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Review Article

A review on mouth dissolving dosage forms

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ABSTRACT

For pharmaceutical dosage forms, the most convenient route for drug administration is the oral route. Nowadays the fast-dissolving drug delivery system is rapidly gaining interest in the pharmaceutical industry among the various novel drug delivery systems. It attracts pediatric and geriatric patients as this kind of dosage form overcomes the swallowing or chewing barrier. Overcoming these barriers leads to improved patient compliance. For the systemic delivery of active pharmaceutical ingredients for over-the-counter medications, a fast-dissolving drug delivery system is a proven and accepted technology. It can be swallowed easily without the requirement of water which is a major advantage over conventional dosage form. It may be possible to achieve rapid absorption of drugs and increased bioavailability, reduced toxicity, rapid onset of therapeutic action, improved delivery of poorly water-soluble drugs, and also it is regarded as the most economical and safest method of drug delivery.

Keywords: Mouth Dissolving Tablets, Mouth Dissolving Films, Pediatric, Geriatric, Patient Compliance.

INTRODUCTION

For the enhancement of patient compliance Fast dissolving drug delivery system emerged as a preferred alternative to the conventional oral dosage form. The research has focused on the development of new dosage forms with better compliance rather than different dosage forms because the development of a new generic molecule is costly. Not only this, but it is also of utmost importance to keep the taste of the active molecule in mind, as taste plays a vital role in mouth dissolving dosage form, without which the patient compliance will not take place. Therefore, if the drug used is bitter, it becomes mandatory to mask the bitter taste of the drug. Then only it can be considered to formulate it into any dosage form. [1] Recent advancements in novel drug delivery systems aim to enhance the safety of drugs while maintaining its therapeutic efficacy. The therapeutic effect of the Fast dissolving dosage forms arises as this type of delivery system when comes in contact with saliva rapidly disintegrates and dissolves and then releases the

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pharmaceutically active ingredients, without any requirement of water. [2,3]

Fast dissolving dosage forms are of two types:

1. Tablets
2. Films.

Characteristics of fast dissolving dosage forms [4]

- It does not require water as these dosage forms disintegrate and dissolve rapidly as they come in contact with saliva.
- It is best suited for both pediatric and geriatric patients, due to their easy intake procedures and a pleasant mouthfeel.
- It gives rapid onset of action which is required in many of the cases.
- Due to its pregastric absorption, the bioavailability is enhanced and the dose required is less.

Ideal drug candidate for fast dissolving dosage forms [5]

- The taste of the drug must be pleasant, if it is not so then it necessary to firstly mask the unpleasant or bitter taste of the drug.
- It must be stable in saliva and water.
- The dose should not be more than 20mg.
- Molecular weight must be small to medium.
- It must have the ability to permeate the mucosal membrane in the oral cavity.
- It must have the ability to diffuse and partition into the gastrointestinal upper epithelium.

MOUTH DISSOLVING TABLETS

There are various names given to mouth dissolving tablets such as "fast-melting or melt in the mouth, porous tablet, fast-dissolving, orally disintegrating or orodispersible". The best-suited drug candidates for this system comprises of analgesics, antiallergics, neuroleptics, cardiovascular agents, and drugs for erectile dysfunction. In Mouth Dissolving Tablets, some are designed to dissolve within few seconds after coming in contact with saliva are known as true-fast dissolving tablets whereas others contain some agents to enhance the disintegration rate of the tablet in the oral cavity and these are then more appropriately termed as fast disintegrating tablets because they can take around one minute to disintegrate completely. They are distinguished from lozenges, buccal tablets, and conventional sublingual tablets, which need more than a minute to dissolve in the mouth.[6] some examples of commercially available mouth dissolving tablets are given in Table No.1.

Advantages of mouth dissolving tablets [7]

- It is economical for industries and patients as well.
- It is easy to administer with those with swallowing difficulty.
- It disintegrates in the mouth without chewing.
- In the case of insoluble and hydrophobic drugs, the bioavailability of the drug is enhanced due to the rapid disintegration and dissolution of tablets.

Limitations of mouth dissolving tablets [8]

- Drugs with larger doses are not a suitable candidate for this type of dosage forms.
- Careful handling of the tablet is required due to its insufficient mechanical strength.
- For proper stabilization of the tablet, it is necessary to provide it with special packaging.
- Proper formulation of the tablet is necessary, if not done so it can leave unpleasant mouth feels, thus reducing patient compliance.

Techniques employed in the preparation of mouth dissolving tablets [9,10,11]

There are various techniques which can be employed in the formulation of mouth dissolving tablets are enlisted below:

- Sublimation
- Spray drying
- Direct compression
- Mass extrusion
- Freeze-drying/ lyophilization
- Tablet moulding.

Sublimation: It is the technique in which highly volatile ingredients like urea, naphthalene, benzoic acid, ammonium bicarbonate, phthalic anhydride are added to the tablet excipients and compressed. A highly porous matrix is generated by the removal of highly volatile material by sublimation. The tablets produced by this technique have an enhanced dissolution rate.

Spray drying: In this technique, gelatin can be used as a matrix and supporting agent, mannitol as a bulking agent, and sodium starch glycolate/ croscarmellose/ crospovidone as super disintegrants. This spray-dried powder which is then compressed into a tablet showed quick disintegration and enhanced dissolution.

Direct compression: This technique is the easiest and economical method to manufacture a tablet. On improved excipients like super disintegrants and sugar-based excipients, this technique can be employed for the preparation of mouth dissolving tablets. The incorporation of the super disintegrant, the rate of disintegration and dissolution can be enhanced.

Mass extrusion: In this technique, the water-soluble polyethylene glycol and methanol soften

the active blend. This softened mass is then expulsed through an extruder or syringe to get a cylinder of product into even segments using a heated blade to formulate a tablet. The dried product can be used for coating bitter drug granules and hence mask their taste.

Freeze drying: In this technique, the water is sublimed from the product after it is frozen. The amorphous porous structure which dissolves rapidly can be obtained by this technique.
In this technique, the drug is dissolved /dispersed in an aqueous solution of a carrier/polymer. The resultant mixture is then poured into the wells of preformed blister packs. Trays that are holding blister packs are passed through a liquid nitrogen freezing tunnel so that to freeze the drug solution or dispersion. The frozen blister packs are then placed in refrigerated cabinets to continue freeze-drying, after which the aluminium foil backing is applied on a blister sealing machine. Finally, they are packed and shipped. This technique has demonstrated improved absorption and bioavailability. The major limitation of this technique is that its time consuming and expensive, poor stability in stressed conditions.

Molding
Two types of molding methods are there that are enlisted below:

- Solvent method
- Heat method

Solvent method: In this method, the hydroalcoholic solvent is used to moisten the powdered blend which is then compressed at low pressure in molded plates to form a wetted mass which is then air-dried to remove the solvent.

Heat method: In this method, a suspension drug, agar, and sugar preparation takes place, which is then poured into the blister packaging wells. The agar is solidified at room temperature to form jelly which is dried under vacuum at 30^0C. The molded tablets are less compact than compressed tablets, which enhances disintegration/dissolution and finally results in the enhancement of absorption.

Patented technologies for mouth dissolving films [12]

- Zydis technology
- Durasolv technology
- Flash dose technology
- Oraquick technology
- Frosta® Technology
- WOWTAB® Technology
- Flashtab® Technology
- Dispersible Tablet Technology
- Quicksolv technology
- Pharmabrust technology
- Advatab
- OraSolv® and DuraSolv® Technology.

Evaluation of mouth dissolving tablet [13,14]
Hardness: Monsanto or Pfizer tester is used for determining the hardness of the tablet.

Wetting time: In a petri dish, 5ml of water was taken into which a piece of twice folded tissue paper was placed. On this tissue paper, a pre-weighed tablet was placed and the time required for complete wetting was characterized by the coloring of the tablet.

Friability: Roche friabilator is used for determining the friability of the 20 tablets. The pre-weighed tablets are placed in a friabilator and then rotated at 25 rpm for 4 min. These operated tablets were dusted and reweighed. The compressed tablets shouldn't lose more than 1% of their weight. The % friability is given by

$$Percentage\ friability = \frac{[Initial\ weight - Final\ weight]}{Initial\ weight} \times 100$$

Weight variation: 20 tablets are randomly selected and weighed individually for determining weight variation. According to IP weight variation specification is given in Table No.2.

Disintegration test: The standard procedure of the disintegration test has to be modified as disintegration is required without water. The test must mimic disintegration in the mouth within saliva. It should be less than 1 min.

Modified disintegration test: In a petri dish containing 10ml of water, a tablet was placed carefully at the center. The time for the tablet to completely disintegrate into fine particles was noted.

Dissolution study: The dissolution study for mouth dissolving tablets is similar to that of conventional tablets using USP dissolution apparatus 2 (paddle type) at 25-75 rpm. Buffers of pH 4.5 and 6.8, 0.1N HCl should be used for the evaluation of these tablets.

Packaging of fast-dissolving tablets: During the manufacturing and storage of fast dissolving dosage forms expensive packaging, specific processing, and special care are required to protect it. There are various options for packaging of these dosage forms, like blister card with multiple units, single pouch, multiple-unit dispenser, and continuous roll dispenser; all these varieties of packaging depends on the application and marketing objectives.

Mouth Dissolving Film: In the late 1970s, oral film technology was first invented so that swallowing difficulties can be overcome which are generally faced by geriatric and pediatric patients but nowadays it is trending in the pharma industry due to less fragility than other oral dosage forms, dosage accuracy, rapid release, ease of administration.[15,16]

Mouth dissolving film is a type of drug delivery system based on the technology of the transdermal patch developed for the oral delivery of the drug. It consists of thin film, which is placed on the patient's tongue or mucosal tissue; it instantly gets wet by the saliva which results in rapid disintegration and dissolution of the film which gets absorbed by the mucosal membrane of the oral cavity. [17,18,19,20]

A hydrophilic polymer is the kind of polymer which rapidly dissolves on the tongue or buccal cavity and is used in the preparation of mouth dissolving oral film. The dissolution of the drug occurs as it comes in contact with the saliva or liquid due to which the drug then reaches the systemic circulation without any delay.

Fast dissolving oral film has emerged an advanced alternative to the traditional tablets, capsules, and liquids often associated with prescription and OTC medications. Similar in size, shape, and thickness to a postage stamp thin-film strips are typically designed for oral administration, with the user placing the strip on or under the tongue (sublingual) or along the inside of the cheek (buccal). In this type of drug delivery, first pass metabolism of the drug is bypassed thereby making the medication more bioavailable. As the oral thin film dissolves, the drug enters the bloodstream through enteric, buccal, or sublingual. [21,22]

Taste masking is one of the major challenges besides improving the aqueous solubility of the drug as medications that enter the oral cavity, it is very important to have an acceptable pleasant taste of the drug no matter whichever may be the mode of administration, namely, swallowing and sublingual or oral inhalation. The unacceptable taste of active pharmaceutical ingredients (APIs) in these dosage forms is one of the major barriers that prevent a patient from adhering to a prescribed medication regimen. Taste has an important role in the development of oral pharmaceuticals, concerning patient acceptability and compliance, and is one of the prime factors determining the market value and commercial success of oral formulations, especially in pediatric medicine. [23,24,25]

Advantages of mouth dissolving film [26]

- No special setup is required in the industry.
- Accurate dosing can be obtained.
- Handling and transportation of the dosage form is easy.
- It has no choking risk.
- Non-invasive.
- The dissolution rate is high and thus gives a rapid onset of action.
- Dissolves rapidly as it comes in contact with saliva without any need for liquid.
- Patient compliance gets improved.

Limitation of mouth dissolving film [27]

- These must be stored in humid free conditions as they are sensitive to moisture.
- It is limited to a smaller dose only, as a higher dose cannot be incorporated in it.
- For the stability and safety of the dosage form, they require special packaging for the product.

Method of preparation of mouth dissolving film

Mouth dissolving films can be prepared by employing the following methods that are enlisted below:

a) Solvent casting method
b) Solid dispersion extrusion
c) Semisolid casting method
d) Hot-melt extrusion
e) Rolling method

a) Solvent casting method[28]

It is a method in which the drug along with other excipients is dissolved in a suitable solvent whereas water-soluble polymer into another suitable solvent. Then these different solutions are mixed and stirred. This solution is then degassed under vacuum to settle the air bubbles. Then into the petri dish, this bubble-free solution is then finally casted and dried.

b) Solid dispersion [29]

When one or more active ingredients in an inert carrier in a solid-state in the presence of amorphous hydrophilic polymers are dispersed it is known as a solid dispersion. In this method, a suitable solvent is taken in which the drug is dissolved and this solution is then incorporated into the melt of polyethylene glycol below 70˚C. Then by using dies the solid dispersions are finally shaped.

c) Semi-solid casting method [30]

In this method solution of water-soluble film-forming polymer is prepared. And then this solution is incorporated into a solution of acid-insoluble polymer (Examples: cellulose acetate phthalate, cellulose acetate butyrate, etc). Then the

plasticizer, in appropriate amount is added to obtain a gel mass. Using heat controlled drums this gel mass is casted into the films or ribbons. The thickness of the films should be about 0.015-0.05 inches. The ratio of the acid-insoluble polymer to film-forming polymer should be 1:4.

d) Hot melt extrusion[31,32]

In this method, a polymer film is shaped into a film via the heating process. The hopper is filled with a blend of pharmaceutical ingredients including API in the dry state which is then conveyed, mixed and subjected to the heating process, and then extruded out in molten state melted by the extruder. The film is casted by the resultant molten mass. The casting and drying process is a critical step. This technique has many advantages, such as this process involves lower temperature and shorter residence times of the drug carrier mix, absences of organic solvents, continuous operation possibilities, minimum product wastage, good control of operating parameters, and possibilities to scale up.

e) Rolling method[33]

In this method, a solution or suspension containing a drug is rolled on a carrier. In which the water and mixture of water and alcohol are mainly used as a solvent. On the rollers, the film is dried and cut into desired shapes and sizes. Using a high shear processor, other ingredients including active agents are dissolved in a small portion of the aqueous solvent. The homogenous viscous solution can be obtained by dissolving water-soluble hydrocolloids in water.

Types of film

- Flash dispersable film
- Flash release film
- Medium disintegrating mucoadhesive films
- Non-disintegrating mucoadhesive films.

Technologies employed in the preparation of oral film[34]

- Soluleaves
- Wafertab
- Rapid film
- Foamburst (a special variant of soluleaves)
- Xgel.

Evaluation of mouth dissolving oral film[1,35,36,37,38,39,40,41,41]

1. **Thickness**

Baker precision measuring instrument, china is used to measure the thickness of all the variety of films. It was measured by placing each film between the anvil and the presser foot of the dial gauge at 5 different locations and the average thickness was calculated.

2. **Tensile strength**

It is the maximum stress to which a film specimen brakes. It is calculated by the load at rupture divided by the cross-section area of the film.

$$Tensile\ Strength = \frac{(F\ max)}{(A\ \max)}$$

3. **Folding Endurance**

Folding endurance is determined by repeated folding of the film at the same place until the film breaks. The number of times the film is folded without breaking is measured as the folding endurance value.

4. **Drug content**

Determines the percentage of drug content of formulation from the calibration curve by using the UV spectrometer.

5. **Weight of films**

The weight of oral mouth dissolving film can be weighed on an analytical balance and the average weight of each film can be determined. Films should have nearly constant weight. It is useful to ensure that a film contains the proper amount of excipients and APIs.

6. **pH value**

One mouth dissolving film is dissolved in 10ml distilled water and then from this solution pH can be measured. The measured pH value of the solution must be uniform.

7. **Percentage Elongation**

When stress is applied, a film sample stretches and this is referred to as a strain. A strain is the deformation of the film divided by the original dimension of the sample. Generally, the elongation of the film increases as the plasticizer content increases.

$$\text{Percentage Elongation} = \frac{(\text{Increase in length of strip})}{(\text{Initial length of strip})} \times 100$$

8. **Swelling property**

In a pre-weighed stainless steel wire mesh, a pre-weighed sample of each film is placed. Then the mesh containing film sample is submerged into 15ml medium (simulated saliva solution) in a plastic container. An increase in the weight of the film was determined at preset time intervals until a constant weight was observed.

$$Degree\ of\ swelling = \frac{(weight\ of\ film\ at\ time\ t - initial\ weight\ of\ film)}{(initial\ weight\ of\ film)}$$

9. Stability Studies

For determination of the effect of temperatures and humidity on the stability of the drug, stability studies on the optimized mouth dissolving film is carried out. The films are stored in an aluminium foil and subjected to stability at room temperature. The interval at which the sample is withdrawn is after 3 months and 6 months and this is subjected for cumulative % drug release and in vitro dissolution studies to determine disintegration time and disintegration test.

CONCLUSION

Nowadays mouth dissolving drug delivery system is gaining interest as pharmaceutical industries have embraced mouth dissolving dosage forms as a practical and accepted alternative to conventional or traditional dosage forms. In the pharmaceutical industries, this technology is good for increasing the patent life of the existing product.This kind of drug delivery system has solved the problem encountered by the pediatric and geriatric population. This system best suits mentally ill, bedridden patients as it shows a rapid onset of action improving bioavailability as well as patient compliance. Therefore, the above study concludes that the mouth dissolving dosage forms works best for pediatric and geriatric patients when a rapid onset of action is needed in a condition where, the suitable resources which are needed for the administration of the drug are not available, following patient compliance.

Table No.1: Some Commercially available Fast Dissolving Tablets

S.No.	Brand Name	Active Ingredient	Application	Company
1.	Claritin RediTabs	Loratadine	Antihistamine	Schering corporation
2.	Pepcid ODT	Famotidine	Anti-ulcer	Merck
3.	Zofran ODT	Ondansetron	Anti-emetic	Glaxo Smith Kline
4.	Feldene melt	Piroxicam	NSAID	Pfizer
5.	Triaminic Softchews	Various combinations	Pediatric cold, cough and allergy	Novartis Consumer Health
6.	Imodium instant melts	Loperamide HCl	Anti-diarrheal	Jannsen
7.	Cibalginadue FAST	Ibuprofen	NSAID	Novartis Consumer Health
8.	Benadryl Fastmelt	Diphenhydramine citrate	Allergy, sinus pressure relief	Pfizer
9.	Olanex instab	Olanzapine	Antipsychotic	Ranbaxy lab. Ltd
10.	Romilast	Montelukast	Leukotriene receptor antagonists.	Ranbaxy lab. Ltd

Table No.2: IP Weight Variation Specification of Fast Dissolving Tablet

S.No.	Average tablet weight	% deviation
1.	80 mg or less	±10
2	80-250 mg	±7.5
3	250 mg or more	±5

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