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## A Review on Fast Dissolving Sublingual Film

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### ABSTRACT:

Sublingual route is a useful when rapid onset of action is desired with better patient compliance. The portion of drug absorbed through the sublingual blood vessels bypasses the hepatic first pass metabolism processes giving acceptable bioavailability. Fast dissolving drug delivery is rapidly gaining acceptance as an important new drug delivery technology, which aim to enhance safety and efficacy of a drug molecule to achieve better patient compliance. Many patients find it difficult to swallow tablets and hard gelatin capsules particularly pediatric and geriatric patients and do not take their medicines as prescribed. Difficulty in swallowing or dysphasia is seen to afflict nearly 35% of the general population. In some cases such as motion sickness, sudden episode of allergic attack or coughing and an unavailability of water, the swallowing of tablet or capsules may become difficult in such situation fast dissolving drug delivery system is useful.

**KEY WORDS:** Sublingual film, rapid dissolving, water soluble polymers, patient compliance.

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### INTRODUCTION:

The Fast Dissolving Drug Delivery Systems was an advancement that came into existence in the early 1970's and combats over the use of the tablets, syrups, capsules which are the other oral drug delivery systems. Fast Dissolving Drug Delivery Systems serves as a major benefit over the conventional dosage forms since the drug gets rapidly disintegrated & dissolves in the saliva without the use of water.<sup>1</sup>

It provide the direct entry into the systemic circulation thereby avoiding the hepatic first pass Effect and ease of administration.<sup>2</sup> This delivery system consists of a thin film, is simply place below the tongue, instantly wet by saliva; the film rapidly dissolves. Then it rapidly disintegrates and dissolves to release the medication for systemic absorption This fast dissolving action is primarily due to the large surface area of the film, which wets quickly when exposed to the moist sublingual environment.<sup>3</sup> FDFs are useful in patients such as paediatric, geriatrics, bedridden, emetic patients, diarrhoea, sudden episode of allergic, attacks, or coughing for those who have an active life style.<sup>4</sup>

Sublingual administration of the drug means placement of the drug under the tongue and drug reaches directly in to systemic circulation through the ventral surface of the tongue and floor of the mouth. The drug solutes are rapidly absorbed into the reticulated vein which lies underneath the oral mucosa, and transported through the facial veins, internal jugular veins, and brachiocephalic vein and then drained into systemic circulation. The main mechanism of drugs absorbed through oral

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Oral mucosa is by passive diffusion into the lipid membrane. The absorption via sublingual route is 3 to 10 times higher than oral route and is only suppressed by hypodermic injection.<sup>5</sup>

Sublingual absorption is mostly rapid in action, but also short acting. In terms of the permeability sublingual area of the oral cavity is more permeable than the buccal area, which turn is more permeable than the palatal area. Sublingual films have been developed for certain condition for example, migraines, mental illness for which rapid onset of action is desired.<sup>6</sup>

Approximately one-third of the population, primarily the geriatric and paediatric populations, has swallowing difficulties, resulting in poor compliance with oral tablet drug therapy which leads to reduced overall therapy effectiveness. A new sublingual fast dissolving dosage form such as the fast dissolving tablet or fast dissolving film has been developed which offers the combined advantages of ease of dosing and convenience of dosing in the absence of water or fluid.<sup>7</sup>

However per-oral administration of drugs gives rise to some problems such as hepatic first pass metabolism and degradation within the GI tract. These problems can be overcome by administration through the sublingual mucosa. The sublingual route can produce a rapid onset of action within a short period of time due to high permeability and vascularisation of the sublingual mucosa.<sup>6</sup> Fast dissolving film is prepared using hydrophilic polymers that rapidly dissolves or disintegrates within few seconds.<sup>8</sup>

### OVER VIEW OF THE ORAL CAVITY<sup>9</sup>

The target sites for local drug delivery in the oral cavity include the following: Buccal, Sublingual, Periodontal region, Tongue, Gum. Other desirable targeting sites adjacent to oral cavity include pharynx, larynx, adenoids and tonsils. Within the oral cavity, delivery of drugs via the membranes of the oral cavity is classified into three categories:

#### i) Sublingual delivery

Which is systemic delivery of drugs through the mucosal membranes lining the floor of the mouth to the systemic circulation?

#### ii) Buccal delivery

Which is drug administration through the mucosal membranes lining the cheeks and the area between the gums and upper and lower lips to the systemic circulation?

#### iii) Local delivery

Which is drug delivery to periodontal, gingival, delivery for the local treatment of ulcers, bacterial and fungal infections

and periodontal disease.

Sublingual administration of the drug means placement of the drug under the tongue and drug reaches directly into the blood stream through ventral surface of the tongue and floor of the mouth. The drug solutes are rapidly absorbed into the reticulated vein which lies underneath the oral mucosa, and transported through the facial veins, internal jugular vein, and brachiocephalic vein and then drained in to systemic circulation.

### SUBLINGUAL GLANDS<sup>10</sup>

Salivary glands are present in the floor of the mouth underneath the tongue. They are also known as sublingual glands. They produce mucin in turn produces saliva. The fluid which is produced by the glands gets mix with the food, so the food gets easily chewed. The absorption is transfer of the drug from its site of administration into systemic circulation, so it can be said that absorption is directly proportional layer thickness. The absorption of the drug follows in this way Sublingual > Buccal > Gingival > Palatal. Due to high permeability and rich blood supply, the sublingual route can produce rapid onset of action so the drug with short delivery period can be delivered and dose regimen is frequent.

### Criteria for Sublingual Fast dissolving Drug Delivery System:<sup>11</sup>

- Not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds.
- Be compatible with taste masking.
- Be portable without fragility concern.
- Have a pleasant mouth feel.
- Leave minimum or no residue in the mouth after oral administration
- Exhibit low sensitive to environmental condition as temperature and humidity.
- Allow the manufacture of the tablet using conventional processing and packaging equipments at low cost.

### Advantages of film<sup>12</sup>

- Ease of administration to patients who refuse to swallow a tablet, such as pediatric, geriatric patients and psychiatric patients.
- Convenience in administration of drug and accurate dosing as compared to liquid formulations.
- Water is not required for swallowing the dosage form, which is convenient feature for patients who are travelling and do not have immediate access to water.

- Good mouth feels property helps to change the basic view of medication as "bitter pill", particularly for pediatric patients.
- Fast dissolution of medicament and absorption which will leads to rapid, onset of action.
- Some drugs are absorbed from the mouth pharynx and esophagus as the saliva passes down into the stomach, in such cases bioavailability of drugs is increased.
- It provides advantages of liquid formulations in the form of solid dosage form.
- Pregastric absorption can result in improved bioavailability and as a result of reduced dosage, improved clinical performance through a reduction of unwanted effects.

**Disadvantages of film:**<sup>12</sup>

- Since 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.
- Sublingual medication cannot be used when a patient is unconscious or uncooperative.
- The patient should not smoke while taking sublingual medication, because smoking causes vasoconstriction of the blood vessels. This will decrease of the medication.

**FORMULATION OF FAST DISSOLVING FILMS:**<sup>13,14,15,16, 17</sup>

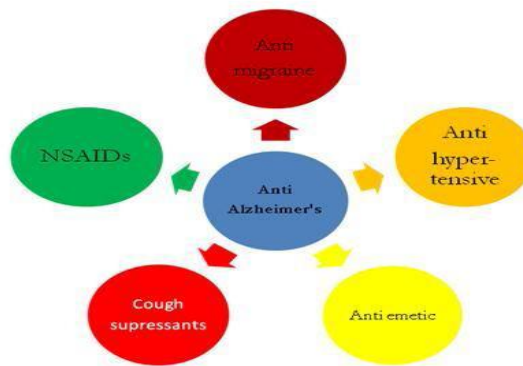
Mouth dissolving film is a thin film with an area of 5-20 cm<sup>2</sup> containing an active ingredient. The immediate dissolution, in water or saliva respectively, is reached through a special matrix from water-soluble polymers. A typical composition contains the following:

**Table 1: Composition of fast dissolving oral film**

Sr. No	Composition of Film	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.	Coloring agent	1%

**1. Active pharmaceutical agent**

The drugs selected for oral 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 Oral fast dissolving film.



**Figure.1: Candidate drugs**

**Table 2: Drugs that can be incorporated in fast dissolving films**

Active pharmaceutical	Therapeutic category	Dose
<b>Category</b>		
Nicotine	Smoking cessation	1-15mg
Nitroglycerin derivatives	Vasodilator	0.3-0.6mg
	Anti migraine	2.5mg
Zolmitriptan	Antimigraine	35.0-70.0mg
Sumatriptan succinate	Antihistaminic	2.50mg
	Anti histaminic	5-10mg
Tiprolidine hydrochloride	Proton pump inhibitor	10-20mg
Loratidine	Anti inflammatory	12.5-25mg
Omeprazole	Anti microbial	0.12%
Ketoprofen	Opoid analgesic	2.5-10mg
Chlorhexidine gluconate	Muscle relaxant	25mg
Oxycodone		
Dicyclomine		

## 2. Film forming polymer

A variety of polymers are available for preparation of fast dissolving films. The polymers can be used alone or in combination to obtain the desired films properties. The films obtained should be tough enough so that there won't be any damage while handling or during transportation.<sup>18</sup> The robustness of the strip depends on the type of polymer and the amount in the formulation. The polymers can be used alone or in combination to obtain the desired strip properties. Water-soluble polymers are used as film formers. The use of film forming polymers in dissolvable films has attracted considerable attention in medical and nutraceutical application. The water-soluble polymers achieve rapid disintegration, good mouth feel and mechanical properties to the films. The disintegration rate of the polymers is decreased by increasing the molecular weight of polymer film base. Both natural as well as synthetic polymers can be used in the formulation of sublingual films. In order to prepare a film formulation that is water-soluble, excipients or polymer must be water soluble with low molecular weight and excellent film forming capacity.<sup>19</sup> At least 45% w/w of polymer should generally be present based on the total weight of dry film.<sup>20</sup> but typically 60-65%w/w of polymer is preferred to obtain desired properties<sup>21</sup>. The polymer employed should be non-toxic, non-irritant and devoid of leachable impurities. It should have good wetting and spread ability property. The polymer should exhibit sufficient peel, shear and tensile strengths. The various natural as well as synthetic polymers to make fast dissolving films include 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. Pullulan is a natural polymer obtained from nonanimal origin and does not require chemical modification.<sup>22</sup>

**Prabhu SC et al** were prepared fast dissolving films of Montelukast sodium by using film forming polymers HPMC E15, Pullulan and Sodium Carboxymethyl Cellulose.

**N.L Prasanthi et al** were prepared Sublingual Fast Dissolving Films for an Antiasthmatic Drug

by using film forming polymers HPC and HPMC 100.

**Mashru et al**, prepared fast dissolving films for sublingual route containing salbutamol sulphate and polyvinyl alcohol as polymer.

## 3. Plasticizers

It helps to improve the flexibility of the strip and reduces the

brittleness of the strip. Plasticizer significantly improves the strip properties by reducing the glass transition temperature of the polymer. Glycerol, propylene glycol, low molecular weight propylene glycols, phthalate derivatives like dimethyl, diethyl and dibutyl phthalate, citrate derivatives such as tributyl, triethyl, acetyl citrate, triacetin and castor oil are some commonly used plasticizer excipients. Typically the plasticizers are used in the concentration of 0-20% w/w of the dry polymer weight. **Honary et al.** studied effect of different molecular weights and concentration of PEG as plasticizer in HPMC films

## 4. Saliva stimulating agent

The purpose of using saliva stimulating agents is to increase the rate of production of saliva that would aid in the faster disintegration of the rapid dissolving strip formulations. These agents are used alone or in combination between 2-6% w/w of the strip. Citric acid, malic acid, lactic acid, ascorbic acid and tartaric acid are the few examples of salivary stimulants.

## 5. Sweetening agents

Sweeteners have become the important part of pharmaceutical products intended to be disintegrated or dissolved in the oral cavity. The classical source of sweetener is sucrose, dextrose, fructose, glucose, liquid glucose and isomaltose. Polyhydric alcohols such as sorbitol, mannitol and isomalt can be used in combination as they additionally provide good mouth feel and cooling sensation. The artificial sweeteners like Saccharin, cyclamate and aspartame are the first generation of the artificial sweeteners followed by acesulfame-k, sucralose, alitame and neotame which fall under the second generation artificial sweeteners. Generally sweeteners are used in the concentration of 3 to 6 %w/w either alone or in combination.

## 6. Flavouring agents

Preferably up to 10%w/w flavors are added in the Fast dissolving film formulations. The acceptance of the oral disintegrating or dissolving formulation by an individual is largely depends on the initial flavor quality which is observed in first few seconds after the product has been consumed and the after taste of the formulation which lasts for at least about 10 min. The geriatric population like mint or orange flavors while younger generation like flavors like fruit punch, raspberry etc. Flavoring agents can be selected from the synthetic flavor oils, oleo resins, extracts derived from various parts of plants like leaves, fruits and flowers. Any flavor can be added such as essential oils or water soluble extracts of menthol, intense mints such as peppermint, sweetmint, spearmint, wintergreen, cinnamon, clove, sour fruit flavor

such as lemon, orange or sweet confectionary. Flavors such as vanillin, chocolate or fruit essence like apple, raspberry, cherry, pineapple.

### 7. Colouring agents

A full range of colors is available including FD&C colors, EU colors, natural coloring agents and natural juice concentrates, pigments such as titanium dioxide, silicon dioxide and zinc oxide and custom pantone matched colors.

## MANUFACTURING METHODS<sup>23,24,25,26</sup>

Following processes can be used to manufacture fast dissolving films:

1. Solvent casting
2. Semi solid casting
3. Hot melt extrusion
4. Solid dispersion extrusion
5. Rolling method

### 1. Solvent casting method

In solvent casting method water soluble polymers are dissolved in water and the drug along with other excipients is dissolved in suitable solvent then both the solutions are mixed and stirred and finally casted in to the Petri plate, dried and cut in to uniform dimensions.

Londhe V Y and Umalkar K B were prepared fast dissolving film of Telmisartan by using solvent casting method

### 2. Semi solid casting method

In semisolid casting method firstly a solution of water-soluble film forming polymer is prepared. The resulting solution is added to a solution of acid insoluble polymer (e.g. cellulose acetate phthalate, cellulose acetate butyrate), which was prepared in ammonium or sodium hydroxide. Then appropriate amount of plasticizer is added so that a gel mass is obtained. Finally the gel mass is casted in to the films or ribbons using heat controlled drums. The thickness of the film is about 0.015-0.05 inches. The ratio of the acid insoluble polymer to film forming polymer should be 1:4.

### 3. Hot melt extrusion method

In hot melt extrusion method firstly the drug is mixed with carriers in solid form. Then the extruder having heaters melts the mixture. Finally the melt is shaped in to films by the dies. There are certain benefits of hot melt extrusion.

- Fewer operation units
- Better content uniformity
- An anhydrous process.

**Cilurzo F et al.** developed fast dissolving film containing maltodextrin using hotmelt extrusion technology

### 4. Solid dispersion extrusion

In this method immiscible components are extrude with drug and then solid dispersions are prepared. Finally the solid dispersions are shaped in to films by means of dies.

### 5. Rolling method

In rolling method a solution or suspension containing drug is rolled on a carrier. The solvent is mainly water and mixture of water and alcohol. The film is dried on the rollers and cut in to desired shapes and sizes.

## Evaluation parameters for sublingual film:<sup>27, 28, 29, 30, 31 32, 33</sup>

### 1. Weight Variations

Four centimeter square of the film was cut at three different places from the casted film. The weight of each film was taken and weight variation was calculated

### 2 .Film thickness

The thickness of the film can be measured by micrometer screw gauge (Acculab) at three different places; averages of three values can be calculated. This is essential to ascertain uniformity in the thickness of the film this is directly related to the accuracy of dose in the film.

### 3. pH value

The pH value can determine by dissolving one oral film in 10ml distilled water and measuring the pH of the obtained solution. It is necessary that film should have nearly uniform pH value.

### 4. Folding endurance<sup>34</sup>

The folding endurance is expressed as the number of folds (number of times the film is folded at the same place, either to break the specimen or to develop visible cracks). This test is important to check the ability of the sample to withstand folding. This also gives an indication of brittleness. The folding endurance of the strips can be determined by repeatedly folding one film at the same place till it broke ribbons using heat. The average weight should not differ significantly from controlled drums the average weight

### 5. Content Uniformity

Drug content can be determined by dissolving the film in 100 ml of suitable solution to get 20 µg/ml solutions. An aliquot of 2ml sample can withdraw and diluted to 10 ml with solution. Then solution can be filtered through whatman filter and solution analyzed spectrophotometrically.

## 6. Young's Modulus<sup>35</sup>

Young's modulus or elastic modulus is the measure of stiffness of strip. It is represented as the ratio of applied stress over strain in the region of elastic deformation. Hard and brittle strips demonstrate a high tensile strength and young's modulus with small elongation.

## 7. InVitro Dissolution Studies<sup>36, 37</sup>

The in vitro dissolution study can be carried out in 500 ml pH 6.8 phosphate buffer using (USP) XIV paddle apparatus II at 37.0±0.5°C and at 50 rpm. Each square cut film sample is submerged into the dissolution media and appropriate aliquots were withdrawn at specific intervals for 30 min. The drug concentration is measured by a UV spectro-photometer.

## 8. Morphology Study

Morphology of the prepared film can be observed under a motic electron photomicrograph. motic electron photomicrographs can be recorded at 100 X magnification.

## 9. Stability Studies.

Stability studies on the optimized formulation of oral fast dissolving film is carried out to determine the effect of temperature and humidity on the stability of the drug. The film can be stored in an aluminum foil and subjected to stability at room temperature. The sample can withdraw at 90 days and 180 days and subjected for disintegration test and in vitro dissolution studies to determine disintegration time and cumulative % drug release.

## CONCLUSION:

Fast dissolving sublingual films have gained popularity because of better patient compliance, rapid onset of action. The drug is directly absorbed into systemic circulation, so drugs which undergo the extensive first pass metabolism sublingual route is very useful. Fast dissolving films are intended to be applied below the tongue and it is a very useful dosage especially for pediatric and geriatric patients. These dosage forms are of very importance in case of emergency conditions such as allergic reactions and asthmatic attacks where immediate onset of action is desired. Sublingual absorption is efficient since the percent of drug absorbed by this route is generally higher than that achieved by oral route. Therefore sublingual thin films are an accepted technology for systemic delivery of drugs.

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