

Orodispersible films as multifunctional drug delivery systems: From conventional formulations to digital manufacturing

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Abstract

Orodispersible films (ODFs) have emerged as an innovative and patient-friendly drug delivery platform that rapidly disintegrates in the oral cavity without the need for water, offering significant advantages over conventional oral dosage forms. ODF technology is particularly beneficial for pediatric, geriatric, dysphagic, and psychiatric patients who experience difficulty swallowing tablets and capsules. The present review provides a comprehensive overview of the fundamental principles, classification, mechanisms, formulation strategies, and therapeutic applications of ODFs. Special emphasis is placed on the role of excipients, including film-forming polymers, plasticizers, sweeteners, and permeation enhancers, in determining the mechanical properties, disintegration behavior, and drug release characteristics of the films. Various manufacturing approaches, such as solvent casting, hot-melt extrusion, electrospinning, rolling methods, and advanced printing technologies, are critically discussed with respect to their advantages and limitations. Furthermore, currently marketed ODF products and their therapeutic indications are summarized to highlight the growing commercial relevance of this dosage form. Recent advances in nanotechnology, biologics delivery, and personalized medicine have expanded the potential applications of ODFs, positioning them as promising platforms for precision drug delivery. Owing to their rapid onset of action, enhanced bioavailability, improved patient compliance, and adaptability to modern pharmaceutical technologies, orodispersible films represent a significant advancement in oral drug delivery systems and hold considerable promise for future therapeutic innovations.

Keywords: Orodispersible Films; Patient-Centric Drug Delivery; Film-Forming Polymers; Personalized Medicine; Oral Mucosal Delivery; Solvent Casting Method

1. Introduction

Oral administration is the most widely used route for drug delivery. In oral dosage forms, the active pharmaceutical ingredient (API) must be absorbed through the gastrointestinal (GI) tract to produce a systemic effect. Although the oral route offers advantages such as improved safety and better patient compliance, several limitations make it unsuitable for the delivery of certain APIs. These limitations include poor oral bioavailability, a slower onset of action compared to intravenous administration, degradation by gastric acid and digestive enzymes, and inconsistent absorption within the GI tract. Factors such as low drug solubility, limited permeability across the GI membrane, and extensive hepatic first-pass metabolism further contribute to these challenges. [1][2]

Oral disintegrating/dissolving films (ODFs) or strips are drug delivery systems designed to rapidly release the drug by dissolving or adhering to the oral mucosa in the presence of saliva within a few seconds after being placed in the oral cavity or on the tongue. Their rapid disintegration is attributed to the presence of water-soluble polymers. The

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sublingual mucosa possesses high membrane permeability because of its thin epithelial structure and rich vascularization. [3]

Enhanced systemic bioavailability is achieved by bypassing hepatic first-pass metabolism, while improved permeability results from the rich blood supply and extensive lymphatic circulation. Furthermore, the oral mucosa serves as an efficient and selective route for systemic drug delivery due to its large absorptive surface area and ease of administration. [4]

2. Orodispersible Films

Fast-dissolving oral delivery systems are solid dosage forms that rapidly disintegrate or dissolve in the oral cavity, typically within one minute, without the need for chewing or water intake. The major challenges in developing these dosage forms include achieving rapid dissolution in the mouth, ensuring adequate mechanical strength and tensile properties for handling and packaging, and effectively masking the unpleasant taste of the drug. [5]

Orodispersible films (ODFs) are thin, flexible dosage forms that rapidly disintegrate in the oral cavity, improving patient compliance, especially in paediatric, geriatric, and dysphagic patients. The performance of ODFs depends on the careful selection and interaction of excipients, including film-forming polymers, plasticizers, and taste-masking agents, which collectively influence mechanical strength, rapid disintegration, and overall product quality. [6]

3. Overview of orodispersible films

Orodispersible films (ODFs) are innovative drug delivery systems that rapidly dissolve in saliva without the need for water, providing a convenient and patient-friendly alternative to conventional dosage forms. Their performance relies on a hydrophilic polymer matrix and carefully selected excipients that optimize disintegration time, mechanical strength, stability, and palatability. By simplifying drug administration and reducing the risk of noncompliance and choking, ODFs are particularly beneficial for paediatric and geriatric patients, with formulations tailored to meet the specific needs of these populations. [7]

3.1. Classification of ODF

Generally, ODFs can be broadly classified into three types.

3.1.1. Type I classification is based on dissolution potential

Based on dissolution potential, it can be divided into three categories,

- fast dissolving (1 to 30 seconds)
- moderately dissolving (1 to 30 minutes) and
- slow dissolving (> 30 minutes)

3.1.2. Type II classification is based on number of layers or multilayered films.

Based on number of layers, it can be broadly divided into three categories,

- Mono- layered
- Bi-layered
- Multilayered or Sandwiched

3.1.3 Type III classification is based on the nature of active ingredient present in ODF.

- ODFs with an Active Pharmaceutical Ingredient (API) obtained via synthetic route. Example: ODF of Sildenafil Citrate manufactured and marketed by various companies in India and abroad.
- ODFs with an API obtained from natural source (plant or animal source). Example: ODF of Tetrahydro Cannabinol (THC), Turmeric and Ginger.

ODFs with other materials namely micronutrients or minerals or essential vitamins or vaccines or probiotics. Example: ODF of Vitamin D manufactured by CURE Pharmaceuticals, USA [8]

3.2. Advantages of orodispersible film

- For pediatric, elderly, and psychiatric patients who have trouble swallowing tablets and other solid dosage forms, it is simple to administer.
- No water is required for swallowing.
- Rapidly acting medications that are poorly water soluble that dissolve and absorb quickly.
- Pregastric absorption can lead to improved clinical performance through a decrease in side effects, greater bioavailability with a smaller dosage.
- Bitter medications have the potential to be taste-masked
- Useful in situations requiring or coughing fit, hypertension, bronchitis, or asthma.
- More affordable.
- The dosing procedure is simple and precise.
- Reasonable transportation. [10]

3.3. Mechanism of Orodispersible film

- An ODF is designed to be placed/administered on the tongue without any mastication.
- Film gets hydrated with saliva in a few seconds, then the film-forming polymer is rapidly dissolved (up to 60 secs) and the active pharmaceutical ingredient (API) begins to dissolve and release.
- Most of the drug is swallowed with the saliva to reach the stomach and then systemic absorption takes place from the gastrointestinal tract; however, absorption of an API fraction through the oral mucosa may occur. [9] The mechanism of Orodispersible film is displayed in fig 1.

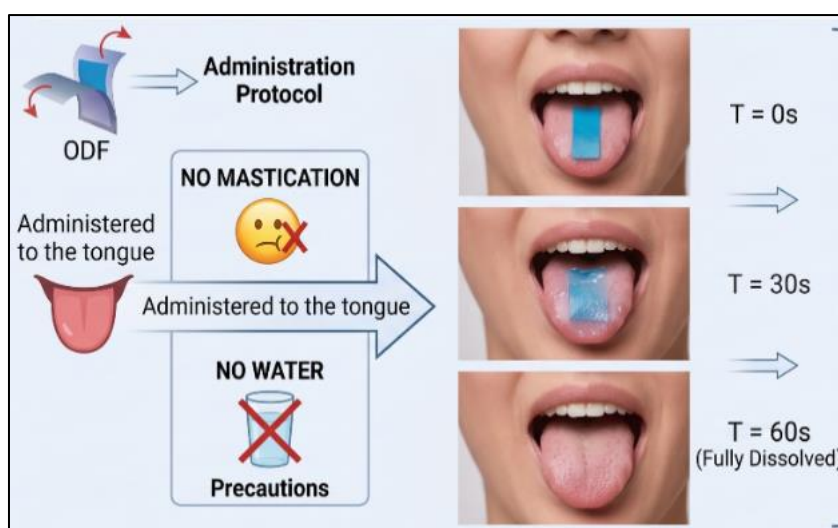


Figure 1 Mechanism of Orodispersible Film

Table 1 Comparative Features of Oral Thin Films and Orally Dissolving Tablets

OTF (Oral Thin Film)	ODT (Orally Dissolving Tablet)
Film dosage form	Tablet dosage form
Faster dissolution due to larger surface area	Slower dissolution due to smaller surface area
More durable compared to ODTs	Less durable than OTFs
Higher patient compliance	Lower patient compliance
Generally suitable for low-dose drugs	Can accommodate higher drug doses
No risk of asphyxiation/choking	Possibility of asphyxiation/choking, especially in vulnerable patients [11] [12]

3.4. Excipients in Orodispersible films

The successful formulation of orodispersible films (ODFs) relies on the careful selection and optimization of excipients. These excipients not only impart structural integrity and mechanical strength but also affect critical parameters such as disintegration time, drug release, taste masking, and patient acceptability. Commonly used excipients in ODFs include film-forming polymers, plasticizers, sweeteners, saliva-stimulating agents, surfactants, and other functional additives. A comprehensive understanding of their properties, selection criteria, and functional roles is essential for developing effective ODF formulations. This review discusses the major excipients used in ODFs, their mechanisms of action, and their significance in overcoming formulation challenges, providing an overview of excipient selection and application in this advanced drug delivery system. [10]

3.5. Film-forming polymers

Film-forming polymers are essential components of orodispersible films (ODFs), as they provide an optimal balance between mechanical strength and rapid disintegration. Hydrophilic polymers are widely employed because they facilitate quick disintegration, improve mouthfeel, and enhance the mechanical properties of the films. Generally, polymers with higher molecular weights increase disintegration time, thereby influencing the dissolution behaviour and drug release profile of the formulation. Moreover, the finished film should possess sufficient strength and flexibility to withstand handling, packaging, and transportation without damage. [13]

Table 2 Film-forming polymers

Polymer	Type	Key Properties	Advantages	Limitations
HPMC	Semi-synthetic	Strong films, good stability	Widely used, good handling	May slow disintegration
Pullulan	Natural	Transparent, fast dissolving	Excellent taste masking	Expensive
PVA	Synthetic	Flexible, stable	Good shelf life	Slower dissolution
PVP	Synthetic	Hydrophilic, enhances solubility	Improves API dispersion	Hygroscopic
Sodium alginate, CMC	Natural	Biocompatible, swellable	Eco-friendly	Weak mechanical strength

3.6. Plasticizers

Plasticizers, including triethyl citrate, polyethylene glycol (PEG), and glycerol, are incorporated into orodispersible films to enhance flexibility and minimize brittleness. An insufficient amount of plasticizer results in brittle and fragile films, whereas excessive amounts lead to sticky films with prolonged disintegration and dissolution times.

3.7. Taste-masking agents, flavors, and sweeteners

These excipients play a crucial role in improving patient compliance and formulation performance. Sweeteners such as aspartame and sucralose, along with flavouring agents like fruit and mint flavours, enhance the palatability of orodispersible films. For bitter drugs, taste masking can be achieved through microencapsulation techniques or the formation of cyclodextrin complexes. Permeation enhancers and pH modifiers, including fatty acids, surfactants, and bile salts, improve transmucosal drug absorption. Additionally, local pH can be adjusted using agents such as sodium bicarbonate or citric acid to increase drug solubility and optimize drug release

- Surfactants: improve wetting of the film
- Fillers: ensure uniform drug dosing
- Preservatives: prevent microbial contamination [14]

4. Method of formulation of ODF

- Casting method
 - i. Solvent casting
 - ii. Semi-solid casting
- Extrusion method
 - i. Hot melt extrusion
 - ii. solid dispersion
- Rolling method
- Electrospinning method
- Printing technology
- 2D Printing – Inkjet printing, Flexographic
- 3D Printing

4.1. Casting Method

- **Solvent Casting:** In the solvent-casting method, the active pharmaceutical ingredients (APIs) and excipients are dissolved in a suitable solvent and blended with film-forming polymers, plasticizers, and other additives to obtain a homogeneous solution. This solution is then cast onto a Petri dish or flat surface and dried at 40–50 °C to produce thin films, which are subsequently cut into the desired dimensions. The method is particularly suitable for heat- and light-sensitive drugs and enables the preparation of multilayer films for fixed-dose combinations. However, its limitations include the possibility of residual solvents and concerns related to solvent flammability.

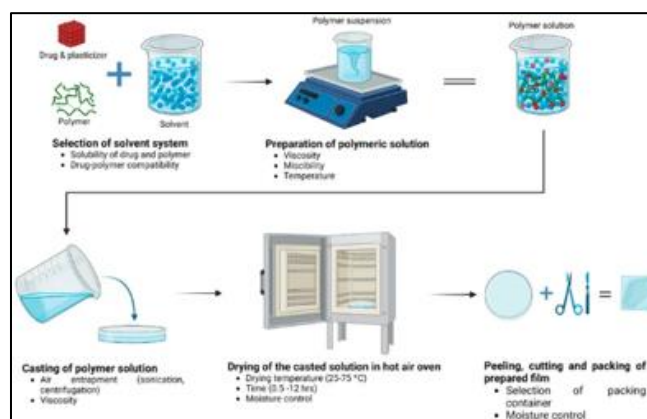


Figure 2 Solvent Casting method

- **Semi-Solid Casting:** This method involves the preparation of a gel mass containing water-soluble and acid-insoluble polymers along with suitable plasticizers. The resulting gel is cast into films or ribbons using heat-controlled drums. It is particularly suitable for the production of films based on acid-insoluble polymers.

4.2. Extrusion Method

- **Hot-Melt Extrusion:** In this method, the drug and excipients are blended and introduced into a heated extruder to produce uniform films without the use of solvents. Hot-melt extrusion improves film elasticity, minimizes environmental and solvent-related hazards, and is suitable for the fabrication of multilayer and gastroretentive films.

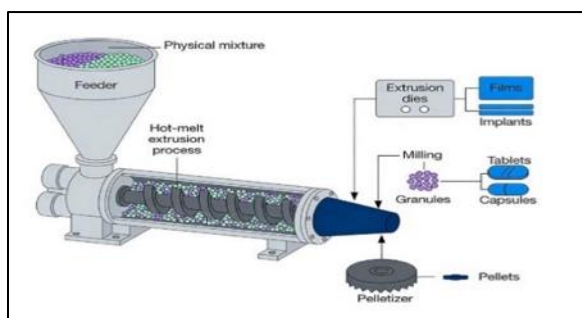


Figure 3 Hot-Melt Extrusion

- **Solid Dispersion Extrusion:** In this method, drugs are dispersed in a non-reactive carrier or polymer melt and subsequently processed into films using dies. This approach enhances drug solubility and improves bioavailability.

4.3. Rolling Method

In this method, a premix of polymers and additives is first prepared, followed by the incorporation of the drug. The resulting mixture is then passed through rollers to form films, which undergo controlled drying and are subsequently cut into the desired dimensions.

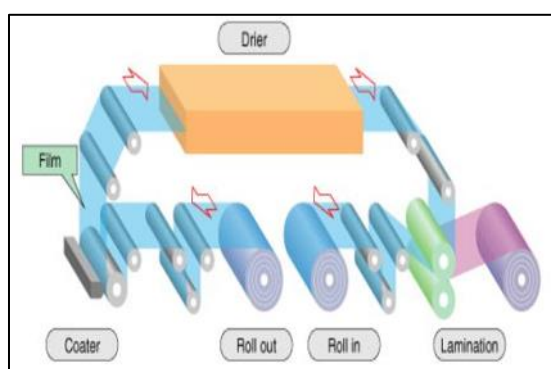


Figure 4 Rolling method

4.4. Electrospinning Method

This technique generates highly porous films by electrospinning polymer–drug solutions under an applied electric field. Polymers such as polyvinylpyrrolidone (PVP), gelatin, and poloxamers are incorporated to improve drug solubility, wettability, and stability. Furthermore, electrospinning can be integrated with inkjet printing to produce advanced and customized film formulations.

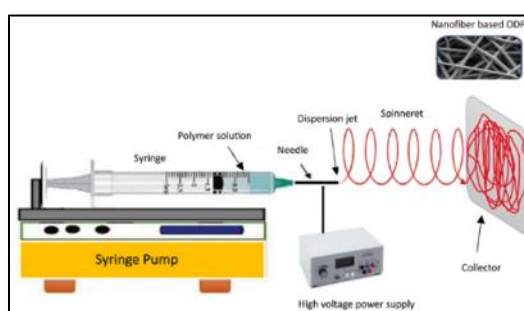


Figure 5 Electrospinning Method

4.5. Printing Technology

- **2D Printing (Inkjet, Flexographic):** Deposits drug-containing ink onto an edible substrate in a controlled pattern.
- **3D Printing:** Enables layer-by-layer construction of complex dosage forms in X, Y, and Z dimensions. Printing methods are mostly suitable for small-scale production and personalized dosing. [15] [16] [17] [18][19][20]

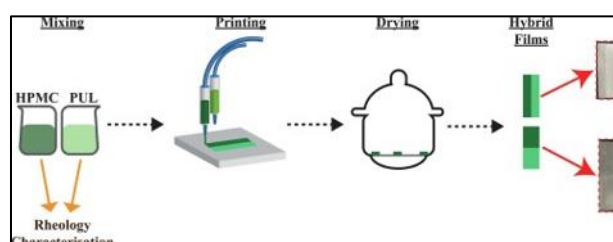


Figure 6 Printing Technology

5. Currently marketed Orodispersible film products

Over the past two decades, Orodispersible films (ODFs) have transitioned from a novel concept to a commercially viable dosage form, with numerous products now approved and available globally. The success of these products is attributable to their superior patient compliance, elimination of the need for water, rapid onset of action, and pre-gastric drug absorption. Table 1 presents a comprehensive overview of currently marketed ODF products across various therapeutic categories worldwide, including the Indian pharmaceutical market. [21][22][23][24]

Table 3 Currently Marketed Orodispersible Film Products (Global and India)

Brand Name	Drug	Indication	Manufacturer	Market
Suboxone	Buprenorphine + Naloxone	Opioid dependence	Indivior	USA / Global
Zuplenz	Ondansetron	Chemotherapy-induced nausea and vomiting	Midatech Pharma	USA
Onsolis	Fentanyl citrate	Breakthrough cancer pain	BioDelivery Sciences International	USA
Striant	Testosterone	Hypogonadism	Endo Pharmaceuticals	USA
Rapifilm	Domperidone	Nausea and vomiting	Mankind Pharma	India
Nicotine ODF (e.g., Nicotine strips)	Nicotine	Smoking cessation	Haleon and other manufacturers	Australia / EU
Melatonin ODF	Melatonin	Sleep disorders	CURE Pharmaceutical	USA
Vitamin D ODF	Cholecalciferol (Vitamin D3)	Vitamin D deficiency	CURE Pharmaceutical / Sun Pharmaceutical Industries	USA / India

6. Future prospects of Orodispersible films

The future of Orodispersible film (ODF) technology is promising, driven by advances in personalized medicine, biologics delivery, nanotechnology, and digital manufacturing. ODFs are particularly suitable for paediatric and geriatric patients due to their ease of administration and potential for individualized dosing through technologies such as 3D printing.

Emerging research is exploring ODFs as needle-free platforms for delivering peptides, proteins, and vaccines via buccal and sublingual routes. The integration of nanoparticles, smart materials, and stimuli-responsive excipients is improving drug solubility, bioavailability, controlled release, and site-specific delivery. [25]

Digital manufacturing techniques, including inkjet printing and 3D printing, are enabling precise, scalable, and cost-effective production of ODFs. Supported by evolving regulatory guidelines and increasing demand for patient-friendly dosage forms, the global ODF market is expected to grow significantly and expand into diverse therapeutic applications. [26]

7. Conclusion

Orodispersible films (ODFs) are an innovative oral drug delivery system that offers improved patient compliance, rapid drug release, enhanced bioavailability, and ease of administration without water, making them particularly suitable for paediatric, geriatric, dysphagic, and psychiatric patients. Their formulation relies on the careful selection of polymers, plasticizers, and taste-masking agents to ensure optimal film properties and patient acceptability. Advances in manufacturing techniques, including solvent casting, hot-melt extrusion, electrospinning, and 3D printing, have improved dose precision and film quality. With growing applications in various therapeutic areas and the integration of nanotechnology, biologics, and personalized medicine, ODFs are emerging as a promising and expanding platform in modern pharmaceutical drug delivery.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declare that they have no conflicts of interest.

Statement of ethical approval

Not applicable. This article is a review study and does not contain any studies with human participants or animals performed by any of the authors.

Statement of informed consent

Not applicable. This study does not involve human participants, clinical trials, or personal patient data.

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