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A REVIEW ON FAST DISSOLVING ORAL FILM

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ABSTRACT

In comparison to other oral dose forms, this review highlights the significance of mouth dissolving films. Solid dose forms that dissolve or disintegrate in the mouth in a matter of seconds without the need for chewing or water are known as fast dissolving oral medication delivery systems. This lessens first-pass effects and promotes quick absorption in the oral cavity. Water-soluble polymers, plasticizers, active pharmaceutical ingredients (APIs), and other excipients are used in the formulation of OFDFs to guarantee stability and effectiveness. Polymers have an influence on mechanical characteristics and water absorption during the production and breakdown of films. For consistent medication delivery, API compatibility and solubility in OFDFs are crucial. Choosing the right ingredients and using a variety of strategies to improve medication delivery are the main goals of formulation development. This kind of technology provides a practical method of administering medication to the general public as well as to specific demographic groups such as children, the elderly, bedridden patients, and mentally ill people. Some businesses have developed more durable fast-dissolving medication delivery systems, including as films that are applied to the tongue's floor or top. The formulation considerations, preparation process, and quality control of the OFDFs are all described in the current review.

KEYWORD: Fast dissolving oral film; film forming polymers; Sustained-release; Active pharmaceutical ingredients; disintegration test time; dissolution; Packaging of OFDFs.

INTRODUCTION

The oral route is the one that patients find most acceptable among the many ways. The majority of pharmaceutical firms have focused their research efforts on creating effective oral dose options for patients who are nauseated, elderly, noncompliant, or juvenile. Oral medication delivery research segment has caused dose formulations to change from basic conventional.

Modified release pills and capsules, oral disintegrating tablets, wafers, and the most current advancements in rapidly dissolving oral films. The late 1970s saw the invention of fast-dissolving medication delivery devices to help children and elderly patients who had trouble swallowing pills and capsules. By skipping the hepatic first pass, it offers immediate entrance into the systemic circulation. impact and simplicity of use. In terms of thickness, size, and form, fast dissolving films resemble extremely thin postage stamp strips. In order to address these issues, fast-dissolving drug delivery devices are receiving a lot of interest. Oral film strips have gained popularity as a novel breath refreshing technique in recent years. These gel-like wafers quickly dissolve in the mouth to release taste. Recent technological advancements have prompted several pharmaceutical companies to explore new avenues for providing precise and timely dosage, which is expected to increase adherence, particularly among youth. Because transmucosal drug delivery techniques offer the potential to address problems associated with oral medicine administration, they have seen tremendous development in recent years. Without measuring or using water, the medication dosage is dissolved and then ingested.

A well-established and globally recognized technique for the systemic distribution of active pharmaceutical ingredients (APIs) is rapid oral films. This was addressed by the development of oral fast disintegrating drug delivery systems, which were first created in the late 1970s as a substitute for tablets, capsules, and syrups for elderly and pediatric patients who have trouble swallowing conventional oral solid dosage forms. Without the need for water, these dose forms often dissolve or disintegrate in the mouth in three minutes. A postage stamp-sized thin film is used as the delivery mechanism. It is applied to the patient's tongue or mucosal tissue, where it immediately hydrates by absorbing saliva. The film then quickly breaks and disintegrates, releasing the medication for oral mucosal absorption. The main cause of this swift dissolving activity is the film's enormous surface area, which wets rapidly in the moist oral environment.

Many medications can be made as films that dissolve in the tongue. Novel drugs might expand therapy options in the following indications.

- Pediatrics (Antitussives, Expectorants, Antiasthamatics).
- Geriatrics (Antiepileptic, Expectorants).
- Gastrointestinal diseases.
- Nausea (due to Cytostatic therapy).
- CNS (Antiparkinsonism therapy).

Fast dissolving drug delivery system (FDDS)

Developed in the late 1970s as an alternative to tablets, capsules, syrups, and other formulations for pediatric and geriatric patients who have trouble swallowing traditional solid dosage forms, the fast dissolving drug delivery system, also known as fast dissolving/disintegrating film, is a new generation delivery system that combines the benefits of both traditional tablet and liquid formulation for the oral delivery of the drugs.

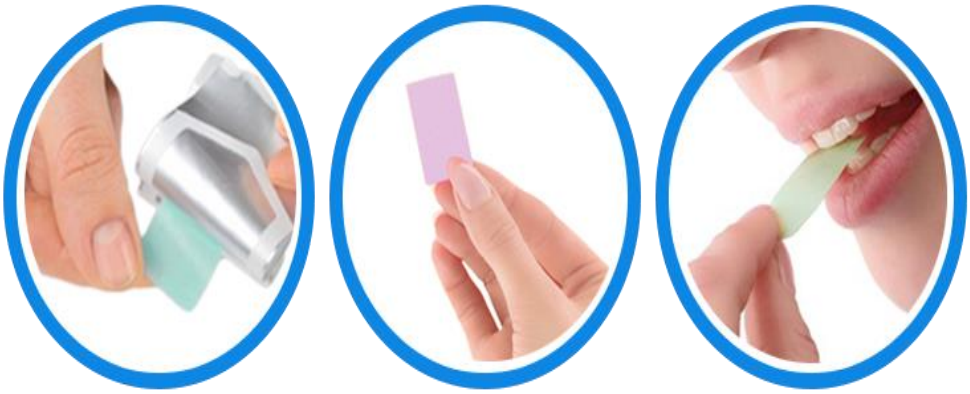

Fig. 1 Oral Film.

Additionally, they offer a rapid commencement of action in a matter of seconds since the medication is absorbed orally and goes straight from the site of administration to the systemic circulation, bypassing first-pass metabolism to achieve the intended effect. The top or bottom of the tongue is where the film is positioned. It sticks to the application site and releases the active ingredient quickly for systemic or local absorption. A fast-dissolving film's result also offers a chance to expand the market chain for a variety of pharmaceuticals, including anesthetics, cardiovascular medications, neuroleptics, and antihistamines, antiasthmatics, and erectile dysfunction therapies. Many medications can be created as films that dissolve in the tongue. Innovative products have the potential to enhance therapy options in the following indication.

- Antihistamines, expectorants, and antititussives for children.
- Antiepileptic, expectorant, geriatric.
- Gastrointestinal disorders.
- Nausea brought on by cytostatic treatment.
- Migraine pain CNS (treatment for antiparkinsonism).

These systems either dissolve or disintegrate generally within a minute without needing water or chewing. These systems offer superior clinical profiles with potential or mucosal absorption thus increasing the drug bioavailability concerning oral administration. Recently thin filmshave been proposed that rapidly dissolve or disintegrate into the buccal cavity. Mouth-dissolving films are novel dosage forms that disintegrate or dissolve in the oral cavity. These are ultra-thin postage stamp sizes with an active agent or pharmaceutical excipients. These dosage forms are placed on the tongue or any mucosal tissue. When wet with saliva, the filmsrapidly hydrate and adhere to the site of application. It rapidly dissolves or disintegrates to release the medicine for mucosal absorption or with modification, allows for oral GIT absorption with quick-dissolving properties.

The buccal drug administration method enhances the therapeutic efficacy of the medication, prolongs the dosage form's residence duration at the site of action, and increases the enzymatic flora for drug absorption. Because it allows for direct drug entrance into the systemic circulation, it circumvents all of the negative effects of oral drug delivery, including hepatic first pass metabolism and pre-systemic GIT removal by enzymatic breakdown. In order to remove blockages and alleviate patients' fear of choking, fast-dissolving films are increasingly being used as an alternative to fast-dissolving medications. Fast-dissolving films are usually composed of plasticized hydrocolloids. Flaking during slitting, cracking during cutting, and foaming during film manufacturing caused by material heating or solvent evaporation are all issues.

Special features of oral films

- Thin elegant film.
- Available in variety of size and shapes.
- Unobstructive.
- Excellent mucoadhesion.
- Fast disintegration.

- Fast release.
- Bypasses first pass effect.

Ideal properties of oral films

- It should have a pleasant mouth gel and an acceptable taste.
- It should be less friable and have a high mechanical strength to withstand the post-production handling.
- The drug should be stabile and soluble in water as well as in saliva.
- It should leave little or no residue in mouth.
- It should dissolve quickly enough to release the drug instantly in mouth. It should be compatible with the other ingredient.

ANATOMY OF ORAL CAVITY

The structure and anatomy of the oral cavity are studied to understand the environment provided for delivering drugs. The oral mucosa allows direct access of drugs to the systemic circulation and avoids first-pass metabolism. The epithelium of the oral cavity is quite similar to that of the skin, with slight differences concerning keratinization, protective and lubricant mucous which is spread across its surface. The permeability of oral mucosa is 4–1000 times greater than that of the skin.

The oral cavity is separated into two areas: the tonsils, the floor of the mouth, and the hard and soft palates. The outer area is the oral vestibule, which is surrounded by the lips and cheeks.

Among all the methods that have been investigated for the systemic distribution of pharmaceuticals via various pharmaceutical products of varied dosageforms, oral drug delivery has long been recognized as the most popular method of administration.

Oraldrug delivery has been known for decades as the most widely utilized route ofadministration among all the routes that have been explored for the systemic delivery of drugs via various pharmaceutical products of different dosage forms.

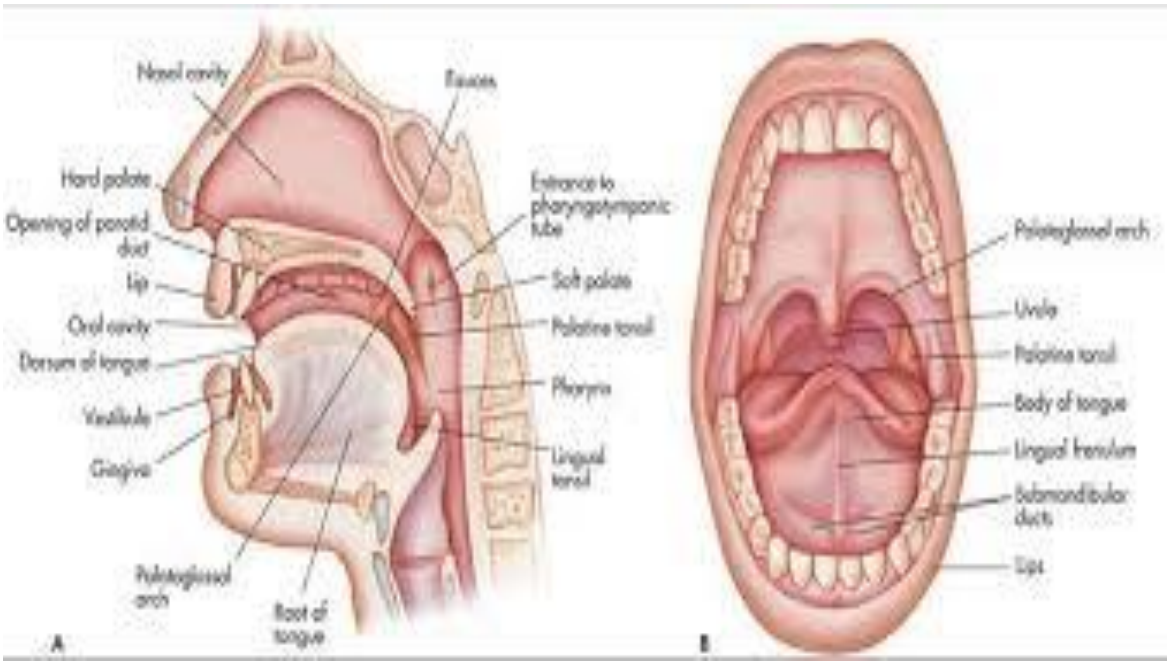

Fig. 2 Anatomy Of Mouth.

Advantages of fast dissolving films

- Taste masking.
- Enhanced stability.
- Improve bioavailability for certain therapeutic ingredient.
- Rapid onset of action.
- No risk of chocking.
- Convenient dosing or accurate dosing.
- No need of water to swallow or chewed.
- Pleasant mouth feel, leave negligible or no residue in the mouth after administration.
- Beneficial in cases such as motion sickness, acute pain, sudden allergic attack, asthmatic attack and coughing, where an ultra-rapid onset of action is required.

Disadvantages of fast dissolving films

- Drugs which are unstable at buccal pH cannot be administered.
- Drugs which irritate the mucosa cannot be administered by this route.
- A drug with small dose requirement can only be administered.
- Taste masking- Most drugs have the bitter taste, and need taste masking.
- It also shows the fragile, granule property.
- It is hygroscopic in nature so it must be kept in dry places.

Limitation of oral fast dissolving films

Since it is challenging to maintain the same dose throughout all strips, the FDOFs have a number of drawbacks with regard to dose uniformity from one strip to the next. Another drawback of the drug loading capacity is that not all prescriptions can be used on the FDOFs because of restrictions, such as the drug's dosage and concentration. Not all drugs can be placed onto the film since the maximum amount that may be loaded is 75 mg. Furthermore, there are restrictions on how the strips may be packed, which calls for certain standards because packing is challenging and the pack must not come into contact with the film.

Types of fast dissolving oral film and their Properties

Sr. No	Property/Sub/Type	Flash Release Water	Mucoadhesive Melt-Away Wafer	Mucoadhesive Sustained Release Wafer
1	Area (cm2)	2-8	2-7	2-4
2	Thickness (µm)	20-70	50-500	50-250
3	Structure	Film: single layer	Single or multilayer System	Multi layer system
4	Excipients	Soluble, highly hydrophilic polymers	Soluble, hydrophilic Polymers	Low/Non-soluble Polymers
5	Drug phase	Solid solution	Solid solution or suspended drug particles	Suspension and/or solid Solution
6	Application	Tongue (upper palate)	Gingival or buccal Region	Gingival, (other region in the oral cavity
7	Dissolution	Maximum 60 sec	Disintegration in a few mins, forming gel	Maximum 8-10 hrs

COMPOSITION OF THE MOUTH-DISSOLVING FILM

Different additives can affect this process and the structure of a film.

Active Pharmaceutical Ingredients (1-25%)

A variety of active pharmacological compounds can be supplied. Because the size of the dosage form is limited, it is difficult to include high-dose drugs within the film. Pharmaceutical ingredients (APIs) for oral films should preferably have a strong, less bitter, and highly lipophilic dynamic voice. The medication makes up between 5% and 30% of the dry film's weight, whereas multivitamins can make up as much as 10%. Active pharmaceutical ingredients that have a bitter taste and/or irritate the tongue and throat are disliked by both kids and a lot of adults.

Ideal characteristics

- The dosage of the drug to be included should be as low as 40 mg.
- Smaller and more moderately sized molecules of drugs are preferable.
- The medication needs to be stable and soluble in saliva and water.
- At the pH of the oral cavity, the medication should be partially unionized.
- The oral mucosa must allow the medication to pass through.

Water Soluble Polymers (40-50%)

The water-soluble polymers provide the films their mechanical qualities, pleasant mouthfeel, and quick disintegration. Increasing the molecular weight of the polymer film base slows down the pace at which the polymers break down. Sublingual films can be made using both natural and synthetic polymers. Excipients or polymers must have a low molecular weight, good film-forming ability, and be water soluble in order to create a water-soluble film formulation. 19. Cellulose ethers that dissolve in water, polyvinyl alcohol, polysaccharides, polyvinylpyrrolidone K-90, polyethylene glycols, pullulan, gelatin, carboxmethyl cellulosecekol 30, hydroxyl propyl methyl ellulose E-3 and K-3, methylcellulose A-3, A-6, and A-15, pectin, sodium alginate, and hydroxypropyl are among the polymers commonly used as film formers.

Film forming polymer

The most crucial component of the quickly disintegrating oral film is polymer. Based on the dry film's total weight, 45% w/w of polymer is often employed. Because of their tensile strength, which is dependent on the kind and quantity of polymer employed, the choice of polymer is one of the most crucial and significant factors for the effective production of oral films. Because the oral strips quickly dissolve in the oral cavity when they come into contact with saliva, they are mostly made of hydrophilic polymers. Nowadays, fast-dissolving films are made using both natural and synthetic polymers. The resulting disintegration period of the prepared film is largely determined by the physicochemical properties of the polymer or polymers chosen for film production. Plasticizers It has been noted that formulation variables (plasticizer, etc.) have a significant impact on the mechanical characteristics of films. The inclusion of plasticizers has also enhanced the films' mechanical qualities, including their tensile strength and elongation. These characteristics might be impacted by changes in their concentration. Among the often utilized plasticizers are polyethylene glycols, dibutylphthallate, and glycerol.

Natural polymer	Synthetic polymer
Starch	Hydroxy propyl methyl cellulose
Pectin	Poly vinyl pyrolidone (PVP)
Gelatine	Polyvinyl alcohol (PVA)
Sodium alginate	Sodium Carboxy methyl cellulose
Maltodextrin	Poly ethylene oxide (PEO)
Pullulan	Kollicoat IR
Xanthan	Hydroxy propyl cellulose (HPC)
Polymerized rosin	Hydroxy ethyl cellulose (HEC)
Gum acacia	Methyl cellulose (MC)

Plasticizers (0-20%)

It has been noted that formulation variables (plasticizer, etc.) have a significant impact on the mechanical characteristics of films. The inclusion of plasticizers has also enhanced the films' mechanical qualities, including tensile strength and elongation. These characteristics might be impacted by variations in their concentration. Among the most widely used plasticizers are polyethylene glycols, di-butylphthallate, and glycerol. Phthalate derivatives such as dimethyl, diethyl, and dibutyl phthalate, low molecular weight polyethylene glycols, castor oil, and citrate derivatives such as tributyl, triethyl, acetyl citrate, triacetin, and glycerol are a few of the frequently used plasticizers. When plasticizer is used improperly, the strip may bloom, split, peel, and shatter the film.

Plasticizers are added to the mixture to improve the elasticity and flexibility of the film, making it easier for patients to handle and guaranteeing correct film formation. Sorbitol, glycerine, and polyethylene glycol (PEG) are examples of common plasticizers.

Surfactants

Surfactants serve as solubilizing, wetting, or dispersing agents, allowing the film to disintegrate in a matter of seconds and release the active ingredient right away. Examples of frequently used substances are tweens, sodium lauryl sulphate, benzoalkonium chloride, and bezthonium chloride. Poloxamer 407 is a crucial surfactant that is utilized as a solubilizing, wetting, and dispersing agent.

Surfactants might be added to the film to help it wet and dissolve quickly in the oral cavity. They improve the bioavailability of the API. Polysorbates and sodium lauryl sulfate are examples of common surfactants.

Sweetening agents

The key component of formulations meant to dissolve or disintegrate in the oral cavity is sweeteners. Sweeteners are often used alone or in combination at concentrations between 3 and 6% w/w. The following sweeteners are often used: dextrose, sucrose, fructose, glucose, isomaltose, and polyhydric alcohols, such as mannitol and sorbitol. It is also possible to employ artificial sweeteners such as cyclamate, aspartame, saccharin, and acesulfame-K, as well as second-generation ones like sucralose, alitame, and neotame.

Saliva stimulating agents

In order to make the formulations of rapid dissolving strips dissolve more quickly, saliva stimulating compounds are used to increase saliva production. In general, acids employed in food preparation can be used to create salivary stimulants. Ascorbic acid, lactic acid, tartaric acid, citric and malic acids, and acid are examples of salivary stimulants. Of these, citric acid is the most preferred.

Flavouring agents

In order to improve the oral dissolving or disintegrating formulation's acceptability after consumption and its aftertaste, which lasts for at least ten minutes, flavors are added to the fast-dissolving film formulations, ideally up to 10%w/w. It is common practice to mix flavor oils (nutmeg, cinnamon, and peppermint) with fruity tastes (vanilla, cocoa, coffee, chocolate, and citrus). Flavors can also be chosen using oleo resins, artificial flavor oils, and extracts derived from various plant parts, including fruits, flowers, etc.

Manufacturing Of Orally Fast Dissolving Film

Following processes can be used to manufacture fast dissolving films:

1. Solvent casting method.
2. Semi solid casting
3. Hot melt extrusion
4. Solid dispersion extrusion
5. Rolling method

1. Solvent casting method

The water-soluble polymers are first dissolved in water at 1,000 rpm, and the mixture is subsequently heated to 60°C. Each additional excipient, including flavoring, coloring, sweetening, and so on, dissolves on its own. Following that, both solutions are thoroughly

mixed while being agitated at 1,000 rpm. After being dissolved in the proper solvent, the API is added to the resulting solution. The trapped air is removed using a vacuum. The resulting solution is cut into the proper size pieces and cast into a film once it has dried.

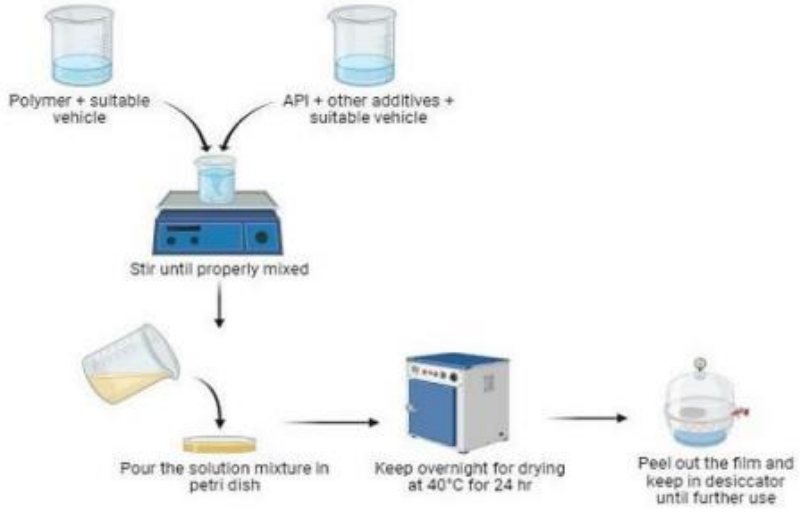

Fig. 3 Solvent Casting Method.

Mixing of drug and polymers

Homonization by magnetic stirrer

Setting a set for 8 hours

Casting on petriplate

Drying in hot air oven 45-50^0 C

Pilling And Cutting

2. Semi solid casting

This method starts with making a solution of a water-soluble film-forming polymer. An acid-insoluble polymer solution (such cellulose acetate phthalate) prepared with sodium hydroxide or ammonium is then combined with the finished solution. The ratio of acid-insoluble polymer to film-forming polymer need to be 1:4. A gel mass is created when the right amount of plasticizer is introduced. Finally, heat-controlled drums are used to form the gel mass into the films or ribbons.

3. Hot melt extrusion

Granules, prolonged release tablets, and transdermal and transmucosal medication delivery devices are frequently made using hot metal extrusion. As early as 1971, the pharmaceutical sector began using melt extrusion as a production technique. around three to four minutes in order for the material to melt completely. The extrudate (650°C is T.)

A film is then produced by compressing the resultant material into a cylindrical calendar. Some benefits of hot melt extrusion include the following: The advantages include reduced product waste, scalability, an anhydrous process, no organic solvents, a drug carrier mix with a lower temperature and residence time, and better content uniformity.

• Steps

1. Melting the polymer and plasticizer.
2. Mixing the API into the molten polymer.
3. Creating a thin film by extruding the mixture through a die.

4. Cooling and solidifying the film.
5. Cutting the film into the desired shape and size (Figure 4).

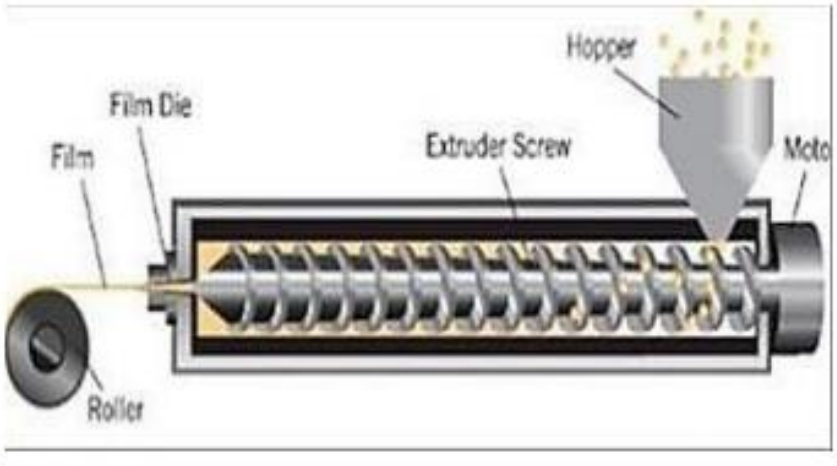

Fig 4 Hot Melt extrusion.

4. Solid dispersion extrusion

The dispersion of one or more active substances in an inert carrier in a solid state while amorphous hydrophilic polymers are present is referred to as a solid dispersion. A appropriate liquid solvent is used to dissolve the drug. After that, the solution is added to the polyethylene glycol melt, which is accessible below 70°C. Lastly, dies are used to form the solid dispersions into the films.

5. Rolling method

Water and water-alcohol mixtures are the primary solvents employed in this process. A tiny amount of aqueous solvent is used to dissolve the active agent and other components using a high shear processor. A uniform viscous solution is created when water dissolves hydrocolloids. After that, the drug-containing solution or suspension is rolled onto a carrier. The resulting film is then cut into the appropriate sizes and shapes.

• Steps

1. Mixing the polymer, plasticizer, and API to form a uniform dough-like mass.
2. Feeding the dough between two closely spaced rollers.
3. Adjusting the gap between the rollers to achieve the desired film thickness.
4. Cutting the film into individual doses.

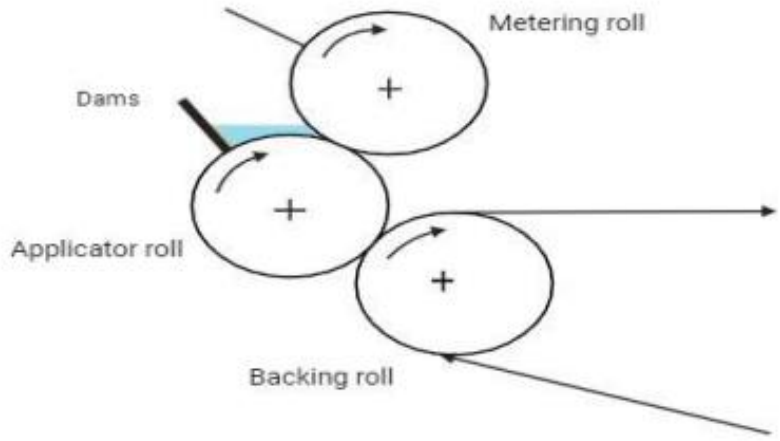

Fig 5 Rolling method for manufacturing of oral films.

Characterization of fast dissolving films

The different tests for characteristic analysis of the oral fast-dissolving films are.

Thickness

A micrometer screw gauge or calibrated digital Vernier calipers at particular critical points can be used to measure the consistent film thickness, which is essential to maintaining consistency in medication content.

Dryness test/tack tests

The term "tack" refers to a material's ability to stick to a surface after being forced against it; this attribute will be investigated in this study with the use of specialist tools.

Tensile strength

According to the above formula, tensile strength—which is the highest stress a material can withstand at the time of rupture—is computed by dividing the applied load at failure by the strip specimen's cross-sectional area.

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

Percent elongation

The stretching that takes place in a strip under stress is referred to as strain, which is the ratio of deformation to starting dimension. A higher plasticizer content results in more elongation.

Transparency

UV spectrophotometers can be used to measure the films' transparency. The film samples were separated into rectangles and then put into the spectrophotometer cell. At 600 nm, the transmittance of films was measured. This is how the transparency of the films was assessed.

$$Transparency = \frac{(logT600)}{b} = -€c\ (logT600)$$

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

Disintegration time

Oral fast-dissolving film strips that do not have established guidelines for disintegration times—which normally range from five to thirty seconds in accordance with Center for Drug Evaluation and Research (CDER) guidelines for oral disintegrating tablets with a disintegration time restriction of 30 seconds or less—are driving up demand for US disintegration equipment.

Dissolution test

The maximum dose of the active pharmaceutical ingredient (API) and sink circumstances, taking into account the possibility of strip floating in paddle equipment, impact the choice of dissolving media and apparatus (conventional basket or paddle gear) for performing dissolution tests.

Stability studies

It is necessary to conduct stability experiments in the humidity chamber under accelerated conditions (65% relative humidity and 35 ºC temperature).

Oral Fast Dissolving film packaging

The packaging used in the pharmaceutical industry must maintain the product's stability and efficacy in order to ensure its therapeutic integrity. Protecting the dosage of other rapidly dissolving dosage forms during production and storage requires expensive packaging, specific processing, and extra caution. For fast-dissolving films, there are a number of packaging options; films are medical products that need to be packaged in singles; the most common package type is an aluminum bag. APR-Labtec developed the Rapid card, a special and exclusive packaging solution designed for the Rapid films. The Rapid card is a credit

card-sized quick card with three raid videos stored on each side, and each dosage can be removed independently. The material must have unique properties as described in our thorough investigation.

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