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MOUTH DISSOLVING TABLETS AS NOVEL WAY FOR ORAL DRUG DELIVERY: A REVIEW

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ABSTRACT

Now days aim of novel drug delivery system to design the dosage form , to be manufactured & administered free of side effects to immediate release and increased bioavailability, for the patient compliance. MDT tablets are solid dosage form that disintegrates within less than one minute in the oral cavity. These tablets have been formulated for pediatric, geriatric, and bedridden patient. This review discusses the method of preparation, properties, advantages, disadvantages, mechanism & various technologies. These are novel dosage form which dissolve in saliva within one minute, when put on tongue MDT can be administered anywhere, anytime, without the need of water. The problems of swallowing are common phenomenon which leads to poor patient compliance. To overcome these problems, mouth dissolving tablet have been developed which are having good hardness, dose uniformity, easy administration and serves as the first choice of dosage form for pediatrics, geriatrics and travelling patient.

INTRODUCTION

It is a type of tablet that disintegrates and dissolves rapidly in the saliva, within a few seconds without the need of drinking water or chewing. A mouth dissolving tablet usually dissolves in the oral cavity with in 15 s to 3 min. Most of the MDT's include certain super disintegrant and taste masking agents. However, this form of dosage has some limitation like motion sickness, sudden episodes of allergic attacks or coughing and unavailability of water, but one important drawback in dysphagia or difficulty or difficulty in swallowing. **(1)**

To overcome the problems, mouth dissolving tablet (MDT) have been developed , which having good hardness , dose uniformity, easy administration.

MDT also known as fast melting, Fast dissolving, oral disintegrating or disperse. Mouth dissolving tablet can define as "A solid dosage form containing medicinal substances, which disintegrate rapidly, usually within a matter of seconds, when placed under the tongue.

MDT has a pleasing mouth feel, and it not required water to swallow. MDT easily dissolved or disintegrate in saliva within a few sec. (15 s to 3 min) without the need of drinking water or chewing.

MDT's are mainly used in some serious condition like:--

- Motion sickness
- Parkinsonism
- Pediatric & geriatric patients
- Unconsciousness
- Mentally disabled patients
- Absence of water

Ideal properties of MDT's :-

A mouth dissolving tablet should:-

1) Not require water or other liquid to swallow.
2) Easily dissolves or disintegrate in saliva within a few seconds.
3) Have a pleasant mouth feel.
4) Be less sensitive to environmental conditions like temperature, humidity etc.
5) Bitter taste to be masked allow high drug loading.**(2)**

ADVANTAGES

- No need of water to swallow the tablet.
- Can be easily administred to pediatric, elderly and mentally disabled patients.
- Accurate dosing as compared to liquids.
- Dissolutions and absorption of drug is fast , offering rapid onset of action.
- Bioavailability of drug is increased
- Transformation
- First pass metabolism is reduced.
- Offering improved safety
- Suitable for sustained / controlled release actives.
- Allow high drug loading**. (3)**

DISADVANTAGES:-

Major disadvantages of MDT's is its mechanical strength.

- Several MDT are hygroscopic.
- MDT tablet is hygroscopic in nature so must be keep in dry place.
- Some time it possesses mouth feeling.
- Sometime it possesses mouth feeling
- MDT requires special packaging for properly stabilization and safety of stable product
- Dose uniformity is a technical challenge.
- Permeability barrier of the oral mucosa
- Delivery device
- Requires formulation for agreeable taste
- Highly enzymatic environment**(4)**

Ingredients used in preparation of MDTs :-

Ingredients used in MDT formulation are help in quick release of the drug, resulting in faster dissolution.

1. **Super disintegrants:-** The most important ingredients of a mouth dissolving tablets are super disintegrants, which play a major role in the disintegration and dissolution of MDT. Sodium starch glycolate , (Crosscarmellose sodium), crospovidone, Microcrystalline cellulose, pregelatinised starch are some of the example of disintegrants. Most of the MDTs consists certain super disintegrants and taste masking agents.Although superdisintegrants

primarily affect the rate of disintegration, high levels, they can also affect mouth feel, tablet hardness and friability. Super disintegrants provide quick disintegration due to combined effect of swelling and water absorption by the formulation.

2. **Flavours :-**Flavours and taste-masking agents make the products more palatable and pleasing for patients. The addition of these ingredients assists in overcoming bitterness and undesirable tastes of some active ingredients. For example, peppermint flavour, cooling flavour, flavour oils and flavouring aromatic oil, peppermint oil, clove oil, etc. Aspartame, sugars derivatives are used as sweeteners.

3. **Fillers :-** selection of fillers also had an important role in deciding the disintegration time. Some examples of fillers are directly compressible spray dried mannitol , sorbitol.

4. **Surface active agents:-** The presence of esterase or bile salts (sodium doecylsulphate, sodium lauryl sulphate, polyoxy ethylene sorbitan fatty acids esters) like surface active agents plays a role in drug release.

5. **Lubricants:-** Lubricants, though not essential excipients, can further assists in making these tablets more palatable after they disintegrate in the mouth. Lubricants remove grittiness and assist in the drug transport mechanism from the mouth down into the stomach. Some example are stearic acid, Magnesium stearate, Talc, Polyethylene.

6. **Binder :-** Binders are added to tablets to add cohesiveness to powders, thus providing the necessary bonding to form granules, which under compaction form a cohesive mass or a compact which is referred to as a tablet. Polyvinyl pyrrolidone, Polyvinyl alcohol, Hydroxyl propyl methyl cellulose.

7. **Colour :-** Sunset yellow, Amaranth, etc.

1. PATENTED TECHNOLOGIES

Zydis technology
Durasolv Technology
Orasolv Technology
Nanocrystal Technology
Dispersible Tablet Technology
Wowtab Technology
Flashtab Technology
LyocTechnology
Pharmaburst Technology
Frosta Technology
Ziplets/Advatab Technology

Zydis Technology

In this technology includes physical trapping of the drug in a matrix composed of a saccharides and a polymer **(5,6).** Polymer generally employed are partially hydrolyzed gelatin, hydrolyzed dextran, dertrin, aliginates, polyvinyal alcohol, polyvinaylpyrrolidine, acacia and a mixture of these. The method involves solution or dispersion of components is prepared and filled in to blisters cavities, which are frozen in a liquid nitrogen environment. **(7)**

Durasolv technology

In which tablet are prepared by using drug, nondirect compression fillers and lubricants. Nondirect compressible fillers and dextrose, mannitol, sorbitol, lactose, and sucrose, which have advantage of quick dissolution and avoid texture, which is generally present in direct compressible sugar. The manufactured tablet obtained are strong and can be packed in conventional packing in bottles and blisters. **(8)**

Orasolv technology

In this technology effervescent disintegrating agents are used to produce the MDT tablet . The tablet produces fizzing sensation, by the evolution of carbon dioxide from the tablet. It is a positive organoleptic property.**(9)**Using Concentration of effervescent mixture to formulate the tablet is 20-25 % of tablet weight. Tablets are prepared at low compression force, they are soft fragile in nature. **(10,11)**

Quicksolv technology

It is used two solvents for formulating a matrix, which disintegrates rapidly. This method includes dissolving matrix components in water and the solution or dispersion is frozen. Then dry the matrix by removing water using an excess of alcohol this is called (solvent extraction). The product formed has uniform porosity and sufficient strength for handling. **(12)**

Nanocrystal technology

Nanocrystal technology includes lyophillization of colloidal dispersion of drug substances and water-soluble ingredients . This method escape following manufacturing process such as :- granulation, blending, and tabeting. This process is useful for small quantities of drug**. (13)**

Dispersible tablet technology

In this technology evalution of MDT tablet with improved dissolution rate by incorporating 8-10 % of organic acids and disintegrating agents. Disintegrating agent help to rapid swelling and good wetting capabilities to the tablets this causes in quick disintegration. Disintegration includes starch, modified starches, microcrystalline cellulose, alginic acid, cross-linked sodium carboxymethoxy and cyclodextrins. Combination of disintegration improved disintegration of tablets usually less than 1 minute. **(14)**

Wowtab technology

WOW means without water. This technology useful for conventional granulation and tableting methods to produce MDT tablet. Low moldability saccharides are lactose mannitol, glucose, sucrose, and xylitol. This tablet showed appropriate hardness and rapid disintegration. **(15)**

Flashtab technology

This technology formulate tablet lubricant and excipient by using wet or dry granulation method , and followed by compressing into tablets. Excipients used in this technology are of two types. These tablets have physical resistance. Disintegration time is within 1 minute**. (16)** High proportion of fillers reduces porosity of tablets due to which disintegration is lowered. **(17)**

Pharmaburst technology

It is used co-processed excipients to evaluate MDT tablet, which dissolves within 30-40 S. This technology involves dry blending of drug, flavour, and lubricant followed by compression into tablets. Tablets formed have sufficient strength so they can be packed in blister packs and bottles. **(18)**

Frosta technology

It which use of formulating plastic granules and compressing at low pressure to produce strong tablets with high porosity. Plastic granules composed of:

1. Porous and plastic material
2. Water penetration enhancement
3. Binder

Zipilets/Advatab technology

They are used water-insoluble ingredients combined with one or more effective disintegrants to produce MDT tablet with improved mechanical strength and disintegration time at low compression force. **(19)**

CONVENTIONAL TECHNIQUES

1. Lyophilization or Freeze-drying
2. Cotton Candy Process
3. Molding
4. Sublimation
5. Spray-Drying
6. Mass-Extrusion
7. Direct Compression

Lyophillization or freeze-drying

Formation of porous product in freeze-dring process to formulating ODT tablet . Lyophillization is a process, which includes the removal of solvent from a frozen suspension or solution of drug with structure-forming additives. Freeze drying of drug with additive formed glossy amorphous structure resulting in highly porous and light weight product.**(20)**

Cotton candy process

This process is used to produce floss-like crystalline structure, which mimic cotton candy. Cotton candy process involves

formation of matrix of ploysacchaides or saccharides by action of flash melting and spinning. However, high-process temperature limits the use of this process.**(21)**

Molding

The Molding process incorporate moistening, dissolving, or dispersing the drug with a solvent then molding the moist mixture into tablets solvent is evaporate from the drug solution. However, molded tablet have low mechanical strength, which results in erosion during handling**.(22)**

Sublimation

In the matrix tablet the presence of highly porous structure they shows rapid disintegration of orally disintegration tablet (ODT). Even though the conventional tablets contain highly water-soluble ingredients , they often fail to disintegrate rapidly because of low porosity. **(23)**

Spray-drying

In this method obtained highly porous, fine powder. The FDT formulation consisted of hydrolyzed/ unhydrolyzed gelatin as supporting agent for matrix , mannitol as bulking agent, and sodium starch glycolate or crosscarmellose sodium as disintegrating agent.**(24)**

Mass-extrusion

The technique involves softening the blend using the solvent mixture of water-soluble polythene glycol and methanol removal of softened mass through the extruder or syringe to get a cylinder of the product into product into even segment using heated blade to form tablets. **(25)**

Direct Compression

It is the most common and easy technique to make tablets. Conventional equipment, commonly available excipients and a limited number of processing steps are involved in direct compression. Disintegrant efficacy is strongly affected on tablet size and hardness. **(26)**

EVALUATIONOF MOUTH DISSOLVING TABLETS

After compression of powder, the tablets were evaluated for physical organoleptic characteristics like color, odor, taste, diameter, thickness, Hardness, Friability, and, Disintegration time, wetting time, Swelling index.

1. General Appearance

The general appearance of a tablet, its visual identification and over all 'elegance' is essential for consumer acceptance. It includes are in tablet's size, shape, color, presence or absence of an odor, taste, surface texture, physical flaws.

2. Tablet Thickness

Tablet thickness is an important characteristic in reproducing appearance and also in counting by using filling equipment. Some filling equipment utilizes the uniform thickness of the tablets as a counting mechanism. Ten tablets were taken and their thickness was recorded using micrometer.**(27)**

3. Uniformity of Weight

I.P procedure for uniformity of weight was followed, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. The weight variation test would be satisfactory method of determining the drug content uniformity.**(28)**

Average of Tablet(mg)	**Maximum % difference allowed**
130 or less	10
130-324	7.5
More than 324	5

4. Hardness

Hardness of tablet is defined as the force applied across the diameter of the tablet in order to break the tablet, the resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its hardness. Hardness of the tablet of each formulation was determined using Pfizer Hardness Tester. **(29)**

5. Friability

Friability of the tablets was determined using Roche friabilator. This device subjects the tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inch in each revolution. Preweighed sample of tablets was placed in the friabilator and were subjected to 100 revolutions. **(30)**

6. *In vitro* Disintegration Test

The *in vitro* disintegration time was determined using Disintegration Test Apparatus. A tablet was placed in each of the six tubes of apparatus and one disc was added to each tube.

7. Wetting Time

The method was followed to measure tablet wetting time. A piece of tissue paper (12 cm X 10.75 cm) folded twice was placed in a small Petri dish (ID = 65 cm) containing 6 ml of Sorenson's buffer (pH 6.8), A tablet was put on the paper, and the time for the complete wetting was measured. Three trials for each batch were performed and the standard deviation was also determined. **(31)**

8. **Swelling index:** Swelling index is defined as the amount of water absorbed by the gum when placed in water for a predetermined time. It gives the percent of weight gain by the gum after absorbing water. **(32)** The swelling behaviour of all formulation were studied. One tablet from each formulation was kept in a petridish containing pH 6.8 phosphate buffer. At the end of 15 sec. and 1 min., the tablet was withdrawn and soaked with tissue paper, then weighed. Then after each mins.weight of tablet are weighed and continued till 3 min. Swelling index is calculated from following equation:

$$\text{Swelling index} = \frac{\text{Final weight of the gum - Initial weight of the gum}}{\text{Initial weight of the gum}} \times 100$$

Conclusion

Mouth dissolving tablets are innovative dosage forms developed and specially designed to overcome some of the problems that seen in conventional solid dosage form i.e. difficulty in swallowing of the tablet in geriatric and pediatric patients. Fast dissolving tablets are designed to dissolve or disintegrate quickly in the saliva generally within less than 60 seconds (range of 5-60 seconds). Fast dissolving tablets have better patient compliance and acceptance may improve biopharmaceutical properties, bioavailability improved efficacy, convenience, and better safety compared with conventional oral dosage forms.

The popularity of MDTs has increased fabulously over the last decade. MDTs need to be formulated for psychotic patients, bedridden, geriatric, pediatric patients, for those patients who may not have access to water, patients who are busy in traveling. MDTs formulations formulated by some of these convetional and patent technologies and MDTs have sufficient mechanical strength, quick disintegration/dissolution in the buccal cavity without water. The newer technologies utilized for the formulation of the MDTs that provide more effective dosage forms with more advantages and minimal disadvantages.st dissolving tablets are innovative dosage forms developed and specially designed to overcome some of the problems that seen in conventional solid dosage form i.e. difficulty in swallowing of the tablet in geriatric and pediatric patients. Fast dissolving tablets are designed to dissolve or disintegrate quickly in the saliva generally within less than 60 seconds (range of 5-60 seconds).

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The newer technologies utilized for the formulation of the MDTs that provide more effective dosage forms with more advantages and minimal disadvantages. Mouth dissolving tablets are innovative dosage forms developed and specially designed to overcome some of the problems that seen in conventional solid dosage form i.e. Dysphagia in geriatric and pediatric patients. These are designed to dissolve or disintegrate quickly in the saliva generally within less than 60 seconds (range of 5-60 seconds) which further results in better patient compliance. These may improve biopharmaceutical properties, bioavailability, efficacy, convenience, and better safety as compared with conventional oral dosage forms.

The popularity of MDTs has increased fabulously over the last decade and is formulated by some of the conventional and patent technologies which results in sufficient mechanical strength, quick disintegration/dissolution in the buccal cavity without water. The newer technologies utilized for the formulation of the MDTs provide more effective dosage forms with more advantages thereby minimizing disadvantages.

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