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Review Article

Orodispersible Films: A Film For Rapid Drug Release And Improved Bioavailability

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ABSTRACT

Orodispersible films (ODFs) have emerged as an innovative and patient-friendly drug delivery system designed to overcome the limitations associated with conventional oral dosage forms. These thin, flexible polymeric films rapidly disintegrate or dissolve when placed on the tongue without the need for water, thereby enhancing patient compliance, particularly among pediatric, geriatric, bedridden, and dysphagic patients. ODFs offer several advantages, including ease of administration, accurate dosing, rapid onset of action, and improved convenience during travel and emergency situations. Various manufacturing techniques such as solvent casting, hot-melt extrusion, semi-solid casting, and rolling methods are employed to produce films with desirable mechanical and physicochemical properties. The large surface area and rapid hydration of the film facilitate quick disintegration and drug release in the oral cavity. Furthermore, drugs absorbed through the oral mucosa may partially bypass first-pass hepatic metabolism, resulting in enhanced bioavailability and therapeutic efficacy. Evaluation of ODFs includes assessment of thickness, weight variation, surface pH, folding endurance, tensile strength, drug content uniformity, disintegration time, dissolution profile, and stability studies. Recent advancements in formulation technologies have enabled the incorporation of a wide range of therapeutic agents, including antihistamines, antiemetics, analgesics, and central nervous system drugs, into ODFs. Due to their rapid drug release characteristics, improved patient acceptability, and potential for enhanced bioavailability, ODFs represent a promising platform for modern oral drug delivery and are expected to play a significant role in the future development of pharmaceutical dosage forms.

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INTRODUCTION

The oral route remains the most preferred and widely accepted method of drug administration due to its convenience, safety, ease of administration, cost-effectiveness, and high patient compliance. Conventional oral dosage forms such as tablets, capsules, and syrups have been extensively used for the treatment of various diseases. However, these formulations present significant challenges for certain patient populations, particularly pediatric, geriatric, bedridden, and dysphagic patients who experience difficulty in swallowing solid dosage forms [1]. Dysphagia is a common condition affecting a substantial proportion of elderly individuals and patients suffering from neurological disorders such as Parkinson's disease, stroke, and Alzheimer's disease. Therefore, there is an increasing need for alternative drug delivery systems that are easy to administer and capable of providing rapid therapeutic action. To address these limitations, pharmaceutical researchers have developed novel oral drug delivery systems designed to improve patient convenience and treatment outcomes. Among these, Orodispersible Films (ODFs), also referred to as Oral Thin Films (OTFs), Fast-Dissolving Films (FDFs), or Mouth-Dissolving Films (MDFs), have emerged as one of the most promising drug delivery technologies [2]. ODFs are ultra-thin, flexible polymeric strips that rapidly disintegrate or dissolve when placed on the tongue or oral mucosa without the need for water. These films release the incorporated drug rapidly, facilitating quick absorption and onset of action. The concept of oral thin film technology evolved from the development of transdermal therapeutic systems and oral dissolving tablets. Advances in polymer science and pharmaceutical formulation have enabled the successful incorporation of a wide variety of active pharmaceutical ingredients into thin film matrices while maintaining adequate

mechanical strength, flexibility, and stability [3]. ODFs generally consist of hydrophilic polymers, plasticizers, sweeteners, flavoring agents, saliva-stimulating agents, coloring agents, and active pharmaceutical ingredients. Upon contact with saliva, the hydrophilic polymers hydrate rapidly, causing the film to swell, disintegrate, and release the drug for absorption [3].

One of the most significant advantages of ODFs is their ability to provide rapid drug release and faster onset of therapeutic action. Due to their large surface area and thin structure, ODFs dissolve quickly in the oral cavity, often within seconds. The released drug may be absorbed through the buccal, sublingual, or gastrointestinal route depending on its physicochemical properties. Drugs absorbed through the oral mucosa can bypass hepatic first-pass metabolism, thereby improving bioavailability and therapeutic effectiveness [4]. This characteristic is particularly beneficial for drugs with extensive first-pass metabolism and poor oral bioavailability.

The oral mucosa offers a highly vascularized environment for drug absorption. The buccal and sublingual regions contain rich blood and lymphatic supplies that facilitate rapid transport of drug molecules into systemic circulation. Compared with conventional oral dosage forms, ODFs may reduce gastrointestinal degradation and hepatic metabolism, leading to enhanced plasma drug concentrations and improved pharmacological responses. Consequently, ODFs have gained considerable attention for the delivery of drugs requiring rapid onset of action, including antihistamines, antiemetics, analgesics, antipsychotics, and cardiovascular agents. The formulation of ODFs requires careful selection of excipients to ensure optimal film characteristics. Film-forming polymers such as hydroxypropyl methylcellulose, pullulan, polyvinyl alcohol,



sodium alginate, maltodextrin, and carboxymethyl cellulose are commonly employed due to their excellent film-forming abilities and compatibility with various drugs. Plasticizers such as glycerol, polyethylene glycol, and propylene glycol are added to enhance flexibility and reduce brittleness. Sweeteners and flavoring agents improve palatability, while saliva-stimulating agents facilitate rapid disintegration and drug release.

Several manufacturing methods have been developed for the preparation of ODFs, including solvent casting, hot-melt extrusion, semi-solid casting, solid dispersion extrusion, rolling method, and electrospinning. Among these techniques, solvent casting is the most commonly used because it produces uniform films with excellent mechanical and physicochemical properties [5]. Recent advances in manufacturing technologies have improved scalability, reproducibility, and commercial feasibility, contributing to the growing popularity of ODF products in the pharmaceutical market.

In addition to improving patient compliance, ODFs offer several practical advantages over conventional dosage forms. They are portable, lightweight, easy to handle, and can be administered without water, making them suitable for pediatric and geriatric patients as well as individuals traveling or experiencing emergencies. Furthermore, ODFs provide accurate dosing, rapid disintegration, reduced risk of choking, improved stability compared with liquid formulations, and enhanced patient acceptability.

Recent research has focused on expanding the applications of ODFs through the incorporation of nanoparticles, liposomes, microspheres, and solid dispersions to improve drug solubility, permeability, and bioavailability. The integration of nanotechnology with oral film formulations has shown significant potential in overcoming the

challenges associated with poorly water-soluble drugs [4]. Moreover, ODFs are being investigated as carriers for peptides, proteins, vaccines, and personalized medicines, highlighting their versatility as a modern drug delivery platform.

Overall, Orodispersible Films represent a significant advancement in oral drug delivery technology. Their ability to provide rapid drug release, improved bioavailability, enhanced patient compliance, and convenient administration has made them an attractive alternative to conventional oral dosage forms. With continuous innovations in formulation strategies and manufacturing techniques, ODFs are expected to play an increasingly important role in the development of patient-centric pharmaceutical products and next-generation drug delivery systems.

1.1 Advantages of Orodispersible Films (ODFs)

1. **Improved Patient Compliance:** Suitable for pediatric, geriatric, and dysphagic patients due to easy administration without swallowing difficulties.
2. **Rapid Drug Release:** Quickly disintegrate in the oral cavity, providing a faster onset of action.
3. **Enhanced Bioavailability:** Buccal absorption may bypass first-pass metabolism, increasing drug availability.
4. **No Water Required:** Convenient for administration anytime and anywhere.
5. **Accurate Dosing:** Ensures uniform drug content and precise dose delivery.
6. **Reduced Risk of Choking:** Safer than conventional tablets and capsules, especially for children and elderly patients.
7. **Better Patient Acceptance:** Pleasant taste and ease of use improve adherence to therapy.
8. **Portable and Convenient:** Thin, lightweight, and easy to carry and store [6-9].



1.3 Disadvantages of Orodispersible Films (ODFs)

1. **Limited Drug Loading Capacity:** ODFs are generally suitable only for low-dose drugs due to their small size and thin structure.
2. **Moisture Sensitivity:** Films are highly sensitive to humidity and require specialized packaging to maintain stability.
3. **Taste Masking Challenges:** Bitter or unpleasant-tasting drugs require effective taste-masking techniques, increasing formulation complexity.
4. **Mechanical Fragility:** Thin films may tear, fold, or break during handling and transportation if not properly formulated.
5. **Limited Suitability for High-Dose Drugs:** Drugs requiring large doses cannot be easily incorporated into ODFs due to size constraints.
6. **Higher Manufacturing Cost:** Specialized equipment and packaging materials can increase production costs compared to conventional tablets.
7. **Drug-Polymer Compatibility Issues:** Interactions between the drug and film-forming polymers may affect stability and drug release characteristics. [10-13]

2 Classification of Orodispersible Films (ODFs)

1. Based on Drug Release Characteristics

- **Immediate Release Films** – Rapidly dissolve and release the drug within seconds to minutes after administration.
- **Modified Release Films** – Designed to provide sustained, controlled, or delayed drug release for prolonged therapeutic action.

2. Based on Site of Drug Absorption

- **Sublingual Films** – Placed under the tongue for rapid absorption through the sublingual mucosa [3].
- **Buccal Films** – Applied to the inner cheek for local or systemic drug delivery.
- **Lingual Films** – Placed on the tongue and dissolve rapidly in saliva.

3. Based on Therapeutic Effect

- **Local Action Films** – Deliver drugs for treatment within the oral cavity (e.g., antifungal and antibacterial agents).
- **Systemic Action Films** – Deliver drugs into systemic circulation through oral mucosal absorption.

4. Based on Composition

- **Single-Layer Films** – Contain one uniform layer of drug and excipients.
- **Multi-Layer Films** – Consist of two or more layers for separation of incompatible drugs or modified drug release. [14,15]

3. Formulation of Orodispersible Films (ODFs)

Orodispersible films are formulated using a combination of active pharmaceutical ingredients (APIs) and suitable excipients to achieve rapid disintegration, acceptable mechanical strength, palatability, and efficient drug release. The major components are:



Table No. 01: Components of Orodispersible Film

Component	Function	Examples
Active Pharmaceutical Ingredient (API)	Provides therapeutic effect	Ondansetron, Rizatriptan, Cetirizine
Film-Forming Polymers	Form the film matrix and provide strength	Hydroxypropyl Methylcellulose (HPMC), Pullulan, Polyvinyl Alcohol (PVA), Sodium Alginate
Plasticizers	Improve flexibility and reduce brittleness	Glycerol, Polyethylene Glycol (PEG 400), Propylene Glycol
Sweetening Agents	Improve taste and patient acceptability	Aspartame, Saccharin Sodium, Sucralose
Flavoring Agents	Mask unpleasant taste	Peppermint, Orange, Lemon, Menthol
Saliva-Stimulating Agents	Enhance saliva production and disintegration	Citric Acid, Malic Acid, Tartaric Acid
Surfactants	Improve wetting and drug solubility	Polysorbate 80, Sodium Lauryl Sulfate
Colouring Agents	Improve appearance	FDA-approved colours, Titanium Dioxide

3.1 Ideal Characteristics of ODF Formulation

- Rapid disintegration (within 30 seconds).
- Good mechanical strength and flexibility.
- Uniform drug distribution.
- Pleasant taste and mouthfeel.
- Non-toxic and non-irritating excipients.
- Adequate stability during storage.

4. Formulation Technique of Orodispersible Films (ODFs)

Several techniques are employed for the preparation of Orodispersible Films (ODFs) depending on the physicochemical properties of the drug, polymer characteristics, and desired film properties.

Table No. 02: Formulation Technique of Orodispersible Films

Sr. No	Technique	Principle	Advantages
01	Solvent Casting Method	Drug, polymer, and excipients are dissolved in a suitable solvent to form a homogeneous solution, cast on a flat surface, and dried to form films.	Most commonly used; produces uniform and smooth films.
02	Hot-Melt Extrusion Method	Drug and polymers are mixed and melted under controlled temperature, then extruded through a die to form films.	Solvent-free process; suitable for large-scale production.



03	Semisolid Casting Method	A gel mass is prepared from polymer solution and cast onto heated drums to obtain films.	Suitable for acid-insoluble polymers.
04	Solid Dispersion Extrusion Method	Drug is dispersed in a carrier matrix and extruded to form thin films.	Improves solubility and dissolution of poorly soluble drugs.
05	Rolling Method	Drug-containing solution or suspension is rolled onto a carrier and dried to form films.	Continuous manufacturing process; suitable for industrial production.
06	Electrospinning Method	Polymer solution is subjected to a high-voltage electric field to produce nanofibrous films.	Produces ultra-thin films with rapid drug release.
07	Spray Technique	Drug-polymer solution is sprayed onto a suitable substrate and dried to obtain thin films.	Uniform coating and controlled film thickness.

1. Solvent Casting Method

The solvent casting method is the most widely used technique for ODF preparation. The polymer is dissolved in water or a suitable solvent, followed by the addition of plasticizers, sweeteners, flavoring agents, and drug. The resulting solution is cast onto a flat surface and dried. After drying, films are cut into the desired size and packaged.

2. Hot-Melt Extrusion Method

In this method, drug and polymer are blended and heated above their glass transition temperature. The molten mass is forced through an extruder to produce films. The process eliminates the use of solvents and offers excellent content uniformity.

3. Semisolid Casting Method

A viscous gel is prepared by mixing water-soluble and acid-insoluble polymers. The gel is cast onto a

substrate and dried under controlled conditions to form films.

4. Solid Dispersion Extrusion Method

The drug is dispersed in a suitable carrier to form a solid dispersion. The mixture is extruded through a heated barrel to produce films with enhanced drug dissolution properties.

5. Rolling Method

A drug-containing solution is continuously rolled onto a carrier material and dried. This technique is suitable for large-scale industrial production of oral films. [16,17]

5. Evaluation of Orodispersible Films (ODFs)

The quality, performance, and stability of Orodispersible Films (ODFs) are assessed through various evaluation parameters.

Evaluation Parameter	Purpose
Appearance	Evaluates color, transparency, smoothness, and absence of air bubbles or cracks.
Thickness	Ensures uniformity of the film using a micrometer screw gauge.



Weight Variation	Determines uniformity of film weight.
Surface pH	Ensures compatibility with oral mucosa and prevents irritation.
Drug Content Uniformity	Confirms uniform distribution of the drug throughout the film.
Folding Endurance	Measures flexibility by counting the number of folds before breaking.
Tensile Strength	Determines the mechanical strength of the film.
Percent Elongation	Evaluates elasticity and flexibility of the film.
Young's Modulus	Measures film stiffness and resistance to deformation.
Disintegration Time	Determines the time required for the film to disintegrate in saliva or simulated saliva.
In Vitro Dissolution Study	Evaluates the drug release profile from the film.
Moisture Content	Assesses the amount of residual moisture present in the film.
Moisture Uptake/Loss	Determines stability under different humidity conditions.
Transparency Test	Evaluates film clarity and appearance.
Stability Studies	Assesses physical, chemical, and drug stability during storage.

4. CONCLUSION

Orodispersible films (ODFs) represent an advanced and patient-friendly drug delivery system that combines the advantages of rapid drug release, ease of administration, and improved patient compliance. Their ability to disintegrate quickly in the oral cavity without the need for water makes them particularly beneficial for pediatric, geriatric, dysphagic, and bedridden patients. The large surface area and rapid hydration of ODFs facilitate fast drug dissolution and absorption, resulting in a quicker onset of therapeutic action. Furthermore, absorption through the oral mucosa can partially bypass hepatic first-pass metabolism, thereby enhancing the bioavailability of many drugs.

Advances in polymer science and manufacturing technologies have enabled the development of ODFs with desirable mechanical properties, improved stability, and effective taste masking. Despite certain limitations such as low drug-loading capacity and moisture sensitivity, continuous research is expanding their applications through the incorporation of novel

excipients, nanocarriers, and personalized drug delivery approaches. Owing to their convenience, efficacy, and potential for enhanced therapeutic performance, oro-dispersible films have emerged as a promising platform for modern drug delivery and are expected to play a significant role in the future of pharmaceutical formulation development.

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