

## OVERVIEW OF GLOBAL REGULATIONS ON PHARMACEUTICAL DRUGS AND DRUG PRODUCTS

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**Abstract:** In 21st century modern world the pharmaceutical, biotechnology and medical device research and development, industries are among the most highly regulated industries in the world. As India is growing very rapidly in pharmaceutical sector, there is a need of regulatory affairs professionals to cater the current needs of industries for the global competition. Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. They are required to be well versed in the laws, regulations, guidelines and guidance of the regulatory agencies of various countries. The present article reviews how drug and drug products are regulated with the GLP, GCP, GMP and other GXP procedures. The impact of fundamental procedures, issues and initiatives on regulatory strategy is also highlighted in this article. The need for inclusion of Regulatory education in modern pharmacy curriculum is also emphasized.

**Keywords:** GMP -Good Manufacturing Practice, GCP -Good Clinical Practice, FDA -Food, Drugs and Administration, CDSCO - Central Drugs Standard Control Organization

## PREPARATION AND CHARACTERIZATION OF CHITOSAN FILM FOR WOUND DRESSING APPLICATIONS

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**ABSTRACT:** A novel chitosan film with viscose nonwoven layer was prepared by casting technique for wound dressing applications. This bilayer dressing consists of a thin film layer as wound contact layer and nonwoven layer as outer layer. Since antibiotic resistance to microorganism is one of the major problems faced in the field of wound care and management, chitosan, a natural polysaccharide, which has main advantages of antibacterial, non-toxic, biodegradable, haemostatic and biocompatible property is used for wound contact layer. Chitosan films were prepared using 1.5% w/v chitosan and three different ratios, 1%, 2%, 3.5% w/v of Acetic acid as cross linking agent. Physical characterization showed that the chitosan film with 2% acetic acid has high water absorbency percentage, water vapour permeability, exhibit microbial resistance with good mechanical strength and elasticity. The significance of the samples were analysed statistically using ANOVA.

**Key words:** Chitosan, Wound dressing, water uptake, water vapor penetration, film elasticity, strength, microbial penetration.

## DESIGN, SYNTHESIS AND MOLECULAR DOCKING STUDIES OF SOME NOVEL MANNICH BASES AS ANTIBACTERIAL AGENTS

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**ABSTRACT:** A series of novel Mannich bases from L-hydroxy proline were synthesized. The synthesized compounds were confirmed by IR, <sup>1</sup>H NMR and Mass spectra. To investigate the antimicrobial data on structural basis, insilico docking studies have been done using Glide software. Out of 5 derivatives, dibutylamine substituted Mannich base (HP-3) is found to be the most potent (glide score = -7.97) in comparison with the cerulenin (which is used currently as the human fatty acid synthase inhibitor). In order to ascertain the pharmaceutical application, antibacterial screening of synthesized compounds were carried out. All compounds showed good antimicrobial activity against the organisms tested. One of the compound 1-((diethylbutylamino) methyl)-3- hydroxypyrrolidine-2-carboxylic acid is found to have significant antibacterial activity than the standard.

**Keywords:** Mannich bases, L-hydroxy proline, antibacterial activity.

## PROSPECTIVE RANDOMISED STUDY OF HOMOCYSTEINE LOWERING VITAMINS IN SEVERE CARDIOVASCULAR DISEASES

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**ABSTRACT:** Elevated plasma total homocysteine (tHCY) has been identified as an independent risk factor for vascular disease. Our study aim is to analyse the risk of total homocysteine levels for cardiovascular disease (CVD); to estimate the potential reduction of cardiovascular disorders mortality by increasing homocysteine lowering vitamins intake. In order to assess the efficacy on lowering plasma total homocysteine levels (fasting), 9 CVD patients were randomly assigned and provided with folic acid (5mg), methylcobalamine (500mg), pyridoxine (10 mg). All the patients were treated for 3 weeks and fasting tHCY were measured before and after treatment. 3 Healthy volunteers served as normal control group for the study. In our randomised study, after administration of folic acid alone in group I results in a mean reduction of tHCY level 3.8 $\mu$ mol/L and folic acid and methylcobalamine in group II produced mean reduction of tHCY level 6.8 $\mu$ mol/L. While group III, by coadministration of folic acid, methylcobalamine and pyridoxine results in a significant mean reduction of 7.1 $\mu$ mol/L implies the significance of folic acid, methylcobalamine and pyridoxine as homocysteine lowering vitamins. Lowering serum concentration of homocysteine has been proven to reduce the risk of adverse cardiovascular events among people. Our study supports the co-administration of folic acid, methylcobalamine and pyridoxine as homocysteine lowering vitamins in cardiovascular disease. This method could be a therapeutic strategy to combat the risk of cardiovascular diseases.

**Keywords:** Homocysteine, Hyper homocysteinemia, Cardio vascular Disease

## FORMULATION AND PHYSICO-CHEMICAL EVALUATION OF FEXOFENADINE HYDROCHLORIDE TRANSDERMAL PATCHES

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**ABSTRACT:** Fexofenadine hydrochloride is a only anti-histaminic drug available in non-sedative category of drug. In this study drug dispersion with different polymers like hydroxyl propyl methyl cellulose (HPMC), polyvinyl pyrrolidone (PVP), ethyl cellulose(EC), either in individual or combination were used, with or with out rate controlling membrane of 1%W/V of ethyl cellulose to formulate matrix type of transdermal patches. All the patches were prepared by added 30%W/V of di butyl phthalate (DBP) as plasticizer to make the film flexible and free from brittleness and the solvent used for dispersion was ethanol as common solvent. The prepared patches were evaluated for various physico-chemical parameters like thickness, weight variation, folding endurance, water absorption capacity, percentage moisture loss, percentage moisture absorption, weight variation, tensile strength & percentage elongation and drug content uniformity.

**Key words:** transdermal therapeutic system (TTS), fexofenadine hydrochloride (CTZ), hydroxy propyl methyl cellulose (HPMC).

## EVALUATION OF ANTIDIABETIC ACTIVITY OF ETHANOLIC EXTRACT OF BISCHOFIA JAVANICA BLUME BARK BY STREPTOZOTOCIN INDUCED DIABETIC MODEL.

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**Abstract:** Diabetes mellitus(DM) is a group of metabolic disorders characterized by hyperglycemia; associated with abnormalities in carbohydrate, fat and protein metabolism; and resulting in chronic complications which include neuropathy, nephropathy etc. It is a major problem of both developed as well as developing countries. The World Health Organization states that diabetes mellitus is going to grow by 40% in developed countries. However, it will increase by 170% in developing countries. There are 170 million diabetic people in the world today as per estimates. The plants provide a potential source of hypoglycemic drugs because many plants and plant derived compounds have been used in the treatment of diabetes. Many Indian plants have been investigated for their beneficial use in different types of diabetes and reports occur in numerous scientific journals. Our aim was to investigate the antidiabetic activity of ethanolic extract of the bark of *Bischofia javanica* Blume in streptozotocin induced diabetic rats. Effect of various doses (100, 200 and 400 mg/ml) of extract by oral route showed the potent antihyperglycemic activity in streptozotocin induced diabetic rats. The significant antidiabetic effect of ethanolic extract at 400mg/kg was seen as compared to diabetic control and glibenclamide(0.6mg/kg). Our results indicate that ethanolic extract of the bark of *Bischofia javanica* Blume have prominent antidiabetic effect in streptozotocin induced diabetic rats.

**Keywords :** Antidiabetic, *Bischofia javanica* Blume, Streptozotocin, glucose, glycogen.

## ANTI-HYPERGLYCEMIC EFFECT OF PAVETTA INDICA, L. AGAINST ALLOXAN - INDUCED DIABETES IN RATS.

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**Abstract :** The Present study was aimed at investigating the anti-hyperglycemic effect of methanolic extract of Pavetta indica, L, (Rubiaceae) leaves (MEPI) in normal as well as alloxan induced diabetic rats and to evaluate its effect on key metabolic enzymes involved in carbohydrate metabolism. MEPI showed significant reduction of blood glucose level both in normal and diabetic ( $P < 0.001$ ) control. There was a significant increase in body weight ( $P < 0.01$ ), glycogen content ( $P < 0.001$ ), and enzymes involved in carbohydrate metabolism namely hexokinase, glucose -6- phosphatase and glucokinase ( $P < 0.001$ ). The activity produced by MEPI was almost comparable to the Glipizide treated group. The study confirmed the anti-diabetic and hypoglycemic activity of leaves of Pavetta indica.

**Key words:** Pavetta indica, alloxan, glipizide, glycogen, diabetes mellitus.