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Review Article

A Review on Fast Dissolving Films

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Abstract:

Fast dissolving films (FDFs) are a revolutionary drug delivery system that has gained significant attention in the pharmaceutical and medical fields in recent years. These films offer several advantages over traditional dosage forms, making them a promising option for patients and healthcare providers. In this review, we will delve into the key features, advantages and disadvantages. Various types of methods utilized for the manufacturing of fast dissolving films like Rolling, Semisolid casting, Solvent casting, Hot melt extrusion, Solid dispersion extrusion is discussed here. Different types of evaluation parameters along with applications of fast dissolving films are also mentioned.

Key words: FDFs, Solvent casting, Hot melt extrusion, Rolling.

Introduction

Nowadays, the oral route is the most commonly used method for drug delivery because it offers numerous advantages over other routes of drug administration; however, oral drug delivery systems still require some advancements due to some drawbacks related to a specific class of patients, which includes geriatric, pediatric, as well as dysphasic patients associated with a variety of medical conditions because they have difficulty chewing or swallowing solid dosage forms. Even with rapid dissolving pills, there is a risk of choking because of their tablet-like form. Among other things, the palatability of pediatric oral drug formulations is one of among the most important elements determining adherence to therapy regimens. [1]

A unique drug delivery technology for the oral distribution of pharmaceuticals is a fast-dissolving oral film, which is an

extremely thin film made using hydrophilic polymers that quickly dissolves on the top

or floor of the tongue or buccal cavity. It is a postage stamp-sized ultrathin strip (50-150 microns thick) containing an active agent and various excipients created on the basis of transdermal patch technology. Over the last decade, they emerged from the confectionery and oral care sectors in the form of breath strips and became a unique and highly recognized dosage form by consumers for delivering vitamins and personal care goods. [2]

These fast-dissolving oral films have continued to grow in sales and have been marketed as patient-friendly and convenient solutions, successfully

resolving concerns for medications and nutraceuticals that have historically been provided as oral solid doses. The delivery method consists of a very thin oral strip that is easily put on the patient's tongue or any oral mucosal tissue. When the film is instantaneously moistened by saliva, it rapidly hydrates and binds to the site of application. It then disintegrates in seconds and dissolves, releasing medicine for Oro mucosal absorption. Fast dissolving oral films are already a well-established and widely recognized method for systemic distribution of active pharmaceutical ingredients (APIs). [3]

Key Features of Fast Dissolving Films [4,5]

- Rapid Dissolution: FDFs are designed to disintegrate and dissolve quickly upon contact with saliva, making them an ideal choice for patients who have difficulty swallowing tablets or capsules.
- Ease of Administration: These films are user-friendly and do not require water for administration, which can be particularly advantageous in situations where access to water is limited.
- Improved Bioavailability: FDFs often exhibit enhanced bioavailability due to their rapid dissolution and absorption in the oral mucosa, bypassing the gastrointestinal tract.
- Precise Dosing: Manufacturers can accurately control the dose of active pharmaceutical ingredients in FDFs, reducing the risk of underdosing or overdosing.
- Patient Compliance: FDFs are preferred by patients, particularly children, the elderly, and individuals with dysphagia, as they are easy to consume and do not involve the unpleasant taste or difficulty associated with swallowing tablets or capsules.

Advantages of Fast Dissolving Films [6]

- Taste masking
- No risk of choking and obstruction.
- Improved patient compliance
- No need of water has led to better acceptability amongst the dysphagic patients
- Improved oral bioavailability of drugs
- Enhanced stability
- Oral films are flexible and they are not as fragile as most of the ODTs
- Reduction in first pass metabolism may lead to reduction in the dose.

Disadvantages of Fast Dissolving Oral Films [7]

- Drugs which are unstable at buccal pH cannot be administered.
- Drugs which irritate the mucosa cannot be administered by this route.
- Drug with small dose requirement can only be administered.
- Taste masking- Most drugs have bitter taste, and need taste masking.
- Special packaging- OFDFs are fragile and must be protected from water so it needs special packaging.
- Dose uniformity is a technical challenge.

Manufacturing Methods

The following procedures are often used to create fast dissolving oral films:

a. Rolling.

b. Semisolid casting.

c. Solvent casting.

d. Hot melt extrusion

e. Solid dispersion extrusion.

a. Rolling

Water and water-alcohol mixtures are the most often employed solvents in this approach. The active substance and other components are dissolved in a tiny amount

of aqueous solvent using a high shear processor. Hydrocolloids that dissolve in water produce a homogeneous viscous solution. The drug-containing solution or suspension is then rolled on a carrier. Finally, the film is cut into the proper shapes and sizes. [8]

b. Semisolid casting

First, a mixture of water-soluble film producing polymer is created in this procedure. The resultant solution is then mixed with an ammonium or sodium hydroxide solution of an acid insoluble polymer (e.g., cellulose acetate phthalate). The acid insoluble polymer to film forming polymer ratio should be 1:4. When a proper quantity of plasticizer is added, a gel mass is formed. Finally, the gel mass is casted into films or ribbons using heat-controlled drums.

c. Solvent casting

Water soluble polymers were dissolved in water in this process, and the medication, along with other components, is dissolved in a suitable solvent. The liquids are then combined and agitated before being cast on a petri dish and dried. [9]

d. Hot melt extrusion

The medicine is initially combined with the carriers in solid form in the hot melt extrusion process. The mixture is then melted using an extruder equipped with heaters. Finally, the dies form the melt into films.

e. Solid dispersion extrusion

To begin, solid dispersion is created by extruding immiscible components with medication and then shaping them into films using dies**. [10]**

Evaluation Parameters of Fast Dissolving Films

A. Thickness:

Because the thickness of the film is directly related to drug content uniformity, it is vital to ensure consistency in the thickness of the film. At several important places, it may be measured with a micrometer screw gauge either calibrated digital Vernier Calipers.

B. Tack testing/dryness tests

The film drying process is divided into eight stages: set to touch, dust free, tack free (surface dry), dry to touch, dry hard, dry through (dry to handle), dry to recoat, and dry print free.

Although these tests are typically utilized for paint films, the majority of the investigations may be meticulously altered to analyze pharmaceutical OFDF. The specifics of evaluating these characteristics may be found elsewhere and are beyond the scope of this study. The tenacity with which the strip sticks to an accessory (a piece of paper) that has been pushed into contact with the strip is referred to as tack. This research also has instruments accessible. [11]

C. Tensile power:

Tensile strength is the greatest stress that may be applied to a strip specimen before it breaks. It is computed by dividing the applied load at rupture by the cross-sectional area of the strip, as shown in the following equation:

$$\textbf{\textit{Tensile Strength}} = \frac{\textbf{\textit{Load at Breakage}}}{\textbf{\textit{Strip thickness}} \text{ x } \textbf{\textit{Strip width}}}$$

D. Elongation in percentage:

When the film breaks, enough force is applied to surpass the elastic limit, the % elongation is measured. The following equation may be used to calculate percentage elongation: [12]

$$\%\ \textbf{\textit{Elongation}} = \frac{\textbf{\textit{Increase in lenth at breaking point}}\ (mm)}{\textbf{\textit{Original length}}\ (mm)} \text{ x } 100$$

E. Palatability test:

The study of palatability is based on taste, which comes after bitterness as well as physical appearance. According to the criteria, all batches are graded A, B, or C. When a formulation receives at least one A grade, it is deemed average. When a formulation receives two A grades, it is

deemed excellent, and when it receives all three A grades, it is regarded very good.

A=very excellent, B=good, and C=poor.

F. Resistance to Tears

Plastic film or sheeting tear resistance is a complicated function of its ultimate resistance to rupture. To quantify the force required to induce tearing, an extremely low rate of loading of 51 mm (2 in)/min is used. The tear resistance value in Newtons (or pounds-force) is the maximal stress or force necessary to tear the specimen (which is usually determined around the commencement of tearing). [13]

G. Endurance in Folding

Folding endurance is measured by repeatedly folding the strip at the same location until the strip breaks. The folding endurance value is calculated by counting the number of times a film can be folded without breaking.

H. Young's Modulus

Young's modulus, also known as elastic modulus, is a measure of strip stiffness. It is expressed as the applied stress over strain ratio in the area of elastic deformation as follows:

$$Young's\ modulus = \frac{Slop\ x\ 100}{Strip\ thickness\ x\ Cross-head\ speed}$$

I. Disintegration time:

The CDER recommendation disintegration time restriction of 30 seconds or less for orally disintegrating tablets may be applied to fast dissolving oral strips. Although no formal guidelines for oral rapid dissolving film strips is available, this may be utilized as a qualitative guideline for the quality control tests or during the development stage. This investigation may make use of pharmacopoeia disintegrating test equipment. Strips often disintegrate after 5-30 seconds.

J. Dissolution examination:

Dissolution testing may be carried out using any of the pharmacopoeia's standard basket / paddle gear. The dissolving medium will be chosen based on the sink conditions and the greatest dosage of the API. When using the paddle equipment, the strip has a propensity to float onto the dissolving liquid, making the dissolution test difficult. [14]

Applications of Fast Dissolving Films: [15]

- Pediatric Medicine: FDFs are widely used for administering medications to children who often have difficulty swallowing tablets or capsules.
- Geriatric Care: The elderly, who may have impaired swallowing reflexes, benefit from the ease of administration provided by FDFs.
- Travel Medicine: Travelers find FDFs convenient, as they don't require access to water for administration.
- Psychiatry and Pain Management: Rapid-acting medications used in psychiatric conditions and pain management can be delivered effectively through FDFs.
- Oral Care: FDFs can also be used for oral care products like breath fresheners, teeth whitening, and oral pain relief.

Conclusion

In conclusion, fast dissolving films represent an innovative drug delivery system with numerous benefits, particularly for patients who have difficulty swallowing traditional dosage forms. While there are challenges associated with their development and regulatory approval, their ease of administration, convenience, and potential for improved patient compliance make them a promising avenue for pharmaceutical companies and healthcare providers. As technology and formulation techniques continue to advance, FDFs have the potential to play a more prominent role in the future of drug delivery.

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