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Review Article

# A REVIEW ON FAST DISSOLVING TABLETS

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## ABSTRACT

As we are aware of the fact that Fast dissolving tablets have made an appearance as one of the most greatly welcomed dosage form, exceptionally between the pediatric patients and also among the geriatric patients, as both the category of patients have weaker muscular and the nervous system in comparison to adults as well as struggle to consume tablets and capsules. In the case of geriatric patients, Parkinson's disorder and hand tremors are a major concern and Fast dissolving tablet is one of the most convenient dosage forms. The oral route is considered one of the best-preferred route to administer the drug in animal body but it also has few limitations too. For example, drugs have to go through first-pass metabolism, not preferred in psychiatric and bedridden patients. The FDTs are structured in a way to dissolve very quickly in saliva and this is the most celebrated property of FDTs, that these tablets disintegrate or dissolve in saliva in less than a minute and this process does not need water. Superdisintegrants like Crosscarmellose Sodium and Sodium Starch Glycolate are the backbones of the FDTs, which amplify the rate of disintegration of tablets inside the buccal cavity, results in faster absorption and finally improved bioavailability. There are a number of advantages are offered by FDTs which includes trouble-free transportation and manufacturing, error-free dose, remarkable physical and chemical stability, and above all, its acceptance among pediatrics and geriatric patients. FDTs provide the benefits of both the conventional tablets as well as of liquid dosage forms. FDTs can be manufactured by a number of conventional and patented technologies such as melt granulation, sublimation, direct compression freeze-drying or lyophilization, cotton candy process, etc. These techniques yield the rapid disintegration of tablets which dissolve in the buccal cavity in five seconds and do not need water and chewing. This review includes the definition, needs, advantages, and limitations, challenges to formulate and to manufacture the FDTs, and also some formulations of fast dissolving tablets which are available in market.

**Keywords:** Fast Dissolving Tablet, drug delivery system, rapid disintegrating, fast melting.

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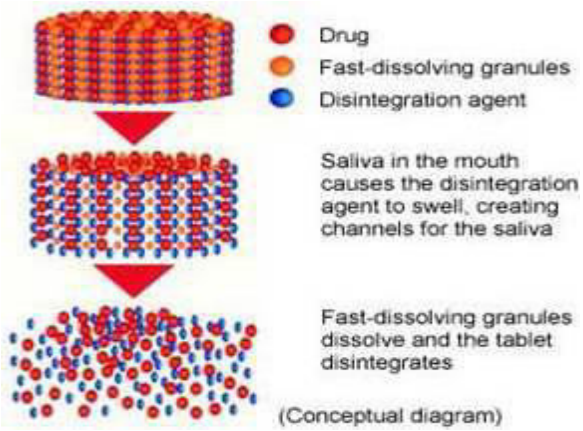
## INTRODUCTION

A broad range of researches are going on and most are working in direction of developing novel drug delivery system or improving the patient compliance. Most preferred and accepted route to administer drug is the oral route, tablets and capsule being the most celebrated dosage form, but difficulty to consume them by the patient is a major problem on other hand FDTs need not to be swallowed. One just has to keep them in the mouth, it will melt itself, and results in better patient compliance, improved bioavailability, quick action, and good stability make FDTs preferred commercial products. Brief information about the FDTs are described in the review.[1-3]

**Concept of FDT**



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**ADVANTAGES OF FDTS**

FDTs are most practical for patients who are out of water, because FDTs dissolve in the buccal cavity within fractions of seconds, results in enhanced patient compliance. FDTs increase the bioavailability of drugs because therapeutic agents absorbed from mouth, pharynx, and esophagus and do not go through the first-pass metabolism. Other benefits of FDTs include good physical and chemical stability, error-free dosing, the desired alternative for pediatric and geriatric patients and are easy to transport.

As FDTs dissolve and absorbed speedily in the mouth, offers almost no suffocation and quick action in critical conditions. No special equipment and process are required for packaging of FDTs, these tablets can be packed through blister packaging which permit affordable manufacturing.[3-5]

**Excipients used for the preparation of FDT**

Superdisintegrants are the most important excipient of FDTs and should have one superdisintegrant, a diluent, and a lubricant while swelling agent, sweeteners, and flavouring agents, permeabilizing agent are optional.

Super-disintegrants [6]

These days rapidly disintegrating solid dosage forms are in high demand, and to formulate such dosage forms disintegrants and superdisintegrants are the key ingredients. Superdisintegrants are much more effective than disintegrants because they possess greater disintegrative properties and are effective at a much lower concentration. The rapid disintegration is achieved in the mouth when saliva is wicked by superdisintegrant results in the generation of hydrostatic pressure and expansion of tablet volume.[7]

**Mechanism of action of superdisintegrants**

Capillary action/Water wicking
Swelling
Heat of wetting
Disintegration particle/particle repulsive forces
Release of gases
Enzymatic action
Due to deformation
Chemical reaction (acid-base reaction)

**Examples of Superdisintegrants**

Croscarmellose Sodium
Crosspovidone
Cross-linked alginic acid
Fenugreek seed mucilage
Sodium starch glycolate
Soy polysaccharide meant for diabetics
Xanthan gum
Banana Powder

**Bulking materials**

Sugar-based bulking materials such as mannitol, lactose derivatives like directly compressible lactose (DCL) and starch hydrolysate improves water solubility and sensory perception. Bulking materials without adding volume and altering the amount of therapeutic agent in the dosage form increases the disintegration rate of formulation in the mouth by improving the texture of the formulation.[8-11]

**Lubricants**

Lubricants make the tablets much more palatable when tablets disintegrate in the buccal cavity. The drug transit process (mouth to the stomach) becomes smoother because grittiness is reduced by lubricants.

Flavoring and sweetening agents [12-13]

Most of the therapeutic agents are bitter and have an unpleasant taste, which is not pleasing to patients, so to improve patient compliance and palatability different flavors and taste masker are added to FDTs. So, the organoleptic property of FDTs can be improved by adding either the natural or artificial flavors. Sweeteners play an important role to improve the taste of formulation and there so many sweeteners are available such as sugar, dextrose, and fructose as well as non-nutritive sweeteners like sodium saccharin, aspartame, sugar alcohols and sucralose.[14]

**EXCIPIENTS COMMONLY USED FOR FDTs PREPARATION [13]**

The composition of fast dissolving tablet must have a superdisintegrant, diluents, a lubricant, a direct compressible binder, and a swelling agent, permeabilizing, sweetening, and flavouring agent.

**Table 1: Name and weight percentage of different excipients**

| Name of the excipients | Percentage used |
|---|---|
| Disintegrants | 1-15% |
| Diluents | 0-85% |
| Binder | 5-10% |
| Antistatic agents | 0-10% |

Techniques for preparing fast dissolving tablets [14, 19]

A number of techniques are there to manufacture Fast Dissolving Tablets. Here we will discuss the techniques which are majorly used to formulate these tablets:

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1.Freeze drying/lyophilization
2.Tablet molding
3.Spray drying
4.Direct Compression
5.Sublimation
6. Mass Extrusion

**Freeze drying**

Lyophilization means drying at low temperature under the condition and in lyophilization water is removed by sublimation. A highly porous structure of the drug is obtained when all the water is freeze-dried at a very low temperature. When these porous structures prepared by lyophilization technique, are placed in the mouth the saliva penetrates so quickly that the disintegration of these structures starts within 5 seconds. In the case of thermolabile drugs, the application of lyophilization is much useful. [15-17]

**Molding**

Water soluble ingredients are used in the molding method because such ingredients help to dissolve tablets completely and quickly. Usually, lower pressure is employed to compress the moistened powder blend with the hydroalcoholic solvent of FDTs than the conventional tablets. Air-drying is used to eliminate the unwanted solvent. Because of lesser compression pressure, these molded tablets are less compact than traditional tablets and their porous structure plays an important role in the faster dissolution.

**Tablet Molding**

Tablet Molding can be done by two methods. The first one is the solvent method and the one is the heat method. The solvent method produces less compact tablets than the compressed ones these fewer compact tablets have a porous structure that improves the dissolution rate. Binding agents are required to enhance the mechanical strength of the formulation. Taste masking in this technology is laborious because drug particles are masked by spray congealing a molten blend of lecithin, cottonseed oil, hydrogenated polyethylene glycol, sodium carbonate, and therapeutic agent into lactose based triturate form. The molding technique can be easily scaled at the industrial level, compared to the lyophilization technique.[18-19]

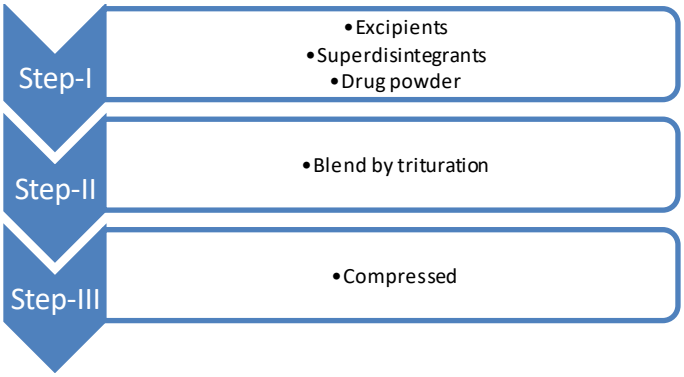
**Spray drying**

Highly porous and fine powders can be obtained with spray drying, such powders dissolve hastily. In this technique, the highly porous and fine powder is formed, when a wet blend of support matrix and other excipients is spray dried. Then, the obtained fine powder is blended with a therapeutic agent and then compressed to form tablets. As a supporting agent hydrolyzed as well as non-hydrolyzed gelatine, as bulking agent mannitol, cross-carmellose as super disintegrants, acid like citric acid, and alkali like sodium bicarbonate embrace the formulation to improve the rates of disintegration and dissolution. Tablets prepared from spray-dried powder, take around 20 seconds to disintegrate when these tablets submerge in the aqueous medium.[20-21]

**Mass Extrusion**

This is a technique in which, methanol and a mixture of aqueous soluble polyethylene glycol are used to soften the mixture of active constituents and other constituents of formulation. Later, this softened blend is squeezed out via syringe, in order to obtain a cylinder of the blend and to obtain tablets this cylindrical blend is chopped by heated knife into uniform parts. In case of a drug with an unpleasant taste, the dried cylinder can be employed to coat the granules.

**Direct Compression Method**




**PREPARATION OF MIXED BLEND OF DRUG AND EXCIPIENTS**

As per the specific formulation weigh the required quantity of all ingredients and then grind them (except magnesium stearate) to obtain the desired fineness and pass them all from the sieve no. 60. The blend of all powders can be evaluated for its properties as follows.

**Angle of repose**

The fixed funnel method can be employed to calculate the angle of repose. Through the funnel pass the powdered mixture to get a verticle cone of maximum height. Then measure the radius of the cone and angle of repose can be determined with the given formula.

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

**Bulk density**

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Using the measuring cylinder, bulk density can be calculated by filling the graduated cylinder with the pre-weighed powdered blend. To determine the bulk density we need to put the value of bulk volume (V) and weight of powder (W) in the given formula.

$$\text{Bulk density} = \frac{\text{Weight of granules (W)}}{\text{Volume of granules (V)}}$$

## Tapped density

The pre-weighed powder is filled in a graduated cylinder and tapped to get the minimum volume (tapped volume) of that powder. Then, put the value of obtained tapped volume ($V_t$) and weight of powdered blend (W) in the formula given below to determine the tapped density.

$$\text{Tapped density} = \frac{\text{Weight of the powdered blend (W)}}{\text{Volume occupied in the cylinder } (V_t)}$$

## Compressibility index (I)

Compressibility is one of the simplest ways to determine the free flow of powder. Compressibility gives the idea about the flow of the materials, that the material has desired flow or not. Compressibility index (I) can be determined by the following formula.

$$I = \frac{\text{Tapped density } (T_d) - \text{Bulk density } (B_d)}{\text{Tapped density } (T_d)} \times 100$$

In the given equation, $V_o$ represents the bulk volume and $V_t$ represents the tapped volume.

For good flow properties the value of compressibility index (I) should be less than 15%, and if the value exceeds 25%, then the flow property is poor.

## Hausner's Ratio

It is an indirect index to measure the flow property of the powder and granules. Hausner's ration can be calculated by the given formula.

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

If the value of Hausner's ratio is less than 1.25 denotes good flow properties than the value of ration of ratio more than 1.25.[22]

## Compression of tablets by using direct compression technique

In case of direct compression technique, some special excipiants like microcrystalline cellulose and magnesium stearate are added to prepare the powdered blend. Then, the prepared blend is compressed at the tablet punching machine.

## EVALUATION OF FAST DISSOLVING TABLETS

### Weight variation

Weight variation is a serious problem, so to make sure that each and every tablet has equal weight, weight variation every batch should be done. Weight variation can be calculated by weighing the 20 tablets of batch and then find the average, the weight of each tablet should not vary much from the average weight of those 20 tablets. To calculate the weight variation, weight of each and every tablet is also determined.

% Weight variation = Individual weight-Average weight/Average weight ×100

### Hardness

Hardness is also called crushing strength (fc) of the tablets, actually, it is measured as the force needed to crush the tablet with the help of an apparatus known as hardness testers like Monsanto hardness tester and Pfizer hardness tester. To measure it take six tablets from each batch and calculate their average and also the standard deviation. The hardness of the tablet is denoted by $Kgcm^{-2}$.

### Friability (F)

Friability is important to measure because the compressed tablets are in direct contact with the packing material which causes abrasion during the transportation, if they are more friable then it will lead to loss of tablet content and there would be more chances of loss of active ingredients may result in a reduced amount of active ingredients than required for their therapeutic action. To determine the friability of tablets, randomly take 10 tablets from the batch and weigh them, then put them in Roche friabilator and set it to rotate at rpm of 25 for 4 minutes. After that collect only the tablets and again weigh them, then put the obtained value in the following formula. The friability is given as the percentage weight loss.

$$\text{Friability } \% = \frac{W_1 \text{ (initial weight)} - W_2 \text{ (final weight)}}{W_2 \text{ (final weight )}} \times 100$$

### Wetting time

The hydrophilicity of excipients and internal structure of tablets, both are closely related to wetting time. The rate of water penetration into the bed of powder is directly proportional to the radius of pores and hydrophilicity of powder affects it as per the equation given by Washburn (1921).

$$l^2 \quad r_{pore} \Upsilon \cos\theta$$

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$$\frac{t}{} = \frac{4\eta l}{}$$

In the above equation l, indicates the penetration length, $r_{pore}$ is the radius of the pore, η represents the surface tension, ϒ is the viscosity of the liquid, and t is the time. From this equation, it is clear that if pore size increases then wetting time will increase and vice-versa. Wetting is necessary for the disintegration of tablets. Wetting time related to the time taken for the tablet to disintegrate when kept motionless on the tongue.

### *In vitro* disintegration time [17]

The disintegration time of tablets can be determined using the modified disintegration method. Take a petridish having a diameter of 10 cm, fill it with 10 ml of distilled water. Then, carefully place the tablet at the center of petridish, and record the time taken by the tablet to disintegrate completely into the fine particles.

### Drug content

The active ingredient is the most important ingredient of any formulation because without this the given dose would not show any therapeutic action. The drug content of tablets can be determined by crushing the five tablets with the help of a mortar pestle and then dissolve the powder in the distilled water and make up the volume up to 100 ml. Then filter this solution through the Whatman filter paper, dilute as per the requirement. Use a UV-visible double beam spectrophotometer to analyze the diluted solution. Analyze them in triplicate to get a precise result.

### *In vitro* drug release

The release of drug in *in vitro* condition can be determined by estimating the dissolution profile, USP 2 Paddle apparatus can be used and for this, the paddle should be allowed to rotate at 50 rpm, use phosphate buffer (PH 6.8) (900 ml) as a dissolution medium at 37±0.5 ℃. Aliquots of dissolution medium should be withdrawn and the absorbance of filtered solutions can be determined by a UV Spectrophotometer. Several sets are advised to perform for each batch to calculate the average percentage drug release with standard deviation should be recorded.[23-24]

## CONCLUSION

FDTs are dosage forms that are formulated to dissolve/disintegrate rapidly in the saliva generally within few seconds. They are specially designed to overcome some of the problems seen in conventional solid dosage form i.e. difficulty in swallowing the tablet in the elderly and for children, especially for infants. FDTs are structured to dissolve or disintegrate swiftly when coming in contact with saliva generally within 60 seconds (range of 5-60 seconds). Fast dissolving tablets have widely accepted patient compliance and acceptance and 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 should be developed for psychotic patients, bedridden, geriatric, pediatric patients, patients who is facing scarcity of drinking water, patients who are travelling most of their time. FDTs formulations formulated by some of these conventional and patent technologies and FDTs have sufficient mechanical strength, quick disintegration/ dissolution in the oral cavity without water. The newer technologies utilized for the formulation of the FDTs provide more effectiveness in comparison to other dosage forms.

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