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Review Article

# Herbal Mouth Dissolving Strip: A Review

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## ABSTRACT

A new drug administration system called Fast Dissolving oral film uses hydrophilic polymers to produce an ultra-thin film that dissolves on speeches or buccal depression bottom or top. It's a postage stamp-sized, ultra-thin strip (50-150 microns thick) that contains an active component and fresh excipients and was created using transdermal patch technology. The film dissolves on the lingo in a matter of seconds after operation, precluding first-pass metabolism and maybe boosting the medicine's bioavailability. Greater faces area availability causes presto salivary stuffiness, which causes decomposition and breakdown in oral depression in a matter of seconds. Mouth Dissolving Films (MDFs) represent a slice-edge advancement in medicine delivery, offering rapid-fire onset of action, enhanced patient convenience, and better remedial efficacy. Their capability to dissolve incontinently in slaver without the need of water makes them particularly to salutary for individualities with dysphagia, pediatric and senior cases, and those taking immediate medicine action. Good taste, great stability, and ease of running are rates that any perfect film should retain. An explanation of the numerous expression ways and their assessments is given in the current review operation of mouth-dispersing films or mouth dissolving films and film compositions.

## INTRODUCTION

A new drug administration system called "presto dissolving oral film" uses hydrophilic polymer to produce an ultra-thin film that dissolves snappily on the lingo's or the buccal depression bottom or top. It's a postage-sized, ultrathin strip (50-150 microns thick) that contains an active component and fresh excipients and was created using transdermal patch technology.

These Herbal Mouth Dissolving Strip increases the demand in cases, and it is effectible and herbal drug. These strips help cases who have issues in swallowing. Recent developments in technology have presented feasible lozenge druthers from oral routes for pediatrics, senior, bedridden squeamish or noncompliant cases. Buccal medicine delivery has recently come an important route of medicine administration. Mouth dissolving film, a new medicine delivery system for the oral delivery of

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medicines, was developed grounded on the technology of the transdermal patch. The delivery system consists of a veritable thin oral strip, which is simply placed on the case's lingo or any oral mucosal towel, in continently wet by slaver the film fleetly hydrates and adheres onto the point of operation. On the other hand, oral depression is veritably well permitted by cases, the mucosa is passable with a strong blood force, it's flexible and recovers snappily from stress or damage and the absence of nearly all Langerhans cells makes the oral mucosa tolerant to implicit allergens. In addition, oral trans, mucosal medicine administration prevents presystemic elimination in the GI tract and first-pass impact. Recent inventions have expanded OFDF capabilities, including the integration of nanotechnology to increase the solubility and bioavailability of weakly-answerable drugs; for case, nanonization and cyclodextrin addition complexes are employed to enhance dissolution. Recently, Guava and Betel leaves were two traditional medicinal shops known for their antimicrobial, antioxidant, anti-inflammatory, and oral hygiene-prompting parcels making excellent campaigners for herbal MDS phrasings. In Guava leaves have capability to reduce goo inflammation and anti-inflammatory effect. It helps with dental care, gingivitis, and bad breath. And Betel leaves enhance oral sanctification, antiseptic, and stimulating parcels. It also provides affable aroma and taste masking on the strip. Antioxidant Neutralizes free revolutionaries and protects oral mucosa. Anti-inflammatory soothes oral vexation and promotes mending, sweet and deodorizing acts as natural mouth fresheners.

**The concept of oral dissolving film:**

- At thin film makes up distribution fashion.
- When the film puts on lingo, it dissolves veritably snappily in matter of alternate.
- Cases who are suffering from dysphasia mean delicate to swallow and without water it's veritably helpful without using water. Not having to worry about like with fast-dissolving tablets.

**Advantages: -**

- Bypassing metabolism in liver Fast Dissolving Oral Film allows for direct immersion into systemic rotation largely vascularized oral mucosa for faster effect.
- Ease to administration and reduce the demand of water and enhance patient adherence to drug.
- For herbal with first-pass metabolism, Herbal Mouth Dissolving Strip can ameliorate their bioavability.
- Herbal Mouth Dissolving Strip is in small, feather light, and makes them easy to carry and administer anytime, anywhere.
- Herbal Mouth Dissolving Oral Strip reduce the threat of choking associated with swallowing solid lozenge forms, which is a major concern for pediatric and senior cases.
- Formulation Herbal Mouth Dissolving Strip, give precise and accurate cure ion each strip.

**Disadvantages: -**

- Medicines that irritate mucosa cannot be given by these routes of administration.
- Medicines that come unstable at buccal pH cannot be given.
- A drug with low cure demand can only be given.

- Taste masking is necessary because the maturity of specifics have a bitter taste.

**Table 1: Percentage of various ingredients used in formulation of Mouth Dissolving Oral Film**

| Sr. | Ingredient | Percentage Amount |
|---|---|---|
| 1 | Drug | 1-30% |
| 2 | Water | 40-60% |
| 3 | Plasticizer | 10-20% |
| 4 | Saliva Stimulant Agent | 2-6% |
| 5 | Surfactant | 0.1-2% |
| 6 | Sweetening Agent | 3-6% |

**Table 2:**

| Sr. | Requirement | Scientific Name | Family | Phytochemical Constituent | Pharmacological Activities | Medicinal/ Traditional Uses |
|---|---|---|---|---|---|---|
| 1. | Peepal Leaves | Ficus religiosa | Moraceae (Mulberry family) | Tannins, Flavonoids (quercetin), β-sitosterol, Vitamin K, Methyl oleanolate, Glucose, Furanocoumarins, Leucocyanidin. | Antioxidants, Antidiabetic, Anti-asthmatic, Antimicrobial, Wound healing | Leaves: Treat asthma, diabetes, constipation, and wounds. Bark & Latex: It is used for toothache, skin disorders, diarrhea, and dysentery. Powder/ Extract: Anti-inflammatory and wound healing. |
| 2. | Betel Leaves | Piper betle | Piperaceae | Chavicol, Eugenol, Phenols, Tannins, Alkaloids, Flavonoids, Saponins | Gastroprotective, Antidiabetic, Immunomodulatory. | Leaves: Carminative, antiseptic, anti-inflammatory, expectorant. Juice: For cough, bronchitis, indigestion. Paste: For headache, wounds, rheumatic pain. |
| | Guava leaf | *Psidium guajava* | Myrtaceae | Flavonoids (Quercetin, Kaempferol), Tannins, Saponins, Carotenoids, Vitamin C, Essential oils, Terpenoids, Polyphenols | Antidiarrheal, Antioxidant, Antidiabetic, Antimicrobial, Anti-inflammatory. | Leaves: Treat diarrhoea, dysentery, gastroenteritis, toothache, diabetes, wounds, sore throat. Tea/ Extract: Antidiabetic, antidiarrheal, weight management. |
| | Neem leaf | Azadirachta indica | Meliaceae | Azadirachtin, Nimbin, Nimbidin, | Antibacterial, Antiviral, Antifungal, | Leaves: Blood purifier, antimalarial, |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | Gedunin, Salannin, Quercetin, Flavonoids, Tannins | Antimalarial, Antidiabetic, Immunostimulant. | antidiabetic, skin disease treatment (eczema, psoriasis, acne). Juice/ Paste: Used for wounds, ulcers, dental care. Oil/ Seed Extract: Insecticide, pesticide. |

**Composition of the system:**

Mouth dissolving film is a thin film with an area of 5- 20 $cm^2$ containing an active ingredient. Water-soluble polymers form a unique matrix that allows for instant disintegration in water or saliva. Up to 30 mg of the medication can be added in a single dose.

**Active Pharmaceutical agents:**

For oral thin film, stronger, less bitter, and highly lipophilic medications should be used. Mouth-dissolving films can be made from a variety of pharmacological classes, such as NSAIDs (Valdecoxib, Meloxicam), expectorants, antitussives, anti-ulcers (Omeprazole), and antiasthmatic (Salbutamol sulphate). To make a film, roughly 5% to 30% w/w of the API can be used. The introduction of high-dose medications is restricted by the size of the dosage form. (8)

These are natural extract can be used as API.

- Betel Leaves (Piper betel)
- Antibacterial & antifungal: Inhibits Streptoco ccus mutants, Candida albican
- Antioxidant: Neutralizes free radicals and protects oral mucosa.
- Anti-inflammatory: Soothes ora irritation and promotes healing.
- Aromatic & deodorizing: Acts as a natural mouth freshener.
- Guava Leaves (Psidium guajava)

**Uses:**

- Antimicrobial: Effective against Streptococcus mutans and Lactobacillus acidophilus (major oral pathogens).
- Anti-inflammatory & antioxidant: Reduces gum inflammation and oxidative stress.
- Astringent: Tightens gums and reduces bleeding.
- Wound healing: Promotes tissue repair in mouth ulcers.

**Film Forming Polymer**

Polymers are the most important ingredients of fat dissolving film. Robustness of film depend on the amount and type of polymer. The polymer should tough enough so that there won't be any damage while handling or during transportation. Generally, 45% of polymer is used which is based on total weight of dry film. Mainly hydrophilic polymer are used in oral strip as they rapidly

disintegrate in oral cavity as they come in contact saliva, the polymer can be use alone or combine to obtain the desire film properties. The physiochemical characteristic of polymer select for the film formulation play a vital role in determine the result disintegrate time of film. (1,2)

**Ideal Properties of Film Forming Polymer (1,2)**

- It should be non-toxic and non-irritant.
- It must be hydrophilic properties.
- It should have demonstrate excellent film for ming capabilities.
- It should exhibit good wetting and spread abi lity properties.
- It should be easily accessible and not be very over costly.
- It should have low molecular weight.
- It should have adequate shelf life. It must be t asteless and colorless.
- It should not induce any secondary infection in oral mucosa.

**Plasticizers:**

Formulation plasticizer variables (their application has been noted as a significant determinant of the mechanical characteristics of films. The inclusion of plasticizers has also enhanced the films' mechanical qualities, including tensile strength and elongation. These characteristics could be impacted by changes in their concentration. Among the most widely used plasticizers are polyethylene glycols, glycerol, and di-butylphthalide. (11)

**Saliva Stimulating Agent:**

Sliva stimulating agent help in increase the saliva in mouth quick breakdown of fast dissolving composition. A few examples of salivary stimulants are citric acid, malic acid, lactic acid, ascorbic acid, and tartaric acid: citric acid being the most usable of these. As a result, the formulations might contain acids that stimulate saliva production as food is being prepared. (12)

**Super disintegrants:**

Super disintegrants, when added to Oral Film formulations, provide rapid disintegration because of the combined effect of both water absorption and swelling. Super disintegrants accelerate disintegration and dissolution by providing absorption and swelling owing to their excessive water absorption. Powerful interaction with saliva is very important for disintegration.

**Surfactants:**

Surfactants are use as solubilising or wetting or dispersing agent so that the film is getting dissolved within seconds and release active agent immediately. Benzalkonium chloride, tweens, polyethylene glycol, sodium lauryl sulphate, and others are examples of surfactants that are frequently utilized. One of the most significant surfactants for solubilizing, wetting, and dispersing materials is poloxamer 407. (13)

**Sweetening Agent:**

These days, sweeteners are an integral ingredient of both nutraceutical and pharmaceutical products. Sweeteners liquefy in the tongue. The following are some sources of sweeteners: glucose, fructose, liquid glucose, maltose, and dextrose. Fructose is commonly used as a sweetener since it is sweeter than sorbitol and mannitol. They also have a cooling effect and a pleasant tongue sensation. First generation artificial sweeteners include

saccharin, cyclamate, and aspartame; second generation artificial sweeteners include acesulfame-K, sucralose, alitame, and neotame. (14)

**Colouring agents:**

Titanium dioxide and other FD & C-approved colouring ants are utilized in the production of oral fast-dissolving films at concentrations no more than 1% w/w. (15)

**Methods Of Preparation of Herbal Mouth Dissolving Film:**

The Mouth dissolving film can be produced using one or a combination of the following methods:

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

**Solvent casting:**

In solvent casting method water soluble polymer are dissolved in water and the drug along with other Excipients is dissolved in suitable solvent then both the solutions are mixed and stirred and finally casted into the Petri plate and dried. Water-soluble polymers are then introduced. Finally, the solution is poured into the petri dish and allowed to dry. (16)

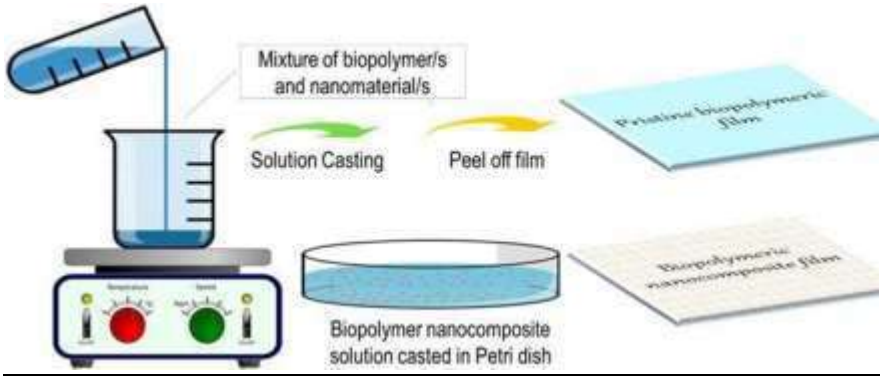


**Fig 1:**

**Semisolid casting:**

This approach creates a uniform viscous solution by mixing a solution of an acid insoluble polymer (such as cellulose acetate butyrate and cellulose acetate phthalate) with a solution of a water-soluble film producing polymer. It is applied on untreated casting film after sonication. The film should have a thickness of 0.015 inches after drying. The film acid insoluble polymer to film-forming ratio needs to be 1:4. (17)

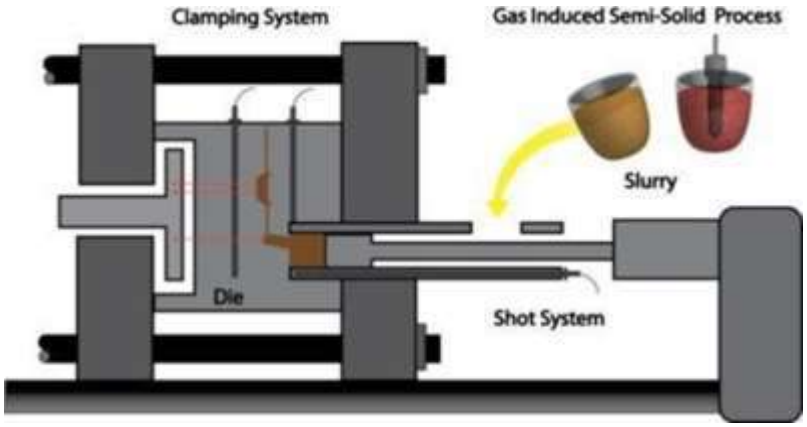


**Fig 2:**

**Solid dispersion extrusion:**

Immiscible components are first extruded with the medicine to create a solid dispersion, which is subsequently formed into films using dies.

**Hot-melt extrusion:**

Granular material is created by mixing the carpeting with carrier. Following drying, these granules are added to the extruder, the screw speed should roughly 15 rpm. The ideal processing temperature is 100 degrees Celsius. To create a film, the extrudate is subsequently squeezed into a cylindrical calendar. (18)

**Rolling Method:**

Water and alcohol-water mixtures are the main solvents used in the rolling process, which involves creating a medication suspension or solution with a film-forming polymer and applying it to the roller. The film is then dried on the rollers and separated into the proper sizes and shapes, with special attention paid to the suspension's or solution's rheology. (19)

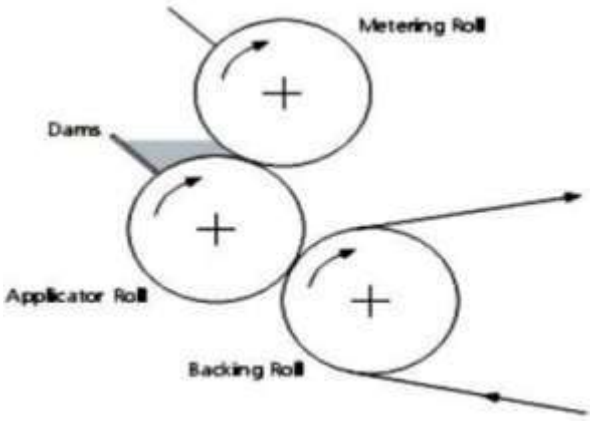


**Fig 3:**

**Evaluation Parameters**

- **Appearance:**

All the produced films can be checked to see if they seem clear or opaque. Although surface characteristics are often assessed visually, instruments like as microscopes can also be used. (20)

- **Thickness:**

The thickness of the resulting coating can be measured using micrometre screw gauges at several strategic locations. To determine the mean thickness, measurements should be taken at five different locations on the film: the centre and each of the four corners. Maintaining uniformity in the film's thickness is essential because it directly affects the strip's dosage accuracy. (21)

- **Weight Variation:**

Weighing each movie separately and calculating the average weights is required. The next step is to deduct the average weight of the films from each one separately. An inefficient mode of administration and pharmaceutical content are suggested by a notable weight variation. (22)

- **Contact Angle:**

The contact angle can be measured at room temperature using the Goniometer (AB Lorentz and Wetter, Germany). This can be done by applying a droplet of distilled water to the surface of a dry film. Ten seconds after the water droplets are deposited, images of them are taken with a digital camera. The contact angle can be measured on both sides of the descent, and an average is calculated. (23)

- **Transparency:**

A simple UV spectrophotometer can be used to evaluate the films' transparency. Place the film into the spectrophotometer cell after cutting it into a rectangle. Determine the transparency of the film at 600 nm. The following T600 = transmittance at 600 nm b = film thickness (mm) C = concentration (24)

- **Moisture Content:**

The degree of moisture affects a film's brittleness and friability. Essentially, the components of the product regulate how much moisture is present in a certain film. In general, the amount of moisture in the film can be ascertained using the weighing method, moisture content measurement apparatus, or Karl Fisher titration method. The amount of moisture in a pre-weighed film of a certain size is shown by the weight difference that results from heating the film to a constant weight, usually between 100 and 120 °C. Use the following formula to determine the moisture content: (25)

% Moisture content = [(Initial weight – Final weight) × 100 / Initial weight].

The moisture content in an ideal film should be < 5%. (26)

## CONCLUSION:

Oral fast disintegrating film (OFDFs) is a novel approach in the oral drug delivery system that fulfills an unmet need in a wide range of populations, including children, paralyzed, nauseated, and non-compliant patients. There is no need for water, measurement and after disintegration; the drug gets absorbed in oral mucosa providing quick onset of action. Their ability to dissolve instantly in saliva without the need for water makes them particularly beneficial for individuals with dysphagia, pediatric and geriatric patients, and those requiring immediate drug action. With continuous innovations in polymer science, nanotechnology, and bio adhesive formulations, MDFs are evolving beyond traditional oral medications, enabling precise dosing, controlled drug release, and Incorporation of novel active ingredients. Future developments in personalized medicine and smart film technologies will further expand their potential, revolutionizing the way medications are administered.

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