



International Journal of Multidisciplinary Research and Growth Evaluation.

Oral Dissolving Film: A Patient-centric Approach to Drug Delivery

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Article Info

ISSN (Online): 2582-7138

Impact Factor (RSIF): 7.98

Volume: 06

Issue: 06

Received: 20-10-2025

Accepted: 23-11-2025

Published: 15-12-2025

Page No: 1182-1191

Abstract

Oral drug delivery films (ODFs) have emerged as a patient-centric alternative to conventional oral dosage forms, offering significant advantages in terms of convenience, compliance, and safety. Designed as thin, flexible strips, ODFs disintegrate or dissolve rapidly in the oral cavity, enabling self-administration without the need for water or chewing. This unique feature makes them especially suitable for pediatric and geriatric populations, bedridden patients, and individuals with swallowing difficulties (dysphagia), Parkinson's disease, mucositis, nausea, or vomiting. By minimizing the risk of choking and enhancing therapeutic compliance, ODFs have gained wide acceptance as fast-dissolving drug delivery systems. Their adaptability in terms of size, shape, and formulation further supports their role as a promising platform in modern drug delivery. This review explores the potential of ODFs as a patient-centric approach, highlighting their formulation aspects, therapeutic applications, and future scope in addressing unmet clinical needs.

DOI: <https://doi.org/10.54660/IJMRGE.2025.6.6.1182-1191>

Keywords: Oral Dissolving Film, Patient-Centric Approach, Methods of Film Production, Evaluation, Future Perspective

1. Introduction

Oral medication delivery has the highest patient acceptance and therapeutic compliance; it is regarded as the most practical method for treating patients. However, solid oral dose forms are challenging for the elderly, mentally ill, the developmentally challenged, noncooperative, nauseated patients, and children^[1]. Pharmaceutical companies are therefore very interested in creating other oral dose forms that can help with swallowing issues^[2].

Recently, fast-dissolving drug delivery systems have started gaining popularity and acceptance. One such example, with increased consumer choice, is oral dissolving film, because of rapid disintegration or dissolution, self-administration even without water or chewing. Oral dispersible films (ODF) are instantly dissolving intraoral dose forms that may be used as alternatives to traditional tablets or capsules to help with swallowing difficulties. Because ODFs are thin, come in a variety of sizes and shapes, don't require water, and don't pose a choking hazard, they can be used to help people with swallowing difficulties. Additionally, ODFs provide the option of dose customization, which is a crucial way to deliver more accurate treatment^[1, 3, 4].

Oral films are designed to be placed directly on the tongue, where they quickly dissolve in saliva without the need to swallow them whole. This makes them especially suitable for children, elderly individuals, bedridden patients, and those with conditions such as difficulty swallowing (dysphagia), Parkinson's disease, mouth inflammation (mucositis), nausea, vomiting, etc^[5-7].

ODF can evade first-pass metabolism of some medications, as it releases the medication in a matter of seconds and allows it to be absorbed through the oral cavity, potentially increasing bioavailability. Rapidly dissolving films (RDF) were first offered for sale as breath fresheners and personal hygiene items like soap and dental care strips. But these for therapeutic purposes, dosage forms are introduced in the pharmaceutical markets of the US and Europe. The well-known pharmaceutical corporation Pfizer created the first oral strips (OS), which they called Listerine®, pocket packs™.

The first therapeutic oral thin films (OTF) containing 7 benzocaine were Chloraseptic® comfort strips, which treat sore throats [4].

Initially, ODFs are generally used to incorporate water-soluble medications, which are the simplest to prepare for quick dissolving and uniform drug distribution. In the pharmaceutical industry, around 90% of pharmaceuticals in the development pipeline and 40% of licensed medications are thought to have poor solubility; thus, their limitations in dissolving and bioavailability have prevented them from being produced in the ODF dosage for [8].

Poor solubility and permeability of certain drugs hamper oral delivery, thus necessitating innovative formulation procedures to increase bioavailability. Advances in pharmaceutical research, such as the creation of controlled-release formulations, nanoparticulate systems, and solid dispersion, have improved the stability, absorption, and overall efficacy of orally taken medications. These technical advances foster the development of oral drug delivery systems that promise better therapeutic outcomes and increased patient adherence [9].

Ideal Properties of Oral Dissolving Film [10, 11]:

1. The film should be thin, lightweight, and aesthetically pleasing.
2. The film should be easily transportable, possess non-sticky properties, and maintain a flat, stable form without curling or rolling.
3. It must provide a pleasant sensation in the mouth during administration.
4. It should be manufactured in various sizes and shapes to accommodate different needs.
5. Rapid disintegration without the need for water is essential, along with quick drug release and effective flavor masking.
6. Minimal or no residue should remain in the oral cavity after use.
7. The formulation should exhibit stability and be resistant to environmental factors such as humidity and temperature.

Advantages of Oral Dissolving Film [11, 12]:

1. No need for water during administration.
2. Rapid disintegration and dissolution in the oral cavity
3. Lightweight and flexible.
4. Suitable for all age groups.
5. Portable and easy to handle.
6. Improve the bioavailability of some API.
7. Beneficial for unconscious, bedridden, pediatric, geriatric, and psychiatric patients.
8. Enhanced stability.
9. Bypassing first-pass hepatic metabolism.
10. Quick onset of action.
11. Non-invasive and pain-free self-administration.
12. There is no risk of choking

Disadvantages of Oral Dissolving Films [11, 13]:

1. Medications that need to be administered in large quantities are unsuitable for film-based delivery.
2. Achieving consistent drug distribution across the film is technically difficult.
3. The films are highly sensitive to moisture, which can affect their stability.
4. They require specialized packaging to maintain integrity and effectiveness.
5. Active pharmaceutical ingredients (APIs) that degrade in the saliva's pH environment are not compatible with this type of delivery system.
6. APIs that may irritate the oral tissues are not appropriate for administration via films.
7. Eating and drinking may need to be avoided temporarily.
8. Impact of thermal process assisted drying on drug & polymer stability.

Classification of oral dissolving film [14]:

Oral films are categorized into three types:

1. flash-release films,
2. mucoadhesive melt-away wafers, and
3. mucoadhesive sustained-release wafers.

Table 1: Types of oral thin films with their properties:

Property / Sub-Type	Flash Release (Water Film)	Mucoadhesive Melt-Away Wafer	Mucoadhesive Sustained-Release Wafer
Area (cm ²)	2–8	2–7	2–4
Thickness (µm)	20–70	50–500	50–250
Structure	Single layer	Single or multilayer system	Multilayer system
Excipients	Soluble, highly 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 site	Tongue (upper palate)	Gingival or buccal region	Gingival or other regions in the oral cavity
Dissolution / Disintegration time	Maximum ~60 seconds	Disintegration in a few minutes, forming gel	Maximum 8–10 hours
Site of action	Systemic or local	Systemic or local	Systemic or local

Composition of film [15]:

The components used in the production of oral films are:

1. Active compounds
2. Polymers
3. Plasticizers
4. Sweeteners
5. Saliva stimulators
6. Colorings
7. flavorings
8. stabilizing agents
9. thickeners etc.

Table 2: Main compounds used in the production of oral films

Component	Concentration
Active compound	5–30%
Water-soluble polymer	45%
Plasticizer	0–20%
Saliva-stimulating agent	2–6%
Surfactant	q.s
Sweetening agents Flavor	3–6%
Color	q.s.

1) Active compound

Various types of active ingredients, whether naturally derived or synthetically produced, can be incorporated into oral films. However, due to the limited size of oral film dosage forms (OFDs), they typically accommodate only small quantities of active substances—usually ranging from 5% to 30% [16].

The quantity of active compound incorporated into oral films is influenced by the film's dimensions. As the concentration of the active ingredient increases, the film tends to become more brittle and exhibits prolonged disintegration times. These factors are critical when determining the appropriate compound and dosage for each film [17, 18].

Ideal Characteristics of a Drug/API for Oral Film Delivery:

- The drug should require a low dosage, typically less than 40 mg.
- Compounds with low molecular weight are favored.
- A pleasant taste is essential to ensure patient acceptability.
- The drug should exhibit adequate stability in both saliva and water.
- It must be capable of effectively permeating the oral mucosal tissues for absorption.

2) Polymer

Various polymers are suitable for making oral films, and they can be used individually or combined, depending on the specific characteristics required for the final product. Water solubility is a key factor when choosing polymers for making orally disintegrating films, as it directly affects how quickly and efficiently the film dissolves in the mouth [19]. Selecting the right polymer for oral film production is crucial, as it largely determines key properties like how quickly the drug is released, how well the film adheres to mucosal surfaces, and its overall strength and flexibility [20].

Choosing the right polymer is a crucial part of developing oral film matrices, as it directly influences the final product's characteristics. The selection should be based on the specific requirements of the intended formulation. It's essential to consider how well the polymer interacts with the active ingredient, as this affects both stability and drug release. Additionally, the mechanical strength of the film must be sufficient to ensure it can be handled and transported without tearing or breaking, while also maintaining the integrity of the active compound until it's released [21].

Ideal Characteristics of Film-Forming Polymers [10]:

- The polymer should be inert, non-toxic, and chemically stable.
- It must be tasteless and free from any harmful or leachable substances.
- It should be cost-effective and readily available.
- The polymer should not interfere with the degradation or

disintegration process of the film.

- It must exhibit excellent wetting and spreading capabilities, along with sufficient flexibility, tensile strength, and peel ability.
- It should not contribute to any oral health issues and must have a long shelf life.

3) Plasticizer

Plasticizers are essential components in oral strip (OS) formulations, as they enhance the strip's flexibility and reduce its tendency to become brittle. They improve the overall performance of the film by lowering the polymer's glass transition temperature, making it easier to handle and more durable.

The choice of plasticizer depends on how well it interacts with the polymer and the type of solvent used during the strip's preparation. Plasticizers also improve the flow characteristics of the polymer and contribute to its mechanical strength.

Commonly used plasticizers include glycerol, propylene glycol, low molecular weight polyethylene glycols, phthalate derivatives (such as dimethyl, diethyl, and dibutyl phthalate), and citrate derivatives (including tributyl, triethyl, acetyl citrate, triacetin), as well as castor oil. These are typically added in concentrations ranging from 0% to 20% of the dry polymer weight.

However, improper use or excessive amounts of plasticizer can lead to issues such as cracking, splitting, or peeling of the film. Additionally, some plasticizers may influence the drug's absorption rate, which should be carefully considered during formulation [22].

4) Sweetening agent

Sweeteners play a vital role in both food products and pharmaceutical formulations designed to dissolve or disintegrate in the mouth. To enhance taste and patient compliance, both natural and artificial sweeteners are commonly used in these preparations. Traditional sweeteners include sucrose (sourced from sugarcane or beet in liquid or dry form), dextrose, fructose, glucose, liquid glucose, and maltose.

Polyhydric alcohols such as sorbitol, mannitol, isomalt, and maltitol are often incorporated—either individually or in combination—not only to improve flavor but also to provide a pleasant mouthfeel and a cooling effect. These sugar alcohols are considered less carcinogenic and do not leave a bitter aftertaste, which is especially important in oral formulations.

However, the use of natural sugars should be carefully limited for individuals following dietary restrictions or managing diabetes [23, 24].

As a result, artificial sweeteners have become increasingly popular in both food and pharmaceutical products. The first generation of these sweeteners includes saccharin, cyclamate,

and aspartame. Later developments led to the second generation, which features compounds such as acesulfame-K, sucralose, alitame, and neotame. These newer sweeteners often offer improved taste profiles, greater stability, and enhanced safety for individuals with dietary restrictions [25].

5) Saliva stimulators

Saliva-stimulating agents are incorporated into rapid dissolving strip (RDS) formulations to promote increased saliva production, which facilitates quicker disintegration of the strip in the oral cavity. Commonly, food-grade acids are employed for this purpose, with citric acid being the most widely used. Other examples include malic acid, lactic acid, ascorbic acid, and tartaric acid. These agents may be used individually or in combination, typically within a concentration range of 2–6% w/w relative to the total strip weight.

In addition to acids, sweeteners also contribute to saliva stimulation. Both natural sugars and synthetic alternatives are effective in this role, especially when used alongside acidulents. Examples of such sweeteners include glucose, fructose, xylose, maltose, and lactose. These ingredients not only enhance palatability but also support the rapid dissolution of the strip.

The ability of sweeteners to stimulate saliva production is closely linked to their relative sweetness. For instance, fructose has a sweetness value of 1.1, making it sweeter than glucose (0.7) and sucrose (1.0). Due to their higher potency, artificial sweeteners are often favored over natural sugars in oral strip formulations. They require lower concentrations to achieve the desired sweetness and, importantly, do not contribute to dental caries even with repeated use. This makes them a practical and health-conscious choice for enhancing palatability and promoting rapid disintegration of the strip [26].

6) Colouring agents

Coloring agents, such as titanium dioxide and FD&C-approved pigments, are added to oral strip (OS) formulations primarily to enhance visual appeal and mask the appearance of insoluble or suspended components. These pigments help ensure a uniform and aesthetically pleasing product, especially when active ingredients or excipients are not fully soluble. Their concentration is typically kept below 1% w/w of the total strip weight to maintain safety and compliance with regulatory standards [27, 28].

7) Flavouring agents

Flavor selection in oral strip (OS) formulations is closely influenced by the nature of the active pharmaceutical ingredient. For instance, mint flavors are commonly used in products targeting gastric issues such as indigestion due to their soothing and refreshing properties.

Consumer acceptance of oral disintegrating or dissolving strips largely hinges on two sensory factors: the initial flavor impression experienced within the first few seconds of administration, and the lingering aftertaste, which can persist for up to 10 minutes [29].

To optimize palatability, flavors may be used individually or in combination.

Examples of flavor oils include:

- Peppermint oil
- Cinnamon oil
- Spearmint oil
- Nutmeg oil

Examples of fruity and essence-based flavors include:

- Vanilla, cocoa, coffee, chocolate, citrus
- Apple, raspberry, cherry, pineapple

The quantity of flavoring agents required to effectively mask unpleasant tastes depends on the specific flavor and its intensity. Typically, up to 10% w/w of the strip's total weight is allocated for flavoring agents. Additionally, cooling agents such as *monomethyl succinate* may be incorporated to enhance flavor perception and improve the overall mouth feel of the product [30, 31].

8) Stabilizing agents and Thickeners

Stabilizing and thickening agents are added to enhance the viscosity and uniformity of the solution or suspension used to prepare the film strips before they are cast. Natural gums such as xanthan gum, locust bean gum, carrageenan, and cellulose-based compounds can be used at concentrations of up to 5% w/w to serve this purpose. Additionally, small amounts of surfactants and emulsifiers are included to improve the physical properties of the strips [31].

Methods of film production

Oral films can be prepared by various manufacturing methods

1) Solvent casting process [15, 32]

This technique involves dissolving polymers, excipients, and active pharmaceutical ingredients (APIs) in water to create a uniform solution, which is then processed into thin films.

- **Polymer Dissolution:** Begin by dissolving water-soluble polymers in water, stirring at around 1,000 rpm and heating to approximately 60°C to ensure complete solubilization.
- **Ingredient Preparation:** In a separate container, blend coloring agents, flavorings, and sweeteners.
- **Solution Integration:** Combine the polymer solution with the prepared excipients, maintaining stirring at 1,000 rpm for homogeneity.
- **API Incorporation:** Introduce the active compound, pre-dissolved in a suitable solvent, into the mixture.
- **Deaeration:** Apply vacuum to eliminate any entrapped air bubbles, ensuring a smooth film texture.
- **Film Casting:** Spread the final mixture evenly onto a flat surface and allow it to dry, forming a thin film.
- **Sizing:** Once dried, the film is cut into specific dimensions as required for application or dosage

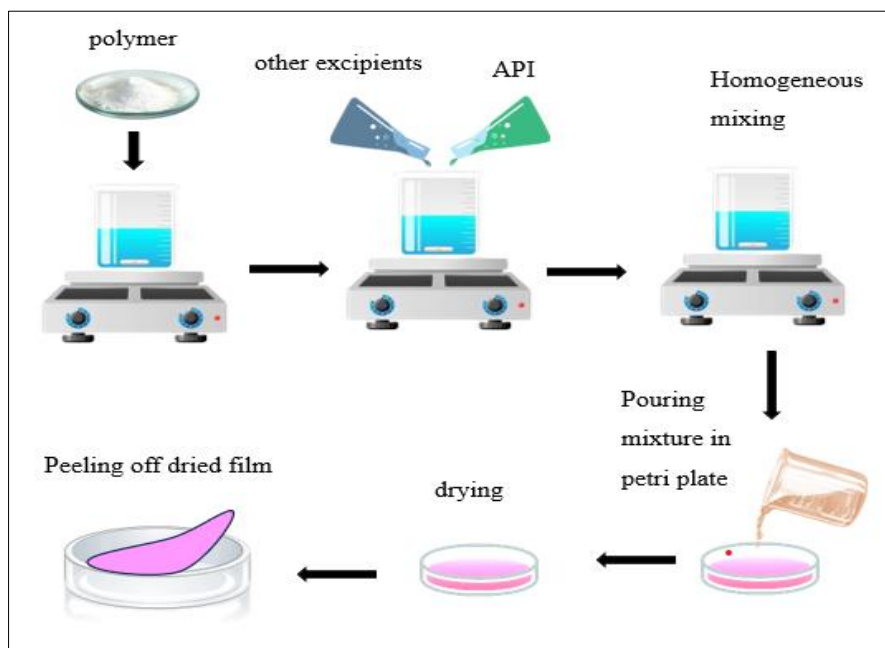


Fig 1: Solvent Casting Method

2) Hot-melt extrusion process

Hot melt extrusion process begins by blending the drug with suitable carrier materials to create a solid mass, then dry the mixture thoroughly. Once dried, feed the granules into an extruder equipped with four temperature zones—800°C,

1150°C, 1000°C, and 650°C. Set the screw speed of the extruder to 15 rpm and process the material for approximately 3 to 4 minutes until it fully melts. Finally, shape the molten mixture at 650°C by pressing it into a cylindrical mold to produce a film (32).

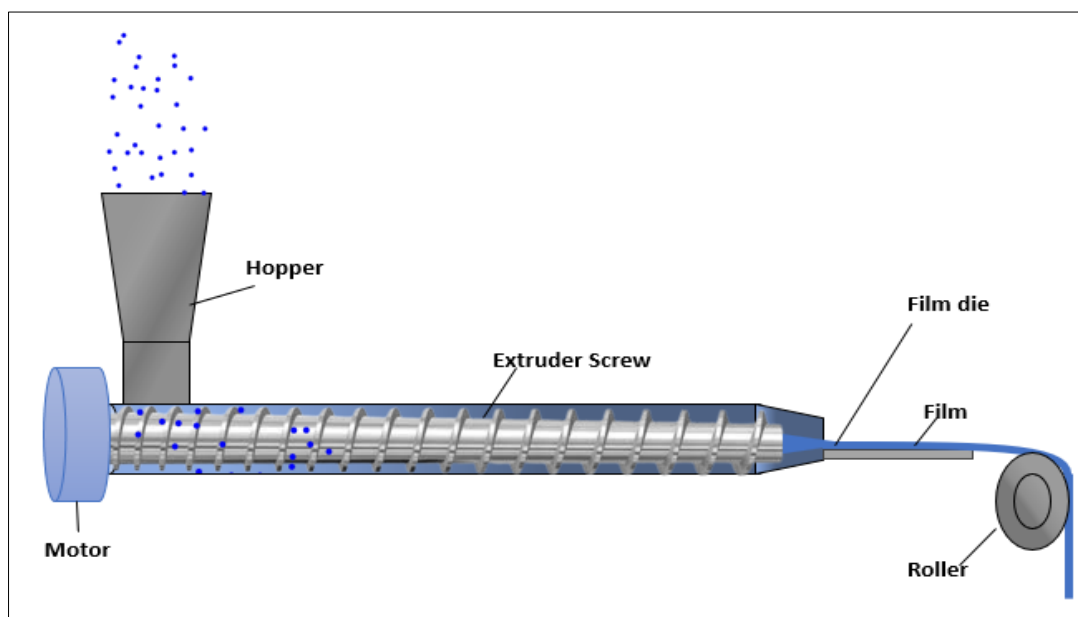


Fig 2: Hot-Melt Extrusion

3) Solid-dispersion extrusion

First, dissolve the drug in an appropriate liquid solvent. Next, gently heat a compatible polymer until it reaches its melting point, ensuring the temperature does not exceed 70°C. Then,

incorporate the drug solution into the molten polymer—retaining the solvent—to form a uniform solid dispersion. Finally, pour the mixture into molds to shape it into thin films [32].

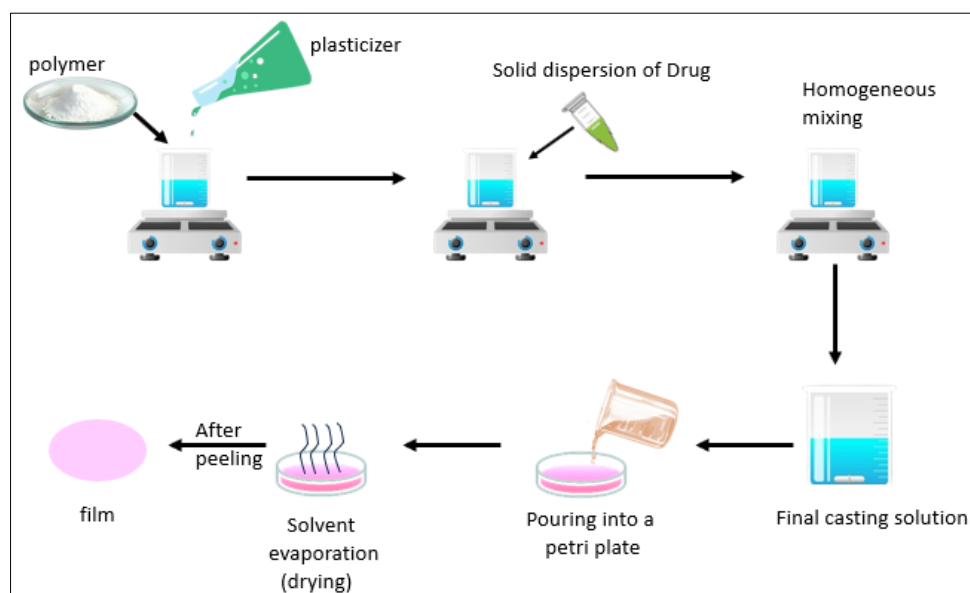


Fig 3: Solid- Dispersion Extrusion

4) Rolling- method

Begin by thoroughly mixing the drug solution with the film-forming polymer solution to achieve a uniform blend. Ensure the mixture exhibits suitable flow characteristics for

processing. Next, pass the mixture through rollers to form a continuous film. Allow the film to dry while on the rollers, and once fully dried, cut it into the required shapes and sizes [32].

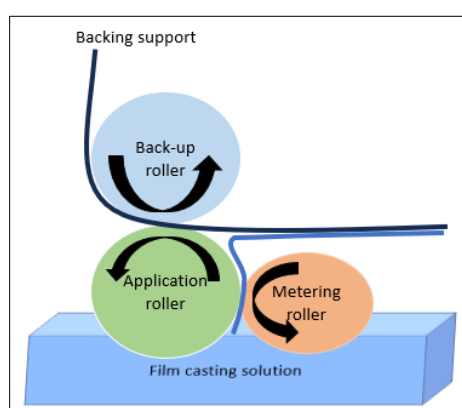


Fig 4: Rolling- Method

5) Semisolid casting method

In this method, a solution of water-soluble film-forming polymer is blended with a solution of acid-insoluble polymer—such as cellulose acetate phthalate or cellulose

acetate butyrate—to produce a homogeneous, viscous mixture. Following sonication, the mixture is applied onto an untreated casting film. The recommended ratio of acid-insoluble polymer to film-forming polymer is 1:4 [33].

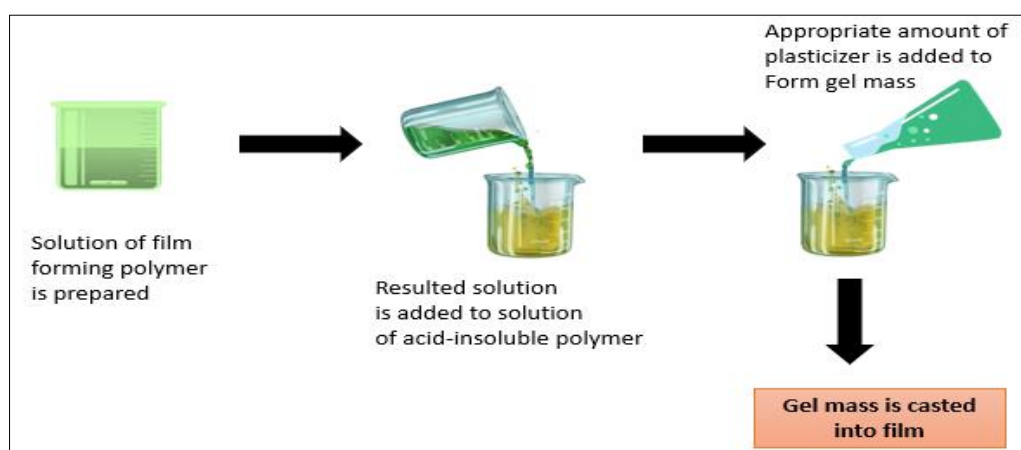


Fig 5: Semisolid Casting Method

Evaluation of film:**1) Weight Variation of Films:**

Oral films are individually weighed using an analytical balance, and their average weight is determined. Maintaining uniform weight across all films is essential to ensure consistent distribution of the active pharmaceutical ingredient (API) and other excipients, thereby guaranteeing accurate dosing and product reliability^[34].

2) Thickness Measurement of Films:

The thickness of each film was assessed at five distinct points using a micrometer screw gauge. From these measurements, the average of three readings was calculated to determine the film's uniformity. Consistent thickness is crucial to ensure accurate dosing, as it directly influences the distribution of the active pharmaceutical ingredient (API) across each film^[34].

3) Folding Endurance Test:

Folding endurance is evaluated by repeatedly folding the same area of the film until it breaks. The number of folds the film withstands before tearing is recorded as its folding endurance value. This test reflects the film's mechanical strength and flexibility, which are important for handling, packaging, and patient use without compromising its integrity^[35].

4) Surface pH Measurement:

To evaluate the potential *in vivo* safety of the film, its surface pH was assessed using a digital pH meter. A test film was placed in a Petri dish and moistened with 0.5 mL of distilled water, allowing it to soak for 30 seconds. After a one-minute equilibration period, the pH meter electrode was gently placed on the film's surface to obtain the pH reading. The measurements were performed in triplicate, and the results are reported as the mean \pm standard deviation^[36].

5) Tack Test:

The tack test, also referred to as the dryness test, evaluates the adhesive strength of a film when applied to a biological surface. Notably, tackiness can still be present even in fully dried films^[37]. This property is typically assessed by applying manual pressure to the film using the thumb^[38].

6) Tensile Strength:

Tensile strength refers to the maximum stress a material can withstand before breaking. It is determined by dividing the force applied at the point of rupture by the cross-sectional area of the test strip^[39].

The formula used is:

$$\text{Tensile Strength} = \text{Load at failure} / \text{Film thickness} \times \text{Film width}$$

7) Percent Elongation:

Percent elongation refers to the extent to which a film sample stretches when subjected to stress, a phenomenon known as strain. Strain represents the deformation that occurs in the material before it ultimately breaks. This property is typically measured using a Hounsfield universal testing machine. In general, the elongation of the film increases with higher concentrations of plasticizer, which enhances flexibility. The percent elongation is calculated using the following

formula:

$$\% \text{ Elongation} = \text{Increase in length of strip} \times 100 / \text{Initial length of strip}$$

8) Young's modulus:

Young's modulus, also known as the elastic modulus, is a fundamental mechanical property that reflects the rigidity of a material. It quantifies how stiff a film is by calculating the ratio between the stress applied to it and the resulting strain, specifically within the range where the material behaves in a linearly elastic manner^[39, 40].

$$\text{Young's modulus} = \text{Slope} \times 100 / \text{Film thickness} \times \text{Cross-head speed}$$

9) Scanning Electron Microscopy (SEM):

Scanning electron microscopy is employed to examine the surface morphology of films, particularly to assess interactions between various excipients and the active pharmaceutical ingredient. The film sample is mounted on a specimen holder, and photomicrographs are captured at a magnification of $\times 1000$. A tungsten filament serves as the electron source during imaging^[41].

10) In-Vitro Disintegration Test:

Disintegration time refers to the duration it takes for an oral film to begin breaking apart when exposed to water or saliva. For fast-dissolving films, this time typically falls within the range of 5 to 30 seconds. The United States Pharmacopeia (USP) disintegration apparatus is commonly used to measure this parameter under standardized conditions^[42].

Alternatively, a simpler visual method involves placing the film in 25 mL of water in a beaker. The beaker is gently shaken, and the time is recorded from the moment the film begins to disintegrate^[43].

11) In-Vitro Dissolution Studies

An *in vitro* dissolution study was conducted using a United States Pharmacopeia (USP) Type II dissolution apparatus, following the paddle-over-disc method. The test was carried out in 500 mL of phosphate buffer (pH 6.8) maintained at a temperature of $37 \pm 0.5^\circ\text{C}$.

Film samples (typically $2 \times 2 \text{ cm}^2$ in size) were affixed to a disc using an acrylate adhesive, and the paddle was rotated at 50 revolutions per minute above the film. At predetermined time intervals (5, 10, 15, 20, 25, and 30 minutes), 5 mL aliquots of the dissolution medium were withdrawn and replaced with an equal volume of fresh buffer maintained at the same temperature to preserve sink conditions.

The concentration of the dissolved substance at each time point was measured using a UV spectrophotometer at an appropriate wavelength. The amount of drug released over time was plotted to generate dissolution profiles^[44].

12) Drug Content uniformity:

It is assessed using a validated assay method specified for the active pharmaceutical ingredient (API) in recognized pharmacopeial standards. The evaluation involves measuring the amount of API present in each individual film strip. According to regulatory guidelines, the acceptable range for content uniformity is typically between 85% and 115% of the labeled claim^[45].

13) Permeation studies:

To evaluate drug permeability, a modified Franz diffusion cell equipped with porcine buccal mucosa can be utilized. This apparatus comprises a donor compartment and a receptor compartment, with the mucosal tissue mounted between them. The mucosa should be cut to match the diameter of the receptor compartment to ensure proper sealing and contact. The receptor chamber is filled with buffer solution and maintained at a temperature of $37 \pm 0.2^\circ\text{C}$. To ensure uniform mixing and thermodynamic stability, a magnetic stirrer operating at 50 rpm is employed. The test film, pre-moistened with simulated saliva, is placed in direct contact with the mucosal surface. The donor compartment is loaded with 1 mL of simulated saliva fluid at pH 6.8. At predetermined time intervals, samples are withdrawn from the receptor compartment and replaced with an equal volume of fresh buffer. The extent of drug permeation is then quantified using an appropriate analytical technique.

14) Stability Testing:

Stability testing is conducted in accordance with ICH

guidelines by storing the oral film under controlled environmental conditions— $25^\circ\text{C}/60\%$ relative humidity and $40^\circ\text{C}/75\%$ relative humidity—for a period of up to 12 months in a stability chamber. Throughout the study duration, various physicochemical parameters such as film thickness, visual appearance, mechanical strength, moisture content, and dissolution behavior are periodically evaluated to assess the formulation's stability and integrity over time^[46].

Commercially available oral film:

Commercially available oral films have already gained wide acceptance in the pharmaceutical as well as consumer health sector. Products like Listerine® pocket packs are popular fast-dissolving oral strips used for instant mouth freshening, while Benadryl® fast-melt films are developed for quick relief in allergic conditions. In addition, several other brands such as Triaminic® thin strips (for cough and cold) and Chloraseptic® relief strips (for sore throat) are available in the market. These examples demonstrate the versatility of oral films in delivering not only therapeutic agents but also providing convenience-based products for everyday use.

Table 3: List of marketed oral films

Product Name	Drug	Company	Use
Listerine	Cool mint	Pfizer	Mouth freshener
Benadryl	Diphenylhydramine HCL	Pfizer	Antiallergic
Triaminic	Phenylephrine HCl/diphenylhydramine HCl	Novartis	Antiallergic (cough and cold)
Chloraseptic	Benzocaine/menthol	prestige	Sore throat
ZenTrip	Meclizine HCl	Sato pharmaceutical	Treatment of nausea
Gas-X	Simethicone	Novartis consumer healthcare	Gas treatment
Nutrasol	melatonin	Kenaf	Restore natural sleep cycle
Monteshil	Montelukast Sodium	Shilpa therapeutics	Anti-Asthmatic / Anti-Allergic
Quicobal	Methylcobalamin	zim	Diabetic Neuropathy
Ondakine-4	Ondansetron	Kinegic pharmaceuticals	Anti Emetic
SYMPAZAN®	clobazam	Assertio	to treat seizures associated with Lennox-Gastaut Syndrome
Livferol-D3	Vitamin D3 (Cholecalciferol)	livkon	maintain optimal Vitamin-D levels.

Future Perspective of Oral Film:

Most oral thin film (OTF) products today are marketed for general use, even though the technology itself is ideally suited for specific populations like children, elderly, emergency care patient, psychiatric patients etc. This gap is likely to due to regulatory simplicity because general-use products face fewer hurdles than niche formulations and market awareness; many consumers and even healthcare providers aren't fully aware of the benefits of OTFs for specific needs.

The future of oral thin films (OTFs) is looking increasingly promising as a patient-centric design, compared to solid oral dosage forms such as tablets and capsules. Continuous research is being conducted on film to bring them into mainstream pharmaceutical form.

There are lot of hurdles related to drug such as poor solubility and dose that limits the incorporation of drug in film. But researchers are pushing these boundaries by continuously innovating the approaches to enhance drug solubility and bioavailability but the the dose limit is still the issue.

Oral film is the best choice for the drug whose rapid onset of action is needed and that are highly potent i.e small quantity

of drug producing the required therapeutic effect.

References:

- Hoffmann EM, Breitenbach A, Breitzkreutz J. Advances in orodispersible films for drug delivery. *Expert Opin Drug Deliv*. 2011;8(3):299-316. doi:10.1517/17425247.2011.553217
- Slavkova M, Breitzkreutz J. Orodispersible drug formulations for children and elderly. *Eur J Pharm Sci*. 2015;75:2-9. doi:10.1016/j.ejps.2015.02.015
- Peck RW. Precision medicine is not just genomics: the right dose for every patient. *Annu Rev Pharmacol Toxicol*. 2018;58:105-122. doi:10.1146/annurev-pharmtox-010617-052446
- Bala R, Pawar P, Khanna S, Arora S. Orally dissolving strips: a new approach to oral drug delivery system. *Int J Pharm Investig*. 2013;3(2):67-76. doi:10.4103/2230-973X.114897
- Hariharan M, Bogue BA. Orally dissolving film strips (ODFS): the final evolution of orally dissolving dosage forms. *Drug Deliv Technol*. 2009;9(2):24-29.
- Rathbone MJ, Hadgraft J, Roberts MS, Lane ME, eds.

- Modified-release drug delivery technology. 2nd ed. Vol. 1. Boca Raton: CRC Press; 2008.
7. Nishimura M, Matsuura K, Tsukioka T, Yamashita H, Inagaki N, Sugiyama T, *et al.* *In vitro* and *in vivo* characteristics of prochlorperazine oral disintegrating film. *Int J Pharm.* 2009;368(1-2):98-102. doi:10.1016/j.ijpharm.2008.10.002
 8. Kalepu S, Nekkanti V. Insoluble drug delivery strategies: review of recent advances and business prospects. *Acta Pharm Sin B.* 2015;5(5):442-453. doi:10.1016/j.apsb.2015.07.003
 9. Şen Karaman D, Patrignani G, Rosqvist E, Smått JH, Orłowska A, Mustafa R, *et al.* Mesoporous silica nanoparticles facilitating the dissolution of poorly soluble drugs in orodispersible films. *Eur J Pharm Sci.* 2018;122:152-159. doi:10.1016/j.ejps.2018.06.027
 10. Jain P, Gupta A, Darwhekar G. A detailed overview on mouth dissolving film. *J Drug Deliv Ther.* 2023;13(7):172-176. doi:10.22270/jddt.v13i7.6121
 11. Meghana R, Velraj M. An overview on mouth dissolving film. *Asian J Pharm Clin Res.* 2018;11(4):44-47. doi:10.22159/ajpcr.2018.v11s4.31712
 12. Seager H. Drug-delivery products and the Zydis fast-dissolving dosage form. *J Pharm Pharmacol.* 1998;50(4):375-382. doi:10.1111/j.2042-7158.1998.tb06876.x
 13. Mahajan A, Chhabra N, Aggarwal G. Formulation and characterization of fast dissolving buccal films: a review. *Der Pharm Lett.* 2011;3(1):152-165.
 14. Patel AR, Prajapati DS, Raval JA. Fast dissolving films (FDFs) as a newer venture in fast dissolving dosage forms. *Int J Drug Dev Res.* 2010;2(2):232-246.
 15. Palezi SC, Fernandes SS, Martins VG. Oral disintegration films: applications and production methods. *J Food Sci Technol.* 2023;60(10):2539-2548. doi:10.1007/s13197-022-05589-9
 16. Singh H, Singla YP, Narang RS, Pandita D, Singh S, Narang JK. Frovatriptan loaded hydroxy propyl methyl cellulose/treated chitosan based composite fast dissolving sublingual films for management of migraine. *J Drug Deliv Sci Technol.* 2018;47:230-239. doi:10.1016/j.jddst.2018.06.018
 17. Cilurzo F, Cupone IE, Minghetti P, Buratti S, Selmin F, Gennari CGM, *et al.* Nicotine fast dissolving films made of maltodextrins: a feasibility study. *AAPS PharmSciTech.* 2010;11(4):1511-1517. doi:10.1208/s12249-010-9525-6
 18. Cilurzo F, Cupone IE, Minghetti P, Buratti S, Gennari CGM, Montanari L. Diclofenac fast-dissolving film: suppression of bitterness by a taste-sensing system. *Drug Dev Ind Pharm.* 2011;37(3):252-259. doi:10.3109/03639045.2010.505928
 19. Alhayali A, Vuddanda PR, Velaga S. Silodosin oral films: development, physico-mechanical properties and *in vitro* dissolution studies in simulated saliva. *J Drug Deliv Sci Technol.* 2019;53:101122. doi:10.1016/j.jddst.2019.06.019
 20. Karki S, Kim H, Na SJ, Shin D, Jo K, Lee J. Thin films as an emerging platform for drug delivery. *Asian J Pharm Sci.* 2016;11(5):559-574. doi:10.1016/j.ajps.2016.05.004
 21. Borges JG, De Carvalho RA. Orally disintegrating films containing propolis: properties and release profile. *J Pharm Sci.* 2015;104(4):1431-1439. doi:10.1002/jps.24355
 22. Dixit RP, Puthli SP. Oral strip technology: overview and future potential. *J Control Release.* 2009;139(2):94-107. doi:10.1016/j.jconrel.2009.06.014
 23. Mennella JA, Beauchamp GK. Optimizing oral medications for children. *Clin Ther.* 2008;30(11):2120-2132. doi:10.1016/j.clinthera.2008.11.018
 24. Hutteau F, Mathlouthi M, Portmann MO, Kilcast D. Physicochemical and psychophysical characteristics of binary mixtures of bulk and intense sweeteners. *Food Chem.* 1998;63(1):9-16. doi:10.1016/S0308-8146(97)00243-4
 25. Prakash I, DuBois GE, Clos JF, Wilkens KL, Fosdick LE. Development of rebiana, a natural, non-caloric sweetener. *Food Chem Toxicol.* 2008;46(Suppl 7):S75-S82. doi:10.1016/j.fct.2008.05.004
 26. Israel K, Leo M. Salivary stimulant. US patent 4,820,506. 1989 Apr 11.
 27. Maibach T. Film comprising nitroglycerin. WO patent 2008/053466. 2008.
 28. Obermeier P, Kohr T, Kramer KT, Klokkeers K. Oral, quickly disintegrating film, which cannot be spit out, for an antiemetic or antimigraine agent. WO patent 2007/009800 A2. 2007.
 29. Technol DBDD. Orally disintegrating tablets-taste over speed. *Cir.nii.ac.jp.* 2003.
 30. McGregor RA, Gravina SA. Fast dissolving film delivery of nucleotides that inhibit the unpleasant taste of bitter tasting medications. WO patent 2004/019885 A3. 2004.
 31. Leung SS, Leone RS, Kumar LD. Fast dissolving orally consumable films. US patent 6,596,298 B2. 2003.
 32. Deshmukh NP, Bobade NN, Wankhade VP, Atram SC, Pande SD, Khedkar SA, *et al.* Oral fast dissolving film: a review. *Asian J Pharm Res Dev.* 2025;13(2):148-156. doi:10.22270/ajprd.v13i2.1553
 33. Garg G, Siddiqui MDN, Sharma P. A short review on “a novel approach in oral fast dissolving drug delivery system and their patents”. *Adv Biol Res.* 2011;5(6):291-303.
 34. Raju S, Reddy PS, Kumar VA, Deepthi A, Reddy KS, Reddy PVM. Flash release oral films of metoclopramide hydrochloride for pediatric use: formulation and in-vitro evaluation. *J Chem Pharm Res.* 2011;3(4):636-646.
 35. Ali S, Quadir A. High molecular weight povidone polymer-based films for fast dissolving drug delivery applications. *Drug Deliv Technol.* 2007;7(6):36-43.
 36. Wadetwar RN, Ali F, Kanojiya P. Formulation and evaluation of fast dissolving sublingual film of paroxetine hydrochloride for treatment of depression. *Asian J Pharm Clin Res.* 2019;12(10):126-132. doi:10.22159/ajpcr.2019.v12i10.34690
 37. Moreira Lana G, Zhang X, Müller C, Hensel R, Arzt E. Film-terminated fibrillar microstructures with improved adhesion on skin-like surfaces. *ACS Appl Mater Interfaces.* 2022;14(41):46239-46251. doi:10.1021/acsami.2c12663
 38. Zaki DY, Safwat EM, Nagi SM, Salem HN, Hamdy TM, Moharam LM, *et al.* A novel dental re-mineralizing blend of hydroxyethyl-cellulose and cellulose nanofibers oral film loaded with nepheline apatite glass: preparation, characterization and *in vitro* evaluation of re-mineralizing effect. *Carbohydr Polym Technol Appl.* 2021;2:100035. doi:10.1016/j.carpta.2021.100035
 39. Felton LA, O'Donnell PB, McGinity JW. Mechanical

- properties of polymeric films prepared from aqueous dispersions. In: Felton LA, ed. Aqueous polymeric coatings for pharmaceutical dosage forms. 3rd ed. Boca Raton: CRC Press; 2008:125-148.
40. Mashru RC, Sutariya VB, Sankalia MG, Parikh PP. Development and evaluation of fast-dissolving film of salbutamol sulphate. *Drug Dev Ind Pharm*. 2005;31(1):25-34. doi:10.1081/ddc-43947
 41. WHO Expert Committee on Specifications for Pharmaceutical Preparations. WHO Technical Report Series, No. 953. Geneva: World Health Organization; 2009.
 42. Dahiya M, Saha S, Shahiwala AF. A review on mouth dissolving films. *Curr Drug Deliv*. 2009;6(5):469-476. doi:10.2174/156720109789941713
 43. Kumar D, Tripathi AK, Yogesh P, Maddheshiya B. Review article on mouth dissolving film. *J Global Pharma Technol*. 2011;3(1):1-8.
 44. Alhamhoom Y, Sharma A, Nanjappa SH, Kumar A, Alshishani A, Ahmed MM, *et al*. Development and evaluation of solid dispersion-based sublingual films of nisoldipine. *Pharmaceuticals (Basel)*. 2023;16(11):1589. doi:10.3390/ph16111589
 45. Sharma R, Parikh R, Gohel M, Soniwala M. Development of taste masked film of valdecoxib for oral use. *Indian J Pharm Sci*. 2007;69(2):320-323. doi:10.4103/0250-474X.33174
 46. Patel R, Poddar S. Development and characterization of mucoadhesive buccal patches of salbutamol sulphate. *Curr Drug Deliv*. 2009;6(1):140-144. doi:10.2174/156720109787048177

How to Cite This Article

Akhare MR, Bakhle SS, Lokhande RA, Kale S. Oral dissolving film: a patient-centric approach to drug delivery. *Int J Multidiscip Res Growth Eval*. 2025;6(6):1182–1191. doi:10.54660/IJMRGE.2025.6.6.1182-1191.

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