



# A Systematic Review on Fast-Dissolving Tablets as an Emerging Oral Drug Delivery System

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## ABSTRACT

Fast dissolving tablets (FDTs) have had a significant rise in demand over the past decade, establishing themselves as a rapidly expanding sector within the pharmaceutical business. Oral drug delivery continues to be the favored method for administering a variety of medications. Recent advancements in technology have compelled scientists to create FDTs that enhance patient compliance and ease. Upon oral introduction, these tablets dissolve or disintegrate in the absence of supplementary water, facilitating the absorption of active medicinal substances. The formulation's popularity and use led to the advancement of several FDT technologies. FDTs are solid unit dose forms that disintegrate or dissolve swiftly in the mouth without the need for chewing or water. FDTs, or orally disintegrating tablets, are particularly beneficial for youngsters and the elderly who experience difficulty swallowing conventional pills and capsules. This review examines lyophilization, molding, sublimation, and compaction processes for fast-dissolving tablets (FDT), along with strategies to improve FDT characteristics, including spray drying and the incorporation of disintegrants. The discussion includes taste-masking technologies, experimental measures of disintegration time, and dissolution.

**KEYWORDS:** Fast Dissolving Tablets (FDTs), Oral Drug Delivery, Superdisintegrants, Patient Compliance, Disintegration Mechanism, Effervescent Excipients, Rapid Drug Release, Bioavailability, Formulation Evaluation, Pharmaceutical Technology

## INTRODUCTION

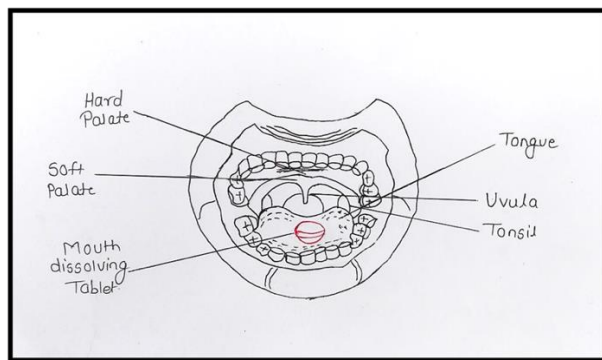
The current fundamental necessity is the transformation of medications into a presentable format. The dosage form is a category of drug delivery system utilized to administer a medication to a living organism. Tablets, syrups, suspensions, suppositories, injections, transdermal patches, and infusions are all examples of dosage forms employing diverse drug delivery systems. Both standard and innovative dosage forms provide distinct advantages and disadvantages. Consequently, under the present conditions, the pharmacist encounters a significant problem in developing an optimal medication distribution system.

For optimal efficacy, the medication must be administered to the target site at a rate and concentration that maximizes therapeutic effects while minimizing adverse symptoms. A comprehensive examination of the physicochemical principles governing a particular medicinal formulation is essential for the development of an appropriate dosage form [1]. Oral medication administration is widely recognized, accounting for 50-60% of total pharmaceutical formulations. Solid dosage forms are favored due to their user-friendliness, precise dosing, facilitation of self-medication, pain mitigation, and, crucially, enhanced patient adherence. Tablets and capsules are the predominant solid dosage forms; nonetheless, certain patients may encounter difficulties in ingesting these formulations. Water consumption is essential for the absorption of oral dosage forms. In the absence of water, patients suffering from motion sickness (kinetosis), acute coughing episodes during the common cold, allergic reactions, and bronchitis often have difficulties in swallowing traditional dosage forms like tablets. Consequently, tablets that rapidly dissolve or disintegrate in the oral cavity have garnered significant interest [2]. Swallowing difficulties are prevalent among elderly patients due to fear of choking, hand tremors, and dysphagia, as well as in adolescents due to immature muscular and neurological systems, and in individuals with schizophrenia, leading to inadequate patient adherence.

Approximately one-third of the population, primarily pediatric and geriatric individuals, experiences dysphagia, leading to suboptimal adherence to oral tablet pharmacotherapy and thus diminishing total therapeutic efficacy. In response, rapidly dissolving or disintegrating pills in the oral cavity have garnered significant interest [3].

A fast dissolving tablet (FDT) is characterized by the US Food and medicine Administration (USFDA) as "a solid dosage form containing a therapeutic drug or active ingredient that disintegrates rapidly, typically within seconds upon contact with the tongue." In the late 1970s, rapidly dissolving drug-delivery systems were created as an alternative to conventional dosage forms for pediatric and geriatric patients. These tablets are designed to dissolve or disintegrate rapidly in the mouth, typically within 60 seconds [4]. To address these medical requirements, pharmaceutical technologists have developed orally disintegrating tablets (ODTs), fast disintegrating tablets (FDTs), mouth melting tablets (MMTs), and mouth dissolving tablets (MDTs), as well as controlled release tablets that dissolve swiftly in saliva, typically within seconds, without the necessity of water. Recent market data indicates that over 50% of patients favor FDTs over conventional dosage forms. The application of super disintegrants, including Croscopovidone, sodium starch glycolate, and croscopovidone, facilitates the production of quick dissolving tablets. An alternative method involves freezing and vacuum drying the tablets to improve their pore structure [4]. Direct compression is favored above other alternative approaches due to its convenience, efficiency, and cost-effectiveness [1]. The bioavailability of certain

medications may be greatly enhanced by their absorption in the oral cavity, together with pregastric absorption of saliva containing dispersed pharmaceuticals that go into the stomach. Moreover, in comparison to traditional tablets, the quantity of medication subjected to first-pass metabolism is reduced [4].



**Figure 1:** Oral cavity showing the site of action for mouth-dissolving tablets.

### Benefits of Rapidly Dissolving Tablets

Fast-dissolving tablets are administered in the pre-gastric region, including the throat and esophagus, leading to an expedited onset of action [5,6]. This may lead to increased bioavailability of active pharmacological agents through dose reduction and enhanced clinical efficacy with less risk of adverse effects [7]. The acceptance of medications with an unpleasant flavor by patients may be improved through the use of fast-dissolving tablets that incorporate effective taste-masking agents, especially among pediatric patients. Another advantage is that it enables the avoidance of obstructing an oral route through the use of a typical dose form [8,9].

### Drawbacks of Rapidly Dissolving Tablets [9]

- The primary disadvantage of FDTs pertains to the mechanical strength of the tablets.
- FDTs are highly porous and soft, either molded or crushed into tablets with low compression, resulting in friable and brittle tablets that are challenging to handle.
- Formulating fast-dissolving tablets (FDT) with unpleasant-tasting medications is challenging; specific precautions must be observed prior to their formulation.
- Several FDTs are hygroscopic and cannot maintain their physical integrity under typical humidity conditions, necessitating specific packaging.
- Individuals with xerostomia resulting from diminished salivary secretion may not be suitable candidates for these tablet formulations.
- Absorption rate from the saliva solution and total bioavailability.
- Stability of pharmaceuticals and dosage forms

### Optimal Characteristics of Pharmaceuticals for the Formulation of Rapidly Dissolving Tablets

In the development of MDTs, different parameters are considered for selecting the medication candidate.

- Pharmaceuticals capable of permeating the epithelial layer of the upper gastrointestinal tract ( $\log P > 2$ ).
- Pharmaceuticals characterized by a brief half-life and need frequent administration.
- Pharmaceuticals that generate hazardous metabolites during the initial phase of metabolism.

- MDTs are inappropriate for medications with prolonged or controlled release properties.

Drugs that possess an intensely bitter flavor or unpleasant taste are unsuitable for MDTs [10].

**Table 1:** Prospective Pharmaceutical Candidates for Rapidly Dissolving Tablets. [11, 12, 13]

Drug Category	Examples of Potential Drug Candidates
<b>Non-steroidal Anti-Inflammatory Drugs (NSAIDs)</b>	Ketoprofen, Piroxicam, Paracetamol, Rofecoxib, Nimesulide, Ibuprofen
<b>Anti-ulcer Drugs</b>	Famotidine, Lansoprazole
<b>Antidepressant Drugs</b>	Mitraxepine, Fluoxetine
<b>Antiparkinsonian Drugs</b>	Selegiline
<b>Antimigraine Drugs</b>	Sumatriptan, Rizatriptan benzoate, Zolmitriptan
<b>Antihistaminic Drugs</b>	Loratadine, Diphenhydramine, Meclizine
<b>Antiemetic Drugs</b>	Ramosetron HCl, Ondansetron, Baclofen

### Prominent characteristics of quick dissolving tablets or rapid dissolving drug delivery systems [14,15,16]

- Simplified administration for patients unable to swallow, including the elderly, stroke survivors, bedridden individuals, those with renal failure, and patients who refuse to swallow, such as pediatric, geriatric, and psychiatric populations.
- Elimination of the necessity for water to ingest the dosage form, providing significant convenience for patients traveling without immediate access to water.
- Swift dissolving and absorption of the drug, resulting in a rapid commencement of action.
- Some pharmaceuticals are absorbed from the oral cavity, pharynx, and esophagus as saliva traverses into the stomach. In these instances, the drug's bioavailability is enhanced.
- Pre-gastric absorption may enhance bioavailability, thereby leading to a decreased dosage.

### Enhance clinical efficacy by minimizing adverse effects

- The favorable mouthfeel feature alters the perception of medication as a bitter pill, especially in pediatric patients.
- The risk of choking or suffocation during the oral administration of conventional formulations due to physical obstruction is mitigated, hence enhancing safety.
- Emerging commercial opportunities such as product diversification, product promotion, patent extensions, and life cycle management.
- Advantageous in situations such as motion sickness, acute allergic reactions, or coughing, where an extremely rapid beginning of action is necessary.
- Enhanced bioavailability, especially for insoluble and hydrophobic pharmaceuticals, resulting from the fast disintegration and dissolving of these tablets. Prolonged stability, as the medication retains its solid dose form until ingestion. It amalgamates the benefits of solid dosage forms regarding stability with those of liquid dosage forms about bioavailability.

- Flexible and compatible with current processing and packaging machinery.
- Facilitates increased drug loading and is cost-effective.

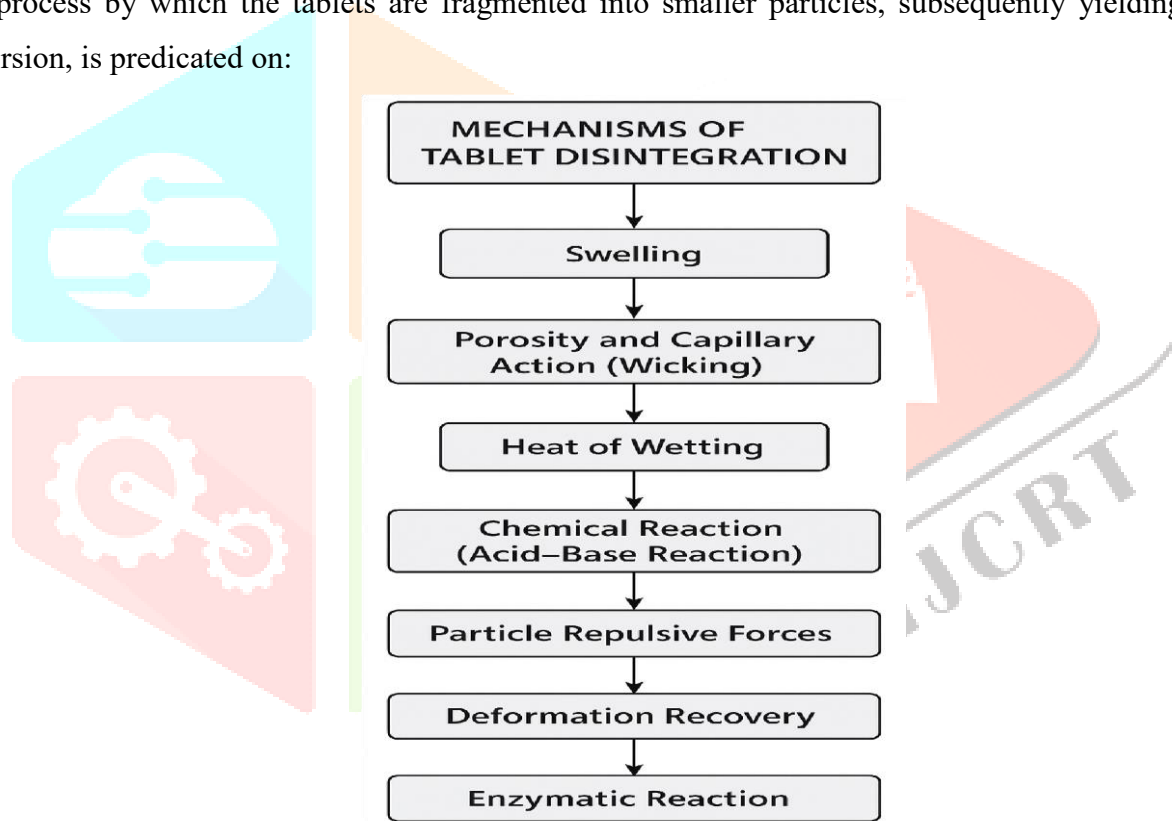
## Superdisintegrants

The demand for a rapidly dissolving formulation increases daily. Consequently, the pharmacist must formulate disintegrants, including super disintegrants, that demonstrate efficacy at low concentrations, have superior disintegration efficiency, and are particularly effective in atypical scenarios.

These super disintegrants function through swelling, leading to the fragmentation of the tablet or the accelerated absorption of water, resulting in a significant increase in the amount of granules, hence facilitating disintegration. [17,18,19]

## Mechanism of Superdisintegrants [20,21,22,23,24]

Superdisintegrants enhance the effectiveness of solid dose forms. This is accomplished by diverse processes. The process by which the tablets are fragmented into smaller particles, subsequently yielding a uniform dispersion, is predicated on:



**Figure 2:** Mechanisms involved in the disintegration of fast-dissolving tablets.

**1. Swelling:** Upon exposure to water, disintegrant particles expand, generating internal pressure that disrupts the tablet matrix. Tablets with minimal porosity exhibit efficient disintegration, while excessive density restricts fluid infiltration and prolongs disintegration.

**2. Porosity and Capillary Action (Wicking):** Water infiltrates capillary channels, displacing air and diminishing interparticle interactions. Hydrophilic excipients and a porous architecture augment this mechanism.

**3. Heat of Wetting:** Specific disintegrants emit localized heat during wetting, resulting in air expansion inside capillaries and facilitating tablet disintegration. This mechanism pertains to specific disintegrants.

**4. Chemical Reaction (Acid–Base Reaction):** Effervescent agents (citric or tartaric acid combined with bicarbonates) produce CO<sub>2</sub> upon hydration, resulting in internal pressure that swiftly disintegrates tablets while enhancing dissolving and flavor masking.

**5. Particle Repulsive Forces:** Guyot-Hermann's theory posits that electrostatic repulsion among hydrated particles and the breaking of hydrogen bonds facilitate disintegration, even in non-swellable disintegrants.

**6. Deformation Recovery:** Disintegrant particles subjected to compression during tableting restore their previous morphology following hydration, generating pressure that disintegrates the tablet (e.g., Crospovidone, starch).

**7. Enzymatic Reaction:** Enzymes can diminish binder-disintegrant interactions, facilitating disintegration via enzymatic breakdown of the matrix and increased water absorption.

### **Considerations For The Selection Of Super Disintegrants [20, 21, 22] Disintegration**

For quick disintegration in the oral cavity, the disintegrant must promptly absorb saliva into the tablet to create the necessary volume expansion and hydrostatic pressure.

#### **Compatibility**

To produce robust tablets that obviate the need for specialized packaging while enhancing production velocity, FDT with suitable hardness and reduced friability at a certain compression force is essential.

#### **Oral Sensation**

A coarse sensation in the oral cavity may be attributed to substantial particles. Small particles are highly suggested. Upon contact with water, the tablet becomes a gel-like consistency, resulting in a sticky flavor that is often unappealing to many customers.

#### **Flow**

Super disintegrants are generally employed in tablet formulations at a concentration of 2-5 wt% of the tablet's total weight. The disintegrant concentration may be significantly elevated in FDT formulation [26]. **Bulking Agents [27,28]**

Bulking agents are essential in the manufacture of fast-dissolving tablets. They function as a diluent, filler, and cost-reduction agent, among other roles. Bulking agents enhance the texture of tablets, facilitating breakdown in the mouth, but also increasing volume and reducing the active concentration in the formulation. To enhance aqueous solubility and sensory perception, bulking agents for this dosage form should be sugar-based, including mannitol, polydextrose, lactose derivatives such directly compressible lactose (DCL), and starch hydrolysate. Mannitol possesses significant aqueous solubility and favorable sensory attributes, since its exothermic heat of solution produces a cooling sensation. Bulking agents are utilized in quantities varying from 10% to 90% by weight of the final product.

The brittleness of excipients is evaluated in descending order as follows: microcrystalline cellulose, alpha lactose monohydrate, spray-dried lactose, anhydrous beta lactose, anhydrous alpha lactose, and dicalcium phosphate dihydrate.



Bulking agents, including dextrose, fructose, lactitol, maltitol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose, and xylitol, are widely utilized sugar-based excipients characterized by high water solubility and sweetness, providing taste masking and an agreeable mouthfeel.

Sugar-based excipients can be categorized according to molding and dissolving rates. **Type 1 saccharides:** such as lactose and mannitol, demonstrate low moldability yet possess a rapid dissolving rate.

**Type 2 saccharides:** maltose and maltitol, which demonstrate strong moldability yet low solubility.

## **METHODS IN THE PREPARATION OF FDTs**

Numerous methodologies have been employed for the formulation of FDTs.

### **Lyophilization**

Lyophilization is the technique of extracting water through sublimation while dehydrating at a low temperature.

The pharmaceutical compound is encased in a hydrophilic matrix, thereafter subjected to freeze-drying to form a porous architecture. Upon insertion of lyophilized tablets into the oral cavity, saliva rapidly infiltrates the pores, resulting in disintegration within five seconds. Heatsensitive drugs, or thermo-labile chemicals, are enhanced by lyophilisation [29].

### **Shaping**

Molded tablets are produced using water-soluble components, enabling them to dissolve completely and rapidly. The powder mixture is moistened with a hydroalcoholic solvent prior to being formed into tablets under lower pressure than conventional tablet compression.

The solvent is subsequently eliminated through air drying. Compressed tablets possess greater compactness than molded tablets. These prostheses possess a porous structure that facilitates disintegration [30].

### **Tablet Molding**

There are two categories of molding processes: solvent and thermal. Tablets made by solvents exhibit lower density compared to compressed tablets and include a porous architecture that accelerates dissolution. The mechanical integrity of molded tablets is a concern that requires attention. Binding agents that enhance the mechanical strength of tablets must be incorporated [31]. The masked medication particles are produced by spray congealing a molten amalgamation of hydrogenated polyethylene glycol, cottonseed oil, lecithin, and sodium carbonate, an active ingredient, into a lactose-based tablet triturate form, thereby addressing the issue of taste masking. In comparison to the lyophilization method, the molding technique yields tablets that are easily scalable for industrial production [32].

### **Direct Compression**

The most economical and uncomplicated method of tablet manufacture is direct compression. This technology is currently applicable in the production of Fast Dissolving Tablets, owing to the improved availability of superior excipients, specifically super disintegrants and sugarbased excipients.

### **Aerosol Drying**

Spray drying can produce diminutive, porous particles that disintegrate rapidly. This technique employs a particulate support matrix, created by spray drying an aqueous formulation that includes the support matrix and additional components, resulting in a highly porous and fine powder. The active components were

subsequently included, and the mixture was compressed into tablets. Hydrolyzed and non-hydrolyzed gelatins serve as supporting agents, mannitol functions as a bulking agent, sodium starch glycolate or crosscarmellose sodium acts as a disintegrating agent, and an acidic and/or alkaline substance (e.g., sodium bicarbonate) is utilized to improve disintegration and dissolution. A tablet formed from spray-dried powder dissolved in 20 seconds when submerged in aqueous media [34,35].

### Mass Extrusion

This method involves softening a mixture of the active drug and additional ingredients with a solvent composed of water-soluble polyethylene glycol and methanol. The softened mass is then extruded through an extruder or syringe to form a cylindrical product, which is subsequently segmented into uniform tablets using heated blades. The desiccated cylinder might be employed to encapsulate bitter-tasting pharmaceutical grains, mitigating their undesirable flavor [36, 37].

Sr. No.	Evaluation Parameter	Purpose / Description
1	<b>Weight Variation</b>	Ensures uniformity of tablet weight within prescribed limits to maintain dose accuracy.
2	<b>Hardness / Crushing Strength</b>	Measures mechanical strength of tablets; ensures tablets can withstand handling yet disintegrate rapidly.
3	<b>Friability</b>	Determines tablet resistance to abrasion or breakage during transport and handling. Acceptable limit $\leq 1\%$ .
4	<b>Thickness and Diameter</b>	Ensures uniform size and shape, aiding in packaging and appearance consistency.
5	<b>Wetting Time</b>	Time required for tablet to absorb moisture; shorter wetting time indicates faster disintegration.
6	<b>Disintegration Time</b>	Evaluates how quickly the tablet breaks down in the oral cavity (ideally <30 seconds).
7	<b>Dissolution Test</b>	Assesses rate and extent of drug release from the tablet in specified medium.
8	<b>Drug Content Uniformity</b>	Ensures each tablet contains the intended amount of active pharmaceutical ingredient (API).
9	<b>In-vitro Dispersion Time</b>	Determines time required for complete dispersion of the tablet in simulated saliva.
10	<b>Moisture Uptake Studies</b>	Assesses hygroscopic nature and storage stability of the formulation.
11	<b>Taste Evaluation</b>	Checks palatability and mouthfeel, critical for patient compliance.
12	<b>Stability Studies</b>	Evaluates formulation integrity and drug content under accelerated and real-time storage conditions.

**Table 2:** Evaluation parameters and quality control tests for Fast Dissolving Tablets (FDTs). [38,39,40,41]

### Conclusion

Fast Dissolving Tablets (FDTs) signify a notable progression in oral medication delivery methods, providing improved patient adherence, particularly for juvenile, geriatric, and dysphagic populations. Their fast disintegration and dissolution in saliva, independent of water, render them optimal for enhancing therapeutic



efficacy and convenience. The inclusion of superdisintegrants and porous excipients enhances the rapidity of action and improves bioavailability.

Moreover, FDTs have created new opportunities in pharmaceutical formulation by integrating patient-centered design with technology advancement. Ongoing study is essential to enhance their mechanical strength, stability, and taste-masking attributes while preserving quick disintegration. FDTs represent a promising and advancing platform in contemporary drug delivery, reconciling efficacy, safety, and patient satisfaction.

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