

## FAST DISSOLVING ORAL FILMS: A COMPREHENSIVE REVIEW ON POLYMERS, TECHNOLOGIES, AND THERAPEUTIC POTENTIAL

Mani Babu Valavala<sup>1</sup> and Nagineni Sudarshan Rao<sup>2\*</sup>

<sup>1</sup>M. Pharm Student, Department of Pharmaceutics, Shri Vishnu College of Pharmacy(Autonomous), Vishnupur, Bhimavaram-534202, West Godavari, Andhra Pradesh, India.

<sup>2</sup>Associate Professor, Department of Pharmaceutics, Shri Vishnu College of Pharmacy(Autonomous), Vishnupur, Bhimavaram-534202, West Godavari, Andhra Pradesh, India.

Article Received: 06 June 2025 | Article Revised: 27 June 2025 | Article Accepted: 18 July 2025

**\*Corresponding Author: Nagineni Sudarshan Rao**

Associate Professor, Shri Vishnu College of Pharmacy (Autonomous), Vishnupur, Bhimavaram -534202, Andhra Pradesh, India.

**How to cite this Article:** Mani Babu Valavala, Nagineni Sudarshan Rao (2025). FAST DISSOLVING ORAL FILMS: A COMPREHENSIVE REVIEW ON POLYMERS, TECHNOLOGIES, AND THERAPEUTIC POTENTIAL. World Journal of Pharmaceutical Science and Research, 4(4), 120-133.



Copyright © 2025 Nagineni Sudarshan Rao | World Journal of Pharmaceutical Science and Research.

This work is licensed under creative Commons Attribution-NonCommercial 4.0 International license (CC BY-NC 4.0)

### ABSTRACT

Fast Dissolving Oral Films (FDOFs) have emerged as an innovative and patient-friendly drug delivery system, offering rapid onset of action, ease of administration, and improved patient compliance, particularly among pediatric, geriatric, and dysphagic populations. These thin, flexible films disintegrate quickly upon contact with saliva, eliminating the need for water or swallowing, which is advantageous in a variety of therapeutic settings. This review provides a comprehensive overview of the key components and formulation strategies involved in FDOF development, with a particular emphasis on the role of polymers—natural, synthetic, and semi-synthetic—in determining film properties such as mechanical strength, disintegration time, and drug release profile. Advanced manufacturing technologies, including solvent casting, hot-melt extrusion, and 3D printing, are critically analyzed for their scalability and suitability across drug types. Furthermore, the article highlights recent advancements in the incorporation of poorly soluble drugs, nanoparticles, and bioactive molecules into FDOFs. The therapeutic potential of FDOFs in delivering analgesics, antiemetics, antihistamines, and vaccines is also discussed, along with regulatory considerations and market trends. Overall, FDOFs represent a promising frontier in oral drug delivery, with continued innovation expected to expand their clinical and commercial applications.

**KEYWORDS:** Fast Dissolving Oral Films, Drug Delivery Systems, Polymeric Films, Solvent Casting Technique, Patient Compliance.

## INTRODUCTION

In recent years, the pharmaceutical industry has witnessed a paradigm shift toward patient-centric drug delivery systems that not only ensure therapeutic efficacy but also enhance convenience and compliance. Among the various novel drug delivery approaches, Fast Dissolving Oral Films (FDOFs) have gained significant attention as a versatile and user-friendly dosage form. These thin, flexible strips are designed to rapidly disintegrate or dissolve upon contact with saliva, releasing the active pharmaceutical ingredient (API) directly into the oral cavity without the need for water or swallowing. This feature is especially beneficial for specific patient populations such as pediatric, geriatric, and mentally challenged individuals who often face difficulty in swallowing conventional solid dosage forms like tablets and capsules.<sup>[1]</sup> FDOFs are primarily composed of hydrophilic polymers, plasticizers, active drugs, and optional excipients such as flavoring agents, sweeteners, and saliva stimulants. The film-forming polymer plays a pivotal role in determining the film's mechanical properties, disintegration time, and drug release profile. Depending on the therapeutic need and the physicochemical properties of the drug, a wide range of natural (e.g., pullulan, starch), synthetic (e.g., polyvinyl alcohol, hydroxypropyl methylcellulose), and semi-synthetic polymers can be utilized. The selection of an appropriate polymer, along with suitable manufacturing technology, is critical to ensure uniformity, stability, and efficacy of the final product. The origin of oral films can be traced back to the confectionery and breath-freshening strips market, but their evolution into pharmaceutical applications has been fueled by advancements in polymer science, formulation technology, and patient demand for non-invasive therapies. Today, FDOFs are being explored for the delivery of a wide spectrum of drugs, including analgesics, antihistamines, antiemetics, antipsychotics, and even vaccines and biologics. The ability to bypass the gastrointestinal tract and avoid first-pass metabolism also enhances the bioavailability of certain drugs, making FDOFs a promising alternative to oral tablets and capsules<sup>2</sup>. One of the most widely adopted methods for the preparation of FDOFs is the solvent casting technique, which allows uniform dispersion of the drug and excipients in the polymer matrix, followed by drying into thin films. Other techniques, such as hot-melt extrusion, electrospinning, and 3D printing, are being actively explored for scalability, precision, and enhanced drug loading capacities. Each method offers unique advantages and limitations in terms of film quality, production cost, and compatibility with heat- or moisture-sensitive drugs.

Beyond the technical and therapeutic advantages, FDOFs also offer significant market potential due to their compact size, portability, and ease of administration. These attributes make them particularly suited for emergency therapies (e.g., anti-anginal or anti-epileptic medications), travel-related conditions (e.g., motion sickness), and pediatric dosing where taste masking is essential. Moreover, the rising demand for over-the-counter (OTC) medications and self-administered therapies further supports the growth of FDOFs in both developed and emerging markets. Despite the promise, there are challenges associated with the development and commercialization of FDOFs. These include ensuring dose uniformity, mechanical stability, moisture sensitivity, and palatability, all of which require careful formulation design and packaging considerations. Regulatory pathways for FDOFs are still evolving, with guidelines differing across regions, especially regarding quality control, excipient limits, and bioequivalence studies. Standardization in testing methods for disintegration and dissolution is also critical for gaining regulatory approval and ensuring consistent therapeutic outcomes.

In light of these developments and ongoing innovations, this review aims to provide a comprehensive overview of fast dissolving oral films. The article will delve into the types of polymers used, formulation considerations, and the various technologies employed in manufacturing FDOFs. Additionally, it will explore current therapeutic applications,

emerging trends such as nanotechnology integration and 3D printing, as well as the regulatory and market landscape shaping the future of this dosage form. Through this review, readers will gain an in-depth understanding of the potential and challenges of FDOFs in modern drug delivery systems and how continued advancements in materials and methods are expanding their role in pharmaceutical sciences.<sup>[3]</sup>

### Classification of Fast Dissolving Oral Films (FDOFs)<sup>[4]</sup>

Fast Dissolving Oral Films (FDOFs) can be classified based on several criteria to better understand their formulation, functionality, and therapeutic use. The most common classification approaches include:

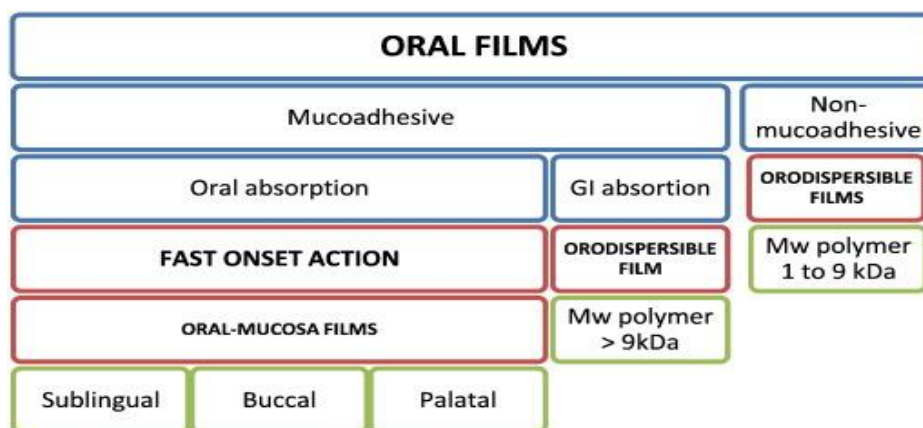


Figure 01: Various types of oral films.

#### 1. Based on Drug Release Profile

- Immediate-Release Films:** Designed to disintegrate and release the drug rapidly (typically within 30 seconds to 1 minute), ensuring fast onset of action. Commonly used for analgesics, antiemetics, and antipyretics.
- Sustained/Controlled-Release Films:** Formulated with polymers or excipients that allow extended drug release over time. Useful for chronic conditions where maintaining therapeutic levels is essential.
- Mucoadhesive Films:** These films adhere to the oral mucosa and slowly release the drug at the site of absorption. Suitable for localized treatment or drugs with poor systemic bioavailability.

#### 2. Based on Polymer Type

- Natural Polymers:** Examples: Pullulan, starch, sodium alginate, pectin, gelatin. Biocompatible and biodegradable, often used for their safety and film-forming abilities.
- Synthetic Polymers:** Examples: Polyvinyl alcohol (PVA), polyethylene oxide (PEO), Eudragit. Offer good mechanical strength and controlled drug release profiles.
- Semi-Synthetic Polymers:** Examples: Hydroxypropyl methylcellulose (HPMC), carboxymethylcellulose (CMC), methylcellulose. Widely used due to their favorable disintegration time, stability, and solubility.

#### 3. Based on Manufacturing Technique

- Solvent Casting Method Films:** The most common method, offering uniform drug dispersion and good film quality.
- Hot-Melt Extrusion Films:** Solvent-free technique, suitable for moisture-sensitive drugs and large-scale production.

- c) **Electrospun Films:** Ultra-thin nanofiber films with high surface area, ideal for rapid drug release and innovative applications.
- d) **3D-Printed Films:** Emerging method allowing precise, customizable dosage forms with tailored drug release kinetics.

#### 4. Based on Therapeutic Application

- a) **Pain Management Films:** Contain analgesics or opioids for fast relief (e.g., fentanyl films).
- b) **Antiemetic Films:** For nausea and vomiting (e.g., ondansetron).
- c) **Antihistaminic Films:** Used in allergy treatment (e.g., diphenhydramine, loratadine).
- d) **Neuropsychiatric Films:** Used for anxiety, epilepsy, or schizophrenia (e.g., clonazepam, risperidone).
- e) **Vaccine/Peptide Delivery Films:** Under development for mucosal immunization and protein delivery.

#### 5. Based on Site of Action

- a) **Systemic Delivery Films:** Designed for rapid absorption into the bloodstream via the buccal or sublingual mucosa.
- b) **Local Delivery Films:** Deliver drugs directly at the site of action within the oral cavity (e.g., antimicrobial films for oral ulcers or dental pain).

#### Special Features of Fast Dissolving Films<sup>[5]</sup>

Fast Dissolving Films (FDFs) offer a unique combination of convenience, efficacy, and patient-centric design, making them an increasingly popular drug delivery system. One of their most notable features is rapid disintegration—typically within seconds—upon contact with saliva, eliminating the need for water or chewing. This is especially beneficial for pediatric, geriatric, and dysphagic patients who often struggle with conventional oral dosage forms like tablets or capsules. FDFs provide a fast onset of action, as the drug can be absorbed directly through the oral mucosa, bypassing first-pass hepatic metabolism. This improves bioavailability for certain drugs. Additionally, FDFs offer enhanced portability and discreet administration, making them ideal for on-the-go or emergency use. Their thin, flexible, and lightweight nature also allows for easy packaging and transportation.

Another key advantage is their ability to incorporate taste-masking agents, which improves palatability—crucial for pediatric formulations. Furthermore, FDFs can be tailored for immediate, sustained, or mucoadhesive drug release, depending on the therapeutic requirement. Their compatibility with a wide range of active pharmaceutical ingredients (APIs), including small molecules, peptides, and even vaccines, further broadens their application. These special features collectively position FDFs as a promising innovation in modern pharmaceutical technology.

#### Advantages of Fast Dissolving Films (FDFs)<sup>[6]</sup>

##### 1. Rapid Disintegration and Absorption

- Dissolve within seconds in the oral cavity without the need for water.
- Enables fast onset of therapeutic action, ideal for emergency medications.

##### 2. Improved Patient Compliance

- Suitable for pediatric, geriatric, and dysphagic patients who have difficulty swallowing tablets or capsules.

##### 3. Convenient and Non-Invasive

- No need for water, chewing, or swallowing.
- Offers discreet administration, which is useful in public or during travel.

**4. Bypass of First-Pass Metabolism**

- Drugs absorbed through the oral mucosa directly enter systemic circulation, enhancing bioavailability.

**5. Enhanced Taste Masking**

- Formulation allows inclusion of sweeteners and flavoring agents to improve palatability, especially important in pediatric use.

**6. Accurate Dosing**

- Delivers a precise, uniform dose of medication, reducing dosing errors compared to syrups or drops.

**7. Portability and Ease of Use**

- Thin, lightweight, and compact—easy to carry and store. Ideal for "on-the-go" lifestyles.

**8. Versatile Formulation Capabilities**

- Suitable for various drug classes including analgesics, antiemetics, antihistamines, and even peptides and vaccines.

**9. Lower Risk of Choking**

- Because the film dissolves quickly in the mouth, the risk of aspiration is minimized.

**10. Reduced Gastrointestinal Side Effects**

- Avoids the stomach and intestines, reducing GI irritation for certain drugs

**Disadvantages of Fast Dissolving Films (FDFs)<sup>[7]</sup>****1. Limited Drug Loading Capacity**

- FDFs can accommodate only small to moderate doses of drugs due to size and thickness constraints.

**2. Stability Issues**

- Sensitive to moisture and humidity, which can affect mechanical strength and drug stability.

**3. Taste Masking Challenges**

- Bitter or unpleasant-tasting drugs require effective taste masking, which can complicate formulation.

**4. Mechanical Fragility**

- Films can be fragile and prone to tearing or breaking if not handled or packaged properly.

**5. Manufacturing Complexity**

- Requires precise control over formulation and drying conditions to achieve uniform films with consistent drug content.

**6. Limited Applicability for Certain Drugs**

- Not suitable for drugs that require high doses or have poor solubility in saliva.

**7. Packaging and Storage Requirements**

- Need specialized packaging to protect from moisture, heat, and physical damage, increasing cost.

**8. Mucosal Irritation Potential**

- Some excipients or drugs may cause irritation or discomfort in the oral cavity.

**9. Variable Saliva Production**

- Efficacy may vary with patients who have dry mouth (xerostomia), affecting disintegration and absorption.

**10. Regulatory Challenges**

- Still evolving regulatory guidelines can complicate approval processes, particularly regarding bioequivalence and quality control.

## Ingredients Used in Fast Dissolving Oral Films<sup>[8]</sup>

Fast Dissolving Oral Films are composed of various components that work together to ensure rapid disintegration, adequate mechanical strength, stability, and patient acceptability. The key ingredients include:

### 1. Film-Forming Polymers

#### Polymers Used in Fast Dissolving Oral Films

Polymers play a critical role in the formulation of Fast Dissolving Oral Films (FDOFs), as they provide the structural matrix that supports drug incorporation and ensures film flexibility, strength, and rapid disintegration. An ideal polymer for FDOFs should be non-toxic, biocompatible, possess good film-forming ability, and dissolve or disintegrate rapidly in saliva without leaving residue.

- **Natural polymers** such as *pullulan*, *gelatin*, *pectin*, *starch*, and *sodium alginate* are widely used due to their biodegradability and safety profile. Among them, **pullulan** is particularly favored for its excellent film-forming capability, transparency, and rapid dissolution. **Gelatin** provides elasticity and mechanical strength but may be sensitive to moisture.
- **Semi-synthetic polymers**, such as *hydroxypropyl methylcellulose (HPMC)*, *carboxymethyl cellulose (CMC)*, and *methylcellulose*, offer a balance of mechanical properties and ease of processing. HPMC, especially grades like E15 or K4M, is commonly used due to its fast hydration, film-forming characteristics, and compatibility with various drugs.
- **Synthetic polymers** like *polyvinyl alcohol (PVA)*, *polyethylene oxide (PEO)*, and *polyvinylpyrrolidone (PVP)* are also employed for their excellent film flexibility, mechanical strength, and solubility. PVA and PVP are particularly useful for their smooth texture and clarity in films.

The selection of polymer(s) depends on factors such as the desired disintegration time, drug-polymer compatibility, film thickness, mechanical strength, and the intended drug release profile. Often, combinations of polymers are used to optimize film characteristics.

Provide the structural matrix for the film.

Should be non-toxic, biodegradable, and capable of forming thin, flexible films.

#### Examples

Natural: Pullulan, starch, gelatin, sodium alginate

Semi-synthetic: Hydroxypropyl methylcellulose (HPMC), carboxymethyl cellulose (CMC), methylcellulose (MC)

Synthetic: Polyvinyl alcohol (PVA), polyethylene oxide (PEO), polyvinylpyrrolidone (PVP)

### 2. Plasticizers

Enhance flexibility and reduce brittleness of films.

Improve the handling properties without compromising film integrity.

**Examples:** Glycerol, polyethylene glycol (PEG), propylene glycol, triacetin

### 3. Active Pharmaceutical Ingredients (APIs)<sup>[9]</sup>

The drug substance to be delivered.

Must be compatible with the polymer and excipients.

Should have appropriate solubility and stability for oral mucosal delivery.

#### 4. Sweeteners and Flavoring Agents

Improve the taste and mask unpleasant drug flavors, enhancing patient compliance.

**Examples:** Sucralose, aspartame, saccharin, maltose, natural and artificial flavors like mint, fruit flavors

#### 5. Saliva Stimulants

Promote saliva secretion to aid film dissolution and drug release.

**Examples:** Citric acid, malic acid

#### 6. Surfactants

Improve wetting properties and drug solubility in saliva, enhancing bioavailability.

**Examples:** Polysorbate 80, sodium lauryl sulfate (SLS)

#### 7. Coloring Agents

Used to improve aesthetic appeal and assist in product identification.

Should be FDA-approved and safe for oral use.

### Recent Methods of Manufacture of Fast Dissolving Oral Films

Fast Dissolving Oral Films (FDOFs) are innovative drug delivery systems designed for rapid disintegration and absorption in the oral cavity. Traditional manufacturing methods such as solvent casting have limitations including lengthy drying times and solvent residue concerns. To overcome these challenges, several recent and advanced manufacturing methods have been developed, focusing on scalability, precision, environmental safety, and enhanced product performance.

#### 1. Solvent Casting Method<sup>[10]</sup>

Though the oldest and most commonly used, the solvent casting method is still foundational. It involves dissolving or dispersing the drug and polymers in a solvent, casting the solution onto a flat surface, and drying it to form films.

**a) Advantages:** Simple, low-cost, widely understood.

**b) Limitations:** Use of solvents, long drying times, scale-up challenges, and residual solvent risks.

#### 2. Hot-Melt Extrusion (HME)<sup>[11]</sup>

Hot-Melt Extrusion is a solvent-free, continuous manufacturing technique gaining prominence for FDOFs.

##### a) Process

Polymers and drugs are heated above their melting point and forced through an extruder die. The melted mass is shaped into films and cooled.

##### b) Advantages

- Eliminates solvents, avoiding residual solvent problems.
- Suitable for moisture-sensitive drugs.
- Scalable and continuous production.
- Uniform drug distribution.

##### c) Limitations

- Restricted to thermally stable drugs.
- Requires precise control of temperature and screw speed.



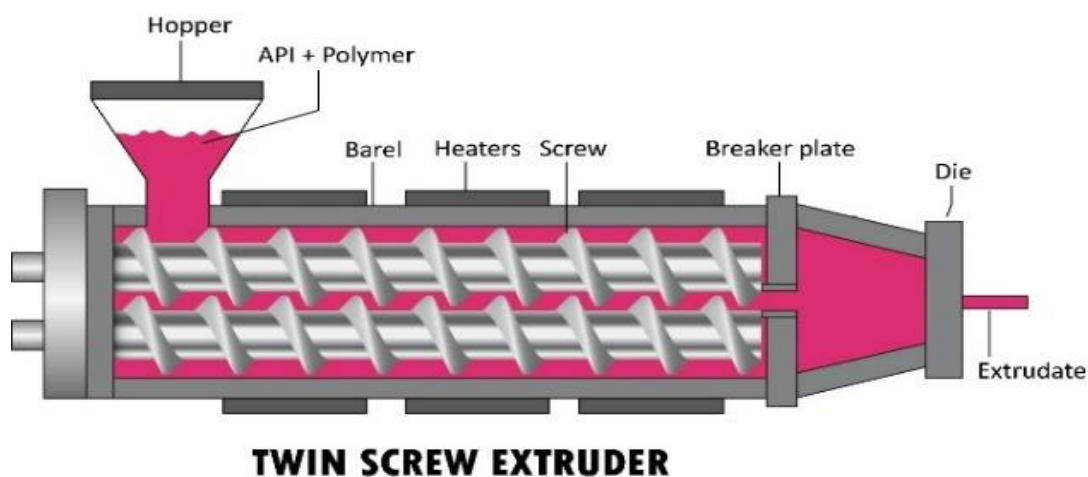


Figure 02: Working of Hot melt extruder.

### 3. Electrospinning<sup>[12]</sup>

Electrospinning is a cutting-edge technique that uses an electrical charge to produce ultrafine polymer fibers, which can be collected as films.

#### a) Process

A polymer-drug solution is ejected through a needle under a high-voltage electric field, forming nano to microscale fibers.

#### b) Advantages

- Produces nanofibrous films with high surface area and porosity.
- Enhances dissolution rates.
- Suitable for poorly soluble drugs and peptides.

#### c) Limitations

- Difficult to scale up industrially.
- Requires optimization of solution properties and processing parameters.

### 4. 3D Printing (Additive Manufacturing)<sup>[13]</sup>

3D printing allows fabrication of FDOFs with customizable geometry, drug dosage, and release profiles.

#### a) Techniques

- **Inkjet printing:** Deposits tiny droplets of drug solution on a substrate.
- **Fused Deposition Modeling (FDM):** Uses thermoplastic filaments melted and extruded layer-by-layer.
- **Stereolithography (SLA):** Photopolymerization using UV light to cure resin films.

#### b) Advantages

- Enables personalized dosing.
- Complex multilayer films possible.
- On-demand production.

#### c) Limitations

- High cost and technical complexity.
- Regulatory hurdles.



### 5. Rolling Method<sup>[14]</sup>

The rolling method is a continuous coating technique where a polymer-drug mixture is spread on a carrier and passed through rollers to form uniform films.

#### a) Advantages

- Good for industrial-scale production.
- Consistent thickness and drug content.

#### b) Limitations

- Needs control over viscosity and drying.
- Limited to certain polymer types.

### 6. Spray Layering Technique<sup>[15]</sup>

Spray layering involves spraying a drug-polymer solution onto a substrate or film to build layers.

#### a) Advantages

- Precise control of drug loading.
- Can produce multilayer films with different release characteristics.
- Suitable for heat-sensitive drugs.

#### b) Limitations

- Requires uniform spray and drying conditions to avoid defects.

### 7. Other Emerging Techniques

- a) **Microwave-Assisted Drying:** Accelerates drying during solvent casting using microwave energy, reducing drying time drastically.
- b) **Spin Coating:** A polymer solution is deposited on a spinning substrate, spreading evenly by centrifugal force, ideal for ultra-thin films.
- c) **Vacuum Drying:** Enhances solvent removal under reduced pressure, preserving heat-sensitive drugs.

### Summary Table of Recent Manufacturing Methods<sup>[16]</sup>

**Table 01: Recent manufacturing methods of fast dissolving oral films.**

| Method             | Key Features                           | Advantages                           | Limitations                      |
|--------------------|--|--------------------------------------|----------------------------------|
| Solvent Casting    | Polymer/drug dissolved in solvent      | Simple, low cost                     | Solvent use, slow drying         |
| Hot-Melt Extrusion | Thermal melting & extrusion            | Solvent-free, scalable               | Thermal limits for drugs         |
| Electrospinning    | Nanofiber formation via electric field | High surface area, rapid dissolution | Scale-up difficulty              |
| 3D Printing        | Layer-by-layer film construction       | Personalized dosing, complex designs | Costly, regulatory issues        |
| Rolling Method     | Continuous coating & rolling           | Industrial scale, uniform films      | Polymer viscosity control needed |
| Spray Layering     | Spraying drug-polymer solution         | Multilayer films, precise dosing     | Requires uniform spraying        |

### Therapeutic Potential of Fast Dissolving Oral Films<sup>[17]</sup>

Fast Dissolving Oral Films (FDOFs) hold immense therapeutic potential as a novel drug delivery platform that enhances convenience, compliance, and clinical effectiveness across various patient populations. Their rapid disintegration in the oral cavity without the need for water makes them particularly advantageous for pediatric, geriatric, and dysphagic patients who often struggle with swallowing conventional tablets or capsules.

FDOFs offer rapid onset of action, making them ideal for **acute conditions** such as migraine, nausea and vomiting, allergic reactions, pain management, and seizures. Drugs like ondansetron, rizatriptan, and loratadine have been successfully formulated into oral films to provide fast symptom relief through buccal or sublingual absorption. Moreover, FDOFs bypass the gastrointestinal tract and first-pass hepatic metabolism when absorbed via the oral mucosa, improving **bioavailability** of drugs with poor gastrointestinal stability or extensive hepatic metabolism. This property is particularly useful for drugs with narrow therapeutic windows or those requiring precise dosing. FDOFs are also emerging as a promising platform for **chronic disease management**, including cardiovascular conditions, psychiatric disorders, and hormone replacement therapies. Their ease of use improves adherence, especially in outpatient settings.

In recent years, FDOFs have been investigated for **vaccine delivery**, **peptide therapeutics**, and **biologics**, expanding their potential beyond conventional small-molecule drugs. The incorporation of nanocarriers and mucoadhesive polymers further enhances drug stability, absorption, and targeted delivery.

### Evaluation of Fast Dissolving Oral Films

Evaluation of Fast Dissolving Oral Films (FDOFs) is essential to ensure their safety, efficacy, mechanical strength, disintegration behavior, and patient acceptability. Various physicochemical, mechanical, and biological tests are employed to assess film quality and performance. Below is a comprehensive overview of key evaluation parameters:

#### 1. Appearance and Surface Morphology<sup>[18]</sup>

- a) **Purpose:** Ensures uniformity, transparency, color consistency, and absence of physical defects (e.g., air bubbles, cracks).
- b) **Method:** Visual inspection under white and polarized light; Scanning Electron Microscopy (SEM) for surface analysis.

#### 2. Thickness<sup>[19]</sup>

- a) **Purpose:** Determines uniformity and influences drug content and mechanical properties.
- b) **Method:** Measured at multiple points using a digital micrometer or Vernier caliper.
- c) **Acceptance:**  $\pm 5\%$  variation is typically acceptable.

#### 3. Weight Uniformity<sup>[20]</sup>

- a) **Purpose:** Ensures consistent drug dosing.
- b) **Method:** Weigh individual films and calculate average weight; deviation should be within pharmacopeial limits.

#### 4. Folding Endurance

- a) **Purpose:** Evaluates mechanical strength and flexibility.
- b) **Method:** Number of times a film can be folded at the same point without breaking.
- c) **Acceptance:** Should withstand at least 100 folds without cracking.

#### 5. Tensile Strength and Elongation

- a) **Purpose:** Measures the film's resistance to breaking under tension.
- b) **Method:** Universal testing machine is used to measure tensile strength, % elongation, and Young's modulus.

## 6. Disintegration Time

- a) **Purpose:** Critical parameter defining how quickly the film dissolves in the oral cavity.
- b) **Method:** Place the film in a petri dish or glass beaker containing simulated saliva fluid (SSF); record the time until complete disintegration.
- c) **Acceptance:** Typically <30 seconds for immediate-release films.

## 7. Dissolution Studies

- a) **Purpose:** Evaluates drug release profile from the film.
- b) **Method:** USP dissolution apparatus (typically paddle method) using simulated saliva or phosphate buffer as medium.
- c) **Analysis:** Drug content in samples analyzed via UV-Vis spectrophotometry or HPLC.

## 8. Drug Content Uniformity<sup>[21]</sup>

- a) **Purpose:** Ensures each film contains the intended amount of API.
- b) **Method:** Films are dissolved in suitable solvent; drug quantified using spectrophotometric or chromatographic methods.
- c) **Acceptance:** 85–115% of the labeled claim as per pharmacopeial standards.

## 9. Moisture Content and Moisture Uptake

- a) **Purpose:** Important for stability, especially since films are hygroscopic.
- b) **Method**
  - **Moisture Content:** Measured using a moisture analyzer or thermogravimetric method.
  - **Moisture Uptake:** Store films in controlled humidity chambers and measure weight gain.

## 10. Surface pH<sup>[22]</sup>

- a) **Purpose:** To ensure compatibility with the oral mucosa.
- b) **Method:** Moisten the film with distilled water and place a pH electrode on the surface.
- c) **Acceptance:** pH should be close to neutral (6.5–7.5).

## 11. Taste Masking Evaluation<sup>23</sup>

- a) **Purpose:** Assesses palatability, especially for pediatric use.
- b) **Method:**
  - **Panel Testing:** Human volunteers assess taste on a standardized scale.
  - **Electronic Tongue:** Objective, instrument-based assessment of bitterness masking.

## 12. Stability Studies<sup>[24]</sup>

- a) **Purpose:** To determine the shelf-life and product integrity over time.
- b) **Method:** Conducted under ICH guidelines (e.g., 40°C ± 2°C / 75% RH ± 5% RH for accelerated testing).
- c) **Parameters monitored:** Physical appearance, drug content, disintegration time, and mechanical properties.

## 13. Mucoadhesion Strength (if applicable)

- a) **Purpose:** For films intended to adhere to mucosal surfaces.

- b) **Method:** Texture analyzer or modified balance method to measure force required to detach film from mucosa or mucin-containing substrate.

## CONCLUSION

Fast Dissolving Oral Films (FDOFs) represent a transformative advancement in drug delivery technology, offering a patient-friendly, non-invasive, and efficient platform for the administration of various therapeutic agents. Their rapid disintegration in the oral cavity without the need for water makes them particularly suitable for pediatric, geriatric, and dysphagic patients. Over the past decade, significant progress has been made in the development of film-forming polymers, both natural and synthetic, which provide the necessary mechanical strength, flexibility, and rapid dissolution characteristics required for effective oral films. Recent innovations in manufacturing techniques—such as hot-melt extrusion, electrospinning, 3D printing, and spray layering—have enhanced the scalability, drug loading efficiency, and customization potential of FDOFs. These technologies not only overcome the limitations of conventional solvent casting methods but also pave the way for personalized and precision medicine applications. Despite the considerable advantages, FDOFs still face challenges such as limited drug loading capacity, stability concerns under humid conditions, and taste masking complexities. Ongoing research into nanotechnology-based formulations, mucoadhesive systems, and multi-layered film designs holds promise to expand their applicability to a broader range of drugs, including biologics and poorly soluble compounds. In conclusion, FDOFs offer a versatile and effective alternative to traditional oral dosage forms, with the potential to revolutionize drug administration practices. As advancements continue in polymer science, formulation strategies, and regulatory frameworks, FDOFs are poised to become a mainstay in the pharmaceutical landscape, addressing unmet clinical needs and improving patient outcomes across diverse therapeutic areas.

**Funding:** Nil

## Conflict of interest

There is no conflict of interest among authors

## ACKNOWLEDGEMENT

Hereby heart fully acknowledged to Shri Vishnu College of pharmacy management and staff for their encouragement in research activities.

## REFERENCES

1. Deshmukh PN, Bobade NN, Wankhade VP, Atram SC, Pande SD, Khedkar SA, Patil AM. Oral Fast Dissolving Film: A Review. *Asian J Pharm Res Dev*. 2025 Apr; 13(2): 148–156. arXiv+15ajprd.com+15Innovare Academics Journals+15
2. Muhammed RA, Yalman Z, Noaman BR, Visht S, Jabbar S, Salih SS. Innovations in Formulation and Evaluation of Oral Fast Dissolving Film. *Eurasian J Sci Eng*, 2023 Jun 20; 9(2): 115–130. eajse.tiu.edu.iq
3. R KD, Keerthy H, Yadav RP. A Review on Fast Dissolving Oral Films. *Asian J Pharm Res Dev*, 2021 Jun; 9(3): 122–128. ajprd.com
4. Sharma D, Kaur D, Verma S, Singh D, Singh M, Garg R. Fast Dissolving Oral Films Technology: A Recent Trend for an Innovative Oral Drug Delivery System. *Int J Drug Deliv*. 2024; [Epub ahead of print]. Wikipedia+15ijdd.arjournals.org+15Innovare Academics Journals+15

5. Bala R, Khanna S, Pawar P, Arora S. Orally dissolving strips: a new approach to oral drug delivery system. *Int J Pharm Investig*, 2013; 3(2): 67–76. SpringerLink
6. Balogh A, Farkas B, Verreck G, et al. AC and DC electrospinning of HPMC with polyethylene oxides as secondary polymer for improved drug dissolution. *Int J Pharm*, 2016; 505: 159–166. SpringerLink+1Wikipedia+1
7. Birer M, Acartürk F. Electrospun orally disintegrating film formulation of telmisartan. *Pharm Dev Technol*. 2021;26(6):661–672. ajprd.com+15SpringerLink+15MDPI+15
8. Borges AF, Silva C, Coelho JFJ, Simões S. Oral films: current status and future perspectives: I-Galenical development and quality attributes. *J Control Release*, 2015; 206: 108–121. SpringerLink+1SpringerLink+1
9. Effiong DE, Umoh RA, Akpabio AE, et al. The oral film delivery-application of nanotechnology and potential in medication adherence. *GSC Biol Pharm Sci*, 2020; 11(3): 34–51. SpringerLink
10. Revolutionizing Healthcare: The Impact of AI on Precision MedicineLakshmi Prasanthi Nori, Maddala Lohitha, Rama Rao Vadapalli, Brahmaiah Bonthagarala, Sudarshan Rao Nagineni and Venkateswara Raju KalidindiInternational Journal of Pharmaceutical Investigation, 15(2): 334-343.DOI: 10.5530/ijpi.20250100
11. Nagineni Sudarshan Rao, P Balaji. Phytonanoformulations as New Frontier in Effective Management of Diabetes Mellitus Type 2. International Journal of Drug Delivery Technology, 2025; 15(2): 884-88. doi: 10.25258/ijddt.15.2.65
12. Gupta MS, Kumar TP. Characterization of orodispersible films: overview and a new disintegration test apparatus. *J Pharm Sci*, 2020; 109(8): 2925–2942. SpringerLink+1SpringerLink+1
13. Banchara Y. Advances in electrospinning technology for fast-dissolving oral film applications. In: *Electrospinning Technology for Oral Films*. 2024. p.133–176. American Chemical Society Publications
14. Wildy M, Lu P. Electrospun nanofibers: shaping the future of controlled and responsive drug delivery. *Materials*, 2023; 16(22): 7062. American Chemical Society Publications
15. Yrysbayeva A, Wang Y, Li J, Chang S, Wang K, Yu DG. Fast Dissolution Electrospun Medicated Nanofibers for Poorly Water-Soluble Drugs. *Curr Drug Deliv*. 2022; 19(4): xxx–xxx. eajse.tiu.edu.iq+14eurekaselect.com+14MDPI+14
16. Bonthagarala B, Alla SD, Nagineni SR, Vadapalli RR, Malakapurapu SR. Formulation Optimization and Evaluation of Herbal Films Containing Ethanol Leaves Extract of *Cassia auriculata* to Treat Chronic Constipation Disorder. International Journal of Drug Delivery Technology, 2024; 14(2): 717-723.
17. Kumar SV, Gavaskar B, Sharan G, Rao YM. Overview on Fast Dissolving Films. *Int J Pharm Pharm Sci*, 2012; 3(2): 47–52. SpringerLink
18. Pimparade MB, Vo A, Maurya AS, et al. Development and evaluation of an oral fast disintegrating anti-allergic film via hot-melt extrusion. *Eur J Pharm Biopharm*, 2017; 119: 81–90. SpringerLink
19. Suryawanshi D, Wavhule P, Shinde U, et al. Cyanocobalamin loaded orodispersible films using hot-melt extrusion: QbD approach. *J Drug Deliv Sci Technol*, 2021; 63: 102559. SpringerLink
20. Nagineni Sudarshan Rao, Rama Rao Vadapalli, Brahmaiah Bonthagarala, Jalluri Charishma Vasavi, Mallabathula Meghana. Improving Solubility and Dissolution Characteristics of Dapoxetine Hydrochloride Through the Liquisolid Compact Method. International Journal of Drug Delivery Technology, 2025; 15(2): 425-32. doi: 10.25258/ijddt.15.2.7
21. Motiwale A, Sengar NPS. Manufacturing Techniques, Applications and Future Perspectives of Mouth-Dissolving Orodispersible Films. *EJPPS*, 2024 Jul 16; 292. EJPPS

22. Peptu C, Blaj DA, Balan-Porcarasu M, et al. Custom-modified oligolactide-cyclodextrin derivatives for electrospun drug formulations. *Eur Polym J*, 2023; 196: 112234. American Chemical Society Publications
23. Okur N, Saricam C, Gocek I, et al. Functionalized PVA nanofiber webs w/  $\beta$ -cyclodextrin/Vitamin C inclusion complex. *J Ind Text*, 2019; 150: 1–11. MDPI
24. Qin ZY, Jia XW, Liu Q, Kong BH, Wang H. Fast dissolving oral films for drug delivery from chitosan/pullulan nanofibers. *Int J Biol Macromol*, 2019; 137: 224–231.