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Mouth Dissolving Tablet Review

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Abstract: *Mouth dissolving tablet are solid dosage form containing drugs disintegrate in oral cavity with in less than one minute. Mouth dissolving tablet are conventional dosage form like tablet .mouth dissolving tablet are developed of good hardness, dose uniformity and easy administration .the serve as first choice of dosage form for pediatrics, geriatrics and travelling patient. MDTs aim are sufficient hardness, integrity and faster disintegration without water. Mouth dissolving tablet are the including content significant, advantages, disadvantages, ideal properties formulation of mouth dissolving tablet, evaluation parameter and selection of super disintegrating agents. Tablet are readily dissolve in saliva within 60 sec.*

Keywords: super disintegrating tablet, Mouth dissolving tablet

I. INTRODUCTION

Mouth dissolving tablet are the most widely preferred commercial product. Mouth dissolving tablet are dissolve oral cavity of attractive site for administration of drug because ease administration. the various dosage form prepared like tablets ,capsules ,liquid preparation are administered to oral cavity. Mouth dissolving tablet (MDTs) technologies make tablet dissolve in mouth without chewing and water intake.

Orally disintegrating tablets are an advantage particularly for pediatric and geriatric populations who have difficulty in swallowing conventional tablets .pediatric patients may suffer from ingestion problems as result of underdeveloped muscular and nervous control.drug candidates that undergo pre-gastric absorption when formulated as MDTs may show increased oral bioavailability. It provides good stability, accurate dosing, and easy manufacturing.The FDT formulation is defined by the Food and Drug Administration (FDA) as ‘‘a solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue’’.

AMLO is a long acting second generation dihydro calcium channel blocker with actions similar to nifedipine used in the management of hypertension and angina pectoris. In hypertension, the usual initial dose is 5 mg daily,increased if necessary to 10 mg once daily. It is well absorbedfollowing oral administration with peak blood concentrationoccurring after 6–12 hours. Elimination from the plasma is biphasic with a terminal elimination half-life of about 30 to 50 h. Absolute bioavailability has been estimated to be between 60 and 65% [5]. Few reports were published on the mouth disintegrating tablets of AMLO. Presently, AMLO is marketed in the form of ODTs (Norvasc).

II. IDEAL PROPERTIES

- Fast onset of therapeutic action as tablet gets disintegrated rapidly along with quick dissolution and absorption in oral cavity.
- Accurate dosing are solid dosage forms, provide luxury of accurate dosing, easy portability and manufacturing, good physical and chemical stability and an ideal alternative for pediatric and geriatric patients.
- Mouth dissolving tablet are the Required no water for oral administration.
- It is harder and less friable.
- It is Leave minimal or no residue in mouth after administration
- Have a pleasing mouth feel.
- It is Allow the manufacture of tablet using conventional processing and packaging equipments.
- Have acceptable taste masking property.
- Allow the manufacture of tablet using conventional processing and packaging equipments
- It is convenient for patients who are traveling and do not have immediate access to water.

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ADVANTAGES

- Administration to the patients who cannot swallow, such as the elderly, bedridden patients, patients affected by renal failure & patients who refuse to swallow such as pediatric, geriatric & psychiatric patients.
- Rapid drug therapy intervention.
- Achieve increased bioavailability/rapid absorption through pre-gastric absorption of drugs from mouth, pharynx & esophagus as saliva passes down.
- Convenient for administration and patient compliant for disabled, bedridden patients and for travelers and busy people, who do not always have access to water.
- The risk of chocking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety

DISADVANTAGES

- It is cost intensive production process.
- It is ability to absorb atmospheric moisture.

FORMULATION OF MDTs

Drug:

- The ultimate characteristics of a drug for dissolution in the mouth and pre gastric absorption from MDTs include:
- It should Free from bitter taste
- It should Dose lower than 20 mg
- It should Small to Moderate molecular weight
- It should Good solubility in saliva Ability to permeate through oral mucosal tissue.

Bulking materials:

- Filling material plays an important role in the rapid development of tablets. The product works as a diluent, filler and cost reducer. In addition, fillers heal damage to the oral cavity by improving the properties of the material; The addition of fillers also reduces the concentration of active substances in the composition.
- The approval laid out in this distribution should be based on sugars such as mannitol, polydextrose, lactitol, DCL (direct lactose) and starch hydrolysates to have more water again and the results are good to understand. Extenders are added in amounts ranging from 10% to 90% by weight of the final composition.

Emulsifying agents:

- Emulsifying agents are important excipients for formulating fast-melting tablets they aid in rapid disintegration and drug release without chewing, swallowing or drinking water. In addition, incorporating emulsifying agents is useful in stabilizing the immiscible blends and enhancing bioavailability.
- A mostly range of emulsifiers is recommended for fast-tablet formulation, including alkyl sulfates, propylene glycol esters, lecithin, sucrose esters and others. These agents can be incorporated in the range of 0.05 percent to assist in the drug transport mechanism from the mouth down into the stomach.

Flavours and sweeteners:

Flavours and taste-masking agents make have the products more palatable and pleasing for patients. The addition of these ingredients assists in overcoming bitterness and undesirable tastes of some active ingredients.

III. SELECTION OF SUPERDISINTEGRANTS

While superdisintegrants generally affect disintegration, when used in large amounts they can affect mouthfeel, tablet hardness and friability.

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Therefore, many ideal factors need to be taken into account when choosing a superdisintegrant suitable for the formulation:

- It should be Produce rapid disintegration, when tablet comes in contact with saliva in the mouth/oral cavity.
- It should be compactable enough to produce less friable tablets.
- It should be Produce good mouth feel to the patients. Thus, small particle size is preferred to achieve patient compliance.
- It should be good flow, since it improves the flow characteristics of total blend.

Various manufacturing techniques for MDDDS include:

- Disintegrate addition
- Freeze drying
- Sublimation
- Direct compression
- Flash Dose

Disintegrate addition

Disintegrate addition technique is one popular techniques for formulating Fastdissolving tablets because of its easy implementation and cost-effectiveness. The basic principle involved in formulating Fastdissolving tablets by disintegrates addition technique is addition of super disintegrants in optimum concentration so as to achieve mouth dissolving along with the good mouth feel.

Freeze drying :

A process in which water is sublimated from the product after freezing. Lyophilization is a pharmaceutical technology which allows drying of heat sensitive drugs and biological at low temperature under conditions that allow removal of water by sublimation. Lyophilization results in preparations, which are highly porous, with a very high specific surface area, which dissolve rapidly and show improved absorption and bioavailability. The various steps involved in freeze drying technique.

Drug + matrix
↓
Preparation of suspension
↓
Adjust dosing system to delivery correct weight of suspension
↓
Dosing of suspension into preform blisters
↓
Freeze blister trays and content
↓
Collect and store frozen blister tray
↓
Subject blister tray to lyophilization
↓
Seal and pack blister

Sublimation:

The slow dissolution of the compressed tablet containing even highly water-soluble ingredients is due to the low porosity of the tablets. Inert solid ingredients that volatilize readily (e.g. urea, ammonium carbonate, ammonium bicarbonate, hexa methelene tetramine, camphor etc.) were added to the other tablet ingredients and the mixture is compressed into tablets. The volatile materials were then removed via sublimation which generates porous structures. Additionally, several solvents (e.g. cyclohexane, benzene) can be also used as pore forming agents.

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Spray drying :

Spray drying produces fine powders that are porous and dissolve quickly. The process includes hydrolyzed and non-hydrolyzed gelatin as a support, mannitol as a filler, sodium starch glycolate or cross carmellose sodium as a separating agent, improving dispersion and dispersion. as sodium bicarbonate). Solve it. Tablets compressed from spray-dried powder disintegrate within 20 seconds when immersed in an aqueous medium.

Direct compration:

The direct comparison method is the easiest way to make tablets. Direct compression involves traditional materials and some minimally invasive procedures, often using adjuvants. Large doses can also be administered, as the final weight of the tablet is easier than with other production methods. Disintegration and dissolution of directly compressed tablets depend on the separate or combined action of disintegrants, water-soluble excipients and effervescent substances.

Flash Dose Technology:

Flash dose technology was invented by Fuiaz Technologies, USA, now owned by Biovail (Canada). Fuisz Technologies has developed three oral drug delivery systems that involve fast dissolution. The first two generations are quick-dissolving Soft Chew and EZ Chew tablets which require some chewing. Most recently Fuisz also developed Flash dose technology, which uses a unique spinning mechanism to produce a flash-like crystalline structure, much like cotton candy.

These crystalline sugars can then incorporate APIs and be compressed into tablets. Flashdose® dosage form utilizes the shearform technique in association with CeformTM to mask the bitter taste of the medicament. CeformTM technique which produces uniform microspheres with very narrow particle size distribution has been patented by Fuisz. The shearform technology used in the preparation of the matrix is known as floss, which is made from a combination of excipients.

The floss cotton candy-like fibers are made up of saccharides including sucrose, dextrose, lactose and fructose. Sucrose required a temperature of 82–130 °C to be transformed into fibers while other polysaccharides such as polymaltodextrins and polydextrose require 30–40 % lower temperature than sucrose. Hence, it is used for incorporation of thermolabile drugs into the formulation. Highly porous and hydrophilic tablets were produced by Flashdose® because of relatively low compression pressure during the tableting. Flashdose® tablets containing a matrix of sugar fibers disintegrate very rapidly within few seconds on contact with saliva.

Super Disintegrants Used in MDTs :

As day's passes, demand for faster disintegrating formulation is increased. So, pharmacist needs to formulate disintegrants i.e. Superdisintegrants which are effective at low concentration and have greater disintegrating efficiency and they are more effective intragranularly. This superdisintegrants act by swelling and due to swelling pressure exerted in the outer direction or radial direction, it causes tablet to burst or the accelerated absorption of water leading to an enormous increase in the volume of granules to promote disintegration.

Various types of Super disintegrants used are as follows –

- It is used Cross povidone
- It is used Microcrystalline cellulose
- It is used Sodium starch glycolate
- It is used Sodium carboxy methyl cellulose
- It is used Crosscarmellose sodium
- It is used Calcium carboxy methyl cellulose
- It is used Modified corn starch.
- It is used Sodium starch glycollate has good flow ability than crosscarmellose sodium.
- It is used Kyron T-314.

Evaluation of Mouth dissolving Tablets:

Hardness test:

Hardness of the tablets was measured by using hardness testers like Monsanto hardness tester, Pfizer hardness tester etc. The pressure required to break the tablets is measured as a function of hardness (kg/ cm2). The values obtained must meet the standard value.

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Friability:

Friability is to measure the extent of tablet breakage during physical stress conditions like Packing, transportation etc. A sample of randomly selected 6 tablets was evaluated for friability using Roche friabilator at 25 rpm for 4 minutes. The % weight loss is calculated by measuring the total weight of 6 tablets before and afteroperation. Formula for calculating the % weight loss is given below:

$$\% \, Weightloss = \frac{\text{Totalweight of tablet before} - \text{Total weight of tablets after} \times 100}{\text{Total weight of tablets}}$$

Weight variation test:

Randomly selected 20 tablets were taken and their individual weights & the average weight of 20 tablets were determined. The deviation of each individual tablet from the average weight was calculated and compared with the standard values given in Pharmacopoeia

$$\% \, WeightVariation = \frac{\text{Individual weight of each tablet} - \text{Averageweight of 20 tablets} \times 100}{\text{Average weight of 20 tablets}}$$

Water absorption ratio:

Similar to the procedure followed in determination of wetting time. However, here the initial weight and the final weight (after complete wetting) of tablet were calculated and the water absorption ratio was calculated by given formula:

$$R = \frac{\text{Wa} - \text{Wb} \times 100}{\text{Wb}}$$

Disintegration time:

Disintegration time for randomly selected 6 tablets was measured using disintegration test apparatus. The average time required for disintegration was calculated and compared with standards.

Taste or mouth feel:

Healthy human volunteers were used for evaluation of mouth feel of the tablet. One tablet was evaluated for its mouth feel. A panel of 5 members evaluate the mouth feel by time intensity method. Sample equivalent to 40 mg was held in mouth for 10 seconds and the opinion is rated by giving different score values. (0: good, 1: tasteless, 2: slightly bitter, 3: bitter, 4: awful).

Stability studies:

Various stability studies like accelerated stability study, intermediate and long term stability studies were done during preformulation. The sample was subjected to higher temperature or humidity or both, to know their impact on the stability of mouth dissolving tablet.

Uniformity of dispersion:

Two randomly selected tablets were kept in 100 ml water and stirred for two minutes. The dispersion was passed through 22 meshes. The tablets were considered to pass the test if no residue remains on the screen.

IV. 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 have sufficient mechanical strength, quick disintegration/dissolution in the mouth without water. There is a clear opportunity for new enhanced oral products arising within this market segment. Approximately one-third of the population, primarily the geriatric and pediatric populations, has swallowing difficulties, resulting in poor compliance with oral tablet drug therapy which leads to reduced overall therapy effectiveness.

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