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MOUTH DISSOLVING FILMS: A REVOLUTIONARY PLATFORM FOR RAPID DRUG DELIVERY

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ABSTRACT

Oral drug delivery is the most preferred route for medication due to its convenience, cost-effectiveness, and ease of administration. However, approximately 28% of the population experience difficulty swallowing conventional solid dosage forms, which affects patient compliance. Fast dissolving oral films (FDOFs), also known as mouth dissolving films (MDFs), offer an innovative solution by disintegrating quickly in the oral cavity without the need for water, thereby enhancing patient adherence. These ultra-thin films (50–150 µm) are composed of hydrophilic polymers, plasticizers, sweeteners, flavoring agents, saliva stimulants, and colorants, with active pharmaceutical ingredients (APIs) incorporated up to 30% w/w. The films are designed to dissolve within seconds, facilitating rapid absorption through the highly vascularized oral mucosa, offering high bioavailability and bypassing first-pass hepatic metabolism. Various manufacturing techniques include solvent casting, hot- melt extrusion, solid dispersion, semisolid casting, and rolling methods. The choice of polymer and excipients plays a critical role in the film's mechanical strength, disintegration time, and drug release profile. While MDFs offer advantages such as pain-free administration, portability, and rapid onset of action, limitations include moisture sensitivity, dosage uniformity, and incompatibility with high-dose or mucosa-irritating drugs. Overall, mouth dissolving films present a promising alternative dosage form, particularly for pediatric, geriatric, and non-cooperative patients.

INTRODUCTION

Oral drug delivery stands as the predominant method for administering medications to the general populace. Its popularity stems from its ease of use, enabling self- medication, precise dosing, pain avoidance, non-invasiveness, adaptability, patient adherence, and cost-effectiveness for pharmaceutical companies.[1] Approximately 28% of the population encounter frequent issues swallowing medications, impacting patient compliance.[1] Fast dissolving delivery systems provide a solution to these challenges.[2] Among the dosage forms developed forfacilitating ease of medication, the orally disintegrating system have been the favourite of product development scientists. Due to their thin size and flexibility, they are found to be gaining attention.[3] These are drug delivery systems that they are quickly releasing the drug by dissolving or adhering in the mucosa with saliva within a few seconds due to it contains water soluble polymers when it placed in the mouth cavity or on the tongue. The sublingual mucosa has high membrane permeability due to its thin membrane structure and high vascularization. Due to this rapid blood supply, it offers very good bioavailability.[4] Absorption of drug by oral mucosa into systemic circulation is an attractive approach because it is highly vascularized and hence highly permeable.[4] A thin film that readily dissolves in the oral cavity is commonly referred as mouth dissolving film or orodispersible film. Although, oral films initially appeared as innovative breath freshening formulations, it rapidly evolved to give response to different market needs, namely an easy-to-carry and easy-to-swallow drug delivery system.[5] Fast dissolving oral films are ultra-thin film 50-150 µm, having size of postage stamp, which dissolves within a few seconds in the oral cavity after being in contact with the saliva leading to fast absorption and instant bioavailability of the drugs.[6] Fast disintegrating thin films having an area ranging from 5 to 20 cm^2 in which drug is incorporated in the form of matrix using hydrophilic polymer. Active pharmaceutical ingredient can be incorporated up to 1 to 30% w/w of the active pharmaceutical ingredient along with other excipients i.e., plasticizers, colorants, sweeteners, taste masking agents, etc.[7]

Composition of Mouth dissolving film

Table: Composition of Mouth dissolving film.

Sr. No.	Ingredients	Quantity (%)
1	API(Drug)	01-25
2	Hydrophilic polymer/Film former	40-50
3	Plasticizer	00-20
4	Flavoring agent	02-10
5	Sweetening agent	03-10
6	Saliva stimulating agents	02-06
7	Color	01

The ideal characteristics of an API to be selected in MDF[8]

- Taste of API - pleasant.
- The API dose - up to 40 mg.
- The molecular weight of API preferably smaller.
- API should be stable in the fluid present in mouth.
- API should be moderately unionized in oral cavity fluid.
- Permeability through mucosal tissue.

Hydrophilic polymer/film formers[9]

The oral films are essentially complex polymeric matrices that may be used efficiently as drug release platforms. The successful development of an MDF is a function of justified selection and concentration of polymers as the mechanical strength of films is strongly associated with these factors. These polymeric matrices may be composed by several components to achieve well-designed drug-delivery platforms, but usually hydrophilic polymers are its main core. Polymers are the backbone of film formulations and are responsible for the strength of the film. The concentration of used polymers is also important factor while developing an MDF. Properties of polymer play a significant role in disintegration time of film. Generally, polymer concentration used in preparing ODFs is around 45% w/w of total weight of dry thin strip, however, it can be increased up to 60–65% w/w to attain the film of desired attributes and characteristics. Several frequently used water-soluble polymers/film formers are hydroxypropyl methylcellulose, methylcellulose, pullulan, carboxymethyl cellulose, polyvinyl pyrrolidone, etc.

Ideal properties of hydrophilic polymers[9]

- Polymer should be not irritant to oral mucosa, inert, and non-toxic.
- Should not delay or extend the disintegration time of film.
- Polymer should possess good mechanical properties.
- Polymer should be affordable.

Plasticizer: It avoids breakability of films[10]

The addition of a plasticizer is often necessary to obtain flexible, non-brittle film. They tend to reduce the brittleness of the strip by lowering glass transition temperature [Tg] of polymers thereby improving the flexibility of the films. The choice of plasticizer will depend on upon its compatibility with the polymer and nature of the solvent employed in the casting of the strip. Plasticizers may affect solubility of the API and drug absorption. High concentrations of plasticizers may cause an impaired moisture resistance, resulting in stability problems or tacky films. Some excipients are such as polyethylene glycol, phthalate, citrate derivatives, and castor oil used as plasticizer in formulation of film.

Sweetening agents[11]

Artificial or natural sweetening agents can be used in MDFs. Examples of some sweetening agents are sucrose, fructose, aspartame, sorbitol, acesulfame-K, and sucralose, etc.

Saliva stimulating agents[12]

The purpose of using saliva stimulating agents is to increase the rate of production of saliva that would aid in the faster disintegration of the rapid dissolving strip formulations. Generally, acids which are used in the preparation of food can be utilized as salivary stimulants. e.g., Citric acid, malic acid, lactic acid, ascorbic acid, and tartaric acid. These agents are used alone or in combination between 2 to 6%w/w of weight of the strip.

Flavouring agents[13]

Flavouring agents are necessary for taste and odour masking of the drug and to increase the appeal of the film. Also, the choice of flavours depends on age, taste and liking of the people. Younger people like fruit punch, raspberry etc. while the geriatric patient prefer orange, lemon, and mint flavour.

Colouring agents[14]

F&D approved colours are used to give aesthetic appearance to films. Colouring agent like titanium dioxide is used in making films.

Ideal characteristics of mouth dissolving films[15,16]

- It should be thin, flexible, and easy to handle.
- The films should be transportable, not sticky and keep a plane form without rolling up.
- It should be easy to administer.
- The film should offer agreeable taste and a satisfying mouthfeel.
- The disintegration time should be as rapid as possible.
- Film surface should be smooth and uniform.
- It should remain physically and chemically stable during its shelf life.

- It should be cost effective and ease of commercial production.
- It should have low sensitivity to environmental/atmospheric conditions such as humidity and temp.
- Size of a unit film should not be too bulky that it will affect the patient's compliance.

Advantages of mouth dissolving films[16]

- It can be taken without water.
- It disintegrate/dissolve quickly in mouth.
- Flexible and light in weight.
- It is appropriate to all age group.
- Appropriate for patients who are ill or uncooperative.
- Films remain stable for longer time as it is a solid dosage form until its administration.
- The drug absorbed directly from film formulation into the blood, so it avoids undergoing first- pass hepatic metabolism which seen in conventional dosage forms.
- Rapid disintegration of film gives quick onset of action; thus, it enriches safety and efficacy profile of active pharmaceutical ingredient (API)
- Pain-free self-administration is possible.

Disadvantages of mouth dissolving films[16]

- Drugs which requires to take in high doses cannot be incorporated into films.
- Maintaining dosage uniformity is challenging task for the films.
- Moisture sensitivity.
- Require special packaging.
- API's which are unstable at pH of the saliva cannot be designed in the form of film.
- API's which can cause irritation of the oral mucosa cannot be administered.

Methods Used in preparation of MDFs[17,18,19]

The methods for manufacturing oral thin films include:

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

1) Solvent casting method

Polymers that are water soluble are dissolved to create a homogeneous solution. Drugs and other water-soluble ingredients are given a little amount of water to dissolve in. Continuous stirring is used to combine the two solutions. Applying a vacuum removes air bubbles that have become entrapped. The produced solution is cast onto Petri dish and kept for drying. After complete drying it is cut into specific size for evaluation.

ADVANTAGES

- Better uniformity in thickness and better clarity.
- Films possess fine gloss and free from defects.
- Films possess more plasticity and better physical properties.
- Solvent-casting is ideal for manufacturing films containing heat-sensitive

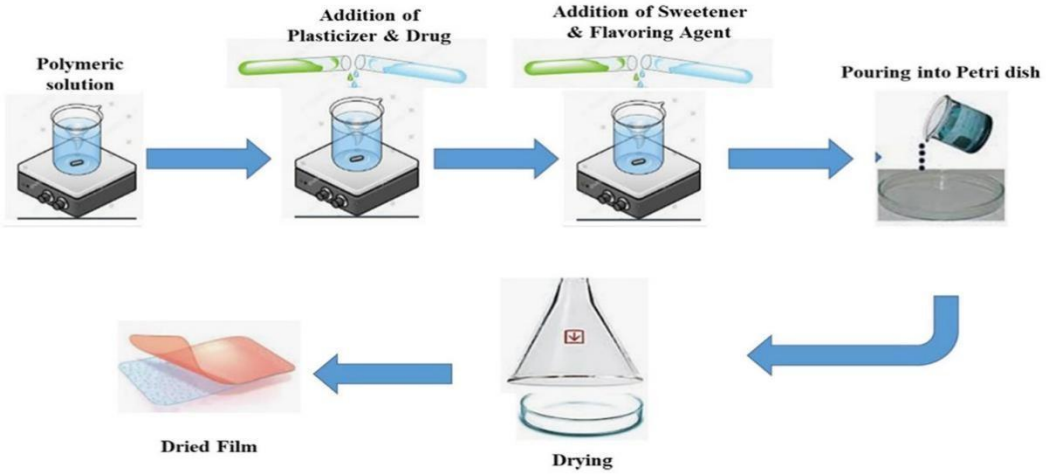

Figure 1: Solvent casting method.

2) Semisolid casting method

When acid-insoluble polymers are required for the film preparation, this approach is preferred. Gel mass is cast into the films or ribbons using the semisolid casting technique, which uses heat-controlled drums. Gel mass is created by mixing a film- forming solution with an acid-insoluble polymer solution in sodium hydroxide or ammonium hydroxide. The polymers cellulose acetate phthalate and cellulose acetate butyrate are insoluble in acids. The proportion of 1:4 acid insoluble polymer to film- forming polymer should be taken.

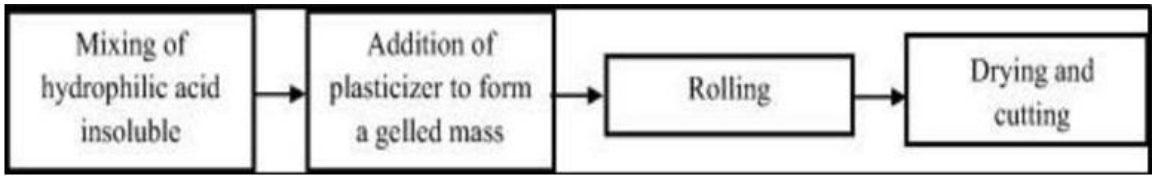

Figure 2: Flow chart of semisolid casting method.

3) Hot-melt extrusion technique

In the hot melt extrusion procedure, the drug and carriers are first combined in solid form. After that, dry granular material is poured to the extruder. Processing of the granules inside the extruder barrel for about 3–4 minutes, the speed of screw is set at 15 rpm. The recommended processing temperatures are 650C, 800C, 1150C, and 1000C for zones one through three zone. The extrudate was subsequently compressed insight cylindrical calendar to produce a film.

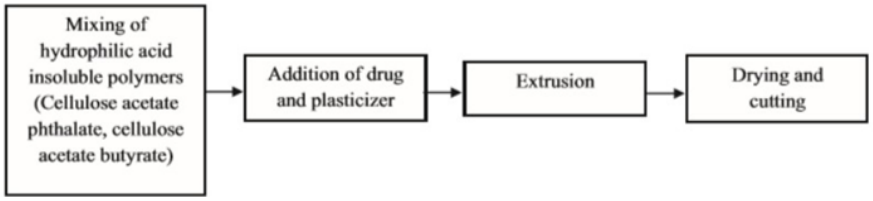

Figure 3: Flow chart of hot melt extrusion technique.

4) Solid dispersion method

In this approach, more than one drug candidate is dispersed in a non-reactive carrier in a conventional dosage form while amorphous hydrophilic polymers are present. To create a solution, Active pharmaceutical ingredient is dissolved in an appropriate solvent. A solution is incorporated to the melt of an appropriate polymer (PEG) beneath 70° C without extracting the liquid solvent. Finally, solid dispersion is formed into films using dies.

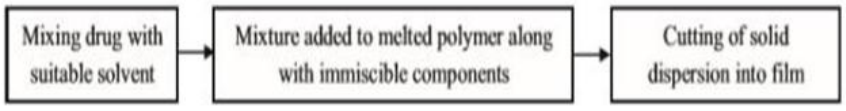

Figure 4: Flow chart of solid dispersion method.

5) Rolling method

The rolling approach involves preparing a drug solution or suspension with a film- forming polymer before putting it through the roller. Specific rheological considerations should be made for the suspension. Most of the solvent is composed of water and an alcohol-water mixture. After the film has dried on the rollers, it is cut into the desired shapes and sizes.

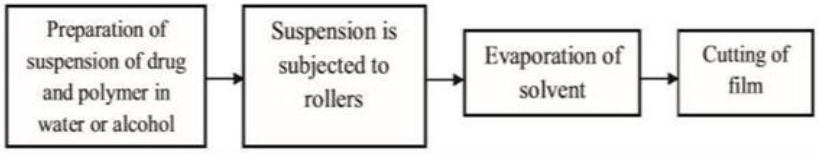

Figure 5: Flow chart of rolling method.

Evaluation Parameter of mouth dissolving films[20,21,22,23,24,25,26]

1.) Thickness

Thickness was measured by micrometer screw gauge at three different locations, and the average of three readings is then calculated.

2.) Folding endurance

It was measured by continuing the number of folds, until it breaks. The folding endurance value is determined by counting how many times the film was folded without breaking. The ability of a film to withstand folding and measure its brittleness is called folding endurance. It was performed three times and average of readings was taken.

3.) Surface pH

The test film was put in Petri dish, moistened with 10 ml of distilled water, and allowed to stand for 30 seconds. After one minute of equilibration, the pH meter's electrode was in contact with the formulation's surface, the pH was recorded. For each formulation, an average of three determinations was made.

4.) Tensile strength
The highest stress that can be applied to a strip specimen before it breaks is its tensile strength. As shown in equation below, it is calculated by dividing the applied load at rupture by the strip's cross-sectional area. Tensile strength was measured using fabricated tension meter.
Load at failure × 100 / Strip thickness × strip width =Tensile strength

5.) Uniformity of drug content
A 2×2 cm^2 film was taken into a 10 ml volumetric flask and dissolved in 5ml of methanol and then final volume was made up with methanol. Samples were collected and then suitably diluted with buffer solution and the absorbance was measured at 286 nm. The estimations were carried out in triplicate.

6.) Disintegration time
The disintegration time is the time when a film breaks. A 2×2 cm^2 film was placed in a beaker with 25 ml of phosphate buffer pH 6.8 and stirred gently, and time is noted when film begins to break apart. The estimations were carried out in triplicate.

7.) In vitro dissolution studies
Dissolution studies: As the MDFs are not official in any pharmacopoeia the following dissolution methods were used for testing the in vitro drug release profiles from MDFs.

Beaker Stirring Method (Method I)
The in vitro dissolution studies were conducted using 150 ml glass beaker with 125 ml of 6.8 phosphate buffer dissolution medium. Film (2×2 cm^2) was placed on one side of the beaker using double-sided tape. Medium was stirred at a speed of 200 rpm using magnetic stirrer bar. 5ml samples were withdrawn at different time intervals and every time replaced with 5ml of fresh dissolution medium. The samples were analysed by measuring UV absorbance at 286nm. The dissolution experiments were conducted in triplicate.

Dissolution Apparatus 5 (Method II)
The in vitro dissolution studies were conducted using 600mL of artificial saliva as dissolution medium with modified type 5 dissolution apparatus. A temperature of 37º C and 50 rpm were used. Each film with dimension (4×4 cm2) was placed on a watch glass covered with nylon wire mesh. The watch glass was then dropped into dissolution flask. 5mL samples were withdrawn at 10, 20, 30, 40, 50, 60, 80, 100, 120 sec time intervals and every time replaced with 5mL of fresh dissolution medium. The samples were analyzed by measuring absorbance at 223nm. The dissolution experiments were conducted in triplicate.

Figure 6: Dissolution setup for beaker method and dissolution apparatus method.

8.) Weight variation
Weight variation of the film 2x2 cm2 film was cut at five better places in the caste film. Each film strip weight was measured and average weight film was calculated.

9.) Swelling Index
To determine the swelling index of the film, pH 6.8 simulated salivary fluid was used. A film sample with a surface area of 4 cm^2 was weighed and placed on pre-weighed stainless steel wire mesh. The mesh containing the film sample was then submerged

in 50 ml of pH 6.8 SSF in a mortar. The stainless steel mesh was periodically removed from the film and any excess moisture was gently removed by using absorbent tissue before re-weighing the mesh to determine the degree of swelling. The calculation for the degree of swelling was based on the following formula:

$SI = (Wt – W0)/W0$
Where, SI = swelling index
Wt = weight of the film at time t W0 = weight of the film at t=0.

10.) Stability testing
For stability testing, oral wafers were stored under controlled conditions of 25°C/60% RH and 40°C/75% RH over a period of 12 months, in accordance with ICH guidelines. During storage, the oral wafers should be assessed for their morphological properties, mass, thickness and reduction of film thickness, tensile properties, water content, and dissolution behavior. Additionally, pH and content during storage should be monitored.

CONCLUSION
Mouth dissolving films (MDFs) represent a novel and

patient-friendly drug delivery system offering rapid onset of action, improved bioavailability, and enhanced patient compliance, especially among pediatric, geriatric, and dysphagic populations. These ultra-thin, flexible films dissolve quickly in the oral cavity without the need for water, bypassing hepatic first-pass metabolism. Their formulation involves carefully selected components like hydrophilic polymers, plasticizers, sweeteners, and saliva- stimulating agents, ensuring mechanical strength, taste masking, and fast disintegration. Various preparation methods and evaluation parameters are used to ensure quality and consistency. Despite certain limitations, MDFs hold significant potential for future pharmaceutical innovations and therapeutic advancements.

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