

## **FORMULATION AND EVALUATION OF FAST DISSOLVING TABLET: A REVIEW**

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### **ABSTRACT**

Over the past three decades, Orally Disintegrating Tablet (ODT) has gained much attention as a preferred alternative to conventional oral dosage form such as tablet and capsules. These dosage forms are placed in the mouth, allowed to disperse in the saliva, to produce a suspension which can be easily swallowed by the patient. In addition, patients suffering from dysphagia, motion sickness, repeated emesis and mental disorders prefer these medications because they cannot swallow large quantity of water. Further, drugs exhibiting satisfactory absorption from the oral mucosa or intended for immediate

pharmacological action can be advantageously formulated in these dosage forms. Fast dissolving tablets are solid dosage forms containing drugs that disintegrate in the oral cavity within less than one minute leaving an easy-to-swallow residue. These dosage forms are placed in the mouth, allowed to disperse or dissolve in the saliva. The release the drug as soon as they come in contact with the saliva, thus obviating the need for water during administration. The aim of this article is to review the progress of the evolving technologies and super disintegrating agents in the formulation, manufacturing and evaluation of these tablets. Various modifications in the conventional evaluation and use of specialized instruments are found to be essential in the testing of these dosage forms. In the present review the formulation techniques and different technologies are discussed.

**KEYWORDS:** Fast Dissolving Tablets, orally disintegration tablet, Freez drying, moulding.

### **INTRODUCTION**

In recent decades, a variety of pharmaceutical research has been conducted to develop new dosage forms. Considering quality of life, most of these efforts have been focused on ease of medication. Among the various dosage forms developed to improve the ease of

administration, the fast dissolving tablet (FDT) is the most widely preferred commercial products.<sup>[1]</sup> Rapid-breakdown or fast disintegrating tablet of the type of those intended to undergo disaggregation in the mouth in contact with the saliva in less than 60 seconds, preferably in less than 40 seconds, forming a suspension which is easy to swallow. It is better known by the phrase "orodispersible tablets".<sup>[2,3]</sup>

The concept of Fast Dissolving Drug Delivery System emerged from the desire to provide patient with more conventional means of taking their medication. It is difficult for many patients to swallow tablets and hard gelatin capsules. Hence they do not comply with prescription, which results in high incidence of non-compliance and ineffective therapy. In some cases such as motion sickness, sudden episodes of allergic attacks or coughing and unavailability of water, swallowing conventional tablets may be difficult. Particularly the difficulty is experienced by pediatric and geriatric patients. Such problems can be resolved by means of Fast Dissolving Tablet. When put on tongue, this tablet disintegrates instantaneously, releasing the drug, which dissolves or disperses in the saliva. 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 tablet dosage form.<sup>4</sup> Orally disintegrating dosage forms can serve as an effective alternative mode of drug delivery in such situations. When put in the mouth, these dosage forms disintegrate instantly to release the drug, which dissolves or disperses in the saliva. Thereafter, the drug may get absorbed from the pharynx and oesophagus or from other sections of g.i.t as the saliva travels down. In such cases, bioavailability is significantly greater than that observed from conventional tablet dosage form.<sup>[5-6]</sup>

The oral cavity is an attractive site for the administration of drugs because of ease of administration. Various dosage forms like Tablets, Capsules, Liquid preparations are administered by oral route.<sup>[7]</sup>

Orally disintegrating tablets provide an advantage particularly for pediatric and geriatric populations who have difficulty in swallowing conventional tablets and capsules. Additionally, pediatric patients may suffer from ingestion problems as a result of underdeveloped muscular and nervous control. Moreover, patients traveling with little or no access to water, limit utility of orally administered conventional tablets or capsules. Fast dissolving of tablet results in quick dissolution and rapid absorption which provide rapid onset of action. Moreover, drug candidates that undergo pre-gastric absorption when

formulated as FDTs may show increased oral bioavailability. It provides good stability, accurate dosing, easy manufacturing.<sup>[8,9]</sup>

### **Ideal Properties.**<sup>[10,11]</sup>

An ideal FDT should:

1. Require no water for oral administration.
2. Have a pleasing mouth feel.
3. Have an acceptable taste masking property.
4. Be harder and less friable.
5. Leave minimal or no residue in mouth after administration.
6. Exhibit low sensitivity to environmental conditions (temperature and humidity).
7. Allow the manufacture of tablet using conventional processing and packaging equipments.

### **Advantages**<sup>[10,11]</sup>

1. Administration to the patients who cannot swallow, such as the elderly, bedridden patients, patients affected by renal failure & patients who refuse to swallow such as pediatric, geriatric & psychiatric patients.
2. Rapid drug therapy intervention.
3. Achieve increased bioavailability/rapid absorption through pre-gastric absorption of drugs from mouth, pharynx & esophagus as saliva passes down.
4. Convenient for administration and patient compliant for disabled, bedridden patients and for travelers and busy people, who do not always have access to water.
5. Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patients.
6. The risk of choking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety. New business opportunity like product differentiation.

### **Salient Features.**<sup>[10]</sup>

- Ease of administration to patients who refuse to swallow a tablet, such as pediatric and geriatric patients and, psychiatric patients.
- Convenience of administration and accurate dosing as compared to liquids.

- Rapid dissolution of drug and absorption which may produce rapid, onset of action. Some drugs are absorbed from the pharynx and oesophagus as the saliva passes down into the stomach, in such cases bioavailability of drugs is increased.
- Ability to provide advantages of liquid medication in the form of solid preparation.
- Pre-gastric absorption can result in improved bioavailability and as a result of reduced dosage, improved clinical performance through a reduction of unwanted effects.

### **Technology for Fast dissolving Tablets:**

#### **Conventional Techniques.<sup>[7]</sup>**

**Disintegrates addition:** Disintegrate addition technique is one popular techniques for formulating Fast-dissolving tablets because of its easy implementation and cost-effectiveness. The basic principle involved in formulating Fast-dissolving tablets by disintegrates addition technique is addition of superdisintegrants in optimum concentration so as to achieve mouth dissolving along with the good mouth feel.

#### **1. Molding**

In this method, molded tablets are prepared by using water-soluble ingredients so that the tablets dissolve completely and rapidly. The powder blend is moistened with a hydro-alcoholic solvent and is molded into tablets under pressure lower than that used in conventional tablet compression. The solvent is then removed by air-drying. Molded tablets are very less compact than compressed tablets. These possess porous structure that enhances dissolution.

#### **2. Freeze drying**

A process in which water is sublimated from the product after freezing. Lyophilization is a pharmaceutical technology which allows drying of heat sensitive drugs and biological at low temperature under conditions that allow removal of water by sublimation. Lyophilization results in preparations, which are highly porous, with a very high specific surface area, which dissolve rapidly and show improved absorption and bioavailability.

#### **3. Sublimation**

The slow dissolution of the compressed tablet containing even highly water-soluble ingredients is due to the low porosity of the tablets. Inert solid ingredients that volatilize.

## Micromeritic properties

### 1. Determination of bulk density and tapped density:

A weighed amount of blend was poured into a graduated cylinder and the volume (V<sub>0</sub>) was noted. Then the graduated cylinder was fixed on the density apparatus and the timer knob is set for 100 tapping and after that volume (V<sub>f</sub>) was measured and continued operation till the two consecutive readings were equal. The bulk density and tapped density were calculated by using the following formulae.

$$\text{Bulk density} = W / V_0$$

$$\text{Tapped density} = W / V_f$$

Where W = weight of the powder.

V<sub>0</sub> = Initial volume of the powder. V<sub>f</sub> = Final volume of the powder.

### 2. Carr's Compressibility Index:-

Compressibility Index is an important measure to calculate the flowability of powders. This can be obtained from bulk and tapped densities. It is represented as percentage. In theory, the less compressible a material the more flowable it is.

$$\text{Compressibility [\%]} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

**Table: 1-Grading of the powders for their flow properties according to Carr's index:-**

Consolidation index (Carr. %)	Flow
5-15	Excellent
12-16	Good
18-21	Fair to passable
23-35	Poor
33-38	Very Poor
>40	Very Very Poor

### 3. Hausner's ratio

It indicates the flow properties of the powder and is measured by the ratio of tapped density to bulk density.

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

**Table: 2-Grading of the powders for the flow properties according to Hausner's ratio:-**

Hausner's ratio	Property
< 1.2	Free flowing
1.2 – 1.6	Cohesive powder

#### 4. Angle of Repose

The flow characteristics are measured by angle of repose. Improper flow properties are due to frictional forces between the particles. These frictional forces are quantified by angle of repose.

Angle of repose is defined as the maximum angle possible between the surface of a pile of the powder and the horizontal plane.

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

Where h = height of pile

r = radius of the base of the pile.

$\theta$  = angle of repose.

**Procedure:** A funnel was held in plane with a clamp on a ring support over a plate. 50 g of powder was transferred into the funnel, keeping the orifice of the funnel blocked by the thumb. As the thumb is removed, the powder is emptied from the funnel then the height of the pile [h] and the radius of the base [r] are measured.

**Table: 3-Relationship between angle of repose & powder flow:-**

Angle of repose	Flow
< 25	Excellent
25 – 30	Good
30 – 40	Passable
> 40	Very Poor

**4. Spray-Drying:** Spray drying can produce highly porous and fine powders that dissolve rapidly. The formulations are incorporated by hydrolyzed and non hydrolyzed gelatins as supporting agents, mannitol as bulking agent, sodium starch glycolate or cross carmellose sodium as disintegrating and an acidic material (e.g. citric acid) and or alkali material (e.g. I sodium bicarbonate) to enhance disintegration and dissolution. Tablet compressed from the spray dried powder disintegrated within 20 seconds when immersed in an aqueous medium.

**5. Mass-Extrusion:** This technology involves softening the active blend using the solvent mixture of water soluble polyethylene glycol, using methanol and expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated

blade to form tablets. The dried cylinder can also be used to coat granules of bitter tasting drugs and thereby masking their bitter taste.

**6. Direct compration:** Direct compration method is the easiest way to manufacture tablets. Conventional equipment, commonly available excipients and a limited number of processing steps are involved in direct compression. Also high doses can be accommodated and final weight of tablet can easily exceed that of other production methods. Directly compressed tablet's disintegration and solubilization depends on single or combined action of disintegrants, water soluble excipients and effervescent agent.

**Various types of Super disintegrants used are as follows –**

Crosspovidone

Microcrystalline cellulose Sodium starch glycollate

Sodium carboxy methyl cellulose or cross carmellose sodium Pregelatinized starch

Calcium carboxy methyl cellulose

Modified corn starch. Sodium starch glycollate has good flowability than crosscarmellose sodium

**Evaluation of fast dissolving Tablets By-**

**Thickness**<sup>[14]</sup> Tablet thickness can be measured using a simple procedure. 5 tablets were taken and their thickness was measured using Varnier calipers.

**Hardness**<sup>[12,15]</sup>

It is the force required to break a tablet by compression in the radial direction, it is an important parameter in formulation of Fast dissolve tablets because excessive crushing strength significantly reduces the disintegration time. In the present study the crushing strength of the tablet was measured using Pfizer hardness testers. An average of three observations is reported.

**Uniformity of weight.**<sup>[16,12]</sup>

I.P. procedure for uniformity of weight was followed, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight

of one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of determining the drug content uniformity.

**Disintegration time<sup>[15]</sup>**

The test was carried out on 6 tablets using the apparatus specified in I.P.-1996 distilled water at  $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$  was used as a disintegration media and the time in second taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured in seconds.

**Friability test<sup>[18,13]</sup>**

Friability of the tablets was determined using Roche friability (Electrolab, Mumbai). This device subjects the tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inches in each revolution. Preweighed sample of tablets was placed in the friabilator and were subjected to 100 revolutions. Tablets were de dusted using a soft muslin cloth and reweighed. The friability (f) is given by the formula.  $f = (1 - W_0 / W) \times 100$  Where,  $W_0$  is weight of the tablets before the test and  $W$  is the weight of the tablet after the test.

**In-vitro dispersion time test<sup>[15]</sup>**

To determine dispersion time 10 ml measuring cylinder was taken in which 6 ml distilled water was added and tablet was dropped in it. Time required for complete dispersion was determined.

**Wetting time<sup>[15,17]</sup>**

Five circular tissue papers of 10 cm diameter are placed in a petridish with a 10 cm diameter. Ten millimeters of water-containing Eosin, a water-soluble dye, is added to petridish. A tablet is carefully placed on the surface of the tissue paper. The time required for water to reach upper surface of the tablet is noted as a wetting time.

**Water absorption ratio<sup>[17]</sup>** A piece of tissue paper folded twice was placed in a small Petri dish containing 6 ml of water. A tablet was put on the paper & the time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio (R), was determined using following equation,  $R = 10 (W_a / W_b)$  Where-  $W_b$  is weight of tablet before water absorption &  $W_a$  is weight of tablet after water absorption.

**Accelerated Stability study.<sup>[17]</sup>**

The Orally disintegrating tablets are packed in suitable packaging and stored under the following conditions for a period as prescribed by ICH guidelines for accelerated studies. (i)



$40 \pm 1^\circ\text{C}$  (ii)  $50 \pm 1^\circ\text{C}$  (iii)  $37 \pm 1^\circ\text{C}$  and Relative Humidity =  $75\% \pm 5\%$  The tablets were withdrawn after a period of 15 days and analyzed for physical characterization (Visual defects, Hardness, Friability, Disintegrations, and Dissolution etc.) and drug content. The data obtained is fitted into first order equations to determine the kinetics of degradation. Accelerated stability data are plotting according Arrhenius equation to determine the shelf life at  $25^\circ\text{C}$ .

### Packaging<sup>[8]</sup>

Packaging special care is required during manufacturing and storage to protect the dosage of other fast-dissolving dosage forms. Quick-dispersing and/or dissolving oral delivery systems, the system can be packaged using various options, such as single pouch, blister card with multiple units, multiple unit dispenser, and continuous roll dispenser, depending on the application and marketing objectives.

### CONCLUSION

Fast dissolving Tablets is the general form of nomenclature for tablets that disintegrate rapidly or instantly in the oral cavity. FDTs have better patient acceptance and compliance and may offer improved biopharmaceutical properties, improved efficacy, and better safety compared with conventional oral dosage forms. FDTs can be prepared in different ways and product performance depends upon the drug suitability and excipients selections in the delivery system. In combination with other technologies such as modified release and microencapsulation, FDTs will continue to provide enhanced commercial and therapeutic benefits. FDT is a growing technology, offering considerable benefits for lifecycle management<sup>16</sup>, development timelines, patient convenience and market share. By paying close attention to advances in technologies, pharmaceutical companies can take advantage of FDTs for product line ex-tensions or for first-to-market products. With continued development of new pharmaceutical excipients, one can expect the emergence of more novel technologies for FDTs in the days to come. The successful marketed FDTs have good taste and rapid release properties. With rapid acceptance of FDTs by patients and pharmaceutical companies, the market for this dosage form is promising, and the product pipeline continues to grow rapidly

**REFERENCES**

1. S. J.R., Nayak S., Amlan S., Deep V.V., Khemariya P., Sumbhate S., Nayak S., Taste masking of Lornoxicam by polymer carrier system and formulation of oral disintegrating tablets; *International Journal of Drug Delivery*., 2009: 27-31.
2. Schiermeier S, Schmidt P C. Fast dispersible ibuprofen tablets, *Eur. J. Pharm. Sci.* 2002; 15: 295-305.
3. Dobbetti L. Fast-melting tablets: development and technologies, *Pharm. Technol. Drug Deliv.*, 2001; 44-45.
4. L.H.Reddy, et al., "Fast dissolving drug delivery systems:A review of the literature", *IJPS*. , July 2002: 331-336
5. Ghosh TK, Pfister WR (ed.), Quick dissolving oral dosage forms: Scientific and regulatory considerations from a clinical pharmacology and biopharmaceuticals perspective; In: *Drug delivery to the oral cavity: Molecules to market*. New York, CRC Press 2005; 337-356.
6. Dobbetti L. Fast melting tablets: Developments and technologies. *Pharm Technol Drug Deliv Suppl* 2001; 44-50
7. Sharma S., (2008)., New generation of tablet: Fast dissolving tablet; Latest review Vol VI .
8. Prajapati G.B., Patel S.B., Formulation, Evaluation and Optimization of Orally Disintegrating Tablet of Piroxicam; *International Journal of PharmTech Research*., 2010: 1893-1899.
9. Mohan A. and Ghosh S.K., Fast Dissolving Tablets: Past, Present and Future; *Indian drug*, 2010: 47(6): 5-11.
10. Sharma S., (2008)., New generation of tablet: Fast dissolving tablet; Latest review Vol VI
11. Kumari S., Visht S., Sharma P.K., Yadav R.K., Fast dissolving Drug delivery system : Review Article; *Journal of Pharmacy Research*, 2010; 3(6): 1444-1449
12. Bhowmik et al., Fast Dissolving Tablet: An Overview; *Journal of Chemical and Pharmaceutical Research*., 2009: 163-177.
13. O.M. Javier, Hong M., M.G. Aubey, T.M. Jason., Orally Disintegrating Tablets using starch and fructose; *Pharmaceutical Technology*.,2010; 92-99.
14. Shaikh S et al., Formulation and evaluation of orodispersible tablets of piroxicam, *IJPI's Journal of Pharmaceutics and Cosmetology*., 2010: 2-8.
15. Panigrahi R., Behera S., A Review On Fast Dissolving Tablets., *WebmedCentral Quality and patient safety WMC00809*., 2010: 1-15.

16. Mahaveer Pr. Khinchi., Orally disintegrating tablets: A future prospectus., Int J Pharm Sci Bio., 2010: 71-79.
17. Modasiya M.K. et al., Design and Characterization of Fast Disintegrating Tablets of Piroxicam., International Journal of PharmTech Research., 2009: 353-357.