Pinki Bhalse *et al*, International Journal of Pharmaceutical Sciences and Medicine (IJPSM),
Vol.9 Issue. 1, January- 2024, pg. 82-93

ISSN: 2519-9889
Impact Factor: 5.9

A REVIEW ON MOUTH DISSOLVING FILM

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DOI: 10.47760/ijpsm.2024.v09i01.007

ABSTRACT:- Oral route is considered as one of the most convenient route for administration of various pharmaceutical dosage forms like, tablet, capsule, syrup, suspension and emulsion. Fast Dissolving Drug Delivery systems have developed various fast disintegrating preparations like mouth dissolving film, MDT. Oral thin film are new dosage form that are prepared from hydrophilic polymer which are when placed in mouth, buccal cavity disintegrate rapidly. Mouth dissolving film is superior as compare to mouth dissolving tablet as the cost of production is low. Geriatric and pediatric patients are facing difficulty in swallowing of tablet and capsule, the oral film can bypass it, along with that it has other advantages like self-administrable, fast dissolving, rapid absorption that make it versatile dosage form. The aim of present study is to enlighten specifically different polymer along with their concentrations and applications. This study also focuses on use of plasticizer, polymer, sweetener, different methods which are used for the preparation of oral films and various evaluation parameter of the film

KEYWORDS: Mouth dissolving film, solvent casting, fast disintegration, oral mucosa, polymer

1. INTRODUCTION

Among the many delivery systems, the oral route of administration is the most practical and recommended one. Due to the lack of discomfort and variety (to accept many types of medication candidates), more than 70% of pharmaceuticals are available on the market in the form of oral drug delivery systems. Fast dissolving tablets, which were created in the early 19th century to address a variety of swallowing issues, were gradually improved upon, resulting in the creation of fast dissolving films (FDFs). The buccal region of the oral mucosa is one of the hypothesized medication delivery channels. In addition, the gastrointestinal tract's enzyme flora is optimized for drug absorption by preventing hepatic first-pass metabolism. As early as the 1970s, a fast-dissolving drug delivery device when it comes to administering medications, the

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Impact Factor: 5.9

oral mucosa is a significant channel. One of the most common methods of developing bioadherent mucosal dosage forms is using a polymer matrix. Dosage forms have grown in significance as a result of their special characteristics. They can be supplied without water.

Oral disintegrating/dissolving films or strips may be defined as drug delivery systems that rapidly release the drug by dissolving or adhering to the mucosa with saliva within a few seconds. This is due to the presence of water-soluble polymers when the film or strip is placed in the oral cavity or on the tongue. The sublingual mucosa, characterized by its thin membrane structure and high vascularization, exhibits high membrane permeability. As a result of its rapid blood supply, it offers excellent bioavailability. Enhanced systemic bioavailability is attributed to the avoidance of the first-pass effect, while improved permeability is attributed to the presence of high blood flow and lymphatic circulation. Furthermore, the oral mucosa is an exceptionally efficient and selective pathway for delivering drugs systemically due to its extensive surface area and ease of absorption. In general, orally disintegrating thin films (OTFs) are characterized by a thin and flexible polymer layer, with or without plasticizers. Their thin and flexible nature makes them less intrusive and more agreeable to patients.

Mouth Dissolving Film is also known as Fast dissolving film, Quick dissolving film, Rapid dissolving film, Oral thin film, Orally Dissolving Films. Bioavailability of drug in film dosage form is greater than the convectional dosage form.

Description of Oral Mucosa

Structure:- The uppermost layer of the oral mucosa is made up of a stratified squamous epithelium. The sub mucosa is the next inner membrane. Squamous stratified epithelium, which can be found all over the body, is comparable to the epithelium here. The epithelial cell expands in size and flatten as they travel from the basal layer to the superficial layer. Oral epithelial formation has been documented in 5–6 days. If you have a cavity, the oral mucosa will be thicker than normal. This mucosa is 500–800 microns thick, and the epithelium's makeup varies depending on where in the mouth you are. Triglycerides in the keratinized epithelium serve as a barrier. However, the non-keratinized epithelium lacks triglycerides, making it relatively impermeable. Small quantities of cholesterol, ceramides, and other polar lipids are also present. Evidence suggests that epithelial water permeability exceeds that of keratinized epithelium.

IJPSM

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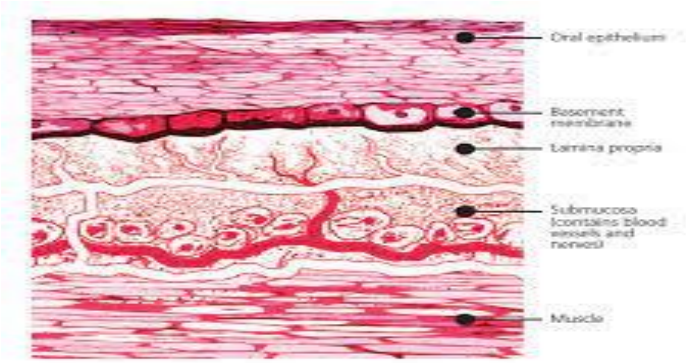

Figure 1 :- structure of oral mucosa

Absorption mechanism through oral mucosa

Absorption mechanism through the cheek mucosa: Mucosal absorption through the cheeks two main penetration channels for passively delivering drugs exist (Fig. 4). Penetrates can use any route, although depending on the drug's physicochemical qualities, one route is preferred over another. Due to the water-soluble nature of the intercellular cytoplasm, lipid medicines become less soluble. Cell membranes are lipidic, and hydrophilic substances have a low partition coefficient, which makes them difficult to flow through. The intercellular gaps become the primary barrier to lipophilic chemicals' penetration, whereas the cell membrane becomes the primary barrier to water-soluble compounds' transport. These two transport channels can be used in conjunction with each other to allow for solute penetration through the oral epithelium.

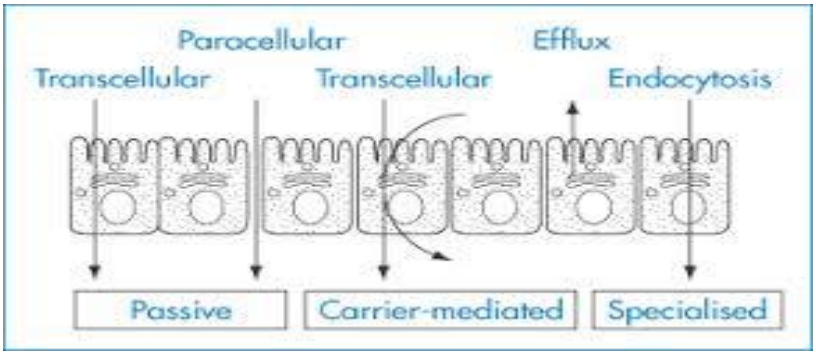

Figure 2 :- Absorption mechanism through oral mucosa

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Special features of Fast Dissolving Films

- Thin elegant film
- Available in various size and shapes
- Unconstructive
- Fast disintegration
- Rapid release
- Have an acceptable taste.
- Give a pleasing mouth feel.
- Should not leave residue in mouth
- It should be ionized in the oral cavity pH
- It should be able to penetrate the oral mucosa

Advantages:-

The administration of ODFs has numerous advantages and some of them are as follows:

- It provides more accurate dosage when compared to liquid dosage forms
- No need to measure, which is an important disadvantage in liquid dosage forms
- Leaves a good feeling in the mouth
- Provides rapid onset of effects in conditions requiring urgent intervention, for example, allergic attacks such as asthma and intraoral diseases
- Improves the absorption rate and amount of drugs

Disadvantages

- ✓ Dose uniformity is a technical challenge
- ✓ Hygroscopic in nature
- ✓ High doses cannot be incorporated
- ✓ Require special packaging for products stability and safety

General composition of MDF

Ingredients	Concentration %
API	01-25
Plasticizer	00–20
Flavoring agents	02–10
Sweetening agents	03–06
Hydrophilic polymer / film former	40–50
Saliva stimulating agents	02–06

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Color	01
Surface active agent	Quantity sufficient

Table 01 :- ingredients composition

Material used in the preparation of MDF

Mouth dissolving film is a thin film with an area of 2-8 cm2 containing an active ingredient. The immediate dissolution, in water or saliva is reached through a special matrix from water-soluble polymers. Components of mouth dissolving film includes-

1. **Active Pharmaceutical agents:-** Active pharmaceutical substance can be from any class of pharmaceutically active substances that can be administered orally or through the buccal mucosa. It includes antiulcers, antiasthmatics, antitussive, antihistaminic, antiepileptic, expectorants, antianginal etc. For the effective formulation, dose of drug should be in mgs (less than 20 mg/day).

The ideal characteristics of a drug to be selected are as follows-

- ✓ The drug should have pleasant taste.
- ✓ The drug to be incorporated should have low dose generally less than 20mg.
- ✓ The drugs with smaller and moderate molecular weight should be preferable.
- ✓ The drug has should be stable and soluble in water as well as in saliva.
- ✓ It should be partially unionized at the pH of oral cavity.
- ✓ It should have the ability to permeate oral mucosal tissue.

2. **Water soluble polymers:** The water-soluble polymers achieve rapid disintegration, good mouth feel and mechanical properties to the films. Some of the water soluble polymers used as film former are HPMC , Carboxymethylcellulose, Polyvinylpyrollidone PVP K-90, Pectin, Gelatin, Sodium alginate, Hdroxypropylcellulose, Polyvinyl alcohol, Maltodextrins and Eudragit-RD10. Polymerized rosin is a novel film forming polymer.

3. **Plasticizers:** Formulation considerations have been reported as important factors affecting mechanical properties of films. The mechanical properties such as tensile strength and elongation to the films have also been improved by the addition of plasticizers. Variation in their concentration may affect these properties. The commonly used plasticizers are glycerol, di-butylpthallate and polyethylene glycols etc

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4. **Saliva Stimulating Agent:** More saliva production helps in the faster disintegration of the fast dissolving film formulations. So the formulations should contain acids which are used in the preparation of food as salivary stimulants. Citric acid, malic acid, lactic acid, ascorbic acid and tartaric acid are the few examples of salivary stimulants, citric acid being the most preferred amongst them.

5. **Flavoring agents:** Flavoring agents can be selected from the synthetic flavor oils, oleo resins, extract derived from various parts of the plants like leaves, fruits and flowers. Flavors can be used alone or in the combination. Any flavor can be added such as essential oils or water soluble extracts of menthol, intense mints such as peppermint, sweet mint, spearmint, wintergreen, cinnamon, clove, sour fruit flavor such as lemon, orange or sweet confectionary flavors such as vanillin, chocolate ,or fruit essence like apple , raspberry, cherry and pineapple. The amount of flavor needed to mask the taste depends on the flavor type and its strength.

6. **Sweetening agents:** Sweeteners have become the important part of pharmaceutical products intended to be disintegrated or dissolved in the oral cavity. The classical sources of sweetener are sucrose, dextrose, fructose, glucose, liquid glucose and iso-maltose. The artificial sweeteners have gained more popularity in pharmaceutical preparations. Saccharin, cyclamate and aspartame are the first generation of the artificial sweeteners .

7. **Coloring agents:** FD&C approved coloring agents are used (not exceeding concentration levels of 1 percent; w/w) in the manufacturing of orally fast dissolving films, eg. Titanium dioxide.

8. **Surfactants:** Surfactants act as solubilizing or wetting or dispersing agent in formulation so the film gets dissolved within seconds and releases active agent quickly. Some of the commonly used surfactants are sodium lauryl sulfate, benzalkonium chloride, tweens etc. One of the most important surfactant is polaxamer 407 that is used as solubilizing, wetting and dispersing agent **Methods of preparation:-** One or more of the following process can be used to manufacture the mouth dissolving films

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

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Solvent Casting Method:- Films can be prepared using this method, the ingredients which are water-soluble are taken inaccurate quantity and are mixed well in beaker to make a clear solution. In other beaker containing suitable solvent add accurately weighed API and other ingredients. Then, both beakers containing formulation ingredients are mixed with stirring and finally cast into the Petri plate then allow it to dry for some period and cut the film in to the appropriate size.

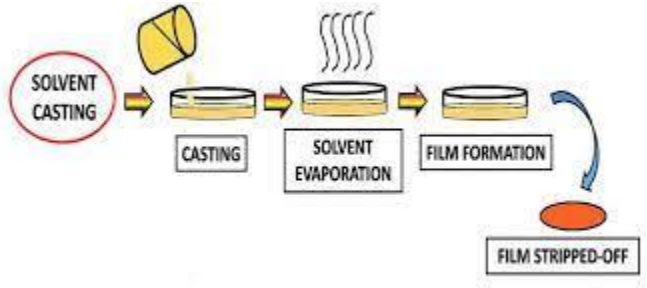

Figure 3 :- Solvent Casting Method

Hot Melt Extrusion:- In this method, all substances required to make films are taken together into its solid powder form. Then, this mixture is melted using extruder which having heaters into it and the melt is shaped into film. It is then cooled, cut, and packaged. This method has some advantages over the other methods such as minimum product wastage and better content uniformity.

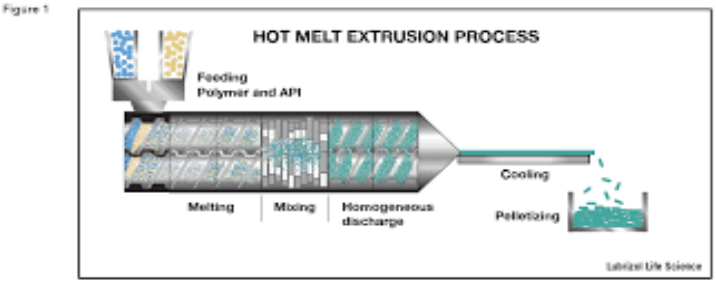

Figure 4 :- Hot Melt Extrusion

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Semisolid Casting Method:- If films formulation contains some acid insoluble polymers, then this technique is appropriate . The examples of such polymers are cellulose acetate butyrate cellulose acetate phthalate. In general, film former and acid insol. polymer used in ratio of 1:4.

Rolling Method:- API containing suspension or solution is taken on a carrier and allowed to move onto it. Then keep to drying for some period and finally cut in appropriate dimensions.

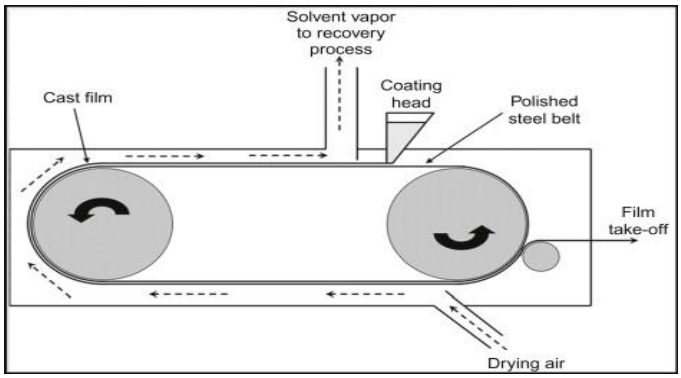

Figure 5 :- Rolling Method

Solid Dispersion Extrusion:- When some immiscible substances are extruded with API in this methodology is followed. Solid dispersions are prepared, and then these are designed into thin films using dies.

3. Evaluation Mouth Dissolving Film:

Morphology study

The morphology of the films can be observed using scanning electron microscopic (SEM) at definite magnification.

Dryness/ Tack test

Dryness is the property to measure the solvent or water content present in the film whereas tack is the tenacity with which the film adheres to any piece of paper which is pressed into contact with the strip. Eight stages of film drying process have been recognized i.e. set-to-touch, dust free, tack-free, dry-to-touch, dry-hard, dry through; dry-to-recoat & dry print free.

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Weight variations

Weight variation can be determined by individually weighing 10 randomly selected films and calculating the average weight of the films. The average weight should not deviate significantly from the weight variation limit.

Thickness

The thickness of film is determined by screw gauge or micrometer at different points of the films.

Drug content

A film of 2 cm2 size is cut and put into volumetric flask containing solvent. This is then shaken in a mechanical shaker for 2hrs to get a homogeneous solution and filtered. The drug content is determined by UV spectrophotometer after appropriate dilution.

Tensile strength

Tensile strength of films can be determined using an apparatus fabricated in laboratory. A small film (2cm2) is cut and fixed to assembly. The weight required to break the film is noted and simultaneously film elongation is measured with the help of pointer mounted on the assembly.
Tensile strength = break force /ab (1+ ΔL/L)
Where a, b and L are width, thickness, and length of the strip, and ΔL is the elongation at break.

Percentage elongation

It can be determined by noting the distance travelled by pointer before break of the film on the graph paper.
% Elongation = Increase in length/original length X 100.

Percentage moisture loss

To determine percentage moisture loss films of area 2 cm2 are cut and weighed accurately. After weighing, the films were kept in desiccators containing fused anhydrous calcium chloride. The films should be kept for 72 hrs in the desiccator. After 72 hrs, they are taken out and again weighed and the percentage moisture loss of films was measured by using the formula:
Percent moisture loss = (Initial weight - Final weight)/Initial weight × 100
The percentage moisture loss studies are done to determine physical stability and integrity of the film.

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Folding endurance

It involves determination of the folding capacity of the films when subjected to frequent extreme condition of folding. It is determined by repeatedly folding the film at same place until it broke**.**

Surface pH of film

The pH value of a film is usually determined by putting the prepared film in Petri dish and subsequently film is made wet by using distilled water and noting pH by touching the film surface with a pH meter electrode. Determination of surface pH is vital as acidic or basic pH is liable to cause oral mucosal irritation.

Disintegration time:

Disintegration apparatus mentioned in official pharmacopoeias is used for determining the disintegration time of a film. Normally, the disintegration time is the function of composition of film as it varies with the formulation and generally ranges from 5 to 30 s. Mostly, the USP disintegration apparatus is used for this test. There are no official guidelines available for determining disintegration time of orally fast disintegrating films. There are two methods for determining disintegration time of film.

- **Slide frame method**: A drop of distilled water is poured onto the film clamped into slide frames placed on Petri dish. Time taken by the film to dissolves noted.
- **Petri dish method:** A film is placed into 2 ml distilled water taken in Petri dish. Time taken by the film to dissolve completely is considered as the disintegrating.

4. CONCLUSIONS

The MDF formulations are one of the cutting-edge strategies in the pharmacy industry, and in the future, they may turn into one of the promising dosage forms for treating illnesses or disorders. In comparison to standard formulations, these innovative formulations have better patient acceptance and compliance as well as greater safety and effectiveness. MDF offers a host of benefits and enhances therapeutic response. MDF are of great importance during the emergency cases such as allergic reactions and asthmatic attacks whenever immediate onset of action is desired. Today MDF are a proven and accepted technology for the systemic delivery of APIs for over the counter (OTC) medications and in the early to mid- development stages for prescription drugs.

ISSN: 2519-9889
Impact Factor: 5.9

5. AKNOWLEDGEMENT: The author is thankful to the management of Swami Vivekanand College of Pharmacy, Indore. For providing necessary facilities to carry out the research work and heartily thankful to my Co-Guide and guide for providing all the support and encouragement to carry out this studies.

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