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Oral Fast-Dissolving Films: Innovations in Formulation, Characterization, and Emerging Drug Delivery Strategies

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ABSTRACT

Fast-dissolving films (FDFs), also called as oral thin films or Oro dispersible films, are a new way to deliver drug that breaks down quickly in the mouth without the need for water. These thin strips of polymer make it easier for patient to take their medicine, especially for children, older adults, and patient with dysphagic who have trouble swallowing regular tablets and capsules. Fast-dissolving films have many benefits, such as quick action, easy administration, precise dosing, and better bioavailability because they can be absorbed through the mouth and under the tongue. Fast-dissolving films attracted considered interest in pharmaceutical research and development because of their distinct benefits and patient-friendly attributes. This review emphasizes the formulation constituents, preparation techniques, and assessment.

Keywords: Fast dissolving films, oral thin films, film forming polymers, Sublingual drug delivery, Solvent casting method, Bioavailability enhancement, Patient-friendly dosage forms.

1. INTRODUCTION:

Fast-dissolving films (FDFs), also called as oral thin films or Oro dispersible films, are a novel drug-delivery system that breaks down quickly and dissolve in the mouth without requiring water. These dosage forms are typically thin, flexible polymeric strips that release the active pharmaceutical ingredient (API) when placed on the tongue or buccal mucosa (1). The development of FDFs has gained significant attention in the pharmaceutical industry because they improve patient compliance, especially among pediatric, geriatric, and dysphagic patients who experience difficulty swallowing conventional tablets or capsules (2). The concept of oral thin films originated from the confectionery industry and was later adapted for pharmaceutical applications. After administration, the films rapidly hydrate with saliva, leading to disintegration and dissolution within a second. The drug can be absorbed either through the oral mucosa for rapid systemic action or swallowed with saliva for gastrointestinal absorption. Due to this rapid disintegration property, FDFs provide a faster onset of action compared to many conventional oral dosage forms (3,4).

2. ADVANTAGES OF FDFS (5)

- No need for water during administration.
- Rapid onset of action due to fast disintegration.
- Improved patient compliance for pediatric and geriatric patients.
- Avoidance of first-pass metabolism in some drugs through buccal absorption.
- Convenient and portable dosage form.
- Accurate dosing compared with syrups.
- Reduced risk of choking compared with tablets.
- Good stability and flexibility when appropriate polymers are used.

3. Disadvantages of FDFs

- FDFs show limited drug loading capacity (generally < 30 – 40mg).
- Moisture sensitivity, requiring protective packaging.
- Taste masking is required for bitter drugs.
- Mechanical strength issues if polymer concentration is not optimized.
- Specialized manufacturing equipment may be required.
- Higher cost compared with conventional tablets.

4. Composition of fast dissolving films:

Oral fast-dissolving films are composed of several excipients that help in film formation, drug release, stability, and palatability. The typical formulation contains a drug, film-forming polymers, plasticizer, saliva-stimulating agents, sweeteners, flavors, and other additives (6,7).

4.1. Active Pharmaceutical Ingredient (API):

The drug is the therapeutic agent incorporated into the film. For fast-dissolving films, the drug should preferably have a low dose (generally ≤ 30mg), good solubility, and rapid absorption in the oral cavity. Typical concentration is about 1-25% of the film's weight (8). For example: Ondansetron, Rizatriptan, Sumatriptan.

Table 1. General Composition of FDFs

Ingredients	Concentration (%)
Active Pharmaceutical Ingredient	1-25
Polymer	40-50
Plasticizer	0-20
Colors, Flavor, Fillers	0-40

4.2. Film- Forming Polymers:

Film-forming polymers are natural, synthetic, or semi-synthetic macromolecules that can produce a thin, continuous, and flexible film when processed through solvent evaporation or heat-based techniques. These polymers serve as the primary framework in film-based drug delivery systems such as oral thin films, buccal films, and transdermal patches (7). They have the capacity to form a cohesive and uniform matrix, within which active pharmaceutical ingredients (APIs) and excipients are incorporated, ensuring appropriate mechanical integrity, flexibility, and drug release behavior. For Example: Hydroxypropyl Methylcellulose (HPMC), Pullulan, Maltodextrin.

4.3. Plasticizers:

Plasticizers are low molecular weight substances added to polymer formulations to improve flexibility, reduce brittleness, and enhance film-forming properties. They function by inserting themselves between polymer chains, thereby reducing intermolecular forces such as hydrogen bonding and van der Waals interactions. This results in increased polymer chain mobility, making the film softer, more pliable, and easier to handle without cracking or breaking. For Example: Glycerol, Propylene Glycol, Polyethylene Glycol 400, and Triethyl Citrate.

4.4. Sweetening Agent:

Sweetening agents are substances incorporated into pharmaceutical formulations to impart sweetness and improve palatability, particularly in dosage forms such as oral thin films, syrups, and chewable tablets. They play a crucial role in masking the unpleasant taste of active pharmaceutical ingredients (APIs), thereby enhancing patient compliance, especially in pediatric and geriatric populations. For example: Sucralose, Saccharine Sodium, Aspartame, and Mannitol.

4.5. Saliva-Stimulating Agents:

Saliva-stimulating agents are excipients incorporated into oral pharmaceutical formulations to enhance the production of saliva in the oral cavity. They play an important role in facilitating the rapid disintegration and dissolution of dosage forms such as oral thin films, buccal tablets, and lozenges. These agents typically act by activating salivary glands through gustatory (taste) stimulation, particularly via acidic or tangy substances, which in turn improves the wetting, breakdown, and drug release from the formulation (2). For Example: Citric acid, malic acid, Tartaric acid.

4.6. Surfactant:

Surfactants (surface-active agents) are substances that reduce the surface and interfacial tension between two phases, such as liquid–liquid, solid–liquid, or liquid–air systems. In pharmaceutical formulations, they are used to enhance wetting, solubilization, and dispersion of active pharmaceutical ingredients (APIs), thereby improving drug dissolution and bioavailability. They possess both hydrophilic (water-attracting) and hydrophobic (water-repelling) regions, enabling them to accumulate at interfaces and form structures like micelles that facilitate drug incorporation. For Example: Polysorbate 80, Sodium Lauryl Sulfate, and Poloxamer 407.

4.7. Flavoring Agents:

Flavoring agents are substances added to pharmaceutical formulations to impart a pleasant taste and aroma, thereby improving the overall acceptability of the dosage form. They are especially important in formulations such as oral thin films, syrups, chewable tablets, and lozenges, where the drug comes in direct contact with taste buds. These agents help in masking unpleasant tastes and odors of active pharmaceutical ingredients (APIs) and work synergistically with sweeteners to enhance patient compliance, particularly in pediatric and geriatric populations. For Example: Peppermint oil, orange oil, lemon flavor, and chocolate flavor.

4.8. Coloring Agents:

Coloring agents are substances added to pharmaceutical formulations to impart color and enhance the visual appearance of dosage forms. They play an important role in improving patient acceptability, product identification, and aesthetic appeal, especially in formulations such as oral thin films, tablets, capsules, and syrups. In addition to aesthetics, coloring agents help in distinguishing between different formulations or strengths, thereby reducing the risk of medication errors. For example: Titanium dioxide, Food-grade colorants.

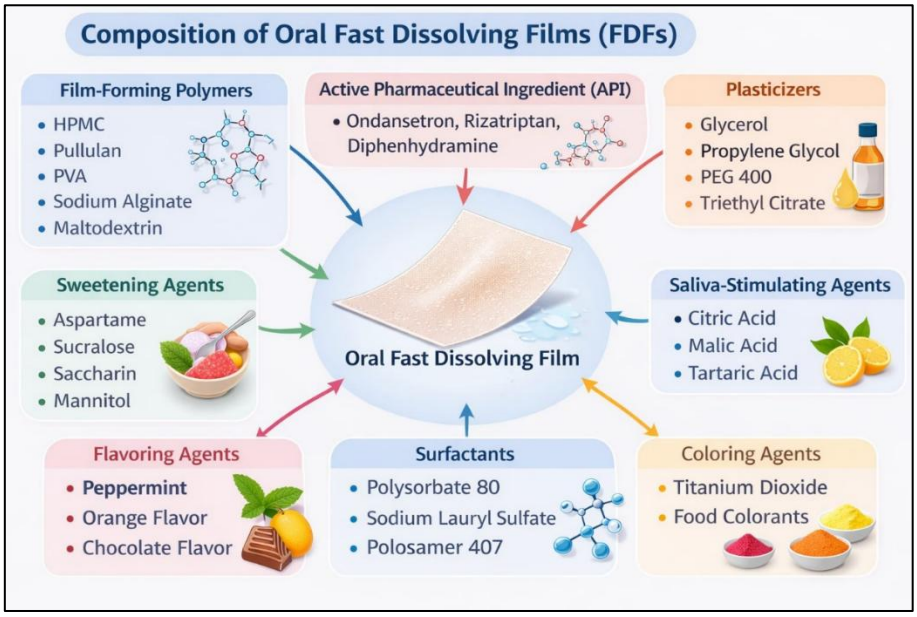

Fig 1. Composition of oral fast-dissolving films

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5. Mechanism of drug release:

Fast-dissolving films (FDFs) are thin polymeric strips composed of hydrophilic film- forming polymers that rapidly disintegrate in saliva when placed on the tongue. Drug release occurs via hydration, swelling, disintegration, and dissolution of the polymeric matrix (9). When the films come into contact with saliva, water molecules penetrate the polymer network, causing the films to swell and disintegrate. This leads to rapid dissolution of the drug, which may then be absorbed through the oral mucosa (sublingual or buccal route) or swallowed and absorbed through the gastrointestinal tract (10).

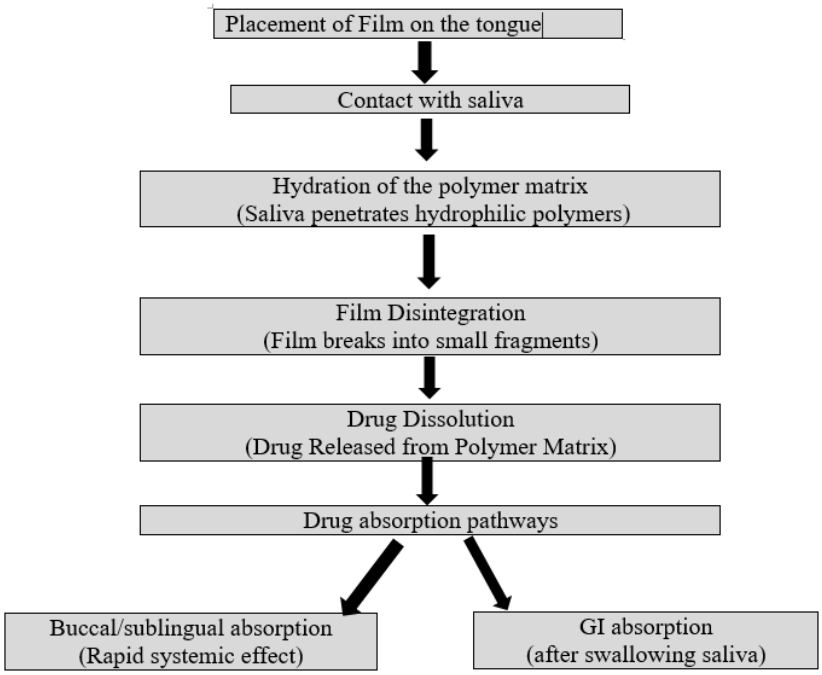

Fig 2. Flow diagram of the mechanism of drug release

6. Method of preparation of FDFs (11):

The following methods are used for the preparation of mouth-dissolving films.

- Solvent Casting Method
- Hot Melt Extrusion Method
- Semi-Solid Casting Method
- Solid Dispersion Method
- Rolling Method

6.1. Solvent casting method:

In this method, the polymer is dissolved in water or other organic solvents. To this, plasticizer, sweetener, and other excipients are mixed properly. Then dissolve the drug in the polymer solution. Pour or cast the solution onto a glass plate or petri dish. The solvent is evaporated under controlled conditions. After drying the films, cut them into the desired size (12).

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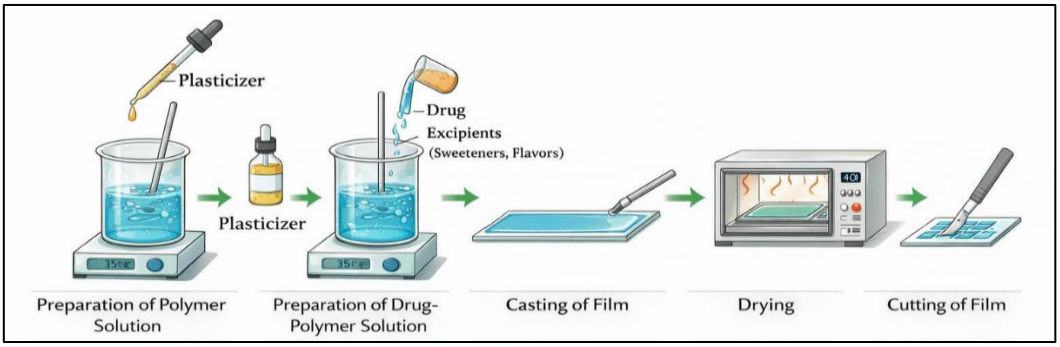

Fig 3. Solvent Casting Method for Films

6.2. Hot melt extrusion method:

Both the drug and the polymer are mixed and heated. After a continuous stirring pass, the mixture is passed through an extruder under pressure. The molten mass is extruded through flat dies, and films are cooled and cut into the desired size (13).

6.3. Semi- solid casting method:

A water-soluble polymer, such as HPMC, is dissolved in distilled water to form a viscous solution. To prepare an acid-insoluble polymer solution polymer like cellulose acetate phthalate is dissolved in an organic solvent such as ethanol (14). These two polymer solutions are mixed under continuous stirring to form a homogeneous solution. Plasticizers are added to improve flexibility, and the drug, along with other excipients (sweeteners, flavoring agents), is incorporated.

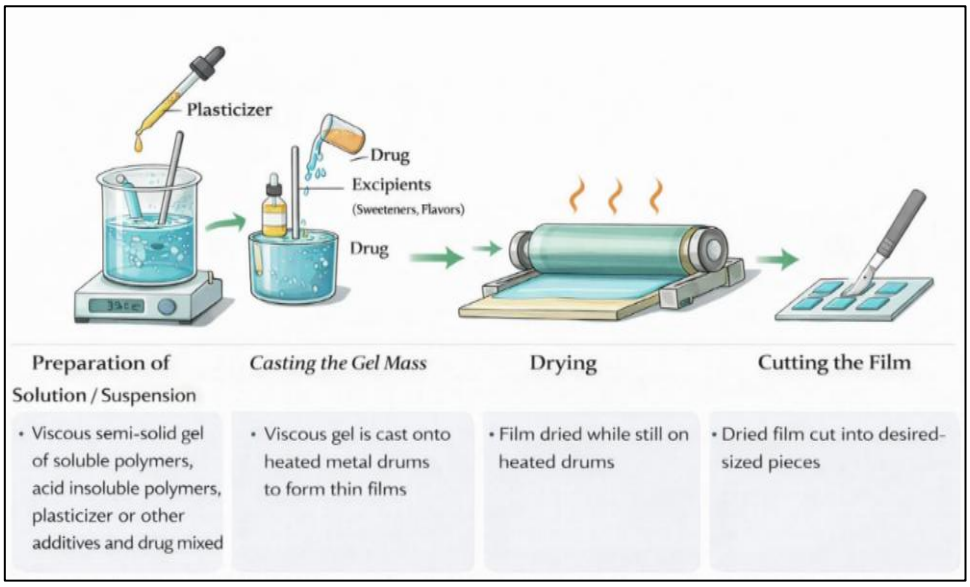

Fig 4. Semi-Solid Casting Method for Films

The mixture becomes a semi- solid gel mass due to increased viscosity. The gel mass is spread uniformly on glass plates or casting trays using a calibrated applicator. The cast film is dried in an oven or drying chamber at a controlled temperature. The dried film is peeled off and cut into uniform strips containing the required drug dose.

6.4. Solid dispersion extrusion:

The term solid dispersion refers to the dispersion of one or more active ingredients in an inert carrier in a solid state in the presence of an amorphous hydrophilic polymer. The is dissolved in a suitable liquid solvent. The solvent is mixed with the polymer to form a solid dispersion below 70°C. The solid dispersion is dried and extruded to form thin films (14).

6.5. Rolling method:

The suspension containing the drug solution is prepared. The solution is rolled onto the carrier surface at a particular temperature the solvents evaporate to form a film. After the films are dried it cut into the required size (15).

7. Evaluation parameters:

Evaluation tests are carried out to ensure the quality, uniformity, and performance of the films.

7.1. Thickness:

The thickness of the films is measured using a micrometer screw gauge or digital caliper at different locations of the films (at least 5 locations). This test is essential to evaluate the uniformity of the films, which is directly related to the accuracy of the dose in the film (14).

7.2. Weight variation:

Weight variation is measured using individual films by randomly selecting 10 films. The average weight of the films should not differ significantly from the average weight.

7.3. Tensile strength:

Tensile strength is used to evaluate the strength and durability of the fast-dissolving films (FDFs). It indicates the maximum stress applied to the point until the film can withstand before breaking when a force is applied (16).

$$Tensile\ Strength = \frac{Force\ at\ Break}{Film\ Thickness \times Film\ Width} \quad (N / mm^2\ or\ MPa)$$

7.4. Folding endurance:

It is used to measure the film's flexibility and mechanical strength of film by repeatedly folding the strips at the same place till the strip breaks. The number of times the strips are folded without breaking is considered folding endurance. Typically, the strips showing > 200 folds indicate good flexibility (17).

7.5. Disintegration time:

Disintegration time is the time required for films to completely break down in saliva. The film was placed in 10-20 ml simulated saliva at pH 6.8, and the time of complete disintegration was recorded. The standard disintegration time for oral film is 5-60 seconds (18).

7.6 DISSOLUTION STUDY:

The dissolution study is carried out using the USP dissolution apparatuses I (basket) and II (paddle). The dissolution medium used for films is phosphate buffer, pH 6.8, at a temperature of 37± 0.5°C, at a rotation of 50-75 rpm. The samples are taken and analysed spectrophotometrically. (19).

8. Packaging of fast dissolving films:

Packaging plays a critical role in maintaining the stability, integrity, and moisture protection of oral fast-dissolving films. Because these films are thin, fragile, and highly sensitive to humidity, a suitable packaging system is necessary to prevent mechanical damage and degradation (6).

8.1. Unit Dose Packaging:

Unit-Dose Packaging is the most commonly used packaging system for oral films. Each film strip is individually packed in a protective pouch to prevent contamination and exposure to moisture.

The common materials used for unit-dose packaging are aluminum foil laminates and polyester-aluminum-polyethylene laminate pouches. For example: Individual sachets used for products like ondansetron oral films.

8.2. Multi-Unit Packaging:

In multi-unit packaging, several films are packaged together in a single container, such as a blister pack or dispenser. There are 3 types of packing in multi-unit packaging: they are

- Blister packs
- Plastic dispensers
- Strip packs

8.2.1. Blister Packaging:

Blister packaging is widely used in pharmaceutical products to provide mechanical protection and moisture resistance. Materials used in blister packaging are aluminum-aluminum blister packs and PVC/Aluminum blister packs (20,21).

8.2.2. Foil-Foil Laminated Pouches:

Foil laminate pouches are highly effective because aluminum layers act as excellent barriers against moisture, oxygen, and light. These pouches ensure long-term stability of the oral films.

8.2.3. Automatic Film Packaging System:

Modern manufacturing uses automated packaging machines that cut and pack films simultaneously. This process ensures high precision and industrial scalability.

There are some typical steps included in automatic film packaging, such as Film cutting, placement into the packaging cavity, Heat sealing, and labeling (22,23).

9. Marketed films:

Table 2. Marketed oral fast-dissolving films

Product Name	Drug Used	Therapeutic use
Zuplenz	Ondansetron	Prevention of chemotherapy-induced nausea and vomiting
Setofilm	Ondansetron	Antiemetic for nausea and vomiting
Suboxone	Buprenorphine+ Naloxone	Treatment of opioid dependence
Onsolis	Fentanyl	Breakthrough cancer pain
Belbuca	Buprenorphine	Severe chronic pain
Sympazan	Clobazam	Treatment of seizures
Zentrip	Meclizine Hydrochloride	Motion sickness
Vinix ODF	Sildenafil	Erectile dysfunction
Zolmitriptan Rapid film	Zolmitriptan	Migraine treatment
Donepezil Rapid film	Donepezil	Alzheimer's disease

10. CONCLUSION:

Fast-dissolving films (FDFs) represent an innovative and patient-friendly drug delivery system that has gained significant importance in modern pharmaceutical research. These thin polymeric films rapidly disintegrate in the oral cavity when they come into contact with saliva, releasing the drug without the need for water. This unique characteristic makes them highly suitable for pediatric, geriatric, bedridden, and dysphagic patients who experience difficulty swallowing conventional dosage forms such as tablets and capsules. Although fast-dissolving films offer several advantages, such as rapid onset of action, ease of administration, and improved bioavailability, certain limitations, like low drug loading capacity and moisture sensitivity, still exist. However, continuous research in polymer science, formulation technology, and packaging systems is expected to overcome these challenges. Overall, fast-dissolving films represent a versatile and patient-friendly drug delivery platform with significant potential for future pharmaceutical development and commercialization.

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