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Mouth-Dissolving Film: Innovation in Rapid Drug Delivery System

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ABSTRACT:

Any drug delivery system's ultimate objective is to successfully deliver the medicine to the body, but patient compliance shouldn't be overlooked. For both the general public and specific demographic groups with swallowing difficulties, such as children and the elderly, fast-dissolving drug delivery methods, such as mouth-dissolving films (MDF), offer a convenient way to take medication is a new type of dosage form that dissolves and breaks down in the mouth and avoids first-pass metabolism and allows for a quick onset of action. Lower unit doses are providing better pharmacological effects and achieving the intended therapeutic effect.

KEY WORDS: Mouth-dissolving film, patient compliance, swallowing problem, first-pass metabolism.

1. INTRODUCTION

Mouth-dissolving films offer an advanced way to administer medications systemically. Because a well-supplied drug delivery system prevents the first-pass effect and increases systemic bioavailability. Figure 1 is showing mouth-dissolving film; it is a type of dosage form that is disintegrates quickly in the mouth. The result of this procedure is increased permeability. The oral mucosa is also a particularly desired and selective location for systemic drug administration due to its enormous surface area of absorption, ease of ingesting and swallowing, and absence of discomfort. Recent advances in technology have made oral dosing options viable for a variety of cases. A popular medication administration method in recent years is buccal drug delivery. In the late 1970s, fast-dissolving drug delivery systems were created as a substitute for tablets, capsules, and syrups for elderly and juvenile patients who had trouble swallowing conventional oral solid-dosage forms. Other names for the new oral fast-dispersing dosage form technology include quick dissolve, rapid melt, and quick disintegration. All of these dose forms, however, have a common concept and objective. An oral fast-dispersing or fast-dissolving dose form is a solid that dissolves or disintegrates rapidly in the oral cavity to create a solution or suspension without the requirement for water administration.

Figure 1: Mouth-Dissolving Film

1.2. Advantages of Mouth-Dissolving Film

1. Simple administration can help patients who refuse to swallow, including those with mental health conditions, stroke victims, the elderly, bedridden individuals, toddlers, and those suffering from renal failure.
2. Patient compliance for those who are bedridden, incapacitated, or on the go and do not have simple access to water.
3. The good mouthfeel property of MDDDS helps to change the common perception of medication as a "bitter pill," especially for pediatric patients, because it improves the taste of bitter medications.
4. The accuracy in dosage and ease of administration in contrast to liquid formulations.

5. The advantage of solid preparation of liquid medication.

1.3. Disadvantages of Mouth-Dissolving Film

There are several limitations with Mouth-Dissolving Films (MDF), including
1. Because of the buccal cavity's small surface area, only little dosages of medication may be administered.
2. Problems with stability such brittleness and moisture absorption when being stored.
3. It's forbidden to provide medications that cause mucosal irritation.
4. It is impossible to administer a drug that is incompatible with buccal pH.

1.4. Applications of Mouth-Dissolving Film

For local action and the treatment of problems of the central nervous system, pain, allergies, sleeplessness, etc., oral films are recommended.

- **Topical applications**

Dissolvable films may be able to deliver active ingredients, such as analgesics or antimicrobial components, for wound care and other purposes.

- **Systems for gastro-retentive dosage**

Dissolvable films are being studied for application in dosage forms that comprise compounds with different molecular weights that are both water soluble and poorly soluble in a film format. Treatment of gastrointestinal diseases may involve the use of the films, which dissolve when the pH of the gastrointestinal system or enzyme secretions force it to.

- **Diagnostic device**

Sensitive reagents can be put onto dissolvable films to permit controlled release in the presence of biological fluids, or they can be used to separate several reagents and form isolation barriers that allow a timed response inside a diagnostic instrument.

1.5. Characterization of Mouth-Dissolving Film

i. It is best to utilize simple, harmless, and unremarkable polymers.
ii. It should be easy to get and reasonably priced.
iii. During the deteriorating encounter, it shouldn't be a significant obstacle.

2. METHOD OF PREPARATION OF MOUTH-DISSOLVING FILM

Methods of preparation of mouth-dissolving films include:

- Solvent casting method
- Semisolid casting method
- Hot melt extrusion method
- Solid dispersion extrusion method

- **Solvent casting method**

To produce a homogeneously smooth combination, water-soluble polymers must first dissolve in water. Then, a tiny bit of water is added to the drugs and other materials that dissolve in water to guarantee adequate mixing. These two mixes are combined while being continuously stirred. After that, a vacuum is used to remove any trapped air bubbles from the solution. After that, the mixture is transferred to a Petri plate and allowed to set. When it's ready, it's chopped into pieces.

- **Semisolid casting method**

This method is very useful when making films that need to resist acid. It uses a process called semisolid casting to put a gel-like material onto heated drums to produce thin films or ribbons. The gel is created by mixing a solution of an acid-resistant polymer, like cellulose acetate butyrate or cellulose acetate phthalate, with a film-forming solution in sodium hydroxide or ammonium hydroxide. Because they don't dissolve in acidic conditions and are ideal for certain applications, these specific polymers were chosen.

- **Hot melt extrusion method**

Using a procedure called hot melt extrusion, the drug is initially mixed with other substances in a solid state. Dry granules are then added to the extruder. The machine runs at a screw speed of fifteen rpm while the material is treated within the barrel for around three to four minutes. The recommended temperatures for the different heating zones are 65°C, 80°C, 115°C, and 100°C. After the material leaves the extruder, it is pressed into a

thin layer using a cylindrical roller.

- **Solid dispersion extrusion method**

This method combines several medicinal components into a common dose form using water-loving (hydrophilic) polymers and a non-reactive carrier. The active drug is first dissolved in a suitable liquid (solvent) to form a solution. This solution is then combined with a melted polymer, such PEG, which melts at temperatures lower than 70°C. The solvent is not eliminated in this stage. Lastly, the mixture is shaped into thin films using specialized molds called dies.

3. INGREDIENTS OF MOUTH-DISSOLVING FILM

S.N.	Ingredients
1	Drug
2	Polymer
3	Plasticizer
4	Surfactant
5	Sweetening agent
6	Coloring agent
7	Agent of flavoring
8	Superdisintegrating agent

Table 1: Ingredients of Mouth-Dissolving Oral Film

Drug

The medications chosen for oral films should be stable in water and saliva at low concentrations. Because it will enhance the film's texture and promote more homogeneity and disintegration in oral fast-dissolving films. Mouth-dissolving films are made with a variety of antiasthmatic drug classes (montelukast, salbutamol sulfate), antihistamine drugs (levocetirizine), antianginal drugs (verapamil), antiulcer drugs (omeprazole), antiemetic drugs (domperidone), expectorants, antitussives, and NSAIDs (valdecoxib, paracetamol, meloxicam, etc).

Suitable Polymers

The strength of the film depends on the kind and quantity of polymer used in the formulation; a higher molecular weight of the polymer film bases reduces the rate of disintegration; water-soluble grades of cellulose ethers, polyvinyl alcohol, polysaccharides, and other polymers are frequently used as film formers due to their quick disintegration, mechanical properties, and pleasing mouthfeel. Moreover, hydroxypropyl methyl cellulose E-3 and K-3, methylcellulose A-3, A-6, and A-15, pullulan, gelatin, polyvinylpyrrolidone K-90, polyethylene glycols, pectin, sodium alginate, hydroxylpropyl cellulose, maltodextrins, and eudragit RD10 and 11 are polymers that are frequently employed as film formers.

Plasticizers

It has a crucial role in oral thin films. Tensile strength and elongation are two mechanical properties of the film that are improved by the plasticizers. In addition, it lessens the film's fragility. It might improve the polymer's strength and flow. Selecting plasticizers requires serious consideration. It should have a good interaction with the medication, the polymers, and the other excipients. If you make the incorrect choice, the film may peel, break, and crack. Examples of commonly used plasticizers include propylene glycol, polyethylene glycol, glycerol, actyl citrate, triethyl, tributyl, trimethyl, dibutyl, diethyl phthalate, and triacetin.

Surfactants

Surfactants disintegrate the film in a few seconds and immediately release the active component when employed as dispersing, wetting, or solubilizing agents. Tweens, sodium lauryl sulfate, bezathonium chloride, polaxamer 407, and other substances are commonly utilized. Of them, poloximer 407 is the most often used surfactant.

Sweetening Agent

Sweeteners are an essential part of every drug that dissolves or breaks down in the mouth these days. Among the often-used sweeteners include glucose, fructose, sucrose, dextrose, isomaltose, and polyhydric alcohols (sorbitol, mannitol), among others. Acesulfame K, sucralose, alitame, and neotame (second generation) and saccharin, cyclamate, and aspartame (first generation) are examples of artificial sweeteners that can also be used.

Agent of flavoring

Methyl salicylate, eucalyptol, thymol, fake vanilla, cinnamon, other fruit tastes, mints like peppermint and menthol, and essential oils are examples of both natural and artificial flavors that can be used separately or in combination.

Coloring agent

Film coloring often involves the use of pigments like titanium dioxide, natural colors, and integrated coloring additives.

Super Disintegrating Agent

Fast disintegration results from the combined effects of swelling and water absorption when super disintegrants are added to oral film formulations. Because of their high-water absorption, super disintegrates provide swelling and absorption, accelerating breakdown and disintegration. To break down substances like sodium croscarmellose, sodium starch glycolate, etc., strong contact with saliva is essential.

4. EVALUATIONS PARAMETERS OF MOUTH-DISSOLVING FILM

Look or Appearance

The mouth-dissolving film's look is evaluated by examining its color uniformity, surface smoothness, and transparency. There should be no cracks, air bubbles, or spots on the film. Its thickness and flexibility are also visually inspected.

Film thickness

A micrometer screw gauge was used to measure the film's thickness three times, and the average of the three readings was computed. This is necessary to ensure consistency in the film's thickness, which has a direct bearing on how accurately the dose is administered.

Weight or weight variation

An analytical balance was used to calculate the oral fast-dissolving films' average weight. The weight of the films should be almost consistent. Making ensuring a film has the right amount of API and excipients is advantageous.

Folding stamina of Film

One essential physical property needed for simple application on the administrative site is the flexibility of the film. The film's strength may be quantified by looking at how easily it folds. Endurance only by folding the mouth dissolving film three hundred times without breaking or at a 180° angle to the surface at the same layer until it breaks. The folding endurance value is determined by taking the number of folds that the film can withstand before breaking.

Content uniformity of Film

To ascertain content consistency, standard test procedures outlined for each drug candidate in standard pharmacopoeias are employed. The regularity of the Material is assessed by figuring out how much API is in each individual video. A content homogeneity of 85–115% is the upper limit.

Disintegration period

The disintegration time informs the dissolution and disintegration characteristics of the film. 25 cc of pH 6.8 artificial saliva is put through a stainless-steel wire mesh, and it is filled with the required size of film (2 x 2 cm2). A film's in vitro disintegration time is how long it takes for it to shatter and disintegrate.

5. CONCLUSION

Solid dosage form problems can be avoided with MDFs, which are reliable and useful dosage forms. Although they were first used commercially in over-the-counter (OTC) markets, MDFs are now also found in prescription drugs. MDF is favored over MDT because of their fragility, which calls for expensive production and specialized packaging. The physicomechanical properties of MDF are greatly influenced by the selection of plasticizers and polymers. Factors such as the glass transition temperature and the molecular weight of the polymers have a major impact on the mechanical properties of MDF. Therefore, with the correct polymer-plasticizer combination, the desired MDF can be produced and used as a reliable delivery system for most therapeutic agents.

6. REFERENCES

1. Ghodake, P.P., Karande, K.M., Osmani, R.A., Bhosale, R.R., Harkare, B.R. and Kale, B.B., (2013) Mouth dissolving films: Innovative vehicle for oral drug delivery. *International Journal of Pharma Research & Review,*2 (10), pp. 41-47.
2. Wilson CG, Washington N, Peach J, Murray GR, Kennerley J. (1987) The behavior of a fast-dissolving dosage form (Expidet) followed by g-scintigraphy. *Int J Pharm*., 40 (1-2), pp.119-123.
3. Rajat, P., Ravi, S., Pravin, S. and GN, D., (2019) A Review on Mouth Dissolving Film. *Journal of Drug Delivery & Therapeutics*, 9 (6), pp. 206-210.
4. Kshirsagar, T., Jaiswal, N., Chavan, G., Zambre, K., Ramkrushna, S. and Dinesh, D., (2021) Formulation & evaluation of fast dissolving oral film. *World J. Pharm. Res*, 10(9), pp.503-561.
5. Nalluri, B.N., Sravani, B., Anusha, V.S., Sribramhini, R. and Maheswari, K.M., 92013) Development and evaluation of mouth dissolving films of sumatriptan succinate for better therapeutic efficacy. *Journal of applied pharmaceutical science*, 3 (8), pp.161-166.
6. Dahiya, M., Saha, S. and Shahiwala, A.F., (2009) A review on mouth dissolving films. *Current drug delivery*, 6 (5), pp.469-476.
7. Shukla, D., Chakraborty, S., Singh, S. and Mishra, B., (2009) Mouth dissolving tablets II: An overview of evaluation techniques. *Scientia Pharmaceutica*, 77 (2), pp.327-342.
8. Raza, S.N., Kar, A.H., Wani, T.U. and Khan, N.A., (2019) Formulation and evaluation of mouth dissolving films of losartan potassium using 3^2 factorial designs. *Int. J. Pharm. Sci. Res*, 10 (3), pp.1402-1411.
9. Maheswari, K.M., Devineni, P.K., Deekonda, S., Shaik, S., Uppala, N.P. and Nalluri, B.N., (2014) Development and evaluation of mouth dissolving films of amlodipine besylate for enhanced therapeutic efficacy. *Journal of pharmaceutics*, 2014 (1), pp.1-10.
10. Tomar, A., Sharma, K., Chauhan, N.S., Mittal, A. and Bajaj, U., (2012) Formulation and evaluation of fast dissolving oral film of dicyclomine as potential route of buccal delivery. *Int J Drug Dev Res*, 4 (2), pp.408-417.
11. Deepthi, A., Reddy, B.V. and Navaneetha, K., (2014) Formulation and evaluation of fast dissolving oral films of zolmitriptan. *American journal of advanced drug delivery*, 2 (2), pp.153-163.
12. Nagaraju, T., Gowthami, R., Rajashekar, M., Sandeep, S., Mallesham, M., Sathish, D. and Shravan Kumar, Y., (2013). Comprehensive review on oral disintegrating films. *Current drug delivery*, 10(1), pp.96-108.
13. Prabhu, P., Malli, R., Koland, M., Vijaynarayana, K., D'Souza, U., Harish, N.M., Shastry, C.S. and Charyulu, R.N., (2011) Formulation and evaluation of fast dissolving films of levocitirizine di hydrochloride. *International journal of pharmaceutical investigation*, 1 (2), pp. 99-104.
14. Patel, R., Naik, S., Patel, J. and Baria, A., (2009) Formulation development and evaluation of mouth melting film of ondansetron. *Arch Pharm Sci Res*, 1 (2), pp.212-17.
15. Bhura, N., Sanghvi, K., Patel, U. and PARMAR, B., (2012) A review on fast dissolving film. *The International Journal of Pharmaceutical Research and Bio-Science*, 1 (3), pp.66-89.
16. Gandhi, A., (2012) Mouth dissolving tablets: a new venture in modern formulation technology. *The pharma innovation*, 1(8, Part A), pp.14-31.
17. Juluru, N.S., (2013) Fast dissolving oral films: A review. *Int. J. Adv. Pharm. Biol. Chem*, 2 (1), pp.108-112.
18. Nagansurkar, S.B., Bais, S.K. and Khilare, S.K., (2023) Review on polymers used in oral dissolving film. *International journal of pharmacy and herbal technology*, 2 (1), pp.132-142.
19. Khairnar, A., Jain, P., Baviskar, D. and Jain, D., 2009. Development of mucoadhesive buccal patch containing aceclofenac: in-vitro evaluations. *International Journal of Pharmaceutical Technology Research,* 1 (4), pp.978-81.
20. Vishwakarma, D.K., Tripathi, A.K., Yogesh, P. and Maddheshiya, B., 2011. Review article on mouth dissolving film. *Journal of global pharma Technology*, 3 (1), pp.1-8.
21. Chaturvedi, K., Sharma, P.K., Dwivedi, S., Sharma, R. and Darwhekar, G.N., 2024. Fast Dissolving Oral Film: An Innovative Approach for Drug Delivery. *Current Research in Pharmaceutical Sciences*,14 (01), pp.01-09.
22. Sastry, S.V., Degennaro, M.D., Reddy, L.K. and Khan, M.A., 1997. Atenolol gastrointestinal therapeutic system. I. Screening of formulation variables. *Drug development and industrial pharmacy,* 23 (2), pp.157-165.
23. Kumar SR, "Mouth dissolving thin films: An appropriate dosage form for fast releases", *International Journal of Pharmaceutical Sciences,* 2016; 38(1), pp.282-289.
24. Priyanshi J, Ashish G, Gajanan D. A Detailed Overview on Mouth Dissolving Film. *Journal of Drug Delivery & Therapeutics.* 2023;13 (7), pp.172-6.