Review Article

Fast dissolving films: Brief review on preparation methods, ingredients and technology used

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Abstract

The Oral fast dissolving drug delivery system is defined as dissolved or disintegration in few seconds or within a few minutes hold in the mouth without water and swallowing. In recent years oral fast dissolving films is promising drug delivery system due to several advantages for pediatric and geriatric patient who have trouble to swallowing conventional oral dosage types. over few decades fast disintegrating tablets have gained significant attention alternative to conventional tablet and capsule due to good patient compliance FDTs are solid dosage form which is rapidly disintegrate usually in seconds or minutes when placed on the tongue but there are still some changes due to chocking. Oral fast dissolving films is another way to solve this issue, as oral strips have been novel for the past few years and are well accepted by customers for distribution. Nowadays, breath strips, supplements and a variety of personal care items are commonly used by consumers. This review consists of updates on methods, ingredients and different technology used in fast dissolving film.

***Keywords*:** Fast dissolving films, Oral strip, pediatric patient, geriatric patient

Introduction

Among the drug delivery routes, oral route is one of the most convenient, cost-effective and favoured route of drug administration. However, certain patients, particularly paediatrics and geriatrics, have trouble swallowing or chewing some oral firm dosage types, such as tablets and hard gelatin capsules (Joshua et al., 2016) One of the most crucial routes of administration of a high-credit drug to achieve systemic effect is oral administration for its simplicity, comfort by not causing pain compared to systemic administration, and other remarkable benefits over other routes (Jassim et al., 2018).

There is an increasing need for innovative drug formulations to satisfy the needs of the paediatric and geriatric community Several quick disintegrating drug delivery devices have been developed and sold to support or accommodate these patients. However, certain fast disintegrating solid preparations suffer from some significant disadvantages, including risk of choking/swallowing, smell and friability, and the need for advanced and expensive packaging. In order to overcome these disadvantages and satisfy the needs of the consumer, intraoral film has been developed (Panda et al., 2016).

The current and novel oral drug delivery system dissolves or disperses rapidly in a few seconds after it is put in the mouth without drinking or chewing. As fast dispersing films are inserted in the mouth, the dosage type disintegrates instantaneously or within a few seconds, releasing medications that dissolve or spread in saliva. Sublingual mucosa is relatively permeable due to thin membranes and broad veins. It provides rapid absorption and instant bioavailability of medications due to high blood flow. Here an effort is made to investigate various polymers for use in the formulation of fast-dissolving strips (Kulkarni et al., 2010).

FDF's technologies continue to be seen as an alternative for FDT products that offer a superior obstacle to over-the-

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counter brands' generic entry and consumer competition. Registered oral disintegrating films technique is beneficial from a commercial point of view. The grant of marketing exclusivity over a new dosage form would help to produce more sales. Various synonyms used by FDFs include mouth dissolving films, oral disintegrating films, molten in-mouth films, oro-dispersible, quick dissolving and rapid disintegrating films (Mandeep et al., 2013).

Dissolving the mouth film provides a promising pathway for systematic drug distribution. The systemic bioavailability is increased due to the first-pass bypass effect and the permeability of the well-supplied vascular and lymphatic drainage. Large absorption surface, quick administration, pain avoidance, and selective drug delivery sites make oral mucosa very attractive and effective (Ghodake et al., 2013).

Active Pharmaceutical Ingredient

A conventional film composition includes 1 to 25% w/w of the substance. Fast dissolving films can exhibit a wide range of APIs. Small dose molecules are the good candidates for incorporation into OFDFs. Multivitamins up to 10% w/w of dry film weight was incorporated in the films with dissolution time of less than 60 seconds. It is a advantageous to have micronized API because it improves the texture of the film as well as for better Dissolution and uniformity of the OFDFs. Many APIs that may be candidates for OFDF technologies have a bitter taste.

This makes the formulation unpalatable, especially in pediatric preparations. As a result, before adding the API into the OFDF, the taste must be masked. To enhance the palatability of the formulation, alternative methods may be used. Among the methods used, the simplest involves combining and co-processing bitter tasting API with pleasant tasting excipients. This is often referred as an obscuration technique (Bhyan et al., 2011).

Drug Selection Criteria

The taste of this drug should be pleasant and low dose up to 40 mg should be used with the medication, the medications of smaller and moderate molecular weight are preferred. It is necessary to have good solubility in water as well as in saliva and also good stability is required. It should be partially unionized at the pH of oral cavity and ability to permeate the oral mucosal tissue (Mandeep et al., 2013; Bala et al., 2013).

Polymer Selection

The polymer choice during the formulation development of

Table 1. Natural Polymers used in the formulation of fast dissolving film (Bala et al., 2013; Nair et al., 2015; Joshua et al., 2016; Patil et al., 2020; Pathare et al., 2013)

Polymers	Molecular Weight	Source	Used As
Maltodextrin	504.5 g/mol	Maltodextrin is an oligosaccharide It is produced from starch by partial hydrolysis and is usually found as a white hygroscopic spray-dried powder	Film forming polymer
Chitosan	1526.5 g/mol	which is mainly made from crustacean shells	Film forming polymer
Gelatin	10000 g/mol	Gelatin is prepared by the thermal denaturation of collagen, isolated from animal skin, bones and fish skins	Film base
Sodium Alginate	216.12 g/mol	Alginate is an indigestible biomaterial produced by brown algae (Phaeophyceae, mainly Laminaria)	Film forming polymer
Rosin	296.31 g/mol	Rosin is a thermoplastic acidic product isolated from exudates of living pine trees & from freshly cut and stump wood of various species of pine	Film forming polymer
Pectin	194.14 g/mol	Pectin is a heterogeneous grouping of acidic structural polysaccharides, found in fruit and vegetables and mainly prepared from citrus peel and apple pomace	Film forming polymer
Starch	359.33 g/mol	Starch is the major carbohydrate reserve in plant tubers and seed endosperm Biopolymer starch is composed of glucose units and having two main constituents are, amylose and amylopectin	Film forming polymer
Gum Carrageenan	551.8 g/mol	linear chain of partially sulphated galactans These sulphated polysaccharides are extracted from the cell walls of various red seaweeds (Rhodophyceae)	Mucoadhesive, Film forming polymer
Pullulan	574.570 g/mol	extracellular microbial polysaccharide produced by the fungus-like yeast, Aureobasidium pullulans	Film forming polymer

polymeric matrices may be a crucial parameter. Several examples were provided relevant to the polymer's ability to affect the mechanical and texture properties of the films, as well as their effect on drug release. However, the presence of the drug material in the polymer matrix may have a major impact on the mechanical properties of the film. Aesthetic and performance characteristics should also be evaluated when choosing a polymer. This dosage formulation is intended for oral administration and may have some residence time in the oral mucosa. As a result, polymers that have the potential to be unpleasant should be avoided. Therefore, as result, factors such as taste masking, physical appearance and mouth feel should be evaluated. Hydrophilic polymers are the most often used in the preparation of oral film matrix, helping the film to dissolve smoothly and gently in the oral cavity. Low-molecular-weight polymers dissolve more quickly in general. But polymers with a higher molecular mass, on the other hand, build films with superior mechanical properties. Furthermore, the polymer should be preferentially ready-to-use, non-toxic or not-irritant to the oral mucosa, and preferably in expensive. In order to optimize and improve the final polymeric matrix properties, it is desirable to use a polymer mixture rather than a one-polymer-based film (Karki et al., 2016; Borges et al. 2015).

Challenges

The following are some of the challenges in developing a fast-dissolving oral film and trying to elaborate and solve these issues like drug insolubility, reduced film drying time, taste masking of bitter and obnoxious drug, incorporation of a high dose in the film then the use of two or more drugs at the same time. stability of film against humidity and temperature it is necessary to use special packaging, dosage uniformity is also important challenge in film development (Jadhav et al., 2013; Singh et al., 2018).

Technologies

1. Soluleaves

Technology is used to create a variety of oral delivery films that can contain active ingredients, colours and flavors Soluleaves film can be developed to dissolve easily contact with saliva, releasing the active ingredient and flavors quickly. This consistency makes edible film an excellent distribution system for a wide variety of products requiring accelerated release into the mouth. For the pharmaceutical process this method of treatment is particularly useful for pediatric and aged patients who may have trouble swallowing conventional tablets and capsules the delivery system may be used for coughing cold gastrointestinal, pain therapeutic areas offering nutritious products with flavor-release products such as mouth fresheners, confectionery and vitamin products. Soluleaves films can also be built to bind to mucous membranes and release active ingredients slovely over 15 minutes (Kalra et al., 2012).

2. X-gel

X-Gel is at the heart of Meldex's multinational intellectual properties used in all of its film systems and its ingestible delivery technologies. X-Gel film Technology, produced by Bio Progress, is creating a revolution in the product offerings and manufacturing methods currently applicable to the pharmaceutical industry. X Gel film, potentially enhance the product stability. ostomy pouches, sanitary and healthcare devices. The development and manufacture of X-Gel films uses a means called "solution casting"(Mandeep et al., 2013).

3. Wafertab

Patented 'Wafertab' is a wafer used as a drug delivery system that uses a unique process to prepare drug-loaded thin films that can be used for topical or oral applications. After casting, the active ingredients are incorporated into the film. The system provides accelerated dissolution and release of active pharmaceutical agents as the strip comes into contact with salivary secretions within the buccal cavity. The wafertab film strip can be flavored for better taste masking. The wafertab device provides several possibilities for creative product design, allowing several films of various active ingredients to be bound together. Wafertab can be prepared in a variety of shapes and sizes and is an ideal method for the administration of therapeutic

Table 2. Synthetic Polymers used in the formulation of fast dissolving film (Bala et al., 2013; Nair et al., 2015; Joshua et al., 2016; Patil et al., 2020; Pathare et al., 2013)

Polymers	Molecular Weight	Source	Used As
Polyethylene glycol 400	380-420 g/mol	Polyethylene glycol is a polyether compound derived from petroleum, depending on its molecular weight.	Stabilizer, plasticizer
Kollicoat	250,000 g/mol	Kollicoat a polyvinyl alcohol–polyethylene glycol graft copolymer	Film forming polymer
Poly Vinyl Alcohol	44.05 g/mol	Polyvinyl alcohol (PVA), which is essentially made from polyvinyl acetate through hydrolysis	Plasticizer, Film forming polymer
Poly Vinyl Pyrrolidone	111.14 g/mol	this polymer made from the monomer *N*-vinylpyrrolidone	Film forming polymer

agents that require fast release or for use in patients that have trouble swallowing (Panda et al., 2016).

4. Foamburst

Foamburst is a patent issued in September 2004 for foam film capsules. During processing, gas is blown into the film, resulting in a film with a honeycombed structure. the voidsin in the film can be gas-filled, empty or filled with other materials for the development of special flavour characteristics or for the distribution of active drugs. The light honeycombed composition results in capsules that dissolve instantly, creating a feeling of melting in the mouth. 'FOAMBURST' has attracted from and confectionary manufacturers as a way of conveying and releasing flavours (Mandeep et al., 2013).

5. Micap

Micap plc signed a choice agreement in 2004 to merge its experience in micro-encapsulation processing with Bio progress water-soluble films. Developments would be targeted at offering alternative distribution channels for the $1.4 billion worldwide demand for smoking cessation products (SCPs). Various FDOF products available on the global market (Panda et al., 2016).

Formulation Methods

The manufacturing of orally dissolving films is done by various methods such as:

Solvent casting method

In this method, water-soluble polymers are dissolved in an appropriate solvent and the drug and other excipients are dissolved in an appropriate solvent. Then both solutions are mixed and stirred together. This solution is then degassed under vacuum to settle the air bubbles. This bubble-free solution is then finally cast onto the Petri plate and dried (Musazzi et al., 2020).

Semisolid casting method

This process is preferably used where acid insoluble polymers are used in film preparation. acid Insoluble polymers used for film development include: phthalate cellulose acetate, butyrate cellulose acetate. Acid insoluble polymer and film forming polymer can be used at a ratio of 1:4. Solution of water-soluble film forming polymer is formulated Resulting solution is added to an acid-insoluble polymer solution Sufficient amount of plasticizer is added such that the gel mass is collected. The gel mass is then cast into the film or ribbons using heat-controlled drums. (Rathod et al., 2013) The thickness of the film should be about 0.015-0.05 Inches (Joshua et al., 2016).

Hot melt extrusion method

The hot melt extrusion is basically same as the melting process, except that the intense mixing of the materials is induced by the extruder. In the hot melt extrusion process, the drug is first combined with the carrier in solid form. And the extruder with the heater melts the mixture. In the end, the melt is shaped by the cavities of the dies and formation of films. There are some advantages of hot melt extrusion, in other words. Few processing units, better content uniformity and anhydrous phase (Jadhav et al., 2013).

Rolling method

A solution or suspension of a drug with film forming polymer is prepared and subjected to a roller by the rolling method. Specific rheological consideration should be given to the solution or suspension. The solvent is mostly water and a combination of alcohol and water. The film is dried on the rollers and cut to the appropriate shapes and sizes (Bhyan et al., 2011).

Solid dispersion extrusion

The term solid dispersion refers to the dispersion of one or more APIs in an inert carrier in a solid state in the presence of amorphous hydrophilic polymers using methods such as HME. In this method, immiscible components are extruded with drug and then solid dispersions are prepared. In the end, solid dispersions are formed into films by means of dies (Mandeep et al., 2013).

Evaluation parameters commonly used

Physicochemical Evaluation

The Physicochemical assessment of the substance like

Table 3. Semi- Synthetic Polymers used in the formulation of fast dissolving film (Bala et al., 2013; Nair et al., 2015; Joshua et al., 2016; Patil et al., 2020; Pathare et al., 2013)

Polymers	Molecular weight	Source	Used as
Hydroxypropyl cellulose	806.9 g/mol	Hydroxypropyl cellulose as partially substituted poly (hydroxypropyl) ether of cellulose	Film forming polymer
HPMC E3 HPMC E5 HPMC E15	1261.4 g/mol	Cellulose derivatives are polysaccharides composed of linear chains of β (1–4) glucosidic units with methyl, hydroxypropyl or carboxyl substituents	Film forming polymer

colour, odour and shape are commonly used. All films were examined physically for colour and shape. In-vitro methods using taste sensors, specially built apparatus, and drug release through designed pharmacopeial methods are being used for this purpose (Bhyan et al., 2011).

Mechanical Properties

Thickness

All batches were tested for thickness using a calibrated digital micrometre. Three measurements from all batches were taken and the mean thickness was measured (Saini et al., 2011).

Dryness/tack test

There are nearly eight phases of the film drying process that have been described, and they are set-to-touch, dust-free, Dry-to touch, tack-free (surface dry), dry-hard, dry-through (dry-to-handle), dry-to-recoat and dry print-free. Although these experiments are mainly used to evaluate paint films, the majority of the studies can be elegantly designed to evaluate pharmaceutical OFDF. The aspects of evaluating these criteria can be found elsewhere and are beyond the scope of this paper. Tack is the tenacity of which the strip adheres to an accessory (a sheet of paper) that has been pressed into contact with the strip. Instruments are also available for this test (Bhyan et al., 2011).

Tensile Strength (Bhyan et al., 2011)

Tensile strength is the maximum stress applied to a point at which the film specimen breaks It is calculated by the applied load at rupture divided by the cross-sectional area of the film.

Tensile strength is measured using Formula:

$$\text{Tensile strength} = \frac{\text{Force at break}}{\text{Strip thickness} \times \text{Strip Width}}$$

% Elongation (Tope et al., 2014)

When stress is applied, a film sample stretches and this is referred to as strain. Strain is basically the deformation of film divided by original dimension of the sample. Generally, elongation of film increases as the plasticizer content increases.

$$\%\ \text{Elongation} = \frac{\text{Increase in length}}{\text{Original length}} \times 100$$

Young's Modulus (Jadhav et al., 2013)

Young's modulus or elastic modulus is the measure of stiffness of film. ratio of applied stress over strain in the region of elastic deformation as follows

$$\text{Youngs modulus} = \frac{\text{Slope}}{\text{Film thickness} \times \text{cross} - \text{head speed}} \times 100$$

Tear Resistance

Plastic film has tear resistance is a complex property of its ultimate rupture resistance. The force used to initiate tearing is measured using a very low rate of loading of 51 mm

(2 in)/min. The tear resistance value in Newtons (or pounds force) is the highest stress or force needed to tear the specimen (which is usually located at the beginning of tearing) (Bhyan et al., 2011).

Folding Endurance

The number of folds, i.e., how many times the film is folded at the same position that allowed the film sample to be broken, is known as folding endurance. This term gives an indicator of film brittleness that the strip was continuously subjected to this examination by film folding at the same point before a visible crack was found, the values are taken as folding endurance (Jassim et al., 2018).

Moister Contain (Nirmala et al., 2016)

The prepared films were weighed and stored at room temperature in a vacuum desiccator containing anhydrous silica. The film was measured several times until it indicated a stable weight. The formula was used to calculate the percentage of moisture content,

$$\%\text{Moisture Content} = \frac{(\text{Initial weight of the film} - \text{Final weight of the film})}{\text{initial weight of the film}} \times 100$$

Swelling Test

Swelling tests are carried out using a simulated saliva solution. Each film sample is weighted and put in a stainless-steel wire mesh that has been pre weighed. In a plastic container, the mesh holding the film sample is immersed in 15ml medium. The weight of the film was measured at fixed intervals before it reached a steady weight.

Following parameters were used to measure the degree of swelling.

$$\alpha = \frac{wt - w}{wo}$$

where,

wt is weight of film at time t, and

wo is weight of film at time zero (Bhyan et al., 2011).

Surface ph

When film is inserted in the oral cavity for dissolution, the film's surface pH should be close to that of saliva, i.e., 6.8, to avoid irritation. The pH of each sample was measured in triplicate and found to be between 6.75 and 6.85, with an average of around pH 6.80, indicating that the pH range was within the target pH and suitable for the oral cavity (Reddy and Ramana Murthy, 2018).

Contact Angle

At room temperature, a goniometer (AB Lorentz and wettre, Germany) is used to calculate the contact angle. Apply a drop of distilled water to the surface of a dry film. A digital camera was used to capture images of water droplets within 10 seconds of their deposition. On both sides of the drop, the contact angle was determined, and the average was taken (Saini et al., 2012).

Transparency

A basic UV spectrophotometer can be used to calculate the transparency of the films.

Cut the film into a rectangle and insert it into the spectrophotometer cell. Determine the film transparency at 600nm. The film's transparency was measured as follows:

Where,

$$\text{Transparency} = \frac{(\log T600)}{b} - \epsilon C$$

T600= transmittance at 600nm

b= film thickness (mm)

C= concentration (Saini et al., 2012)

Content Uniformity

This is calculated by any standard assay procedure defined in any of the standard pharmacopoeias for the specific API. The drug content in each film is estimated to determine content uniformity. The content uniformity limit is 85-115 % (Saini et al., 2012).

In-Vitro Disintegration Time

The disintegration time is measured by modified disintegration procedure, that the product (film) was placed in a petri dish that hold 10 ml of specified buffer (pH 6.8 phosphate buffer); the time when the film is completely disintegrated was documented as disintegration time. (Jassim et al., 2018)

Disintegration of orally fast dissolving films requires USP disintegration apparatus. The disintegration time limit of 30 seconds or less for orally disintegrating tablets described in CDER guidance can be applied to fast dissolving oral strips. Disintegration time will vary depending on the formulation but typically the disintegration range from 5 to 30 seconds. Although, no official guidance is available for oral fast disintegrating films strips (Bhyan et al., 2011).

In-Vitro Dissolution Studies

Dissolution study was carried out in USP basket type (apparatus using the stimulated salivary fluid (pH 6.8) as a dissolution medium at 50 rotations per minute. 10 ml aliquots were withdrawn at one minute time intervals and same amount of fresh dissolution medium was added. The aliquots were assayed for drug content at maximum wavelength of drug using UV-spectrophotometer. The cumulative percentage drug release was Calculated (Saini et al., 2011).

Permeation Studies

Permeation studies are carried using the modified Franz diffusion cell by using porcine buccal mucosa. The mucosa is mounted between the donor & receptor compartment of Franz diffusion cell. The receptor compartment is filled with buffer & maintained at 37 °C ± 0.2°C & the hydrodynamics were maintained by stirring with a magnetic bead at 50 rpm. One previously weighed film is placed in intimate contact with the mucosal surface of the membrane that should be previously moistened with a few drops of simulated saliva.

The donor compartment is filled with 1 ml of simulated saliva of pH 6.8. Samples are withdrawn at suitable interval, replacing the same amount with the fresh medium.

The percentage of drug permeated is determined by measuring the absorbance by selected analytical method (Abd and Mostafa, 2018).

Conclusion

The demand for fast dissolving film is increases now a days because several advantages and good patient compliance. It is rapidly growing to create a new tomorrow, as a revolutionary and an innovative dosage forms for all age groups, specifically paediatric, geriatric patients and patients with swallowing difficulties. developer try to several APIs incorporated into this innovative oral film dosage form. Research and development persons believe that during the next 5-10 years because of the immediate release and ease of processing, fast dissolving film would capture the pharmaceutical industry's attention in a big way.

Abbreviations

FDT – Fast Dissolving Tablet, FDF – Fast Dissolving Film, API – Active Pharmaceutical Ingredient, NSAID – Nonsteroidal Anti-Inflammatory Drugs, HPMC – Hydroxy Propyl Methyl Cellulose, OFDF – Oral Fast Dissolving film, USP – United States Pharmacopeia, CDER – Center for Drug Evaluation and Research.

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