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A Review on Mouth Dissolving Film

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Abstract

As an alternative to fast-dissolving tablets, fast-dissolving films have garnered attention recently. The films may be consumed without the need for extra liquid since they are made to disintegrate in a matter of seconds when they come into touch with a wet surface, like the tongue. This simplicity of use boosts patient compliance and offers a marketing benefit. Since the medication enters the bloodstream immediately, first pass effects and gastrointestinal tract degradation are prevented. Because of these features, this formulation is most well-liked and accepted by older and pediatric patients as well as those who are afraid of choking. In the US market, over-the-counter films are marketed for pain relief and motion sickness. Transdermal medication delivery technology is being used by several businesses to create thin film forms.

Recent developments in the formulation of fast-dissolving buccal films and associated assessment criteria are collected in this study.

Key-words: Mouth dissolving, Films, Applications

Introduction

The oral route is currently the most popular method of drug delivery because it has so many benefits over other forms of drug administration. However, oral drug delivery systems still need to make significant advancements because of certain drawbacks specific to a patient class that includes pediatric, geriatric, and dysphagia patients who have trouble swallowing or chewing solid dosage forms due to a variety of medical conditions. Because of the tablet-like structure of their doses, there is still a chance of choking even with quickly dissolving pills. One of the key factors influencing treatment regimen compliance in pediatric oral medication formulations is palatability, among other things(Naziya, K.,*et.al*.,2013).A unique drug delivery method that offers enhanced bioavailability, a quick beginning of action, and avoids first-pass metabolism is quick dissolving oral films. The permeability of the oral mucosa is 4-1000 times greater than that of the skin. The purpose of creating such a dosage form was to address the issue of children and elderly people having trouble swallowing. Along with various excipients including sweetener, flavor, color, binder, stabilizing agent, saliva stimulating agent, preservative, etc., it contains an active medicinal component and a water soluble polymer. Water soluble polymers such as Pullulan, Gelatin, Sodium Alginate, Pectin, Rosin, Starch, Chitosan, and cellulose ether are used to aid in quick dissolution in the buccal cavity or on the tongue (Pratapwar, A.S., *et.al*.,2023).A fast dissolving oral film, which is an ultra-thin film composed of hydrophilic polymers and dissolves quickly on the tongue or base of the buccal canal, is a unique drug delivery device for the oral delivery of medications.

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It's an ultrathin (50–150 microns thick) postage stamp-sized strip containing an active medication and extra excipients created with trans dermal patch technology(Chaudhary, H., *et.al.,*2013).

Mouth Dissolving Film

Mouth dissolving film (MDF) is applied to the tongue, it dissolves and/or dissolves quickly, releasing the active ingredient from the dosage form and instantaneously hydrating the mouth. MDFs are very mild formulations that are frequently made with hydrophilic polymers, which enable rapid dissolution in saliva. For elderly and juvenile patients who have difficulty swallowing conventional dosage forms, such as fast-disintegrating tablets and capsules, these systems were created in the latter part of the 1970s as an alternative (Shimoda, H., *et.al*., 2009). A unique characteristic of mouth-dispersing films (Sharma, P.K., *et.al*., 2017).

1. Elegant thin film.
2. Unconstructive.
3. It comes in various shapes and sizes.
4. Rapid disintegration
5. Rapid onset of action.
6. Provide a pleasant mouth feel.
7. Have a pleasant taste.

Composition of Mouth Dissolving film-

The film that encloses the active ingredient has a surface area of 2 to 8 cm and dissolves in the mouth. In water or saliva, the special water soluble polymer matrix dissolves fast. The medication can be used in single doses up to 40 mg. Ingredients in oral dissolving films include(Rathore, A.S.., *et.al*., 2009).

a) Active Pharmaceutical Agents:

A pharmacologically active substance is any class of chemical substances that are pharmaceutically active and can be taken orally or buccally. Drugs falling into different categories include antiemetic, neuroleptics, cardiovascular agents, analgesics, antiallergic, antiepileptic, anxiolytics, sedatives, hypnotics, diuretics, anti-bacterial agents, medications for erectile dysfunction, anti-alzheimers, expectorants, and antitussives(Visser, J.C., *et.al*., 2015).

Here are the desirable characteristics of a drug to choose from:

- The drug should have pleasant taste.
- The drug should be used in small amounts, usually less than 40mg.
- Drugs with lower and more moderate molecular weights should be recommended.
- Drugs must be reliable and soluble in water and saliva.
- It should bind slightly when it reaches the pH of your mouth.
- It must be able to penetrate the tissue of the oral mucosa.

b) Water soluble polymers:

Films using water soluble polymers have quick disintegration, a smooth mouthfeel, and mechanical qualities.The rate of polymer disintegration is decreased by raising the molecular weight of the polymer film basis(Hariprasanna, R.C., *et.al*., 2010).

c) Plasticizers:

By utilizing plasticizer, it was observed that the mechanical characteristics of the film were significantly influenced by the formulation parameters.Plasticizers have also improved the mechanical properties of the films, such as elongation and tensile strength. These attributes could be impacted by variations in their concentration(Bukka, R., *et.al.,*2012).

d) Saliva stimulating agent:

Increased saliva production aids in the fast dissolving film compositions' quick disintegration. As a result, food preparation acids ought to be incorporated into formulations as salivary stimulants(Vasconcelos, T., *et.al.,* 2007).

e) Flavoring agents:

select flavoring agents from artificial aromatic oils, oleoresins, and plant extracts including leaves, fruits, and flowers. flavors that can be had separately or combined. It is possible to add any flavor, such as water soluble essential oils or menthol extracts, powerful mints like peppermint, sweetmint, wintergreen, cinnamon, and cloves, fruit flavors like lemon and orange, chocolate, or fruit essences like apple, raspberry, cherry, and pineapple. The type and strength of the perfume determine how much is needed to cover up the flavor(Siddiqui, M.N., *et.al*., 2011).

f) Sweetening agents:

Sweeteners are now a crucial component of pharmaceutical preparations meant to dissolve or disintegrate in the mouth. The traditional sweeteners are glucose, fructose, sucrose, dextrose, and liquid glucose. The use of artificial

sweeteners in pharmacological formulations has grown in popularity.

The first generation of artificial sweeteners includes aspartame, cyclamate, and saccharin. The second generation includes acesulfame ±K, sucralose, alitame, and neotame(Khatoon, N., *et.al.,* 2013).

g) Surfactants:

Surfactants facilitate the fast dissolution of films and the release of active chemicals in formulations by acting as solubilizers, wetting agents, or dispersants. Benzalkonium chloride, tweens, sodium lauryl sulfate, and others are examples of surfactants that are frequently employed(Sievens-Figueroa, L., *et.al.,* 2012).

Table 1: Typical composition of a mouth dissolving film(Chaudhary, H., *et.al*.,2013**).**

Ingredient	Quantity	Use (Examples)
Drug	5-30 %w/w	Drug should be in low dose
Water soluble polymer	45% w/w	Film forming capability (Methyl cellulose A3, A6, A15, Polyvinyl alcohol, Maltodextrin Polyvinyl pyrollidon K-90, HPMC E3, E5, E6, E15, K3,Pectin, gelatin, Sodium alginate, Hydroxy propyl cellulose, Pullulan,)
Plastisizers	0-20 %w/w	Increases the flexibility and reduces the brittleness of film (Glycerol, Polyethylene gycol, Butylphthalide, triethyl citrate)
Surfactant	Q.S.	Used as solubilizing and wetting agents (Tween 80, Sodium lauryl sulphate)
Sweetning agent	3-6 %w/w	Increasing the palatability of the film (Aspartame, Saccharin, Cyclamate, Alitame and Neotame, Acesulfame-K)
Saliva Stimulating agent	2-6 %w/w	Increases saliva stimulation to facilitate film rupture (Citric acid, Malic acid)
Colors, Flavors	Up to 1% w/w	Silicon dioxide (pigment) is used as coloring agents. Fruity flavors like cocoa, apple, raspberry are widely used.

Advantages (Choudhary, D.R., *et.at.,* 2012**).**

i. Oral Thin Films improve the drug's bioavailability, resulting in a faster onset of effect.
ii. The amount of medicine that has to be loaded is less when using oral thin films since they avoid the first pass effect, in contrast to conventional dose forms.
iii. Oral thin films offer more stability than liquid dose forms.
iv. Oral thin films do not need specific packaging since the medication is included into an abuse-resistant matrix.
v. Oral thin films have less brittleness than tablets.
vi. Oral thin films have been shown to have less negative effects.
vii. mouth thin films dissolve and disintegrate more quickly because of the mouth cavity's larger surface area.
viii. Simple to transport.
ix. can be used to provide medications in a non-invasive way, such as by delivering opioids via buccal or sublingual delivery, which lessens the need for invasive procedures like parenteral injections.

Clinical Advantages

i. Because oral thin films are administered orally, administering them is simple because this method uses the oral channel.
ii. There's less chance of choking or suffocating in older and pediatric patients.
iii. For those who experience nausea, oral thin films are a preferable option.
iv. It is not necessary to ingest oral thin films with water.

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Market Advantages

i. Pharmaceutical firms with patents about to expire may boost their income cycles with this innovative medication delivery technology.
ii. OTFs discourage the abuse, manipulation, and misuse associated with certain prescription pharmaceuticals as they contain precisely the right quantity of substance in each film.
iii. Currently in its infancy, the oral thin film industry is restricted to a few over-the-counter medications that are sold in the EU, US, and Japan. Therefore, there is a lot of opportunity for research and business development to create new, less expensive technologies and to synthesize medications that haven't been put into OTFs before.

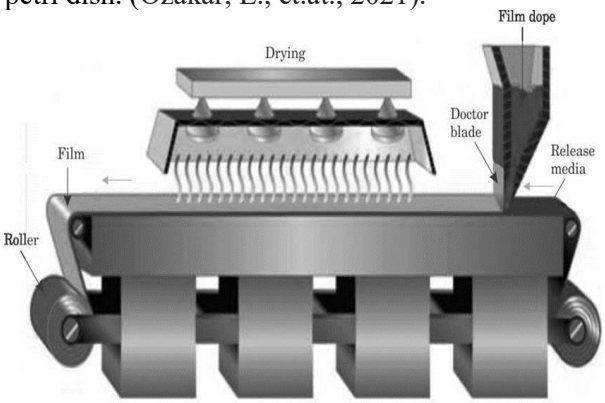
Disadvantages (Cilurzo, F., *et.at*.,2010**)**.

i. The drying time needed for the OTFs is a major production challenge that manufacturers face. The manufacturing pace is lowered because drying the films at room temperature takes a day since thermolabile medications prevent the use of hot air ovens and high temperatures.
ii. The films tend to lose stability in settings with high relative humidity because they are very hygroscopic.
iii. It is challenging to obtain dose consistency in oral thin films.
iv. It is not possible to synthesize medications into thin films that irritate the oral mucosa or are unstable at the buccal pH.
v. The dissolving time is impacted;therefore, co-administration of many medications continues to be difficult.3.
vi. Only medications with tiny dosage requirements can be given.5.
vii. Drugs with bitter tastes require taste masking.
viii. OTFs must be packaged specifically to keep water out of them.1.

Method of preparation:

A. Solvent casting method:

The medicine is introduced after the excipients have been dissolved in water and a water-soluble polymer has been added. After that, the mixture was agitated to create a uniform solution. The liquid is dried after it has been poured into the petri dish. (Özakar, E., et.at., 2021).



B. Semi-solid casting:

In this procedure, a solution of a film-forming polymer (such as cellulose acetate butyrate) is combined with a homogenous, viscous solution of an acid-insoluble polymer. It works well with movies that haven't had any post-sonication processing. After drying, the film should be between 0.015 and 0.05 inches thick. A 1:4 ratio should be maintained between the acid-insoluble and film-forming polymers(Ghuge, V.D.,*et.al*.,2012).

Hot melt extrusion:

Prior to hot melt extrusion, a solid mixture of the medication and carrier is prepared. After the liquid has melted using the extruder heater, this is utilized to mold the melt into a fim. Among the benefits of hot extrusion are: - Less operation units improved consistency of the material, a dry processing method(Yasmeen, B.R.,*et.al*.,2021).

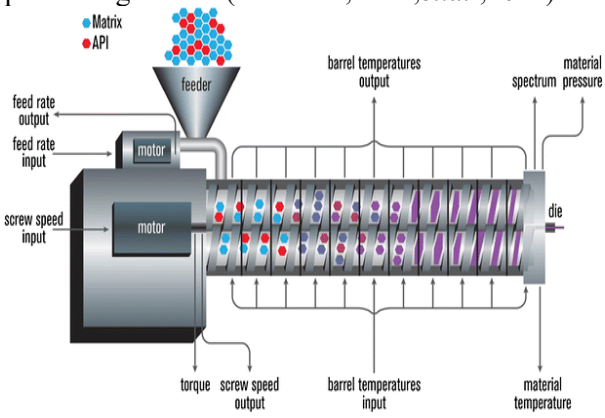


Figure 3:- Hot Melt Extrusion

Solid Dispersion Extrusion Method: -

Domperidone was effectively dissolved into a solid using beta-cyclodextrin, PEG400, and

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HPMC E15. The solid dispersion extrusion method was then used to produce the films(Visht, S.,*et.al.*, 2012).

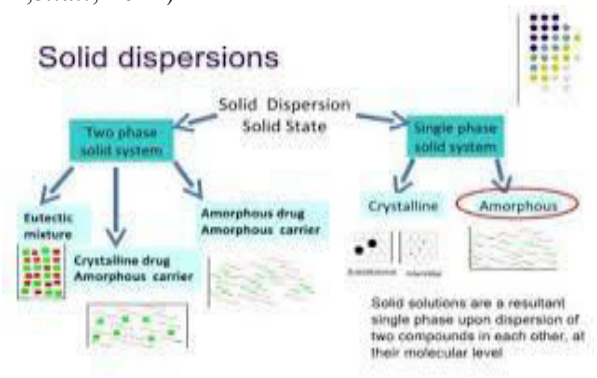

Figure 4: - Solid dispersion method

Rolling Method: -

Using the rolling method, a drug-containing solution or suspension is rolled onto a carrier.

Mixtures of water and alcohol make up the majority of solvents. The film is trimmed to the appropriate size and form once it has dried on the drum. Using a high shear processor, dissolve the other components, including the active substance, in a tiny amount of aqueous solvent.

It is dissolved in water soluble hydrocolloids to create a homogenous viscous solution**.**

Evaluation of mouth dissolving films: -

The following factors were taken into consideration while evaluating mouth dissolving film: surface pH, assay, stability testing, tensile strength, thickness test, folding endurances, and swelling index**:**

Thickness test

A micrometer screw gauge placed at several key points can be used to measure the thickness of the mouth dissolving films. This is necessary to keep the film's thickness consistent since it has a direct bearing on the dose's current in the strip (Dahiya, M.,*et.al*.,2011).

Weight variation of the film

Five superior locations were sliced into the 2x2 cm2 film for the caste. The weight of each film strip was measured, and the average film weight was determined(Maske, R.R.,*et.al.,* 2022).

3. Tensile strength

The greatest applied tension at which a film breaks is known as its tensile strength. This test is used to evaluate a film's mechanical strength. The following equation can be used to calculate it by dividing the applied load at rupture by the strip cross-sectional area (Patil, M.P.,*et.al.,* 2021).

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

Folding endurance

The folding endurance of a film indicates its brittleness. The film specimen (2 x 2 cm2) is folded repeatedly at the same spot until it breaks or a visible fracture is observed in order to assess the endurance value. The amount of times the film can fold is the measured folding endurance value. Be folded without shattering or showing any obvious fissures(Someshwar, K.,*et.al.,* 2011).

Surface pH

The surface pH of the mouth dissolving film is estimated to assess the risk of any inside adverse effects. Since acidic or alkaline pH might irritate the oral mucosa, it is important to keep the surface pH as close to neutral as possible.[33] For this, a mixed pH electrode is used. With the aid of water, the mouth film is slightly moist. The pH is determined by placing the electrode on the surface of the mouth film. Six films of each formulation were used in this investigation, and the mean ± S.D. were determined(Saini, P.,*et.al.,*2011).

Assay/Drug Content and Content Uniformity

Can consult any pharmacopoeia pertinent to a particular active ingredient to verify its uniformity and assay/drug content. This entails calculating the API content for each unique strip. Between 85% and 115% is the permissible range for content uniformity. In compliance with accepted protocols(Gurpreet, S.,*et.al*., 2011).

Dissolution test

The dissolution test can be conducted using a standard basket or paddle apparatus, as described in relevant pharmacopoeia, in simulated saliva solution or pH 6.4 phosphate buffer at a temperature of 37±0.5°C. At regular time intervals, samples are taken out and analyzed through a UV-Visible spectrophotometer(Sharma, R*., et.al*., 2017).

Disintegration time

World Journal of Pharmaceutical Research To determine the disintegration time of orally mouth dissolving films, a U.S.P. apparatus is required. The disintegration time of 30 seconds or less, as described in C.D.E.R. guidance for orally disintegrating tablets, can be applied to mouth dissolving strips. Disintegration time may vary

depending on the formulation, but typically ranges from 5 to 30 seconds. However, there is no official guidance available for oral mouth dissolving films (Kothawade, S.N.,*et.al*., 2010).

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 cm2 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(Visser, J.C.,*et.al*., 2015). 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.

Stability testing

In compliance with ICH recommendations, oral wafers were kept for a duration of 12 months at regulated temperatures of 25°C/60% RH and 40°C/75% RH for stability testing. The oral wafers should be evaluated for their morphological characteristics, mass, and water content, tensile characteristics, dissolving behavior, and thickness and reduction of the film. Monitoring of the pH and content during storage is also recommended (Zoabi, A., *et.al.,*2021).

Conclusions

oral administration is easy to administer and has a cheap cost of therapy, it is the most popular route for administering therapeutic chemicals through an orally dissolving membrane. This helps to enhance patient compliance. The oral dissolving film is seldom discussed or examined in the literature, but it appears to be the best dose form for usage in young children, particularly in patients who are younger and older. They blend the superior application of a liquid with the enhanced durability of solid dosage forms. Oral films that dissolve in the mouth provide a number of benefits over traditional dosing forms.Therefore, they play a crucial role in emergency situations including allergic reactions and attacks or any situation when prompt response is needed. More significantly, mouth dissolving films are convenient dose forms for travel in situations where a patient or individual may not be able to carry water. Therefore, mouth dissolving film becomes a special, sophisticated, useful, and necessary dosage form.

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