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A Review on Fast Dissolving Sublingual Films

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ABSTRACT

Fast-dissolving films are a new technology that has a quick onset of action and improves patient compliance. These formulations are appropriate for colds, allergic rhinitis, asthma attacks, and CNS disorders that have a rapid onset. For faster relief, the sublingual route of drug administration is very effective because the drug passes through the hepatic first-pass metabolic process and has a higher bioavailability. Sublingual drugs enter the systemic circulation directly through the ventral surface of the tongue and the floor of the mouth. New sublingual technologies address a wide range of pharmaceutical and patient needs, from improved lifecycle management to convenient dosing for dysphagic pediatric, geriatric, and psychiatric patients. Fast-dissolving films can be made using different processes such as Solvent casting, Semi-solid casting, Hot melt extrusion, Solid dispersion extrusion, Rolling method. Films are characterised by tensile strength, weight variations, moisture content, mucoadhesion strength, disintegration study, *in-vitro* dissolution study, uniformity of drug content, surface pH, folding endurance. This article highlights an overview of the formulation aspects, manufacturing methods and evaluation parameters of fast-dissolving sublingual films.

INTRODUCTION:

Sublingual refers to a method of administering a substance via mouth in such a way that the substance is rapidly absorbed via blood vessels under the tongue. Sublingual administration of the drug entails placing the drug under the tongue, and the drug enters the bloodstream directly through the ventral surface of the tongue and the floor of the mouth. The drug solutes are rapidly absorbed into the reticulated vein beneath the oral mucosa, then transported through the facial veins, internal jugular vein, and brachiocephalic vein before draining into the systemic circulation. The routes of absorption via the highly vascularized buccal mucosa allow the substance to enter the bloodstream more directly, allowing for direct systemic administration.[1]

There has been a tremendous amount of effort put into developing novel drug delivery systems over the last two decades (NDDS). The reason for this technological advancement is the relatively low development cost and time required for introducing an NDDS when compared to introducing a new chemical entity. Conventional or classical therapy has some limitations as well, such as the difficulty of swallowing tablets in the case of oral dosage forms, the difficulty of patient compliance among pediatric and geriatric patients, the difficulty of taking these dosage forms without water while traveling, and these systems also show less absorption, resulting in a slow onset of action. A novel drug delivery system, such as designing a sublingual delivery of a drug, is one of the better solutions to these problems. Because of its thin membrane and large veins, the sublingual mucosa is relatively permeable. Because of the high blood flow, the sublingual mucosa allows for rapid absorption and immediate bioavailability of drugs. Because rapid absorption is possible, a rapid onset of action may be observed.[2]

Sublingual absorption is mostly quick, but it is also brief. The sublingual area of the oral cavity is more permeable than the buccal area, which is more permeable than the palatal area in terms of permeability. Sublingual films have been developed for conditions such as migraines and mental illnesses that require a quick onset of action. [3]

Approximately one-third of the population, primarily the elderly and children, has swallowing difficulties, resulting in poor adherence to oral tablet drug therapy and reduced overall therapy effectiveness. A new sublingual fast-dissolving dosage form, such as a fast-dissolving tablet or fast-dissolving film, has been developed that combines the benefits of ease of dosing with the convenience of dosing in the absence of water or fluid.[4]

SUBLINGUAL GLANDS:[5]

Salivary glands can be found beneath the tongue on the floor of the mouth. Sublingual glands are another name for them. They produce mucin, which causes saliva to be produced. The fluid produced by the glands mixes with the food, making it easier to chew. Absorption is defined as the transfer of a drug from its site of administration into systemic circulation; thus, absorption is directly proportional to layer thickness. In this manner, the drug is absorbed. Sublingual > Buccal > Gingival > Palatal. Because of the sublingual route's high permeability and rich blood supply, the drug can be delivered with a short delivery period and a frequent dose regimen.

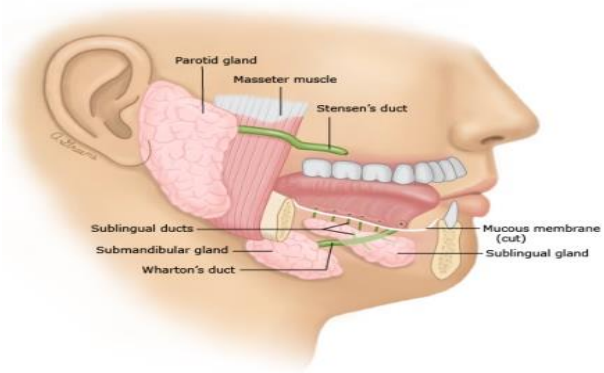

Fig no 1: Sublingual gland

SUBLINGUAL ABSORPTION: [6]

Sublingual drug solutes are rapidly absorbed into the reticulated vein beneath the oral mucosa and transported through the facial veins, internal jugular vein, and brachiocephalic vein before being drained into the systemic circulation. Sublingual administration allows the drug to enter the bloodstream directly through the ventral surface of the tongue and the floor of the mouth. The primary mechanism for drug absorption into the oral mucosa is passive diffusion into the lipoidal membrane. Sublingual absorption is 3 to 10 times greater than oral absorption and is only surpassed by hypodermic injection.

MECHANISM OF SUBLINGUAL ABSORPTION:

The mucosal lining consists of three distinct layers. The outermost layer is the epithelial membrane, which consists of stratified squamous epithelial cells and has a protective barrier function. The innermost layer of the epithelial membrane is called the basement membrane that replenishes the epithelium. Below the epithelium lies the lamina propria followed by the

submucosa. The lamina propria is a hydrated and less dense layer of connective tissue containing collagen and elastic fibres [3]. The oral submucosa is also richly supplied with blood vessels [4].

The following absorption through the mucous membrane in the sublingual region, the drug instantly diffuses into venous blood. The venous blood from the sublingual region of the oral cavity drains into a common trunk, which then drains via the internal jugular vein, the subclavian vein, and the brachiocephalic vein directly into the superior vena cava. 8Thus, venous return from these regions enter the systemic circulation, bypassing the pre-systemic drug elimination, unlike in oral administration. Direct drainage into systemic circulation results in the immediate systemic availability of the drug and rapid onset of action. It should be noted that smoking, which causes vasoconstriction, may affect drug absorption [5].

DRUGS FOR SUBLINGUAL ADMINISTRATION: [7,8]

The drugs selected for films should possess good stability in saliva and water with low dose. The film should consist of 1-25% w/w of the drug. Small dose molecules are the best candidates to be incorporated in Oral fast dissolving film. Multi vitamin sup to 10% w/w of dry film weight was incorporated in the films with dissolution time of less than 60seconds. It is always useful to have micronized API which will improve the texture of the film and also for better dissolution and uniformity in the fast dissolving film.

Sublingual drug administration is used in the medical field for cardiovascular drugs, steroids, some barbiturates, and enzymes. It has been a growing field in the administration of many vitamins and minerals that have been discovered to be readily and thoroughly absorbed by this method. Sublingual nutrition, which avoids exposure to the gastric system and liver, results in direct nutritional benefits, which are especially important for those suffering from gastrointestinal issues such as ulcers, hyperactive gut, coeliac disease, those with compromised digestion, the elderly, and invalids - the nutritional benefit is independent of gastrointestinal influences.

Antianginals such as nitrites and nitrates, antihypertensives such as nifedipine, analgesics such as morphine, and bronchodilators such as fenoterol are examples of drugs administered via this route. Certain steroids, such as estradiol, and peptides, such as oxytocin, can also be administered, such as fentanyl citrate, apomorphine, prochlorperazine dimaleate PRO, and hydrazine HCl HYD.

- No bitter taste
- Dose lowers than 20mg, e.g. nifedipine
- Small to moderate molecular weight
- Good stability in water and saliva
- Partially non-ionized at the oral cavities pH
- Undergoing first pass effect e.g. ketotifen fumarate

FACTORS AFFECTING THE SUBLINGUAL ABSORPTION: [8]

- Lipophilicity of the drug: For a drug to be completely absorbed via the sublingual route, it must have slightly higher lipid solubility than that required for GI absorption.
- Solubility in salivary secretion: In addition to high lipid solubility, the drug must be soluble in aqueous buccal fluids, implying that biphasic drug solubility is required for absorption.
- pH and pKa of saliva: Because the average pH of saliva is 6.0, this pH promotes the absorption of drugs that are still unionized. Additionally, drugs are absorbed through the oral mucosa if the pKa is greater than 2 for an acid and less than 10 for a base.
- Binding to the oral mucosa: Drugs that bind to the oral mucosa have a low systemic availability.
- Oral epithelium thickness: The thickness of sublingual epithelium is 100200 m, which is less than buccal thickness. As a result of the thinner epithelium and drug immersion in a smaller volume of saliva, drug absorption is faster.
- Compounds with favorable oil-to-water partition coefficients are easily absorbed through the oral mucosa. For drugs to be absorbed sublingually, an oil-water partition coefficient range of 402000 is considered optimal.

ADVANTAGES OF FILMS: [9]

• Ease of administration to patients who refuse to swallow a tablet, such as pediatric, geriatric, and psychiatric patients.

• Convenience and accuracy in drug administration when compared to liquid formulations.

• Water is not required for swallowing the dosage form, which is a useful feature for patients who are on the go and do not have easy access to water.

• The good mouth feel property helps to change the basic perception of medication as a "bitter pill,", especially in paediatric patients.

• Rapid dissolution and absorption of the medication, resulting in a rapid onset of action.

• Some drugs are absorbed from the mouth, pharynx and esophagus as saliva passes down into the stomach, increasing drug bioavailability.

• It offers the benefits of liquid formulations in the form of solid dosage form.

• Pregastric absorption can improve bioavailability and, as a result of lower dosage, clinical performance by reducing unwanted effects.

DISADVANTAGES OF FILMS:[9]

• Because sublingual administration of drugs interferes with eating, drinking, and talking, this route is generally considered unsuitable for prolonged administration.

• Although this site is not well suited to sustained delivery systems.

• Because smoking causes vasoconstriction of the blood vessels, the patient should not smoke while taking sublingual medication. This will reduce the medication's effectiveness.

FORMULATION OF FAST DISSOLVING FILMS:[10,11,12,13]

A mouth-dissolving film is a thin film with an active ingredient that has a surface area of 5-20 cm2. The immediate dissolution in water or saliva is achieved via a special matrix made of water-soluble polymers. A typical composition includes the following elements:

Table no 1: Composition of strip

SI.NO	COMPOSITION OF STRIP	QUANTITY
1.	Active pharmaceutical agent	1-25%
2.	Film-forming polymer	40-50%
3.	Plasticizer	0-20%
4.	Saliva stimulating agent	2-6%
5.	Sweetening agent	3-6%
6.	Flavoring agent	10%
7.	Colouring agent	1%

1. Active pharmaceutical agent:

The drugs chosen for oral films should be stable in saliva and water at low doses. The drug should be present in the film at a concentration of 1-25% w/w. Small dose molecules are the most likely candidates for incorporation into an oral fast-dissolving film. With a dissolution time of less than 60 seconds, multivitamins up to 10% w/w of dry film weight were incorporated in the films. Micronized API is always beneficial for improving the texture of the film as well as for better dissolution and uniformity in the Oral fast dissolving film.

2. Film-forming polymer:

To achieve the desired strip properties, the polymers can be used alone or in combination. Natural and synthetic polymers can both be used in the formulation of oral films. Excipients or polymers must be water soluble with a low molecular weight and excellent film-forming capacity to prepare a water-soluble film formulation. The polymer used must be non-toxic, non-irritant, and free of leachable impurities. It should have a good wetting and spreading ability. The polymer should have adequate peel, shear, and tensile strengths. In genera To make fast-dissolving films, natural and synthetic polymers such as cellulose or cellulose derivatives, pullulan, gelatin, hypromellose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, carboxymethyl cellulose, polyvinyl alcohol, sodium alginate, xanthan gum, tragacanth gum, and guar gum are used. Pullulan is a natural polymer derived from non-animal sources that do not require chemical processing, at least 45% w/w polymer should be present based on the total weight of the dry film.

3. Plasticizers:

It aids in the improvement of the strip's flexibility and decreases its brittleness. Plasticizer significantly improves strip properties by lowering the polymer's glass transition temperature. Plasticizer excipients include glycerol, propylene glycol, low molecular weight propylene glycols, phthalate derivatives such as dimethyl, diethyl, and dibutyl phthalate, citrate derivatives such as tributyl, triethyl, acetyl citrate, triacetin, and castor oil. Plasticizers are typically used in concentrations ranging from 0 to 20% w/w of the dry polymer weight.

4. Saliva stimulating agent:

The use of saliva-stimulating agents is intended to increase the rate of saliva production, which will aid in the faster disintegration of the rapid dissolving strip formulations. These agents are used alone or in combination in amounts ranging from 2-6% w/w of the strip. Salivary stimulants include citric acid, malic acid, lactic acid, ascorbic acid, and tartaric acid.

5. Sweetening agents:

Sweeteners have become an essential component of pharmaceutical products that are disintegrated or dissolved in the oral cavity. Sucrose, dextrose, fructose, glucose, liquid glucose, and isomaltose are the most common sweeteners. Polyhydric alcohols such as sorbitol, mannitol, and isomalt can be combined because they provide a good mouth feel and a cooling sensation. Saccharin, cyclamate, and aspartame are examples of first-generation artificial sweeteners, followed by acesulfame-k, sucralose, alitame, and neotame, which are examples of second-generation artificial sweeteners. Sweeteners are typically used in concentrations ranging from 3 to 6%w/w, either alone or in combination.

6. Flavouring agents:

Fast-dissolving film formulations should contain up to 10%w/w flavours. An individual's acceptance of an oral disintegrating or dissolving formulation is largely determined by the initial flavour quality observed in the first few seconds after the product has been consumed, as well as the after taste of the formulation, which lasts for at least 10 minutes. The elderly prefer mint or orange flavours, whereas the younger generation prefer fruit punch, raspberry, and so on. Flavoring agents can be chosen from a variety of synthetic flavour oils, oleo resins, and extracts derived from various plant parts such as leaves, fruits, and flowers. Essential oils or water-soluble extracts of menthol, intense mints such as peppermint, sweet

mint, spearmint, wintergreen, cinnamon, clove, sour fruit flavour such as lemon, orange, or sweet confectionary can all be added. Vanillin, chocolate, or fruit essences such as apple, raspberry, cherry, or pineapple.

7. Colouring agents:

FD&C colours, EU colours, natural colouring agents and natural juice concentrates, pigments such as titanium dioxide, silicon dioxide, and zinc oxide, and custom Pantone-matched colours are all available.

MANUFACTURING METHODS: [14,15,16,17]

Fast-dissolving films can be made using the following processes:

1. Solvent casting

2. Semi solid casting

3. Hot melt extrusion

4. Solid dispersion extrusion

5. Rolling method

1. Solvent casting technique

Water-soluble polymers are dissolved in water and the drug, along with other excipients, is dissolved in a suitable solvent. Both solutions are then mixed and stirred before being casted in a Petri plate, dried, and cut to uniform dimensions.

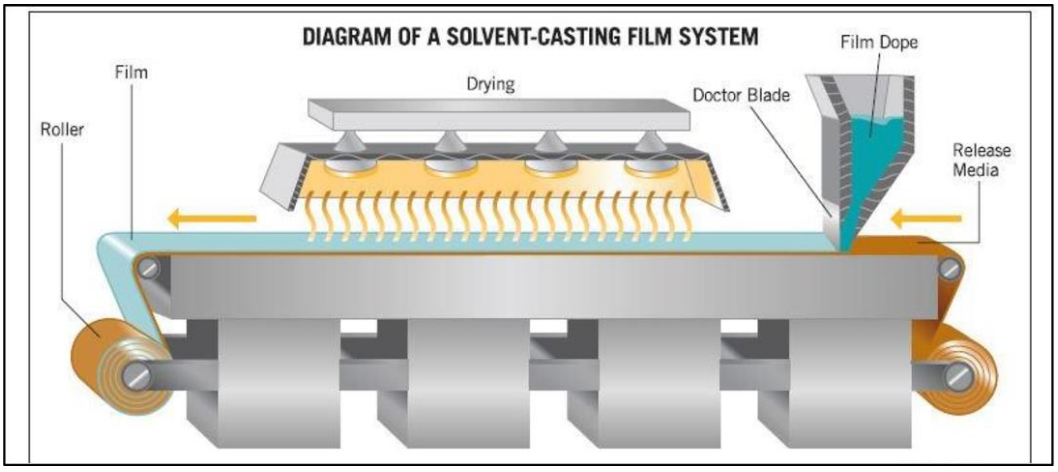

Fig no 2: A Solvent casting film system.

2. Semi-solid casting technique

A solution of water-soluble film-forming polymer is first prepared in the semisolid casting method. The resulting solution is mixed with an ammonium or sodium hydroxide-prepared solution of an acid-insoluble polymer (e.g., cellulose acetate phthalate, cellulose acetate butyrate). The appropriate amount of plasticizer is then added to form a gel mass. Finally, using heat-controlled drums, the gel mass is cast into the films or ribbons. The film's thickness ranges between 0.015 and 0.05 inches. The acid-insoluble polymer-to-film-forming polymer ratio should be 1:4.

3. Hot melt extrusion method

The drug is first mixed with carriers in solid form in the hot melt extrusion method. The mixture is then melted by an extruder equipped with heaters. Finally, the dies shape the melt into films. There are some advantages to using hot melt extrusion.

• A reduction in the number of operational units

• Better content uniformity

• An anhydrous process.

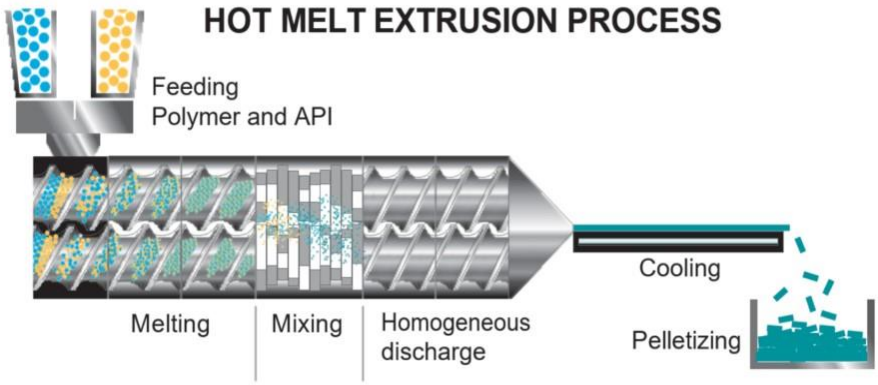

Fig no. 3: Hot melt extrusion process.

4. Solid dispersion extrusion

Immiscible components are extruded with the drug in this method, and then solid dispersions are prepared. Finally, dies are used to shape the solid dispersions into films.

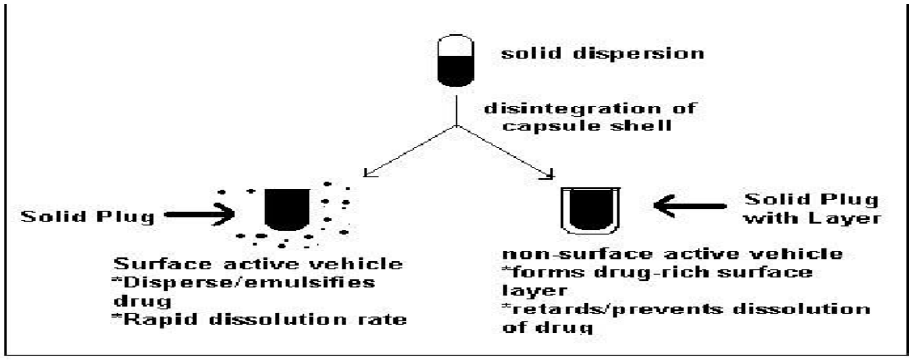

Fig no. 4: Solid dispersion method.

5. Rolling method

A drug-containing solution or suspension is rolled on a carrier in the rolling method. The solvent is mostly water or a water-alcohol mixture. The film is dried on rollers before being cut into desired shapes and sizes.

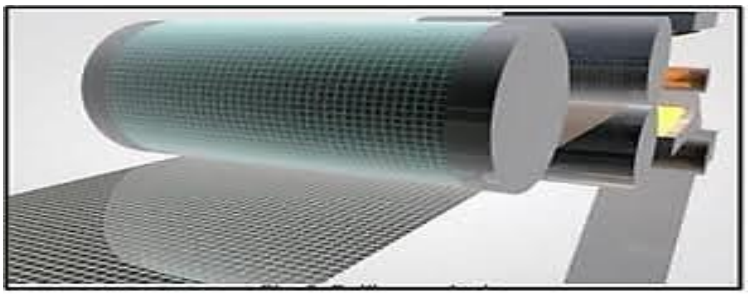

Fig no. 5: Rolling method.

PACKAGING:[18]

In the pharmaceutical industry, the package chosen must be adequate for preserving the product's integrity. To protect the dosage of other fast dissolving dosage forms, expensive packaging, specific processing, and special care are required during manufacturing and storage. Fast-dissolving films come in a variety of packaging options. For films, single packaging is required. The most common packaging format is an aluminium pouch.

1. **Foil, paper, or plastic pouches:** The flexible pouch is a packaging concept capable of providing not only a temperature-resistant package, but also, through proper material selection, a package with a high degree of environmental protection. During the product-filling operation, a flexible pouch is typically formed using either vertical or horizontal forming, filling, or sealing equipment. Single pouches or aluminum pouches can be used.

2. **Single pouch and Aluminum pouch:** Soluble film drug delivery pouches are peelable pouches for "quick dissolve" soluble films with high barrier properties. The pouch is clear to allow for product display. Using a two-structure combination allows one side to be clear while the other uses a low-cost foil lamination. The foil lamination allows virtually no gas or moisture transmission. For nutraceutical and pharmaceutical applications, the package offers a flexible thin film alternative. The single-dose pouch protects both the product and the dosage. The most common type of pouch is an aluminium pouch.

3. **Blister card with multiple units:**The blister container is made up of two parts: the blister (the formed cavity that holds the product) and the lid stock (the material that seals to the blister). Heat-softening a sheet of thermoplastic resin and vacuum-drawing the softened sheet of plastic into a contoured mould are used to create the blister package. After cooling, the sheet is removed from the mould and transported to the packaging machine's filling station.

EVALUATION PARAMETERS:[19,20,21,22,23]

1. Thickness:

The patch's thickness was measured using a digital Vernier Calliper with a minimum count of 0.01 mm at various locations on the film. The patch's thickness was measured at three different locations, and an average and standard deviation were calculated.

2. Weight variation:

The cast film was cut into four-centimeter squares at three different locations. The weight of each film was measured, and the weight variation was computed.

3. Folding endurance:

Folding endurance was determined by folding the film repeatedly at the same location until the strip broke. The folding endurance value was calculated by counting the number of times the film could be folded without breaking.

4. Tensile strength:

Tensile strength is defined as the maximum stress that can be applied to a film specimen before it breaks31. It is calculated as follows: applied load at rupture divided by the cross-sectional area of the film.

Tensile strength = Load at failure ×100/ Film thickness × film width

5. Percentage elongation:

When a film sample is stressed, it stretches, which is referred to as a strain. Strain is defined as the deformation of a film divided by its original dimension. As the plasticizer content increases, so does the length of the film.

Percent Elongation= L * 100/ Lo

Where, L = Increase in length of film,

Lo = Initial length of film.

6. Percentage elongation:

When a film sample is stressed, it stretches, which is referred to as strain. Strain is defined as the deformation of a film divided by its original dimension. As the plasticizer content increases, so does the length of the film.

7. Drug content uniformity:

This parameter was determined by dissolving one 2 x 2cm film by homogenization in 100 ml of pH 6.8 stimulated saliva for 30 minutes with continuous shaking. 10 mL of this was diluted to 50 mL with simulated salivary fluid. A UV spectrophotometer was used to measure absorbance. The experiments were carried out in triplicate for all formulations of films, and average values were recorded.

8. Surface pH:

The test film was placed in a petri dish and moistened with 0.5ml of distilled water for 30 seconds. After bringing the electrode of the pH metre into contact with the surface of the formulation and allowing equilibration for 1 minute, the pH was measured. For each formulation, an average of three determinations was performed.

9. *In vitro* dissolution studies:

The dissolution profile of fast-dissolving films was performed using a USP type II (paddle apparatus) and 300 mL of simulated salivary fluid (pH 6.8) as the dissolution medium 37 ±

0.5^0C.At 100 rpm, the medium was stirred. Every 30 seconds, samples were withdrawn and replaced with fresh medium in the same amount. A UV spectrophotometer was used to determine the amount of drug in the withdrawn samples. The percentage of drug released was plotted versus time.

10. *Ex vivo* permeation experiments on porcine oral mucosa:

The modified Franz diffusion cell with an internal diameter of 2.5 cm was used for permeation studies. The freshly sacrificed pig's buccal pouch was obtained from the local slaughterhouse. The buccal mucosa was excised and evenly trimmed from the sides before being washed in an isotonic phosphate buffer with a pH of 6.6 and used immediately. The donor and receptor compartments were separated by the mucosa. The receptor compartment was filled with 200 mL of isotonic phosphate buffer with a pH of 7.4 and kept at 37 0.2oC with a magnetic bead stirring at 50 rpm to maintain the hydrodynamics. One previously weighed 2 x 2 cm film was placed in close contact with the mucosal surface of the membrane, which had been moistened with a few drops of simulated saliva. 1 mL of pH 6.8 simulated saliva was placed in the donor compartment. At appropriate intervals, samples were withdrawn and replaced with fresh medium in the same amount. The absorbance in a UV Visible Spectrophotometer was used to calculate the percentage of drug permeated.

CONCLUSION:

In conclusion, fast-dissolving films are intended to be applied in the mouth and are a very innovative dosage, particularly for pediatric and geriatric patients. Fast-dissolving sublingual films have grown in popularity due to improved patient compliance and a faster onset of action. Because the drug is directly absorbed into the systemic circulation, drugs that undergo extensive first-pass metabolism are very useful via the sublingual route. These dosage forms are critical in emergencies such as allergic reactions and asthmatic attacks, where immediate action is required. Sublingual absorption is efficient because the percentage of drug absorbed is higher than that achieved by the oral route. As a result, sublingual thin films are a well-accepted technology for systemic drug delivery.

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