An Overview of Current Developments In Oral Disintegrating Tablets (ODT’s)

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Received Date : 16.09.2013 Accepted Date : 13.11.2013

ABSTRACT

The current work focuses on need of product extension by oral dispersible tablets (ODT) of an existing marketed product in its terminal period of patent. While designing ODTs, it is mandatory to consider the physiochemical and pharmaceutical aspects of the drug as well as the biopharmaceutical aspects. Methods of preparation include freeze drying, cotton candy, molding, spray drying, compaction and mass extrusion. With a historical background on ODTs, a detailed explanation is given not only on the preparation methods, but also on various evaluation parameters. In the evaluation process, although many parameters are of that of the tablets, the standard pass range varies so as to meet the requirement of a fast disintegrating properties of the formulation.

INTRODUCTION

In the present pharmaceutical scenario, research is focusing towards patient-friendly as well as patient complied dosage forms. Thus, a vast spectrum of formulation technologies has been observed which accounts safety and efficacy of the formulations. As it takes huge investment, both in terms of cost and time, a lot of risk factors are hidden in coming out with a new molecular entity including active pharmaceutical ingredient (API). Thus towards the termination period of patency (10 to 15 years) of a product, competitors are investing research on product extensions rather than investing on a new active drug molecule offering great scope for bioavailability and bioequivalence studies (BA/BE). Oral disintegrating tablet (ODT) is one of the best examples of dosage forms supporting the above discussion since the need depends on augmenting the bioavailability and patient compliance. Various synonyms of ODT’s include Oro Dispersible tablets, Quick Disintegrating tablets, Fast Dissolving tablets, Rapid Disintegrating tablets and Rapimelts.1 The US pharmacopoeia approved all the above named terms as Oral Disintegrating Tablets (ODT’s). According to US pharmacopoeia “ODT’s are the one which disperses rapidly within 3 min in the buccal cavity before swallowing” thus these are those dosage forms that are intended to dissolve in the buccal saliva and facilitate for swallowing without water. These came into existence when the first ODT’s were formulated to increase the ease of administering vitamins in pediatric use. In the recent contemporary ODT technologies, micro particles incorporated with the API are punched into tablet form by which bitter tasted drugs can be prepared in a palatable form and also improves the stability of the drug. This ODT was not disintegrated through dissolution but by effervescence. Three companies Catalant Pharma Solutions (formerly named as Scherer DDS) in the UK, Cima labs in the US and Takeda pharmaceutical company in Japan had taken the first step for the development of ODT’s.

Table - 1 : USFDA approved ODT’S products:

<table>
<thead>
<tr>
<th>S. No</th>
<th>USFDA approved products</th>
<th>Year</th>
<th>Type of formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Claritin (Loratidine)</td>
<td>Dec 1996</td>
<td>Zydis formulation</td>
</tr>
<tr>
<td>2</td>
<td>Klonopin (Clonazepam)</td>
<td>Dec 1997</td>
<td>Zydis formulation</td>
</tr>
<tr>
<td>3</td>
<td>Maxalt (Rizatriptan)</td>
<td>Dec 1998</td>
<td>Zydis formulation</td>
</tr>
</tbody>
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July - December 2013 International Journal of Pharma Research
A validated HPTLC method for the estimation of flavonoid in the roots of *Aegle marmelos*

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Received Date : 31.07.2013 Accepted Date : 27.09.2013

ABSTRACT

*Aegle marmelos* (L) Correa., commonly known as bael, is widely used herb in Ayurveda. In the present study, densitometric method has been developed for the validation of rutin content present in the roots of *Aegle marmelos*. Compounds were separated from the ethyl acetate and methanolic extracts of the plant, by analyzing on silica gel 60F254 plate using ethyl acetate-acetic acid- formic acid -water, 100:11:11:26 (v/v) as mobile phase. Detection by measurement of absorption by 254 nm. The Rf value was found to be 0.35. The Rutin content of the extracts were calculated statistically, comparing with Rutin standard. The developed methods were found to be precise and accurate. The linear range of the method was 400 -1000 ng per band. The amount of Rutin content in ethyl acetate and methanol extracts were ranging from 0.32 - 0.54 and 0.12-0.28 mg per gm respectively. This technique will be used for routine standardization of the Rutin content of *Aegle marmelos* extracts.

ODUCTION

The roots of *Aegle marmelos* (L) Correa., commonly known as Bael belonging to the family Rutaceae used in Ayurvedic system of medicine since antiquity. This plant grows wild in the sub-Himalayan tract, central and southern India1.

Various reports indicate, the methanolic extracts from the root of *Aegle marmelos* inhibited the beating rate by approximately 50% of cultured mouse myocardial cells2. Recent studies have revealed potential health benefits of Aegle such as antibacterial3, anti ulcer4, anti allergic5 and as an effective antidiarrhoeal agent6. Alcoholic extracts of the roots and fruits showed hypoglycemic activity7 and the stem bark able to inhibit the in vitro proliferation of human tumor cell lines8.

In *Aegle marmelos*, the bioactive compounds are reported to be coumarins1, 4, alkaloids1, 8, and sterols3,4. Recently, the concept of marker-based standardization of herbal drugs is gaining momentum. Identification of major and unique compounds in herbs as markers and development of analytical methodologies for monitoring them are the key steps involved in marker-based standardization. Being the major active principles largely responsible for bio-potency of many crude drugs, flavonoids are recognized as one of the marker compound. There are some reports on the presence of total phenolics and flavonoids in roots were estimated through colorimetric technique9, but attempt to validate the Rutin content of *Aegle marmelos* are not available. Hence, in this study, a simple, rapid and sensitive HPTLC method has been described to quantify Rutin content in the roots of *Aegle marmelos* extracts.

2. Experimental

2.1. Reagents, standard solutions, and materials

Solvents used were n-hexane, chloroform, ethyl acetate and methanol which were analytical grade and obtained from Qualigens. Flavonoid standard Rutin was purchased from Himedia.

Stock solution (2mg mL⁻¹) of the standard was prepared daily in methanol immediately before use.
Prevalence of Cancer In Malwa Area of Punjab

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ABSTRACT

The objectives of our study was to identify individuals showing the warning sign /symptom of cancer, to locate & find the number of already diagnosed existing cancer cases and to determine the number of death due to cancer in the last five years. Door to door survey was conducted among the four districts of Malwa area including Faridkot, Ferozepur, Moga and Ludhiana. Based on the survey Moga was observed at higher risk of cancer cases. Moga has higher incidences of suspected, confirmed and death cases of cancer as compared to other districts. Major cause of cancer being the indiscriminate use of pesticides, consumption of tobacco, alcohol and unsafe drinking water. Hence provisions should be made to avoid use of pesticides and provide safe drinking water to the population.

Key words : Malwa, Cancer, Deaths

INTRODUCTION

Punjab is one of India’s most prosperous states and this prosperity has been largely due to its success in the every culture especially in green revolution. But unfortunately this cause of prosperity has changed the face of Punjab. Malwa area of Punjab is known as Cancer Bowl of country (SHSRC). The incidence of cancer is much more in Punjab as compared to other states of India. To aware the people’s of Punjab about the cancer and its severity a train has been started from “Bathinda to Bikaner” and has been designated as “Cancer Train”.

Cancer has become one of the ten leading cause of death in developed nation. Cancer in uncontrolled multiplication and spread of abnormal form of body’s own cells. It is estimated that of ten million new cases of cancer diagnosed every year, over half are from the developing world. National Cancer Registration Programme indicate that the leading sites of cancer are oral cavities and lungs in males and cervix and breast in females which accounts for over 50% of all cancerous deaths in India (NCCP).

METHOD

Survey Technique: Door to door survey was done in the four districts of Malwa region. Cross sectional study was conducted by the pre-designed and pre-evaluation questions. Standard questionnaire as established by govt. of Punjab was used and it was associated with interview. Questionnaire was printed in two languages Punjabi and English. Using the village profile Performa the information was recorded about village population, cropping pattern, water sources. Information was gathered if there was any member in the household who had signs and symptoms of cancer.

Sampling was random and no inclusion-exclusion criteria was maintained as the survey was conducted an almost whole population.

Study Tools; A detailed district wise environmental profile of the area was prepared. Information was gathered related to the source of water, tobacco use, use of pesticide in last 2 years. It also included inquiries on symptoms of cancer, diabetes, heart diseases and asthma among family members of household’s deaths in households during last 2 years. For any suspected case of cancer in the household, a detailed history of symptoms, signs, investigation, and treatment was taken, which was reviewed by two physicians to diagnose cancer cases.
Study of prescription pattern of antihypertensive medications in Type - 2 Diabetic patients

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ABSTRACT

Hypertension is highly prevalent in diabetic patients and its control is very important to prevent the complications. Various classes of drugs are available in the market to treat Hypertension. A cross sectional study was conducted prospectively to observe prescription pattern of antihypertensive medications in diabetic patients in a tertiary care hospital in south India. A total of 735 Diabetes Mellitus patients were admitted from Jan to Oct 2008. 49% of the total diabetic patients had hypertension. Majority of patients were in the age group of 60-69 years and male predominance was observed. Monotherapy was commonly prescribed to about 52.2% of the patients. Among monotherapy, calcium channel blockers (40.4%) were the mostly prescribed drug class. Out of the calcium channel blockers, amlodipine (93.4%) was the most prescribed drug. In dual drug therapy, combination of calcium channel blockers and angiotensin converting enzyme inhibitors were the most prescribed drugs in about 19.2% patients. Antihypertensive therapy for patients with complications and those with other co morbidities along with hypertension and diabetes, calcium channel blockers were the mostly prescribed class of drugs except for patients with Ischemic heart disease. Calcium channel blockers are the most commonly prescribed drug in diabetic hypertensives.

Key words : Hypertension, diabetes, prescription pattern, calcium channel blockers

INTRODUCTION

Diabetes mellitus (DM) comprises a genetically and clinically heterogeneous group of chronic metabolic disorders that are characterized by hyperglycemia.1 Hypertension in diabetes is a widespread, substantial, and treatable cardiovascular risk factor. The prevalence of hypertension in the diabetic population is 1.5–3 times higher than that of nondiabetic age-matched groups. Hypertension ultimately affects approximately 20–60% of patients with type 2 DM, depending on age, ethnicity, and obesity.2

The Joint National Committee (JNC) VII guidelines for treating hypertension are consistent with recommendations from the American Diabetes Association (ADA) and the World Health Organization (WHO). Recommended therapy for Hypertension with Diabetes should begin with an Angiotensin-converting enzyme (ACE) inhibitor or an AngiotensinII receptor blockers (ARBs), titrated upward as needed. If Blood Pressure remains above the target level (130/80 mm Hg), either a thiazide diuretic or Calcium Channel Blockers (CCBs) should be added to the treatment regimen.3

Kasturba Hospital is a tertiary care university hospital in the west coast of India. Approximately 2000 diabetic patients are treated as inpatients every year. Nearly 50% of these patients present with hypertension along with diabetes, and various classes of drugs are used for treating hypertension. Treatment targets from guidelines cannot always be achieved in everyday clinical practice. Hence it is important to monitor trends in hypertension control in defined population (Type 2 Diabetes), as limited data exists on the patterns of anti-hypertensive use in this population and if they are consistent with current guidelines. Thus there is a need exist for robust data from the specified population through a
Anti-inflammatory effect of Curcuma longa extract- An In vitro and In vivo study

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ABSTRACT
Curcumin is one of the major constituents of Curcuma longa has lots of medicinal values in traditional medicine. This dried rhizome powder extract had been studied extensively in animal models and proved with anti-inflammatory activity and its effectiveness in reducing inflammation in osteoarthritis, rheumatoid arthritis and as an antiproliferative agent in few malignancies. To determine the effect of C. longa extract in histamine induced Bronchospasm in animal model. To compare anti-inflammatory activity and percentage inhibition of fibroblast cell growth of C. longa extract with methyl prednisolone. The dried rhizomes of Curcuma longa were powdered to prepare successive extract as per the standard technique using chloroform and ethanol as solvents adapting Soxhlation procedure. In fibroblast cell growth study 100, 300, 600, 900 and 1200µg of the extract was used. To assess the bronchodilatation 50, 100, 200mg/kg dose of curcumin extract was used. Guinea pigs exposed with three different doses of extract were studied at weekly interval after daily oral administration to prevent the histamine aerosol induced bronchospasm using histamine chamber to observe the occurrence of PCD (Preconvulsive Dyspnea). In connective tissue fibroblast cell culture study after 24h of the drugs (prednisolone or extract) treatment, the cell viability was measured by 10µl of MTT. The intensity of formazan blue formation was measured at 570nm. The IC50 was calculated by using Grapad PRISM software. C. longa extract produces definite connective tissue fibroblast cell growth inhibition when compared to prednisolone and protect animals against histamine induced bronchospasm at the doses level between 100-200mg/day. C. longa extract has a role in chronic inflammation based on the inhibitory role on connective tissue cell fibroblast proliferation when compared with the known established anti-inflammatory agent methyl prednisolone.

Key words : Curcumin Anti-inflammatory Fibroblast cell

INTRODUCTION
Curcumin is an active principle obtained from the plant curcuma longa which is not a new therapeutic tool but proved long time back with lots of medicinal values in traditional medicine.1 The dried rhizome powder extract had been studied extensively in animal models and proved with anti-inflammatory activity.2 Many human studies had proved its anti-inflammatory action and its effectiveness in reducing inflammation in osteoarthritis and its benefits in rheumatoid arthritis.3 Because this extract widely used for anti-inflammatory action in arthritis and help in healing a wound we had planned to compare the effectiveness with known anti-inflammatory agent steroid. Many animal and in vitro studies express the effectiveness of curcumin shown to promote apoptosis, inhibit telomerase activity in tumor development few malignancies.4 Many Research reported that yellow pigment curcumin has the ability to modulate the COX-2, inducible nitric oxide synthase (iNOS) to bring out the anti-inflammatory changes.5 These references strongly reflect the anti-inflammatory potency but no comparison between the strongest anti-inflammatory agent corticosteroids. Hence this study had planned to rule out the potency of C. longa extract in fibroblast cell culture model using methyl prednisolone as a standard anti-inflammatory agent.
Pharmacoeconomic Evaluation of add on Therapy of Vildagliptin Against Pioglitazone In Type 2 Diabetic Patients: A Prospective Observational Study

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Received Date : 13.09.2013 Accepted Date : 18.11.2013

ABSTRACT
Pharmacoeconomic evaluation of addition of vildagliptin against pioglitazone by using HbA1C reduction as the primary outcome. Materials and Methods: One year study was designed to compare vildagliptin against pioglitazone as add on therapy in type 2 diabetes patients, inadequately controlled by other established combination therapies. Patients added with vildagliptin (n=62) or pioglitazone (n=48) were selected. The primary efficacy endpoint was change in HbA1c from baseline to follow up value. Secondary endpoints included FBS and PPBS. Patient’s medication adherence was assessed using Morisky Medication Adherence Scale (MMAS-8) and treatment satisfaction was assessed by Diabetes Treatment Satisfaction Questionnaire (DTSQ). Direct medical costs were also analyzed. Results: Both the drugs exhibited significant reduction in HbA1c. FBS was found to be more reduced in patients using pioglitazone while PPBS was more effectively reduced by vildagliptin. Majority of patients exhibited excellent adherence in case of both drug groups. Satisfaction was found to be comparatively more with pioglitazone group. Statistical significance was not established in any of these outcomes. (P > 0.05) Individual drug cost was significantly less with pioglitazone while PPBS was more effectively reduced by vildagliptin. Majority of patients exhibited excellent adherence in case of both drug groups. Satisfaction was found to be comparatively more with pioglitazone group. Statistical significance was not established in any of these outcomes. (P > 0.05) Individual drug cost was significantly less with pioglitazone. Conclusion: Vildagliptin is found non inferior to pioglitazone in glycemic control, as add on therapy, with good tolerability profile. But cost analysis clearly indicates that vildagliptin is much expensive and contributes to the financial burden in developing country like India where majority of patients lack health insurance and diabetes become a common disease even in very low income people as well. All these factors emphasize importance of pioglitazone with unique action on adipose tissues.

Key words : Gliptins, Pioglitazone, Add on therapy, HbA1c, Direct medical cost.

INTRODUCTION
Diabetes is a chronic metabolic disease with alarming increase in prevalence. According to recent estimates, approximately 285 million people worldwide (6.6%) in the 20–79 year age group have diabetes and by 2030, 438 million people (7.8%) of the adult population is expected to have diabetes¹. According to Indian Council of Medical Research – India Diabetes (ICMR-INDIAB) Study, prevalence in India is progressing rapidly across the nation, reaching a total of 62.4 million persons with diabetes.² Because of the rising prevalence, the management of this chronic condition will become a serious clinical and financial burden to patients as well as all health-care systems³ Although lifestyle modification is the most cost-effective intervention for the prevention of diabetes, this alone may not be sufficient to control progression of disease for many of the patients⁴. Oral anti diabetic drugs (OADs) are the first line of drug treatment for type 2 diabetes, in which metformin is the first drug of choice worldwide. However, the progressive nature of this disease usually requires a combination of two or more oral agents in the long term, often before initiating insulin therapy⁵. Sulfonylurea and/or pioglitazone are used in case of
Neutralisation of Cobra Venom Effects by Indian Medicinal Plants

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Received Date : 24.10.2013 Accepted Date : 12.11.2013

ABSTRACT

Ayurvedic system of medicine makes use of hundreds of plants in the treatment of snakebite. Although these are time tested, there has been no scientific validation of their efficacy. To develop herbal remedies in this area, detailed evaluation of folkloric plants in a systematic manner is necessary. In the present research, the aqueous extracts of the areal parts of Hedyotis corymbosa, fruit peel of Punica granatum and tubers of Cyperus rotundus were tested for the neutralization of various snake venom effects. The extracts were prepared by the methods adopted by Vishavaidya’s in Kerala and tested against freeze dried cobra venom (Naja naja). Parameters like inhibition of lethal activity and neutralization of various enzyme activities were studied to evaluate the anti venom effect. All the three extracts antagonized various venom effects and prevented lethality in albino mice. The results of the study proved the venom neutralizing capacity of the extracts and thus support their traditional use in snake bite therapy.

Key words : Naja naja, antivenom activity, Hedyotis corymbosa, Punica granatum, Cyperus rotundus

INTRODUCTION

Snake bite is a major cause of death in many parts of the world especially in India. It is estimated that deaths due to snake bite in the Indian subcontinent is more than 25000 every year1. Naja naja and Viper russelli are the common snakes in India and a large number of deaths occur due to envenomation by these snakes2. The most effective and accepted therapy for snake bite is the immediate administration of anti venom. In spite of the high cost for this therapy, there are many demerits including hypersensitivity and untoward serum reactions3. In this context, many attempts have been made over the years for the development of snake venom antagonists from plant sources. A number of plants have been used by traditional healers for the treatment of snake bite and many of these are not scientifically evaluated4. Hedyotis corymbosa (Rubiaceae) is a spreading, annual weed plant found in the fields throughout India, usually found during the rainy season. It is well known for its effectiveness in jaundice and other liver disorders. Cyperus rotundus (Cyperaceae) is a perennial plant mentioned in Ayurveda for treating fevers, digestive disorders, wounds, bruises etc. Punica granatum (Punicaceae) is a fruit bearing deciduous shrub cultivated throughout India. In ancient medicine, it has been used for treating diarrhea, dysentery, haemorrhoids and to arrest bleeding. The present study investigates the venom antagonizing activity of these three plants used for snake bite therapy by the ‘Vishavaidyas’ (traditional healers of venom) in Kerala.

MATERIALS AND METHODS

Venom :

The freeze dried cobra venom was obtained from Irula snake catcher’s Industrial co-operative society, Chennai, India. It was dissolved in 0.9% saline and centrifuged. The supernatant was used as venom and expressed in terms of dry weight.
Evaluation of Antioxidant and anti Inflammatory Activity of Hippeastrum puniceum.(Lam.)Voss. Bulb Extract

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ABSTRACT

Inflammation is a major cause behind various chronic diseases like Rheumatoid arthritis, Ulcerative colitis, Atherosclerosis, Inflammatory bowel syndrome, Crohn’s disease, Bronchial asthma etc. The acceptance level of many synthetic anti-inflammatory drugs in the market had been decreased over the years due to their unwanted effects mainly gastrointestinal problems. Thus many traditionally used medicinal plants were scientifically evaluated for the anti-inflammatory activity. Antioxidant activity being the prime factor in preventing inflammation. Thus most of the plants with antioxidant potency exhibits anti-inflammatory activity also. In the present study a traditionally used plant with anti-inflammatory activity, Hippeastrum puniceum.(Lam.) Voss(Amaryllidaceae) was selected for evaluating antioxidant and anti inflammatory activity by in-vitro models. Antioxidant activity was evaluated by iron chelating and total antioxidant assay. Protein denaturation and Proteinase inhibition methods were used for evaluating anti-inflammatory activity. A preliminary phytochemical analysis was carried out, which showed the presence of many active constituents like alkaloids, carbohydrates, flavonoids, phenolics, terpenoids amino acids and saponins. The results of the study revealed the antioxidant and anti-inflammatory potential of aqueous bulb extract which could be attributed to the presence of flavonoids and phenolics.

Keywords : Anti-inflammatory, Antioxidant, Hippeastrum puniceum, Preliminary phytochemical screening.

INTRODUCTION

Avery large population of developing countries still relay on herbal medicine and India has a rich tradition of herbal medicine as evident from Ayurveda. Over the years the acceptance of synthetic drugs had declined drastically due to their unwanted side effects, toxicity and inefficiency. In addition to the emergence of new infectious diseases, proliferative disorders such as cancer and growing multidrug resistance in pathogenic microorganisms have prompted renewed interest in the discovery of potential drug molecules from medicinal plants. Traditional medicine, including tribal medicine is to be studied and documented, as a part of preservation of our ancient knowledge and culture.

Antioxidants are our first line of defence against free radical damage, and are critical for maintaining optimum health and wellbeing. Apart from the dietary sources, Indian medicinal plants also provide antioxidants. Most of the plants with antioxidant potential do prevent inflammation, thus the antioxidant potential is an essential factor in curing inflammatory disorders. As the demand of herbal medicine is increasing in both developing and developed countries, many studies have been conducted on various medicinal plants and their antioxidant and anti-inflammatory potential were successfully proven.

The present study was undertaken as a small step in scientifically proving the claimed pharmacological use of the plant Hippeastrum puniceum in preventing inflammation. The bulbs of the plant were traditionally used in curing tumours and various inflammatory disorders. Some of tribal community used the bulbs in healing wounds and in treating piles. It is a bulbous perennial ornamental plant belonging to Amaryllidaceae family distributed worldwide (Figure 1). Although this plant has been used in the tribal and folkloric medicine for many decades, no attempts were so far made to scientifically evaluate its therapeutic utility. The present study is undertaken to evaluate the in-vitro antioxidant