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ORAL FAST-DISSOLVING FILMS AS CARRIERS FOR SOLID DISPERSION SYSTEMS: A REVIEW

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ABSTRACT

Fast dissolving oral films (FDOFs) have emerged as an advanced oral drug delivery system aimed at improving patient compliance, rapid onset of action, and bioavailability, particularly for poorly water-soluble drugs. Oral delivery remains the most preferred route due to its convenience and cost-effectiveness; however, limitations such as poor solubility and first-pass metabolism necessitate innovative approaches. FDOFs disintegrate rapidly in the oral cavity without the need for water, allowing pre-gastric absorption through buccal and sublingual mucosa. The incorporation of solid dispersion techniques—such as melting, solvent evaporation, hot melt extrusion, and lyophilization enhances drug solubility, dissolution rate, and uniformity by reducing particle size and crystallinity. Various polymers including HPMC, pullulan, PVA, starch derivatives, and xanthan gum have demonstrated excellent film-forming properties and rapid disintegration. Literature findings confirm that FDOFs exhibit superior physicochemical characteristics, faster drug release, and improved therapeutic efficacy compared to conventional dosage forms, making them a promising alternative for pediatric, geriatric, and dysphagic patients.

KEYWORDS: Fast dissolving oral films; Solid dispersion; Bioavailability; Rapid disintegration; Oral drug delivery.

INTRODUCTION

Since oral drug delivery is simple, convenient, safe, noninvasive, and cost-effective, it remains the most preferred route of administration. Consequently, researchers continue to explore and incorporate advanced technologies into oral formulations, as even minor improvements in drug delivery can significantly enhance patient compliance and bioavailability.[1]

The oral fast dissolving drug delivery system is a unique approach designed to improve patient compliance due to its rapid disintegration and ease of self-administration without the need for swallowing or chewing. Oral drug delivery has evolved from conventional dosage forms to modified-release systems, including orally disintegrating tablets and oral disintegrating films. While most orally disintegrating tablets are fragile and require special packaging for storage and transportation, oral films are more flexible, durable, and easier to handle.[2]

Effective drug delivery within the oral cavity can be achieved through the buccal, sublingual, palatal, and gingival regions. Among these, the buccal and sublingual areas are most commonly utilized and are suitable for the treatment of both local and systemic conditions. The permeability of the oral mucosa is largely influenced by the physical properties of the tissue. Compared to the buccal mucosa, the sublingual mucosa is thinner and more permeable, and due to its large surface area and rich blood supply, it serves as an ideal site for achieving rapid drug absorption and onset of action. Consequently, the sublingual route is frequently employed in the management of acute conditions; however, its application may not be suitable in all cases.[3]

This is due to the fact that the surface is continuously exposed to saliva and tongue movement, making it difficult to maintain prolonged contact between the dosage form and the mucosa. In contrast to the sublingual region, the buccal mucosa provides several advantages owing to its smooth, relatively stationary surface and its suitability for the placement of controlled-release systems, which are well accepted by patients. As a result, the buccal mucosa serves as an effective route for both local and systemic drug delivery, helping to overcome the limitations associated with conventional routes of administration.[3]

Solid dispersion is defined as dispersion of one or more active ingredients (hydrophobic) in an inert carrier (hydrophillic) at solid state prepared by melting (fusion), solvent, melting

solvent method. The product formed contains different components i.e. a hydrophillic matrix and a hydrophobic drug.

CLASSIFICATION OF SOLID DISPERSION

Based on molecular arrangement, solid dispersions are classified into several types

1. **Eutectic mixtures** – Solid eutectic systems are typically prepared by rapidly cooling the molten mixture of two components, resulting in a physical blend of extremely fine crystalline particles of each component.

2. **Solid solutions** – According to the degree of miscibility, solid solutions are further classified as

a. Continuous solid solutions – In these systems, the components are completely miscible in all ratios, indicating that the interaction between different components is stronger than the interactions within the individual components.

b. Discontinuous solid solutions – These systems exhibit limited solubility, where each component can dissolve only to a certain extent in the other.

Based on the spatial distribution of solute molecules within the solvent, solid solutions may be further divided into

a. Substitutional crystalline solid solutions – These are crystalline systems in which solute molecules replace solvent molecules at specific lattice positions.

b. Interstitial crystalline solid solutions – In these systems, the solute molecules occupy the interstitial spaces present between solvent molecules within the crystal lattice.

3. **Amorphous solid solutions** – In amorphous solid solutions, solute molecules are uniformly dispersed at a molecular level within an amorphous carrier but lack a regular crystalline arrangement.

4. **Glass solutions and glass suspensions** – A glass solution is a homogeneous system where the solute is dissolved in a glassy solvent. The glassy state is defined by its transparency and brittle nature below the glass transition temperature. The term “glass” refers to a pure substance or a combination of substances existing in a non-crystalline, glassy state.[4]

Fast-dissolving oral thin films are solid dosage forms that rapidly disintegrate or dissolve within one minute when placed in the oral cavity, without the need for water or chewing.

Upon disintegration in the mouth, the drug may exhibit enhanced therapeutic efficacy due to pre-gastric absorption through the oral cavity, pharynx, and esophagus as saliva carries the drug toward the stomach. As a result, drug bioavailability is often significantly higher compared to that achieved with conventional tablet formulations. Fast-dissolving films are generally preferred over adhesive tablets because of their greater flexibility and improved patient comfort. Furthermore, they overcome the limitation of oral gels, which have a short residence time on the mucosa and are easily washed away by saliva.[5]

Advantages of FDF

- Easy to administer to pediatric, geriatric, bedridden, and psychiatric patients, particularly those who are unwilling or unable to swallow conventional tablets.
- Does not require water for administration, making it highly convenient for patients during travel or in situations where water is not readily available.
- Provides rapid dissolution and drug absorption, leading to a faster onset of therapeutic action.
- Certain drugs can be absorbed through the oral cavity, pharynx, and esophagus as saliva moves toward the stomach, thereby improving drug bioavailability.
- Pleasant mouth-feel helps in masking the bitterness of drugs and improves patient acceptance, especially in pediatric patients.
- Eliminates the risk of choking or suffocation associated with conventional solid dosage forms, thereby enhancing patient safety.
- Particularly useful in conditions requiring rapid onset of action, such as motion sickness, acute allergic reactions, coughing, bronchitis, or asthma.[6]

Disadvantages of FDF

- Drugs that are unstable at buccal pH are unsuitable for administration through this route.
- Medications that cause irritation to the oral mucosa cannot be delivered using this method.
- Only drugs requiring a low dose are appropriate for administration via this system.
- Taste masking is essential, as most drugs possess a bitter taste that can affect patient acceptability.
- Oral fast dissolving films are delicate and highly sensitive to moisture; therefore, specialized protective packaging is required.

Preparation of solid dispersions

1. **Melting method (fusion method).**

Drug + Polymer
↓
Mixing
↓
Heating at 70 °C (Fusion)
↓
Homogeneous Melt
↓
Rapid Solidification
↓
Desiccation
↓
Crushing and Sieving (0.63 mm)
↓
Solid Dispersion[7]

2. **solvent evaporation method.**

Drug + Polymer
↓
Dissolution in Ethanol (10 mL)
↓
Heating on Water Bath (40–45 °C)
↓
Solvent Evaporation with Stirring
↓
Solid Mass Formation
↓
Pulverization
↓
Sieving (No. 80)
↓
Free-Flowing Solid Dispersion
↓
Storage in Desiccator.[8]

3. **Melt Extrusion Method**

Drug + Carrier
↓
Premixing
↓
Feeding into Corotating Twin-Screw Extruder
↓
High-Speed Rotation at Melting Temperature
↓
Simultaneous Melting and Homogenization
↓

Extrusion
↓
Shaping (Tablets / Granules / Pellets / Sheets / Sticks / Powder).[9]

4. Lyophilization (freeze drying).

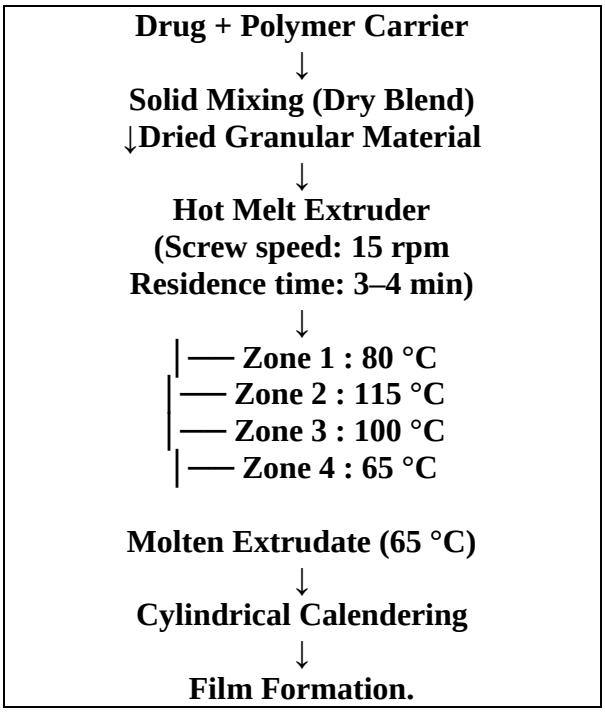
Drug + Polymer/Excipient (accurately weighed)
↓
Dissolution in suitable solvent (usually water)
↓
Filling into trays / vials
↓
Freezing of solution at low temperature (–40 to –80 °C)
↓
Primary drying (sublimation under high vacuum)
↓
Removal of ice as water vapor
↓
Secondary drying (desorption of bound moisture)
↓
Formation of dry, porous lyophilized product then Sealing and storage.[9]

Preperation of Fast dissolving oral film[10]

1. Solvent Casting Method

Dissolution of polymer in suitable solvent (water / hydro-alcoholic / organic) with continuous stirring
↓
Addition of plasticizer and mixing
↓
Drug dissolution or dispersion in the polymeric solution
Addition of other excipients
↓
kept aside to remove air bubbles
Casting of the solution on a leveled glass plate / Petri dish Drying at room temperature or controlled oven temperature
↓
Peeling of dried film
↓
Cutting into desired size and packaging.

2. Hot Melt Extrusion



3. Semisolid casting

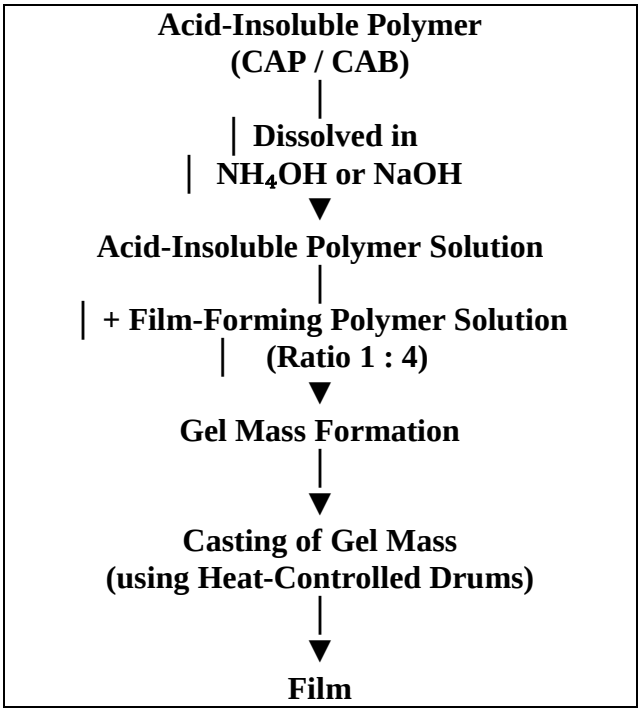


Table 01: Classification of polymer Used in Fast Dissolving Oral Films.[12]

Based on source	
1. Synthetic polymer	Cellulose derivatives, Poly (acrylic acid) polymers, Poly (hydroxyethyl methyl acrylate), Poly (ethylene oxide), Poly (vinyl alcohol), Poly (vinylpyrrolidone), Thiolated polymer, Polyurethanes.
2.Natural polymer	Tragacanth, Sodium alginate, Agarose, Guar gum, Xanthan gum,

	Karaya gum, carrageenan, Chitosan, Soluble starch, Pectin, Gelatin.
Based on solubility	
1.Water-soluble polymer	Hydroxy Ethyl Cellulose, Hydroxy Propyl Cellulose, PAA, Sodium CMC, HPMC, Sodium alginate, Carbopol
2.Water-insoluble polymer	Chitosan, Ethyl cellulose, Polycarbofil.
Based on charge	
1.Cationic	Chitosan, Dimethylamine ethyl-dextran, Amino dextran .
2.Anionic	Chitosan-EDTA, CMC, CP, pectin, PC, PAA, xanthan gum, sodium CMC, alginate.
3.Non-ionic	Hydroxyethyl starch, PVA, PVP HPC, scleroglucan, poly (ethylene oxide).
Based on generation	
1.First generation	Chitosan, dimethyl amino ethyl-dextran, Amino dextran Chitosan-EDTA,CMC, CP, pectin, PC, PAA, sodium, xanthan gum, sodium CMC alginate, Hydroxy ethyl starch, PVA, PVP HPC, Scleroglucan, Poly (ethylene oxide)
2. Second generation	Lectins, Thiolated polymers
Based on potentialbioadhesive forces	
1.Covalent bond	Cyanoacrylate
2.Hydrogen bond	CP, PVA, PC, Acrylates
3.Electrostatic bond	Chitosan

Table 02: Recently reported research work on Fast Dissolving Oral Films.

SL NO	Product Name	Active Ingredient (API)	Manufacturer / Marketed By	Use / Category
1.	Zolmitriptan Rapidfilm	Zolmitriptan	Labtec (Germany)	Migraine relief
2.	Setofilm®	Ondansetron	BioAlliance Pharma (Europe)	Antiemetic
3.	Donepezil Rapidfilm®	Donepezil	Labtec (Europe & US	Alzheimer's
4.	Suboxone® Film	Buprenorphine	Monosol Rx	Opioid dependence
5.	Klonopin Wafers	Clonazepam	Solvay Pharmaceuticals	Antianxiety

Table 03: Physicochemical Characteristics of Fast Dissolving Oral Films.

SL. NO	Parameter	Description
1.	Thickness	Uniform thickness (usually 50–150 µm) ensures dose accuracy and reproducibility.
2.	Weight variation	Indicates uniform distribution of drug and excipients throughout the film.
3.	Surface pH	Should be close to salivary pH (≈ 6.5–7.0) to avoid oral mucosal irritation.
4.	Drug content uniformity	Ensures each film contains the intended dose; typically 85–115% of label claim.
5	Moisture content	Low moisture content is essential to prevent microbial growth and maintain stability.
6	Disintegration time	Typically less than 30 seconds; ctical for fast dissolving

		behavior.
7	In-vitro dissolution time	Rapid drug release, usually within 1–5 minutes.
8	Folding endurance	Indicates flexibility and mechanical strength; higher values suggest better film integrity.

Table 04: Summary of Published Fast Dissolving Oral Films Formulation Studies.[11-29]

Sl No	Author	excipients	Method	Observation
1	Sabar et al ., (2013)	PVP Sodium CMC Citricacid HPMC SodiumSaccharin PEG6000 Glycerin, Dichloromethane Ethanol Hydrochloric acid	solvent evaporation	✓ Higher drug-to-polymer ratios and PEG6000 showing better performance than PVP ✓ drug release decreased with increasing polymer concentration and increased with higher plasticizer content
2	Kamala et al.,(2025)	Hydroxylpropyl methyl starch 1500 Xanthan Gum	Solvent casting method	✓ Nine formulations were evaluated and found to possess acceptable thickness, mechanical strength, uniformity, and rapid disintegration (26–60 s) ✓ films containing 40 mg starch 1500 were reported to exhibit a superior dissolution profile and good stability
3.	Budarapu et al.,(2024)	PEG4000 Pullulan PVA	Solvent casting method	✓ Sertraline hydrochloride fast-dissolving films with pullulan showed rapid disintegration, quick wetting, and high drug release, indicating improved solubility. ✓ XRD and in-vivo studies confirmed reduced crystallinity, higher Cmax, lower Tmax, and faster onset compared to marketed tablets.
4.	Fatima et al.,(2022)	HPMC Sodiumsaccharin Propylene Glycol Croscarmillosesodium Methanol	Solvent casting method	✓ Rapid disintegration was observed for all formulations (within 60 seconds), with propylene glycol enhancing faster disintegration. ✓ The optimized formulation showed rapid and almost complete drug release (~99.5% within 30 minutes)
5.	Kanna et al., (2023)	Propyleneglycol, HPMC, Sodiumstarchglycolate, Aspartame,	Solvent casting method	✓ Optimized rivaroxaban oral thin film showed very rapid disintegration (~33 s) with fast drug release (~93.5% within 60 s), indicating quick onset of action ✓ Drug–excipient compatibility and uniform drug content confirmed a stable, effective, and patient-friendly fast-acting oral delivery system.

6.	Yadav et al.,(2020)	HPMC PVA Sodiumalginate SLS Glycerol Citricacid Sodium Saccharin Xanthan Gum, Peppermint oil.	Solvent casting method	✓ Fast dissolving films showed rapid disintegration (<30 s) with high drug release (~95% in 90 s), especially with the optimized PVA:sodium alginate(2:1)formulation ✓ Use of water, glycerol, and citric acid improved film flexibility, smoothness, and patient acceptability, confirming suitability for buccal delivery.
7	Ghatiyala et al.,(2024)	HPMC XanthanGum, Polyethyleneglycol, Citricacid, Sacralose, Menthol,	Solvent casting method	✓ The formulation contained Haloperidol with Xanthan gum, polyethylene glycol, Citricacid, Sucralose, Menthol,,showed the fastest disintegration and optimal drug release especially in HPMC-based films. ✓ Stability studies showed good physical and chemical stability at room temperature for 45 days, while films stored at 45–50 °C became brittle.
8	Bhavitha et al.,(2023)	HPMCE3, HPMCE50, Propyleneglycol, CitricAcid, and Aspartame	Solvent evaporation	✓ The 1:4 drug–HPMC E3 solid dispersion showed highest solubility and drug content ✓formulation containing Tadalafil: HPMC E3 SD (1:4), HPMC E50, Propyleneglycol,CitricAcid,Aspartame,Water showing maximum release (99%)
9	Gautam et al.,(2025)	HPMC Sucrose Glycerol PEG400, Citric acid Pineapple	Solvent casting method	✓ Highlighted Fast dissolving oral films are an innovative drug delivery system offering advantages over conventional dosage forms. ✓ They are especially suitable for pediatric, geriatric, and dysphagic patients, improving compliance and reducing choking risk. ✓ FDOFs provide rapid onset of action and can be prepared using various technologies based on formulation needs.
10.	Shashank et al.,(2025)	HPMC PEG400 SSG Croscarmellose sodium	Solvent casting method	✓ reviewed intended to draw attention to these new dosage forms of drugs pertinent to the field of mental health prevention and therapy. ✓ This is a overview about development, evaluation of fast dissolving oral film implementation in mental disorder treatment.
11.	Wankhede et al., (2024)	HPMC PVA Sodiumalginate, SLS Glycerol, Citricacid, Sodium saccharin. Xanthangum, Peppermint Oil	Solvent casting method	✓ Reviewd Fast dissolving oral films provide rapid action with improved bioavailability and high patient compliance, especially in pediatric and geriatric patients ✓ Oral films are a promising and revolutionary drug delivery system due to rapid dissolution and wide therapeutic applicability.

12	Gajshri et al.,(2022)	HPMC PEG 400 sodium starch glycolate croscarmellose sodium	Solvent casting method	✓ These fast dissolving formulations are prepared in such a way that the total time taken by the active pharmaceutical ingredient to disintegrate is very less as compared to other formulations. ✓ This technique allows the drug to dissolve at a much faster rate thus reducing the time for the onset of action
13.	Mehta et al., (2021)	Polyethylene glycol400, Hydroxypropylcellulose HPMCE3, PolyVinyl Alcohol	Solvent casting method	✓ Highlated Fast dissolving tablets and films allow rapid disintegration and onset of action without the need for water, making them suitable for pediatric, geriatric, bedridden, and dysphagic patients. ✓ The present investigation aims to analyze and review rapidly disintegrating dosage forms prepared by methods such s casting, spraying, and extrusion
14	Bhyan et al.,(2013)	HPMC, Propyleneglycol Aspartame Citricacid Pineapple	Solvent casting method	✓ Reviewd Orally fast dissolving films are a novel and patient-friendly drug delivery system offering advantages over conventional dosage forms.. Literature highlights their formulation aspects, preparation methods, and quality control, indicating their growing importance in pharmaceutical research.
15	Hiwse et al.,(2022)	ImipramineHcl, HPMC Glycerol, Mannitol, Citric acid.	Solvent casting method	✓ Imipramine HCl was confirmed by UV spectroscopy, which showed a prominent absorbance maximum (λmax) at 255 nm, matching the reported standard value. ✓ The melting point of the pure drug was found to be 174 °C, indicating its purity. Calibration curves of Imipramine HCl were prepared in distilled water and phosphate buffer (pH 6.8) at 255 nm.
16	Banerjee et al.,(2015)	HPMC Propyleneglycol CMC Saccharin, citric acid pineapple	Solvent casting method	✓ These thin films dissolve rapidly in the oral cavity without water, allowing direct absorption through the buccal or sublingual mucosa and avoiding first-pass metabolism. ✓ The review highlights formulation methods, evaluation parameters, and applications of mouth dissolving films in enhancing bioavailability and therapeutic efficacy.

17	Jain et al.,(2018)	HPMC HPMCE3 PolyVinylAlcohol Polyethylene glycol 400	Solvent casting method	✓ Highlighted Fast dissolving oral films bypass first-pass metabolism, reduce gastric degradation, and enhance oral bioavailability. ✓ The present review summarizes recent advancements and technologies in the design and development of fast dissolving oral films.
18	Singh et al.,(2024)	PolytheneGlycol CMC Aspartame, Citric acid	Solvent casting method	✓ This review provides an overview of the many techniques used for preparing oral films, including the selection of suitable polymers for formulation. ✓ It also discusses the several technologies involved in the process, as well as the assessment criteria used to assess the quality of the films. Finally, the article explores the various uses of oral films.
19	Nautiyal et al.,(2022)	Hydroxyethylcellulose Sodiumalginate Pullulan Polyvinylalcohol, Polyethyleneglycol Mint, Cross povidone,	Solvent casting method	✓ Reviewd the future of fast dissolving buccal films is promising, with ongoing research and development focused on improving formulation techniques, expanding applications, and incorporating novel technologies. ✓ These advancements have the potential to enhance drug delivery efficacy, patient compliance, and personalized therapy, ultimately improving patient outcomes.
20	Bhikshapathi et al., (2014)	HydroxyPropyl Methylcellulose, Vanilla, Aspartame, Propylene glycol PEG-400, Citric acid	Solvent casting method	✓ The optimized formulation (S11) with HPMC E6 showed rapid disintegration (10 s) and 98.23% drug release within 6 minutes with good film properties. ✓ DSC and FTIR studies confirmed drug–excipient compatibility, indicating the formulation's potential for rapid migraine relief.

CONCLUSION

From the reviewed literature, it can be concluded that fast dissolving oral films (FDOFs) represent an effective and patient-friendly drug delivery system for enhancing the solubility, dissolution rate, and bioavailability of poorly water-soluble drugs. The incorporation of solid dispersion techniques, particularly solvent evaporation and solvent casting methods, significantly improves drug dissolution through particle size reduction, enhanced wettability, and reduced crystallinity. Various polymers such as HPMC, pullulan, PVA, starch derivatives, and xanthan gum, along with suitable plasticizers, have demonstrated excellent film-forming ability, rapid disintegration, and uniform drug distribution. Most formulations

showed disintegration within seconds, rapid drug release, acceptable mechanical properties, and good stability. Comparative studies confirmed superior performance of FDOFs over conventional tablets, with faster onset of action and improved patient compliance, especially in pediatric, geriatric, and dysphagic patients. Overall, fast dissolving oral films offer a promising alternative to conventional oral dosage forms with broad pharmaceutical applications and strong future potential.

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