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# FAST DISINTEGRATING TABLETS- A REVIEW

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## ABSTRACT

Oral route is the most effective and safest route of drug delivery because of wide range of drugs are administered through the oral route. When compared with conventional dosage form FDT can be a useful alternative as well. FDT's are advantageous particularly for paediatric, geriatric and mentally ill patients who have difficulty in swallowing conventional tablets and capsules. Fast dissolving tablet (FDT) is one type of an innovative, unique drug delivery system and the field has become a fast-growing area in the pharmaceutical industry. Fast dissolving Tablets are disintegrated or dissolved rapidly with the saliva. Some tablets are designed to dissolve in saliva usually fast, within a few seconds, and are true fast-dissolving tablets. Disintegrants are substances or combination of substances added to a drug formulation to aid in the breaking up or disintegration of tablet or capsule content into smaller fragments that dissolve more quickly. Several newer agents of disintegrants known as 'Super-disintegrants'. Super disintegrants are classified as natural, synthetic, semi-synthetic, and co-processed blends have been used to create effective mouth dissolving tablets and overcome the limitations of traditional tablet dosage form. Others contain agents to enhance the rate of tablet disintegration in the oral cavity, and are more appropriately termed fast-disintegrating tablets, as they may take up to a minute to completely disintegrate. This review article contains different techniques used for preparing FDT, sailent features, various patented technologies, mechanism of super disintegration, evaluation tests, challenges faced and the limitations.

**KEYWORDS:** Fast disintegrating tablets, Disintegrants, Bioavailability, Sublimation, Freeze Drying, Moulding, Fast Dissolving Film.

## INTRODUCTION

### Tablets

Tablets are the one of the most popular conventional solid unit dosage forms and regarding self-administration, easy to swallow, suitable for sustain, controlled, extended, prolonged, fast release and also contains an API, excipients which are prepared by compressed powder drug into solid and smooth pill. These are also known as Pills.[1]

The tablet drugs are in the different variety in shapes, size and colours.

It can be classified as Fast disintegrating tablets, Sustained release tablets, Controlled release tablets and moulded tablets.

### Fast Dis-integrating tablets

Fast disintegrating tablets are defined as solid unit dosage form which dissolves rapidly in the mouth without masticate and having benefit for child, old patients who are not able to swallow.[2]

### Requirements for FDT's

Patient factors: Paediatric, Geriatric and Bedridden patients

Efficacy factor: Great bioavailability, shows fast action.

### Advantages[3,4]

- Drug release occurs by without any solvent internally in the body and most convenient form.
- Physical and chemical stability.
- Rapid disintegration in oral cavity along with dissolution.
- Rapid drug therapy intervention.

### Disadvantages[3,4]

- Very porous which makes tablet Friable and Brittle.
- Hygroscopic so that they cannot maintain physical integrity.
- Not suitable for candidates with dry mouth due to lack of saliva production.

### Disintegration[3]

Mechanical breakup of a compressed tablet into small granules upon intake into the body.

**Disintegrant**[10]

Disintegrants helps a tablet to fast break-down after oral administration.

**Super disintegrants**

These are most effectively and very low concentrated forms which shows fast disintegration & greater therapeutic efficacy. These are interacted with saliva and to produce hydrostatic pressure, volume expansion which is helpful for rapid disintegration of the tablet.

- **Factors for selection of super disintegrants**[5]

➢ Disintegration
➢ Compatibility
➢ Mouthfeel
➢ Flow

**Table No. 01: Example of super disintegrants.**[5]

| S. No. | Super disintegrant | Mechanism of action | Specific properties |
|---|---|---|---|
| 1. | Gollan Gum | Good Swelling property whenever contacted with the water. | Anionic polysaccharide, good super-disintegrant. |
| 2. | Xanthan Gum | Extensive Swelling Property | Greater Hydrophilicity, Very Low Gelling tendency & Water Solubility. |
| 3. | Cross-linked alginic acid | Hydrophilic Colloidal substance | Swelling and Wicking action. |
| 4. | Soy Polysaccharide | Rapid dissolution | These products are used in Diabetics due to absence of Sugars and Starch. |
| 5. | Sodium-Starch Glycolate | Good Swelling Property | Rapid absorption of water causes 6% of Swelling & High concentration causes Gelling. |
| 6. | Cros-povidone | Swelling & Wicking Action | Efficacy Concentration 1-3%. It is available in Micronized Grades, Rapid dispersion and swells in water. |

**Selection of super disintegrants**[6]

The ideal properties of disintegrants having the following characteristics-

1. Less solubility.
2. Low gel formation.
3. Super hydration capacity.

4. Good moulding and flow properties.
5. Better Taste compliance.
6. And also be compatible with the other Excipients and Having suitable tableting properties.[6]

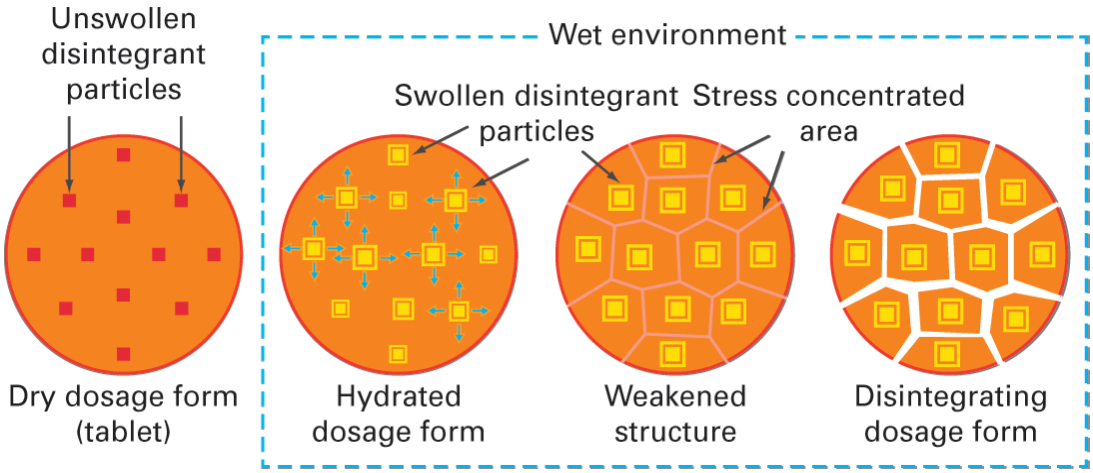


**Figure 01: Disintegration mechanism of super disintegrant materials.**

**Methods of incorporating disintegrants into tablets[6]**

2 types of methods, they are:

1. **Internal addition (Intragranular):** Before wetting the powder mixtures with the granulating fluid, the disintegrant is mixed with other powders Thus the disintegrant is incorporated within the granules. Thus, the disintegrant is incorporated within the granules.
2. **External addition (Extra-granular):** In this method, the disintegrant is added to the sized granulation with mixing prior to the compression.
3. **Partly Internal and External:** In this, the disintegrant is added in partly called internally and externally.

The two-step method is produces better disintegration compared to normal methods of disintegrants added to the granulation surface.

**Mechanism of super disisntegrants[7]**

1. **Capillary action:** Disintegrants Pulls water into the pores and reduces the bonding physical force between the particles.
2. **Wicking action:** It is used as common mechanism of action for the tablet disintegration is Swelling/Wicking. Tablets having high porosity property and show poor disintegration

because of poor swelling action. So, an adequate swelling force is pulled into the tablet with low porosity. The compaction in tablet is high, so that fluid is inadequate to penetrate into the tablet thereby the rate of disintegration is reduced.

3. **Repulsive forces of particles:** According to Guyot-Hermann particle repulsion theory, it was observed that nonswelling particle and cause disintegration of tablets. The mechanism of disintegration is required for the electric repulsive forces between the particles and requirement of water for it.
4. **Deformation:** The particles which disintegrate gets deformed, these deformed particles are get into their normal structure when they contact with water.

**Classification of super disintegrants**

There are 3 types of Classification in Super Disintegrants. They are:

1. **Natural super disintegrants:** These are Obtained from Natural sources like Plants & Animals.

   **Ex:** Ispaghula Husk Mucilage (Plantago Ovata), Gollan-Gum Gollan, Locust Bean gum, Polysaccharide, Pectin of Mango peel, Banana Powder etc.,
2. **Synthetic super disintegrants:** These are prepared synthetically by several methods.

   **Ex:** croscarmellose, cross-povidone, sodium starch glycolate, and magnesium aluminium silicate.

**Techniques for preparing fast disintegrating tablets[5,8]**

1. **Disintegrant addition**- Super Disintegrants and added to the formulation in optimum concentration to promote a drug release by the fast disintegration.

**For example:** MCC, sodium starch glycolate, Crystalline cellulose, Cross-povidone, croscarmellose.

**Characteristics:** Equal to the convenient form of tablets which are having greater percentage of disintegrants, higher percentage of friability & lower hardness.

2. **Lyophilization or freeze drying**- The process in which water in the product is converted to ice, by the phase changes to liquid to solid. Mostly used in food industries and Veterinary purposes by the stored in the liquid Nitrogen Freezing funnel to Freeze the liquid Drug. The frozen blister packs are placed in refrigerated cabinets to continue the freeze drying. The blisters are packaged and shipped.

**Characteristics:** The preparations are highly porous, dissolve rapidly, eventually show improved absorption and bioavailability.

3. **Moulding-** The API and Excipients are mixed together and compressed into tablets then placed into a specially designed and heated to a specific temperature and pressure.

**Characteristics:** Rapid disintegration by porosity, consistence production of dosage form with uniform shape, size & weight and Stability of the drug.

4. **Sublimation**- Inert solid ingredients like camphor ammonium carbonate, ammonium bicarbonate etc were added to the other tablet ingredients and compressed into tablet form. The volatile substances were then removed through sublimation process which are present in the compressed tablet. Thereby, generates porous structure and rapid release of drug occurs.

**Characteristics**: porous structure causes enhanced dissolution by using volatile substances.

5. **Spray-Drying**- By using supporting agents like hydrolysed and non-hydrolysed gelatines, bulking agent like mannitol, disintegrating agents such as sodium starch glycolate or croscarmellose sodium and an acidic material (e.g., citric acid) and / or alkali material (e.g., Sodium bicarbonate) to improve disintegration /dissolution.

**Characteristics:** whenever prepared tablet immersed in an aqueous medium disintegrates within 20 seconds.

6. **Mass-Extrusion**- This Involves softening of active blend by using the solvent mixture of water-soluble PEG, methanol and expulsion of softened mass occurs through the extruder

**Characteristics:** The dried product can be used to coat granules of bitter tasting drugs and thereby masking their bitter taste.

7. **Direct compression** – It incorporates the mixing and processing a tablet formulation ingredients process before compression to generate tablets by mixing API, powdered excipients.

**Characteristics:** It is most effective tablet manufacturing technique.

8. **Cotton candy process**- It involves the formation of matrix of polysaccharides. The formed candy floss matrix is milled and blended with API and excipients after re-crystallization and later it is compressed to get FDT.

**Characteristics:** It can load high doses of drug and improves mechanical strength.

9. **Compaction-** It is the process by which the pressure is applied on solid material causes the material to stick together and change to Strong.

a) Melt granulation b) Phase-transition process

**Characteristics:** By this process the compatibility increases and gains sufficient hardness by the formulation.

10. **Nano-ionization**- It involves size reduction of drug to nano-ionize by milling the drug. The nanocrystals of the drug are stabilized against coagulation by surface adsorption on selected stabilizers by adding to the formulation.

**Characteristics:** It is used for poorly water-soluble drugs, leads to higher bioavailability and reduction in dose, cost effective manufacturing process, conventional packaging due to exceptional durability and wide range of doses.

11. **Fast dissolving films**- Water soluble polymer film like CMC, HPMC and methylcellulose etc., forming can be prepared by using a non-aqueous solution, taste masking ingredients are used to form a film after evaporation of solvent. If it is a bitter drug, resin adsorbate of the drug can be incorporated into the film.

**Characteristics:** Dissolution occurs in 5 Sec and instant drug delivery.

**Evaluation tests for fast disinegrating tablets**[9,10]

**Size and Shape:** Size, shape of the tablet can be dimensionally described, monitored and controlled.

**Thickness & Diameter:** The Thickness, diameter of the tablet is expressed in mm by using a micro-meter screw gauge or vernier calliper.

**Weight variation test:** 20 tablets are randomly selected from the batch and to calculate the average weight of total 20 tablets and compare with each individual tablet weight to the average weight and expressed in %. To calculate weight variation by using the formula as follows

$$weight\ variation = \frac{Individual\ weight - Average\ weight}{Average\ weight} \times 100$$

**Hardness/Crushing strength:** The Force required to break a tablet called hardness (crushing strength). The resistance of the tablet chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its hardness. The Hardness test is performed by using a Monsanto or Pfizer Hardness Tester.

**Friability:** It is used to measure the mechanical strength of tablets. Roche friabilator was used to determine the friability of the tablet. A pre weighed tablets were placed in the friabilator. Fibrillatory consist of a plastic-chamber that revolves at 25 rpm, dropping those tablets at a distance of 6 inches with each revolution. The tablets were rotated in the friabilator for at least 4 minutes. At the end of test tablets were dusted and reweighed, the loss in the weight of tablet is the measure of friability and is expressed in percentage as;

**%Friability = loss in weight / Initial weight x 100**

**Wetting time:** The method is used to measure wetting time of the tablet. A piece of tissue paper folded twice was placed in a small petri-dish containing 10ml of any liquid like water, buffer. A tablet was put on the paper, and the time for complete wetting was measured. Three trials for each batch and the standard deviation were also determined.

**In-vitro dispersion time:** In vitro dispersion time was measured by dropping a tablet in a beaker containing any liquid like water, buffer. 3 tablets from each formulation were randomly selected and in vitro dispersion time was performed.

**Measurement of tablet porosity:** Porosity of tablet can be determined by using mercury penetration porosimeter. The tablet porosity (ε) can be calculated.

**Porosity** (ε) **= (1-m/$p^t$ v).100**

Where, p = density m = mass v = void ratio

**Water absorption ratio:** A tablet is placed on the paper and the time required for complete wetting and it is determined by

**$R=100*(W_a-W_b)/W_b$**

Where, $W_a$ = weight of tablet after absorption,

Wb = weight of tablet before absorption

**In-vitro disintegration time:** This test is performed on 06 tablets, by placing tablets into each tube of disintegration apparatus using the disintegration media like Water, 0.1N HCl, Buffers etc at 37±2 $^0$C to find out the disintegration time.

**In-vitro dissolution study:** Dissolution study is carried out by using USP type-II apparatus. The dissolution test is performed using 900 ml of the dissolution medium at 50 rpm and 37±0.5°C. A sample of 05 ml were periodically withdrawn and the sample volume was

replaced with an equal volume of fresh dissolution medium to maintain sink conditions. The collected samples are analysed spectrophotometrically at the specific wavelength.

**Stability studies:** These studies are conducted to evaluate the stability of the drug product under various storage conditions. The goal of stability studies is to ensure that the drug product maintains its Quality, Efficacy and Safety throughout its shelf-life.

## CONCLUSION

Fast disintegration tablets having mouth dissolving property and innovative drug which disintegrates and dissolves rapidly to obtain maximum Bioavailability to get an effective therapeutic efficacy and patient compliance especially in geriatric and paediatric to attain a safety of the patients. These are obtained by different technologies to formulate the super disintegration tablets/fast disintegration tablets. They are convenient to manufacture with sufficient mechanical strength, easy administration, rapid onset of action and provide wide marketing through the successful formulation of dosage form in the market.

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