Review Article

Fast Dissolving Oral Films: A Novel Approach for Efficient Drug Delivery

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ABSTRACT

Fast dissolving oral films (FDOFs) are an innovative drug delivery system that dissolves or disintegrates quickly in the mouth, releasing the active pharmaceutical ingredient. This system offers several advantages, including ease of administration, rapid onset of action, and improved patient compliance. FDOFs are particularly beneficial for patients with dysphagia, pediatric, and geriatric populations. The films are composed of a polymer, plasticizer, surfactant, sweetening agent, saliva stimulating agent, flavoring agent, and coloring agent. Various technologies, such as solvent casting, hot melt extrusion, and solid dispersion extrusion, are used to prepare FDOFs. These films have potential applications in the treatment of various diseases, including cardiovascular disease, diabetes, and neurological disorders. This review provides an overview of the salient features, ideal characteristics, advantages, disadvantages, and applications of FDOFs. Overall, FDOFs offer a promising approach for efficient drug delivery and improved patient outcomes.

Keywords: Fast dissolving oral films, Drug delivery system, Patient compliance, Polymer, Plasticizer.

1. INTRODUCTION

Fast-dissolving oral delivery methods are solid dose forms that, when placed in the mouth without being chewed or drunk, dissolve or disintegrate quickly (less than a minute). Maltodextrins (MDX) plasticized by glycerin have recently been proposed as one of the many polymers available as film-forming ingredients to generate fast-dissolving films by solvent casting and hot-melt extrusion [1]. Oral fast dissolving films, or OFDFs, originated as breath strips in the confection and oral care industries and have since developed into an innovative and extensively embraced delivery system for vitamins and personal hygiene goods [2].

A novel method of medicine delivery for these patients is the fast-dissolving film. Because of their special properties, fast-dissolving films have become more important in the pharmaceutical business characteristics and benefits. Within a minute, they dissolve in the salivary fluids of the mouth, releasing the active pharmaceutical component [3]. In terms of comfort and flexibility, fast dissolving films might be chosen over sticky pills. Furthermore, they can avoid the oral gels comparatively brief duration on the mucosa, as saliva readily washes and removes them [4].

The fast-dissolving oral films is a thin, square or rectangle shaped strip that is moistened by saliva and placed on the patient's tongue or other oro-mucosal tissue [5]. Most fast-dissolving delivery system films must contain compounds that conceal the taste of the active ingredient [6]. The idea behind the fast-dissolving drug delivery method was to give patients a traditional way to take their prescription [7]. These are extremely thin strips that dissolve or disintegrate quickly in the mouth, allowing the drug to be absorbed via the oro-mucosal pathway. The buccal cavity's strong blood flow and permeability allow for rapid medication bioavailability [8]. The usage of super disintegrants allows fast dissolving tablets to dissolve or disintegrate rapidly [9]. Patients who are bedridden, elderly, or pediatric can benefit from quick-dissolving oral films. These are also helpful in certain situations, like diarrhea, unexpected allergic reactions, and when a local anesthetic is needed for toothaches, mouth ulcers, cold sores, or teething [10]. A mouth dissolving film, what is an extremely fine oral strip, gets applied to the patient's tongue or any other oral mucosal tissue (such the sublingual mucosa) when saliva is being given. It quickly hydrates and sticks to the application site before dissolving and dissolving to release the medication for oromucosal absorption [11].

OFDFs are now in the early to mid-stages of development for prescription drugs and are a validated and recognized technology for the systemic administration of APIs for over-the-counter (OTC) treatments [12]. They also provide distinct product distinction, making it possible to utilize them as line extensions for already-available commercial items. In addition to helping the business meet its existing needs, this innovative drug delivery technology may also help with enhanced solubility/stability and medicine bioavailability improvement [13]. The technology of the transdermal patch was used to develop fast dissolving films (FDF), a sort of oral drug delivery system for the oral delivery of the medication [14]. Dissolvable oral thin film, often known as oral strips, originated in confection and oral care advertisements and evolved into a revolutionary and widely accepted structure by retail [15].

2. SALIENT FEATURES

1. Simplicity of administration for individuals with mental illness and poor cooperation.

2. Does not require water; the dosage form dissolves and disintegrates quickly [16].

3. No chance of choking [17].

4. They are mucoadhesive, so they attach to the mouth cavity for faster hydration, which leads to rapid dissolution of the film [18].

5. Overcome the unpleasant taste of the medications.

6. It can be made to have a nice mouth feel and to leave little to no residue in the mouth after use.

7. Ability to give the benefits of liquid medication in the form of a solid formulation.

8. Adaptable and compatible with existing processes and packaging.

9. Cost effective [19].

3. IDEAL CHARACTERISTICS

1. The medication dissolves or disintegrates in the mouth in a matter of seconds and doesn't require water when taken orally.

2. The drug should taste pleasant.

3. Possess a passable ability to hide flavour.

4. Be less brittle and tougher.

5. The dosage of the integrated medication should be low, less than 30 mg.

6. It is better to use medications with a moderate and smaller molecular weight.

7. The drug should be stable and soluble in both saliva and water [20].

8. It ought to partially unite at the oral cavity's pH.

9. It should be able to penetrate the mucosal tissue of the mouth [21].

4. ADVANTAGES

1. The simplicity of giving films to individuals with dysphagia, recurrent vomiting, motion sickness, and mental health issues

2. Accuracy of dose [22].

3. Offers quicker dissolution and disintegration in the oral cavity because of the greater surface area.

5. It is possible to prevent the stomach's acidic environment.

6. Local and site-specific actions [23].

7. The possibility of suffocation in the airways because of a physical obstruction when ODTs are ingested; as a result, they enhance safety and adherence to dosage instructions [24].

8. Suitable for elderly patients, those with swallowing issues, people with mental illnesses, people with developmental disabilities, and patients who are ill-mannered, on limited liquid intake regimens, or who feel queasy.

9. Steering clear of water makes it easier to use, even when traveling [25].

10. Drugs that experience first pass effect a portion of the drug that enters the systemic circulation straight from the oral mucosa improve bioavailability.

11. Very well-liked by patients because it's simple to use, handle, and store [26].

4.1 Clinical Advantages [16].

1. Better oral absorption.

2. Increased bioavailability as a result of less medication degradation.

4.2 Medical Advantages [16].

1. Better patient compliance, particularly for patients with dysphasia and the juvenile and geriatric populations;

2. Employ taste masking pollutants to mask up the bitter taste of medicinal products, therefore minimizing their unpleasant smell.

4.3 Technical Advantages [16].

1. Have sugars and additional GRAS excipients in them.

2. Increased stability as a result of superior packing.

3. The industry doesn't require any specific setup.

5. DISADVANTAGES

1. Oral films express the delicate, granular property and are hygroscopic by nature, thus they must be stored in dry environments [27].

2. Only one drug with a minimal dosage requirement may be administered.

3. Since most drugs have a harsh taste, taste masking is required [28].

6. CLASSIFICATION

6.1 Lyophilized systems:

The technology underlying these systems forms tablet-shaped units by combining a medication suspension or solution with additional structural excipients and using a mold or blister pack. After that, the tablets or units are frozen and lyophilized inside the mold or pack. Due to their extremely high porosity, the resultant units dissolve and absorb water or saliva very quickly [29].

6.2 Tablet moulding:

The medications are moistened, dissolved, or dispersed using a solvent in this procedure, and the moist mixture is then formed into tablets. To increase the solubility, the powder combination may be sieved before preparation. A hydro-alcoholic solvent is used to wet the powder blend before it is molded into tablets at a pressure lower than that of traditional tablet compression [18].

6.3 Thin film strips:

In recent years, oral films also known as oral wafers have developed from breath strips used in the confection and oral care industries to become an innovative and well-liked method of distributing vitamins and personal care items to consumers. For the systemic administration of APIs for over-the-counter (OTC) pharmaceuticals, FDFs are currently a validated and approved technology. For prescription drugs, they are currently in the early to mid-development phases of development. Customers have linked this to the success of breath freshener goods like Listerine Pocket Paks in the US market. Such devices generate a 50-200 mm film by using different hydrophilic polymers. The film is produced as a big sheet, which is subsequently divided into discrete dosage units for packaging in a variety of formats that are approved by pharmaceutical companies [29].

7. COMPONENTS

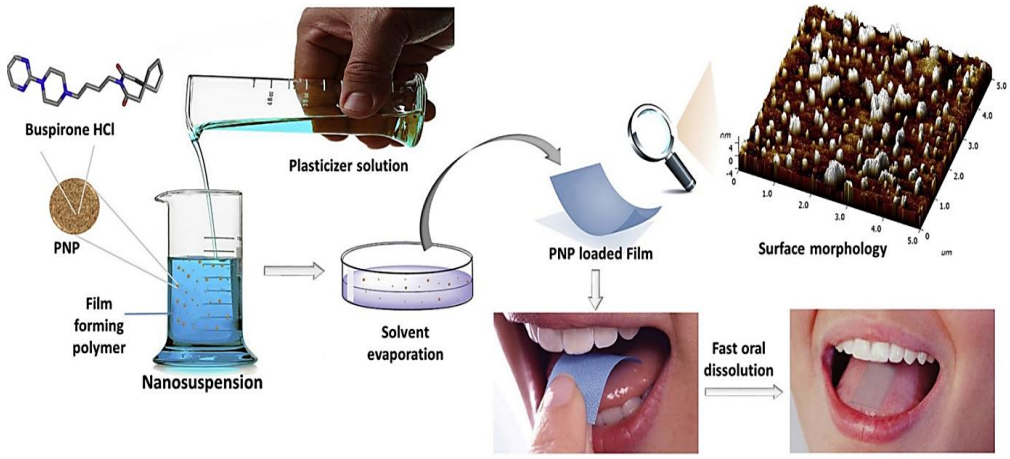

Figure 1: Components of fast dissolving films [30].

7.1 Drugs (Active pharmaceutical ingredients)

The medication oral films that are chosen should have adequate stability in both saliva and water at low dosages [31]. The drug makes up one to two quarters of the film's usual content. Fast-solving films can be used to deliver a range of APIs. The ideal compounds to include in ODFs are small dosage ones [19]. Micronized API is a must for efficient formulation since it improves the film's texture and offers uniformity, quick dissolution, and fast dissolving speed [22]. Drugs belonging to different classes. Since saliva oral dissolving films are derived from blood plasma, they contain many of the antiasthamatics and antitussives that are present in plasma. This includes antiulcer medications like omeprazole. The primary factor influencing the composition of salivary pectorants, antihistaminics, and NSAIDs (like paracetamol) is the flow rate, which in turn influences meloxicam and valdecoxib [32].

7.2 Polymer

The primary and most important component of FDOFs is polymer. To prepare oral films, a range of polymers are available. These are utilized at a concentration of roughly 40–45% w/w of the total weight of the film but can be increased to 65% w/w of the film weight alone or in combination to get the desired properties of the film [33]. Excipients or polymers with a low molecular weight and good film-forming ability must be water soluble to construct a water-soluble film formulation [23]. Pullulan; carboxmethyl cellulosecekol 30, HPMC E3, E5, E15, and K-3; Methyl cellulose A-3, A-6, and A-15; Pectin; Gelatin; Sodium Alginate; Hydroxypropylcellulose; Polyvinyl alcohol; and other water-soluble polymers are some of the ones employed as film formers. Eudragit RL100; maltodextrins and Eudragit RD 108, 9, 10, 11, and 12. One new polymer that forms films is polymerized rosin [34].

7.3 Plasticizer

Plasticizer is an essential component of OS formulation. It improves the strip's brittleness and helps to its greater adaptability [35]. In this work, two plasticizers are used, glycerol and PEG 400, To alter the film-forming land and raise the versatile of the which results thin films [11]. How well a plasticizer dissolves in the polymer sets which plasticizer is most suited to the job. Plasticizers increase ODFs mechanical strength and folding endurance. Furthermore, plasticizers improved the film's mechanical properties, specifically their tensile strength and elongation [26].

7.4 Surfactant

In a formulation, surfactants function as solubilizing, wetting, or dispersing agents to dissolve the film fast and release the active ingredient. Benzalkonium chloride, tweens, sodium lauryl sulphate, and others are examples of surfactants that are frequently employed. Poloxamer 407 is a crucial surfactant that serves as a solubilizing, wetting, and dispersion agent [21].

7.5 Sweetening agent

The prevalence about sweeteners in pharmaceutical and food preparations that should be dissolve or disintegrate in the mouth has grown. Both artificial and natural sweeteners are employed to increase the mouth-dissolving formulations' palatability. Xylose, ribose, glucose, sucrose, maltose, stevioside, and other water-soluble natural

sweeteners are examples of acceptable sweeteners [16]. Aspartame, a dipeptide-based sweetener [36].

7.6 Saliva stimulating agent

To facilitate the faster disintegration of the rapid dissolving strip formulations, saliva stimulating chemicals are used to boost the rate of saliva production. These agents can be used in combinations or alone, making up 2-6% w/w of the strip. Salivary stimulants include, among others, tartaric acid, ascorbic acid, lactic acid, malic acid, and citric acid [37]. Saliva stimulating compounds are used to stimulate saliva production, which aids in the quick disintegration of formulations for rapid dissolving strips. Salivary stimulants include lactic acid, tartaric acid, malic acid, and citric acid [27].

7.7 Flavoring agents

Flavoring agents can be chosen from a variety of plant components, including leaves, fruits, and flowers, as well as synthetic flavor oils and oleo resins. Any flavor can be added, including sour fruit flavors like lemon and orange, sweet confectionary flavors like vanillin and chocolate, or fruit essences like apple, raspberry, cherry, and pineapple. Other flavor options include intense mints like peppermint, sweet mint, spearmint, wintergreen, cinnamon, and clove. The type and strength of the flavor determine how much flavor is required to cover up the taste [38]. The kind of API being used dictates the flavor to use [39].

7.8 Coloring agent

One of the FD and C-approved coloring compounds utilized in the creation of oral fast-dissolving films is titanium dioxide, with concentration levels not going over 1% (w/w) [28]. Formulations may contain up to 1% by weight of FD and C approved colorants, EU approved colorants, natural coloring agents, or pigments [39].

Table 1: Ingredients used in fast dissolving oral Film [39].

Ingredients	Concentration
Medication	1-30%
Film forming polymer	40-50%
Plasticizer	0-20%
The Saliva stimulating agent	2-6%
Sweatning agent	3-6%
Flavoring agent	QS
Surfactant	QS
Colour and filler	QS

8. PROCEDURE

8.1 Solvent Casting method

Solvent casting is the most traditional method for creating FDFs. With the use of this water-based technique, which can heat both stable and unstable pharmaceuticals, dosage forms can be prepared without the need for a solvent and can be heated to evaporate. In order to prepare plant extracts or active pharmaceutical ingredients, the active ingredients are first dissolved in distilled water or another volatile solvent that dissolves the drugs quickly. The resulting solution is then mixed, cast as a film, and allowed to dry before being cut into the appropriate size pieces [19].

Advantages

1. Better to extrusion when it comes of thickness homogeneity and bitter clarity.
2. The film has a high sheen and is devoid of flaws like die lines.
3. Film has superior physical qualities and is more flexible. Typically, a final film thickness of 12-100µm is desirable, but different thicknesses may be needed to suit API loading and dissolving requirements [19].

Disadvantages

1. Water or a volatile solvent must dissolve the polymer.
2. The goal is to create a stable solution with a viscosity and minimal acceptable solid content.
3. It must be feasible for a homogenous film to form and for the casting support to be released [19].

8.2 Semisolid casting

This approach creates a uniform viscous solution by mixing a solution of an acid-insoluble polymer (such as cellulose acetate butyrate) with a solution of a water-soluble film-forming polymer.It is coated on untreated casting film following sonication. After drying The film has a thickness of about 0.381-0.27cm. The acid insoluble polymer and film-forming polymer have a ratio of 1:4 [32]. After that, the films or ribbons are cast from the gel bulk utilizing drums with a heat control system [28].

8.3 Hot melt extrusion

Using heat, a polymer is shaped into a film using this approach. The hopper is filled with a mixture of dry pharmaceutical components, including API, which is then transported, mixed, heated, and extruded out in a melted condition by the extruder. The film is cast using the molten mass that is so created. A crucial stage is the casting and drying process. Numerous benefits come with this technology, including the ability to scale up operations, minimal product waste, continuous operation possibilities, absence of organic solvents, lower temperature and shorter residence durations of the drug carrier mix, and good control over operating parameters [33].

The following are some advantages of hot melt extraction

1. Reduced number of operation units.
2. Improved substance homogeneity.
3. Anhydrous processing [37].

Advantages

1. Without using any water or solvents.

2. Less stages involved in the processing.
3. The API's compressibility qualities might not matter.
4. Better substitute for medications that dissolve poorly.
5. More even dispersion because of vigorous agitation and mixing.
6. Less energy in comparison to high shear techniques. Thermal deterioration as a result of using high temperatures processing rbecause oflymer's flow characteristics; there are only a limited number of polymers available; and all excipients must be free of water or other volatile solvents [32].

Disadvantages

1. Thermal deterioration because of using high temperatures.
2. Processing requires the polymer's flow characteristics.
3. There are only a limited number of polymers available.
4. All excipients must be free of water or other volatile solvents [41].

8.4 Solid dispersion Extrusion

Using this technique, drug-immiscible components are extruded, and solid dispersions are subsequently created. Ultimately, dies are used to mold the solid dispersions into films [20]. This approach involves dissolving the medicine in a suitable liquid solvent, adding the solution to a polyethylene glycol melt that may be reached below 70˚C, and then using dies to mold the solid dispersions into films [37].

8.5 Rolling method

A drug-containing solution or suspension is rolled on a carrier using the rolling method. The primary solvents are alcohol and water mixtures [40]. After being dried on the rollers, the film is cut into the appropriate sizes and shapes [42].

9. VARIOUS TECHNOLOGIES USED IN ORAL FILM FORMULATION

9.1 XGel

The core of Meldex International's intellectual property, which powers both its ingestible delivery technologies and its entire film system, X Gel film may improve the stability of the product. Additionally, it has been developed for non-food uses, including ostomy pouches, cosmetics, sanitary products, and medical equipment. The process of "solution casting" is used as the producer of XGel films [29].

9.2 Soluleaves

The film releases its API when it stays on the tongue and comes into mixing with saliva. The film sticks to the mucous membrane during this phase, allowing the medication to be released gradually over a 15-minute period. Moreover, flavors are employed in this method [26].

9.3 Foamburst

In this version of the SoluleavesTM technology, an inert gas is injected into the film while it is being made. As a result, a honeycomb-structured film is produced, which dissolves quickly and produces a strange mouthfeeling [41].

9.4 Micap

To combine its knowledge of micro encapsulation technology with the water-soluble BioProgress films, Micap plc signed an option agreement in 2004 [37].

9.5 Wafertab

Wafertab is a medication administration technology that combines ingestible films with pharmacological actives. This can be applied topically or orally, opening a wide range of creative drug design options and allowing for the bonding of numerous films containing various active ingredients [27].

9.6 Rapid film

Applied Pharma Research (APR) has created a new thin-film technology. It is a drug-containing thin film having a surface area of 1–10cm in twenty seconds, total disintegration takes place [27].

10. APPLICATION

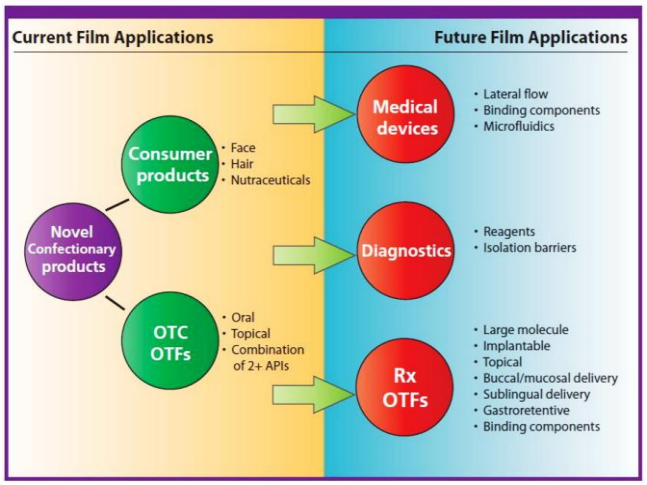

Figure 2: Application of Fast dissolving films [43].

CONCLUSION

Fast dissolving oral films offer a novel approach for efficient drug delivery, providing several advantages over traditional dosage forms. These films are particularly beneficial for patients with swallowing difficulties, pediatric, and geriatric populations. The use of FDOFs can improve patient compliance, reduce the risk of choking, and provide a rapid onset of action. Various technologies are available for preparing FDOFs, and the choice of technology depends on the specific requirements of the formulation. Overall, FDOFs have the potential to revolutionize the way medications are administered, and further research is needed to fully explore their applications and benefits. With their potential to improve patient outcomes and enhance the quality of life, FDOFs are an exciting area of research and development in the pharmaceutical industry.

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