IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 2, September 2025
Impact Factor: 7.67

Review Article – An Overview on Fast Dissolving Oral Film

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Abstract: *In the late 1970s, fast-dissolving drug delivery methods were initially created as an alternative to conventional dosage forms. An inventive method of drug delivery based on transdermal patch technology is the oral thin film. Solid dose forms that dissolve and disintegrate rapidly in the mouth without the need for water make up these systems. Two varieties of fast-acting pharmaceutical delivery systems include oral thin films (OTFs) and oral disintegrating tablets (ODTs). ODTs are defined as "A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue." Consequently, OTFs quickly hydrate before dissolving or disintegrating, enabling local absorption of the medication. The goal of the current study was to create TC with fast-dissolving films that could be locally administered to the oral cavity. A variety of polyhydric alcohols, film forming agents, and film modifiers were assessed in order to maximise the composition of films that dissolve quickly. It was examined whether poloxamer 407 and hydroxypropyl-β-cyclodextrin (HPBCD) could increase the solubility of TC. Xanthan gum, xylitol, and hydroxypropyl methylcellulose (HPMC) were combined to create fast-dissolving films. The solubility of TC was significantly improved by the use of poloxamer 407 and HPBCD. TC-Poloxamer 407 and TC-HPBCD complex were used to make fast-dissolving films, which were then assessed for their in vitro microbiological test and dissolution profile.*

Keywords: Mouth dissolving film, Solvent casting, Hot melt extrusion, Advantages

I. INTRODUCTION

Herbal medicine has gained international recognition and been increasingly integrated into the traditional healthcare system in recent years. People of many ethnicities, genders, and socioeconomic backgrounds use herbal therapy in both developed and developing countries. Numerous causes, including low cost, broad acceptance as a natural therapy with low toxicity and success in a variety of challenging conditions, and flexibility in accessibility, preparation, and application, have been cited as contributing to this surge in consumption and patronage. One Herbal medications are complex chemical mixes made from plants with limited effectiveness that are used extensively for therapeutic purposes in both developed and developing nations because of their poor oral absorption.One of the most convenient, cost-effective, and preferred drug delivery modalities is the oral route of medicine administration. However, some individuals have difficulty swallowing or digesting different oral solid dose forms, like tablets and hard gelatin capsules, especially those who are young or elderly. They can't take these dosage types since they're afraid of To solve this problem, a variety of fast dissolving drug delivery systems (FDDDS) were created. It is essential to administer drugs through the buccal cavity. It is possible to prevent problems such excessive first pass metabolism and drug degradation in the gastrointestinal environment by administering the medication via the buccal route.

Need of preparing fast dissolving oral film: -

The necessity of creating oral thin coatings that dissolve quickly It can be difficult for people with central nervous system diseases, children, the elderly, bedridden people, and people who get nausea to swallow solid prescriptions. As a

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result, they avoid taking their prescribed medications for fear of choking. Asphyxia is a concern even with oral disintegrating tablets (ODTs). On the other hand, when a novel OTF is placed on the floor or tip of the tongue, saliva rapidly hydrates the thin film, facilitating its speedy disintegration to release the drug. Oral thin-film drug delivery technologies dissolve rapidly, providing a promising alternative for patients who have trouble swallowing or chewing solid medication, in contrast to ODTs, which can be brittle and shatter during handling and transportation.

Characteristics of Oral Thin Film

- The film should be attractive and thin.
- Available in several shapes and sizes.
- It ought to stick to the mouth cavity with ease.
- It should disintegrate quickly without the need for water.
- It ought to taste excellent.
- Drugs should be particularly moisture resistant and penetrate the oral mucosa.
- It need to possess suitable resistance to strain.

Oral thin film benefits :

- Easy dosage.
- No water is required.
- There is no chance of choking.
- Masking taste.
- Increased stability.
- Better adherence from patients.
- The medication has a lessened hepatic first pass effect when it enters the bloodstream.
- Local and site-specific activity.
- A high surface area that facilitates quick dissolution and disintegration within the oral cavity.
- Increases bioavailability by avoiding the gastrointestinal tract.
- Compared to liquid dose forms, it offers a more precise dosage.
- One significant drawback of liquid dose forms is that there is no need to measure.

Oral Thin Film drawbacks

- The inability to include high-dose medications within the film.
- It is not possible to give medications that irritate the mucosa
- It needs specific packaging because it is delicate and needs to be kept dry.
- Maintaining dose consistency is challenging.
- Only minimal doses of active medicinal substances can be included. OTFs disintegrate rapidly, making dosage termination impossible.

Types of Oral Thin Film

There are three types of Oral Thin Film:

1. Flash Release
2. Mucoadhesive Melt Release.
3. Mucoadhesive Sustained Release.

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Formulation Consideration:-

Formulation additives

Active Pharmaceutical Ingredient:

The active component of a medication Antiemetic, neuroleptic, antihypertensive, cardiovascular, analgesic, antiallergic, antiepileptic, anxiolytic, sedative, hypnotic, diuretic, antiparkinsonian, antibacterial, antialzheimer, expectorant, anitussive, and erectile dysfunction medications are the types of medications that can be included in FDFs.

Film forming agents:

Different hydrophilic polymers can be used into the film formulation up to 40% w/w of the film content in order to prepare FDF. The polymers are in charge of the film's overall strength. To avoid deterioration during handling and transit, the film should be durable. These polymers include alginates, polyvinyl alcohol, maltodextrose, polyox, carboxymethyl cellulose, pullulan, gelatin, polyvinyl pyrolidone (PVP), cross-linked PVP, hydroxyl propyl methyl cellulose (HPC), hydroxyl propyl methyl cellulose (HPMC), and modified starch. Of them, pullulan and HPMC are the most appropriate polymers for FDF preparation. Similar to amylose, dextran, and cellulose, pullulan is a neutral glucan whose chemical structure varies somewhat depending on the carbon supply, the microbe that produces it, and the conditions of fermentation. Propylene glycol ether of methylcellulose is known as HPMC.

Disintegrating Agent :

In order to increase the accessible surface area and facilitate a quicker release of the medicinal material, disintegrating agents are added to FDF formulations to encourage its breakdown into smaller fragments in an aqueous environment. Materials such as Ac-Di-Sol, sodium starch glycolate, cross povidone, and microcrystalline cellulose are utilised singly or in combination.

Flavouring agent :

Artificial vanilla, cinnamon, peppermint, menthol, and essential oils like thymol, eucalyptol, and methyl salicylate are examples of natural and artificial flavours that can be used singly or in combination.

Sweetening agent :

Monosaccharides, disaccharides, and polysaccharides like xylose, ribose, glucose, mannose, galactose, fructose, dextrose, sucrose, maltose, partly hydrolysed starch, or corn syrup solids, as well as sugar alcohols like sorbitol, xylitol, and mannitol, can all be used as natural sweeteners. Artificial sweeteners that dissolve in water include cyclamate salts, acesulfam-K, soluble saccharin salts, and dipeptide-based sweeteners. For flavour masking, aspartame and neotame are also effectively utilised.

Saliva stimulating agent

Saliva stimulating agents are chemicals are used to speed up the production of saliva, which will help the FDF break down more quickly. Acids that are typically used as salivary stimulants include citric acid, malic acid, lactic acid, ascorbic acid, and tartaric acid. Of these, citric acid is the most commonly used salivary stimulant. Between 2 and 6% of these agents are used either alone or in combination.

Cooling agent :

Cooling agents contributes to strengthening the flavour to improve the product's mouthfeel. Flavours can be used with other cooling agents such as WS3, WS23, and Utracoll-II.

Colouring Agent :

When certain formulation materials or medications are present in insoluble or suspension form, titanium dioxide or FD&C-approved colouring ants are added to the FDF formulation at concentrations no higher than 1%w/w.

Surfactant :

Surfactants are employed as dispersing, wetting, or solubilising agents. When surfactant is used, the film dissolves in a matter of seconds and releases the active ingredient right away. Using a surfactant can increase the solubility of poorly soluble medications in quickly dissolving oral films. Poloxamer 407, sodium lauryl sulphate, benzalkonium chloride, benzthonium chloride, tweens, and spans are a few examples.

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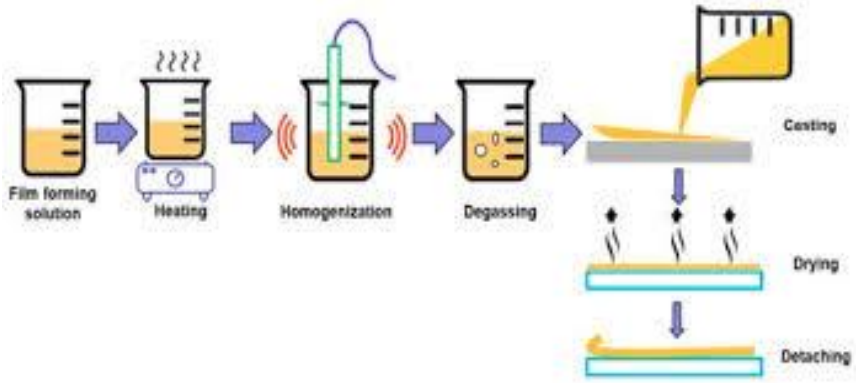
Stabilizing and thickening agent

Before casting, stabilising and thickening chemicals are used to increase the film preparation's viscosity and consistency of dispersion or solution. Stabilising and thickening agents include natural gums such as xanthan gum, locust bean gum, carragenan, and cellulosic derivatives. They are utilised up to 5%w/w in concentration.

Preparation Methods Of Oral Thin Films :-

1) Solvent casting method

Before casting, stabilising and thickening chemicals are used to increase the film preparation's viscosity and consistency of dispersion or solution. Stabilising and thickening agents include natural gums such as xanthan gum, locust bean gum, carragenan, and cellulosic derivatives. They are utilised up to 5%w/w in concentrationlid Casting .



2) Semisolid Casting :-

semisolid Casting when making films with acid-insoluble polymers, this approach is the one that should be employed. Using heat-controlled drums, gel mass is cast into the films or ribbons in the semisolid casting process. By mixing a film-forming solution with an acid-insoluble polymer solution in sodium hydroxide or ammonium, gel mass is produced. Both cellulose acetate butyrate and cellulose acetate phthalate are acid insoluble polymers. The ratio of film-forming polymer to acid-insoluble polymer should be 1:4.

3) Hot melt extrusion

The medication and carriers are initially combined in a solid state using the hot melt extrusion process. The extruder is then filled with dry granular material. To process the granules inside the extruder's barrel for roughly three to four minutes, the screw speed should be set at 15 rpm. Zone 1 should be 80°C, Zone 2 should be 115°C, Zone 3 should be 100°C, and Zone 4 should be 65°C. A film was then produced by pressing the extrudate into a cylindrical calendar.

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4) Solid dispersion extrusion

This technique creates solid dispersions by extruding drug-immiscible components. Lastly, dies are used to mould the solid dispersions into films.

5) Rolling method

A medication suspension or solution containing a film-forming polymer is made and fed through a roller in the rolling method. Particular rheological considerations should be made for the suspension or solution. Water and a combination of water and alcohol make up the majority of the solvent. The film is cut into the appropriate sizes and shapes after drying on the rollers.

6) Spray Drying technique

To obtain the film, a solvent system including a film former and additional excipients is sprayed or coated over an appropriate carrier material, dried, and then peeled off. Glass, non-siliconized kraft paper, and polyethylene film are the carrier materials utilised for film.

Evalution Parameters

1) Organoleptic Properties

Organoleptic characteristics for a fast-dissolving formulation: The formulation should have the right organoleptic pleasant properties because it will dissolve in the mouth; he helps patients accept a formulation; and when oral films are given to children, they should have an appealing colour; therefore, the colour of the formulation should be consistent and appealing; colour can be evaluated visually; and the smell is another organoleptic characteristic; the flavour added to the recipe should give it a pleasing aroma; the smell of the polymer, medication, and any other excipient should be covered up by the use of a flavouring ingredient.

Another important factor that must be taken into account is taste. To evaluate the flavour, specialised human taste panels are used. Electronic tongue measurements have also been used in trials to show that taste-masking compositions can distinguish between various sweetness levels.

2) Surface PH test

Evaluation of the surface pH of the film is essential because the rapid dissolving strip's surface pH can have deleterious effects on the oral mucosa. The pH of the film's surface should be 7 or nearly neutral. For this, a mixed pH electrode can be employed. After lightly moistening OTF with water, an electrode was placed across the oral film's surface to

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measure its pH. In order to calculate the mean and standard deviation (SD), at least six films of each formulation should be used in this study.

3) Thickness

Micrometer screw gauges or calibrated digital Vernier Calipers are used to measure film thickness. The recommended range for film thickness is 5-200 m. It is crucial to determine uniformity in the thickness of the film since this is directly connected to the accuracy of the dose distribution in the film. The thickness should be assessed at five distinct points .

4) Dryness

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 are the eight different drying phases for films. Tack is the degree to which a strip adheres to an object (such a piece of paper) when it is rubbed up against it. Additional tools are available for this study.

5) Drug content

A 2 cm2 film is sliced and placed in a solvent-filled volumetric flask. After two hours of shaking in a mechanical shaker, this is filtered to produce a homogenous solution. A UV spectrophotometer measures the medication content following the proper dilution.

6) Weight Variation

By weighing ten randomly chosen films one at a time and figuring out their average weight, one can ascertain weight fluctuation. The weight variation limit should not be substantially exceeded by the average weight.

7) Transparency

A straightforward UV spectrophotometer can be used to measure the transparency of a film. The film sample is positioned inside the spectrophotometer cell.

The following formula is used to determine a film's transparency :

$$-\epsilon c = (\log T600)/b = \text{transparency}$$

-where b is the film thickness (mm),
c is the concentration,
and T600 is the transmittance at 600 nm.

8) Percentage moisture loss

Films with an area of 2 cm2 are precisely cut and weighed to calculate the percentage moisture loss. The films were stored in desiccators with fused anhydrous calcium chloride after being weighed. The films must remain in the desiccator for 72 hours. They are removed after 72 hours, weighed once more, and the formula below is used to determine the films' percentage moisture loss: (Initial weight - Final weight)/Initial weight × 100 is the percentage of moisture loss. The purpose of the percentage moisture loss research is to ascertain the film's physical stability and integrity.

9) In-vitro drug release

Any of the pharmacopoeia's descriptions of the basket or paddle apparatus can be used for dissolution testing. The dissolution medium will primarily be chosen based on the drug's maximum dosage and sink circumstances.

10) Disintegration Test

The disintegration time, which is measured in seconds, is the amount of time it takes for a film to dissolve or scatter when it comes into contact with saliva or water. The thin film starts to disintegrate or break down at this precise instant. The weight and thickness of water-soluble films greatly influence their properties. The disintegration test tools specified in pharmacopoeias can be used to calculate the disintegration times of OFDFs. Depending on the formulation

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content, the disintegration period of film compositions typically ranges from 5 to 30 seconds. There is no official guide available to determine the disintegration times of films that degrade quickly.

Packaging of oral thin film

It is crucial for the pharmaceutical sector that the packaging used maintains the product's integrity. To preserve the dosage of other fast-dissolving dosage forms, costly packaging, particular processing, and extra caution are needed during manufacturing and storage. There are numerous packaging choices for oral films that dissolve quickly. The chosen material needs to possess the following qualities:

They have to shield the preparation from the elements. They need FDA approval. They must not be harmful. They have to fulfil the relevant tamper-resistant requirements. They shouldn't respond negatively with the merchandise. They must not add flavours or smells to the product.

II. CONCLUSION

Traditional tablets are being replaced with rapidly dissolving oral thin films as the preferred product type for many pharmaceutical medications. With the added benefits of quicker absorption and more covert use, these films provide the same advantages as tablets, including precise dosage and easy application. They can be used by persons of all ages and are especially helpful in situations where prompt action is needed. Furthermore, without sacrificing patient safety, this novel drug delivery technology offers a strong basis for creating new drugs and prolonging the lives of current ones. Further uses for this technology are being investigated by ongoing research, such as the application of multilayer films containing incompatible active pharmaceutical ingredients.

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