

Mouth Dissolving Film: A Review

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ABSTRACT : -

Fast-dissolving films, which bypass hepatic first-pass metabolism and offer quick therapeutic impact, are now more widely accepted and accurate oral dosage forms. The main components of this system are patient compliance and industrial compatibility. Advantages of oral disintegrating dose forms versus solid dosage forms Recently, mouth-dissolving films have entered the market because they are more convenient and simple to use than other dosage forms, such as orally disintegrating pills. The type of drug delivery method known as a mouth dissolving film dissolves or disintegrates when placed in the oral cavity in a matter of seconds without the need for water. This technique is mostly employed in specific populations like children, the elderly, patients who are bedridden, patients who are mentally ill, and the general public. The present review provides various formulation considerations, methods of preparation, and evaluations of film.

I. INTRODUCTION

Oral administration is the most popular route due to ease of ingestion, pain avoidance, versatility (to accommodate various types of drug candidates), and most importantly, patient compliance also, solid oral delivery systems do not require sterile conditions and are, therefore, less expensive to manufacture. Patients with geriatric, pediatric, nauseated, bedridden, and noncompliance issues typically have trouble swallowing the traditional oral dose form and do not take their medications as directed. This problem is thought to have affected 50% of the population, which ultimately increases the likelihood of noncompliance and unsuccessful therapy. Due mostly to longer life expectancies, the elderly makes up a significant segment of the population nowadays. The biggest issue with tablets is their size and potential choking hazards. Patients with geriatric and pediatric conditions, as well as those

who are travelling and may not have easy access to water, are more likely to have trouble swallowing medicines. To get around this Oral fast disintegrating drug delivery system were created as an alternative to tablets, capsules, and syrups for pediatric and geriatric patients who have trouble swallowing conventional oral solid dosage forms.

These systems were first created in the late 1970s. These dose forms either dissolve or disintegrate in the mouth without water in around three minutes. Due to improved patient compliance, oral fast disintegrating dose forms are starting to gain favor as an innovative drug delivery technology. An oral fast-dispersing dosage form is, by definition, a solid that quickly dissolves or disintegrates in the mouth to generate solution or suspension without the need for water to be administered. Dysphagia, or trouble swallowing, affects people of all ages, but it's more prevalent among the elderly. It can also make it difficult to take regular tablets and capsules. Various medical diseases, including stroke, Parkinson's, AIDS, thyroidectomy, head and neck thyroid treatment, and other neurological conditions, such as cerebral palsy, are linked to dysphagia. Rapid dissolving films and mouth-dissolving tablets make up the oral rapid disintegrating dosage form. Tablets that dissolve in the mouth are linked to a few issues, including residues that produce a grittiness in the mouth, a fear of choking, and difficulty swallowing tablets. A new drug delivery method for the oral distribution of the pharmaceuticals, called as Fast dissolving films/oral dispersible film/mouth dissolving films/oral disintegration film/oral dissolving film, was investigated to overcome the problems with mouth dissolving tablets.^[1,2]

History of Fast Dissolving Oral Films: -

In 1970, fast-dissolving oral films were introduced to North America. Oral films were first launched at that time as staff care products and

mouth fresheners. Fast-dissolving films, also known as Listerine® pocket packs TM and used as breath fresheners, were invented by Pfizer. However, the United States and European markets quickly framed rapid dissolving films. There are currently 15 businesses creating oral fast-dissolving films using a constantly evolving tablet dose form. According to the article, Labtech GmbH, APR, established a novel method for the creation of oral fast-dissolving films. Oral strips have gained popularity in the past few years for their ability to quickly dissolve and release a minty flavor while also refreshing the breath. Pharmaceutical companies are now making these oral strips as over the counter and prescription pharmaceuticals.

The more recent technology used in the production of oral disintegrating dose forms are oral films. They are attractive thin films made of ingestible, water-soluble polymers in a range of dimensions, such as square, rectangle, and disc. The stripes could be clear or opaque, flexible, or brittle. They are created to break down quickly on the tongue without the aid of water. The specific surface area for disintegration in fast disintegrating films (FDFs) is considerable. The films overcome the shortfalls of oral rapid dissolving pills by reducing the risk or worry of choking, making them simple to handle and administer and easy to make. These dosage forms' low medication loading capacity and limited flavor masking possibilities are significant drawbacks.^[3,4]

Salient feature of fast dissolving drug delivery system: -

- Convenience in administering to mentally sick, disabled, and recalcitrant patients.
- Don't need water.
- Gets through the medicines' unpleasant taste.
- May be created to leave little to no aftertaste in the mouth and to provide the user a satisfying mouthfeel.
- The ability to offer liquid medicinal benefits in the form of a solid formulation.
- Cost effective.

Advantage of Fast Dissolving Oral Films: -

- Convenient dosing.
- No water needed.
- No risk of choking
- Taste masking.
- Enhanced stability.
- Improved patient compliance.
- The drug enters the systemic circulation with reduced hepatic first pass effect.

- Site specific and local action.
- Availability of large surface area that leads to rapid disintegration and dissolution within oral cavity.
- Dose accuracy in comparison to syrup.

Disadvantages: -

- High doses cannot be incorporated.
- Excessive bitter drugs are not feasible.
- Dose uniformity is a technical challenge.
- They require special packaging for the products stability and safety.
- Drugs which irritate the oral mucosa cannot be administered by this route.

Overview of the oral cavity: -

The outermost layer of stratified squamous epithelium makes up the oral mucosa. A basement membrane, a lamina propria, and the submucosa—the deepest layer—are located beneath this. In terms of permeability, the oral mucosa falls somewhere between the intestinal mucosa and the epidermis. The buccal mucosa's permeability is thought to be 4–4000 times larger than the skins. Because oral mucosa has various shapes and functions, there are significant variances in permeability between different areas of the oral cavity.^[3,5]

Mechanism of Absorption through Oral Mucosa: -

For passive drug transference, the oral mucosa has two transcellular (intracellular, passing into the cell) and paracellular penetration passageways (intercellular, passing around the cell). Drug fragments can be used simultaneously on different tracks, but depending on the physicochemical properties of the drug, one track is preferred over the other. Due to its lipophilic nature and low partition coefficient, the cell membrane has difficulty allowing hydrophilic solutes to pass through. Due to the intercellular spaces acting as a barrier to permeation, the lipophilic substances have low solubility in passive transport systems. In the meantime, the fusion of these two itineraries stratifies the oral epithelium and convokes solute permeation. The pathway that has the fewest barriers to passage is therefore preferred over the other for penetration through the oral mucosa.

Factors affecting absorption: -

- Biphasic solubility of the medicine is required for absorption in addition to high lipid

- solubility when determining the drug's ability to dissolve in salivary secretions.
- Binding to the oral mucosa: Drugs that bind to the oral mucosa are not widely available in the system.
- Saliva's typical pH is 6.2-7.6, which favors the absorption of medicines that are still unionized. Saliva's pH and pKa. If the pKa for an acid is greater than 2 and for a base is less than 10, the medications are also absorbed via the oral mucosa.
- Lipophilicity of the drug.
- Passive permeation requires a medicine to have a little higher lipid solubility than that needed for GI absorption for it to be entirely absorbed through the sublingual route.
- Oral epithelium thickness: As contrast to buccal thickness, the sublingual epithelium is thinner at 100–200 m. As a result of the thinner epithelium and the drug's immersion in a smaller volume of saliva, the absorption of medicines is accelerated.^[11,15]

SR. No.	Oral Disintegrating Tablets	Orally Dissolving Films
1	It is a tablet	It is a film
2	Lesser dissolution due to less surface area	Greater dissolution due to larger surface area
3	Less durable as compared with oral films	Better durable than oral disintegrating tablets
4	Less patient compliance than films	More patient compliance
5	High dose can be Incorporated	Low dose can only be Incorporated
6	It has a fear of choking	No risk of choking

Table no.01: - Comparison between Fast Dissolving oral Films and Tablets.

FORMULATION CONSIDERATION: -

- Active pharmaceutical ingredient
- Film forming polymer
- Plasticizer
- Sweetening agent
- Saliva stimulating agent
- Surfactant
- Super disintegrants
- Flavoring agent
- Coloring agent

Ingredients	Amount (w/w)
Drug	5-30 %
Water Soluble Polymer	45 %
Plasticizer	0-20 %
Saliva Stimulating Agent	2-6 %
Surfactant	q.s
Sweetening Agent	3-6 %
Flavor, Color, Filler	q.s

Tables no.02: - Ingredients and amount in percent

Active Pharmaceutical Ingredient: - The amount of the active pharmaceutical ingredient in the film formulation ranges from 1-30% w/w. Always use minimal doses of the active pharmaceutical ingredients because it is challenging to combine big doses of the medicine into a film that dissolves quickly. Several drugs, such as antihistamines, anti-diarrheal, anti depressants, vasodilators, anti-asthmatics, and antiemetics, can be utilized as fast-dissolving oral films. Fast-dissolving films can deliver a variety of APIs.

Choice of drug: -

- ✓ Drug should pleasant taste.
- ✓ Drug dose quantity are less up to 40 mg.

- ✓ Drug should be smaller molecular size and low molecular weight.
- ✓ Drug should be good stability and solubility in water as well as saliva.
- ✓ Drug should be partially unionized at the pH of oral cavity.
- ✓ It should have the ability to permeate oral mucosal tissue.
- ✓ Drug Lipophilicity.

Film forming polymer: - All thin film oral dose forms depend mainly on the disintegration in the oral cavity's saliva, hence the final film utilized must unavoidably be water soluble. Excipients or polymers must be water soluble, have a low

molecular weight, and have an excellent ability for film formation to create a thin film formulation that is water soluble.

Examples of polymers are,

- ✓ Pullulan
- ✓ Polyvinyl alcohol
- ✓ Hydroxy propyl methyl cellulose
- ✓ Starch
- ✓ Polyethylene oxide
- ✓ Hydroxy propyl cellulose
- ✓ Sodium carboxy methyl cellulose
- ✓ Maltodextrins^[1,3]

Ideal properties of the polymers used in the oral film

- ✓ Polymers should be made of nontoxic, bland, and painless materials.
- ✓ It should not have any flavor.
- ✓ There shouldn't be any drainable poisons in it.
- ✓ It needs to be simple to obtain and tiny.
- ✓ It shouldn't be an overwhelming obstacle during the deterioration interaction.
- ✓ It needs to have outstanding wetting and spreading abilities.
- ✓ It needs to be ductile, shear, and strippable enough.
- ✓ It should be long-lasting and realistically usable, and it shouldn't spread oral illness.

Plasticizer: -It is an important factor of oral films. The choice of plasticizer is affected by the polymer's compatibility as well as the different type of solvent used in the film casting process. It lessens the brittleness of the film and increases its flexibility. Reducing the polymer's glass transition temperature considerably enhances the strip characteristics of the plasticizer. They are used in concentrations between 1 - 20% weight per weight of dry polymer.

Examples of plasticizer,

- ✓ Glycerol
- ✓ Propylene glycol (PG)
- ✓ Polyethylene glycol (PEG)
- ✓ Diethyl phthalate
- ✓ Triethyl citrate

Sweetening agent: - Sweeteners now have an important function in pharmaceutical products which are intended to dissolve or disintegrate in the mouth. Sucrose, dextrose, fructose, glucose, liquid glucose, and isomaltose are the traditional sources of sweetness. When compared to sucrose and dextrose, fructose's sweetness is more quickly tasted in the mouth. Because fructose is sweeter

than sorbitol and mannitol, it is a common sweetener. The most popular sweeteners include sucrose and low molecular weight carbohydrates. Sucrose has a high solubility in water and doesn't give the final formulation any unfavorable color because it is colorless. Over the pH range of 4 to 8, it is stable.^[8,10]

Saliva stimulating agent: -

The objective of using saliva stimulating agents is to enhance saliva production, which will help the formulations for rapid dissolving film dissolve more quickly. Broadly speaking, salivary stimulants can be made from acids that are used in meal preparation. These agents are used along are in combination between 2-6 % w/w of the film.

Examples are,

- ✓ Citric acid
- ✓ Malic acid
- ✓ Tartaric acid
- ✓ Ascorbic acid
- ✓ Lactic acid

Surfactant: - Surfactants are used as solubilizers, wetting agents, and dispersants, causing the film to quickly degrade and enabling the delivery of the active treatment. In quickly dissolving buccal films, surfactants also aid in the decomposition of ineffectively solvent drugs. Poloxamer 407, sodium lauryl sulphate, benzalkonium chloride, benzethonium chloride, tweens, and spans etc.

Super disintegrants: - When super disintegrants are added to OTF formulations, the combined effects of swelling and water absorption result in fast disintegration. Due to their high-water absorption, superdisintegrants provide absorption and swelling, which speeds up disintegration. Strong saliva interaction is essential for disintegration.^[1,2]

Flavoring agent: -In the OFDF formulations, flavors are added up to 10%w/w preferably. The initial flavor quality, which is noticed in the first few seconds after the product has been consumed, and the after taste of the formulation, which lasts for at least about 10 minutes, are the two main factors that determine whether an individual will accept an oral disintegrating or dissolving formulation. The sort of medicine to be included in the formulation will determine what fragrance is used.

Coloring agent: - FD&C approved coloring agents are used (not exceeding concentration levels of 1percent; w/w) in the manufacturing of orally fast dissolving films. e.g., titanium dioxide.^[11,13]

METHOD OF PREPARATION: -

Different methods for achieving fast dissolving film formulation by the following,

1. Solvent casting
2. Semisolid casting
3. Hot melt extrusion
4. Solid dispersion extrusion
5. Rolling

1.Solvent Casting: -

The most popular method for creating ODFs that uses de-ionized water as a solvent is called solvent casting. High shear pressures produced by a shear processor are then applied to the mixture to make it homogeneous. Fast-dissolving buccal films are typically created using the solvent casting method, in which the water-soluble ingredients are combined to create a clear, viscous solution, and the drug and other excipients are dissolved in a suitable solvent. After the two solutions have been combined and stirred, the mixture is then cast into a Petri dish and allowed to dry. In the solvent casting method, a film-forming polymer is typically immersed in a suitable solvent for the duration of the night.

Procedure: -Water soluble polymers are dissolved in water when using the solvent casting method, while the drug and other excipients are dissolved in a suitable solvent. The two solutions are then combined and mixed before being cast into a Petri dish, dried, and then cut into the required size pieces.

Advantages: -

- Simplicity.
- Room temperature operation.
- Suitable for heat sensitive drugs.
- Better uniformity of thickness and better clarity than extrusion.
- This method is suitable for films containing heat sensitive drug/API as the temperature needed to remove the volatile solvents is comparatively low than hot melt extrusion method.

Disadvantages: -

- Water or a volatile liquid must be soluble in the polymer.

- It is important to create a stable solution with a suitable minimum solid content and viscosity.
- Depending on the fluid rheology, the intended applied mass, and the necessary dosage uniformity, a variety of casting techniques may be chosen.^[1,2]

2. Semisolid Casting: -

A water-soluble film-forming polymer solution is made. To Prepare the solution of water-soluble film forming polymer. The resulting solution is mixed with an acid- insoluble polymer solution (e.g., cellulose acetate phthalate, cellulose acetate butyrate). The right quantity of plasticizer is applied to produce a mass of gels. Then, using heat- controlled drums, the gel mass is cast into the films or ribbons. The film should be between 0.015 and 0.05 inches thick. The ratio of film-forming polymer to acid- insoluble polymer should be 1:4.

3. Hot melt extrusion: -

This method is solvent free process. Granules, sustained release tablets, transdermal drug delivery systems, and transmucosal drug delivery systems are all frequently created through hot metal extrusion. Since 1971, the pharmaceutical sector has employed melt extrusion as a manufacturing method. With this technique, polymer is heated and formed into a thin layer. The drug and polymer combination are first poured into a hopper and then transported, mixed, and melted by an extruder. A die molds the liquid into the desired shape. This technique calls for a low temperature and a short (2 minute) residence time for the drug polymer mixture. This technique doesn't use organic solvents and it can run continuously with little product waste. This technique effectively controls operating factors. solvent free process due to processing of thermolabile substance is a major drawback of this process due to the use of high temperature during extrusion.

4. Solid dispersion extrusion: -

Dispersion of one or more active materials in an inert carrier in a solid state in presence of amorphous,

- ✓ hydrophilic polymer is said to be solid dispersion.
- ✓ Drug is dissolved in a liquid solvent. The solution is incorporated in to melt of Polyethylene Glycol obtained below 70°C.

- ✓ The solid dispersion is shaped into the film by means of dies.

5. Rolling Method:

The water or a water and alcohol combination is used as the solvent. Film-forming polymer, a polar solvent, and an additional ingredient should be prepared as a premix. Fill the master batch input tank with premix. It was fed to one or both first and second mixers using a first measuring pump and control valve. To create a consistent matrix, combine the drug with the master batch premix. The pan is then fed with a predetermined quantity of uniform matrix using second metering pumps. Finally, the film is pressed firmly against the base before being removed by the support roller. Then, using controlled bottom drying, the wet sheet is dried.^[11,13]

Various Technology used in Oral Film Formulation: -

- **XGel:** - Xgel film technology allows for the incorporation of active pharmaceutical components and can be taste-masked, colored, and layered. Any oral dosage form can be made to encapsulate it, and it can be made to dissolve in either cold or hot water. The first powder fill version of its Xgel Film System was marketed by Bio Progress Technology International, a UK-based company that developed it.
- **Sol leaves:** - This is applied to goods that release flavor, like vitamins, candy, and mouth fresheners. Utilizing SOLULEAVES technology, active ingredients can be effectively, pleasantly, and conveniently transported to the oral region.
- **Foam burst:** - The FOAMBURST drug delivery device uses foamed film formed from capsules. During manufacture, gas is blown into the film, creating a honeycombed structure. The void in the film may be filled with gas, left empty, or filled with another substance to provide a particular taste and texture or to deliver an active drug. The quick dissolution of capsules with a light honeycomb structure that melt in the tongue.
- **WaferTab:** - A trying to cut quick oral administration device called WAFERTAB produces drug-loaded thin films that can be applied orally using a special method. After casting, the active ingredient is integrated. This technology is one of the patent technologies in

which the drug is been incorporated with a suitable film for oral or topical application.

- **MiCap:** - Micro encapsulation technology is combined by Micap and Bio Progress to create water-soluble films. New delivery methods for the \$1.4 billion global market for smoking cessation medications will be provided by the advances (SCPs). Micap signed an agreement in 2004 to get the expertise in the microencapsulation technology with the bio progress water soluble films.

EVALUATION OF FAST DISSOLVING FILM: -

- Organoleptic evaluation
- Weight variation/ Weight of film
- Thickness
- Folding endurance
- Surface pH
- Swelling index
- Moisture loss
- Moisture uptake
- In vitro disintegration test
- Drug content uniformity
- Dissolution Test

❖ **Organoleptic evaluation: -**

Color, odor, and taste were assessed as an organoleptic property.

❖ **Weight variation/ Weight of film: -**

Weight variation is studied by individually weighing 10 randomly selected films and by calculating the average weight.

❖ **Thickness: -**

The thickness of the film was measured using a Digital vernier caliper at five distinct locations, and an average of three readings was derived. The precision of the dose in the film is closely related to the uniformity of film thickness, hence this is crucial for measuring.

❖ **Folding endurance: -**

Repeated folding of the strip at the same location until the strip breaks is used to measure folding endurance. The folding endurance value is calculated as the number of folds the film can endure without breaking.

❖ **Surface pH: -**

The test film was put in a Petri dish, wet with 2 ml of distilled water, and allowed to stand for 30 seconds. After bringing the electrode of the pH

meter into contact with the formulation's surface and giving it a minute to equilibrate, the pH was recorded. For each formulation, an average of three determinations were performed.

❖ **Swelling index: -**

The swelling studies of films are examined using simulated saliva. A stainless-steel wire mesh with a predetermined initial weight for the film is then used. The film containing the mesh is then submerged in a simulated saliva solution. Until there is no more an increase in weight, the weight of the film continues to increase at constant pre- determined time intervals. Several factors determine the swelling's degree,

Degree of swelling = final weight (wt.) – Initial weight (w0)/ Initial weight (w0)

Wt = weight of film at time interval t, w0 =weight of film at time 0.

❖ **Moisture uptake: -**

A film's ability to absorb moisture is evaluated by first cutting it to a 2x2 cm² size. These strips are later placed for 7 days at 40°C temperature to an atmosphere with a relative humidity of 75%. The percentage weight increase of the strips is used to calculate moisture absorption.

Percentage moisture uptake = final weight(w2) – Initial weight(w1) / Initial weight(w1)

❖ **Moisture loss: -**

It is determined by first finding the initial weight of the film, afterward, putting this film in desiccators for three days. Desiccators possess calcium carbonate. After three days, strips are taken out and weighed again. Moisture loss is determined by applying the following formula,

Percentage moisture loss = Initial weight(w1) – final weight(w2) / Initial weight(w1) *100

❖ **In vitro disintegration test: -**

The disintegration time of a film is calculated using disintegration equipment that is listed in authorized pharmacopoeias. The disintegration time often varies depending on the formulation and generally occurs between 5 and 30 seconds. For this test, the USP disintegration apparatus is typically used. For calculating the disintegration time of orally fast disintegrating films, there are no official guidelines available. Disintegration time is the time when an oral film starts breaking when brought in contact with water or saliva.

❖ **Drug content uniformity: -**

A standard assay procedure that is prescribed for each specific drug according to different pharmacopoeia is used to determine a film's contents. 20 samples are used in this test, which is carried out utilizing analytical methods. According to the Japanese Pharmacopoeia, the test's acceptance value is less than 15%. USP27 states that the contents should range between 85% and 115%, with a standard deviation of no more than 6%. For determining the number of drugs in each individual film, content uniformity is calculated.

❖ **Dissolution Test: -**

Any of the pharmacopoeia's standard basket or paddle apparatus can be used for dissolution testing. The sink conditions and API dose will primarily be taken into consideration while selecting the dissolving medium. The tendency of the strip to float onto the dissolving media when the paddle equipment is used frequently makes the dissolution test challenging.

II. CONCLUSION:-

The current review demonstrates that mouth dissolving films are one of the innovative pharmaceutical sciences formulations. In comparison to other conventional dose forms, they have superior acceptance and patient compliance, no risk of choking, and better safety and efficacy. The usual oral dose form is typically difficult for patients with geriatric, paediatric, sick, bedridden and noncompliance challenges to swallow, and they frequently do not take their prescriptions as prescribed. A solid that quickly dissolves or disintegrates in the mouth to produce a solution or suspension without the requirement for water to be delivered is by definition an oral fast-dispersing dose form. Dysphagia, or difficulty swallowing, affects people of all ages, but the elderly are more likely to have it. Fast dissolving films, also known as oral dispersible films, mouth dissolving films, oral disintegration films, or oral dissolving films, are a new drug delivery technique for the oral distribution of drugs that was researched to address the drawbacks of mouth dissolving tablets.

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