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Original Research Article

An Overview on Mouth Dissolving Tablets

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Abstract

Oral route if drug delivery has been used from many decades and it is one of the most preferred routes of administered. Mouth dissolving tablets (MDTs) are the tablets which gets disintegrates very quickly and release medicaments instantaneously. In the present study we have discussed about ideal properties of MDTs along with their advantages and disadvantages. Different types of manufacturing technique are employed such as Freeze drying, Molding, Tablet Molding, Direct Compression, Spray drying and Mass Extrusion, which are discussed below. There are many evaluation parameters like General Appearance, Size, Shape, Thickness and diameter, Uniformity of weight, Hardness of tablets, Friability of tablets, Disintegration time, In-vitro dispersion time test, Wetting time, Water absorption ratio, In vitro dissolution test as well as Accelerated Stability study for MDTs.

Keywords MDTs, freeze drying, Mass extrusion, Disintegration time, Accelerated stability study.

Introduction

For many years now, it has been widely accepted that oral drug delivery is the most popular method for delivering medications systemically through various pharmaceutical products. The convenience of the oral route may be a contributing factor to its widespread adoption.

Orodispersible tablets, melt-in-your-mouth tablets, rapimelts, rapid dissolving tablets, porous tablets, and fast dissolving tablets are various names for the same type of pill. When placed on the tongue, mouth dissolving tablets immediately dissolve or disseminate the medicine in the saliva. The quicker the medicine dissolves, the sooner it will take action clinically. An MDT formulation is "a solid dosage form containing medicinal substances that disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue," as described by the FDA.[1]

The quick breakdown period necessitates that MDTs be administered in a way that is distinct from the administration of regular tablets. Since the patient's saliva serves as the disintegration fluid, they should dissolve or disintegrate in the mouth without water or with only a trace quantity of water. For optimal mouth feel and easy swallowing, the dissolved tablet should turn into a soft paste or liquid solution. If a tablet is supposed to dissolve or disintegrate quickly, it ought to do so in under a minute.[2]

Ideal Properties of MDTs [3]

i. Can be taken orally without the need for water.
ii. Be effective in masking unpleasant flavors.
iii. Leave a good taste in your tongue.
iv. Be easily swallowed and leave behind no or very little aftertaste.
v. Harden up and stop crumbling.
vi. Be mostly unaffected by their surrounding climate (in terms of both temperature and humidity).
vii. Tablet production should work with current processing and packaging methods.

Advantages of Mouth Dissolving Tablets [4]

1) Rapid delivery of drug treatment.
2) Increase the drug's bioavailability and speed up its absorption by having it absorbed in the oral, pharyngeal, and esophageal cavities before it reaches the stomach.
3) Access to water is not always available to persons who are handicapped, bedridden, or traveling for business or pleasure.
4) The potential for physical blockage during oral administration of standard formulations is eliminated, resulting in increased safety.

Limitations of Mouth Dissolving Tablets [5]

1) Improperly manufactured pills might have an unpleasant aftertaste and/or a gritty texture in the tongue.
2) Antibiotics like ciprofloxacin have adult dosage tablets containing roughly 500 mg of the medication, making them challenge to mix into MDT.
3) Patients using anticholinergic drugs at the same time may not be good candidates for MDT, for three reasons. Patients with low saliva production, which can cause oral dryness, may not benefit from these tablet formulations either.

Different Techniques Used in The Preparation of MDTs [6,7,8,9]

The various methods have been attempts for formulation of MDTs like

a) Molding
b) Freeze drying
c) Mass Extrusion
d) Tablet Molding
e) Direct Compression
f) Spray drying

a. Molding:

In this technique, water-soluble chemicals are used to make molded tablets that dissolve quickly and completely in the mouth. The powder mixture is wetted with a hydroalcoholic solvent & compressed into tablets at a lower pressure than is typically utilized. After that, air drying gets rid of the remaining solvent. When compared to compressed tablets, molded tablets are noticeably bulkier. Because of their porous form, they dissolve more quickly.

b. Freeze drying

Lyophilization refers to a process of low temperature drying where the water is removed by sublimation. Medication in a very porous, freeze-dried, water-soluble matrix. When lyophilized tablets are placed in the mouth, the saliva quickly dissolves them because the pores in the tablet are so small. This process takes less than 5 seconds. Drugs that are sensitive to heat, or thermo-labile compounds, benefit from lyophilization.

c. Mass Extrusion

This method involves softening a mixture of active drug and other ingredients in a solvent mixture of water-soluble polyethylene glycol and methanol before extruding the resulting mass through an extruder or syringe to create a cylinder of product, which is then divided into uniform segments using heated blades. The granules of bitter-tasting medications can have their unpleasant flavor disguised by coating them with the dried cylinder.

d. Tablet Molding

There are two distinct molding processes—the solvent approach and the heat method. Tablets made using the solvent approach have a porous structure that speeds up dissolving as well as are less compact than compacted tablets. It is of major concern that moulded tablets lack sufficient mechanical strength. Improve the tablets' mechanical stability by including binding agents33. The disguised drug particles are made by spray congealing a molten combination of hydrogenated polyethylene glycol, cottonseed oil, lecithin, as well as sodium carbonate, the active component, into a lactose-based tablet triturate form, which presents its own set of challenges. The moulding method is more amenable to industrial scale production of tablets than the lyophilization method.

e. Direct Compression:

The production of tablets using direct compression is the simplest and least expensive method. This method may now be used for the manufacturing of Fast Dissolving Tablets due to the availability of enhanced excipients, in particular superdisintegrants as well as sugar-based excipients.

f. Spray drying

Powders made with spray drying are very fine and porous, thus they dissolve quickly. The basis of this method is a powdered support matrix that has been made by spray drying an aq. mixture including the matrix and other components. The mixture was then pressed into tablets after being combined with the active components. The formulations may also include an acidic material (like citric acid) and/or an alkaline material (like sodium bicarbonate) to improve disintegration and solubility. Other ingredients may include mannitol, sodium starch glycolate, and crosscarmellose sodium. When placed in water for 20 seconds, the spray-dried powder tablet that was crushed from it completely dissolved.

Evaluation of Mouth Dissolving Tablets [10,11,12]

1) **Size, Shape, Thickness and diameter:** The tablet's dimensions may be specified, tracked, and adjusted with relative ease. The thickness of tablets is critical for both their visual appeal and their accurate counting when employing filling machinery. Tablets with a consistent thickness may be counted by some filling machines. Take ten tablets and use a vernier caliper to measure their thickness.
2) **Uniformity of weight:** Uniformity of weight was ensured in the Indian pharmacopoeia by weighing ten or twenty tablets separately and as a group using a computerized weighing scale. Then, the total weight of the tablets must be divided by the number of tablets to obtain an average tablet weight. To check for consistency in drug content, a simple weight difference test would suffice.
3) **Tablet Hardness:** The hardness of a tablet is measured by the force required to crack it across its diameter. The tablet's hardness determines how well it holds up against chipping, abrasion, and fracture during the storage, transformation, and handling processes that precede actual use. The Monsanto hardness tester was used to measure the tablet hardness of each formulation.
4) **Tablet friability:** The plastic chamber of the friabilator revolves at 25 revolutions per minute, and the tablets are dropped from a height of 6 inches with each rotation. For at least four minutes, the friabilator rotated the tablets. At the conclusion of these tests, the tablets must be dedusted and reweighed; the percentage of weight loss is the measure of friability.

$$\% \text{ Friability} = [(W1-W2)100]/W1$$

Where, W1= Weight of tablet before test,
W2 = Weight of tablet after test

5) **Disintegration time:** Tablets are inserted in the disintegration tube as

well as the time is recorded, as per the pharmacopoeia. The European pharmacopoeia specifies that rapid disintegrating or orodispersible tablets must disintegrate in the mouth in three minutes.

6) **In vitro dispersion time:** Dropping a tablet into 6 milliliters of distill water in a 10-milliliter measuring cylinder will give you the dispersion time. Finally, a dispersion time was calculated as the time needed for full dispersion.
7) **Wetting time:** In a petri dish of the same diameter, lay five circular tissue sheets (10 cm in this case). Petridish must be dissolved in ten millimeters of water containing the water-soluble dye Eosin. Then, gently lay the tablet on top of the tissue. Wetting time is measured from the moment water hits the tablet to the moment it reaches the top.
8) **The ratio of water absorbed:** Tissue paper should be folded in half and placed in a 6 ml Petri dish of water. Put a tablet on the paper and time how long it takes to get completely saturated. Next, record how much a pill has weighed after being wet. The final step is to use the following equation to get the water absorption ratio (R):

$$R = 100 \times Wa-Wb / Wb$$

Where-
Wb is weight of tablet before water absorption.
Wa is weight of tablet after water absorption.

9) **In vitro dissolution test:** A USP class II apparatus (paddle type) [Electrolab (ETC -11L) Tablet dissolution tester] rotated at 50 rpm is required for the in vitro dissolving investigation. Mainly used as a dissolving media, phosphate buffer pH 6.8, 900 milliliters must be kept at 370.5°C. At 2-minute intervals, aliquots of the dissolving media (10 ml) must be withdrawn and subjected to filtering. By measuring the sample's absorbance, a UV Spectrophotometer (Shimadzu, Japan) calculated the quantity of medication that had been dissolved. The standard deviation and mean percentage of drug release from three experiments per batch were reported.
10) **Stability study (Accelerated):** MDTs are kept in accordance with ICH recommendations for accelerated studies for the following time period and in the following container.

a) 40 ± 1°C
b) 50 ± 1°C
c) 37 ± 1°C and Relative Humidity= 75% ± 5%

After 15 days, take the tablets out of the bottle and have them tested for visual faults, friability,
hardness, disintegrations, as well as dissolution. Degradation kinetics are calculated by fitting the collected data into first order equations. To calculate the storage life at 25 degrees Celsius, the accelerated stability data is plotted using the Arrhenius equation.

Conclusion

First-dissolving tablets (FDTs) are a type of oral dosage form designed to dissolve or disintegrate quickly in the mouth, usually in a matter of seconds. Advantages of MDTs over more traditional dose forms are numerous. Making the tablet matrix porous or adding a super disintegrant as well as effervescent excipients are two ways to speed up the disintegration, dissolving, or melting in the oral cavity that is crucial to MDT formulations. MDTs made by direct compression often have strong mechanical qualities, and further treatments such moisture treatment can increase strength even more. Given their numerous advantages, MDTs will eventually be used in the preparation of the bulk of oral formulations

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