

Fast Dissolving Films: A Novel Approach for Rapid Drug Delivery – A Review

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Abstract

Fast dissolving films (FDFs) have become a promising and innovative drug delivery system. These systems offer a prominent alternative to conventional dosage forms as it disintegrates and dissolves rapidly in saliva without the need of water and swallowing making them particularly advantageous for pediatric, geriatric, and dysphagic patients who experience difficulty in swallowing conventional oral dosage forms. The increasing demand for rapid drug delivery and patient-friendly dosage form has given rise to the extensive research in the development of FDFs. This review provides an in- depth overview of the Fast dissolving films along with their advantages, disadvantages, formulation strategies, key components, manufacturing technologies involved in their development and their evaluation parameters Furthermore, this review also discusses about the selection of suitable film-forming polymers, plasticizers, sweeteners, and active pharmaceutical ingredients and other excipients which are important for achieving the desired mechanical properties, rapid disintegration, and drug release profiles.

Keywords: Fast Dissolving Films, Polymers, Plasticizers Solvent Casting Method.

1. Introduction

In recent years, Fast dissolving films have gained significant attention in pharmaceutical field due to their ability to improve patient compliance. The oral route is the most preferred routes for drug administration because it is more convenient, cost-effective and ease of administration leads to a high level of patient compliance. Sometimes the oral route is problematic because of the swallowing difficulty for pediatric and geriatric patients who have fear of choking. Patient convenience and compliance-oriented research have resulted in introducing newer and safer drug delivery systems. Recently, oral fast-dissolving drug delivery systems (fast dissolving tablet, fast dissolving film) have begin obtaining popularity and acceptance because of increased consumer choice, for the reason of rapid disintegration or dissolution, provide rapid onset of action, self-administration possible even without water or mastication^[1,2].

The development of fast dissolving films involves the careful selection of film-forming polymers, plasticizers, taste-masking agents, and other excipients to achieve desired mechanical strength, disintegration time, and drug release profile. Various methods such as solvent casting, hot melt extrusion, and electro-spinning are employed to manufacture these films at both laboratory and industrial scales.^[3]

1.1 ANATOMY OF ORAL MUCOSA

1.1.1. Structure: The oral mucosa forms the inner lining of the oral cavity covering the cheeks, lips, hard and soft palates and tongue. It is composed of three main layers: an outermost layer of stratified squamous epithelium, lamina propria as the middle layer followed by the submucosa as the innermost layer^[4]

Within the oral cavity, the masticatory mucosa has a keratinized or cornified epithelium and covers the stress-enduring area such as the gingival and the hard palate, this masticatory mucosa providing chemical resistance and mechanical strength. The lining mucosa, which gives elasticity, in contrast, is contained of noncornified surface epithelium covering relax of the regions including the lips, cheeks, floor of the mouth, and soft palate. The third type of mucosa is the specialized mucosa containing of both keratinized and non-keratinized layers and is restricted to the dorsal surface of the tongue. The intercellular spaces contain water, lipids, and proteins.

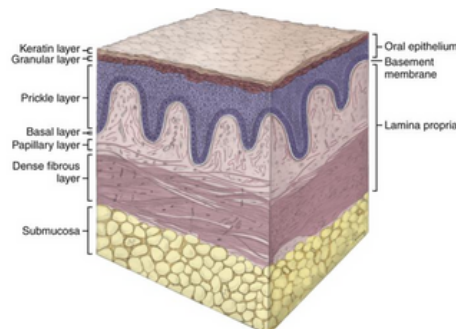


Fig. 1: Structure of oral mucosa

1.1.2.Permeability of oral mucosa: The oral mucosa is somewhat leaky epithelia in between that of the epidermis and intestinal mucosa. The penetrability of the buccal mucosa is 4-4000 times greater than the skin. The difference in permeability is due to diverse structure and function of the diverse oral mucosa. The permeability of the oral mucosa is found to decreases in this order of sublingual>buccal >palatal. This order depends on the thickness and degree of keratinization of these tissues, with the sublingual mucosa being relatively thin and non-keratinized, the buccal mucosa thicker and non-keratinized and the palatal mucosa intermediate in thickness but keratinized. [5,6]

1.2 FAST DISSOLVING DRUG DELIVERY SYSTEM

Fast dissolving drug delivery systems were first developed in the 1970s as an alternative to conventional oral dosage form such as tablets, capsules and syrups for pediatric and geriatric patients. Oral fast - dissolving film (OFDF) is also known as mouth dissolving film (MDF), oral strips, Oro-dispersive films (ODF) and quick-dissolving film. [7] Fast dissolving films are thin flexible polymeric films that are placed on patient's tongue where they absorb water, get hydrated and adhere to the site of application. Due to hydration, the film disintegrates and release drug which gets directly absorbed into the systemic circulation; thereby increasing the bioavailability of drug by avoiding first pass metabolism. [8]

1.2.1. Advantages of Oral Fast Dissolving Film [9]

- It is easy for self-administration.
- Do not require water as it is dissolved by saliva.
- It is convenient for children (paediatric), elderly people (geriatric) and patients with swallowing difficulty (dysphagia).
- It disintegrates and dissolves rapidly in the oral cavity due to the larger surface area of the films.
- It has rapid onset of action and improved bioavailability as it bypasses hepatic first pass metabolism.
- It reduces dose, enhances the efficacy, safety profile of the drug

and reduced side effects.

- It is flexible and easy to handle.
- Its transportation and storage and more economical.
- Its administration is easy for mentally retarded, disabled, uncooperative patients and for the patients who are on reduced liquid intake plans.
- It is beneficial in cases such as nausea, motion sickness, acute pain, sudden allergic attack, asthmatic attack and coughing, where rapid onset of action is required.
- It provides longer stability for extended period of time.
- More accuracy in dose as compared to liquid dosage form.
- It has pleasant mouth feel.

1.2.2. Disadvantage of Oral Fast Dissolving Film ^[10]

- Drugs that are not stable at salivary pH cannot be administered.
- Drugs that irritate the mucosa cannot be administered by this route.
- Drugs with low dose requirements can only be administered.
- Taste masking- Most drugs have a bitter taste and need taste masking.
- Special packaging- OFDFs are fragile and must be protected from water so it needs special packaging

1.2.3. Ideal Characteristics for Oral Fast Dissolving Film ^[11]

- It should be thin, flexible, and easy to handle.
- It should be transportable, not sticky, and keep a plane form without rolling up.
- It should be easy to administer.
- The film should offer pleasant taste and a satisfying mouth-feel.
- The disintegration time of the film should be as rapid as possible.
- The film's surface should be smooth and uniform.
- The film should remain physically and chemically stable during its shelf life.
- It should be cost-effective and ease for commercial production.
- It should have low sensitivity to humidity and temperature.
- The size of a unit film should not be too bulky that it will affect the patient's compliance.

2. FORMULATION ASPECTS

Fast dissolving films are thin films (Area: 5 -20 cm²) ^[12], composed of hydrophilic, film forming polymeric matrix that incorporates the active pharmaceutical ingredients to form a flexible, rapidly disintegrating film. The careful selection of ingredients plays an important role in the formulation and optimization of FDFs to ensure the uniformity,

palatability, mechanical strength, and rapid dissolution. Table No. 1 shows the essential formulation components and their functions in the development of FDFs.

Table 1: Composition of Fast dissolving films

S. No.	Component	Examples	Typical Concentration	Function
1	Film-forming polymer	HPMC, PVA, Pullulan, Sodium alginate	45–65%	Forms the film matrix
2	Plasticizer	PEG 400, Glycerol, Propylene glycol	10–20%	Improves flexibility
3	API	Tramadol, Ondansetron, Loratadine	1–40 mg	Therapeutic agent
4	Sweetener	Sucralose, Mannitol, Aspartame	2–5%	Improves taste
5	Flavoring agent	Mint, Strawberry, Lemon	1–3%	Enhances palatability
6	Saliva stimulant	Citric acid, Tartaric acid	1–3%	Stimulates saliva production
7	Surfactant	SLS, Tween 80, Poloxamer	0.5–2%	Enhances solubility and dispersion
8	Colouring agent	Titanium dioxide	1%	Provide colour

2.1 Film Forming Polymers

Polymers play a key role in the development of fast dissolving films. They must be non-toxic, non-irritant, and capable of forming flexible, transparent, and smooth films. Hydrophilic polymers are used because they absorb water and swells up leading to faster disintegration and dissolution. Single polymer or a combination of polymers can be used to get the desired film properties. The robustness of the film depends on the type and amount of polymer in the formulation. Now a day's both natural and artificial polymers are used in the oral cavity. A Natural polymer is safe, effective and has less side effects, so these are more preferred than the artificial polymers. The concentration of these polymers typically ranges from 45% to 65% w/w of the total f

pormulation. Commonly used film-forming polymers include hydroxypropyl methylcellulose (HPMC), which is widely used due to its good film-forming ability, non-toxicity, and ease of processing. ^[13] Some of the commonly used polymers are shown in Table 2.

Ideal properties of the polymers used in the oral FDF ^[14]

- It should be non-toxic and non- irritant.
- It should be tasteless.
- It should be free from leachable impurities.
- It should be inexpensive and readily available.
- It should not be a hurdle in the disintegration time.
- Polymers should have good wetting and spreadability property.
- It should show adequate peel, shear, and tensile strength.
- It should have an adequate shelf life.
- It should not cause secondary infection in the oral cavity.

Table 2: List of polymers used in oral thin films. ^[15]

Group	Example	Properties
Natural	Pullalan, pectin, sodium alginate, maltodextrin, Sodium starch glycolate (SSG), Gelatin, Polymerized resin (novel film former)	Natural polymers are safe, effective and lacking side effects also biodegradable, biocompatible, and non-toxic so more preferred than artificial polymers. · Pullulan is a water-soluble natural polymer, forms clear, tasteless films with good strength. · sodium alginate, a natural polymer, offers good mucoadhesive and film-forming characteristics · Maltodextrin is often used in combination with other polymers to improve solubility and disintegration.
Synthetic	Hydroxypropyl methylcellulose (HPMC) Methylcellulose, Carboxy methyl cellulose secekol- 30, Sodium carboxy methyl cellulose, Microcrystalline cellulose, Croscarmellose sodium (CCS)., Poly vinyl pyrrolidone, Poly vinyl alcohol, poly ethylene oxide, Eudragit.	Synthetic polymer is created artificially in lab by human being. A variety of chemical reactions since they do not exist in nature. It is further classified in two major categories i.e., Biodegradable synthetic polymers and Non-biodegradable synthetic polymer · HPMC is widely used due to its good film-forming ability, non-toxicity, and ease of processing. · Polyvinyl alcohol (PVA) is valued for its high mechanical strength and elasticity.

2.2 Plasticizers

Plasticizers play a crucial role in enhancing the flexibility, elasticity, and handling characteristics of films. They help reduce brittleness and prevent cracking during storage, thereby maintaining the integrity of the

film. Commonly used plasticizers include glycerol, polyethylene glycol (PEG 400 and PEG 600), propylene glycol, and triethyl citrate. Typically, plasticizer concentrations range from 10% to 20% w/w of the dry polymer weight. The type and amount of plasticizer used significantly affect the film's tensile strength and disintegration profile. ^[16, 17]

2.3 Active Pharmaceutical Ingredients (APIs)

Active Pharmaceutical Ingredients (APIs) in fast dissolving films (FDFs) should ideally be potent and require low doses because the high dose of the drugs is difficult to incorporate in the film. Variety of APIs can be delivered through fast dissolving films. Micronized API should be used because it enhances the texture of the film and also results in better dissolution and uniformity in the fast-dissolving film. Many APIs, which are potential candidates for fast dissolving film technology, features a bitter taste which makes the formulation unpalatable, especially for pediatric preparations. Thus, before including such APIs in fast dissolving films, taste-masking is an essential step. Several methods can be used to enhance the palatability of the formulation, but the simplest method is mixing and co-processing of bitter-tasting API with flavoring or sweetening agent. For poorly water-soluble drugs, solubility enhancement strategies such as solid dispersion, complexation with cyclodextrins, or nano formulations are commonly employed to improve their performance. ^[18] Various categories of drugs such as antiemetic, neuroleptics, antihypertensive, cardiovascular agents, analgesics, antiallergic, antiepileptics, anxiolytics, sedatives, hypnotics, diuretics, anti-parkinsonism, antibacterial, anti-Alzheimer, expectorants, antitussive and drugs used for erectile dysfunction can be incorporated in FDFs. ^[19]

The ideal characteristics of an API to be selected in oral FDF ^[20]

- The dose of API should be- up to 40 mg.
- The molecular weight of API preferably smaller.
- API should be stable in the fluid present in the mouth.
- API should be moderately unionized in saliva present in oral cavity.
- Permeability through mucosal tissue.

2.4 Sweeteners

Sweeteners are an important component used in oral films. Generally, sweeteners are used for the taste masking of bitter taste drugs so that drugs are palatable. Sweeteners are used alone or in combination between the concentrations of 2-5%w/w. Natural and artificial sweeteners are used in the preparation of the oral film. Natural sweeteners used are xylose, ribose, glucose, sucrose, maltose, stevioside, dextrose, fructose, liq. glucose and isomaltose. Fructose is

sweeter than sorbitol and mannitol and thus widely used as a sweetener. Artificial sweeteners utilized in oral films are sodium or calcium saccharin salts and cyclamates salts. [21]

2.5 Flavoring Agents

Flavoring agents are those ingredients that impart flavor to the formulations. Any US-FDA approved flavor can be added to the formulation according to the choice of the individuals of various age groups. Flavoring agent should not be interacting with the drug and other excipients. Flavoring agents are selected depending on their flavor impact in the first few seconds and it's after taste. Flavoring agent can be added in concentration of up to 5% for the oral film formulation. [22]

2.6 Saliva Stimulating Agents

Saliva-stimulating agents are added to fast dissolving films (FDFs) to enhance the rate of secretion saliva, which aids in the rapid disintegration and dissolution of the film in the oral cavity. Typically used in low concentrations ranging from 1%-3% w/w. Common examples of these agents include citric acid, tartaric acid, and malic acid. Citric acid is most commonly used as a saliva stimulating agent. [23]

2.7 Surfactants and Solubilizers

Surfactants are incorporated into fast dissolving films (FDFs) as solubilizing or wetting or dispersing agent so that the film is getting dissolved within seconds and release active pharmaceutical agent immediately. Some of the commonly used surfactant are sodium lauryl sulfate (SLS), Poloxamer 407, benzalkonium chloride, benzethonium chloride, tweens, etc. [24]

2.8 Colouring Agents

Coloring agent use to improve appearance and make them attractive. FD & C approved coloring agents are used for fast dissolving films like titanium dioxide. [25]

3. MANUFACTURING TECHNIQUES

Their successful development depends significantly on the manufacturing technique, which determines the film's quality, mechanical properties, uniformity, and drug release profile. Selecting an appropriate manufacturing method depends on the physicochemical characteristics of the drug, type of polymer, production scale, and desired film properties. Some of the important methods are discussed below:

3.1 Solvent Casting Method

In this method, the film forming polymers and plasticizers are dissolved in dist. water and stirred for 4 hours to make the transparent viscous

solution. The solution was kept aside for 1 hr to remove air bubbles. In a separate container, remaining water-soluble excipients like saliva stimulating agents, sweeteners, flavoring agents etc. are dissolved in water and stirred for 45 min. After stirring, both the solutions are mixed together with continuous stirring for 1 hour and kept aside for 1 hour. The solution was then poured in the petri dish to form a thin film. The film thus formed is then dried under the oven and after complete drying the film is removed carefully ^[26, 27].

3.2 Semisolid Casting Method

In this method, firstly a solution of water-soluble film-forming polymer is prepared. Then this solution is added to a solution of acid-insoluble polymer (e.g. cellulose acetate phthalate, cellulose acetate butyrate), which was prepared in ammonium hydroxide (NH₄OH) or sodium hydroxide (NaOH). Then an appropriate concentration of plasticizer is added so that a gel mass is obtained. Finally, the gel mass is cast into the films using heat controlled drums. The ratio of the acid-insoluble polymer to film-forming polymer should be 1:4. ^[28]

3.3 Hot Melt Extrusion Method

In this method, the polymers which have low molecular weight and low viscosity are used. The drug is assorted with the carrier in the solid form so that granular material is formed. These granules are then dried and then introduced into the extruder. The speed of the screw should be around 15rpm. The processing temperatures should be 80°C, 115°C, 100°C, and 65°C. The extrudate (65°C temperature) then pressed into a cylindrical calendar to obtain a film. ^[29]

3.4 Solid Dispersion Extrusion Method

In the solid dispersion extrusion method, immiscible components are extruded with drugs and then solid dispersions are prepared. Finally, the solid dispersions are shaped into films using dies. ^[30]

3.5 Rolling method

In the rolling method, a solution or suspension containing drug (API) is rolled on a carrier. Water or mixtures of water and alcohol are used as the solvent in this method. The film is dried on the rollers and cut into desired shapes and sizes. ^[31]

4. EVALUATION OF ORAL FAST DISSOLVING FILM

4.1 Thickness of films

Thickness of the film was measured by micrometer screw gauge at three different places; averages of three values were calculated. ^[32]

4.2 Weight variation

For the evaluation of weight variation of the fast-dissolving film of size

2×2cm² were cut and 3 films of each formulation were taken and weight individually using electronic balance. The average weight was calculated. ^[33]

4.3 Folding endurance

Folding endurance is related to the flexibility of a film. The folding endurance expressed as the number of folds (number of times of film is folded at the same plain) required breaking the film or developing visible cracks. This gives an indication of brittleness of the film. A small film 2×2cm² was subjected to this test by folding the film at the same plane repeatedly several times until a visible crack was observed. The number of times the film could be folded at the same place without breaking/cracking gave the value of folding endurance. ^[34]

4.4 Tensile strength

Tensile strength is the maximum stress applied to a point at which the strip specimen breaks. It is calculated by the applied load at rupture divided by the cross-sectional area of strip as given in the equation below: ^[35]

Tensile strength = Load at failure × 100/Strip thickness × Strip width

4.5 Surface pH

The surface pH of fast dissolving film was determined to investigate the possible side effects due to change in pH in-vivo, since an acidic or alkaline Ph may irritate the oral mucosa. The surface pH was determined by using pH meter. This test was evaluated by placing the film in a petri dish. Then it was moistened with 0.5 ml of phosphate buffer and kept for 30s. The pH was noted after bringing the electrode of the pH meter in touch with the surface of the formulation and allowing equilibration for 1 min. The average of three determinations for each formulation was taken. ^[36]

4.6 Drug Content Uniformity

The films were tested for content uniformity. Films of size 2×2 cm² were cut, placed in 100 ml volumetric flask and dissolve in phosphate buffer pH 6.8. Volumetric flask was shaken continuously for 10 min. Then solution was filtered through whatman filter paper. After filtration, 1 ml of solution was withdrawn from the above solution in 10 ml volumetric flask and dilute up to 10 ml of phosphate buffer pH 6.8. Solution was analyzed by UV spectrophotometer at relevant λ_{max} of drug to calculate the concentration of drug present in the film. ^[37]

4.7 In-vitro disintegration test

Disintegration time of fast dissolving film measured by placing the film area (2×2cm²) in a petridish containing 6 ml phosphate buffer pH 6.8. Time required for complete disintegration of the film was noted. ^[38]

4.8 In-vitro drug release

In-vitro drug release of fast dissolving film of was studied in USP Type II (Paddle type) dissolution test apparatus using phosphate buffer pH 6.8 (250 ml) as the dissolution medium. Film of area $2 \times 2 \text{ cm}^2$ was cut and fixed to a piece of metal wire slab and placed at the bottom of the dissolution vessel. The temperature was maintained at $37 \pm 0.5^\circ\text{C}$ with paddle speed rotation 50 rpm. 5ml Sample was withdrawn at specific time intervals and the same quantity was replaced with phosphate buffer pH 6.8 to maintain volume of dissolution medium. The sample were filtered immediately through whatman filter paper and analyzed by UV spectrophotometrically at relevant λ_{max} of the for the drug concentration and calculated the % of drug dissolved or release. [39, 40]

4.9 Stability Study

In the humidity chamber, an accelerated environment with 65% relative humidity and 35°C temperature is used to conduct the stability investigation. After three months, the drug content, disintegration time, and physical appearance of films are evaluated. [41]

5. MARKETED FORMULATIONS OF FAST DISSOLVING FILMS

Since the early 2000s, several FDF products have entered the market, including Ondansetron oral disintegrating film (Zuplenz®), delivering effective antiemetic therapy, and Suboxone® film for opioid dependence treatment. These successful launches have paved the way for the development of various FDFs in different therapeutic areas. There are several marketed products of fast dissolving films (FDFs) available in the market. Here are a few examples: (Table 3).

Table 3: Marketed formulations of fast dissolving films [42]

S.NO.	Brand name	API	Manufacturer
1	Orazel	Menthol/ Pectin	Del
2	Gas-X	Simethicone	Novartis
3	Benadryl	Diphenylhydramine HCl	Pfizer
4	Chloraseptic	Benzocaine	Prestige
5	Ondansterone	Ondansetrone	Labtec
6	Maxalt MLT	Rizatriptan	Merck
7	Zoming-ZMT	Zolmitriptan	AstraZeneca
8	Febrectol	Paracetamol	Prographarm
9	Nimulid	Nimesulide	Panacea Biotech
10	Torrox MT	Rofecoxib	Torrent Pharmaceuticals
11	Romilast	Montelukast	Ranbaxy
12	NuLev	Hyoscyamine sulfate	Cima Labs
13	FazaClo	Clozapine	AzurPharma
14	Mirtazapine	Mirtazapine	Teva Pharmaceuticals
15	Parcopa	Carbidopa/Levodopa	Schwarz Pharma
16	Theraflu	Dextromethorphan HBr	Novartis
17	Triaminic	Phenylephrine HCl	Novartis
18	Donepezil	Donepezil HCl	Labtec
19	Sudafed	Phenylephrine HCl	Pfizer
20	Rapid film	Ondansetron	GmbH
21	Klonopin Wafers	Clonazepam	Solvay pharmaceuticals
22	Listerine cool mint pocket packs	Cool Mint	Cool Mint
23	Listerine	cool mint	Pfizer
24	Sudafed PE	Phenylephrine	Wolters Kluwer Health Lipson
25	SupressR	Menthol	InnoZenR, Inc

6. CONCLUSION

Fast dissolving films offers a promising and alternative way of drug delivery system, particularly suitable for pediatric, geriatric, and dysphagic patients. While conventional dosage provides slower action and are difficult to swallow, fast dissolving films are palatable and offer faster dissolution and rapid onset of action. Their rapid disintegration in the oral cavity, without the need for water, enhances patient compliance and ensures quick onset of action. By carefully selecting appropriate polymers, plasticizers, and other excipients, FDFs can be effectively formulated to deliver a wide range of drugs. With ongoing advancements in formulation techniques and materials, FDFs continue to gain attention as an innovative alternative to conventional oral dosage forms.

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