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Fast Dissolving Drug Delivery System (FDDDS)

A Uday, Maya Patel, Pramod Kumar Singh , Dr. Gyanesh Kumar Sahu, Suchita Wamankar, Anjali Sahu

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Abstract
The pharmaceutical industry is becoming increasingly interested in the fast dissolving drug delivery system (FDDDS), one of many innovative drug delivery methods. As an alternative to traditional tablets, capsules, and syrups, FDDDS were created. These come in the form of FDTs, or fast dissolving tablets. and oral films that dissolve quickly (FDOFs). These crumble or dissolve in a matter of minutes without the need for chewing or water, improving the chance of increased compliance in elderly and paediatrics patients who have trouble swallowing pills or liquids. FDOFs are utilised as a useful substitute for FDTs because they offer instantaneous breakdown after being placed on the tongue, resulting in quick drug absorption and prompt bioavailability. These films may serve as drug delivery mechanisms. It has been utilised for local action as well as systemically through intragastric, sublingual, or buccal route of delivery. An account of numerous formulation concerns, preparation techniques, applications, and comparisons of the two fast-dissolving tablets/films are presented in the current review.
Keywords:- FDDDS, pharmaceutical industry, FDOFs, FDTs, instantaneous.

I. Introduction

Oral thin films (OTF), oral wafers, oral strips (OS), fast-dissolving oral films (FDOFs), and sublingual strips due to its greater comfort and flexibility, oral solid dose forms are at their most advanced. It increases the effectiveness of APIs by dissolving in the oral cavity in a matter of seconds after coming into touch with saliva, necessitating neither chewing nor the use of water for delivery. Due to the strong blood flow and instantaneous bioavailability of medications, it provides rapid absorption and The oral mucosa is 4–1000 times more permeable than the skin. FDOFs are helpful for patients who have an active lifestyle or who are bedridden, emetic, have diarrhoea, have sudden episodes of allergies, or are coughing. Whether local action is sought, such as a local anaesthetic for toothaches, oral ulcers, cold sores, or teething, it is also helpful. Currently, the market offers zolmitriptan in the form of pills and nasal sprays. These dosage forms don't go over well with the patient. Consequently, oral disintegrating films become a crucial tool for increasing patient compliance.

Fast dissolving Oral Film

Due to their greater comfort and flexibility, fast dissolving oral films (FDOFs) are the most modern oral solid dose form. It enhances the medicines' effectiveness by dissolving in the oral cavity in a matter of minutes after coming into touch with saliva, without chewing and without the need for water for delivery. Due to the increased blood flow and permeability, medicines are quickly absorbed and instantly bioavailable. FDOFs are helpful for patients who have an active lifestyle or who are bedridden, emetic, have diarrhoea, have sudden episodes of allergies, or are coughing. Whether local action is sought, such as a local anaesthetic for toothaches, oral ulcers, cold sores, or teething, it is also helpful. Oral films that dissolve quickly are based on the transdermal patch's technology. films are a lot like In terms of form, dimension, and thickness, a postage stamp. To cover up the flavour of the active ingredient, taste-mapping substances are occasionally added. Fast-acting oral films avoid first pass metabolism, are more stable, long-lasting, and speedy than other standard dose forms. They also feature a nice mouthfeel, precise dosing, a quick beginning of action, and don't require water for patient compliance. Additionally, portability and ease of handling

Advantage

- Reducing the chance of blocking
- A faster start of effect at lower dosages is achieved by avoiding first pass metabolism.
- It is palatable, stable, and doesn't require water.

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- Large surface areas allow for quick dissolution and disintegration in the oral cavity.
- The ease with which patients with dysphagia, frequent emesis, motion sickness, and mental illnesses can be given films
- Dose accuracy

Disadvantages

Drugs with excessive doses cannot be used in the film, and neither can drugs that irritate the mucosa. must be given It needs specific packaging because it is delicate and needs to be shielded from moisture.

Composition

The oral dissolving film is a small, 5–20 cm2 thin film. include a medication. The maximum single dose of the medications that can be loaded is 30 mg. From a regulatory standpoint, every excipient used in the formulation must be accepted for use in oral pharmaceutical dosage forms and must be generally recognised as safe.

1. Drug
2. Plasticizers
3. Saliva stimulating agent
4. Sweetening agent
5. Flavouring agent
6. Surfactant
7. Coors, Filler
8. Film foaming polymer

Drug

Several classes of medications, including as anti-ulcers (such as omeprazole), anatiasthmatics (such as salbutamol sulphate), antitussives, and others, can be made as mouth-dispersing films. expectorants, antihistaminics, and NSAIDs (such as valdecoxib, meloxicam, and paracetamol)

Water soluble polymers

Polymers can be employed alone or in combination to provide the desired film characteristics. In general, films are made of water-soluble polymers. since they give the films a quick disintegration, a pleasant mouthfeel, and mechanical qualities. The kind of polymer and its quantity in the formulation affect the film's tensile strength. The disintegration rate of the polymer is reduced by increasing the molecular weight of the polymer film basis. Water-soluble cellulose ethers, polyvinyl alcohol, polysaccharides, polyvinylpyrrolidone K-90, polyethylene glycols, pollutant, gelatine, Hydroxy propyl methyl cellulose E-3 and K-3, methyl cellulose A- 3, A-6, and A-15, pectin, sodium alginate, hydroxypropyl cellulose, maltodextrins, and eudragit RD10.

Plasticizer

It has been noted that formulation concerns (plasticizer, etc.) are significant factors determining the mechanical properties of films. the automated. The use of plasticizers has also enhanced the films' tensile strength and elongation capabilities. These qualities could be impacted by variations in their concentration. Glycerol, di-butylpthallate, polyethylene glycols, etc. are among the regularly used plasticizers.

Surfactant

Surfactants are employed as a wetting, solubilizing, or dispersing agent to breakdown the film quickly and release the active ingredient.immediately. Polaxamer 407, bezathonium chloride, sodium lauryl sulphate, tweens, benzalkonium chloride, and other substances are frequently used. Out of these, polaxamer 407 is the surfactant that is most frequently utilised.

Sweetening agent

Dextrose, sucrose, fructose, glucose, isomaltose, polyhydric alcohols (sorbitol, mannitol), and others are some of the sweeteners that are frequently used.

Coloring agent

Commonly used colouring compounds in products include FD&C colours, natural hues, and pigments like titanium dioxide.

Flavoring agent

The kind and strength of the flavour determine how much flavouring agent is needed to cover up the taste. Fruity tastes are frequently used. (vanilla, cocoa, coffee, chocolate, citrus), and flavouring oils like nutmeg, peppermint, and cinnamon. Flavours can also be selected from oleo resins, artificial flavour oils, and extracts made from different plant components like fruits, flowers, and so forth.

Saliva stimulating agent

In order to speed up the breakdown of the quick dissolving strip, saliva production is stimulated using substances known as saliva stimulating agents. formulations. Citric acid, malic acid, lactic acid, ascorbic acid, and tartaric acid are a few substances that stimulate saliva production. Citric acid is the one that is most favoured among these.

Manufacturing Methods

One or combination of the following process can be used to manufacture the mouth dissolving films

i) Solvent casting
ii) Semisolid casting
iii) Hot melt extrusion

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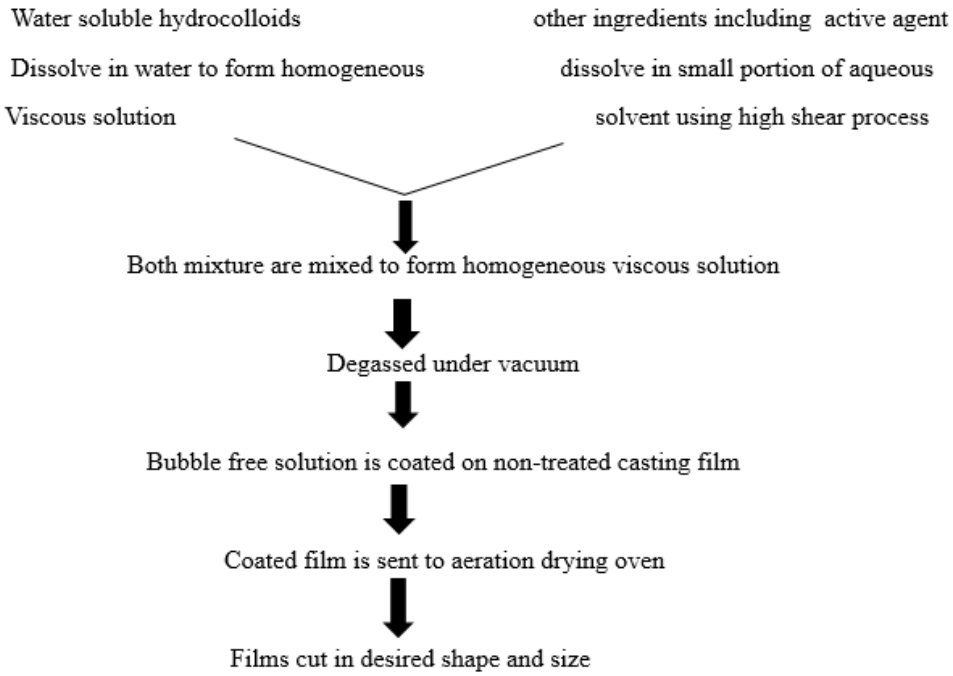
iv) Solid dispersion extrusion
v) Rolling

Solvent casting method
Water-soluble polymers are dissolved in water in the solvent casting process, and the medicine and other excipients are dissolved in a suitable solvent after that. After being combined and agitated, the solutions are ultimately cast into the Petri plate and dried.



Semi solid casting
Creating a water-soluble film-forming polymer solution is the first step in the semisolid casting process. The outcome is mixed with an acid solution. Insoluble polymer that was made in ammonium or sodium hydroxide, such as cellulose acetate phthalate or cellulose acetate butyrate. 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 0.015 and 0.05 inches thick. The ratio of the film-forming polymer to the acid-insoluble polymer should be 1:4.

Hot melt extrusion
The medicine and carriers are initially combined in solid form when using the hot melt extrusion process. After that, dry granular material is added to the extruder. The screw speed ought to be set. for around 3–4 minutes, processing the granules inside the extruder barrel, at 15 rpm. 800C (zone 1), 1150C (zone 2), 1000C (zone 3), and 650C (zone 4) should be the processing temperatures. A cylindrical calendar was used to press the extradite (T = 650C) in order to create a film. The use of hot melt extrusion has some advantages28, 29.
-Lesser operation units
-More consistent content
A process that is anhydrous

Solid dispersion method
Immiscible components are extruded with the medication in this process, and solid dispersions are subsequently made. Finally, dies are used to mould the solid dispersions into films.

Rolling method
The rolling method involves rolling a drug-containing solution or suspension on a carrier. Water and an alcohol-water mixture make up the majority of the solvent. The film is now gone. trim the rollers into the correct shapes and sizes.

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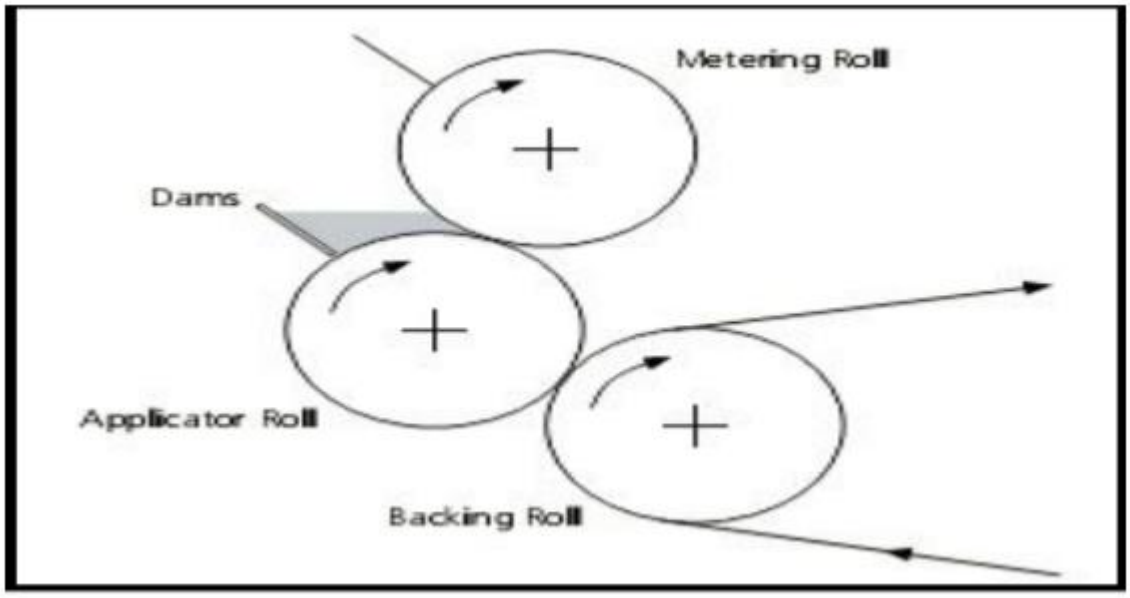

Fig.- Three roll coating unit

Evaluation parameter

1.. Mechanical property

Films' mechanical characteristics are assessed. TA.XT2 texture analyser equipment from Intron is employing a 5 kg load cell. There are two film projectors. clamps that are spaced 3 cm apart. The strips were pulled during measurement at a rate of 2mm/sec. When a film breaks, the force and elongation were measured. Tensile strength, elastic modulus, and present elongation are three mechanical parameters that are calculated .

a. Tensile strength-

Tensile strength is calculated by formula = force at break/initial cross sectional area of film in mm^2

b. Elastic modulus-

Elastic modulus is calculated by formula =

$$\frac{\text{Force at corresponding strain}}{\text{Cross sectional area } (mm^2)} \times \frac{1}{\text{Corresponding strain}}$$

c. % Elongation –

it is calculated by

$$\frac{\text{increase in length}}{\text{Original length}} * 100$$

d. Folding endurance –

Folding durability is assessed by repeatedly folding sheets with constant thickness and cross sectional area.

2. Dissolution test

The typical basket or paddle apparatus described in can be used to conduct dissolution testing in simulated saliva solution or pH 6.4 phosphate buffer. at 37 0.5 °C, any of the pharmacopoeia. Samples are taken out and examined using UV-Visible spectrophotometers at regular intervals.

3. Disintegration time

In a glass dish filled with 25ml of distilled water, the disintegration time is measured visually while being swirled every 10 seconds. When the disintegration time occurs, the film begins to crack or fall apart.

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4. Swelling property

Each film sample is weighed before being put into a stainless steel wire mesh that has been reweighed. The mesh carrying a sample of the film is then dipped into simulated saliva solution in 15ml of medium in a plastic bottle. At predetermined intervals, the weight of the film increased until a steady weight was noticed.

Degree of swelling = Wt. - Woo /Woo

Where, Wt. is weight of film at time t, and Woo is weight of film at time zero

5. pH value

One oral film is dissolved in 10 ml of distilled water, and the pH of the resulting solution is then measured. The solution should have a virtually consistent pH value.

6. Folding endurance

It is calculated by repeatedly folding films with the same cross sectional area and thickness at the same location until it breaks.

II. Conclusion:

In this study we basically discuss about the fast dissolving films as a part of fast dissolving drug delivery system (FDDDS)., along with composition, required ingredients, methods of formulation and advantages ,disadvantages of this drug delivery system. In this study we also discuss about various evaluation methods or parameters for same and basically focus on the "Solvent Casting method "because our next study on the same formulation by using this method.

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