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Fast Dissolving Oral Films A Review with Future Prospects Practices

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Abstract: *Fast dissolving oral films (FDOFs) have gained significant recognition as an innovative and patient-friendly drug delivery system aimed at improving safety, efficacy, and treatment adherence. These thin, flexible, water-soluble films rapidly disintegrate when placed on the tongue, releasing the drug into saliva for absorption in the oral cavity or gastrointestinal tract. This eliminates the need for water, reduces the risk of choking, and offers improved mouthfeel, making FDOFs particularly suitable for pediatric, geriatric, and dysphagic patients who face difficulties swallowing conventional tablets or capsules. This review provides a comprehensive assessment of oral mucosal absorption, formulation components, and key manufacturing techniques such as solvent casting, hot-melt extrusion, electrospinning, and emerging 3D printing. Critical quality attributes, bioavailability enhancement strategies, and current pharmaceutical and nutraceutical applications are highlighted. Challenges, including dose limitation, moisture sensitivity, and scale-up issues, are also discussed. Future prospects emphasize personalized medicine, smart responsive films, biodegradable polymers, and advancing industrial technologies, positioning FDOFs as a promising next-generation dosage form.*

Keywords: Fast dissolving oral films, Patient-centric drug delivery, Nanotechnology, Future pharmaceutical prospects.

I. INTRODUCTION

Among the various routes of drug administration, the oral route remains the most preferred and widely utilized due to its convenience, safety, cost-effectiveness, and high patient compliance. Approximately 90% of therapeutic agents are administered orally for the treatment of diverse disorders, as this route allows simple self-medication and avoids the discomfort associated with parenteral delivery. In oral administration, the drug is either dissolved or swallowed, subsequently entering systemic circulation to exert its pharmacological effect. Despite substantial advancements in drug delivery technologies, the oral route continues to dominate systemic drug administration because of its ease of use, noninvasive nature, and patient acceptability.

1.1 Anatomy of the Oral Cavity

A clear understanding of the anatomy and physiology of the oral cavity is crucial for designing effective oral drug delivery systems. The oral mucosa provides a highly vascularized environment that permits direct absorption into systemic circulation while partially bypassing first-pass metabolism. Structurally, the oral mucosal epithelium resembles that of the skin but differs in its degree of keratinization and the presence of protective, lubricating mucus. Its permeability is significantly higher estimated to be 4 to 1000 times greater than that of the skin making it a promising target for rapid drug absorption. The oral cavity comprises the oral vestibule, bounded externally by the lips and cheeks, and the oral cavity proper, which includes the hard and soft palates, floor of the mouth, and tonsillar region. Due to these anatomical and physiological advantages, the oral cavity has long been recognized as an important site for systemic drug delivery across a range of pharmaceutical dosage forms.

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1.2 Fast Dissolving Drug Delivery System (FDDS)

The fast dissolving drug delivery system (FDDS) represents a new-generation oral drug delivery platform, also referred to as fast-dissolving or fast-disintegrating films. This system emerged in the late 1970s as an alternative to conventional tablets, capsules, syrups, and other formulations, particularly for pediatric and geriatric patients who experience difficulty swallowing traditional solid dosage forms. FDDS combines the advantages of both conventional tablets and liquid formulations, providing ease of administration and improved patient compliance, especially for elderly, pediatric, mentally challenged, nauseated, or uncooperative individuals.

FDDS consists of very thin oral strips that dissolve rapidly typically within seconds upon placement on the tongue or other oral mucosal surfaces, without the need for water. The film becomes instantly hydrated by saliva, which leads to quick dissolution and disintegration, releasing the drug for oro-mucosal absorption. These fast dissolving oral films are widely preferred by patients and caregivers because of their portability, ease of delivery, and accurate dosing. The mechanical strength and overall robustness of the film depend on the type and concentration of polymers used, while the typical dissolution time ranges from 5 to 20 minutes, as per pharmacopoeial standards.

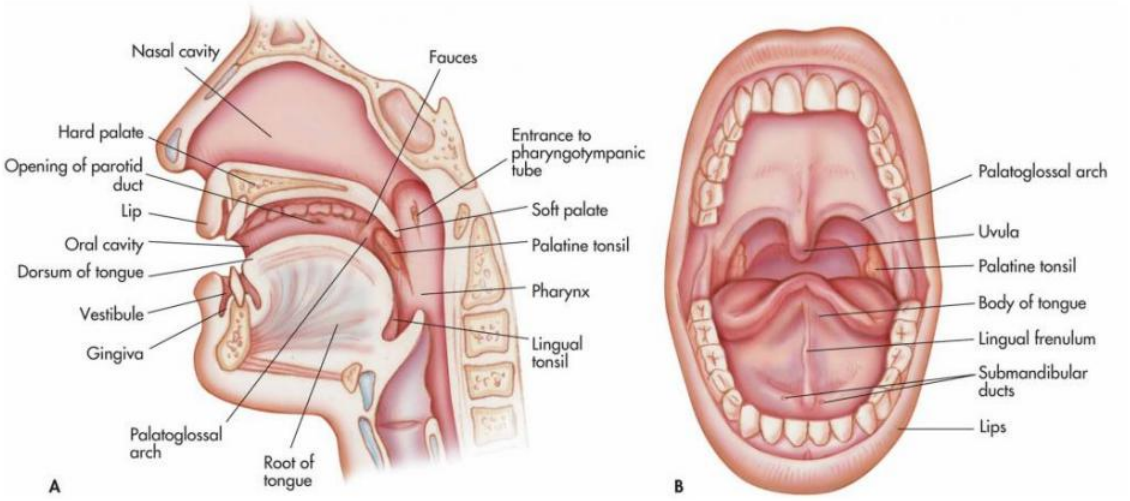

Figure 1: Anatomy of the oral cavity.

1.3 Advantages of Fast Dissolving Oral Films (FDOFs)

Rapid Disintegration and Dissolution

Large surface area allows fast wetting and dissolution in seconds, resulting in quick onset of action.

No Need for Water

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

Improved Patient Compliance

Suitable for mentally ill, bedridden, nauseated, or uncooperative patients.

Bypass of First-Pass Metabolism

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

Accurate Dosing

Each film provides a precise dose, unlike liquid formulations that may require measuring.

Portability and Convenience

Small, thin, and flexible strips are easy to carry, store, and use anywhere.

Better Stability than Liquids

Films are more stable and less prone to contamination than syrups.

No Risk of Choking

Useful for children and elderly individuals at risk when using solid oral dosage forms.

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Ease of Manufacturing and Scalability
Solvent casting and hot-melt extrusion are relatively simple and cost-effective.
Commercial and Marketing Benefits
Supports product differentiation, patent extension, and lifecycle management.

1.4 Disadvantages of Fast Dissolving Oral Films (FDOFs)

Limited Drug Loading Capacity
Only small amounts of drug can be incorporated; unsuitable for high-dose medications.
Moisture Sensitivity
Films absorb moisture easily and require special packaging to maintain stability.
Taste Masking Challenges
Bitter drugs require effective taste-masking techniques to ensure patient acceptability.
Mechanical Fragility
Although flexible, films may tear or wrinkle if not formulated properly.
Restricted to Potent Drugs
Only drugs effective at low doses (<30 mg typically) are suitable.
Irritation Potential
Some drugs or excipients may irritate oral mucosa.
Complexity of Uniformity
Achieving uniform drug distribution across the film can be challenging.
Specialized Packaging Requirements
Unit-dose packaging is often required to prevent degradation by moisture, oxygen, or light.

1.5 Comparison between Fast Dissolving Oral Films and Fast Dissolving Tablets

Sr. No.	Fast Dissolving Oral Films (FDOFs)	Fast Dissolving Tablets (FDTs)
1	Large surface area, enabling faster dissolution.	Smaller surface area causes slower dissolution compared to FDOFs.
2	Flexible and durable; less fragile.	Brittle and less durable; requires special packaging.
3	Suitable only for low-dose drug incorporation.	Can accommodate higher drug doses.
4	Thin films with a thickness of **0.015–0.05 inches**.	Similar in size and shape to conventional tablets.
5	Higher patient compliance due to ease of use and no need for water.	Lower patient compliance compared to FDOFs.

II. FORMULATION COMPONENTS OF FDOFS

2.1 Active Pharmaceutical Ingredient (API)

FDOFs typically contain **1–30% w/w** of the active ingredient. Low-dose drugs are preferred because high doses are difficult to incorporate into thin films. A wide range of APIs can be used, including antihistamines, antidepressants, antiemetics, vasodilators, antiasthmatics, and antidiarrheals. Examples include **salbutamol sulfate, ondansetron, cetirizine, verapamil, indomethacin, rizatriptan benzoate, dexamethasone**, and others.

2.2 Film-Forming Polymers

Polymers form the backbone of FDOFs and determine film strength, flexibility, and disintegration properties. Typically, **~45% w/w** polymer is used. Hydrophilic polymers are preferred as they hydrate and dissolve quickly in saliva.
Natural polymers: pullulan, pectin, sodium alginate, maltodextrin, gelatin.
Synthetic polymers: HPMC, methylcellulose, CMC, PVP, PVA, polyethylene oxide, Eudragit grades.

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2.3 Plasticizers

Plasticizers improve flexibility and reduce brittleness by lowering the polymer's glass transition temperature. They are used at **0–20% w/w** of dry polymer. Common examples include **glycerol, propylene glycol, PEGs, phthalate esters, citrate esters (triacetin, triethyl citrate), and castor oil.**

2.4 Surfactants

Surfactants enhance wetting and promote rapid film dissolution. Commonly used surfactants include **poloxamer 407, sodium lauryl sulfate, benzalkonium chloride,** and **Tweens**.

2.5 Sweetening Agents

Sweeteners improve palatability. Common natural sweeteners include **sucrose, dextrose, fructose, sorbitol, mannitol,** while artificial sweeteners such as **saccharin, aspartame, sucralose, alitame, and neotame** are also used.

2.6 Saliva-Stimulating Agents

Used to enhance saliva production and accelerate film disintegration. Examples include **citric acid, tartaric acid, malic acid, lactic acid,** and **ascorbic acid.**

2.7 Flavouring Agents

Flavours must be safe, soluble, and compatible with other excipients. Preferred flavours depend on drug taste—e.g., **cherry, raspberry, orange** for antibiotics**; wild cherry, chocolate-mint** for bitter drugs**; vanilla and fruit flavours** for sweet drugs.

2.8 Colouring Agents

Colourants include FD&C-approved dyes, natural colours, and pigments like **titanium dioxide.** They are used at concentrations **below 1% w/w.**

III. MANUFACTURING METHODS OF FAST DISSOLVING ORAL FILMS (FDOFS)

3.1. Solvent Casting Method

Water-soluble ingredients dissolved
↓
API + other excipients dissolved separately
↓
Both solutions mixed
↓
Entrapped air removed (vacuum)
↓
Casting of solution onto film support
↓
Drying
↓
Cutting into desired size
↓
Packaging

3.2 Hot Melt Extrusion (HME) Method

API + polymers + excipients blended
↓
Heating and melting under controlled temperature

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↓

Extrusion of molten mass into thin film

↓

Film passed through drying tunnel (controlled air & temperature)

↓

Slitting

↓

Punching

↓

Pouching/Sealing

3.3 Semisolid Casting Method

Water-soluble polymer solution prepared

↓

Acid-insoluble polymer solution prepared

↓

Both mixed to form homogeneous viscous mass

↓

Sonication to remove air

↓

Casting onto untreated film support

↓

Drying (film thickness 0.381–1.27 mm)

↓

Cutting

↓

Packaging

3.4 Solid Dispersion Extrusion Method

Preparation of solid dispersion (drug + immiscible carriers)

↓

Melting and mixing

↓

Forming solid dispersion

↓

Shaping into films using dies

↓

Cooling

↓

Cutting

↓

Packaging

3.5 Rolling Method

Drug solution/suspension prepared

↓

Solution rolled onto carrier film

↓

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Drying on rollers
↓
Film formed
↓
Cutting into required size
↓
Packaging

IV. EVALUATION PARAMETER

Sr. No.	Evaluation Parameter	Description / Method
1	Thickness	Measured using micrometer screw gauge or digital calipers; range: 5–200 µm.
2	Dryness/Tack Test	Assesses surface dryness; stages include set-to-touch, dust-free, tack-free, dry-hard, dry-through, dry-to-recoat, dry print-free.
3	Tensile Strength	Maximum stress applied before film breaks; calculated as applied load at rupture ÷ cross-sectional area.
4	Percent Elongation	Measures strain; elongation increases with higher plasticizer content.
5	Young's Modulus	Stiffness of film; ratio of stress/strain in elastic deformation region.
6	Tear Resistance	Force required to initiate tearing; measured at low loading rate, reported in Newtons or pounds-force.
7	Folding Endurance	Number of times film can be folded at the same place without breaking.
8	Organoleptic Evaluation	Taste, color, texture assessed via human taste panels or in-vitro taste sensors.
9	Surface pH	Determined by placing film on 1.5% agar gel and using pH paper (range 1–11).
10	Swelling Property	Measured in simulated saliva; degree of swelling = (Wt – W0) / W0 × 100.
11	Transparency	Determined using UV spectrophotometer at 600 nm; calculated using transmittance, thickness, and concentration.
12	Assay / Content Uniformity	API content per strip; acceptable range: 85–115% of label claim.
13	Disintegration Time	Measured using USP disintegration apparatus; typical range: 5–30 seconds.
14	Dissolution Test	Standard basket or paddle apparatus; dissolution medium selected based on API solubility; strip floating may be an issue.

Research date of oral fast dissolving film of last five years

Year	Title of Paper	Journal	Authors	Key Conclusion / Findings
2025	*Oral Fast Dissolving Film: A Review*	Asian Journal of Pharmaceutical Research and Development	Deshmukh P. Nishant, Nishan N. Bobade, Vikrant P. Wankhade, Sandeep C. Atram, Shrikant D. Pande, Anuradha S. Khedkar	Provided an up strategies, manufacturing methods, evaluation parameters, and highlighted growing acceptance of ODFs in pharmaceutical development.-to-date review of formulation
2025	*Recent advances in oral thin film drug delivery systems: a review*	International Journal of Pharmaceutical Sciences and	Pratima Bisen & Surendra Pardhi	Summarized modern manufacturing and quality control methods; concluded that FDOFs are increasingly relevant as alternative dosage forms for

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		Research (IJPSR)		populations with swallowing difficulties.
2025	*Oral fast dissolving film: Pharmaceutical development and approaches*	Int. J. Pharm. Res. Dev.	Kusum Dhankar, Harsh K. Tamrakar, Sanjay Deshmukh, Gurtej S. Wadhwa, Morlin A. Toppo, Jaya Shree & Rajesh Choudhary	Reviewed different types of oral films (flash-release, mucoadhesive, sustained-release), their formulation strategies, advantages, and challenges; highlighted future potential and need for more research on stability and scalability.
2024	*Fast Dissolving Oral Thin Films: A Review*	Research & Reviews: A Journal of Drug Design & Discovery	Chenna M. Shalini, Asireddy Sathvika Reddy, Vallarapu Nanda Krishna Veni, Madhira Jayaprakash & Rama Rao T.	Affirmed that FDOFs are a significant advancement over conventional oral solid dosage forms, especially for patients with swallowing difficulties, due to rapid dissolution, taste masking, and improved compliance.
2023	*Fabrication and characterization of orodispersible films loaded with solid dispersion to enhance Rosuvastatin calcium bioavailability*	Saudi Pharmaceutical Journal	Madhira Jayaprakash	Demonstrated that formulating rosuvastatin as a solid-dispersion in an FDOF improved its in-vitro dissolution and potentially its bioavailability compared to conventional forms.
2021	*A review on orally disintegrating films (ODFs) made from natural polymers such as pullulan, maltodextrin, starch, and others*	International Journal of Biological Macromolecules	Mahendra A. Patil	Emphasized the potential of natural, biodegradable polymers in ODF formulation, noting their biocompatibility and rapid disintegration—offering a greener, patient-friendly alternative.

V. FUTURE PROSPECTS OF FDOFS

Advancements in Oral Drug Delivery:

Shift from conventional tablets/capsules to fast dissolving and rapidly acting films.

Overcomes limitations like low bioavailability, inconvenient injections, and inaccurate dosing of liquids.

Market Growth and Acceptance:

Good user acceptance of over-the-counter (OTC) oral thin films.

Increasing development of prescription drugs in oral thin film format.

Diverse Formulations:

Development of oral dispersible, sublingual, and buccal films.

Hormones and vaccines are also being formulated into oral thin films for improved patient compliance.

Industry Adoption:

Key players: MonoSol Rx, Applied Pharma Research/Labtec GmbH, BioDelivery Sciences, NAL Pharma.

Collaborations for lifecycle management of branded drugs post-patent expiry.

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Regulatory Considerations:

ANDA route for bioequivalent products; new clinical studies required for new dosage forms (505(b)(2) route).

Provides marketing exclusivity of 3 years for new clinical study products.

Preclinical toxicity may not be required if API is previously approved; safety, tolerability, and efficacy must be demonstrated.

Technological Innovations:

Rapid introduction of new technologies for thin film preparation.

Potential for stable market growth and expanded applications in the future.

VI. CONCLUSION

Fast Dissolving Oral Films (FDOFs) represent an innovative and patient-friendly dosage form that offers improved patient compliance and enhanced biopharmaceutical properties compared to conventional oral formulations. They provide superior efficacy and safety, particularly benefiting pediatric and geriatric populations, and are suitable for a wide range of drugs including NSAIDs, antiulcer agents, antihistamines, sedatives, antipsychotics, antiemetics, antimigraine, and antidepressants. With their rapid onset of action, often within a minute, FDOFs are highly desirable for prompt therapeutic effects. Moreover, their development opens avenues for market expansion, product line extensions, and broader clinical applications. Given the increasing patient demand and acceptance, FDOFs are poised to become a widely prescribed and commercially successful oral drug delivery system in the future.

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