



**INTERNATIONAL JOURNAL OF  
PHARMACEUTICAL SCIENCES**  
[ISSN: 0975-4725; CODEN(USA): IJPS00]  
Journal Homepage: <https://www.ijpsjournal.com>



## Review Article

# Mouth Dissolving Films for Oral Drug Delivery: A Review

**Sayali Bedare\*, Dr. Sachin Hangargekar, Amruta Magar, Vikas Bhosale, Gangaram Kartale**

*Department of pharmaceuticals Shivlingeshwar College of Pharmacy, Almala. Tq. Ausa, Dist. Latur – 413520, Maharashtra (MH), India.*

### ARTICLE INFO

Published: 05 April, 2025

**Keywords:**

Mouth Dissolving Film,  
Composition, Evaluation,  
Casting Approaches.

**DOI:**

10.5281/zenodo.15151951

### ABSTRACT

Recent trends are shifting toward the design and development of novel drug delivery systems for currently available medications since the process of discovering and creating new chemical agents may be difficult, costly, and time-consuming. Mouth Dissolving Films are made using a variety of techniques and are an excellent substitute for medications that have an adverse effect on the stomach environment and first-pass metabolism. This review briefly outlines the advantages and drawbacks, offers details on the formulation processes used to create MDFs, and provides assessment criteria for the same. These days, MDFs are employed as a medication delivery method for a variety of therapies. Because of its advantages such as self-administration, pain relief, high patient compliance, and creative flexibility the oral route of administration is the recommended method. To achieve the intended pharmacologic effect, medicine can be delivered in a variety of ways.

## INTRODUCTION

In addition to the active ingredients, Mouth Dissolving Films (MDFs) contain a variety of excipients, including polymers, and additional additives, including plasticizers, flavors, colors, sweeteners, surfactants, thickening agents, and disintegrants [1]. MDFs are a new technology designed for oral administration of active ingredients. To provide a therapeutic or

pharmacological impact, a medication is frequently delivered systemically using mouth dissolving film (MDF). Because MDF formulations avoid first-pass metabolism, they have better systemic bioavailability. [2] There is no need for water because MDFs dissolve rapidly with secretion when placed on the tongue. As a result, they have a full impact on the drug's bioavailability, which speeds up the onset of the desired effect. [1] The oral mucous membrane is

**\*Corresponding Author:** Sayali Bedare

**Address:** Department of pharmaceuticals Shivlingeshwar College of Pharmacy, Almala. Tq. Ausa, Dist. Latur – 413520, Maharashtra (MH), India.

**Email** ✉: [sayalibedare2018@gmail.com](mailto:sayalibedare2018@gmail.com)

**Relevant conflicts of interest/financial disclosures:** The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



more porous and has a large blood supply. One possible location for a rapid, continuous, and regulated medication delivery system is the oral mucous membrane [3] Research models now in use indicate that insoluble particles, such as silica and MCC (microcrystalline cellulose), can also be used as disintegration enhancers in place of disintegrants. [4]. help overcome issues with ingesting the solid dose form (capsule, pill). The technique of oral film was created. [1] The introduction of MDF into the market was closely associated with patient education regarding appropriate administration, such as "do not chew/do not swallow. [5] Generally speaking, an ODF is the size of a postage stamp. The quickly disintegrating film was first offered on the market as mouth fresheners and personal hygiene items including soap and dental care strips. Nonetheless, various dosage forms are being offered for the therapeutic advantages of prescription medications in the pharmaceutical marketplaces of the United States and Europe [6]. Because of its many benefits, such as ease of consumption, pain avoidance, adaptability, and most importantly patient compliance, the oral route of administration is still the most popular. Tablets and capsules are the most often used dosage forms. A great deal of research has been conducted in this field over the past 20 years as a result of the increased need for patient compliance. Approximately 350 medication delivery systems have been created with patient compliance in mind. Elderly individuals may have trouble chewing and swallowing the pills, which might lead to noncompliance and inefficient treatment. Mouth dissolving pills are an excellent solution to these issues. Without the use of water, they dissolve and disintegrate more quickly in saliva. Good patient compliance is thus explained. [7]. In 1996, the market for this mouth-dissolving technology was worth around 16.50 billion US dollars, but it is currently predicted to increase to

almost 80 billion US dollars annually. A more recent dose form, known as mouth-dissolving pills or films, has been developed to address these issues in elderly individuals. One of the innovative methods is the quick breakdown or disintegration of the dose form in the mouth without the need of water. A drug's dosage form is a formulation that may be given to a patient via a variety of methods in order to diagnose or treat a condition. Appropriate dosage forms are required to shield the medication from harmful effects of moisture or oxygen in the air, to shield the medication from stomach acid when taken orally, to cover up unpleasant odors and bitter tastes, to prolong the duration of the medication's action through a controlled release mechanism, etc. The medication is used with the following agents in the appropriate dose form. [ 8]. Due to their convenience and flexibility, fast-dissolving films are the most sophisticated oral dose form. It dissolves in the oral cavity in a matter of minutes, increasing the effectiveness of the active medicinal substances. When it comes to bedridden, comatose, elderly, and pediatric patients, this kind of technology is really helpful. This dosage form offers rapid absorption and high permeability of about 4-1000 times in the oral mucosa, without the requirement for water administration.[9]

### **Special features of fast dissolving oral film**

- Thin elegant film
- Available in various size and shapes
- Unobstructive
- Excellent mucoadhesion
- Fast disintegration and rapid release

### **Ideal characteristics of a suitable Drug candidate**

- The drug should have pleasant taste
- The drug to be incorporated should have low dose up to 40 mg



- The drugs with smaller and moderate molecular weight are preferable
  - The drug should have good stability and solubility in water as well as saliva
  - It should be partially ionized at the pH of oral cavity
  - It should have the ability to permeate oral mucosal tissue.
- Packaging of films requires special equipment and it is difficult to pack.
  - Need special packing has they must be protected from water.
  - A high dose cannot be incorporated into the oral film.
  - Eating and drinking may become restricted.
  - Drugs unstable in oral pH can't be administrated.

#### **ADVANTAGES: [2,5,10]**

- No need for water to swallow.
- Available in various sizes and shapes.
- Hydrate and dissolve in the oral cavity within a fraction of seconds.
- Fast disintegration or dissolution.
- Taste masking
- Reduced gastrointestinal irritation
- No special training is required for administration.
- Improved oral absorption and bioavailability
- Enhanced stability.
- Improved patient compliance
- Ease of handling and transportation
- No risk of choking.
- Rapid onset of action.
- Minimized first-pass effect.

#### **DISADVANTAGES: [ 2,5,10]**

There are numerous advantages of the MDF but a few disadvantages lead to a main challenging formulation.

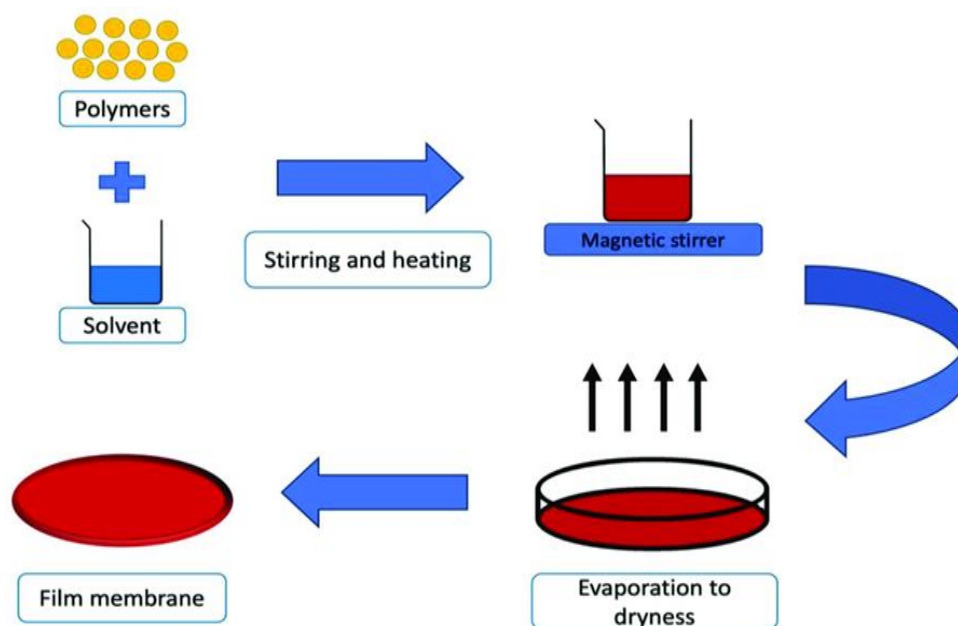
- It is hygroscopic in nature so it must be kept in dry places.

#### **METHOD OF PREPARATION:**

##### **Mouth dissolving films can be prepared by**

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

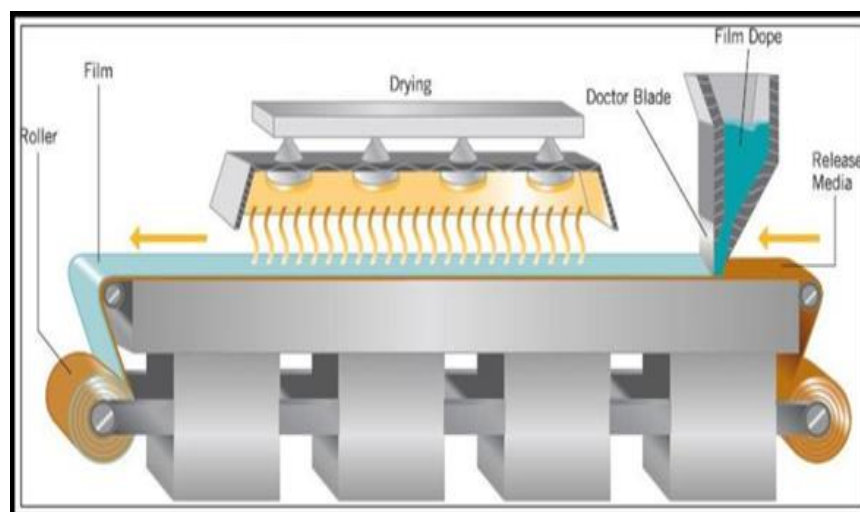
**Solvent Casting Method:** One of the earliest and most straightforward processes for making films is solvent casting, which was first created for the photography industry more than a century ago. In the 1950s, thermoplastic polymer film extrusion took over as the primary production method, but solvent casting is regaining popularity as a means of creating high-quality films. Using this procedure, a viscous solution is first created by mixing water-soluble components. A lesser volume of solution is used to dissolve the API and the other components. A high shear process is used to mix the two solutions. The trapped air is removed using a vacuum. After the solution has formed, it is poured into a glass mold and let to dry in an oven set at 45 to 50 degrees Celsius. Next, cut into the appropriate-sized and shaped pieces. [1]



**Solvent Casting Method**

**2. Semisolid casting method:** This method is appropriate if film compositions include certain acid-insoluble polymers. This technique started with a water-soluble polymeric solution. The solution containing the acid-insoluble polymer (such as cellulose acetate butyrate or phthalate)

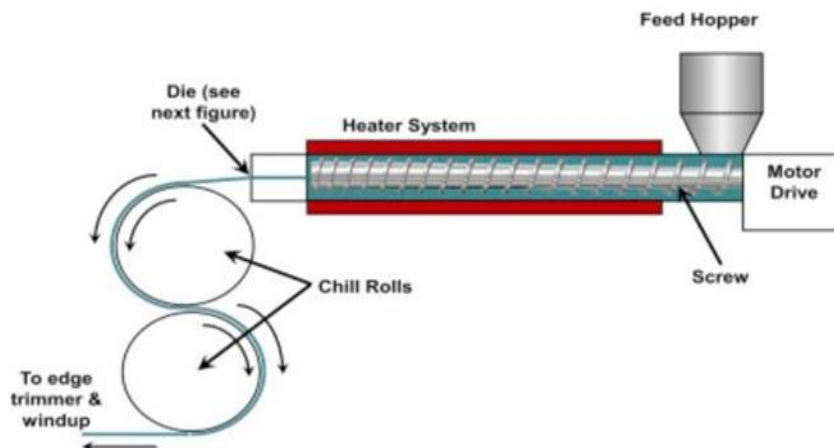
was then mixed with this solution. To generate a gel mask, the appropriate amount of plasticizer is applied. Exploitation heat management drums are then used to cast it into the films or ribbons. The ratio of the film-forming polymer to the acid-insoluble polymer remains at 1:4. [5,6,11]



**Semisolid Casting Method**

**3. Hot-melt extrusion:** Granular material is created by mixing the carpeting with a solid carrier. After drying, these granules are added to the extruder. For the granules to stay within the

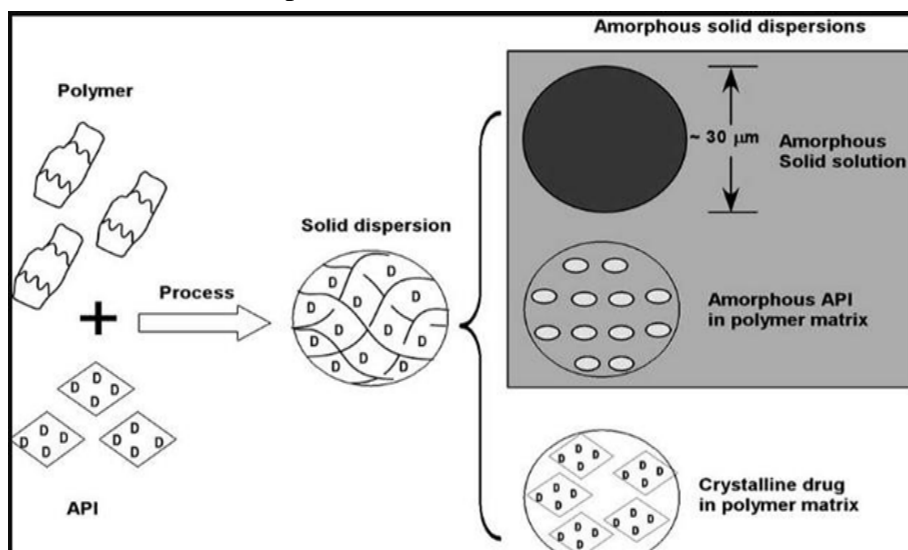
extruder for three to four minutes, the screw speed should be roughly 15 rpm. 100°C is the ideal processing temperature. To create a film, the extrudate is subsequently squeezed into a cylindrical calendar. [11,12,13]



### Hot-Melt Extrusion

**4. Solid Dispersion Extrusion:** The weakly water-soluble drug's solubility can also be increased using this technique. The dispersion of one or more active substances in a solid-state, highly inert carrier while amorphous hydrophilic polymers are present is referred to as solid dispersion. To obtain the solid dispersion, the

medication is dissolved in a suitable liquid solvent, and the resulting combination is then added to the previously dissolved polymeric solution that is accessible below 70°C without the liquid solvent being removed. Lastly, dyes are used to shape the solid dispersions into films. [ 6]

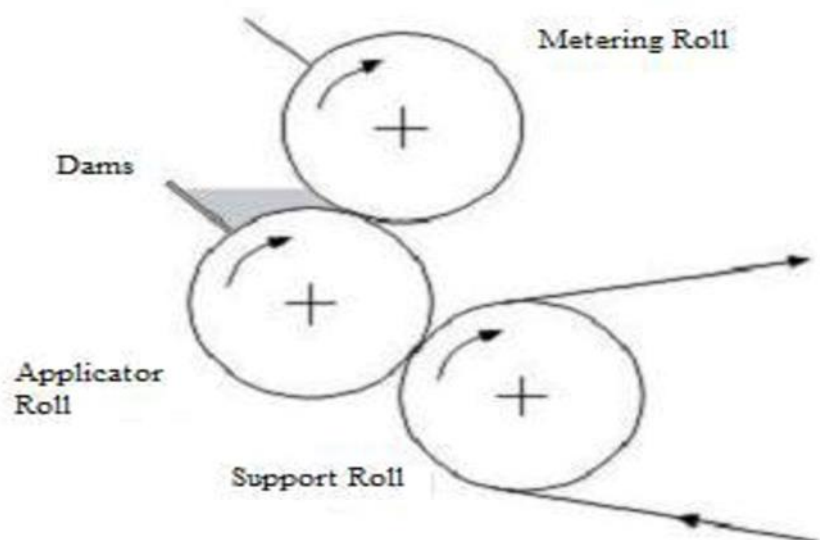


### Solid Dispersion Technique

One of the examples of film formation by means of solid dispersion method is as follows: Solid dispersion of domperidone using beta-cyclodextrin, PEG400, and HPMC E15 was successfully prepared and films were cast using solid dispersion extrusion method. [5,14,15]

**5. Rolling method:** Using this procedure, an API-containing suspension or solution is made. The film-forming polymer solution is then thoroughly combined with this solution. After the solution was ready, it was put on a carrier and left there. Consideration should be given to specific

rheological characteristics of the solution. After drying on the rollers, the films are cut into the appropriate sizes and shapes.[ 5,6,16]



**Rolling Method**

### **Assessment Criteria for Oral Fast-Dissolving Film**

1. Appearance
2. Thickness of film
3. Weight of films / weight variation
4. Folding endurance
5. pH value
6. Dryness / Tack test
7. Content uniformity
8. Disintegration time
9. In-vitro dissolution studies

### **CONCLUSION**

The present review shows that mouth disintegrating films are one of the novel approaches in the field of pharmaceutical sciences. They have improved acceptance and patient compliance with no risk of choking associated with better safety and efficacy in comparison with conventional dosage forms. The main idea behind formulation of MDFs was to cope with the difficulty in swallowing

conventional oral dosage forms among pediatric, geriatric and psychiatric patients, MDFs are widely available for hypertension, acidity, allergy, pain, etc. reflecting their importance. Major advantages of such dosage form are their administration without the use of water fulfilling the need of target population seeking convenience in drug administration along with bypassing the hepatic metabolism, consequently, leading to improved therapeutic response.

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**HOW TO CITE:** Sayali Bedare\*, Dr. Sachin Hangargekar, Amruta Magar, Vikas Bhosale, Gangaram Kartale, Mouth Dissolving Films for Oral Drug Delivery: A Review, *Int. J. of Pharm. Sci.*, 2025, Vol 3, Issue 4, 597-603 <https://doi.org/10.5281/zenodo.15151951>