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Formulation and Evaluation of Bioadhesive Buccal Tablets of Esomeprazole

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Abstract- Esomeprazole is an anti-ulcerative agent (proton pump inhibitor) which is used in treating gastro esophageal reflux disease. The main objective of the study was to formulate and evaluate bioadhesive buccal tablets to overcome the degradation in the acidic media of gastrointestinal tract, and to avoid the first pass metabolism in liver. Bioadhesive buccal tablets were prepared by direct compression method using bioadhesive polymers like Xanthane gum, Chitosan, guar gum and hydroxy propyl methyl cellulose LV- 15 in different ratios. The physicochemical compatibility of drug and polymers was studied by FT-IR spectroscopy. Prepared tablets were evaluated for permeation study through porcine buccal mucosa, *in vitro* drug release, bioadhesion strength, swelling index, moisture absorbance, surface pH, *ex vivo* residence time. Among the prepared formulation containing guar gum (Fc2) was found to be optimized formulation which showed the higher flux 2.471 mg $hr^{-1}cm^{-2}$ than the pure drug solution (0.496 $mghr^{-1}cm^{-2}$), and bioadhesive strength of 2.68±0.03 N and 0.95±0.08 mJ. *In vitro* percentage drug release of optimized formulation was 98.32%±0.23 at the end of 6 hours. The Fc_2 values of percentage drug release put in kinetic data, it followed Higuchi model (R^2 is 0.982).

Keywords: Bioadhesive buccal tablet, Chitosan, Esomeprazole, Guar gum, Xanthane gum.

I. INTRODUCTION

The buccal delivery is defined as the drug administration through the mucosal membranes lining the cheeks and lips (buccal mucosa).The future challenge of pharmaceutical scientists is to develop effective non-parenteral delivery of intact proteins and peptides to the systemic circulation [1]. Based on our current understanding of biochemical and physiological aspects of absorption and metabolism of many biotechnologically produced drugs, they cannot be delivered effectively through the conventional oral route [2]. Because after oral administration many drugs are subjected to pre-systemic clearance extensively in liver, which often leads to a lack of significant correlation between membrane permeability, absorption and bioavailability [3]. Difficulties associated with the parenteral delivery and poor oral bioavailability provided the impetus for exploring alternative routes for the delivery of such drugs. These include routes such as pulmonary, ocular, nasal, rectal, buccal, sublingual, vaginal, and transdermal [4].

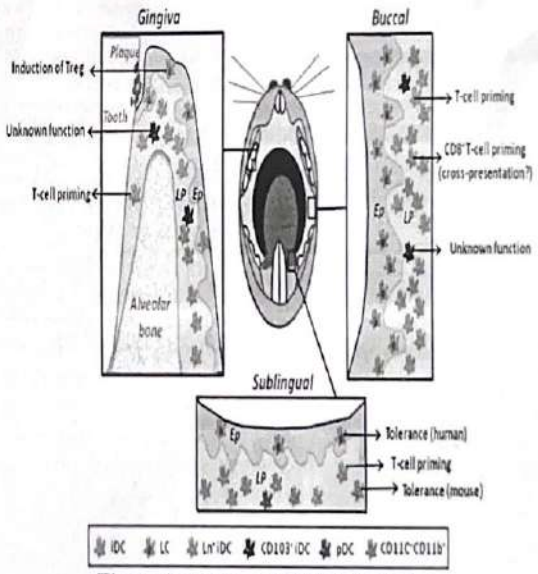

Figure 1: Anatomy of buccal mucosa

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Advantages of buccal release system

- Administration of compounds via the mucosa of the oral cavity avoids pre-systemic metabolism in the GIT.
- The buccal mucosa is a well vascularized tissue & is easily accessible for both application & removal of delivery device.
- It's having facility to include permeation enhancer/enzyme inhibitor (or) pH- modifier in the formulation.
- The drug is protected from degradation due to pH and digestive enzyme of the middle GI tract, Avoid the GIT irritation.
- Improved patient compliance.
- Avoid the hepatic first pass metabolism
- Easy administration for those is not able to swallow.
- No need of water for administration, painless administration.
- Produce site specific action [5].

Disadvantages of buccal release system

- The low permeability of the buccal membrane specifically when compared to the sublingual membrane and a smaller surface area.
- The total surface area of the membranes of the oral cavity available for drug absorption is 170 cm^2 of which ~50 cm^2 represents non-keratinized tissues, including the buccal membrane.
- The continuous secretion of saliva (0.5–2 L/day) leads to subsequent dilution of the drug.
- Swallowing of saliva can also potentially lead to the loss of dissolved or suspended drug and ultimately the involuntary removal of the dosage form.
- In addition to the swallowing, there is another inconvenience of such dosage form during drinking and eating by the patient [6].

The aim of present work is to formulate and evaluate bioadhesive buccal tablets of anti ulcer drug Esomeprazole to release the drug unidirectional in the buccal cavity in order to avoid first pass metabolism, prolonging duration of action of drug. To enhance the bioavailability of drug by using bioadhesive polymers like Xanthane gum, Chitosan, Guar gum, and Hydroxy propyl methyl cellulose LV-15 in different ratios.

II. MATERIALS AND METHODS

Esomeprazole was obtained as a gift sample from Aurobindo Ltd., (Hyderabad). Hydroxy Propyl Methyl Cellulose (HPMC LV-15) (Rohm Pharma GmbH, Germany), Chitosan, Guar gum, Xanthane gum were used as polymers. Micro Crystalline Cellulose (SD Fine Chemicals) served as diluents. Magnesium oxide, methyl paraben, PVP K-30, Menthol, Talc, Magnesium stearate is obtained from SD Fine Chemicals.

Preparation method

Buccal tablets were prepared by direct compression method, before going to direct compress the all ingredients were screened through sieve no.100. Esomeprazole was mixed manually with different ratios of Xanthane gum, Chitosan, Guar gum and HPMC LV-15 as mucoadhesive polymers and microcrystalline cellulose as diluents, magnesium oxide as an alkaline stabilizer, PVP K-30 as a dry binder, Menthol as permeation enhancer for 10 min. The blend was mixed with Magnesium stearate for 3-5 min and then compressed into tablets by the direct compression method using 6 mm flat faced punches. The tablets were compressed using a sixteen station rotary tablet-punching machine [7].

Table 1: Composition of buccal tablets of Esomeprazole

	Formulation Code								
Ingredients (mg)	**Fa1**	**Fa2**	**Fa3**	**Fb1**	**Fb2**	**Fb3**	**Fc1**	**Fc2**	**Fc3**
Esomeprazole	20	20	20	20	20	20	20	20	20
Xanthane gum	10	15	20	–	–	–	–	–	–
Chitosan	–	–	–	10	15	20	–	–	–
Guar gum	–	–	–	–	–	–	10	15	20
HPMC LV-15	10	15	20	10	15	20	10	15	20
MCC	21.65	11.65	1.65	21.65	11.65	1.65	21.65	11.65	1.65
MgO	50	50	50	50	50	50	50	50	50
Methyl paraben	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15
PVP K-30	3	3	3	3	3	3	3	3	3
Menthol	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Magnesium stearate	3	3	3	3	3	3	3	3	3
Talc	1	1	1	1	1	1	1	1	1

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Effect of Hydrophillic Polymers on Gastro Retentive Floating Matrix Tablets of Lisinopril

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ABSTRACT

In the present research work gastro retentive floating matrix formulation of Lisinopril by using various hydrophilic polymers were developed. Then the formulation was developed by using different concentrations of polymers of HPMC K 4 M, HPMC K 15 M and HPMC K 100M as polymeric substances. The formulation blend was subjected to various preformulation studies, flow properties and all the formulations were found to be good indicating that the powder blend has good flow properties. Among all the formulations the formulation F5 with HPMC K 15 M was retarded the drug release (96.73 %) desired time period. The dissolution data of optimized formulation (F5) was subjected to release kinetics; from the release kinetics data it was evident that the formulation followed Zero order release kinetics (R^2=0.996).

Keywords: Lisinopril, Floating tablets. HPMC K 4 M, HPMC K 15 M, HPMC K 100 M, Release Kinetics.

INTRODUCTION

Oral delivery of drugs is the most preferable route of drug delivery. Oral route is considered most natural, uncomplicated, convenient and safe due to its ease of administration, patient compliance and flexibility in formulation and cost effective manufacturing process [1]. Many of the drug delivery systems, available in the market are oral drug delivery type systems Pharmaceutical products designed for oral delivery are mainly immediate release type or conventional drug delivery systems, which are designed for immediate release of drug for rapid absorption [2].

Tablets are the most conventional and economic pharmaceutical formulations prepared to release the medicament after oral administration. Time and cost effectiveness make tablets still the favored dosage forms. The performance of tablet depends on its matrix and surface properties, which govern the mechanical and chemical properties of tablet. Conventional release tablets result in relatively increased number of dosages. These conventional tablets may show more fluctuations in plasma drug concentration. To avoid the fast sub-therapeutics level of the drug another dose is usually given for treating chronic diseased conditions [3].

To overcome the limitation of conventional tablets, development of various modified release drug products is gaining more attention to control the drug release [4]. Modified release products use polymers to alter the rate of drug release under controlled pH conditions of gastrointestinal tract (G.I.T). The term controlled-release was originally used to depict various extended release formulations such as prolonged action, sustained-release, slow-release, long-action and programmed delivery [5]. The basic rational of controlled or sustained release formulation is to control drug at target site, avoiding the frequent dosing and improve efficacy effect of a drugs by altering its pharmacokinetics and pharmacodynamic profile [6].

However, such controlled delivery systems extend limited advantages for bioactives having narrow therapeutic window. Various drugs such as gliclazide and pioglitazone are absorbed from duodenum and jejunum [7]. However, limited absorption may be possible at these sites due to the quick passage of dosage form (about 1-2 h) [8-11]. To meliorate the

oral availability of these therapeutics, the retention time of the delivery system need to be extended in the stomach, so that the drug will be available in the solution form when it reached to the area from where its maximum absorption is possible [12]. This can be successfully accomplished by developing gastroretentive controlled release carrier that can resist the grinding, crushing, contractions, and peristaltic movements and allow prolonged drug release [13-15]. Retention for prolonged period of time leads to improved oral bioavailability, and clinical efficacy, also reduces the number of dosage administration and improves patient compliance [16]. Hence, extended release drug delivery systems with gastric retention are recommended as potential delivery systems for effective drug delivery [17].

Advantages of Floating tablets

- Floating drug delivery offers several applications for drugs having poor Bioavailability because of the narrow absorption window in the upper part of the gastrointestinal tract.
- It retains the dosage forms at the site of absorption and thus enhances the Bioavailability.
- Sustained Drug Delivery
- Site Specific Drug Delivery
- Improved plasma levels [18].

Disadvantages

- High variability in gastric emptying time due to variations in emptying process.
- Unpredictable bioavailability.
- Floating system is not feasible for those drugs that have solubility or stability problem in gastric fluids.
- The dosage form should be administered with a minimum of glass full of water.
- The drugs, which are absorbed throughout gastro-intestinal tract, which under go first-pass metabolism (Nifedipine, Propranolol etc.) are not desirable candidate.
- Some drugs present in the floating system causes irritation to gastric mucosa [19].

Absorption of Lisinopril is slow, variably, and incomplete (~30%) after oral administration. To overcome this limitation of Lisinopril, the present study was designed to develop floating gastroretentive tablets by wet granulation technique. Lisinopril is lysine derivative of enalapril. It is competitive inhibitor of angiotensin converting enzyme which inhibits conversion of angiotensin I into angiotensin II which is potent vasoconstrictor. Angiotensin II causes the release of aldosterone from adrenal cortex. Lisinopril is used primarily in treatment of hypertension, congestive heart failure, and heart attacks, and in preventing renal and retinal complications of diabetes. Its indications, contraindications, and side effects are as those for all ACE inhibitors [20].

The main aim of the Research work is to study the effect of polymers on drug release of gastro retentive floating tablets of Lisinopril using various hydrophilic polymers and Sodium Bicarbonate as effervescent agent. The main objectives include optimizing the concentration and viscosity of various hydrophilic polymer of HPMC. To formulate and perform the various *in vitro* evaluation test parameters for Gastro retentive floating tablets.

METHODOLOGY

The entire research work was followed the plan of methodology [21]

1. Literature survey
2. Selection and procurement of suitable drug candidate and excipients.
3. Preparation of standard graph of Lisinopril.
4. Preformulation studies
   - Drug and excipient compatibility studies using FTIR.
5. Formulation of floating tablets of Lisinopril
   - Optimization of sodium bicarbonate
   - Formulation development of Lisinopril floating tablets using various polymers
6. Evaluation parameters
   - Pre compression parameters
   - Angle of repose
   - Bulk density
   - Tapped density
   - Carr's Index
   - Hausners ratio
   - Post compression parameters
   - Thickness

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SIMULTANEOUS ESTIMATION OF SERTRALINE AND ALPRAZOLAM IN ITS BULK AND PHARMACEUTICAL DOSAGE FORM BY RP-HPLC METHOD

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Abstract:

A simple, accurate, rapid and precise isocratic reversed-phase high- performance liquid chromatographic method has been developed and validated for simultaneous determination of Sertraline and Alprazolam in tablets. The chromatographic separation was carried out on an cosmosil packed column 5c-18 ms II (250×4.6 i.d) with a mixture of acetonitrile: methanol: phosphate buffer pH 3 adjusted with orthophosphoric acid (20.50:30, v/v) as mobile phase; at a flow rate of1.0 ml/min. UV detection was performed at 239 nm. The retention times were 4.915 and 8.056 min. for Sertraline and Alprazolam respectively. Calibration plots were linear (r^2>0.998) over the concentration range 10-60 µg/ml for sertraline and 10-60 µg/ml Alprazolam. The method was validated for accuracy, precision, specificity, linearity, and sensitivity. The proposed method was successfully used for quantitative analysis of tablets. No interference from any component of pharmaceutical dosage form was observed. Validation studies revealed that method is specific, rapid, reliable, and reproducible. The high recovery and low relative standard deviation confirm the suitability of the method for routine determination of Sertraline and Alprazolam in bulk drug and tablet dosage form.

Keywords: *Sertraline, Alprazolam, RP-HPLC, Simultaneous estimation.*

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Please cite this article in press B.Sanghavi et al, ***Simultaneous Estimation Of Sertraline And Alprazolam In Its Bulk And Pharmaceutical Dosage Form By RP-HPLC Method.,*** *Indo Am. J. P. Sci, 2022; 09(12).*

INTRODUCTION:

Sertraline is indicated for the management of major depressive disorder (MDD), post-traumatic stress disorder (PTSD), obsessive-compulsive disorder (OCD), panic disorder (PD), premenstrual dysphoric disorder (PMDD), and social anxiety disorder (SAD).[1] Common off-label uses for sertraline include the prevention of post stroke depression, generalized anxiety disorder (GAD), fibromyalgia, premature ejaculation, migraine prophylaxis, diabetic neuropathy, and neurocardiogenic syncope.[2] Sertraline selectively inhibits the reuptake of serotonin (5-HT) at the presynaptic neuronal membrane, thereby increasing serotonergic activity. This results in an increased synaptic concentration of serotonin in the CNS, which leads to numerous functional changes associated with enhanced serotonergic neurotransmission.[3] These changes are believed to be responsible for the antidepressant action and beneficial effects in obsessive-compulsive (and other anxiety related disorders). It has been hypothesized that obsessive-compulsive disorder, like depression, is also caused by the disregulation of serotonin.[4] IUPAC name of Sertraline is (1S,4S)-4-(3,4-dichlorophenyl)-N-methyl-1,2,3,4-tetrahydronaphthalen-1-amine. Molecular Formula is $C_{17}H_{17}NCl$. Molecular Weight is 306.23.

Alprazolam is indicated for the acute treatment of generalized anxiety disorder in adults.[5] Alprazolam is also indicated, either as a standard or extended-release formulation, for the treatment of panic disorder with or without agoraphobia in adults. Neurotransmission relies on excitatory and inhibitory signalling. γ-aminobutyric acid (GABA) type-A receptors (GABAARs) are members of the pentameric ligand-gated ion channel (PLGIC) superfamily located synaptically and perisynaptically to mediate phasic inhibition and extrasynaptically to mediate tonic inhibition. GABAARs comprise a variety of subunits from a homologous family whose members are named based on sequence identity as one of α1-6, β1-3, γ1-3, δ, ε, θ, π, and ρ1-3. IUPAC name of Alprazolam is 3-O-(1-benzhydrylazetidin-3-yl) 5-O-propan-2-yl 2-amino-6-methyl-4-(3-nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate. Molecular formula is $C_{33}H_{34}N_4O_6$. Molecular Weight is 582.6. Alprazolam is soluble in organic solvents such as ethanol, DMSO, and dimethyl formamide (DMF), which should be purged with an inert gas. The solubility of Alprazolam in ethanol is approximately 15 mg/ml and approximately 30 mg/ml in DMSO and DMF. Alprazolam is sparingly soluble in aqueous buffers.

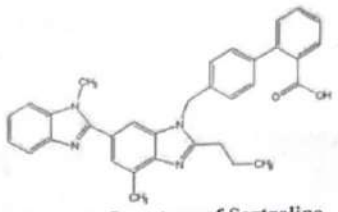

Figure 1: Structure of Sertraline

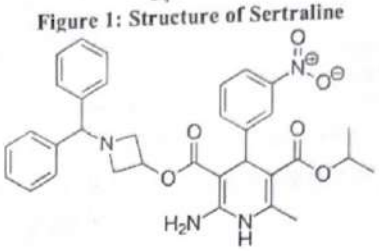

Figure 2: Structure of Alprazolam

Literature survey shows that a number of methods have been reported for estimation of Sertraline and Alprazolam individually or in combination with other drugs. [6-10] However, there is only few HPLC methods are reported for the simultaneous estimation of these drugs in combined dosage forms. I got better results than already published one. The aim of the present study was A New Rp-Hplc Method for Simultaneous Estimation of Sertraline and Alprazolam in Its Bulk and pharmaceutical Dosage Form and Its Force Degradation Studies as Per Ich.

MATERIALS AND METHODS:

Chemicals and Reagents: Sertraline and Alprazolam were Purchased from Sun Pharma India Limited. NaH_2PO_4 was analytical grade supplied by Finerchem limited, Orthophosphoric acid (Merck), and Water and Methanol for HPLC (Lichrosolv (Merck).

Equipment and Chromatographic Conditions: The chromatography was performed on a Waters 2695 HPLC system, equipped with an auto sampler, UV detector and Empower 2 software. Analysis was carried out at 239 nm with column cosmosil packed column 5c-18 ms II (250×4.6 i.d), dimensions at 25°C temperature. The optimized mobile phase consists of acetonitrile: methanol: phosphate buffer pH 3 adjusted with orthophosphoric acid (20:50:30, v/v). Flow rate was maintained at 1 ml/min.

Preparation of solutions:

Standard solutions and calibration graphs for chromatographic measurement:

Stock standard solutions were prepared by dissolving separately 5 mg of Alprazolam and

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SIMULTANEOUS ESTIMATION OF PRAZOSIN AND POLYTHIAZIDE IN BULK AND FIXED DOSE COMBINATION (TABLETS) BY RP-HPLC

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Abstract:

A simple, Accurate, precise method was developed for the simultaneous estimation of the Prazosin and Polythiazide in Tablet dosage form. Chromatogram was run through Std Discovery C18 150 x 4.6 mm, 5µ. Mobile phase containing Buffer 0.1%OPA: Acetonitrile taken in the ratio 60:40 was pumped through column at a flow rate of 1 ml/min. Buffer used in this method was 0.1% OPA buffer. Temperature was maintained at 30°C. Optimized wavelength selected was 270.0 nm. Retention time of Prazosin and Polythiazide were found to be 2.316 min and 3.176. %RSD of the Prazosin and Polythiazide were found to be 0.5 and 0.7 respectively. %Recovery was obtained as 100.49% and 100.40% for Prazosin and Polythiazide respectively. LOD, LOQ values obtained from regression equations of Prazosin and Polythiazide were 0.079, 0.240 and 0.03, 0.08 respectively. Regression equation of Prazosin is y = 50050x + 7773 and of Polythiazide was y = 95434x + 6175. Retention times were decreased and run time was decreased, so the method developed was simple and times were decreased and run time was decreased, so the method developed was simple and economical that can be adopted in regular Quality control test in Industries.

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Please cite this article in press M. Suma Pallavi et al, ***Simultaneous Estimation Of Prazosin And Polythiazide In Bulk And Fixed Dose Combination (Tablets) By RP-HPLC.,*** *Indo Am. J. P. Sci, 2022; 09(12).*

NTRODUCTION:

Prazosin is indicated for the treatment of hypertension (high blood pressure). Prazosin can be given alone or given with other blood pressure-lowering drugs, including diuretics or beta-adrenergic blocking agents Label. Prazosin does not negatively impact lung function, and therefore may be used to manage hypertension in patients who are asthmatic or patients with chronic obstructive lung disease It belongs to the class of drugs known as alpha-1 antagonists.[1] Recently, many studies have evaluated the benefits of this drug in controlling the symptoms of post-traumatic stress disorder (PTSD) and associated nightmares.[2] IUPAC name 2-[4-(furan-2-carbonyl) piperazin-1-yl]-6,7-dimethoxyquinazolin-4-amine. Chemical formula $C_{19}H_{21}N_5O_4$. Molecular weight 383.41. Prazosin (hydrochloride is soluble in the organic solvent DMSO at a concentration of approximately. 0.1 mg/ml.

Polythiazide a thiazide diuretic with actions and uses similar to those of hydrochlorothiazide. As a diuretic, polythiazide inhibits active chloride reabsorption at the early distal tubule via the thiazide-sensitive Na-Cl cotransporter (TSC), resulting in an increase in the excretion of sodium, chloride, and water. Thiazides like polythiazide also inhibit sodium ion transport across the renal tubular epithelium through binding to the thiazide sensitive sodium-chloride transporter. This results in an increase in potassium excretion via the sodium-potassium exchange mechanism. The antihypertensive mechanism of polythiazide may be mediated through its action on carbonic anhydrases in the smooth muscle or through its action on the large-conductance calcium-activated potassium (KCa) channel, also found in the smooth muscle. IUPAC name 6-chloro-2-methyl-1,1-dioxo-3-{[(2,2,2-trifluoroethyl) sulfanyl]methyl}-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulfonamide Chemical formula $C_{11}H_{13}ClF_3N_3O_4S_3$ Molecular weight 439.88.

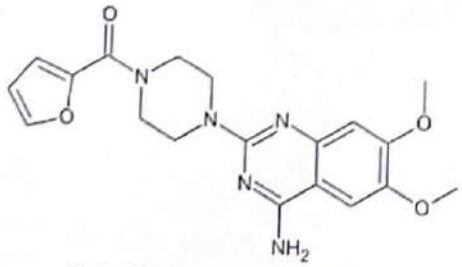

Figure 1: Structure of Prazosin

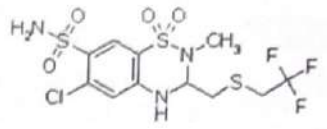

Figure 2: Structure of Polythiazide

Prazosin and Polythiazide is a fixed dose combination drug for treatment of hypertension. Literature review reveals that very few analytical methods has been reported for the determination of Prazosin and Polythiazide individually and with other combinations which includes high performance liquid chromatography (HPLC)[3-19], UV-Visible-Spectrophotometric[20-23] and LC-MS[24,25]. The present study was intended to develop a new validated method for the simultaneous estimation of Prazosin and Polythiazide with forced degradation studies as per ICH guidelines[26].

MATERIALS AND METHODS:

Chemicals and Reagents: Prazosin and Polythiazide were obtained as a gift sample from Sun pharma India Pvt. Ltd, Hyderabad. Sodium hydroxide, hydrochloric acid, Methanol for HPLC (Merck), Acetonitrile for HPLC (Merck) and Water for HPLC (Merck).

Equipment and Chromatographic Conditions: The chromatography was performed on a HPLC equipped with Auto Sampler and PDA Detector and Empower 2 software. Analysis was carried out at 270 nm with column Discovary 150 x 4.6 mm, 5µ dimensions at 0^0C temperature. The optimized mobile phase consists of0.1% Ortho phosphoric: Acetonitrile in the proportion of 60:40, Flow rate was maintained at 1.0 ml/min and run time for 6 min at Temperature 30 ° C

Preparation of solutions:

Preparation of buffer:

0.1% OPA Barrier: 1ml of ortho phosphoric acid was watered down to 1000ml with HPLC quality water.

Preparation of mobile phase:

Mobile stage was prepared my mixing 0.1% Ortho phosphoric: Acetonitrile in the ratio of 60:40 and also sonicated making use of ultrasonic bathroom to degas as well as based on vacuum purification with 0.45 Millipore Nylon filter.

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TO DEVELOP A VALIDATED ANALYTICAL METHOD FOR THE SIMULTANEOUS ESTIMATION OF METFORMIN, GLICLAZIDE AND VOGLIBOSE BY RP-HPLC

B.Nishanth, V.Kiran Kumar

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Abstract:

Another technique was built up for concurrent estimation of Metformin and Gliclazide and Voglibose RP-HPLC strategy. Metformin and Gliclazide was unreservedly solvent in water and liquor. Voglibose was uninhibitedly solvent in liquor and sparingly dissolvable in water. Methanol and potassium dihydrogen ortho phosphate (pH 3) was picked as the versatile stage. The run season of the HPLC strategy was 5 minutes. The strategy was approved for framework appropriateness, linearity, exactness, precision, explicitness, roughness vigor, LOD and LOQ. The framework appropriateness boundaries were inside breaking point, subsequently it was presumed that the framework was reasonable to play out the examine. The strategy shows linearity between the focus scope of 10-100 µg/ml. The % recuperation of Metformin, Gliclazide and Voglibose were seen as in the scope of 99.23 % - 98.11 %. As there was no impedance due to excipients and portable stage, the technique was seen as explicit. The technique was powerful and rough as seen from immaterial variety in the consequences of examination by changes in Flow rate and Mobile stage sythesis independently and investigation being performed by various investigators.

Keywords: *Metformin, Gliclazide and Voglibose, RP-HPLC, Simultaneous estimation.*

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Please cite this article in press ***B.Nishanth et al, To Develop A Validated Analytical Method For The Simultaneous Estimation Of Metformin, Gliclazide And Voglibose By RP-HPLC.,*** *Indo Am. J. P. Sci, 2022; 09(12).*

INTRODUCTION:

Metformin is an antihyperglycemic agent of the biguanide class, used for the management of type II diabetes. Metformin is considered an antihyperglycemic drug because it lowers blood glucose concentrations in type II diabetes without causing hypoglycemia. Metformin is commonly described as an *insulin sensitizer* leading to a decrease in insulin resistance and a clinically significant reduction of plasma fasting insulin levels [1]. Metformin's mechanisms of action are unique from other classes of oral antihyperglycemic drugs. Metformin decreases blood glucose levels by decreasing hepatic glucose production (gluconeogenesis), decreasing the intestinal absorption of glucose, and increasing insulin sensitivity by increasing peripheral glucose uptake and utilization. It is well established that metformin inhibits mitochondrial complex I activity, and it has since been generally postulated that its potent antidiabetic effects occur through this mechanism. The above processes lead to a decrease in blood glucose, managing type II diabetes and exerting positive effects on glycemic control [2-3]. IUPAC name 3-(diaminomethylidene)-1,1-dimethylguanidine.
Molecular weight is 129.16. Molecular formula is $C_4H11N5.HCl$.

Gliclazide is an oral antihyperglycemic agent used for the treatment of non-insulin-dependent diabetes mellitus (NIDDM). It has been classified differently according to its drug properties in which based on its chemical structure, gliclazide is considered a first-generation sulfonylurea due to the structural presence of a sulfonamide group able to release a proton and the presence of one aromatic group.[4] On the other hand, based on the pharmacological efficacy, gliclazide is considered a second-generation sulfonylurea which presents a higher potency and a shorter half-life. Gliclazide belongs to the sulfonylurea class of insulin secretagogues, which act by stimulating β cells of the pancreas to release insulin. Sulfonylureas increase both basal insulin secretion and meal-stimulated insulin release. Medications in this class differ in their dose, rate of absorption, duration of action, route of elimination and binding site on their target pancreatic β cell receptor. Sulfonylureas also increase peripheral glucose utilization, decrease hepatic gluconeogenesis and may increase the number and sensitivity of insulin receptors.[5] IUPAC name 3-[(3aR,6aS)-octahydrocyclopenta[c]pyrrol-2-yl]-1-(4-methylbenzenesulfonyl) urea. Molecular Weight is 323.4. Molecular formula is $C_{15}H_{21}N_3O_3S$.

Voglibose is for the treatment of diabetes. It is specifically used for lowering post-prandial blood glucose levels thereby reducing the risk of macrovascular complications. Alpha-glucosidase inhibitors are saccharides that act as competitive inhibitors of enzymes needed to digest carbohydrates: specifically alpha-glucosidase enzymes in the brush border of the small intestines.[5] The membrane-bound intestinal alpha-glucosidases hydrolyze oligosaccharides, trisaccharides, and disaccharides to glucose and other monosaccharides in the small intestine. Acarbose also blocks pancreatic alpha-amylase in addition to inhibiting membrane-bound alpha-glucosidases.[6] Pancreatic alpha-amylase hydrolyzes complex starches to oligosaccharides in the lumen of the small intestine. Inhibition of these enzyme systems reduces the rate of digestion of complex carbohydrates.[7] IUPAC name is (1S,2S,3R,4S,5S)-5-[(1,3-dihydroxypropan-2-yl) amino]-1-(hydroxymethyl) cyclohexane-1,2,3,4-tetrol. Molecular Weight is 267. Molecular formula is $C_{10}H_{21}NO_7$.

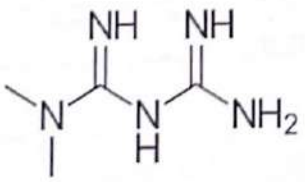

Fig no: 1 Structure of Metformin

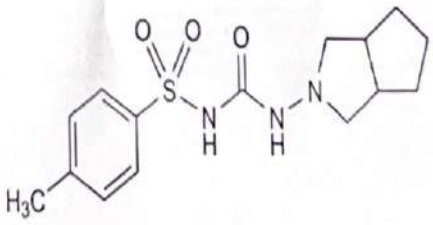

Fig no: 2 Structure of Gliclazide

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METHOD DEVELOPMENT AND VALIDATION FOR MEROPENEMAND VABORBACTAM BY RP-HPLC METHOD

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Abstract:

A simple, Accurate, precise method was developed for the simultaneous estimation of the Meropenem and Vaborbactam in Tablet dosage form. Chromatogram was run through Inertsil ODS C185µm (4.6 x 250mm). Mobile phase containing Phosphate buffer and Acetonitrile in the ratio of 30:70 was pumped through column at a flow rate of 1ml/min. Buffer used at pH 4.6. Temperature was maintained at Ambient. Optimized wavelength for Vaborbactam and Vaborbactam was 260nm. Retention time of Meropenem and Vaborbactam were found to be 2.395min and 3.906min. The % purity of Meropenem and Vaborbactam was found to be 100.6% and 101.3% respectively. The system suitability parameters for Meropenem and Vaborbactam such as theoretical plates and tailing factor were found to be 1.3, 1012.4and 1.2, 1848.2 the resolution was found to be 9.0.The linearity study for Meropenem and Vaborbactam was found in concentration range of 1µg-5µg and 100µg-500µg and correlation coefficient (r2) was found to be 0.999 and 0.999, % mean recovery was found to be 100.1% and 100.4%. %RSD for repeatability was0.31 and 0.38, % RSD for intermediate precision was 0.12 and 0.15 respectively. The precision study was precise, robust and repeatable. LOD value was 2.94 and 3.03, and LOQ value was 9.87 and 10.1 respectively.

Keywords: Meropenem, Vaborbactam, RP-HPLC

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INTRODUCTION:

Meropenem is for use as single agent therapy for the treatment of the following infections when caused by susceptible isolates of the designated microorganisms: complicated skin and skin structure infections due to Staphylococcus aureus (b-lactamase and non-b-lactamase producing, methicillin-susceptible isolates only), Streptococcus pyogenes, Streptococcus agalactiae, viridans group streptococci, Enterococcus faecalis (excluding vancomycin-resistant isolates), Pseudomonas aeruginosa, Escherichia coli, Proteus mirabilis, Bacteroides fragilis and Peptostreptococcus species; complicated appendicitis and peritonitis caused by viridans group streptococci, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Bacteroides fragilis, B. thetaiotaomicron, and Peptostreptococcus species. Also for use in the treatment of bacterial meningitis caused by Streptococcus pneumoniae, Haemophilus influenzae (b-lactamase and non-b-lactamase-producing isolates), and Neisseria meningitidis. The bactericidal activity of Meropenem results from the inhibition of cell wall synthesis. Vaborbactam readily penetrates the cell wall of most Gram-positive and Gram-negative bacteria to reach penicillin-binding- protein (PBP) targets. Its strongest affinities are toward PBPs 2, 3 and 4 of Escherichia coli and Pseudomonas aeruginosa; and PBPs 1, 2 and 4 of Staphylococcus aureus. IUPAC name (4R,5S,6S)-3-{[(3S,5S)-5-(dimethylcarbamoyl) pyrrolidin-3-yl] sulfanyl}-6-[(1R)-1-hydroxyethyl]-4-methyl-7-oxo-1-azabicyclo [3.2.0] hept-2-ene-2-carboxylic acid. Molecular formula is $C_{17}H_{25}N_3O_5S$. Molecular Weight is 383.4.

Vaborbactam is indicated in combination with Vaborbactam for the treatment of patients 18 years of age and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: Escherichia coli, Klebsiella pneumoniae, and Enterobacter cloacae species complex. Vaborbactam is a cyclic boronic acid pharmacophore β-lactamase inhibitor that elicits potent inhibition of Klebsiella pneumoniae carbapenemase (KPC) enzymes and other Ambler class A and C enzymes such as serine β-lactamases that confer resistance to commonly-used antibiotics such as Carbapenems.1 Vaborbactam is a potent inhibitor of class A carbapenemases, such as KPC, as well as an inhibitor of other class A (CTX-M, SHV, TEM) and class C (P99, MIR, FOX) beta-lactamases. Vaborbactam interacts with β-lactamases of Ambler classes A and C via precovalent and covalent binding.[3] It exerts no inhibitory actions on class D or class B carbapenemases.[4] IUPAC Name 2-[(3R,6S)-2-hydroxy-3-[2-(thiophen-2-yl) acetamido]-1,2-oxaborinan-6-yl]acetic acid. Molecular Formula $C_{12}H_{16}BNO_5S$. Molecular Weight 2971.

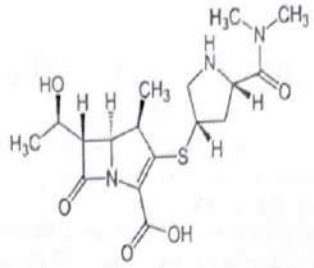

Figure 1: Structure of Meropenem

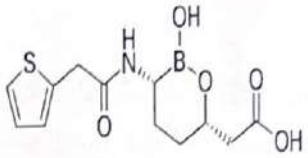

Figure 2: Structure of Vaborbactam

The literature survey revealed that There are very few methods reported in the literature for analysis of Meropenem and Vaborbactam alone or in combination with other drugs in the pure form and pharmaceuticals formulations by RP-HPLC.[3-9] In view of the need for a suitable, cost-effective RP-HPLC method for routine analysis of Meropenem and Vaborbactam Simultaneous estimation of in pharmaceutical dosage form. Attempts were made to develop simple, precise, accurate and cost-effective analytical method for the estimation of Meropenem and Vaborbactam. The proposed method will be validated as per ICH guidelines. The objective of the proposed work is to develop a new, simple, sensitive, accurate and economical analytical method and validation for the Simultaneous estimation of Meropenem and Vaborbactam in pharmaceutical dosage form by using RP-HPLC. To validate the developed method in accordance with ICH guidelines for the intended analytical application i.e., to apply the proposed method for analysis of the drug in its dosage form.

MATERIALS AND METHODS:

Chemicals and Reagents: Meropenem and Vaborbactam were Purchased from market. NaH_2PO_4 was analytical grade supplied by Finerchem limited, Orthophosphoric acid (Merck), and Water and Methanol for HPLC (Lichrosolv (Merck).

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DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF GABAPENTINE AND NORTRYPTALINE

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Abstract:

A simple, precise, rapid, specific and accurate stability indicating reverse phase high performance liquid chromatography method was developed for simultaneous estimation of Gabapentin (GPT) and Nortriptyline (NTL) in pharmaceutical tablet dosage form. Chromatographic separation was performed on Agilent C8, (150 X 4.6mm, 5µm) column, with mobile phase comprising of mixture of buffer: (0.1M ammonium acetate) and methanol in the ratio of 70:30v/v, at the flow rate 1.0 ml/min. The detection was carried out at 254 nm. The retention times of GPT and NTL were found to be 2.66 and 3.58 mins respectively with a run time of 6 mins, theoretical levels for GPT and NTL were 8734 and 8648 respectively, with a resolution of 6.56. As per ICH guidelines the method was validated for linearity, accuracy, precision, limit of detection and limit of quantitation, robustness and ruggedness. Linearity of GPT was found in the range of 800-2400 µg/mL and that for CPG was found to be 20-60 µg/mL. The correlation coefficient for GPT and NTL were 0.999 and 1.000 respectively. The LOD values for GPT and NTL were 2.936 and 2.927 µg/mL respectively. The LOQ values for GPT and NTL were and 9.786 and 9.756 µg/mL respectively. This demonstrates that the developed method is simple, precise, rapid, selective, accurate and reproducible for simultaneous estimation of GPT and NTL tablet dosage form.

Keywords: *Gabapentin (GPT), Nortriptyline (NTL), RP-HPLC Method Development and Validation*

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INTRODUCTION:

Gabapentin is in the United States, gabapentin is officially indicated for the treatment of postherpetic neuralgia in adults and for the adjunctive treatment of partial-onset seizures, with or without secondary generalization, in patients 3 years of age and older.[1] In Europe, gabapentin is indicated for adjunctive therapy in the treatment of partial-onset seizures, with or without secondary generalization, in patients 6 years of age and older and as monotherapy in patients 12 years of age and older. It is also used in adults for the treatment of various types of peripheral neuropathic pain, such as painful diabetic neuropathy.[2]

The precise mechanism through which gabapentin exerts its therapeutic effects is unclear.[3] The primary mode of action appears to be at the auxillary α2δ-1 subunit of voltage-gated calcium channels (though a low affinity for the α2δ-2 subunit has also been reported).4 The major function of these subunits is to facilitate the movement of pore-forming α1 subunits of calcium channels from the endoplasmic reticulum to the cell membrane of pre-synaptic neurons.[5] IUPAC name is 2-[1-(aminomethyl)cyclohexyl]acetic acid. Molecular Formula is $C_9H_{17}NO_2$. Molecular weight is 171.2.

Nortriptyline is indicated for the relief of the symptoms of major depressive disorder (MDD).[6] Some off-label uses for this drug include treatment of chronic pain, myofascial pain, neuralgia, and irritable bowel syndrome.[7] Though prescribing information does not identify a specific mechanism of action for nortriptyline [8], is believed that nortriptyline either inhibits the reuptake of the neurotransmitter serotonin at the neuronal membrane or acts at the level of the beta-adrenergic receptors. It displays a more selective reuptake inhibition for noradrenaline, which may explain increased symptom improvement after nortriptyline therapy. Tricyclic antidepressants do not inhibit monoamine oxidase nor do they affect dopamine reuptake.[9] As with other tricyclics, nortriptyline displays affinity for other receptors including mACh receptors, histamine receptors, 5-HT receptors, in addition to other receptors. IUPAC name is methyl (3- {tricyclo [9.4.0.0^{3,8}] pentadeca-1(15),3,5,7,11,13-hexaen-2-ylidene}propyl)amine. Molecular Formula is $C_{19}H_{21}N$. Molecular weight is 263.3.

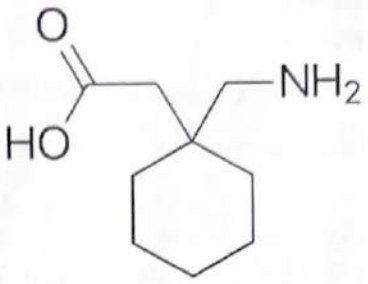

Figure 1: Structure of Gabapentin

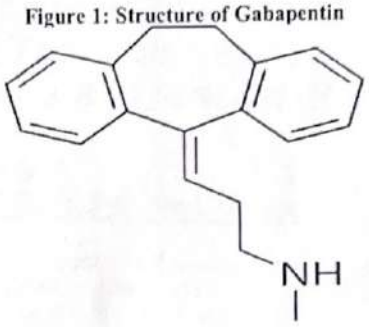

Figure 2: Structure of Nortriptyline

The literature survey revealed that There are really few approaches reported in the literary works for evaluation of Gabapentin and Nortriptyline alone or in combination with various other drugs in the pure form as well as drugs formulations by RP-HPLC [9-12]. In view of the demand for an appropriate, cost-effective RP-HPLC method for routine analysis of Gabapentin and Nortriptyline synchronized evaluation of in pharmaceutical dose type. Attempts were made to establish easy, precise, accurate as well as cost-efficient logical method for the estimate of Gabapentin and Nortriptyline. The recommended approach will be validated according to ICH guidelines. The objective of the recommended work is to establish a brand-new, simple, delicate, exact and economical logical method as well as recognition for the Synchronized evaluation of Gabapentin and Nortriptyline in pharmaceutical dose kind by utilizing RP-HPLC. To verify the established method based on ICH standards for the desired analytical application.

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DEVELOPMENT AND VALIDATION OF STABILITY INDICATING METHOD FOR SIMULTANEOUS ESTIMATION OF EFAVIRENZ AND PYRAZINAMIDE BY USING RP-HPLC METHOD

V.Haritha, P.Prapulla

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Abstract:

A basic and specific LC strategy is depicted for the assurance of Efavirenz and pyrazinamide measurements structures. Chromatographic partition was accomplished on a c18 segment utilizing portable stage comprising of a blend of Sodium di hydrogen phosphate cushion (KH2PO4 and K2HPO4) Acetonitrile (40:60v/v), with identification of 252nm. Linearity was seen in the range 100-500 µg/ml Efavirenz (r2 =0.99) and 100-500µg/ml for pyrazinamide (r2 =0.999) for the measure of medications assessed by the proposed strategies was in acceptable concurrence with the name guarantee. The proposed techniques were approved. The exactness of the techniques was evaluated by recuperation learns at three distinct levels. Recuperation tests showed the nonattendance of obstruction from usually experienced pharmaceutical added substances. The strategy was seen as exact as demonstrated by the repeatability examination, indicating %RSD under 2. Every single factual datum demonstrates legitimacy of the techniques and can be utilized for routine investigation of pharmaceutical measurement structure. 400 volumes of pottasium di hydrogen phosphate and Di potasium hidrozen phosphate support and 600 volumes of ACN were readied. The versatile stage was sonicated for 10min to evacuate gases.

Keywords: *Efavirenz, Pyrazinamide, RP-HPLC, Simultaneous estimation.*

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INTRODUCTION:

Efavirenz is a non-nucleoside reverse transcriptase inhibitor (NNRTI) and is used as part of highly active antiretroviral therapy (HAART) for the treatment of a human immunodeficiency virus (HIV) type 1.[1] For HIV infection that has not previously been treated, efavirenz and lamivudine in combination with zidovudine or tenofovir is the preferred NNRTI-based regimen. Efavirenz is also used in combination with other antiretroviral agents as part of an expanded postexposure prophylaxis regimen to prevent HIV transmission for those exposed to materials associated with a high risk for HIV transmission.[2] IUPAC Name is (4S)-6-chloro-4-(2-cyclopropylethynyl)-4-(trifluoromethyl)-2,4-dihydro-1H-3,1-benzoxazin-2-one. Molecular formula is $C_{14}H_9ClF_3NO_2$. Molecular weight is 315.6 g/mol.

Pyrazinamide is an antituberculosis agent used as a component of tuberculosis (TB) treatment. Pyrazinamide diffuses into active M. tuberculosis that express pyrazinamidase enzyme that converts pyrazinamide to the active form pyrazinoic acid. Pyrazinoic acid can leak out under acidic conditions to be converted to the protonated conjugate acid, which is readily diffused back into the bacilli and accumulate intracellularly. The net effect is that more pyrazinoic acid accumulates inside the bacillus at acid pH than at neutral pH. Pyrazinoic acid was thought to inhibit the enzyme fatty acid synthase (FAS) I, which is required by the bacterium to synthesise fatty acids. However, this theory was thought to have been discounted.[3] However, further studies reproduced the results of FAS I inhibition as the putative mechanism first in whole cell assay of replicating M. tuberculosis bacilli which have shown that pyrazinoic acid and its ester inhibit the synthesis of fatty acids.[4] IUPAC Name is pyrazine-2-carboxamide. Molecular formula is $C_5H_5N_3O$. Molecular weight is 123.1 g/mol.

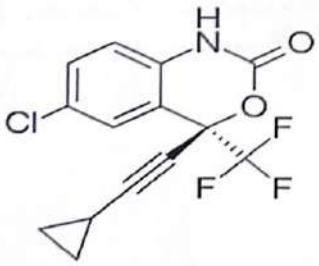

Figure 1: Structure of Efavirenz

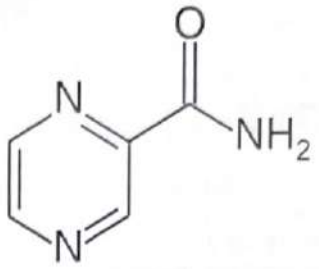

Figure 2: Structure of Pyrazinamide

The literature survey revealed that There are Various analytical methods were carried out for the estimation of Efavirenz and Pyrazinamide as a single or combined with other drugs in pharmaceutical dosages Literature survey reveals that the retention time for the simultaneous estimation of Efavirenz and Pyrazinamide is more. Hence the present study, we had made an attempt to develop simple, accurate, precise, less time consuming and with less retention time using RP-HPLC for the simultaneous estimation of Efavirenz and Pyrazinamide in bulk and pharmaceutical dosage form by RP-HPLC [5-12]. To validate the developed method in accordance with ICH guidelines for the intended analytical application i.e., to apply the proposed method for analysis of the drug in its dosage form.

MATERIALS AND METHODS:

Chemicals and Reagents: Efavirenz and Pyrazinamide were Purchased from market. NaH_2PO_4 was analytical grade supplied by Finerchem limited, Orthophosphoric acid (Merck), and Water and Methanol for HPLC (Lichrosolv (Merck).

Equipment and Chromatographic Conditions: The chromatography was performed on a Waters 2695 HPLC system, equipped with an auto sampler, UV detector and Empower 2 software. Analysis was carried out at 252 nm with column INERTSIL column, C18(150x4.6 ID) 5µm, dimensions at 25°C temperature. The optimized mobile phase consists of Mixed phosphate buffer: Acetonitrile (30:70). Flow rate was maintained at 1 ml/min.

Determination of Working Wavelength (λmax)

In simultaneous estimation of two drugs isobestic wavelength is used. Isobestic point is the wavelength where the molar absorptivity is the same for two substances that are interconvertible. So this wavelength is used in simultaneous estimation to estimate both drugs accurately.

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METHOD DEVELOPMENT AND VALIDATION FOR DEFERIPRONE BY RP-HPLC METHOD

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Abstract:

Another investigative technique was set up for estimation of RP-HPLC strategy utilizing deferiprone cases. The chromatographic conditions were effectively created for the partition of Deferiprone by utilizing INERTSIL column, C18(150x4.6 ID) 5µm, stream rate 1.0ml/min, versatile stage proportion Triethylamine Buffer: ACN (50:50v/v), recognition frequency was 280nm. The maintenance time was seen as 4.9mins. The % virtue of deferiprone was seen as 99.08%. The framework appropriateness boundaries for deferiprone, for example, hypothetical plates and following elements were seen as 2567,1.512. The logical technique was approved according to ICH guidelines (ICH, Q2, (R1)). The linearity concentrate for Deferiprone was found in fixation scope of 125-375µg/ml and relationship coefficient were seen as 0.994. The % recuperation was seen as 98.40%. The %RSD was seen as 0.28. The accuracy study was precise, robust and repeatable. LOD esteem was 22.93µg/ml and LOQ esteem was 96.37µg/ml. As this strategy has shorter maintenance time and high goal, makes the technique more satisfactory and financially savvy and can be viably applied for routine examination in research establishments, quality control divisions in ventures and in clinical pharmacokinetic concentrates in not-so-distant future.

Keywords: Deferiprone, RP-HPLC, Method development, Validation

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INTRODUCTION:

Deferiprone is indicated in thalassemia syndromes when first line chelation agents are not adequate to treat transfusional iron overload. Deferiprone is an iron chelator that binds to ferric ions (iron III) and forms a 3:1 (deferiprone:iron) stable complex and is then eliminated in the urine. Deferiprone is more selective for iron in which other metals such as zinc, copper, and aluminum have a lower affinity for deferiprone.[1-3] IUPAC name is 3-hydroxy-1,2-dimethyl-1,4-dihydropyridin-4-one. Molecular formula $C_7H_9NO_2$. Molecular Weight is 139.15. Deferiprone is highly soluble in water at pH 1-7.5 and has high permeability, thus is a BCS class I drug.

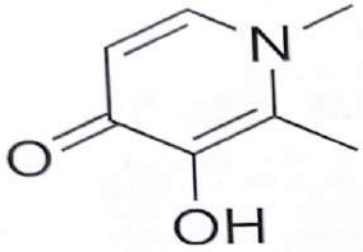

Figure 1: Structure of Deferiprone

The literature survey revealed that There are very few methods reported in the literature for analysis of Deferiprone alone or in combination with other drugs in the pure form and pharmaceuticals formulations by UV and RP-HPLC.[4-7] In view of the need for a suitable, cost-effective RP-HPLC method for routine analysis of Deferiprone estimation of in pharmaceutical dosage form. Attempts were made to develop simple, precise, accurate and cost-effective analytical method for the estimation of Deferiprone. The proposed method will be validated as per ICH guidelines. The objective of the proposed work is to develop a new, simple, sensitive, accurate and economical analytical method and validation for the estimation of Deferiprone in pharmaceutical dosage form by using RP-HPLC. To validate the developed method in accordance with ICH guidelines for the intended analytical application i.e., to apply the proposed method for analysis of the drug in its dosage form.

MATERIALS AND METHODS:

Chemicals and Reagents: Deferiprone were Purchased from market. NaH_2PO_4 was analytical grade supplied by Finerchem limited, Orthophosphoric acid (Merck), and Water and Methanol for HPLC (Lichrosolv (Merck).

Equipment and Chromatographic Conditions: The chromatography was performed on a Waters 2695 HPLC system, equipped with an auto sampler, UV detector and Empower 2 software. Analysis was carried out at 280 nm with column INERTSIL column, C18(150x4.6 ID) 5µm, dimensions at Ambient temperature. The optimized mobile phase consists of Triethylamine Buffer: ACN (50:50v/v). Flow rate was maintained at 1 ml/min.

Preparation of solutions:

Preparation of Triethylamine buffer

5ml of triethylamine in 1000ml of water and its pH was maintained at by using orthophosphoric acid.

Mobile Phase

A mixture of 50 volumes of Triethylamine pH 3.5 & 50 volumes of Acetonitrile were prepared. The mobile phase was sonicated for 10min to remove gases.

Preparation of orthophosphoric acid

3ml orthophosphoric acid is diluted in 10ml water

Preparation of standard stock solution of Deferiprone

10mg of Deferiprone was weighed and transferred in to 10ml volumetric flask and dissolved in methanol and then make up to the mark with methanol and prepare 10 µg/ml of solution by diluting 1ml to 10ml with methanol.

Preparation of mixed standard solution

Weigh accurately 10 mg of Deferiprone in 10 ml of volumetric flask and dissolve in 10ml of mobile phase and make up the volume with mobile phase. From above stock solution 250µg/ml of Deferiprone is prepared by diluting 2.5 ml of Deferiprone to 10ml with mobile phase. This solution is used for recording chromatogram.

Preparation of sample solution

5 Capsules (each Capsules contains 250 mg of Deferiprone) were weighed and taken into a mortar and make it fine powder and uniformly mixed. Capsules stock solutions of 250µg/ml were prepared by dissolving weight equivalent to 10 mg of Deferiprone dissolved in sufficient mobile phase. After that filtered the solution using 0.45-micron syringe filter and sonicated for 5 min and dilute to 10 ml with mobile phase. Further dilutions are prepared

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DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR DETERMINATION OF CANAGLIFLOZIN IN BULK AND TABLET DOSAGE FORM

P.Shravani Mary, V.Kiran Kumar

Mother Teresa College of Pharmacy, Ghatkesar, NFC Nagar, Hyderabad, Telangana, India

Abstract:

A simple, specific and accurate reverse phase high performance liquid chromatographic method for the determination of Canagliflozin in bulk and pharmaceutical dosage forms. The method is optimized on INERTSIL C18 column (150mm×4.6mm,5µm) with a mobile phase combination of Methanol: Acetonitrile: Water (30:50:20 v/v/v) at a flow rate 1.0ml/min and the eluents were monitored at 250nm. Under these LC conditions Canagliflozin peak was eluted at 3.367 min. The developed method was validated as per ICH guidelines. The correlation coefficient values in linearity were found to be 0.999 and concentration range of 20-60µg/ml for canagliflozin and the mean percentage assay was found to be 99.89%. The method was found to be precise as indicated by the repeatability analysis, showing %RSD less than 2. All statistical data proves validity of the methods and can be used for routine analysis of pharmaceutical dosage form.

Keywords: Canagliflozin, RP-HPLC, Method development, Validation

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INTRODUCTION:

This drug is used in conjunction with diet and exercise to increase glycemic control in adults diagnosed with type 2 diabetes mellitus Label. Another indication for canagliflozin is the prevention of major cardiovascular events (myocardial infarction, stroke, or death due to a cardiovascular cause) in patients with type 2 diabetes, as well as hospitalization for heart failure in patients with type 2 diabetes.[1-2] In addition to the above, canagliflozin can be used to lower the risk of end-stage kidney disease and major increases in serum creatinine and cardiovascular death for patients with a combination of type 2 diabetes mellitus, diabetic nephropathy, and albuminuria.[3] The sodium-glucose co-transporter2 (SGLT2), is found in the proximal tubules of the kidney, and reabsorbs filtered glucose from the renal tubular lumen. Canagliflozin inhibits the SGLT2 co-transporter. This inhibition leads to lower reabsorption of filtered glucose into the body and decreases the renal threshold for glucose (RTG), leading to increased glucose excretion in the urine. IUPAC name is 2-(3-{[5-(4-fluorophenyl) thiophen-2-yl] methyl}-4-methylphenyl)-6-(hydroxymethyl) oxane-3,4,5-triol. Molecular formula $C_{24}H_{25}FO_5S$. Molecular Weight is 444.51. Canagliflozin is soluble in organic solvents such as ethanol, DMSO, and dimethyl formamide, which should be purged with an inert gas. The solubility of canagliflozin in these solvents is approximately 30 mg/ml.

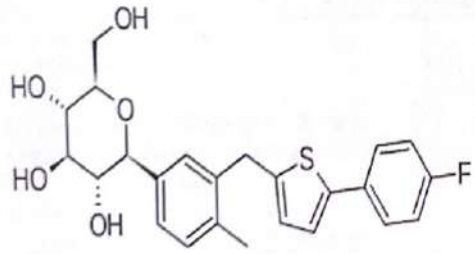

Figure 1: Structure of Canagliflozin

Literature review of Canagliflozin shown that there were several analytical methods like were several analytical methods like UV spectroscopy [3], LCMS [4], HPLC [5-11], HPTLC [12] and only few methods were reported for RP-HPLC for the estimation of this drug in bulk and in its formulation. Hence the present work targeted to develop a new precise, accurate and sensitive RP-HPLC method for the determination of Canagliflozin in API and formulation. The developed method validated as per ICH guidelines. [13-15]

MATERIALS AND METHODS:

Chemicals and Reagents: Canagliflozin were Purchased from market. NaH_2PO_4 was analytical grade supplied by Finerchem limited, Orthophosphoric acid (Merck), and Water and Methanol for HPLC (Lichrosolv (Merck).

Equipment and Chromatographic Conditions: The chromatography was performed on a Waters 2695 HPLC system, equipped with an auto sampler, UV detector and Empower 2 software. Analysis was carried out at 250 nm with column INERTSIL column, C18(150x4.6 ID) 5µm, dimensions at Ambient temperature. The optimized mobile phase consists of Methanol: Acetonitrile: water (30:50:20 v/v/v). Flow rate was maintained at 1 ml/min.

Preparation of solutions:

Preparation of mobile phase

A mixture of 30 volumes of Methanol and 50 volumes of Acetonitrile and 20 volumes of water were prepared. The mobile phase was sonicated for 10min to remove gases.

Preparation of mixed standard solution of Canagliflozin:

Weigh accurately 10mg of Canagliflozin in 25ml of volumetric flask and dissolve in 25ml of mobile phase and make up the volume with mobile phase. From above stock solution 40µg/ml of Canagliflozin is prepared by diluting 1ml of Canagliflozin to 10ml with mobile phase. This solution is used for recording chromatogram.

Preparation of sample solution of Canagliflozin:

5 tablets (each tablet contains 100mg of Canagliflozin) were weighed and taken into a mortar and crushed to fine powder and uniformly mixed. Tablet stock solutions of 40µg/ml were prepared by dissolving weight equivalent to 10mg of Canagliflozin dissolved in sufficient mobile phase. After that filtered the solution using 0.45-micron syringe filter and sonicated for 5 min and dilute to 25ml with mobile phase. Further dilutions are prepared in 5 replicates of 40µg/ml of Canagliflozin was made by adding 1ml of stock solution to 10 ml of mobile phase.

Preparation of standard stock solution of Canagliflozin

10mg of Canagliflozin was weighed and transferred in to 25ml volumetric flask and dissolved in methanol and then make 1 up to the mark with

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RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANIOUS ESTIMATION OF ATAZANAVIR AND COBICISTAT IN TABLET DOSAGE FORM

M.Swathi, V.Kiran Kumar

Mother Teresa College of Pharmacy, Ghatkesar, NFC Nagar, Hyderabad, Telangana, India

Abstract:

A simple sensitive, and precise high performance liquid chromatographic method for the analysis of atazanavir and cobicistat has been developed and validated for the simultaneous determination of compounds in commercial pharmaceutical products. The compounds were well separated on ODS intersil C18 reverse phase column by the use of mobile phase of Orthophosphoric acid acetonitrile in a ratio of 45:55 v/v at a flow rate of 1.0 ml/min with detection wavelength at 272 nm. The retention time of atazanavir and cobicistat was found to be 4.135min and1.668min the method was validated in terms of linearity, precision, accuracy, and specificity. robustness, ruggedness and solution stability Degradation studies like acid. base. peroxide. thermal, uv and water. The method dies require only 10 min as run time for analysis which prove the adoptability of the method for the routine quality control analysis of the drug.

Keywords: *Atazanavir and Cobicistat, RP-HPLC, Simultaneous estimation.*

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INTRODUCTION:

Atazanavir is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 3 months of age and older weighing at least 5kg.[1] Atazanavir is also indicated in combination with cobicistat and other antiretrovirals for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35kg.[2] Atazanavir selectively inhibits the virus-specific processing of viral Gag and Gag-Pol polyproteins in HIV-1 infected cells by binding to the active site of HIV-1 protease, thus preventing the formation of mature virions. Atazanavir is not active against HIV-2. IUPAC name methyl N-[(1S)-1-{N'-[(2S,3S)-2-hydroxy-3-[(2S)-2-[(methoxycarbonyl)amino]-3,3-dimethylbutanamido]-4-phenylbutyl]-N'-{[4-(pyridin-2 yl) phenyl]methyl}hydrazinecarbonyl}-2,2-dimethylpropyl]carbamate. Molecular formula $C_{38}H_{52}N_6O_7$. Molecular Weight 704.8.

Cobicistat is a CYP3A inhibitor indicated to increase systemic exposure of atazanavir or darunavir (once daily dosing regimen) in combination with other antiretroviral agents in the treatment of HIV-1 infection.[3] It is not interchangeable with ritonavir to increase systemic exposure of darunavir 600 mg twice daily, fosamprenavir, saquinavir, or tipranavir due to lack of exposure data.[4] Cobicistat is a mechanism-based inhibitor of cytochrome P450 3A (CYP3A) isoforms. Inhibition of CYP3A-mediated metabolism by cobicistat increases the systemic exposure of CYP3A substrates atazanavir and darunavir and therefore enables increased anti-viral activity at a lower dosage. Cobicistat does not have any anti-HIV activity on its own. IUPAC Name 1,3-thiazol-5-ylmethyl *N*-[(2*R*,5*R*)-5-[[(2*S*)-2-[[methyl-[(2-propan-2-yl-1,3-thiazol-4-yl)methyl]carbamoyl]amino]-4-morpholin-4ylbutanoyl]amino]-1,6 diphenylhexan-2-yl]carbamate. Molecular Formula $C_{46}H_{53}N_7O_5S_2$. Molecular Weight 776.

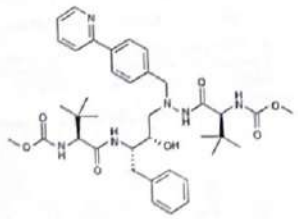

Figure 1: Structure of Atazanavir

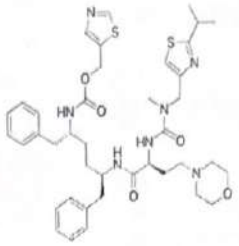

Figure 2: Structure of Cobicistat

The literature survey revealed that There are very few methods reported in the literature for analysis of Atazanavir and Cobicistat alone or in combination with other drugs in the pure form and pharmaceuticals formulations by RP-HPLC.[5-14] In view of the need for a suitable, cost-effective RP-HPLC method for routine analysis of Atazanavir and Cobicistat Simultaneous estimation of in pharmaceutical dosage form. Attempts were made to develop simple, precise, accurate and cost-effective analytical method for the estimation of Atazanavir and Cobicistat. The proposed method will be validated as per ICH guidelines. The objective of the proposed work is to develop a new, simple, sensitive, accurate and economical analytical method and validation for the Simultaneous estimation of Atazanavir and Cobicistat in pharmaceutical dosage form by using RP-HPLC. To validate the developed method in accordance with ICH guidelines for the intended analytical application i.e., to apply the proposed method for analysis of the drug in its dosage form.

MATERIALS AND METHODS:

Chemicals and Reagents: Atazanavir and Cobicistat were Purchased from Sun Pharma India Limited. NaH_2PO_4 was analytical grade supplied by Finerchem limited, Orthophosphoric acid (Merck), and Water and Methanol for HPLC (Lichrosolv (Merck).

Equipment's: The Waters HPLC system with a UV or photo diode array detector was used for method development and validation. The output signal was monitored and processed by using Empower software. Chromatographic condition: The mobile phase used 0.1% Orthophosphoric acid, buffer and Acetonitrile in the gradient mode employing at a flow rate of 1.2 ml/min. The analytical column used Inertsil ODS 3V (4.0 x 250mm, 5µm). The detection was carried out at a wavelength of 270nm for a run time of 10 min. Diluent used as Acetonitrile and hplc grade water %B 0.00 90.0 10.0 3.00 40.0 60.0 5.00

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FORMULATION AND EVALUATION OF MUCOADHESIVE BUCCAL PATCHES OF LOSARTAN POTASSIUM

[1]N. Sheshu Kumar, [2]D. Rajkumar
[1]Mother Teresa College of Pharmacy

Article Received: December 2022 **Accepted:** January 2023 **Published:** February 2023

Abstract:

The mucoadhesive Buccal Patches of losartan potassium could be prepared using locustbean gum and HPMC K4M by direct compression method.The IR spectra revealed that, there was no interaction between polymers and drug. All polymers used were compatible with drug.All the prepared tablets were in acceptable range of weight variation, hardness, thickness, friability and drug content as per pharmacopoeial specification.The surface pH of prepared Buccal Patches was in the range of salivary pH, suggested that prepared tablets could be used without risk of mucosal irritation.All the Buccal Patches showed good residence time of 7.2 H to >10 h, indicated good adhesive capacity of polymers used.The CCD was used to find out the effect of independent varibles on the dependable variables. The result of CCD revealed that the locustbean gum and HPMC K4M have significant effect on the mucoadhesion strenth, swelling index, the drug release at 1 h and drug release at 8 h. The observed independent variables were found to be very close to predicted values of optimized formulation which demonstrates the feasibility of the optimization procedure in successful development of buccal tablet containing losartan potassium by using locustbean gum and HPMC K4M. The drug release form the optimized formula was found to be following the zero order kinetics and n value range of the Peppas equation is 0.521, which indicates fickian diffusion mechanism. Thus the release of drug from the dosage form was found to be time dependent.The stability studies revealed that there was no significant change in buccal tablet properties with aging at different storage conditions.Hence, the mucoadhesive Buccal Patches of losartan potassium can be prepared with enhanced bioavailability and prolonged therapeutic effect for the better management of hyper tension.

Keywords: *Losartan potassium, Buccal patches, Mucoadhesive, Formulation, Evaluation*

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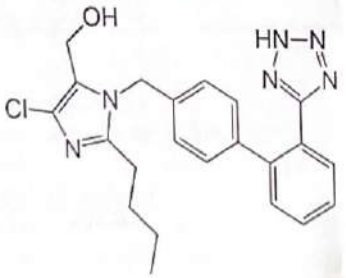
INTRODUCTION:

Amongst the various routes of drug delivery, oral route is perhaps the most preferred to the patient and the clinician alike 1. Bioadhesion is the ability of a material (synthetic or biological) to adhere to a biological tissue for an extended period of time 2-4. The biological surface can be epithelial tissue or it can be the mucous membrane adhere on the surface of a tissue. If adhesion is to a mucous coat, the phenomenon is referred to as mucoadhesion. The use of mucoadhesive polymers in buccal drug delivery has a greater application3.Various mucoadhesive devices, including tablets, films, patches, disks, strips, ointments and gels have recently been developed. However, buccal patch offer greater flexibility and comfort than the other devices. In addition, a patch can circumvent the problem of the relatively short residence time of oral gels on mucosa, since the gels are easily washed away by saliva. Buccal route drug delivery provides the direct entry to the systemic circulation through the jugular vein bypassing the first pass hepatic metabolism leading to high bioavailability 5-7. Other advantages such as excellent accessibility, low enzymatic activity, suitability for drugs or excipients that mildly and reversibly damage or irritate the mucosa, painless administration, easy withdrawal, facility to include permeation enhancer/ enzyme inhibitor or pH modifier in the formulation, versatility in designing as multidirectional or unidirectional release system for local or systemic action 8-10.

Drug Profile: Losartan is an angiotensin II receptor blocker (ARB) used to treat hypertension. Angiotensin-converting enzyme (ACE) inhibitors are used for a similar indication but are associated with a cough. When patients with ACE inhibitor associated, coughs are switched to ARBs like losartan, they have an incidence of cough similar to placebo or hydrochlorothiazide. Losartan is available as losartan potassium oral tablets as well as a combination tablet of losartan potassium and hydrochlorothiazide. Patients taking losartan should have their renal function and potassium levels monitored 11. IUPAC name potassium 5-(4'-{[2-butyl-4-chloro-5-(hydroxymethyl)-1H-imidazol-1-yl] methyl)-[1,1'-biphenyl]-2-yl)-1,2,3,4-tetrazol-2-uide. Molecular formula is C22H22ClKN6O. Molecular weight is 461. Losartan (potassium salt) is soluble in organic solvents such as ethanol, DMSO, and dimethyl formamide. The solubility of losartan (potassium salt) in these solvents is approximately 20 mg/ml.

Figure 1: Chemical structure:



The objective of the present research work is to formulate and evaluate bilayered buccoadhesive tablet containing losartan potassium as a drug to achieve unidirectional drug release and to increase bioavailability of the drug.

MATERIALS AND METHODS:

Materials:

Losartan Potassium was received as gift sample from Zydus Cadila Healthcare Ltd, Hyderabad, India. Hydroxy- propylmethyl cellulose K100 (HPMC K100) was obtainedas gift sample from Vergo Pharmaceutical, Goa, India. All other chemicals and reagents that were of analytical grade were used.

Methods:

Drug excipients compatibility studies: The FT-IR spectrum of Losartan Potassium, Physical mixture of Losartan Potassium with Guar Gum and HPMC K100 were analyzed to verify the compatibility between the pure drug and polymers using FT-IR (Make Varian care, Model-510) by KBr disc method. The procedure consisted of dispersing a sample (drug alone or mixture of drug and polymers) in KBr and

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FORMULATION AND EVALUATION OF FLOATING TABLET OF RISEDRONATE

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Article Received: December 2022 **Accepted:** January 2023 **Published:** February 2023

Abstract:
Single and multi-unit skimming systems of risedronate sodium were readied utilizing Gelucire 43/01 by lessen cementing and separate granulation framework, solely. The controlled delivery drifting systems were assessed for in vitro and in vivo skimming limit and in vitro quiet delivery. Impact of creating on Gelucire 43/01 was overviewed by hot stage microscopy (HSM), isolating electron microscopy (SEM). differential taking a gander at calorimetry (DSC), in vitro skimming limit, and in vitro fix discharge. Multi-unit framework got has shown starting affected delivery, which was covered in single unit structure. Both single-and besides multi-unit structures displayed expansion in pace of medication discharge on creating because of changes in the properties of the Gelucire 43/01. Multi-unit structures picked up by separate granulation were adequately less mentioning for scale up and valuable if the essential burst discharge doesn't make any indispensable clinical misery.

Keywords: *Formulation, Evaluation, Floating Tablet, Risedronate*

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INTRODUCTION:

The major challenge in the development of an oral sustained release drug delivery system is not just to sustain the release of drug but also to prolong the presence of the dosage form within the gastrointestinal tract (GIT) until all the drug is completely released at the desired period of time [1]. Gastro-retentive drug delivery systems have gained significant interest in the past few decades. Most of the conventional oral delivery systems have shown some limitations related to fast gastric-emptying time [2]. Garg and Gupta [3] classified the gastro-retentive dosage forms into four main classes: (A) floating systems [4], (B) expandable systems [5], (C) bioadhesive systems [6] and (D) high density systems [7]. Floating systems are of two types: (i) effervescent systems, depending on the generation of carbon dioxide gas upon contact with gastric fluids, and (ii) non-effervescent systems. The latter systems can be further divided into four sub-types, including hydrodynamically balanced systems [8], microporous compartment systems [9], alginate beads [10] and hollow microspheres or microballons [11]. In addition, super-porous hydrogels [12] and magnetic systems [13]. In floating dosage forms (FDs), the dosage form remains buoyant on the gastric fluid when the stomach is full. However, as the stomach empties and the tablet reaches the pylorus, the buoyancy of the dosage form may be reduced. It may be due to passage of the dosage form through the pylorus into the small intestine. Thus, the buoyancy of floating dosage form in the stomach may be limited to only 3–4 h. Furthermore, FDs do not always release the drug at the intended site. In a bioadhesive drug delivery system, the mucous secreted by the mucosa lining of stomach wall may detach the drug from stomach wall due to high mucous turnover. Then the detached tablet may emptyed from the stomach along with its contents [14]. A floating-bioadhesive drug delivery system (FBDDS) would overcome these drawbacks of floating and bioadhesive systems and would have a significant effect on improving the therapeutic effect of the drug involved [15].

Risedronate sodium (RS) is a potent pyridinyl bisphosphonate that binds to bone hydroxyapatite and inhibits osteoclast-mediated bone resorption. In preclinical studies, risedronate demonstrated potent anti-osteoclast and anti-resorptive activity, increasing bone mass and biomechanical strength. It is a third generation bisphosphonate and is relatively rapidly absorbed from the upper gastrointestinal (GI) tract with a short biological half-life of 1.5 h [16]. Due to these characters it is considered as a potential candidate for development of floating-bioadhesive drug delivery system.

MATERIALS:

Table 1: Materials used

S.NO	MATERIALS USED
1	Residronate sodium
2	NaCMC
3	Guargum
4	Sodium bicarbonate
5	MCC
6	Magnesium stearate
7	Talc

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DESIGN AND PREPARE AND CHARECTERIZATION OF THE RAMIPRIL LOADED SOLID LIPID NANO PARTICLES

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Article Received: December 2022 **Accepted:** January 2023 **Published:** February 2023

Abstract:
The aim of the study was Design and prepare and characterization of the ramipril loaded solid lipid nano particles. Structure and plan and portrayal of the ramipril stacked strong lipid nano particles The chitosan is utilized as polymer. The nano particles is planned by applying by nano precipitation technique. After definition improvement the assessment boundaries played out totally went under the scope of limits. The medication discharge the advanced detailing F8 was seen as 99.76%.The motor profile performed for streamlined plan they follow the zero request and higuchi condition. The security reads did for 90 days there is no corruption in streamlined definition in tranquilize delivery and medication content examinations.

Keywords: *Design, Charecterization, Ramipril, Solid Lipid Nano Particles*

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INTRODUCTION:

In the recent years, with the advent of Nanomedicine, engineered tunable devices with the size in the order of billions of meters have been proposed as an intriguing tool potentially able to solve the unmet problem of enhancing drug transport across the BBB [1]. Amongst different devices, nanoparticles (NPs) technology is rapidly advancing. Nanotechnology refers to structures with a size range of 1–100 nm in at least one dimension [2]. Nanotechnology is the application of science and technology to control matter at the molecular level. At the nanoscale level, the properties of matter are significantly different from their macroscopic bulk properties [3]. Nanotechnology also refers to the ability for designing, characterization, production and application of structures, devices and systems by controlling shape and size at the nanometer scale. One area where nanotechnology has the potential to make a significant impact is drug [4]. This impact has already been felt with the translation of several nanoscale drug delivery systems into the clinic, although the full potential of these systems is only starting to be explored. Nanoscale drug delivery vehicles have shown the ability to encapsulate a variety of therapeutic agents such as small molecules (hydrophilic and/or hydrophobic), peptides, protein-based drugs, and nucleic acids [5]. Because of their unique size range, nanoparticles exhibit "enhanced permeability and retention effect" (EPR) which confirm their potential in specific targeting so as to maximize the therapeutic effects and minimize the undesirable effects [6]. Amongst various nanoparticles, solid lipid nanoparticles (SLNs), introduced in 1991 represent an alternative carrier system to traditional colloidal carriers, such as emulsions, liposomes and polymeric nanoparticles [7]. SLNs are small sized lipid nanoparticles composed of biocompatible and biodegradable solid lipids. Their matrix is composed of physiological lipids which reduce the danger of acute and chronic toxicity [8]. Irrespective of their small size (10-1000nm), they offer a high drug loading capacity, larger surface area and thus enhanced bioavailability. These characteristics make SLNs an interesting drug delivery system [9].

Ramipril is an ACE inhibitor used for the management of hypertension and the reduction of cardiovascular mortality following myocardial infarction in hemodynamically stable patients with clinical signs of congestive heart failure.

Ramipril inhibits the RAAS system by binding to and inhibiting ACE thereby preventing the conversion of angiotensin I to angiotensin II. 5 As plasma levels of angiotensin II fall, less activation of the G-protein coupled receptors angiotensin receptor I (AT1R) and angiotensin receptor II (AT2R) occurs. AT1R mediates vasoconstriction, inflammation, fibrosis, and oxidative stress through a variety of signaling pathways. [10] These include Gq coupling to the inositol triphosphate pathway, activation of phospholipases C, A2, and D which contribute to eicosanoid production, activation of Ca2+-dependent and MAP kinases, Gi and G12/13, and eventual activation of the Jak/STAT pathway leading to cell growth and production of extracellular matrix components. AT1R activation also leads to increased activity of membrane-bound NADH/NADPH oxidase which contributes to production of reactive oxygen species. Decreased activation of this receptor mediates the renoprotective, antihypertensive, and cardioprotective effects of ramipril by reducing inflammation and vasoconstriction.

The aim of the study was Design and prepare and characterization of the ramipril loaded solid lipid nano particles.

MATERIALS:

Ramipril Purchased from Sun pharma. Chitosan and chloroform from Colorcon Asia Pvt. Ltd.

METHODOLOGY:

Preformulation studies:

Organoleptic characters: It is one of the important prerequisite in development of any drug delivery system. Pre-formulation studies were performed on the drug, which included organoleptic characters, determination, solubility and compatibility studies

Solubility: solubility of the Ramipril was determined in water, acetone, methanol, practically insoluble in ethanol (95%), chloroform and ether.

Compatibility Studies: Compatibility with excipients was conformed by carried out I R studies. The pure drug and polymer formulations along with excipients were subjected to IR studies

Preparation of Standard Calibration Curve of Ramipril:

METHOD:

10mg Ramipril was precisely gauged and moved into 10ml volumetric carafe. It was broken down and weakened to volume with CH3)2CO to give stock arrangement containing 1000µg/ml The standard stock arrangement was then sequentially taken 1ml of arrangement from first stock arrangement weakened with CH3)2CO to get 1 to 100µg/ml or auxiliary stock arrangement. From optional stock arrangement take 1ml of the answer for get 10µg/ml or tertiary stock arrangement. The absorbances of the

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FORMULATION AND EVALUATION OF THE LORNOXICAM SUSTAINED RELEASE TABLETS BY USING NATURAL POLYMERS

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Abstract:

The main aim of the study formulation and evaluation of the lornoxicam sustained release tablets by using natural polymers. Definition and assessment of the continued delivery tablets of the Lornoxicam. For improvement of the tablets diverse excipients are utilized. The utilized avrious excipients are the karayagum, sodium alginate , pvpk30, Mg.sterate, Talc. MCC utilized as the diluents, Mg.sterate utilized as the ointments. Powder is utilized as Glidant. The plan is created by the utilizing direct pressure method.The detailing is set up by utilizing distinctive excipients .The excipients are hpmc and xanthin gum in different arrangements for medication to deliver in 10hrs. The pre pressure boundaries are done, for example, the mass thickness ,tap thickness, compressability file, Hauners proportion, Angle of rest. The all boundaries are gone under inside range great stream. The post pressure boundaries are done, for example, the saddle, thickness, weight variety, friability, breaking down. The assessment boundaries of theoptimised plan F8 tablets esteems.The weight variety of network tablets, 4 00mg. The hardness of the network tablets, 3.1(Kg/cm2).Thickness of the network tablets, 2.50mm. Breaking down of the framework tablets,25 mins. Friability of the network tablets, 0.256 % . In-vitro tranquilize disintegration investigations of the oral dispersible tablets, 98.65%. The all boundaries go under adequate standards inside scope of limts. The In-vitro medicate discharge examines are finished by USP-II mechanical assembly paddle strategy. The improved definition F9gives the drag out delivery upto 10hrs the medication discharge

Keywords: *Formulation, Evaluation, Lornoxicam, Sustained Release Tablets, Natural Polymers*

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INTRODUCTION:

Natural polymers are polymers that break down in a normal and biocompatible way and lose their individuality when they come into contact with biological components.1 These polymers are chosen over semi-synthetic and synthetic excipients. Bacterial growth, lot to lot variation, unpredictable ratio of hydration, and lower thickness during preservation are all issues that need to be addressed. Incorrect mechanical characteristics and low strew.2 Chemical adjustments were performed to improve the stability and process ability of newly discovered gums. If the newly created gums are biodegradable and biocompatible, they can be employed; if not, a biodegradable component can be added to make them biodegradable.3 To alter of molecular interaction between polymers, a variety of techniques can be applied. There are two approaches to choose from: physical and chemical.4 Physical technique Dry heat, water-logged steam, microwave, UV, even gamma radiation can all be utilized to generate a molecular interaction between polymers.5 Polymers are treated with chemicals such aldehydes, epichlorohydrin, borax, or glutaraldehyde in the chemical approach. Temperature cross-linking is single of the greatest advantageous cross-linking operations as it eliminates the need for harsh organic chemicals in large-scale production, as well as the associated equipment and methods.6 Because of the increased dose flexibility for design, the oral route of delivery for sustained release systems had gained considerable attention. The type of delivery system, the ailment being handled, the patient, the duration of medication, and the drug quality are all significant considerations in the design of oral sustained release delivery systems.7 The major goal of therapy is to keep the amount of drug in the blood at a steady level for a longer time. A major component of reaching this goal is the establishment of appropriate dose regimens. Sustained-release dosage forms are a type of drug administration that releases medication continuously over time to give long-term therapeutic benefit. Dosage is given in a single dose.8 Lornoxicam, a non – steroidal anti-inflammatory medication (NSAID) from the oxicam family, has been proven to have significant anti-inflammatory and analgesic properties. Lornoxicam is commonly used to treat symptomatic ache and infection in people with osteoarthritis and rheumatoid arthritis, as well as pain from gynecological, orthopedic, gastrointestinal and dental treatment.9-10 The main aim of the study formulation and evaluation of the lornoxicam sustained release tablets by using natural polymers.

MATERIALS:

Table 1: Materials used to be formulate

S.No.	MATERIALS	SOURCE
1.	Lornoxicam	RA chem Pharma
2.	Sodium alginate	Arun Pharma
3.	Karayagum	Shinetsu company
4.	MCC	Evonik company
5.	Talc	Evonik company
6.	Pvpk 30	Laxmi chem. Pvt.ltd
7.	Magnesium stearate	Clariant pharma

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FORMULATION AND EVALUATION OF SIMVASTATIN MATRIX TABLETS

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Abstract:
The Purpose of this Research work was to Formulate and Evaluate Anti-Hyperlipidemic Drug (HMG-coA reductase Inhibitor) in a Controlled discharge dose type of Simvastatin Matrix Tablets.The Tablets were Prepared by utilizing HMPC K15M, HMPC K100M, MicroCrystalline Cellulose , sodium CMC, Magnesium Streate and concentrated with various rate Controlling polymers. The Technique Employed is the Preparation of Matrix Tablet framework by direct Compression Matrix.The Sustainability of the medication is safe,Effective and stable Controlled Release Dosage type of HMPC K100M at centralization of 40mg in blend with Ethyl Cellulose at20mg was seen as acceptable Sustainability and 99% medication discharge in 24 hrs. The enhanced Formulation was assessed with Parameters like Thickness, friability , weight Variation, medicate Content, Invitro Drug discharge and Results were seen as inside the Limits.

Keywords: *Matrix tablets, HMPC K15M, HMPC K100M, MicroCrystalline Cellulose, Controlled discharge, Simvastatin*

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INTRODUCTION:

Atherosclerosis is a general term describing any hardening (loss of elasticity) of the medium of large arteries (in Greek, "Arterio" meaning artery and "sclerosis" meaning hardening), is a condition in which fatty material collects along the walls of arteries. This fatty material thickens, hardens, and eventually blocks the arteries [1]. Simvastatin is a lipid-lowering agent that is derived synthetically from a fermentation product of Aspergillus terreus. After oral ingestion, simvastatin, which is an inactive lactone, is hydrolyzed to the corresponding β-hydroxyacid form. This is an inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase. This enzyme catalyzes the conversion of HMG-CoA to mevalonate, which is an early and rate-limiting step in the biosynthesis of cholesterol. Also, it has been reported [2, 3] that simvastatin is more efficiently extracted by the liver than its corresponding hydroxy acid with subsequent minimization of systemic burden [4]. This suggests that compared to a conventional dosage form, a sustained/controlled release dosage form of simvastatin might provide similar or better efficacy [5]. One of the most feasible approaches for achieving a prolonged and predictable drug delivery in the GI tract is to control the gastric residence time (GRT), i.e. gastro retentive drug delivery system (GRRDS). GRRDS extend significantly the period of time over which the drugs may be released. They not only prolong dosing intervals but also increase patient compliance beyond the level of existing controlled release dosage form [6]. A number of approaches have been used to increase the GRT of a dosage form in stomach by employing a variety of concepts such as Floating Systems [7], Bio/Mucoadhesive Systems [8], and Swelling and expanding systems [9], High-Density Systems [10], Incorporation of passage delaying food agents [11], Ion exchange resins [12], and Osmotic regulated systems [13].

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Oral drug delivery is the simplest and easiest way of administering drugs. Because of the greater stability, accurate dosage and easy production, solid oral dosage forms have many advantages over other types of oral dosage forms [1,2] . Therefore, most of the new chemical entities (NCE) under development these days are intended to be used as a solid dosage form that originate an effective and reproducible in vivo plasma concentration after oral administration [3] . In fact, most new chemical entities's are poorly water soluble

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FORMULATION AND IN-VITRO CHARACTERIZATION OF THE ITRACONAZOLE LIPOSOMAL DRUG DELIVERY

Chitharam Srihari, D.Rajkumar
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Article Received: December 2022 **Accepted:** January 2023 **Published:** February 2023

Abstract:
The main aim of the present work is Formulation and in-vitro characterization of the Itraconazole liposomal drug delivery. The objectives are liposomes are prepared by using film hydration technique by using rotary evaporator, For the preparation of liposomes cholesterol and cholins are used, to improve the bio availability of a drug, to enhance the patient compliance, Finally, completion of formulation the evaluation parameters were conducted. It was concluded that the optimized formulation F9, followed zero order release where the regression value was found to be 0.900It was also found that the drug was released by diffusion as the regression in Higuchi's plot was 0.988. The ideal liposomes film showed upheld appearance of the medicine stood out from the relieved film containing the free prescription.The in vitro release energy of medicine from the liposomes suspension and liposomes film followed the Higuchi scattering model. Moreover, the in vivo study in bunnies showed in a general sense higher rate and level of ketoconazole ingestion from sublingual fast dissolving liposomes film appeared differently in relation to that from oral business tablets.

Key words: *Formulation, In-Vitro Characterization, Itraconazole Liposomal Drug Delivery*

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INTRODUCTION:

Liposome is a microparticulate colloidal vesicle, in which aqueous medium is surrounded by single or multiple concentric layers of phospholipids. Due to their size, both hydrophilic and hydrophobic drugs (besides biocompatibility) can be incorporated, water-soluble drug being entrapped in aqueous core and fat-soluble drug in phospholipids [1,2]. It offers controlled release, targeted drug delivery, thus enhancing therapeutic efficacy, and reduced dosing frequency. Therapeutically, these are used as a carrier for drugs, viruses, bacteria, antigen, peptides, antibiotics, vaccines, genes, and diagnostic agents [3,4]. Liposomes are small artificial vesicles of spherical shape that can be created from cholesterol and natural nontoxic phospholipids. Liposome properties differ considerably with lipid composition, surface charge, size, and the method of preparation. Furthermore, the choice of bilayer components determines the "rigidity" or "fluidity" and the charge of the bilayer. For instance, unsaturated phosphatidylcholine (PC) species from natural sources (egg or soybean PC) give much more permeable and less stable bilayers, whereas the saturated phospholipids with long acyl chains (e.g., dipalmitoyl PC) form a rigid, rather impermeable bilayer structure [2]. In general, liposomes are definite as spherical vesicles with particle sizes ranging from 30 nm to several micrometers. They consist of one or more lipid bilayers surrounding aqueous units, where the polar head groups are oriented in the pathway of the interior and exterior aqueous phases. On the other hand, self-aggregation of polar lipids is not limited to conventional bilayer structures which rely on molecular shape, temperature, and environmental and preparation conditions but may self-assemble into various types of colloidal particles [5]. Liposomes are prepared using sonication, thin-film hydration, solvent dispersion method, and detergent removal methods. Drug loading can be attained either passively (i.e., the drug is encapsulated during liposome formation) or actively (i.e., after liposome formation) [6]. The liposome size can vary from very small (0.025 μm) to large (2.5 μm) vesicles. Moreover, liposomes may have one or bilayer membranes. The vesicle size is an acute parameter in determining the circulation half-life of liposomes, and both size and number of bilayers affect the amount of drug encapsulation in the liposomes. Liposomes can also be classified into one of two categories: (1) Multilamellar vesicles (MLV) and (2) unilamellar vesicles. Unilamellar vesicles can also be classified into two categories: (1) Large unilamellar vesicles and (2) small unilamellar vesicles. In unilamellar liposomes, the vesicle has a single phospholipid bilayer sphere enclosing the aqueous solution. In multilamellar liposomes, vesicles have an onion structure. Classically, several unilamellar vesicles will form on the inside of the other with smaller size, making a multilamellar structure of concentric phospholipid spheres separated by layers of water [7-9]. Liposomes are found to be suitable for localization of topically applied drugs at or near the site of application because they may act as slowreleasing vehicles. Topical drug delivery is a pleasing route for local and systemic treatment. The delivery of drug through topical route is the most effective treatment for the skin diseases [10]. Finally, liposomal drugs exhibit reduced toxicities and retain enhanced efficacy compared with free complements. However, based on the pharmaceutical applications and available products, liposomes have definitely established their position in modern delivery systems [6]. Fluconazole (FLZ) is a first-generation water-soluble triazole antifungal medication that is administered orally or intravenously. It is used to treat a variety of fungal infections, especially Candida infections of the vagina, mouth, throat, bloodstream, fungal keratitis, tinea infection, and coccidioidal meningitis. It is now available as tablet, capsule, injection, and eye drop formulations. The dosage forms have well-known side effects including nausea, vomiting, diarrhea, headache, and abdominal pain. To reduce the disadvantages, the topical gel formulation has been proposed [11]. A gel is a two-component, crosslinked three-dimensional network consisting of structural materials interspersed by an adequate but proportionally large amount of liquid to form an infinite rigid network structure, which immobilizes the liquid continuous phase within [12]. Both hydrophilic and lipophilic drugs can be easily encapsulated in liposomal formulation, and dispensing in the form of carbopol gel was found to be well suited and sound approach to obtain stable liposomal formulation [13].

Itraconazole One of the triazole antifungal agents that inhibits cytochrome P-450-dependent enzymes resulting in impairment of ergo sterol synthesis. It has been used against histoplasmosis, blastomycosis, cryptococcal meningitis & aspergillosis.Itraconazole interacts with 14-α demethylase, a cytochrome P-450 enzyme necessary to convert lanosterol to ergosterol. As ergosterol is an essential component of the fungal cell membrane, inhibition of its synthesis results in increased cellular permeability causing leakage of cellular contents. Itraconazole may also inhibit endogenous respiration, interact with membrane

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TO FORMULATION AND *IN-VITRO* EVALUATION OF LIPOSOMAL DRUG DELIVERY SYSTEM OF DECITABINE

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Abstract:
The medicine launch from Liposomes depends upon many aspects consisting of the structure of Liposomes, the kind of medicine encapsulated and nature of the cell. Once it is released a medicine that generally goes across the membrane of a cell will certainly enter the cell, various other medicines will not go into. Decitabine is a short biological half-life. This research study targeted at Formula As well as In-Vitro Assessment Of Liposomal Drug Shipment System Of Decitabine in order to boost its bioavailability. In examination study the result of the differing make-up of lipids on the residential or commercial properties such as encapsulation efficiency, fragment size as well as medication release were researched. Stage change research was executed to validate the total interaction of Decitabine with bilayer structure of liposome. Moreover, the launch of the drug was likewise modified as well as crossed a duration of 8 h in all solutions. F1 became one of the most acceptable formula in so far as its residential or commercial properties were concerned. Additionally, release of the medicine from the most sufficient formula (F1) was assessed via dialysis membrane layer to get the idea of medication launch.

Keywords: *Liposomes, Decitabine, Bioavailability.*

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INTRODUCTION:

The most recent development in vesicle design for transcutaneous bioactive delivery is the use of elastic liposomes, which differ from conventional liposomes due to their characteristic fluid membrane with high elasticity [1]. Elastic liposomes have been defined as specially designed vesicular particles, consisting of at least one inner aqueous compartment surrounded by a lipid bilayer with appropriately tailored properties. Elastic liposomes consist of phospholipids, surfactants such as edge activators, and an inner aqueous compartment enclosed within a lipid bilayer capable of encapsulating hydrophilic (in an aqueous chamber) and lipophilic (in a lipid bilayer) molecules [2].

Drug delivery systems using vesicular carriers have soft, flexible, self-regulating, and self-optimizing vesicular characteristics. Greater flexibility of elastic liposomal membranes is achieved by mixing suitable surface-active components in the proper ratios [3]. These properties allow them to penetrate more easily into deeper layers of the skin and circulation. In Elastic liposomes, elasticity is stress controlled, owing to the composition dependence of the membrane bending energy [4]. They are elastic, very deformable vesicles which consist of phosphatidylcholine in combination with an edge-active surfactant like sodium cholate and span 80. Elastic liposomes are applied non-occluded to the skin and are reported to permeate through the stratum corneum lipid lamellar regions as a result of the hydration or osmotic force in the skin [5]. Elastic liposomes passage through the normally confining pores is then governed by the basic principles of elasto mechanics. However, elastic liposomes resemble lipid vesicles, liposomes, in morphology but functionally; elastic liposomes are sufficiently deformable to penetrate pores much smaller than their own size. They are metastable, which makes the vesicle membrane ultra flexible and thus the vesicles are highly deformable [6]. Decitabine is a cytidine deoxynucleoside analog, which acts by inhibiting DNA methyltransferase, inducing DNA hypomethylation [7,8]. It is used for the treatment of acute myeloid leukemia (AML) in patients aged ≥65 years. However, it can only be administered intravenously due to very low oral bioavailability and a large distribution volume. Decitabine is a hydrophilic drug (log P=−2.2), with a short half-life (25 minutes), and is sensitive to harsh conditions [9].

The aim of the present study is To Formulation and In-vitro evaluation of liposomal drug delivery system of Decitabine.

MATERIALS:

Decitabine Purchased from Aurobindo Laboratories Ltd. Cholesterol, Chloroform from S.D.Fine chemicals Pvt.Ltd, Mumbai. Soybean lecithin, Tween 80 from Merck specialities Pvt.Ltd., Mumbai.

METHODOLOGY:

Preformulation study:

Standardcalibration curve:

Criterion calibration curve of Decitabine was developed using phosphate buffer pH 7.4 and approximated by UV-Visible spectrophotometer at 243nm.

General Treatment For The Prep Work Of Calibration Contour By Uv:

A gracefully cure of (1mg/ml) of basic medication was readied, later called for weakenings were made with a phosphate obstruction pH 7.4. To an assortment of 10ml volumetric carafes aliquots normal choices were taken and the amount was utilized a phosphate boundary pH 7.4. The absorbance of these arrangements was estimated at specific wave size of ideal absorbance, utilizing 1cm quartz cuvette in UV-Noticeable spectrophotometer. Absorbance esteems were plotted as opposed to comparing fixation to get regular alignment bend.

Medication excipient similarity explores:

Infrared (IR) spectroscopy was performed utilizing a FTIR Spectrophotometer (Bruker) and furthermore the range was recorded in the frequency district of 4000 to 400 cm − 1. The strategy contained scattering a model (drug alone or mix of medicine just as excipients) in KBr and squeezing into circles by applying a worry of 5 parcels for 5 minutes in a water driven press. The pellet was put in the light course and furthermore the range was obtained.

Methodology For The Preparation Of Decitabine Liposome:

The planning of liposomes with Soybean lecithin was set up by dried out meager film hydration strategy utilizing a revolving evaporator (Aditya logical). Soyalecithin, cholesterol tween 80 and were disintegrated in 10 mL chloroform in 250mL round base (RB) jar. The chloroform was disintegrated under vacuum using turning streak evaporator, which empowers soya lecithin to frame a dainty totally dry film on the dividers of the carafe. This framework was kept up at vacuum and 40 ° C for an additional 10min, after complete end of natural dissolvable as appeared by visual perceptions. Rankles were set up by hydrating the lipid film within the sight of 10mL phosphate support pH 7.4. Liposomes made were

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APPLICATION OF BOX-BEHKEN DESIGN FOR PREPARATION OF LOMEFLOXACIN LOADED SOLID LIPID NANO PARTICLES FOR OCULAR DELIVERY

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Abstract:
The aim of the present study was to optimize a solid lipid nanoparticle (SLN) of Lomifloxacin by investigating the relationship between design factors and experimental data using response surface methodology. A Box-Behnken design was constructed using solid lipid (X1), surfactant (X2), and drug/lipid ratio (X3) level as independent factors. SLN was successfully prepared by a modified method of melt-emulsion ultrasonication and low temperature- solidification technique using glyceryl monostearate as the solid lipid, and poloxamer 188 as the surfactant. The dependent variables were entrapment efficiency (EE), drug loading (DL), and turbidity. Properties of SLN such as the morphology, particle size, zeta potential, EE, DL, and drug release behavior were investigated, respectively. As a result, the nanoparticle designed showed nearly spherical particles with a mean particle size of 248 nm. The polydispersity index of particle size was 0.277 ± 0.058 and zeta potential was - 8.74 mV. The EE (%) and DL (%) could reach up to 83.29% ± 1.23% and 10.11% ± 2.02%, respectively. In vitro release studies showed a burst release at the initial stage followed by a prolonged release of Lomefloxacin from SLN up to 48 hours. The release kinetics of the optimized formulation best fitted the Peppas–Korsmeyer model. These results indicated that the Lomefloxacin-loaded SLN could potentially be exploited as a delivery system with improved drug entrapment efficiency and controlled drug release.

Keywords: *Box-Behken Design, Lomefloxacin, Solid Lipid Nano Particles, Ocular Delivery*

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INTRODUCTION:

Pharmaceutical nanoparticles (NPs) are ultrafine colloidal particles with a size ranging from 10 to 1000 nm that contain drugs and exhibit distinct properties from their source materials [1]. Antimicrobial-loaded NPs, for example, can enter cells via endocytosis and release the medicine, thereby eliminating microbe-induced intracellular infections [2]. NPs have a number of advantages, including the capacity to extend drug release. For example, in ocular delivery, they have been observed to enhance the time spent on the corneal surface, boosting ocular bioavailability and lowering systemic toxicity. They also allow lower drug concentrations to be employed in the formulation while generating high drug concentrations at the site of action by enhancing bioavailability [3]. Because of their small size, NPs are particularly well suited to this task, as particles smaller than 10 nm often cause no or very little discomfort [4,5]. Another element to examine before the commercial production of particle systems is stability [6].

Lomefloxacin is a fluoroquinolone used to prevent and treat a wide variety of infections in the body. Lomefloxacin is a bactericidal fluoroquinolone agent with activity against a wide range of gram-negative and gram-positive organisms. The bactericidal action of lomefloxacin results from interference with the activity of the bacterial enzymes DNA gyrase and topoisomerase IV, which are needed for the transcription and replication of bacterial DNA. DNA gyrase appears to be the primary quinolone target for gram-negative bacteria. Topoisomerase IV appears to be the preferential target in gram-positive organisms. Interference with these two topoisomerases results in strand breakage of the bacterial chromosome, supercoiling, and resealing. As a result DNA replication and transcription is inhibited.

The aim of the present study was to optimize a solid lipid nanoparticle (SLN) of Lomifloxacin by investigating the relationship between design factors and experimental data using response surface methodology.

MATERIALS:

The powered Lomefloxacin was supplied by Micro lab, Poloxamer 188 was purchased from Lobachem, Mumbai, Glyceryl Monostearate were pur- chased from Colorcon Asia Pvt. Ltd., Goa, Methanol was of high-performance liquid chromatography (HPLC) grade. All other reagents and solvents were of analytical reagent grade

METHODOLOGY:

Preparation of SLN

SLN was prepared according to previous articles with some modification [184] by the following melt-emulsion ultrasonica- tion and low temperature-solidification methods. In brief, aqueous and oil phases were separately prepared in glass vials. Drug and a specified amount of GMS were dissolved in a spec- ified volume of ethanol (2 mL) and heated above the melting temperature of GMS (70 ^{0}C). Hydrophilic surfactants and dou- ble distilled water were mixed at 70^{0}C and added to the melted oil phase. The resulting suspension was continually stirred by mechanical agitation (DC-40, Hangzhou Electrical Engineer- ing Instruments, China) at 400 rpm for 15 minutes at 70 ^{0}C. The original warm emulsion was further treated for 5 minutes (work 2 seconds and stand 3 seconds) by a Lab ultrasonic cell pulverizer (JY92-II, Ningbo Scientz Biotechnology Co., Ltd. China) at 600 W to form a nanoemulsion. This was rapidly cooled by immersing the beaker into icy water. Agitation continued until the nanoemulsion yielded a uniform disper- sion of nanoparticles.

Experimental design:

In this study, a 17-run, 3-factor, 3-level Box-Behnken design was employed to construct polynomial models for the optimization process, because it requires few runs with 3 or 4 variables. This design was suitable for investigating the quadratic response surface and for constructing a second- order polynomial model using Design-Expert software (Trial Version7.1.6, Stat-Ease Inc., MN).The design consisted of replicated center points and a set of points lying at the midpoints of each edge of the multidimensional cube, which defined the region of interest used to evaluate the main effects, interaction effects, and quadratic effects of the formulation ingredients, and to optimize the formulation. The non-linear quadratic model generated by the design was:

$Y = A_0 + A_1X_1 + A_2X_2 + A_3X_3 + A_4X_1X_2 + A_5X_2X_3 + A_6X_1X_3 + A_7X_1^2 + A_8X_2^2 + A_9X_3^2$, in which Y is the measured respons of the dependent variables associated with each factor-level combination; A_0 - A_1 are the regression coefficients of the respective variables and their interaction terms computed from the observed experimental values of Y; and X_1 , X_2 , X_3 are the coded levels of independent variables. The term $X_1 X_2$ and X^2 (i = 1, 2 or 3) represent the interaction and quadratic terms respectively [185].Factors evaluated in this study were the amount of GMS (X_1), concentration of poloxamer (X_2) and the ratio of drug/lipid (X_3) as the independent variables which were represented by -1, 0 and +1, analogous to the low, middle, and high values respectively as described in Table 1. The studied dependent responses were

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PREPARATION AND CHARACTERIZATION OF DILTIAZEM HYDROCHLORIDE TABLETS FOR CONTROLLED RELEASE

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Abstract:
The aim of the present study was to prepare and characterize controlled-release matrix tablets of Diltiazem hydrochloride using various viscosity grades of hydrophilic polymers and hydrophobic polymers in three different proportions were prepared by wet granulation method and subjected to in vitro drug release studies. The studies shows that formulation of drug with polymers like hydrophilic HPMC K4M >HPMC K15M >HPMC K100M and hydrophobic polymers like Eudragit RL100 >Eudragit RS100> Ethyl cellulose showed the drug release in decreasing order. Among that D1C which containing HPMC K100M with ethyl cellulose in the ratio of 1:2 showed the best controlled release of diltiazem hydrochloride. Thus the above study clearly indicated that diltiazem HCl may be formulated as Controlled release tablets using HPMC K100M with ethyl cellulose by wet granulation method which will provide continuous release of drug at a predetermined rate and for a predetermined time.

Keywords: *Controlled release, Matrix tablets, Diltiazem hydrochloride, Wet granulation method.*

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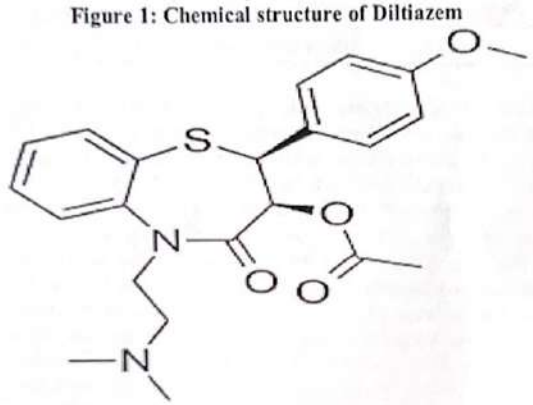
INTRODUCTION:

Oral route is the most preferred route for administration of drugs. Tablets are the most popular oral formulations available in the market and preferred by the patients and physicians alike. In long-term therapy for the treatment of chronic disease conditions, conventional formulations are required to be administered in multiple doses, and therefore have several disadvantages [1]. Controlled release (CR) tablet formulations are much desirable and preferred for such therapy because they offer better patient compliance, maintain uniform drug levels, reduce dose and side effects, and increase safety margin for high potency drugs [2]. Controlled release products are designed to maintain constant therapeutic plasma concentration of the drug within the therapeutic range of the drug over prolonged periods [3]. Matrix is defined as a well-mixed composite of one or more drugs with gelling agent i.e., hydrophilic polymers [4]. Matrix technologies have often proven popular among the oral controlled drug delivery technologies because of their simplicity, ease in manufacturing, high level of reproducibility, stability of the raw materials and dosage form and ease of scale-up and process validation [5]. Diltiazem hydrochloride is a widely used as a calcium channel blocking agent. It has a short biological half-life of 3-4.5 hrs and it is rapidly eliminated from the body. Its effects last only for few hours and hence it needs to be administered 3 to 4 times a day. Diltiazem is completely absorbed in gastrointestinal tract but exhibits very low oral bioavailability due to extensive first pass metabolism in the liver by the enzyme CYP3A of cytochrome P450 enzyme group. Hence there is every need for formulating a sustained release dosage form for Diltiazem hydrochloride to improve its therapeutic efficacy and patient compliance [6-9].

Figure 1: Chemical structure of Diltiazem



The aim of the present study was to prepare and characterize controlled-release matrix tablets of Diltiazem hydrochloride using various viscosity grades of hydrophilic polymers and hydrophobic polymers in three different proportions were prepared by wet granulation method and subjected to in vitro drug release studies.

MATERIALS:

Diltiazem hydrochloride Purchased from Dr.Reddy's (Hyderbad,India). HPMCK4M, HPMCK15M, HPMCK100M from Colorcon, Goa. EDGT RS 100, EDGT RL 100 from Evonik Degussa India Pvt Ltd, Mumbai. Lactose monohydrate, MCC from S.D. Fine Chem. Limited, Mumbai, India.

METHODOLOGY:

Determination of λ_{max} of Diltiazem Hydrochloride in distilled water:

Stock solution: Diltiazem Hydrochloride in distilled water (100 mg in 100 ml) **Scanning**: From the stock solution, a suitable concentration of Diltiazem Hydrochloride (10 µg / ml) was prepared in distilled water and UV scan was takenfor the above stock solutions between the wavelengths of 200- 400 nm.. The absorption maximum was found to be 236 nm and this wavelength was selected and utilized for further studies.

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FORMULATION AND OPTIMIZATION OF MOUTH DISSOLVING TABLET CONTAINING INDOMETHACIN SOLID DISPERSION

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Article Received: January 2023 **Accepted:** January 2023 **Published:** February 2023

Abstract:

Indomethacin is a non-steroidal anti-inflammatory drug mainly used for musculo skeletal & joint disorders including ankylosing, spondilitis, osteoarthritis, rheniatiod arthiritis acute gout & in inflammation and pain. The major drawback of this drug is its very low water solubility and low erratic absorption from GIT. The purpose of the present investigation was to increase the solubility and dissolution rate of Indomethacin by the preparation of its solid dispersion with polyvinyl pyrrolidone k30, PEG-4000and PEG-6000 using solvent evaporation and physical mixture method and preparation of MDT of indomethacin with different superdisintegrant and sublimable material.Drug polymer interaction were investigated (XRD) and (FTIR). The DSC, XRD and FTIR results showed no drug-polymer chemical interaction in the solid dispersion. Indomethacin solid dispersion with PVP K-30 (1:5) by solvent evaporation was used for the preparation of mouth dissolving tablet with various superdisintegrant by direct compression and sublimation method. The formulated fast dissolving tablets were evaluated for hardness, friability, wetting time, disintegration and in vitro drug released. The hardness of the prepared tablets were found in the range of 2.4 kg/cm2 to 3.2 kg/cm2. The friability values were less than 1%. All the formulation had disintegration time less than 1 min. The formulation SBP3 containing 4% crosspovidone showed 99.93% drug released within 5 min. FT-IR spectra revealed no chemical incompatibility between the drug and PVP K-30. The stability studies were conducted as per ICH guidelines and the formulations were found to be stable with insignificant change in the hardness, disintegration and in vitro drug released pattern.

KEYWORDS: *Indomethacin; Solid dispersion, polyvinyl pyrrolidone K-30; mouth dissolving tablet; superdisintigrants.*

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INTRODUCTION:

Over the past three decades Mouth Dissolving Tablets (MDTs) have gained much attention as a preferred alternative to conventional oral dosage forms such as tablets and capsules. An MDT is a solid dosage form that disintegrates and dissolves in the mouth (either on or beneath the tongue or in the buccal cavity) without water within 60 seconds or less and absorption is systemic without first pass metabolism. For people who are having the problem in the swallowing or chewing can take it easily as the disintegrated mass can slide down smoothly with the help of saliva. An MDT is formulated as a bioequivalent line extension of an existing oral dosage form. Superdisintigrants are used for the rapid dissolution and sublimating agents are used to increase porosity. [1-5] he application of an optimization technique consisting of statistical design to pharmaceutical formulation development would provide an efficient and economical method to acquire the necessary information to understand the relationship between controllable (independent)variables and performance or response (dependent)variables [6-9].

Indomethacin is a member of the non-steroidal anti-inflammatory drugs (NSAIDS), chemically [1-(4-chlorobenzoyl)-5-methoxy-2-methylindole-3-Yl] acetic acid. It is used in musculo skeletal and joint disorders including ankylosing spondylitis, osteoarthritis, rheumatoid arthritis and acute gout and in peri-articular disorder such as buritis and tendinitis may also be used in inflammation, pain and oedema following orthopaedic procedures. The drug is described as practically insoluble and highly permeable (Class-II) drug. Because water insoluble drug often show low absorption and weak bioavailability, improvement in dissolution rate and/or solubility are important for development of drug preparations. The successful formulation of poorly water soluble drugs is one of the major problems in pharmaceutical manufacturing. Indomethacin may show low and erratic oral bioavailability due to poor dissolution of the drug in the fluids of gastrointestinal tract additionally, this undesirable physical property may increase the incidence of irritating side effects on the gastrointestinal tract because of a prolonged contact time with the mucosa. .[10-13]

Therefore in the present study an attempt will be made to formulate mouth dissolving tablets of Indomethacin using superdisintegrants and solid dispersion technique to improve the dissolution rate of this widely used anti rheumatic agent, to obtain more rapid and complete absorption and greater patients compliance.

MATERIALS:

Indomethacin Purchased from SUN pharma. Polyethylene glycol 4000 LR, Polyethylene glycol 6000 LR, Polyvinyl pyrrolidone-K30, Microcrystalline cellulose, Camphor, Magnesium stearate, Lactose from SD fine-chem. Limited, Mumbai.

METHODOLOGY:

Determination of λ_{max} for Indomethacin in phosphate buffer pH (6.8) 100mg of pure drug transferred into 100ml of phosphate buffer pH (6.8) in a volumetric flask. Withdrawn 10ml from this solution and diluted to 100ml it make 100mcg/ml (stock solution) then concentration made by withdrawing 0.5,1, 1.5, 2, 2.5, 3, 3.5 and 4ml from stock solution and diluted to 10ml it makes solution of concentration 5 g/ml, 10 g/ml, 15 g/ml, 20 g/ml, 25 g/ml, 30 g/ml, 35 g/ml, 40 g/ml and sample were scanned between 200-400 nm regions using Shimadzu UV/visible 1700 spectrophotometer; to determine the λ_{max} of Indomethacin in phosphate buffer pH (6.8).

Determination of λ_{max} for Indomethacin in methanol: 100mg of pure drug transferred into 100ml of methanol in a volumetric flask. Withdrawn 10ml from this solution and diluted to 100ml it make 100mcg/ml (stock solution) then diluted to 10ml it makes solution of concentration 5 g/ml, 10 g/ml, 15 g/ml, 20 g/ml, 25 g/ml, 30 g/ml, 35 g/ml, 40 g/ml and sample were scanned between 200-400 nm regions using Shimadzu UV/visible 1700 spectrophotometer; to determine the λ_{max} of Indomethacin in phosphate buffer pH (6.8).

Standard calibration curve of Indomethacin in phosphate buffer pH (6.8)100mg of pure drug transferred into 100ml of phosphate buffer (pH6.8) in a volumetric flask. Withdrawn 10ml from this solution and diluted to 100ml it make 100mcg/ml (stock solution) then concentration made by withdrawing 0.5, 1,1.5, 2, 2.5,3,3.5,4ml from stock solution and diluted to 10ml it makes solution of concentration 5 g/ml, 10 g/ml, 15 g/ml, 20 g/ml , 25 g/ml, 30 g/ml & 40 g/ml.Solution ranging from 5 to 40 g/ml were prepared using phosphate buffer (ph 6.8); separately, absorbance was measured for each solution at λ_{max} of 319nm using Shimadzu UV/visible 1700 spectrophotometer, graph was

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FORMULATION DEVELOPMENT OF IRBESARTAN (POORLY WATER-SOLUBLE DRUG) FOR ORAL ADMINISTRATION

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Abstract:

The aim of the present study is to increase the solubility of poorly water soluble drug Irbesartan by using surfactants and formulating into immediate release tablets by using super disintegrants. Surfactants such as sodium lauryl sulfate, polysorbate, and poloxamer 800 are used for increasing the solubility of drug in water by micellisation technique. Super disintegrant such as croscarmellose sodium was used for fast disintegration. Physical properties for granules such as Bulk density, Tapped density, Hausners ratio, % compressibility, % LOD and physical characteristics for Irbesartan IR tablets such as weight variation, friability, hardness, thickness, disintegration, in-vitro dissolution were studied. % cumulative drug release of formulation T3 (having 2% Tween 80) matched with the innovator product Avapro and the similarity factor between innovator and T3 was 97.

Keywords: *Formulation, Development, Irbesartan (Poorly Water-Soluble Drug), Oral Administration*

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INTRODUCTION:

The active pharmaceutical ingredient in a solid dosage form must undergo dissolution before it is available for absorption from the gastrointestinal tract. For hydrophobic drugs, the dissolution process acts as the rate-controlling step and, which determines the rate and degree of absorption. Consequently, many hydrophobic drugs show erratic and incomplete absorption from the gastrointestinal tract of animals and humans. Thus, one of the major challenges to drug development today is poor solubility, as an estimated 40% of all newly developed drugs are poorly soluble or insoluble in water1 . In addition, up to 50% of orally administered drug compounds suffer from formulation problems related to their low solubility and high lipophilicity2-5 . Irbesartan (IBS), 2-butyl-3[[2-(1Htetrazole-5-yl) (1,1- biphenyl)-4yl]metyl]-1,3 diazaspiro[4,4] non-1-en-4-one antagonizes angiotensin II by blocking AT1 receptors is indicated for treatment of hypertension6 . It belongs to class II drug according to biopharmaceutical classification system (BCS) i.e. low solubility and high permeability. According to BCS drug substance is considered to be highly soluble when highest dose of drug dissolve in less than 250 mL of water. It is considered to be highly permeable when the extent of absorption in human is more than 90 % of an administered dose. Although it has excellent oral bioavailability (60-80%), but theoretically IBS exhibit solubility limited bioavailability and it would be advantageous to increase the solubility of such molecule7. Solubility of IBS was found to be increased after complexation with polymer like β-CD8.

Different methods are employed to improve the dissolution characteristics of poorly water-soluble drugs, like solubilization, pH adjustment, cosolvents, microemulsion, self-emulsification, polymeric modification, drug complexation, particle size reduction, use of a surfactant as a solubilizing agent, the pro-drug approach, and solid solutions9-10. Amongst these the most promising method for promoting dissolution is the use of the liquisolid (LS) system11-12

The objective of the present work is to perform preformulation studies to develop a portfolio of information about the Irbesartan by determining its essential physical and chemical properties like solubility, pKa, lipophilicity, solid state properties, stability drug excipient compatibility. Along with preformulation the aim of the present study was to develop Irbesartan IR tablets using different surfactants for improving the dissolution rate of Irbesartan.

METHODOLOGY:

Determination of saturation solubility:

Prior to the experimentation, water sample of Irbesartan scanned for λ max. of the drug. Taking different standard concentrations of sample plotted a standard graph. Adding excess solid (150 mg) to 100 mL deionized water placed in stoppered conical flask, pre-equilibrated to 37 ± 0.5 °C. The flasks were mechanically shaken in a shaking water bath at 100 rpm. And shake for 24 hrs. And it was filtered to get a supernatant solution. From this solution pipette out 1ml and it was diluted to 10ml with water. And the absorbance checked at 220 nm for 3 times and the average value of the absorbance was taken for calculations to get concentration of drug.

Determination of log p by shake flask method:

The partition coefficient of Irbesartan was determined in n-octanol-water systems Aqueous solution of 150mg of Irbesartan in 100 ml was prepared. To the aqueous phase 100 ml of n-octanol was added. The flasks were stoppered and agitated at room temperature for 2 h to achieve complete equilibration. The aqueous phase was analyzed by a UV apparatus for absorbance and its concentration was calculated from a preconstructed calibration curve.

Determination of pka by spectrofluorimeter:

pH measurements were made using a Radiometer PHM 84 pH meter , with a Crison 5209 combined glass electrode. An Ag/AgCl reference system was used with 3 M KCl saturated in AgCl as electrolyte. Excitation and emission spectra and relative fluorescence intensity measurements of Irbesartan solutions were obtained using a Shimadzu RF-540 spectrofluorimeter controlled by a Shimadzu DR-3 data recorder. A quartz cell of 1 cm of optic length was used. Data collection was made by means of FLUORIM software. This program allows the digital collection of the main types of scans that a commercial. Spectrofluorimeter can perform: emission, excitation and synchronic; as well as the measurement of the relative fluorescent intensity as a function of time. A Haake D8 thermostatic bath was used to keep the temperature constant, 20 + or - 0.5°C.

Drug-excipients compatibility studies:

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FORMULATION AND EVALUATION OF FAST DISSOLVING TABLETS OF AN ANTI-ANGINAL DRUG

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Abstract:
The aim of this work is to prepare fast dissolving tablets of Diltiazem Hydrochloride to inprove patient compliance. Tablets containing Diltiazem hydrochloride were formulated using various superdisintegrants like crospovidone (CRP), Croscarmellose sodium(CCS) and sodium starch glycolate(SSG) in concentrations ranging from 2-6%. The tablets were prepared bydirect compression method. The flow properties of the granules (F1-F11) were evaluated by determining theCarr's index, Hausner ratio and angle of repose. Poured density values of different batches were found to range between 0.518 and 0.585gm/ml^3, whereas tapped density values were found to vary from 0.641 to 0.668gm/ml^3. Carr's index, Hausner ratio and angle of repose were range between 18.24 to 20.30, 1.22 to 1.25, and 21°40' to 29°66' respectively, which indicates that granules prepared exhibit good flow properties. Tablets (F1-F11) were evaluated for tablet properties like thickness, hardness, friability, disintegration time, weight variation, wetting time and drug content uniformity. Disintegration time of formulations (F10 and F11) prepared by sublimation technique was found to be in the range 25.32±0.258 sec to 26.12±0.215 sec. In vitro dissolution study of formulation of F10 (which gave least disintegration time of 25.32±0.258 sec) showed a cumulative release of 78.115 ± 0.162 after 10 min

Keywords: *Formulation, Evaluation, Fast Dissolving Tablets, Anti-Anginal Drug*

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INTRODUCTION:

The oral passage of medicament administration for illness is measured as the most conventional route. Tablet is a commonly prescribed dosage form as of its accessibility in terms of self-administration, solidity and simplicity in development. Patients particularly pediatric and geriatric, often experience trouble in swallowing conventional tablets and this problem may prove worst during the traveling conditions due to the non-availability or restricted availability of water. These problems of conventional dosage forms can be encountered by the development of mouth dissolving tablets [1, 2, 3] These tablets disintegrate in the mouth within a very short span i.e. 20-30 sec and comes in contact with saliva resulting in the therapeutic action of active agent [4, 5]. Mouth dissolving tablets show better patient compliance and acceptance with improved bioavailability, efficacy and biopharmaceutical properties, in contrast to conventional tablets [6].

Diltiazem hydrochloride is a calcium ion cellular influx inhibitor (slow channel blocker) used to treat angina and hypertension. It acts by inhibiting the cellular influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle. The aim of this work is to prepare fast dissolving tablets of Diltiazem Hydrochloride to improve patient compliance. Specific objective of the research is as follows, Formulation of fast dissolving tablets of Diltiazem Hydrochloride-drug using various Superdisintegrants by various methods, Evaluation of the prepared FDTs for dissolution, disintegration, wetting time, hardness, etc.

MATERIAL AND METHODS:

Materials: Diltiazem Hydrochloride procured from Anglo-French Drugs and Industries Ltd., Bangalore, India. Crospovidone from International Speciality Product, Hong kong Ltd. Sodium starch glycolate, Mannitol, Magnesium stearate, Ammonium bicarbonate are from S.D. Fine Chemicals Limited, Mumbai. Microcrystalline Cellulose, Croscarmellose Sodium from The Anglo-French Drug Co. Limited, Bangalore. The materials used in the present investigation were either AR/ LR grade or the best possible pharma grade.

UV SPECTROPHOTOMETERIC METHOD FOR DILTIAZEM HCL:

UV SCANNING:

Procedure:

100mg of Diltiazem Hydrochloride was accurately weighed and dissolved in 100ml of phosphate buffer pH 6.8 to get a stock solution of 1mg/ml. Further, an aliquot was pipetted out and diluted suitably to get the concentration in the Beer's range and was scanned in the wavelength region of 200-350nm to record the wavelength of maximum absorption (λ_{max}). Diltiazem hydrochloride was reported to exhibit λ_{max} at 237nm.

Calibration curve for Diltiazem Hydrochloride:

Preparation of standard stock solution:

An accurately weighed quantity of Diltiazem Hydrochloride (100mg) was dissolved in small quantity of phosphate buffer pH 6.8. The volume was made up to 100 ml with phosphate buffer pH 6.8 to generate a primary stock solution of 1mg/ml. 1ml of the primary stock solution was further diluted to 50ml to produce a secondary stock solution having concentration of 20µ/ml.

Preparation of working standard solution:

Working standard solutions having concentrations 2 to 12 µg/ml were prepared by appropriately diluting the stock solution. The absorbance of the working standard solution was recorded and a graph of concentration of the solution was plotted against absorbance using Microsoft Excel software

DRUG EXCIPIENTS INTERACTION STUDY

Fourier Transform Infra-Red (FT-IR) Spectroscopy:

The infrared spectra of Diltiazem Hydrochloride and physical mixture of Diltiazem Hydrochloride and other excipients were recorded using a FT-IR spectrophotometer. The IR spectra's of physical mixture were compared with that of Diltiazem Hydrochloride to check for any possible drug-excipients interaction.

Differential Scanning Calorimetry:

The samples were hermetically sealed in flat-bottomed aluminum pans and heated over a temperature range of 40-240°C at a rate of 10°C/min using alumina as areference standard. Thermograms of drugs of optimized batches were recorded using a differential scanning calorimeter and were compared.

FORMULATION OF FAST DISSOLVING TABLETS

By Direct Compression Technique:

Tablets containing Diltiazem hydrochloride were formulated using various superdisintegrants like crospovidone (CRP), Croscarmellose sodium(CCS) and sodium starch glycolate(SSG) in concentrations ranging from 2-6%. The tablets were prepared by direct compression method.

Procedure: The tablets were prepared by direct compression method. All the ingredients were passed

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DESIGN AND *IN-VITRO* EVALUATION OF FAST DISINTEGRATING TABLETS OF AN ANTIHYPERTENSIVE DRUG

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Abstract:

Aim:The aim of the work was an attempt to make the formulation of fast disintegrating tablets of Diltiazem HCl by direct compression method with the aid of superdisintegrants addition.

Method: Fast disintegrating tablets of Diltiazem HCl were prepared by direct compression method. Nine formulations were developed by using three different superdisintegrants in varying concentrations in such a way that total weight of the tablet remains same. The drug-polymer incompatibility was ruled out by FTIR studies. All the formulated tablets were subjected for pre and post-compression evaluation parameters. A comparison of in vitro drug release of optimized formulation (DF9) was compared with marketed product (Dilzem).

Result: From the FTIR studies, the drug-polymers compatibilities were confirmed. All the formulated tablets were showing satisfactory results which comply with the official limits.

Conclusion: Among the nine formulations, the formulation containing 4.5% crospovidone (DF9) showed highest drug release of 95.72% as compared to other formulations. A comparison of in vitro drug release was made with marketed product of Diltiazem HCl (Dilzem) which shows 92.53% drug release in 1 hour. From this study we can make the conclusion that the formulated tablets of Diltiazem HCl containing crospovidone are better and effective than conventional tablets to meet patient compliance along with fast relief from hypertention and angina.

Keywords: *Formulation; FTIR studies; In vitro drug release; Diltiazem HCl; Fast disintegrating tablets; Superdisintegrant etc.*

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INTRODUCTION:

Oral drug delivery system is the most convenient form of drug delivery, having the largest degree of patient compliance. Tablet is the most preferred dosage form of oral drug delivery system among all dosage forms existing today because of its convenience of self-administration, compactness and easy manufacturing [1]. Many patients find it inconvenience to swallow tablets and capsules and do not take their medication as prescribed. It is estimated that 50% of the population is affected by this problem which result in a high incidence of non-compliance and ineffective therapy. The difficulty is occurred individually by pediatric and geriatric patients, but it also applies to people who are bedridden and to those active working patients [2].

A FDT is a tablet that dissolves or disintegrates in the oral cavity without requirement of water as well as chewing. The active ingredient is then swallowed by the patient's saliva along with the soluble and insoluble excipients [3]. These are also called melt-in-mouth tablets; repi melts, porous tablets, orodispersible, quick dissolving or rapid disintegrating tablets [4].

One important drawback of this conventional dosage forms for some patients, is the difficulty to swallow, drinking water plays an important role in the swallowing of oral dosage forms. Often sometimes people experience inconvenience in swallowing conventional dosage forms such as tablet when water is not available, in the case of the motion sickness (Kinetosiss) and sudden episodes of coughing during the common cold, allergic condition and bronchitis [5].

Antihypertensive drugs like Propranolol, Metoprolol, Oxprenolol, Diltiazem hydrochloride have the oral problems like difficulty in swallowing, less oral bioavailability, first pass metabolism in conventional tablet dosage forms. To overcome such problems the antihypertensive drugs can be formulated in the form of fast disintegrating tablets where the drug is rapidly disintegrated in mouth within fraction of seconds and improves the oral drug bioavailability. Fast disintegrating tablets can be prepared by methods like direct compression, wet granulation, sublimation, effervescent methods along with superdisintegrants to increase in vitro dispersion time. Some of the newer methods to formulate quick release dosage forms include Zydis, Orasolv, Flashtab, Wowtab, oraquick, Ziplet, etc.

Diltiazem hydrochloride is a Antihypertensive drug, which undergoes extensive hepatic degradation, which have poor bioavailability (40%) for overcoming this problem fast disintegrating tablets of Diltiazem hydrochloride can be formulated which avoids extensive first pass metabolism and improvement in dissolution efficacy, disintegration time which results in improvement in bioavailability. This formulation can be effectively used in case of hypertensive patients as it can be administered without the intake of water. Therefore the main objective of the present work is to develop fast disintegrating tablets for Diltiazem hydrochloride to improve bioavailability, disintegration time, dissolution efficacy and patient compliance. [6-9]

Hence, in the present study an attempt has been made to formulate fast disintegrating tablets of Diltiazem HCl by direct compression method using three superdisintegrants sodium starch glycolate, (SSG) crosscarmellose sodium and crospovidone, microcrystalline cellulose (MCC) as diluent with other excipients like sweetener and flavour with a view to develop a convenient means of administration to those patients suffering from difficulties in swallowing.

MATERIAL AND METHODS:

Materials: Diltiazem Hydrochloride procured from Srushti Pharmaceutical, Bangalore, India. Crospovidone from Shreeji chemicals, Mumbai. Sodium starch glycolate, Mannitol, Magnesium stearate, Ammonium bicarbonate are from S.D. Fine Chemicals Limited, Mumbai. Microcrystalline Cellulose, Croscarmellose Sodium from S.D. Fine Chemicals Limited, Mumbai. The materials used in the present investigation were either AR/ LR grade or the best possible pharma grade.

METHODS

Preformulation studies

Preformulation testing is the first step in the rationale development of dosage forms of a drug substance. It can be defined as an investigation of physical and chemical properties of a drug substance alone and when combined with excipients. It gives extensive information to bring out good quality at high standard at which optimal dosage desired. Preformulation studies were performed on the drug (API), which included melting point determination, solubility and compatibility studies.

The following preformulation studies were performed for Diltiazem HCl and polymers;

natural remedy to treat a variety of health conditions including diabetes, hypertension and cancer related ailments. Moreover, its effectiveness also has been proven in treating rheumatism, inflammation, gastric pain, ulcers and body revitalization (Khan et al., 2013; Er et al., 2010; Abd Malek et al., 2009, 2008; Tan et al., 2005). Traditionally, Pereskia bleo has been consumed in the form of concoction brewed from dried plant or conventionally eaten raw as vegetables (Sim et al., 2010a; Abd Malek et al., 2008; Er et al., 2007). Pereskia bleo was found to be rich in alkaloids, flavonoids, phytosterol glycosides, lactones, phenolic compounds, sterols, terpenoids and carotenoids (Zareisedehizadeh et al., 2014).

The purpose of the study is to analyse the phytochemical components and examine the antimicrobial activity of Pereskia bleo leaves extract in various concentrations.

The objectives of the study are:

1. To obtain dichloromethane extract from the leaves of Pereskia bleo by using Soxhlet apparatus.
2. To identify the phytoconstituents present in the Pereskia bleo leaves extract using standard phytochemical screening.
3. To formulate Pereskia bleo leaves extract ointment using petrolatum jelly as ointment base.
4. To scrutinize the antimicrobial activity of Pereskia bleo leaves extract and its ointment formulations against selected microbes.

Using this study as a reference, substantial data on antimicrobial activity of Pereskia bleo can be used to facilitate exploration in terms of academic contribution or research development. This study will also impart a better insight on Pereskia bleo and favours individuals interested in this field of study. Despite the fact that there are plenty of synthetic drugs readily available in the market for the treatment of infections, some of these drugs appeared to have severe side effects as compared to herbal medicine. Mentioned observations will therefore be able to analyse the possibility of extracting a new, inexpensive and reliable natural drug from Pereskia bleo. As it is more accessible and beneficial compared to synthetic drugs, the usage of Pereskia bleo is predicted to serve as a better alternative healing agent to be used for infection treatment.

MATERIALS AND METHODS

Plant material and sample preparation

Collection and identification of plant material: Pereskia bleo's leaves were identified and assembled. For identification and authentication, a sample was sent to the CMAP(Center for medicinal and aromatic plants), Hyderabad.

Site of experimental study: The experimental study was conducted in the laboratory of Sultan-Ul-Uloom College of Pharmacy.

Preparation of plant extract

The fresh green leaves of Pereskia bleo were assembled and washed with distilled water and dried for about a week under the shade at ambient temperature. Using electronic blender, the dried leaves were then grounded into powder form. In a Soxhlet extractor, 445 g of dry finely grounded leaves were then extracted using dichloromethane as a solvent. The extraction method was established as per the technique. The extraction procedure was repeated 3 times to achieve sufficient extract quantity for further testing. The extract was subsequently mixed and filtered to remove impurities using filter paper. Following filtration, dicloromethane extract was concentrated under low pressures at 45 ° C using rotary evaporator and left until fully dry (Er et al., 2010) for evaporation. For further testing, the resulting extract was then stored in a plastic container.

Percentage yield of plant extract

The percentage yield of plant extract was determined using the following formula (Dawoud et al., 2015):

$$\text{Percentage of extraction yield (\%)} = \frac{\text{weight of sample extract obtained (g)}}{\text{weight of finely grounded plant material used (g)}} \times 100$$

Phytochemical screening

Numerous phytochemical studies were performed to evaluate the concentrations of different phytoconstituents like those of alkaloids, phytosterols / sterols, flavonoids, terpenoids, fats and oils, phenolic derivatives, and lactones in the Pereskia bleo leaves dichloromethane extract.

Determination of alkaloids

The Mayer's and Hager's experiments were conducted to identify the presence of alkaloids in Pereskia bleo's dichloromethane leaves extract. A tiny part of the extract of dichloromethane was transferred to a tidy test tube. Then dilute hydrochloric acid was added to the test tube and the mixture was shaken well to mix the contents thoroughly. The solution was further filtered using filter paper and the following reagents were added to the filtrate:

(i) Mayer's test: A few drops of Mayer's reagent (potassium mercuric iodide solution) was added into 2 mL filtrate and the mixture is stirred well. Formation of precipitate in the test tube indicates the presence of alkaloids.

(ii) Hager's test: 2 mL filtrate was treated with a few drops of Hager's reagent (saturated picric acid solution). The presence of alkaloids is identified by the formation of yellow coloured precipitate.

Determination of phytosterols/ sterols

Detection of phytosterols/ sterols in the dichloromethane extract of Pereskia bleo leaves was carried out via Salkowski test, Liebermann-Burchard reaction and Liebermann's reaction.

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PHYTOCHEMICAL ANALYSIS AND EVALUATION OF ANTIMICROBIAL ACTIVITY OF PERESKIA BLEO (KUNTH) DC.

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ABSTRACT

Antimicrobial resistance has emerged as a cause of public health threat all over the world at a terrifying rate. The emergence of these global issues compels the continuous exploration of natural products containing antimicrobial activity. *Pereskia bleo*, a medicinal plant belongs to the Cactaceae family. This plant has been used traditionally for various medicinal purposes. However, previous studies regarding antimicrobial activity of *Pereskia bleo* leaves are still lacking. Hence, the present study was carried out to identify the phytochemical constituents and investigate the antimicrobial activity of *Pereskia bleo* leaves extract in different concentrations. Several phytochemical test were conducted to ascertain the presence of various phytoconstituents in the dichloromethane extract of *Pereskia bleo* leaves. The antimicrobial activity of four different concentrations of dichloromethane extract (50, 100, 150 and 200 mg/mL) and its ointment formulations (5, 10, 15 and 20% w/w) were evaluated by using agar well diffusion method against *Bacillus subtilis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Escherichia coli*. The phytochemical screening depicted that the leaves extract of *Pereskia bleo* revealed the presence of fats and oils, phytosterols/sterols, flavonoids, terpenoids, and phenolic derivatives whereas both alkaloids and lactones were absent in it. The extract showed antimicrobial activity against *Bacillus subtilis*, *Staphylococcus aureus and Pseudomonas aeruginosa* whereas no activity was observed for *Escherichia coli*. However, when the dichloromethane extract incorporated into petroleum jelly, all the extract ointments revealed no inhibitory effect against the selected bacteria. In summary, it is believed that dichloromethane extract of *Pereskia bleo* leaves might be beneficial towards bacterial infection related disease and has much potential to be developed as a phytomedicine. The inhibitory effect of this particular plant might be attributed by the presence of flavonoids and terpenoids. However, further investigation of *Pereskia bleo* are required in terms of *in vitro* and *in vivo* approaches in order to ensure the effectiveness and safety of the plant.

KEYWORDS: *Pereskia bleo*; phytochemical screening; antimicrobial activity; agar well diffusion method.

INTRODUCTION

There is a presence of Microbial infections in human beings since the past decades. While there are diverse synthetic antimicrobial agents accessible in the market for the remedy of microbial infections but pervasive and abusage of these medications may lead to evolution of antimicrobial resistance. As per World Health Organization (WHO), antimicrobial resistance has emerged as a cause of public health threat around the globe at a formidable rate. This is because antimicrobial resistance may lower the effectiveness of treatment resulting in extended duration of illness and infection, which would pre-eminently surge cost for therapy, death risk and disability of patients. The emergence of these global issues compels the nonstop exploration of natural products containing antimicrobial activities. It is reported to be widespread among the rural communities in the Chinese, Indian and South East Sub-continent. As per Mojiol et al., (2010), around 1,200 species in Malaysia have been proven to contain medicinal properties. The Pereskia bleo is one of these plants comprising discrete medicinal properties.

Pereskia bleo (Kunth) DC. belongs to the family of *Cactaceae*. This specific leaf cactus is sourced from Latin America and promptly dispensed to the oriental region (Khan et al., 2013). Pereskia bleo is widely cultivated in various countries for therapeutic and non-therapeutic purpose (Wiart, 2006) due to its heterogeneous composition. Being one of the most recognisable medicinal plants, Pereskia bleo is broadly cultivated and utilised by indigenous groups in different parts of the world. It is prominently believed from ancient times until now that this plant can be used as a

differential scanning colorimetry. *In vitro* release and solubility of the drug from nanoparticles were determined. *In vivo* Drug release, tissue uptake and kupffer cell uptake was determined with optimized nanoformulation in rats after intravenous administration. Cell viability assay was determined using breast cancer cell line MD-MB-231. Entrapment efficiency for prepared nanoparticle was above 95%. The polyethylene glycol-albumin-curcumin nanoparticles exhibited an interesting release profile with small initial burst followed by slower and controlled release. Solubility of the drug from the formulation was increased. A sustained release of drug from nanoparticles was observed for 35 days in both *in vitro* and *in vivo* studies with the optimized formulation. Polyethylene glycol-albumin-curcumin nanoparticles showed lesser liver and kupffer cell uptake as compared to that of curcumin-albumin nanoparticles suggesting the bestowment of stealthness to nanoparticles with pegylation. Also, the antiproliferative activity of polyethylene glycol-albumin-curcumin nanoparticle formulation was more as compared to native curcumin. Polyethylene glycol-albumin-curcumin nanoparticles thus developed can be conveniently used in breast cancer with improved efficacy compared to conventional therapies and as an alternate to nanoparticle albumin bound

Preparation and Characterization of PEG-albumin-curcumin Nanoparticles Intended to Treat Breast Cancer

R. Thadakapally, Arshiya Aafreen, J. Aukunuru,* M. Habibuddin,[1] and S. Jogala

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Abstract

Go to: ▸

The aim of present research was to prepare novel serum stable long circulating polymeric nanoparticles for curcumin with a modification to the well known and novel nanoparticle albumin bound technology. polyethylene glycol-albumin-curcumin nanoparticles were prepared using serum albumin and poly ethylene glycol using desolvation technique. Nanoparticles were characterized for encapsulation efficiency, particle size and surface morphology. Drug excipient compatibility was determined using fourier transform infrared spectroscopy. Physical state of the drug in the formulations was known by differential scanning colorimetry. *In vitro* release and solubility of the drug from nanoparticles were determined. *In vivo* Drug release, tissue uptake and kupffer cell uptake was determined with optimized nanoformulation in rats aft[redacted] intravenous ad[redacted]

Feedback

ABSTRACT

The aim of this study was to prepare novel ocular mucoadhesive microbeads of Moxifloxacin HCl to increase its residence time on the ocular surface and to enhance its therapeutic efficacy in ocular bacterial keratitis. Microbeads were fabricated with Microcrystalline cellulose (MCC) as polymer. Microbeads were evaluated for their particle size, surface morphology, encapsulation efficiency, FTIR, DSC and in vitro drug release studies. The average particle size of Microbeads was found to be less than 12.1 µm. MCC Microbeads were found to have a smoother surface. Entrapment efficiency was enhanced with an increased polymer concentration and viscosity. In vitro release of Moxifloxacin HCl from Microbeads was retarded with increased viscosity and concentration of polymers, and was controlled by diffusion as well as polymer relaxation. By comparing profiles of all the formulations, the formulation F6 showed the smallest particle size of 12.1 µm and also showed the controlled drug release of 8hrs. These optimized microbeads showing controlled drug release can be further incorporated into bioadhesive polymer to prepare

DESIGN AND EVALUATION OF MOXIFLOXACIN MICROBEADS BY COVALENT CROSS – LINKING METHOD

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ABSTRACT

The present investigation was aimed to develop sustained release transdermal therapeutic system containing Telmisartan with different ratios of Eudragit RS 100 and polyvinyl alcohol (PVA) by solvent-evaporation technique. Delivery of the drug via skin would provide a useful alternative to oral delivery, which has undesirable side effects, such as upper respiratory infections and disturbance of normal gut flora. The physicochemical compatibility of the drug and the polymers was by Fourier Transform Infra-Red (FTIR) and DSC. The results suggested no physicochemical incompatibility between the drug and the polymers. Blank films were prepared and evaluated characteristics like smoothness and flexible. Further drug loaded films were prepared and evaluated for thickness, tensile strength, weight uniformity, drug content, moisture content, moisture uptake, swelling index, water vapor transmission and in-vitro-drug permeation study. The results followed zero order kinetics and the mechanism of release was diffusion controlled release and further it was found to be linear with korsemeyer-peppas equation and confirmed that diffusion

FORMULATION AND OPTIMIZATION OF TELMISATRAN SUSTAINED RELEASE TRANSDERMAL FILMS

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Table 1: Formulation of SR Matrix tablets of Metformin.

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9
Metformin	**500**	**500**	**500**	**500**	**500**	**500**	**500**	**500**	**500**
Guar gum	100	150	200	-	-	-	-	-	-
Xanthane gum	-	-	-	100	150	200	-	-	-
Carbomer	-	-	-	-	-	-	100	150	200
PVP K-30	20	20	20	20	20	20	20	20	20
Magnesium stearate	06	06	06	06	06	06	06	06	06
Talc	06	06	06	06	06	06	06	06	06
MCC pH 102	168	118	68	168	118	68	168	118	68
Total wt	800	800	800	800	800	800	800	800	800

Evaluation

Preformulation studies

Selection of wavelength for analysis of metformin: The prepared concentration of 10 µg/ml was used for initial spectral scan in the UV range of 200-400 nm to detect maximum wavelength and further dilutions for linearity were prepared from the stock solution by allegation method.[7]

FTIR Compatibility Studies

FTIR spectra of pure drug and formulation with other ingredients were recorded by using FTIR Spectroscopy.[8,9]

Post-compression parameters

Thickness, Weight variation test, Friability study, Hardness, Drug content, and *in-vitro* dissolution studies were performed for prepared sustained release tablets.[10,11,12]

RESULTS AND DISCUSSION

The present study was aimed to developing Sustain release tablets of Metformin using various polymers. All the formulations were evaluated for physicochemical properties and *in vitro* drug release studies.

Analytical Method

Graphs of Metformin were taken in 0.1N HCl and pH 6.8 phosphate buffers at 235 nm and 237 nm respectively.

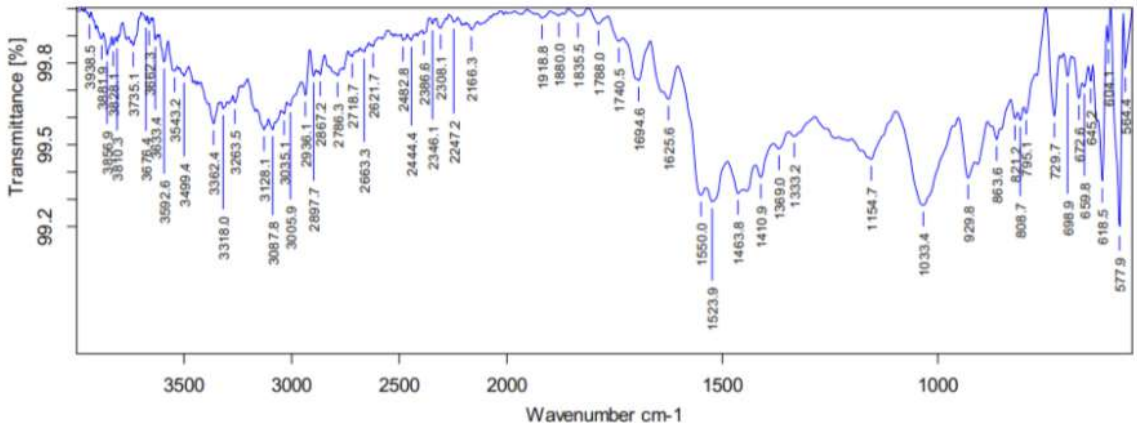

Figure 1: FTIR studies of pure drug Metformin.

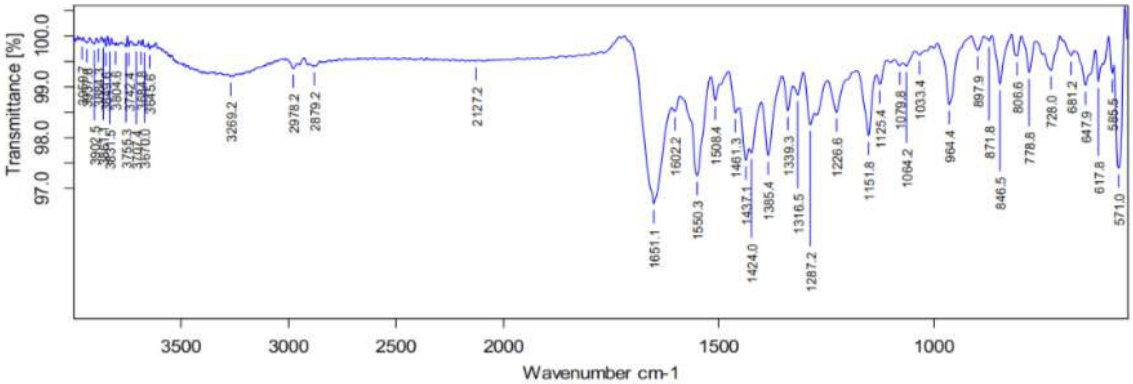

Figure 2: FTIR compatibility studies of optimized formulation (F2).

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DESIGN AND EVALUATION OF SUSTAINED RELEASE MATRIX TABLETS OF METFORMIN BY NATURAL POLYMERS

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ABSTRACT

The aim of the present study was to develop sustained release matrix formulation of Metformin to maintain constant therapeutic levels of the drug for over 12 hrs. Guar gum, Xanthane gum and Carbomer were employed as polymers. Formulations were prepared by wet granulation technique. All the formulations were passed various physicochemical evaluation parameters and they were found to be within limits. From the dissolution studies it was evident that the formulation (F2) showed better and desired drug release pattern i.e., 99.65±0.05% in 12 hours. It contains the guar gum polymer. It followed Higuchi order release kinetics mechanism.

KEYWORDS: Carbomer, Guar gum, Metformin, Sustained release tablets, Xanthane gum.

INTRODUCTION

Sustained release tablets are commonly taken only once or twice daily, compared with counterpart conventional forms that may have to take three or four times daily to achieve the same therapeutic effect.[1] The advantage of administering a single dose of a drug that is released over on Sustained period of time to maintain a near-constant or uniform blood level of a drug often translates into better patient compliance, as well as enhanced clinical efficacy of the drug for its intended use.[2,3]

Advantages of SR tablets

1. Sustained release dosage forms provide a better control of plasma drug levels, less dosage frequency, less side effect, increased efficacy and constant delivery.
2. If the active compound has a long half-life, it is sustained on its own.
3. If the pharmacological activity of the active is not directly related to its blood levels.
4. If the absorption of the drug involves an active transport and.
5. If the active compound has very short half-life then it would require a large amount of drug to maintain a prolonged effective dose.[4]
6. Aim of the study was to formulation and *in vitro* characterization of sustained release matrix tablets of Metformin using natural polymers. The main objective of this study was to prolong the drug release of metformin to reduce the dosage frequency. Metformin was a antidiabetic drug for type –I diabetes.

MATERIALS AND METHODS

Metformin was obtained as a gift sample from Aurobindo Ltd., (Hyderabad). Guar gum, Xanthane gum, Carbomer was used as polymers. Micro Crystalline Cellulose (SD Fine Chemicals) served as diluents. PVP K-30, Talc, Magnesium stearate is obtained from SD Fine Chemicals.

Preparation method

Intra granular: Drug and required ingredients were individually passed through sieve no # 60. All the ingredients were weighed ascending order and mixed thoroughly by triturating up to 15 min. IPA was added little amount as granulating agent. Wet mass prepared and sifted through the sieve no #60 to get granules. Obtained granules were kept a side for air drying.[5]

Extra granular: After drying the granules, Lubricant (Mg. stearate) and glidant (talc) was added to increase the flow properties. The tablets were compressed using a sixteen station rotary tablet-punching machine.[6]

KEYWORDS: Food and Drug, Prebiotic, Probiotics, Synbiotic.

INTRODUCTION

Increasing awareness on healthy foods has led to increasing interests on natural food products and nutraceuticals such as Probiotics. Probiotics have been defined as 'living microorganisms which when administered in adequate amount confer a health benefits on the host' (FAO/WHO 2001). Probiotic microorganisms have shown much health beneficial effects via *in vivo* trials, accompanied by much promising new potentials as developed by *in vitro* experiments.[1] In general, probiotics have been demonstrated to improve intestinal microbial balance, provide protection against gut pathogens and modulate immune system. Trend for probiotics products was first observed to gain momentum in Japan in late 1980 and soon spreaded into areas such as Asia Pacific, European Union and United States.[2] In present, given the greater understanding of the linkage between diet, nutrition and health, market for functional foods especially the probiotics are rapidly expanding. The public has also been increasingly accepting alternative therapies which include probiotics, in replacing synthetic drugs.[3]

What is Probiotic

A probiotic is a live micro-organism which, when given in adequate quantity, has a beneficial effect on the host. Probiotics can be formulated into many different types of products, including foods, drugs, and dietary supplements. The Greek word probiotic means **"for life",** was introduced by Parker. Definition put by FDA and WHO jointly is "Live microorganisms which when administered in adequate amounts confer a health benefit to the host.[4-6]

History of probiotics development

The knowledge of the beneficial effects of lactic acid fermentation on human health dates back to ancient times. The Bible mentions sour milk several times. Ancient Romans and Greeks knew various Nutrients recipes for fermented milk. A specific type of sour milk, called "leben raib", prepared from buffalo, cow, or goat milk, was consumed in ancient Egypt. In India, fermented milk drinks were known already 800–300 years B.C., and in Turkey in the 8th century.[7]

A milk drink called "ajran" was consumed in Central Russia in the 12th century, and "tarho" was consumed in Hungary in the 14th century.[8]

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A REVIEW ON: PROBIOTIC PREBIOTICS AND SYMBIOTICS – AS FOOD, DRUG AND DIETARY SUPPLEMENT

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ABSTRACT

Probiotics are living microorganisms which when taken in adequate amount provides benefit to the host. While this beneficial effect was originally thought to stem from improvements in the intestinal microbial balance. Identification of clinical characteristics of effective probiotic strains, their mechanisms of action and testing of probiotic-based treatment may provide the true beneficial effect of probiotics in various disorders. Probiotics have been investigated as a potential dietary supplement that can positively contribute to an individual's health. This health benefits are not limited to the intestinal tract, but also include amelioration of systemic metabolic disorders, such as Type – II Diabetes Mellitus and Cardiovascular diseases. Prebiotics are dietary substances that consist of non-starch polysaccharides and oligosaccharides. These are poorly hydrolyzed by digestive enzymes and preferably favour for the growth of probiotics such organism are *Lactobacillus* and *Bifidobacter* that are helpful in gut health maintenance, treat cancer, cardiovascular diseases and protect from colitis condition, improve immunity system. Hence prebiotics are widely used in food industry and pharmaceutical formulations. Synbiotic contain both probiotic bacteria and prebiotic sugars. The microbial additions (probiotics) may be used in conjugation with specific substrates (prebiotic) for growth. Synbiotics. are used not only for the improved survival of beneficial microorganisms added to food or feed, but also for the stimulation of the proliferation of specific native bacterial strains present in the gastrointestinal tract. The present review summarizes and discusses the effects of probiotic, prebiotic or synbiotic administration on growth performance, stress tolerance, intestinal microbiota, immune response and as well as food and drug.

Table1: Formulation of Metaclopromide-HCl oral fast dissolving films

CODE	DRUG (mg)	HPMC E5 (mg)	HPMC E15 (mg)	PEG-400 (mg)	Ascorbic Acid (mg)	Aspartame (mg)
FA	95.70	500	-	-	-	-
FB	95.70	450	-	-	-	-
FC	95.70	400	-	-	-	-
FD	95.70	350	-	-	-	-
F1	95.70	300	-	0.113	10	50
F2	95.70	-	300	0.113	10	50
F3	95.70	250	50	0.113	10	50
F4	95.70	200	100	0.113	10	50
F5	95.70	150	150	0.113	10	50
F6	95.70	100	200	0.113	10	50
F7	95.70	50	250	0.113	10	50

Drug = Metaclopromide-HCl, PEG = Propylene glycol
From the above formulations the first FOUR Formulations (FA, FB, FC, and FD) are designed to optimize the concentration of polymer to use for the preparation of films.

Evaluation oral fast dissolving films Metaclopromide HCl

Organoleptic characteristics

Organoleptic characteristics oral fast dissolving films Metaclopromide hydrochloride observed homogeneity, colour, smell and texture seen visually [7].

Uniformity of weight and thickness of the film

For the evaluation of the weight of the film, six sheets of film from every result of the formula is taken and weighed one by one then standard deviation were determined. The film thickness was measured at the centre and four corners, calculated the average and standard deviation [8].

Folding endurance:

The number of folds i.e. how many times the film being folded at same place that required to disrupt the film sample or developing a noticeable cracks, this is known as folding endurance. This term provide an indication of film brittleness, that a strip has been subjected to this test through film folding at same point repeatedly for many times until a noticeable crack was detected, the values are stated [9].

Content uniformity of Metaclopromide hydrochloride in Film

One sheet of film dissolved with phosphate buffer pH 6.8 in a flask of 25 ml, 0.5 ml of the solution is then diluted with phosphate buffer pH 6.8 to 10 ml. Levels of Metaclopromide hydrochloride content is determined by spectrophotometry at a wavelength of 270 nm [10].

Disintegration time

Films were put in each tube of the basket, and then the tool is run by using the medium of pH 6.8 phosphate buffer solution temperature of 37 ± 0.5°C. Disintegration time was observed in each film. Film said to be destroyed when no longer film is left in the basket [11].

***In vitro* Dissolution test**

The dissolution test performed with type-two dissolution apparatus, rotational speed 50 rpm, dissolution medium pH 6.8 phosphate buffer 900 ml of 37 ± 0.5°C. A film was put in dissolution apparatus. 2 ml solution was taken at the second 15, 30, 45, 60, and 90. The same medium was replaced with 2 ml so that the volume remained. Absorption solution is calculated at the maximum wavelength [12].

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Formulation Development and Evaluation of Oral Fast Dissolving Films of Metaclopromide HCL

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ABSTRACT

Metaclopromide-HCl is an Anti-emetic used to treat nausea, vomiting and to increase gastric motility. The present work aimed at preparing oral fast dissolving films of Metaclopromide-HCl with the purpose of developing a dosage form for a very quick onset of action, which is very convenient for administration, without the problem of swallowing and using water. Oral fast dissolving films of Metaclopromide-HCl were prepared using HPMC (E5, E15) polymers as film forming agents and polyethylene glycol-400 as plasticizer by solvent casting method. FTIR showed that there is no interaction between drug and excipients. Dissolution of prepared fast dissolving oral films of Metaclopromide-HCl was performed using USP type II apparatus in pH 6.8 phosphate buffer medium at 50 rpm with temperature being maintained at 37±0.5º C. The films prepared were evaluated for various parameters like thickness, drug content uniformity, weight variation, disintegration time, folding endurance and *in vitro* drug release and were showed satisfactory results. In conclusion, development of oral fast dissolving oral films using HPMC polymer gives rapid drug delivery and rapid onset of action.

KEYWORDS: *Oral fast dissolving films, Metaclopromide, HPMC*

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INRODUCTION

One of the most crucial routes of administrating a drug with high credit to obtain a systemic effect is the oral administration for its simplicity, comfortability by producing no pain compared with the systemic administration and other remarkable benefits over the other routes[1]. However, it also comes with disadvantages in case of certain dosage forms as capsules and tablets, as problems of swallowing especially for children and infants and for elders leading to incompliance and disadherence to the treatment [2]. This was proved by evidence that approximately 35% of the population showed dysphasia and troubles with swallowing as an example, people with sea/ motion sickness, hiccups, gagging and obstruction of the esophagus pathway will be force to search for other alternatives which favor the systemic drug delivery such as fast dissolving medication [3]. Oral fast-dissolving film is new drug delivery system developed on the basis of the Transdermal patch [4]. It consists of a very thin oral strip, which is simply placed on the tongue or oral mucosal tissue, instantly wet by saliva; the film rapidly hydrates and adheres onto site for rapid disintegration and release [5].The objective of the present study was to develop Oral fast dissolving films (OFDFs) of Metaclopromide- HCl as Anti-emetic and to provide a convenient means of administration to those patients suffering from nausea and vomiting and to increase gastrointestinal motility.

MATERIALS AND METHODS

Metaclopromide- HCl was obtained as a gift sample from Aurobindo Ltd., HPMC E5, E15 was used as polymers, PEG 400, Ascorbic acid, and Aspartame is obtained from SD Fine Chemicals.

Formulation of Metaclopromide-HCl oral fast dissolving films

The procedure of making of Metaclopromide HCl ODF

All materials were weighed. Some polymers are dissolved in distilled water. Then left in for 10 minutes to swell. Drug is dissolved in distilled water, then added aspartame and ascorbic acid. The solution was stirred until all the material is completely dissolved. Drug substance solution is added to the base polymer. PEG 400 was added to the polymer solution while stirring. The solution was left in at room temperature to remove air bubbles. After the air bubbles disappear, the solution was poured into a mold 9 cm x 10 cm until blended. Film dried at 40°C in the drying cabinet for 24 hours. After drying, the film removed from the mold carefully and cut the size of 2 cm x 3 cm [6]. The components of the formulation were shown in Table 1.