

**FAST DISSOLVING TABLETS: A REVIEW****Bhumika Verma\*, Vivek Patel and Dr. Pranav Upadhyay**

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Fast dissolving tablets emerge as one of the popular and widely accepted dosage forms, especially for pediatric patients because of incomplete development of the muscular and nervous system and a case of geriatric patients suffering from Parkinson's disorder or hand tremors. Few solid dosage forms like capsules and tablets are present days facing the problems like difficulty in swallowing (dysphagia), resulting in many incidences of non-compliance and making the therapy ineffective. Oral dosage form and oral route are the most preferred route of administration for various drugs have limitations like first-pass metabolism, psychiatric patients, bedridden and uncooperative patients. FDTs are disintegrating or dissolve quickly in the saliva without a need of water. Fast dissolving tablets are designed to dissolve in saliva remarkably faster, within a few seconds (less than 60 seconds), and those are real fast-dissolving tablets. FDTs

formulations contain super disintegrants to enhance the disintegration rate of a tablet in the buccal cavity. FDTs have advantages such as easy portability and manufacturing, accurate dosing, good chemical and physical stability and an ideal alternative for geriatric and pediatric patients. FDTs have disintegrated quickly, absorb faster so, in vitro drug release time improve and this property of drugs (dosage form) enhanced bioavailability. FDT formulations have the advantage of both conventional tablet formulation and liquid dosage form. There are several technologies that are conventional or patented based on spray drying, cotton candy process, sublimation, melt granulation, direct compression freezes drying/lyophilization, phase transition process, mass extrusion, etc. have been developed for manufacturing of FDTs. In this review contain brief information about FDTs including definition, advantages, needs or requirements of FDTs, salient features of FDTs, limitations, challenges to developing FDT, marketed formulations of fast dissolving tablets, etc.

**KEYWORDS:** Fast dissolving tablets, FDTs, Superdisintegrants, Mouth dissolving tablets, MDTs

## INTRODUCTION

Formulation of drugs into a presentable form is the basic requirement and need of today. The dosage form is a mean of drug delivery system, used for the application of the drug to a living body. Various type of dosage forms are available such as tablets, syrups, suspensions, suppositories, injections, transdermal and patches having a different type of drug delivery mechanisms. These classical/ modern dosage forms have some advantages and disadvantages. Therefore, the development of an ideal drug delivery system is a big challenge to the pharmacist in the presence scenario. In order to get the desired effect, the drug should be delivered to its site of action at such rate and concentration to achieve the maximum therapeutic effect and minimum adverse effect. For the development of a suitable dosage form a thorough study about the physicochemical principles that governs a specific formulation of a drug should be subjected.<sup>[1]</sup> Oral routes of drug administration have wide acceptance up to 50- 60% of total dosage forms. Solid dosage forms are popular because of ease of administration, accurate dosage, self-medication, pain avoidance and most importantly the patient compliance. The most popular solid dosage forms are being tablets and capsules; one important drawback of this dosage forms for some patients is the difficulty to swallow. Drinking water plays an important role in the swallowing of oral dosage forms. Often times people experience inconvenience in swallowing conventional dosage forms such as tablet when water is not available, in the case of the motion sickness (kinetosis) and sudden episodes of coughing during the common cold, allergic condition and bronchitis. For these reason, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention.<sup>[2]</sup> The problem of swallowing is a common phenomenon in a geriatric patient due to fear of choking, hand tremors, dysphasia and in young individuals due to underdeveloped muscular and nervous systems and in schizophrenic patients which leads to poor patient compliance. Approximately one-third of the population (mainly paediatric and geriatric) has swallowing difficulties, resulting in poor compliance with oral tablet drug therapy which leads to reduced overall therapy effectiveness. For these reason, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention.<sup>[3]</sup> United States Food and Drug Administration (USFDA) defined fast dissolving tablet (FDT) as “a solid dosage form containing a medicinal substance or active ingredient which disintegrate rapidly usually within a matter of seconds when placed upon the tongue”.<sup>[3]</sup> Fast

dissolving drug delivery systems were first developed in the late 1970s as an alternative to conventional dosage forms for the pediatric and geriatric patient. These tablets are designed to dissolve or disintegrate rapidly in the saliva generally less than 60 seconds.<sup>[5]</sup> To fulfill these medical needs, pharmaceutical technologists have developed a novel oral dosage forms known as orally disintegrating (dispersible) tablets (ODTs) or Fast disintegrating (dissolving) tablets (FDTs) or mouth melting tablets (MMTs) or mouth dissolving tablets (MDTs), immediate release tablets which disintegrate rapidly in saliva, usually in a matter of seconds, without the need to take water. Recent market studies indicate that more than half of the patient population prefers FDTs to other dosage forms. Mouth dissolving tablets are formulated mainly by two techniques first use of super disintegrants like Croscarmellose sodium, sodium starch glycolate and crospovidone. Another method is maximising pore structure of the tablets by freeze drying and vacuum drying.<sup>[5]</sup> In all methods, direct compression is preferred because of its effortlessness, quick procedure and cost-effectiveness.<sup>[1]</sup> The bioavailability of some drugs may be increased due to absorption of drugs in oral cavity and also due to pregastric absorption of saliva containing dispersed drugs that pass down into the stomach. Moreover, the amount of drug that is subjected to first pass metabolism is reduced as compared to standard tablets.<sup>[5]</sup>

**Requirements of fast dissolving tablets Patient factors<sup>[3]</sup>** Fast dissolving dosage forms are suitable for those patients (particularly pediatric and geriatric patients) who are not able to swallow traditional tablets and capsules with an 8-oz glass of water. These include the following:

- Patients who have difficulty in swallowing or chewing solid dosage forms.
- Patients in compliance due to fear of choking.
- Very elderly patients of depression who may not be able to swallow the solid dosage forms
- An eight-year-old patient with allergies desires a more convenient dosage form than antihistamine syrup.
- A middle-aged patient undergoing radiation therapy for breast cancer may be too nauseous to swallow her H<sub>2</sub>-blocker.
- A schizophrenic patient who may try to hide a conventional tablet under his or her tongue to avoid their daily dose of an atypical antipsychotic.
- A patient with persistent nausea, who may be a journey, or has little or no access to water.

**Effectiveness factor<sup>[5]</sup>** Increased bioavailability and faster onset of action are a major claim of these formulations. Dispersion in saliva in oral cavity causes pregastric absorption from some formulate ions in those cases where drug dissolves quickly. Buccal, pharyngeal and gastric regions are all areas of absorption for many drugs. Any pre-gastric absorption avoids first pass metabolism and can be a great advantage in drugs that undergo hepatic metabolism. Furthermore, safety

profiles may be improved for drugs that produce significant amounts of toxic metabolites mediated by first-pass liver metabolism and gastric metabolism, and for drugs that have a substantial fraction of absorption in the oral cavity and pre-gastric segments of GIT. Manufacturing and marketing factors<sup>[11]</sup> As a drug nears the end of its patent life, it is common for pharmaceutical manufacturers to develop a given drug entity in a new and improved dosage form. A new dosage form allows a manufacturer to extend market exclusivity, unique product differentiation and extend patent protection. For examples, Eisai Inc. launched Aricept FDT, a line extension of donepezil for Alzheimer's disease, in Japan in 2004 and in the U. S. in 2005 in response to a generic challenge filed in the U. S. by Ranbaxy.

### Limitations of fdts<sup>[4,5]</sup>

The major disadvantages of FDTs is related to the mechanical strength of tablets.

- FDT are very porous and soft molded metrics or compressed in a tablet with low compression, which makes tablet friable and brittle which difficult to handle.
- Bad tastes drugs are difficult to formulate as FDT; special precaution should have to be taken before formulate such kind of drug.
- Several FDT are hygroscopic cannot maintain physical integrity under normal condition from humidity which requires specialized package.
- Dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations.
- Rate of absorption from the saliva solution and overall bioavailability.
- Drug and dosage form stability.
- Bulking materials<sup>[7,23]</sup> Bulking materials are important in the development of fast dissolving tablets. They contribute the functions of a diluent, filler and cost reducer. Bulking agents improve the texture of the tablets that consequently enhances the disintegration in the mouth, besides adding volume and reducing the concentration of the active in the formulation. The bulking agents for this dosage form should be more sugar-based such as mannitol, polydextrose, lactose derivatives such as directly compressible lactose (DCL) and starch hydrolysate for higher aqueous solubility and good sensory perception. Mannitol especially has high aqueous solubility and good sensory perception, as it provides a cooling effect due to its negative heat of solution. Bulking agents are added in the range of 10% to about 90% by weight of the final composition. The descending order of brittleness of excipients is ranked as microcrystalline cellulose>alpha

lactose monohydrate>spray-dried lactose>anhydrous beta lactose>anhydrous alpha lactose>> dicalcium phosphate dihydrate. The commonly used sugar-based excipients are especially bulking agents (like dextrose, fructose, lactitol, maltitol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol) which exhibit high aqueous solubility and sweetness thereby contribute taste masking property and provide pleasant mouth feel. Sugar based excipients can be of types on the basis of moulding and dissolution rate: Type 1 saccharides: (lactose and mannitol) which exhibit low moldability but high dissolution rate. Type 2 saccharides: (maltose and maltitol) which exhibit high moldability but low dissolution rate.

- Emulsifying agents<sup>[5,23]</sup> Emulsifying agents are significant for formulating fast dissolving tablets as they help in quick disintegration and drug release without the need for chewing, swallowing or drinking water. Also, emulsifying agents stabilize the immiscible blends and increase bioavailability. A variety of emulsifying agents for fast dissolving tablet formulations include alkyl sulfates, propylene glycol esters, lecithin, sucrose esters and others. These can be added in the range of 0.05% to about 15% by weight of the final formulation.
- Lubricants<sup>[5,12]</sup> Though not essential excipients, these can aid in making the tablets more palatable after they disintegrate in the mouth. Lubricants reduce grittiness and help in the drug transit process from the oral to the stomach.
- Flavours (taste masking agents) and Sweeteners.<sup>[5,23]</sup> Flavours and taste masking agents make the products more palatable and pleasing for patients. The incorporation of these ingredients assists in overcoming bitterness and undesirable tastes of some actives. Natural as well as synthetic flavours can be used to enhance the organoleptic characteristic of fast dissolving tablets. A wide range of sweeteners including sugar, dextrose and fructose, as well as non-nutritive sweeteners such as aspartame, sodium saccharin, sugar alcohols and sucralose are available. The addition of sweeteners imparts a pleasant taste as well as bulk to the formulation. Techniques for preparing fast dissolving tablets Conventional technologies Various conventional manufacturing techniques for FDDDS.

## CONCLUSION

Fast 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. Fast dissolving tablets are

designed to dissolve or disintegrate quickly in the saliva generally within less than 60 seconds (range of 5-60 seconds). Fast dissolving tablets have better patient compliance and acceptance may improve biopharmaceutical properties, bioavailability improved efficacy, convenience, and better safety compared with conventional oral dosage forms. The popularity of FDTs has increased fabulously over the last decade. FDTs need to be formulated for psychotic patients, bedridden, geriatric, pediatric patients, for those patients who may not have access to water, patients who are busy in traveling. FDTs formulations formulated by some of these conventional and patent technologies and FDTs have sufficient mechanical strength, quick disintegration/dissolution in the buccal cavity without water. The newer technologies utilized for the formulation of the FDTs that provide more effective dosage forms with more advantages and minimal disadvantages.