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Polyherbal Antibacterial Vaginal Spray - Formulation and Evaluation

Vedangi P Wadafale[1], Vaishnavi V Kale[1], Ram D Bawankar[1*], D R Mundhada[1]

Abstract: An attempt has been made to formulate and evaluate polyherbal antibacterial vaginal spray with respect to its organoleptic characteristics. Antibacterial vaginal spray was prepared using herbal extracts of Liquorice, Ashwagandha (Root powder), Ocimum sanctum (Tulsi), Neem leaves, *Syzygium cumini* root powder (Jamun tree), Tamhan bhasma (calcined borax), Turmeric, Menthol, Leaflets (Symplocos bark powder), Triphala and Aloevera gel in six different formulations (F1- F6) and were evaluated for organoleptic properties like colour, odour, homogeneity, density, viscosity, pH, quantity delivery in single spray and found within standards. Antimicrobial study of polyherbal formulations was performed by cup plate method for zone of inhibition and two folds dilution method for MIC (Minimum Inhibitory Concentration) and showed excellent antibacterial activity against *E. coli* by F6 formulations as compare to F1-F5. Optimized F6 formulation was subjected for stability studies at different temperature like 25°C, 37°C and 45°C for 2 weeks, showed no change in color as well as phase separation.

INTRODUCTION

Plants are the oldest source of pharmacologically active compounds and have provided human kind with many medicinally useful compounds from centuries. Today, more than two thirds of the world's population relay on plant derived drugs. The origin of many effective drugs is found in the traditional medicinal practices and in view of this, it is very important to undertake studies pertaining to screening of the medicinal plants for their pre claimed biological activity. Numerous studies have been conducted with the extracts of various plants, screening antibacterial activity. [1-3]

Herbal extracts are primarily intimate female hygiene preparations due to several associated properties such as antioxidant, antibacterial and anti-inflammatory properties. [4]

Literature review elucidate herbs contains various medicinal properties and formulated as herbal hand sanitizer from Indian herbs, [5] novel herbal ointment for the treatment of fungal infection, [6] herbal antibacterial face packs, [7] antibacterial efficacy of water-based herbal hand sanitizer gel, [8] poly herbal lotion containing *Trigonella foenum-graecum*, *Citrus lemon*, *Matricaria chamomilla* and *Cymbopogon citratus*, [9] evaluation of gels and creams preparation for *in-vitro* antibacterial activity, [10] assessment of chemo preventive, radioprotective and antineoplastic properties, [11] antimicrobial efficacy and safety of herbal sanitizer, [12] anti-bacterial and anti-fungal activity of a herbal ointment containing *Aloe-vera*, *Azadirachta indica* and *Curcuma- longa*. [13]

Female suffer from vaginal infection on daily basis and most of the problems arise by using public and unhygienic toilets. Sometimes because of hygiene reasons, some females do not use toilets or urinals. To eliminate the risk of urinary tract infections or any other infection which may rise to many other diseases, there is a need of an antibacterial formulation which may use on daily basis after urination to maintain female hygiene and eliminate vaginal infection. Natural remedies are more acceptable in the belief as they are safer with fewer side effects than the synthetic ones. [14] Herbal formulations have emergent demand in the global market. By considering importance of this, an attempt has been made to develop herbal spray.

MATERIALS AND METHODS

The study was conducted between 02 January 2022 to 20 April 2022 and carried out in Pharmaceutical Microbiology Laboratory of Agnihotri College of Pharmacy, Wardha. *Ocimum Sanctum* (Tulsi), *Syzygium cumini* root power (Jamun tree), Tamhan bhasma (calcined borax), Leaflets (Symplocos bark powder) was collected from Dhanvantar Ayurveda Hospital, Chandrapur whereas Ashwagandha, Liquorice, Neem leaves, Menthol, Glycerin, Rose water, Triphala, Propylene glycol, Turmeric, Aloevera gel were collected from Agnihotri College of Pharmacy, Wardha. Ingredients used for the preparation of polyherbal antibacterial vaginal spray, stock solution and various polyherbal formulations are shown in Figure 1 and Figure 2 respectively and enlisted in Table 1.

Preparation of Extract

Antibacterial polyherbal formulations (F1 – F6) were prepared separately by measured quantity of ingredients as shown in Table 2 and was extracted by Soxhlet extraction, filtered by using whatman filter paper and filled in an empty transparent refillable spray bottle.

Evaluation of Polyherbal Antibacterial Vaginal Spray

1. Determination of pH

pH of the prepared formulations was measured using digital pH meter.

2. Determination of Organoleptic Parameters

The colour, odour and homogeneity of prepared formulations were visually determined.

3. Determination of Viscosity

Viscosity of prepared formulations was evaluated by using Ostwald viscometer.

4. Determination of Spray Volume

Quantity of spray volume was measured by spraying number of sprays in measuring cylinder and calculated volume milliliter.

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(RESEARCH ARTICLE)

Development and validation of simultaneous estimation of drugs in combination from pharmaceutical formulation by RP-HPLC method

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Abstract

Metformin is recommended as a first-line agent for monotherapy and combination therapy for patients with type 2 diabetes mellitus (T2DM). Patients whose glycaemic control deteriorates over time with metformin monotherapy will require additional anti-diabetic medication. The development of HPLC method for simultaneous estimation of anti-diabetic drugs in combination from solid dosage form by HPLC method. To validate the developed HPLC method as per ICH guidelines. The System suitability test (Capacity factor, Tailing factor, Resolution, Selectivity, Separation factor, Theoretical plates, Regression coefficient, STD for intercept, LOD (limit of detection), LOQ (limit of quantification, Repeatability, Precision studies (Intra-day and Interday/Intermediate), Linearity/Calibration studies, Robustness, Force degradation/Stability indicating studies, Specificity, Drug recovery/accuracy studies are performed. The system suitability test performed for canagliflozin and metformin hydrochloride has achieved all guideline criteria; including tailing factor (T), separation factors (α), theoretical plates (N), capacity factor (k'), resolution (R) and RSD (%). force degradation studies were also performed for both these drugs. So conclusively we concluded that the proposed reverse phase chromatographic (RP-HPLC) analytical method for the simultaneous estimation in both bulk and tablet formulation have complied the ICH and US-FDA guidelines.

Keywords: Sanagliptin hydrochloride; Metformin; RP-HPLC; Diabetes mellitus

1. Introduction

According to statements by the American Diabetes Association/European Association for the Study of Diabetes and the American Association of Clinical Endocrinologists/American College of Endocrinology, metformin is recommended (unless specifically contraindicated) as a first-line agent for monotherapy and combination therapy for patients with type 2 diabetes mellitus (T2DM). This recommendation is based primarily on metformin's glucose lowering effects, absence of weight gain, generally low level of side effects, and relatively low cost [1,2]. However, many patients, particularly those with higher baseline glycated haemoglobin (HbA1c) values, may not achieve their glycaemic goals on metformin monotherapy despite titration to maximally tolerated doses, and therefore require additional medication [3, 4]. Patients whose glycaemic control deteriorates over time with metformin monotherapy will require additional anti-diabetic medication. Although multiple classes of anti-diabetic agents are available, there remains a need for agents with different mechanisms of action that offer improved efficacy and/or better tolerability profiles and can be used

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A REVIEW ARTICLE

METHOD DEVELOPEMNT AND VALIDATION ON HPLC METHOD

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ABSTRACT:

Chromatography, although primarily a separation technique, is mostly employed in chemical analysis, in which High-Performance Liquid Chromatography (HPLC) is an extremely versatile technique. Now a day reversed-phase chromatography is the most commonly used separation technique in HPLC. HPLC is an analytical tool which is able to detect, separate and quantify the drug, its various impurities and drug related degradants that can form on synthesis or storage. A number of chromatographic parameters were evaluated in order to optimize the method. An appropriate mobile phase, column, column temperature, wavelength and gradient must be found that affords suitable compatibility and stability of drug as well as degradants and impurities. The objective of this article is to review the method development, optimization and validation. Validation of HPLC method as per ICH Guidelines covers all the performance characteristics of validation, like accuracy, precision, specificity, linearity, range and limit of detection, robustness and system suitability testing etc. All the validation parameters are used in the routine and stability analysis. These articles discuss strategies and the issues pertinent to designing HPLC method development and validation.

Keyword : HPLC, Method Development ,Validation.

INTRODUCTION

Analytical chemistry is used to determining the qualitative and quantitative composition of material under study. Both these aspects are necessary to understand the sample material. Analytical chemistry is divided into two branches quantitative and qualitative. A qualitative analysis gives us the information about the nature of sample by knowing about the presence or absence of certain components. A quantitative analysis provides numerical information as

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AN OVERVIEW: NATURAL HERBS AS AN ATHERO-THROMBOLYTICS

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ABSTRACT

Atherosclerosis is the preliminary lipid disorder in which arterial blood vessels become hard and thicken due to multiple plaque formation within blood vessels. These soft multiple plaques suddenly ruptures out, leading to the formation of thrombus that rapidly slow down or stop the blood flow and obstruct the oxygen supply to the targeted tissues. These free floating thrombi can be circulated anywhere in the cardiovascular system including lung, brain, heart or deep veins of leg and leads to serious complications as atherothrombotic diseases (myocardial or cerebral infarctions), coronary artery diseases (CAD), peripheral vascular diseases, pulmonary thromboses, cerebro-vascular disease and heart failure. Pulmonary thrombosis is a inevitable condition commonly appear in Covid-19pneumonia patients due to fully or partially block blood supply to artery of lung and is characterized by inexplicable breathing difficulties, hemoptysis and chest pain. Similarly cardiac arrhythmias is on rise worldwide and is leading cause of morbidity, mortality and disabilities, is associated with shortness of breath, syncope, angina or fatally even death. A Cardio vascular disease (CVD) is the highly implacable disease and often impacting most productive and precious years of individuals throughout the world and hence requires very accurate diagnosis and treatment. Commonly used conventional antithrombotic drugs such as t-PA, Urokinase, Streptokinase, Aspirin, Anisteplase and so forth, play dazzling role in CVD management and other related disorders. However, available thrombolytics still have noticeable shortcomings including bleeding, lysis of hemolytic plug, antigenicity, defective coagulation, gastrointestinal and cerebral hemorrhage. In view of the inadequacies of conventional thrombolytics, efforts have made to understand significant value of herbal drugs for treating coronary arterial disease and related problems. As diabetes mellitus, hypertension, smoking cigarettes, dislipidemia, dyspnea and pneumonia are the prime causes of increasing severity of atherosclerosis and Covid-19 diseases, includes aggregation of platelets which eventually results in thrombus formation and hypoxia. Moreover, covid- 19 death rate is more common among people with such diseases and disorders. Hence food and dietary herbals with antithrombotic characteristics may be used to improve such diseases which ultimately maintain the health and signals healthy state of mind. The present review is focused on the availability of medicinal plants that have antithrombotic, anti- platelets and fibrinolytic potential, which can be explored for the effective treatment of thrombotic diseases, lifestyle disorders and future pandemics like Covid-19.

KEYWORDS: Atherosclerosis, Blood thrombus, Natural herbs.

1. INTRODUCTION

Nature has conceived a system, the body uses to maintain and restore itself, when the vascular system is injured, body responds very quickly to cease the bleeding and repair the damage. Platelets and certain proteins in plasma work together to stop the bleeding by initiating a clot formation over the injury.[1] The process of coagulation occurs through the cascade of several sequential reactions that forms enzyme thrombin, which in turn transform soluble fibrinogen into insoluble fibrin.[2] Thrombin activate platelets in order to enhance platelet aggregation thereby initiate the process of coagulation by converting the blood prothrombin to to thrombin to form a clot.[3] The activation of the coagulation cascade and platelets is usually made possible by atherosclerotic plaque rupture or cardio embolic thrombosis. In the cascade, free floating inactive coagulation factor zymogens converted into an activated factor by interaction with atherosclerotic plaque. Further activated platelets induce the interaction within activated factors to assist in the generation of thrombin by transformation of the soluble protein fibrinogen to insoluble fibrin thus forming a blood clot.[4] Likewise addition to the zymogens, protein cofactors and surface membrane of phospholipids and calcium ion take part in development of the fibrin clot.[5] Thrombus is established

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Development and Validation for Simultaneous Estimation of Drug in Combination from Pharmaceutical Formulation by RP-HPLC Method

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Abstract : In present work development and validation of new reverse phase high performance liquid chromatography method for estimation of Ivabradine (IVA) and Metoprolol Succinate (MET)from their combined tablet dosage form was carried out. The method was performed on Shimadzu SPD-10Avp, inbuilt with UV detector, Ultra5ll-MCX 5µ, 100 X 2.1mm ID Column and 15mM Ammonium Formate: MeOH (15:85 v/v) as mobile phase at ambient temperature. Detection was carried out at 223 nm and 230 nm. Concentration range 5-25 µg/ml for Ivabradine and 25-75 µg/ml for Metoprolol Succinate. The Percentage recovery of Ivabradine and Metoprolol succinate was found to be in the range of 98.06±1.70 % – 101.47±1.18 and 99.17±0.93 % – 101.2±1.00 % respectively. Correlation coefficient for Ivabradine and Metoprolol succinate was found 0.9995 and 0.9999 respectively. The Rt values for Ivabradine and Metoprolol succinate were found to be 1.78 min and 5.18 min respectively. The method was validated according to the guidelines of International Conference on Harmonization (ICH) and was successfully employed in the estimation of commercial formulations.

Keywords : Ivabradine, Metoprolol, Mobile Phase, Reverse-Phase High Performance Liquid Chromatography, Stability indicating method

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Mouth Dissolving Film of Antidiabetic Drug: Formulation & Optimization by 3^2 factorial design

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Abstract : The objective of the present study was to formulate and evaluate Mouth Dissolving film of Voglibose. Voglibose with t1/2 4 hrs and absolute oral bioavailability about 60-65%,are Alpha-glucosidase inhibitors that act as competitive inhibitors of enzymes needed to digest carbohydrates: specifically alpha-glucosidase enzymes in the brush border of the small intestines. The films were prepared using solvent casting method using HPMCe-15, PVA as polymer and Polyethylene glycol 400 as plasticizer. HPMCe-15 was selected as polymer on the basis of their film forming property and inertness, while Aspartame is used as a sweetening agent, Pineapple flavor is used as a flavouring agent and to analyse the usefulness of DOE in the development and optimization of a Mouth Dissolving film of a model drug employing 3^2 full factorial statistical design. The drug-polymer compatibility study was carried out to determine the interactions, if any between the drug and the polymers used in the study. The FTIR and DSC study revealed that, polymers and excipients used were compatible with drug. Evaluation of mouth dissolving film for physical appearance, surface texture, thickness measurement, weight uniformity, drug content, folding endurance, surface pH, *In vitro* disintegration time, % Moisture Content, % Moisture uptake, % Moisture uptake as well as *Ex-vivo* permeation studies. Formulation MDF3 disintegrated in 27.46±0.5 seconds. The formulation MDF3 showed maximum % drug release of 94.68±1.02% in 10 minutes and concluded that MDF3 was superior and effective in achieving patient compliance. Optimized MDF3 batch when subjected to stability at 40± 2°C temperature with relative humidity 75±5% for three months, indicating there was no degradation and change in film.

Keywords : Voglibose, Mouth dissolving Film, HPMCe15, PVA, PEG 400, FTIR, DSC, SEM, 3^2 Factorial Design.

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Research Article

Method Development, Validation and Stability Indicating Studies for Simultaneous Estimation of Anti-Hypertensive Drugs from Pharmaceutical Formulation by RP-HPLC

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ABSTRACT

Objective: Method development, validation & stability indicating studies for simultaneous estimation of Anti-Hypertensive drugs, Bendipine (BEN) and Metoprolol (MET) from pharmaceutical formulation by RP-HPLC.

Methods: For present work, reverse phase chromatography was selected as its suggested use for ionic and moderate to non-polar compounds. Reverse phase chromatography is simple, reliable, better regarding efficiency, stability, and reproducibility. C18 packed column, a 100 X 2.1mm, ID column of 5.0 µm particle packing, was selected for separation of BEN and MET. Different solvent systems were tried and optimized in combinations as mobile phase. BEN (4 µg/ml) and MET (50 µg/ml) in 20mM ammonium formate: Methanol (15:85 v/v) was developed as it was showing good peak shapes and a significant amount of resolution. The mobile phase was flowed at 1.2 ml/min with detection at BEN analytes at 236 nm and MET analytes at 225 nm respectively.

Result: Method development was done, Specificity, Linearity, accuracy, precision, robustness, limit of detection and limit of quantitation were used to accomplish validation. The method was found linear from 31.5 – 500 µg/ml[-1] for both BEN and MET individually. The percentage recovery of BEN when placed for period of 12 hours was found to 100% in 0.1N/N NaOH at 60°C and Thermal (50°C). 12 % degradation in 0.1N/M HCl at 60°C, Oxidation (3-6% H_2O_2) at room temperature whereas for MET was 100 % in 0.1N/N NaOH, 0.1N/M HCl at 60°C, at thermal (80°C) as well as oxidation for 3-6% H_2O_2 in room temperature.

Conclusion: Developed analytical method for the simultaneous estimation of Bendipine (BEN) and Metoprolol (MET) in both bulk and tablet formulation has obliged the ICH guidelines including tailing factor (T), separation factors (α), theoretical plates (N), capacity factor (k'), resolution (R) and RSD (%). The validated stress degradation studies under thermal, oxidative, alkali and acid constituted few degradation products for Bendipine whereas the Metoprolol was confronted with forced degradation studies.

Keywords: Bendipine, Metoprolol, Reverse Phase High Performance Liquid Chromatography, Stability indicating method.

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1. INTRODUCTION

New analytical technologies that are continuously being developed and also been used when it is appropriate to develop stability indicating method. The unknown impurity, which is observed during the analysis, pharmaceutical development, stress studies and formal stability studies of the drug substances and drug product, can be separated and analyzed by using various chromatographic techniques like reversed phase high performance liquid chromatography (RP-HPLC)[1-4].

Importantly, few publications reported the simultaneous analysis of both Bendipine and Metoprolol on C18 column[5]

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Formulation and Evaluation of Rapimelt Tablet of Anti-Vertigo Drug (Lorazepam)

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Abstract : A. Rapimelt tablet of Lorazepam was prepared by direct compression method using Indion 414, Cross Carmellose Sodium and sodium starch glycolate as superdisintegrants with aim to get rapid onset of action, improve bioavailability and to give pleasant taste and better mouth feel. The tablets prepared were evaluated for various parameters like various density parameters, thickness, hardness, friability, disintegration time, wetting time and in-vitro dissolution time and were found to be within limits as per Indian Pharmacopoeia. FT-IR spectra of physical mixture of Lorazepam with Indion 414showedretention of basic peaks of Lorazepam. The developed formulation of Lorazepam batch F5 (10% Indion 414) showed good palatability and dispersed within 30 seconds as compared to Croscarmellose Sodium batches F1-F3 and Sodium starch glycolate batches F6-F9.
Keywords : Rapimelt Drug Delivery System, Lorazepam, Anti-Vertigo, FTIR.

1. Introduction:

Oral routes of drug administration have wide acceptance up to 50-60% of total dosage forms. Solid dosage forms are popular because of ease of administration, accurate dosage, self-medication, pain avoidance and most importantly the patient compliance. One important drawback of this dosage forms for some patients, is the difficulty to swallow. Drinking water plays an important role in the swallowing of oral dosage forms. Often times people experience inconvenience in swallowing conventional dosage forms such as tablet when water is not available, in the case of the motion sickness (kinetosis) and sudden episodes of coughing during the common cold, allergic conditions and bronchitis. For these reasons, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Or dispersible tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people. Rapimelt tablets are also called as mouth-dissolving tablets, melt-in mouth tablets, Orodispersible tablets, rapimelts, porous tablets, quick dissolving etc. Rapimelt tablets are those when put on tongue disintegrate instantaneously releasing the drug which dissolve or disperses in the saliva. Faster the drug into solution, quicker will be absorption and onset of clinical effect[1-3].

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Cultivation, Extraction and Evaluation of Antibacterial Activity of *Carthamus tinctorius* (Safflower) oil against *E. coli*

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ABSTRACT:

Carthamus tinctorius (Safflower) is a profoundly expanded, herbaceous, thorn like yearly therapeutic plant which has been cultivated commercially for vegetable and medicinal applications. The Safflower seed was cultivated in Chandrapur region of Maharashtra in month of March to June. Seed has been procured for cultivation from Agriculture Department, Maharashtra. It was planted in the soil at distance of 2x3 ft. in lines. The seeds have been collected from plant after appropriate maturing in the long stretch of May. Then it was further proceeded for oil extraction. The oil was removed by oil extractor machine which works on principle of friction and continuous pressure. The safflower seed oil is viewed as a superior oil since it contains higher measure of oleic and linoleic acid than other oil seed crops. Safflower oil has various applications in food, beautifiers, medicinal and feed industry.

Antibacterial action of safflower oil has been performed against bacterial culture of *E. Coli*. The activity was observed by well diffusion method. By this method safflower oil shows zone of inhibition against bacterial culture of *E. coli*. Study shows that Safflower oil is work as a potential antibacterial agent against *E. coli*. Additionally, Safflower oil used to treat skin diseases, bone related issues, menopause and atherosclerosis.

Keywords: Antibacterial activity, Carthamus tinctorius, *E. coli*.

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Review on Ubrogepant for Episodic Migraine

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ABSTRACT:

The aim of this review was to judge the effectiveness and tolerability of ubrogepant in patients with episodic head ache.Migraine is that the primary headache disorder poignant a big population worldwide. Ubrogepant is associate oral, small-molecule thyrocalcitonin gene-related amide receptor antagonist for acute head ache treatment. Ubrogepant, overprescribed below the trade name Ubrelvy, could be a medication used for the acute (immediate) treatment of head ache with or while not aura (a sensory development or visual disturbance) in adults. it's not indicated for the preventive treatment of head ache.Migraine is associate often-disabling condition that affects associate calculable thirty seven million folks within the U.S.," same Billy Dunn, MD, acting director, workplace of neurobiology, Center for Drug analysis and analysis, FDA, in a very statement. "Ubrelvy represents a vital new possibility for the acute treatment of head ache in adults, because it is that the initial drug in its category approved for this indication."

Keywords: Migraine, Ubrogepant, Efficacy, Tolerability,Neuroscience.

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Pixantrone: A Review in Relapsed or Refractory Aggressive Non-Hodgkin's lymphoma

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Abstract:

Pixantrone is associate degree cytotoxic aza-anthracenedione with a completely unique mode of action than not absolutely approved within the EU to be used of monotherapy in adult patients with multiply relapsed aggressive B-cell Non-Hodgkin's lymphoma.It directly alkylates polymer forming stable polymer adducts and cross-strand breaks. The counseled dose of pixantrone is 50 mg/m2 administered on days 1, 8, and 15 of each 28-day cycle for up to 6 cycles. The foremost common facet effects with pixantrone were bone marrow suppression (particularly of the leukocyte lineage) nausea, vomiting, and infirmity.Treatment of patients with relapsed or refractory aggressive non-Hodgkin B-cell lymphoma remains associate unmet clinical want, and the progressive cardiac muscle toxicity associated with additive , dose-dependent injury evoked by anthracyclines represents a difficult issue within the designing of medical aid. Pixantrone may be a promising aza-anthracenedione with reduced cardiotoxicity and Vital antineoplastic activity, and has been investigated in solid and hematological tumors in several Phase I, II, and III trials. The aim of this review is to summarize the data reported so far on pixantrone as a salvage therapy in relapsed/refractory non-Hodgkin B-cell lymphomas.

Keywords: pixantrone, aggressive non-Hodgkin B-cell lymphoma, relapsed/refractory

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Formulation and Evaluation of Orodispersible Tablet for Anti-Asthamatic Drug

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Objective of the present work is to develop orodispersible tablets of Salbutamol to improve bioavailability, disintegration time, dissolution efficacy and patient compliance. Orodispersible tablets are the fast growing and highly accepted drug delivery system in now days mainly to improve patient compliance. Orodispersible tablets have number of advantages over conventional dosage forms, because of that Orodispersible tablets have emerged as an alternative to conventional dosage forms. Orodispersible tablets dissolve or disintegrates instantly on the patient tongue or buccal mucosa. Orodispersible tablets of salbutamol were prepared using superdisintegrants, Crospovidone,Mannitol (Pearlitol SD-200), as diluents by direct compression method. Nine formulations were prepared using the superDisintegrants at lower, intermediate & higher concentration. Mannitol is used to enhance the organoleptic properties of tablets. Tablets were evaluated for uniformity of weight, hardness, friability,

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ESTIMATION AND VALIDATION OF ANTIDIABETIC DRUG FROM SOLID DOSAGE FORM BY RP-HPLC METHOD Validation of Antidiabetic drug by RP-HPLC

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Abstract: Type 2 diabetes mellitus (T2DM) is characterized by abnormalities of glucose and lipid homeostasis, which exhibit the micro- and macrovascular. Remogliflozin etabonate is the ester prodrug of remogliflozin (20), which is selectively inhibits SGLT2. It causes a concentration dependent increase in urinary glucose excretion in mice and rats. In that article develop the method and validate it by estimation of antidiabetic drugs in solid dosage form by RP-HPLC, by using System suitability test, Repeatability, Precision studies (Intra-day and Interday/Intermediate), Linearity/Calibration studies, Robustness, Force degradation/Stability indicating studies, Specificity, Drug recovery/accuracy studies. From the results we conclude that, this developed and validated method for investigation by reverse phase high performance liquid chromatography (RP-HPLC) can be used for routine analysis of estimation of remogliflozin (REM) from marketed formulation.

Key Words: Type 2 diabetes mellitus, Remogliflozin etabonate, RP-HPLC, Glucose, Lipid homeostasis

I.INTRODUCTION

Clinical evidence indicates that maintaining glycaemic control and reducing postprandial glucose excursions can lower the risk of diabetic complications, e.g. reduce the risk of myocardial infarction, renal disease and retinopathy(1,2).the clinical management of T2DM remains challenging, with the majority of patients failing to achieve and maintain target glycaemic levels in practice (3).Under normal physiological condition when the glomerular filtrate reaches the proximal tubule, glucose is primarily reabsorbed through the active sodium dependent glucose transporter 2 (SGLT2) located on the apical or luminal membrane of the epithelial cell in the S1 segment(4-6). SGLT1 is a high-affinity, low-capacity glucose/galactose co-transporter primarily expressed in the intestine and in the kidney (7,8). Together, SGLT1 and SGLT2 are responsible for the active reabsorption of glucose across the renal luminal membrane (9,10). In humans, genetic aberrations in SGLT2 increase renal glucose excretion (up to 200 g/day) with no apparent adverse effects on renal function or carbohydrate metabolism (11).

Remogliflozin etabonate is the ester prodrug of remogliflozin (12), which is the active entity that selectively inhibits SGLT2. Remogliflozin etabonate causes a concentration dependent increase in urinary glucose excretion in mice and rats (12, 13). Unlike earlier SGLT inhibitors, such as phlorizin and T-1095, remogliflozin displays a high level of selectivity for SGLT2 over SGLT1 (14, 15).

The most commonly used aqueous phase is H3PO4 in water i.e. phosphate buffer. The pH of a phosphate buffer is easily adjusted by using mono-, di-, or tribasic phosphate salts. However, when phosphate salts are used the solution should be filtered to remove insoluble particles with 0.22μm filter paper. Other non-UV active acids and bases may also be used to effect differences in peak shape and retention (16).

High Performance Liquid Chromatography (HPLC) is more versatile than gas chromatography (GC) since, it is not limited to volatile and thermally stable samples, and the choice of mobile and stationary phases is wider (17,18).

Choice of buffer is typically governed by the desired pH. The typical pH range for reversed phase on silica-based packing is pH 2 to 8. It is important that the buffer has a pKa close to the desired pH since buffer controls pH best at this pKa. A rule is to choose a buffer with a pKa value (19 - 23).

The mobile phase effects resolution, selectivity and efficiency. In reverse phase chromatography, the mobile phase consists of an aqueous buffer and a non-UV active water miscible organic solvent. The effect of the organic and aqueous phase and the proportions in which they are mixed will affect the analysis of the drug molecule. Selection of the mobile phase and gradient conditions is dependent on the ionogenic nature of the analyte and the hydrophobicity of the analytes in the mixture respectively. The aqueous buffer serves several purposes. At low pH, the mobile phase promotes free silanols on the column and reduces peak tailing. At sufficiently low pH basic analytes are protonated, often ionized the analyte will elute more quickly but with improved peak shape. Acidic analytes in buffers of sufficiently low pH will remain un-charged, increasing retention (24).

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A REVIEW: PHARMACEUTICAL PACKAGING MATERIAL

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ABSTRACT

Pharmaceutical packaging is an art of designing and protecting dosage form by transforming into an attractive marketable product. Packaging must be in such a manner that it will provide speedy packaging, protection, identification of product quality, information against the physical damage, loss of content or ingredients. Due to the advancement of pharmaceutical analysis, it has been observed that most serious issues like stability of product, safety, sell, market complaint, product quality all occur due to packaging material. Packaging is a key of sale, safety and quality. Stability of drug products are mostly dependent on the ability of the packaging materials. The main purpose of review is to provide essential information of pharmaceutical packaging material, various advancement in packaging technique, type of packaging in pharmaceutical industry.

KEYWORDS: Packaging, Materials, Tamper Resistant Packaging.

INTRODUCTION

Packaging is used to protect the product against the deterioration effect caused by exposure to and usage in an external environment. Packaging preserves the stability and quality of pharmaceutical products and protects them against all forms of spoilage and tampering. Packaging may be defined as the collection of different components which surround the pharmaceutical products from the time of production until its use.

The quality of the packaging of pharmaceutical products provides an important role in the quality of products. It must.[1]

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EFFECT OF COVID-19 ON CHILDREN

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ABSTRACT

SAR-COV-2 RNA virus that arises in December 2019 in the city of Wuhan, Hubei Province in China. COVID-19 pandemic is a major catastrophe affecting the whole world. It affects children as well as all age groups. SAR-COV-2 which is transmitted by droplets and by the way of contact with surface contaminated by these droplets, is generally transmitted to children by close family contact. Similar to adults, primary symptoms include fever, cough, sore throat, malaise, nasal discharge and sometimes vomiting and diarrhoea in children. Asymptomatic paediatric patients are of great significance in terms of transmission of the infection to others and who carry high risk of spreading this infection. Prevention of infection is extremely important to reducing new cases. However, it is also important to understand that life-threatening negative physical health situations are going to be faced by few but almost everyone is facing negative mental health consequences of the pandemic.

KEYWORDS: COVID-19, SAR-COV-2, Children, HCWs.

INTRODUCTION

In December 2019, there was a cluster of pneumonia cases in the city of Wuhan, Hubei province in China.[1] Some of the early cases are reported visited or working in seafood live animal marketing in Wuhan. Further investigation found the disease was caused by newly discovered coronavirus by Chinese authorities on January 7, 2020.[2] Subsequently it got spread throughout China and to the rest of the world. On January30, 2020 WHO declared an outbreak of public health emergency of international concern. On February11, 2020 WHO named the disease associated with the 2019 novel coronavirus as the coronavirus disease

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Simultaneous estimation and validation of analgesic and antipyretic drugs in combination from solid dosage form by RP-HPLC

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ABSTRACT

To develop the RP-HPLC method for simultaneous estimation of analgesic and antipyretic drugs in combination from solid dosage form by RP-HPLC method.To validate the developed RP-HPLC method as per ICH guidelines. Tramadol hydrochloride is a centrally actinganalgesic. HPLC is a chromatographic technique that can separate a mixture of compounds and is used in biochemistry and analytical chemistry to identify, quantify and purify the individual components of the mixture. System suitabilitytest in that Capacityfactor, Tailingfactor, Resolution, Selectivity, Separationfactor, Theoreticalplate, Regression co efficient, STD deviationcase, LOQ, LOD, Repeatability, Precision studies, Linearity/Calibrationstudies, Robustness, Force degradation/Stability indicatingstudies, Specificity, Drug recovery/accuracy studies.The system suitability test parameters for acetaminophen and tramadol has achieved all guideline criteria, including, tailing factor (T), separation factor (α), theoretical plates (N), capacity factor(k'), resolution (R) and RSD (%) values as per the obligatory requirements of ICH and USP-PDA.The validated stress degradation studies under thermal, oxidative, alkali and acid ascertained no possible degradation products developed for tramadol but as observed acetaminophen was slightly degraded inalkali HCl (0.1NHCl) and peroxide (3%H2O2). This developed method by reverse phase liquid chromatography (HPLC) can be used for routine analysis of simultaneous estimation of acetaminophen and tramadol in its high precision, reproducibility, and accuracy for any marketed formulation containing either or both of acetaminophen andtramadol.

INTRODUCTION

Paracetamol or acetaminophen, chemically recognized as N-(4-hydroxyphenyl) acetamide, is most widely used drugs for the treatment of pain and fever.[1] The opiates is almost as effective in intenseepain and has no depressant effect on respiration. The major advantage of PR lies in its relative lack of serious side effects.[2] Tramadol is an effective and well-tolerated agent that reduces pain resulting from trauma, renal or biliary colic, and labor, and also for the management of chronic pain of malignantornon-malignantorigin. The analgesic efficacy of tramadol can further be improved by combination with a non-opioid analgesic.[3] various analytical procedures for the assay of PR in bulk powder and dosage forms including cerium sulphatetitrimetry, the assay of the bulk powder whereas HPLC is used for the capsules.[4] Several analytical procedures have been reported for the determination of the two components.[5] TR was determined in different matrices using a variety of analytical techniques including HPLC [6], gas chromatography with mass spectrometry (GCMS) [7], thin layer chromatography (TLC) densitometry [8], capillary electrophoresis [9], adsorptive stripping voltammetry[10], square-wave voltammetry and flow injection analysis system with amperometric detection[11], selective PVC membrane electrodes [12], spectro-fluorimetry

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VULNERABILITY OF CORONAVIRUS DISEASE (COVID-19) ON HUMAN FOETUS: A REVIEW

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Abstract
At Present Coronavirus Disease COVID – 19 is a pandemic and a serious health problem throughout the globe. The gravidical women are more susceptible than other human beings. As Pregnant women are more likely to catch any bacterial or viral infections because of the neurological changes a normal flu can also worsen the condition. The data on Covid-19 from China shows that COVID -19 infected pregnant women are not to develop complications and there is no transmission through the placenta to the baby, although they are more likely to catch infections. Even better, it does not pass to breast milk either. The analysis of thirty eight infected pregnant women and their neonates in China describe that the effect of SARS-CoV-2 on mother and infants including fetal, laboratory and virologic data, and the transmissibility of the virus from mother to fetus reveals that COVID-19 did not lead to maternal deaths, while coronavirus infections of pregnant women caused by SARS.

Keywords: COVID-19; SARS-CoV-2; Flu; Morbidity; Infection.

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INTRODUCTION

Among the living organisms which includes human and animal the corona viruses are the vulnerable pathogen. Now it is being termed as COVID-19 labeled by World Health Organization (WHO), as per the recent update the epidemic of COVID-19 began in China, presently the pathogen was spread to Wuhan and then spread across the globe. Around 234073 people around globe have been infected and 9840 people were died till March 17th 2020, since first case observed in China.

WHO declared the outbreak as a Public Health Emergency of International Concern on 30th Jan 2020, scale of international experts tried to manage the outbreak using specialized patients the symptoms like Pneumonia is caused by COVID-19 and is highly contagious and worldwide health emergency. Researcher revealed the way of transmission of disease is through the respiratory droplet by sneezing and coughing by infected human if in contact with other normal human. With the spread of COVID-19 globally the health of pregnant women and her fetus is such a important and grave concern for health care team and of society.

Death in pregnancy or pregnant women is due to the viral Pneumonia, further the symptoms of Pneumonia are quite differ if compared with non-pregnant women pertaining to this the symptoms of COVID-19 are similar to it which creates a difficulty in diagnosing and treating the patient. The intrauterine transmission of COVID-19, the maternal and neonatal death, complication in pregnancy, premature birth are the important issues to be dealt with.

So the present review aimed to review the published evidence in respect to health of pregnant women, dealing with the viral infection its diagnosis, rate of recovery and mother and therapy decline the mortality rate, other all the requirements in diagnosis and treatment by providing the research data to doctors and research physician.

COVID-19 in Pregnancy

Schwartz D. A. Graham A. L. reported the death in COVID -19 infected 232 children and 33 neonates most of them were suffer Data with disease and little number of patients with severe illness

To study of Fever of pregnancy symptoms, early and sampling, indicators of timeline and accurate and an breast feeding are recommended to manage the spread of infection, but these are not well established to impact the risk of transmission. It is for all viral infection and for COVID-19 as well. Centers for Disease Control and Prevention (CDC) also provide the guidelines for pregnant women those are infected with COVID-19, but are not sufficient or more data to be obtained with respect to their infection.

The recent data on SARS-CoV-2 reveals the vertical transmission is not common most of the case report published in regards that no transmission or harm to children of SARS-CoV infected mothers while the most adverse effects observed in Middle East women infected with COVID-19.

Zhu et al. reported the symptoms were observed at different time intervals in COVID-19 infected mothers, in four cases before delivery, in two patients at time of delivery and in three cases after delivery. This may be due to the different incubation time in respective women or they may infect at different time interval.

Clinical Cases

With the pandemic, earlier Zika, SARS and now SARS-CoV-2 outbreak we must prepare for the management of such deadly diseases. How considering the pregnant women having the chronic illness or some maternal complications are more susceptible to such deadly viruses? Therefore the immediate management has to be established to cope up.

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RESEARCH ARTICLE

Preclinical Evaluation of Antihypertensive Activity of Combination of Herbs Extract in Wistar Rats

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ABSTRACT:

Hypertension is the most common cardiovascular disease and is a major public health issue in developed as well as developing countries. In hypertension systolic blood pressure (SBP) rises above of 140 mmHg while diastolic blood pressure (DBP) is above of 90 mmHg. Hypertension is one of the leading cause of global burden of disease. It is one of the major cause of cardiovascular mortality, which is estimated to be 1.5 million deaths per year in India. The currently available antihypertensive drugs are not as efficient. Many ayurvedic herbs have shown antihypertensive activity. *Brassica oleracea* and *Apium graveolens* are two drugs that act on different pathophysiological mechanisms of hypertension. Hence the aim of this study was to evaluate the synergistic potential of the combination in hypertension. Antihypertensive activity of combination with doses (100, 200, 400 mg/kg) was carried out with two i.e. 2K1C model and fructose induced hypertension. Biochemical estimations of Triglycerides, LDL, HDL, and Creatinine were carried out along with cardiac parameters like SBP, DBP, And Mean Blood Pressure. The results indicated dose dependent antihypertensive action of combination of drug. The antihypertensive action of combinations was found to be significantly greater than that of individual drugs thereby justifying the synergistic effect of the two drugs.

KEYWORDS: Hypertension, *Brassica oleracea*, *Apium graveolens*, 2KC, DBP, SBP.

INTRODUCTION:

Hypertension is defined as a condition in which pressure in the blood vessels is higher than normal (1). Hypertension is the most common cardiovascular disease and is a major public health issue in developed as well as developing countries. In hypertension systolic blood pressure (SBP) rises above of 140 mmHg while diastolic blood pressure (DBP) is above of 90 mmHg. Hypertension is the largest attributable risk factor for mortality worldwide, and is responsible for more than half of all instances of stroke and coronary heart disease (CHD).

The problem is increasing, with predictions that one-third of adults worldwide will have hypertension by 2025. Despite public health programmes and effective pharmacotherapy for hypertension in developed economies, approximately 25% of adults have hypertension. It remains untreated in up to 50% of these individuals, and, disappointingly, BP is controlled to guideline driven targets in only 50% of those hypertensive patients advised to take treatment.

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Original Article

Withaferin A attenuates Alcohol Abstinence Signs in Rats

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ABSTRACT

Background: Withania somnifera (WS) have been reported to inhibit acquisition and expression conditioned place preference, self-administration and withdrawal anxiety of psychostimulants. In the present work, we have assessed the effect of Withaferin A on somatic and affective symptoms of ethanol withdrawal syndrome in rats. **Methods:** Animals had given free access to ethanol uninterrupted for 21 days through liquid diet. Withaferin A (5, 10 and 20 mg/kg) was injected (ip) either during the development of ethanol dependence phase (days 15 – 21 or 30 min before ethanol-withdrawal assessment. Withdrawal signs characterized by changes in somatic signs were measured in the open field followed by evaluation of anxiety parameters, locomotion, and depressive behavior. **Results:** Withaferin A treatment 30 min before 24 h post-ethanol withdrawal assessment did not alter the scores of somatic behavioral signs in ethanol abstinence animals. However, withaferin A (10 and 20 mg/kg, ip) from day 15-21 prevented the ethanol withdrawal-induced elevated scores of somatic behaviors, hyperlocomotion, depressive behavior, and anxiety. Withaferin A treatment did not influence the blood ethanol levels in dependent and withdrawn animals. However, withaferin A administration attenuated the elevated plasma corticosterone and ACTH levels in ethanol-withdrawn rats, suggesting withaferin A induced anti-stress effect and stabilization of HPA axis activity could have facilitated the inhibitory effect of withaferin A on ethanol withdrawal syndrome. **Conclusion:** The finding supports further investigation of Withaferin A and other bioactive components of WS in alcohol addiction.

Key words: Anxiety, Corticosterone, Ethanol withdrawal, HPA axis, Withaferin A.

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INTRODUCTION

Alcohol withdrawal syndrome is potentially life-threatening in addicted people and associated maladies constitute a serious health and social issue.[1] Abstinence from chronic ethanol consumption leads to the manifestation of a variety of somatic and affective symptoms attributed to central nervous system hyperexcitability, like irritability, anxiety, restlessness and dysphoria.[2] Despite the tremendous advances made in the treatment of alcoholism and/or its abstinence, remarkably, the majority of these agents, including naltrexone and benzodiazepines etc. have unpleasant side effect.[3-6]

Withaferin A is a steroidal lactone, an active compound isolated from *Withania somnifera* (WS) (Family- Solanaceae). WS, known as ashwagandha in Ayurveda or its active principles, including withaferin A has been used as an antioxidant, adaptogen, antistress,[7,8] anti-inflammatory, neuroprotective, anxiolytic, antidepressant, immunomodulatory, memory enhancer, anti-ulcer and anti-carcinogenic agents.[9-13] In addition, WS extract has been inhibited the morphine-induced acquisition and expression in conditioned place preference,[14] ethanol conditioned place preference[15] and self-administration,[16] ethanol withdrawal induced anxiety in rats.[17] In the present work, we have assessed the effect of withaferin A on somatic and affective symptoms of ethanol withdrawal syndrome in rats.

MATERIALS AND METHODS

Subjects

Adult healthy Sprague Dawley rats weighing 200-220 g (3-4 months old) were group housed (four per cage) under controlled temperature (23±2°C) and light (12 h light/dark cycle, light on at 07.00 am) environment with free access to food and water. Experimental protocols were approved by the Institutional Animal Ethical Committee and executed in strict accordance with the guidelines of Committee for the Purpose of Control and Supervision of Experiments on Animals, Govt. of India. The behavioral assessments were conducted during the light cycle.

Drugs

Withaferin A was purchased from Natural Remedies Private Limited, Bangalore, India and administered intraperitoneally (ip) as a solution (1 ml/kg) in dimethylsulphoxide (DMSO) prepared just before the experiments. Ethanol (99% w/v) (Merck, India)

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Sofosbuvir for chronic hepatitis C: A review

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Abstract

Hepatitis C virus (HCV) infection affects as many as 185 million people worldwide. Since the emergence of new direct-acting agents (DAAs), interferon-free therapy has become the cornerstone of treatment. Major changes have emerged during the last few years in the therapy of patients with chronic hepatitis C (CHC). Several direct acting antiviral agents have been developed showing high potent activity against hepatitis C virus and incrementally improving the rates of sustained virological response (SVR), even in difficult-to-treat CHC patients. Sofosbuvir, a new nucleotide analog, HCV NS5B polymerase inhibitor, represents the first key step towards the new era in the management of CHC, since it is the first approved DAA with excellent tolerability and favorable pharmacokinetic profile, limited potential for drug interactions, potent antiviral activity and high genetic barrier against all HCV genotypes. Sofosbuvir has recently become commercially available in combination with ribavirin, with or without pegylated interferon, achieving high SVR rates after 12-24 weeks of therapy. Finally, since interferon-free regimens are close to becoming the new standard of care in CHC patients, sofosbuvir has an ideal profile to be the cornerstone antiviral agent, especially in difficult-to-treat CHC patients, given in combination with other new DAAs. This review summarizes the main updated issues related to the efficacy and safety of sofosbuvir-containing regimens in CHC patients.

Keywords: sofosbuvir, hepatitis C, direct acting antiviral agents, efficacy, safety

Introduction

Hepatitis C virus is associated with a substantial disease burden in the western world. It is the leading cause of chronic hepatitis, cirrhosis, and liver cancer, and is a primary indication for liver transplantation [1]. As many as 185 million persons worldwide, including 3.4 to 4.4 million in the United States, are chronically infected with HCV; 3 to 4 million individuals are estimated to be newly infected each year [2, 3]. Acute infection develops within 2 to 26 weeks after HCV exposure [4, 5]. Some of these acutely infected patients may spontaneously clear HCV, but the majority will progress to chronic infection [6]. Approximately 25% of chronically infected persons will develop cirrhosis. Progression to cirrhosis was thought to occur gradually death [7]. Upwards of 350,000 people worldwide die from HCV-related complications each year non-structural proteins. The structural proteins include capsid protein C and the envelope glycoproteins E1 and E2. The non-structural proteins include p7, autoprotease and assembly factor NS2, serine protease and RNA helicase NS3, NS3 protease co-factor NS4A, the organizer of replication complex and membranous web NS4B, the regulator of replication and viral assembly NS5A, and RNA-dependent RNA polymerase NS5B. The resulting HCV polypeptide is cleaved by cellular proteases and viral NS2/3 and NS3/4A proteases to release the ten HCV proteins [8]. The replication complex is formed next. NS5A plays an important role in the formation of this replication complex [9, 10]. Two NS3-4A serine protease inhibitors, boceprevir and telaprevir, were the first generation DAAs approved for clinical use in genotype 1 CHC patients in mid 2011. With the triple combination of pegIFN, RBV and boceprevir or telaprevir, the probability of SVR increased by 20% in naïve patients, by 30-40% in relapsers and by 25% in null responders [11]. Monotherapy should be avoided in both female partners and female partners of male patients who receive any current sofosbuvir containing regimen and for at least 6 months following cessation of therapy [12]. No dose adjustment of sofosbuvir is recommended for patients with moderate and severe hepatic dysfunction [13].

Mechanism of action

Sofosbuvir is a newer antiviral drug which upon its conversion in the liver to its active form, gained to a nucleotide polymerase inhibitor. The activated drug (2'-deoxy-2'-α-fluoro-β-C-methyluridine-5'-triphosphate), serves a definitive substrate for the RNA polymerase. Once this analogue is bound to the RNA polymerase, further synthesis of viral RNAs are inhibited which in turn leads to the termination of viral replication [14, 15, 16].

Pharmacokinetic-pharmacodynamics of sofosbuvir

Sofosbuvir, originally termed as PSI-7977, is a nucleotide prodrug that undergoes intracellular metabolism to form the pharmacologically active uridine analog triphosphate (GS-461203), which can be incorporated into HCV RNA by the NS5B RNA-dependent RNA polymerase (RdRp) acting as a chain terminator. Studies in replicon cells containing different HCV genotypes showed that sofosbuvir is active against all HCV genotypes without any antagonistic effect in co-administration of interferon or RBV [14]. Sofosbuvir results in

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DIABETIC MELLITUS -A METABOLIC DISORDER AND ITS TREATMENT

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ABSTRACT

Diabetes mellitus (DM) is a metabolic disorder resulting from a defect in insulin secretion, insulin action, or both. Insulin deficiency in turn leads to chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism. It is the most common endocrine disorder and by the year 2010, it is estimated that more than 200 million people worldwide will have DM and 300 million will subsequently have the disease by 2025. As the disease progresses tissue or vascular damage ensures leading to severe diabetic complications such as retinopathy, neuropathy, nephropathy, cardiovascular complications and ulceration. Thus, diabetes covers a wide range of heterogeneous diseases. Diabetes mellitus may be categorized into several types but the two major types are type 1 and type 2.High blood glucose levels are symptomatic of diabetes mellitus as a consequence of inadequate pancreatic insulin secretion or poor insulin-directed mobilization of glucose by target cells. Diabetes mellitus is aggravated by and associated with metabolic complications that can subsequently lead to premature death. This review explores diabetes mellitus in terms of its historical perspective, biochemical basis, economic burden, management interventions along with the future perspectives. Oral hypoglycaemic agents include sulphonylureas, biguanides, alpha glucosidase inhibitors, meglitinide analogues, and thiazolidenediones. The main objective of these drugs is to correct the underlying metabolic disorder, such as insulin resistance and inadequate insulin secretion. They should be prescribed in combination with an appropriate diet and lifestyle changes. The main side effects are weight gain and hypoglycaemia with sulfonylureas, gastrointestinal (GI)

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Design and Development of Niosomal Delivery System for Ketoprofen

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Abstract:

Niosomes are efficient carriers for controlled drug delivery, to entrap hydrophilic drugs in the larger internal aqueous layer, whereas, lipophilic drugs in the outer lipid bilayers. Since, the niosomes are biodegradable and non toxic and hence, a good carrier for targeting of therapeutic agents at the site of interest with reduced systemic toxicity. The film formation method was used for the preparation of the niosomes due to simplicity, reproducibility and high drug entrapment efficiency. Six various types of Surfactant (Span 60) Cholesterol and Dicetyl phosphate (DCP) were used for the preparation of the niosomes. The molar ratio of 47.5:47.5:5 was found to be most suitable in terms of maximal *in vitro* drug entrapment efficiency and an *in vitro* drug release. The average size of niosomes was observed as 4.5 μ m with drug entrapment efficiency of 62.4%. The *in vitro* drug release study was carried out using dialysis membrane in Phosphate buffer saline (PBS, pH 7.4) for 24 hrs. The result showed a cumulative drug release of 68% in 4 hrs. from the free drug, against 92 % drug release in 24 hrs. With optimized niosomal formulation. The optimized niosomal formulation showed a sustained action of about 10 hrs was subjected to *in vivo* studies (anti-inflammatory activity). This formulation was found to be more effective in reducing edema after 2 hrs as compared to the free drug.

Key-words: - Niosomes, biodegradable, film formation method, drug entrapment efficiency, dialysis membrane

1) Introduction:-

Target oriented drug delivery systems are the areas of the major interest in the modern pharmaceutical research. The selective drug delivery to the target tissues increases the therapeutic efficacy of the drug and reduces its undesirable effect in non target tissues. The concept of drug targeting or site specific drug delivery was introduced first time by Paul Ehrlich in 1908, when he reported 'magic bullet' to deliver a drug to the desired site of action without affecting the non target organs or tissues (Jahnavi, 1980) by associating the drug with a pharmacologically "inactive carrier" capable of conveying the drug selectively towards its target cells. Niosomes are efficient carriers for controlled drug delivery, to entrap hydrophilic drugs in the larger internal aqueous layer, whereas, lipophilic drugs in the outer lipid bilayers. Since, the niosomes are biodegradable and non toxic and hence, a good carrier for targeting of therapeutic agents at the site of interest with reduced systemic toxicity. Ketoprofen, non-steroidal anti-inflammatory drug, is used for the treatment of rheumatoid arthritis, osteoarthritis, degenerative joint conditions and musculoskeletal disorders, involving long term therapy. Ketoprofen has various side effects like gastric, peptic ulcer and bleeding, along with short biological half life (0.5-2 hrs) which calls for frequent administration. Thus, a novel and controlled drug delivery system need to be developed in order to increase its therapeutic effects with reduced side effects. The result obtained in our findings reveals that vesicular niosomes may be very useful as a sustained release delivery system of ketoprofen as compared to the free drug.

2) Materials & Methods:-

It is given in table 1 & 2.

2.1) Method:-

2.1.1) Preparation of different batches of Niosomes:-

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Spectrophotometric and HPTLC Method for Simultaneous Estimation of Pantoprazole and Domperidone in Their Pharmaceutical Preparations

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A simple, rapid, spectrophotometric and HPTLC method has been developed for the simultaneous estimation of pantoprazole and domperidone in their pharmaceutical preparations. Developed spectrophotometric method employs simultaneous equation method to estimate both the drugs in the formulation. Pantoprazole and domperidone showed maximum absorbance at 331 and 284 nm, respectively. Pantoprazole and domperidone obeyed Beer-Lambert's law in the concentration ranges from 10-50 and 10-50 µg/mL, respectively. In HPTLC method, the mobile phase consists of acetone : ethanol : methanol : glacial acetic acid (2 : 8 : 2 : 0.1) using a precoated silica gel 60 F_{254} TLC plate. The plate was scanned by computer controlled HPTLC scanner with Camag Cats software and quantified at 298 nm. Both the methods were found to be precise and accurate and can be adopted in routine analysis of drugs in formulation.

Key Words: Pantoprazole, Domperidone, Spectrophotometry, HPTLC.

INTRODUCTION

Pantoprazole (PAN) is a proton pump inhibitor. It is an anti-ulcerative drug and used in the treatment of peptic ulcer and gastro-oesophageal reflux diseases. It causes irreversible inhibition of proton pump (H^+K^+ ATPase) function. It is rapidly activated under strongly acidic condition. It is official in Martindale Extra Pharmacopoeia. The other reported methods for estimation of pantoprazole were HPLC[1], RP-HPLC[2] for determination of enantiomer, capillary electrophoresis[3] and difference spectroscopy[4].

Domperidone (DOM) comes under the categories of prokinetics agent. It is peripheral dopamine antagonist. It is used as anti-emetic for the short-term treatment of nausea and vomiting of various etiologies including that associated with cancer therapy. It is official in British Pharmacopoeia[5]. Chemically it is 5-chloro-1-[1[3-(2,3-dihydro-2-oxo-1H-benzimidazole-1-yl)propyl]-4-piperidinyl]-1,3-dihydro-2H-benzimidazole-2-one. The other reported methods for estimation of domperidone alone as well as in combination with other drugs were

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Antineoplastic Agent: Chemotherapeutic Treatment to Fight against Cancer

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Abstract

A neoplasm or tumor is a abnormal mass of tissue, the growth of which exceeds and is uncoordinated with that of the normal tissue and continues in the same manner after cessation of the stimuli which have initiated it.
A malignant tumor grows rapidly and continuously, and even when it has impoverished its host and source of nutrition, still retains the potentiality for further proliferation. Besides, malignanat tumors invade and destroys neighbouring tissues and possess no effective capsule, a malignant tumors readily ulcerate and soon sooner or later disseminate and form metastases.
Key-Words:- neoplasm, stimuli, malignant tumor, metastases.

1) Introduction

1.1) About Cancer:

Neoplasm is derived from Greek word neos means new and plasma means formation. Cancer is a genetic disease that can occur in all types of body tissues. It is found in many forms, including solid tissue formation (tumors or neoplasm), leukaemia (*blood cancer*) and lymphomas (Cancer of lymphoid cells). Cancer is due to a reduction or loss of control of growth of cells. This leads to proliferation of cell growth. In its early stages the cells formed by this growth resemble the parent but as the cancer progresses they loss the appearance and function of the parent cell. Cancer cells are invasive. As the cancer grows the cell lose their adhesion and the malignant cell are carried in the blood the other part of body.

The neoplasm may be benign or malignant. Benign tumors do not metasticise, malignant tumors (cancer) do.

A neoplasm or tumor is a abnormal mass of tissue, the growth of which exceeds and is uncoordinated with that of the normal tissue and continues in the same manner after cessation of the stimuli which have initiated it.

A malignant tumor grows rapidly and continuously, and even when it has impoverished its host and source of nutrition, still retains the potentiality for further proliferation. Besides, malignanat tumors invade and destroys neighbouring tissues and possess no effective capsule, a malignant tumors readily ulcerate and soon sooner or later disseminate and form metastases.

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Niosome – A Novel Drug Delivery System

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Abstract

The concept of drug targeting'or site specific drug delivery was introduced first time by Paul Ehrich in 1909, when he reported 'magic bullet' to deliver a drug to the desired site of action without affecting the non target organs or tissues (Juliano, 1980) by associating the drug with a pharmacologically "inactive carrier" capable of conveying the drug selectively towards its target cells. The main goal of a site specific drug delivery system is not only to increase the selectivity and drug therapeutic index, but also to reduce the toxicity of the drug.

Key-Words: magic bullet, inactive carrier, target cells, drug therapeutic index, site specific drug delivery system, toxicity.

Introduction

Target oriented drug delivery systems are the areas of the major interest in the modern pharmaceutical research. The selective drug delivery to the target tissues increases the therapeutic efficacy of the drug and reduces its undesirable effect to non target tissues. The main goal of a site specific drug delivery system is not only to increase the selectivity and drug therapeutic index, but also to reduce the toxicity of the drug. (Widder *et al.*, 1982). Rheumatoid arthritis (RA) is a chronic, inflammatory condition of unknown etiology that affects about 1% of general population (Feldmann *et. al.*, 1996) and is the most common cause of chronic inflammatory synovitis (Watson-Clark *et al.*, 1998). Although spontaneous remission can occur, it often progresses to chronic state associated with significant

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A REVIEW ON STUDY OF SWINE FLU

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ABSTRACT

Swine flu, also called Hog or Pig Flu, is an infection caused by any one of the several types of Swine influenza virus (SIV) which is common throughout pig population world wide. The term "influenza" derived from Italian word" influenza" was coined in 1357 AD as the disease was thought to be caused by influence of stars. India has had over 1,000 confirmed cases of swine flu so far that's roughly one case per every million people in the nation. The first case of death had its epicenter in Pune. Schools and Colleges were closed and all were running to the nearby chemists to buy mask, where the price of mask had a maximum all over the nation. From the normal cost of Rs.5 or 10 it went to Rs.500 to 1000. H1N1 influenza or swine flu is a contagious disease that is caused by the influenza virus. Infection with the H1N1 influenza virus can result in severe illness and life-threatening complications. Symptoms of H1N1 flu are similar to those of the common flu and scientists are actively studying the situation to better understand its range of symptoms and how it is spread.

Key words: Swine flu, H1N1 influenza, life-threatening, common flu

INTRODUCTION

The classical swine flu virus an influenza type A (H1N1) virus was first isolated from a pig in 1930. Swine flu viruses cause high level of illness, but low death rates in pigs. Like all influenza viruses, swine flu viruses change constantly. Pigs can also be infected by avian influenza and human influenza viruses. When influenza viruses from different species infect pigs, the viruses can reassort (i.e. swap genes) and new viruses that are a mix of avian, human and/or swine influenza viruses can emerge.

Definition of Cases of Pandemic (H1N1) 2009 (Swine Flu)

Suspect Case:

A suspect case is defined as an individual with fever (temperature 100.4°F/ 38°C) and one or more of the following manifestations- cough, sore throat, or shortness of breath.

Probable Case:

A probable case is defined as an individual with an influenza test that is positive for influenza A, but is unsubtypable by reagents used to detect seasonal influenza virus infection or an individual who died of an unexplained acute respiratory illness.

Confirmed Case:

A confirmed case is defined as an individual who is confirmed in the laboratory with PCR or virus culture for pandemic influenza virus 2009.

Cluster:

A cluster of pandemic influenza 2009 is defined as two or more persons, probable or confirmed cases of pandemic influenza 2009 found at a time in a localized area, having evidence of transmission among them.

HISTORY OF SWINE FLU

Swine flu, also called Hog or Pig Flu, is an infection caused by any one of the several types of Swine influenza virus (SIV) which is common throughout pig population world wide. The term "influenza" derived from Italian word" influenza" was coined in 1357 AD as the disease was thought to be caused by influence of stars.

Influenza pandemics are believed to have occurred at unpredictable intervals for many centuries. Outbreaks of swine flu are common and cause significant economical losses.

Influenza, the flu, is believed to have been around for a few thousand years. Hippocrates, who is considered to be the father of modern medicine, has described the symptoms of the flu in 412 BC in Pretonia in North Greece.

1. In 855 the flu was mentioned a serious epidemic resembling flu that started in Central Asia and spread across Persia.
2. In 1580 an illness with flu like symptoms killed thousands of people in Britain, including the mayor.
3. In 216 a flu pandemic originated in Africa and spread across Europe.
4. In 1580 a pandemic originated in the North Africa during summer, spread to Italy, and then up through Italy, through Europe and to North America. It had a high mortality rate and killed 8000 people in Rome alone.
5. In 1688 an outbreak, described as being like the plague because of the death toll, swept through England, Ireland and Virginia.
6. In 1699 an influenza outbreak occurred in Europe and America and Massachusetts. The sickness extended to almost all families.
7. In 29 a pandemic originated in Russia, and re-emerged in Sweden in September and in Vienna in October. In November it spread across Europe, and reached America in 1733. Deaths were most numerous amongst the elderly and pregnant women.
8. In 1781-82 an influenza pandemic affected one-thirds of the people of Russ and three-quarters of the population of Britain.

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A review on study of microsphere.

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ABSTRACT:
A plastic compound used in some dermal fillers for the correction of wrinkles that are filled with a substance and released as the shell disintegrates.

Controlled release delivery Biodegradable microspheres are used to control drug release rates thereby decreasing toxic side effects, and eliminating the inconvenience of repeated injections.

Microparticulate carrier system can be administered through different routes such as i.v, ocular, i.m,subcutaneous arterial,etc. Each route has its own biological significance, limitation AND pharmaceutical feasibility.

KEYWORDS: dermal fillers, Biodegradable microspheres, Controlled release, biological significance

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INTRODUCTION OF MICROSPHERES[1,2]

There is growing interest in the development of homogeneous monolithic drug release systems for various routes of administration. One very attractive type of such dosage form is micro spheres.

- Flexibility in design and development.
- Attractive in appearance.
- Better, improve the safety and efficiency of bio-active agents.
- Desired release pattern can be engineered.

WHAT IS A MICROSPHERE?

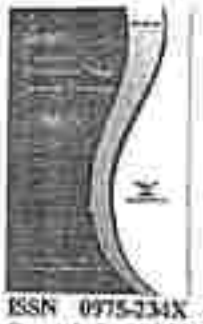
"Microspheres are defined as solid spherical particles containing dispersed drug in either solution or micro-crystalline form".
"A plastic compound used in some dermal fillers for the correction of wrinkles that are filled with a substance and released as the shell disintegrates"
"Small, hollow glass spheres used as fillers in epoxy and polyester compounds to reduce density"

ADVANTAGE OF MICROSPHERE

1 Controlled release delivery Biodegradable microspheres are used to control release rates thereby decreasing toxic side effects, and eliminating the inconvenience of repeated injections.
2 Biodegradable microspheres have the advantage over large polymer implants in that they do not require surgical procedures for implantation and removal.
3. PLGA copolymer is one of the synthetic biodegradable and biocompatible polymers that have reproducible and slow-release characteristics in vivo.

TYPE OF MICROSPHERES[3,4] :

Two types of micro sphere
(1) Microcapsule-where the entrapped substance is completely surrounded by distinct capsule wall.
(2) Micro matrices-where the entrapped substance is dispersed throughout the Polymer matrix.



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Review Article

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A Overview on Study of Floating Drug Delivery Systems

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ABSTRACT:

Gastro-retentive floating drug delivery systems have emerged as an efficient means of enhancing the bioavailability and controlled delivery of many drugs. The controlled gastric retention of solid dosage forms may be achieved by the mechanisms of mucoadhesion, flotation, sedimentation, expansion, modified shape systems, or by the simultaneous administration of pharmacological agents that delay gastric emptying. Based on the approaches, classification of floating drug delivery systems (FDDS) has been described in detail. In vivo/in vitro evaluation of FDDS has been discussed by scientists to assess the efficiency and optimum of such systems. Several recent examples have been reported showing the efficiency of such systems for drugs with bioavailability problems.

KEYWORDS: Gastro-retentive floating drug delivery, mucoadhesion, flotation, sedimentation, expansion, modified shape systems, gastric emptying.

INTRODUCTION:

Gastric emptying of dosage forms is an extremely variable process and ability to prolong and control the emptying time is a valuable asset to dosage forms, which reside in the stomach for a longer period of time than conventional dosage forms. Several difficulties are faced in designing controlled release systems for better absorption and enhanced bioavailability. One of such difficulties is the inability to confine the dosage form in the desired area of the gastrointestinal tract. Drug absorption from the gastrointestinal tract is a complex procedure and is subject to many variables. It is widely acknowledged that the extent of gastrointestinal tract drug absorption is related to contact time with the small intestinal mucosa. The small intestinal transit time is an important parameter for drugs that are incompletely absorbed. Basic human physiology with the details of gastric emptying, motility patterns, and physiological and formulation variables affecting the gastric emptying are summarized[1].

Gastroretentive systems can remain in the gastric region for several hours and hence significantly prolong the gastric residence time of drugs. Prolonged gastric retention improves bioavailability, reduces drug waste, and improves solubility for drugs that are less soluble in a high pH environment. It has applications also for local drug delivery to the stomach and proximal small intestines. Gastro retention helps to provide better availability of new products with new therapeutic possibilities and substantial benefits to patients[2-5].

The controlled gastric retention of solid dosage forms may be achieved by the mechanisms of mucoadhesion, flotation, sedimentation, expansion, modified shape systems, or by the simultaneous administration of pharmacological agents that delay gastric emptying.

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Niosome – The Magic Bullet

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Abstract

Target oriented drug delivery systems are the areas of the major interest in the modern pharmaceutical research. The selective drug delivery to the target tissues increases the therapeutic efficacy of the drug and reduces its undesirable effect to non target tissues.The concept of drug targeting or site specific drug delivery was introduced first time by Paul Ehrich in 1906, when he reported "magic bullet" to deliver a drug to the desired site of action without affecting the non target organs or tissues (Juliano, 1981) by associating the drug with a pharmacologically "inactive carrier" capable of conveying the drug selectively towards its target cells. Niosomes or nonionic surfactant vesicles are microscopic lamellar structures formed on admixture of nonionic surfactant of the alkyl or dialkyl polyglycerol ether class and cholesterol with subsequent hydration in aqueous media. In niosomes, the vesicles forming amphiphile is a nonionic surfactant such as span 60 which is usually stabilized by addition of cholesterol and small amount of anionic surfactant such as dicetyl phosphate. Niosomes can entrap both hydrophilic and lipophilic drugs, either in aqueous layer or in vesicular membrane made of lipid materials. It is reported to attain better stability than liposomes. It can prolong the circulation of the entrapped drugs. Because of the presence of nonionic surfactant with the lipid, there is better targeting of drugs to tumour, liver and brain. It may prove very useful for targeting the drug for treating cancers, parasitic, viral and other microbial disease more effectively.

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A study on wheat grass and its Nutritional value

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Abstract
Wheat Grass refers to the young grass of the common wheat plant, Triticum aestivum that is freshly juiced or dried into powder for animal and human consumption. Both provide chlorophyll, amino acids, minerals, vitamins, and enzymes. Wheat grass is a humble weed that is a powerhouse of nutrients and vitamins for the human body. In the form of fresh juice, it has high concentrations of chlorophyll, active enzymes, vitamins and other nutrients.
Key-Word: - Wheat Grass, human consumption, Triticum aestivum, enzymes, vitamins, nutrients.

1) Introduction

Wheatgrass juice will provide you with more energy by fulfilling nutritional deficiencies and by removing wastes that clog your cells, blood, tissues and organs.
Wheat Grass refers to the young grass of the common wheat plant, Triticum aestivum that is freshly juiced or dried into powder for animal and human consumption. Both provide chlorophyll, amino acids, minerals, vitamins, and enzymes. Wheat grass is a humble weed that is a powerhouse of nutrients and vitamins for the human body. In the form of fresh juice, it has high concentrations of chlorophyll, active enzymes, vitamins and other nutrients.
Although the wonder benefits of wheat grass are being discovered only now in India, they have been known in the West for years. Wheat grass juice has chlorophyll that neutralizes infections, heals wounds, overcomes inflammations and gets rid of parasitic infections the three most important effects of wheat grass on the human body are: blood purification, liver detoxification and colon cleansing. This is because wheat grass juice is the richest source of vitamins A, B, C, E and K, calcium, potassium, iron, magnesium, sodium, sulphur and 17 forms of amino acids.

1.1) Green Blood Therapy

Green Blood Therapy is the use of wheat grass juice which has also been called the green blood.
The wheat grass juice contains all the nutrients the body requires and is considered a complete food.

1.2 Green Blood Therapy: Cure for Many Diseases

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Ischaemic Heart Disease: An Overview to Heart Disease

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Abstract
Ischaemic Heart Disease is a condition that affects the supply of blood to the heart. The blood vessels are blocked due to the deposition of cholesterol plaques on their walls. This reduces the supply of oxygen and nutrients to the heart musculature, which is essential for proper functioning of the heart. This may eventually result in a portion of the heart being suddenly deprived of its blood supply leading to the death of that area of heart tissue, resulting in heart attack.

In 1963 the Ministry of Railways carried out a survey with a view to ascertaining the number of deaths due to ischemic heart disease among railway populations in different parts of the country. The method employed was to obtain data from all the railway zones on a proforma based on W.H.O. classification 420, for arteriosclerotic, including coronary heart disease.

The epidemiology studies have provided several key points of information related to the risk of developing IHD. First, several specific risk factors for IHD have been identified. Second, evidence that these factors are closely related to environmental and life-style changes implies that risk factors are potentially alterable. Third, these studies have stimulated further consideration and investigation of the basic mechanism of atherosclerosis. Angiographic studies have indicated a direct relationship between the risk factors and the severity of coronary disease.

Key-Words:- Ischaemic Heart Disease, oxygen, nutrient, W.H.O. epidemiology

Introduction

Ischaemic Heart Disease is a condition that affects the supply of blood to the heart. The blood vessels are blocked due to the deposition of cholesterol plaques on their walls. This reduces the supply of oxygen and nutrients to the heart musculature, which is essential for proper functioning of the heart. This may eventually result in a portion of the heart being suddenly deprived of its blood supply leading to the death of that area of heart tissue, resulting in heart attack.

As the heart is the pump that supplies oxygenated blood to the various vital organs, any defect in the heart immediately affects the supply of oxygen to the vital organs like the brain, kidneys etc. This leads to the death of tissue within these organs and their eventual failure or death. Ischaemic coronary artery disease is a condition in which fatty deposits accumulate in the cells lining the wall of the coronary arteries. These fatty deposits build up gradually and irregularly in the large branches of the two main coronary arteries which emerge from the heart and are the main source of its blood supply. This process is called atherosclerosis which leads to narrowing or hardening of the blood vessels supplying blood to the heart muscle. This results in ischemia (inability to provide adequate oxygen).

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Review Article

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Niosomes – An Overview

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ABSTRACT:
Non-ionic surfactant vesicles (or niosomes) are now widely studied as alternates to liposomes. An increasing number of non-ionic surfactants has been found to form vesicles, capable of entrapping hydrophilic and hydrophobic molecules. The drug disposition by niosomal drug delivery proved that the drug accumulated in visceral organ (lung, kidney, liver, spleen) was lower than free drug. Niosomes are uni or multilamellar vesicles formed from synthetic, non-ionic surfactant of alkyl or dialkyl poly glycerol ether class, offering an alternative to liposomes as drug carriers. Niosomes can entrap solutes in a manner analogous to liposomes, are relatively more stable in vitro and can improve the stability of entrapped drug as compared with stability in conventional dosage forms.

KEYWORDS: Non-ionic surfactant, liposomes, visceral organ, multilamellar vesicles, niosomes, entrapped drug

INTRODUCTION:

Niosomes are a novel drug delivery system in which the medication is encapsulated in a vesicle. The vesicle is composed of a bilayer of non-ionic surface active agents and hence the name niosomes. The niosomes are very small, and microscopic in size. Their size lies in the nanometric scale. Although structurally similar to liposomes, they offer several advantages over them. Niosomes have recently been shown to greatly increase transdermal drug delivery and also can be used in targeted drug delivery, and thus increased study in these structures can provide new methods for drug delivery. Niosomes are formed mainly by cholesterol incorporation as an excipient. Other excipients can also be used. Niosomes have more penetrating capability than the previous preparations of emulsions. They are structurally similar to liposomes in having a bilayer, however, the materials used to prepare niosomes make them more stable and thus niosomes offer many more advantages over liposomes.

1) Structure of niosome:

Niosomes are microscopic lamellar structures, which are formed on the admixture of non-ionic surfactant of the alkyl or dialkyl polyglycerol ether class and cholesterol with subsequent hydration in aqueous media.

Structurally, niosomes are similar to liposomes, in that they are also made up of a bilayer. However, the bilayer in the case of niosomes is made up of non-ionic surface active agents rather than phospholipids as seen in the case of liposomes. Most surface active agents when suspended in water yield micellar structures, however some surfactants can yield bilayer vesicles which are niosomes.

Niosomes may be unilamellar or multilamellar depending on the method used to prepare them. The niosome is made of a surfactant bilayer with its hydrophilic ends exposed on the outside and inside of the vesicle, while the hydrophobic chains face each other within the bilayer. Hence, the vesicle holds hydrophilic drugs within the space enclosed in the vesicle, while hydrophobic drugs are embedded within the bilayer itself. The figure 1 will give a better idea of what a niosome is made of and where the drug is located within a vesicle.

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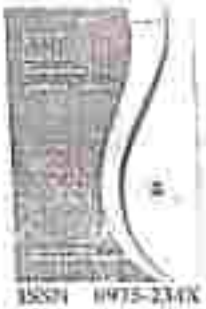

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Review Article

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Analytical Method Development and Validati of Pharmaceutical Technology: An Overview

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ABSTRACT:

Analytical method development followed by method validation is important process in the drug discovery. Although the drug shows potency, lack of validated analytical method will not allow the drug to enter the market. This is to ensure the quality and safety of the drug. The objective of this review is to give an idea about the old and novel techniques available for the analysis of drugs in their raw material and formulated form, to check the stability of the drugs in the presence of the excipients and at various conditions experienced during their shelf life period. Analytical methods development and validation play important roles in the discovery, development and Manufacture of pharmaceuticals. Method development is the process of proving that an analytical method is acceptable for its intended purpose. Method validation is the process used to confirm that the analytical procedure employed for a specific formulation is suitable and reliable for its intended use. Method validation is essential for analytical method development and is routinely required for specificity, linearity, accuracy, precision, range, detection limit, quantitation limit, and robustness. In summary, analytical method development and validation allows to confirm that an accurate and reproducible measurement of a pharmaceutical preparation can be performed.

KEYWORDS:

INTRODUCTION:

Quality control and quality assurance are the major areas in pharmaceutical industry dealing with the analysis of materials starting from the raw material, intermediate products, API's and finished products and thus new techniques are being developed all over the world. As a result classical methods have changed to instrumental methods and finally hyphenated techniques. Each technique is found to be superior to the previous methods.

The number of drugs introduced into the market is increasing every year. These drugs may be either new entities or partial structural modification of the existing one. Very often there is a time lag from the date of introduction of a drug into the market to the date of its inclusion in pharmacopoeias. This happens because of the possible uncertainties in the continuous use and misuse of these drugs, system of new preventive measures in their withdrawal from the market, development of patient resistance and introduction of better drugs by competitors. Under these conditions, standards and analytical procedures for these drugs may not be available in the pharmacopoeias. It becomes necessary, therefore, to develop newer analytical methods for these drugs.[1-3]

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INHIBITION OF RENAL CALCULI FORMATION BY *CITRUS DECUMANA* FRUIT EXTRACT ON ETHYLENE GLYCOL AND AMMONIUM CHLORIDE INDUCED UROLITHIASIS RAT MODEL.

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ABSTRACT

OBJECTIVE: To investigate the Antiurolithic activity of *Citrus decumana* Fruit Extract on Ethylene Glycol and Ammonium Chloride Induced Urolithiasis Rat Model.

METHODS: Renal calculi were induced in Rats by supplementing with 0.75%v/v ethylene glycol & 0.5%w/v Ammonium chloride in drinking water *ad libitum*. Daily for 28 days. Then Antiurolithic activity was measured by estimation of Biochemical parameters:-
a) Kidney homogenate analysis:-Calcium, Phosphorus, Oxalate.
b) Serum analysis: – Urea, Creatinine, Uric acid.
c) Histopathological examinations.

CONCLUSION: The findings suggest that the Antiurolithic activity of *Citrus decumana* Fruit Extract plays a role in the prevention of Renal Calculi Formation and recurrence in Urolithiasis.

Key Words: Antiurolithic activity, *Citrus decumana* Fruit Extract, Kidney homogenate analysis, Renal Calculi, Urolithiasis Rat Model.

INTRODUCTION

Urolithiasis is the presence of calculi in the urinary tract. Eighty percent of calculi are composed of calcium (either oxalate or phosphate), with others composed of struvite, uric acid, xanthine or cystine.[1]

Annual incidences of kidney stones are about 0.1-0.4% of the population. Kidney stones occur more frequently with increasing age and among men. Within two years, the disease usually recurs in more than 50% of patients. Nowadays, about 85% of all kidney stones contain calcium salts (calcium oxalate and/or calcium phosphate) as their main crystalline components. Because human urine is commonly supersaturated with respect to calcium salts as well as to uric acid, crystalluria is very common, i.e. healthy people excrete up to few millions of micro crystals every day. Recurrent stone formers appear to excrete lower amounts or structurally defective forms of crystallization inhibitors which allows for the formation of large crystal aggregates as precursors of stones. Alternatively, crystal adhesion to urothelial surfaces may be enhanced in stone formers.[2]

In addition, once stone formation has been found to exist and if treatment is able to resolve the stones that are present, it is known that there is still a high rate of recurrence. Rat experimental models of Calculi Urolithiasis, induced by ethylene glycol (EG) alone, or in combination with other drugs such as ammonium chloride (AC), are often used to study the pathogenesis of kidney crystal deposition.[3] Dietary sources of citrate may be considered as option or alternative to pharmacologic agents. Fruits and fruit juices with high citrate content generally are assumed to deliver an alkali load. However, previously published studies on the influence of different citrate-rich fruit juices/beverages on the risk for stone formation have provided conflicting results, with some beverages decreasing the risk for stones whereas others have either no effect or increase the risk.Citrate sources and juices such as lemon, or orange, mandarin, tomato may be an equivalent to pharmacologic citrate treatment because they are a natural and rich sources of citrate.[4] Also present study investigates antiurolithiatic activity *Citrus decumana* plant.

Methods

Materials

Per day fresh fruit juice of *Citrus decumana* was extracted by mechanical process. Ethylene glycol (AR Grade), Ammonium chloride, EDTA & Formalin was obtained from Merck Laboratories, Mumbai, India. Cystone (The Himalaya Drug Company, Makali, and Bangalore, India) was used as standard antiurolithiatic drug.

Animals

Wister rats of either sex weighing between 150 and 250 g were selected for acute toxicity studies and antiurolithiatic activity. The animals were acclimatized to standard laboratory conditions of temperature (22±3°C) and maintained on 12:12 hr light: dark cycle. They were provided with regular rat chow (Lipton India Ltd., Mumbai) and distilled water *ad libitum*. The experimental protocol described in present study was approved by Institutional animal ethical committee (IAEC) Pinnacle Biomedical Research Institute. The experiment was conducted as per the permission of Institutional animal ethical committee (IAEC) of PBRI (Regd. No. 1283/c/09/CPCSEA). All conditions were maintained according to CPCSEA norms.

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A Review on study of Buccal Drug Delivery System

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ABSTRACT

Buccal drug delivery is a promising area for continued research with the aim of systemic delivery of orally inefficient drugs as well as a feasible and attractive alternative for non-invasive delivery of potent peptide and protein drug molecules. However, the need for safe and effective buccal permeation absorption enhancers is a crucial component for a prospective future in the area of buccal drug delivery. Buccal nitroglycerin, can use for acute therapy for an anginal attack as well as for chronic prophylaxis Novel liquid aerosol formulation of insulin Development of suitable delivery devices, permeation enhancement, and Buccal delivery of drugs that undergo a first-pass effect, such as cardiovascular drugs, analgesics, and peptides Research yield some successes Promote further research; more companies Rest depend on delivery technology

Key word : Buccal, first-pass effect, suitable delivery devices, permeation enhancement.

INTRODUCTION

Amongst the various routes of drug delivery, oral route is perhaps the most preferred to the patient and the clinician alike. However, administration of drugs has disadvantages such as hepatic first pass metabolism and enzymatic degradation within the GI tract, that prohibit oral administration of certain classes of drugs especially peptides and proteins.

The nasal cavity as a site for systemic drug delivery has been investigated by many research groups[1,2] and the route has already reached commercial status with several drugs including LHRH [3,4] and

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Review Article

NIOSOMAL DRUG DELIVERY SYSTEM – A REVIEW

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ABSTRACT

Niosomes represent a promising drug delivery module. They present a structure similar to liposome and hence they can represent alternative vesicular systems with respect to liposomes, due to the obvious ability to encapsulate different type of drugs within their multi environmental structure. Niosomes are thought to be better candidates drug delivery as compared to liposomes due to various factors like cost, stability etc. Various type of drug deliveries can be possible using niosomes like targeting, ophthalmic, topical, parenteral, etc.

Keywords: Niosomes, Liposome, Targeting, Ophthalmic, Topical, Parenteral.

INTRODUCTION

At present an available drug delivery system advocates the site specific delivery with controlled release kinetics of drug in predictable manner. Paul Ehrlich, in 1909, initiated the era of development for targeted delivery when he envisaged a drug delivery mechanism that would target directly to diseased cell. Since then, number of carriers were utilized to carry drug at the target organ/tissue, which include immunoglobulins, serum proteins, synthetic polymers, liposomes, microspheres, erythrocytes, niosomes etc. Among different carriers liposomes and niosomes are well documented drug delivery. Drug targeting can be defined as the ability to direct a therapeutic agent specifically to desired site of action with little or no interaction with non-target tissue. Niosomes or non-ionic surfactant vesicles are microscopic lamellar structures formed on admixture of non-ionic surfactant of the alkyl or dialkyl polyglycerol ether class and cholesterol with subsequent hydration in aqueous media. In niosomes, the vesicles forming amphiphile is a non-ionic surfactant such as Span – 60 which is usually stabilized by addition of cholesterol and small amount of anionic surfactant such as dicetyl phosphate. Schematic representation of a drug targeting through its linkage to niosome via antibody is shown in Figure 1.[1,2]

Advantages of Niosomes

The application of vesicular (lipid vesicles and non ionic surfactant vesicles) systems in cosmetics and for therapeutic purposes may offer several advantages: - The vesicle suspension is water-based vehicle.[3,4]

- This offers high patient compliance in comparison with oily dosage forms. They possess an amphiphilic consisting of hydrophobic, amphiphilic and lipophilic moieties together and as a result can accommodate drug molecules with a wide range of solubilities.
- The characteristics of the vesicle formulation are variable and controllable. Altering vesicle composition, size, lamellarity, trapped volume, surface charge and content rates can modify the vesicle characteristics.
- The vesicles may act as a depot, releasing the drug in a controlled manner. Other advantages of niosomes include:
- They are osmotically active and stable, as well as they increase the stability of entrapped drug.
- Handling and storage of surfactants requires no special conditions.
- They improve oral bioavailability of poorly absorbed drugs and enhance skin penetration of drugs.
- They can be made to reach the site of action by oral, parenteral as well as topical routes.

METHODS

Ether injection method

This method provides a means of making niosomes by slowly introducing a solution of surfactants dissolved in diethyl ether into warm water maintained at 60°C. The surfactant mixture in ether is injected through 14 gauge needle into an aqueous solution of material. Vaporization of ether leads to formation of single layered vesicles. Depending upon the conditions used, the diameter of the vesicle range from 50 to 1000 nm.[5]

Hand shaking method (Thin film hydration technique)

The mixture of vesicle forming ingredients like surfactant and cholesterol are dissolved in a volatile organic solvent (diethyl ether, chloroform or methanol) in a round bottom flask. The organic solvent is removed at room temperature (20°C) using rotary evaporator leaving a thin layer of solid mixture deposited on the wall of the flask. The dried surfactant film can be rehydrated with aqueous phase at 0-60°C with gentle agitation. This process forms typical multilamellar niosomes. Thin of lipid on the wall of rotary flask evaporator. The aqueous phase containing drug was added slowly with intermittent shaking at flask at room temperature followed by sonication.[6]

Sonication

A typical method of production of the vesicles is by sonication of solution as described by Cable. In this method an aliquot of drug solution in buffer is added to the surfactant/cholesterol mixture in a 10-ml glass vial. The mixture is probe sonicated at 60°C for 3 minutes using a sonicator with a titanium probe to yield niosomes.[6]

Micro fluidization

Micro fluidization is a recent technique used to prepare unilamellar vesicles of defined size dimension. This method is based on submerged jet principle in which two fluidized streams interact at ultra high velocities in precisely defined micro channels within the interaction chamber. The impingement of thin liquid sheet along a common front is arranged such that the energy supplied to the system remains within the area of niosomes formation. The result is a greater uniformity, smaller size and better reproducibility of niosomes formed.[7,8]

Multiple membrane extrusion method

Mixture of surfactant, cholesterol and dicetyl phosphate in chloroform is made into thin film by evaporation. The film is hydrated with aqueous drug solution and the resultant suspension extruded through polycarbonate membranes, which are placed in series for upto 5 passages. It is a good method for controlling vesicle size.[9]

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Niosomal Drug Delivery System: The Magic Bullet

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ABSTRACT

The concept of drug targeting or site specific drug delivery was introduced first time by Paul Ehrlich in 1909, when he reported 'magic bullet' to deliver a drug to the desired site of action without affecting the non target organs or tissues (Juliano, 1980) by associating the drug with a pharmacologically "inactive carrier" capable of conveying the drug selectively towards its target cells. The methods of preparation of niosomes such as hand shaking, ether injection and sonication (developed on the basis of liposome production techniques) have been reviewed by Khandare et al. 1994. The hand shaking method form vesicles with greater diameter (0.35 – 13 [illegible]) as compared to those prepared by ether injection method ([illegible]). The film formation method was used for the preparation of the niosomes due to simplicity, reproducibility and high drug entrapment efficiency.

Keywords: Magic bullet, hand shaking, ether injection, sonication, film formation method.

INTRODUCTION

The main goal of a site specific drug delivery system is not only to increase the selectivity and drug therapeutic index, but also to reduce the toxicity of the drug (Widder et al., 1982). [illegible] present no available drug delivery system achieves the site specific delivery with controlled release kinetics of drug in predictable manner. Paul Ehrlich, in 1909, initiated the era of development for targeted delivery when he envisaged a drug delivery mechanism that would target directly to diseased cell. Since then, number of carriers were utilized to carry drug at the target organ/tissue, which include immunoglobulins, serum proteins, synthetic polymers, liposomes, microspheres, erythrocytes, niosomes etc. Among different carriers liposomes and niosomes are well documented drug delivery. Drug targeting can be defined as the ability to direct a therapeutic agent specifically to desired site of action with little or no interaction with nontarget tissue. Niosomes or non-ionic surfactant vesicles are microscopic lamellar structures formed on admixture of non-ionic surfactant of the alkyl or dialkyl polyglycerol ether class and cholesterol with subsequent hydration in aqueous media. In niosomes, the vesicles forming amphiphile is a non-ionic surfactant such as Span – 60 which is usually stabilized by addition of cholesterol and small amount of anionic surfactant such as diacetyl phosphate. Schematic representation of a drug targeting through its linkage to niosome via antibody is shown in figure 1.

Vanlerberghe et al. (1972) first reported the niosomes as a feature of cosmetic industry. In 1979, Handjanivila et al. reported that the hydration of a mixture of cholesterol and single alkyl chain, resulted in formation of non ionic surfactant vesicular systems (i.e. Niosomes). [illegible] Okhata et al. reported the formation of such vesicles by dialkyl polyoxyethylene ether with [illegible]

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Review Article

NIOSOMES – CHALLENGE IN PREPARATION FOR PHARMACEUTICAL SCIENTIST

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ABSTRACT

Target oriented drug delivery systems are the areas of the major interest to the modern pharmaceutical research. The selective drug delivery to the target tissues increases the therapeutic efficacy of the drug and reduces its undesirable effect to non target tissues. The concept of drug targeting or site specific drug delivery was introduced first time by Paul Ehrlich in 1906, when he reported "magic bullet" to deliver a drug to the desired site of action without affecting the non target organs or tissues (Julliano, 1980) by associating the drug with a pharmacologically "inactive carrier" capable of conveying the drug selectively towards its target cells. Drug targeting is defined as the ability to direct a therapeutic agent specifically to the desired site of action with little or no interaction with non target tissues (Devender, 1992).

The main goal of a site specific drug delivery system is not only to increase the selectivity and drug therapeutic index, but also to reduce the toxicity of the drug. (Webster et al., 1992).

Keywords: Magic bullet, Niosomes, Inactive carrier, Drug therapeutic index.

INTRODUCTION

Target oriented drug delivery systems are the areas of the major interest to the modern pharmaceutical research. The selective drug delivery to the target tissues increases the therapeutic efficacy of the drug and reduces its undesirable effect to non target tissues. The concept of drug targeting or site specific drug delivery was introduced first time by Paul Ehrlich in 1906, when he reported "magic bullet" to deliver a drug to the desired site of action without affecting the non target organs or tissues (Julliano, 1980) by associating the drug with a pharmacologically "inactive carrier" capable of conveying the drug selectively towards its target cells. Drug targeting is defined as the ability to direct a therapeutic agent specifically to the desired site of action with little or no interaction with non target tissues (Devender, 1992).

The main goal of a site specific drug delivery system is not only to increase the selectivity and drug therapeutic index, but also to reduce the toxicity of the drug. (Webster et al., 1992).

Vanlerberghe et al. [1972] first reported the niosomes as a feature of cosmetic industry. In 1979, Handjaniyla et al. reported that the hydration of a mixture of cholesterol and single alkyl chain resulted in formation of non ionic surfactant vesicular system (i.e. Niosomes).

These non ionic surfactant vesicles can entrap both hydrophilic and lipophilic drugs, either in aqueous layer or in the vesicular membrane made of lipid materials, which can be used in pending the circulation of the entrapped drugs. Due to the presence of non ionic surfactant and the lipid, there is a better targeting of drug(s) to tumor, liver and brain. Thus, they are useful in targeting of the drug for treating cancers, parasites, viral and other microbial diseases more effectively.

Merits of Novel Drug Delivery System

1. Reduction in the total amount of drug administered over the period of drug treatment. This contributes to the reduced incidence of systemic and local side effects.
2. Devoid of first pass metabolism and gastrointestinal tract degradation.
3. Improved patient compliance resulting from the reduction in the frequency of dose required to maintain the desired therapeutic response.
4. Targeting of the drug molecule towards the tissue (set organ reduces the toxicity to the normal tissues.
5. Pinocytic and pit dispersion systems release the drug afterward the body elements.
6. Biocompatibility.

Limitations of Novel Drug Delivery System

1. The drugs having biological half-life of 1 hr or less are difficult to be formulated as sustained release formulations. The high cost of formulation of such drugs from the body needs an excessively large maintenance dose which provides a 12 hrs of continuous therapy.
2. These products usually contain a large amount of drug. There is a possibility of unsafe dose dumps, if the product is improperly made and the total drug contained therein is released at one time or over too short time interval.
3. If it is ever administered, it may be difficult to stop the therapy for reasons of toxicity or any other reasons.
4. It may be unwise to include potent drugs in such systems.

Rationale for Site Specific Drug Delivery (Tuncilason, 1984)

1. To reach previously inaccessible domains e.g. intracellular site, bacteria, viruses parasites etc.
2. Facilitate drug delivery to the specific cells or diseased site in the body.
3. Reduction in the drug dose and side effects.
4. To control the rate and frequency of drug delivery at the pharmacological receptor.
5. To protect the drug and the body from one another until it reaches at the desired site of action.

Factors Affecting Variable Size, Entrapment Efficiency and Release Characteristics

a) Drug

The entrapment of the drug in niosomes results in an increase in vesicle size, probably by interaction of solute with surfactant head groups, increasing the charge and mutual repulsion of the surfactant bilayer thereby increasing vesicle size (Shaffiee et al., 1985). In polyoxyethylene (PEG) coated vesicles, some drug are entrapped in long PEG chains thus reducing the tendency to increase the size (Chandler, and Lawrence, 1979).

The degree of entrapment is affected by the hydrophilic-lipophilic balance of a drug. For a series of Spans and Tweens, Baroli et al., 1994 reported the successful entrapment of water-soluble drug (Diclofenac sodium) in hydrophilic surfactant. Tween and Cholesterol niosomes et al., 1993 reported maximum entrapment of

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RESEARCH ARTICLE

Formulation Development and Evaluation of Metoprolol Succinate Er and Amlodipine Besilate Bilayer Tablet

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ABSTRACT:
According to the (WHO), hypertension is the most common cardiovascular condition in the world and there are about 600 million people at risk for heart attack, stroke and cardiac failure. High BP is estimated to cause 7.1 million deaths, about 13 percent of the global fatality total. It is believed this number will grow to approximately 1 million by the year 2020.

The Formulation of Metoprolol Succinate ER and Amlodipine Besilate were prepared by using different polymer (HPMC, Methocel, Carbopol) with different diluents (MCC, Cellulose Phosphate, Starch, Croscarmellose Sodium) and then evaluated. The experimental work was divided into preformulation studies, formulation development, and evaluation. Standardization of drug and excipients confirmed the authentification of the samples. Thus it can be concluded that a stable bilayer tablet of Metoprolol succinate ER and Amlodipine besilate can be prepared by using HPMC K 15 M and carbomer as a polymer. It was found that the in vitro drug release of Metoprolol succinate ER was best explained by first order (r^2 =0. 9984), as the plot showed the highest linearity, followed by Higuchi's equation (r^2 = 0.9974) and zero-order (r^2 = 0.9472).

KEYWORDS: BP, Blood Pressure; ER: Extended Release, HPMC: Hydroxy Propyl Methyl Cellulose, MCC: Methyl Carboxy Cellulose

INTRODUCTION:

This is novel type of dosage form for oral administration in which one layer contains extended release metoprolol succinate and another layer contains immediate releasing drug amlodipine besilate. Therapy with metoprolol alone and the combination of metoprolol and amlodipine was well tolerated in patients with mild to severe heart failure, as evidenced by a lack of adverse effects on functional status improvement with long-term treatment.

Amlodipine besilate is an oral long-acting dihydropyridine calcium channel blocker. It is indicated for the treatment of hypertension, chronic stable angina, vasospastic angina (Prinzmetal's variant angina) and angiographically documented coronary artery disease. Metoprolol is a beta1-selective (cardio selective) adrenoreceptor-blocking agent. It is indicated as for the treatment of hypertension, angina pectoris, heart failure and also for symptomatic heart failure of ischemic, hypertensive, or cardiomyopathic origin.
The present work aims to develop a stable and extended bilayer dosage form containing one immediate release drug amlodipine besilate and another extended release drug metoprolol succinate as extended release dosage form.

MATERIAL AND METHOD :

Experimental Details :-

Table No. 1 Brief summary of Formulation of Metoprolol succinate

Formulation Ingredients	1	2	3	4	5	6	7	8
Metoprolol succinate	47.5	47.5	47.5	47.5	47.5	47.5	47.5	47.5
MCC	30	28	47	43	32	23	37	33
HPMC	50	45	30	36	33	22	60	60
Carbomer	–	15	18	22	18	22	18	22
Povidone	25	25	30	30	[illegible]	30	30	30
Isopropyl alcohol	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
HPMC	45	40	30	30	30	30	40	40
Magnesium stearate	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5

Table No. 2 Brief summary of Formulation of Amlodipine Besilate

Formulation Ingredients	1	2	3	4
Amlodipine Besilate	6.95	6.95	6.95	6.95
Microcrystalline cellulose	41.8	37	37	37
Anhydrous Calcium Hydrogen Phosphate	41	41	41	41
Croscarmellose Sodium	3.0	3.0	3.0	3.0
Lake of sunset yellow	0.5	0.5	0.5	0.5
Purified water	q.s.	q.s.	q.s.	q.s.
Starch paste	4.0	4.0	4.0	4.0
Sodium Starch Glycollate	–	6.0	6.0	6.0
Colloidal silicon dioxide	1.5	1.5	1.5	1.5
Magnesium stearate	1.0	1.0	1.0	1.0
Lake of sunset yellow	0.25	0.25	0.25	0.25

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Three-wavelength Spectrophotometric Method for Simultaneous Estimation of Pantoprazole and Domperidone in Pharmaceutical Preparations

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Introduction

Experimental

Materials and Equipments

Preparation of standard stock solutions

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Duvertepe Kaolin Deposits in Balikesir (North-west Turkey) and Ceramic Properties

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The Duvertepe kaolin deposit (Çaldıkabaz and Bağyurdu) were characterized and assessed potentially in the ceramic industry. The particle size, colour measurement, viscosity, plastic limits, liquid limits, firing shrinkage, water absorption, water-soluble matter and moisture were tested by chemical, physico-mechanical, mineralogical and the thermal analysis techniques (TG-DTA) and their firing behaviours were investigated. The technological properties of Duvertepe kaolins were determined concerning shrinkage, firing and colour. From these studies, it was understood that the Duvertepe kaolin could be used for ceramic industry, fabrication of tiles, bricks and sanitary wares.

Key Words: Kaolin evaluation, Ceramic, Duvertepe, Technological properties.

INTRODUCTION

Kaolinite is one of the most important clay minerals occurring in large amounts in sediments and sedimentary rocks or as alteration product in crystalline rocks. Because of widespread occurrence, and its physical and chemical properties, kaolinite is widely used in certain technical applications regarding physical, chemical, mineralogical properties and thermal behaviour, e.g., ceramic industry, filling material and refractory materials[1-3].

This study deals with the chemical-mineralogical characterization and the technological properties of kaolins from Duvertepe (Balikesir, Turkey). Several kaolin mineralizations occur in this district. The deposits of this area have a high economic potentiality and thus a study of the ceramic properties has been carried out. The reserves of kaolinitic materials have been estimated to amount to 30 million tons[4].

The relationship between the technological characteristics and the mineralogical and chemical features were investigated. The influences of some minor elements (iron, magnesium and sulphur) on the ceramic properties of final products were also taken into account. The comparison between chemical-min-

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...sian Journal of
Pharmaceutics

Original Research Articles

STUDIES OF OLEORESINS AS PENETRATION ENHANCER FOR TRANSDERMAL PATCH OF KETOPROFEN

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ABSTRACT:

The study deals with the effect of oleoresins (nutmeg, capsicum [illegible]) as penetration enhancer for transdermal patch of ketoprofen. The transdermal patches [illegible] technique and evaluated. In vitro release was found to be more [illegible] through cellophane membrane in capsicum oleoresin. In vivo study indicated that capsicum [illegible] edema inhibitions and transdermal patch without penetration enhancer [illegible]. This indicated that the formulation containing oleoresin capsicum [illegible] edema inhibition. The more [illegible] and greatest flux of ketoprofen was [illegible] by capsicum oleoresin. From Overall study, it can be concluded that to deliver the drug through [illegible] penetration enhancer play a vital role. So to deliver the drug into systemic circulation [illegible] transdermal therapeutic system of ketoprofen, using natural oleoresins as penetration [illegible].

In nutshell the oleoresins like Oleoresin nutmeg, Oleoresin capsicum [illegible] Oleoresin [illegible] shows penetrability and drug with maximum flux. Amongst [illegible] performance as penetration enhancer.

...words: Ketoprofen, penetration enhancer, transdermal drug delivery system and oleoresins

...TRODUCTION

...sdermal Drug Delivery System (TDDS) can deliver ...ain medication to systemic circulation in a more con...nient and effective way that is possible with conven...al dosage form. Main objective of transdermal drug ...ery system is to delivery of drugs in systemic circu...n at predetermine rate, with no or minimal inter or ...a patient variation. Transdermal delivered drugs ...d first pass metabolism, decrease dose to be ad...istered, decreases side or unwanted effects, de...ses gastrointestinal side effects, easy to discon...e in case of toxic effects.[1]

...etration enhancers or promoters are agents that ...y therapeutic properties of these own but can trans... the sorption of drug from drug delivery system, on ...e skin or their subsequent transdermal penetra... through skin. The acceleration across the keratin...ized and leaches out essential structural materials from the stratum corneum, thus reducing diffusional resistance and increasing the permeability of drug through skin. An effective amount of penetration enhancer increases the skin permeability and correspondingly the desired depth of permeation rate and [illegible] of drug delivered.[2]

Oleoresins are homogenous mixture of resins and volatile oils. Pharmaceutical oleoresins are derived from ginger, capsicum, nutmeg, coriander, garlic etc. Oleoresins also occur with gums, are called as oleo-gum resins include asafoetida and myrrh. Terpenes and terpenoids are usually the constituents of volatile oil. Their chemical structures consist of repeated isoprene (C_5H_8) units and classified according to number of isoprene units. Sesquiterpenes have three (C_{15}) and Di terpenes have four (C_{20}). Terpenes may also classified as acyclic/linear, monoterpenes and bicyclic. Terpenes have been utilized for number of therapeutic purpose such as antimi...

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Design and Development of Hydrodynamically Balanced Tablet of Itopride

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ABSTRACT

Hydrodynamically Balanced Systems is an approach to increase the gastric residence time of drugs in stomach. This system is designed for site-specific oral drugs with low bulk density than gastric fluid so as to buoyant the dosage form in stomach to increase the residence time of the drug. In the present investigation, an attempt has been made to design hydrodynamically balanced drug delivery systems for itopride using HPMC K$_{15}$M, HPMC K$_4$M and Xanthan gum polymers. Different batches of matrix tablets of itopride were prepared using various drugs to polymer ratio by direct compression method. The compressed tablets were evaluated for physical characteristics, drug content, floating time, floating lag time, in-vitro dissolution, stability study and FTIR spectroscopy. FTIR study showed that there is no chemical interaction between drug and excipients. All the formulation passes various physico-chemical tests. F4 formulation showed a buoyancy lag time of less than 75 Sec and floating time of more than 12hrs. From the in vitro drug release profile it was found that matrix tablet containing HPMC K$_4$M showed 95.88% drug release in 12 hrs. It can be concluded that itopride released from the tablet follows zero order kinetics with peppas model with non Fickian diffusion.

Key words: Hydrodynamically Balanced Systems, Floating matrix tablet, Itopride and Xanthan gum.

INTRODUCTION

The hydrodynamic balanced system (HBS) also called Floating drug delivery system (FDDS) is an oral dosage form (capsule or tablet) designed to prolong the residence time of the dosage form within the GIT [1,2]. It is a formulation of a drug with gel forming hydrocolloids meant to remain buoyant in the stomach contents[3]. Drug Delivery Systems (FDDS) have a bulk density lower than gastric fluids and thus remain buoyant in the stomach for a prolonged period of time, without affecting the gastric emptying rate. While the system is floating on the gastric contents, the drug is released slowly at a desired rate from the system.[4] After the release of the drug, the

Formulation and Evaluation of Fast Dissolving Tablet of An Antihypertensive Drug

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Introduction:

[illegible]

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FAST RELEASE CARBAMAZEPINE TABLET FOR KIDS

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Abstract:

This work describes a new approach to prepare a fast release dosage form of carbamazepine for kids involving the use of solid dispersion (SD) process to enhance the solubility of carbamazepine. In particular, the SD of carbamazepine and polyethylene glycol (PEG) in 6:1 ratio was prepared by melt granulation method. The subsequent steps encompassed the direct compression of tablet using different super-disintegrants and evaluated for various official parameters and effect of percentage of super-disintegrants. All tablets fulfilled the official requirements. The tablets formulated by employing crospovidone gave rise to amelioration of the disintegration and dissolution performance and proved best formulation for kids.

Introduction:

Carbamazepine is a first line drug for the treatment of epilepsies and trigeminal neuralgia. Carbamazepine is white to off-white powder and practically insoluble in water. Gastrointestinal (GI) absorption of Carbamazepine in humans is slow, unpredictable and erratic.[1] The neutral drug is highly lipophilic, and its absorption would be expected to be rapid if the higher of the Carbamazepine is dissolved in the GIT, suggesting that the rate limiting step is dissolution in the overall absorption process.[2,3]

Int. J. Chem. Sci.: 7(3), 2009, 1315-1320

SYNTHESIS OF NEWER MANNICH BASES OF QUINOLINE DERIVATIVE FOR ANTIMICROBIAL ACTIVITY

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ABSTRACT

Antimicrobial agents are widely used in the management of infectious diseases but most of them have developed resistance to micro-organism. The cinchophen, which is water insoluble compound, has reported antimicrobial activity. To overcome this problem and to lower the side effects, many approaches can be utilized and Mannich base approach is one of them. In the present study, cinchophen having carboxylic acid (-COOH), group was converted to amide (-CONH$_2$) and it is utilized to synthesize Mannich bases. At first cinchophen **I**, was synthesized by Doebner synthesis, then it was converted to cinchophen chloride **II**, using oxalyl chloride. Cinchophen chloride was converted to cinchophen amide **III**, using ammonia. The Mannich bases **IVa-e** have been synthesized by reaction of cinchophen amide with formaldehyde and secondary amine. The prepared Mannich bases were subjected to physicochemical studies like melting point determination, TLC and % yield. The structures of Mannich bases were characterized by UV, IR, Mass and NMR spectroscopy. Antibacterial screening of newly synthesized compounds **IVa-e** was carried out against *E. coli*, *P. aeruginosa*, *S. aureus* and antifungal activity against *C. albicans* and *A. niger* according to cup-plate method.

Key words : Mannich base, Cinchophen, Antimicrobial

INTRODUCTION

The prevalence of heterocyclic ring among drugs and biological agents of mammalian origin can lead to the erroneous assumption that the presence of such rings in drugs means that this moiety necessarily constitutes a part of pharmacophore. Replacement of the particular ring system in such cases leads to loss of desirable biological activity. Recognition of pharmacophoric functions is still largely an empirical art[1].

The diversity of biological effects is possessed by benzofused six membered

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ANTIHYPOXIC ACTION OF 5-PHENYLPROPYNYLIDENE RHODANINE DERIVATIVE IN HYPOXIA-INDUCED RAT

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1. Introduction

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INHIBITION OF RENAL CALCULI FORMATION BY *CITRUS DECUMANA* FRUIT EXTRACT ON ETHYLENE GLYCOL AND AMMONIUM CHLORIDE INDUCED UROLITHIASIS-RAT MODEL.

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ABSTRACT

OBJECTIVE: [illegible]

METHODS: [illegible]

CONCLUSION: [illegible]

Key Words: [illegible]

INTRODUCTION

[illegible]

[illegible]

[illegible]

[illegible]

Methods

Materials

[illegible]

Animals

[illegible]

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Research report

Protection of cholinergic and antioxidant system contributes to the effect of berberine ameliorating memory dysfunction in rat model of streptozotocin-induced diabetes

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ABSTRACT

Memory impairment induced by streptozotocin in rats is a consequence of … secondary to chronic hyperglycemia, impaired oxidative stress, cholinergic … glucagon-like peptide (GLP). Treatment with antihyperglycemics, antioxidants … are required to produce beneficial effect in this model. Berberine, an isoquinoline … to exhibit anti-diabetic and antioxidant effect, acetylcholinesterase (AChE) … release. However, no report is available on influence of berberine on streptozotocin … impairment. Therefore, we tested its influence against cognitive dysfunction … diabetic rats using Morris water maze paradigm. Lipid peroxidation and gluta… of oxidative stress and choline esterase (ChE) activity as marker of cholinergic … the cerebral cortex and hippocampus. Thirty days after diabetes induction … in learning and memory associated with increased lipid peroxidation, decline … and elevated ChE activity. In contrast, chronic treatment with berberine (25 … 30 days) improved cognitive performance, lowered hyperglycemia, oxidative … in diabetic rats. In another set of experiment, berberine (100 mg/kg) treatment … also improved learning and memory, lowered hyperglycemia, oxidative stress … treatment (30 days) with vitamin C or metformin, and donepezil during … diabetes induced memory impairment and reduced oxidative stress and/or … conclusion, the present study demonstrates treatment with berberine prevents … stress and ChE activity, and consequently memory impairment in diabetic rat…

1. Introduction

Diabetes mellitus (DM) is the most common endocrine disorder characterized by increased blood glucose levels resulting from defective insulin secretion, resistance to insulin action or both that is associated with long term complications and affects eyes, kidneys, blood vessels, heart, and nerves [23,40]. DM is strongly associated with degenerative and functional disorders of the central nervous system (CNS) [31,49]. These effects of diabetes in the CNS are a series of neurochemical, neurophysiological, and structural abnormalities [7,58]. DM is often associated with severe complications, and there is an increasing … tive function declines in DM [13,14,53,… and adults exhibit reduced psychomotor … ability, and rapid information-processing … diabetic patients also seem to double the … Alzheimer's disease and other dementias … suggest the strong association between … tion.

The mechanism causing brain damage … a multi-factorial process. A growing body … diabetes-related cognitive dysfunction is … of changes within the CNS that are … hyperglycemia [7,15,35,41–43,59]. The … [32,40,70], oxidative stress [5,52], … end products [66,67], and impairments … naling systems [26] are thought to be the … diabetic dementias. Moreover, anti-oxidant …

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Research Article

A NOVAL THERMOREVERSIBLE PHASE TRANSITION SYSTEM WITH FLUX ENHANCERS FOR OPTHALMIC APPLICATION

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ABSTRACT

The objective of this study is to investigate effect of flux enhancing polymers on ocular release through thermo sensitive gelling solution of poloxamer 407 a triblock copolymer exhibiting the phenomenon of reverse thermal gelation used with different polymers including HPMC and hitosan resulting in sustained delivery of drug. Addition of PVA (0.25w/v – 0.5% w/v) to the gelling systems shows significant increase in the percentage drug release and prolong the residence time. These transition temperature of these systems ranged from 28.0–29.0°C, depending on the concentration of Poloxamer 407 and chitosan. The formulation contained of 20% Pluronic and 0.2% chitosan and PVA 0.5%w/w, with the highest release efficiency [49.63 ± 0.18%] may be suggested as a suitable ophthalmic preparation for sustained release of ciprofloxacin. Release rate of the system composed of P407/chitosan/ PVA (20/0.2/0.5%, w/v respectively) was significantly larger than that without PVA. Viscosity of the formulation was in suitable range at 25°C and provide plastic behavior was found to be at 35°C. Antimicrobial effect of the solutions was studied in nutrient agar in comparison to marketed solutions of ciprofloxacin using Staphylococcus aureus by the agar diffusion test using the cup-plate technique. The zone of inhibition for both studied bacteria was significantly greater for tested formulation than the marketed eye drops of ciprofloxacin. The formulation exhibited an 8 hour sustained release of CFX (ciprofloxacin).

Keywords: Poloxamer, Ciprofloxacin, Gelling solution, PVA

INTRODUCTION

Several approaches have been tried towards the development of viable sustained release in-situ ophthalmic gel so as to overcome problems associated with conventional ophthalmic dosage form. Conventional liquid ophthalmic drugs exhibit a short pre-corneal residence time and poor bioavailability due to rapid and extensive elimination of drugs from pre-corneal lachrymal fluid by solution drainage, lachrymation, and non-productive absorption by conjunctiva[1]. In situ gel system is formulated as liquid preparation suitable to be instilled into eyes which upon exposure to the physiologic environment changes to gel results in in-situ gel, thus increasing the precorneal residence time of the delivery system, and enhance the ocular bioavailability of the drug. But Conventional in-situ gel was found to be unsatisfactory. There is a need to study effect of various polymers on release rate, to develop a new ophthalmic gelling system that undergo thermoreversible phase transition and release the drug with higher release efficiency once administered in the cul-de-sac[2]. Ciprofloxacin HCl was used as a model drug to study the effect of various polymers on ocular drug release. Ciprofloxacin is a synthetic fluoroquinolone antibiotic with a broad spectrum antimicrobial activity.

The typical dosage of ciprofloxacin HCl eye drops is one to two drops of 0.3% solution in the affected eye every 4 h or hourly over in the case of severe infection. One of the major drawbacks of an ocular eye drops is the palatable drug level with a transient systematic period of overdose followed by an extended period of sub-therapeutic levels before the next dose is administered. In development of thermoreversible phase transition system, Poloxamer 407 or Pluronic F 127 was used to different concentration so that it should always show phase transition at physiological temperature when are alone and in combination with different polymers. Poloxamer 407 was unable to show any phase transition when used in or below 15% w/w[3].

The different gelling solutions were made with poloxamer in combination with different polymers such as HPMC, Chitosan and were optimized considering phase transition temperature, physical appearance, gelling capacity. On the basis of parameters mentioned above the formulation were optimized and effect of PVA on the optimized solutions on in vitro drug release for each optimized formulation was studied.

MATERIALS AND METHODS

Materials

Polaxamers P407 was obtained from BASF Corp. (Ludwigshafen, Germany). Ciprofloxacin was kindly gifted from Ranbaxy Healthcare Pvt. Ltd. (INDIA). Chitosan and Polyvinyl alcohol (PVA) were purchased from HIMEDIA, Triethanolamine, Benzalkonium chloride were obtained from Research lab fine chem industries (MUMBAI), all other chemicals used were commercially available products of analytical grade.

Preparation of Formulations

Selection of vehicle

Poloxamers (trade name Pluronics), ABA triblock copolymers consisting of hydrophilic polyoxyethylene (PEO) and hydrophobic polyoxypropylene (PPO) units, are known for exhibiting the phenomenon of reverse thermal gelation under certain concentration (critical micellization concentration) and temperature (critical micellization temperature) [1, 4,7]. At a concentration of 15% (w/w) or higher in an aqueous solution, poloxamer 407 (P407) is transformed from a low-viscosity solution to a semi-solid hydrogel upon being exposed to gradual temperature. Considering the lachrymal fluid dilution, a relatively higher polymer concentration is essential for the P407 solution to form gel under physiological conditions[5].

Sample preparation

Table 1 shows the different compositions of gelling solution of ciprofloxacin HCl. The formulations were prepared on a weight/weight basis using the cold method. In case of poloxamer certain volume of distilled water was cooled down to 4°C. An appropriate amount of P407 was then slowly added to the cold water with continuous stirring. The dispersions were stored in a refrigerator at 4°C over night resulted in clear solution [7]. Gelling solution based on poloxamer and Chitosan were prepared as follows: Chitosan was initially dissolved in a solution of acetic acid (0.5% v/v) and used as a solvent for the Poloxamer dispersion [8]. In case of poloxamer and HPMC appropriate amount of HPMC was dissolved in warm water and mixed with poloxamer solution previously refrigerated overnight. For preparation of drug-containing polymer solutions, Ciprofloxacin was dissolved in 0.5 to 0.6% solution and incorporated manually

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DEVELOPMENT OF TOPICAL FORMULATIONS CONTAINING BIOACTIVE VOLATILE OILS: RELATIVE CHARACTERIZATION OF DRUG RELEASE FOR CREAM OINTMENT AND GEL

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racts:

ical or dermatological preparations are preferred for many of the dermatological conditions due to well-known lesired effects of oral drugs for skin care function. In recent times, some herbal drugs have also proved to have ficient skin care properties, which may also be used in clinical practice in the area of skin care. Such products are ecompatible and non-toxic. In this study garlic and ginger oil were used as a bioactive extracts for development topical formulation. Creams, ointment and gels were formulated and drug release form these formulation were udied. It has been found that gels were extremely suitable as a final formulation for bioactive oils.

K rds: *Allium sativum, Zingiber officinale* Creams, Ointments, Gels.

Introduction:

There are several reports in the ethno pharmacological literature regarding the antimicrobial activity of plant extracts[1]. However, which plant part is responsible for activity, further which of the plant extractives are active, particularly on which organism, whether effective in skin pathogens is of much interest[2]. They are most frequently caused by *Staphylococcus aureus, Streptococcus pyogenes*, and corynefoom bacteria. Impetigo, folliculitis, boils, and erythrasma are common examples[3]. Systemic infections may also have skin manifestations. Secondary infections originate in diseased skin as a superimposed condition[4]. Intertrigo and tee web infections are examples of

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Research Pap

New Method for Sustained Ocular Drug Delivery: Based on Polymeric Combination with Thermo Sensitive Gelling Agent

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ABSTRACT

The objective of the present work is the attainment of an effective drug concentration at the intended site of action for a desire length of time in a consistent and predictable fashion. Thermoreversible insitu gel system was formulated for prolong ocular drug delivery for better patient compliance. Ciprofloxacin HCl was used as model drug. Optimized formulation was evaluated on different parameters like pH, Drug content uniformity, gelation capacity, Measurement of phase change temperature, Isotonicity, Rheology, In-vitro drug release and stability studies.

Key Words: insitu, prolong release, Bioavailability, poloxamer.

INTRODUCTION

The unique anatomy, physiology and biochemistry of eye offer many challenges to developing effective ophthalmic drug delivery systems. Topical delivery into sul-de-sac is, by far the most common route of ocular drug delivery. Though various ophthalmic formulations exists in market but are not able to provide highest bioavailability related to administered dose[1].

Whenever an ophthalmic drug is applied to the anterior segment of the eye, only small amount (5%) actually penetrates the cornea and reaches the anterior tissue of the eye[2,3].

Factors that affects drug bioavailability includes rapid solution drainage by Gravity, Induced lachrymation, Blinking reflex, Normal tear turnover, Superficial absorption of drug into the conjunctiva and sclera and rapid removal by the peripheral blood flow, Low corneal permeability (Act as lipid barrier). Thus objective of this study was to develop an ophthalmic system that shows prolonged contact time with corneal epithelium. Simplicity and installation by patient, Non-irritable and comfortable form and with appropriate rheological considerations. Ciprofloxacin HCl (1-Cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(piperazin-1-yl)-1,4-dihydroquinoline-3-carboxylic acid hydrochloride) was used as model drug.

It shows its Pharmacological action by Inhibition of DNA gyrase (Topoisomerase II) which mediate the formation of supercoils of DNA

EXPERIMENTAL

Material

Poloxamer P407 was obtained as a gift sample from BASF Corp. (Ludwigshafen, Germany); Ciprofloxacin HCl was kindly gifted from Inventia healthcare Pvt. Ltd. (INDIA). HPMC and PVA were purchased from MERK. Triethanolamine, Benzalkonium chloride was obtained from Research lab fine chem. Industries (INDIA). All other chemicals used were of analytical grade.

Methods

Formulation of Poloxamer-HPMC Ophthalmic Gel

The formulations were prepared on a weight/weight basis using the cold method. In case of poloxamer only, certain volume of bidistilled water was cooled down to 4°C. Appropriate amounts of P407 were then slowly added to the cold water with continuous stirring. The dispersions were stored in a refrigerator at 4°C overnight results in clear solution[4]. While in case of poloxamer and HPMC, appropriate amount of HPMC was dissolved in warm water[5], after permitted to cool to room temperature solution was mixed with poloxamer solution which was previously refrigerated overnight.

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Research Article

FEASIBILITY, FORMULATION AND CHARACTERIZATION OF INNOVATIVE MICROPARTICLES FOR ORAL DELIVERY OF PEPTIDE DRUG

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ABSTRACT

Serratiopeptidase (SRP) was use as a model peptide. Microparticles were formulated with phase-separation coacervation method. SRP was entrapped in bovine serum albumin and then enteric coated with Eudragit S-100. The microspheres were characterized for morphology, particle size, encapsulation efficiency, drug release and in-vitro Proteolytic activity. The preliminary studies show that albumin and Eudragit were compatible with SRP. Drug release was also studied with colonic caecal contents to access colonic delivery of peptide. These microspheres are able to entrap the peptide at high levels where the inner albumin core containing the drug would allows kinetic control of release and coating ensures drug core localization in intestinal tract. Enteric coated cross linked albumin microspheres can be considered as promising delivery systems for oral delivery of peptide drugs like serratiopeptidase.

Keywords: Serratiopeptidase and Microparticles.

INTRODUCTION

Oral rout of administration has been most popular from the decade and still preferred by patients and Physicians. Solid dosage forms have inherent advantages because they have a high metering accuracy, the application of them is very easy and comfortable to formulator, patient and Physicians and their stability is very good. The successful oral administration of therapeutic peptides and proteins remains one of the main challenges for pharmaceutical technologists. The enzymatic degradation in GI tract and low membrane permeation due to hydrophilic characteristics of proteins and peptide attribute to low bioavailability of this therapeutics[1,2].

The unique structural characteristics of amino acid based biopharmaceuticals make the formulation and development more challenging than for more conventional drugs. Firstly, the backbone and folding structure of proteins must be retained during manufacturing consideration and storage. Second and most critical challenge in such drug delivery approach is to preserve the formulation during its passage through the stomach, under degradative conditions, such as the presence of enzymes and about first six meters of the small intestine[3], in order to ensure efficient delivery. Various approaches have been described in the literature to overcome these barriers, including the co-administration of protease inhibitors[4], the

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Research Pa

Enteric Coated Cross Linked Albumin Microparticles of Serratiopeptidase: Effect of Intestinal Luminal Contents on Drug Release

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ABSTRACT

The structural characteristics of amino acid based biopharmaceuticals make the formulation and developme more challenging than for conventional drugs. The aim of present work was to evaluate the effect of intestin luminal contents on drug release properties of enteric microparticles of serratiopeptidase. The batches we prepared to formulate mixed walled microparticles of serratiopeptidase with albumin and finally coated wi eudragit S-100. The activity of peptide was also studied for batches prepared and also in presence of intestin luminal contents. Drug release studies were performed on microparticles prepared with and without albumi initially drug release studies were performed by exposing microparticles to hydrochloric acid pH 1.2 and phosphate buffer pH 6.8. Rapid release of drug was observed when phosphate buffer was replaced wi colonic caecal contents. The backbone and folding structure of proteins must be retained duri manufacturing consideration and storage. The conformational aspects of the peptide should be considere during intestinal release from microparticles. This should be carefully taken into account when defining th experimental conditions for drug release measurements from this type of advanced drug delivery system.

INTRODUCTION

Oral route of administration has been most popular from the decade and still preferred by patients and Physicians. Solid dosage forms have different advantages because they have a high metering accuracy, the application of them is very easy and comfortable to humanbeing, patient and Physicians and their stability is very good. The successful oral administration of therapeutic peptides and proteins remains one of the main challenges for pharmaceutical technologists. The enzymatic degradation in GI tract and low membrane permeation due to hydrophilic characteristics of proteins and peptide attribute to low bioavailability of this therapeutics[1,2].

The unique structural characteristics of amino acid based biopharmaceuticals make the formulation and development more challenging than for conventional drugs. Firstly, the backbone and folding structure of proteins must be retained during manufacturing consideration and storage. Second and most critical challenge in each drug delivery approach is to preserve the formulation during its passage through the stomach, under digestive conditions, such as the presence of enzymes and about first six meters of the small intestine[3], in order to ensure efficient delivery. Various approaches have been described in the literature to overcome these barriers, including the co-administration of protease inhibitors[4], the utilization of multifunctional polymers[5] and micro /nanoparticulate drug delivery systems[6].

One strategy to overcome body's natural process is to alter the environment for maximum solubility and enzyme stability of protein by using formulation excipients such as buffer systems and protease inhibitor. If the enzyme attack can be defeated or delayed, the protein can be presented for absorption as well as mean colonic transit time in humans is reported to be as high as 33 h in male and 47 h in women[7], therefore such approach can be utilized for prolong systemic delivery of therapeutic proteins and peptides.

In-Vitro release testing is usually carried out in buffer solutions using shaking, which may strongly influence the peptide stability[8]. During in vitro release, the peptide may also adsorb on the surface of the microparticles, leading to an underestimation of the amount of peptide effectively released. For example, insulin was found to have a higher affinity to the lower molecular weight (40000) DL-PLA than to the higher one (140000)[9]. The degree of adsorption and the formation of peptide: protein multilayers around biodegradable microparticles

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THE INTEGRITY OF PROTEIN ASSOCIATED WITH ENTERIC COATED TABLET EXCIPIENT IN FORMULATION AND ITS DEGRADATION IN SIMULATED INTESTINAL FLUID

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Abstract:

The excipients induced instability in protein and peptide drug may follow the physical and chemical degradation of native protein. Serratiopeptidase (SRP) was used as a model peptide. SRP was studied for *in-vitro* degradation characteristics with enteric polymeric excipients such as eudragit S-100. Assessment and type of degradation was analysed by Spectrophotometry, kinetic mode UV spectroscopy and sodium dodecyl sulphate polyacrylamide gel electrophoresis (SDS-PAGE). The above investigation reveals that the model protein follows degradation with eudragit S-100 in SIF with no new fragments. Therefore it may be concluded that when such peptides are formulated with enteric excipients the aggregation follows with adsorption on enteric polymers in simulated intestinal fluid.

Keywords: Serratiopeptidase, Eudragit S-100, SDS-PAGE, Spectrophotometry.

Introduction

Protein and peptides are important class of potent therapeutic drugs. However their susceptibility to chemical and physical degradation makes formulation and development more challenging than conventional drugs. This is in

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COMPARATIVE EVALUATION OF THEOPHYLLINE MICROSPHERE PREPARED USING VARIOUS BIODEGRADABLE POLYMERS

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ABSTRACT

The present investigation was to formulate theophylline loaded microspheres using different grade of chitosan, tripolyphosphate - sodium alginate and chitosan-albumin by the following methods such as phase separation emulsification, modified emulsion gelation and heat solidification method. The prepared microspheres were evaluated in terms of drug content, incorporation efficiency, entrapment studies, moisture content and *in vitro* drug release profile. Chitosan –sodium alginate combination produced microspheres with spherical, smooth surface and free flowing. It exhibited incorporation efficiency above 75% and size range between 999-934 µm. The drug release from the microspheres follows first order kinetics and the mechanism is Higuchi's diffusion. Theophylline loaded microspheres prepared from Chitosan-sodium alginate combination exhibited good sustained release characteristics and was found suitable for chronic obstructive pulmonary disease (COPD) and nocturnal asthma.

Key words: Microsphere, Chitosan, Sodium alginate, Albumin, Theophylline, Nocturnal Asthma, *in vitro* release.

INTRODUCTION

Microspheres are widely accepted and become one of the successful carriers in overcoming the problems caused by conventional therapy and also widening the therapeutic margin of the drugs currently used in clinical practice[1]. An important requirement of biodegradable polymers is that the degradation products should be non-toxic because they enter systematic circulation or result in tissue deposition. Biodegradable carrier matrices can be designed to deliver the therapeutic agent for prolonged time[2]. Theophylline, methyl xanthenes has proven efficacy in chronic obstructive pulmonary

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Design and Development of Hydrodynamically Balanced Tablet of Itopride

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ABSTRACT

Hydrodynamically Balanced System is an approach to increase the gastric residence time of drugs to stomach. This system is designed for site-specific oral drugs with low bulk density than gastric fluid so as to buoyant the dosage form in stomach to increase the residence time of the drug. In the present investigation, an attempt has been made to design hydrodynamically balanced drug delivery system for itopride using HPMC K4M, HPMC K15M and Xanthan gum polymers. Different batches of matrix tablets of itopride were prepared using various drugs to polymer ratio by direct compression method. The compressed tablets were evaluated for physical characteristics, drug content, floating lag time, floating duration, swelling study and and FTIR spectroscopy. FTIR study showed that there is no chemical interaction between drug and excipients. All the formulation passes various physicochemical tests. The formulation showed a buoyancy lag time of less than 75 Sec and floating time of more than 12hrs. From the in vitro drug release profile it was found that matrix tablet containing HPMC K 4M showed 93.88% drug release in 12 hrs. It can be concluded that itopride released from the tablet follows zero order kinetics with peppas model with non-Fickian diffusion.

Key words: Hydrodynamically Balanced Systems, Floating matrix tablet, Itopride and Xanthan gum.

INTRODUCTION

The hydrodynamic balanced system (HBS) also called Floating drug delivery system (FDDS) is an oral dosage form (capsule or tablet) designed to prolong the residence time of the dosage form within the GIT [1-2]. It is a formulation of a drug with gel forming hydrocolloids meant to remain buoyant on the stomach contents[3]. Drug Delivery Systems (FDDS) have a bulk density lower than gastric fluids and thus remain buoyant in the stomach for a prolonged period of time, without affecting the gastric emptying rate. While the system is floating on the gastric contents, the drug is released slowly at a desired rate from the system [4]. After the release of the drug, the

Inhibitory influence of mecamylamine on ethanol withdrawal-induced symptoms in C57BL/6J mice

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Several reports show the involvement of neuronal nicotinic acetylcholine receptors (nAChRs) in the behavioral effects of ethanol, including ethanol drinking and relapse. Therefore, this study evaluated the effects of mecamylamine, a nAChR antagonist, on ethanol withdrawal signs. Ethanol dependence was induced in C57BL/6J mice by ethanol liquid diet administration. Animals were provided with nutritionally balanced control liquid diet (600 kcal/l) as their sole nutrient source on day 0; from days 1 to 4, 4% v/v of ethanol, followed by 6% v/v of ethanol (from days 5 to 7), and 10% v/v of ethanol (from days 8 to 10) were incorporated into the liquid diet. On day 11, ethanol liquid diet was replaced with nutritionally-balanced control liquid diet, and ethanol withdrawal-induced physical signs were recorded. Results showed that acute administration of mecamylamine (1–4 mg/kg, intraperitoneally) dose-dependently attenuated ethanol withdrawal-induced signs, and these effects were comparable with those of diazepam (1–2 mg/kg, intraperitoneally). In addition, chronic administration of mecamylamine into ethanol diet-fed mice markedly attenuated the ethanol withdrawal sign scores, thus supporting the contention that nAChR is involved in ethanol dependence. In conclusion, our results suggest that mecamylamine exhibited inhibitory effects on ethanol withdrawal signs which could be mediated through nAChR. Behavioural Pharmacology 00:000–000 © 2019 Wolters Kluwer Health | Lippincott Williams & Wilkins.

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Keywords: addiction, diazepam, ethanol dependence, ethanol withdrawal, mice, neuronal nicotinic acetylcholine receptor

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Introduction

Ethanol is one of the most widely used addictive drugs and has numerous health consequences resulting from its chronic use. Numerous studies have shown that alcohol use and smoking frequently cooccur and both environmental and genetic factors contribute to overlap between these two behaviors. Abrupt reduction or total cessation of long-term ethanol consumption produces a well-defined cluster of symptoms called ethanol withdrawal. It is suggested that cessation is the only effective measure to prevent or limit the long-term negative effects of smoking and drinking (WHO, 2004; De Bisio and Salas, 2008). Most smokers and alcoholics are aware of the negative effects of drug abuse on health and prefer to quit, but despite of many attempts very few succeed (Gulliver *et al.*, 2006; De Bisio and Salas, 2008). A major obstacle in long-term abstinence is the presence of withdrawal symptoms, and in fact, the duration and severity of withdrawal are strong predictors of relapse to drug use (West *et al.*, 1989; Baracchi *et al.*, 2003).

Several electrophysiological and behavioral studies have shown an interaction between pentameric neuronal nicotinic acetylcholine receptors (nAChRs) and ethanol (Narahashi *et al.*, 1999; Larsson and Engel, 2004; Ford *et al.*, 2009). Reports have also shown high-to-moderate densities of nAChs receptors in mesolimbic dopaminoinnervated areas (Clarke *et al.*, 1984; Klink *et al.*, 2001; Wonnacott *et al.*, 2005; Champtiaux *et al.*, 2006). It is also reported that ethanol acts at *N*-methyl-D-aspartate (NMDA) receptors (Faingold *et al.*, 1998), which are reported to be implicated in chronic ethanol withdrawal-induced behavioral effects (Nagy, 2008; Beattie *et al.*, 2009). Interestingly, mecamylamine, a nAChR antagonist, is reported to concompetitively inhibit NMDA receptors (O'Dell and Christensen, 1988; McDonough and Shih, 1995; Fu *et al.*, 2006). Ethanol withdrawal symptoms are also related to decreased function of γ-aminobutyric acid (GABA) receptors (Lumpp *et al.*, 2003; Ali-Daoud *et al.*, 2006), and nAChRs, which are abundantly present on GABAergic neurons in different areas of the brain regulate the release of GABA (Alkondon and Albuquerque, 2002; Zarindast *et al.*, 2008; Araoz *et al.*, 2009). Moreover, mecamylamine is reported to enhance the spontaneous release of GABA in hippocampus (Kamo *et al.*, 2005).

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Research Article

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To Access the Efficacy of Rutin on 6-Hydroxydopamine induced Animal Model of Memory Impairment in Parkinson's Disease.

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ABSTRACT:
The core finding of the present study is that administration of ethanol fraction of Rutin is remarkable neuroprotective on rats against 6-Hydroxydopamine induced cytotoxicity. Parkinson's disease (PD) is a chronic and progressive neurodegeneration disease with multiple motor and non-motor features that contribute to the impairment of health-related quality of life (QOL). It is characterized by reduced movement, rigidity, and tremor. It is characterized by a preferential loss of the dopaminergic neurons of the substantia nigra pars compacta. Rutin (3-[6-O-6-deoxy-α-L-mannopyranosyl-β-D-glucopyranosyl]-5,7,3',4'-tetrahydroxyflavone-5-diosmoglucoside) was a citrus flavonoid glycoside. Flavonoids are polyphenolic compounds that occur ubiquitously in foods of plant origin. It acts as a antioxidant and can prevent injury caused by reactive oxygen species (ROS) in various ways. Rutin was found to be a neuroprotective agent. Rutin was identified in the region LDL antioxidant constituent of authority in an in vitro study. Rutin acts as a memory enhancer and an anti-oxidant Rutin treatment prevents behavioral changes, and significantly attenuated oxidative damage and improved mitochondrial complexes enzyme activities in different regions (striatum, cortex and hippocampus) of rat brain against 6-OHDA induced neurotoxicity. ICV. administration of 6-Hydroxydopamine is known to produce hypomotivity that resembles juvenile onset and advanced Parkinson's disease in rats. The results show that Rutin treatment is effective in various behavioural models, thus it could be used as an effective therapeutic agent in the management of Parkinson's disease and related conditions. We attempted to investigate the neuroprotective effect of Rutin in animal model of Parkinson's disease, and here it shows the effect of Rutin on 6-hydroxydopamine induced memory impairment in Parkinson's disease in Rodents.

KEYWORDS: 6- OHDA, ICV., Parkinson Disease, Memory impairment, Rutin.

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1. INTRODUCTION:

1.1 Parkinson Disease:

Parkinson's disease (PD) is a chronic and progressive neurodegenerative disease with multiple motor and non-motor features that contribute to the impairment of health-related quality of life (QOL) [1]. It is characterized by reduced movement, rigidity, and tremor [2]. It is characterized by a preferential loss of the dopaminergic neurons of the substantia nigra pars compacta.

Parkinson's disease (PD) was first associated with the loss of the heavily pigmented dopaminergic neurons from the substantia nigra. Later, it was postulated that the progressive loss of dopamine-producing cells in the substantia nigra pars compacta of the ventral midbrain caused PD symptomatology. In addition, PD is also associated with the presence of intracytoplasmic inclusions known as Lewy bodies (LBs), which are composed largely of alpha-synuclein [3-5].

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INHIBITION OF RENAL CALCULI FORMATION BY *CITRUS DECUMANA* FRUIT EXT[illegible] ETHYLENE GLYCOL AND AMMONIUM CHLORIDE INDUCED UROLITHIASIS RAT[illegible]

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ABSTRACT
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INTRODUCTION

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Materials

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Animals

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