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A Review on Mouth Dissolving Film

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ABSTRACT:

Mouth dissolving film is the most advanced oral solid dosage form due to its flexibility and comfort in use. Mouth dissolving films are oral solid dosage form that disintegrate and dissolve within a minute when placed in mouth without taking water or chewing. This dosage form allows the medication to bypass the first pass metabolism so bioavailability of medication may be improved. Mouth dissolving film has potential to improve onset of action lower the dosing and eliminate the fear of choking. Formulation of mouth dissolving films involves both the visual and performance characteristics as plasticized hydrocolloids, API taste masking agents are being laminated by solvent casting and semisolid casting method. Solvent casting method being the most preferred method over other methods because it offers great uniformity of thickness and films prepared having fine glossy look and better physical properties. Mouth dissolving films are evaluated for its various parameters like thickness, physical property like folding endurance, disintegration and dissolution time. This review gives an idea about formulation techniques, evaluation parameters, overview on packaging and some available marketed products of mouth dissolving films.

KEY WORDS: Mouth dissolving film, solvent casting, fast disintegration

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INTRODUCTION:

The oral route of drug administration is the most important method of administration of drug for systemic effect, despite of tremendous advancement in drug delivery system. Its ease of administration, pain avoidance and various advantages over other routes is the reason that the oral route achieved such recognition. But the most evident drawback of oral dosage forms like tablets and capsules is difficulty in swallowing, leading to patient's in compliance particularly in case of paediatric and geriatric, bedridden, nauseous patients. An improved interest has been addressed to oral solid dosage forms designed for quick availability of therapeutic dose. Mouth dissolve products (tablets and films) may show greater patient acceptability and convenience. Fast-dissolving oral delivery systems are solid dosage forms, which disintegrate or dissolve within 1 min when placed in the mouth without drinking of water or chewing.^[1-2] After disintegrating in mouth, enhanced the clinical effect of drug through pre-gastric absorption from mouth pharynx and esophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is considerably greater than those observed from conventional tablet dosage form. More recently, Fast-dissolving buccal film drug delivery systems have rapidly gained acceptance as an important new way of administration of drugs. They are generally used for pharmaceutical and nutraceutical products. It is the newest leading edge in drug delivery technology that provides a very convenient means of taking medications and supplements. MDFs are also applicable when local action in the mouth is desirable such as local anesthetic for toothaches, oral ulcers, cold sores, or teething and also used where quick onset of action of drug is required^[3-5]. Fast dissolving film is prepared using hydrophilic polymers that rapidly

dissolve/disintegrate in the mouth within few seconds without water and eliminates the fear of choking as an alternative to fast dissolving tablets. Mainly the fast dissolving film can be considered as an ultra thin strip of postage stamp size with an active pharmaceutical ingredient and other excipients. Most fast dissolving films are having taste masked active ingredients. These masked active ingredients are swallowed by the saliva of patients along with the soluble and insoluble excipients.

The advantages of convenience of dosing and portability of mouth dissolving film have led to wider acceptability of this dosage form by paediatric as well as geriatric patients. They also impart unique product differentiation, thus enabling use as line extensions for existing commercial products. This novel drug delivery system can also be beneficial for meeting the current needs of the industry are improved solubility/stability, biological half life and bioavailability enhancement of drugs. Also due to ease of transportation of mouth dissolving film than ODT helpful for reducing damage cost compared to ODT and other liquid formulation.

Formulation of mouth dissolving film involves the application of both aesthetic and performance characteristics such as strip-forming polymers, plasticizers, active pharmaceutical ingredient, sweetening agents, saliva stimulating agent, flavoring agents, coloring agents, stabilizing and thickening agents. From the regulatory perspectives, all excipients used in the formulation of oral drug strips should be approved for use in oral pharmaceutical dosage forms. Mouth dissolving films evolved over the past few years from the confection and oral care market in the form by consumers for delivering vitamins as well as personal care products.

SPECIAL FEATURES OF MOUTH DISSOLVING FILMS

- Thin elegant film
- Unconstructive
- Available in various size and shapes
- Fast disintegration
- Rapid release
- Give a pleasant mouth feel.
- Have an acceptable taste.
- Should not leave residues in mouth.

ADVANTAGES

- Availability of larger surface area that leads to quick disintegration and dissolution in the oral cavity within a matter of seconds.
- Fast Dissolving Film is flexible so they are not as fragile so does not need any kind of special package for protection during transportation and storage as compared to FDT.
- No need of water has led to better suitability amongst the dysphasic patients.

- No fear of choking as compared to FDT.
- The large surface area available in the film dosage form allows rapid wet by saliva then quickly disintegrates and dissolve and absorbed directly and can enter the systemic circulation without undergoing first-pass hepatic metabolism and an increase the bioavailability.
- Bypassing hepatic first pass effect leads to reduction in dose which can lead to reduction in side effects associated with the molecule.
- The dosage form can be consumed at any place and any time as per convenience of the individual.
- Precision in administered dose.

DISADVANTAGES

- Dose uniformity is a technical challenge.
- Hygroscopic in nature.
- High doses cannot be incorporated (<40 mg/4cm²piece)
- Require special packaging for products stability and safety.^[6-8]

TYPICAL COMPOSITION OF MOUTH DISSOLVING FILM:^[9]

Composition	Concentration
Drug	1-25%
Water soluble polymer	40-50%
Plasticizers	0-20%
Fillers, colors ,flavors	0-40%

FORMULATION ASPECTS FOR MOUTH DISSOLVING FILMS:^[10, 11,12]

Formulation of FDFs involves the intricate application of aesthetic and performance characteristics such as taste masking, fast dissolution, physical appearance, mouth feel etc. From the regulatory perspectives, all excipients used in the formulation of oral strips should be Generally Regarded as Safe (i.e. GRAS-listed) and should be approved for use in oral pharmaceutical dosage forms.

A) Drug Category

This technology has the potential for delivery of variety of APIs. However since the size of the dosage form has limitation, high dose drugs are difficult to be incorporated in films. Less bitter, potent and highly lipophilic drug should be preferred for oral thin film as in case of fast dissolving tablets.

The ideal characteristics of a drug to be selected:

- 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 in saliva.
- It should be partially unionized at the pH of oral cavity.
- It should have an ability to permeate oral mucosal tissue.

Various categories of drugs such as antiemetic neuroleptics, cardiovascular agents, analgesics, antiallergic, antiepileptics, anxiolytics, sedatives, hypnotics, diuretics, anti-parkinsonism agents, anti-bacterial agents and drugs used for erectile dysfunction, antialzheimer's, expectorants, etc

Drug candidates suitable for MDF are shown in below mentioned figure 1^[32]:



Figure 1: Suitable Drug candidates

B) Film Forming Polymers

Water-soluble polymers are used as film formers as they provide quick disintegration, good mouth feel, and mechanical strength to the films. The robustness of the strip depends on the type of polymer and its amount in the formulations. A variety of polymers are available for preparation of films of which pullulan, gelatin and hypromellose are most commonly used. Examples of water-soluble polymers include: Pullulan, Gelatin, guar gum, xanthan gum, Hydroxyl propyl methyl cellulose (HPMC), Modified starches, PVPK30, PVA etc.

Among this the Pullulan and HPMC are the best suitable polymers for the preparation of FDF. Pullulan is a neutral glucan (like Amylose, Dextran, Cellulose), with a chemical structure somewhat depending on carbon source, producing microorganism (different strains of Aureobasidium pullulans), fermentation conditions. HPMC is propylene glycol ether of methylcellulose. The low viscosity grades of HPMC are use for the preparation of MDF like

HPMC E3/E5/E6/E15.

Ideal properties of the polymers used in the oral film:

1. Polymers should be non toxic, non- irritant and non-bitter.
2. Polymers should be tasteless
3. It should be devoid of leachable impurities
4. It should be inexpensive and readily available
5. It should not be an obstacle in the disintegration time
6. It should have good wetting and spreadability property
7. It should exhibit sufficient peel, shear and tensile strength
8. It should not cause secondary infection in the oral cavity and should have sufficient shelf life.

C) Plasticizers

Plasticizer is a crucial ingredient of the mouth dissolving films. The selection of plasticizer depends upon its compatibility with the polymer and the type of solvent employed in the casting of film. It helps to improve the flexibility of the film and reduces the brittleness of the film. Plasticizer significantly improves the strip properties by reducing the glass transition temperature of the polymer. Typically the plasticizers are used in the concentration of 1 - 20%w/w of dry polymer weight. The Plasticizer should be volatile in nature. Examples include: Glycerol, Propylene glycol, Low molecular weight polyethylene glycols, Phthalate derivatives like dimethyl, diethyl, dibutyl derivatives, Citrate derivatives like triacetin acetyl citrate, etc.

D) Sweetening agents

Sweeteners have become an important part of the food products as well as pharmaceutical products intended to be disintegrated or dissolved in the oral cavity. Natural sweeteners as well as artificial sweeteners are used to improve the palatability of the mouth dissolving formulations. Some suitable sweeteners include:

- (1) Water soluble natural sweetener: xylose, ribose, glucose, sucrose, maltose, stevioside etc.
- (2) Water soluble artificial sweetener: sodium or calcium saccharin salts, acesulfame-K etc.
- (3) Dipeptide based sweetener: aspartame

E) Plasticizers

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G) Cooling agents

Cooling agents akin to monomethyl succinate can be added to improve the flavor strength and to enhance the mouth-feel effect of the product. Additional cooling agents like WS3, WS23 and Utracoll II can also be used in conjunction with flavors.

H) Flavoring agents

Perception for the flavor changes from individual to individual depending on the ethnicity and liking. Flavoring agents can be selected from synthetic flavor oils, oleo resins extract derived from various parts of the plants like leaves, fruits and flowers. The amount of flavor needed to mask the taste depends on the flavor type and its strength.

I) Coloring agents

Pigments such as titanium dioxide or FD&C approved coloring agents are incorporated (not exceeding concentration levels of 1%w/w) in oral strips when some of the formulation ingredients or drugs are present in insoluble or suspension form.

J) Surfactants

Surfactants are used as solubilizing or wetting or dispersing agents as a result that the film gets dissolved within seconds

and release active agent immediately. Surfactants also improve the solubility of poorly soluble drugs in fast dissolving buccal films. E.g.: Polaxamer 407, sodium lauryl sulfate, benzalkonium chloride, benzthonium chloride, tweens and spans etc.

K) Stabilizing and thickening agents

The stabilizing and thickening agents are employed to improve the viscosity and consistency of dispersion or solution of the strip preparation solution or suspension before casting. Natural gums like xanthan gum, locust bean gum, carrageenan and cellulosic derivatives can be used.

METHOD OF PREPARATION OF FAST DISSOLVING FILM:^[13, 14, 15, 16]

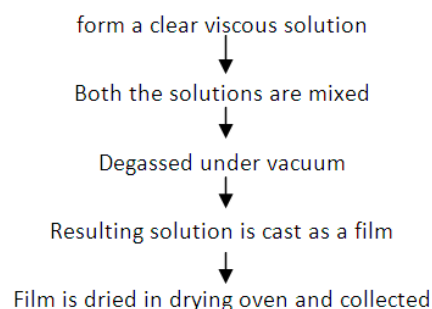
One or a combination of the following processes can be used to manufacture the Mouth dissolving film:

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

1. Solvent casting method

Fast dissolving films are preferably formulated using the solvent casting method, whereby the water soluble ingredients are dissolved to form a clear viscous solution and the drug along with other excipients are dissolved in suitable solvent then both the solutions are mixed and stirred and finally casted in to the Petri plate and dried.

Water soluble ingredients are dissolved in water and API and other agents are dissolved in suitable solvent to



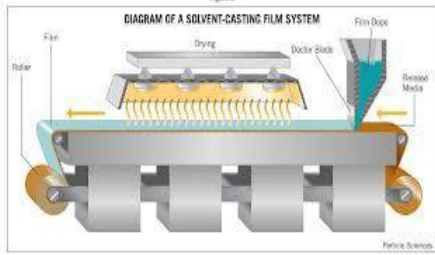


Figure 2 Solvent casting method

2. Hot melt extrusion

Hot melt extrusion method has various benefits; those are fewer operation units, minimum product wastage, better content uniformity, an anhydrous process, absence of organic solvents.

In hot melt extrusion method-

- Drug is mixed with carriers in solid form.
- ↓
- The extruder having heaters melts the mixture
- ↓
- Finally the melt is shaped in films by the dies.

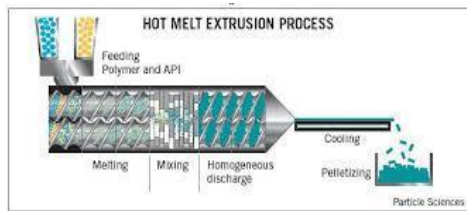
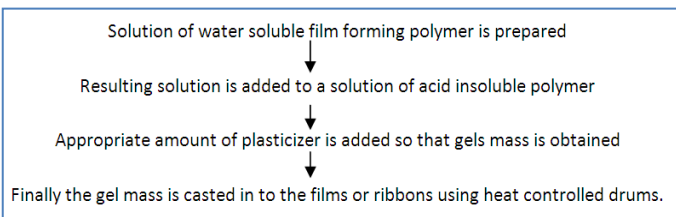


Figure 3 Hot melt extrusion

3. Semisolid casting method

This method is preferably adopted when acid insoluble polymers are to be used in the preparation of the films. Acid-insoluble polymers used to prepare films include: cellulose acetate phthalate, cellulose acetate butyrate. Acid insoluble polymer and film forming polymer should be used in the ratio of 1:4.



4. Solid dispersion extrusion method

The term solid dispersions refer to the dispersion of one or more active ingredients in an inert carrier in a solid state in the presence of amorphous hydrophilic polymers.

- Drug is dissolved in a suitable liquid solvent
- ↓
- Then solution is incorporated into melt of polyethylene glycol, obtainable below 70oC
- ↓
- Finally the solid dispersions are shaped into the films by means of dies

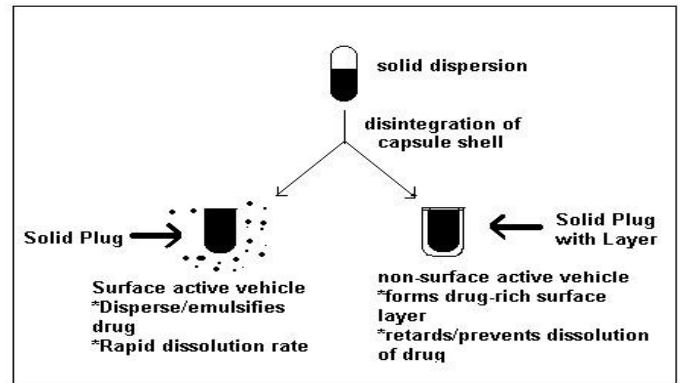


Figure 4 Solid dispersion extrusion method

Precautions while preparing solid dispersions: the selected solvent or dissolved drug may not be miscible with the melt of polyethylene glycol and polymeric form of drug precipitated in the solid dispersions may get affected by the liquid solvent used.

5. Rolling method

In this method the film is prepared by preparation of a pre-mix, addition of an active and subsequent formation of a film.

- Prepare pre-mix with film forming polymer, polar solvent and other additives except a drug
- ↓
- Add pre mix to master batch feed tank
- ↓
- Fed it via a 1st metering pump and control valve to either or both of the 1st and 2nd mixer
- ↓
- Add required amount of drug to the desired mixer
- ↓
- Blend the drug with master batch pre mix to give a uniform matrix
- ↓
- Then a specific amount of uniform matrix is then fed to the pan through 2nd metering pumps.
- ↓
- The film is finally formed on the substrate and carried away via the support roller.
- ↓
- The wet film is then dried using controlled bottom drying

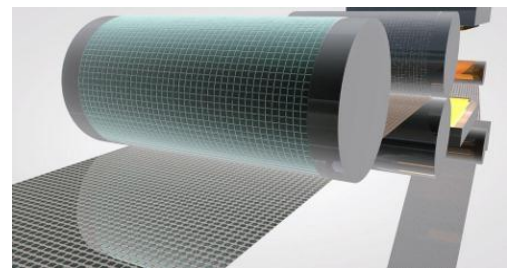


Figure 5 Rolling method

EVALUATION PARAMETERS:

- ✚ Mechanical properties
- Thickness
- Dryness/tack test
- Tensile strength
- Young's modulus
- Tear resistance
- Folding endurance

- ✚ Organoleptic test
- ✚ Surface pH test
- ✚ Swelling property
- ✚ Transparency
- ✚ Assay/content uniformity
- ✚ Disintegration test
- ✚ In-vitro dissolution test

Thickness

The thickness of film is determined by screw gauge or micrometer at different points of the films. This is essential to determine uniformity in the thickness of the film as this is directly related to the accuracy of dose in the strip^[17].

Dryness/Tack test

About eight stages of film drying process have been identified and they are set-to-touch, dust-free, tack-free (surface dry), dry-to-touch, dry-hard, dry through (dry-to-handle), dry-to-recoat and dry print-free. Although these tests are primarily used for paint films, most of the studies can be adapted intricately to evaluate pharmaceutical orally fast dissolving film. Tack is the tenacity with which the strip adheres to an accessory (a piece of paper) that has been pressed into contact with the strip. Instruments are available for this study^[18].

Tensile strength

Tensile strength is the maximum stress applied to a point at which the strip specimen breaks^[19]. It is calculated by the applied load at rupture divided by the cross-sectional area of the strip as given in the equation below

Tensile strength = Load at breakage / Strip thickness × Strip Width

Percentage elongation

When stress is applied, a strip sample stretches and this is referred to as strain. Strain is basically the deformation of strip divided by original dimension of the sample. Generally elongation of strip increases as the plasticizer^[20].

% Elongation = Increase in length × 100 / Original length

Young's Modulus

Young's modulus or elastic modulus is the measure of stiffness of strip. It is represented as the ratio of applied stress over strain in the region of elastic deformation.

Hard and brittle strips demonstrate a high tensile strength and young's modulus with small elongation.

Tear resistance

Tear resistance of plastic film or strip is a complex function of its ultimate resistance to rupture. Basically very low rate of loading 51mm (2 in)/min is employed and is designed to measure the force (that is generally found near the onset of tearing) required to tear the specimen is recorded as the tear resistance value in Newton's (or pounds-force)^[21].

Folding endurance

Folding endurance is determined by repeated folding of the strip at the same place till the strip breaks. The number of times the film is folded without breaking is computed as the folding endurance value.

Organoleptic evaluation

For evaluation of psychophysical evaluation of the product, special controlled human taste panels are used. In-vitro methods of utilizing taste sensors, specially designed apparatus and drug release by modified pharmacopoeial methods are being used for this purpose. These in-vitro taste assessment apparatus methodologies are well suited for high-throughput taste screening of oral pharmaceutical formulations^[22-23].

Morphology Studies

Scanning electron microscopy (SEM) study refers the differences between upper and lower side of the films. It also helps in determination of the distribution of API.

Near-infrared chemical imaging (NIR-CI) study helps in determining the difference between drug distributions in drug loaded films and recrystallization^[24].

Surface pH of film

Surface pH of films is determined by placing the film on the surface of 1.5% w/v agar gel followed by placing pH paper (pH range 1-11) on films. The change in the color of pH paper was observed and reported.

Swelling property

Film swelling studies is conducted using simulated saliva solution. Each film sample is weighed and placed in a pre-weighed stainless steel wire mesh. The mesh containing film sample is submerged into 15ml medium in a plastic container. Increase in the weight of the film was determined at preset time interval until a constant weight was observed^[25].

The degree of swelling was calculated using parameters

$$S.I = W_t - W_0/W_0$$

Where S.I is the swelling index, W_t is the weight of the film at time " t ", and W_0 is the weight of film at $t = 0$.

Transparency

The transparency of the films can be determined using a simple UV spectrophotometer. Cut the film samples into rectangles and placed on the internal side of the spectrophotometer cell. The determine transmittance of films at 600 nm. The transparency of the films was calculated as follows:

$$\text{Transparency} = (\log T_{600})/b = -\epsilon c$$

Where T_{600} is transmittance at 600 nm and b the film thickness (mm) and c is concentration^[26-27].

Assay/ Content uniformity

This is determined by any standard assay method described for the particular API in any of the standard pharmacopoeia. Content uniformity is determined by estimating the API content in individual strip. Limit of content uniformity is 85–115 percent.

Disintegration time

The disintegration time limit of 30 s or less for orally disintegrating tablets described in CDER guidance can be applied to fast dissolving oral strips. Although, no official guidance is available for oral fast disintegrating films strips, this may be used as a qualitative guideline for quality control test or at development stage. Pharmacopoeial disintegrating test apparatus may be used for this study. Typical disintegration time for strips is 5–30 s^[28].

Dissolution test

Dissolution testing can be performed using the standard basket or paddle apparatus. The dissolution medium will essentially be selected as per the sink conditions and highest dose of the API. Many times the dissolution test can be difficult due to tendency of the strip to float onto the dissolution medium when the paddle apparatus is employed^[29].

PACKAGING:

A variety of packaging options are available for fast dissolving films. Single packaging is mandatory for films. Which are pharmaceutical products; an aluminium pouch is the most commonly used packaging system. Applied Pharma Research

(Switzerland)-Labtec GmbH of Germany has developed the Rapid Card, a proprietary and patented packaging system which is specifically designed for the Mouth dissolving Films. The Rapid Card is exactly the same size as a credit card and holds three Mouth dissolving Films on each side. Every dose can be taken out individually, allowing the patient to carry six single, packaged doses of his medication in his wallet or purse and have it readily available when required^[30].

LIST OF SOME MARKETED PRODUCTS AVAILABLE AS MOUTH DISSOLVING FILMS:^[31]

Brand name	Manufacturer /Distributor	API (strength	Uses
Klonopin Wafers	Solvay Pharmaceutical s	Clonazepam (0.125mg, 0.25mg, 0.5mg, 1mg and 2mg.)	Treatment of Anxiety
Listerine Cool Mint Pocket Paks	Pfizer, Inc	Cool mint	Mouth Fresheners
Sudafed PE	Wolters Kluwer Health, Inc.	Phenylephrine	Relieving Congestion
Suppress®.	InnoZen®, Inc	Menthol (2.5 mg)	Cough Suppressants
Theraflu	Novartis	Dextromethorp han HBR(15 mg)	Cough Suppressant
Orajel	Del	Menthol/pectin (2mg/30mg)	Mouth ulcer
Gas-X	Novartis	Simethicone (62.5mg)	Anti Flatuating

CONCLUSION:

The present review conclude that mouth dissolving film is the most acceptable and accurate oral dosage form which bypass the hepatic first pass metabolism and so bioavailability of drug improved that will leads to better therapeutic response. There is no fear of choking of the dosage form as compared to conventional solid dosage forms (tablets and capsules) as well as no gritty mouth feel which occurs in case of ODT .Due to above mentioned characteristics it leads to better patient compliance (especially pediatric, geriatric and dysphasic).When it is placed in mouth it will quickly wet by saliva, Disintegrated within a minute and gives quick drug release which leads to quick onset of action. It is also well accepted dosage form as industry point of view due to its ease

of manufacturing (i.e less tedious method of mfg.)

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