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A REVIEW ON MOUTH DISSOLVING TABLETS-A POTENTIAL DRUG DELIVERY SYSTEM

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ABSTRACT

Mouth dissolving tablet is one of the popular and widely excepted dosage form especially for pediatric patients, geriatric patient and few solid dosage form like capsule and tablet are fasting the problem like difficulty in swallowing (Dysphagia) resulting in many incidences of noncompliance and making the therapy in effective. Oral dosage form or oral route are most preferred route of administration for various drugs have limitation like first pass metabolism, Psychiatrics patient , Bedridden and uncooperative patient. FDT_s formulation are designed to dissolve in saliva remarkably faster, within a few second (less than 60 sec), and content superdisintegrants to enhance disintegration rate of tablet in an oral cavity. This review depicts various technology with add of superdisintegrants; enhance bioavailability and solubility with fast onset of action then other oral and parenteral route of administration.

KEYWORDS: Mouth dissolving, Super-Disintegrants, Dysphagia, Bioavailability.

INTRODUCTION

The oral route is the most common route for drug administration. It is the most preferred route, due to its advantages, such as non-invasiveness, patient compliance, and convenience of drug administration. Oral dosage forms are used around 60% of established small-molecule drug products available commercially are administered via the oral route. Current estimates indicate that oral formulations represent about 90% of the global market share of all pharmaceutical formulations intended for human use.[1]

Mouth Dissolving Tablet (MDT)

Mouth-dissolving tablet dissolves and disintegrates rapidly in saliva, within a few seconds without the need for water or chewing. A mouth-dissolving tablet usually dissolves or disintegrates in the oral cavity within 15 s to 3min. Most of the MDTs include a certain type of super Disintegrants and taste masking agents.[2]

Mechanism[3]

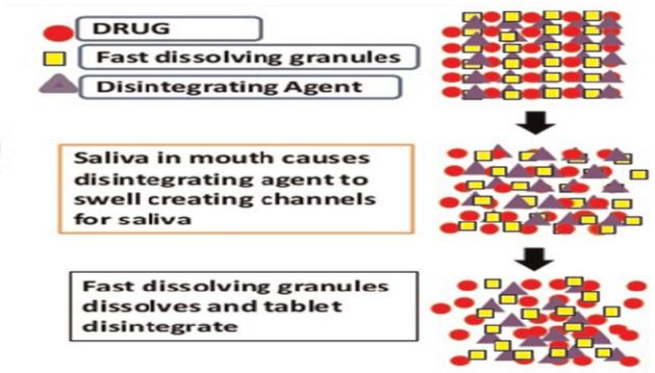

Fig. 1.1: Disintegration Mechanism of MDT.

Advantages of MDT[4][5]

- Ease of administration to patients who cannot swallow, such as the elderly, stroke victims, and bedridden patients; patients who should not swallow, such as renal failure patients; and who refuse to swallow, such as pediatrics, geriatric and psychiatric patients.
- Patient's compliance for disabled bedridden patients and for travelling and busy people who do not have ready access to water.
- No need of water to swallow the tablet.
- Accurate dosing as compared to liquids.
- Dissolution and absorption of drugs is fast, offering rapid onset of action.
- Bioavailability of drug is increased as some drugs are absorbed from mouth, pharynx and esophagus through saliva passing down into the stomach.
- Transportation
- First pass metabolism is reduced, thus offering improved bioavailability and thus reduced dose and side effects.
- Free of risk of suffocation due to physical obstruction when swallowed, thus
- Offering improved safety.
- Suitable for sustained/controlled release actives.

- Allows high drug loading.

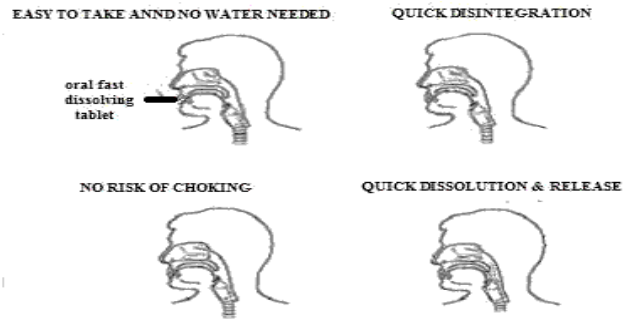

Fig. 1.2: Orodispersible tablet.

Disadvantages of MDT[6]

- Patients have to stop chewing, eating, and possibly talking during drug therapy to keep the drug in sublingually.
- Swallowing part of the tablet before it is absorbed sublingually is also a potential problem of Mouth dissolving tablet.
- Patient who may feel foreign objects in their mouth usually pull the tablet out before the active ingredients have been released from the formulation.
- Sometimes MDTs can result in tooth discoloration and decay may occur.
- MDTs are hygroscopic in nature and therefore needed to be placed in dry place and it also require special packaging for properly stabilization and safety of product.

Ideal properties of MDTs[7,8]

They should

- Not required water to swallow and should dissolve or disintegrate in the mouth within a few seconds.
- Allow high drug loading.
- Be compatible with taste masking and other excipients.
- Have a pleasing mouth feel.
- Leave minimal or no residue in the mouth after oral administration.
- Have a sufficient strength to withstand the rigors of the manufacturing process and post manufacturing handling.
- Be adaptable and amenable to environmental condition such as humidity and temperature.
- Allow the manufacture of tablets using conventional processing and packaging equipments at low cost.

- Well suited with taste masking and have need of pleasant feel.
- It should not need water to show its action.

Formulation of MDT

Drug selection Criteria of MDTs[9]

- No bitter taste.
- Drug with lower than 20mg dose.
- Drug with small to moderate molecular weight.
- Good stability in water and saliva.
- Partially none ionized at ph of the oral cavities.
- Drug able to diffuse and partition into the epithelium of the upper GIT.
- Drug able to permeate oral mucosal tissue.
- Very bitter or unacceptable taste because taste masking cannot be achieved required controlled or sustained release.

Ingredients used in preparation of MDTs: Ingredients used in MDT formulation are help in fast release of the drug, resulting in rapid dissolution.

Super Disintegrants[10]

Super Disintegrants affect the disintegration, and also can affect mouth feel, friability and hardness. Super Disintegrants provide faster disintegration due to combined effect of water absorption and swelling by the formulation. The wetted surface of the carrier increase by swelling of superdisintegrants which promotes the wet ability and dispensability of the system, hence, enhance the dissolution and disintegration.

Binders[11]

Main role of binders is to keep the composition of these fast dissolving tablets together during the compression stage. Binders can be liquid, solid, semi solids or mixture of varying molecular weights such as polyethylene glycol.

Antistatic agent[11]

An antistatic agent is used for materials or this surface to lower or eliminate buildup of static electricity which caused is by turboelectric effect.

Lubricants[10]

Lubricants not more essential ingredients, can further assist in making these tablets more palatable after they disintegrate or dissolve in the mouth. Lubricants assist for the drug transport mechanism from the mouth down into the stomach and remove grittiness.

Fillers[10]

Filler had an important role in deciding the disintegration time. Directly compressible spray dried Mannitol, Sorbitol, xylitol, calcium carbonate, magnesium carbonate, calcium are some example of fillers.

Flavors[10]

To make the products pleasing and more palatable for patient's flavors and taste-masking agents are used in MDTs. Addition of these excipients helps in overcoming undesirable tastes and bitterness of some active ingredients.

Saliva Stimulating Agents [12]

MDT are supposed to be administrate without water, they need to be dissolved in saliva. To increase the rate of dissolution and disintegration in oral cavity, the saliva stimulating agents can be used in some formulation of MDTs.

Coloring Agent[12]

Some drug and excipients have non-uniform appearance and different shades of color are not attractive for the patients. Therefore, coloring agents are used to maintain a uniform color and appearance.

Conventional Techniques for preparing mouth dissolving Tablet

1. Sublimation
2. Spray drying
3. Molding
4. Lyophilization Freeze drying
5. Direct compression
6. Mass Extrusion
7. Melt Granulation
8. Cotton Candy Process
9. Addition of superdisintegrants

Sublimation[13]

It includes addition of inert volatile substances to bulk and them volatile material get sublimated that result in the formation of pores on the tablet structure which helps in fast dissolution when tablet comes in contact with saliva.

Spray Drying[13]

Spray drying is a technique which results in porous and fine powder. In this technique an effervescent component is added to improve rate of disintegration and dissolution and them mixed with active ingredient and compressed into tablet that result in quick disintegration when tablet comes in contact with saliva.

Lyophilization or Freeze-drying[14]

Formation of porous in freeze-drying process is utilized in formulation of MDTs. The process, which includes the removal of solvent from a frozen solution or suspension of drug with structure-forming additives are lyophilization. Freeze-drying of drug with additives makes glossy amorphous structure and leads to highly porous and light weight product.

Molding[14]

In this technique, molded tablet are prepared by using water-soluble excipients so that the tablets result fast and complete dissolution. The hydro alcoholic solvent is used to moisten powder blend and molded into tablets under pressure lower than the pressure used in compression of conventional tablet. The solvent is removed by air drying. Molded tablets have very less compact than the compressed tablets. These pose porous structure that improves dissolution.

Direct compression methods[14]

This technique is easy to formulate MDTs. It has low manufacturing cost, limited number of processing steps and also accommodate high dose the final weight of tablet can easily exceed that of other production method. The rate of disintegration and dissolution of directly compressed tablet depends on single or combined effect of disintegrate, effervescing agents and water soluble excipients. Disintegrants efficacy is affected by size of tablet and hardness. Disintegration properties can be optimized by low or medium tablet size, low hardness and low physical resistance. It is essential to choose a suitable and an optimum concentration of Disintegrants to ensure rapid disintegration and dissolution rates. The addition of effervescent agent or water soluble excipients can further improve dissolution or disintegration properties.

Super Disintegrants provide rapid disintegration due to combine effect of water absorption and swelling. By the swelling of super Disintegrants the wetted surface of the carrier increases, which promotes dispensability and wet ability of the system and increase the rate of disintegration and dissolution. The optimum concentration of superdisintegrants can be taken according to critical concentration of Disintegrants.

Mass extrusion[13]

In this technique the blend of active ingredients is softened by polyethylene glycol and mannitol. The softened mass get extruded using extruded or syringe to get the product which then cut into segments to get tablets with the help of sharp blades.

Cotton candy process[14]

Cotton Candy process is a unique spinning mechanism to produce floss-like crystalline structure, which is cotton candy. This process involves formation of polysaccharides or saccharine by continues action of fast melting and spinning. The matrix formed is partially re-crystallized to have increased flow properties and compressibility.

Melt granulation[14]

In this process, mouth dissolving tablets can be prepared by incorporating a hydrophilic waxy binder PEG-6-stearate. Super pulsate is a waxy material having melting point of 33-37 ^{0}C and a hydrophilic- lipophilic balance. It not only acts as a binder and increases the physical resistance of tablets, but it also helps in the disintegration or dissolution of tablet as it melts in the mouth and dissolves rapidly leaving no residue in oral cavity.

Addition of super-Disintegrants[13]

The tablet Disintegrants to smaller particles by following mechanism of action by.

- Swelling: swelling is the most important mechanism of action for tablet disintegration. Tablet with highly porous in nature show low disintegration due to lack of swelling force. But in case of low porosity tablet sufficient swelling force is applied.
- Capillary action: When tablet to be put on suitable aqueous solution, then solution penetrates into tablet and removes absorbed from tablet which result in weakening of intermolecular bond and disintegrate or break tablet into tiny particles.
- Releasing of gases: Local stress is generated due to capillary expansion when Disintegrants gets wetted and, results in disintegration of tablet.
- Enzymatic action: Enzymes present in body act as Disintegrants, these enzymes

Evaluation Parameters

To design tablet and later monitor tablet production quality, quantitative evaluation and assessment of tablet chemical, physical and bioavailability properties must be made.

Physical appearance

The general appearance of tablets, its visual identity and overall elegance is essential for consumer acceptance. Such as tablet size, shape, color, presence or absence of odor, taste, surface texture and consistency of any identification marks.

Hardness test

This is the force required to break a tablet in a diametric compression. Hardness of the tablet is determined by Stock's Monsanto hardness tester which consists of a barrel with a compressible spring.

Thickness

Control of physical dimension of the tablets such as size and thickness is essential for consumer acceptance and tablet-tablet uniformity. The diameter size and punch size of tablets depends on the die and punch selected for masking the tablets.

Friability

This test is performed to evaluate the ability of tablets to withstand abrasion in packing, handling and transporting. Initial weight of 20 tablets is taken and these are placed in the Roche friabilator, rotating at 25rpm for 4min.

%Friability= (W1-W2)/W1×100

Where,W1= weight of tablet before test\ W2= weight of tablet after test.

Weight Variation

It is desirable that all the tablets of a particular batch should be uniform in weight. If any weight variation is there, that should fall within the prescribed limits.

Wetting Time

A piece of tissue paper folded twice was kept in a Petridis containing 6ml of purified water. The tablet was placed on the tissue paper and allowed to wet completely. The time for the tablet to complete wetting of the tablet was then recorded.

Disintegration Test

Disintegration time is considered to be one of the important criteria in selection the best formulation. To achieve correlation between disintegration time in-vitro and in-vivo, several methods were proposed, development and followed at their convenience.

In-dispersion time

The in vitro dispersion time was measured by dropping tablet in a beaker containing 100ml of water and stirring gently. The time for the tablet to completely disperse into fine particles was note.

CONCLUSION

The FDTs have potential advantages over conventional dosage forms, with their improved patient compliance, convenience, bioavailability and rapid onset of action had drawn the attention of many manufactures over a decade. FDTs formulations obtained by some of these technologies.

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