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Review Article

Oral Fast Dissolving Film: A Review

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A B S T R A C T

Fast-dissolving films are becoming a popular alternative to fast-dissolving tablets. These films dissolve quickly when they come in contact with a wet surface, like the tongue, and can be taken without needing extra liquid. This makes them convenient and helps patients stick to their treatment, especially children, older adults, and people who have trouble swallowing pills or fear choking. Because the drug in these films is absorbed directly into the bloodstream through the mouth, it avoids problems in the digestive system and bypasses the first-pass effect (which happens when the liver breaks down the drug before it reaches the rest of the body). This type of formulation is gaining popularity in over-the-counter products in the U.S. for things like pain relief and motion sickness.

Keyword: Fast dissolving films, Oral mucosa, Permeability, Solvent casting, Disintegration

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INTRODUCTION

Oral dosage forms are popular because they are easy to use, convenient for patients, require minimal cleanliness, and can be designed in various ways. However, they can be challenging for certain groups like the geriatric, pediatric, people with swallowing difficulties, and even animals. These systems allow the drug to dissolve quickly in the mouth without needing water, enabling faster absorption into the blood stream and bypassing the liver's first-pass metabolism.ODFs should be thin, flexible, stable during manufacturing, packaging, and transport. They need to taste good, feel pleasant in the mouth, and dissolve quickly (within 1 minute) [1]. Solid dosage forms like tablets and capsules are generally accepted by older children and adults, but younger children often prefer liquids because they are easier to swallow. The U.S. Food and Drug Administration defines ODTs as solid oral medications that disintegrate in the mouth in about 30 seconds or less, according to specific testing methods.). ODFs are ultra-thin strips, about the size of a postage stamp, containing an active ingredient and other components. Their convenience and portability make them popular among both children and older adults. When ODTs were introduced to the market, it was important to educate people on how to use them properly, including instructions not to swallow or chew.[2] Research has advanced oral drug delivery from basic tablets and capsules to modified release forms, then to oral disintegrating tablets (ODTs), wafers, and now to oral fast dissolving films (OFDFs). Among these options, oral strip technology is gaining significant attention.[3] Buccal and sublingual drug administration has been known for centuries to allow for rapid absorption into the veins under the oral mucosa, which then carry the drugs into systemic circulation. The buccal area of the mouth is a good choice for delivering drugs because it has a rich blood supply and is relatively permeable.[4]Various hydrophilic polymers are used as film-forming agents due to their rapid dissolution, good mechanical properties, and pleasant mouthfeel. Pullulan, a natural polysaccharide made of repeating malt triose units, is available in food and pharmaceutical grades. Commonly used as a low-calorie food additive, pullulan retains moisture and prevents fungal growth, making it effective for food preservation.[7] Unlike traditional fast-dissolving tablets, which can be soft and brittle, buccal films are designed to adhere to the oral tissue, dissolve quickly, and can be formulated to allow for

gastrointestinal absorption if swallowed. Formulating these films involves selecting various ingredients, including polymers, plasticizers, active ingredients, sweeteners, and flavourings. All components must be approved for oral use. Recent developments have even enabled vaccines to be delivered via these films, particularly in underprivileged areas.[8]

Overview of the Oral Cavity [9-12]

The oral cavity is the area inside the mouth, defined by the lips, cheeks, hard palate, soft palate, and floor of the mouth. It has two main parts:

1. **Outer Oral Vestibule:** This is the space bounded by the cheeks, lips, teeth, and gums.
2. **Oral Cavity Proper:** This area extends from the teeth and gums to the back of the mouth, leading to the throat. The roof is formed by the hard and soft palate, while the tongue is located on the floor of the cavity. When drugs are administered through the oral mucosa, they enter the bloodstream via a network of arteries and capillaries. The main blood supply to the oral cavity comes from the external carotid artery, while the venous blood drains through capillaries and veins into the jugular vein.

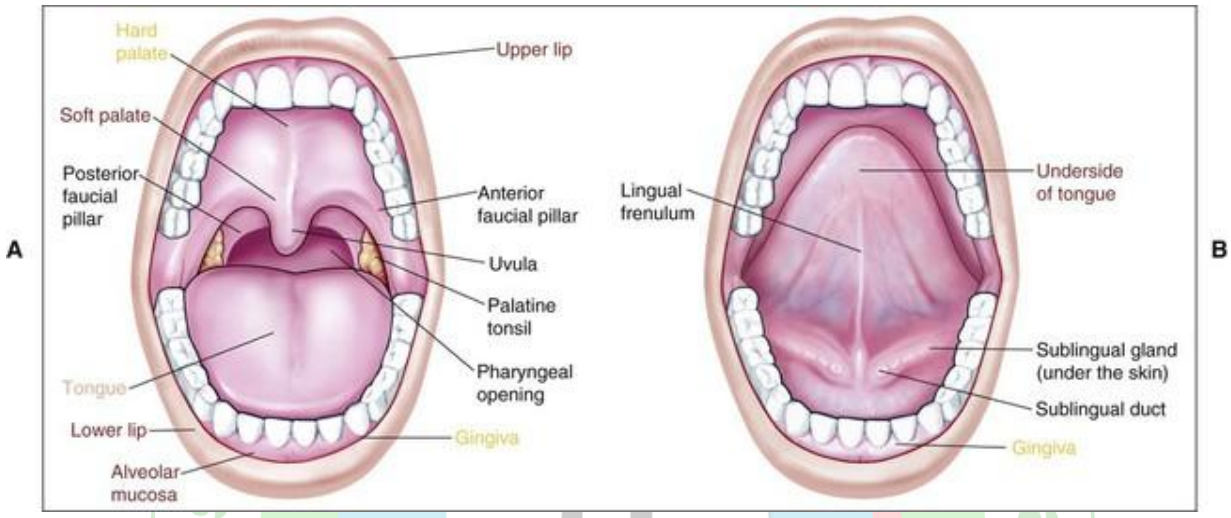

Figure 1: Structure of oral cavity

Structural Features of Oral Mucosa

The oral mucosa is different from other parts of the gastrointestinal tract and resembles skin more closely. It has several layers:

1. Stratified Squamous Epithelium: This is the outermost layer.
2. Basement Membrane: Below the epithelium.
3. Lamina Propria: This layer contains connective tissue.
4. Submucosa: The innermost layer.

There are three types of oral mucosa:

1. **Masticatory Mucosa:** This covers the gums and hard palate. It has a tough, keratinized epithelium that is firmly attached to the underlying tissue, making it strong enough to handle chewing forces.
2. **Lining Mucosa**: This covers all other areas of the mouth, except for the top surface of the tongue. Each type of mucosa serves a specific function related to its location and role in the mouth Characteristics of Oral Mucosa The turnover time for the buccal epithelium is about 5-6 days, which likely represents the entire oral mucosa. The thickness of the mucosa varies by location Buccal Mucosa 500-800 micrometres. Hard and Soft Palate, Floor of the Mouth, Ventral Tongue, and Gingiva: About 100-200 micrometres. The type of epithelium also differs depending on the area. The gingival and hard palate mucosa are keratinized, similar to skin, and contain ceramides and acyl ceramides that help with barrier function. In contrast, the mucosa of the soft palate, sublingual area, and buccal regions are non-keratinized, making them relatively impermeable to water and containing fewer ceramides and small amounts of neutral lipids. Non-keratinized epithelia are significantly more permeable to water than keratinized ones. Overall, the oral mucosa has permeability characteristics that fall between those of skin and intestinal mucosa. he permeability of the buccal mucosa is estimated to be 4 to 4,000 times greater than that of the skin. Additionally, there are significant differences in permeability among various regions of the oral cavity.[10]

a. Composition of The Oro mucosal Region

Oro mucosal cells are made up of proteins and carbohydrates, giving them an adhesive quality that reduces friction between cells. Mucus in the oral cavity helps with the bio adhesion of drug delivery systems. Unlike other body parts, where goblet cells produce mucus, in the oral mucosa, mucus is secreted by the major and minor salivary glands as part of saliva. The minor salivary glands contribute about 70% of the mucin in saliva.

Saliva is a digestive fluid produced by three pairs of salivary glands: the parotid, submandibular, and sublingual glands. It is mostly water, containing about 1% organic and inorganic materials. Salivary amylase, an enzyme in saliva, breaks down starch into smaller glucose

chains. Since saliva comes from blood plasma, it contains many of the same chemicals.[12]

b. Benefits of Oral Fast Dissolving Films [13]

1. Rapid Disintegration: Larger surface area allows for quick disintegration and dissolution in the mouth.
2. Flexibility: Oral films are less fragile than ODTs, making them easier to transport and handle.
3. Precise Dosage: They offer accurate dosing without the risk of choking.
4. Comfort: Improved mouth feel enhances user experience.
5. Patient Compliance: Easier to swallow, no water needed, which is beneficial for dysphagic patients.
6. Convenience: Can be taken anywhere, anytime.
7. Direct Absorption: Highly vascularized buccal mucosa allows drugs to enter the bloodstream directly, avoiding first-pass metabolism.
8. Enhanced Bioavailability: Improved absorption for drugs affected by the first-pass effect.
9. Lower Dosage Requirements: Reduced dose can decrease potential side effects.
10. Fast Action: Typically dissolve on the tongue in seconds, providing rapid release of active ingredients.

c. Advantages of Oral Fast Dissolving Film [8]

1. No risk of chocking.
2. Convenient dosing or accurate dosing.
3. No need of water to swallow or chew.
4. Small size for unproved patient compliance.
5. Rapid onset of action.
6. Ease of handling and transportation.
7. Improve bioavailability for certain therapeutic ingredient.
8. Enhanced stability.
9. Ease of administration to pediatric, geriatric, bedridden patients and psychiatric patients who refuse to swallow tablets.
10. No need of water to swallow the dosage form, which is highly convenient feature for patients who are traveling.
11. Rapid dissolution and absorption of drug, which may produce rapid onset of action.
12. Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patient.
13. Pregastric absorption can result in improved bioavailability and as a result of reduced dosage; improved clinical performance through a reduction of unwanted effects.
14. Some drugs are absorbed from the mouth, pharynx and oesophagus as the saliva passes down into the stomach, which enhances bioavailability of drugs.

d. Disadvantages of Oral Fast Dissolving Film [8]

1. It is hygroscopic in nature so it must be kept in dry places.
2. It also shows the fragile, granule property.s
3. They require special packaging for the products stability and safety.
4. High dose cannot be incorporated into the oral film.
5. Drugs which are unstable at buccal pH cannot be administered.
6. Drugs which irritate the mucosa cannot be administered by this route.
7. Drug with small dose requirement can only be administered.

Classification of fast dissolving technology [9-10]

For ease of description, fast-dissolve technologies can be divided in to three broad groups:

a) Lyophilized systems,

b) Compressed tablet-based systems,

c) Thin film strips.

a) The lyophilized systems: This system has been the most successful in terms of sales, volume, and global product approvals. The technology involves combining a drug suspension or solution with other structural elements to create a simplified form**.**This system works by mixing a drug with excipients (inactive ingredients), then shaping it into tablets using a mould or blister pack. The tablets are frozen and dried in a process called lyophilization. This makes the tablets highly porous, so they quickly dissolve when they come in contact with water or saliva. The ability to handle the dose depends on whether the drug is soluble or not, with soluble drugs having a slightly lower dose capacity compared to some traditional tablets. These units can also include materials that mask the taste and dissolve faster than regular tablets**.**

b) **Compressed tablet-based systems**: This system is made using regular tablet-making technology, where excipients (inactive ingredients) are directly compressed into tablets. The way they're made affects their hardness and how easily they break apart, which in turn affects how quickly they dissolve and what type of packaging is needed—ranging from standard bottles or blister packs to more specialized packaging for protection, like CIMA Labs' Pack Solv. Fast-dissolving tablets are made by using water-soluble excipients or special ingredients to help the tablet break down quickly when it contacts water.

An exception to this is Biovail's Fuisz technology, which uses a unique method called Shear form to make drug-loaded candy floss, which is then turned into tablets with other excipients. These tablets can hold larger doses and include taste-masked ingredients, but they take longer to dissolve compared to thin-film or freeze-dried tablets. Some companies are increasingly using a loose compression method to create fast-dissolving tablets for both brand-name and generic drugs.

c) **Oral Thin Films (OTF):** Oral films, also known as oral wafers, are thin, flat films that dissolve when placed in the mouth. Though they've been around for a while, they've recently gained popularity for delivering fast-dissolving drugs. These films evolved from products like breath strips, which were first used for things like freshening breath, and have now become common for delivering vitamins and personal care products.Companies that already made drug-delivery products for the skin (like patches) started applying that technology to create these oral films. Today, oral thin films (OTFs) are widely used for over-the-counter (OTC) medications and are being developed for prescription drugs as well.

These films are made using hydrophilic (water-attracting) polymers, and they can include soluble or insoluble drugs, or even drugs with a taste-masking coating. The films are created as large sheets and then cut into individual doses, which are packaged in various formats suitable for use.

MANUFACTURING METHODS [14]

Fast dissolving films are manufacture with the help of different methods. One or combination of the following process can be used to manufacture the mouth dissolving films.

1) Solvent casting method
2) Semi solid casting method
3) Hot melt extrusion method
4) Solid dispersion extrusion method
5) Rolling method

1. Solvent Casting

Method:

- Dissolve Polymers: First, dissolve water-soluble polymers in water while stirring at 1,000 rpm and heating up to 60°C.
- Prepare Other Ingredients: Mix colours, flavouring agents, and sweeteners in a separate container.
- Combine Solutions: Mix the polymer solution with the other ingredients, stirring at 1,000 rpm.
- Add API: Add the active ingredient (API) dissolved in a suitable solvent to the mixture.
- Remove Air: Use a vacuum to get rid of any trapped air.
- Cast the Film: Pour the mixture onto a flat surface to form a film and let it dry.
- Cut the Film: Once dry, cut the film into the desired sizes.

Advantage:

- The film has great uniformity of thickness and better clarity than extrusion.
- Films have fine gloss & freedom from a defect such a die liner.
- Films have a lot of flexibility & good physical properties.

Disadvantage:

- The polymer must be soluble in volatile solvent or water.
- The stable solution with reasonable minimum solid content.

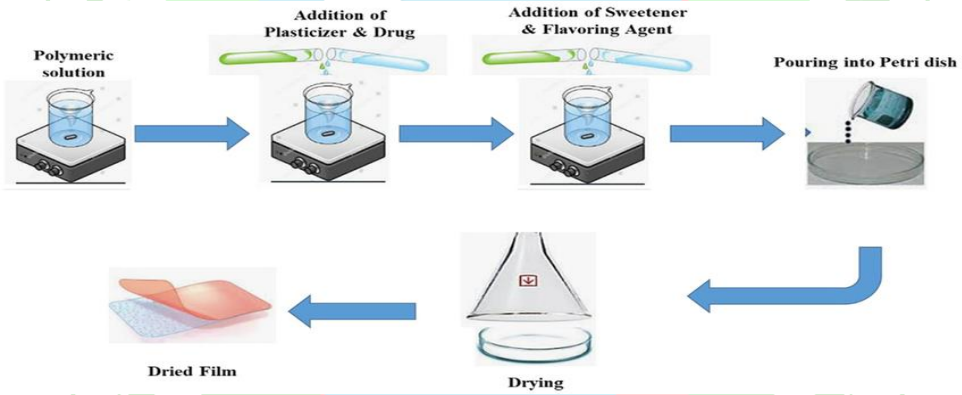

Figure:2 Solvent Casting Method

2. Solid Dispersion Extrusion:

- Dissolve Drug: Dissolve the drug in a suitable liquid solvent.
- Melt Polymer: Heat a suitable polymer until it melts, keeping the temperature below 70°C.
- Combine: Add the drug solution to the melted polymer without removing the solvent to create a solid dispersion.
- Shape into Films: Use Molds (dyes) to shape the solid dispersion into films.

3. Hot-Melt Extrusion:

- Prepare Initial Mass: Mix the drug with carriers to form a solid mass, then dry it.
- Feed into Extruder: Place the dried granules into the extruder, which has four temperature zones: 800°C, 1150°C, 1000°C, and 650°C.
- Melt the Mixture: Set the extruder screw speed to 15 rpm and process the granules for about 3-4 minutes until the mass melts.
- Form into Film: Press the melted mixture (at 650°C) into a cylindrical Mold to create a film.

Benefits of Hot-Melt Extrusion:

- Fewer equipment needs
- Less product waste
- Scalable for larger production
- No water or organic solvents used
- Short processing time and lower temperatures
- Improved uniformity of the final product.

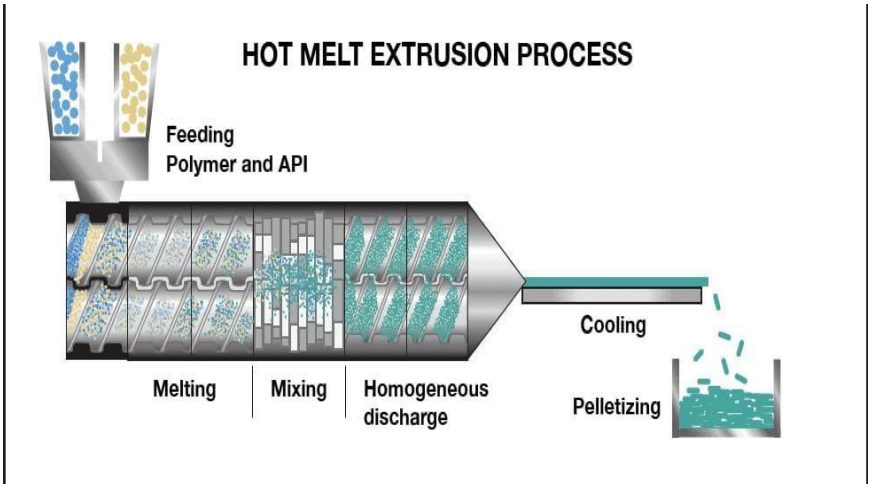

Figure: 3 Hot- Melt Extrusion

4. Solid Dispersion Extrusion:

- Dissolve the Drug: Dissolve the drug in a suitable liquid solvent.
- Melt the Polymer: Heat a suitable polymer until it melts, keeping the temperature below 70°C.
- Combine: Add the drug solution to the melted polymer without removing the solvent to create a solid dispersion.
- Shape into Films: Use Molds (dyes) to shape the solid dispersion into films.

5. Rolling Method:

- Mix Solutions: Combine the drug solution with the film-forming polymer solution thoroughly.
- Prepare for Rolling: Ensure the mixture has the right flow properties.
- Roll the Mixture: Pass the mixture through rollers to form a film.
- Dry the Film: Allow the film to dry on the rollers.
- Cut into Shapes: Cut the dried film into the desired shapes and size

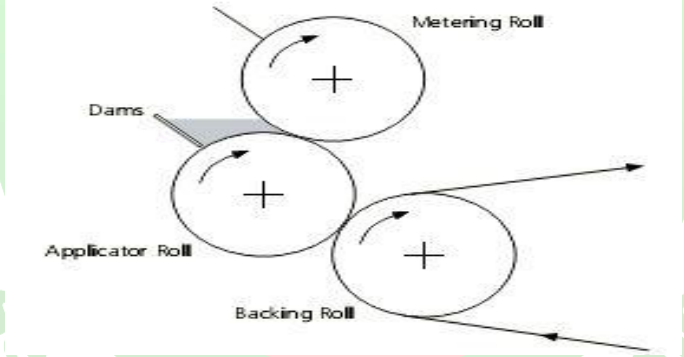

Figure: 4 Rolling Method

FORMULATION CONSIDERATION [16-23]

Formulating fast-dissolving films involves creating a product that has the right taste, texture, and performance characteristics. These films are thin (5-20 cm² in size) and dissolve quickly in water or saliva. The key ingredients are water-soluble polymers that form a matrix to hold the drug. A typical dose of the drug is around 15 mg.To ensure the film works well, formulation factors like the glass transition temperature (the temperature at which the film becomes flexible) are important. This can be adjusted to improve the film's performance. The excipients (additional ingredients) used must be safe for consumption, meaning they should be on the GRAS (Generally Recognized As Safe) list and approved for use in oral medicines.In simple terms, it's about making sure the film dissolves quickly, tastes good, and is safe for use, with carefully chosen ingredients that work together to achieve these goals.

Table 1: Formulation of film

Sr. No	Composition of Film	Quantity
1	Active pharmaceutical ingredient	**5-30%**
2	Film forming polymer	**40-50%**
3	Plasticizer	**0-20%**
4	Saliva stimulating agent	**2-6%**
5	Sweetening agent	**3-6%**
6	Surfactant, Flavour, Colouring agent	**Q.S**

6. Active pharmaceutical ingredient:

Thin film strips are mostly used for consumer vitamins, supplements, and over-the-counter (OTC) products. Suitable active ingredients for these films include vitamins, melatonin, CoQ10, and some OTC ingredients. Various types of medicines, such as those for coughs, colds, and sore throats, can be included in these film strips.Oral strips (OS) can deliver a variety of drugs, including those for erectile dysfunction, antihistamines, asthma, digestive issues, nausea, pain relief, and central nervous system disorders (like Parkinson's disease). They can also be used for caffeine, snoring aids, multivitamins, and sleep aids.However, there are limitations, as high-dose drugs are difficult to fit into these small strips. Typically, they can hold 5% to 30% of the active ingredient by weight. One challenge is that many active ingredients have a bitter taste, especially for pediatric use, so taste-masking is necessary. Several methods are available to improve taste.OS technology is especially useful in situations where rapid drug release is needed, such as for pain relief, migraines, sore throats, coughs, and allergies

Below List of few drug that can be incorporated in fast dissolving film:

Table 2: List of drug that can be incorporated in fast dissolving film:

Drug	Dose	Therapeutics Action
Azatadine Maleate	1Mg	Anti Histaminic
Nicotine	2Mg	Smoking cessation
Loperamide	2Mg	Anti Diarrhoeal
Ondansetron	2.5Mg	Anti emetic
Tripodine Hcl	2.5mg	Anti Histaminic
Zolmitriptan	2.5 mg	Anti Migraine
Salbutamol	4 Mg	Anti Histaminic
Chlorpheniramine Maleate	4 Mg	Anti Histaminic
Cetirizine	5-10 Mg	Anti Histaminic
Acrivastine	8 Mg	Anti Histaminic
Loratadine	10 Mg	Anti Histaminic
Omeprazole	10-20 Mg	Proton Pump Inhibitor
Famotidine	10 Mg	Antacid
Ketoprofen	12.5 Mg	Analgesic
Dicyclomine Hcl	25 Mg	Muscle Relaxant
Diphenhydramine Hcl	25 Mg	Anti Allergic
Sumatriptan Succinate	35-70 Mg	Anti Migraine

7. Plasticizer:

Plasticizers are important for making oral films. They help make the film more flexible and less brittle. The choice of plasticizer depends on how well it works with the polymer (the main material in the film) and the solvent used to make the film. By lowering the polymer's glass transition temperature, plasticizers improve the strip's properties. They are usually used in amounts ranging from 1% to 20% of the dry polymer weight. Some common examples of plasticizers are glycerol, propylene glycol, polyethylene glycols, triacetin, acetyl citrate, dimethyl or diethyl phthalates, and castor oil.

8. Sweeteners:

Sweeteners are important ingredients in oral films, especially for making them taste better, and they're particularly useful in children's medicines. They are usually added in amounts ranging from 3% to 6% of the total weight. Both natural and artificial sweeteners are used to improve the taste of mouth-dissolving drugs.

Here are the types of sweeteners used:

- **Natural sweeteners (water-soluble)**: Ribose, xylose, glucose, sucrose, maltose.
- **Artificial sweeteners (water-soluble)**: Cyclamate salts, calcium saccharin, sodium salts, acesulfame-K.
- **Dipeptide sweeteners**: Aspartame.
- **Protein-based sweeteners**: Thaumatin I and II.

Fructose is sweeter than sorbitol and mannitol and is absorbed faster in the mouth, making it a common sweetener in oral films. Polyhydric alcohols like sorbitol, mannitol, isomalt, and maltitol are also used because they give a pleasant feeling in the mouth and a cooling effect. Aspartame is used in valdecoxib oral films, while sucralose, maltodextrin, and neotame are used to mask the bitter taste of drugs like diclofenac, ondansetron, and piroxicam in fast-dissolving films.[20]

9. Saliva-stimulating agents:

Saliva-stimulating agentshelp fast-dissolving oral films break down by encouraging the production of saliva in the mouth. These agents are usually acidic. Common examples include citric acid, ascorbic acid, lactic acid, malic acid, and tartaric acid.[21]

10. Surfactants:

Surfactants help oral films break down quickly and release the drug inside. They also improve the solubility of drugs that are hard to dissolve in fast-dissolving films. Some common surfactants used are poloxamer 407, benzathine chloride, sodium lauryl sulphate, tweens, and benzalkonium chloride. Poloxamer 407 is the most commonly used because it has many benefits.[21]

11. Stabilizing and thickening agents:

Stabilizing and thickening agents are used in fast-dissolving oral films to improve the thickness and consistency of the film mixture before it's made into strips. Natural gums like xanthan gum, locust bean gum, carrageenan, and cellulosic derivatives are commonly used for this purpose, usually in amounts up to 5% of the total weight.[22]

12. Flavouring agents:

Flavouring agents are added to oral medicines to make them taste better, which is important for patient satisfaction and can also help with sales. Both natural and artificial Flavors are used, and the amount needed depends on the type and strength of the flavour. Flavors are usually added in amounts up to 10% of the total weight.Flavouring agents can come from synthetic oils, oleo resins, or extracts from various parts of plants like leaves, fruits, and flowers. They can be used alone or in combination. Some examples of flavour oils are cinnamon, peppermint, spearmint, and nutmeg oils. Fruity Flavors include cocoa, vanilla, coffee, chocolate, citrus, and fruit essences like pineapple, apple, cherry, and raspberry.[23]

13. Cooling agents:

Cooling agentslike monomethyl succinate are added to improve the taste and feel of the product in the mouth. Some cooling agents, such as WS3, WS23, and Ultracool II, can also be combined with Flavors to enhance the experience.

14. Colouring agents:

Colouring agents are added to give the film colour and are usually chosen to match the flavour. These agents are typically FD&C-approved. The most common colouring agent used in fast-dissolving oral films is titanium dioxide. Colouring agents should not make up more than 1% of the total weight [22]

EVALUATION [23-30]

The fast-disintegrating oral films are evaluated for the following parameters:

1. **Weigh variation of Films:** The mouth-dissolving oral films were weighed on an analytical balance, and the average weight of each film was calculated. It's important for the films to have a consistent weight. This helps ensure that each film contains the right amount of ingredients, including the active pharmaceutical ingredient (API) and other necessary substances.[23]
2. **Visual inspection:** The colour, uniformity, and transparency of the prepared orally disintegrating film can be checked by looking at it with the eyes.[24]
3. **Thickness Test:** The thickness of the film was measured at five different spots using a micrometre screw gauge, and the average of three readings was calculated. This helps ensure the film has a uniform thickness, which is important for making sure the correct dose is in each film.[25]
4. **Folding Endurance:** Folding endurance is tested by folding the same spot on the film repeatedly until it breaks. The folding endurance value is the number of times the film can be folded before it breaks.[25]
5. **Tensile strength:** Tensile strength is the maximum stress applied to a point at whichthe strip specimen breaks. It is calculated by the applied load atrupture divided by the cross-sectional area of strip as given inthe equation below:

   Tensile strength = Load at failure × 100/Strip thickness × Stripwidth
6. **Percent elongation:** When stress is applied on a film (2 × 2 cm2) sample it getsstretched, this is referred to strain. Strain is basically thedeformation of strip before it gets broken due to stress. It ismeasured by using Hounsfield universal testing machine.[23] Generally elongation of strip increases as the plasticizer contentincreases. It is calculated by the formula:

   % Elongation = Increase in length of strip × 100/Initial lengthof strip
7. **Tear resistance:** Tear resistance is the resistance which a film offers when someload or force is applied on the film specimen. The load mainlyapplied is of very low rate 51 mm/min. The unit of tear resistanceis Newton or pounds-force. In other words, it is the maximumforce required to tear the specimen.[26]
8. **Percentage moisture loss:** To determine percentage moisture loss films of area 2 × 2 cm2 are cutand weighed accurately on an electronic balance. After weighing, thefilms were kept in desiccators containing fused anhydrous calciumchloride. The films should be kept for 72 h in the desiccator. After72 h, they are taken out and again weighed and the percentagemoisture loss of films was measured by using the formula:

   Percent moisture loss = (Initial weight - Final weight)/Initialweight × 100

   The percentage moisture loss studies are done to determinephysical stability and integrity of the film.[27]
9. **Transparency:** To determine transparency of oral film, a simple ultraviolet (UV) spectrophotometer can be used. The film specimen is placed onthe internal side of spectrophotometer cell. The transparency offilms is calculated as follows:

Transparency = (log T600)/b = −€c

Where T600 is the transmittance at 600 nm and b is the filmthickness (mm) and c is concentration.[28]

Young's modulus: Young's modulus or elastic modulus is the measure of stiffness ofstrip. It is represented as the

Ratio of applied stress over strain in theregion of elastic deformation as follows:

Young's modulus = Slope × 100 Strip thickness × cross - head speed

Hard and brittle strips demonstrate a high tensile strength and Young's modulus with small elongation.[29]

10. **Wetting time:** To test the wetting time, a circular paper is placed in a petri dish, and 6 ml of a 0.1% amaranth dye solution is added. A 2x2 cm film strip is placed on top of the tissue paper. The wetting time is the amount of time it takes for the dye to appear on the surface of the film.[30]

11. **Surface pH:** The test film was placed in a petri dish and moistened with 0.5 ml of distilled water for 30 seconds. After that, the pH meter electrode was placed on the film's surface, and the pH was measured after 1 minute. The pH was measured three times for each film, and the average was calculated.[31]

12. **Disintegration time:**To test how quickly a film disintegrates, the official disintegration apparatus (used in pharmacopeia's) is often used. The time it takes for the film to break down depends on its ingredients and can range from 5 to 30 seconds. There are no official rules for measuring disintegration time for fast-dissolving films, but two methods are commonly used:

    a) **Slide Frame Method**: A drop of distilled water is placed on the film, which is clamped in a slide frame and put on a petri dish. The time it takes for the film to dissolve is recorded.
    b) **Petri Dish Method**: The film is placed in a petri dish with 2 mL of distilled water. The time it takes for the film to fully dissolve is measured.[32]

13. **Dissolution test:** Dissolution testing is done using a standard basket or paddle apparatus, as described in pharmacopeia. The liquid used for the test is chosen based on the conditions needed for the drug to dissolve and the highest dose of the active ingredient (API). Sometimes, the test can be tricky because the film strip may float on top of the liquid when using the paddle apparatus.[33]

14. **Contact Angle:** Contact angle measurements are done at room temperature using a goniometer. A drop of distilled water is placed on the dry film's surface, and a digital camera captures images of the water droplet within 10 seconds. The images are then analysed using software to measure the contact angle.[34]

15. **Stability Testing:** Stability is tested by storing the oral strip under controlled conditions, at 25°C with 60% humidity and at 40°C with 75% humidity, for up to 12 months in a stability chamber, following ICH guidelines. During this time, different properties like thickness, appearance, strength, moisture content, and how it dissolves are checked.[35]

Packaging of Fast Dissolving Oral Film[36-38]

When packaging fast-dissolving oral films, it's important to choose the right materials to keep the product safe and effective. Here are the key factors to consider:

1. **Nontoxic**: The packaging must be safe and not harmful.
2. **FDA-approved**: Packaging materials should be approved by the FDA for use with oral products.
3. **Non-reactive**: The packaging should not react with the film or affect its quality.
4. **No taste or Odor**: The packaging must not change the taste or smell of the film.
5. **Temperature resistance**: The packaging must handle the required temperature range without affecting the film.Additionally, packaging should include clear instructions, barcodes, and features like child-resistant seals and senior-friendly designs to ensure ease of use and safety.

Types of Packaging for Fast-Dissolving Oral Films:

1. **Pouches (Foil, Paper, or Plastic):**
    - **Tamper-resistant**: Keeps the product safe and secure from being tampered with.
    - **Environmental Protection**: Offers protection from environmental factors like moisture, light, and air.
    - **Flexible Design**: The pouches are flexible and are sealed during the filling process, which can be done using vertical or horizontal equipment.

2. **Single Pouches or Aluminium Pouches:**
    - **Peelable Pouch**: Easy to open, designed for "quick dissolve" films.
    - **High Barrier Protection**: One side is clear, and the other is made of foil to prevent gas and moisture from getting in.
    - **Protects Product and Dosage**: The pouch keeps the film safe and maintains the correct dosage.

3. **Multiple-Unit Blister Card:**
    - **Two Parts**: The blister is made of plastic to hold the product, and the lid is made of aluminium to seal it.
    - **Manufacturing Process**: A thermoplastic sheet is heated and softened, then vacuum-formed into a Mold. After cooling, the sheet is removed.
    - **Packing**: The product is placed in the formed blister and sealed with a heat-sensitive backing material.

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