

## FAST DISSOLVING TABLET A NEW DRUG APPROACH IN NDDS: OVERVIEW

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### ABSTRACT

Tablets are rapidly emerging as one of the most popular and well-accepted forms of treatment, especially in pediatric patients due to insufficient development of the muscular and nervous systems and in geriatric patients. There are a few solid forms of treatment such as capsules and tablets today that face problems such as difficulty eating (dysphagia), which leads to many cases of non-compliance and makes the treatment ineffective. effectiveness. The dosage form and the oral route are the preferred methods of administration for various drugs with limitations such as first pass metabolism, psychiatric patients, hypnotics and those who do not support it. TDF breaks down or dissolves easily in water without the need for water. Fast-dissolving tablets are designed to dissolve quickly in water, within seconds (less than 60 seconds), and are fast-dissolving tablets. The FDT formulation contains highly dispersive agents to enhance the rate of diffusion of the tablet into the oral cavity. FDT has advantages such as low portability and manufacturing, accurate dosing, good chemical and physical stability and is a good choice for geriatric and pediatric patients. FDT disperses quickly, penetrates quickly, the in vitro drug release time is improved and this drug property (dosage form) improves bioavailability. The FDT method has the advantages of both the tablet form and the liquid form of treatment. 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, Bioavailability, Methods, Hypnotics, Pediatric.

### INTRODUCTION

Dosage forms are pioneers in drug delivery systems. The oral route of drug administration is widely used and accepted. Oral dosage forms are used for ease of self-administration and low cost compared to other dosage forms.<sup>[1]</sup> However, it is associated with some disadvantages such as dysphagia (difficulty swallowing), low bioavailability and delayed onset of action. To overcome these problems, researchers have long investigated the "oral side" to use its negative effects to improve the drug's potency and bioavailability. The "oral space" has a positive potential because the oral mucosa is less keratinized than the oral mucosa.<sup>[2]</sup> The drug that is injected through the "oral cavity" directly enters the systemic circulation through the jugular vein, which makes the onset of action faster, avoiding the first pass of metabolism, drug damage in the gastric region and enzymatic hydrolysis in the intestine.<sup>[3]</sup> Considering the advantage of "mouth space", dispersible tablets, often called fast-dissolving tablets, are a well-accepted method. According to the European Pharmacopoeia,

"ODT (Oral Dispersible Tablet) is expected to disperse or dissolve in less than 3 minutes after being placed on the tongue." Fast Dissolving Drug Delivery System (FDDDS) is a new concept that combines the advantages of liquid and solid systems and offers advantages over conventional dosage forms. Fast dissolving tablets are novel drug delivery system that dissolves, disintegrate or disperse the API in saliva within few seconds with or without intake of water. The faster the dissolution of drug into the solution, quicker is the absorption and onset of clinical effect. The bioavailability of some drugs may increase due to absorption of drugs in oral cavity or also due to pregastric absorption of drug from saliva that pass down into the stomach.

### Salient Feature of Fast Dissolving Drug Delivery System

Easy patient compliance and tablet administration is suitable for patients suffering from dysphagia, cardiac and renal problems/injured patients, sleep-deprived patients and patients who refuse to swallow

such dosage forms as pediatric, geriatric and psychiatric patients.<sup>[6]</sup>

- Oral dispersal of the tablet eliminates the use of water, making it ideal for traveling patients who do not have easy access to water.
- Rapid onset due to rapid spread followed by spread.
- Increased bioavailability, due to absorption through the oral mucosa with better permeability properties.
- The increase in pregnancy, where it is good, will result in improved bioavailability, reduced dose and other side effects, thus improving clinical performance.<sup>[8]</sup>
- FDT will give a good effect in the mouth, especially in pediatric patients, where more emphasis is placed on the organoleptic properties.
- FDT will be safer than conventional dosage forms as it eliminates choking, or airway obstruction.
- Better business opportunities like, product differentiation, product endorsement, patent extensions and life cycle management.<sup>[9]</sup>
- Favorable in cases which require an immediate and rapid onset of action e.g. motion sickness, sudden episodes of allergic attack or coughing.

### Challenges to develop FDTs<sup>[3,10]</sup>

#### Palatability

Since most drugs are not safe, FDT often contains the drug in the form of a mask. After administration, FDT spreads or dissolves in the oral cavity of the patient, leaving active substances that enter the taste contact. Therefore, covering the growth of the drug becomes important for patient acceptance.<sup>[3,11]</sup>

**Mechanical strength and downtime** In order to make FDTs expandable in the mouth, they are made with a large-pore, soft molded matrix or incorporated into tablets with a low compression ratio, which makes the tablets the body is soft and/or brittle, difficult to handle and often demanding, special peel packaging that can increase its cost.<sup>[3,11]</sup> Only wow tab and durasolv technology can produce hard and durable tablets that allow them to be placed in multidose bottles.<sup>[3]</sup>

**Hygroscopic** Most types of oral dispersants are hygroscopic and cannot maintain their integrity under normal temperature and humidity conditions.<sup>[3,11]</sup> Therefore, they need protection from moisture, which requires special packaging.<sup>[3]</sup>

**Number of drugs** The application of the technology used for FDT is the amount of drug that can be applied in each minute. For the dried formulation, the dosage should be less than 400 mg for insoluble drugs and 60 mg for soluble drugs.<sup>[3,11]</sup> This limit is especially difficult when producing fast-melting edge films or wafers.<sup>[3]</sup>

**Aqueous solubility** Water softeners cause various structural problems because they create a eutectic mixture, which leads to the depression of the hot spot and the formation of a hard glass that can collapse when

drying due to the loss of support during the sublimation process.<sup>[3,5,11]</sup> Such failure can sometimes be avoided by using different matrix forming agents such as mannitol which can cause crystallization and therefore give strength to the amorphous mixture.<sup>[3]</sup>

**Tablet size** It is easy to manage the tablet depending on its size. It has been reported that the easiest tablet size to swallow is 7 to 8 mm, while the easiest size to handle is greater than 8 mm. Therefore, tablet sizes that are easy to take and handle are difficult to achieve.<sup>[3,5]</sup>

**Mouthfeel** TDF should not be dispersed into large particles in the oral cavity. The products produced after the sale of TDF will be as small as possible. In addition, the addition of flavoring and refreshing substances such as menthol makes the taste better.<sup>[5]</sup>

**Impact on environmental conditions** FDT is expected to have a low impact on environmental conditions such as humidity and temperature, because most of the materials used in FDT are intended to dissolve in a small amount of water.<sup>[5]</sup>

### Criteria for excipient used in formulation of FDTs

- Their individual properties should not affect the FDTs.
- It must be able to disintegrate quickly.
- It should not have any interaction with drug and other excipients.
- When selecting binder (a single or combination of binders) care must be taken in the final integrity and stability of the product.
- The melting point of the excipients used should be in the range of 30-35 °C.
- It should not interfere in the efficacy and organoleptic properties of the product.
- The binder may be in liquid, semi-solid, solid or polymeric in nature

### Mechanisms of fast dissolving tablets

To achieve the tablets fast dissolving properties

- Water must quickly enter into the tablet matrix to cause rapid disintegration and instantaneous dissolution of the tablet.
- Incorporation of an appropriate disintegrating agent or highly water soluble excipients in the tablet formulation.
- There are some undermentioned mechanisms by which the tablet is broken down into the smaller particles and then subsequently result a solution or suspension of the drug. The mechanisms are:
  - High swellability of disintegrants
  - Chemical reaction
  - Capillary action<sup>[12]</sup>

### Techniques for Preparing Fast dissolving

**Tablets** Many techniques have been reported for the formulation of Fast dissolving tablets or Orodispersible tablets. Here we have discussed the six major techniques

which are widely used for the formulation of these tablets.<sup>[14,15]</sup>

Freeze drying/ Lyophilisation  
Tablet moulding  
Spray drying  
Direct Compression  
Sublimation  
Mass Extrusion

### Evaluation of Tablet

#### Pre-formulation studies

##### Angle of Repose ( $\theta$ )

Angle of repose is defined as the calculation of the maximum possible angle between the surface of the pile of the powder and the horizontal plane of the powder blend. When more quantity of the powder is added to the pile, it slides down, until the mutual friction of the particles producing a surface angle  $\theta$ , is equilibrium with the gravitational force.<sup>[7]</sup>

The angle of repose is determined by the funnel method suggested by the scientist Newman. Angle of repose is determined by the following formula

$$\tan \theta = h/r$$

$$\theta = \tan^{-1} h/r$$

Where  $\theta$  = Angle of repose

r = Radius of the cone

h = height of the cone

##### Bulk Density

Density of powder is defined as weight per unit volume. Bulk density is defined as the mass of the powder that divided by the bulk volume of powder and is expressed as gm/ cm<sup>3</sup>. The bulk density of a powder primarily depends on its particle shape, size, distribution and the adhering properties of particles to adhere together. There are two types of bulk density.<sup>[8]</sup>

##### Low bulk density

The particles are pack in such a way so as to leave large gaps between their surfaces resulting up in light powder of low bulk density.

##### High bulk density

Here the smaller particles shift between the large particles resulting in heavy powder of high bulk density.

##### Tapped Density (Dt)

It was the ratio of total mass of the powder to tapped volume of the powder. Volume was represented by tapping the powder for 500 times and the tapped volume was recorded, if the difference between these two volumes was less than 2%. If it more than 2%, then tapping was continued for 750 times and tapped volume was noted. Tapping was continued until the difference between volumes was less than 2% in bulk density apparatus. It was expressed in g/ml and was given as following,

$$Dt = M/Vt$$

Where, M is the mass of powder

Vt is the tapped volume of the powder.<sup>[9]</sup>

##### Carr's index (or) % compressibility

Carr's index indicates powder flow properties. It is expressed by percentage and is given by:

$$I = \frac{Dt - Db}{Dt} \times 100$$

Where, Dt denotes the tapped density of the powder

And

Db is the bulk density of the powder.<sup>[9-10]</sup>

##### Hausner ratio

Hausner ratio is an indirect index of ease of powder flow properties. It is calculated by the following formula

$$\text{Hausner ratio} = \frac{Dt}{Db}$$

Where, Dt show the tapped density.

Db is the bulk density.

Lower hausner ratio (<1.25) indicates better flow properties than higher ones (>1.25)<sup>[11]</sup>

### CONCLUSION

Fast Dissolving tablets are considered to be contemporary dosage forms. These dosage forms and their route of administration results in better efficacy, rapid onset of action, enhanced bioavailability, and improved patient compliance. There are many marketed product of this category which have been introduced in the recent past. Some of the recent product in the Indian and global market are listed in table for ready reference (Table 6). The primary attractive factor of MDT is quick disintegration in oral cavity without the aid of water, along with sufficient mechanical strength. This feature makes this formulation a highly recommendable choice for geriatric and pediatric patients. FDT in the near future is expected to grow at a great and rapid pace, owing to the advancement in the scientific research and discovery of new excipients, resulting in a future-ready, combative arena of pharmaceutical drug delivery systems.

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