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FAST DISSOLVING ORAL FILMS AS A PATIENT-CENTRIC DRUG DELIVERY SYSTEM: A COMPREHENSIVE REVIEW

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Abstract:

Fast dissolving oral films (FDOFs) have emerged as a novel and patient-friendly drug delivery system designed to overcome the limitations associated with conventional oral dosage forms. These thin polymeric films rapidly disintegrate in the oral cavity without the need for water, providing ease of administration, improved patient compliance, and rapid onset of therapeutic action. FDOFs are particularly beneficial for pediatric, geriatric, and dysphagic patients, as well as in situations requiring immediate drug action. The formulation of fast dissolving films involves the careful selection of film-forming polymers, plasticizers, and taste-masking agents to achieve optimal mechanical strength, rapid disintegration, and acceptable palatability. Various manufacturing techniques, including solvent casting, hot-melt extrusion, and emerging technologies such as 3D printing, have been explored to enhance scalability and product quality. This review highlights the composition, manufacturing methods, evaluation parameters, advantages, applications, and recent research advancements in fast dissolving oral films, emphasizing their growing potential in modern pharmaceutical drug delivery.

Keywords: *Fast dissolving oral films, Oral thin films, Patient compliance, Solvent casting, Rapid drug release, Buccal drug delivery.*

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INTRODUCTION:

Fast dissolving oral films (FDOFs) represent an advanced and patient-centric solid oral drug delivery system designed to rapidly disintegrate or dissolve when placed on the tongue or buccal mucosa, without the requirement of water or mastication (Bala *et al.*, 2013; Mahajan *et al.*, 2011). Upon contact with saliva, the thin polymeric film hydrates quickly, leading to rapid drug release and subsequent absorption through the oral mucosa or gastrointestinal tract. Typically, complete disintegration occurs within a few seconds to one minute, enabling a faster onset of therapeutic action compared to conventional solid dosage forms (Pandya *et al.*, 2013; Joshua *et al.*, 2016).

Over the past two decades, FDOFs have gained significant attention as an effective alternative to tablets, capsules, and liquid formulations, particularly for special patient populations such as pediatric, geriatric, bedridden, and dysphagic individuals who often experience difficulty in swallowing solid oral medications (Salawi, 2022; Paul & Ray, 2023). Additionally, patients suffering from nausea, vomiting, or acute conditions where immediate drug action is required benefit greatly from this dosage form. The discreet nature of oral films, ease of self-administration, and portability further enhance their acceptability and convenience in routine clinical practice (Kanhed *et al.*, 2024; Bala *et al.*, 2013).

The rapid onset of action associated with fast dissolving oral films is primarily attributed to the high surface area of the thin film and the rich vascularization of the oral mucosa, which may facilitate partial or complete absorption of the drug directly into the systemic circulation (Elshafeey & El-Dahmy, 2021; Alkahtani *et al.*, 2021). This mechanism can potentially bypass hepatic first-pass metabolism, resulting in improved bioavailability for drugs susceptible to extensive first-pass effect. Moreover, FDOFs offer uniform dosing accuracy, reduced risk of choking, and improved stability compared to liquid formulations (Latif & Ashfaq, 2019; Mahaparale & Wagh, 2021).

From a formulation perspective, fast dissolving oral films are composed of hydrophilic polymers that provide mechanical strength and rapid hydration, along with plasticizers, sweeteners, flavors, and other excipients to ensure flexibility, palatability, and patient comfort (Bhattacharyya & Rangarao, 2022; Kumar *et al.*, 2024). Due to their thin and elegant design, these films are especially suitable for low-dose, potent drugs requiring rapid therapeutic action. Owing to these advantages, fast dissolving oral films have emerged as a promising platform in modern drug delivery systems and continue to be explored for a wide range of therapeutic applications (Paul & Ray, 2023; Salawi, 2022).

Advantages

One of the primary factors driving the development and widespread acceptance of fast dissolving oral films (FDOFs) is their ability to significantly enhance patient compliance (Bala *et al.*, 2013; Mahajan *et al.*, 2011). Conventional oral dosage forms such as tablets and capsules often present swallowing difficulties, particularly for pediatric, geriatric, and dysphagic patients (Salawi, 2022; Paul & Ray, 2023). In addition, the requirement of water for administration may pose challenges in emergency situations, during travel, or for patients with limited mobility. Fast dissolving oral films effectively overcome these limitations by dissolving rapidly in the saliva when placed in the oral cavity, thereby eliminating the need for water and ensuring convenient administration under diverse conditions (Kanhed *et al.*, 2024; Pandya *et al.*, 2013).

FDOFs also help reduce the psychological barrier commonly associated with “pill swallowing fear,” which is a frequent cause of non-adherence to medication regimens (Joshua *et al.*, 2016; Mahaparale & Wagh, 2021). The thin, flexible, and non-invasive nature of oral films makes them more acceptable to patients, leading to improved adherence and better therapeutic outcomes. Their discreet administration further adds to patient convenience, allowing dosing without drawing attention in public or clinical settings (Paul & Ray, 2023; Bala *et al.*, 2013).

Another significant advantage of fast dissolving oral films is their ability to provide rapid onset of action. The oral cavity is highly vascularized, allowing drugs released from the film to be absorbed directly through the oral mucosa into systemic circulation (Elshafeey & El-Dahmy, 2021; Alkahtani *et al.*, 2021). This absorption pathway can partially or completely bypass first-pass hepatic metabolism, particularly for drugs susceptible to extensive hepatic degradation. As a result, FDOFs may enhance the bioavailability of certain drugs while enabling faster therapeutic effects compared to conventional oral dosage forms (Latif & Ashfaq, 2019; Mahaparale & Wagh, 2021).

Furthermore, the large surface area of the thin film facilitates quick hydration and rapid drug release, contributing to uniform dosing and consistent drug delivery (Bhattacharyya & Rangarao, 2022; Kumar *et al.*, 2024). FDOFs also reduce the risk of choking, which is a critical safety advantage in vulnerable populations. Collectively, these attributes ease of administration, improved patient compliance, rapid absorption, enhanced bioavailability, and faster onset of action position fast dissolving oral films as a highly advantageous and patient-friendly oral drug delivery system (Kanhed *et al.*, 2024; Paul & Ray, 2023).

Composition and Functional Excipients

The successful formulation of fast dissolving oral films (FDOFs) depends on the judicious selection and optimization of both functional and aesthetic excipients, as these components collectively influence film integrity, performance, patient acceptability, and therapeutic efficacy (Kanhed *et al.*, 2024; Paul & Ray, 2023). Each excipient plays a specific and critical role in ensuring rapid disintegration, adequate mechanical strength, uniform drug distribution, and pleasant organoleptic properties (Bala *et al.*, 2013; Salawi, 2022).

Film-forming polymers constitute the primary structural component of fast dissolving films and are responsible for providing the required mechanical strength, flexibility, and rapid hydration characteristics. Commonly used hydrophilic polymers include hydroxypropyl methylcellulose (HPMC), pullulan, polyvinyl alcohol (PVA), sodium alginate, maltodextrin, and hydroxypropyl cellulose (Shah *et al.*, 2024; Kumar *et al.*, 2024). The molecular weight, viscosity grade, and concentration of the polymer significantly affect film thickness, tensile strength, folding endurance, and disintegration time. An ideal polymer should be non-toxic, non-irritant, tasteless, and capable of forming a smooth, uniform film that dissolves rapidly upon contact with saliva (Mahaparale & Wagh, 2021; Paul & Ray, 2023).

Plasticizers are incorporated into the formulation to improve the flexibility and elasticity of the film and to prevent brittleness during handling, packaging, and storage. Common plasticizers such as glycerol, polyethylene glycol (PEG), propylene glycol, and triacetin reduce intermolecular forces between polymer chains, thereby enhancing film softness and folding endurance (Kanhed *et al.*, 2024; Chavan *et al.*, 2023). The type and concentration of plasticizer must be carefully optimized, as excessive amounts may lead to tackiness, prolonged disintegration time, or reduced mechanical strength (Shah *et al.*, 2024).

Sweeteners, flavors, and taste-masking agents are essential aesthetic excipients that significantly influence patient acceptance, particularly in pediatric and geriatric populations. Both natural sweeteners (e.g., sucrose, mannitol, xylitol, and stevia) and artificial sweeteners (e.g., aspartame and sucralose) are commonly employed (Bhattacharyya & Rangarao, 2022; Ramji *et al.*, 2022). Flavoring agents such as peppermint, orange, strawberry, or vanilla help mask the unpleasant taste of the drug, while taste-masking techniques, including the use of ion-exchange resins or complexation, may be employed for bitter APIs (Sajayan *et al.*, 2023; Elshafeey & El-Dahmy, 2021).

The active pharmaceutical ingredient (API) selected for incorporation into fast dissolving films should ideally be potent at low doses, typically less than 30 mg per strip, to ensure uniform drug distribution and acceptable film thickness (Nehete *et al.*, 2023; Latif & Ashfaq, 2019). Additionally, the drug should possess suitable solubility and permeability characteristics to facilitate rapid release and absorption in the oral cavity. Drugs with extensive first-pass metabolism, short half-lives, or a need for rapid onset of action are particularly well suited for this dosage form (Kanhed *et al.*, 2024; Paul & Ray, 2023). Proper compatibility between the API and excipients is also essential to maintain stability and ensure consistent performance of the formulation (Bhattacharyya & Rangarao, 2022; Kumar *et al.*, 2024).

Manufacturing Technologies

Various manufacturing technologies have been developed for the preparation of fast dissolving oral films (FDOFs), each offering distinct advantages and limitations in terms of scalability, cost, formulation flexibility, and product quality. The selection of an appropriate manufacturing method depends on factors such as the physicochemical properties of the drug and excipients, desired film characteristics, and production scale.

The solvent casting method is the most commonly employed and well-established technique for the fabrication of fast dissolving oral films. In this method, film-forming polymers, plasticizers, and other excipients are dissolved or dispersed in a suitable solvent system, typically water or a mixture of water and organic solvents. The active pharmaceutical ingredient is then incorporated into the polymeric solution with continuous stirring to ensure uniform distribution. The resulting homogeneous solution is cast onto a flat surface or mold and dried under controlled temperature and humidity conditions to evaporate the solvent and form a thin, cohesive film. This method offers advantages such as simplicity, low processing temperatures, excellent content uniformity, and smooth film appearance. However, limitations include long drying times, potential residual solvent issues, and challenges in large-scale manufacturing.

Hot-melt extrusion (HME) is an alternative solvent-free technique that involves melting the polymer and blending it with the drug and other excipients under controlled temperature and shear conditions. The molten mass is then extruded through a die to form films of uniform thickness. This method eliminates the need for solvents, thereby reducing drying time and solvent-related safety concerns. Hot-melt extrusion is suitable for continuous manufacturing and offers good content uniformity; however, its application is limited to drugs and excipients that are thermally stable, as high processing temperatures may degrade heat-sensitive compounds.

The semisolid casting method involves the preparation of a viscous gel or semisolid mass by dissolving water-soluble polymers in an aqueous solution, followed by the incorporation of plasticizers and other excipients. The semisolid mass is then cast onto a suitable substrate and dried to obtain films. This method is particularly useful when acid-insoluble polymers are used in combination with water-soluble polymers. Although semisolid casting allows better control over film thickness and uniformity, it may involve more complex processing steps and longer drying times.

Recent advancements have introduced three-dimensional (3D) printing technology as a novel approach for the fabrication of fast dissolving oral films. This technique enables precise control over film dimensions, drug loading, and spatial distribution of the active ingredient, facilitating personalized and on-demand drug delivery. 3D printing also allows the incorporation of multiple drugs or layered structures within a single film. Despite its promising potential, the technology faces challenges related to limited excipient availability, high equipment costs, and regulatory considerations.

Applications and Therapeutic Potential (Elaborated)

Fast dissolving oral films (FDOFs) have demonstrated wide-ranging applications across multiple therapeutic categories due to their rapid disintegration, ease of administration, and ability to provide fast onset of action. These attributes make them particularly suitable for drugs that require immediate therapeutic effect or improved patient compliance. Consequently, FDOFs have been extensively explored for the delivery of analgesics, antiemetics, antihistamines, cardiovascular agents, and central nervous system (CNS) drugs**,** among others.

In the management of acute conditions such as pain, nausea, vomiting, and allergic reactions, fast dissolving oral films offer a significant advantage by enabling rapid drug release and absorption in the oral cavity. Analgesic agents such as nonsteroidal anti-inflammatory drugs (NSAIDs) and centrally acting analgesics formulated as oral films provide prompt pain relief, while antiemetic films are especially beneficial for patients experiencing nausea or vomiting, where swallowing conventional tablets may be difficult. Similarly, antihistamine-loaded films are effective in the rapid management of allergic symptoms, offering quick relief and improved convenience.

FDOFs have also shown promise in the delivery of cardiovascular and CNS drugs, where rapid onset of action and enhanced bioavailability are often desirable. Drugs used in conditions such as angina, hypertension, anxiety, and migraine can benefit from sublingual or buccal absorption, which may partially bypass first-pass hepatic metabolism and result in faster therapeutic effects. In CNS disorders, fast dissolving films facilitate easy dosing and improved adherence, particularly in elderly patients or those with neurological impairments.

In addition to systemic drug delivery, fast dissolving oral films can be formulated for local therapeutic action within the oral cavity. Such films are useful in the treatment of oral mucosal infections, aphthous ulcers, inflammation, and pain. By incorporating mucoadhesive polymers, the films can be retained at the site of action for prolonged periods, enhancing local drug concentration and therapeutic efficacy while minimizing systemic exposure.

The versatility of fast dissolving oral films also allows for the development of multifunctional and advanced formulations. These include films with integrated taste-masking strategies, controlled or modified drug release characteristics, and multilayered structures capable of delivering multiple drugs simultaneously. Furthermore, the incorporation of mucoadhesive polymers and permeability enhancers can prolong residence time and improve drug absorption. Such formulation flexibility highlights the potential of FDOFs as a promising platform for both conventional and innovative drug delivery applications, supporting their expanding role in modern pharmaceutical therapy.

Table 1: Literature survey on fast dissolving oral film formulations and their key outcomes

S. No.	Author (Year)	Drug / System Studied	Polymer(s) / Key Materials	Method	Major Findings
1	Kanhed et al. (2024)	Oral fast dissolving films (Review)	Various hydrophilic polymers	Review	OFDFs rapidly dissolve without water, enhance patient compliance, and allow fast absorption via buccal mucosa
2	Atneriya et al. (2024)	Furosemide	Pullulan, glycerol, Lepidium sativum mucilage	Solvent casting	Optimized batch showed 98.75% drug release in 8 min; disintegration time 23 sec
3	Kumar et al. (2024)	Lornoxicam	HPMC	Solvent casting	Films showed rapid disintegration (10–42 s), good tensile strength, and enhanced dissolution
4	Paul & Ray (2023)	OFDFs (Review)	Water-soluble polymers	Review	Classification, formulation strategy, and future potential of OFDFs discussed
5	Nadendla et al. (2023)	Rivaroxaban	Superdisintegrants	Solvent casting + 2^2 factorial design	Optimized film showed 93.47% drug release in 60 s, first-order kinetics
6	Chavan et al. (2023)	Captopril	Pectin, PEG 400	Solvent casting	Optimized batch showed complete drug release within 6 min
7	Sajayan et al. (2023)	Mefenamic acid	β-Cyclodextrin, crospovidone	Solvent casting	Optimized film released 97.41% drug in 180 s with good stability
8	Nehete et al. (2023)	Risperidone	HPMC K4M, PEG 400	Solvent casting	Optimized batch showed 95.11% drug release in 10 min
9	Gharat et al. (2023)	Rizatriptan benzoate	HPMC, plasticizer	Box–Behnken design	Optimized film showed 99.58% drug release and 9 s disintegration time
10	Sudhir et al. (2022)	Hydralazine HCl	HPMC E3/E15, PVP	Solvent casting	Improved dissolution and rapid onset of action
11	Agrawal et al. (2022)	Telmisartan	HPMC E15, SSG	Factorial design	Optimized film showed 91.83% drug release and 29 s disintegration
12	Salawi (2022)	ODFs (Review)	Hydrophilic polymers	Review	Highlighted advantages in pediatric and geriatric therapy

13	Bhattacharyya & Rangarao (2022)	Fexofenadine HCl	Pullulan, HPMC	Solvent casting	Pullulan films showed better flexibility and dissolution
14	Ramji et al. (2022)	Rizatriptan benzoate	Film-forming polymers	Solvent casting	Optimized film showed higher dissolution than marketed product
15	Elshafeey & El-Dahmy (2021)	Paroxetine nanosuspension	OFDF matrix	Factorial design	Optimized film showed 96.02% drug release and enhanced permeation
16	Alkahtani et al. (2021)	Quetiapine + Escitalopram	Electrospun fibers	Coaxial electrospinning	Films disintegrated in 2 s with rapid drug release
17	Bhatt et al. (2021)	Frovatriptan	HPMC E3/E15	Solvent casting	Taste masking and rapid disintegration achieved
18	Mahaparale & Wagh (2021)	Glycopyrrolate	Pullulan, PEG 400	CCD optimization	Optimized film disintegrated in 14 s with 85.6% release
19	Puttaswamy (2020)	Ramipril	β-Cyclodextrin, HPMC	Solvent casting	Optimized film disintegrated in 9 s with 99.98% drug content
20	Latif & Ashfaq (2019)	Alprazolam	HPMC-based films	Solvent casting	Optimized film released 106.6% drug in <2 min
21	Solanki et al. (2019)	Olanzapine	HPMC	Solvent casting	98.78% drug release within 15 min
22	Wadetwar et al. (2019)	Paroxetine HCl	Pullulan	Solvent casting	Optimized film showed >92% permeation
23	Bala et al. (2013)	Fast dissolving films (Review)	Hydrophilic polymers	Review	Highlighted advantages over MDTs and commercial viability
24	Panchal et al. (2012)	Ropinirole HCl	Pullulan, PEG 400	Factorial design	Optimized film showed 99.48% drug release in 60 s
25	Mahajan et al. (2011)	Buccal films (Review)	Various polymers	Review	FDDFs improve bioavailability and patient compliance

Future Trends

Recent research trends highlight the integration of novel technologies like 3D printing for personalized film fabrication, and development of multilayered films that can tailor release profiles. Advances in excipient science are also expanding the repertoire of polymers and functional agents that improve film performance, taste masking, and stability. As regulatory frameworks evolve and manufacturing technologies mature, FDOFs are expected to occupy an increasingly significant niche in modern drug delivery, particularly for patient-centric therapeutics.

CONCLUSION:

Fast dissolving oral films offer a convenient, patient-friendly alternative to conventional oral dosage forms by rapidly dissolving in the oral cavity without the need for water. Their ability to provide quick onset of action, improved patient compliance, and potential enhancement of bioavailability makes them suitable for a wide range of therapeutic applications. With continued advancements in formulation strategies and manufacturing technologies, fast dissolving oral films are expected to gain greater importance in modern drug delivery systems.

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