



## Fast Dispersing Tablets (FDT) Based Technology: A Review at a Glance

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### ABSTRACT

Easy management and quality patient compliance are essential attributes for the development of any drug delivery system, oral drug delivery system, being the most convenient, least expensive and safest method is the preferred route amongst all. "Mouth Dissolving Tablets [MDTs]" have received ever-boosting demand during the last decades. These tablets are made to dissolve in the saliva very quickly, within a few seconds, and are true tablets that disperse quickly. Difficulty in swallowing conventional tablets and capsules problem can be resolved by the new drug delivery system by making "oral tablets" [MDTs]. Fast-dispersing tablets (FDTs), categorized under the umbrella of MDT have become a fast-growing area in the pharmaceutical industry. Fast disintegrating tablets (FDTs) are those dosage forms that are placed on the tongue or in the mouth cavity, dispersed or dissolved immediately, and release the drug, within a few seconds without the need for water. This may be due to the action of superdisintegrant or enlarging the pore structure in the formation etc. Fast disintegrating tablets (FDTs) aim to design dosage forms that are ready to be administered with no side effects, providing an immediate release for the quick action and improved bioavailability, to achieve better patient compliance. The purpose of this review article is to provide a framework for the composition of FDT, the prerequisite for the selection of key ingredients, its desirable features and development challenges, and various technologies developed to achieve fast dissolution/dispersion of tablets in the oral cavity. Besides this, the review also explores the various key mechanism of tablet disintegration techniques used for the formulation of oral mouth dissolving tablets along with its evaluation.

**Keywords:** Fast dissolving tablet, Patients compliance, Superdisintegrants, Freeze-drying, Bioavailability.

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### INTRODUCTION

The drug delivery system is a competent marketing tool, which combines the product life cycle and production opportunities. The oral route of drug delivery remains the preferred method of administering therapeutic agents due to accurate dosage, affordable treatment, self-medication, non-invasive method, and ease of administration up to a patient compliance level<sup>1</sup>. Over the past decade, there has been an increased need for patient-responsive and compliant dosage forms<sup>2</sup>. Many patients have difficulty swallowing hard tablets and gelatin tablets and then do not take the medication as prescribed. It is estimated that 50% of the population suffers from this disorder, resulting in a high rate of non-compliance and ineffective treatment<sup>3</sup>. To overcome this difficulty, pharmacologists have made significant efforts to develop a new type of oral dosage form recognized as oral dispersible tablets [ODTs]<sup>4</sup>.

These are novel types of tablets that dissolve/disperse the saliva within a few seconds without water<sup>5</sup>. These types of

doses are dispersed/dissolved in the mouth within minutes without the need for water or chewing, anywhere, at any time. This leads to their suitability for elderly, paediatric, and dysphasic patients<sup>6</sup>. Technology is also referred to as fast disintegrating tablets, fast dispersing tablets, rapid dissolve tablets, rapid melt tablets, quick disintegrating tablets, and orally disintegrating tablets<sup>7</sup>. If the drug is hydrophilic, the dosage form is known as rapidly dissolving tablets otherwise if the drug is hydrophobic it is known as rapidly dispersing tablets<sup>8</sup>. There are two different types of dispersing tablets; one dose form is immediately dispersed in the mouth, so that it can be swallowed without the need for drinking water, while the other form of the tablet can be easily dispersed in water, to form a dispersion, easy for the patient to swallow<sup>9</sup>. FDDS includes tablets and films<sup>10</sup>. FDT also has liquid dosage-like benefits, such as ease of administration and no risk of suffocation caused by physical inhibition of the dosage form<sup>11</sup>. The bioavailability of some drugs may be increased due to the absorption of the drug into the oral cavity and also due to the absorption of saliva<sup>12</sup>. Fast-melting delivery films are essential for incorporating active ingredient flavors<sup>13</sup>. This hidden active ingredient is swallowed by the patient's saliva and soluble and insoluble substances<sup>14</sup>. FDT is also known for fast melting, fast dispersing, rapid dissolving, rapid melt, and/or quick disintegrating tablets<sup>15</sup>. These dosage forms are also used to obtain a high dosage of the drug through rapid action<sup>16</sup>.



High drug load, as well as a pleasant sensation in the mouth, is some of the benefits offered by FDTs<sup>17</sup>. The most commonly used methods for preparing these tablets include; Freeze drying/Lyophilization, tablet shaping, and direct compression methods<sup>18</sup>. Such a tablet disperses into small particles or melts in the mouth from a solid gel-like substance, allowing patients to swallow it easily<sup>19</sup>. These dosage forms also work when local action in the mouth is needed as a local anaesthetic for toothache and mouth ulcers etc.<sup>20</sup>. Recently, European Pharmacopeia adopted the term orodispersible tablet that dissolves or disperses less than 3 minutes in the mouth before swallowing<sup>21</sup>. Patients with persistent nausea, walking, or with little or no water are also well-responded to FDTs<sup>22</sup>. Many patients have difficulty swallowing regular tablets when there is no water, in case of motion sickness [kinetosis], and the immediate occurrence of coughing during a cold, allergic condition, and bronchitis<sup>23, 24</sup>. It is also an easy mode of administration for the elderly, bedridden patients, or infants with difficulty swallowing tablets and tablets<sup>25</sup>. Thus, the development of the Melt-In-Mouth tablet, which disperses rapidly without the need for drinking water, provides ease of management, patient compliance, and rapid onset of action<sup>26</sup>. Rapidly dispersed tablets [FDT] also help to cope with phagophobia, a problem of odynophagia types<sup>27,28</sup>. Most FDT technologies use special types of flavour masking as well. The main method of flavouring concealer involves adsorption or combination with carriers and spraying of drug particles<sup>29</sup>. Recent advances in the Novel Drug Delivery System [NDDS] aim to improve the safety and efficacy of a drug molecule by creating a dosage-appropriate form of administration and achieving better patient compliance. One such method is the "Fast Disruptive Tablet"<sup>30</sup>. ODTs with good taste and flavour increase the acceptance of bitter drugs by various groups of people<sup>31</sup>. The United States Food and Drug Administration [USFDA] has clearly defined ODT as a dosage form that includes drugs that dispense rapidly, usually within seconds, when placed on the tongue<sup>32</sup>. The great advantage of ODT formulation is that it combines the benefits of both liquid and conventional tablet formulations<sup>33</sup>. They provide the comfort of tablet formation and allow for the firmness of the swallow provided by the formation of the liquid<sup>34</sup>. There are many dosage forms available such as over-the-counter tablets, dry tablets, and chewing gum tablets, which are often used to strengthen patient compliance but MD tablets can be dispersed or dispersed in the mouth and attract great attention<sup>35,38,39</sup>. The US Food and Drug Administration Centre for Drug Evaluation and Research [CDER] identifies, in their "Orange Book" ODT as a solid dosage form containing medicinal substances, which disperse rapidly, usually in a matter of seconds, once to be found upon the tongue<sup>36,40</sup>. Researchers have developed ODT for a variety of drugs, which are used for treatment where high plasma concentrations are rapidly needed to achieve the expected drug response<sup>37, 41</sup>.

### Difficulty for Existing Original Form

- Patients may suffer from tremors and may have difficulty taking powder and liquids. In the case of dysphasia, physical obstruction and adhesion to the oesophagus may cause intestinal ulcers.
- Swallowing solid dosage forms such as tablets and capsules creates difficulties for young adults with partial muscular and nervous system development and elderly patients suffer from dysphasia.
- Liquid medicaments [suspension and emulsion] are packed in a multidose container; therefore, achieving uniformity in the content may be difficult
- The buccal and sublingual formation may irritate the oral mucosa, so patients refuse to take such medications.
- Product costs are a major factor as parental products are very expensive and uncomfortable.

### The benefits of Oro dispersible tablets

Benefits of ODT include:

- Patients with intellectual disabilities, mental disabilities, and bedridden patients, who have difficulty swallowing a tablet.
- Orodispersible tablets do not require swallowing water, unlike typical doses. This is much easier for patients who are in ambulant condition or do not have able to take water, and as a result, provides better patient compliance.
- Being a unit of solid dosage forms, it provides the comfort of precise volume, ease of use and production, good physical and chemical strength, and is an ideal alternative for children and adolescent patients.
- Drug bioavailability is improved due to absorption in the mouth, pharynx, and esophagus.
- Pregnancy and before pregnancy can result in improved bioavailability and due to reduced dosage, improved clinical performance by reducing unwanted side effects. Rapid onset of therapeutic action as the tablet disperses rapidly as well as rapid dispersion and absorption into the oral cavity.
- Good mouth feels, especially in paediatric patients as the method of concealing the taste is used to avoid the bitter taste of the drug.
- Less risk of constipation on airways due to physical barriers, when ODTs are swallowed up, thus providing greater security and compliance with their management plans.
- Immediate drug treatment interventions are possible.



- Conventional packaging and packaging equipment allows for the manufacture of tablets at a lower cost.
- No specific packaging is required. It may be covered with push-up blisters.
- Provide new business prospects in the form of product classification, patent extensions, variations, line extensions, life cycle management, and product marketing options.

### Factors to be well-thought-out before choosing a super disintegrants

#### Dispersion

The disintegrant should immediately spread over saliva to the tablet to produce the increase in volume and hydrostatic pressure needed to provide rapid dispersion in the mouth.

#### Compatibility

It is desirable to have ODT with acceptable hardness and low friability in the operative pressure provided to produce solid tablets that avoid the need to use special packaging while increasing production speed.

#### Mouthfeel

Large particles can lead to a gritty feeling in the mouth. Thus, smaller particles are selected. When the tablet forms a gel-like consistency when in contact with water. However, it produces a sticky consistency that many consumers find unpleasant.

#### Flow

In normal tablet formulations, super disintegrants are used in 2-5 wt. % of tablet builds. With ODT formation, the disintegrant rate can be very high.

### Important Conditions for Assistants Used in ODT Development

- It must be able to disperse quickly.
- Their individual properties should not affect ODT.
- It should not interact with drugs and other helpful substances.
- It should not interfere with the efficiency and organoleptic properties of the product.
- When choosing a bond [one or more combinations] care must be taken to maintain the integrity and stability of the product.
- The melting point of the auxiliary materials used should be at 30-35°C.
- The bond may be liquid, slightly firm, solid, or naturally polymeric.

### Desirable features and development challenges

#### Immediate Dispersion

FDT dosage forms, also known as fast melt, quick melt, oral dispensers, and orodispersible systems, have a unique structure for dispersing the tablet in the mouth in seconds.

#### Taste for Active Ingredients

Taste-disposal technology focuses mainly on bitter and anti-inflammatory drugs such as macrolide antibiotics, non-inflammatory drugs, and penicillin.

#### Medicinal Properties

Medicines suitable for Biopharmaceutical Classification System Class II, i.e., less soluble and highly accessible drugs are the most suitable components of FDT in doses of 125 and 250 mg. Tizanidine HCl, Oxybutynin HCl, Rofecoxib, Ibuprofen, Promethazine theoclate, prednisone, Indomethacin, Griseofulvin, Hydrochlorolazazide, and Nimesulide are just a few examples of fast-acting drug delivery formulas such as drug delivery system that have been implemented quickly.

#### Tablet Strength and Porosity

FDTs comprise a framework of two components of lyophilized matrix systems that work together to ensure successful structural development. The first component of water-soluble polymers such as gelatin, dextran, alginate, and maltodextrin. This component maintains the shape and provides mechanical strength to the [binder] tablets. The second component is matrix-support / disintegration-enhancing agents such as sucrose and mannitol, which work by strengthening the perforated structure, provided by water-soluble polymer and accelerating the dissolution of FDT.

#### Moisture Sensitivity

FDTs should have low humidity sensitivity. This problem can be especially challenging because many water-soluble auxiliary substances are used in production to improve the soluble properties faster and to generate a better oral taste.

### Requirements for Implementation of Various Fast Disintegrating Tablets<sup>5</sup>.

#### Patient features

- Elderly patients suffer from conditions such as tremors and dysphasia.
- Paediatric patients are unable to swallow easily because their central nervous system and internal muscles are not fully developed.
- Travelling patients suffering from motion sickness and diarrhoea do not have easy access to water.
- Patients with prolonged nausea cannot swallow. Especially patients with cancer after taking their chemotherapy also have nausea to swallowing



various medications like H2 blockers, which are prescribed to avoid stomach ulcers.

- Psychiatric patients, bedridden patients.

#### **Efficiency feature**

- Any pre-gastric absorption avoids first-pass metabolism and can be of great benefit to drugs that undergo hepatic metabolism.
- In addition, safety profiles may be enhanced by drugs that produce significant amounts of toxic metabolites that mediate first-pass metabolism of the liver and gastric metabolism, as well as drugs that play a major role in the absorption of the oral cavity and frontal organs of the GIT.

#### **Common Excipients Used For FDT**

The most common helpful substances in FDT are as Table 1 at least one disintegrant, diluent, lubricant, and optional inflammatory agent, permeabilizing agent, sweetener, and flavoring agent.

**Table 1:** Name and Weight Percentage of Various Excipients

Sr. No.	Name of the excipients	Percentage used
1	Disintegrant	1-15%
2	Binder	5-10%
3	Anti-static	0-10%
4	agent Diluents	0-85%

#### **Super disintegrants**

Super disintegrant brings rapid dispersion due to the combined effect of swelling and water absorption by the structure of the tablet.

$$\text{Indication of Inflammation} = \frac{[\text{Last volume} - \text{First volume}]}{\text{first volume}} \times 100$$

Example: Croscopovidone, Carmellose, Croscarmellose sodium, Carmellose calcium, Sodium starch glycolate ion exchange resins [e.g., Indion 414]. Sodium starch glycollate has a better flow than Croscarmellose sodium. Cross povidone is found to be naturally fibrous and highly bonded.

#### **Binders**

An important role of Binders is to maintain the composition of these tablets which quickly dissolve together during congestion.

Example: Common Bonds are Cellulosic polymers, Povidones, Polyvinyl alcohols, and acrylic polymers.

#### **Antistatic Agent**

An antistatic agent is a compound used to treat substances or their properties to reduce or eliminate the formation of dry matter usually caused by a triboelectric effect.

Example: Talc, Maltodextrins, Colloidal silica [Aerosil], Precipitated silica, Beta-cyclodextrin, etc.

#### **Lubricants**

Lubricants remove grittiness and contribute to the process of transporting drugs from the mouth down to the stomach.

Example: Talc, Magnesium lauryl sulphate, Magnesium stearate, Stearic acid, Leucine, Sodium benzoate, Liquid paraffin, etc.

#### **Flavors**

The flavor is something that gives a certain flavor to the substance, which alters the solute properties, making it sweet, sour, sweet, etc.

Example: Flavor agents like, vanilla, citrus oils, Peppermint oil, Clove oil, anise oil, Eucalyptus oil, etc.

#### **Sweeteners**

A sweetener is a substance added to convey a sweet taste, either because it contains a certain type of sugar, or because it contains something that holds a sweet sugar. Many artificial sweets have been developed and are now being used commercially.

Example: Sorbitol, Mannitol, Xylitol, Erythritol, Sucrose, Fructose, Aspartame, Sugar derivatives, etc.

#### **Fillers**

Fillers or diluent excipients are used to increase the volume of substances that allow for the processing of ingredients and to form a suitable size. In addition, they can sustain the product and support it during production.

Example: Direct compressible Mannitol, Sorbitol, xylitol, and Calcium carbonate. Pregelatinized Starch, Magnesium carbonate, Calcium phosphate, Magnesium trisilicate, Aluminum hydroxide, etc.

#### **Surface active agents**

A surface-active agent (SAA) is a substance that reduces the water content of a liquid where it dissolves, thereby increasing its diffusion and moisture content.

Example: Sodium dodecyl sulfate, sodium lauryl sulfate, Tweens, Spain, Polyoxyethylene stearate.

#### **Key mechanism of tablet disintegration**

Disintegrants are substances commonly incorporated into tablets and other hard-shell capsules to promote the penetration of moisture and dissolution of the matrix form of the volume into the molten liquid. In recent years, many new agents have been established as "Super disintegrants". These innovations work best in low concentrations with high dispersion efficiency and performance efficiency. Several methods [ref. table 2] proposed for this concern include water brushing, swelling, reversal, and expulsion. It gives the impression that there is no single way to determine the complex behaviour of



disintegrants. However, each of these expected approaches offers consideration of different aspects of the disintegrant action.

**Table 2:** Mechanism of super disintegrants

Sr. No.	Mechanism of disintegration	Example of super disintegrant
1	Wicking	Cross-linked cellulose, cross-linked PVP, calcium silicate
2	Swelling	Cross-linked starch
3	Both wicking and swelling	Cross-linked PVP, Cross-linked alginic acid

**Table 3:** Angle of Repose as an Indication of Powder Flow Properties

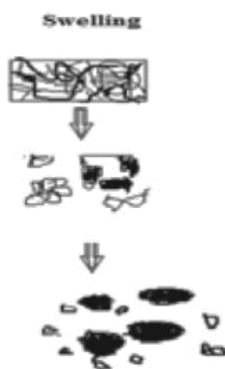
Sr. No.	The angle of Repose [θ]	Type of Flow
1	< 20	Excellent
2	20 – 30	Good
3	30 – 34	Passable
4	> 34	Very Poor

**Table 4:** Relationship between % compressibility and flowability

Sr. No.	% Compressibility	Flowability
1	5 – 12	Excellent
2	12 – 16	Good
3	18 – 21	Fair Passable
4	23 – 35	Poor
5	33 – 38	Very Poor
6	< 40	Very-very Poor

**Swelling**

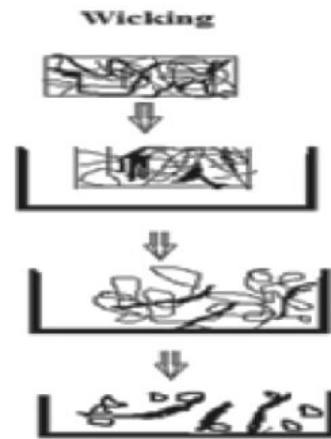
Although water infiltration is an important step in dispersing, inflammation is probably the most commonly used method of disintegration of tablet disintegration. For inflammation to act as a means of dispersion, they are a requirement to be a large structure where the disintegrant is inflated.



**Figure 1:** Inflammation [Particles swell and break matrix form internally; inflammation stops; localized stress spread throughout the matrix]

**Water wicking**

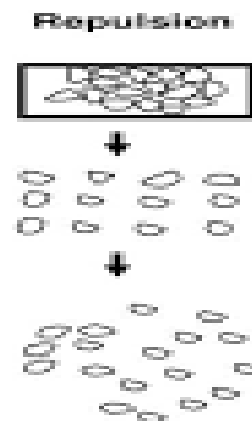
If we place the tablet in the correct disperse area, the contents enter the tablet and replace the air that is presented in the particles, which weakens the intermolecular bond and divides the tablet into particles. The absorption of water by the tablet depends on secondary factors, the hydrophilicity of the drug, the environment, and production conditions.



**Figure 2:** Tablet Disintegrate by Wicking

**Particle repulsive forces**

According to this theory, water enters the tablet through hydrophilic pores, and a continuous starch network is made unable to transport water from one particle to another, reporting high hydrostatic pressure. Water previously flows between the starch grains due to its linking to the starch surface, thus breaking the hydrogen bonds and other forces that hold the tablet together.



**Figure 3:** Repulsion Theory. [Particles repel each other by electric force by attracting water to a small pore]

**Deformation [elastic recovery]**

In all tablet compression, the separated particles deformed, and these deformed particles enter their normal structure when they come in contact with liquid media.

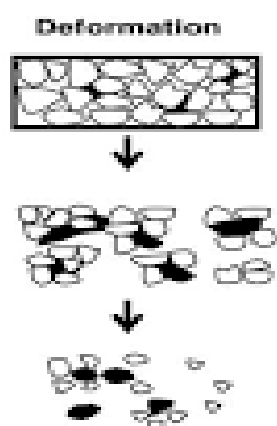


Figure 4: Elastic recovery

### Techniques Used for Formulation of Oral Mouth Dissolving Tablets

Existing techniques for oral mouth dissolving tablets:

#### Freeze Drying

ZYDIS® [R.P. Scherer, Swindon, UK], using ice-drying systems, is one of the first generations of volatile forms. This method involves a drug in a water-soluble matrix, which is then transferred to a preformed blister with peelable foil, as Zydys units do not have enough strength to withstand the pressure of the conventional blister lid. Freezing is done to remove water by sublimation.

#### Moulding

In this way, the molded tablets are prepared by dissolving the ingredients in the water so that the tablets dissolve completely and quickly.

#### Compression molding

The production process involves wetting the powder mixture with a hydroalcoholic solution followed by pressing it into mold plates to form a liquid mass, which is then air-dried to remove the solvent.

#### Heat moulding

The molten matrix in which the drug is dispersed or dispersed can be directly formed into ODT. Pills are prepared using a heat-forming process that involves the preparation of a molten mass containing a dispersed or melted substance.

#### Molding of vacuum evaporation without lyophilization

This process involves the evaporation of solvents in a solution or suspension at standard pressure.

#### Spray Drying

The formulation contains hydrolyzed and non-hydrolyzed gelatin as matrix support, mannitol as filler, and sodium starch glycolate/croscarmellose as disintegrant. Dispersion and dissolution were further enhanced by the addition of acid [e.g., citric acid] or alkali [e.g., sodium bicarbonate]. The suspension of the excipient was spray-dried to obtain a porous powder compressed into tablets. Tablets made

this way will disintegrate in less than 20 seconds. in the aqueous environment.

#### Direct Pressure Method [Disintegrant Addition]

This is a method of mixing a drug and an excipient and directly compressing the tablet without pre-treatment. The evolution of carbon dioxide as a disintegration mechanism named OROSOLV and DURASOLV is described in two US patents assigned to CIMA Lab.

#### Sublimation

Sublimation has been used to produce MDTs with high porosity. The perforated matrix is formed by compressing flexible ingredients and other secondary substances into tablets, which eventually undergo a melting process. Strong solvents with high flexibility [e.g., ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, naphthalene, phthalic anhydride, urea, and urethane] have been used for this purpose. Solvents such as cyclohexane and benzene were also elevated to produce porosity in the matrix.

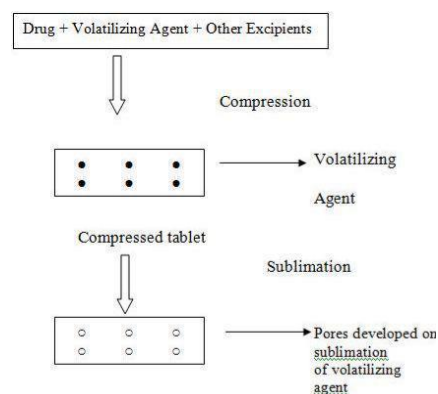


Figure 5: Steps Involved in Sublimation.

#### Phase transition process

In this method, ODT is obtained by compressing and heating a tablet containing two sugar alcohols, one with a higher melting point and one with a lower melting point. The combination of low- and high-melting sugar alcohols and the phase transition during the production process are important to manufacture ODT without special equipment.

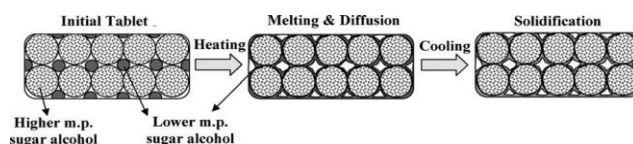


Figure 6: A schematic diagram of a fast disintegration tablet formulated by the phase transition method using a high melting [erythritol] and a low melting [xylitol] sugar alcohol.

#### Melt the granules

Granular melting is a process in which pharmaceutical powders are finely mixed using a binder that can be soluble, solid, or solid soluble during the process.

### Mass Extrusion

This generation consists of softening the active mixture the usage of a solvent agglomerate of water-soluble polyethylene glycol with methanol and expulsion of softened mass over the extruder or syringe to reap cylinder of the product into even segments employing a heated blade to form a tablet.

### Oral Disintegrating Thin Films

In this process, the polymer forms a water-soluble film [pullulan, carboxymethylcellulose, hydroxypropyl methylcellulose, hydroxyl ethyl cellulose, hydroxyl propyl cellulose, polyvinyl pyrrolidone, polyvinyl alcohol or polyvinyl alcohol, etc.] The drug and other flavor enhancers are dissolved by adding a non-aqueous solvent to prepare an aqueous solution, which forms a film after the solvent evaporates.

### Evaluation of Fast Disintegrating Tablets

Tablets from all formulations under the following quality control testing.

#### General Appearance

The typical appearance of the tablet, its appearance, and "elegance" above all are important in customer acceptance, and the size of the tablet, texture, color, presence or absence of odor, taste, texture, physical flaws, and consistency and sensitivity of any identification markings.

#### Size and Shape

The size and shape of the tablet can be dimensionally defined, monitored, and controlled.

#### Tablet thickness

Tablet thickness is an important factor in repetitive appearance and calculation using filling apparatus. Some filling apparatuses use to measure the identical thickness of tablets in a calculation method. Ten tablets were taken, and their intensity was recorded using a micrometer.

#### Weight variation

The 20 tablets were randomly selected and weighed individually to test for weight loss. Specification of weight differences as stated by I.P. is shown in the following [Table 5].

**Table 5:** Weight variation specification as per I.P

Sr. No.	Average Weight of Tablet	% Deviation
1	80 mg or less	±10
2	80 mg to 250 mg	±7.5
3	250 mg or more	±5

#### Hardness

Tablet Hardness is defined as the force applied to the tablet width to break the tablet. The resistance of the tablet to cracks, abrasions, or fractures under the

condition of modification and handling of the tablet before use depends on its Hardness. The hardness of each tablet is determined using a Monsanto Hardness tester or Fizer Hardness tester.

#### Friability

The friability of the tablet is determined using a Roche friabilator. The device is under the tablet in the combined effect of abrasion and shock in the rotating plastic chamber at 25 rpm and crosses the tablet at a height of 6 inches in each revolution. A sample of pre-weighted pills is placed in a friabilator and under 100 revolutions. Friability [F] is given the formula.

$$F = [W_{int.} - W_{fin}] / W_{int.}$$

$W_{int}$  - Weight of tablets before revolutions.

$W_{fin}$  - Weight of tablets after the revolutions.

#### Wetting Time

The wetting time of the volume form is related to the contact angle. It needs to be tested to provide insight into the properties of the dispersion of tablets; low wetting time means faster dispersion of the tablet. For this purpose, the tablet is placed on a piece of double-folded tissue paper and stored in a small Petri container [ID = 6.5 cm] containing 6 ml of water, and the duration of complete wetting is measured.

#### Water Absorption Rate

A piece of double-sided tissue paper was placed in a small Petri dish containing 6 ml of water. The tablet was wrapped in paper and the time required for complete wetting was measured. The wet tablet was then weighed. The water absorption rate, R, was determined using the following calculation,

$$R = 10 [W_a / W_b]$$

$W_a$  is the weight of the tablet before water absorption &

$W_b$  is the weight of the tablet after water absorption.

#### In-vitro disintegration Test

The *in-vitro* dispersion time was measured by dropping the tablet into a beaker containing 50 ml of Sorenson's buffer pH 6.8. The three pills from each formulation were randomly selected and an *in-vitro* dispersion period was performed.

#### In-vitro Dissolution Test

The formulation of disposal methods for FDTs is comparable to that of conventional tablets and is similar in practice. Drug termination conditions listed in the pharmacopeia monograph, are a good place to start with a running test to obtain a bioequivalent FDT. Other media such as 0.1 M HCl and buffer [pH 4.5 and 6.8] should be tested for FDT in the same way as their regular tablet counterparts. It has been suggested that the USP 2 paddle apparatus is the most suitable and common choice for oral



dispersed tablets, with a rowing speed of 50 rpm commonly used.

#### **Drug stability test [temperature-based stability studies]**

Fastly dispersed tablets are packaged in appropriate packaging and stored under the following conditions for a period as determined by the ICH guidelines for accelerated studies.

- 1)  $40 \pm 1^\circ \text{C}$
- 2)  $50 \pm 1^\circ \text{C}$
- 3)  $37 \pm 1^\circ \text{C}$  and RH  $75\% \pm 5\%$

The tablets were withdrawn after 15 days and analyzed to identify physical characteristics [Visual Conditions, Hardness, Friability, Disintegrations, and Dissolution, etc.] and drug content. The obtained data were included in the first program estimates to determine the kinetics of the destruction. Accelerated hardness data is sorted according to the Arrhenius number to determine the shelf life of  $25^\circ \text{C}$ .

#### **Packing**

Products derived from the lyophilization process including various technologies such as Zydis, Lyoc, Quicksolv, and Nanocrystal are porous, have less physical resistance, are sensitive to moisture, and may be harmful in high humidity conditions. For the above reasons the obtained products require special packaging. Zydis units are usually packed with peelable supporting foil. Paksolv is a special packing unit, with a dome-shaped blister, which prevents direct movement of the tablets inside the depressant and prevents the tablets from breaking during storage and

transport. Some of the products were obtained from Durasolv. WOW Tab, Pharmaburst OraQuick, Zipllets, etc. the technology is strong enough for the equipment to withstand the movement of objects and to hold the shock so they are usually packed in push blisters or bottles.

**Table 6:** Name and Weight Percentage of Various Excipients

Sr. No.	Name of the excipients	Percentage used
1	Disintegrant	1-15%
2	Binder	5-10%
3	Anti-static agent	0-10%
4	Diluents	0-85%

**Table 7:** Various ingredients for FDTs

Sr. No.	Component	Example
1	Water-soluble	Compressible sugars, binders, surfactants, flavoring agents
2	Water-insoluble	Microcrystalline cellulose, di- or tri-basic calcium phosphate
3	Disintegrants	Modified celluloses e.g., cross-linked sodium carboxymethyl cellulose [Sodium-CMC], cross-linked polyvinyl pyrrolidone [PVP], microcrystalline cellulose, starch, and modified starch.

**Table 8:** Technologies Used for Masking the Taste of Active Ingredients

Sr. No.	Technology	Excipients	Active Ingredient	Method
1	Fluidized bed coating	Methyl cellulose [MC], Acesulfame [AS], HPMC	Norethindrone, tamoxifen, caffeine, Acetaminophen, Rilmafazone HCl	-MC and AS solution charged to fluidized bed drier containing sieved norethindrone. -Internal temperature maintained at $115^\circ \text{F}$ . -Coating completed in 3, min.
2	Agglomeration process	Sweetener: - Sodium saccharin; acesulfame Dry blend: - HPMC, Silica dioxide.	Polythiazide	-Sweetener solution is sprayed on a dry blend to form agglomerated granules. -Wet mixture was dried in a convection oven at $103^\circ \text{F}$ for 17 hrs. -Dried product size reduced, sieved [#100]
3	Palletization process	Dry Blend: - Aspartame, HPC and Gum Arabic	Loratadine	-Crushed ice was mixed with a dry blend mixture to form spherical particles. -Wet spherical particles were dried in a tray drier at $55^\circ \text{C}$
4	Infusion method	Dry blend: - Sucralose, Fluoxetine, and Polyvinyl pyrrolidone	Fluoxetine	-Propylene glycol: water [40:60] was used to mix the dry blend, and HPMC was added. Mixing was continued at high speed for 3 min. -The particles obtained were screened [#100]



## CONCLUSION

Clinical studies show that FDTs can improve patient compliance, provide a faster initial onset of action, and increase bioavailability. Considering the many benefits of FDTs, it is only a matter of time until most of the oral formulation is prepared in FDT forms. With a strong focus on technological advances, pharmaceutical companies can use FDTs to expand the product line or market-first products. With the continued development of new medical assistants, one can expect the emergence of new FDTs technology in the coming days. Successfully marketed FDTs achieved global acceptance owing to their good taste and fast-release properties. With the rapid adoption of FDT by patients and pharmaceutical companies, the market for this dosage form is promising, and the pipeline product continues to grow.

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