

**A REVIEW ON MOUTH DISSOLVING FILMS****Vaibhav Prataprao Patange\* and Prof. A. S. Pratapwar**

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445204.**ABSTRACT**

The oral route is one of the most important routes for local and systemic drug delivery, because of its large surface area, high permeability, and abundant blood supply. Mouth dissolving film is the most advanced oral solid dosage form because it provides convenience and ease of use over other dosage forms such as orally disintegrating tablets, tablets and sublingual tablets, therefore mouth dissolving films are gaining popularity in the pharmaceutical industry. Fast dissolving drug delivery system were invented in late 1970s as an alternative to capsules, syrup and tablet for elderly and young patients who have difficulty swallowing conventional oral solid-dose forms. Mouth dissolving films are dissolve and disintegrate in less than a minute

when placed in mouth without drinking water or chewing. This dose form allows the medication to skip first pass metabolism, potentially improving drug bio-availability. The preparation method of mouth dissolving films are solvent casting method, semisolid casting, hot melt extrusion, solid dispersion, rolling method are used. The solvent casting method is the most favoured method above others because it provides excellent thickness uniformity and produces films with a fine glossy appearance and excellent physical properties. Mouth dissolving films are evaluated for its various parameters like thickness property, folding endurance, disintegration and dissolution time. This article presents a comprehensive review of the different formulation techniques, evaluation parameters, and packaging considerations for mouth dissolving films, as well as a survey of some of the currently available commercial products in the market.

**KEYWORDS:** Mouth dissolving films, Solvent casting method, Fast disintegration, Pediatric patients, Bio-availability.

## INTRODUCTION

To date, the oral route is the most preferred route for drug delivery because it offers numerous advantages over other routes of drug administration; however, oral drug delivery systems still require some significant advances due to some disadvantages related to a specific class of patients, which includes geriatric, pediatric, and dysphagia patients associated with a variety of medical conditions because they have difficulty swallowing or chewing solid dosage forms. Even with rapid dissolving tablets there is a risk of choking due to their tablet type doses form. Among other things, the palatability of pediatric oral drug formulations is one of the most important factor determining compliance with treatment regimens.<sup>[1]</sup> Quick dissolving oral films are a novel system of drug delivery that provides improved bio-availability, rapid onset of action, and avoids first-pass metabolism. Oral mucosa has a permeability that is 4-1000 times larger than skin. The goal of developing such a dose form was to solve the swallowing difficulty in children and geriatric patients. It combines Active pharmaceutical ingredient, water soluble polymer, and other excipients such as sweetener, flavour, colour, binder, stabilizing agent, saliva stimulating agent, preservative, etc. To facilitate fast dissolving in the buccal cavity or on the tongue, water soluble polymers such as Pullulan, Gelatin, Sodium Alginate, Pectin, Rosin, Starch, Chitosan, and cellulose ether are used.<sup>[2]</sup> A novel drug delivery system for the oral delivery of drugs is a fast dissolving oral film, which is an ultra-thin film made using hydrophilic polymers that rapidly dissolves on the top or base of the tongue or buccal cavity. It is a postage stamp-sized ultra thin strip (50-150 microns thick) with an active drug and additional excipients made using trans dermal patch technology.<sup>[3]</sup>

### What is Mouth Dissolving Film?

Mouth dissolving film (MDF) when placed on tongue, instantly hydrates by absorbing saliva following disintegration and/or dissolution, releasing active pharmaceutical agent from the dosage form within seconds. MDF s are quite formulations that are commonly prepared incorporating hydrophilic polymers that allow for quick dissolve when in contact with saliva. These systems were developed in the later 1970s as an alternative to traditional dose forms, such as fast disintegrating tablets and capsules, for geriatric and pediatric patients who have trouble swallowing traditional dosage forms.<sup>[4]</sup>

### Special Feature of Mouth Dissolving Films<sup>[5,6]</sup>

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.

#### **Advantages of Mouth Dissolving Film<sup>[7]</sup>**

1. Affordable dosage.
2. There is no need for water.
3. There is no danger of choking.
4. Masking the taste.
5. More stability.
6. Increased patient compliance.
7. The drug reaches the body general bloodstream with a minimized of the liver's first pass metabolisms.
8. In comparison to syrup, dose accuracy.

#### **Disadvantages of mouth dissolving film<sup>[8-9]</sup>**

1. Dose uniformity is a technical challenge.
2. Hygroscopic in nature
3. Large doses cannot be incorporated.
4. To ensure safety and stability of the product, it necessitates specific packaging.

**Table No. 1: Comparison between Fast Dissolving Tablets and mouth dissolving Films.<sup>[10]</sup>**

<b>Fast Dissolving Tablets</b>	<b>Mouth Dissolving Films</b>
It is a type of medication in tablet form that dissolves quickly in the mouth	It is a type of medication in film form that also dissolves quickly in the mouth.
lesser dissolution rate due to their smaller surface area	greater dissolution rate due to their larger surface area.
Less durable compared to mouth dissolving films	Better durable as compared to fast dissolving tablets.
Patients may be less compliant	More patient compliance
tablets are able to incorporate high doses of drug	Films are only able to incorporate lower doses of drug.

**FORMULATION OF MOUTH DISSOLVING FILM****Table No. 2: Composition of mouth dissolving film.<sup>[11]</sup>**

Sr	Ingredient	Amount (w/w)
1	Active Pharmaceutical Ingredient	5-30 %
2	Film Forming Polymer	40-50 %
3	Plasticizers	0-20 %
4	Surfactant	9.5 %
5	Sweetening Agent	3-6 %
6	Saliva Stimulating Agent	2-6 %
7	Coloring Agent	1 %
8	Flavouring Agent	1 %

**A. Active Pharmaceutical Ingredient**

oral films typically contain 5-30w/w of the drug. For mouth dissolving films, it is important to use drugs that are stable in saliva and water, and can be administered in low doses. To improve the texture of the film and achieve better dissolution and uniformity, micronized API can be used. Various classes of drugs, such as antiasthmatics (Salbutamol sulphate, Montelukast), antihistamines (Levocetirizine), antianginals (Verapamil), antiulcers (Omeprazole), antiemetics (Domperidone), expectorants, antitussives, and NSAIDs (Valdecoxib, Meloxicam, paracetamol), can be formulated as mouth dissolving films.<sup>[12]</sup>

**The Ideal characteristics of the drug to be selected<sup>[2]</sup>**

1. The medication should taste good.
2. The therapeutic dose of the drug should not exceed 40 mg.
3. The medicine should have a small molecular size and a low molecular weight.
4. The drug should be sufficiently soluble and stable in both water and saliva.
5. It should be partially unionised at the pH of the oral cavity.
6. The drug should be resistant to environmental changes.
7. It should be permeable to the oral mucosa.
8. Polymers that are soluble in water are generally used in film formers.

**B. Film Forming Polymer<sup>[6]</sup>**

Water-soluble polymers are commonly used as film formers due to their ability to provide fast disintegration, good mouth feel, and mechanical strength to the films. The strength of the films depends on the type and amount of polymer used. Pullulan, gelatin, and hypromellose are among the most commonly used polymers for preparing films. Other examples of water-soluble polymers include guar gum, xanthan gum, hydroxypropyl methylcellulose (HPMC),

modified starches, PVP K30, and PVA. HPMC can come in various grades, such as E3, E5, E6, and E15, etc.

### **Ideal properties of the polymers used in the mouth dissolving film**

1. Polymers should be non-toxic and non-irritating. It is also important that they have no taste.
2. It should be free from leachable impurities.
3. It should be inexpensive and easily available
4. It should not be an impediment during the disintegration time.
5. It should have good wetting and spreadability property.
6. It should have enough peel, shear, and tensile strength.
7. It must not induce secondary infection in the oral cavity and must have a long enough shelf life.

### **C. Plasticizers<sup>[13]</sup>**

The plasticizer is an important component that improves film flexibility and reduces brittleness. Inadequate plasticizer use can cause film cracking, splitting, and peeling. The plasticizer is added to the formulation in concentrations ranging from 0 to 20% to affect the mechanical characteristics of the film, such as tensile strength and percent elongation. PEG, glycerol, diethyl phthalate, triethyl citrate, and tributyl citrate are examples of plasticizers.

### **D. Surfactant<sup>[14]</sup>**

Surfactants are used as solubilizing or wetting or dispersing agent so that the films gets dissolve quickly and release the active agent instantly. Several numbers of surfactants are used in mouth dissolving films. Poloxamer 407 is a commonly used surfactant that serves as a solubilizing, wetting, and dispersing agent in many applications. Example of Surfactant commonly used in mouth dissoving film are sodium lauryl sulfate, poloxamer, and tweens.

### **E. Sweetening agents<sup>[15]</sup>**

Sweeteners have been the most significant component in oral formulations designed to be dissolved or disintegrated. In the composition of mouth dissolving films, both artificial and natural sweeteners are used, with concentrations typically ranging from 3-6% w/w. polyhydric alcohols like mannitol, sorbitol, and isomalt are often combined with sweeteners to provide a cooling sensation and good mouth-feel. However, it is important to be cautious when using these substances with children. Natural sweeteners used are glucose, ribose,

xylose, sucrose, maltose, steviosides, dextrose, fructose and isomalt. Fructose is sweeter than sorbitol and mannitol and Artificial sweeteners used in are aspartame, sodium or calcium saccharine salts, cyclamates salts, Acesulfame potassium etc.

#### **F. Coloring Agent<sup>[15]</sup>**

Mouth Dissolving Films can incorporate FD&C approved coloring agents. Colouring agent is used in concentration range 1% w/w in mouth dissolving film. Titanium dioxide is the most used colouring agent.

#### **G. Saliva Stimulating Agent<sup>[10]</sup>**

These are used to increase the secretion of saliva so that the oral film disintegrates and dissolves faster in the oral cavity. The acids that are employed in the preparation of food are typically used as saliva stimulators. Citric acid, malic acid, lactic acid, ascorbic acid, and tartaric acid are substances that can act as saliva stimulating agents.

#### **H. Flavouring Agent<sup>[16]</sup>**

Flavoring agents are ingredients that provide taste to a formulation. Since the perception of flavor can vary based on an individual's ethnicity, preferences, and age, any flavor approved by the US FDA can be added to the formulation to cater to the varying tastes of different age groups. For instance, the elderly population may prefer mint or orange flavor, whereas the younger generation may prefer fruity flavors like raspberry or strawberry. When selecting a flavoring agent, it's crucial to ensure that it's compatible with the drug and other excipients. Flavoring agents are chosen based on their initial flavor impression and aftertaste. They can be extracted from various parts of plants, such as leaves, flowers, fruits, bark, and seeds.

### **METHOD OF PREPARATION**

Following methods can be used for the preparation of mouth dissolving films:

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

## 1. Solvent casting method

This method is the most preferred way to manufacture mouth dissolving films. In this method, firstly, water soluble solvent ingredients are mixed in water to form a viscous solution. Using a high shear processor, the initially mixed small amount of solution prepared by dissolving API and remaining ingredients is combined with the bulk. A vacuum is used to remove the air entrapped. The solution is cast as a film by pouring it into a glass mold and allowing it to dry in an oven at 45-50°C, which forms the mouth dissolving film. is then cut into pieces of the desired size.<sup>[7]</sup>

### Advantages

1. Improved film clarity and thickness consistency over extrusion method.
2. Film with a high gloss and no die lines.
3. This method achieves films that are more flexible and have better physical qualities.

### Disadvantages

1. The polymers utilized must be soluble in volatile solvents.
2. A stable solution with a significant minimum solid content and viscosity is necessary, which is challenging to achieve.
3. Achieve homogeneous film preparation with adequate drug release from casting support.

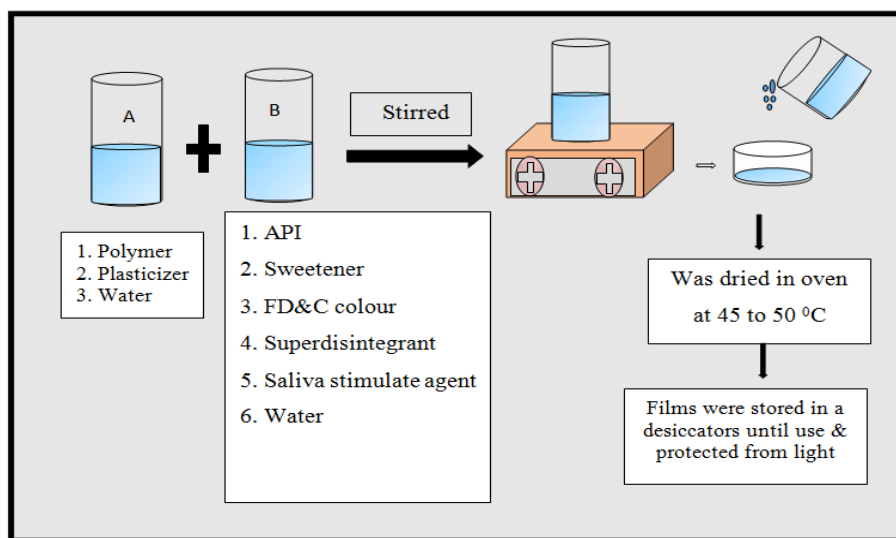


Fig. Solvent casting method.

## 2. Semi-solid casting method<sup>[17]</sup>

A solution of water-soluble film forming polymer is generated using this method. This solution is then mixed with an acid-insoluble polymer solution (Examples: cellulose acetate

phthalate, cellulose acetate butyrate, etc. The plasticizer is then added in the right amount to create a gel mass. This gel mass is casted into the films or ribbons using heat controlled drums. The thickness of the films should be between 0.015 and 0.05 inch. The acid-insoluble polymer to film-forming polymer ratio should be 1:4.

### 3. Hot melt extrusion

In this procedure, the drug and carriers are first combined in solid form. The mixture is then melted by the heaters in the extruder, and the melt is then shaped into films by the dies. Hot melt extrusion has some advantages, includes,

1. There are fewer operation units.
2. A more homogeneous content.
3. A processing of anhydrous.

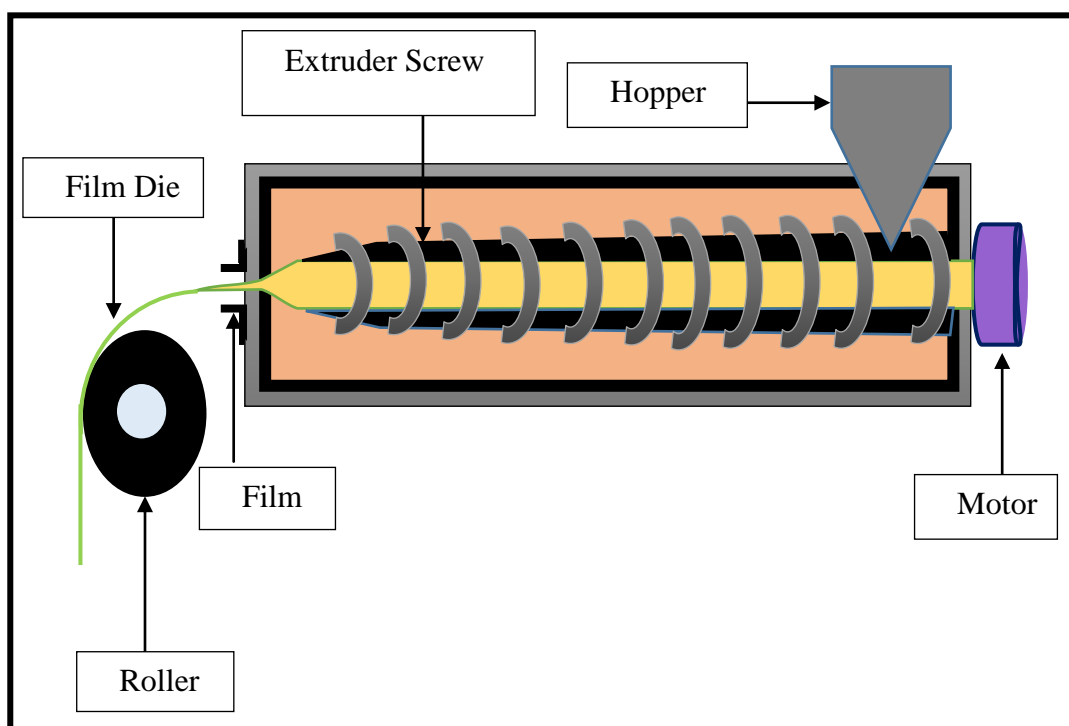


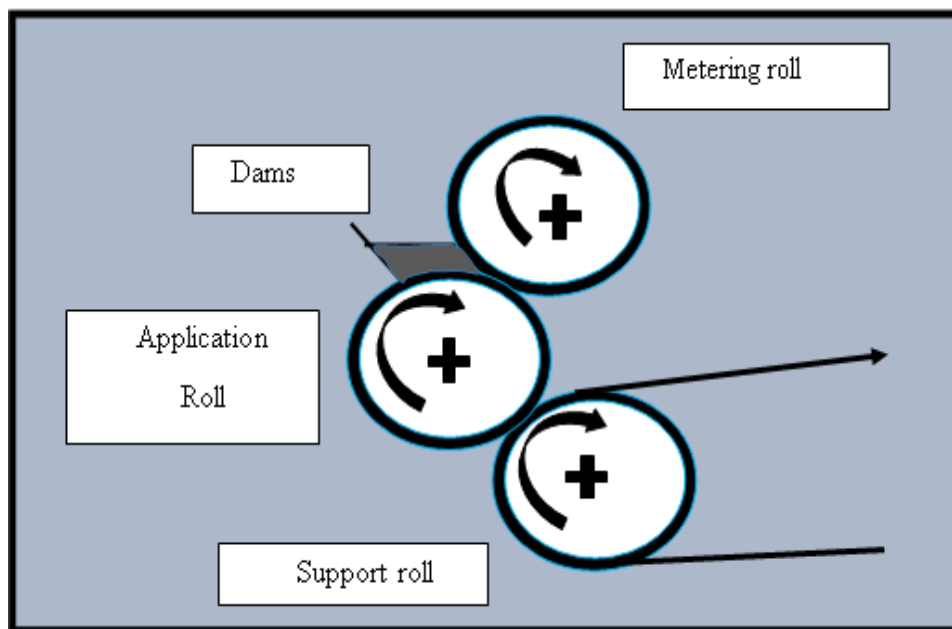
Fig. 2: Hot melt extrusion method.

### 4. Rolling Method<sup>[9]</sup>

According to this method, a premix is prepared, an active is added, and then a film is created. Create a premix using a polar solvent, film-forming polymer, and additional ingredients other than a drug. Fill the master batch feed tank with premix. It was fed to either the first mixer or both the first and second mixer using a first metering pump and control valve. Add the necessary amount of the drug to the chosen mixer. To create a homogeneous matrix, combine



the drug with the master batch premix. The pan is then supplied with a predetermined quantity of homogeneous matrix using the second metering pumps. Finally, the film is created on the substrate and removed using the support roller. Then, employing controlled bottom drying, the wet film is dried.



**Fig. 3: Rolling method**

### 5. Solid dispersion extrusion<sup>[11]</sup>

The dispersion of one or more active ingredients in an inert carrier in a solid state in the presence of amorphous hydrophilic polymers is called as solid dispersion. In this method, drugs are dissolved in appropriate solvents and then incorporated into a polyethylene glycol melt at temperatures below 70°C. The solid dispersion are then shaped into films using dies.

### EVALUATION OF MOUTH DISSOLVING FILMS

Mouth dissolving film was evaluated for thickness test, weight variation, tensile strength, folding endurances, disintegration time, dissolution time, surface pH, assay, stability testing, swelling index given as follow:

#### 1. Thickness test

The thickness of the mouth dissolving films can be measured by a micrometer screw gauge at different strategic locations. This is essential to maintain uniformity in the thickness of the film as this is directly related to the current of the dose in the strip.<sup>[19]</sup>

## 2. Weight variation of the film

2x2 cm<sup>2</sup> film was cut at five better places in the caste film. Each film strip weight was measured and average weight film was calculated.<sup>[20]</sup>

## 3. Tensile strength

Tensile strength is defined as the highest applied stress at which the film breaks. This test is used to determine the mechanical strength of films. It may be determined by dividing the applied load at rupture by the strip cross-sectional area, as shown in the equation below.<sup>[21]</sup>

$$\text{Tensile strength} = \text{Load at breakage} / \text{Strip thickness} \times \text{Strip Width}$$

## 4. Folding endurance

The brittleness of a film is determined by folding endurance. To evaluate endurance value, the film specimen (2x2 cm<sup>2</sup>) is folded repeatedly at the same point until it breaks or a visible fracture is noticed. The measured folding endurance value is the number of times the film can be folded without breaking or displaying any visible cracks.

## 5. Surface pH

The surface pH of the mouth dissolving film is estimated to assess the risk of any in side 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.<sup>[33]</sup> 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  $\pm$  S.D. were determined.<sup>[22]</sup>

## 6. Assay/Drug Content and Content Uniformity

Can refer to any pharmacopoeia relevant to a specific active ingredient to check its assay/drug content and content uniformity. This involves measuring the API content in an individual strip. The acceptable range for content uniformity is between 85% and 115%, according to established guidelines.<sup>[19]</sup>

## 7. 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  $37 \pm 0.5^\circ\text{C}$ . At regular time intervals, samples are taken out and analyzed through a UV-Visible spectrophotometer.<sup>[23]</sup>

## 8. Disintegration time

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.

## 9. Swelling index

To determine the swelling index of the film, pH 6.8 simulated salivary fluid was used. A film sample with a surface area of 4 cm<sup>2</sup> was weighed and placed on pre-weighed stainless steel wire mesh. The mesh containing the film sample was then submerged in 50 ml of pH 6.8 SSF in a mortar. The stainless steel mesh was periodically removed from the film and any excess moisture was gently removed by using absorbent tissue before re-weighing the mesh to determine the degree of swelling. The calculation for the degree of swelling was based on the following formula:

$$SI = (W_t - W_0)/W_0$$

Where,

SI = swelling index,

W<sub>t</sub> = weight of the film at time t,

W<sub>0</sub> = weight of the film at t=0.

## 10. Stability testing

For stability testing, oral wafers were stored under controlled conditions of 25°C/60% RH and 40°C/75% RH over a period of 12 months, in accordance with ICH guidelines. During storage, the oral wafers should be assessed for their morphological properties, mass, thickness and reduction of film thickness, tensile properties, water content, and dissolution behavior. Additionally, pH and content during storage should be monitored.<sup>[24]</sup>

## Packaging of Mouth Dissolving Film

Various packaging options are available for mouth dissolving films, but single packaging is mandatory. The most commonly used packaging material is an aluminum pouch. The mouth dissolving films can be packaged using various methods, including single pouches, blister cards with multiple units, multiple unit dispensers, and continuous roll dispensers. The packaging process involves the use of vertical or horizontal form-fill-seal equipment to create flexible pouches, with single or aluminum pouches being the preferred choice. The pouch

may be transparent to allow for product display, with one side being transparent and the other side having foil lamination to prevent the transmission of gas and moisture. Aluminum pouches are the most commonly used packaging option. Blister cards consist of two components: the blister, which holds the product, and the lid stock, which seals the blister.

#### The ideal properties of material selected for packaging include

1. Protection from environmental conditions: The packaging material should protect the product from moisture, light, and other environmental factors that could degrade its quality.
2. Approval by FDA: The packaging material must be approved by the FDA for use in pharmaceutical products.
3. Non-toxic: The packaging material must be non-toxic and safe for human consumption.
4. They must be inert and not react with the product.
5. No taste or odor: The packaging should not impart any taste or odor to the product that could affect its acceptability or efficacy.

#### Commercially Available Mouth Dissolving Films

**Table no 4: marketed formulation.**<sup>[13]</sup>

Sr. No	Product	API	Use /Category	Manufacture By
1	Labtec	Ondansetron	Anti emetic	Labtec Pharma
2	Zuplenz	Ondansetron	Anti emetic	Strativa Pharmaceutical, Par Pharmaceutical Company
3	Bendryl	Diphenhydramine Hydrochloride	Pfizer	Anti-Allergic
4	Listerine	Cool Mint	Pfizer	Mouth Ulcer
5	Gas-X	Simethicone	Novartis	Antiflatuating
6	Smart Film	Sildenafil Citrate	Erectile dysfunction	Pfizer Inc
7	Setofilm	Ondansetron	Anti Emetic	Norgine Pharmaceutical Ltd

#### CONCLUSION

The current review demonstrates that one of the unique techniques in the world of pharmaceutical sciences is the use of mouth dissolving films. In comparison to conventional dose forms, they have higher acceptance and patient compliance with no risk of swallowing and enhanced safety and efficacy. The major goal of Formulation of mouth-dissolving films was to address the problem of paediatric, geriatric, and psychiatric patients with dysphagia having issues swallowing traditional oral dose forms. Presently, mouth dissolving films are widely available for hypertension, acidity, allergy, pain, etc. reflecting their importance. Major advantages of such dosage form are their administration without the utilization of

water fulfilling the need of target population seeking convenience in drug administration along with bypassing the hepatic metabolism, consequently, leading to improved therapeutic response.

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