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A REVIEW ON: NOVEL DRUG DELIVERY SYSTEM OF MOUTH DISSOLVING TABLET

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ABSTRACT:

The main aim of novel drug delivery system is to develop a dosage form which is easy to administer, free from side effects, exhibit immediate release and offer enhanced bioavailability for better patient compliance. To achieve such results oral drug delivery system, preferably, tablets are the most widely accepted dosage forms which offer numerous advantages. The past decade has thrown open the doors for continuous technological advancements in the pharmaceutical sector. Mouth Dissolving Tablets are one of the fruitful results of these technological advancements. MD tablets play a major role in improving the patient's compliance. They rapidly disintegrate in the saliva hence obviating the need of the water. With the increasing incidences of non-compliance among the patients, Mouth dissolving tab lets are the perfect answer to all these problems. A variety of drugs can be administered in the form of MD tablets as they give the advantage of the liquid medication in the solid preparation. These novel types of dosage forms have found acceptance among the geriatric, pediatric and dysphagia patients.

Key words: Mouth dissolving tablets, novel drug delivery, patient's compliance.

INTRODUCTION:

Patient compliance is one of the most important aspects in the pharmacy practice. Now a days, pharmacy companies are coming up with development of new drug delivery systems to ensure the delivery of the drugs to the patients efficiently and with fewer side effects. This objective led to the emergence of the concept of Mouth Dissolving Tablets. In most cases, A tablet that dissolves or disintegrants in the oral

cavity without the need of water or chewing. Most fast dissolving delivery system films must include substances to mask the taste of the active ingredient. This masked active ingredient is then swallowed by the patient's saliva along with the soluble and insoluble excipients. This attribute makes these dosage forms highly attractive product for the pediatric, geriatric and dysphagia

Mouth Dissolving Tablet (MDT):

These dosage forms rapidly disintegrate and dissolve to release the drug when they come in contact with saliva, Thus there is no need of water during administration, an attribute that makes them highly suitable for pediatric and geriatric patients. A mouth dissolving tablet dissolves in the oral cavity within 15 s to 3 min and mainly contains certain super disintegrants.

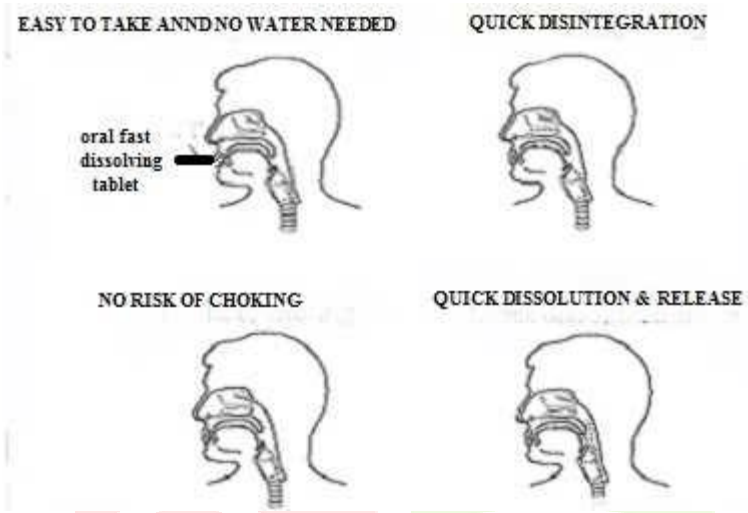

Fig. Advantages of MDT

Ideal Properties of MDT:

Mouth Dissolving Tablet should:

a. Easily dissolve or disintegrate in salivary fluid within a few seconds.

b. Have a gratifying taste.

c. Leave negligible or no residue in the mouth when administered.[1]

d. Be portable and easy to transport.

e. Manufacturing procedure is simple and within low budget.

f. exhibit low sensitivity to environmental conditions like temperature, humidity etc.[1,2]

Advantages of MDT:

a. Do not require water to swallow the tablet.[3]

b. It can be easily administered to pediatric, elderly and mentally disabled patients.

c. Accurate dosing[4] as compared to liquids.

d. Rapid onset of action as dissolution and absorption of drug.

f. First pass metabolism is reduced, thus offering improved bioavailability and thus reduced dose and side effects.

g. Free of risk of suffocation due to physical obstruction when swallowed, thus offering improved safety.

h. Suitable for sustained/controlled release actives.[5]

i. Allows high drug loading[6]

Limitations of Mouth Dissolving Tablets:

1. Mechanical strength of final product.

2. Drug and dosage form stability.

3. Mouth feel.

4. The tablets may leave unpleasant taste or grittiness in mouth if not formulated properly.

5. Dissolution rate of formulated drug in saliva.

6. Swallow ability.

7. Rate of absorption of drug from the saliva fluids.

8. Overall bioavailability.

9. Decreased saliva production leads to dryness of mouth which may not be good candidates for these tablet formulations.

Criteria For Drug Selection:

The main criteria's for a drug to be selected are as follows:

• It should not have bitter taste.

• The dose should be less than 20mg.

• Moderate molecular weight should be small.

• Should be of good solubility in water and saliva.

• Should have extensive First pass metabolism

• Should have oral tissue permeability.

FORMULATION OF MDTs[7,8,9,10]:

The ideal characteristics of a drug for dissolution in the mouth and pre gastric absorption from MDTs include:

1. Free from bitter taste.

2. Dose lower than 20 mg.

3. Small to Moderate molecular weight.

4. Good solubility in saliva.

5. Ability to permeate through oral mucosal tissue.

Bulking materials: Bulking materials are significant in the formulation of mouth dissolving tablets. These improve the textural characteristics that successively enhance the disintegration in the mouth, besides this adding bulk material also reduces the concentration of the active material in the composition. The suggested bulking agents for this delivery system ought be more sugar-based such as mannitol, polydextrose, lactitol. DCL (direct compressible lactose) and starch hydrolystate for higher aqueous solubility and good sensory perception. From these Mannitol in particular has high aqueous solubility and good sensory perception. Bulking agents are incorporated in the range 10 percent to 90 percent by weight of the final composition.

Emulsifying agents: Emulsifying agents are important excipients for formulating these tablets, they aid in rapid disintegration and drug release without chewing, swallowing or drinking water. Incorporating emulsifying agents is useful tool in stabilizing the immiscible blends and enhancing bioavailability. A wide range of emulsifiers are present for fast-tablet formulation, including alkyl sulphate, propylene glycol esters, lecithin, sucrose esters and others. These agents are added in the range of 0.05 percent to about 15 percent by weight of the final composition.

Lubricants: Lubricants, although not an essential excipient, but can make 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 e.g. Magnesium Stearate.

Flavours and sweeteners: Flavours and taste-masking agents make the products more appetizing for patients. These are added to overcome bitterness and undesirable tastes of some active ingredients. Both natural and synthetic flavours can be used to boost the organoleptic characteristic of these tablets. Formulators can choose a wide range of sweetening agents including sugar, dextrose and fructose, as well as non-nutritive sweeteners such as aspartame, sodium saccharin, sugar alcohols and sucralose. The addition of these agents contributes a pleasant taste as well as bulk to the composition.

Superdisintegrants: Use of disintegrants is the basic approach in development of MDTs. Disintegrants play a vital role in the disintegration and dissolution of MDT. It is essential to choose a suitable disintegrant in a suitable concentration so as to ensure fast disintegration and high dissolution rates.[11] The quick action is due to combined effect of swelling and water absorption by the formulation. Due to swelling of superdisintegrants, the wetted surface of the carrier increases, this promotes the wettability and dispersibility of the system, thus enhancing the disintegration and dissolution.[12,13] The desired concentration of the superdisintegrant can be selected according to critical concentration of disintegrant. Below this concentration, the tablet disintegration time is inversely proportional to the concentration of the superdisintegrant, whereas if concentration of superdisintegrant is above critical concentration, the disintegration time remains almost constant or even increases. Sodium starch glycolate, crosscarmellose sodium, Crospovidone, Microcrystalline cellulose, Pregelatinised starch are some of examples of disintegrants

Conventional Techniques For Mouth Dissolving Tablets:

There are many conventional techniques for the formulation of MDT's. These are as follows[14]:

- Freeze drying/Lyophilization
- Spray drying
- Sublimation
- Direct compression
- Mass extrusion
- Tablet molding

Freeze drying[15]: Pills for dry suspension or lyophilisation are very worms in nature and deteriorate or melt quickly when they come in contact with saliva. In this process, water is reduced from the product after cooling. First, the material is frozen to bring it under its eutectic point. After that the main drying is done to reduce the humidity to about 4% w/w of dry product. Finally, a second drying is done to reduce the bound moisture to the required volume. As a result of lyophilization, the bulking agent and sometimes the drugs acquire a shiny amorphous structure so the solubility is improved. A tablet that dissolves rapidly in an aqueous solution incorporates a slightly collapsed matrix network that has dried over the deteriorating matrix temperature. The matrix is slightly dried below the freezing point of the matrix. The tablet freezer above its fall temperature, instead of freezing structural integrity, while rapidly decreasing at normal prices

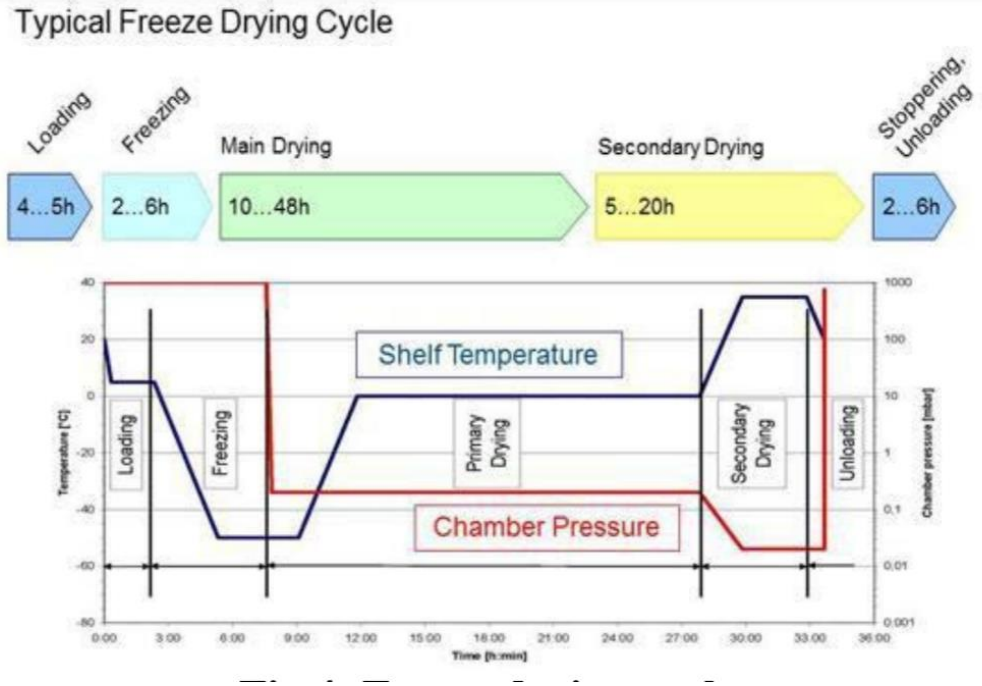

Fig. Freeze Drying

Spray drying: The bold and well-prepared powder is prepared by drying the spray into a liquid form containing a support matrix and other materials. This is then combined with the active ingredient and pressed on the tablet. Allen and Wang[16] used this method to prepare oral contraceptives, which last between 20 s

Sublimation: This process involves the addition of certain unhealthy substances such as urea, urethane, naphthalene, camphor, etc. Sublimation removal[17] by sublimation creates pores in the structure of the tablet, because the tablet dissolves when it comes in contact with saliva. In addition several solvents such as cyclohexane, benzene etc. can be used as pore forming agents. Mouth-melting tablets have a very strong structure and good mechanical strength developed in this way.[18,19]

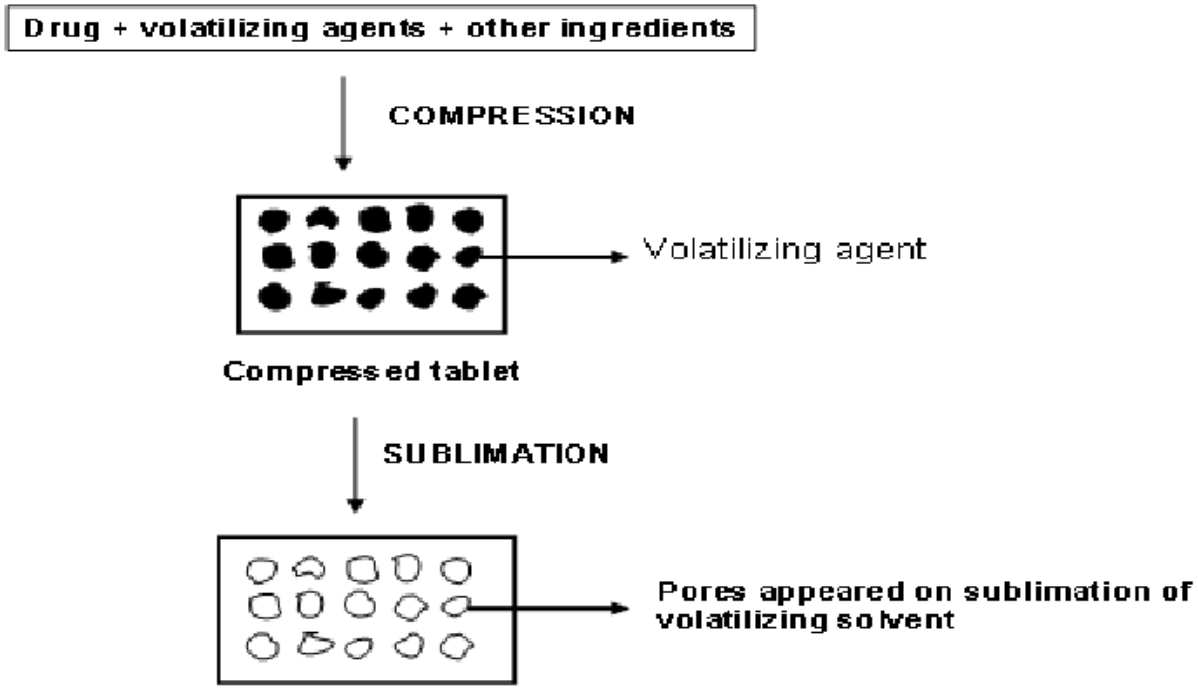

Fig. Sublimation.

Direct compression: Separate supplement technology[20,21] (direct compression) is the most preferred method of making pills due to certain benefits: a. Higher doses can be applied and the final weight of the tablet may exceed that of other alternatives. b. An easy way to make pills. c. Common resources and commonly available resources use d. No restrictions. Processing steps are involved. e. Cost - efficiency. Tablet size and stiffness significantly affect degraded performance. Sturdy and large tablets have more time to disperse than usual. Soft and very thin tablets with minimal repair power. Therefore, the appropriate type and concentration of degradation should be selected in order to achieve rapid dispersion and high levels of elimination. In addition to the critical concentration level, however, the dispersion time remains almost constant or increased.[22]

Mass extrusion[23,24] : In this process a mixture of the active ingredient and other ingredients is diluted with a solution of watersoluble polyethylene glycol, methanol and the softened mass extracted by an extruder or syringe to obtain a product cylinder, which is then cut in half with the help of thick leaves to get the pills. The dry cylinder can be used to cover the granules of spicy drugs and thus obscure their bitter taste Moulding: Tablets prepared in this way are strong dispersions. The type of drug itself in the pills depends on how much of it is dissolved and to what extent in the amount of water[25] .The drug can be discrete particles or small particles in the matrix. It can be completely dissolved into a solid solution or slightly dissolved in the dissolved carrier and, if present, remain undefined and dispersed in the matrix.[26] Duration of failure, rate of drug withdrawal and oral sensitivity will depend on the type of dispersion.

Different moulding techniques can be used to prepare mouth-dissolving tablets:

a. Compression moulding: The powder mixture previously wetted with a solvent like ethanol/water is compressed into mould plates to form a wetted mass.

b. Heat moulding: A molten matrix in which drug is dissolved or dispersed can be directly moulded into Mouth dissolving tablets.[27]

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. The technology described in this article indicates that recent developments have taken place development and processing technology meets the efforts to achieve complex drugs delivery system. Oral contraceptives, geriatric, sensible patients, bedridden and those who are busy traveling and do not need to check watering. Drugs delivered to MDT'S can enter very pregastric sites.

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