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Review Article

A Comprehensive Review on Fast Dissolving Tablets

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Abstract



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The oral route is the most preferred route of administration due to its low cost, ease of administration, and patient compliance. Pharmaceutical technologists introduced the novel dosage forms known as oral disintegrating tablet (ODT), fast disintegrating tablet (FDT), and mouth dissolving tablet (MDT). According to the United States Food and Drug Administration (FDA), it is defined as a solid dosage form containing a medicinal substance or medicament that disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue. FDT tablets dissolve quickly in saliva, without requiring water. Recently FDTs have been the most popular and effective dosage form. It is used as an alternative to conventional dosage forms for elderly and pediatric patients. Fast-dissolving tablets improve patient compliance and quicker onset of action. Superdisintegrants play an important role in the formulation of fast-dissolving tablets that increase the tablet disintegration in the buccal cavity. This review describes the various technologies used to develop the fast-dissolving tablet. This review describes the technologies of sublimation, molding, spray drying, melting the granulation, and the cotton candy process. This review also describes the advantages, disadvantages, challenges, salient features of FDT, and evaluation of various evaluation parameters of FDT.

Keywords: FDTs, FDA, Fast-dissolving tablet, Superdisintegrants

Introduction

Despite the tremendous advancement in drug delivery, the oral route is the most preferred route for administering therapeutic agents due to its low cost, ease of administration, and increased patient compliance.¹ One significant disadvantage of these dosage forms is dysphagia, or difficulty swallowing, which affects about 50% of the population.² Tablets and capsules are the most popular solid dosage forms; certain patients may have trouble swallowing them. People with motion sickness, neurological disorders, radiation therapy, Parkinson's disease, AIDS, and other conditions that cause dysphasia frequently find it difficult to swallow traditional dosage forms like pills when water is unavailable.³ In the late 1970s, fast-dissolving drug delivery systems were first created as a substitute for traditional dosage forms for elderly and pediatric patients.⁴ Pharmaceutical technologists have created a novel oral dosage to address these medicinal needs known as oral disintegrating tablets (ODTs), fast disintegrating tablets (FDTs), mouth melting tablets

(MMTs), or mouth dissolving tablets (MDTs).⁵ United States The Food and Drug Administration (FDA) defined Mouth /A Fast-dissolving tablet is "a solid dosage form containing a medicinal substance or active ingredient that disintegrates rapidly, usually within a matter of seconds when placed upon the tongue."⁶ These tablets dissolve in the mouth in just 20 to 30 seconds. A tablet dissolves or disintegrates instantly when placed on the tongue without chewing or water, and it dissolves in the presence of the salivary fluid.⁷ According to the European pharmacopoeia, "ODT (Oral Dispersible Tablet) should disperse or disintegrate in less than 3 minutes when placed on the tongue".⁸ Pregastric absorption from the mouth, pharynx, and esophagus can improve the medication's clinical efficacy while the tablet dissolves in the mouth. In such cases, bioavailability of the drug is greatly increased by avoiding first-pass hepatic metabolism compared to that observed with traditional tablets.⁹ The current study focuses on the production, features, and advantages; medications incorporated into ODT; and assessments of the oral disintegrating tablet.¹⁰

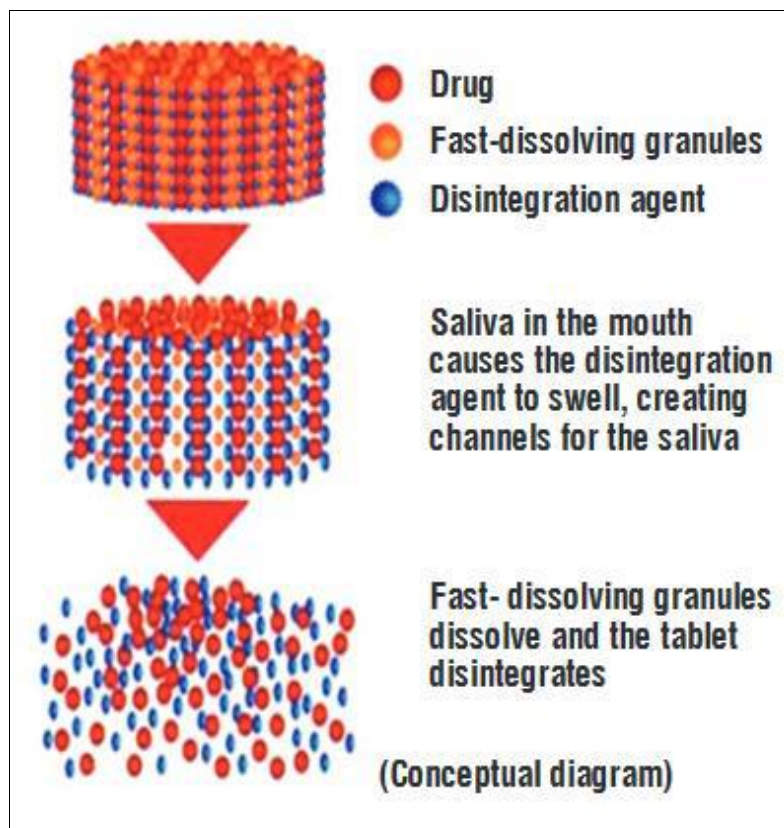


Figure 1: Mechanism of Fast Dissolving Tablet¹¹

Desired criteria for FDTs ^{12,13}

1. Water should not be necessary for swallowing.
2. After taking the tablet, the mouth should feel pleasant.
3. After oral administration, there should be very little or no residual in the mouth.
4. Show minimal sensitivity to environmental factors like temperature and humidity.
5. Have no fragility concerns and be portable
6. It possesses adequate mechanical strength and a well-designed container.
7. The properties of the drug and excipients should not impact the FDTs.

Salient Characteristics of Fast Dissolving Dosage Form ¹⁴

1. Simple administration for children, elderly, and psychiatric patients who would rather not swallow medication.
2. A precise dose is more practical than a liquid dosage form.
3. Patients with depression or epilepsy will find it convenient, as there is no need for water.
4. Good oral taste qualities are very advantageous for kids.

5. Solid unit dosage forms that offer precise dosage, strong stability, compact packaging, simplicity in production, and portability.
6. Quick medication absorption and breakdown results in quick action.
7. Quick medication absorption from the mouth, pharynx, and esophagus, reducing adverse effects, increasing bioavailability, lowering dosage, and improving clinical effectiveness.

Advantage of FDTs ^{15,16}

1. The tablet's superior flavor contributes to a shift in the perception of pharmaceuticals as the "bitter pill," especially among younger patients.
2. It is feasible to intervene quickly with medication therapy.
3. Pre-gastric absorption from the mouth, pharynx, and esophagus results in faster drug absorption.
4. There is no chance of asphyxia because of physical restriction when ingested, providing increased security.
5. Water is not required for swallowing.
6. Enhanced stability

Disadvantages of FDTs ^{4, 17}

1. The mechanical strength of the tablets is typically inadequate. Thus, handling must be done carefully.
2. The tablets could leave grit and an unpleasant taste in the mouth if improperly formulated.

3. It is challenging to formulate drugs with higher dosages into FDT, e.g., rifampicin (600 mg) and ethambutol (1000 mg).
4. These tablet formulations might not be suitable for people with dry mouth brought on by a decrease in salivary flow.
5. The rate of absorption and total bioavailability from the saliva solution.

Drug's Suitable for Fast Dissolving Tablets

Table 1: Some drug's suitable for Fast Dissolving Tablets ^{18,19}

Class of Drug	Drug
Analgesic/Anti-inflammatory Agents	Piroxicam, Ibuprofen, Mefenamic Acid ,Etodolac, etc
Anti-Bacterial Agents	Erythromycin, Tetracycline, Doxycycline ,Rifampicin, etc
Anti-Fungal	Griseofulvin, Miconazole
Anti-Malarial	Chloroquine, Nifedipine
Anti-Gout	Allopurinol, Probenecid
Anti-Arrhythmic Agents	Amiodarone HCL, Disopyramide, Flecainide acetate
Anti-Coagulants	Glipizide, Tolbutamide
Anti-Protozoal	Benznidazole, Tinidazole
Anti-Thyroid	Carbimazole
Cardiac Inotropic Agents	Digitoxin, Digoxin
Gastro-Intestinal Agents	Omeprazole , Ranitidine , Famotidine
Nutritional Agents	Vitamin A ,Vitamin B, Vitamin D, etc
Oral Vaccines	Influenza, Hepatitis, Polio, Tuberculosis, etc ¹⁸
Antiemetic Drugs	Ramosetron HCl, Ondansetron, Baclofen ¹⁹
Anti-Parkinsonian Drugs	Selegiline ¹⁹
Antidepressant Drugs	Mirtazapine, Fluoxetine ¹⁹

Challenges in formulating Fast dissolving tablets

Tablet Strength, Friability, and Porosity

Fast-disintegrating tablets are formed of either extremely porous or soft-molded matrices or compacted into tablets with very little compression force, which makes the tablets brittle or friable and challenging to handle. Usually needing specific peel-off blister packaging.²⁰

Hygroscopicity

Due to their hygroscopic nature, a number of FDTs are unable to retain their physical integrity in typical humidity and temperature circumstances. They therefore require humidity protection, necessitating the use of specific product packaging.²¹

Drug Properties

The final tablet's strength and rate of dissolving can be greatly influenced by a drug's solubility, crystal structure, particle size, moisture absorption, compressibility, and bulk density. According to the

biopharmaceutical classification system, drugs with high permeability and low water solubility are classified as Class II. The medication must be administered infrequently and have a biological half-life.²²

Amount of Drug

The amount of medication that can be induced in each unit dose restricts the usage of FDT technology. The drug dose for lyophilized dosage forms must be less than 60 mg for soluble medications and less than 400 mg for insoluble medications. When creating fast-dissolving oral films or wafers, that parameter is very difficult.²³

Palatability

FDTs typically include the medication in a taste-masked form because most medications are unpleasant. After being administered, it dissolves or disintegrates in the patient's mouth, releasing the active chemicals that come into contact with the taste buds. Therefore, taste-masking medications are essential to patient compliance.²⁴

Excipients Commonly used for FDTs preparation

Table 2: Name, examples and weight percentage of different excipients²⁵

Excipients	Examples	w/w
Super disintegrants	Croscopovidone, Microcrystalline cellulose, sodium starch glycolate, sodium carboxy methyl cellulose etc. Sodium starch glycolate has good flowability than croscarmellose sodium. Croscopovidone is fibrous nature and highly compactable	1-15%
Binde	Polyvinylpyrrolidone(PVP), Polyvinyl alcohol(PVA), Hydroxy propyl methylcellulose etc.	5-10%
Antistatic agents	Sodium lauryl sulfate, sodium dodecyl sulfate, polyoxyethylene stearates, polyoxyethylene sorbitan fatty acids esters etc.	0-10%
Lubricants	Magnesium carbonate, calcium sulphate, magnesium trisilicate etc	0-85%

Superdisintegrants

Superdisintegrants are substances that are added to tablet formulations in order to accelerate the tablets' disintegration into smaller pieces in an aqueous environment, expanding the surface area that is available and encouraging a quicker release of the therapeutic ingredient.²⁶

Mechanism of superdisintegrant

There are following mechanisms of superdisintegrants:

By capillary action (wicking)

Disintegration by capillary action is always the initial phase. The intermolecular connection is weakened, and the tablet is broken into fine particles when it is submerged in an appropriate aqueous solution, which enters the tablet and replaces the air absorbed on the particles. The hydrophilicity of the medication or excipient and the tableting circumstances determine how much a tablet absorbs. By forming a hydrophilic network surrounding the drug particles, these disintegrants aid in disintegration by maintaining a porous structure and low interfacial tension toward aqueous fluid.²⁷

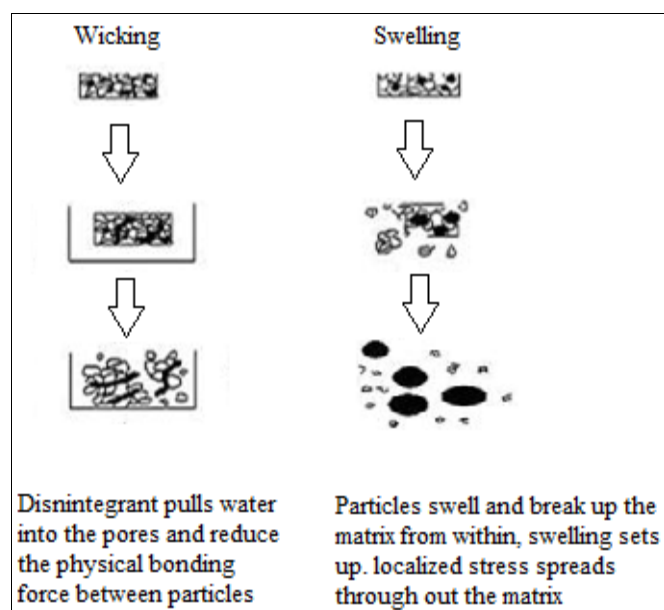


Figure 2: Mechanism of Wicking and swelling²⁸

By Swelling

Swelling is perhaps the most recognized general mode of action for tablet disintegration. Because they don't have enough swelling power, tablets with high porosity disintegrate poorly. Conversely, the tablet with poor porosity exerts enough swelling force. It is important to remember that a very high packing fraction prevents moisture from penetrating the tablet and slows down disintegration once again.²⁹

Because of heat of wetting

Capillary air expansion causes localized stress when exothermic disintegrants are wetted, which aids in tablet breakdown. However, the majority of contemporary disintegrating agents cannot be explained by this hypothesis, which is restricted to a small number of disintegrant agents that work.²⁹

Due to the release of gases

When tablets are wet, carbonate and bicarbonate react with citric and tartaric acids to release carbon dioxide. The pressure inside the tablet causes it to dissolve. Experts use this effervescent mixture to manufacture tablets that dissolve very quickly. Strict environmental control is necessary during tablet production since these disintegrants are extremely sensitive to even little variation in temperature and humidity. The effervescent mixture can be applied in two different formulation fractions or just prior to compression.³⁰

Enzymatic Action

Certain enzymes in our bodies operate as disintegrants by reducing the binder's capacity to bind, which causes tablets to break down. More water absorption leads to an excessive granular volume, which encourages the tablet disintegration, or swelling causes pressure in the outer direction, which causes the tablet to explode. The enzymes in our bodies that aid in tablet breakdown. Examples of enzymes that act as superdisintegrants are amylase, protease, cellulase, and invertase.³¹

Due to Disintegrating Particle/Particle Repulsive Forces

The swelling of tablets manufactured with "nonswellable" disintegrants is explained by another process of disintegration. Based on the finding that non-

swelling particles also contribute to tablet disintegration, Guyot-Hermann developed a particle repulsion theory. Water is required for the disintegration process, which is caused by the electric

repulsive interactions between particles. Researchers discovered that wicking is more important than repelling.³²

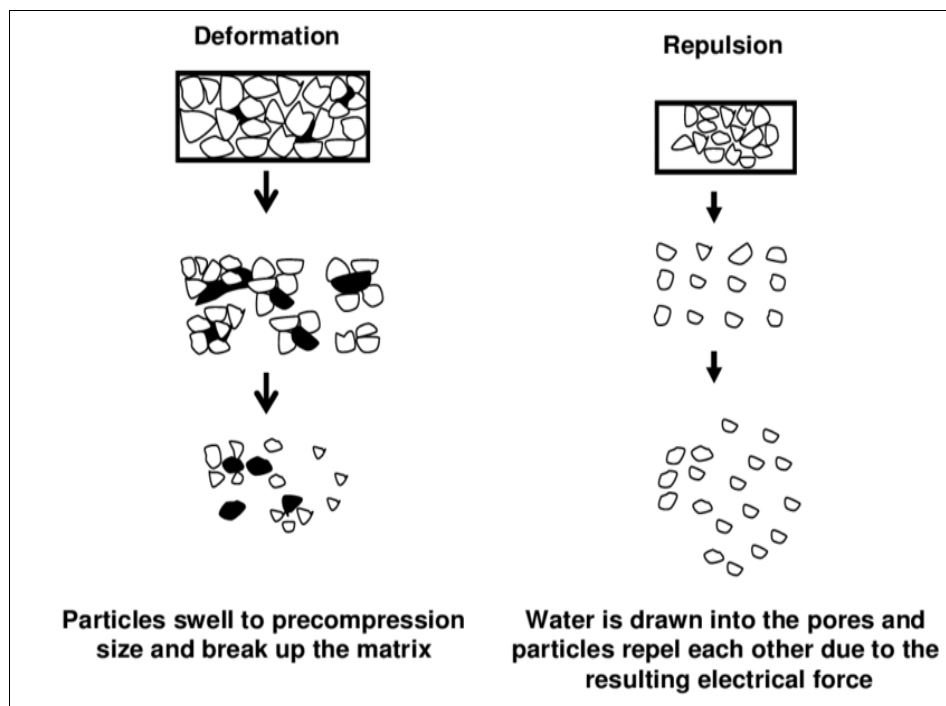


Figure 3: Mechanisms of Deformation and Repulsion ⁹

Due to Deformation ³³

It is generally believed that starch grains are “elastic,” which means that when pressure is released, grains that have been distorted will revert to their original shape. However, these grains are thought to be more permanently deformed due to the compression force involved in tableting, and they are referred to as “energy-rich,” with this energy being released when they come into contact with water. In other words, “energy-rich” starch grains have a greater capacity to swell than starch grains that have not undergone pressure deformation.

Techniques in Preparation of FDTs

Conventional technologies

Various technologies are used for the preparation of fast-dissolving tablets, or orodispersible tablets.

1. **Freeze drying/lyophilization:** The procedure known as “freeze drying” involves sublimating water from a frozen substance. An amorphous porous structure that dissolves quickly is produced by this method. This article describes a common process used in the production of FDT utilizing this method.³⁴
2. **Tablet molding:** There are two ways to mold a tablet. The solvent approach is the first, while the heat method is the second. Compared to compressed tablets, the solvent approach yields fewer compact tablets. Because of their porous texture, these smaller tablets dissolve more quickly. To improve the formulation’s mechanical strength, binding agents are needed. Because drug particles are concealed by spray-congealing a molten mixture of lecithin, cottonseed oil, hydrogenated polyethylene glycol, sodium carbonate, and a therapeutic agent into lactose-based triturate form, taste masking in this method is time-consuming. Unlike the lyophilization approach, the molding technique can be easily scaled at the industrial level.³⁵
3. **Spray drying:** This method uses gelatin as a matrix and supporting agent, mannitol as a bulking agent, and superdisintegrants such as sodium starch glycolate, croscarmellose, or crospovidone. It has been observed that tablets made from the spray-dried powder dissolve in an aqueous solution in 20 seconds.³⁶
4. **Direct Compression:** The simplest and most economical way to produce FDTs is by direct compression. Using standard tablet machinery, a powder blend including the active ingredient, superdisintegrants, and other excipients is compressed into tablets. Optimizing the compression process and choosing the right excipients are essential to this method’s effectiveness.³⁷
5. **Sublimation:** Because of the tablet’s limited porosity, even highly water-soluble substances dissolve slowly in compressed tablets. Sublimation was then used to remove the volatile components, creating porous structures. Additionally, a number of

- solvents, including benzene and cyclohexane, can be employed as pore-forming agents.³⁸
6. **Mass Extrusion:** This method involves using a solvent mixture of water-soluble polyethylene glycol and methanol to soften a mixture of active drug and other ingredients. The softened mass is then extruded through an extruder or syringe to create a cylinder of product, which is then cut into even segments using heated blades to create tablets. Bitter-tasting prescription grains can be coated with the dried cylinder to lessen their disagreeable taste.³⁹
 7. **Cotton Candy Process:** This method gets its name from the unique spinning mechanism it uses to create a crystalline structure that resembles floss and is similar to cotton candy. In this method, flash melting and spinning are used simultaneously to create a matrix of polysaccharides. After recrystallization, this candy floss matrix is ground and mixed with active ingredients and excipients before being compressed to FDT.⁴⁰
 8. **Melt the granules:** Pharmaceutical powders are finely blended during the granular melting process using a binder that might be solid, liquid, or both.⁴¹
 9. **Nanonization:** A recently created Nanomelt technology uses a proprietary wet-milling method to reduce the drug's particle size to nanosize. Surface adsorption on specific stabilizers prevents the drug's nanocrystals from clumping together. These stabilizers are then added to mouth-dissolving tablets. This method is particularly useful for medications that are poorly soluble in water.⁴²
- Patented technologies that are used in the preparation of FDT**
1. **Zydis technology:** It is the first tablet technology to be sold. In this case, the medication is made by lyophilizing, or freeze-drying, it in a gelatin matrix. This results in an extremely lightweight product that comes in blister packs. Additionally, it uses microencapsulation with certain polymers and resins to cover up the drug's harsh taste. In comparison to other traditional tablets, this technology promises higher bioavailability. Convenience is the primary benefit of this technology; nevertheless, the cost of manufacturing the freeze-drying process is a major drawback. After opening, Zydis formulation should be used within six months.⁴³
 2. **DuroSolv:** Tablets made with this technology dissolve quickly and are sturdy. Direct compression methods are used in the production of these tablets; they contain water-soluble excipients. Nevertheless, Durosolv does not use any immediately compressible diluents in the form of fine particles. The dissolving rate is accelerated by the large surface area of the diluents utilized. Instead of disintegrating, the tablet "melts" or dissolves when a large amount of these diluents is added. Wicking agents help water enter the tablet's body, while swelling disintegrants are not used.⁴⁴
 3. **Flashtab technology:** Another tablet composition that dissolves and disintegrates quickly is the Flashtab technology. The Flashtab technology has been patented by Prographarm laboratories. The majority of the excipients used in the traditional compressed tablets are also used. In this formulation, coated medication particles are combined with a swelling and disintegrating agent to create a tablet that dissolves in the mouth in less than a minute.⁴⁵
 4. **Wowtab technology:** Wowtab technology was patented by Yamanouchi Pharmaceutical Co. WOW stands for "without water." Up to 50% of the tablet's weight can be made up of active substances. The granules in this technology are prepared by both high and low moldability saccharides. The highly formable material dissolves slowly because of its strong compressibility. Tablets with the right hardness are produced by combining high and low moldability. After being combined with low-moldable saccharides, the active ingredients are granulated with high-moldable saccharides and compressed into tablets. The Wow Board product melts in less than 13 seconds. The Wow tab tablets are available in blisters or traditional vials.⁴⁶
 5. **OraSolv technology:** OraSolv was CIMA's original fast-disintegrating/dissolving formulation. With this method, the FDTs dissolve in the saliva, which causes effervescence. The pharmaceutical powder is released in less than a minute once the tablet matrix dissolves in saliva. There are other ways to cover up a drug's unpleasant flavor besides sweeteners and taste. Effervescence and coating the pharmaceutical powder are both used in OraSolv technology to mask the flavor. Its mechanical strength is the main drawback of the OraSolv formulation.⁴⁷
 6. **Flash dose technology:** Fuisz was the patent holder for the flash dosage technique. Biovali Corporation's first commercial product is Nurofen Meltlet, a revolutionary type of ibuprofen as melt-in-mouth tablets made using flash dosage technology. The self-binding shear form matrix known as "floss" makes up flash dosage tablets. Flash heat processing is used to create shear form matrices.⁴⁸
 7. **Pharmaburst technology:** SPI Pharma is patenting Pharmaburst technology. Tablets made using this process can be put in bottles and blister packs because they are strong enough. This method creates tablets by compressing a dry mixture of a medication, flavorings, and lubricant into tablets that dissolve in 30 to 40 seconds.⁴⁹
 8. **Frosta technology:** Akina is the patent holder of this technology. Strong tablets with high porosity are created by preparing and compressing plastic granules at low pressure. The porous plastic material is mixed with a water penetration enhancer and then granulated with a binder. Depending on the size of

the tablet, it disintegrates quickly between 15 and 30 seconds and has exceptional hardness.⁴⁹

Evaluation parameters of FDT

Precompression Parameters

Determination of bulk density and tapped density: A graduated cylinder was filled with a weighed amount of mix, and the volume (V_0) was recorded. The graduated cylinder was then fixed to the density apparatus, and the timer knob was set for 100 taps. The volume (V_f) was then measured, and the process was resumed until the two successive readings were equal. The bulk density and tapped density were calculated by using the formulae.⁵⁰

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

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

Where W = weight of the powder.

V_0 = Initial vol. of the powder.

V_f = Final vol. of the powder.

Car's index: The Car's index was calculated using the bulk density and tapped density readings. To determine the Carr's index, the following formula was applied:⁵¹

$$\text{Carr's index} = \frac{(\text{tapped density} - \text{bulk density})}{\text{tapped density}} * 100$$

Hausner's ratio: It is the ratio of tapped density to the bulk density of the powder and displays the flow properties of powder⁵¹

$$\text{Hausner's ratio} = \frac{\text{tapped density}}{\text{bulk density}}$$

Angle of repose: It can be defined as the maximum angle that can exist between the surface of the powder pile and the horizontal plane. Newman's funnel method was used to determine the angle of repose. The following formula determines the angle of repose:⁵²

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

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

Table 3: Angle of Repose as an Indication of Powder Flow Properties⁵³

Sr.no.	Angle of Repose	Type of Flow
1	< 20	Excellent
2	20-30	Good
3	30-34	Passable
4	>34	Very Poor

Post compression parameters

Shape and Size: The shape and size of the tablet can be dimensionally described, monitored, and controlled.⁵⁴

Weight variation: The average weight of 20 tablets should be determined by weighing each one separately. The weight of each tablet should be compared to the average tablet weight.⁵⁵The weight variation specification according to I.P is displayed in Table 4.

Table 4: Accepted percent deviation and weight fluctuation⁵⁶

Average weight of tablet	% Deviation
250mg or more	5.0
More than 80mg but less than 250mg	7.5
80mg or less	10.0

Hardness: The power needed to shatter a tablet across its diameter is known as its hardness or crushing strength. A tablet's hardness affects its ability to break, chip, and abrade during handling and storage. The Monsanto hardness tester is used to measure the hardness. Kg/cm² is the unit of measurement.⁵⁷

Thickness: Using the Vernier caliper, measure the thickness of ten tablets. It is the crucial factor in counting by counting filling machines since they only use tablets with uniform thickness in their counting process.⁵⁷

Disintegration test: Six glass tubes that are 3" long, open at the top, and held against 10" screens at the bottom end of the basket rack assembly served as the USP device for the rest of the disintegration. Each tube is filled with one tablet, and the basket rack is positioned in a one-liter beaker of distilled water at 37±2 degrees Celsius such that the tablets stay below the liquid's surface as they rise and fall, no closer than 2.5 centimeters from the beaker's bottom.⁵⁸

Drug content: Ten tablets were ground, and 100 mg of drug-equivalent powder was diluted in 0.1 N HCl or an appropriate media buffer. Medium yielded a solution up to 100 ml in volume. The drug content of a single tablet was calculated after the solution was filtered, diluted 100 times, and spectrophotometrically examined.⁵⁸

Friability: This method is used to determine the mechanical strength of tablets. A more brittle tablet may shatter during handling, shipping, or packing. The friability is tested using the Roche Friabilator. 10 pre-weighed tablets were rotated at 25 rpm for four minutes, or 100 times, dropping a tablet at a height of 6 inches with each revolution. The tablets were then reweighed. The percentage of weight loss is determined by the following formula^{59, 60}

$$F = \frac{(W_i - W_f) * 100}{W_i}$$

Where W_i = Initial Weight of Tablet, W_f = Final Weight of Tablet

Dissolution test: The dissolution test for mouth-dissolving tablets is the

same as that of conventional tablets. The test must be conducted according to the guidelines in the monograph. The evaluation may make use of buffers (pH 4.5 to 6.8) and media like 0.1N HCl.⁶¹

Wetting time: Measure the tablet wetting time using this method. A tiny petridish (ID = 6.5 cm) with 6 ml of Sorenson's buffer pH 6.8 was filled with simple tissue paper (12 cm * 10.75 cm) that had been folded twice.

The amount of time it took for a tablet to completely moisten the paper was measured. Each batch included three trials, and the standard deviation was also calculated.⁶²

Stability study: To evaluate the long-term stability and shelf life of FDTs under varied storage conditions, stability testing is conducted. Samples are routinely examined for physical, chemical, and microbiological stability, and the tablets are kept at predetermined temperatures and humidity levels.¹¹

Conclusion

It is to be concluded that the formulation of fast-dissolving tablets has a significant advantage of oral drug delivery. The fast-dissolving tablets are an innovative dosage form, specifically designed to overcome limitations of conventional dosage forms, such as dysphagia and difficulty swallowing, in pediatric or elderly patients. Fast-dissolving tablets are used as an alternative to conventional tablets. These tablets dissolve or disintegrate quickly in saliva, typically in a matter of seconds. They offer various advantages, i.e., improved stability, quicker onset of action, quick dissolution, and improved bioavailability. There are many challenges shown to develop fast-dissolving tablets, such as palatability, hygroscopicity, drug properties, taste making, and tablet strength. To overcome these challenges, various technologies are used to develop the FDT, like freeze-drying, direct compression, molding, spray drying, and mass extrusion.

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