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**Review Article**

# Review On Mouth Dissolving Film: The Advancement In Oral Drug Delivery

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## ABSTRACT

Mouth dissolving films are the kind of drug delivery system which is gaining interest from a wide range of pharmaceutical industries. This is due to there convenience and it's easy to use than other dosage forms like buccal tablets and sublingual tablets. By studying transdermal patch technology, mouth dissolving film was formulated. Thin, solid dosage forms called mouth dissolving films dissolves in the mouth within seconds to a minute without chewing or water intake. Because of the oral buccal mucosa's high vascularization, medications can be absorbed immediately and reach the bloodstream without first going through the liver for metabolism. By using this advantage, products containing first-pass effect molecules with increased oral bioavailability can be created. Pediatric, geriatric, and immobile patients can easily administer medication with the use of these films. The use of thin films for sublingual and buccal drug delivery may help medications work more quickly,need less dosage, and have better safety and effectiveness profiles. Good taste, great stability, and ease of handling are qualities that any perfect film should possess. An explanation of the many formulation techniques and their assessments is given in the current review applications of mouth-dispersing films Or mouth dissolving films and film compositions.

## INTRODUCTION

Mouth dissolving films present an appealing option for systemic medication delivery. A well-supplied arterial and lymphatic drainage promotes systemic bioavailability by bypassing the first pass effect and increasing permeability. Furthermore, because of its enormous surface area for absorption, ease of administration, swallowing, and pain avoidance, the oral mucosa is a highly elegant and selective site for systemic drug distribution [1-2].Fast dissolving tablets were developed in the late 1970s as an alternative to traditional dosage forms for pediatric and geriatric patients who have trouble swallowing traditional

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oral solid dosage forms. These tablets are made with hydrophilic and superdisintigrant ingredients, which have a higher bioavailability, a quicker action, and the highest patient compliance. Many FDTs are made by the pricey lyophillisation process, which can make them fragile and friable and occasionally difficult to handle, carry, and store.fear of choking on a quickly dissolving pill as well [3]. To overcome the disadvantages of quick dissolving tablets, a rapid dissolving film might be applied. In terms of shape, size, and thickness, fast dissolving films resemble ultra-thin postage stamp strips. Polymers, active pharmaceutical ingredients (API), plasticizers, saliva stimulating agents, sweeteners, flavors, preservatives, and colors are all used in the formulation of fast dissolving films. Simply apply the fast-dissolving film to the patient's tongue or any other oral mucosal tissue. When saliva contacts the film, it quickly hydrates and sticks to the application site.It then swiftly disintegrates and dissolves to release the drug for oromucosal absorption, or with formula adjustments, it will keep the quick-dissolving properties and allow for gastrointestinal absorption when ingested [4].Based on the technique of transdermal patches for oral medication delivery, a fast-dissolving oral film was created[5]. The delivery device consists of a postage stamp-sized thin film that is applied to the patient's tongue or mucosal tissue and absorbs saliva to quickly hydrate the area; In order to release the medication for oral mucosal absorption, the film then quickly melts and disintegrates. Large surface area of the film, which wets quickly when exposed to the moist oral environment, is principally responsible for this fast dissolving action[6].

## WHAT IS MOUTH DISSOLVING FILM?

This delivery mechanism is made up of a thin The film dissolves quickly after being placed on the tongue, avoiding first-pass metabolism and possibly increasing the drug's bioavailability [7]. Because saliva wets a wider surface area more quickly, it dissolves and disintegrates in the mouth cavity within seconds [8]. Compared to fast-dissolving tablets, oral dissolving film is more flexible, making it less fragile and requiring no special packaging for protection during transportation and storage. Better acceptance and satisfaction among dysphasic patients when traveling without water has resulted from not needing water. Unlike quickly dissolving tablets, there is no risk of choking. The Film dosage form's wide surface area facilitates rapid salivary wetting, which in turn permits the substance to dissolve and absorb quickly, entering the systemic circulation without first passing through hepatic metabolism and increasing bioavailability[9]. As per the convenience of the individual, the dose form can be taken at any time and anywhere. By avoiding the first pass impact, the dosage can be lowered, perhaps resulting in a decrease in the molecule's negative effects [10]. Individuals who are unable to swallow significant amounts of water, such as those with dysphagia, repeated vomiting, hypertension, heart attacks, asthma, motion sickness, paralysis, and mental illnesses, prefer this dosage form[11].

## ADVANTAGES AND DISADVANTAGES:

### ADVANTAGES[12-15]:

- There's no requirement for water to administer.
- Ideal for individuals with dysphasia, the elderly, and children who struggle with swallowing.
- Because of the films' greater surface area, they dissolve and disintegrate quickly in the oral cavity.
- Since it avoids the hepatic first pass effect, it has a rapid beginning of action and enhanced bioavailability.
- Lowering the dosage improves the medication's safety and efficacy while minimizing adverse effects.

- Because of their flexibility and portability, they are simple to handle, transport, and store.
- Simplicity of delivery to patients with limited liquid intake plans, nausea, mental illness, disability, and uncooperative behavior.
- Helpful in situations when an extremely quick start of action is needed, such as motion sickness, severe discomfort, an unexpected allergic reaction, an asthmatic attack, and coughing.
- Stability for an extended period of time due to the medication's solid dose form until it is ingested.
- Dosage accuracy in comparison to liquid formulations.
- Provides a pleasant mouthfeel and leaves minimal or no residue after ingestion.

**DISADVANTAGES:**

- It is not possible to incorporate high doses.
- Using bitter medications is not viable.
- Dose homogeneity is a technical difficulty.
- Special packaging is required to ensure product stability and safety.
- Drugs that irritate the oral mucosa cannot be administered by this route.

**THE IDEAL CHARACTERISTICS.[12,15,16]**

- The medicine should have a pleasing flavor. The medicine should be modest in molecular size and weight.
- The drug should be soluble and stable in both water and saliva.
- Ensure partial unionization at the pH of the oral cavity.
- The medicine should be less sensitive to environmental factors.
- The product should have the ability to penetrate oral mucosal tissue.
- The therapeutic dose of the medicine should not exceed 40mg.

Classification of Fast Dissolving Technology[23]

Fast-dissolve technology can be categorized into three main classes for convenience of description:

- Lyophilized system
- Compressed tablet-based systems
- Thin film strip

**1. Lyophilized systems:**

The technique behind these systems involves generating tablet-shaped units from a medication suspension or solution with various structural excipients using a mould or blister pack. The units or pills are then frozen in the pack or mould before being lyophilized. The resultant units have a high porosity, allowing water or saliva to penetrate and disintegrate quickly.

**2. Compressed tablet-based systems:**

This method is manufactured utilizing normal tablet technology through direct compression of excipients. The hardness and friability of tablet technology vary depending on how they are manufactured. Fast dissolve tablets disintegrate faster than ordinary tablets because they are formulated with water-soluble excipients, superdisintegrants, or effervescent components that allow water to penetrate the tablet's core quickly.

**3. Thin film strips:**

Oral films, also known as oral wafers, originated in the confection and oral care markets as breath strips and have now evolved into an innovative and highly accepted manner of delivering vitamins and personal care goods to customers. FDFs are now a well-established and widely acknowledged technology for the systemic administration of APIs in over-the-counter (OTC) treatments, and they are in the early to mid stages of research in prescription drugs. This has been ascribed to the popularity of consumer-owned breath freshener goods such as Listerine Pocket Paks in the US market. A 50–200 mm film is created by these systems using a range of hydrophilic polymers. A broad sheet of the film is produced, which is subsequently divided into discrete dosage units for

packaging in a variety of formats that are approved by pharmaceutical companies.

**Classification of Oral Films**

Oral film further classified into three types:

- Lash Release Wafers
- Mucoadhesive Melt Away Wafers
- Mucoadhesive Sustained Release Wafers

**1. Flash Release Wafer:**

The film's area and thickness are around 2-8 sq.cm and 20-70µm, respectively. It is a single-layered structural system that requires the use of soluble, highly hydrophilic polymers for preparation. It is placed on the upper palate of the tongue and has a maximum disintegration duration of sixty seconds.

**2. Mucoadhesive melt away wafers:**

It is a single or multilayer system that requires soluble, hydrophilic polymers as excipients. The drug phase can be a solid solution or suspended drug particles. The application location is the gingival or buccal region. It disintegrates in a matter of minutes, forming a gel. The film has a thickness of 50-500µm and an area of 2-7 sq. Cm.

**3. Mucoadhesive sustained release wafers:**

It is applied to the gingival (an additional oral cavity region) and uses a multilayer system. The drug phase may be in a solid solution or in a suspension, and the excipients may be low- or non-soluble polymers. Because of its 2-4 sq. Cm area and thickness of 50-250µm, it dissolves in 8–10 hours.

## MATERIALS AND METHODS

## MATERIALS:

**Composition of film:**

A fast dissolving film is a thin layer that has an active component and measures 2 to 8 cm square. The quick breakdown, in Water is converted into saliva or water through a unique matrix. Polymers that dissolve. Medication may be added up to 30 mg single dose. It has been found that formulation concerns have a significant impact on the mechanical properties of the films. There is also a thorough discussion of the excipients utilized in the composition of quick dissolving films. According to regulatory perspectives, every excipient utilized in the formulation has to be approved for use in oral pharmaceutical dosage forms and generally recognized as safe (i.e., GRASlisted)[17]. All the ingredients with respect to it's percentage amount is listed in table no:1.

**Table no:1. Composition of film including various ingredients [18]**

| Sr. No. | Category | Percentage Amount |
|---|---|---|
| 1. | Drug (API) | 1-30% |
| 2. | Polymer | 40-50% |
| 3. | Plasticizer | 0-20% |
| 4. | Surfactant (Solubility Enhancer) | q.s |
| 5. | Saliva stimulating agent | 2-6% |
| 6. | Sweetening agent | 3-6% |
| 7. | Flavoring agent | 0-10% |
| 8. | Coloring agent | q.s |
| 9. | Stabilizing agent or Thickening agent | 0-5% |

**COMPONENTS:**

Active Pharmaceutical Ingredient[19]:

The active medicinal ingredient makes up 1-30% w/w of the film composition. Because high doses of drugs are difficult to combine into fast-dissolving films, it is always best to employ low dose active pharmaceutical ingredients. Several medications, such as antihistamines, antidiarrheal, antidepressants, vasodilators, anti-asthmatic, antiemetic, etc., can be utilized as fast-dissolving oral films. For taste masking, ODFs can also contain dimenhydrinate. Table 2 include some common medications that were formulated as film.

**Table 2: List of few drug that can be incorporated in fast dissolving film[19].**

| Sr. No. | Drug | Dose | Therapeutic action |
|---|---|---|---|
| 1. | Ondansetron | 2.5mg | Anti emetic |
| 2. | Sumatriptan succinate | 35-70mg | Anti migraine |
| 3. | Famotidine | 10mg | Antacid |
| 4. | Nicotine | 2mg | Smoking cessation |
| 5. | Omeprazole | 10-20mg | Proton pump inhibitor |
| 6. | Diphenhydramine hydrochloride | 25mg | Anti allergic |
| 7. | Ketoprofen | 12.5mg | Analgesic |

**Hydrophilic polymers[20]:**

The films' quick disintegration, pleasant mouthfeel, and mechanical qualities are all made possible by the water-soluble polymers.By raising the molecular weight of the polymer film bases, the rate of polymer disintegration is slowed down. HPMC E-3 and K-3, Methyl cellulose A-3, A-6, and A-15, Pullulan, carboxmethylcellulosecekol 30, Polyvinylpyrollidone PVP K-90, Pectin, Gelatin, Sodium Alginate, Hydroxypropylcellulose, Polyvinyl alcohol, Maltodextrins, and EUDRAGITRD10 are a few examples of water-soluble polymers used as film formers.One new polymer that forms films is polymerized rosin.

**Plasticizers:**

It has been reported that formulation factors (plasticizer, etc.) have a significant impact on the mechanical properties of films. The addition of plasticizers has also enhanced the mechanical qualities of the films, such as tensile strength and elongation. These attributes could be impacted by variations in their concentration. Common plasticizers include polyethylene glycols, di-butylphthallate, and glycerol.

**Surfactants[20]:**

In order to dissolve films quickly and release active agents right away, surfactants are utilized as solubilizing, wetting, or dispersing agents. Benzalkonium chloride, bezthonium chloride, sodium lauryl sulfate, tweens, and others are a few of the often utilized. As a solubilizing, wetting, and dispersion agent, polaxamer 407 is one of the most significant surfactants.

**Saliva stimulating agent:**

The goal of using saliva stimulating chemicals is to boost saliva production in order to facilitate the quick disintegration of fast-dissolving film formulations. Generally speaking, salivary stimulants can be made from acids that are used in meal preparation. Ascorbic acid, tartaric acid, lactic acid, malic acid, and citric acid, for example. Between 2 and 6% w/w of the film's weight, these agents are used alone or in combination.[20]

**Sweetening agents:**

Sweeteners are now a crucial component of pharmaceutical preparations meant to dissolve or disintegrate in the mouth. Sucrose, dextrose, fructose, glucose, liquid glucose, and isomaltose are the traditional sources of sweeteners. The use of artificial sweeteners in pharmacological formulations has grown in popularity. The first generation of artificial sweeteners includes aspartame, cyclamate, and saccharin. The second generation includes acesulfame K, sucralose, alitame, and neotame.

**Flavoring agents:**

Flavoring agents can be chosen from a variety of plant components, such as leaves, fruits, and flowers, as well as synthetic flavor oils and oleo resins. You can use flavors separately or in combination. Any taste Addable like water or aromatic oils menthol soluble extracts and strong mints like wintergreen, peppermint, sweet mint, spearmint, cinnamon, clove, and sour fruit

fragrances like lemon, orange, or chocolate; sweet confectionary flavors like vanillin; or fruit essences like pineapple, apple, raspberry, cherry, and raspberry. The type and strength of the flavor determine how much flavor is required to cover up the taste.

**Coloring agents:**

When making Orally Fast Dissolving Films, approved coloring agents (FD & C) are employed, with concentration levels not to exceed 1 percent w/w. [20], e.g. Dioxide of Titanium

## METHODS:

The oral dissolving films can be made using one or more of the following processes.[20]

A. Solvent casting
B. Semisolid casting
C. Hot melt extrusion
D. Solid dispersion extrusion
E. Rolling methods

**A. Solvent casting method:**

In the solvent casting process, the medicine is added after the excipients have been dissolved in water and the mixture has been agitated to create a homogenous solution. Next, water-soluble polymers are added. Lastly, the solution is cast into the petri-plate and then subject it for drying.

**B. Semisolid Casting:**

This approach creates a homogenous viscous solution by mixing a solution of an acid-insoluble polymer (such as cellulose acetate butyrate) with a solution of a water-soluble polymer that forms films.It is coated on untreated casting film following sonication. After drying, the film should have a thickness of between 0.015 and 0.05 inches. The acid insoluble polymer to film-forming polymer ratio need to be 1:4.

**C. Hot Melt Extrusion:[20]:**

Using the hot melt extrusion process, the medication is first combined with solid carriers. The mixture is then melted by the extruder, which has heaters, and the melted material is then formed into films by the dies. Hot melt extrusion has some advantages, such as:

a. Fewer operating units
b. Improved content homogeneity
c. Anhydrous processing

D. **Solid dispersion extrusion[21]:**

The dispersion of one or more active substances in an inert carrier in a solid state while amorphous hydrophilic polymers are present is referred to as a solid dispersion. An appropriate liquid solvent is used to dissolve the drug. After that, the solution is added to the polyethylene glycol melt, which can be reached below 70°C. Ultimately, dies are used to form the solid dispersions into the films.

**E. Rolling Method:**

A drug-containing solution or suspension is rolled on a carrier in the rolling technique. Water and a combination of water and alcohol make up the majority of the solvent. After being cured on rollers, the film is cut into the appropriate sizes and shapes. Using a high shear processor, other ingredients, including the active agent, are dissolved in a tiny amount of aqueous solvent. A homogenous, viscous solution was created by dissolving water-soluble hydrocolloids in water[20].

## EVALUATION PARAMETERS[22]:

**1. Physical Parameters:**

**a. Appearance:**

It is possible to verify if all of the created films appear clear or opaque. Although surface qualities are usually determined visually, tools like as microscopes can also be employed.

**b. Thickness:**

Micrometer screw gauges can be used at various key spots to measure the thickness of the produced film. Five places on the film, namely the center and each of the four corners, should be measured in order to establish the mean thickness. Ensuring consistency in the thickness of the film is crucial since it has a direct impact on the accuracy of the dose in the strip.

**c. Weight variation:**

It is necessary to weigh each film individually and compute the average weights. Subtracting the average weight of the films from each individual film is the next step. A significant variance in weight suggests an ineffective method of administration and maybe non-uniform medication content.

**d. Contact angle:**

At room temperature, the Goniometer (AB Lorentz and wettre, Germny) can be used to measure the contact angle. This can be accomplished by taking a dry film and put a droplet of distilled water to its surface. A digital camera is used to capture pictures of the water droplets within ten seconds after their deposition. Both sides of the descent can have the contact angle measured, and an average is taken.

**d. Transparency:**

The films' transparency can be assessed with a basic UV spectrophotometer. After cutting the film into a rectangle, insert it into the spectrophotometer cell. Find the film's transparency at 600 nm.One can compute the film's transparency using the formula below:

**Transparency= (log T600)/b = —єC**

Where,

T600= transmittance at 600nm

b= film thickness (mm)

C= concentration.

**e. Moisture content:**

The degree of moisture has an impact on the friability and brittleness of films. In essence, the product's ingredients control the amount of moisture in a given film. Generally speaking, the Karl Fisher titration method, moisture content testing equipment, or weighing method can be used to determine the quantity of moisture present in the film. A pre-weighed film of a specific size is typically heated to between 100 and 120 °C until it achieves a steady weight; the weight disparity shows the amount or degree of moisture in the film. To calculate moisture content, use the following formula:

**% Moisture content= [(Initial weight – Final weight) ×100/Initial weight].**

The moisture content in an ideal film should be <5%.

**2. Chemical Parameters:**

**a. Surface pH test:**

The surface pH of the film can be tested by laying it on 1.5% w/v agar gel and then applying pH paper (pH range 1-11) to the film. The color of pH paper is monitored and reported.

**b. Disintegration time:**

The disintegration time of a film gives information on its dissolution and disintegration properties. A stainless steel wire mesh containing 25 ml of simulated salivary fluid with a pH of 6.8 is filled with film of the requisite size (2 x 2 cm2). The duration required for a film to shatter and disintegrate is known as the in-vitro disintegration period.

**c. In vitro dissolution test:**

Any of the pharmacopoeia's standard basket or paddle gear can be used to conduct a dissolution test. The maximal dose of the API and the sink conditions will largely determine which dissolving medium is used. Because the strip has a propensity to float onto the dissolving medium when the paddle equipment is used, the dissolution test can frequently be challenging.

**d. Thermal analysis:**

A differential scanning calorimeter can be used to record thermograms of the samples, revealing information on the drug molecules' state within the film. Any change in the endothermic or exothermic peak, as well as the extension of the peak area, suggests that the drug molecule trapped within the film is undergoing a phase transition, recrystallization, or molecular interaction. To test, heat the sample in an aluminum pan at a predefined rate (~10°C/min) from room temperature to a high temperature (~500°C).

**e. Crystallinity:**

Using an X-ray diffractometer for X-ray crystallographic examinations, it is feasible to easily determine if the drug molecule is crystalline or amorphous within the film. The films can be placed in the sample holder, and XRD transmission diffractograms can be generated using a specific X-ray source with a start-to-finish diffraction angle, scan range, and scan speed.

**f. Assay / Content uniformity:**

Any standard pharmacopoeia describing the individual API's assay method will be utilized to determine this. Estimating the API content in each strip enables us to evaluate content consistency. The content uniformity range is 85–115%.

**3. Mechanical Parameters:**

**a. Dryness / Tack test:**

Tenacity is the degree to which the film adheres to any piece of paper put against the strip; on the other hand, dryness is the property used to determine the solvent or water content of the film. The film drying process consists of eight stages that is, set-to-touch, dust-free, tack-free, dry-to-touch, dry-hard, dry-through, dry-to-recoat, and dry paper free. These properties can now be measured using a number of technologies. To accomplish this, push your thumb against the film at lab scale.

**b. Tensile strength:**

Tensile strength is defined as the maximum stress applied to the point at which the film specimen breaks. The applied load at rupture can be computed using the following equation, which uses the mean of three measurements and the cross-sectional area of the fragmented film:

**Tensile strength = [Breaking force /Cross sectional Area of sample]**

**c. Percentage elongation:**

One sort of distortion is elongation. Anything that is under stress experiences a straightforward change in shape, which may be measured with a texture analyzer. To put it another way, a sample that experiences tensile stress deforms, lengthens, or elongates. The following formulae can be used to compute it by measuring the increase in film length following tensile measurement:

**Percent Elongation = [L-L0] X 100 / L0**

Where L be the final length and L0 is initial length.

**d. Young's Modulus:**

Film stiffness is measured by its elastic modulus, also known as Young's modulus. Here, too, the tensile strength measurement techniques might be applied. It can be shown as the following ratio of applied stress to strain in the elastic deformation region

**Young's Modulus= Slope x 100/ Film thickness x cross head Speed**

A hard, brittle film with little elongation exhibits a high Young's modulus and tensile strength.

**e. Tear Resistance:**

Plastic film or sheeting's resistance to tearing is a complicated byproduct of its final resilience to rupturing. To quantify the force required to induce tearing, a relatively low rate of loading—51 (2 in.) /min—is essentially used. The value of tear resistance in Newtons (or pounds-force) represents the maximum stress or force—which is often found close to the beginning of tearing—necessary to tear the specimen.

**f. Folding endurance:**

One essential physical attribute required for simple deployment on the administration site is the film's flexibility. The film's flexibility can be quantitatively assessed using folding endurance. This is ascertained by folding the film 300 times without breaking or repeatedly at a 180° angle to the same plane until it breaks. The folding endurance value is calculated as the number of times the film can be folded without breaking.

**4. In Vivo test:**

Two approaches to simulating in vivo disintegration include contact angle measurements and thermomechanical studies of film swelling behavior. In vivo testing, which is carried out with

the help of a tasting panel and human volunteers, focuses on the taste of the films as well as their in vivo disintegration time. An electronic tongue tester is also used to examine the films flavor.

**5. Other tests:**

The viscosity of the polymer solution, content homogeneity, and residual solvent determination are other methods for characterizing and controlling the quality of ODFs. Garsuch and Breitkreutz found that ODFs with varying top and lower surfaces showed signs of caffeine recrystallization through the use of near-infrared chemical imaging, X-ray diffraction, and scanning electron microscopy. Technologies like Raman and near-infrared spectroscopy can be used to identify and measure the active ingredients in the films. The glass transition temperature and crystallinity are examined using X-ray diffraction, thermo-mechanical analysis, and differential scanning calorimetry. Gaisford et al. used isothermal calorimetry to track the crystallization of medications derived from ODFs. Weight and dynamic vapor sorption are employed to determine hygroscopic and residual water content. Given established standards, more research into microbiological investigations and stability testing is required.

## CONCLUSION

As this review shows, mouth-dissolving films are a novel strategy in the pharmaceutical industry. These days, several pharmaceutical companies and organizations use this technique to prolong the patent life of their current drugs. MDF can be prepared using a variety of methods. The primary motivation behind the creation of MDFs was to solve the difficulty that dysphasic medical specialty, geriatric, and psychiatric patients had ingesting regular oral dose forms. By delivering the medication straight into the bloodstream, the formulation increases safety, decreases side effects, and enhances absorption. Because it doesn't need water to be administered, this dosage form is affordable and portable. Mouth dissolving film therefore becomes a special, tasteful, essential, and selective dosage form.

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## CONFLICT OF INTEREST

None. Any interest, financial relationship, personal relationship, religious or political beliefs that might influence the objectivity of the author can be considered as a potential source of conflict of interest. All manuscripts submitted to the journal must include a conflict of the interest disclosure statement or a declaration by the authors that they do not have any conflicts of interest to declare

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