WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 14, Issue 10, 29-40. Review Article ISSN 2277–7105

A REVIEW ON: FAST-DISSOLVING TABLET

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Article Received on
31 March 2025,

Revised on 20 April 2025,
Accepted on 10 May 2025

DOI: 10.20959/wjpr202510-36306

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ABSTRACT

Fast dissolving Tablets are disintegrating and/or dissolving in saliva without the need for water. Some tablets are designed to dissolve in saliva remarkably fast, within a few seconds, and are true fast-dissolving tablets. Others which are better referred to as fast disintegrating tablets since they may take up a minute to fully dissolve include substances that speed up the pace up tablet breakdown in the oral cavity.Oral delivery is currently the gold standard in the pharmaceutical industry; it is regarded as the safest, most convenient, and most economical method of drug delivery with the highest patient compliance. This tablet format is designed to allow administration of an oral solid dose form in the absence of water or fluid intake. Such tablets readily dissolve or disintegrate in the saliva within >60 seconds.super disintegrates are a component of FDT formulations that increase a tablet rate of disintegration in the buccal cavity among the benefits of FDT and there easy manufacture and transportation, precise dosing, good chemical and physical stability, and an ideal alternative for geriatric and pediatric patients. drugs(dosage form) with FDTs have better invitro drug release quicker absoption, and faster disintegration, all of wich increase bioavailability.FDT formulations have the advantage of both conventional tablet formulation and liquid dosage form. There are several technologies that are conventional or patented based on spray drying, the cotton, melt granulation, direct compression-drying, phase transition processes, etc. A FDTs are maintained by a manufacturer, along with definitions, demandes or requirements of FDTs,

salient features of FDTs, limitations, challenges to developing FDT formulations of fast-dissolving tablets, etc.

KEYWORDS: fast-dissolving tablets, FDTs, superdisintegrants, mouth-dissolving tablets, MDTs.

INTRODUCTION

The formulation of drugs into a presentable form is the basic requirement and need of today. The medicine is applied to a living organism using the dosage form, wich is drug delivery mechanism. There are many different kinds of dosage form are available, such as tablets, syrups, suspensions, suppositories, injections, transdermal patches, and different types of drug delivery mechanisms.

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, patient compliance.

The tablets and capsules are the most widely used solid dosage form; nevertheless, some patients may find these forms difficult to swallow.

Drinking water plays an important role in the swallowing of oral dosage forms. Oftentimes, people experience inconvenience in swallowing conventional dosage forms such as tablets when water is not available in the case of motion sickness, nervous illness, radioactivity therapy, Parkinson's disease, and AIDS, which face the dysphasia condition.

The United States Food and Drug Administration (USFDA) defined a fast-dissolving tablet as "a solid dosage form containing a medicinal substance or active ingredient that disintegrates rapidly,, usually within a matter of seconds,, when placed upon the mouth." Approximately one-third of the population (primarily pediatric and geriatric) has swallowing difficulties, which result in poor compliance with oral tablet drug therapy and reduce overall therapy effectiveness. Swallowing difficulties are common in elderly patients due to hand tremors, dysphasia, and choking anxiety; in young people, they are caused by an underdeveloped neurological and muscular system; in patients with schizophrenia, they lead to poor patient compliance.

fast-dissolving drug delivery systems were first developed in the late 1970s as an alternative to conventional dosage forms for the pediatric and geriatric patient.in less than 60 sec these tablets are intended to dissolve or disintegrate quickly in the saliva.

Fast-dissolving tablets are also called as mouth dissolving tablets, melt-in-mouth tablets, orodispersible tablets, rapimelts, porous tablets, quick-dissolving, etc.

When placed on tongue, fast dissolving tablets break down instantly, releasing the medication that dissolve are spreads in the saliva.

The faster the drug into solution, the quickercker the absorption and onset of clinical effect. As saliva flows down into the stomach, some medications are absorbed from the mouth, throat an esophagus.

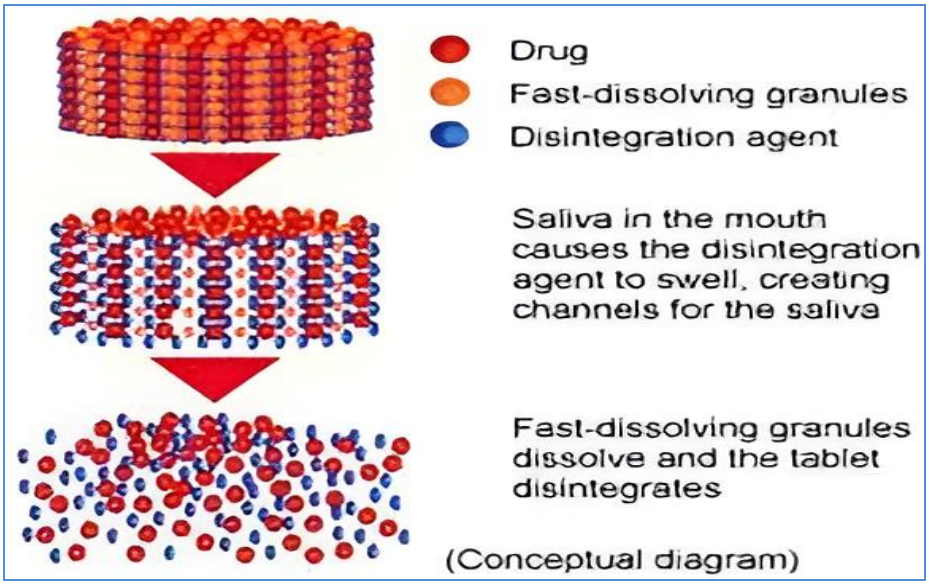
Advantages of fast-dissolving tablets

- No need of water to swallow the tablet.
- FDTs can be easily administered to pediatric, elderly and mentally challenged individuals.
- Precise dosing as compared to liquids.
- Dissolution and absorption of the drug is fast, offering rapid onset of action.
- •Bioavailability of drugs is increased, as some drugs are absorbed from the mouth, pharynx, and esophagus through saliva passing down into the stomach.
- Advantageous over liquid medication in terms of administration as well as transportation.
- improving safety by lowering first – pass metabolism, which improves bioavailability and consequently, dosage and side effects.
- Offering improved safety.

Limitations of FDTS

- The major disadvantage of FDTs is related to the mechanical strength of tablets.
- FDTs are very porous and soft molded metrics or compressed in a tablet with low compression, which makes tablets friable and brittle, which is difficult to handle.
- Bad-tasting drugs are difficult to formulate as FDT; special precautions should have to be taken before formulating such kinds of drugs.
- Several FDTs are hygroscopic and cannot maintain physical integrity under normal conditions from humidity, which requires specialized packaging.

- These tablets formulations might not be suitable people who have dryness of mouth from reduced saliva production.
- The total bioavailability and the rate of absorption from the saliva solution.
- stability of drugs and dosage forms.



PICTURE NO: 1

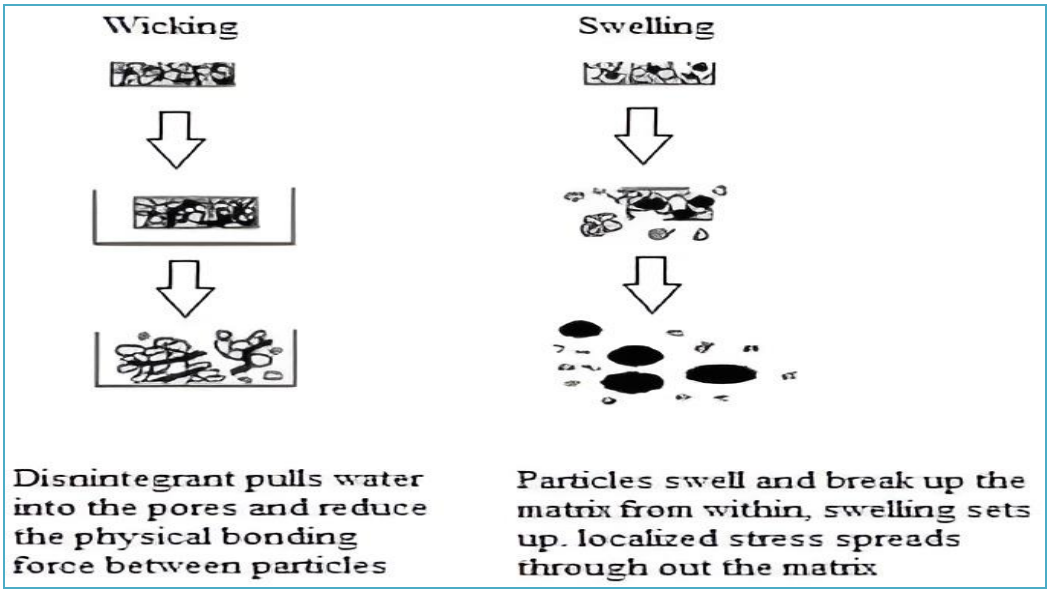
Superdisintegrants

Superdisintegrants are essential components in the formulation of fast-dissolving tablets (FDTs), as they facilitate rapid disintegration of the tablet matrix. The compared to conventional disintegrants, these agents are more effective and required lower concentrations to provide greater mechanical strength and disintegration, superdisintegrants are added to FDT formulations to promote the tablets rapid oral breakdown, which accelerates medication release and increase patient compliance.

Mechanism of Superdisintegrants: There are four major mechanisms for tablets disintegration as follows:

1. Swelling: Perhaps the most widely accepted general mechanism of action for tablet disintegration is swelling. High porosity tablets disintegrate poorly because they don't have enough swelling force.

On the other hand, sufficient swelling force is exerted in the tablet with low porosity. It is worthwhile to note that if the packing fraction is very high, fluid is unable to penetrate the tablet, and disintegration again slows down.



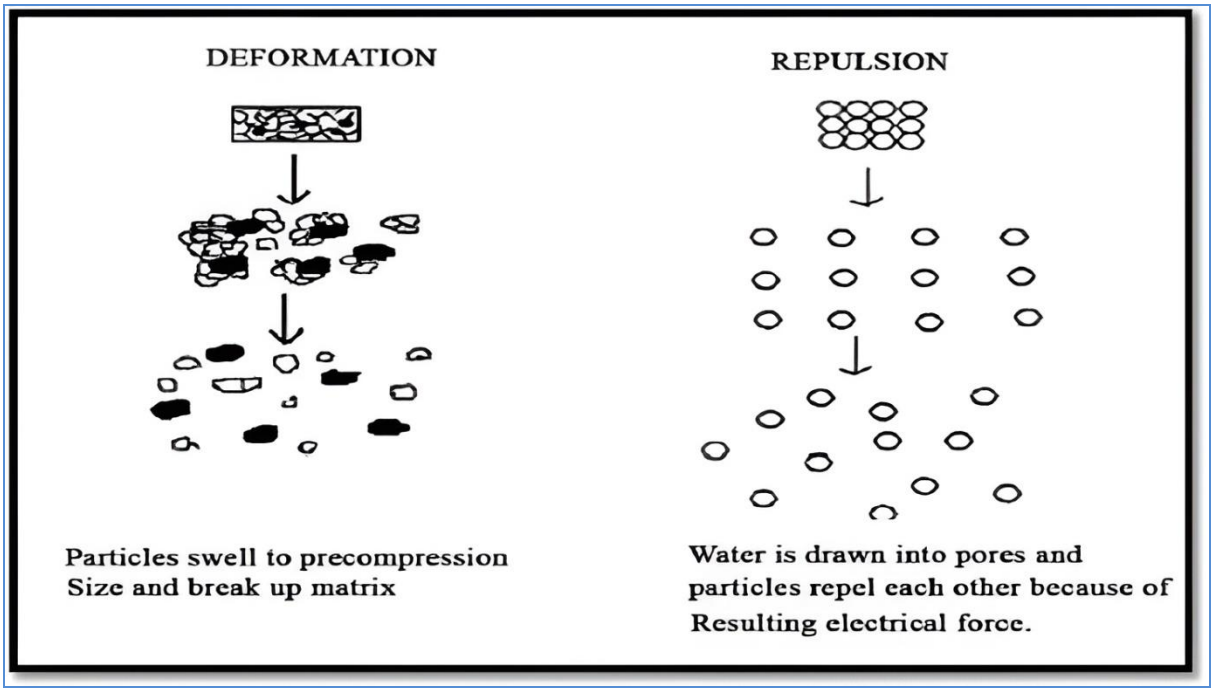
PICTURE NO: 2.

2. Porosity and capillary action (Wicking): the initial phase is invariably capillary action – induced disintegration.the tablet breaks into tiny particles when it is placed in an appropriate aqueous medium because the medium seeps in to the tablet and replaces the air that as been absorbed on the particles, weakening the inter molecular connection. The hydrophilicity of the medication are excipients and tableting. For these types of disintegrants, maintenance of a porous structure and low interfacial tension towards aqueous fluid is necessary, which helps in disintegration by creating a hydrophilic network around the drug particles.

3. Due to disintegrating particle/particle repulsive forces: The swelling of tablets prepared with "nonswellable" disintegrants is attempted to be explained by another disintegration process. Based on the finding that nonswelling particles also contribute to tablet disintegration, Guyot-Hermann developed a particle repulsion theory.

The method of disintegration, which involves the electric repulsive interactions between particles, requires water. Researchers found that wicking is more important than repelling.

4. Due to deformation: During tablet compression, disintegrated particles get deformed, and these deformed particles get into their normal structure when they come in contact with aqueous media or water. Occasionally, the swelling capacity of starch was improved when granules were extensively deformed during compression. This increase in size of the deformed particles produces a break-up of the tablet. This may be a mechanism of starch and has only recently begun to be studied.



PICTURE NO: 3.

TABLE NO: 1.

SUPERDISINTEGRANT	CHEMICAL NAME	MECHANISM OF ACTION	CONCENTRATION RANGE
Croscarmellose sodium	Crosslinked sodium carboxymethycellulose	Swelling,Wicking	0.5-5.0%
Crospovidone	Crosslinked polyvinylpyrrolidone	Wicking,deformation	2.0-5.0%
Sodium starch glycolate	Sodium carboxymethyl starch	Swelling	2.0-8.0%
Calcium silicate	Calcium silicate	Wicking	0.5-5.0%
Skollidon CL-SF	Crosslinked polyvinylpyrrolidone	Wicking,deformation	0.5-3.0%

Techniques for Preparing Fast-Dissolving Tablets

Many techniques have been reported for the formulation of fast-dissolving tablets or Orodispersible tablets.

1. Freeze drying / lyophilization

2. Tablet Moulding

3. Spray drying

4. Sublimation

5. Direct compression

6. Mass extrusion

1. Freeze-Drying or Lyophilization: Freeze-drying is the process of removing water from a product after it has been frozen. This method produces a porous, amorphous structure that dissolves quickly. This article discusses a common process used in the production of ODT utilizing this method. A carrier or polymer's aqueous solution dissolves or disperses the active medication. The liquid is poured into the premade blister packs' walls based on weight. The medicinal solution or dispersion is frozen by passing the blister pack trays through a liquid nitrogen freezing tunnel.

To complete the freeze-drying process, the frozen blister packs are subsequently put in refrigerator cabinets. The aluminum foil backing is placed on a blister-sealing machine after it has been freeze-dried. The blisters are then packed and sent out. Increased bioavailability and better absorption have been shown with the freeze-drying method. The lyophilization technique's main drawbacks are its high cost and time commitment, its poor stability under stressful conditions, and its fragility, which renders traditional packaging inappropriate for these items.

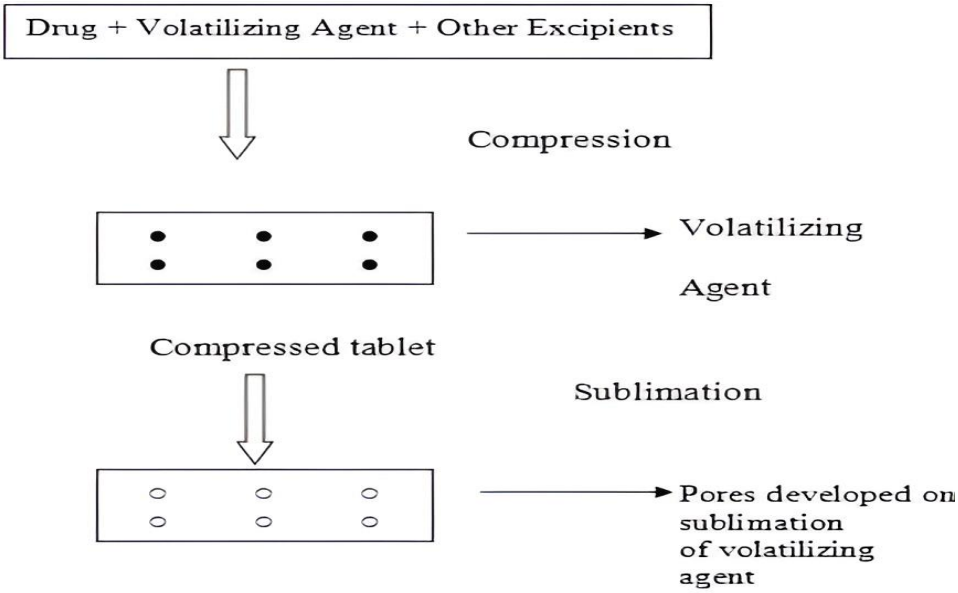
2. **Tablet Molding:** The solvent technique and the heat method are the two types of molding processes. The solvent technique creates a wetted mass (compression molding) by moistening the powder mix with a hydroalcoholic solvent and then compressing it under low pressure in molded plates. After that, the solvent is eliminated by air drying. The resulting tablets have a porous structure that speeds up dissolving and are less compact than compacted tablets. A medication, agar, and sugar (such as lactose or mannitol) are combined to create a suspension, which is then poured into blister packing wells, allowed to solidify at room temperature to form a jelly, and then dried under vacuum at 30°C.

It is necessary to include binding agents, which give the tablets more mechanical strength. Another issue with this technology is taste masking. Spray congealing a molten combination of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethylene glycol, and an active component into a lactose-based tablet triturate form produced the taste-masked drug particles. Tablets made using the molding technique are simpler to scale up for industrial manufacturing than those made using the lyophilization technique.

3. 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 crosscarmellose 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 agents like mannitol and lactose, a superdisintegrant like sodium starch glycolate & croscarmellose sodium, and acidic ingredients (citric acid) and/or alkaline ingredients (e.g., sodium bicarbonate). This spray-dried powder, which compressed into tablets, showed rapid disintegration and enhanced dissolution.

4. Sublimation: Rapid disintegration and dissolution is acquired by formulating into a porous mass by incorporating inert solid ingredients that volatilize rapidly like urea, camphor ammonium carbonate, ammonium bicarbonate, and hexamethylene-tetramine. They were mixed with other ingredients and compressed. The volatile material is evolved by



PICTURE NO: 4.

reduced pressure and applying slight temperature, leaving the mass in porous form. Characteristics of the sublimation method are that they are porous in nature, and solvents like cyclohexane and benzene can be used.

5. Direct compression: The disintegrant addition technology (direct compression) is the most preferred technique to manufacture the tablets due to certain.

Advantages

- High doses can be accommodated, and the final weight of the tablet can exceed that of other methods.
- The easiest way to manufacture the tablets.

- Conventional equipment and commonly available excipients are used.
- A limited number of processing steps are involved.
- Cost-effectiveness.

The effectiveness of the disintegrant is significantly impacted by tablet size and hardness. Large, hard pills take longer to dissolve than is often needed. Tablets that are tiny and extremely soft have little mechanical strength. Therefore, to achieve rapid disintegration and high dissolution rates, the best type and concentration of disintegrant should be selected. However, the disintegration time stays roughly constant or even rises above the critical concentration level.

6. Mass-extrusion: In this, the mixed ingredients are softened by a water-soluble ingredient, i.e., polyethylene glycol, using methanol as a solvent, passing through an extruder to form thin cylinders. Which further gets sliced with a heated blade to form small tablets. Characteristics of this method are that these products can be used to mask bitter-tasting drugs, making small granules, thus enhancing oral bioavailability.

Evaluation Parameters for Fast Dissolving Tablets

The evaluation of FDTs involves both pre-compression and post-compression parameters to ensure the quality and performance of the final product.

1. Pre-compression parameters

1. Angle of Repose: The angle of repose measures the friction forces in a loose powder and indicates its flow properties. It is determined by measuring the maximum angle between the surface of the powder pile and the horizontal plane.

2. Bulk Density: Bulk density is determined by streaming the powder blend into a graduated cylinder and measuring the volume and weight of the powder. It delivers information about the packing behavior of the powder.

3. Tapped Density: Tapped density is measured by subjecting the powder blend to a constant of taps in a graduated cylinder and determining the final volume and weight. It desired the ability of the powder to determine and compact.

4. Carr's Compressibility Index: Carr's index is a measure of the compressibility and flowability of the powder. It is calculated based on the difference between the tapped density and bulk density of the powder.

5. Hausner's Ratio: Hausner's ratio is an indirect measure of the ease of powder flow. It is calculated as the ratio of tapped density to bulk density. Lower values indicate better flow properties

2. Post-compression parameters

1. Tablet Hardness and Thickness Tablet hardness is measured using a hardness tester and uttered in units of force, such as kilogram-force or Newton. The thickness of the tablet is determined using a micrometer or vernier caliper. These parameters indicate the mechanical strength and uniformity of the tablets.

2. Friability: Friability testing evaluates the capability of the tablets to withstand friction and mechanical stress during handling and packaging. It is determined by subjecting a sample of tablets to a specified number of rotations in a friabilator and measuring the percentage weight loss.

3. Drug Content Uniformity: Drug content uniformity is assessed by determining the amount of active ingredient present in a sample of tablets. It assures that each tablet contains the labeled amount of the drug within specified limits.

4. Weight Variation: Weight variation is determined by weighing a sample of tablets individually and calculating the average weight and percentage deviation from the average. It ensures consistency in the weight of the tablets.

5. Wetting Time and Water Absorption Ratio: The amount of time needed for a tablet to get totally wet when set on a damp surface is known as the wetting time. The weight of the pill before and after water absorption is compared to get the water absorption ratio. These variables shed light on the tablets' hydrophilicity and disintegration characteristics.

6. In-vitro Disintegration Time: In-vitro disintegration time is measured using a disintegration apparatus as specified in pharmacopeias. It determines the time required for the tablets to disintegrate completely under simulated conditions.

CONCLUSION

When compared to traditional oral dosage forms, the popularity of fast-dissolving tablets (FDTs) has grown rapidly over the past ten years. FDTs are innovative dosage forms that were specifically created to address some of the issues with conventional solid dosage forms, such as difficulty swallowing the tablet in pediatric and geriatric patients. FDTs are designed to dissolve or disintegrate quickly in the saliva, usually within less than 60 seconds (range of 5-60 seconds). They have better patient compliance and acceptance; they may improve biopharmaceutical properties, bioavailability, efficacy, convenience, and safety.

FDTs must be developed for patients with psychosis, those who are bedridden, elderly, children, patients who might not have access to water, and patients who are on the go. FDTs made using some of these traditional and proprietary methods dissolve or disintegrate quickly in the buccal cavity without the need for water and have enough mechanical strength. More effective dose forms with more benefits and fewer drawbacks are offered by the more recent technology used to formulate the FDTs.

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