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REVIEW ARTICLE

Oral Thin Film - A Promising Platform for Fast Dissolving Drug Delivery

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ABSTRACT
Oral thin films (OTFs), also referred to as mouth-dissolving films, represent an advanced drug delivery system designed for rapid disintegration and dissolution in the oral cavity without the need for water. These films are primarily composed of hydrophilic polymers that enable fast hydration and facilitate drug release, allowing absorption through the oral mucosa directly into systemic circulation. This mechanism effectively bypasses the gastrointestinal tract and minimizes first-pass metabolism. OTFs are particularly suitable for drugs that exhibit poor bioavailability due to hepatic metabolism, cause gastrointestinal irritation, or require rapid onset of action. Furthermore, this dosage form enhances patient compliance, especially in pediatric, geriatric, and dysphagic populations who may experience difficulty swallowing conventional dosage forms. The present review provides a comprehensive overview of the critical parameters involved in the development of OTFs, including drug selection criteria, formulation components, manufacturing techniques, and evaluation methods. Emphasis is also placed on the advantages and potential applications of OTFs in modern pharmaceutical research.
Keywords: *Oral thin films; Mouth-dissolving films; Drug delivery system; First-pass metabolism; Bioavailability; Hydrophilic polymers; Fast dissolving systems; Patient compliance; Formulation development; Evaluation parameters*

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INTRODUCTION

The oral route is widely favored for drug administration due to its convenience, non-invasive nature, and high levels of patient compliance. In this method, drugs are ingested through the mouth and absorbed primarily through the gastrointestinal tract. Traditional oral dosage forms, such as tablets and capsules, are dominant in the market because they are easy to produce, provide precise dosing, and are familiar to patients [7]. However, these conventional forms may not be ideal for all individuals, especially those who have difficulty swallowing, such as pediatric, geriatric, or bedridden patients, as well as those prone to nausea or vomiting [6. 9]. Recent advancements in drug delivery technology have aimed to address limitations in traditional oral dosage forms by developing alternatives that improve patient compliance and enhance therapeutic efficacy [25]. One such innovation is the bioadhesive mucosal dosage form, which includes adhesive tablets, gels, patches, and particularly oral thin films. OTFs are ultra- thin, flexible films that quickly dissolve upon contact with the tongue, releasing the active pharmaceutical ingredient (API) directly into the oral cavity. This method allows the drug to be absorbed through the mucosal lining, bypassing the gastrointestinal tract and liver's first-pass metabolism, leading to faster onset of action and potentially better bioavailability. OTFs present several benefits compared to traditional oral dosage forms. Their thin, flexible design allows for easy administration without the need for water, offering added convenience for use. The rapid disintegration and dissolution in the mouth also improve patient compliance, especially for individuals with difficulty swallowing. Moreover, OTFs ensure a precise and consistent dose, which is essential for medications that require careful dose control [31]. Another key

advantage is their ability to bypass the first-pass metabolism, enhancing drug bioavailability, making OTFs particularly useful for drugs with poor oral absorption [26, 20].

The development of OTFs utilizes several advanced pharmaceutical manufacturing techniques, including solvent casting, hot-melt extrusion, and semisolid casting. These methods allow for the inclusion of various active pharmaceutical ingredients (APIs), polymers, plasticizers, sweeteners, and other excipients, enabling the customization of the film's properties such as disintegration time, mechanical strength, and taste [23]. Despite the many advantages, OTFs pose certain challenges in formulation and manufacturing. Achieving uniform dosing can be difficult due to the small size of the film and the need for precise API distribution. Additionally, the hygroscopic nature of the films requires specialized packaging to protect them from moisture, which could affect their stability and effectiveness [32]. Furthermore, the capacity of the films limits the incorporation of high drug doses, typically restricting the dose to under 40mg per 4cm^2 piece [31]. OTFs are widely used in various therapeutic areas, including pain management, antihistamines, and antiemetics. Their ability to provide rapid relief is particularly beneficial in acute care situations and for conditions that require quick therapeutic action. The ease of use and non-invasive administration also contribute to their strong clinical relevance and patient acceptance [28, 20].

ADVANTAGES OF OTFs

Oral thin films offer several distinct benefits over other oral dosage forms, including:

- Rapid dissolution and disintegration in the oral cavity due to their large surface area, which shortens the dosage interval, enhances the onset of action, and improves the efficacy and safety of treatment.
- Oral films are flexible, compliant, and less brittle compared to orally disintegrating tablet, making them more user-friendly.
- They are easy to handle, store, and transport.
- Each film ensures precise dosing, providing accuracy in the administered dose.
- Oral films have gained acceptance from both pharmaceutical companies and consumers as an alternative to traditional over-the-counter dosage forms such as tablets and capsules.
- They are particularly beneficial for patients with conditions like motion sickness, dysphasia, frequent vomiting, and mental health disorders.
- From a commercial perspective, oral films open new opportunities for product differentiation, marketing, and promotion [14]

DISADVANTAGE OF OTFs

- A primary drawback of oral films is the difficulty in incorporating high doses of medication into a single strip [30].

CHARACTERISTICS OF ORAL SOLUBLE FILM

Large surface area- OTFs have a thin structure and a relatively large surface area, which allows them to dissolve and disintegrate quickly in the oral cavity.

Superior to dispersible tablets- Unlike dispersible tablets, which are prone to breaking easily due to their low hardness, OTFs are less fragile. This makes them easier to handle and transport without the need for special packaging to protect them during storage.

Better than liquid dosage forms- Unlike oral liquids such as solutions, syrups, and suspensions, which may have dosing accuracy issues, OTFs are unit dose formulations, similar to tablets and capsules. They combine the advantages of both solid and liquid dosage forms. Additionally, they offer better stability compared to liquid forms.

Aesthetic qualities- OTFs are visually appealing with their thin, flexible structure. They are available in various sizes and shapes, and they dissolve quickly, providing a pleasant mouth feel and fair taste.

Convenient- There is no need to take OTFs with water, making them easy to use [16].

COMPOSITION OF OTFs

General composition and their concentration range required for preparation of OTFs are mentioned below in table 1.

Table 1: Composition of OTFs [22]

S. No.	Ingredient	Concentration
1	Active Pharmaceutical Ingredient (API)	1-30%
2	Film Forming Polymer	40-50%
3	Plasticizer	0-20%
4	Saliva Stimulating Agent	2-6%
5	Sweetening Agent	3-6%
6	Flavoring Agent	q.s.
7	Color	q.s.

Active pharmaceutical ingredient (API)

Selecting the right API for OTFs is a critical task, as the capacity for drug loading into the film is typically limited to around 40mg.The chosen drug should not cause irritation or have a bitter taste. Drugs that tend to cause gastric irritation or undergo significant first-pass metabolism are often suitable for film formulation. Additionally, the drug should exhibit good water solubility and permeability, ideally falling within BCS Class I drugs [21].

Film forming polymer

The breakdown time of the film is significantly influenced by the properties of the polymer. Commonly used water-soluble polymers include hydroxyl propyl methyl cellulose, methylcellulose, pullulan, carboxy methyl cellulose, and polyvinyl pyrrolidone. Newer film-forming substances like polymerized resins are also utilized.

Plasticizer

Plasticizers prevent the film from breaking or rupturing and must be compatible with other ingredients. Some commonly used plasticizers include castor oil, phthalates, and polyethylene glycol.

Sweetening agent

OTFs must have an acceptable taste, as they dissolve without the need for water. Examples of sweetening agents include sucrose, fructose, aspartame, sorbitol, and sucralose.

Saliva stimulating agent

These agents help increase saliva production, which aids in the rapid break down of the film. Acids like tartaric acid, lactic acid, malic acid, ascorbic acid, and citric acid are commonly used.

Flavoring agent

To improve patient acceptance, common flavoring agents like citrus, vanilla, coffee, cocoa, and chocolate are used in mouth-dissolving films.

Coloring agent

Dyes such as titanium dioxide are often used to enhance the aesthetic appeal or appearance of the films. F D & C certified colors, which are insoluble, are preferred for this purpose. A maximum concentration of 1% w/w dye is recommended.

Surfactant

Surfactants are used as wetting, dispersing, or dissolving agents and help improve the solubility of poorly soluble drugs. Examples include poloxamer, sodium lauryl sulfate, and benzethonium chloride [29, 30].

METHODS OF PREPARATION OF OTFs

Solvent casting method

This is one of the most frequently used methods for preparing OTFs. In this technique, excipients, polymers, and water-soluble active pharmaceutical ingredients (APIs) are mixed with deionized water. The mixture is homogenized using high shear forces from a shear processor. Once a uniform solution is obtained, it is poured into a petri dish, and the solvent is evaporated under heat, resulting in a high-quality film. The film-forming polymer is typically soaked overnight in a suitable solvent before use. The selection of the solvent depends on the physicochemical properties of the API, such as its melting point and sensitivity to shear forces. The mixture is degassed using a vacuum pump to remove air bubbles that could affect the film's consistency.

Semi-solid casting method

In this method, a water-soluble polymer solution is prepared first. An acid-insoluble polymer, such as cellulose acetate-phthalate or cellulose acetate-butyrate, is then added to the polymer solution. A plasticizer is incorporated into the resulting gel mass in an appropriate quantity. The gel is poured onto a

temperature-controlled drum or a ribbon, and a film of thickness between 0.015 to 0.05 inches is formed. The film-forming polymer and the acid-insoluble polymer are typically mixed in a ratio of 1:4.

Hot melt extrusion

In this process, the API is combined with a solid carrier, and the mixture is melted using an extruder equipped with a heating mechanism. Once melted, the mixture is shaped into a film. This method allows for precise control over the film's properties.

Solid dispersion extrusion

Solid dispersion extrusion involves dispersing one or more APIs in an inert carrier in an amorphous hydrophilic polymer matrix. The API is dissolved in a suitable solvent, and the mixture is then combined with molten polyethylene glycol at temperatures under 70°C. The solid dispersion is then molded into a film.

Rolling method

In the rolling method, the solution created must possess specific rheological characteristics for effective rolling. A suspension of the API and polymer in water or alcohol is prepared, and the roller action is employed to shape and form the film. The solvent is evaporated during the rolling process, leaving behind a uniform film [12, 18, 30].

EVALUATION PARAMETERS FOR OTFs:

Evaluation parameters are essential for confirming the quality, safety, and efficacy of OTFs. The following sections describe each parameter and its significance.

Film thickness

Consistent film thickness is necessary for even drug distribution, ensuring consistent therapeutic effects. Variations in thickness may lead to uneven dissolution rates, affecting drug release and the film's overall performance. The thickness of the film significantly influences its dissolution rate. A thicker film generally results in a slower dissolution rate, whereas a thinner film dissolves more quickly. To determine the film thickness, measurements should be taken at 5 different locations across the film, and the average value should be calculated. Film thickness can be measured using instruments such as a digital vernier caliper, a micrometer screw gauge, or a dial gauge tester [15, 3, 28].

Weight variation

Weight variation testing ensures that each unit of a mouth dissolving film contains a consistent amount of the API. This is important for maintaining accurate dosing and therapeutic efficacy. Uniform weight across the films ensures that patients receive the correct dose each time. Variations in weight can lead to incorrect dosing, which could result in either under-dosing or overdosing. This is especially critical for drugs with a narrow therapeutic index, where dosage precision is necessary. For its determination cut the film into 2×2 cm^2 pieces and measure the weight using a digital analytical balance. Weigh three film samples and calculate the average. This test helps confirm that the film has the correct amount of drug and excipients [23, 17].

Folding endurance

Folding endurance measures the film's ability to withstand repeated folding without breaking. A higher number of folds indicates better flexibility and durability, which is crucial for patient handling and ensuring that the film does not break during normal use. The film is repeatedly folded at the same spot until it breaks, and the number of folds is recorded. Typical value for folding endurance is in between 100-150 [24, 17].

Tensile strength

Tensile strength testing evaluates how resistant the film is to breakage under tension. Films must be strong enough to withstand mechanical stress during handling, packaging, and administration. Insufficient tensile strength can lead to tears, affecting the film's integrity and usability. Tensile testing machines are used to apply increasing tension until the film breaks, and key parameters such as maximum load and elongation at break are measured [24, 8].

Drug content uniformity

Ensuring uniform distribution of the drug across the film is essential for accurate dosing. Techniques such as HPLC or UV-Visible spectroscopy are used to ensure that the API is evenly distributed throughout the film. Cut the film into 2 × 2 cm pieces and dissolve the cut piece in 10 ml of phosphate buffer 6.8 pH. Measure the absorbance of the resulting solution at the appropriate wavelength using a UV spectrophotometer. Calculate the amount of drug present in the film based on this data [2-5, 11].

Surface pH

Maintaining the surface pH of the film within the physiological range (around 6.5 to7.5) is critical to avoid irritation to the oral mucosa. A pH outside this range could lead to discomfort, which would negatively

affect patient compliance. Additionally, the stability and effectiveness of some drugs may be compromised if the pH is not optimal [2, 3].

Disintegration time

Disintegration time refers to the period required for a mouth dissolving film to break down when it comes into contact with saliva in the oral cavity. This is a crucial parameter for ensuring the rapid release of the API and improving patient compliance. The ideal disintegration time should range from a few seconds to a minute to facilitate efficient drug absorption through the mucosa. Cut the film according to the required dose. Take 10 ml of phosphate buffer with a pH of 6.8 and add the film to it. Record the time taken for the film to completely disintegrate in the buffer solution [10, 1].

***In-vitro* dissolution study**

The *in-vitro* dissolution study was performed using a USP paddle-type dissolution apparatus. A total of 900 ml of phosphate buffer pH 6.8 is prepared and transferred into the dissolution vessel. The temperature is maintained at 37 ± 0.5 °C, and the paddle rotation speed was set to 50 rpm. The film is placed into the vessel, and 5 ml samples are withdrawn at 1 minute intervals. After each withdrawal, an equal volume of fresh phosphate buffer is added to maintain sink conditions. A total of six samples are collected, and the cumulative drug dissolution is determined using UV-Visible spectrophotometer [9].

Burst strength

Burst strength refers to the amount of force necessary to rupture or break the film. It serves as an indicator of the film's mechanical integrity and flexibility [24].

Stability study

The stability study primarily evaluates the impact of temperature and humidity on the film formulation. For this purpose, the samples are initially packaged in aluminum foil and then stored under accelerated conditions at 40°C and 75% relative humidity. Samples are withdrawn at intervals of 3 and 6 months to assess drug content using UV-Visible spectrophotometer, along with evaluation of physical appearance. If no significant changes are observed, the formulation is considered to have passed the stability test [13].

CONCLUSION

The main motivation behind developing OTFs is to address challenges faced by pediatric, geriatric, and psychiatric patients with dysphasia, who struggle with swallowing conventional oral medications. These rapidly dissolving films offer enhanced patient compliance due to their ease of use, quick onset of action, and direct absorption into the bloodstream. When compared to traditional dosage forms, oral films provide several advantages. The key benefit of this form is that it can be administered without water, making it more convenient for patients while avoiding hepatic metabolism, which leads to improved efficacy. As a result, they are particularly beneficial in situations requiring rapid effects, such as asthma, allergies, and short-term spasms. In conclusion, OTFs are a notable advancement in oral drug delivery systems.

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