



## A Comprehensive Review on Pharmaceutical Oral Dissolving Films

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### ABSTRACT

Oral fast dissolving films are novel approach which are used now a days due to better patient compliance, rapid dissolution, onset of action . It was designed to overcome the disadvantages of orally disintegrating tablets. This technology is now found to be more effective and convenient as comparison to conventional dosage forms . These oral films are having water soluble polymers that quickly hydrate through saliva got disintegrate and starts its effect. Now a days this formulation is found to be more beneficial for both gediatric and pediatric patients . These films have greater advantage that it bypass the first pass effect due to which it directly reaches to its maximum concentration and produces good therapeutic effect.

**Keywords:** Dissolution, Conventional dosage form, gediatric, pediatric.

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### INTRODUCTION

In sublingual drug distribution, the delivery take place by placing drug beneath tongue from where drug directly reaches to the blood and also through the floor of oral cavity. Sublingual delivery requires small quantity of saliva to break the dosage form into the oral cavity.<sup>1</sup> Dysphasia a kind of trouble in gulping is very common issue for all age group particularly kids, elders and also those patients who are not cooperative or having lesser liquid diet they experience gulping issues to these dose shapes.<sup>2</sup> This delivery system is different because in this drug is kept under the tongue so it passes immediately to blood by passing via ventral surface and the floor of the oral mucosa<sup>3</sup>. This route got unaffected by first pass metabolism and due to this degradation will also not take place and it proves to be better option for dysphagic patients, pediatric, geriatric patients. This occurs because of more permeability of sublingual route than buccal area. This route is effective but has some limitation that all molecules cannot be given through it.<sup>4</sup>

There are some factors which are taken into consideration :

- Drug Lipophilicity
- Solubility.
- pH and pK<sub>a</sub> of saliva
- Drug release from the formulation

### Advantages<sup>5</sup>

- Easy to take by all types of patient i.e. pediatrics, geriatrics, and unconscious patient.
- By pass first pass effect and reduces its side effects.
- Low dose of drug produce great action .
- As saliva increases drug absorption through esophagus and pharynx so drug bioavailability will be increased .
- Fast drug absorption which leads to rapid onset of action.
- Commonly used drug delivery system in emergency condition e.g. asthma.

### Disadvantages<sup>6</sup>

- This route is not suitable for prolonged action.
- Not suitable for sustainable drug delivery.
- Un effective for non-cooperative patients.

### ORAL DISSOLVING FILMS

Oral dissolving films is a forms that disperse or disintegrates directly into oral cavity, in the absence of water. Alternative to fast dissolving tablets it eliminates panic patients of chocking.

**Release Mechanism**<sup>7-9</sup>

The release mechanism starts when drug was placed beneath tongue and got wet by saliva due to the availability of excipients and polymer that are hydrophilic leads to rapid hydration of film and due to this drug got adhere to the site of action and start release and produces good therapeutic response .

**Special features**<sup>10-12</sup>

1. Thin elegant film.
2. Rapid dissolution or disintegration.
3. Immediate release, Mucoadhesive and quick dissolving.
4. Had pleasant feel in mouth.
5. Mask unpleasant taste.

**Advantages**

1. Provides large surface area that leads to rapid dissolution.
2. No choking risk.

3. Better patient compliance.
4. Rapid and quick onset of action.
5. Easy to handle.
6. Bioavailability enhanced along with stability.
7. By pass first pass metabolism.

**Disadvantages**

1. Irritating drugs can't be administered.
2. Stricted for only small doses.

**Classification of Oral Films**<sup>13</sup>

There are three different subtypes

- a) Flash release.
- b) Mucoadhesive melt-away wafer.
- c) Mucoadhesive sustained-release wafers.

**Table 1: Different type of film**

Sub type	Flash release wafer	Mucoadhesive melt -away wafer	Mucoadhesive sustained release Wafer
Area (cm <sup>2</sup> )	2-8	2-7	2-4
Thickness (µm)	20-7	50-500	50-250
Structure	Single layer	Single or multilayer System	Multi layer system
Excipients	Soluble, highly hydrophilic polymers	Soluble, hydrophilic Polymers	Low/Non soluble polymers
Drug phase	Solid solution	Solid solution or suspended drug particles	Suspension and/or solid Solution
Application	Tongue(upper palate)	Gingival or buccal region	Gingival and other region of oral cavity
Dissolution	Maximum 60 seconds Maximum 8-10 Hours	Disintegration in a few Minutes forming, gel	Maximum 8-10 hours
Site of action	Systemic or local	Systemic or local	Systemic or local

**Manufacturing of Film**

- Film forming agent
- Plasticizers
- Flavoring and sweetening agent
- Surfactant
- Thickener and Stabilizers
- Saliva stimulating agent
- Coloring agent

**Film forming agent**

These ODFs contain film-forming polymers such as hydroxyl propylmethyl cellulose (HPMC), hydroxyl propyl cellulose (HPC), pullulan, carboxy methyl cellulose (CMC), pectin, starch, polyvinyl acetate (PVA), and sodium alginate.<sup>14</sup> These polymers are water soluble and can be used alone or in combination to obtain the desired strip properties. They comprise the physical structure of the films, affording their

integrity. The robustness of the strip depends on the type of polymer and the amount in the formulation.<sup>15</sup> . The dissolution rate of dissolving polymer is inversely related to the molecular weight of the polymer.

**Plasticizers**

It improves the flexibility of film and decrease the brittleness of the polymer film. Plasticizers such as glycerin, sorbitol Propylene Glycol, Glycerol, castor oil, and other citrate esters, can be added to the formulation to alter mechanical properties of final film.<sup>16</sup>

**Flavoring and sweetening agent:**

The flavors enhance the acceptance of the formulation and enhance the elegance properties of film. Any flavor can be added such as essential oil or water soluble extracts of menthol, intense mints such as peppermint, sweet mint, spearmint, wintergreen, cinnamon, clove, sour fruit flavor such as lemon, orange or sweet confectionary.

### Surfactant agent

These are used to enhance the solubility and wetting property of film to release within minute the drug. There are many surfactants which are used i.e. benzalkonium chloride, sodium lauryl sulfate, benzathonium chloride, tween and polaxamer.

### Coloring agents

Coloring agents may include FD & C coloring agents, natural coloring agents, and natural juice concentrates, pigments such as titanium oxide, silicon dioxide and zinc oxide.

### Thickener and Stabilizers

These stabilize and enhance the viscosity i.e. xanthan gum, carrageenan and derivatives of cellulose.<sup>24</sup>

### Saliva stimulating agent

These activate the salivary gland to produce the saliva which helps in rapid disintegration of the film. Some acids are used as saliva stimulating agent i.e. citric acid, ascorbic acid, lactic acid, tartaric acid.<sup>25</sup>

### Method of preparation of sublingual films

- ✚ Semisolid casting method
- ✚ Hot melt extrusion method
- ✚ Solvent casting method
- ✚ Rolling method
- ✚ Solid dispersion extrusion

#### Solvent casting method:

This method is very old method used for the preparation of sublingual film. In this method, initially all the polymers are dissolved in the suitable solvent and the drug and other additives are dissolved in the other beaker containing suitable solvent. After that mix both the solution and stir it for some time. Then the solution is subjected to the sonicator to remove the air bubble. Finally that solution is poured into Teflon or glass petri plate and then kept in oven for overnight at 50-60°C for drying. Peel out the film and kept in the desiccator till further use.

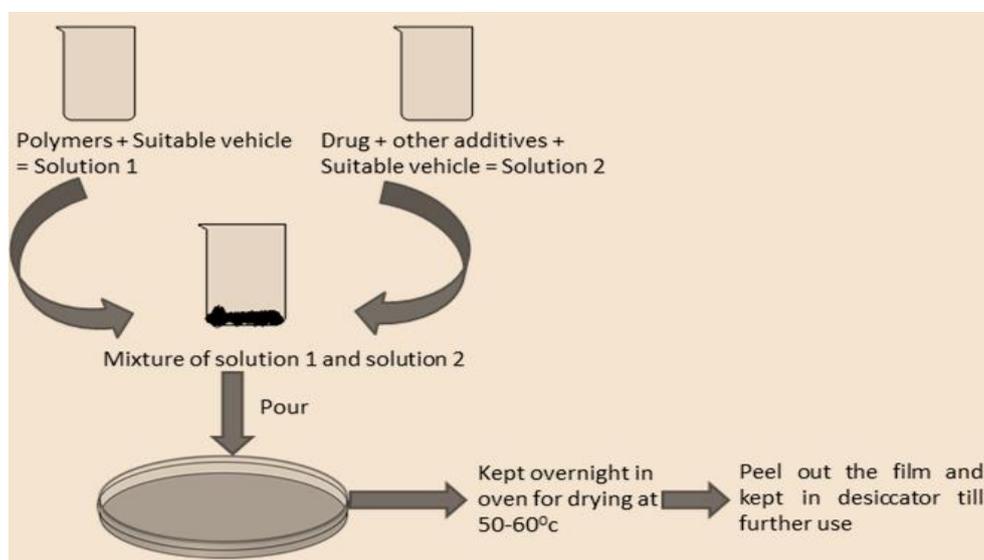


Figure 1: Solvent Casting Method

### Hot melt extrusion:

In this method generally the polymer, drug and other additives are mixed together in the dried form and then the whole mixture is subjected to heating process. Due to

heating the solid content in converts into the molten state and the film is extruded out<sup>17</sup> The solvent is evaporated by using the suitable method. The prepared film is kept in the desiccator till further use.

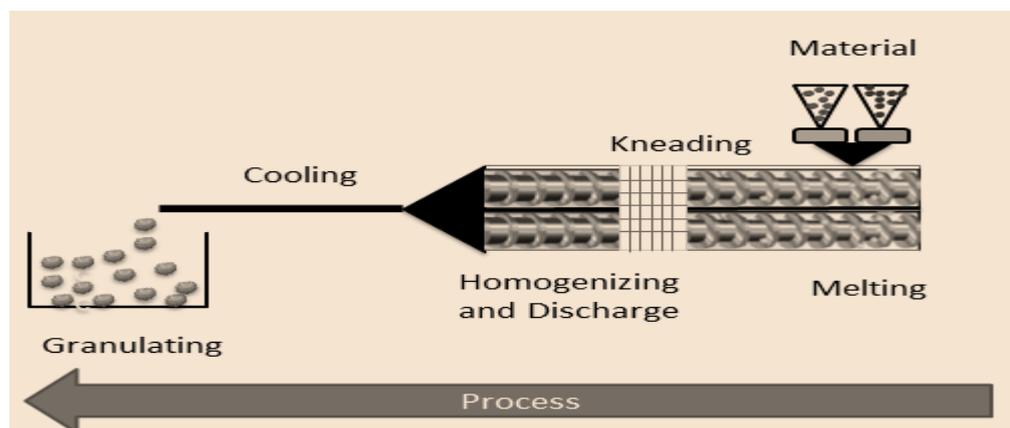


Figure 2: Hot melt extrusion process

## Evaluation parameters for Oral film of Sumatriptan Succinate

1. Preformulation studies
2. Physical Appearance
3. Solubility
4. Melting Point
5. Fourier Transform Infrared (FTIR) Analysis
6. Analytical method development
7. Drug Excipients Compatibility studies
8. Drug content uniformity
9. *In-vitro* drug release
10. *In-vitro* permeation study
11. Stability study

## PHARMACEUTICAL APPLICATIONS OF ORAL FILM

There are various applications of oral films. They are as follows:

1. **Allergic Reaction** : Fast dissolving films are used to treat allergic reactions because of their better response
2. **CNS Disorder**: These films are proved to be beneficial for CNS Disorder because of their better therapeutic response.
3. **Topical Applications**: The films are used topically as analgesic or antimicrobial agents for treating wound and care.
4. **Gastroretentive dosage forms**: These films are used to treat GIT disorder.
5. **Vaccines**: Fast dissolving films can be delivered in the form of vaccine to treat **various** diseases. For ex: Rotavirus vaccine which is prepared in US.

Table: 2 List of Oral Film Available in the market<sup>25,26</sup>

S.No.	Oral film	Active Ingredient	Category
1	Klonopin Wafers	Clonazepam	Antianxiety
2	Chloraseptic	Menthol/Benzocaine	Sore throat
3	Gas-X	Simethicone	Antiflatuating
4	Supress R	Menthol	Cough Suppressant
5	Triaminic	Diphenhydramine HCL	Anti allergic

## CONCLUSION:

It has been concluded that fast dissolving films are proved to be more promising and beneficial delivery system due to their better patient compliance, therapeutic effect and response. They have potential to deliver medicinal product to treat various disease condition like gastro retentive diseases, allergic reactions etc. They can be used to refresh breath .Now a days various companies are moving towards oral films instead of preparing tablet formulation because of their better response .This technology is being studied and have great future scope.

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