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A DETAILED REVIEW ON FAST DISSOLVING ORAL FILM

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ABSTRACT

The oral route of drug administration is one of the most preferred routes of drug administration because of its low cost and ease of administration increases patient compliance. Fast-dissolving drug delivery systems (FDDDS) were developed for those patients who have difficulty swallowing tablets and hard gelatine capsules especially geriatric and pediatric patients. This dosage form is an alternative to tablets, capsules, and syrups. Fast-dissolving oral thin film is a more acceptable and accurate oral dosage form that bypasses hepatic first-pass metabolism and provides a therapeutic response by increasing bioavailability. This technology has been used for local action and rapid release of the drug. It is relatively a new dosage form in which thin film is prepared using hydrophilic polymers, which rapidly disintegrate or dissolve on the tongue or in the oral cavity. The present review gives an account of different formulations, methods of preparation, and quality control of thefast-dissolving oral thin films.

KEYWORDS: Oral Film, Patient compliance, first-pass metabolism, hydrophilic polymers.

INTRODUCTION

Oral route (solid drug delivery) is the most popular route due to ease of administration, pain avoidance, versatility (to accommodate different drugs), and, most importantly, patient compliance. Solid oral delivery systems do not require sterile conditions and are thus less expensive to manufacture. Several innovative oral administration systems have recently become available to address medication physicochemical and pharmacokinetic properties while enhancing patient compliance. However, some patients, especially pediatrics and geriatrics, have difficulties swallowing or chewing some oral solid dosage forms like tablets and hard gelatine capsules. Because of the fear of choking, they are unable to take these dosage forms. Problems such as excessive first-pass metabolism and drug degradation in the gastrointestinal environment can be avoided by delivering the medicine by oral absorption. To overcome this problem, fast-dissolving drug delivery systems (FDDDS) were developed. Fast-dissolving oral thin films are ultra-thin films that contain a hydrophilic polymer that quickly hydrates or clings to the tongue or oral cavity when put there. These films crumble or dissolve in seconds, releasing the active substance without the need for drinking or chewing. These dose forms do not require water to be administered. Because the oral mucosa is heavily endowed with blood flow, medicines are absorbed quickly and have immediate bioavailability. The bypassing of first-pass metabolism leads in immediate bioavailability. As a result, they are typically created for medications with high first-pass metabolism in order to improve bioavailability. Oral thin-film technology is still in its early phases, but it has a promising future due to patient compliance.

Some Factors are taken into Consideration

- Drug Lipophilicity.
- Solubility
- PH and pKa of saliva.
- Drug release from the formulation.

Salient Feature of Fast Dissolving Drug Delivery System

- Ease of administration for patients who are mentally ill disabled and uncooperative.
- Require no water.
- Overcomes unacceptable taste of the drugs.
- Can be developed to leave minimal residue in the mouth after delivery while simultaneously providing a pleasant mouth feel.

- Capability to give the benefits of liquid medication in the form of a solid preparation.
- It is economical.

Types of Fast-Dissolving Oral Film

There are three subtypes:

- Flash release.
- Mucoadhesive melt release.
- Mucoadhesive sustained release.

Advantages

- It can be taken without water.
- A large surface area provides rapid disintegration and dissolution in the oral cavity.
- It should be flexible and light in weight.
- It is appropriate for all age groups.
- Appropriate for patients who are ill or uncooperative.
- Avoiding the risk of choking
- Avoid first-pass metabolism and provide a quicker onset of action at lower doses.

Disadvantages

- High doses cannot be incorporated.
- Dose uniformity is a technical challenge.
- Hygroscopic in nature.
- Require special packaging for products.
- Stability and safety.

Ideal Characteristics of Suitable Drug Candidate

- The drug should have a pleasant taste.
- The drug to be incorporated has a low dose of up to 40 mg.
- Smaller and intermediate molecular weight medicines are preferred.
- The medicine should be stable and soluble in water as well as saliva.
- It should be partly unionized at the oral cavity's pH.
- It should be able to penetrate oral mucosal tissue.

Standard Composition of Fast-Dissolving Oral Thin Film

It is a thin film having an area of 5-20 cm 2 containing the drug. The drugs can be loaded up to a single dose of 30 mg. From the regulatory perspective, all the excipients used in the formulation must be generally regarded as safe (i.e., GRAS-listed) and must be approved for use in oral pharmaceutical dosage forms. A typical formulation contains the following ingredients

- Active Pharmaceutical Ingredient
- Film Forming Polymer
- Plasticizer
- Sweetening Agent
- Saliva Stimulating Agent
- Flavouring Agent
- Colouring Agent

Table 1: concentration of compositions.

Sr No.	Ingredients	Concentrations
1	Active Pharmaceutical Ingredient	1-25%
2	Film Forming Polymer	40-45%
3	Plasticizer	1-20%
4	Sweetening Agent	3-6%
5	Saliva Stimulating Agent	2-6%
6	Flavouring Agent	5-10%
7	Colouring Agent	0-1%

Active Pharmaceutical Ingredient

A typical film composition includes 1-25% w/w of the medication. A wide range of APIs can be supplied using fast-dissolving films. Small dosage compounds are the greatest candidates for incorporation into OFDFs. Multivitamins up to 10% w/w of dry film weight were integrated into the films with a disintegration time of less than 60 seconds. It is usually beneficial to have micronized API, which improves the texture of the film as well as the dissolution and homogeneity of the OFDF. Many APIs that may be candidates for OFDF technology have a harsh flavor. This renders the formulation unpleasant, particularly for pediatric medicines. As a result, before merging the API into the OFDF, the flavor must be muted. To increase the palatability of the formulation, many ways might be applied.

Film Forming Polymers

Water-soluble polymers are utilized to produce films because they give the finished products an excellent mouth feel, quick disintegration, and mechanical strength. The kind of polymer and how much of it is included in the formulations determines how sturdy the strip will be. A water-soluble polymeric film binds to the buccal mucosa and quickly enters the systemic circulation to administer medicine, according to Department of Pharmaceutics AACOP, Akkalkuwa. Pullulan, gelatin, and hypromellose are the most often utilized polymers among the several that are available for the creation of films. The overall weight of the dry film should typically contain 45%w/w of polymer.

Table 2: Film Forming Polymers.

Natural polymer	Synthetic polymer
Pullulan	Hydroxypropyl methylcellulose
Xanthan gum	Polyvinyl pyrrolidone
Pectin	Polyvinyl alcohol
Starch gelatine	Carboxymethylcellulose
Sodium Alginate	Polyethylene oxide
Maltodextrin	Hydroxypropyl cellulose
Polymerized rosin	Kollicoat

Ideal Property of Film Forming Polymers

- It should be non-toxic and non-irritant
- The polymer must be hydrophilic
- It should have an excellent film-forming capacity
- It should have good wetting and spreadability property
- Polymer should be readily available & should not be very expensive.
- Polymers should have low molecular weight.
- It should have a sufficient shelf-life.
- The polymer must be tasteless, and colorless.
- It should not cause any secondary infection in the oral mucosa.
- It should exhibit adequate peel, shear, and tensile strengths.

Plasticizers

It is a necessary component of the oral films. The choice of plasticizer is based on how well it works with the polymer and the kind of solvent used in the film's casting process. It improves the flexibility of the film and reduces the brittleness of the film. The strip properties of plasticizers are significantly improved by reducing the glass transition temperature of the

polymer. They are used in the concentration of 1 – 20%w/w introduction Department of Pharmaceutics AACOP, Akkalkuwa. 12 of the dry polymer weight. Examples include Glycerol, propylene glycol, Low molecular weight polyethylene glycols, Citrate derivatives like triacetin, acetyl citrate, phthalate derivatives like dimethyl, diethyl, dibutyl derivatives, Castor oil, etc.

Sweetening agents

Sweeteners are now a crucial component of every formulation that is meant to dissolve or disintegrate in the mouth. Typically, sweeteners are employed at a concentration of 3-6% weight to weight. The creation of these quickly dissolving films involves the use of both natural and artificial sweeteners. Because they also have a pleasant mouthfeel and a cooling effect, polyhydric alcohols like sorbitol, mannitol, and isomalt can be used in combination. However, it should be emphasized that persons who are on a diet or those who have diabetes should limit the use of natural sugars in such preparations. Artificial sweeteners are becoming more widely used in pharmaceutical and culinary preparations as a result.

The first generation of the artificial sweeteners are

- Saccharin
- Cyclamate
- Aspartame

Saliva Stimulating agents

The purpose of utilizing saliva stimulating drugs is to boost saliva production, which will help the formulations for rapid dissolving strips dissolve more quickly. In general, acids that are employed in food preparation can be used to stimulate salivary glands. Examples are

- Citric acid
- Malic acid
- Lactic acid
- Ascorbic acid
- Tartaric acid

These agents are used along are in combination between 2-6 % w/w of the stripes.

Flavoring agents

In the OFDF formulations, flavors are preferably added up to 10% by weight. The initial flavor quality noticed in the first few seconds after the product has been ingested and the

aftertaste of the formulation, which lasts for at least 10 minutes, are the two main factors that determine a person's willingness to accept an oral disintegrating or dissolving formulation. The geriatric population likes mint or orange flavors like fruit punch, raspberry, etc. It can be selected from synthetic flavor oils, oleoresins peppermint oil, cinnamon oil, spearmint oil, and oil of nutmeg are examples of flavor oils while vanilla, cocoa, coffee, chocolate, and citrus are fruity flavors. Apple, raspberry, cherry, and pineapple are a few examples of fruit Essence types.

Coloring agents

FD&C-approved coloring agents are used (not exceeding concentration levels of 1 percent; w/w) in the manufacturing of orally fast-dissolving films. E.g., titanium dioxide.

METHODS OF PREPARATION OF FAST-DISSOLVING ORAL FILMS

One or a combination of the following processes can be used to manufacture the mouth-dissolving films.

- Solvent casting method
- Semisolid casting method
- Hot melt extrusion method
- Solid dispersion extrusion
- Rolling method

Solvent Casting Method

In this procedure, distilled water is used to dissolve a plasticizer and water-soluble polymer. To release all trapped air bubbles, the solution is agitated in the magnetic stirrer for two hours before being set aside. Excipients and API are being dissolved while being thoroughly agitated for 30 minutes. Both solutions are then combined. Finally, a suitable flat surface is used to cast the solution to create a film. Once dry, the film is carefully peeled away.

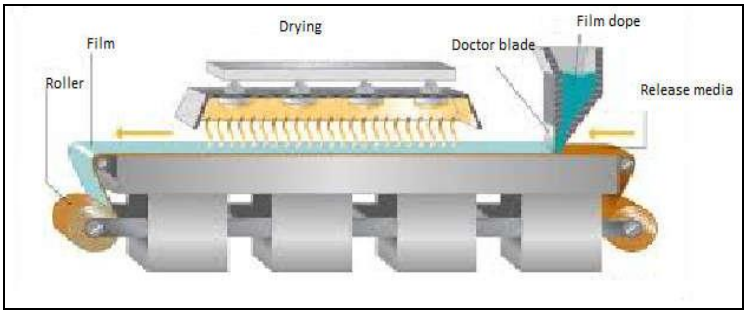

Fig. 1: Diagram of Solvent Casting Film System.

Advantage

- Great uniformity of thickness and greater clarity than extrusion.
- Films have fine gloss & freedom from defects such as die liners.
- Films have more flexibility & better physical properties.

Semisolid Casting Method

The water-soluble film-forming polymer solution is first made in the semisolid casting process. To an acid-insoluble polymer solution that was made in ammonium or sodium hydroxide, such as cellulose acetate phthalate or cellulose acetate butyrate, the resultant solution is added. After that, the proper quantity of plasticizer is added to create a gel mass. Finally, using heat-controlled drums, the gel mass is cast into the films or ribbons. The film is between 0.15 and 0.5 inches thick. The ratio of the film-forming polymer to the acid-insoluble polymer needs to be 1:4. The two mixes are combined to create a homogeneous, viscous solution that is then vacuum-discharged. Untreated casting film is covered with a bubble-free solution before being placed in an aeration drying oven. The movie is split into the desired shape and size.

Hot Melt Extrusion

In the hot melt extrusion method firstly, the drug is mixed with carriers in solid form. Then the extruder having heaters melts the mixture. Finally, the melt is shaped into films by the dies. There are certain benefits of the hot melt extrusion method:

- Fewer operation units
- Better content uniformity
- An anhydrous process

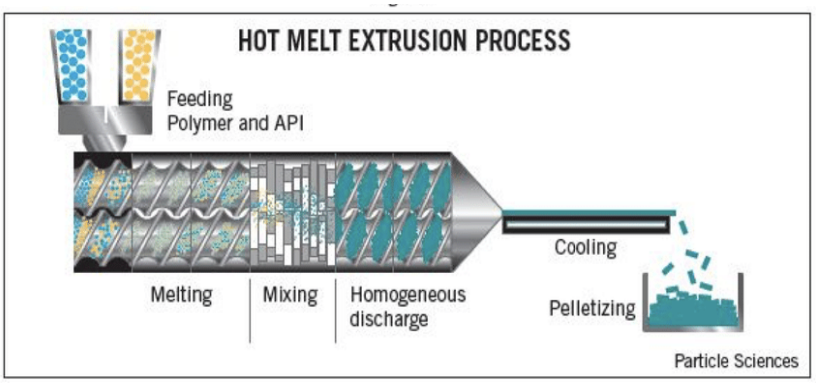

Fig. 2: Diagram of Hot Melt Extrusion Method.

Solid Dispersion Extrusion

Solid dispersion refers to the dispersion of two or more active ingredients in an inert carrier in the presence of amorphous hydrophilic polymers in the solid state. The API is dissolved in a suitable solvent and incorporated into PEG. The drug and solvents are immiscible. Solid dispersions are then shaped into films through dies.

Rolling Method

In a rolling method, a solution or suspension of the drug with a film-forming polymer is prepared and subjected to the roller. The solution or suspension should have specific rheological considerations. The solvent is mainly water and a mixture of water and alcohol. The film is dried on the rollers and cut into desired shapes and sizes. ble flat surface to form a film. The film is dried and carefully removed.

EVALUATION OF FAST-DISSOLVING ORAL FILMS

Prepared films are evaluated for the following parameters.

1. Organoleptic Evaluation

As the film disintegrates in the oral cavity, it should have acceptable organoleptic characteristics like color, flavor, and taste.

2. Weigh of Films

Oral films that dissolve in the mouths were weighed on an analytical scale, and the average weight of each film was calculated. The weight of films should be essentially constant. Making ensuring a film has the right number of excipients and API is helpful.

3. Thickness of Films

The thickness of the film was measured using a micrometer screw gauge at five distinct locations, and an average of three readings was computed. The precision of the dosage in the film is closely tied to the uniformity of the film thickness, hence this is crucial to establish.

4. Folding Endurance

A strip of film is cut and repeatedly folded at the same location until it breaks to assess folding endurance. The value of folding endurance is determined by how many times the film could be folded in the same position without breaking. The film's typical folding endurance ranges from 100 to 150.

5. Tensile Strength

Tensile strength is the maximum stress applied to a point at which the strip specimen breaks. It is calculated by the formula,

$$Tensile\ strength = \frac{load\ at\ failure\ X\ 100}{\text{strip thickness X strip width}}$$

6. Percent Elongation

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

It is calculated by the formula,

$$\%\ Elongation = \frac{\text{Increase in length of strip X 100}}{\text{Initial length of strip}}$$

7. Surface pH

The film to be tested was placed in a Petri dish and was moistened with 0.5 ml of distilled water and kept for 30 s. The pH was noted after bringing the electrode of the pH meter in contact with the surface of the formulation and allowing equilibration for 1 min. The average of three determinations for each formulation was done.

8. In Vitro Disintegration Test

When an oral film comes in touch with saliva or water, it begins to disintegrate at that point. The time of disintegration for a fast-dissolving film should be between 5 and 30 seconds. Disintegration time can be investigated using a USP (United States Pharmacopoeia) disintegration device. Another approach involves dipping the film in 25 ml of water in a beaker to visually assess the disintegration time. The film should be gently shaken in the beaker, and the moment when it begins to shatter or fall apart should be observed.

9. Drug Content Uniformity

This is established using any standard assay technique specified for the specific API in any of the standard pharmacopeia. Estimating the API content in individual strips allows for the determination of content homogeneity. 85-115% is the maximum level of content homogeneity.

10. In-Vitro Drug Release Study

By this method, cumulative drug release and cumulative percentage of drug retained were calculated. In-vitro drug dissolution was performed using a USP paddle-type apparatus. The studies were carried out at 37°C with a stirring speed of 75 rpm in 500 ml phosphate buffer (pH 6.8). 5 ml of samples were withdrawn at predetermined time intervals of 3, 6, 9…, and 30 min and replaced with the same volume of buffer. The samples were collected and the concentration was determined at the appropriate wavelength using a UV-visible spectrophotometer.

11. Stability Testing

Stability measurement is done by storing the oral strips under controlled conditions of 25ºC/60% RH as well as 40°C/75% for 3 months in a stability chamber according to the ICH guideline. During the storage period, various evaluating parameters like thickness, morphological properties, tensile strength, water content, and dissolution behavior are checked.

CONCLUSION

The Pharmaceutical oral wafer is considered a novel work in the pharmaceutical field, this approach of a delivery system is best suited for geriatric, pediatric, and psychiatric patients who have difficulty swallowing, so this approach exhibits less risk and improved patient compliance with higher safety. Since FDOFs bypass the hepatic metabolism, their ease of administration and requirement of no water at the time of drug administration make this delivery a unique one and improve the therapeutic response significantly.

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