Encyclopedic Overview on Orodispersible Films

Miss. Vaishnavi K. Mokate¹, Miss. Kalyanee V. Gavande², Dr. Amol N. Khedkar³, Mr. Mahesh B. Kolpe⁴

¹,⁴Student, Department of Pharmaceutical Science, Saikrupa Institute Of Pharmacy, Ghargaon, Ahmednagar, Maharashtra, India -413728
²Assistant Professor, Department of Pharmaceutical Science, Saikrupa Institute Of Pharmacy, Ghargaon, Ahmednagar, Maharashtra, India -413728
³Principal, Department of Pharmaceutical Science, Saikrupa Institute Of Pharmacy, Ghargaon, Ahmednagar, Maharashtra, India-413728

ABSTRACT:
Fast-dissolving drug delivery systems have gained attention and acceptance recently as innovative drug delivery methods that seek to improve patient compliance while improving the safety and effectiveness of a therapeutic molecule by preparing it for administration in a traditional oral dosage form. Some businesses unveiled more durable fast-dissolving medication delivery systems. The tongue is either the floor or the top of the film. This film instantly dissolves when applied to the tongue, releasing the medication, which then dissolves in saliva. The saliva travels down into the stomach, where it absorbs some medications from the mouth, throat, and esophagus. In this instance, improving drug absorption, reducing choking danger, and improving mouth feel are important.

Keywords: Fast Dissolving Films, Solvent Casting Technique, Rapid Disintegrating, Patented Technology.

1. INTRODUCTION:
For a systemic effect, the oral mode of administration is the most recommended. The majority of formulations—roughly 60%—have solid dose forms. Because tablets are easier to manufacture and transport, they are the most popular dose form [1]. The majority of elderly, young, and bedridden patients have trouble swallowing the traditional oral dosage form. Oral fast-dissolving films are a unique formulation that was created to solve this issue. Formulation, such as oral fast-dissolving films, was created. The trans-dermal patch technology served as the foundation for the development of a medication delivery system intended for oral administration. With this delivery method, a thin film is applied to the patient's tongue or mucosal tissue and quickly moistened by saliva. The film then quickly dissolves. Then, it quickly .To release the drug or allow oral mucosal absorption, it dissolves and disintegrates quickly [2, 3]

1.1 Fast Dissolving Drug Delivery System (FDDDS):
FDDDS were developed in 1970 to provide pediatric and geriatric patients with an alternative to tablets, syrups, and capsules. They dissolve quickly in saliva and can be easily taken without the need for water, which is a significant advantage over traditional dosage forms [4]. Due to their special qualities and
benefits—such as having a larger surface area that promotes rapid disintegration and dissolution in the oral cavity, the absence of water requirement, precise dosing, a quick start of action, ease of handling and transport, a pleasant taste, and increased patient compliance—fast dissolving drug delivery systems have grown significantly in importance within the pharmaceutical industry.

**Definition of FDF:**
The most advanced solid dosage form is the fast-dissolving film because of its versatility. Comparing the oral cavity to a dissolving tablet, it improves the effectiveness of the active pharmaceutical ingredient (API) dissolving in a shorter amount of saliva after contact.

Owing to their increased comfort and flexibility, fast dissolving oral films (FDOFs) represent the most advanced oral solid dosage form. By dissolving instantly in the mouth cavity upon contact with saliva, without the need for chewing, and without requiring water for administration, it increases the effectiveness of medications.

![Figure 1: Oral Thin Film](image)

The high blood flow and permeability cause drugs to be absorbed quickly and become bio-available instantly. For individuals who lead an active lifestyle, FDOFs can be helpful in treating conditions like diarrhea, allergic reactions that happen suddenly, bedridden patients, emetic patients, and coughing. It is also helpful for localized actions like teething, mouth ulcers, toothaches, and cold sores where a local anesthetic is desired.[10, 11] The technology of transdermal patches is the foundation for fast-dissolving oral films. When it comes to size, shape, and thickness, films are very similar to postage stamps [.12]. Taste-masking agents are occasionally added in addition to active ingredients to cover up their taste.

Fast-dissolving oral films have the following benefits: they dissolve more steadily, quickly, and efficiently than other traditional dosage forms; they prevent first-pass metabolism; they have a pleasant mouth feel; they can be accurately dosed; they act quickly; and they don't require water when patients comply. Additionally, portability and ease of handling.[14] As indicated in Table, there are a number of marketed FDOF products available.

<table>
<thead>
<tr>
<th>Product</th>
<th>Active drug</th>
<th>Dose strength</th>
<th>Application</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triaminic</td>
<td>Diphenhydramine HCL</td>
<td>12.5</td>
<td>Thin strip for long acting cough</td>
<td>Novartis</td>
</tr>
<tr>
<td>Gas-x</td>
<td>Simethicone</td>
<td>62.5</td>
<td>Gas-x Thin strip Anti gas</td>
<td>Novartis</td>
</tr>
<tr>
<td>Suppress</td>
<td>Menthol</td>
<td>2.5</td>
<td>Suppress herbal cough relief strip</td>
<td>InnoZen</td>
</tr>
<tr>
<td>Orazel</td>
<td>Menthol /pectin</td>
<td>2/30</td>
<td>Cough and cold relief strip</td>
<td>Del</td>
</tr>
<tr>
<td>---------</td>
<td>------------------</td>
<td>------</td>
<td>----------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Donepezil</td>
<td>Donepezil HCL</td>
<td>5/10</td>
<td>In Alzheimer’s disease</td>
<td>Labtee GmbH</td>
</tr>
<tr>
<td>Ondansetron</td>
<td>Ondensteron</td>
<td>4/8</td>
<td>Antiemetic help nausea, vomiting</td>
<td>Labtec GmbH</td>
</tr>
<tr>
<td>Triaminic</td>
<td>Dextromethorphan HBr</td>
<td>5/7.5</td>
<td>Seasonal allergy</td>
<td>Novaertis</td>
</tr>
<tr>
<td>Benadryl</td>
<td>Diphenhydramine HCL</td>
<td>12.5</td>
<td>Antihistaminic oral strip</td>
<td>Pfizer</td>
</tr>
</tbody>
</table>

### 1.3 Special Feature: [15]
- Available in a range of forms and sizes
- Elegantly thin film
- Unobtrusive
- Quick disintegration or disappearance
- Swift discharge

### 1.4 Advantages:
- No chance of choking;
- Easy or precise dosing
- No need for water to chew or swallow
- Small size for better patient compliance

### 1.5 Disadvantages:
- It must be kept in dry environments due to its hygroscopic nature.
- The granule-like fragility is also evident.
- To ensure the products' safety and stability, they need to be packaged specifically.
- The oral film is unable to include a high dosage.

### Table 2: Comparisons between fast dissolving Tablets and films.

<table>
<thead>
<tr>
<th>Fast Dissolving Tablet</th>
<th>Fast Dissolving Film</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is a tablet.</td>
<td>It is a film</td>
</tr>
<tr>
<td>Lesser dissolution due to less surface area</td>
<td>Greater dissolution due to large surface area</td>
</tr>
<tr>
<td>Less durable as compared with oral film</td>
<td>Better durable than oral disintegrating tablet</td>
</tr>
<tr>
<td>Less patient compliance than film</td>
<td>More patient compliance</td>
</tr>
<tr>
<td>High dose can be incorporated</td>
<td>Low dose can only be incorporated</td>
</tr>
<tr>
<td>It has a fear of choking</td>
<td>No risk of choking</td>
</tr>
</tbody>
</table>

### 1.6 Ideal Properties of Fast Dissolving Films:
- The other ingredients should be able to work with it. Its taste ought to be satisfactory.
- The mouth feel ought to be pleasant. To survive handling after manufacturing,
- It should be less friable and possess strong mechanical properties.

### 2. CLASSIFICATION OF ORAL FILM [16]:
There are three different subtypes of oral films:

1. **Flash release**
2 Mucoadhesive melt-away wafer
3 Mucoadhesive sustained-release wafers

Table 3: Type of oral film and their properties:

<table>
<thead>
<tr>
<th>Property/Sub type</th>
<th>Flash release</th>
<th>Mucoadhesive melt-away wafer</th>
<th>Mucoadhesive sustained release wafer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Area (cm²)</td>
<td>2-8</td>
<td>2-7</td>
<td>2-4</td>
</tr>
<tr>
<td>Thickness (um)</td>
<td>20-70</td>
<td>50-500</td>
<td>50-250</td>
</tr>
<tr>
<td>Structure</td>
<td>Film-single layer</td>
<td>Single or multilayer system</td>
<td>Multilayer system</td>
</tr>
<tr>
<td>Excipient</td>
<td>Soluble, highly hydrophilic polymers</td>
<td>Soluble, hydrophilic polymers</td>
<td>Low non soluble polymer</td>
</tr>
<tr>
<td>Drug phase</td>
<td>Solid solution</td>
<td>Solid solution /suspended drug particles</td>
<td>Solid solution, Suspension</td>
</tr>
<tr>
<td>Application</td>
<td>Tongue</td>
<td>Gingival or buckle region</td>
<td>Gingival</td>
</tr>
<tr>
<td>Dissolution</td>
<td>Maximum 60 second</td>
<td>Disintegration in a few minutes</td>
<td>Maximum 8-10 hours</td>
</tr>
</tbody>
</table>

3. METHODS OF PREPARATION OF FDF
There are following methods which can be used for preparation of fast dissolving film such as:
1. Solvent casting method
2. Semisolid casting method
3. Hot melt extrusion
4. Solid dispersion extrusion
5. Rolling method

3.1 Solvent Casting Method:
Using this method, the drug and other excipients are dissolved in a suitable solvent along with the water soluble polymers. Following the mixing and stirring of the two solutions, the Petri plate is cast and dried.
Polymer dissolved in solvent + Drug & excipient

To form solution solvent

Both solution are mixed with rapid stirring

Homogenous solution is then spread on flat surface Dried

Film formed [17,18]
3.1.1 Advantage:
- Excellent clarity and thickness uniformity after extrusion.
- Films are free of flaws like die lines and have a beautiful gloss.
- Films are more adaptable and have superior physical qualities.

3.1.2 Disadvantage:
- The polymer needs to dissolve in either water or a volatile solvent.
- The goal is to create a stable solution with a minimum acceptable solid content and viscosity.

3.2 Semisolid Casting Method:

Solution of water soluble film forming polymer is prepared

The resulting solution is mixed with an acid-insoluble polymer solution (such as cellulose acetate butyrate or phthalate).

To create gel mass, the right amount of plasticizer is added.

Using heat-controlled drums, gel mass is cast into the films or ribbons.

The film should have a thickness of approximately 0.015-0.005 inches. Film-forming polymer and acid insoluble polymer should have a 1:4 ratio [19, 20].
3.3 Solid Dispersion Extrusion:

The dispersion of one or more active ingredients in an inert carrier in a solid state while amorphous hydrophilic polymers are present is referred to as a solid dispersion.

- Drug is dissolved in a suitable liquid solvent
- Incorporated solution into the melt of polyethylene glycol, below 70°C
- Solid dispersions are shaped into the films by means of dies[21, 22]

3.4 Hot Melt Extrusion:

The medication is combined with solid carriers.

- The mixture is melted by an extruder with heaters.
- Ultimately, the dies from the melted mixture into films [23, 24].
3.4.1 Advantages:
➢ Fewer operational units
➢ More consistency in the content
➢ An absence of water

3.5 Rolling Method:
A drug suspension is rolled onto a carrier. The primary solvents are alcohol and water mixtures. The film takes on the required size and shape after being dried on rollers [2, 22, 25].

4. Advance technology used in FDA
4.1 Soluleaves
This technology creates a film that, when it comes into contact with saliva, releases the active ingredients. For elderly and pediatric patients who might have trouble swallowing regular tablets, this approach is very helpful. In order to release the medication gradually over a 15-minute period, SOLULEAVES are made to stick to mucous membranes [26].

4.2. Foamburst:
A new patent, FOAMBURST, for foamed film capsules was awarded in September 2004. During the filming process, gas is blown into the picture, giving it a honeycombed structure. The film's voids can be filled with gas, left empty, or packed with different substances to deliver active medications or create particular taste-burst effects. The capsules dissolve quickly due to their light honeycomb structure, giving them a melt-in-your-mouth feel [26].

4.3. XGel:
Film XGel Now that the pharmaceutical industry had access to Bio Progress's technology; it was revolutionizing both product offerings and manufacturing techniques. The product stability may be improved by XGel film. In addition to being created for non-ingestible uses like cosmetics, ostomy pouches, sanitary products, and medical equipment, the films can be colored or printed during the manufacturing process for branding and coding [27, 28].

4.4. WaferTab:
WaferTab is an edible film dosage form that is distinct, inventive, and incredibly stable. Pharmacological active ingredients are combined with an edible film strip to create the WaferTab drug delivery technology. When the mouth salivary strip comes into contact with it, it offers quick dissolution and release of the active pharmaceutical ingredient. To further enhance taste-masking, the WaferTab film strip can also be flavored. A fused's body incorporates the active ingredient. Film can be made in a range of sizes and forms, making it a perfect way to administer medications that need to release quickly as well as for patients who have trouble swallowing.[29]

4.5 Biodegradable transmucosal film:
Biodegradable transmucosal films have been developed by Auxilium Pharmaceuticals that stick to the upper gum, ideally above the back molar, and dissolve entirely there. When compared to other conventional dosage forms, where drug absorption is lower due to shorter onset of action or reduction of first pass metabolism and likely less frequent dosing, biodegradable transmucosal films are the most effective way to deliver drug substance and to achieve the same therapeutic levels with lower doses. The company is utilizing this method to include medication for the management of pain, androgen replacement therapy, and overactive bladder.
4.6 Thinsol (TM):
One more patent-pending invention from Paladin Labs is Thinsol(TM). It is a carboxymethyl cellulose film that is based on water and is digested by enzymes. It can be used to quickly deliver active ingredients including medications and nutritional supplements. Compared to other edible film technologies, Thinsol may provide a number of advantages. For example, it can be used to formulate products that other technologies might not be able to in a film strip format, like those that need high drug loads per strip or those that are heat sensitive. As opposed to most film strip technologies, Thinsol allows for the incorporation of active ingredients up to 60% of the total weight of the films, enabling the creation of a film strip with more than 100 mg of the substance. The manufacturing process for Thinsol does not require heat.

4.7 Versafilm TM:
IntelGenx Technologies Corp. developed the Versafilm patent technology. An edible film called Versafilm TM is used to quickly impart savory flavors to food substrates. Versafilm is employed as the preferred system when quick action is needed. Versafilm TM allows for the incorporation of up to 40 mg of the medication, with the option to sublingually administer it and adjust the disintegration time from 30 seconds to 10 minutes.

4.8 Rapidfilms®:
Labtec GmbBH is the company that developed and markets the patented technology known as Rapidfilms®. Rapidfilms® are non-mucoadhesive, quickly dissolving thin films composed of water-soluble polymers that come in single or multilayer design options. These films combine the stability and dosing accuracy of a tablet with the ease of a liquid, providing patients with several benefits. The film's foundation is a PVA-starch mixture that PEG plasticizes. You can add as much as 30 mg of the medication to Rapidfilms®.

4.10 Quicksol®:
Quicksol® technology was created by SK Chemicals and is capable of handling a broad range of drug substances. However, only two medications made using Quicksol® technology are marketed today: Mvix-S ODF (mirodenafil) and Montfree ODF (monteleukast). Mvix-S is a light-colored, thin oral film with 50 mg. Absorption of Mvix ODF exceeds that of Mvix tablet by 16.7%.

4.11 Bio-FX®:
Bio-FX® fast onset oral cavity ODF was created by NAL Pharmaceuticals. It is an oral film that is designed with a BIOFX® absorption enhancer system, which increases the drug's absorption through the oral mucosa and sublingual area. By avoiding gastrointestinal degradation and first pass metabolism, the goal is to increase the drug's oral bioavailability. Bio-FX® films are composed of mucoadhesive polymers such as polyvinylpyrrolidone, and are formulated as single layers.

4.12 Schmelzfilmen:
Melting films, or Schmelzfilmen, were created by the Hexal Company. The four products that the company offers for sale are risperidone, donepezil, olanzapine, and sildenafil. The majority of these films are made of cellulose. The film-forming polymer in the olanzapine oral film is ethyl cellulose, and dibutylsebacate was used to plasticize the film.

5. FORMULATION CONSIDERATION:
The drug-loaded FDF area should have a size of 1 to 20 cm². The medication has a maximum loading dose of thirty milligrams.
Every excipient used in the fast-dissolving film ought to be approved for use in oral strips and generally recognized as safe (GRAS-listed). There have been reports of significant formulation considerations influencing the mechanical properties of the films [30]

<table>
<thead>
<tr>
<th>DRUG</th>
<th>DOSE</th>
<th>THERAPEUTIC EFFECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Azatidine Maleate</td>
<td>1mg</td>
<td>Anti histaminic</td>
</tr>
<tr>
<td>Nicotine</td>
<td>2mg</td>
<td>Smoking cessation</td>
</tr>
<tr>
<td>Loparamide</td>
<td>2mg</td>
<td>Anti diarrheal</td>
</tr>
<tr>
<td>Ondnesetron</td>
<td>2.5mg</td>
<td>Anti emetic</td>
</tr>
<tr>
<td>Triplodine</td>
<td>2.5mg</td>
<td>Anti histaminic</td>
</tr>
<tr>
<td>Zolmitripan</td>
<td>2.5mg</td>
<td>Anti migraine</td>
</tr>
<tr>
<td>Salbutamol</td>
<td>4mg</td>
<td>Anti histaminic</td>
</tr>
<tr>
<td>Chlorpheniramine Maleate</td>
<td>4mg</td>
<td>Anti allergic</td>
</tr>
<tr>
<td>Cetirizine</td>
<td>5-10mg</td>
<td>Anti histaminic</td>
</tr>
<tr>
<td>Acrivastine</td>
<td>8mg</td>
<td>Anti histaminic</td>
</tr>
<tr>
<td>Loratidine</td>
<td>10mg</td>
<td>Anti histaminic</td>
</tr>
<tr>
<td>Omiprazol</td>
<td>10-20mg</td>
<td>Protein pump inhibitor</td>
</tr>
<tr>
<td>Famotidine</td>
<td>10mg</td>
<td>Antacid</td>
</tr>
<tr>
<td>Ketoprofen</td>
<td>12.5mg</td>
<td>Anagesic</td>
</tr>
<tr>
<td>Dicyclomine hydrochloride</td>
<td>25mg</td>
<td>Muscle relaxant</td>
</tr>
<tr>
<td>Diphenhydramine hydrochloride</td>
<td>25mg</td>
<td>Anti allergic</td>
</tr>
<tr>
<td>Sumatriptan saccinate</td>
<td>35-70mg</td>
<td>Anti migraine</td>
</tr>
</tbody>
</table>

5.1 Active Pharmaceutical Ingredient:
The active pharmaceutical ingredient makes up 1-30% w/w of the film's unique composition. It is always best to use low dose active pharmaceutical ingredients because it is more challenging to incorporate high dose drugs into films that dissolve quickly. Micronized API is helpful because it improves the film's texture and offers better uniformity and dissolution in the quickly dissolving film. Many medications can be used as oral films that dissolve quickly [1, 2, ]

<table>
<thead>
<tr>
<th>Plasticizers</th>
<th>Sweetening agent</th>
<th>Saliva stimulating agent</th>
<th>surfactant</th>
<th>Flavorsing agent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerol</td>
<td>Sorbitol</td>
<td>Citric acid</td>
<td>Polaxamer 407</td>
<td>Peppermint oil</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Sucrose</td>
<td>Malic acid</td>
<td>Sodium lauryleusfate</td>
<td>Sinnamon oil</td>
</tr>
<tr>
<td>Polyethylene Glyco 1 400,200,600</td>
<td>Cyclamate Erosine red</td>
<td>Lactic acid</td>
<td>Tweens</td>
<td>Menthol</td>
</tr>
</tbody>
</table>
5.2 Film Forming Polymers:
The oral fast-dissolving film's primary ingredient is polymers. The amount of polymer added to the oral strip determines how robust the film is. Mostly, the medical and nutraceuticals industries have shown a great deal of interest in these polymers. Based on the overall weight of the dry film, 45% w/w of polymer is typically used. Oral strips are primarily made of hydrophilic polymers, which break down quickly in the mouth when they come into contact with saliva [23].

5.2.1 Ideal Property of Film Forming Polymer:
➢ It must not be irritating or harmful.
➢ Hydrophilic polymers are required. It ought to have a great ability to form films.
➢ Its spreading and wetting abilities should be good.
➢ Both polymer and its cost should be reasonable and easily accessible.
➢ Low molecular weight polymers are ideal. It ought to last long enough on the shelf.
➢ Colorless and tasteless polymer is required.
➢ There shouldn't be any further infections in the oral mucosa as a result.
➢ Its peel, shear, and tensile strengths should be sufficient.

5.3 Plasticizers:
An essential component of oral strip formulation is plasticizer. The fast dissolving film's flexibility and brittleness are enhanced, and tensile strength and elongation can be increased by adding plasticizers. The choice of plasticizer will be based on how well it works with the polymer and what kind of solvent is used to cast the oral strip [1, 21].

5.4 Sweetening Agent:
Sweeteners are now a necessary component of pharmaceutical and food products meant to dissolve or disintegrate in the oral cavity. To increase the fast dissolving film's palatability, both artificial and natural sweeteners are used in the recipe. Typically, sweeteners are employed in formulations at 3-6% w/w concentrations, either singly or in combination [2, 19]

5.5 Saliva Stimulating Agent
Saliva stimulating agents are used with the intention of increasing saliva production, which will help the fast dissolving film formulations dissolve more quickly. Salivary stimulants can generally be made from acids used in food preparation, such as citric acid, malic acid, lactic acid, ascorbic acid, etc. They can be used in combination or alone, with a concentration of 2 to 6% w/w of the film. Sweeteners also function as agents that stimulate saliva [3, 15, 20].

5.6 Surfactant:
Surfactants are used as a solubilizing, wetting, or dispersing agent to dissolve films quickly and release active ingredients instantaneously. In an oral strip, several surfactants are used. Poloxamer 407, which is used as a solubilizing, wetting, and dispersing agent, is one of the most significant surfactants [30].

<table>
<thead>
<tr>
<th>Dimethyl dicetyl dibutyle phthalate</th>
<th>Aspartmate Orange oil Mamelocheite green</th>
<th>Ascorbic acid</th>
<th>Spans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triacetin</td>
<td>Neotame</td>
<td>Tatic acid</td>
<td>Benzalkonium cloride</td>
</tr>
<tr>
<td>Castor oil</td>
<td>Saccharine</td>
<td></td>
<td>Lemon oil Chloroform</td>
</tr>
<tr>
<td>citraether</td>
<td>Mannitol</td>
<td></td>
<td>water</td>
</tr>
</tbody>
</table>
5.7 Flavoring Agent:
Which flavor to use in the formulation depends on the kind of drug that will be used. Individuals are able to identify an oral disintegrating/dissolving formulation based on the initial flavor quality that they detect in the first few seconds after consuming the product and the aftertaste that persists for at least ten minutes. Depending on the kind and intensity of the flavor, a certain quantity of flavor is needed to cover the taste. The formulation calls for a 10%w/w flavoring agent concentration [31].

5.8 Coloring Agent:
The fast-dissolving film contains a coloring agent that has been approved by FD & C. In fast dissolving films, coloring agents are typically not concentrated above 1%w/w. The formulation primarily uses titanium dioxide [1, 2].

Table 6: Formulations

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Amount (w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug</td>
<td>1/30 %</td>
</tr>
<tr>
<td>Film forming polymer</td>
<td>40/50%</td>
</tr>
<tr>
<td>Plasticizer</td>
<td>0/20%</td>
</tr>
<tr>
<td>Saliva stimulating agent</td>
<td>2/6%</td>
</tr>
<tr>
<td>Sweetening agent</td>
<td>3/6%</td>
</tr>
<tr>
<td>Flavoring agent</td>
<td>q-s</td>
</tr>
<tr>
<td>Surfactant</td>
<td>q-s</td>
</tr>
<tr>
<td>Color Filter</td>
<td>q-s</td>
</tr>
</tbody>
</table>

6. Quality control test for Fast Dissolving Film:

6.1 Morphology Study:

6.1.1 Weight Variations:
Oral re-strips are morphologically studied using scanning electron microscopy (SEM) at a specific magnification. The study discusses the variations between the films' upper and lower halves. It also aids in figuring out where API is distributed [32].

Ten randomly chosen films are individually weighted in order to measure weight variation. There should be no discernible difference between the average weight and the average weight [33].

6.1.2 Thickness:
The film's thickness is measured using a micrometer screw gauge at five different locations: the center and each of the film's four corners. The mean thickness is then computed. Five films are chosen at
random for thickness uniformity measurement, and each formulation's thickness is measured there. The films' thickness should vary no more than 5% and mean±S at most. Dis computed [15, 34].

6.1.3 Dryness Test/Track Tests:
It has been determined that there are approximately eight stages in the film drying process: set-to-touch, dust-free, track-free, dry to touch, dry hard, dry through, dry-to-recoat, and dry print free. The specifics of this parameter's evaluation can be examined. The film's adherence to an accessory that makes contact with the strip is known as its tack [1, 36]

6.1.4 Tensile Strength:
Using the maximum amount of stress up until the oral film breaks, one can determine the tensile strength of a film. The following equation can be used to calculate it: applied load at rupture divided by oral film cross section area [3, 37].

\[
\text{Tensile strength} = \frac{\text{Load at break}}{\text{Strip break } \times \text{Strip Width}}
\]

6.1.5 Percentage Elongation:
The distance a pointer travels before the film breaks on the graph paper is used to calculate the percentage elongation. Oral strips typically elongate as the amount of plasticizer increases [2, 38].

\[
\% \text{ Elongation} = \frac{L}{L^i} \times 100
\]

Where, \( L \) = Increase in the length of film, \( L^i \) =Initial length of film

6.1.6 Folding Endurance
:Folding endurance is determined by manually folding film repeatedly in the same spot until it breaks. The folding endurance value is the number of times the film can be folded without breaking [1, 39].

6.1.7 Tear Resistance:
The maximum force required to tear the film is recorded as the tear resistance Value. It is expressed in Newton or (pounds-force) [2, 40,41].

6.1.8 Transparency:
A basic UV spectrophotometer can be used to measure the transparency of the oral film. The film sample should be cut into rectangles and positioned on the inside of the spectrophotometer cell. Calculate the film's transmittance at 600 nm now. According to [1, 41, 42], the transparency of the film was computed.

\[
\text{Transparency} = \frac{\log T_{600}}{b} = CC
\]

Where, \( T_{600} \) = Transmittance, \( b \) = Film thickness  \( C \) =Concentration

6.1.9 Young's Modulus:
Young's modulus is used to determine the stiffness of oral film. It is represented as the ratio of applied stress over strain in the region of elastic deformation. It is calculated as follows: [2, 42, 43, 44].

\[
\text{Young's modulus} = \text{Slope} \times 100 / \text{Strip thickness} \times \text{Cross head speed}
\]

6.1.10 Assay/drug Content and Content Uniformity:
Any standard assay method that is specified for the specific API in any standard pharmacopoeia can be used to determine the assay, drug content, and drug content uniformity. 85–115% content uniformity is the limit [45,46].

6.1.11 Disintegration Time:
According to the CDER guideline, the disintegration time limit for oral disintegrating tablets is 30 seconds or less. This can be applied to oral film that dissolves quickly. For oral fast-dissolving films, there are no official guidelines available. For this investigation, pharmacopoeia disintegrating test equipment might be utilized. Film typically disintegrates in 5 to 30 seconds (42, 43, 44).
6.1.12 In-vitro Dissolution Test:
In vitro the paddle or basket apparatuses mentioned in the pharmacopoeia can be used to carry out a dissolution study. Basically, the dissolution medium volume will be chosen based on the API's highest dose and sink condition. For the oral strip dissolution test, paddle type dissolution apparatus is typically utilized because the tendency of the strip to float onto the dissolution medium can occasionally make the test challenging [50,51, 52].

6.1.13 Stability Testing:
According to the ICH guideline, stability measurement is carried out by storing the oral strip in a stability chamber for a period of 12 months under controlled conditions of 25°C/60%RH as well as 40°C/75% [53,54].
Many evaluating parameters, including thickness, morphological characteristics, tensile strength, water content, and dissolution behavior, are examined throughout the storage period [55, 56,57].

7. Future scope:
The majority of products come in strengths that correspond to conventional dosage forms. Not all of our patients’ needs can be met by commercially available fast-dissolving pharmaceutical products. Compounding may be a novel approach for pharmacists to address unmet patient needs. For this type of medication delivery, pharmacists are now required to take extra precautions when filling new prescriptions. For this system to be used effectively, more products must be made available for purchase. To investigate the efficacy of these products, specialized in vitro and in vivo testing techniques are needed.

8. Future Challenges:
- As new technologies and products advance, fast dissolving intraoral products encounter numerous challenges, some of which are listed below.
- For most medications, taste masking is required.
- Since tablets are delicate, they should be kept dry. It therefore requires special packaging.
- The process of creating a novel manufacturing process is difficult. Upgrades to machinery, technology, and
- Small tablet size, taste masking, and technological limitations limit drug loading. More clinical trials are necessary to investigate more clinical and medicinal benefits.
- A shift in flavor and dissolve too quickly is beneficial for older patients.
- One significant issue is the product's cost.

6. CONCLUSION:
Due to improved patient compliance, a quick start of action, and the fact that the medication is immediately absorbed into the systemic circulation, fast dissolving films have become more and more popular. Compared to traditional dosage forms, oral films offer a number of benefits. They are therefore crucial in emergency situations involving allergies, short-term spasms, and asthma when prompt action is required.
OTCs are now used for purposes other than immediate-release oral dosage forms. The proven stability, robustness, and flexibility of this delivery format have enabled the development of novel forms such as topical films, probiotic strips, and controlled-release OTF products. The way OTF is formulated and
processed in the future will be a direct reflection of how healthcare needs are changing. Given their ageing populations, established markets tend to have simpler, easier-to-dose products. Providers are always searching for ways to improve compliance, lower costs, and minimize dosage levels and frequency, especially as emerging markets demand flexibility in the number of units dispensed at any instant. The answer to all of these needs is becoming more and more in the form of OTFS. Furthermore, by customizing the technology for their program, development teams can leverage the flexibility of OTFs.

REFERENCES


