning Validation And Its Importance In Pharmaceutical Industries

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Cleaning Validation is related to validation of equipment cleaning procedures used in Pharmaceutical Industry to prevent cross contamination or adulteration of drug product that would alter safety, identity, strength, quality or purity of the drug beyond acceptable standards. Cleaning validation is documented evidence that provides a high degree of assurance that a specific cleaning procedure, when performed appropriately, will consistently clean a particular piece of equipment to a predetermined level of cleanliness. The cleaning of the manufacturing equipment is an important aspect of good manufacturing practice. The process of demonstrating the efficiency of the cleaning procedure is known as cleaning validation. Objective of cleaning validation is assure that intermediates, cleaning agent, excipients & drug ingredients from previous batch do not contaminate next product. Before proceeding for cleaning validation one must be aware of sources of contamination and general cleaning methods and concept as approach may vary according to manual, semiautomatic and automatic methods of cleaning. Complexity of cleaning process, variety of facilities, variety of product and variety of equipment are few important considerations for cleaning validation in a pharmaceutical industry which helps to plan for cleaning continuum. Grouping philosophies makes complex cleaning validation program more manageable. Sampling techniques and analytical methods both plays an important role in making cleaning validation program successful. A Pharmaceutical industry must have a rational for deciding acceptance criteria for obtained results of cleaning validation which should be practical, verifiable and scientifically sound.

Keywords: Evidence, Efficiency, Semiautomatic and automatic methods

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Development And Validation Of Analytical Method For The Estimation Of Ofloxacin In

Ophthalmic Dosage Form

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A simple, rapid, sensitive, specific and accurate HPLC method for the determination of Ofloxacin in ophthalmic commercial dosage form was developed. For Ofloxacin chromatographic separation was achieved on Shimadzu C₁₈ column with mobile phase of Buffer: Acetonitrile in the ratio 76:24 with flow rate of 1ml/min was used. Detection was carried out at 289 nm using PDA detector. The retention time for Ofloxacin was found to be 2.690 min. Validation parameters were performed to demonstrate system suitability, specificity, precision, linearity, range, accuracy, ruggedness & robustness. The method was linear over the concentration range of 5-30µg/ml. The method show good recoveries (99.5-103%) indicating no interference of HPMC. The result demonstrates that the proposed method is accurate, Precise, and reproducible while being simple and rapid for determination of Ofloxacin in ophthalmic dosage form.

Keywords: Detection, Ophthalmic, System suitability

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Validated RP-HPLC Method Development For The Simultaneous Estimation Of Irbesartan And Hydrochlorothiazide In Combined Dosage Form

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ABSTRACT

Irbesartan (antihypertensive) and Hydrochlorothiazide (diuretic) are frequently available as combined dosage form. Present research work aims to develop simple, precise and accurate HPLC Internal Standard method for the estimation of Hydrochlorothiazide.Chromatographic separation was achieved on Qualisil 5 BDS C18 column in low pressure gradient mode with mobile phase Acetonitrile: water (pH adjusted to 3.3 with orthophosphoric acid) in the ratio (42:58) with flow rate and injection volume were 1.1ml/min and 10 µL respectively and monitored on PDA detector at 254nm. The developed method was found to be linear for Irbesartan and hydrochlorothiazide in the range of 12-84μg/ml and 1-7μg/ml with correlation coefficient (r²) 0.9997 and 0.9992 respectively. The proposed method was validated as per ICH Q2B guidelines. Assay of the marketed formulation was found to be 98.26% and 98.47% for Irbesartan and hydrochlorothiazide respectively. In accuracy study the recovery at 80%, 100% and 120% was found to be in the range of 98.80% to 101.78%.RP-HPLC Internal Standard method was developed for simultaneous estimation of Irbesartan and Hydrochlorothiazide using Telmisartan hydrochloride as internal standard. The developed HPLC method was validated and found to be simple, specific, reproducible, precise and accurate.

Keywords: Irbesartan, Marketed formulation, Reproducible

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Solubility Enhancement By Solid Dispersion

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solubility or dissolution enhancement technique remain most vibrant field for researchers which includes core concept of any physical or chemical science including biopharmaceutical and pharmacokinetic consideration in therapy of any medicine. For enhancement of solubility and dissolution following methods are used such as. Solid dispersion, pH adjustment, salt formation, cosolvents, polymeric alteration, micronization, particle size reduction, evaporation. These techniques are used for increase the solubility and dissolution. This review is focussed on solubility enhancement through preparation at solid dispersion by using technique as. Fusion method, spray drying, lyophilization, holt melt extrussion. Most of the drugs coming from hythroughput synthetic posses, poor solubility, which is major problem for therapeutic succes. By improving solubility leads to enhanced **Keywords:** Micronization, Lyophilization, Extrussion

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