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Mouth Dissolving Tablet Is A Medical Boon To Achive The Therapeutic Effect Of Medicaments

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Abstract:

Mouth dissolving tablet is a rapidly dissolving dosage form that dissolves in the mouth without the intake of water and is mainly used for pediatric and geriatric patients due to its flexibility and patient compliance due to saliva components. It is a potential dosage form for drugs having high metabolism and low bioavailability. Solvent casting, hot melt extrusion, solid dispersion, semisolid casting, rolling, and other processes can all be used to create mouth dissolving tablet, but solvent casting is the most popular due to its consistency and superior physical properties. Mouth dissolving tablet is evaluated for the following parameters like physical parameters and chemical parameters some time it is also known as a orodispersible which disperse or disintegrate into oral cavity. The time required to disintegrate should be not more than 3 minutes. Dosage forms in which they are available are tablets and mouth dissolving tablets which when placed in oral cavity release drug instantaneously with rapid onset of action.

Keywords: MDT, Casting Tactics, Patient compliance, Geriatric Patients, Pediatric Patients.

INTRODUCTION

Mouth dissolving tablets, a new drug delivery system for the oral delivery of the drugs, was developed based on the technology of the transdermal patch. The delivery system consists of a very thin oral strip, which is simply placed on the patient's tongue or any oral mucosal. Oral route is commonly used route for the delivery of the drugs till date as it bears various advantages over the other route of drug delivery, but oral drug delivery systems still a date need some advancements to be made because of their some drawbacks related to particular class of patients which includes geriatric, pediatric patients associated with many medical conditions as they have difficulty in swallowing or chewing solid dosage forms.¹ Many pediatric and geriatric patients who having difficulty in swallowing are unwilling to take solid preparations as a result of concern of choking. So, fast-dissolving drug-delivery systems came into existence in the late 1970's as another to tablets, capsules and syrups for pediatric and geriatric patients who experience difficulties in swallowing traditional oral solid-dosage forms. It was developed on the basis of technology of the transdermal patch. The fast dissolving drug delivery system consists of a very thin strip that is just placed on the patient's tongue or any oral mucosal tissue, instantly wet by secretion the tablet rapidly hydrates and adheres onto the location. It then quickly disintegrates and dissolves to release the drug for oromucosal and intragastric absorption. Mouth dissolving tablets offers an elegant route for systemic drug delivery. The improved systemic bioavailability results from bypassing first pass effect and better permeability due to a well supplied vascular and lymphatic drainage.²

Special features of Mouth dissolving tablets

1. Thin elegant tablet
2. Available in various size and shape
3. Unobstructive
4. Excellent mucoadhesion
5. Fast disintegration
6. Rapid release

Advantages of fast dissolving tablets

1. Convenient dosing.
2. No water needed.
3. No risk of choking
4. Taste masking.
5. Enhanced stability.

METHOD OF PREPARATION

Mouth dissolving tablets can be prepared by

1. Solvent casting method
2. Semisolid casting method
3. Hot-melt extrusion
4. Solid dispersion extrusion
1. **Solvent Casting Method:**

In this method firstly water-soluble ingredients are mixed in water to form a viscous solution. API and remaining ingredients are dissolved in a smaller amount of solution. Both the solutions are combined by using a high shear Process. Vacuum is used to remove the air entrapped. The solution formed is then poured into a glass mold and allowed the solution to dry in the oven at 45-50°C. Then cut into pieces of desired size and shape.

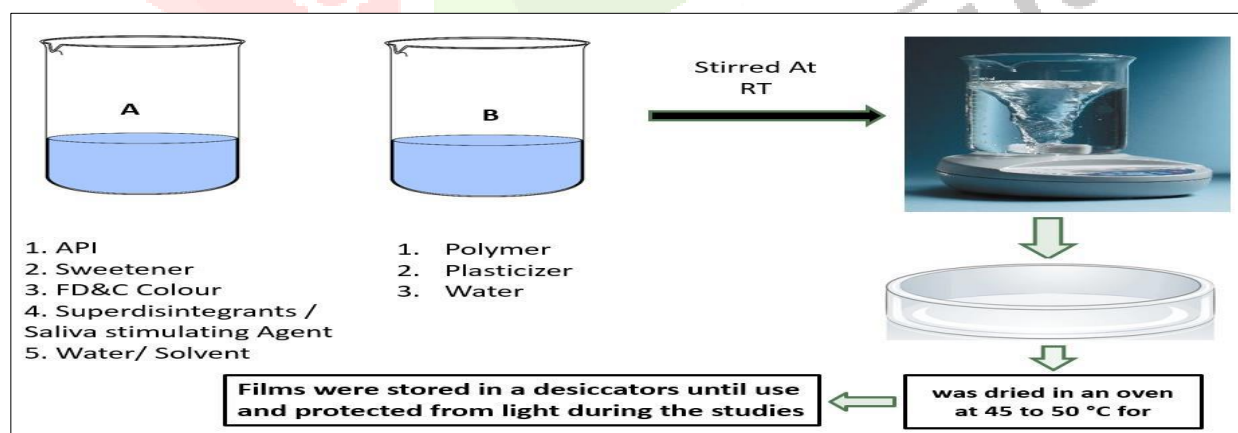


Figure no.1. Solvent Casting Method

2. Semisolid casting method:

If tablet formulations contain some acid-insoluble polymers, then this system is acceptable. In this method initially prepared water-soluble polymeric solution. Then this solution was added to the solution containing acid-insoluble polymer (Examples: cellulose acetate phthalate, cellulose acetate butyrate, etc.). The plasticizer is added in applicable quantity in order that a gel mask is created. It is then cast into the

tablets or ribbons by exploitation heat management drums. The ratio of the acid-insoluble polymer and tablet-forming polymer keep as 1:4.

3. Hot-melt extrusion:

The rug is mixed with carrier in the solid form so that Granular material is formed. These granules are then dried and then introduced into the extruder. The speed of the screw should be around 15rpm so that the granules reside inside the extruder for about 3-4 min. The processing temperature should be 100°C. The extrudate is then pressed into a cylindrical calendar to obtain a tablet.

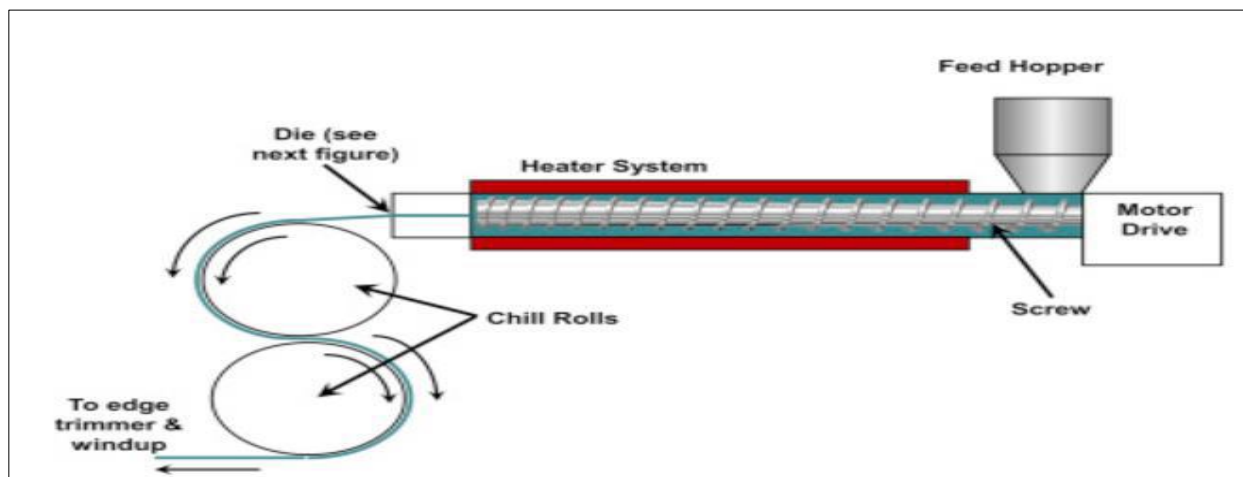


Figure no.2. Hot-melt extrusion

3. Solid Dispersion Extrusion

This method is also used to improve the solubility of the poorly water-soluble drug. The term solid dispersion is used for the dispersion of one or additional active ingredients in a very inert carrier in a solid-state within the presence of amorphous hydrophilic polymers.[2]The drug is dissolved in an appropriate liquid solvent and obtained resultant mixture is further added to the previously dissolved polymeric solution available below 70°C while not removing the liquid solvent to get the solid dispersion. Finally, the obtained solid dispersions are formed into tablets by using dyes.

5. Rolling method.

In this method, suspension or solution containing API is prepared. Then this solution is completely mixed with the solution of tablet-forming polymer. The prepared solution was placed on a carrier and allowed to move onto it. Certain rheological properties of the solution should take into consideration. Tablets are dried on the rollers and cut into desired shapes and sizes

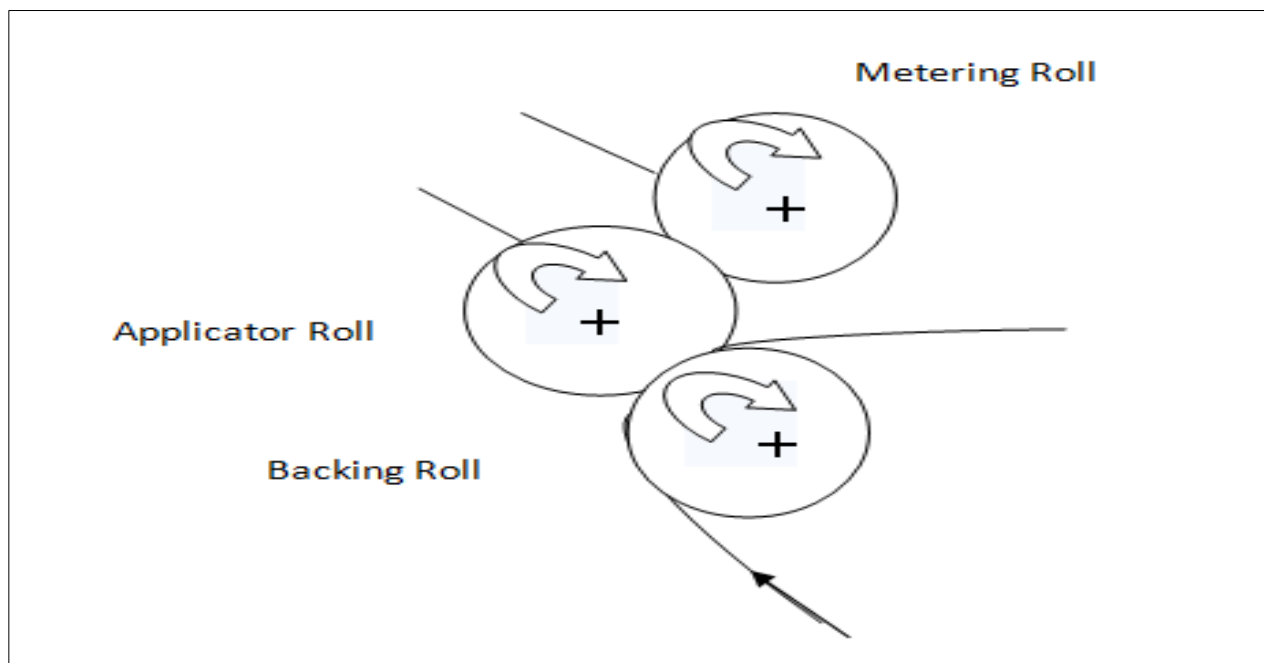


Figure no.3. Rolling method

Evaluation parameters of mouth dissolving tablets

Drug-excipients interaction studies

Assessment of possible incompatibilities between an active drug substance and different excipients plays an important part of the formulation stage during the development of solid dosage form. Fourier Transformer Infra Red Spectrum (FTIR), Differential scanning calorimeter (DSC), thin layer chromatography and X Ray Diffraction (X-RD) can be used to assess possible drug excipient interaction. DSC allows the fast evaluation of possible incompatibilities, because it shows changes in appearance, shift of melting endotherms and exotherms, and variation in the corresponding enthalpies of the reaction.

Folding endurance

To determine folding endurance, a strip of tablet is cut and repeatedly folded at the same place till it broke. The number of times the tablet could be folded at the same place without breaking gives the value of folding endurance.

Thickness

Thickness test can be carried out using an electronic micrometer. The thickness of the tablet sample should be measured at five locations (center and four corners), and the mean thickness is calculated. Samples with air bubbles, nicks or tears and having mean thickness variation of greater than 5% are excluded from analysis.

Swelling index

The studies for swelling index of the tablet are conducted in stimulated salivary fluid. The tablet sample is weighed and placed in a pre weighed stainless steel wire sieve. The mesh containing the tablet is submerged into 50 ml of stimulated salivary medium contained in a mortar. Increase in weight of the tablet is determined at each interval until a constant weight is observed. The degree of swelling is calculated using the formula.

$$SI = \frac{wt - w_o}{w_o}$$

Where SI is the swelling index,

wt is the weight of the tablet at time “t”,

w_0 is the weight of tablet at $t = 0$

Folding endurance

To determine folding endurance, a strip of tablet is cut and repeatedly folded at the same place till it broke. The number of times the tablet could be folded at the same place without breaking gives the value of folding endurance.

Tensile strength

The tensile strength (psi) is the property of the tablet that requires a load to cause load deformation failure of tablet. Evaluated this mechanical property by using Testing Instrument. Tablet strips in special dimension and free from air bubbles or physical imperfections were held between two clamps positioned at a distance of 3 cm. During measurement, the strips were pulled by the top clamp at a rate of 100 mm/min; the force and elongation were measured when the tablet broke. Results from tablet samples, which broke at and not between the clamps, were not included in the calculations. Measurements were run in triplicate for each tablet. Tensile strength is also defined as the maximum stress applied to a point at which the tablet specimen breaks and can be computed from the applied load at rupture as a mean of three measurements and cross-sectional area of fractured tablet from the following equation.

Tensile strength (N/mm²) = breaking force (N)/ cross sectional area of sample (mm²)

Disintegration test:

Disintegrating time is defined as the time (second) at which a tablet breaks when brought into the contact with water or saliva. The disintegration time is the time when a tablet starts to break or disintegrate. Thickness and mass play a role in determining the dissolvable tablets physical properties. Disintegration test is done by Disintegration apparatus.

Dissolution test:

Dissolution is defined as the amount of drug substance that goes into the solution per unit time under standardized conditions of liquid/solid interface, temperature and solvent concentration. In vitro release studies are carried out in modified USP XXIII apparatus (paddle over disk).

Barrier Tablets

Many drug preparations are extremely sensitive to moisture and therefore require high barrier tablets. Several materials may be used to provide moisture protection such as Polychlorotrifluoroethylene (PCTFE) tablet, Polypropylene. Polypropylene does not stress crack under any conditions. It is an excellent gas and vapour barrier. Lack of clarity is still a drawback.

Conclusion

This review shows that mouth dissolving tablets are promising dosage form as they have more patient compliance and rapid onset of action. Moreover they are potential candidate for oral route as they can deliver drug locally as well as systematically. MDF are used for pediatric and geriatric population or for patient those who have difficulty in swallowing. Due to these advantages MDF used to treat patient efficiently Deliver of drug through oral thin tablet provides several advantages. MDT are a very suitable dosage form for children and the elderly, because they are easy to swallow and involve no risk of choking. They usually consist of tablet-forming polymers, plasticizers and further excipients, for example, for improvement of taste. The main disadvantage of MDT is the limited drug load. MDT are commonly manufactured by solvent casting. Basic characterization methods are determination of mechanical properties and disintegration behavior.

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