IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Fast Dissolving Tablets: A Revolution In Oral Drug Delivery

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Abstract: Fast Dissolving Tablets (FDTs) have emerged as a popular dosage form due to their rapid disintegration, enhanced patient compliance, and suitability for pediatric and geriatric populations. A variety of FDTs are available globally across multiple therapeutic categories such as migraine, pain relief, allergies, gastrointestinal disorders, and nutritional supplementation. Leading pharmaceutical companies like GlaxoSmithKline, Eli Lilly, and Merck & Co. market well-known brands such as Zofran ODT, Zyprexa Zydis, and Maxalt-MLT. These tablets are widely distributed in regions including the USA, Europe, India, and Asia-Pacific. With growing demand for ease-of-use medications, the development and market expansion of FDTs continue to thrive, making them a key innovation in modern drug delivery systems.

Keywords: Fast Dissolving Tablets, Patient Compliance, Oral Drug Delivery, Therapeutic Categories, Marketed Formulations

I. INTRODUCTION

In recent years, advancements in pharmaceutical technology have emphasized the development of novel drug delivery systems that enhance therapeutic efficacy while improving patient compliance. Among these innovations, Fast Dissolving Tablets (FDTs)—also referred to as Orally Disintegrating Tablets (ODTs)—have gained considerable attention. FDTs are solid dosage forms designed to disintegrate and dissolve rapidly in the oral cavity, typically within 30 seconds to a few minutes, without the need for water. This unique feature makes them particularly advantageous for patients who experience difficulty swallowing conventional tablets or capsules, such as pediatric, geriatric, and psychiatric populations [1,2].

FDTs offer a combination of benefits from both liquid and solid dosage forms. They facilitate ease of administration, faster onset of therapeutic action in some cases, and enhanced patient adherence. Moreover, FDTs may allow for partial or complete pre-gastric absorption through the oral mucosa, which can bypass first-pass hepatic metabolism and potentially improve bioavailability [3].

The successful formulation of FDTs requires the incorporation of functional excipients such as superdisintegrants, sweeteners, flavoring agents, and binders, to ensure rapid disintegration, acceptable taste, and adequate mechanical strength. Manufacturing techniques such as direct compression, lyophilization (freeze-drying), and spray drying are commonly employed based on the properties of the active pharmaceutical ingredient (API) and the intended therapeutic application

Despite formulation challenges such as taste masking, moisture sensitivity, and drug-loading limitations, continuous research and technological advancements are expanding the potential of FDTs. As patient-centered drug delivery becomes increasingly significant in healthcare, fast dissolving tablets are emerging as a preferred and effective oral dosage form [4].

➢ **Mechanism**

Mouth dissolving tablets (MDTs) rapidly disintegrate in the oral cavity upon contact with saliva, usually within seconds, without the need for water. Superdisintegrants within the tablet absorb saliva, swell, and break apart the tablet matrix. This releases the active pharmaceutical ingredient (API), which may then dissolve in saliva and begin absorption through the oral mucosa (buccal or sublingual routes) or be swallowed for gastrointestinal absorption. This mechanism enables faster onset of action, improved patient compliance, and is especially beneficial for populations with swallowing difficulties, such as pediatric and geriatric patients. Taste-masking agents enhance palatability during disintegration.

➢ **Salient Features of Fast Dissolving Tablets (FDTs)**

1. **Rapid Disintegration**- FDTs typically disintegrate in the oral cavity within 30 seconds to 3 minutes without the need for water.
2. **Improved Patient Compliance**- Especially beneficial for pediatric, geriatric, and psychiatric patients who have trouble swallowing.
3. **No Need for Water**- Enables easy administration anywhere and anytime without the need for water, increasing convenience.
4. **Fast Onset of Action**- Some FDTs allow pre-gastric absorption, leading to a quicker onset of therapeutic action.
5. **Effective Taste Masking**- Necessary for palatability since the drug dissolves in the mouth and can be bitter [5].
6. **Bypass of First-Pass Metabolism**- Drugs absorbed through the oral mucosa bypass the liver, potentially increasing bioavailability [6].
7. **Ease of Administration**- No chewing or swallowing required; ideal for dysphagic patients and in emergency situations [7].
8. **Portability and Convenience**- Lightweight, small tablets can be easily carried and used discretely, enhancing patient lifestyle [8].

➢ **Ideal properties of FDT**

1. **Fast Disintegration:** An ideal FDT should disintegrate within 30 seconds to 3 minutes in the oral cavity without the need for water.
2. **Acceptable Taste and Mouthfeel:** It should possess pleasant taste and smooth texture to improve patient acceptability, especially since it dissolves in the mouth.
3. **Sufficient Mechanical Strength:** Despite being porous and light, FDTs should have enough hardness and friability resistance to withstand handling and transport.
4. **Rapid Drug Release:** The tablet should release the active pharmaceutical ingredient (API) quickly after disintegration for rapid therapeutic effect.
5. **Moisture Resistance:** Since FDTs are hygroscopic, they must be resistant to moisture and have suitable packaging to ensure shelf-life.
6. **Low Tablet Weight:** Ideal FDTs are lightweight and small to enhance ease of use and fast disintegration.
7. **Good Stability and Compatibility:** The tablet must remain physically and chemically stable during storage and compatible with excipients.

8. **Dose Uniformity:** Each tablet should deliver an accurate and uniform dose of the active ingredient to ensure efficacy and safety.

➢ **Challenges of FDT**

1. **Mechanical Fragility:** FDTs are often soft and porous, making them prone to breakage or crumbling during packaging, handling, or transport.
2. **Taste Masking Difficulties:** Many drugs have an inherently bitter or unpleasant taste, requiring complex taste-masking techniques for patient acceptability.
3. **Moisture Sensitivity:** FDTs are highly hygroscopic and may degrade or lose integrity upon exposure to humidity without proper packaging.
4. **Limited Drug Load Capacity:** Due to their structure and size, FDTs can typically accommodate only low to moderate doses, making them unsuitable for high-dose drugs.
5. **Drug Stability Issues:** Some APIs may be unstable when exposed to saliva, moisture, or heat, affecting the shelf-life and efficacy of the product.
6. **Complex Manufacturing Process:** Technologies such as lyophilization or sublimation can be costly and time-consuming, requiring specialized equipment.
7. **Low Flow Properties of Powders:** The excipients used for rapid disintegration often have poor flowability, complicating the tablet compression process.
8. **Regulatory and Evaluation Challenges:** There is a lack of standardized evaluation parameters for disintegration time and in vivo performance specific to FDTs.

➢ **Mechanism of Superdisintegrants**

Superdisintegrants are specialized excipients used in tablet formulations, particularly in fast-dissolving tablets (FDTs), to promote rapid breakup of the tablet into smaller fragments, enhancing dissolution and drug absorption.

Mechanism of Superdisintegrants –

1. **Swelling**- Superdisintegrants absorb water rapidly and swell, exerting pressure within the tablet matrix that causes it to burst apart.
2. **Wicking (Capillary Action)**- They draw water into the pores of the tablet via capillary action, reducing particle-particle bonding and initiating disintegration.
3. **Strain Recovery (Elastic Recovery)**- Upon wetting, superdisintegrant particles recover their original shape and size, helping to break apart the compacted tablet.
4. **Heat of Wetting**- Some Superdisintegrants create localized heating as they absorb water, reducing bonding and promoting faster disintegration.
5. **Porosity and Capillarity Enhancement**- They increase the porosity of the tablet matrix, allowing more rapid water penetration and disintegration.
6. **Combination Mechanism**- Most superdisintegrants work through a synergistic combination of swelling and wicking mechanisms for optimal performance [9].

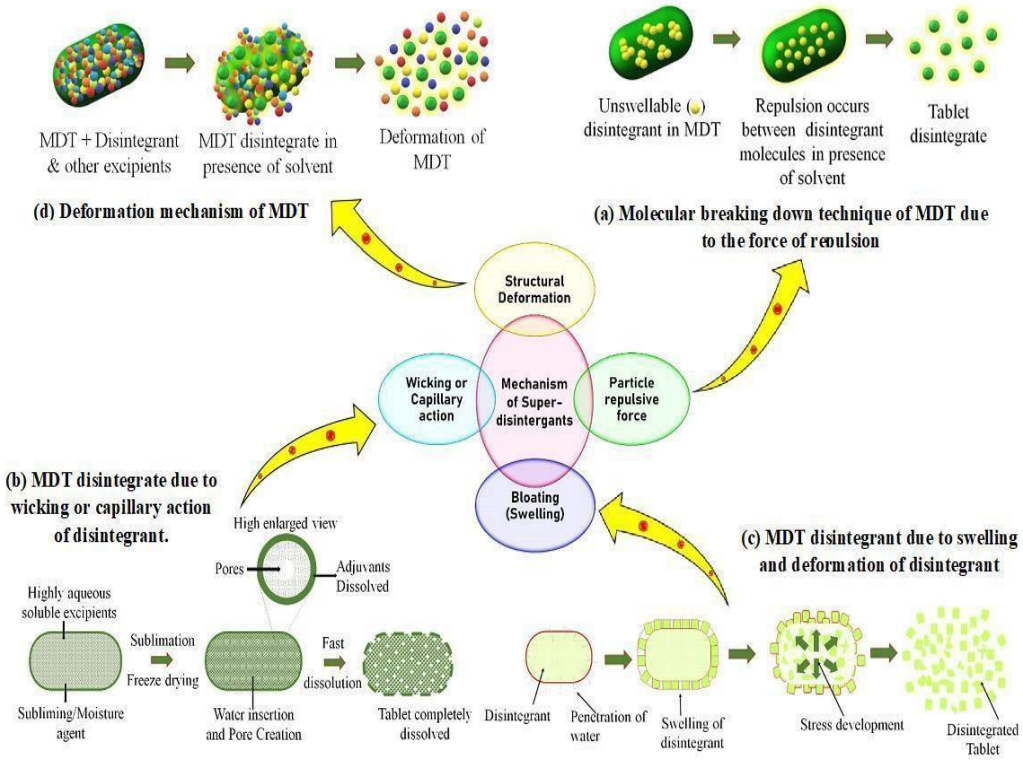

Fig. 1 Mechanisms of Superdisintegrants

Table 1. Various Superdisintegrants with Mechanism, Use

Superdisintegrant	Brand Name(s)	Mechanism(s) of Action	Typical Use (%)
Croscarmellose Sodium	Ac-Di-Sol®, Vivasol®	Swelling and wicking	0.5–5%
Sodium Starch Glycolate	Explotab®, Primojel®	Rapid swelling	2–8%
Crospovidone	Polyplasdone XL®, Kollidon® CL	Capillary action and strain recovery	2–5%
Low-Substituted HPC	L-HPC	Swelling and capillary action	1–6%
Alginic Acid	—	Swelling	1–5%
Modified Cellulose	Avicel® (Microcrystalline Cellulose)	Wicking and surface wetting	5–15%
Ion Exchange Resins	Indion 414®, Tulsion 339®	Swelling and ionic interactions	2–10%

- **Selection Criteria for Drug Candidates in Fast Dissolving Tablets (FDTs)**

1. **Low Dose Requirement** - Ideal drugs for FDTs should have a low therapeutic dose, usually below 20–30 mg, to allow compact and effective tablet formulation.
2. **High Aqueous Solubility** - Drugs with good solubility in saliva are preferred to ensure quick dissolution and absorption in the oral cavity.

3. **Pleasant Taste or Taste-Masking Feasibility** - Since the tablet dissolves in the mouth, taste masking is essential for drugs with bitter or unpleasant taste.
4. **Stability in Saliva and Moisture** -The drug should be chemically and physically stable in saliva and not degrade on contact with moisture.
5. **Suitable for Buccal or Pre-Gastric Absorption** -Drugs that undergo first-pass metabolism or benefit from buccal absorption are good candidates.
6. **No Irritation to Oral Mucosa** -The drug should not cause irritation, burning, or numbness when retained in the mouth for short durations.
7. **Rapid Onset of Action Required** -FDTs are ideal for drugs used in acute conditions like pain, allergy, or nausea where immediate action is beneficial.
8. **Moderate Molecular Weight** -Drugs with low to moderate molecular weight tend to be more permeable and faster absorbing through the oral mucosa.

➢ **Selection of Excipients in Fast Dissolving Tablets (FDTs)** [10]

1. The selection of excipients in fast dissolving tablets (FDTs) is critical to ensure rapid disintegration, pleasant mouthfeel, and mechanical strength.
2. Superdisintegrants such as crospovidone, croscarmellose sodium, and sodium starch glycolate are essential to promote quick tablet breakup upon contact with saliva.
3. Fillers like mannitol and microcrystalline cellulose are chosen for their good mouthfeel, compressibility, and low hygroscopicity.
4. Sweeteners (e.g., aspartame or sucralose) and flavoring agents improve patient compliance by masking the bitter taste of the active pharmaceutical ingredient (API).
5. Lubricants like magnesium stearate must be used in minimal quantities to avoid interfering with tablet disintegration.
6. Binders such as PVP K30 help in maintaining tablet integrity without compromising disintegration time.
7. The excipients must be non-toxic, chemically stable, and compatible with the drug and other formulation components.
8. Overall, the ideal excipient combination balances mechanical strength, fast disintegration, and acceptable organoleptic properties.

➢ **Method of preparation of FDT**

1. Direct Compression (Conventional Method) [11]

Direct compression is the simplest and most economical method for preparing FDTs. It involves blending the active pharmaceutical ingredient (API) with superdisintegrants and other excipients, followed by compression into tablets using a tablet press. Superdisintegrants such as crospovidone and croscarmellose sodium facilitate rapid tablet breakup upon contact with saliva. This method requires APIs with good flowability and compressibility. It is widely used in the pharmaceutical industry due to minimal processing steps and ease of scalability.

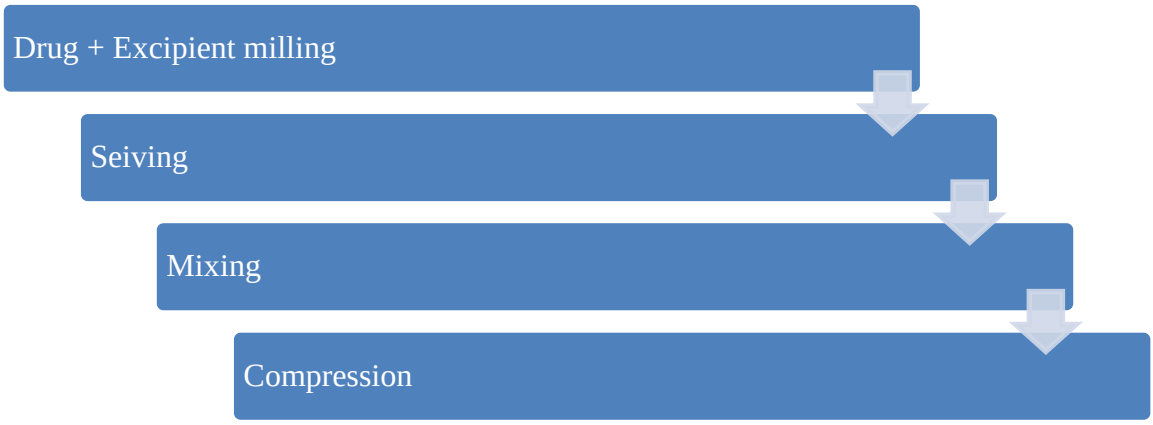

Fig. 2 Direct Compression (Conventional Method)

2. Lyophilization (Freeze Drying)

Lyophilization involves freezing a solution or suspension of the drug and excipients, followed by sublimation of the solvent under vacuum. This results in highly porous tablets that dissolve rapidly in the mouth. Lyophilized FDTs offer extremely fast disintegration times and are ideal for heat-sensitive drugs. However, they are fragile, require specialized packaging, and involve higher manufacturing costs. Commercial products like Zydis are made using this technique. The method enhances bioavailability by improving the dissolution profile.

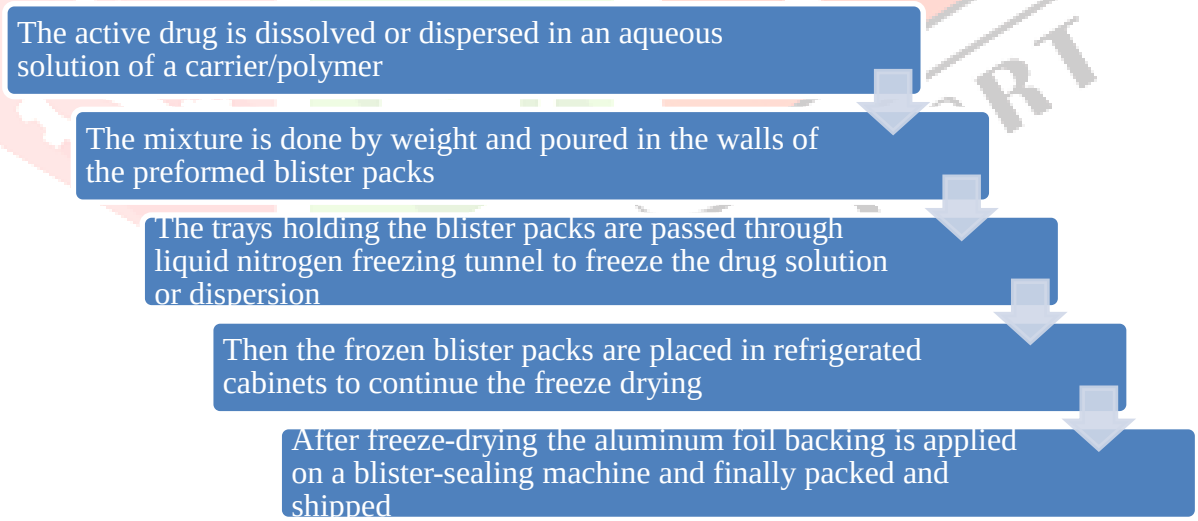

Fig. 3 Freeze Drying

3. Sublimation

In the sublimation method, volatile substances such as camphor, menthol, or ammonium bicarbonate are incorporated into the tablet formulation and later removed by sublimation under controlled conditions. This creates pores in the tablet structure, enhancing water penetration and disintegration. The process improves the tablet's dissolution rate and palatability. It requires an additional sublimation step post-compression, increasing complexity. Sublimation is particularly useful when a porous structure is needed for rapid disintegration without affecting drug stability.

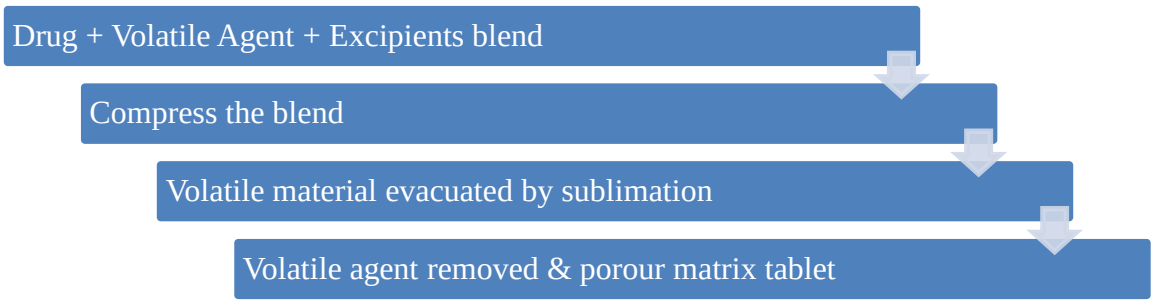

Fig. 4 Sublimation

4. Molding [12]

Molding involves dissolving or dispersing the drug in a water-soluble matrix (like PEG or sugars) and shaping it into tablets using a mold under pressure or heat. Molded tablets have a smooth texture, high porosity, and rapid dissolution. This method can be done at low temperatures, preserving thermolabile drugs. However, the tablets often lack sufficient mechanical strength and require careful handling. Molding is beneficial for enhancing mouthfeel and is deal for pediatric or geriatric formulations needing pleasant administration.

5. Spray Drying [13]

Spray drying produces fast dissolving powders or granules by atomizing a liquid mixture containing the drug, superdisintegrants, and excipients into a hot air chamber. The solvent evaporates instantly, forming dry, porous particles that can be compressed into tablets. This technique ensures uniform distribution of components, improved wettability, and rapid disintegration. Spray drying is especially effective for moisture-sensitive drugs and is used in technologies like OraSolv. It provides good scalability and can be integrated into continuous manufacturing lines.

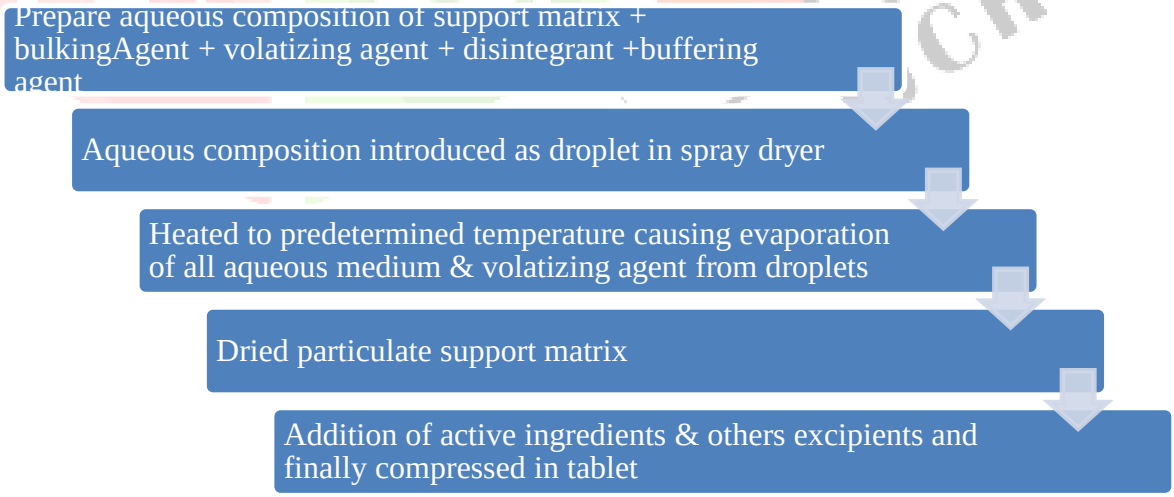

Fig.5 Spray Drying

6. Mass Extrusion

Mass extrusion involves softening a blend of drug and water-soluble polymers (e.g., PEG) using solvents such as ethanol or water, followed by extrusion and cutting into tablets or granules. This technique is valuable for taste masking and producing uniform drug dispersion. The extrudate is typically cooled and cut into appropriate sizes for dosage forms. Although less common, mass extrusion offers advantages in formulating FDTs with improved taste and fast dissolution, particularly when handling bitter-tasting or poorly water-soluble drugs.

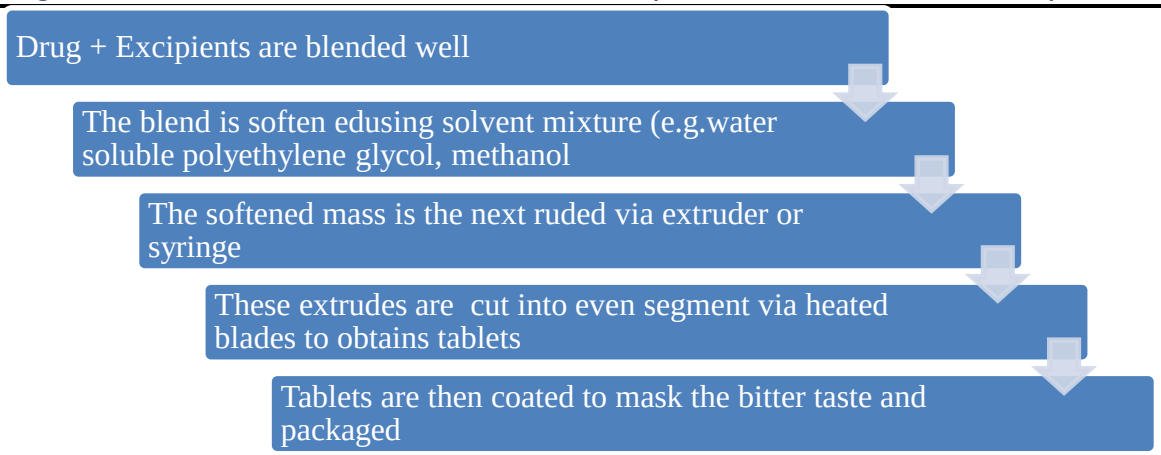

Fig. 6 Mass Extrusion

7. Cotton Candy Method [14]
The cotton candy process involves the formation of a matrix by simultaneous flash melting and spinning of saccharides (like sucrose or mannitol) into a floss-like structure. This matrix is then ground and compressed with the drug and excipients into tablets. It produces tablets with high porosity and rapid disintegration. The process is named for the resemblance to cotton candy fibers. Though it improves taste and mouthfeel, it requires high temperature and specialized equipment, making it a costly process.

8. Tablet Molding (Compression Molding) [15]
Tablet molding compresses a moist blend of drug and excipients in a mold to create tablets. Unlike direct compression, this technique avoids dry granulation. The use of a solvent (e.g., ethanol or water) helps bind ingredients and improves dissolution. After molding, the tablets are dried. This method allows better taste masking and faster drug release than conventional tablets. However, molded tablets are typically softer and may require special packaging to avoid breakage during transport or handling.

9. Phase Transition Process
In this method, tablets are prepared using two sugar alcohols with different melting points (e.g., xylitol and erythritol). After compression, the tablet is heated to a temperature between the melting points of the two alcohols, causing partial melting. On cooling, recrystallization occurs, creating a hardened matrix with high porosity. This enhances the disintegration and dissolution rate. The method improves mechanical strength of FDTs and reduces friability without sacrificing rapid disintegration, making it suitable for robust tablet formation.

10. Melt Granulation Technique [16]
This method uses meltable binders (such as PEG or glyceryl behenate) to agglomerate drug particles and excipients at elevated temperatures. The molten mass is cooled, granulated, and compressed into tablets. It eliminates the need for solvents, which is advantageous for moisture-sensitive drugs. Melt granulation enhances flow and compressibility of powders and provides taste masking through drug entrapment. The method is cost-effective, scalable, and suitable for drugs that can withstand moderate heat during processing.

11. Effervescent Method [17]
Effervescent FDTs are formulated by combining effervescent agents (e.g., citric acid and sodium bicarbonate) with other ingredients. Upon contact with saliva or water, these agents react to release carbon dioxide, which aids in tablet disintegration and creates a pleasant fizzing sensation. This technique improves patient compliance, especially for pediatric and geriatric populations. It also enhances taste masking and mouthfeel. The tablets must be stored in moisture-resistant packaging to prevent premature reaction and degradation.

Table 2. Evaluation Parameters of Fast Dissolving Tablets (FDTs) [18,19,20,21,22]

Parameter	Description
Weight Variation	Ensures uniformity in tablet weight; 20 tablets are weighed individually and the average weight is compared.
Hardness (Crushing Strength)	Measures mechanical strength using a hardness tester; tablets must withstand handling and packaging without breaking.
Friability	Assesses tablet resistance to abrasion and breakage using a Friabilator; should be less than 1% weight loss.
Disintegration Time	Key test for FDTs; determines how quickly the tablet breaks down in saliva or simulated fluid. Standard limit: <30 seconds.
Wetting Time	Time taken for water to reach the upper surface of the tablet; shorter time indicates faster disintegration.
Water Absorption Ratio	Measures how quickly the tablet absorbs water - calculated from weight change after immersion. Higher ratio supports faster disintegration.
Drug Content Uniformity	Ensures consistent active drug content across tablets - typically 85%–115% of the label claim.
In-vitro Dissolution	Determines the rate and extent of drug release; essential for bioavailability prediction. Dissolution media: 900 mL of buffer (pH 6.8), 37 ± 0.5°C.

➢ **Patented Fast Dissolving Tablet Technologies**

1. Zydis – Catalent Pharma Solutions
- **Technology**: Lyophilized, freeze-dried tablets that dissolve on the tongue in seconds [23].

2. OraSolv – CIMA Labs (Teva Pharmaceuticals)
- **Technology**: Direct compression using effervescent agents and taste-masked drug particles [24].

3. DuraSolv – CIMA Labs (Teva Pharmaceuticals)
- **Technology**: Similar to OraSolv but offers higher tablet hardness and packaging flexibility.

4. WOWTAB – Yamanouchi Pharmaceutical Co. (Japan)
- **Technology**: Combines highly and poorly moldable sugars for rapid dissolution and mouthfeel [25].

5. FlashTab – Ethypharm (France)
- **Technology**: Combines microgranules of drug with disintegrating agents using direct compression [26].

6. Lyoc – Cephalon (France)
- **Technology**: Freeze-dried tablets using a sugar-based carrier for rapid disintegration [27].

7. FlashDose – Fuisz Technologies (Biovail Corporation)
- **Technology**: Cotton candy process producing a floss-like matrix that rapidly dissolves [28].

8. OraQuick – KV Pharmaceuticals
- **Technology**: Utilizes taste-masked microencapsulation with rapid saliva dispersion [29].

9. QuickSolv – Janssen Pharmaceuticals
- **Technology**: Drug is uniformly dispersed in a gelatin matrix with superdisintegrants [30].

10. Ziplet – Eurand International

- **Technology**: Targets poorly water-soluble drugs using high-performance disintegrants [31].

11. AdvaTab – Eurand International (Now Aptalis)

- **Technology**: Combines taste-masked microencapsulation with controlled drug release in a fast-melt tablet [32].

Table 3. Fast Dissolving Films Available in the Market [33,34,35,36,37]

Brand Name	API (Drug)	Therapeutic Use	Manufacturer	Market/Region
Suboxone® Film	Buprenorphine + Naloxone	Opioid dependence	Indivior	USA, Europe
Zuplenz®	Ondansetron	Nausea & vomiting (CINV)	Galena Biopharma	USA
Ondansetron ODF	Ondansetron	Nausea & vomiting	Various generic manufacturers	Global
Donepezil ODF	Donepezil HCl	Alzheimer's disease	Eisai/Pfizer	Japan, Global
Listerine PocketPaks®	Flavor only (non-drug)	Breath freshener	Pfizer (formerly Warner-Lambert)	Global
Zuventus® ODF	Various (Domperidone, etc.)	GI conditions, antiemetic	Zuventus Healthcare	India
Azelastine ODF	Azelastine HCl	Allergy, antihistamine	ARx LLC	USA
Oravig®	Miconazole	Oral fungal infections	Strativa Pharmaceuticals	USA
Theraflu® Strip	Acetaminophen + Diphenhydramine	Cold & flu symptoms	GSK Consumer Healthcare	North America
Benadryl® Itch Relief Film	Diphenhydramine	Itch relief	Johnson & Johnson	USA
Caffeine Films	Caffeine	Alertness, energy	QuickStrip™, RapidDose Therapeutics	Canada, USA
Vitafilm®	Vitamin B12 (Cyanocobalamin)	Dietary supplement	IntelGenx	North America, Europe

Table 4. Fast Dissolving Tablets Available in the Market [38,39,40]

Brand Name	API (Drug)	Therapeutic Use	Manufacturer	Market/Region
Zyprexa Zydis	Olanzapine	Schizophrenia, Bipolar Disorder	Eli Lilly	Global
Zofran ODT	Ondansetron	Nausea, Vomiting	GlaxoSmithKline	Global
Maxalt-MLT	Rizatriptan	Migraine	Merck & Co.	Global
Zelapar	Selegiline	Parkinson's Disease	Valeant Pharmaceuticals	Global
Claritin RediTabs	Loratadine	Allergy	Schering-Plough	Global
Allegra ODT	Fexofenadine	Allergic Rhinitis, Urticaria	Sanofi Aventis	Global
Benadryl FastMelt	Diphenhydramine	Allergy	Pfizer	Global
Calpol Fast Melts	Paracetamol	Pain	McNeil Healthcare UK	UK
Nurofen Meltlets	Ibuprofen	Pain, Fever, Inflammation	Reckitt Benckiser	Global
Prevacid SoluTab	Lansoprazole	GERD, Ulcers	Takeda Pharmaceuticals	Global
Parcopa	Carbidopa/Levodopa	Parkinson's Disease	Schwarz Pharma	Global
Risperdal M-Tab	Risperidone	Schizophrenia, Bipolar Disorder	Janssen Pharmaceuticals	Global
Remeron SolTab	Mirtazapine	Major Depressive Disorder	Merck & Co.	Global
Clarinex RediTabs	Desloratadine	Allergy	Schering-Plough	Global
Abilify Discmelt	Aripiprazole	Schizophrenia, Bipolar Disorder	Otsuka America/Bristol-Myers	Global
Adzenys XR-ODT	Amphetamine	ADHD	Neos Therapeutics	USA
Feldene Fast Melt	Piroxicam	Pain Relief	Pfizer	Global
Pepcid RPD	Famotidine	GERD, Ulcers	Merck & Co.	Global
Zomig-ZMT	Zolmitriptan	Migraine	AstraZeneca	Global
Nimulid MDT	Nimesulide	Pain, Inflammation	Panacea Biotech	India

Torrox MT	Rofecoxib	Pain, Inflammation	Torrent Pharmaceuticals	India
Olanex Instab	Olanzapine	Schizophrenia, Bipolar Disorder	Ranbaxy Laboratories	India
Etizest MD	Etizolam	Anxiety, Insomnia	Consern Pharma	India
Vometa FT	Domperidone	Nausea, Vomiting	Dexamedica	India
Deva B-12 Fast Dissolve	Cyanocobalamin (B12)	Vitamin B12 Supplement	Deva Nutrition	USA, Europe

➢ Conclusion

Fast Dissolving Tablets (FDTs) represent a significant advancement in drug delivery, offering rapid disintegration, enhanced patient compliance, and suitability for pediatric, geriatric, and dysphagic patients. With a growing number of marketed products across therapeutic areas like pain, allergies, CNS disorders, and gastrointestinal issues, FDTs combine convenience with efficacy. Innovations in formulation methods and patented technologies continue to expand their clinical utility. As the demand for user-friendly dosage forms rises, FDTs are poised to remain a preferred choice in modern pharmacotherapy.

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