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An Overview on Mouth Dissolving Films

[1]Abilash K, [1]Dinesh G, [1]Janarthanan S, [1]Praveena J, [1]Vanitha G [2]Jeevanandham S, [3]Gokul Manikandan P

[1,] Students, PPG College of Pharmacy, Coimbatore, Tamil Nadu
[2]Principal, PPG College of Pharmacy, Coimbatore, Tamil Nadu
[3]Assistant professor, PPG College of Pharmacy, Coimbatore, Tamil Nadu
Corresponding Author: Abilash K

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ABSTRACT: The present work aimed at preparing mouth dissolving films 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 need of water. The fast dissolving oral films were designed using optimal design and numerical optimization technique which was applied to find out the best formulation. The formulated Mouth dissolving films were evaluated for physical characteristics such as uniformity of weight, thickness, Folding endurance, drug content uniformity, surface pH, percentage elongation, and tensile strength, and gave Satisfactory results. The FTIR and DSC studies revealed that there is no physicochemical interaction between excipients and the drug[2]. It can be concluded in this study that the Mouth dissolving film can be a potential novel drug dosage form for poorly water soluble drugs[3]. Fast dissolving drug delivery systems such as mouth dissolving films (MDF) are novel dosage forms that disintegrate or dissolve within the oral cavity[9]. Fast dissolving oral films are found to be satisfactory in many situations like allergic conditions, cold and cough, sore throat, nausea, pain, mouth ulcers, CNS disorders and CVS disorders[6]. The fast dissolving oral films are planned to prepare by utilizing different active drug ingretients (API), film forming polymers, plasticizer, flavors, colors and sweeteners. At first FDOFs are up to breath strips, dessert and oral consideration markets[7].

KEYWORDS: Oral mucosa, Fast dissolving films, Innovative drug delivery, FTIR, Solvent casting method.

I. INTRODUCTION

Mouth dissolving drug delivery systems (MDDDS) are the new generation formulations on which combines the advantages of both liquid and conventional tablet formulations, and at the same time, which offers the added advantages over the traditional dosage forms. Formulation is especially designed for dysphagic, Geriatric, pediatric, bed-ridden, travelling and psychotic patients who are unable to swallow or refuse to swallow conventional oral formulations[1]. In the recent days, several new advanced technologies have been introduced for the formulation of mouth dissolving films (MDF) with very interesting features, like extremely low disintegration time, exceptional taste masking ability, pleasant mouth feel and sugar free film for diabetic patients[1]. The technologies utilized for the fabrication of MDDDS include lyophilization , moulding , direct compression , cotton candy process , spray drying , sublimation, mass extrusion, nanonization and quick dissolve film formation[1].These fast dissolving films contain active Ingredient embedded in matrix of film forming polymers that disintegrates within few seconds in saliva when taken orally without need of water or chewing. Hence the patient compliance is more in patients with difficulty in swallowing and chewing[3]. The delivery system consists of a very thin oral strip, which is simply placed on the patient's tongue or any oral mucosal tissue, which get instantly wet by saliva, the film rapidly hydrates and adheres onto the site of application[4].Various Film formers like Polyvinyl alcohol, Polyvinyl pyrrolidone (PVP), Maltodextrin, Hydroxy Propyl Methyl Cellulose (HPMC), Hydroxy Propyl Cellulose (HPC), Methyl Cellulose (MC), Sodium Carboxy Methyl Cellulose (Na CMC), Chitosan and some natural gums have been used in the production of films[4].These drug delivery options allow the medication to bypass the first pass metabolism, thereby increasing its bioavailability. As the strip dissolves, the drug get enter the blood stream primarily buccally and sublingually[9].

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OVERVIEW OF ORAL MUCOSA

The oral mucosa is composed of an outermost layer of stratified squamous epithelium. Below this lies a basement membrane, a lamina propria followed by the sub mucosa as the innermost layer. The epithelium is similar to stratified squamous epithelia found in the rest of the body in that it has a mitotic ally active basal cell layer, advancing through a number of differentiating intermediate layers to the superficial layers, where cells are shed from the Surface of the epithelium.

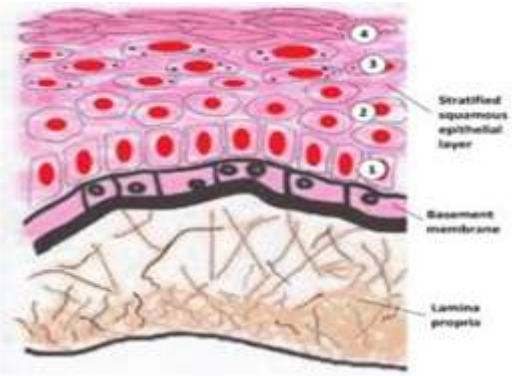

Figure 1: Various Layers of Oral mucosa

The oral cavity comprises the lips, cheek, tongue, hard palate, soft palate and floor of the mouth.The lining of the oral cavity is referred to as the oral mucosa, and which includes the buccal, sublingual, gingival, palatal and labial mucosa. The buccal, sublingual and the mucosal tissues at the ventral surface of the tongue accounts for about 60% of the oral mucosal surface area. The top quarter to one-third of the oral mucosa is made up of closely compacted epithelial cells.

The primary function of the oral epithelium is to protect the underlying tissue against potential harmful agents in the oral environment and from fluid loss. Beneath the epithelium are the basement membrane, lamina propia and submucosa. The oral mucosa also contains many sensor receptors including the taste receptors of the tongue .

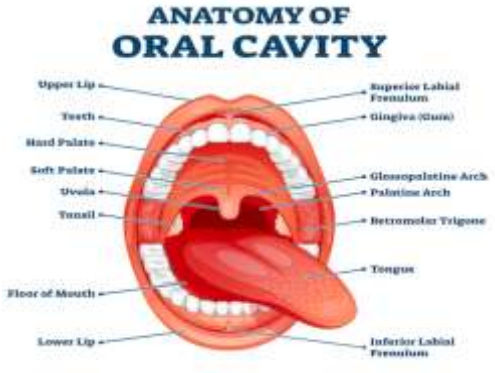

Figure No:2 Structure of oral/buccal cavity

.PHYSIOLOGICAL BARRIERS FOR ORAL TRANSMUCOSAL DRUG DELIVERY[4]

The environment of the oral cavity presents some significant challenges for systemic drug delivery. The drug needs to be released from the formulation to the delivery site (e.g. buccal or sublingual area) and pass through the mucosal layers to enter the systemic circulation. Certain physiological aspects of the oral cavity play significant roles in this process, including pH, fluid volume, enzyme activity and the permeability of oral mucosa. The oral mucosa is a squamous cell epithelium comprised of highly proliferating basal keratinocytes which replenish the overlying epithelial cells which differentiate and eventually shed as the cells become more superficial (Fig 1). The permeability barrier is responsible for preventing exogenous and endogenous materials from entering the body across the oral mucosa and prevents loss of fluid from the underlying tissues to the environment. There is variation in permeability across different regions of the oral mucosa due to the differing thickness of the epithelium and degree of keratinisation at different sites.

Keratinised tissues display a lower permeability than non-keratinised tissues, this is however due to the lipid composition of the membrane coating granules in the keratinised vs.non-keratinised tissues rather than the presence of keratin itself.The degree of permeability is least in keratinized gingiva followed by the buccal mucosa with the most easily permeated area of the oral mucosa being the sublingual mucosa. (Fig 2)

The principle physiological environment of the oral cavity, in terms of pH, fluid volume and composition, is shaped by the secretion of saliva. The main functions of saliva are to lubricate the oral cavity, facilitate swallowing and to prevent

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demineralisation of the teeth. It also allow carbohydrate digestion and regulates oral microbial flora by maintaining the oral pH and enzyme activity. The daily total salivary volume is between 0.5 and 2.0 L. However, the volume of saliva constantly available is around 1.1 ml, thus providing a relatively low fluid volume available for drug release from delivery systems compared to the GI tract. In addition, saliva is a weak buffer with a pH around 5.5-7.0. Ultimately the pH and salivary compositions are dependant on the flow rate of saliva which in turn depends upon three factors, the time of day, the type of stimulus and the degree of stimulation.

Saliva provides a water rich environment of the oral cavity which can be favourable for drug release from delivery systems especially those based on hydrophilic polymers.

PHYSIOLOGICAL OPPORTUNITIES FOR ORAL TRANSMUCOSAL DRUG DELIVERY[4]

Despite the physiological challenges, the oral mucosa, due its unique structural and physiological properties, offers several opportunities for systemic drug delivery. As the mucosa is highly vascularized any drug diffusing across the oral mucosa membranes has direct access to the systemic circulation via capillaries and venous drainage and will bypass hepatic metabolism. The rate of blood flow through the oral mucosa is substantial, and is generally not considered to be the rate-limiting factor in the absorption of drugs by this route. In contrast to this harsh environment of the GI tract, the oral cavity offers relatively consistent and friendly physiological conditions for drug delivery which are maintained by the continual secretion of saliva.

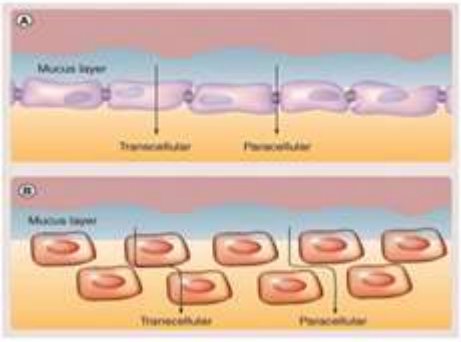

Figure No:3 Schematic representation of different route of drug permeation

Compared to secretions of the GI tract, saliva is a relatively mobile fluid with less mucin, limited enzymatic activity and virtually no proteases. The buccal and sublingual routes are the focus for drug delivery via the oral mucosa because of the higher overall permeability compared to the other mucosa of the mouth. There are three methods of diffusion across the oral mucosa's permeability barrier,
(i) Passive diffusion including trans-cellular (through cells) and para-cellular (where material passes through lipid rich domains around the cells), (ii) Carrier mediated transport, and (iii) Endocytosis/exocytosis where material is actively taken up and excreted by cells via the endocytic pathway.

ADVANTAGES [2]

- Larger surface area promotes rapid disintegration and dissolution in the oral cavity.
- Oral films are flexible and thus less fragile as compared to ODTs. Hence, there is ease of transportation and during consumer handling and storage.
- Precision in the administered dose.
- No risk of choking.
- Good mouth feel.
- With the help of Mouth dissolving film drug delivery system those drugs can be given to the patients that are not crushed and not injected by patients.
- Improved patient compliance.
- Ease of swallowing and no need of water have led to better acceptability amongst the dysphagic patients.
- Dosage form can be consumed at any place and anytime as per convenience of the individual.
- Enhanced oral bioavailability of molecules.
- That undergoes first pass effect.
- Bypassing the first pass effect leads to reduction of dose which can lead to reduction in side effects associated with the molecules.
- Mouth dissolving films are typically the size of a postage stamp and disintegrate on a Patient's tongue in a matter of seconds for the rapid release of one or more APIs.

DISADVANTAGES[6]

- Packing requires special equipment. So, difficult to pack.
- Not suitable for drugs which irritate and are unstable at buccal pH.

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- Only small dose of drug can be administered.
- Hygroscopic in nature. So, longer preservation is difficult.
- Drugs which are absorbed only by passive diffusion can be administered by this route.
- Restriction of eating and drinking for sometime after consumption of oral film.
- Method for preparation is expensive as compared to oral dissolving Tablets.

IDEAL PROPERTIES [6]

- Should have pleasant taste.
- Dose upto 40mg can be incorporated.
- Drug should be stable to moisture overtime and soluble in saliva.
- Should exhibit suitable tensile strength.
- Should not stick to the packing material and fingers.
- Should be ionized at pH of oral cavity.
- Should be able to permeate the oral mucosal tissue.
- Should not be bitter and have quick onset of action.
- Drug with smaller and moderate molecular weight are preferable.
- Drug should have high first pass metabolism.

METHODS

1. Solvent casting method[6]

In this method, prepared solution is poured into the petridishes and covered with the inverted funnels to allow the evaporation of solvents. The amount of flavor to be used depends upon the type of drug used. Flavors that can be added are essential oils like menthol, intense mints like peppermint, sweet mint, spearmint, wintergreen, cinnamon, clove, sour fruit flavor such as lemon, orange or sweet confectionary flavors such as vanillin, chocolate. They can be used alone or in combination.

2. Semisolid casting method[6]

In this method, acid insoluble polymer and film forming polymer ratio should be 1:4. The films thickness formed by this method is about 0.015-0.05 inches prepare a solution of water soluble film forming polymer prepared solution is added to the solution of acid insoluble polymer, prepared in ammonium or sodium hydroxide like cellulose acetate phthalate, cellulose acetate butyrate. Appropriate amount of plasticizer is added to obtain a gel mass gel mass is casted into the film or ribbon using heat controlled drums mixture is degassed under vacuum bubble free solution is coated on non-treated casting film coated film is dried in aeration drying oven and cut into desired shape and size.

3. Hot melt extrusion method[6]

The processing temperatures should be 80 in 1st zone, 115 in 2nd zone, 100 in 3rd zone and 65 in 4th zone. The screw speed should set at 15 rpm to set the granules inside the extruder for approximately 3-4 min. Drug and polymer are blended in sigma blade mixer for 10 min.Plasticizer is added slowly granulation of mixture in the presence of anti-sticking agent granules are stored overnight and sieved through 250µm sieve dried granules are fed into the extrude processing is done for 3-4 minutes at temperature as mentioned above exudate is pressed at temperature 65ºC to obtain a film of thickness 200 µm

4. Solid dispersion extrusion [6]

This method involves dispersion of one or more active ingredients in an inert carrier in a solid state in the presence of amorphous hydrophilic polymer. Immiscible drug is dissolved in suitable solvent. Solid dispersions are prepared by incorporating above solution into Melted polyethylene glycol: below 70ºC finally dispersions are shaped into the films by means of dies.

5. Rolling method[8]

Solution or suspension of the drug is prepared with film forming polymers and this is subjected to the roller. The rheological properties for solution or suspension of the drug should be considered before processing them. The solvent which is mainly used is water or mixture of water with alcohol. The film which is placed on the roller is dried and then after drying film is cut into specific pieces of desired shapes and sizes.

6. Spray drying[8]

A solvent system containing film former and other excipients are sprayed or coated on suitable carrier material, dried and peeled off to get the film. The carrier materials used for the film are glass, non siliconized kraft paper or polyethylene film etc.

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LIST OF POLYMERS USED IN ORAL THIN FILMS [6]

GROUP	CLASS	EXAMPLES
1. Nature	➢ Carbohydrates	Pullalan,Pectin,Sodium alginate, Maltodextrin, Sodium strach glycolate(SSG)
	➢ Proteins	Gelatin
	➢ Resin	Polymerized rosin(novel film polymer).
2.Synthetic	➢ Cellulose derivatives	Hydroxy propylmethy cellulose (E3,E5,E15,K3,K15,K50), Methyl cellulose (A3,A6,A15), Caroboxy methyl cellulose, Sodium corboxymethyl cellulose,
	➢ Vinyl polymers	Microcrystalline cellulose, Croscarmellose sodium (CCS)
	➢ Acrylic polymer	Poly vinyl pyrrolidine (K-90,K-30), Poly vinyl alcohol, Poly ethylene oxide EUDARGIT(RD-100,9,10,11,12 and RL-100)

INGREDIENTS USED IN THE FAST DISSOLVING FILMS

FILM FORMING POLYMERS [8]

These are the agents which are used as film formers. It is used as the base of the FDF´s. It helps in the rapid disintegration and provides mechanical properties To the FDF´s. It provides good mouth feel also. The disintegration rate of the polymer is decreased by increasing the molecular weight of the polymer film base. Polymers which are mainly used in the FDF´s are HPMC (Hydroxyl Propyl Methyl Cellulose), PVA (Polyvinyl Alcohol), Pullulan, Eudragit, Sodium alginate, Gelatin, Pectin etc.

PLASTICIZER[8]

These plasticizers are important for providing the mechanical properties to the FDF´s. Mechanical properties which are mainly improved by using these plasticizers are percentage elongation and tensile strength. Optimized amount of plasticizers are used to get a better FDF´s. The commonly used plasticizers are polyethylene glycol (PEG 400, 4000 etc.).

FLAVORS[8]

Flavors are added to provide taste to the film. There are various flavors which are added to the film formation. Any flavor can be added i.e. intense mint, sour fruits flavor, or other sweet

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confectionary flavors are also added to the fast dissolving film formulation. Optimized amount of flavor was added to the FDF´s. These flavoring agents should be compatible with the drug and other ingredients. The choice of flavors changes with the conditions like age i.e. geriatric patients like mint or orange flavor, while youngsters like fruit flavors.

COLORING AGENTS[8]

The coloring agents are added to the film formation to impart color to the FDF´s. Coloring agents should be compatible with the drug and other ingredients.

SWEETENING AGENTS[8]

It is the most important part of the oral pharmaceutical product. Sweetening agents helps in the taste masking of the bitter drugs. There are varieties of Sweetening agents which are used in the formulation of FDF´s i.e. sucrose, dextrose, fructose, glucose, etc. There are also polyhydric alcohols such as sorbitol, mannitol and isomalt. These are preferably used in the combination for having less carcinogenic activity and also used as cooling agents.

SALIVA STIMULATING AGENTS [13]

Saliva stimulating agents are used to increase the rate of production of saliva that would aid the faster disintegration of ODF. Citric acid, malic acid, lactic acid, ascorbic acid and tartaric acid are few examples of salivary stimulants. Citric acid has melting point around 100°C and softens at 75°C .

COMPOSITION OF ORAL THIN FILMS [6]

S.no	Name of the excipients	Quantity
1.	Drug	5-30%
2.	Film forming polymers	40-50%
3.	Plasticizer	0-20%
4.	Saliva stimulating agent	2-6%
5.	Sweeting agent	3-6%
6.	Surfactant	Q.s
7.	Flavouring agent	Q.s
8.	Colouring agent	Q.s

PREFORMULTAION STUDIES[2]

During this evaluation, possible interaction with various inert ingredients intended for use in final dosage form was also considered in the present study.

DRUG-EXCIPIENT COMPATIBILITY STUDY [2]

Excipients are integral components of almost all pharmaceutical dosage forms. The successful formulation of a stable and effective solid dosage form depends on the careful selection of the excipients, which are added to facilitate administration, to promote the consistent release and bioavailability of the drug and protect it from degradation. API and excipients were been thoroughly mixed in predetermined ratio and passed through the 40# sieve. The blend was filled in transparent glass vials and were closed with gray coloured rubber stoppers and further sealed with aluminum seal and charged in to stress condition at above condition. Similarly API should also be kept

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at all condition as for the samples. Samples were withdrawn for analysis within two day of sampling date as per the compatibility study plan. Physical observation should be done at every week up to 1 month and FTIR studies and DSC Studies were carried out to determine the compatibility of excipients with the drug.

DRUG-EXCIPIENT COMPATIBILITY STUDIES BY DSC[2]

DSC thermograms of pure drug and its physical mixture with polymers (Pullulan, HPMC, PVA) were carried out to investigate any possible interaction between the drug and the utilized polymer (Pullulan, HPMC, PVA). The selected heating rate is from 50°C to 300°C at an increase of 20°C per minute using Differential Scanning Calorimeter (shimadzu Corporation, Japan).

DRUG-POLYMER COMPATIBILITY STUDY BY FTIR[5]

Drug-drug and drug-excipient compatability studies were recorded by potassium Bromide method using Fourier Transform Infrared spectrophotometer method. The samples were prepared by potassium bromide pellet press method. A base line correction was made using dried potassium bromide and then spectra of dried mixtures of drug and excipients were Scanned over the wave number range of 400-4000^{-1}

SOLUBILITY [2]

1 part of drug was taken and dissolved in 5 ml of ethanol, and found that the drug was Freely soluble in ethanol.

MELTING POINT[7]

Required amount of drug was taken in capillary tube, and then the capillary tube was apparatus used. The melting point was determined by using lab India melting point apparatus.

POST FORMULATION STUDIES

VISUAL INSPECTION OF FILMS[11]

Patient acceptance of dosage form is an important factor for the administration. Clarity, transparency and oiliness are the main parameters for visual inspection. If it was found satisfactory, then the further evaluation was carried out. If the formed films were not satisfactory they were discarded.

THICKNESS[5]

The thickness of film should be measured with the help of micrometre screw gauge. Film should be measured at center of film and around the film and the mean thickness was calculated. It is necessary to determine the uniformity of thickness as it is directly related to the accuracy of dose in the film. In general, ideal film/films thickness should exhibit between 50 and 100 micrometres.

WEIGHT VARIATION[8]

An individual film was weighed on an electronic digital balance and the average weight was calculated. Then the average weight of film is subtracted from the individual weight of the film. A large variation in weight is likely to have non-uniform drug content.

SURFACE pH[6]

Surface pH of film should be close to that pH of buccal cavity that is pH 6.8. The mouth dissolving film was slightly moistened with the help of water. The surface pH was measured by bringing the electrode in contact with the surface of mouth dissolving film.

DRUG CONTENT UNIFORMITY[8]

The drug content uniformity was determined by dissolving the film in 100 ml of water with occasional shaking. Then 5 ml of dissolved solution was taken and it is filtered through 0.45 µm Whatman filter paper. From that take 1ml of filtered solution in a 10 ml volumetric flask and made up to 10 ml of distilled water and shake well before going to UV analysis. Then the drug content was determined by using suitable UV spectroscopy.

FOLDING ENDURANCE[1]

Folding endurance was determined by repeated folding of the strip at the same place till the strip breaks. The number of times the film was folded without breaking is computed as the folding endurance value.

YOUNG'S MODULUS [4]

Young's modulus or elastic modulus is the measure of stiffness of film. It is represented as the ratio of applied stress over strain in the region of elastic deformation as follows:

Young's Modulus = Slope X 100 / Film thickness X Cross head speed

Hard and brittle film demonstrates a high tensile strength and Young's modulus with small elongation.

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INVITRO DISINTEGRATION TIME[4]

Invitro disintegration time is the time required to break the mouth dissolving film when brought in contact with saliva or water. Invitro disintegration time was performed in the USP disintegration time testing apparatus. Phosphate buffer pH 6.8 was used as medium. The films were placed in the tubes of the container and the disks were placed over it.

1.Drop method[4]

In the first method one drop of distilled water was dropped by a pipette onto the oral films. Therefore the films were placed on a glass slide and placed planar on a petridish. The time until the film dissolved and caused a hole within film was measured.

2. Petridish method[4]

In this method 2ml of distilled water was placed in a petridish and one film was added on the surface of the water and the time required until the oral film dissolved completely was measured. Drug-loaded films were investigated under both methods.

INVITRO DISSOLUTION[4]

Invitro dissolution of mouth dissolving film was studied in phosphate buffer pH 6.8 which is used as dissolution medium. The rotation of the stirrer was adjusted to 50rpm. The temperature of the dissolution medium was maintained at 37°C ± 0.5°C throughout the experiment. The samples of 1ml of dissolution medium were withdrawn for 5 minutes at every 30 seconds intervals of time i.e., 30, 60, 90, 120, 150, 180, 210, 240, 270, 300 seconds and analysed for drug release by measuring the absorbance in UV spectroscopy. The volume withdrawn at each time interval was replaced with fresh quantity of dissolution medium. The invitro drug release data of oral marketed immediate release tablet formulation was taken from the article reference number and it was compared with invitro drug release of optimized formulation.

Beaker Stirring Method (Method I)[4]

The invitro dissolution studies were conducted using 150ml glass beaker with 125ml of artificial saliva as dissolution medium. Film (2×2.5 cm^2) was placed on one side of the beaker using double-sided tape. Medium was stirred at a speed of 200rpm using magnetic stirrer bar. 5ml samples were withdrawn at 10, 20, 30, 40, 50, 60, 80, 100, 120sec time intervals and every time replaced with 5ml of fresh dissolution medium. The samples were analyzed by measuring UV absorbance at 282nm. The dissolution experiments were conducted in triplicate.

Dissolution Apparatus 5 (Method II) [4]

The invitro dissolution studies were conducted using 600ml of artificial saliva as dissolution medium with modified type 5 dissolution apparatus. A temperature of 37º C and 50 rpm were used. Each film with dimension (2×2.5 cm^2) was placed on a watch glass covered with nylon wire mesh. The watch Glass was then dropped into dissolution flask. 5ml samples were withdrawn at 10, 20, 30, 40, 50, 60, 80, 100, 120 sec time intervals and every time replaced with 5mL of fresh dissolution medium. The samples were analyzed by measuring absorbance at 282nm.

CONCLUSION

From the present work, it can be concluded that Fast Dissolving Film formulation can be an innovative and promising approach for the delivery of drug with improved bioavailability, enhanced dissolution rate, taste masking, with better patient compliance and as an effective therapy for the treatment. Oral thin films are used as a good tool to increase the life cycle of the existing product by getting patent of same product as fast dissolving oral films. It is proven that the fast dissolving films provides the beneficial activity of rapid onset of action in case of asthmatic attack, cardiac heart failure and in epilepsy conditions.

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