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Recent Advances in Manufacturing Technologies and Future Prospects of Mouth Dissolving Tablets (FDTs)

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ABSTRACT

Due to the increasing demand of novel drug delivery, the fast disintegrating drug delivery system has become one of the mile stone in the novel drug delivery system. The introduction of fast dissolving drug delivery system has encountered the delivery of conventional dosage form. Recent advances in the formulation development and processing technologies meet the efforts to achieve more sophisticated drug delivery system. Mouth dissolving tablets need to be formulated for pediatric, geriatric, psychotic patients, bedridden and for those who are busy in travelling and may not have to assess to water. The drugs delivered in MDT'S may be absorbed in the pregastric sites of highly permeable buccal and mucosal tissues of the oral cavity and they may be suitable of low molecular weight and highly permeable drugs.

Keywords: Mouth dissolving tablets, Zydis technology, Wow tab technology, Oraquick technology, Future prospects

I. INTRODUCTION

Novel technologies with improved performance, patient compliance, and enhanced quality have emerged in the recent past[1]. The fast dissolving drug delivery system started gaining popularity and acceptance as a new drug delivery system because they are easy to administer and lead to better patient compliance. Fast dissolving drug delivery system can be obtained by the various techniques i.e. direct compression, tablet molding, freeze drying, spray drying nanonization[2-3]. Oral fast-dissolving tablets, are an examples of a few existing technologies with the potential to accommodate various physicochemical, pharmacokinetic and pharmacodynamic characteristic of drugs. Despite of tremendous advancements in drug delivery, the oral route remains the perfect route for the administration of therapeutic agents because of low cost of therapy, ease of administration, accurate dosage, self-medication, pain avoidance, versatility, leading to high levels of patient compliance. Tablets and

capsules are the most popular dosage forms. But one important drawback of such dosage forms is 'Dysphagia' or difficulty in swallowing[4].

Ideal Properties of MDT[5]

A Mouth Dissolving Tablet should

a. Not require water or other liquid 5 to swallow.

b. Easily dissolve or disintegrate in saliva within a few seconds.

c. Have a pleasing taste.

d. Leave negligible or no residue in the mouth when administered.

e. Be portable and easy to transport.

f. Be able to be manufactured in a simple conventional manner within low cost.

g. Be less sensitive to environmental conditions like temperature, humidity etc.

Advantages of MDT[6]

a. No need of water to swallow the tablet.

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

c. Accurate dosing as compared to liquids.

d. Dissolution and absorption of drug is fast, offering rapid onset of action.

e. Bioavailability of drugs is increased10as some drugs are absorbed from mouth, pharynx and esophagus through saliva passing down into the stomach

f. Advantageous over liquid medication in terms of administration as well as

g. transportation

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

i. Free of risk of suffocation due to physical obstruction when swallowed, thus

j. offering improved safety.

Approaches for Preparation of MDT[7]

Various technologies used in the manufacture of Mouth Dissolving

Tablets include:

1. Freeze-drying or lyophilization
2. Sublimation
3. Spray drying
4. Moulding
5. Mass extrusion
6. Direct compression

Table 1. Technologies used to manufacturing mouth dissolving tablets

CONVENTIONAL	PATENTED TECHNOLOGIES
Freeze Drying.	Zydis Technology.
Tablet Moulding.	Durasolv Technology.
Sublimation	Orasolv Technology.
Spray Drying.	Flash dose Technology.
Mass extrusion	Wow tab Technology.
Direct Compression	Flash tab Technology
Shea form Technology.	

Freeze drying:

The tablets prepared by freeze-drying or lyophilization are very porous in nature and disintegrate or dissolve rapidly when come in contact with saliva. In this process, water is sublimated from the product after freezing. First of all, the material is frozen to bring it below its eutectic point. Then primary drying is carried out to reduce the moisture to around 4% w/w of dry product. Finally, secondary drying is done to reduce the bound moisture to the required volume. Due to lyophilization, bulking agent and sometimes drug acquire glossy amorphous structure and thus dissolution is enhanced. A tablet that rapidly disintegrates in aqueous solution includes a partially collapsed matrix network that has been vacuum dried above the collapsed temperature of the matrix. The matrix is partially dried below the equilibrium freezing point of the matrix. Vacuum drying the tablet above its collapse temperature, instead of freeze drying below its collapse temperature provides a process for producing tablets with enhanced structural integrity, while rapidly

disintegrating in normal amounts of saliva. However the use of freeze-drying is limited due to high cost of equipment and processing. Other major disadvantages of the final dosage forms include lack of physical resistance in standard blister packs.

Sublimation:

This process involves addition of some inert volatile substances like urea, urethane, naphthalene, camphor, etc to other excipients and the compression of blend into tablet. Removal of volatile material by sublimation creates pores in tablet structure, due to which tablet dissolves when comes in contact with saliva. Additionally several solvents like cyclohexane, benzene etc can also be used as pore forming agents. Mouth dissolving tablets with highly porous structure and good mechanical strength have been developed by this method.

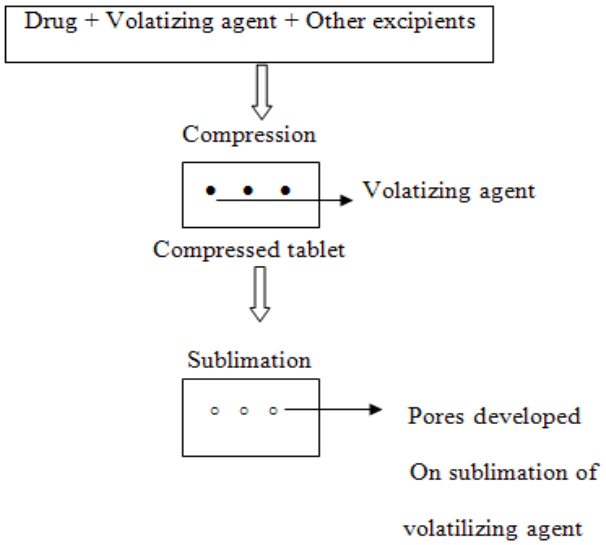

Figure 1. Sublimation

Spray drying:

A highly porous and fine powder is prepared by spray drying an aqueous composition containing support matrix and other components. This is then mixed with active ingredient and compressed into tablet. Allen and Wang used this technique to prepare mouth-dissolving tablets, which disintegrated within 20 s.

Moulding:

Tablets prepared by this method are solid dispersions. Physical form of drug in the tablets depends on whether and to what extent it dissolves in the wetted mass.26 The drug can exist as discrete particles or micro particles in the matrix. It can dissolve totally to form a solid solution or dissolve partially in the molten carrier and remaining, if any, stays undissolved and dispersed in the matrix. Disintegration time, drug dissolution rate and mouth feel 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

c. No vacuum lyophilization: This process involves evaporation of solvent from a drug solution or suspension at a standard pressure. Moulded tablets posess porous structure, which facilitates rapid disintegration and easy dissolution. Moulded tablets offer improved taste due to water-soluble sugars present in dispersion matrix. But moulded tablets lack good mechanical strength and can undergo breakage or erosion during handling and opening of blister packs. However, adding sucrose, acacia or polyvinyl pyrrolidone can increase mechanical strength.

Mass extrusion:

In this technique, a blend of active drug and other ingredients is softened using solvent mixture of water soluble polyethylene glycol, using methanol and then the softened mass is extruded through the extruder or syringe to get a cylinder of product, which is finally cut into even segments with the help of heated blades to get tablets. The dried cylinder can be used to coat the granules of bitter tasting drugs and thereby masking their bitter taste.

Direct compression:

The disintegrant addition technology (direct compression) is the most preferred technique to manufacture the tablets due to certain advantages:

a. High doses can be accommodated and final weight of the tablet can exceed that of other methods.

b. Easiest way to manufacture the tablets.

c. Conventional equipment and commonly available excipients are use.

d. A limited no. of processing steps are involved.

e. Cost-effectiveness.

Tablet size and hardness strongly affect the disintegrant efficacy. Hard and large tablets have more disintegration time than normally required. Very soft and small tablets have low mechanical strength. So, an optimum kind and concentration of disintegrant should be chosen to achieve quick disintegration and high dissolution rates. Above the critical concentration level, however, disintegration time remains approximately constant or even increases.

Patented technologies for MDT's:

The main patented technologies for mouth dissolving tablets are as follows

Zydis technology:

Zydis was the first marketed technology which was developed by R.P. Scherer. Inc., for new generation tablet formation. By freeze drying the drug in a matrix, consisting of gelatin the Zydis tablet was produced. The product is dispensed in a special blister packing because it is very light weight and fragile. Due to freeze drying, there is very little amount of water left in a drug for the attack of microorganism, so this preparation is self preserving. The tablets made by Zydis technology have very few seconds disintegration time[8-9].

Durasolv technology:

This is the CIMA labs patented technology. The tablet consists of drug fillers and a lubricant made by this technology. In this method the tablets are prepared by using conventional tabletting equipment and have good rigidity property[10].

Orasolv technology:

This technology was also prepared by CIMA labs 8. To minimize the oral disintegration and dissolution time, these are prepared by direct compression at low compression force. Orasolv is a slightly effervescent tablet example because it can dissolve rapidly in mouth. In it the active ingredients are dispersed in saliva due to the action of effervescent agent and also taste masked. The low mechanical strength is the major limitation of this technology. The tablets prepared by this method need to be packaged in a specially designed pack because these are very soft and fragile in nature[11].

Wow tab technology:

This technology follows the combination of low and high mouldability saccharides to prepare mouth dissolving tablets by using conventional tablet technique and granulation process. According to patent, the low mouldability saccharides are lactose, mannitol, sucrose and glucose etc, whereas the high mouldability saccharides include maltitol, maltose, oligosaccharides and sorbitol etc. prepared by compressing both low and high mouldability saccharides, only then the desired properties of hardness and quick disintegration in mouth can be achieved[12].

Cotton candy technology:

This technology is patented by Fuisz. This technology produces floss like crystalline structure due to their unique spinning mechanism. The active drug in a tablet can be incorporated by crystalline sugar. The final product prepared by this technology has a very high surface area for dissolution. It disperses and dissolves quickly, when placed on tongue[13].

Oraquick technology:

The patented taste masking technology is utilizes by the mouth dissolving tablet formulation. K V Pharmaceutical company, claims that its taste masking technology i.e. microsphere technology has superior mouth feel over taste masking alternatives. Any kind of solvents are not utilized by taste masking process. Therefore it leads to superior and fast

efficient production. Without disrupting taste masking the tablets of significant mechanical strength are obtained by after compression. Only K V Pharmaceutical has their products in the market in different classes of drugs like cough and cold, analgesic, psychotics and anti-infective in developmental stage[14-15].

Flashtab technology:

The Flashtab technology has patented by Prographarm laboratories 11. In this technology, the tablet which consists an active ingredient in the form of microcrystals are prepared, having rapidly disintegrating property. By using the conventional techniques like microencapsulation, coacervation and simple pan coating drug microgranules can be prepared. The active ingredients into tablets by addition of granulated mixture of excipients prepared by wet or dry granulation method. The tablets prepared by this technology have less than one minute disintegrating time and good mechanical strength[16-18].

Future prospects of MDT

Mouth dissolving tablets can offer several biopharmaceutical advantages such as improved efficiency over conventional dosage forms. For example, they require smaller amounts of active ingredient to be effective, improve absorption profiles, and offer better drug bioavailability than regular tablets and capsules. In addition, MDTs may be suitable for the oral delivery of drugs such as protein and peptide-based therapeutics that have limited bioavailability when administered by conventional tablets. These products usually degrade rapidly in the stomach. Because drugs delivered in MDTs may be absorbed in the pregastric sites of highly permeable buccal and mucosal tissues of the oral cavity, they may be suitable for delivering relatively low-molecular weight and highly permeable drugs. Future possibilities for improvements in MDTs and drug delivery are bright, but the technology is still relatively new. Several drug delivery technologies that can be leveraged on improving drug therapy from MDTs have yet to be fully realized[19-20].

II. CONCLUSION

Recent advances in Novel Drug Delivery Systems (NDDS) aim for designing dosage forms, convenient to be manufactured and administered, free ofside effects, offering immediate release and enhanced bioavailability, so as to achieve better patient compliance. Though oral drug delivery systems, preferably, tablets are the most widely accepted dosage forms, for being compact, offering uniform dose and painless delivery. Yet, dysphagia is the most common disadvantage of conventional tablets. This is seen to afflict nearly 35% of the general population and associated with a number of conditions, like parkinsonism, mental disability, motion sickness, unconsciousness, unavailability of water etc. To overcome such problems, certain innovative drug delivery systems, like 'Mouth Dissolving Tablets' (MDT) have been developed. These are novel dosage forms which dissolve in saliva within a few seconds, when put on tongue. Such MDTs can be administered anywhere and anytime, without the need of water and are thus quite suitable for children, elderly and mentally disabled patients.

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