

## **International Journal of Drug Research and Technology**

Available online at <http://www.ijdr.com/>

### **Review Article**

## **A REVIEW ON EVALUATION AND FORMULATION OF FAST DISSOLVING TABLETS**

**Ashok Kumar\***, Varun Bhushan, Manjeet Singh and Arti Chauhan

Dept of Biotechnology, Himachal Institute of Life Sciences,  
Rampurghat Road, Paonta Sahib -173025,  
Himachal Pradesh, India

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### **ABSTRACT**

The concept of fast dissolving drug delivery system emerged from the desire to provide patient with conventional mean of taking their medication. 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. The excipients that are currently used as well as those that are expected to be used for the future development of improved FDTs are described in the review paper.

**Keywords:** Fast Dissolving tablets, Dosage, Formulation, Excipients.

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### **INTRODUCTION**

Fast dissolving dosage forms can be disintegrated, dissolved, or suspended by saliva in the mouth. This fast dissolving tablet disintegrates instantaneously when placed on tongue and releases the drug dissolves or disperses in the saliva. Fast dissolving tablets are useful in patients, like pediatric, geriatric, bedridden, or mentally disabled, who may face difficulty in swallowing conventional tablets or capsules leading to ineffective therapy, with persistent nausea, sudden episodes of allergic attacks, or coughing for those who have an active life style. Fast dissolving tablets are also applicable when local action in the mouth is desirable such as local anesthetic for toothaches, oral ulcers, cold sores, or teething, and to those who cannot swallow intact sustained action tablets/capsules.<sup>1</sup>

Mouth dissolving drug delivery systems (MDDDS) are a new generation of formulations which combine the advantages of both liquid and conventional tablet formulations, and at the same time, offer added advantages over both the traditional dosage forms. They provide the convenience of a tablet formulation and also allow the ease of swallowing provided by a liquid formulation. MDDDS offer the luxury of much more accurate dosing than the primary alternative, oral liquids. This segment of formulation is especially designed for dysphagic, geriatric, pediatric, bed-ridden, travelling and psychotic patients who are unable to swallow or refuse to swallow conventional oral formulations.<sup>1-3</sup> As they dissolve/disintegrate very fast when placed in the mouth, MDDDS are the most convenient dosage forms for dysphagic, pediatric and geriatric patients with swallowing

problem. They do not require water for administration, thus are good alternative for travelers and for bed ridden patients.<sup>4</sup> They simply vanish when placed in the mouth, so cannot be hidden in mouth by psychotic patients. These products not only increase the patient's compliance but also fetch large revenues to manufacturers due to line extension of the existing formulation. In the recent past, several new advanced technologies have been introduced for the formulation of mouth dissolving tablets (MDTs) with very interesting features, like extremely low disintegration time, exceptional taste masking ability, pleasant mouth feel and sugar free tablets for diabetic patients.<sup>5-8</sup> The technologies utilized for fabrication of MDDDS include lyophilization, moulding, direct compression and cotton candy process, spray drying sublimation, mass extrusion, nanonization and quick dissolve film formation. These techniques are based on the principles of increasing porosity and/or addition of superdisintegrants and water soluble excipients in the tablets. The formulations prepared from these techniques differ from each other on the basis of the factors like mechanical strength of final product, drug and dosage form stability, mouth feel, taste, rate of dissolution of the formulation in saliva, rate of absorption from saliva and overall drug bioavailability. Dosage forms in last two decades, but so far no standardized technique has been designed or mentioned in pharmacopoeias for their evaluation except in European Pharmacopoeia (EP), which defines orodispersible tablets as uncoated tablets intended to be placed in the mouth where they disperse rapidly before being swallowed. EP also specifies that dispersible tablets should disintegrate within 3 minutes when subjected to conventional disintegration test used for tablets and capsules. This article presents a detailed review regarding the evaluation measures available in literature to characterize the MDTs, which have been

designed keeping in view the special features of these novel drug delivery systems.<sup>9</sup>

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. Orodispersible tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people.<sup>4</sup> Fast dissolving tablets are also called as mouth-dissolving tablets, melt-in mouth tablets, Orodispersible tablets, rapimelts, porous tablets, quick dissolving etc. Fast dissolving tablets are those when put on tongue disintegrate instantaneously releasing the drug which dissolves or disperses in the saliva.<sup>5</sup> The faster the drug into solution, quicker the absorption and onset of clinical effect. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablets dosage form. The advantage of mouth dissolving dosage forms are increasingly being recognized in both, industry and academics.<sup>7</sup> According to European pharmacopoeia, the ODT should disperse/disintegrate in less than three minutes. The basic approach in development of FDT is the use of superdisintegrants like cross linked carboxymethyl cellulose (Croscarmellose), sodium starch glycolate (Primogel, Explotab), polyvinylpyrrolidone (Polyplasdone) etc, which provide instantaneous disintegration of tablet after putting on tongue, their by release the drug in saliva. The bioavailability of some drugs may be increased due to absorption of drug in oral cavity and also due to pre-gastric absorption of saliva containing dispersed drugs that pass down into the

stomach.<sup>10</sup> More ever, the amount of drug that is subjected to first pass metabolism is reduced as compared to standard tablet. The technologies used for manufacturing fast-dissolving tablets are freeze-drying, spray-drying, tablet molding, sublimation, sugar-based excipients, tablet compression and disintegration addition. As a result of increased life expectancy, the elderly constitute a large portion of the worldwide population today.<sup>11</sup> A fast-dissolving drug delivery system, in most cases, is a tablet that dissolves or disintegrates 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. These are also called melt-in-mouth tablets, repimelts, porous tablets, oro-dispersible, quick dissolving or rapid disintegrating tablets.<sup>12</sup>

### Requirements of Fast Dissolving Tablets

#### *An ideal FDT should*<sup>6</sup>

- I. Require no water for oral administration, yet dissolve / disperse/ disintegrate in mouth in a matter of seconds.
- II. Have a pleasing mouth feel.
- III. Have an acceptable taste masking property.
- IV. Be harder and less friable.
- V. Leave minimal or no residue in mouth after administration.
- VI. Exhibit low sensitivity to environmental conditions (temperature and humidity).
- VII. Allow the manufacture of tablet using conventional processing and packaging equipments.

#### Advantages of FDT<sup>4,6</sup>

Administration to the patients who cannot swallow, such as the elderly, stroke victims, bedridden patients, patients affected by renal

failure and patients who refuse to swallow such as pediatric, geriatric and psychiatric patients.

- I. Rapid drug therapy intervention.
- II. Achieve increased bioavailability/rapid absorption through pre-gastric absorption of drugs from mouth, pharynx and oesophagus as saliva passes down.
- III. Convenient for administration and patient compliant for disabled, bedridden patients and for travelers and busy people, who do not always have access to water.
- IV. Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patients.
- V. The risk of choking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety.
- VI. New business opportunity like product differentiation, product promotion, patent extension and life cycle management<sup>24</sup>.

### Criteria for Fast dissolving Drug Delivery System

The tablets should-

- I. Not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds.
- II. Be compatible with taste masking.
- III. Be portable without fragility concern.
- IV. Have a pleasant mouth feel.
- V. Leave minimum or no residue in the mouth after oral administration.
- VI. Exhibit low sensitive to environmental condition as temperature and humidity.

- VII. Allow the manufacture of the tablet using conventional processing and packaging equipments at low cost.

### **Salient Feature of Fast Dissolving Drug Delivery System**

- I. Ease of Administration to the patient who cannot swallow, such as the elderly, stroke victims, bedridden patients, patient affected by renal failure and patient who refuse to swallow such as pediatric, geriatric and psychiatric patients.
- II. No need of water to swallow the dosage form, which is highly convenient feature for patients who are traveling and do not have immediate access to water.
- III. Rapid dissolution and absorption of the drug, which will produce quick onset of action.
- IV. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases bioavailability of drug is increased.
- V. Pre-gastric absorption can result in improved bioavailability and as a result of reduced dosage; improve clinical performance through a reduction of unwanted effects.
- VI. Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patient.
- VII. The risk of choking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.
- VIII. New business opportunity like product differentiation, product promotion, patent extensions and life cycle management.
- IX. Beneficial in cases such as motion sickness, sudden episodes of allergic

attack or coughing, where an ultra rapid onset of action required.

- X. An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
- XI. Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.

### **Benefits of Fast Dissolving Tablets<sup>13-16</sup>**

It can be administered without water, anywhere, any time. Suitability for geriatric and pediatric patients, who experience difficulties in swallowing and for the other groups that may experience problems using conventional oral dosage form, due to being mentally ill, the developmentally disable and the patients who are un-cooperative, or are on reduced liquid intake plans or are nauseated. Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing where an ultra rapid onset of action required. An increased bioavailability particularly in cases of insoluble and hydrophobic drugs due to rapid disintegration and dissolution of these tablets. Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.

### **Limitations of Mouth Dissolving Tablets<sup>14</sup>**

- I. The tablets usually have insufficient mechanical strength. Hence, careful handling is required.
- II. The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly.

### **Techniques for Preparing Fast dissolving Tablets**



Many techniques have been reported for the formulation of Fast dissolving tablets or Oro dispersible tablets.

*I. Freeze drying / lyophilization*

*II. Tablet Moulding*

*III. Spray drying*

*IV. Sublimation*

*V. Direct compression*

*VI. Mass extrusion*

*I. Freeze-drying or lyophilization*<sup>17-20</sup>

Freeze drying is the process in which water is sublimed from the product after it is frozen. This technique creates an amorphous porous structure that can dissolve rapidly. A typical procedure involved in the manufacturing of ODT using this technique is mentioned here. The active drug is dissolved or dispersed in an aqueous solution of a carrier/polymer. The mixture is done by weight and poured in the walls of the preformed blister packs. The trays holding the blister packs are passed through liquid nitrogen freezing tunnel to freeze the drug solution or dispersion. Then the frozen blister packs are placed in refrigerated cabinets to continue the freeze-drying. After freeze-drying the aluminum foil backing is applied on a blister-sealing machine. Finally the blisters are packaged and shipped. The freeze-drying technique has demonstrated improved absorption and increase in bioavailability. The major disadvantages of lyophilization technique are that it is expensive and time consuming; fragility makes conventional packaging unsuitable for these products and poor stability under stressed conditions.

*II. Tablet molding*

Molding process is of two type's i.e. solvent method and heat method. Solvent method involves moistening the powder blend with a hydro alcoholic solvent followed by compression at low pressures in molded plates to form a wetted mass. The solvent is then removed by air-

drying. The tablets manufactured in this manner are less compact than compressed tablets and posses a porous structure that hastens dissolution. The heat molding process involves preparation of a suspension that contains a drug, agar and sugar e.g. mannitol or lactose and pouring the suspension in the blister packaging wells, solidifying the agar at the room temperature to form a jelly and drying at 30<sup>0</sup>C under vacuum. The mechanical strength of molded tablets is a matter of great concern. Binding agents, which increase the mechanical strength of the tablets, need to be incorporated. Taste masking is an added problem to this technology. The taste masked drug particles were prepared by spray congealing a molten mixture of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethylene glycol and an active ingredient into a lactose based tablet triturate form. Compared to the lyophilization technique, tablets produced by the molding technique are easier to scale up for industrial manufacture<sup>22</sup>.

*III. Spray drying*

In this technique, gelatin can be used as a supporting agent and as a matrix, mannitol as a bulking agent and sodium starch glycolate or croscarmellose or crospovidone are used as superdisintegrants. Tablets manufactured from the spray-dried powder have been reported to disintegrate in less than 20 seconds in aqueous medium. The formulation contained bulking agent like mannitol and lactose, a superdisintegrant like sodium starch glycolate and croscarmellose sodium and acidic ingredient (citric acid) and/or alkaline ingredients (e.g. sodium bicarbonate). This spray-dried powder, which compressed into tablets showed rapid disintegration and enhanced dissolution.

*IV. Sublimation*

To generate a porous matrix, volatile ingredients are incorporated in the formulation that is later subjected to a process of sublimation. Highly volatile ingredients like ammonium bicarbonate,

ammonium carbonate, benzoic acid, camphor, naphthalene, urea, urethane and phthalic anhydride may be compressed along with other excipients into a tablet. This volatile material is then removed by sublimation leaving behind a highly porous matrix. Tablets manufactured by this technique have reported to usually disintegrate in 10-20 sec. Even solvents like cyclohexane benzene can be used as pore forming agents.

#### V. Direct compression

Direct compression represents the simplest and most cost effective tablet manufacturing technique. This technique can now be applied to preparation of ODT because of the availability of improved excipients especially superdisintegrants and sugar based excipients.

##### a. Superdisintegrants

In many orally disintegrating tablet technologies based on direct compression, the addition of superdisintegrants principally affects the rate of disintegration and hence the dissolution. The presence of other formulation ingredients such as water-soluble excipients and effervescent agents further hastens the process of disintegration.

##### b. Sugar based excipients

This is another approach to manufacture ODT by direct compression. The use of sugar based excipients especially bulking agents like dextrose, fructose, isomalt, lactilol, maltitol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol, which display high aqueous solubility and sweetness, and hence impart taste masking property and a pleasing mouthfeel. Mizumito *et. al.* have classified sugar-based excipients into two types on the basis of molding and dissolution rate.

- Type 1 saccharides (Lactose and mannitol) exhibit low mouldability but high dissolution rate.

- Type 2 saccharides (Maltose and maltitol) exhibit high mouldability and low dissolution rate.

#### VI. Mass-extrusion<sup>24</sup>

This technology involves softening the active blend using the solvent mixture of water-soluble polyethylene glycol and methanol and subsequent expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablet. The dried cylinder can also be used to coat granules for bitter drugs and thereby achieve taste masking.

### Important Patented Technologies for Fast Dissolving Tablets

#### I. Zydis technology

- #### II.
- Zydis formulation is a unique freeze dried tablet in which drug is physically entrapped or dissolved within the matrix of fast dissolving carrier material. When zydis units are put into the mouth, the freeze-dried structure disintegrates instantaneously and does not require water to aid swallowing. The zydis matrix is composed of many material designed to achieve a number of objectives. To impart strength and resilience during handling, polymers such as gelatin, dextran or alginates are incorporated. These form a glossy amorphous structure, which imparts strength. To obtain crystallinity, elegance and hardness, saccharides such as mannitol or sorbitol are incorporated. Water is used in the manufacturing process to ensure production of porous units to achieve rapid disintegration while various gums are used to prevent sedimentation of dispersed drug particles in the manufacturing process. Collapse protectants such as glycine prevent the shrinkage of zydis units during freeze-drying process or long-term storage.

Zydis products are packed in blister packs to protect the formulation from moisture in the environment.

### III. *Durasolv technology*

Durasolv is the patented technology of CIMA labs. The tablets made by this technology consist of drug, filler and a lubricant. Tablets are prepared by using conventional tableting equipment and have good rigidity. These can be packaged into conventional packaging system like blisters. Durasolv is an appropriate technology for product requiring low amounts of active ingredients.

### IV. *Orasolv technology*

CIMA labs have developed Orasolv Technology. In this system active medicament is taste masked. It also contains effervescent disintegrating agent. Tablets are made by direct compression technique at low compression force in order to minimize oral dissolution time. Conventional blenders and tablet machine is used to produce the tablets. The tablets produced are soft and friable.

### V. *Flash dose technology*

Flash dose technology has been patented by fuisz. Nurofen meltlet, a new form of ibuprofen as melt in mouth tablets prepared using flash dose technology is the first commercial product launched by Biovail Corporation. Flash dose tablets consist of self-binding shear form matrix termed as floss. Shear form matrices are prepared by flash heat processing.

### VI. *Wow tab technology*

Wow tab technology is patented by Yamanouchi Pharmaceutical Co. WOW means "Without Water". In this process, combination of low mouldability saccharides and high mouldability saccharides is used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mouldability saccharide e.g. lactose, glucose, and mannitol and granulated with a high

mouldability saccharide e.g. Maltose, Oligosaccharides and compressed into table

### VII. *Flash tab technology*

Prographarm laboratories have patented the Flash tab technology. Tablet prepared by this system consists of an active ingredient in the form of micro crystals. Drug micro granules may be prepared by using the conventional techniques like coacervation, micro encapsulation and extrusion spheronisation. All the processing utilized conventional tableting technology.<sup>21</sup>

Shah *et al*<sup>22</sup> reported on fast dissolving tablets of the drug Metoclopramide hydrochloride using superdisintegrants Crospovidone, Croscarmellose sodium and Sodium starch glycolate by direct compression technique. The prepared tablets were evaluated for hardness, friability, wetting time, weight variation, *in vitro* disintegration time and *in vitro* dissolution study. The hardness of the tablets was in the range of 2.0 - 4.0 Kg/cm<sup>2</sup>. The percentage friability of the tablets was less than one. Weight variation test results showed that the tablets were deviating from the average weight within the permissible limits of  $\pm 7.5\%$ . Drug content uniformity study results showed that uniform dispersion of the drug throughout the formulation i.e. 98.54% to 101.23%. Tablets containing Crospovidone showed better disintegrating character along with the rapid release (97.42% drug within 1 minute).

Nagendrakumar *et al*<sup>23</sup> reported on fast dissolving tablets of granisetron HCl were prepared using novel co-processed superdisintegrants consisting of crospovidone and sodium starchglycolate in the different ratios (1:1, 1:2 and 1:3). Tiwari Vijay *et al*<sup>24</sup> reported on different formulation of solid dispersion is prepared and the batch having the best drug release profile is used for the preparation of nine batches of fast dissolving tablets by direct compression method. The tablet is characterized by hardness, wetting time, weight variation, *in-vitro* drug dissolution, and *in-vivo* taste

evaluation. All batches of solid dispersion and fast dissolving tablets are satisfactory in terms of dissolution profile. The hardness, wetting time, drug content analysis and taste evaluation of tablets are also shows the satisfactory result.

Narmada *et al*<sup>1</sup> reported on to prepare the tablets by using a 2<sup>3</sup> full factorial design. FT-IR and D.T.A studies revealed that there was no physico-chemical interaction between amlodipine besylate and other excipients. All formulations are evaluated for pre-compression and post-compression parameters, wetting time, water absorption ratio. The results obtained showed that the quantity of starch potato, sodium starch glycolate, camphor significantly affect response variables. The results indicate that the optimized tablet formulation provides a short DT of 8 sec with sufficient crushing strength and acceptable friability. Stability studies of optimized formulation revealed that formulation is stable.

Jain *et al*<sup>25</sup> reported on different superdisintegrants by direct compression method. FDTs were evaluated for physicochemical properties and *in vitro* dissolution. Effect of disintegrant on disintegration behaviour of tablet in artificial saliva, pH 5.8 was evaluated. Wetting time of formulations containing crospovidone was least and tablets showed fastest disintegration. The drug release from FDTs increased with increasing concentration of superdisintegrants and was found to be highest with formulations containing crospovidone. The release of valsartan from FDTs was found to follow non-Fickian diffusion kinetics. Jyotsana Madan *et al*<sup>26</sup> reported on fast dissolving tablets of the nutraceutical, freeze-dried Aloe vera gel, were prepared by dry granulation method. The tablets were evaluated for crushing strength, disintegration time, wetting time, friability, drug content and drug release. A response surface plot was also provided to graphically represent the effect of the independent variables on the

disintegration time and wetting time. The validity of the generated mathematical model was tested by preparing a check point batch.

## CONCLUSION

Fast dissolving tablets (FDTs) are prepared by several different methods including crystalline transition, phase transition, sublimation, spray drying, and direct compression. Of these approaches, a conventional tablet compression method is used most widely because of its low cost and ease of manufacturing. The research on FDTs should be focused on decreasing the dissolution time of the tablets in the mouth, while maintaining sufficiently high mechanical strength to withstand handling during manufacturing, packaging and transportation. The key to developing a successful FDT formulation by the compression method is to select the right excipients and the right processing techniques. In general, FDTs are made of highly hydrophilic materials and possess highly porous structures for fast water absorption into the tablet matrix.

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