Swati Singh *et al*, International Journal of Pharmaceutical Sciences and Medicine (IJPSM),
Vol.9 Issue. 2, February- 2024, pg. 36-51

ISSN: 2519-9889
Impact Factor: 5.9

A REVIEW ON MOUTH DISSOLVING FILM- A NOVEL APPROACH

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DOI: 10.47760/ijpsm.2024.v09i02.006

ABSTRACT: The oral route is one of the most important routes for local and systemic drug delivery due to its large surface area, high permeability and blood flow. Mouth dissolving films are the most advanced oral forms as they are simpler and easier to use than other dosage forms such as Oro-soluble tablets, sublingual tablets. Fast dissolving drug delivery system were rapidly developed in the 1970s as an alternative to capsules, syrups, and tablets for adults and adolescents who have difficulty swallowing conventional oral solid dosage form. The Oro- soluble film dissolves and disintegrates in less than a minute when placed in the mouth without drinking water or chewing. This form allows the drug to skip first-pass metabolism, which improve the bioavailability of the drug. This article provides a comprehensive review on mechanism of action, merits, formulation, evaluation and covering the aspects related to novel fast dissolving techniques.

KEYWORDS: Solvent casting method, buccal films, bio-adhesion, hydration, bioavailability.

1. INTRODUCTION

Buccal drug delivery offers several distinct advantages over various other pathways for systemic effect. Many people find it difficult to chew tablets and hard gelatin capsules and may not take their medications as advised. Approximately 35% of the general population suffers from swallowing difficulties. Among the various transmucosal routes, the buccal mucosa is the most suitable for local and systemic drug delivery. Interesting physiological highlights make the buccal mucosa a perfect route for the transport of mucoadhesive drugs. To overcome such problems in elderly patients a new dosage form has been introduced which is considered as tablets or film that dissolve in the mouth. It is a novel approach that involves rapid disintegration or dissolution of the dosage form within the mouth without the need for water.

A dosage form of a drug is a formulation that is convenient for administration to a patient by various routes for diagnosis or treatment of disease. Appropriate dosage forms are needed to protect the drug from its destructive effects atmospheric oxygen or moisture, to protect the drug from destruction by gastric acid upon oral administration, to mask bitter taste and unpleasant smell, to provide extended action of drug through controlled release mechanism etc.

ISSN: 2519-9889
Impact Factor: 5.9

The agents are used with the drug in the appropriate dosage form. Fast dissolving films are the most advanced form of oral dosage form due to its flexibility and convenience. It provides increased effectiveness of active pharmaceutical ingredients by dissolving within minutes in the oral cavity. This type of technology is very useful in case of pediatric, elderly, bedridden and unconscious patients. There is no need for water administration and this dosage form offers rapid absorption and provides approximately 4-1000 times higher permeability across the oral mucosa.

Recent advances in novel drug delivery systems aim to increase the safety of medicines maintaining its therapeutic efficacy. This therapeutic effect of fast-dissolving doses forms arise as this type of delivery system rapidly decomposes on contact with saliva and dissolves and then releases the pharmaceutically active ingredients without Water requirement. Thin-film and strip intraoral dosage forms have been developed by several companies including LTS (Lohmann Therapy-System) AG, Zengen Inc., and Lavipharm Laboratories (Quick-Dis™ and Slow-Dis™ technologies), Pfizer's Warner-Lambert Consumer Healthcare Department (Listerine® PocketPaks™). Chloraseptic® Relief Strips™ were the first oral thin film product to contain the drug and were introduced in the United States in September. 2003 by Prestige Brands International for Sore Throat Relief.

Fast dissolving film, a type of oral drug delivery system for oral delivery of drugs, was developed based on transdermal patch technology. A fast-dissolving oral film is formulated using a hydrophilic polymer that dissolves rapidly in the tongue or bladder cavity, delivering the drug into the systemic circulation by dissolution when in contact with fluids. Fast-dissolving oral film has emerged as an advanced alternative to the traditional pills, capsules, and liquids often associated with prescription and OTC medications. Thin-film strips similar in size, shape, and thickness to a postage stamp are typically designed for oral administration, with the user placing the strip on or under the tongue (sublingual) or on the inside of the cheek (buccal). The main challenges of the present study were taste masking and improving the aqueous solubility of the drug in addition to drugs that enter the oral cavity, regardless of the method of administration, i.e., swallowing and sublingual or oral inhalation.

Have an acceptable taste. One of the major barriers that prevent patient adherence to prescribed medication regimens is known as the unacceptable taste of the active pharmaceutical ingredients (APIs) in these dosage forms. In the development of oral pharmaceuticals, taste plays an important role in terms of patient acceptability and compliance, and is one of the main factors determining market penetration and commercial success of oral formulations, particularly in pediatrics. particularly in pediatrics.

Anatomy And Physiology of Buccal Cavity: The oral mucosa is composed of an outermost layer of stratified squamous epithelium, underlain by a basement membrane and lamina propria, followed by the submucosa as the innermost layer as shown in Figure 1.

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ISSN: 2519-9889
Impact Factor: 5.9

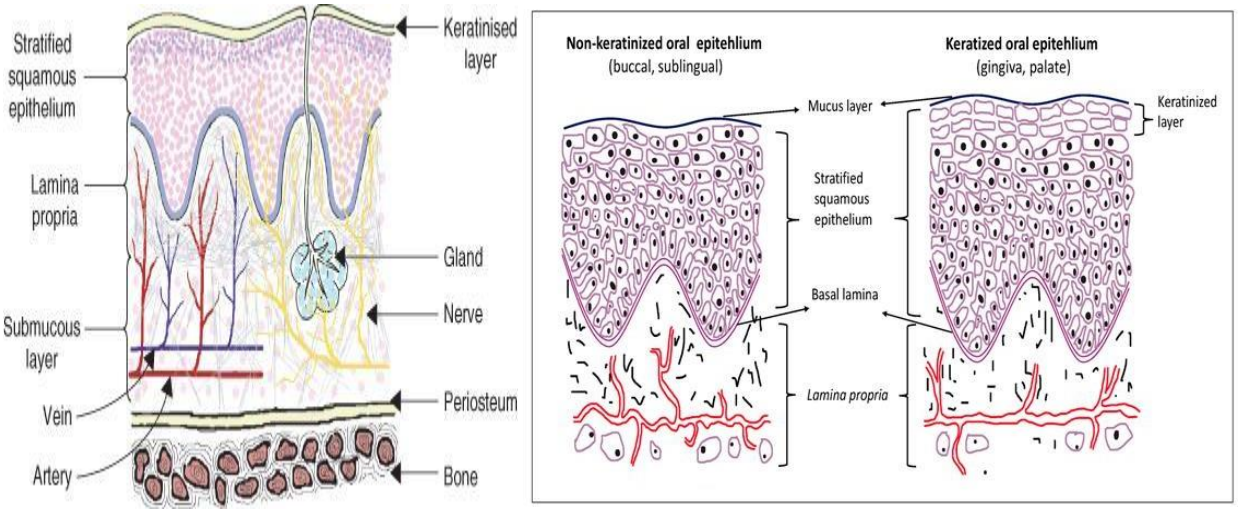

Figure 1: Structure of Oral Mucosa

The epithelium is similar to the rest of the body's stratified squamous. Epithelia in that they have a mitotically active basal cell layer that progresses through a series of developing intermediate layers into the upper layers, where cells emerge from the surface of the epithelium. The buccal mucosa epithelium is 40–50 cell layers thick, while the sublingual epithelium has fewer cells. As they move from the basal to the superficial layers, the epithelial cells increase in size and flatten. The buccal mucosa has a thickness of 500–800µm, while the mucosa of the hard and soft palate, floor of the mouth, ventral tongue and gingiva are 100–200µm thick. The composition of the epithelium also varies accordingly on the site in the oral cavity. The mucosa of areas subjected to mechanical stress (such as the gingiva and hard palate) is keratinized like the epidermis. On the other hand, the soft palate, sublingual and buccal mucosa, are not keratinized. Neutral lipids such as ceramides and acyl ceramides are associated with the barrier function of keratinized epithelia. Non-keratinized epithelia, such as the floor of the mouth and buccal epithelia, contain normal amounts of neutral but polar lipids, mainly cholesterol sulfate and glucosylceramides, and are relatively impermeable to water. These epithelia have been found to be more permeable to water than keratinized epithelia. In both keratinized and non- keratinized epithelia, the cell layers of the oral mucosa contain large amounts of protein in the form of monofilaments.

Mechanism of Buccal Absorption

Buccal drug absorption occurs by passive diffusion of nonionized species through the intercellular spaces of the epithelium, a process largely governed by concentration gradients. The primary transport mechanism is the passive transfer of non-ionic species across the lipid membrane of the buccal cavity. Like many other mucosal membranes, the buccal mucosa is

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considered a lipoidal barrier to drug passage, the more lipophilic the drug molecule, the faster it is absorbed. The kinetics of drug absorption through the buccal mucosa can be adequately characterized by a first order rate process. Several potential barriers to drug absorption through the buccal mucosa have been identified. According to Dearden and Tomlison (1971), salivary secretion alters the buccal absorption kinetics of drug solutions by altering the drug concentration in the mouth. The equation for the linear relationship between salivary secretion and time is given by:

$$-\frac{dm}{dt} = \frac{KC}{ViVt}$$

Where,
M - Mass of drug in mouth at time t.
K - Proportionality constant
Vi- Volume of solution put into oral cavity.
Vt- Rate of Saliva secretion.
C - Concentration of drug in mouth at time.

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Figure:2 Mechanism of Buccal Absorption Physiological Factors Affecting Buccal Bioavailability

1. **Epithelial permeability:** The permeability of the oral mucosal epithelium falls somewhere between that of the skin epithelium, which is highly specialized for the barrier function and of the intestine, which is highly specialized for absorptive function. Buccal mucosa is less permeable than sublingual mucosa within the oral cavity.
2. **Epithelial thickness:** The thickness of the oral epithelium varies greatly between sites in the oral cavity. The thickness of buccal mucosa ranges from 500 to 800µm
3. **Blood supply:** The oral cavity is served by a strong blood supply and lymphatic network in the lamina propria, so drugs that cross the oral epithelium are rapidly absorbed into the systemiccirculation.
4. **Metabolic activity:** Parts of the drug absorbed by the oral epithelium are released directly into the bloodstream, avoiding the first-pass metabolic effects of the liver and intestinal wall.

Consequently, oral mucosal administration may be particularly attractive for enzymatically labile drugs therapeutic peptides and proteins.

5. **Mucus and mucus:** Salivary gland activity indicates that a flow of saliva, approximately 0.5-2L per day, is maintained against oral mucosal surfaces. Since the sublingual area is exposed to a lot of saliva, it can improve the solubility of the drug and thus accelerate the bioavailability.
6. **Maintenance of Delivery System:** Buccal mucosa has a smooth and generally stable surface; it is well suited to adopt retentive delivery systems.
7. **Gender differences:** Because rats have a highly keratinized epithelium, they are not a goodanimal model for investigating buccal drug transport.
8. **Routes and Modes of Transport:** There are two primary pathways for drug penetration

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across the epithelial barrier:

- Paracellular pathway: between adjacent epithelial cells.
- Transcellular route: across epithelial cells, this can be accomplished by passivediffusion, carrier mediated transport or endocytic mechanisms.

Classification of Oral Films: Oral films can be divided into three categories:

1. Flash release films
2. Mucoadhesive melt-away films
3. Mucoadhesive sustained-release films

All these oral dissolving films differ in physical structure, appearance, composition, method of use, characteristics and site of action; are summarized in Table 1.

PROPERTIES	FLASH RELEASE	MUCO-ADHESIVE MELT AWAY WAFERS	MUCO-ADHESIVE SUSTAINED WAFERS
Area(cm2)	2-8	2-7	2-4
Thickness	20-70	50-500	50-250
Structure	Single layer system	Single or multilayer	Multilayer system
Excipients	Soluble hydrophilic polymer	Soluble hydrophilic polymer	Low/non-soluble polymer
Drug phase	Solid solution	Solid solution or suspended solution	Suspension and/or solid solution
Dissolution	60 sec	Few min	Max 8-10 hrs
Application	Tongue	Gingival or buccal region	Gingival (other region in oral cavity)

Table 1: Properties of Film

Special Feature of Mouth Dissolving Films

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

Characteristics of fast dissolving dosage forms

1. It does not require water as these dosage forms disintegrate and dissolve rapidly on contactwith saliva.

2. They are best suited for both paediatric and elderly patients, due to their easy ingestion procedures and pleasant mouthfeel.

3. It gives quick onset of action which is required in many cases.
4. Due to its pre-gastric absorption, bioavailability is increased and required dose is less.

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The Advantages of Oral Films:

1. A sublingually and buccally administered film delivers the drug with a high potential to improve the onset of action, reduce the dose, and enhance the efficacy and safety profile of the drug.

2. All single unit dosage forms, soft gels and liquid formulations enter the bloodstream primarily through the gastrointestinal tract, which leads to degradation of the drug by stomach acid, bile, digestive enzymes and other first pass effects. Consequently, in such formulations high doses are often required and action is usually delayed, which can be overcome by using current oral film drug delivery systems that avoid these problems and offer a rapid onset of action at low doses.

3. Oral film is more stable, durable and faster dissolving than other conventional dosage forms.

4. Oral film enables improved dosing accuracy compared to liquid formulations as each strip is manufactured to contain a specific amount of medication.

5. Oral film ensures more accurate administration of drugs.

6. Oral film dosage form may improve compliance due to intuitive nature and inherent ease of administration. These properties are particularly beneficial for paediatric, geriatric and neurodegenerative disease patients where appropriate and complete dosing may be difficult.

7. The ability of oral films to dissolve quickly without the need for water provides an option for patients with dysphasia and nausea, such as patients receiving chemotherapy.

Fast dissolving Tablets	Fast dissolving Films
Lesser dissolution due to less surface area	Greater dissolution due to large surface area
Less durable as compared with oral films	Better durable than oral disintegrating tablets
Less patient compliance than films	More patient compliance
High dose can be incorporated	Low dose can only be incorporated
It has fear of chocking	No risk of chocking

Figure 3: Comparison Between Fast Dissolving Tablets and Films

Methods of preparation:

1. Solvent casting method
2. Semisolid casting method

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3. Hot melt extrusion
4. Rolling method
5. Solid dispersion extrusion

1. Solvent Casting Method:

This is a very old method of film making. In this method the drug is dissolved or suspended in a solution containing polymers, plasticizers and other excipients which are dissolved in a volatile solvent such as ethanol or water. Known as film dope, it is then poured into petri plates and passed through drying equipment such as ovens to remove all volatile solvents. The dried film is then cut into strips and packed in sealed weatherproof pouches. This method is suitable for films containing heat sensitive drug/API as the temperature required to remove the volatile solvent is comparatively lower than the hot melt extrusion method.

Figure:4 Solvent Casting Method

2. Semisolid Casting Method:

The semi-solid casting method is generally used when acid insoluble polymers are used. In this method, a solution of water-soluble film forming polymer is prepared, then this solution is poured into a solution of acid insoluble polymer, prepared in sodium or ammonium hydroxide. A plasticizer is then added to form a gel mass. The amount of plasticizer added affects the composition of the gel mass. The gel mass is then formed into a film or ribbon using heat-controlled rollers/drums. The ratio of acid insoluble polymer to film forming polymer should be 1:4. Films made by this method have a thickness of about 0.015-0.05 inches.

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Solution of water-soluble film forming polymer is prepared
↓
Resulting solution is added to a solution of acid insoluble polymer
↓
Appropriate amount of plasticizer is added to that gel mass is obtained
↓
Finally, the gel is casted in to the films or ribbons using heat-controlled drums.

3. Hot Melt Extrusion:

This method involves forming the polymer into a film using a heating process. First, the drug- polymer mixture is filled into a hopper and conveyed, mixed and melted by an extruder. The mold shapes the melt into the desired shape. This method involves a lower temperature and a short residence time (< 2 min.) for the drug-polymer mixture. This method does not use organic solvents and can work continuously with minimal product wastage. Operating parameters canbe effectively controlled using this method.

The drug is mixed with carriers in solid form
↓
Extruder having heaters melts the mixture
↓
Finally, the melted mixture is shaped in films by the dies.

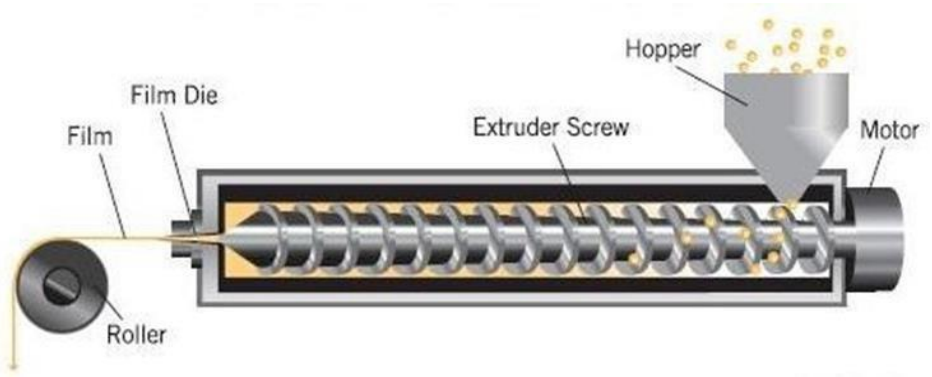

Figure 5: Hot Melt Extrusion

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4. Solid Dispersion Extrusion: The term solid dispersion refers to the dispersion of active ingredients in a passive carrier in the solid state in the presence of an amorphous hydrophilic polymer. Initially, the drug is dissolved in a suitable liquid solvent and later this solution is added to a polyethylene glycol melt below 70C without removing the liquid solvent. And finally, the solids are dispersed and passed through dies to form a film.

Drug is dissolved in a suitable liquid solvent
↓
The solution is incorporated in to melt of Polyethylene glycol obtained below 70°c
↓
Finally, the solid dispersions are shaped in to the films by means of dies

4. Rolling Method:

According to this method, a premix is prepared, an active is added, and then a film is formed. Formulate premixes using polar solvents, film-forming polymers, and additional ingredients other than the drug. Fill the master batch feed tank with the premix. It was fed to the first mixer or to both the first and second mixers using a first metering pump and a control valve. Add the required amount of drug to the selected mixer. Combine the drug with the master batch premix to form a homogenous matrix. The pan is then supplied with a predetermined quantity of homogeneous matrix using a second metering pump. Finally, the film is formed on the substrate and removed using a support roller. Then, using controlled down drying, the wet film is dried.

Prepare pre-mix with film forming polymer, polar solvent and other additives except a drug
↓
Add premix to master batch feed tank, Fed it via a first metering pumps and control valve toeither or both of the 1st and 2nd mixer
↓
Add required amount of drug to the desired mixer
↓
Blend the drug with master batch premix to give a uniform matrix

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↓
Specific amount of uniform matrix is then fed to the pan through 2nd metering pumps
↓
The film is finally forced on the substrate and carried away via the support roller
↓
The wet film is then dried using controlled bottom drying

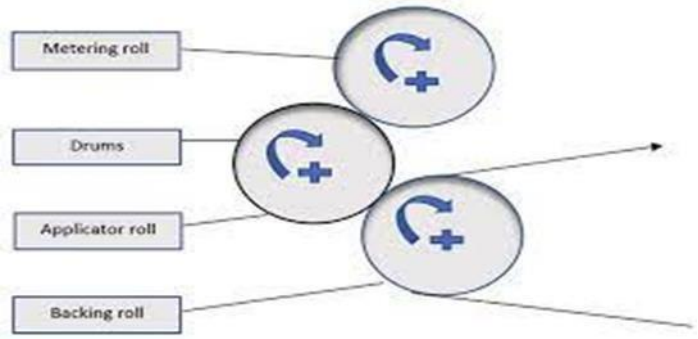

Figure 6: Rolling Method

Novel Technologies Used for Preparation of Mouth Dissolving Films:

1. **Wafertab™:** This is a patented drug delivery system that allows the active ingredients to be administered in the form of ingestible filmstrips. In this delivery system, a pre-measured amount of drug is incorporated into the body of an already formed Xgel™ film. This is done to keep the active ingredient stable while preventing it from being exposed to excessive heat and moisture. They are usually made to be taken orally locally. As soon as the drug comes into contact with saliva, it dissolves quickly.

2. **Soluleaves™:** This technology is used to keep the active ingredient in the oral cavity and is commonly used in flavour-release products such as mouth fresheners and vitamins. When these films come into contact with saliva, they break down rapidly, releasing the drug immediately into the oral cavity.

3. **Foamburst™:** Soluleaves is a type of foam film. During the creation of these films, an inert gas is forced inside, creating a honeycomb structure that allows for rapid release, resulting in amelt-in-the-mouth consistency.

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Composition of the Formulation

1. **Drug (1-25%):** The drugs selected oral films should possess good stability in saliva and water with low dose. It is always useful to have micronized API which will improve the texture of the film and also for better dissolution and uniformity in the oral fast dissolving films. Several class of drugs can be formulated as mouth dissolving films including anti-asthmatic (Salbutamol sulphate, Montelukast), antihistamine (Levocetirizine), antianginal (Verapamil), antiulcer (Omeprazole), antiemetic (Domperidone), expectorants, antitussives, NSAID'S (Valdecoxib, Meloxicam, paracetamol).

2. **Water Soluble Polymers (40-50%):** To obtain the desired film properties, polymers can beused alone or in combination. Generally water-soluble polymers are used as film formers as they achieve rapid disintegration, good mouthfeel and mechanical properties to the films. Thestrength of the film depends on the type of polymer and the amount in the formulation. By increasing the molecular weight of polymer film bases, disintegration rate of the polymer decreases. Polymers frequently used as film formers are water soluble grades of cellulose ethers, polyvinyl alcohol, polysaccharides, polyvinylpyrrolidone K-90, polyethylene glycols, pullulan, gelatine, sodium carboxy methyl cellulose, hydroxy propyl methyl cellulose E-3 and K-3, methyl cellulose A- 3, A-6 and A-15, pectin, sodium alginate, hydroxyl propyl cellulose, maltodextrins.

3. **Plasticizers (0-20%):** Plasticizer is used for improve Flexibility with reduce Brittleness of films. Plasticizer enhances mechanical properties such as tensile strength and elongation to thefilm by reducing the glass transition temperature of the polymer. It also reduces brittleness of the strip as a result improves its flexibility. Choice of plasticizer depends upon type of solvent used and its compatibility with the polymer. Some of the commonly employed plasticizers are phthalate derivatives like dimethyl, diethyl and dibutyl phthalate, low molecular weight polyethylene glycols, castor oil, citrate derivatives like tributyl, triethyl, acetyl citrate, triacetin and glycerol. Improper use of plasticizer may lead to blooming, film cracking, splitting and peeling of the strip.

4. **Surfactants:** Surfactants are used as wetting or solubilising or dispersing agent so that the film is getting dissolved within seconds and release active agent immediately. Commonly employed are poloxamer 407, benzethonium chloride, sodium lauryl sulphate, tweens, benzalkonium chloride, etc. Out of these most predominantly used surfactant is poloxamer 407.

5. **Sweetening agents:** Sweeteners have become an important part of pharmaceutical productsthat are intended to disintegrate or dissolve in the oral cavity. Some of the commonly used sweeteners are dextrose, sucrose, fructose, glucose, isomaltose, polyhydric alcohols

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(sorbitol, mannitol), etc. Saccharin, cyclamate, aspartame (first generation) and acesulfame K, sucralose,alitame, cyclamate, artificial sweeteners. generation) can also be used.

6. **Salivary stimulating agents:** Salivary stimulating agents are used to increase the rate of saliva production which will aid in rapid disintegration of fast dissolving strip formulations. Examples of salivary stimulants are citric acid, malic acid, lactic acid, ascorbic acid and tartaric acid. The most preferred of these is citric acid.

7. **Flavouring agents:** The amount of flavouring agent required to mask the taste depends on the type of flavour and its strength. Fruity flavours (vanilla, cocoa, coffee, chocolate, citrus), flavour oils (peppermint oil, cinnamon oil, nutmeg oil) are commonly used. Flavours can also be selected from oleo resins, artificial flavour oils and extracts obtained from various plant parts such as fruits, flowers etc.

8. **Colouring agents:** Common colouring agents included are FD&C dyes, natural dyes, pigments such as titanium dioxide etc.

Ingredient	Amount	Uses (Example)
Drug	**5-30 %w/w**	**All drug with low dose**
Water soluble polymer	45% w/w	Film forming capability (HPMC E3, E5, E6, E15, K3, Methyl cellulose A3, A6, A15, Pullulan, Polyvinyl pyrollidon K-90, Pectin, gelatin, Sodium alginate, Hydroxy propyl cellulose, Polyvinylalcohol, Maltodextrin)
Plastisizers	0-20 %w/w	Increases the flexibility and reduces the brittleness of film (Glycerol, Polyethylene gycol, Dibutylpthallate,triethyl citrate)
Surfactant	q.s.	They are used as solubilizing and wetting agents making the film to dissolve rapidly within seconds(Tween 80,Sodium lauryl sulphate,benzalkonium chloride)
Sweetning agent	3-6 %w/w	Increasing the palatability of the film (Aspartame, Saccharin,Cyclamate,Alitame and Neotame, Acesulfame-K)
Saliva stimulating agent	2-6 %w/w	Increases the saliva stimulation for faster dissolution of film (Citric acid, Malic acid)
Colors, Flavours	should not exceed 1% w/w	Pigments like titanium dioxide, silicon dioxide are used as prominent coloring agents.Fruity flavors like cocoa, chocolate and fruit essence like apple, raspberry and cherry are most widely used. Essential oils like eucalyptol and thymol.

Figure: 7 Composition of Mouth Dissolving FilmEvaluation of Oral Dissolving Films

1. **Weight variation:** Weight variation is calculated by individually weighing any five filmsfrom the formulation and then computing the average weight.
2. **Thickness:** The thickness of the films is calculated by selecting five films at random and then determining thickness of each film after calibration using a standard digital vernier

ISSN: 2519-9889
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calliper. The thickness of the film is measured at various critical points and average values are reported.

3. **Folding endurance:** Folding endurance is an important method for determining the mechanical properties of a film. This is determined by repeatedly folding the film at the same point until it breaks. Folding endurance values are calculated as the number of times they can be folded without breaking. The greater the folding the higher the endurance value, the higher the mechanical strength of the film.

4. **Surface pH:** The surface pH of the film is determined by soaking it in a petri dish with 10mlof distilled water and then measure it with a pH meter electrode by touching the surface of thefilm and recording the pH value.

5. **Moisture absorption and moisture loss:** The original weight of the film is first determinedand then the film is placed in a desiccator (including calcium carbonate) for three days to determine the moisture percentage. This the films are removed and reweighed after three daysand moisture loss is calculated using the formula:

$$\% \text{ moisture loss} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

The percentage moisture absorption of the film is calculated by exposing it to room temperature for seven days at a relative humidity of 75% and then using the following method to calculate the moisture absorption:

$$\% \text{ moisture uptake} = \frac{\text{Final weight} - \text{Initial weight}}{\text{Initial weight}} \times 100$$

6. **Disintegration time:** Placing the film in a beaker containing 20 ml of distilled water is usedto determine the disintegration time. The disintegration time is the time it takes for the film todissolve completely.

7. **Drug content:** The amount of drug in the orally dissolving film is determined by continuously stirring the strip in 100 ml of water for 4 hours. After that, Whatman filter paper is used to filter the solution and drug content is evaluated using UV Spectro-photometer.

8. **In-vitro drug release:** The USP rotating paddle method is used to perform dissolution studies on films. Distilled water, 6.8 pH phosphate buffer (300 ml), 0.1 N HCl (900 ml) are commonly used as dissolution media. The release rate is determined at a temperature of 37±5ºC with a rotation speed of 50 rpm. The oral dissolving film is then added to the dissolution medium. Samples (2 ml) of dissolved drug are withdrawn at predetermined intervals i.e., every 30 seconds and replaced with fresh medium. The samples are then filtered and analyzed for drug release using a UV spectrophotometer.

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2. CONCLUSION

In the current scenario, it has become really important for formulators to innovate and simultaneously provide consumer satisfaction. Therefore, the same oral dissolving films have been found as a promising and novel approach to maximize the therapeutic action of the drug and also enhance patient compliance. It has been found to be more beneficial than conventional dosage forms. They have the ability to deliver the active ingredient locally and systemically. The accessibility and ease of preparation of the excipient make it a better choice for formulators. It provides precision in administered doses without being susceptible to choking or suffocation. Various innovations have been introduced in the preparation method of ODF such as Wafer tab TM, Soluleaves TM and Foam burst TM which provide greater precision and thus help in enhancing patient compliance.

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