

**NOVEL DRUG DELIVERY SYSTEM BASED FAST DISSOLVING  
ORAL FILMS: A DETAIL REVIEW ARTICLE****\*Atharva Ajit Kolbe, Satyam Narayan Kumbhar, Saniya Amin Jamadar,****Silvie Gonsalvis, Dr. Manoj Kadam, Mr. Pawar Rahul**

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**ABSTRACT**

Fast-dissolving orally disintegrating films are designed to rapidly dissolve when they meet a moist surface or fluids such as saliva, typically within a few seconds. Unlike tablets, capsules, or oral liquids, they do not require the use of additional liquids like water. This makes them a highly convenient dosage form for patients and provides significant marketing benefits. In paediatric, geriatric populations, and in patients who experience a fear of choking, orally disintegrating films are considered a more convenient and widely accepted dosage form. The obtained results indicate that the formulated oral film could serve as an innovative dosage form for enhancing drug delivery and achieving a faster onset of action, while also improving patient compliance. The term “Oro dispersible” refers to dosage forms that rapidly disperse within the oral cavity. The disintegration time for such formulations

should generally not exceed 3 minutes. These dosage forms are commonly available as tablets and mouth dissolving films, which release the drug immediately after placement in the mouth, resulting in a rapid therapeutic effect.

**KEYWORDS:** Oral films, swallow, Fast dissolving, Rapid, Oral mucosa.**INTRODUCTION**

Oral film drug delivery systems are emerging as a modern alternative to conventional oral routes of drug administration. An oral film is a solid dosage form that dissolves quickly in the mouth without the need for chewing or water intake. These films, containing active

pharmaceutical ingredients, are specially developed for oral administration so that the drug can avoid first-pass metabolism in the liver, thereby improving its bioavailability. After dissolution, the drug is absorbed into the bloodstream through enteric, buccal, and sublingual pathways. The preparation of oral films mainly involves the use of hydrophilic polymers, which act as essential components that rapidly dissolve in the buccal cavity and facilitate the delivery of the drug into systemic circulation. This innovative formulation technology was initially developed by Richard Fuisz, Joseph Fuisz, Garry Myers, and Robert Yang, who collectively contributed more than 30 patents in this area.<sup>[1]</sup>

Oral films represent a modern advancement in the formulation of orally disintegrating dosage forms. These films are thin and elegant preparations made from edible, water-soluble polymers and are available in various shapes and sizes, including rectangular, square, and circular forms. The strips may be transparent or opaque and can either be flexible or brittle in nature. They are specifically designed to dissolve rapidly on the tongue without the requirement of water. Fast dissolving films (FDFs) possess a large surface area, which enables quick disintegration. These films help reduce the risk and fear of choking, are simple to administer and handle, and offer convenient packaging and manufacturing processes, thereby overcoming several limitations associated with orally disintegrating tablets. However, some major disadvantages of these dosage forms include limited drug loading capacity and poor taste masking ability.<sup>[2]</sup>

A fast-dissolving film is generally a thin strip with a thickness ranging from 1–10 mm and a surface area between 1–20 cm<sup>2</sup>, which may be prepared in different geometrical designs. Usually, drugs can be incorporated up to a single dose of approximately 30 mg. The rapid dissolution in saliva occurs because of a specially formulated matrix containing water-soluble polymers. These films possess low thickness, making them easy to handle and apply. However, after encountering moisture, the system develops wet tack and mucoadhesive properties that help the film adhere firmly to the site of application. The films are also formulated with adequate flexibility and mechanical strength to support manufacturing operations such as rewinding, die cutting, and packaging. When a fast-dissolving film is placed on the patient's tongue, the saliva immediately wets the mucosal surface, causing the film to hydrate rapidly and attach to the site of administration. It then disintegrates and dissolves quickly, releasing the drug for absorption through the oral mucosa or through the gastrointestinal tract after swallowing.<sup>[3]</sup>

## HISTORY AND BACKGROUND

Oral film technology was initially introduced in the late 1970s to address swallowing difficulties associated with tablets and capsules, particularly among geriatric and paediatric patients. Over time, these films have gained significant popularity in the pharmaceutical industry because of their reduced fragility compared to other oral dosage forms, accurate dosing, rapid drug release, and ease of administration. These formulations are also referred to as oral strips, buccal films, or buccal strips. Various bio adhesive mucosal dosage forms have been developed, including adhesive tablets, gels, ointments, and patches, while polymeric films designed for buccal drug delivery are commonly known as mouth dissolving films. Oral films generally possess a shelf life of about 2–3 years depending on the active pharmaceutical ingredient, although they are highly sensitive to environmental moisture. An ideal oral film should exhibit characteristics such as good stability, portability, convenient handling and administration, no requirement of water during use, and a pleasant taste profile.<sup>[4]</sup>

Due to these advantages, oral films are highly beneficial for paediatric and geriatric patients, bedridden individuals, and patients suffering from conditions such as dysphagia, Parkinson's disease, mucositis, or vomiting. Initially, oral films were introduced into the market as breath fresheners and personal care products, including dental care strips and soap strips. Later, these dosage forms entered the pharmaceutical markets of the United States and Europe for therapeutic applications. The first commercially developed oral strip was introduced by Pfizer under the name Listerine Pocket Aks, which was primarily marketed as a mouth freshener.<sup>[5]</sup>



**Fig. 1: Oral Film.**<sup>[6]</sup>

## OBJECTIVES

1. To improve patient compliance.
2. To achieve a rapid onset of therapeutic action.
3. To enhance the bioavailability of the drug.

4. To provide a dosage form that is easy to carry and convenient to use.<sup>[7]</sup>

### **ADVANTAGES**

1. Does not require water for swallowing the dosage form.
2. Reduces the possibility of choking during administration.
3. Easy and convenient to administer.
4. Taste masking methods are employed to minimize the unpleasant bitter taste of drugs.
5. Provides a pleasant mouthfeel along with an acceptable taste and texture.
6. Disintegrates rapidly within a few seconds, producing a quick therapeutic response.

### **DISADVANTAGES**

1. Drugs that are unstable at buccal pH cannot be administered through this route.
2. Drugs that may cause irritation to the oral mucosa are unsuitable for administration by this method.
3. Only drugs requiring a low dose can be incorporated into the formulation.
4. The drug loading capacity of oral films is limited.
5. Not suitable for drugs that are unstable or irritating in the oral cavity pH conditions.<sup>[8]</sup>

### **APPLICATION**

1. Orally dissolving films are utilized for managing localized pain, allergies, sleep disorders, and conditions affecting the central nervous system (CNS).
2. Soluble films are suitable for topical use as pain-relieving or antibacterial agents in wound care management.
3. Orally disintegrating films may help enhance the bioavailability of drugs with poor absorption characteristics.
4. Dissolvable films can also be applied topically as analgesic or antibacterial agents for treating wounds.
5. The unpleasant taste of medications is masked.<sup>[9]</sup>

### **METHODS OF PREPARATION OF ORAL FILM**

- A. Solvent Casting Method
- B. Hot - Melt Method
- C. Semi – Solid Casting Method
- D. Solid - Dispersion Method
- E. Rolling Method

### **A. SOLVENT CASTING METHOD**

The solvent casting method is one of the most widely preferred techniques for preparing oral dissolving films (ODFs). In this method, water-soluble components are dissolved to obtain a clear and viscous solution. The active pharmaceutical ingredient (API) along with other additives is dissolved separately in smaller quantities and then blended with the main polymeric solution. This mixture is subsequently incorporated into the aqueous viscous solution. Entrapped air bubbles are removed by applying vacuum, as deaeration is essential to produce films with uniform thickness and consistent properties. The final solution is cast into thin films, dried, and then cut into the required dimensions.

The characteristics of the API play an important role in selecting an appropriate solvent. Various physicochemical properties such as compatibility of the API with film-forming excipients, solvent compatibility, polymorphic nature of the drug, and temperature sensitivity must be carefully evaluated. During the manufacturing and packaging of ODFs, special precautions are necessary to minimize the effects of moisture because moisture can greatly influence the film's stability and mechanical strength. Temperature is another critical parameter that must be strictly controlled to maintain proper solution viscosity and to protect temperature-sensitive APIs.<sup>[10]</sup>

### **B. HOT-MELT METHOD**

Hot-melt extrusion (HME) is commonly employed in the preparation of granules, sustained-release tablets, and transdermal or transmucosal drug delivery systems. Recently, this technique has gained considerable importance in the pharmaceutical industry. Drawing knowledge from plastic processing technology, formulators can combine drugs, polymers, and plasticizers and extrude them into different final forms to achieve the required drug release profile. In this method, films are produced through a heating process rather than by the conventional solvent casting technique.

The advantages of HME in film production include:

1. Elimination of solvents or water during processing.
2. Reduction in the number of manufacturing steps.
3. Minimal product wastage.
4. Easy scalability for industrial production.
5. Better control over processing parameters.

During the HME process, the API and excipients are blended in dry form, heated, and converted into a molten mass that is extruded through a hot-melt extruder. A major advantage of this process is the complete removal of solvent-related concerns. The resulting films are cooled and cut into the desired size. Since the process involves high temperatures, it is mainly suitable for thermostable drugs, whereas heat-sensitive drugs are unsuitable for this method.<sup>[11]</sup>

### **C. SEMI-SOLID CASTING METHOD**

In the semi-solid casting technique, a solution containing a water-soluble film-forming polymer is first prepared. This solution is then mixed with an acid-insoluble polymer solution such as cellulose acetate phthalate or cellulose acetate butyrate, previously dissolved in ammonium hydroxide or sodium hydroxide solution. A suitable amount of plasticizer is added to form a gel-like mass. The prepared gel is then cast into films or ribbons using a controlled heat source. The thickness of the resulting films is generally maintained between 0.015 and 0.05.<sup>[12]</sup>

### **D. SOLID-DISPERSION EXTRUSION METHOD**

Solid dispersion refers to the dispersion of one or more APIs within an inert carrier in the solid state using amorphous hydrophilic polymers and methods such as hot-melt extrusion. In solid-dispersion extrusion, immiscible materials are extruded together with the drug to form solid dispersions. These dispersions are further processed into films using dies.

In this technique, the drug is dissolved in a suitable liquid solvent and then incorporated into the molten polymer, such as polyethylene glycol, at temperatures below 70°C without evaporating the solvent. The selected solvent or dissolved drug may sometimes be immiscible with the molten polyethylene glycol. Additionally, the polymorphic form of the precipitated drug within the solid dispersion may be influenced by the type of solvent used during the process.<sup>[13]</sup>

### **E. ROLLING METHOD**

In the rolling method, a drug-containing solution or suspension is spread over a carrier by rolling. The solvent system mainly consists of water or a combination of water and alcohol. The formed film is dried on rollers and later cut into the required shapes and sizes. Film preparation involves first producing a premix, followed by the incorporation of the API.

The premix or master batch consists of the film-forming polymer, polar solvent, and other excipients except the API, and it is transferred into the feed tank. A measured quantity of this master batch is pumped through control valves and metering pumps into the mixers. The required amount of drug is then introduced into the mixer through a separate opening. After thorough mixing to obtain a uniform matrix, the mixture is fed onto the pan using metering pumps. Film thickness is controlled using a metering roller. Finally, the film is formed on a substrate and transported through support rollers. Drying of the wet film is carried out under controlled bottom-drying conditions, preferably without exposure to external air currents or direct surface heating.<sup>[14]</sup>

### COMPONENTS OF AN ORAL FILM

- A) Drug / API
- B) Polymer
- C) Solvent
- D) Plasticizer
- E) Saliva Stimulating Agent.
- F) Flavoring Agent.
- G) Sweetener

#### A) Drug/Active Pharmaceutical Excipient

The active pharmaceutical ingredient (API) constitutes approximately 30–40% of the distinctive composition of the film. Drugs that are highly potent, undergo extensive first-pass metabolism, and are intended for non-compliant patients are considered suitable candidates for fast dissolving buccal films. The presence of the API generally contributes positively to the texture of the film while also improving its dissolution behaviour and content uniformity in oral fast dissolving films. However, especially in paediatric formulations, the unpleasant taste of certain APIs can reduce patient acceptability. Therefore, taste masking is essential before incorporating the API into the oral fast dissolving film. Various approaches are available to improve palatability, among which the most widely used involves blending bitter-tasting APIs with excipients possessing pleasant Flavors. This approach is commonly known as the taste obscuration method. The selection of an API mainly depends on its potency. APIs typically account for 30–40% of the overall film formulation and are selected for drugs that are potent, experience high first-pass metabolism, and are suitable for patients with poor compliance. In addition, APIs can improve the film's texture, dissolution rate, and uniformity

in oral fast dissolving films. Nevertheless, unpleasant taste remains a challenge, particularly in paediatric preparations.

### **Ideal Characteristics of the Selected Drug**

- Drugs with low to moderate molecular weight are preferred, with a maximum dose limit of about 40 mg.
- The drug should be stable and soluble in water as well as saliva, while remaining partially unionized at the pH of the oral cavity.
- It should possess the ability to effectively permeate through the oral mucosal membrane.<sup>[15]</sup>

### **B) Film Forming Polymer**

Polymers are the main constituents of oral rapid dissolving films. The type and amount of polymer used directly influence the mechanical strength of the film. The final film must possess sufficient strength to avoid breaking or damage during handling, storage, or transport. Generally, polymers account for about 45% of the total weight of the dry film. Hydrophilic polymers are mainly used in oral strips because they rapidly disintegrate in the mouth upon contact with saliva. To obtain the required film properties, a single polymer or a combination of different polymers may be used. Pullulan is a naturally derived polymer that can be sourced from non-animal origins and does not require chemical modification.

- a. Natural Polymers:** Examples include cellulose derivatives, pectin, zein, gelatine, shellac, waxes, gums, natural rubber, and chitosan.
- b. Synthetic Polymers:** Examples include polybutadiene, hydrin rubber, silicone rubber, polyisobutylene, acrylonitrile, neoprene, and butyl rubber.
- c. Semi-Synthetic Polymers:** Examples include polyvinyl alcohol, polyvinyl chloride, polyethylene, and polypropylene.<sup>[16]</sup>

### **C) Plasticizer**

Plasticizers are an essential component in oral strip formulations, typically used in concentrations ranging from 0–20% w/w of the dried polymer. They help improve the flexibility of films and reduce their brittleness. The addition of plasticizers can enhance both tensile strength and elongation of the film. They also improve film-forming properties by decreasing the glass transition temperature of the polymer. The selection of a suitable

plasticizer depends on its compatibility with the polymer as well as the type of solvent used during film casting.

However, the inappropriate use of plasticizers may lead to cracking, splitting, or peeling of the film strip. Furthermore, certain plasticizers have been reported to influence the rate of drug absorption.<sup>[17]</sup>

#### **D) Saliva Stimulating Agent**

These agents are incorporated to increase saliva production, helping the oral thin film dissolve more rapidly in the mouth. Salivary flow can be stimulated by using compounds such as citric acid, malic acid, tartaric acid, and ascorbic acid. These ingredients may be used either individually or in combination at concentrations ranging from 2–6% w/w of the strip weight.<sup>[18]</sup>

#### **E) Flavouring Agents**

Flavouring agents are added to mask the unpleasant or bitter taste of the formulation. Any flavour approved by the USFDA may be used for this purpose. These agents can be selected from synthetic flavour oils, oleoresins, or herbal extracts obtained from different plant parts such as fruits, leaves, and flowers. The quantity of flavour used depends on the type of flavouring agent selected. Commonly used Flavors include essential oils like menthol, mint Flavors such as peppermint, spearmint, sweet mint, and wintergreen, spices like cinnamon and clove, citrus Flavors including lemon and orange, as well as sweet Flavors such as chocolate and vanillin.<sup>[19]</sup>

#### **F) Sweetener**

Sweeteners play an important role in pharmaceutical and nutraceutical products that dissolve in the oral cavity. Commonly used conventional sweeteners include sucrose, glucose, dextrose, fructose, liquid glucose, and isomaltose. Fructose is frequently preferred because it provides greater sweetness compared to sorbitol and mannitol. Polyhydric alcohols such as sorbitol, mannitol, and isomaltose may also be used in combination, as they offer a pleasant mouthfeel along with a cooling sensation. In oral formulations polyhydric alcohols are considered beneficial due to their lower cytotoxicity and absence of aftertaste.<sup>[20]</sup>

### **EVALUATION TEST FOR AN ORAL FILM**

➤ Thickness of the Film

- pH Value
- Folding Endurance
- Percent Elongation
- Drug Content Uniformity
- In Vitro Dissolution Study
- Dryness / Tack Test
- Transparency
- Disintegration Time
- Percentage Moisture Loss

**Thickness of the Film:** The thickness of the film is measured using a micrometre screw gauge or a calibrated digital vernier calliper. Measurements are taken at five different locations, including the centre and all four corners of the film, and the average thickness is then determined. Evaluating thickness uniformity is important because it is directly associated with the accuracy and consistency of the drug dose present in the film.<sup>[21]</sup>

**Determination of pH value:** Measuring the pH of oral thin films (OTFs) is important for their solubility and dispersion in the oral cavity, as well as for taste characteristics and rapid drug release. For this purpose, 1.5–2% (w/v) agar is incorporated into an isotonic solution and allowed to dissolve. The prepared solution is then poured into a Petri dish and left to incubate until it gels at room temperature. The thin film samples are placed on the formed gel surface. After this, pH indicator papers with a range of 1–11 are brought into contact with the OTFs, and the pH is estimated based on the resulting colour change of the paper. Usually, oral strips pH normal range is up to 4.5–6.5.<sup>[22]</sup>

**Folding Endurance:** The flexibility of thin films is evaluated by repeatedly folding the film at the same position at a 180° angle until it fractures. The total number of folds the film withstands before breaking is recorded. A film that can endure 300 or more folds is regarded as having excellent flexibility.<sup>[23]</sup>

**Percentage Elongation:** When a tensile (pulling) force is applied, the film undergoes stretching. This stretching continues until the structural integrity of the film begins to fail. The percentage elongation can be calculated by measuring the final length of the film just before it loses its integrity. This value generally increases with an increase in plasticizer

concentration. The percentage elongation of OTF formulations is determined using the following formula:[24]

$$\% \text{ Tensile Strength} = \frac{(\text{Load at Failure})}{(\text{Film Thickness} \times \text{Film Width})} \times 100.^{[24]}$$

**Drug Content Uniformity:** For evaluating content uniformity, each film is dissolved in an appropriate solvent and then filtered. The amount of drug present in every film is analysed using a suitable quantification technique. The relative standard deviation (%RSD) should ideally not exceed 6%.<sup>[25]</sup>

**In Vitro Dissolution Test:** Dissolution studies may be carried out using conventional basket or paddle apparatus specified in pharmacopoeias. The dissolution medium is mainly chosen based on sink conditions and the maximum dose of the drug. However, performing dissolution testing with a paddle apparatus can sometimes be challenging because the film strip may float on the dissolution medium.<sup>[26]</sup>

**Dryness / Tack Test:** Tack refers to the degree of force with which a strip sticks to an accessory or a piece of paper after it has been brought into contact and pressed against the strip. [27]

**Transparency:** The transparency of OTFs can be evaluated using an ultraviolet (UV) spectrophotometer. Samples of the OTF formulation are cut into rectangular shapes and placed in the cuvette of the UV spectrophotometer. The film permeability is then measured at a wavelength of 600 nm. The obtained values are calculated using the following equation.[28]

$$\text{Transparency} = \log T_{600}/b$$

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[T<sub>600</sub>= Transmittance at 600 nm, *b* = film thickness (mm)]

**Disintegration Test:** The acceptable disintegration time for oral films is generally 90 seconds or less, although there are no official guidelines specifically established for oral strips. A pharmacopoeia disintegration test apparatus can be employed for this evaluation. Usually, oral strips disintegrate within 5–30 seconds.

It has been noted that increasing the polymer concentration results in thicker films, which subsequently prolongs the disintegration time. In contrast, MDF showed faster disintegration with higher plasticizer concentration because the hydrophilic plasticizer absorbed water rapidly, causing swelling and quick breaking of hydrogen bonds.<sup>[29]</sup>

**Percentage Moisture Loss:** To assess the physical stability and integrity of the film, a percent moisture loss test was performed. A film sample of size  $2 \times 2$  cm<sup>2</sup> was cut and initially weighed. It was then kept in a desiccator containing fused anhydrous calcium chloride for three days. After this period, the film was removed and weighed again. The percentage moisture loss was calculated using the following formula:<sup>[30]</sup>

$$\text{Percentage moisture loss} = (\text{Initial weight} - \text{Final weight}) / \text{Initial weight} \times 100$$

### **FUTURE PROSPECTIVE AND MARKET REPORTS OF ORAL FILM**

Fast-dissolving oral films (FDOFs) are expected to play a significant role in the pharmaceutical sector because of their many benefits compared with conventional oral dosage forms, along with continuous advancements in research and development. These films help overcome several drawbacks associated with traditional medications by improving patient compliance, enhancing bioavailability, and offering greater ease of use. Their improved bioavailability results from the rapid absorption of drugs through the oral mucosa, which bypasses hepatic first-pass metabolism and may produce faster therapeutic action.

The convenient and discreet administration of FDOFs makes them especially suitable for patients who have difficulty swallowing tablets or capsules, including paediatric, geriatric, and mentally challenged individuals. In addition, FDOFs provide pharmaceutical companies with opportunities to distinguish their products, prolong the patent life of existing drugs, and enter emerging markets. With ongoing technological progress, the application of FDOFs is anticipated to expand beyond conventional medicines to areas such as hormones, vaccines, and other therapeutic systems.

According to the global oral film market report, the oral thin film (OTF) market has experienced rapid growth in recent years. The market value is projected to rise from approximately \$4.07 billion in 2023 to \$4.6 billion in 2024, reflecting a compound annual growth rate (CAGR) of 13.0%. This historical growth has largely been driven by improved patient compliance, increasing use among paediatric and geriatric populations, rapid drug

delivery, the growing prevalence of chronic diseases, and the rising demand for over-the-counter medications.

## CONCLUSION

This technology represents an innovative drug delivery system suitable for all patient populations having trouble in swallowing, particularly paediatric and geriatric patients. It also provides several advantages compared to conventional dosage forms, including enhanced bioavailability and a more rapid onset of action. It is considered one of the most important oral dosage forms, especially useful in emergency situations and when a quick therapeutic effect is required.

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