



# A Review on Fast Dissolving Oral Strip

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## **Abstract:**

As an alternative to fast-dissolving strips, fast-dissolving films have gained popularity recently. The films can be consumed without the need for extra liquid because they are made to disintegrate in a matter of seconds when they come into touch with a wet surface, like the tongue. This ease of use boosts patient compliance and gives a commercial edge. Since the medication enters the bloodstream directly, first pass effects and gastrointestinal tract degradation are prevented. Because of these features, this formulation is most well-liked and acceptable by older and pediatric patients as well as those who are afraid of choking. In the US market, over-the-counter pain relievers and motion sickness films are marketed. Transdermal drug delivery technology is being used by numerous businesses to create thin film formats. Recent developments on the formulation of fast-dissolving buccal films and their assessment criteria are covered in this study.

## **Keywords:**

Mouth Dissolving Strip, Superdisintegration, Taste Masking, Patented Technology.

## Introduction:

An enhanced substitute for the conventional oral drug administration approach is an oral film delivery. When taken as directed, the oral film melts and provides a solid drug dose form. It is not necessary to chew or take the oral film with water. Drug bioavailability is increased by oral films because the active ingredients are formulated for oral administration and can avoid the liver's first-pass metabolism. Because of its numerous and varied advantages, rapid or quick dissolving oral thin film is a medication delivery method that is growing in popularity. Children and the elderly are thought to benefit most from oral films because they dissolve quickly in saliva and don't require water to ingest. Amorphous polymers included in mouth dissolving films help the medications dissolve more quickly. The aforementioned factors increase patient compliance and encourage pharmaceutical manufacturers to spend money on FDFs instead of their previous products.

Some patients, particularly those in the elderly and pediatric demographics, have trouble swallowing hard dose forms and run the danger of choking. Numerous fast-dissolving drug delivery methods have been developed to provide comfort to these individuals. The three main technologies used in the production of fast-dissolving drug delivery systems are freeze drying, wet granulation, and direct compression. Certain dissolving techniques, such high concentrations of effervescent or disintegrating chemicals, are employed by some, causing the dosages to dissolve quickly in the mouth. Due to its convenience of use, self-medication potential, and ability to prevent pain compared to the parenteral route, the oral route of administration is still widely accepted and accounts for 50–60% of all drug formulations. The oral route continues to be the most popular way to administer therapeutic agents despite amazing advancements in drug delivery because of its precise dosage, affordable therapy, self-medication, non-invasive nature, and convenience of administration, which promotes high patient compliance.

However, some elderly patients may find it inconvenient or impractical to take traditional tablets and capsules with a glass of water due to changes in a number of physiological and neurological conditions associated with aging, such as hand tremors, difficulty swallowing (dysphagia), deterioration in eyesight, hearing, memory, and risk of choking, in addition to taste and smell changes. Other patient groups, including youngsters, the mentally challenged, bedridden patients, and recalcitrant patients, also have substantial administration issues when using solid dose forms. Children may experience difficulties with swallowing due to immature muscles and neurological systems. Furthermore, the usefulness of typical pills or capsules taken orally is limited in patients who are traveling with limited or no access to water.

The majority of pharmaceutical researchers are mostly focused on the oral dosage form since it provides a rapid drug release and has a quick onset of action. Mouth Dissolving Films (MDFs) are a cutting-edge and remarkable medication administration technology that improves patient adherence. MDFs systematically administer the medication by the buccal or sublingual routes in addition to providing local action. MDFs are a

thin film that, when placed on the tongue, quickly becomes moistened from saliva. The film subsequently dissolves and disintegrates in a matter of seconds, allowing the medicine to be absorbed. MDFs have an advantage over capsules and other dosage forms since the film dissolves quickly and exhibits an immediate commencement of action. MDFs prevent first pass metabolism, decrease the time to onset, and enhance bioavailability. The most sophisticated type of drug delivery is fast dissolving because it enhances flexibility, disintegration, and dissolution while also improving medication efficacy (27).

Hydroxymethyl cellulose, pullulan, pectin, HPMC, and other water-soluble hydrocolloids; an efficient amount of the active ingredient; and additional excipients, such as flavorings, plasticizers, preservatives, and saliva-stirring agents. Angiotensin-converting enzyme (ACE) inhibitors, such as ramipril, can be used to treat diabetes and high-risk vascular disease. The research studies offered a considerable advantage in reducing numerous CVD outcomes in these patients. In terms of lowering cardiovascular events, heart attacks, heart failure, and heart stroke, the results were encouraging. Among ACE inhibitors, ramipril has a strong history of enhancing cardiovascular outcomes, making it a preferred medication. In persons receiving Ramipril treatment, the chance of death was lowered. Because of its anti-hypertensive properties, which are used to treat high blood pressure, heart failure, diabetic renal disease, and to avoid cardiovascular events, ramipril is preferred in this study.(28)

### **Special Features of Oral Strip:**

- Available in various size and forms.
- Inconspicuous.
- Excellent mucoadhesion.
- Fast disintegration and Rapid release.

### **Ideal Characteristics of a Suitable Drug Candidate:**

- The drug should taste well.
- The medication to be added should only be 40 mg in low doses.
- It is better to use medications with smaller and moderate molecular weights.
- The medication must to be well-stabilized and soluble in both water and saliva.
- At the pH of the oral cavity, it ought to be partially unionized.
- It should have the ability to infiltrate oral mucosal tissue.

### **Benefits of Oral Strip:**

- More surface area encourages faster breakdown and disintegration in the oral cavity.
- Because oral films are more flexible than ODTs, they are less brittle. As a result, handling, storing, and transportation are made easier.
- Accuracy in the dosage that is given.
- There isn't a choke risk.
- Good mouth feel.
- A rise in patient adherence.(3)

**Table 1: formulation of mouth dissolving film -**

Sr. No.	Particulars	Category
1.	Ticagrelor	API
2.	HPMC(Hydroxyl Propyl Methyl Cellulose)	Polymer
3.	Dextrin	Diluent, Viscosity Enhancer
4.	Guar Gum	Binder
5.	Sugar	Sweetening Agent
6.	Amaranth	Coloring Agent
7.	Propylene Glycol	Anti Microbial Preservative
8.	Citric acid (mg)	Saliva Stimulating agent
9.	Water	Filling Agent
10.	Vanilla	Flavoring Agent

1.

**Active Pharmaceutical Ingredients:**

An oral strip's typical composition contains 5–30% w/w of active pharmaceutical ingredients. For oral strips, tiny dosage molecules are typically chosen. The micronization of active pharmaceutical ingredients (APIs) is highly beneficial in enhancing the strip's solubility, resulting in rapid absorption and immediate therapeutic effect. The bitter taste of the medication will be covered up using taste-masking chemicals. For oral strips, highly lipophilic medications are the best option. The oral strips contain a variety of medication types, including NSAIDS (paracetamol, meloxicam, valdecoxib), antiemetic, antiallergic, antiasthmatics (salbutamol sulfate), antitussives, expectorants, and antihistaminics. (9)

**2. Water-soluble polymer:**

Polymer concentration and selection have a significant impact on the film's development and mechanical strength. To improve the mechanical strength and change the characteristics of the film, these polymers can be employed separately or in combination with other polymers. An oral strip is developed using 45% w/w of the polymer's concentration. To get the appropriate qualities, however, it can be raised up to 60-65% w/w.<sup>15</sup> The following characteristics of a polymer should be present in the thin strip formulation.(10).

**Ideal properties of water-soluble polymers:**

- Nontoxic.
- Nonirritant.
- Should not affect the disintegration time of oral strip.

- Should have a moderate half-life.
- Should have good spread ability.

### **3. Plasticizer:** :

In the creation of oral strips, plasticizers are crucial. The film's tensile and mechanical strengths will increase with the addition of plasticizers. The kind of solvent utilized and how well it works with the polymer choose which plasticizer to use. Plasticizers that are frequently employed include castor oil, phthalate derivatives, low molecular weight polyethylene glycol, glycerol, and citrate derivatives such as tributyl, triethyl, and acetyl citrate. It is customary to employ a plasticizer concentration of 0–20% w/w to help prevent the strip from peeling, cracking, and splitting. (11 )

### **4. Surfactant:** :

Surfactants, such as sodium lauryl sulfate, benzalkonium chloride, and tween, are frequently employed to improve the solubility and wetting ability of films in order to facilitate rapid dissolution and medication release within a minute. The most significant surfactant for solubilizing, wetting, and dispersing agents is poloxamer 407 (12).

### **5. Sweetening agent:**

Sweeteners are now a crucial component of pharmaceutical products in order to cover up the bitter taste of the medication. Sweeteners, both natural and artificial, are employed. Both artificial and natural sweeteners, such as soluble saccharin salts, saccharin, cyclamate salts, acesulfame-K, aspartame, and neotame, as well as mono-, dis-, and polysaccharides like galactose, glucose, mannose, fructose, xylose, ribose, dextrose, maltose, sucrose, sugar, sorbitol, xylitol, mannitol, and sucrose, glucose, dextrose, fructose, glucose, liquid glucose, and isomaltose, are examples of natural sweeteners. Artificial sweeteners are becoming more and more common in medicinal formulations these days. The sweetening power of neotame and alitame is greater than 2000–8000 times that of sucrose.(13)

### **6. Saliva stimulating agent:**

Because saliva stimulating chemicals increase the rate of saliva production, they aid in the oral strips' quick breakdown. Among the salivary stimulants are tartaric acid, ascorbic acid, lactic acid, malic acid, and citric acid. Salivary stimulants with a 2-6% w/w concentration are used either alone or in combination in the oral strip. One of the better stimulants utilized in the oral strip is citric acid (14).

## 7. Coloring and flavoring agents :

Natural coloring compounds with FDC approval are frequently utilized. The coloring agent's concentration should not exceed 1% w/w. In order to enhance flavor and draw in pediatric patients, flavoring chemicals are typically added to the formulation. Various flavors, such as water-soluble menthol extract or essential oils can be employed (peppermint, sweet mint). (14)

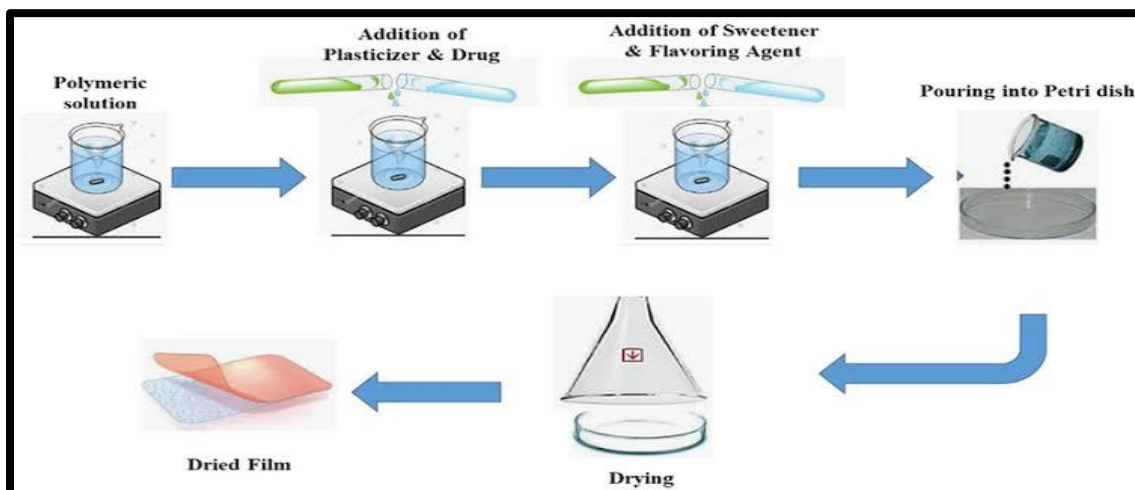
## Methods:

### APPROACHES USED FOR THE FORMULATION OF FAST DISSOLVING STRIP

- Conventional approaches
- Solvent casting method
- Hot-melt extrusion
- Semisolid casting
- Solid dispersion extrusion
- Rolling, Solvent casting method

### **Solvent casting method:**

Using this approach, the water-soluble polymers are first dissolved in 1,000 rpm water, which can be heated to 60°C. Each and every additional excipient, including coloring, flavoring, sweetening, and so forth, is dissolved individually. Then, while stirring at 1,000 rpm, the two solutions are well combined. The API is dissolved in an appropriate solvent and added to the resultant solution. Vacuum is used to release the trapped air. The resultant solution is poured into a film, let it dry, and then cut into the required size pieces (.7).



**Fig 1: solvent casting method.**

- 1) Solvent / Water or a suitable solvent combination
- 2) Incorporate excipients.
- 3) Heating the mixture to 600C while agitating it at 1000 rpm.
- 4) Resupply of vaporized solvent.
- 5) After allowing it cool to ambient temperature, add the polymer and API.
- 6) Soluble evaporation replenishment.
- 7) The cast, transformation, and finished movie

### Hot-melt extrusion:

In the pharmaceutical business, the hot-melt extrusion method is frequently used to prepare several dosage forms, such as transdermal, transmucosal, sustained-release tablet, and granule drug delivery systems. Using this procedure, the medicine and polymer are first mixed together in a mixer for ten minutes. Plasticizer is then gradually added, and the mixer is granulated while the anti-sticking agent is present. The produced granules are allowed to dry overnight at room temperature before being standardized and sieved through a 250 m sieve. The extruder is then filled with the standardized grains. To process the granules inside the drum for less than three minutes at 65 degrees Celsius, the extruder's speed is adjusted to 15 rpm. The granules are then pushed into a cylindrical calendar to create a strip that is roughly 200 m thick. The strip is cut to the appropriate size and shape and kept at 25 C( . 7 -19 ) for additional testing.

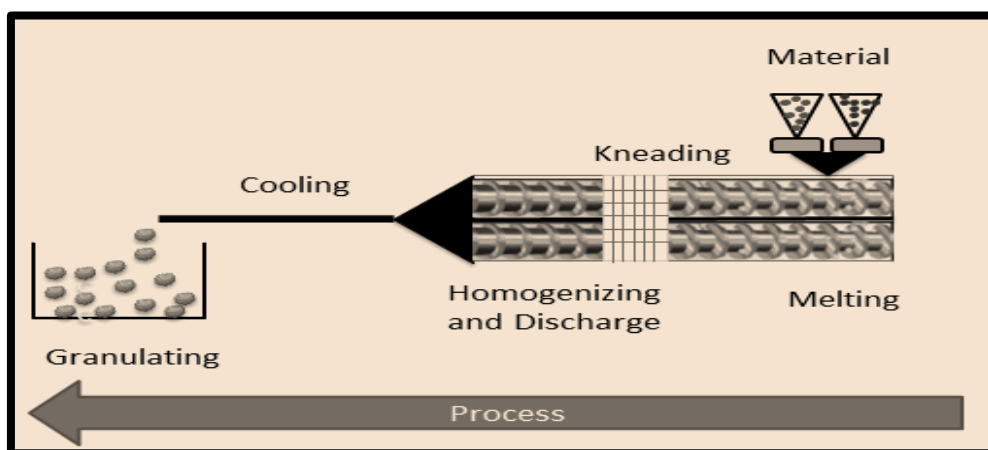


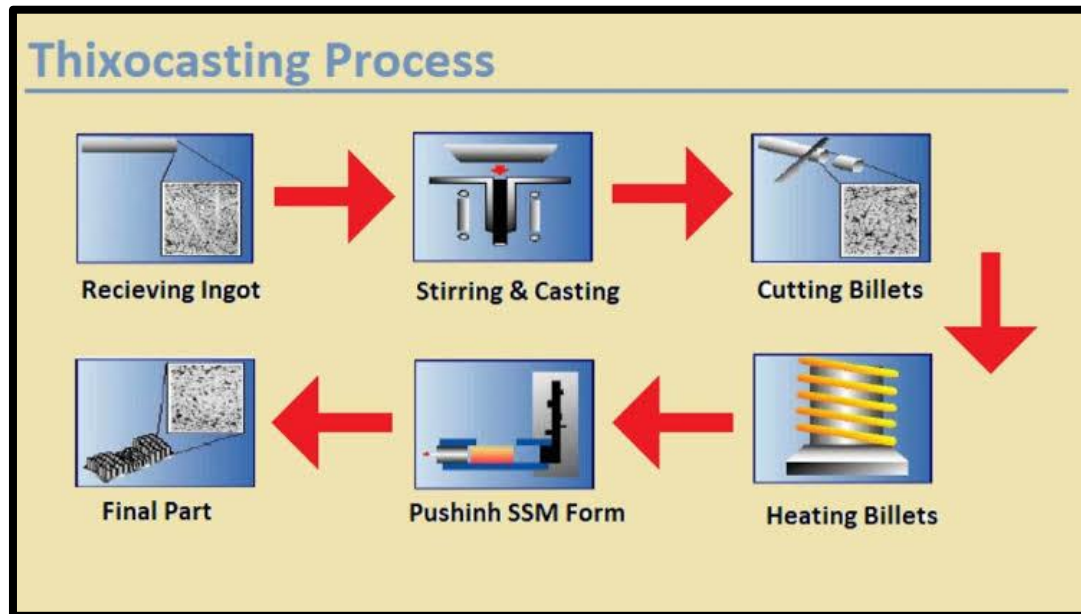
Fig 2: Hot melt extrusion.

### Semi-Solid Casting:

This approach is typically chosen when a polymer that is acid insoluble is used as a film constituent. First, water is used to dissolve the water-soluble polymers. The resulting solution is mixed with the separately generated acid-insoluble polymer solution. The two solutions are correctly combined. Following the mixing of the two solutions, the proper quantity of plasticizer is added to the resultant final solution in order to get the mass of the gel. Finally, using heat-controlled drums, the gel mass is cast onto the films or ribbons. The film should have



a thickness of between 0.015 and 0.05". The acid insoluble polymer and film-forming polymer should have a 1:4 ratio. Cellulose acetate butyrate and cellulose acetate phthalate are two examples of acid-insoluble polymers. (7–19) 2



**Fig 3: Semi-Solid Casting**

## Solid dispersion extrusion:

To enable drug loading, the drug is solidly dispersed and combined with a melted polymer solution. A appropriate polymer that melts below 70°C is mixed with the drug-dissolved liquid solvent (if needed) without draining it to create a solid dispersion. Finally, using dyes, the resulting solid dispersions are formed into films.(7-19

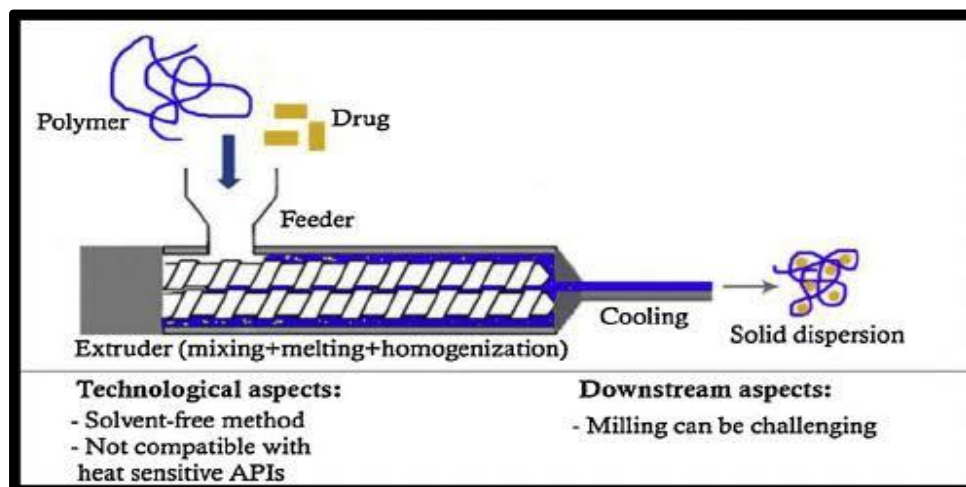


Fig 4: Solid Dispersion Extrusion

## Rolling method:

The drug solution and the film-forming polymer solution are combined completely in the rolling process, and the resulting suspension or solution is then run through a roller. Particular rheological considerations should be made for the suspension or solution. After being cured on rollers, the film is cut into the appropriate sizes and shapes

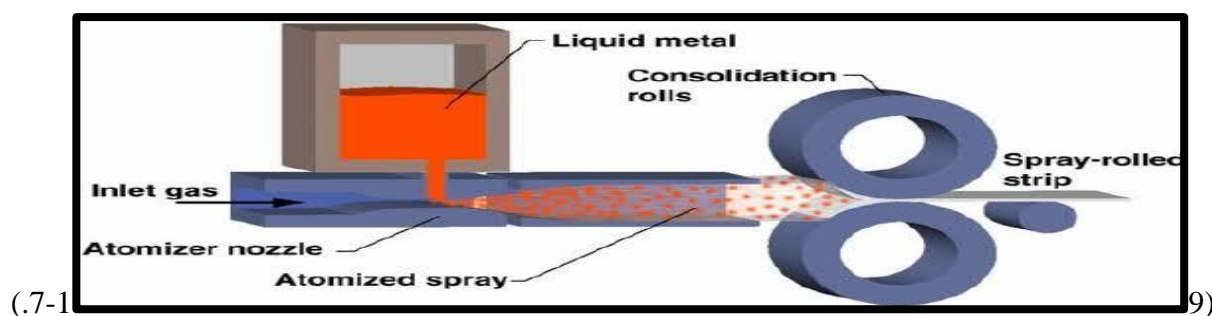


Fig.5: Rolling Method

## Evaluation Test:

### Thickness:

Micrometer screw gauges or calibrated digital Vernier callipers are used to measure the thickness of films. A film should have a thickness between 5 and 200  $\mu\text{m}$ . It is imperative to determine uniformity in the film's

thickness as it is directly related to the precision of the dosage distribution in the film and should be measured at five separate locations—four at the corners and one in the middle. (19–20)

### **Dryness/Tack test:**

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 are the eight stages designated for film drying. The strip's tenacity to stick to an accessory (a piece of paper) after being pressed into contact with it is known as its tack. For this investigation, instruments are also accessible (.21)

### **Tensile strength:**

The maximum stress given to a strip specimen before it breaks is known as its tensile strength. According to the following equation, it is computed by dividing the applied load at rupture by the strip's cross-sectional area:

$$\text{Tensile strength} = \text{Load at failure} \times 100 / \text{Strip thickness} \times \text{Strip width}$$

The percentage of elongation

Strain is the term used to describe the stretching that occurs when stress is applied to a film sample (2 x 2 cm<sup>2</sup>). Essentially, strain is a strip's deformation that occurs just before it breaks from tension. With a house field universal testing machine, it is measured. In general, the more plasticizer there is in the strip, the longer it gets. The formula for calculating it is as follows: %

$$\text{Elongation} = \text{Increase in strip length} \times 100 / \text{Initial length of strip} \quad (.22)$$

### **Percent elongation:**

Strain is the result of a film sample (2 x 2 cm<sup>2</sup>) being stretched under force. In essence, strain is the strip's distortion just before it breaks from tension. A house field universal testing machine is used to measure it. In general, strip elongation rises with increasing plasticizer concentration.<sup>23</sup> The formula to compute it is:

$$\% \text{ Elongation} = \text{Increase in length of strip} \times 100 / \text{Initial length of strip} \quad (.23)$$

### **Tear resistance:**

The resistance a film provides to a load or force applied to the film specimen is known as tear resistance. The primary applied load is at a very slow 51 mm/min. Torr resistance is measured in Newtons, or pounds-force. Stated otherwise, it is the greatest force necessary to rip the specimen (.24).

**Young's modulus:**

Young's modulus, also known as elastic modulus, is a measurement of a strip's stiffness. It can be shown as the following ratio of applied stress to strain in the elastic deformation region:

Young's modulus = Slope  $\times$  100/Strip thickness  $\times$  Cross head Speed.

Strips that are brittle and hard have a modest elongation and a high Young's modulus (24).

**Folding endurance:**

A film's brittleness is attributed to its folding endurance. The procedure followed to determine endurance value is that the film specimen (2 $\times$  2cm<sup>2</sup>) repeatedly folded at the same spot until it breaks or a visible crack is noticed. The computed folding endurance value(25) is the number of times the film can be folded without cracking or breaking.)

**In vitro disintegration test:**

The moment an oral film begins to break when it comes into contact with saliva or water is known as the disintegration period. A film that dissolves quickly should have a disintegration time of between five and thirty seconds. Disintegration time can be studied using the United States Pharmacopoeia (USP) disintegration apparatus.[27] By submerging the film in 25 milliliters of water in a beaker, one can visually ascertain the disintegration time using an alternative method. Gently shake the beaker, and record the moment the film begins to shatter or disintegrate.(25)

**In vitro dissolution studies:**

The amount of medication material dissolved in a solution per unit of time at typical temperatures, solvent concentrations, and liquid/solid interfaces is known as dissolution. For dissolving testing, any of the pharmacopeia's conventional basket or paddle apparatuses can be employed. The greatest dose of API and sink conditions will largely determine the choice of dissolving media. It is recommended to maintain the dissolving media at 37  $\pm$  0.5°C and 50 rpm. One drawback of using the paddle equipment is that oral films tend to float on top of the dissolving media. Mashru et al. dipped salbutamol rapid dissolving film inside the dissolution media using stainless steel wire mesh with a sieve opening of around 700  $\mu$ m.

**Drug content uniformity:**

Any standard assay procedure specified for the specific API in any standard pharmacopeia will determine this. By evaluating the API content in each individual strip, content consistency is ascertained. 85–115% is the maximum content homogeneity.

**Organoleptic test:**

A quick dissolving formulation should have the following required organoleptic qualities: taste, flavor, and color. Given that the formulation would dissolve in the mouth, it ought to have appropriate organoleptic pleasant properties. Patients find a formulation more agreeable when it is colored, and when oral films are given to children, they should also be colorful. Therefore, the formulation's hue should be consistent and appealing. Visual inspection is one method of evaluating color. The smell is the other organoleptic feature. The taste that is incorporated into the recipe should give it a pleasant scent. The addition of a flavoring compound should disguise the smell of the polymer, medication, and any other excipient. Another crucial component that needs to be considered is taste. Specialized human taste panels are employed to assess the flavor. There have also been reports of studies that use electronic tongue measurements to differentiate between different sweetness levels in taste masking formulations. The potentiometric titration method is the foundation upon which the electronic tongue technique operates. In this case, solid samples must first be dissolved in an appropriate solvent before analysis can begin on liquid samples. Using this method, the E-tongue software measures and records the potentiometric difference between each sensor and a reference electrode when the electrodes and reference electrode are submerged in a beaker filled with a test solution for 120 seconds.(26)

**Surface pH test:**

It is important to assess the surface pH of the film since the fast-dissolving strip's surface pH may have an adverse effect on the oral mucosa. The film's surface pH should be 7 or very nearly neutral. A mixed pH electrode can be used for this. The pH of the oral film was determined by slightly moistening the OS with water and placing an electrode against its surface. For each formulation, this investigation should be conducted on a minimum of six films so that the mean  $\pm$  SD may be determined. Another technique for figuring out the surface pH involves placing the films on 1.5%w/v agar gel, followed by the pH paper. The change in color of the pH paper indicates the film's surface pH.

**Transparency:**

An inexpensive ultraviolet (UV) spectrophotometer can be used to measure the transparency of an oral film. The film specimen is positioned on the spectrophotometer cell's interior side. Film transparency is determined using the formula below:

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

Where  $T_{600}$  is the transmittance at 600 nm and

$b$  is the film thickness (mm) and

$c$  is concentration.

**Contact angle:**

The measurement of contact angle forecasts the oral film's wetting behavior, disintegration time, and dissolution. These measurements are performed with help of goniometer (AB Lorentzen and Wettre, Germany) and the measurements should be done at room temperature. Double-distilled water should be utilized to calculate the contact angle. A droplet of doubly-distilled water is applied to the dried film's surface. Using a digital camera, pictures of water droplets are captured within ten seconds of deposition. The image J 1.28v program (NIH, USA) can be used to analyze digital images in order to determine angles.(26)

**Scanning electron microscopy:**

Electron microscopy can be used to examine the surface morphology of films between various excipients and drug scanning. The film samples need to be put in the sample holder. Using tungsten filament as an electron source, different photomicrographs can be taken at a magnification of  $\times 1000$ .

**Permeation studies:**

Permeation tests must to be conducted despite the mouth mucosa's 4-1000-fold higher permeability than the skin's. The permeability can be investigated using the porcine buccal mucosa and a modified Franz diffusion cell. The receptor and donor compartments make up the Franz diffusion cell. The size of the mucosa, which is positioned between the two compartments, should match the size of the receptor compartment head. The buffer-filled receptor compartment is kept at  $37 \pm 0.2^\circ\text{C}$ , and a magnetic bead stirrer running at 50 rpm is employed to preserve thermodynamics. The mucosal surface should be in touch with a film specimen that has been slightly wet with a few drops of artificial saliva. The donor compartment should hold one milliliter of pH 6.8 artificial saliva. Samples are taken out and replaced with the same volume of fresh medium at specific intervals. The percentage of medication that has permeated can be found using an appropriate analytical technique.(26)

**Percentage moisture loss:**

Films measuring  $2 \times 2 \text{ cm}^2$  are precisely cut and weighed using an electronic balance in order to calculate the % moisture loss. The films were weighed and then stored in desiccators with fused anhydrous calcium chloride. In the desiccator, the films should be stored for 72 hours. The films are removed after 72 hours, weighed once more, and the % moisture loss of the films is calculated using the following formula:

$$\text{Percent moisture loss} = (\text{Initial weight} - \text{Final weight}) / \text{Initial weight} \times 100.$$

The percentage moisture loss studies are done to determine physical stability and integrity of the film.

**Determination of % yield of buccal patches:**

Percentage yield of buccal patches can be calculated by the following formula:

% yield = Mass of the buccal patches obtained/Total weight of drug and polymer × 100.

### **Stability study:**

The guidelines set forth by the International Conference on Harmonization should be followed when conducting a stability study. The produced mixture was wrapped in a unique fashion. It was first wrapped in butter paper, and then covered with aluminum foil. The packing was then put inside an aluminum pouch and heat-sealed. Formulations should be stored between 30°C and 60% relative humidity (RH) between 40°C and 75% RH. The films were assessed for drug content, disintegration time, and physical appearance observation after three months.(26)

### **Storage and packaging of OS:**

Single pouches, blister cards with multiple units, multiple-unit dispensers, and continuous roll dispensers can all be used to package fast dissolving strips. Certain fast-dissolving film packaging solutions, such Labtec's Rapidcard and Amcor Flexible's Core-peel, are patented. The fast card has three film slots on each side and is the same size as a credit card. It is possible to remove each dose separately (.26).

### **Conclusion:**

Oral mouth dissolving strips are a novel and promising dosage form, particularly for usage in juvenile and geriatric populations. They are designed for administration within the oral cavity. They bridge the gap between two notions by combining the better application of a liquid and the greater stability of a solid dosage form, combining the best aspects of both into an elegant, stable, and efficient delivery vehicle. Therefore, they play a crucial role in emergency situations including allergic responses and asthma episodes when prompt action is needed. OTFs are now in the early to mid-stages of development for prescription drugs and are a tried-and-true method for the systemic administration of APIs for over-the-counter (OTC) treatments.

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