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FAST DISSOLVING SUBLINGUAL FILMS: AN EMERGING AND PROMISING APPROACH FOR RAPID ORAL DRUG DELIVERY

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ABSTRACT

Fast dissolving sublingual films are thin, flexible polymeric strips placed beneath the tongue, where they rapidly disintegrate or dissolve in saliva without the need for water. This dosage form enables rapid drug release and absorption through the highly vascularized sublingual mucosa, resulting in a quick onset of action and improved bioavailability by partially bypassing first-pass hepatic metabolism. These films are particularly beneficial for paediatric, geriatric, and dysphagic patients due to their ease of administration and improved patient compliance. The formulation typically comprises a film-forming polymer, plasticizer, and other excipients to ensure rapid disintegration, uniform drug distribution, and adequate mechanical strength. This review discusses fast dissolving sublingual film drug delivery systems with emphasis on formulation aspects, advantages, mechanisms of absorption, and preparation technologies.

KEYWORDS: Fast Dissolving, Sublingual Films, Sublingual Drug Delivery, Rapid Disintegration, Oral Thin Films.

INTRODUCTION

Oral drug delivery system

The oral route is the most preferred method of drug administration for systemic effect due to its ease of administration, non-invasiveness, adaptability, patient compliance, and acceptability. Tablets are the most widely used dosage form because of their ease of

manufacturing, transportation, and patient convenience. However, geriatric, pediatric, nauseous, bedridden, and noncompliant patients often experience difficulty in swallowing conventional oral dosage forms and therefore fail to take medications as prescribed. It is estimated that nearly 50% of the population is affected by this problem, leading to increased noncompliance and ineffective therapy.[1]

To overcome these limitations, oral fast-disintegrating drug delivery systems were developed in the late 1970s as an alternative to conventional tablets, capsules, and syrups for pediatric and geriatric patients. These dosage forms dissolve or disintegrate in the mouth within approximately three minutes without the need for water. Due to improved patient compliance, oral fast-disintegrating dosage forms have gained increasing acceptance as a novel drug delivery system.[2]

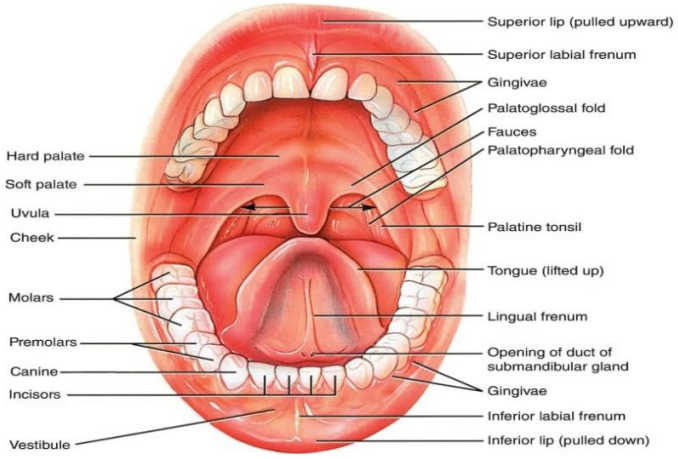

Fig. 1: Structure of oral cavity.

Sublingual drug delivery system

Systemic drug delivery via the sublingual route was developed to achieve a rapid onset of pharmacological action and is particularly beneficial for patients with dysphagia, including elderly, paediatric, uncooperative, nauseated individuals, or those with restricted fluid intake. In sublingual administration, the drug is placed beneath the tongue and absorbed directly into the systemic circulation through the ventral surface of the tongue and the floor of the mouth, primarily by passive diffusion across the lipoidal mucosal membrane. Drug molecules are rapidly taken up by the rich sublingual vasculature, bypassing hepatic first-pass metabolism, resulting in absorption that is 3–10 times greater than the oral route and second only to hypodermic injection. The sublingual region exhibits higher permeability than buccal and palatal areas due to thinner epithelium, greater blood supply, and lower keratinization.

Although sublingual absorption provides rapid therapeutic action with a short duration, it requires only a small volume of saliva for dosage form disintegration and is widely used for conditions requiring quick onset and improved patient compliance, such as migraines and psychiatric disorders.[3]

Sublingual glands

The sublingual glands, located beneath the tongue in the floor of the mouth, secrete mucin that contributes to saliva production and aids chewing. Drug absorption, defined as the transfer of a drug into systemic circulation, is influenced by mucosal thickness and follows the order sublingual > buccal > gingival > palatal. Due to its thin, non-keratinized epithelium, high permeability, and rich blood supply, the sublingual route provides rapid onset of action and is suitable for drugs requiring short duration and frequent dosing. The oral mucosa is relatively leaky, with buccal mucosa being 4–4000 times more permeable than skin, and differences in permeability are mainly due to epithelial thickness and degree of keratinization (buccal > sublingual).[4]

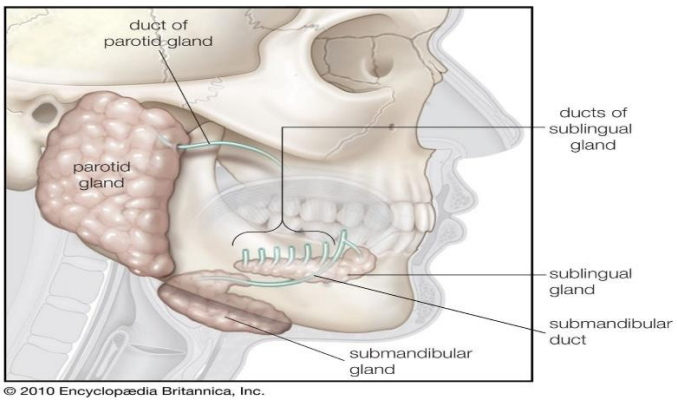

Fig. 2: Sublingual glands.

Mechanism of drug absorption

The absorption of drugs through the sublingual route is mainly influenced by the lipid solubility of the drug, which determines membrane permeability, as well as its degree of ionization (pH) and molecular weight. In addition to passive diffusion, the cells of the oral epithelium and epidermis are capable of drug uptake by endocytosis; however, this mechanism is limited because the engulfed particles are generally too large to diffuse across the stratified epithelium. Active transport processes are unlikely to play a significant role in drug absorption through the oral mucosa. Acidic stimulation may enhance drug uptake into the systemic circulation.[5]

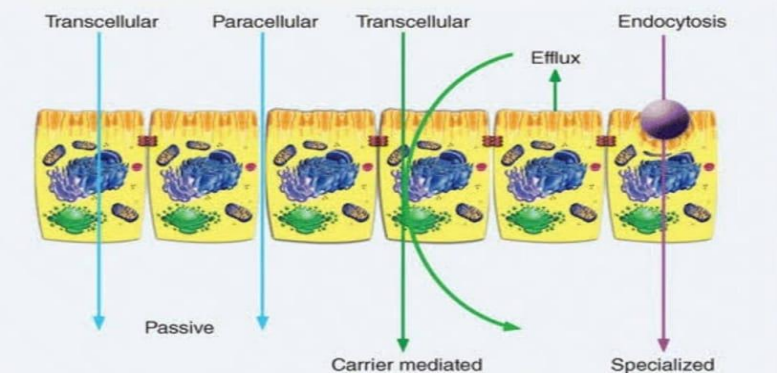

Fig. 3: Mechanism of drug absorption.

Factors affecting drug absorption

- Absorption through the sublingual and buccal routes depends mainly on the residence time of the drug in the oral cavity, which varies with formulation; solutions have shorter residence time than tablets.
- Saliva flow affects drug dissolution, and excessive salivation may cause the drug to be swallowed before absorption; unpleasant taste or irritation may also lead to expulsion.
- During sublingual administration, eating, drinking, talking, smoking, or chewing should be avoided, while in buccal administration talking is allowed but food and drink should be avoided; absorption can be easily terminated in both routes.
- Polar drugs are poorly absorbed, moderately lipophilic drugs are well absorbed, and highly lipophilic drugs show reduced absorption due to low salivary solubility; pH, membrane storage, and binding to oral macromolecules influence absorption.
- Absorbed drugs reach systemic circulation mainly via capillaries, with lymphatic uptake also contributing.[6]

Fast dissolving sublingual films

Fast-dissolving films and mouth-dissolving tablets make up the oral fast-disintegrating dosage form. Mouth dissolving tablets are linked to a number of issues, such as choking anxiety, trouble swallowing tablets, and residues in the mouth that make the mouth feel gritty. A novel drug delivery method for oral drug delivery known as fast dissolving films, oral dispersible films, mouth dissolving films, oral disintegrating films, or oral dissolving films was studied in order to address the problems with mouth-dissolving tablets. A postage stamp-sized thin film is applied to the patient's tongue or mucosal tissue, where it absorbs saliva and promptly hydrates. The film then quickly breaks and disintegrates to release the medication

for oral mucosal absorption. The vast surface area of the film, which wets quickly when exposed to the moist oral environment, is the main cause of this rapid dissolving action.[7]

Table 1: Comparison between fast dissolving films and fast dissolving tablets.[8]

Fast dissolving films	Fast dissolving tablets
It is a film	It is a tablet
Greater dissolution due to larger surface area	Lesser dissolution due to less surface area
Better durable than orodispersible tablets	Less durable as compared with oral films
More patient compliance	Less patient compliance than films
Only low dose can be incorporated	High dose can be incorporated
No risk of chocking	It has a fear of chocking

Advantages of fast dissolving films

- Can be taken without water, anytime and anywhere.
- Large surface area allows very fast disintegration and dissolution in the mouth.
- Thin, flexible, and lightweight, making them easy to carry, handle, and store.
- Suitable for paediatric, geriatric, mentally ill, and uncooperative patients, as well as those with swallowing difficulties or limited fluid intake.
- Useful in conditions requiring rapid action such as motion sickness, acute pain, allergic reactions, and coughing.
- Better stability due to solid dosage form until administration, combining solid stability with liquid-like bioavailability.
- Provides accurate and precise dosing compared to liquid formulations.
- Enables direct absorption through oral/buccal mucosa, avoiding first-pass hepatic metabolism and improving bioavailability.
- Allows faster onset of action with lower dose, improving efficacy and safety.
- Offers opportunities for product differentiation, promotion, and patent extension.[9]

Disadvantages of fast dissolving films

- High drug doses cannot be incorporated; only low doses (about 1–30 mg) are suitable.
- Film preparation has technical limitations, especially in controlling uniform thickness during casting.
- Maintaining dose uniformity across the film is a major technical challenge.
- Packaging requires specialized equipment and is comparatively difficult.[10]

Special features of sublingual films

- Very thin and aesthetically appealing film.
- Can be designed in different sizes and shapes.
- Non-obstructive and comfortable during administration.
- Possess excellent mucoadhesive properties.
- Disintegrate quickly in the oral cavity.
- Provide rapid drug release and onset of action.[11]

Suitable drug candidates for sublingual films

- The drug should have a pleasant taste or only slight bitterness that can be easily masked with sweeteners and flavours.
- The drug dose should be low, preferably up to 40 mg.
- Drugs with small to moderate molecular weight are preferred.
- The drug should be well soluble in water and saliva and should be stable.[12]

Classification of oral thin films

There are 3 different subtypes of oral thin films:

1. Flash release (quick release).
2. Mucoadhesive melt away wafers (mucoadhesive wafer).
3. Mucoadhesive sustained-release wafers (mucoadhesive extended-release wafer).[13]

Table 2: The properties that distinguish the different types of OTFs mentioned above.

Properties	Flash Release	Mucoadhesive Melt Away Wafers	Mucoadhesive Sustained Release Wafers
Area (cm^2)	2-8	2-7	2-4
Thickness(µm)	20-70	50-500	50-250
Structure	Single Layer	Single or Multilayer	Multilayer system
Excipients	Soluble hydrophilic polymers	Soluble hydrophilic polymers	Low/non-soluble polymers
Drug phase	Solid solution	Solid solution or Suspended drug particles	Suspension and/or solid solution
Application	Tongue	Gingival or buccal region	region in the oral cavity
Dissolution	60 s	In few minutes forming Gel	Maximum 8-10 h
Site of Action	Systemic or Local	Systemic or Local	Systemic or Local

Technological classification for fast- dissolving systems

Fast-dissolving oral technologies can be broadly divided into three main categories, as explained in Table 3.

- Lyophilized systems.
- Compressed tablet based systems.
- Fast dissolving oral film.[14]

Table 3: Technological classification for fast-dissolving systems.

Properties	Lyophilized system	Compact tablet-based technology	Fast dissolving Oral film
Composition	Solution or suspension of drug with excipients	Active pharmaceutical ingredient with super disintegrants	Drug- containing hydrophilic polymers with additional excipients
Utilized technology	Transformation into lyophils	Compression done directly	Extrusion using hot melt and solvent casting
Features	High porosity that permits fast breakdown and entry of water or saliva	Variations in the degrees of hardness and friability lead to different requirements for disintegration and packaging.	Extensive surface area causes quick disintegration
Packing	Pack of blisters	High-density bottles made of polyethylene	Multiple units on a blister card

FORMULATION INGREDIENTS

1. Active Pharmaceutical Ingredient (1–25% w/w)

Fast-dissolving films can accommodate a wide range of APIs, with low-dose and highly potent drugs being the most suitable. The use of micronized APIs enhances film smoothness, improves drug uniformity, and promotes faster dissolution. However, many suitable APIs possess an unpleasant bitter taste, which can reduce patient acceptability, particularly in paediatric formulations.

Therefore, effective taste masking is necessary before incorporating such APIs into fast-dissolving films. Among the various approaches available, simple blending or co-processing of the bitter drug with appropriate sweetening and flavouring agents is commonly employed to improve palatability.[15]

2. Film-Forming Polymers (40–50% w/w)

Film-forming polymers are the most important components of fast-dissolving oral films, as they control film strength, flexibility, and disintegration. Generally, about 45% w/w polymer is used, and hydrophilic polymers are preferred to ensure rapid disintegration in saliva. Film-forming polymers should possess non-toxic, non-irritant, tasteless, and colourless

characteristics, with good film-forming ability, wetting and spreading properties, adequate mechanical strength, low molecular weight, long shelf life, and cost-effectiveness.

Both natural and synthetic polymers are commonly employed. Natural polymers include starch, pullulan, sodium alginate, pectin, gelatine, and maltodextrin, while synthetic polymers include polyvinyl pyrrolidone, polyvinyl alcohol, sodium carboxymethyl cellulose, hydroxypropyl cellulose, and hydroxypropyl methylcellulose.[16]

3. Plasticizers (0–20% w/w)

Plasticizers play an important role in fast-dissolving film (FDF) formulation by improving film flexibility and reducing brittleness. They should be compatible with the polymer and solvent, as they enhance polymer flow and mechanical strength. Commonly used plasticizers include propylene glycol, polyethylene glycol, glycerol, phthalate derivatives, citrate derivatives, triacetin, and castor oil. However, improper selection or concentration may cause film cracking, splitting, peeling, or alter drug absorption, and therefore the plasticizer should be volatile and carefully chosen.[17]

4. Saliva-Stimulating Agents (2–6% w/w)

Saliva-stimulating agents are added to fast-dissolving strips to increase saliva flow, thereby promoting quicker film dissolution. These agents are usually food-grade acids, with citric acid being the most commonly used, followed by malic acid, lactic acid, ascorbic acid, and tartaric acid.[18]

5. Sweetening agents (3–6% w/w)

Sweetening agents are essential components of food products and pharmaceutical dosage forms and are used to enhance formulation palatability. Both natural and artificial sweeteners are employed, either alone or in combination, typically in concentrations ranging from about 3 to 6% w/w.[19]

Suitable sweeteners include water-soluble natural sweeteners such as xylose, ribose, glucose, sucrose, maltose, and stevioside; water-soluble artificial sweeteners like sodium or calcium saccharin and acesulfame-K; and dipeptide-based sweeteners such as aspartame.

6. Flavouring agents (2–10% w/w)

Flavors are added to oral films to mask the bitter or unpleasant taste of the drug, and their concentration depends on the type and intensity of the flavour used. Any US-FDA–approved

flavour such as sweet, sour, or mint may be employed; studies have shown that a combination of mint, liquorice, and sucralose effectively masks the bitterness of diclofenac sodium. Electronic tongues are commonly used to evaluate and compare the effectiveness of different taste-masking agents.[20]

7. Colorants (As required)

Colouring agents are added to oral dissolving films to enhance their visual appeal. Pigments are commonly used, with titanium dioxide being the most widely employed colorant. In addition, a wide range of other colorants is available, including FD&C dyes, natural colours, and custom Pantone-matched shades.[21]

MANUFACTURING TECHNIQUES

1. Solvent Casting Method

The solvent casting method is one of the most commonly used techniques for preparing orally fast-dissolving films (OFDFs). In this method, the drug and film-forming polymers are dissolved in a suitable volatile solvent to form a uniform solution. The solution is then cast as a thin layer on a flat surface and dried to obtain a flexible film.

Steps involved

1. Selection of suitable film-forming polymers and plasticizers.
2. Dissolution of polymer, plasticizer, and API in a volatile solvent such as ethanol.
3. Casting of the solution onto a flat surface using a spreader or casting device.
4. Drying to remove the solvent and form a thin film.
5. Cutting the dried film into the required dosage units.[22]

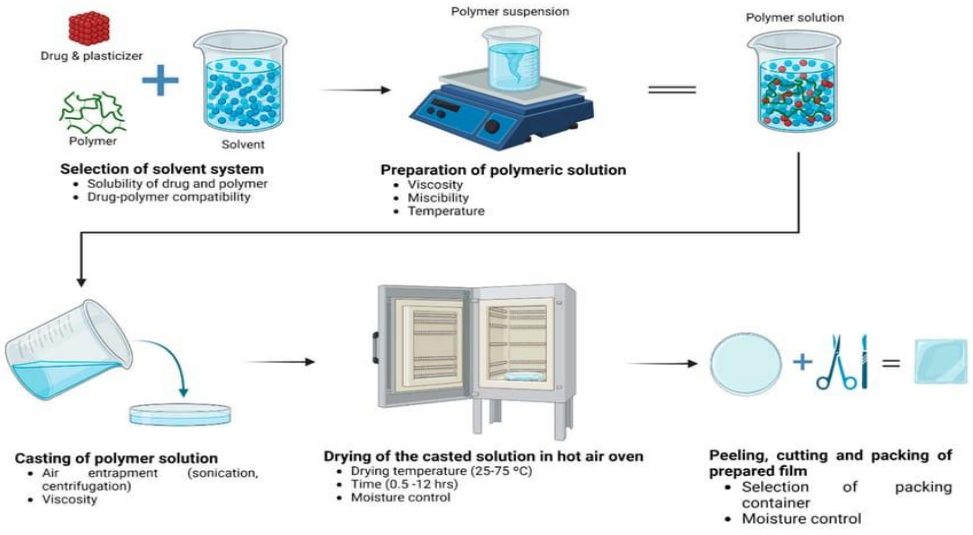

Fig. 4: Solvent casting method.

2. Semisolid Casting Method

The semisolid casting method is mainly used when acid-insoluble polymers are required for film formulation. In this technique, a gel mass is prepared and cast into films using heat-controlled drums. The gel is formed by mixing a solution of the film-forming polymer with an alkaline solution of an acid-insoluble polymer, such as ammonium or sodium hydroxide. Commonly used acid-insoluble polymers are cellulose derivatives like cellulose acetate phthalate and cellulose acetate butyrate. Typically, the acid-insoluble polymer and film-forming polymer are used in a ratio of 1:4.[23]

3. Hot-Melt Extrusion Method

In the hot-melt extrusion method, the drug is mixed with suitable carriers to form a uniform mass, which is dried and converted into granules. These granules are then processed in an extruder under controlled temperature zones and screw speed until the material melts completely. The molten mass is finally passed through a calendar to obtain a film. Advantages include fewer processing steps, minimal material wastage and good scalability, solvent-free (anhydrous) process, short residence time with improved content uniformity.[24]

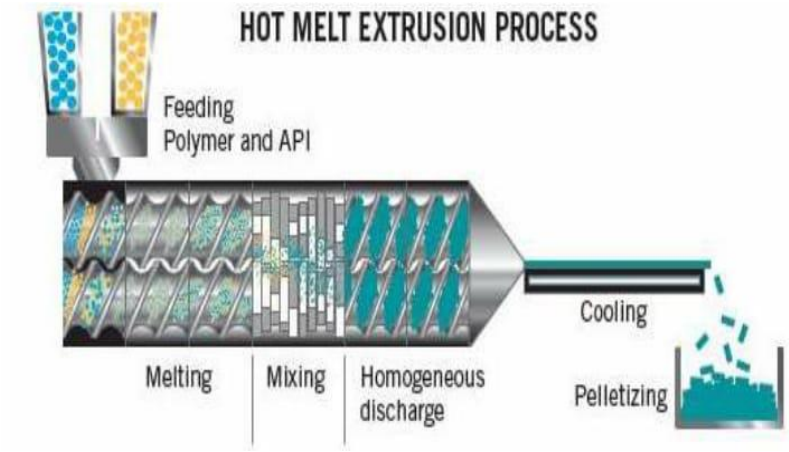

Fig. 5: Hot-melt extrusion method.

4. Solid Dispersion Extrusion

Solid dispersion extrusion involves dispersing the drug in an inert carrier with amorphous hydrophilic polymers in the solid state. The drug solution is added to molten polyethylene glycol below 70 °C and extruded through dies to form films. The solvent used should be compatible with the polymer melt, as poor miscibility or solvent effects may cause drug precipitation or instability in the solid dispersion.[25]

5. Rolling Method

In the rolling method, a drug-containing solution or suspension is spread onto a carrier using rollers. Water or a water–alcohol mixture is commonly used as the solvent. The formed film is dried on the rollers and then cut into the required shapes and sizes.[26]

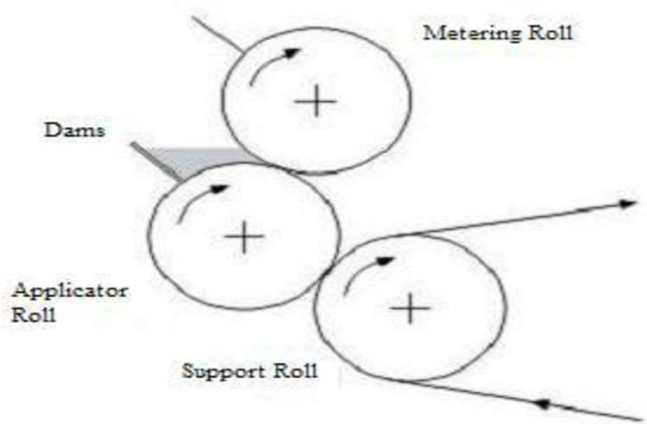

Fig. 6: Rolling method.

Various technologies used in oral film formulation

1. Soluleaves™

Soluleaves films are formulated to dissolve quickly when they come in contact with saliva, releasing the drug and flavour rapidly. This technology is used for cough and cold, gastrointestinal disorders, pain management, and nutritional supplements.

2. Wafertab™

Wafertab is an oral filmstrip system in which pharmaceutical drugs are incorporated into an edible film. The film dissolves rapidly in the mouth upon contact with saliva, ensuring quick drug release. Flavouring agents can be added to improve taste masking.

3. Foamburst™

Foamburst is a modified form of Soluleaves technology. During manufacturing, an inert gas is introduced into the film, creating a honeycomb-like structure. This structure allows very fast dissolution and provides a unique mouthfeel.

4. Xgel™

Xgel is a proprietary oral film technology used in various ingestible dosage forms. It is non-animal derived and manufactured using a continuous production process, making it cost-effective and suitable for large-scale pharmaceutical and healthcare applications.[27]

EVALUATION PARAMETERS

1. Thickness of the film

Film thickness is measured at three different points using a micrometre screw gauge, and the average value is calculated. Uniform thickness is essential, as it directly affects dose uniformity and accuracy in the film.[28]

2. Folding Endurance

Folding endurance is used to evaluate the mechanical strength of a film by repeatedly folding it at the same point until it breaks. The number of folds a film withstands without breaking represents its folding endurance, with higher values indicating greater mechanical strength. Since mechanical strength depends on plasticizer concentration, folding endurance is also indirectly influenced by the amount of plasticizer used.[29]

3. Percent Elongation

Percent elongation indicates the extent to which a film stretches when subjected to stress, reflecting the strain developed in the film. It is defined by the change in film length relative to its original length. The percentage of elongation increases with higher plasticizer content, as greater plasticizer levels enhance film flexibility. It is calculated using the formula:[30]

Percentage elongation = (change in length / initial length) × 100.

4. Tensile Strength

Tensile strength refers to the maximum stress a film can withstand before breaking and is used to evaluate its mechanical strength. It is calculated by dividing the load applied at the point of rupture by the cross-sectional area of the film, as shown below:[31]

Tensile strength = (load at failure / strip thickness × strip width) × 100

5. Weight Variation

Weight variation is assessed by weighing ten randomly selected films individually and calculating their average weight. The individual film weights should fall within the acceptable weight variation limits.[32]

6. Surface pH of Film

The surface pH of fast-dissolving films is measured to assess the risk of irritation to the oral mucosa, as extreme pH values may cause discomfort in vivo. Therefore, the surface pH is maintained close to neutral. The film surface is slightly moistened with water, and the pH is

measured using a combined pH electrode placed on the film surface. Measurements are carried out in triplicate, and the mean value is recorded.[33]

7. Content Uniformity / Drug Content

Content uniformity is evaluated to ensure consistent drug distribution within the film. The drug content is determined using simulated salivary fluid, and the results are assessed according to USP limits, which require the drug content to be within 98–101%. The final values are reported as the mean of three determinations.[34]

8. Disintegration Test

The disintegration time for oral films should be 90 seconds or less, although no official guidelines are currently available for oral strips. Pharmacopoeial disintegration test apparatus can be used to evaluate this parameter. Typically, oral films disintegrate within 5–30 seconds.[35]

9. *In-vitro* Dissolution Studies

In-vitro dissolution studies are carried out using simulated salivary fluid to evaluate the drug-release behaviour of fast-dissolving films. The studies are performed under physiological conditions, and drug release is analysed spectrophotometrically. Dissolution data are expressed as the percentage of drug released at different time intervals and plotted against time to obtain the dissolution profile.[36]

10. Stability Studies

Stability studies are conducted under different storage conditions to assess the stability of oral films. The films are evaluated at predetermined intervals for physical appearance, surface pH, drug content, and *in-vitro* drug release to determine any changes over time.[37]

PACKAGING

Proper packaging is essential to maintain the stability and integrity of fast dissolving films. Since these films are sensitive to environmental conditions, single-unit packaging is mandatory, with aluminium pouches being the most commonly used option. Packaging materials should be FDA approved, non-toxic, non-reactive, tamper-resistant, and capable of protecting the product from moisture, gases, and other environmental factors without affecting taste or odour.

Common packaging formats include foil, paper, or plastic pouches; single-dose and aluminium pouches with high barrier properties; and blister packs containing multiple units. Among these, aluminium pouches and blister cards with aluminium foil backing provide excellent protection against moisture and gas and are widely used in pharmaceutical applications.[38]

CONCLUSION

Fast dissolving sublingual films represent a novel and effective drug-delivery system designed for rapid action and improved patient convenience. These films are especially beneficial for paediatric, geriatric, and psychiatric patients who experience difficulty in swallowing conventional dosage forms. Their ability to disintegrate quickly in the oral cavity makes them highly suitable for emergency conditions such as allergic reactions and asthmatic attacks, where immediate drug action is required. Sublingual administration provides efficient absorption, often resulting in higher bioavailability than the conventional oral route, while also partially bypassing hepatic first-pass metabolism. Overall, fast dissolving sublingual films enhance patient compliance, safety, and therapeutic efficacy, making them a promising and widely accepted technology for systemic drug delivery.

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