



## Oro-Dispersible Film: An Effective Approach for the Quick Drug Release

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### ABSTRACT

Hydrophilic polymers are used to create oro-dispersible film (ODF), a form of drug delivery device that can be produced in a variety of sizes and shapes and is simple to transport and store. The drug may be absorbed from the pharynx and oesophagus or from other GIT secretions as the saliva travels down. It is made up of a very thin, elegant oral strip about the size of a postage stamp that, when placed in the oral cavity, dissolves or disperses in the saliva in a matter of seconds without the need for water. This kind of technology provides an easy approach to administer medication to the general community as well as to special demographic groups like children, the elderly, patients who are bedridden, and people who are mentally ill. The current review gives an account of numerous formulation factors, the preparation process, and ODF quality control. Polymers, plasticizers, saliva-stimulating agents, colours, flavours, and sweeteners are used in the formulation of oral films. Different methods are reported in literature as solvent casting method, hot melt extrusion method, rolling method and solid dispersion method for the preparation of film. The objective is to provide rapid onset of action and to mask bitter taste of drugs. Overall, it leads to patient compliance with improved therapeutic success.

**Keywords:** Oro-dispersible film, Solvent casting, Pediatric, Geriatric.

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### INTRODUCTION

Despite significant advancements in drug delivery systems, the oral route of drug administration remains the most crucial form of drug administration for a systemic effect.<sup>1,2</sup> It is the most popular method of drug delivery since it offers many benefits over other methods of drug administration.<sup>3,4</sup> Its convenience of use, ability to reduce pain, and inexpensive cost of therapy result in high levels of patient compliance.<sup>5,6</sup>

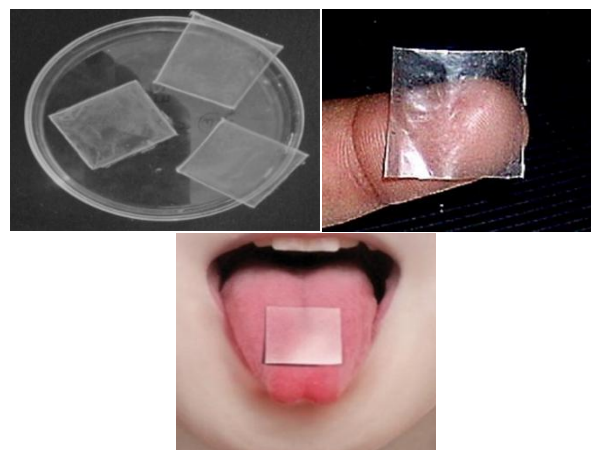
But oral drug delivery systems still need some advancements to be made. However, oral medication delivery methods still need to be improved due to some issues with a specific class of patients, such as elderly, paediatric, and dysphasic patients who have trouble swallowing or digesting solid dosage forms due to a variety of medical disorders.<sup>7,8</sup>

The difficulty ingesting oral solid dose forms led to the development of oral fast-dissolving drug delivery devices in the late 1970s. These systems use oral dispersible tablets (ODT), which dissolve and break down quickly in the mouth.<sup>9,10</sup> However, because of their tablet-like form

and fear of choking many paediatric and geriatric patients are reluctant to consume even ODTs.<sup>11</sup>

Also, the manufacturing of orally disintegrating tablet formulations may be more difficult and costly, and they may experience challenges with hardness and friability during production, storage, handling, and administration.<sup>12</sup>

Oro-dispersible films, a new technology, were created to address these drawbacks. A new medication delivery method called oro-dispersible film (ODF) formulation uses hydrophilic polymers to prepare the drug for rapid release.



**Figure 1:** Example of oro-dispersible film.

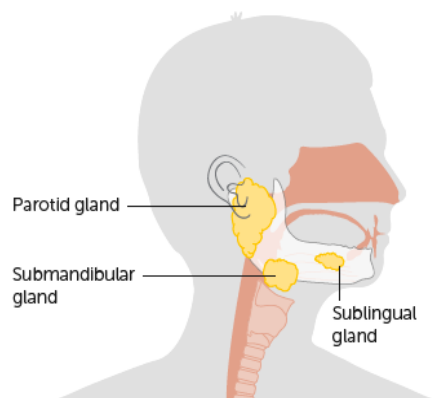
As shown in the Figure 1, orodispersible film is a flexible, square or rectangle-shaped oral strip that is postage stamp-sized, very thin, and visually appealing. It is made of polymers that, when applied to the tongue of a patients or

any other mucosal tissue, instantaneously become moistened by saliva and quickly decompose to release the medicine, which dissolves or disperses in the saliva. As the saliva descends, the medication may be absorbed from the pharynx, oesophagus, or other GIT secretions. When compared to conventional dosage forms, bioavailability is higher in certain situations.<sup>12,13,14</sup>

**Table 1:** Comparison between Oro-dispersible film and Oro-dispersible tablet.<sup>15,16</sup>

Oro-dispersible film	Oro-dispersible tablet
Large surface area gives greater dissolution.	Less surface area gives less dissolution than ODF
Fast dissolving films are flexible and durable.	Fast dissolving tablet are brittle and less durable than ODF.
Fast dissolving films are of thickness 0.015-0.05 inches.	Fast dissolving tablet are of same size of convention tablet
Patient compliance is more	Patient compliance is less than ODF

Three salivary glands—the parotid, submandibular, and sublingual—located in the mouth cavity as shown in the fig.2. The salivary glands secrete saliva, which is a weak buffer with a pH range of 5.5-7 and is comparatively less viscous than GI fluids. It mostly consists of water and 1% organic and inorganic material. The salivary gland produces 0.5-2 liters of saliva in total, which is sufficient to hydrate an oral mucosal dosage form. Without the use of water, oro dispersible films quickly break down in a matter of seconds when they come into touch with saliva.<sup>6</sup>



**Figure 2:** Salivary glands

#### Special features of ODFs:<sup>15</sup>

- Available in various size and shape.
- Thin elegant film.
- Un-obstructive.
- Fast disintegration or dissolution.
- Rapid release.
- Have an acceptable taste.

- Give a pleasing mouth feel.

#### Advantages of Oro-dispersible film:<sup>6,15,17.</sup>

- No risk of choking.
- Improved patient compliance.
- It is compatible with taste masking.
- It leaves less or no residue in the mouth.
- Ease of handling and transportation.
- Enhanced stability.
- Requires no water, have quick disintegration and dissolution of the dosage form.
- Ease of administration for patients who are mentally ill-disabled & uncooperative.
- It is useful in case of rapid onset of action required such as sudden episodes of allergic attack or coughing, in motion sickness, bronchitis or asthma.
- Improve bioavailability for certain therapeutic ingredient.

#### Disadvantages of Oro-dispersible film:<sup>18</sup>

- Drugs which cause irritation to the mucosa cannot be administered.
- As it is fragile and must be protected from water, it requires special packaging.

#### FORMULATION INGREDIENTS<sup>18</sup>

An oro-dispersible film is a thin, drug-containing layer with a surface area of 5 to 20 cm<sup>2</sup>. Up to 30 mg of the medications can be put into a single dose. All excipients employed in the formulation must be accepted for use in oral pharmaceutical dosage forms and must be generally recognised as safe (i.e., GRAS-listed) from a regulatory perspective. Commonly used ingredients in formulation of oro-dispersible films are listed in the table 3.

#### Active Pharmaceutical Ingredient<sup>15</sup>

A film comprises 1 to 30 % W/W of the active ingredient by weight, which dissolves when it comes into contact with saliva in the oral cavity. Low doses of active pharmaceutical ingredients are preferable since big doses of medication are challenging to include into oro dispersible films. Anti-emetic (Ondansetron), anti-histaminic (Levocetizine), anti-hypertensive (Diltiazem HCL), and other medications can be made as oro-dispersible films.

#### Film forming polymer<sup>17</sup>

It serves as a medicine delivery system. The most common polymers utilised are hydrophilic ones such sodium alginate, PEG, and HPMC and CMC in various degrees. The film needs to be sturdy enough to avoid being harmed when being handled or while being transported. The kinds and quantities of polymers used in films affect the tensile strength.

**Table 2:** Types of Oro-dispersible Films and Their Properties:<sup>19</sup>

Property/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)	20-70	50-500	50-250
Structure	single layer	Single layer or multilayer	Multilayer 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, other region in the oral cavity
Dissolution	Maximum 60 Seconds	Disintegration in a few minutes, forming gel	Maximum 8-10 hours

**Table 3:** A typical formulation ingredients of oro-dispersible films

Sl. No	Ingredients	Concentration W/W
1	Drug (API)	1-30%
2	Film forming polymer	30-40%
3	Plasticizer	0-20%
4	Saliva stimulating agent	2-6%
5	Sweetening agent	3-6%
6	Flavouring agent	q.s
7	Surfactant	q.s
8	Colour, filler	q.s

**Ideal Properties of film forming polymer:**

- It should be non-toxic and non-irritant.
- Polymer must be hydrophilic.
- It should have excellent film forming capacity.
- Polymer should be readily available & should not be very expensive.
- Polymer should have low molecular weight.
- It should have sufficient shelf-life.
- Polymer must be tasteless, colourless.
- It should not cause any secondary infection in oral mucosa.

Currently, both natural (pullulan, Sodium alginate etc)& synthetic polymers (HPMC, CMC etc) are used for the preparation of Oro-dispersible film.

**Plasticizer:**<sup>17</sup>

It improves the flexibility of films and decrease the brittleness of polymer films.

There are many plasticizers in use i.e., Propylene Glycol, Glycerol, castor oil etc.

**Saliva stimulating agent:**<sup>17</sup>

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. These agents can be used alone or in combination form between 2 to 6%.

**Sweetening agent:**<sup>17</sup>

Sweeteners have become the important part of the food products as well as pharmaceutical products intended to be disintegrated or dissolved in the oral cavity. The sweet taste in formulation is more important in case of paediatric population. Both natural (Glucose, sucrose, maltose etc) and artificial sweetening agents (Aspartame, sodium or calcium saccharin salts etc) are used to improve the palatability of the formulations.

**Surfactant:**<sup>19</sup>

Surfactants are used as solubilising or wetting or dispersing agent so that the film is getting dissolved within seconds and release active agents immediately. The most commonly used surfactants are poloxamer 407, sodium lauryl sulphate, tweens etc.

**Flavouring agent:**<sup>20</sup>

The quantity of flavouring agent required to mask the taste depends on the flavour type and its strength. Commonly employed flavouring agents are fruity flavours (vanilla, chocolate, citrus etc.), flavour oils (peppermint oil, cinnamon oil). Flavours can also be chosen from oleo resins, and extract derived from various parts of the plants like fruits, flowers etc.

**Colouring agent:**<sup>15,16</sup>

FD & C approved colouring agent is incorporated in fast dissolving films. Generally colouring agent is not exceeding



in concentration level of 1%w/w in fast dissolving film. Eg: titanium dioxide.

#### Methods of preparation:<sup>18,21</sup>

The methods for the preparation of oro-dispersible films are

- Solvent casting
- Hot-melt extrusion
- Semisolid casting
- Rolling

Among this, the most commonly used industrial methods are solvent-casting method and Hot melt extrusion method.

#### Solvent casting method:

Water soluble polymers and plasticizers are dissolved in a suitable volatile solvent like Ethanol or distilled water to form a clear viscous solution. Solution is stirred for 2hrs in the magnetic stirrer and kept aside. Then API and other ingredients are dissolved in aqueous solvent and are combined with the bulk. The entrapped air is removed by vacuum or allowing it to stand for overnight. Finally, the solution is casted into a suitable petri dish and dried in an oven at 50°C for 24 hrs. Then the film is cut into desired size and shape.

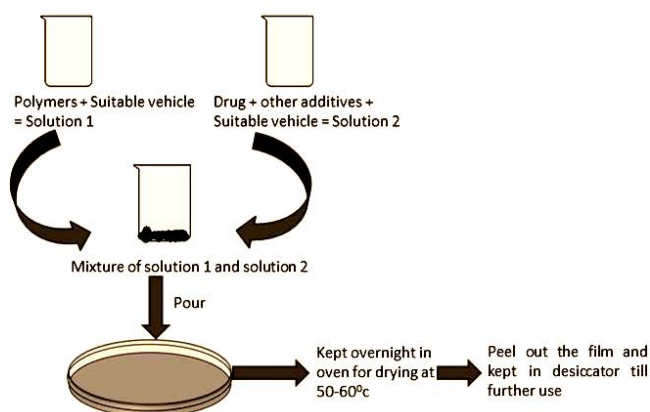


Figure 3: Solvent casting method

#### Hot melt extrusion method:

It is usually used to prepare granules, sustained release tablets, transdermal and transmucosal drug delivery systems. Initially the drug is mixed with carriers in solid form. Melt the mixture by the extruder having heaters. Finally, the melt is shaped into films by the dies.

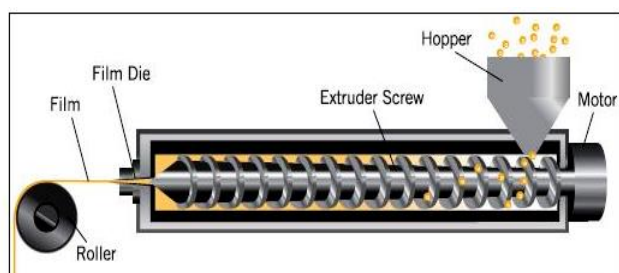


Figure 4: Hot melt extrusion

#### Semisolid casting method:

In this method, a solution of water-soluble film forming polymer is prepared first. It is poured into the solution of acid insoluble polymers in the ratio of 1:4 (e.g., cellulose acetate phthalate, cellulose acetate butyrate). A gel mass is obtained by the addition of relevant amount of plasticizer. Then it is casted into the films or ribbons by using heat-controlled drums. The thickness of the film should be about 0.015-0.05 inches.

#### Rolling method:

Initially a pre-mix is prepared by film forming polymers, polar solvent and other additives except the drug. Then required amount of drug is added to the pre-mix and blended to obtain uniform matrix. The mixture obtained is fed into the roller. Film is formed and carried away by support roller. Wet film is then dried using controlled bottom drying. Film is cut into desired size and shape.

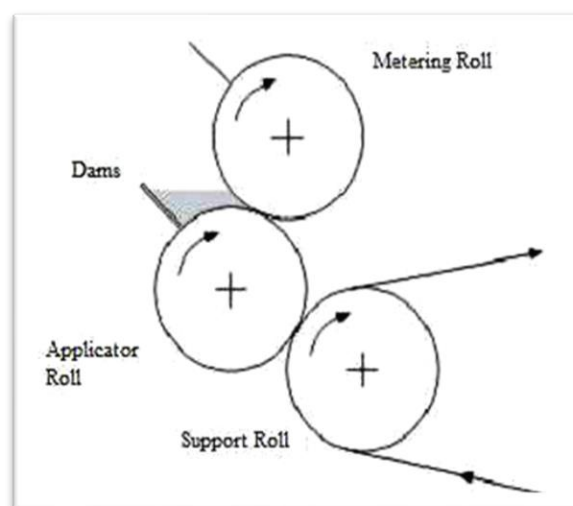


Figure 5: Rolling method

#### EVALUATION PARAMETERS

##### Visual appearance:<sup>9,22</sup>

Physical appearance of the film is checked by visual inspection and surface texture is evaluated by touch or feel of the film.

##### Weight variation:<sup>23</sup>

The assessment of weight variation is performed by weighing individually five films of every formulation on a digital balance.

The average weight is calculated and the standard deviation from the average weight is measured.

##### pH measurement:<sup>24,25,26</sup>

The pH value can be determined by dissolving one oral film in 10ml distilled water and measuring the pH of the obtained solution. The pH is noted after bringing the electrode of the pH meter in contact with the surface of the formulation and allowing equilibration for 1 min. The average of three determinations for each formulation is done.

**Thickness:**<sup>27,28</sup>

The thickness of film can be measured by micro meter screw gauge at different strategic locations (at least 5 locations). This is essential to determine uniformity in the thickness of the film as this is directly related to the accuracy of dose in the film.

**Folding endurance:**<sup>29,30</sup>

Folding endurance of the films determine the flexibility of the films. It is determined by repeatedly folding a small strip at the same place until it breaks. The number of times strips could be folded at the same place, without breaking gives the value of folding endurance.

**Tensile strength:**<sup>27,31</sup>

Tensile strength is the maximum stress applied to a point at which the strip specimen breaks. It is calculated by the applied load at rupture divided by the cross-sectional area of the film as given below:

$$\text{Tensile strength} = \frac{\text{Load at breakage}}{\text{Strip thickness} \times \text{Strip width}}$$

**Swelling index:**<sup>32,33</sup>

Each film sample is weighed and placed in a pre-weighed stainless steel wire mesh. Then the mesh containing film sample is submerged into 15ml medium (simulated saliva solution) in a plastic container. Increase in the weight of the film is determined at pre-set time interval until a constant weight was observed. The degree of swelling is calculated using the formula;

$$\text{Degree of swelling} = \frac{W_t - W_0}{W_0}$$

Where,  $W_t$  is weight of film at time  $t$ ,  
and  $W_0$  is weight of film at time zero.

**In vitro disintegration time:**<sup>34,35</sup>

Disintegration test is performed by taking 5 ml of pH 6.8 phosphate buffer in a petri plate and the film is placed on its surface. The time taken for the disintegration of film is noted as the disintegration time. This experiment is done on three films of the same batch and the average of the three values is taken.

**Drug content uniformity:**<sup>31</sup>

The film having the specific dimension is dissolved phosphate buffer pH 6.8. It is sonicated for 15 min, and then filtered using Wattmann filter paper. The absorbance is measured using an UV spectrophotometer and then concentration of drug is determined.

**In vitro dissolution studies:**<sup>18,35,36</sup>

The release rate of drug is determined using USP Dissolution type II testing apparatus (paddle type). The film of appropriate size is cut and placed in dissolution media. The dissolution medium consists of 300 ml freshly prepared phosphate buffer (pH 6.8), maintained at  $37 \pm 0.5$  °C and stirred at 50 rpm. Samples of 5 ml is Withdrawn at various time intervals of 2, 4, 6, 8, 10, 12, 14, 16, 18, 20 min & replaced with fresh medium. The samples are subjected to UV analysis and percentage of drug release is calculated.

**Stability studies:**<sup>37,38</sup>

The stability study of the formulated Oro-dispersible films is carried out under different environmental conditions. The formulations packed in aluminium foil is subjected to accelerated stability testing for 3 months as per ICH forms at a temperature  $40 \pm 2$  °C and relative humidity  $75 \pm 5\%$ . Samples are taken at regular time intervals of 1month for over a period of 3months and analysed for the change in physical appearance and for other parameters by procedure stated earlier.

**CONCLUSION**

The oro-dispersible films are elegant, stable and effective forms for delivery of different drugs for example antiemetics, antiallergics, antiasthmatic etc for immediate onset of action of the drug. The Orodispersible films have better patient compliance in the case of geriatrics and pediatrics patients. Oral films can replace over-the-counter (OTC) drugs, generic and name brand from market due to lower cost and consumer's preference. Due to immediate release and ease of manufacturing this approach will take attention and increased business of Pharmaceutical industry in future.

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