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Oral mouth dissolving films

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Abstract
Oral Mouth Dissolving Films (OMDFs) represent an innovative drug delivery system designed for rapid disintegration and absorption in the oral cavity without the need for water. These thin, flexible strips improve patient compliance, particularly in paediatric, geriatric, and dysphagic populations. OMDFs offer advantages such as fast onset of action, bypassing of first-pass metabolism, accurate dosing, ease of transport, and enhanced bioavailability. They are formulated using hydrophilic polymers, plasticizers, and taste-masking agents, and are manufactured through techniques like solvent casting or hot-melt extrusion. OMDFs are widely used for systemic and local drug delivery and are gaining popularity due to their convenience, cost-effectiveness, and versatility. With growing market demand and ongoing research, OMDFs are poised to become a preferred alternative to traditional oral dosage form[1]

Keywords: Oral mouth dissolving films, rapid disintegration, patient compliance, hydrophilic polymers, solvent casting

Introduction
The oral route is the most preferred for drug administration due to its ease, non-invasiveness, and patient compliance. To address challenges in pediatrics, geriatrics, and patients with swallowing difficulties, novel drug delivery systems have been developed. Among them, bioadhesive mucosal dosage forms like gels, patches, and tablets have shown promise. Recently, orally disintegrating films (ODFs) have gained attention for their rapid disintegration in the buccal cavity. Made with hydrophilic polymers, ODFs dissolve quickly upon contact with saliva, releasing the drug effectively. Developed alongside oral disintegrating tablets (ODTs) in the late 1970s, these systems aimed to replace traditional tablets and capsules. Unlike ODTs, which required counseling to prevent chewing or swallowing, ODFs eliminate such risks, offering a safer and more patient-friendly alternative, especially for vulnerable populations.

Classification [2, 3]
Three categories of fast-dissolve technology include
1. Oral Thin-Film Strips
2. Compressed Tablet-Based Systems
3. Lyophilized Systems.

The Ideal Characteristics of Drug to Be Selected.
1. The drug should have pleasant taste. The drug should have small molecular size and low molecular weight.
2. The drug should have good solubility and stability in water as well as in saliva.
3. It should be partially unionized at the pH of oral cavity.
4. The drug should exhibit low sensitivity to environmental conditions.
5. It should have the ability to permeate oral mucosal tissue.
6. The therapeutic dose of the drug should not be greater than 40 mg [4, 5, 6].

List of some film forming polymers [7]

Natural polymer	Synthetic polymer
Starch	Hydroxy propyl methyl cellulose
Pectin	Poly vinyl pyrrolidone (PVP)
Gelatin	Poly vinyl pyrrolidone (PVP)
Sodium alginate	Sodium carboxy methyl cellulose
Maltodextrin	Kolli coat IR
Pullulan	Hydroxy propyl cellulose
Xanthan	Hydroxy ethyl cellulose (HEC)
Poluyumerized rosin	Hydroxy ethyl cellulose (HEC)
Gum acacia	Methyl cellulose (MC)

Mechanism of film forming

When Film Forming Systems (FFS) are applied to the skin, the solvent evaporates and leaves a very thin, nonvisible film on the surface of the skin. It raises the drug concentration on the skin in such a manner that it can even reach the threshold of its supersaturation without risking the skin. This can contribute to improved absorption of the drug. The skin barrier thickness and the segments of concentrations of drug can influence drug penetrations according to Fick's law. Modified as such, the law correlates flow of drug through thermodynamic activity. In this way, FFS attains drug channelling through the skin by creating a super-saturation state after application. Such formulations, with or without enhancers, could contribute theoretically to as much as seven-fold increases in ethinyl estradiol as compared with commercial patches, according to studies. These devices act as viable alternatives to the conventional transdermal patch and enhance the skin absorption characteristics [8].

List of few drugs that can be incorporated in fast dissolving films [9,10]

S. No	Drug	Dose	Therapeutic action
1.	Azamatadine maleate	1mg	Anti histaminc
2.	Nicotine	2mg	Somking cessation
3.	Loperamide	2mg	Anti diarrhoeal
4.	Ondansetron	2.5mg	Anti emetic
5.	Triplodine hydrochloride	2.5mg	Anti histamine
6.	Zolmitriptan	2.5mg	Anti migraine
7.	Salbutamol	4mg	Anti histamine
8.	Chlorpheniramine maleate	4mg	Anti allergic
9.	Cetirizine	5-10mg	Anti histaminic
10.	Acrovastine	8mg	Anti histaminic
11.	Loratadine	20mg	Lantihistamini
12	Omeprazole	10-20mg	Proton pump inhibitor
13.	Famotidine	10mg	Antacid
14.	Ketoprofen	12,5mg	Analgesic
15.	Dicyclomine hydrochloride	25mg	Muscle relaxant
16.	Diphenhydramine hydrochloride	25mg	Anti allergic
17.	Sumatriptan succinate	35-70mg	Anti migraine

Formulation of fast dissolving films

Key ingredients are used in the formulation of fast-dissolving films (FDFs) to guarantee both efficient drug administration and quick disintegration. The primary component is a film-forming polymer, such as pullulan, HPMC, or PVA, which gives the film structure and facilitates its rapid dissolution in saliva. Plasticizers, such as PEG or glycerine, are added to improve flexibility and avoid brittleness. The film has a consistent distribution of the active pharmaceutical ingredient (API). Particularly for usage in children and the elderly, sweeteners, flavourings, and saliva-stimulating substances enhance taste and patient acceptability. Drug solubility can be improved by using surfactants. The formulation needs to be flexible, stable, and dissolve in the tongue without water in 30 to 60 seconds. In order to create high-quality films with consistent thickness and medication content, proper blending, casting, and drying procedures are necessary.

A typical composition contains the following ingredients

S. No	Agents	Concentration
1	Drug	1-25%
2	Water soluble polymer	40-50%
3	Plasticizers	0-20%
4	Fillers, colours, flavours etc.	0-40%

Method Of Preparations of Fast Dissolving Film

A variety of techniques, such as solvent casting, hot-melt extrusion, semisolid casting, solid dispersion extrusion, and rolling, can be used to create mouth dissolving films (ODFs).

1. Solvent casting
2. Hot-Melt Extrusion
3. Semi solid casting method
4. Solid dispersion extrusion method
5. Rolling method
6. Spray technique

Solvent Casting

The most popular approach for creating fast-dissolving films is solvent casting. This process creates a homogenous solution by dissolving water-soluble polymers, the active medication, and excipients in an appropriate solvent, usually deionized water. Homogeneity is ensured by high shear mixing. To create thin films, the solution is subsequently placed onto a level surface (such as a petri dish) and dried at a regulated temperature. A vacuum pump is used for deaeration prior to drying in order to eliminate air bubbles that can compromise the quality of the film. The kind of solvent and the concentration of the polymer (pullulan 2–8%, for example) affect the viscosity and film-forming capacity. Drug characteristics like solubility and melting point need to be taken into account. The preparation of tianeptine, Mosa pride, and anastrozole films has been accomplished with success using this technique [11, 12].

Hot-Melt Extrusion

It is a process in which polymer undergoes melting due to applied heat and pressure. It is mostly used in the preparation of SR-tablets, granules. This method breaks the ancestral way used for preparation of ODF. In this film is prepared through heating process. Ingredients are mixed in a dry state after the process of heating it's taken out in a molten state. Molten mass obtained is used to cast film. Then films are cooled and cut. Major drawback of this technique is the Active Ingredients is deactivated due to the high temperature. Vital step in this technique is casting and drying (Figure 2). Correlated to HME technique solvent casting occurred to be more up righted process for production of ODF [13, 14, 15].

Semi solid casting method

Fast-dissolving films are made via the semi-solid casting method, which creates a thick, gel-like material. Using this procedure, the active medication and water-soluble polymers (such as HPMC or PVA) are dissolved in an appropriate solvent to create a semi-solid mass. In order to increase flexibility, a plasticizer is applied. After that, a blade or applicator is used to cast the mixture onto a level surface in order to create a consistent layer. To eliminate the solvent and solidify the film, it is dried at a regulated temperature after casting. Because it requires lower drying temperatures than other methods, this method is perfect for medications that are sensitive to heat. The films that are produced are homogeneous, smooth, and transparent. The semi-solid mass's viscosity and film thickness are essential for both drug content and optimal film formation.

Solid Dispersion Extrusion Method

Solid dispersion of domperidone using beta cyclodextrin, PEG400 and HPMC E15 was successfully prepared and films were casted using solid dispersion extrusion method [16, 17]

Rolling Method

Plot of rolling method is prepared solution should possess specific rheological properties for rolling onto the drum. Preparation of suspension of drug and polymer in water or alcohol Suspension is subjected to rollers Suspension is subjected to rollers Evaporation of solvent Evaporation of solvent [18, 19].

Spray technique

Drug substance, polymers and all other excipients are dissolved in a suitable solvent to form a clear solution. This clear solution is then sprayed onto suitable material such as glass, polyethylene film of non-siliconized Kraft paper or Teflon sheet [20]

Recent Manufacturing Technologies

- **Gel-based films** are plant-derived, water-soluble, and customizable in shape and size. They mask taste and colour, offering enteric properties, ideal for vegetarians.
- **Solu leaves** deliver active ingredients quickly via saliva-triggered dissolution and are suitable for confectionery, vitamins, and paediatric or geriatric patients.[21]
- **Oral thin film strips** evolved from breath fresheners and can include soluble, insoluble, or taste-masked drugs, produced as large sheets and cut into doses.[21]
- **Water tabs (Wafer tabs)** are pre-cast films where drugs are added later, offering fast drug release and enhanced taste, stability, and patient compliance.[21]
- **Foam burst** films have a gas-blown, honeycomb structure, giving a melt-in-mouth feel for fast disintegration.[21]
- **Micap technology** uses microencapsulation with water-soluble films for controlled release in pharma and food sectors

Packaging of orally disintegrating films

Packing considerations are critical for storage, protection and stability of dosage form. Packaging for oral thin films includes foil paper or plastic pouches, single pouch, aluminium pouch, blister packaging with multiple units and barrier films. Barrier films are most commonly used for those drugs which are extremely moisture sensitive.[22] Rapid film technology developed by Labtech GmbH describes primary packaging made of a sealing pouch affords enough space for logos, codes, instructions or other information. The films are manufactured by a laminating process and packaging costs are comparable to tablets. [23]

Conclusion

Fast Dissolving Films (FDFs) have recently gained significant popularity due to their rapid onset of action, patient compliance, and ability to bypass hepatic first-pass metabolism, leading to enhanced therapeutic effects. They offer a balance between the stability of solid dosage forms and the ease of administration typical of liquids. FDFs are especially suitable for paediatric and geriatric patients, making them an ideal alternative to tablets and capsules. Their low manufacturing cost, consumer preference, and versatility make them attractive for both over-the-counter and prescription drugs. Pharmaceutical companies use this technology for product life cycle management to extend patent life. With potential for both systemic and local drug delivery, FDFs are evolving rapidly and are considered a proising platform for a wide range of active pharmaceutical Agent

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