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FAST ORAL DISSOLVING FILMS REVIEW

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ABSTRACT

Fast oral dissolving films represent an advanced oral solid dosage form, offering flexibility and user comfort. These films rapidly disintegrate and dissolve within one minute when placed in the mouth, without the need for water or chewing. This dosage form enables medication to bypass first-pass metabolism, potentially enhancing bioavailability. Mouth dissolving films may improve onset of action, reduce required dosing, and mitigate the risk of choking. Their formulation incorporates both visual and performance characteristics, utilizing plasticized hydrocolloids and active pharmaceutical ingredient (API) taste-masking agents, which are laminated by solvent casting or semisolid casting methods. The solvent casting method is preferred due to its ability to produce films with uniform thickness, a glossy appearance, and superior physical properties. Evaluation of mouth dissolving films includes assessment of parameters such as thickness, folding endurance, disintegration time, and dissolution time.

KEYWORDS: Fast oral dissolving films, Mouth dissolving films, Oral thin films, Solvent casting method.

1. INTRODUCTION

The oral route is the most preferred method of drug administration due to its ease of use, non-invasiveness, adaptability, and high patient compliance and acceptability. Numerous alternatives have been developed using novel technologies to address the needs of pediatric, geriatric, nauseous, and non-compliant patients, bioadhesive mucosal dosage forms, such as adhesive tablets, gels, and patches, are products of these technological advancements. Among these, polymeric films for buccal drug delivery have shown significant potential in recent years. Orally disintegrating films (ODFs), when placed on the tongue, rapidly hydrate with saliva, leading to disintegration or dissolution and subsequent release of the active pharmaceutical ingredient. ODFs are typically formulated with hydrophilic polymers to enable rapid dissolution upon contact with saliva. Oral disintegrating tablets (ODTs) and orally disintegrating films (ODFs) are representative examples of orally disintegrating drug delivery systems. These systems were introduced in the late 1970s as alternatives to conventional dosage forms, such as fast-disintegrating tablets and capsules, particularly for geriatric and pediatric patients who experience difficulty swallowing traditional formulations. A typical ODF is approximately the size of a postage stamp.[1] Quick dissolving oral films are an innovative drug delivery system that offers improved bioavailability, rapid onset of action, and bypasses first-pass metabolism. The oral mucosa is 4 to 1000 times more permeable than skin. This dosage form was developed to address swallowing difficulties in children and elderly patients. It combines

an active pharmaceutical ingredient with water-soluble polymers and excipients such as sweeteners, flavors, colors, binders, stabilizers, saliva stimulants, and preservatives. Water soluble polymers like Pullulan, Gelatin, Sodium Alginate, Pectin, Rosin, Starch, Chitosan, and cellulose ether facilitate rapid dissolution in the buccal cavity or on the tongue and fast dissolving oral films are ultra-thin strips, typically 50 to 150 microns thick, containing the active drug and excipients, and are produced using transdermal patch technology[2] The oral route of administration is the most practical and advised of the several delivery methods. Over 70% of medications are available on the market in the form of oral drug delivery systems due to the lack of discomfort and versatility (to accept many types of medication candidates). Fast dissolving tablets, which were established in the early 19th century to solve a variety of swallowing challenges, were steadily improved upon, resulting in the creation of fast dissolving films.[3] Drugs with low bioavailability and shorter half-lives are easily administered. Compared to traditional drug delivery methods used in the treatment of many illnesses, buccal films can release topical drugs with sustained, controlled effects and profitability. For its itemising, the oral film combines a number of ingredients, including polymers, dynamic pharmaceutical fixing, film offsetting administrators, sugars, flavours, colours, salivation strengthening experts, added substances, surfactants, etc. However, the first and most fundamental fixing that aids in film advancement is a polymer. For the preparation of mouth films that dissolve quickly, a variety of polymers are available.[4] A typical oral degradation film is around the size of a postage stamp.[5] Oral dissolving tablets were available at the commercial center to advise patients about correct organization, including cautions such as "don't bite/don't swallow." Biting and gulping were common in spite of these limitations. But oral humiliating films freed most people from these tragedies.[6]

1.2 Advantages of Fast oral dissolving films

- Single unit dosage forms, soft gels, and liquid formulations primarily enter the bloodstream via the gastrointestinal tract. This route results in drug degradation due to stomach acid, bile, digestive enzymes, and other first-pass effects. As a result, higher doses are often necessary and therapeutic action is typically delayed. These limitations can be addressed by employing current oral film drug delivery systems, which circumvent these issues and provide rapid onset of action at lower doses.
- Compared to liquid formulations, oral film allows for better dosage precision because each strip is made to contain a precise amount of medication.
- A film that is supplied sublingually and buccally has a high potential for improving the drug's efficacy and safety profile, lowering the dosage, and improving the beginning of action.
- Oral films' ability to dissolve fast without the need for water makes them an alternative for individuals with dysphasia and nausea, such as those undergoing chemotherapy.
- Oral dissolving films disintegrate immediately within second when placed on tongue without need of water.[7]

1.3 Disadvantages of Fast oral dissolving films

- A drug with a low dose requirement can only be administered.
- Taste masking is important because most drugs have
- Drugs that irritate the mucosa cannot be given through this route of administration.
- Drugs that are unstable at buccal pH cannot be administered.[8]

2. Composition of Fast oral Dissolving Films

- Drug (Active pharmaceutical component)
- film forming agent
- Plasticizer
- Saliva stimulating agent
- Sweetening agent
- Flavoring agent
- Surfactant
- Coloring agent

2.1 Active Pharmaceutical component

An active pharmacological substance is any class of pharmaceutically active medication that can be administered orally or through the buccal mucosa. such as antiemetics, expectorants, antitussives, antianginals, antihistaminics, antiepileptic, antianalgesics, and antiulcer drugs.[9]

Perfect medication choice for medication administration

- A low dosage less than 40 mg is necessary.
- Drugs with low molecular weight are better.
- It should taste well.
- It should to be fairly stable in water and saliva.
- It must be able to pierce the oral cavity's tissue that covers the mouth.

2.2 Film forming agent

Water-soluble polymers are used as film formers because they provide fast disintegration, a pleasant mouthfeel, and mechanical properties. Polymers can be used alone or in combination with others to make films with the required hydrophilicity, flexibility, mouth feel, and solubility. The rate of polymer disintegration decreases as the molecular weight of polymer film bases rise.[10]

Ideal polymer characteristics

- It is best to employ simple, harmless, and unexpressive polymers.
- It should to be flavourless. There should be no poisons that can be drained.
- It should be easy to get and affordable.
- The degradation interaction shouldn't be significantly hampered by it.

- It must to have outstanding spreading and wetting properties. It needs to be able to strip, shear, and be suitably flexible.
- It should have a long practical utilisation period and not cause further oral diseases.

2.3 Plasticizer

It is an essential part of oral thin films. The plasticizers help to improve the mechanical properties of the film, such as its tensile strength and elongation. Additionally, it reduces the film's brittleness. It may improve the strength and flow of the polymer. The choice of plasticizers must be carefully considered. It should be compatible with the polymers, medication, and other excipients. The wrong choice could cause the film to peel, break, or crack. Some commonly used plasticizers include dimethyl, dibutyl, diethyl phthalate, tributyl, triethyl, actyl citrate, triacetin, propylene glycol, polyethylene glycol, and glycerol.[11]

2.4 Saliva stimulating agent

Saliva stimulating drugs are used to increase salivation in order to speed the oral film's disintegration and breakdown in the mouth. It can be used individually or in combination, with a range of 2-6%. Ascorbic acid, tartaric acid, lactic acid, citric acid, and malic acid are often used saliva-stimulating agents. The most common one is citric acid.[12]

2.4 Sweetening agent

Sweeteners are commonly used to mask the bitter taste of several medications. Natural and artificial sweeteners can be used individually or in combination. Natural sweeteners include corn syrup solids, xylose, ribose, glucose, mannose, galactose, fructose, dextrose, and sucrose, as well as artificial sweeteners like aspartame, cyclamate, and saccharin. Acesulfame K, Sucralose, Alitame, and Neotame.[13]

2.5 Flavoring agent

Natural and artificial flavours, including methyl salicylate, eucalyptol, thymol, artificial vanilla, cinnamon, various fruit flavours, mints like peppermint and menthol, and essential oils, can be used individually or in combination.[14]

2.6 Surfactant

Surfactants are substances that are used as a solubilising, wetting, or dispersing agent. The film is rapidly broken down by a surfactant, which releases the active substance. In oral films that dissolve quickly, surfactant can improve the solubility of poorly soluble medications. Examples are tweens, spans, benzalkonium chloride, benzthonium chloride, polaxamer 407, and sodium lauryl sulphate.[15]

2.7 Coloring agent

When some of the chemicals or medications in the formulation are insoluble or suspended, titanium dioxide or FD&C approved coloring additives are used (not exceeding concentration levels of 1%w/w).[16]

3. Method of Preparation

3.2 Solving casting method: This method can be used to make films; water-soluble chemicals are taken in an incorrect amount and thoroughly combined in a beaker to create a clear solution. Add precisely weighed API and other ingredients to another beaker filled with an appropriate solvent. After mixing the formulation ingredients in both beakers while stirring, the mixture is cast into the Petri plate, allowed to dry for a while, and the film is cut to the proper size.

3.3 Hot Melt Extrusion: In this process, all of the materials needed to create films are combined and ground into a solid powder. The mixture is then melted using an extruder with heaters, and the melt is formed into a film. After cooling, it is cut and packaged. Some benefits of this approach over the others include less product waste and improved content consistency.

3.4 Semisolid Casting Method: If the film formulation contains any acid insoluble polymers, this process is suitable. Examples of such polymers are cellulose acetate butyrate and cellulose acetate phthalate. In general, film former and acid-insoluble polymer are employed in a 1:4 ratio.

3.5 Solid Dispersion Extrusion: When some immiscible substances are extruded using API, this method is used. Solid dispersions are developed and then used to create thin films with dies.

3.6 Method of Rolling: The prepared solution for the rolling technique plot needs to have certain rheological characteristics in order to roll onto the drum. making a drug and polymer solution in water or alcohol Rollers are applied to suspension. Rollers are applied to suspension. Solvent evaporation Solvent evaporation.

4. Evaluation Parameters

4.1 Thickness test: The thickness of a film is measured using a calibrated digital micrometre, and the mean average is calculated. Generally, three readings from each batch are taken and the average is calculated. The weight variation of a film is calculated in triplicate by cutting the film and weighing each film separately. Uniformity in thickness is significant because it is directly proportional to the film's dosage accuracy.[17]

4.2 Tensile strength: The highest applied stress at which a film fractures is known as tensile strength. This test is essentially used to gauge a film's mechanical strength. The following equation can be used to compute it by dividing the applied load at rupture by the strip cross-sectional area: Tensile strength is calculated as follows: load at breakage × strip thickness × strip width.[18]

4.3 Content uniformity: The contents of a film are determined using a standard assay method prescribed for each specific medicine in different pharmacopoeias. This test is carried out on 20 samples using analytical methods. The test has an acceptability value of less than 15%, according to Japanese pharmacopoeia standards. According to USP27, the contents should range from 85% to 115% with a standard deviation of less than or equal to 6%. Content uniformity is calculated for calculating drug contents in each film.[19]

4.4 Percentage elongation: When sample films are subjected to tensile stress, they distort, resulting in stretch or elongation of the sample. It is used to predict the ductility of polymers with a texture analyzer. It is calculated using a formula. % Elongation = Increase in length ×100 / Original length

4.5 Folding endurance: A section of film is cut and folded repeatedly at the same location until it breaks in order to measure folding endurance. The folding endurance value is determined by how many times the film can be folded at the same location without breaking. A film's typical folding endurance is between 100 and 150.

4.6 Swelling property: Simulated saliva solution is used to test the swelling properties of films. The initial weight of the film is established and then inserted in a pre-weighed stainless steel wire mesh. This mesh-containing film is then immersed into simulated saliva solution. The weight of the film increases at constant predetermined time intervals until there is no more growth in weight. The following parameters determine the degree of swelling: Degree of swelling = final weight (wt) - initial weight (w0) / initial weight (w0) Wt = weight of film at time interval t, w0 =weight of film at time 0.

4.7 Surface pH: The pH value of a film is normally determined by placing the prepared film in a Petri dish, wetting it with distilled water, and then measuring the pH by touching the film surface with a pH meter electrode. Surfaces pH determination is critical because acidic or basic pH can irritate the oral mucosa.

4.8 Disintegration time: The disintegration time of a film is calculated using the disintegration apparatus specified in official pharmacopoeias. The disintegration time typically ranges from 5 to 30 seconds and depends on the composition of the film. For this test, the USP disintegration apparatus is typically utilized. The disintegration time of oral rapid disintegrating films cannot be determined using established rules. There are two ways to calculate the film's disintegration time.[20]

4.9 In vitro dissolution tests: The standard official basket or paddle apparatus is used to conduct dissolution investigations on film. Sink conditions must be maintained throughout dissolution. During this technique, film may float over the medium, making it difficult to execute the test accurately. This problem is more likely to arise with the paddle approach, hence the basket equipment is chosen. The media used were 6.8 pH phosphate buffer (300 mL) and 0.1 N HCl (900 mL). The temperature is kept at 37 ±0.5 C, and the rotation speed of 50 rpm is typically regulated Drug samples are collected at predetermined intervals and examined using a UV-spectrophotometer. Despite its widespread use, the dissolution test is nonetheless prone to notable inaccuracies and tests that fail.[21]

Special Features of Oral dissolving films

- Thin and elegant film
- Not constructive.
- Available in several sizes and forms.
- Fast disintegration.
- Quick release.
- Provide a pleasant mouth sensation
- Have a good taste.
- Shouldn't leave residues in mouth.

CONCLUSIONS

Fast dissolving oral films have become a popular dosage form due to their accuracy, patient acceptability, and ability to bypass the hepatic system, resulting in improved therapeutic response. They offer the ease of administration found in liquid forms and the stability of solid dosage forms. Pharmaceutical companies favor these films for their high patient compliance, particularly among geriatric and pediatric populations, as well as their industrial viability. Oral films are positioned to replace many over-the-counter, branded, and generic drugs because of consumer preference and lower costs. This technology also serves as an effective tool for product life cycle management by extending the patent life of existing products.

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