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Review Paper

Review On Fast Disintegrating Tablets

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ABSTRACT

Fast disintegrating tablets (FDTs) have emerged as an innovative oral solid dosage form designed to disintegrate or dissolve rapidly in the mouth, typically within seconds, without the need for water. This drug delivery system enhances patient compliance, particularly among pediatric, geriatric, and dysphagic populations, offering a convenient alternative to conventional tablets and capsules. The present review provides an extensive overview of the design and development of FDTs, emphasizing formulation strategies, disintegration mechanisms, preparation methods, and evaluation parameters. It also discusses the role of excipients, particularly superdisintegrants, in achieving rapid disintegration and optimal mouthfeel. Various manufacturing techniques such as direct compression, lyophilization, molding, sublimation, and novel nanotechnology-based approaches are described in detail. Recent advances including 3D printing, co-processed excipients, and the use of natural superdisintegrants are also explored. Challenges in formulation, packaging, and regulatory perspectives are addressed, along with future prospects such as personalized FDTs and green manufacturing. Overall, this review highlights the growing importance of FDTs in modern pharmaceutical technology as a patient-friendly, efficient, and market-driven oral drug delivery system.

INTRODUCTION

1.1 Definition and Concept of FDTs

Fast disintegrating tablets (FDTs), also known as orally disintegrating tablets (ODTs), are solid unit dosage forms that disintegrate or dissolve rapidly on the tongue without the need for water. Typically, disintegration occurs within 30 seconds to 2 minutes, releasing the drug into the saliva for subsequent swallowing and absorption (1–3). FDTs are particularly useful for drugs requiring rapid onset of action, such as analgesics, antiemetics, antipyretics, and cardiovascular drugs.

1.2 Historical Background and Evolution

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The concept of fast disintegrating dosage forms was first introduced in the late 1970s by the company Zydis®, which pioneered the freeze-dried oral lyophilized tablet(4). Since then, numerous technological advancements have been made to improve tablet strength, taste masking, and stability. Over the decades, the technology has evolved from lyophilization-based systems to more cost-effective and scalable methods such as direct compression and spray drying(2,5,6).

1.3 Need and Significance in Modern Drug Delivery

FDTs address the growing demand for patient-centric drug delivery, particularly for populations facing difficulty swallowing traditional tablets and capsules. Studies indicate that up to 35% of the general population, including elderly and pediatric patients, experience dysphagia(7,8). Additionally, FDTs improve adherence in psychiatric and emergency settings, where immediate dosing is essential.

1.4 Advantages over Conventional Dosage Forms

Compared to conventional tablets, FDTs offer several distinct advantages:

- Ease of administration: Can be taken without water, beneficial for travelers and bed-ridden patients.
- Rapid onset of action: Faster absorption due to pre-gastric dissolution and absorption from the oral cavity(9,10).
- Enhanced bioavailability: Some drugs show improved absorption due to avoidance of first-pass metabolism.
- Improved patient compliance: Especially advantageous for pediatric and geriatric patients(11).
- Versatility: Suitable for a wide range of drugs and therapeutic classes.

2.5 Market Potential and Regulatory Perspectives

The global FDT market is expanding rapidly due to increased patient demand and technological innovation. According to recent pharmaceutical market analyses, the FDT segment is expected to grow at a compound annual growth rate (CAGR) of over 10% in the coming years (12,13). Regulatory bodies such as the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have defined FDTs as tablets that disintegrate within 30 seconds in the oral cavity. Compliance with ICH guidelines ensures product safety, stability, and efficacy (14,15).

3. Ideal Characteristics of Fast Disintegrating Tablets

An ideal FDT should satisfy both patient-related and formulation-related requirements. The following characteristics define an optimized formulation (3,6,16,17):

1. Rapid Disintegration: The tablet should disintegrate or dissolve completely within seconds (ideally <30 seconds) upon contact with saliva.
2. Pleasant Mouthfeel and Taste: The formulation must mask any unpleasant taste of the drug to ensure patient acceptability.
3. Adequate Mechanical Strength: Tablets should withstand handling, packaging, and transportation without breaking.
4. Low Sensitivity to Environmental Factors: FDTs should be stable under normal temperature and humidity conditions.
5. Compatibility with APIs and Excipients: Chemical stability between drug and excipients must be ensured through compatibility studies such as DSC or FTIR analysis.
6. Non-irritant to Oral Mucosa: The formulation should not cause irritation or discomfort upon contact with the oral cavity.

7. Ease of Manufacturing: The process should be simple, cost-effective, and scalable for commercial production.

The balance between mechanical integrity and rapid disintegration remains a key challenge in FDT formulation design.

4. Formulation Aspects

The formulation of fast disintegrating tablets (FDTs) demands careful selection of both active pharmaceutical ingredient (API) and excipients, to ensure fast disintegration, good mouthfeel, mechanical integrity, and drug stability(1,2,6,7).

4.1 Active Pharmaceutical Ingredient (API)

The selection of a suitable API is the first step in designing an effective FDT. The key considerations include:

- Dose and solubility: APIs with low to moderate doses (generally below 50 mg) and good aqueous solubility are preferable for FDT formulations to achieve rapid dissolution (2,8,10).
- Taste and mouthfeel: Drugs with a bitter or unpleasant taste must be masked using flavoring agents, sweeteners, or polymeric coatings(3,11).
- Chemical and physical stability: The API must remain stable during processing (compression, drying) and storage under ambient conditions.
- Compatibility with excipients: Compatibility studies using Differential Scanning Calorimetry (DSC), Fourier Transform Infrared Spectroscopy (FTIR), and X-ray diffraction (XRD) are essential to prevent chemical degradation or phase transformation (18,19).

4.2 Excipients

Excipients play a crucial role in determining the performance of FDTs. Their selection is based on desired disintegration time, tablet strength, taste masking, and process feasibility.

4.2.1 Superdisintegrants

Superdisintegrants are the backbone of FDT formulations. They promote rapid tablet disintegration by facilitating water uptake and swelling within the matrix. Common examples include:

- Crospovidone (Polyplasdone® XL, XL-10): Works through capillary and wicking mechanisms.
- Croscarmellose sodium (Ac-Di-Sol®): Exhibits both swelling and wicking properties.
- Sodium starch glycolate (Explotab®, Primogel®): Rapidly swells 200–300 times its volume in water(4,6,11,15).
- Natural superdisintegrants: Recent studies report the use of plant-derived agents such as Plantago ovata, Lepidium sativum, and Fenugreek mucilage as eco-friendly alternatives (20,21).

4.2.2 Diluents

Diluents add bulk and influence mouthfeel. Mannitol and xylitol impart a pleasant cooling sensation, while microcrystalline cellulose (MCC) enhances compressibility. Other common diluents include lactose, dicalcium phosphate, and sorbitol (3,6,14,16).

4.2.3 Binders

Binders ensure mechanical strength without excessively delaying disintegration. Common binders are polyvinylpyrrolidone (PVP), hydroxypropyl methylcellulose (HPMC), polyethylene glycol (PEG), and pregelatinized starch (9,17,22).

4.2.4 Lubricants

Lubricants minimize friction during compression and ejection. Magnesium stearate, talc, and

sodium stearyl fumarate are widely used, but their concentration must be optimized since over-lubrication can retard disintegration (4,8,10).

4.2.5 Flavoring and Sweetening Agents

Taste masking is crucial for patient acceptability. Agents like aspartame, saccharin sodium, sucralose, and acesulfame potassium are common. Natural flavors such as mint, orange, and strawberry are added for palatability (12,16).

4.2.6 Saliva-Stimulating Agents

Acidic excipients such as citric acid and malic acid enhance saliva production and contribute to faster disintegration(7,15,23).

5. Mechanism of Disintegration

The rapid disintegration of FDTs results from complex physicochemical interactions between tablet components and water.

- **The following mechanisms have been proposed (2,4,11,18,24):**

1. Swelling Mechanism: Superdisintegrants absorb water and swell, exerting pressure that leads to tablet rupture. Sodium starch glycolate and croscarmellose sodium primarily follow this mechanism.
2. Capillary (Wicking) Mechanism: Water is drawn into the porous matrix by capillary action, weakening the intermolecular bonds between particles. Crospovidone mainly acts via wicking.
3. Particle Repulsion Theory: Electrostatic repulsion among particles after wetting causes rapid dispersion.
4. Enzymatic Action: Certain natural polymers may degrade enzymatically, leading to disintegration.
5. Deformation and Recovery: During compression, disintegrant particles deform; upon contact with water, they recover to their original shape, contributing to breakup.

In practice, a combination of swelling and wicking mechanisms dominates most FDT formulations, ensuring optimal balance between strength and rapid disintegration.

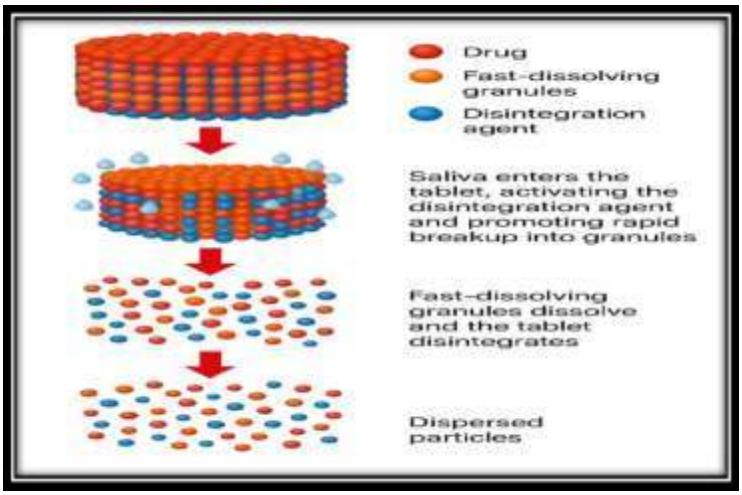

Figure 1 : Mechanism of Disintegration

6. Methods / Techniques for Preparation

A variety of manufacturing technologies are employed to produce FDTs, depending on the drug's properties and desired disintegration profile(2,5,6,12,13,22,25).

6.1 Direct Compression

The most economical and widely used technique. It involves blending API, excipients, and superdisintegrants, followed by compression into tablets.

- Advantages: Simplicity, low cost, scalability.
- Limitations: Low mechanical strength for highly porous tablets; requires directly compressible excipients such as MCC and mannitol.

Figure 2: Direct Compression Method

6.2 Lyophilization (Freeze Drying)

In this method, a drug solution or suspension is frozen and the solvent sublimed under vacuum to create a porous matrix that dissolves rapidly in saliva.

- Example: Zydis® technology.
- Advantages: Extremely fast disintegration (<10 s).
- Limitations: Expensive, fragile tablets, special packaging required.

Figure 3: Lyophilization Technique

6.3 Molding Method

Involves preparing a wet mass containing drug and excipients , which is molded into tablets and dried.

- Advantages: Good mouthfeel and taste masking.
- Limitations: Poor mechanical strength.

6.4 Sublimation Method

Volatile substances such as camphor, urea, or ammonium bicarbonate are incorporated into the mixture and later sublimed to create pores that accelerate disintegration(3,6,8).

6.5 Spray Drying

A solution containing API and excipients is sprayed into a hot chamber, forming porous,

highly dispersible particles. Croscarmellose sodium, gelatin, and mannitol are commonly used in this method.

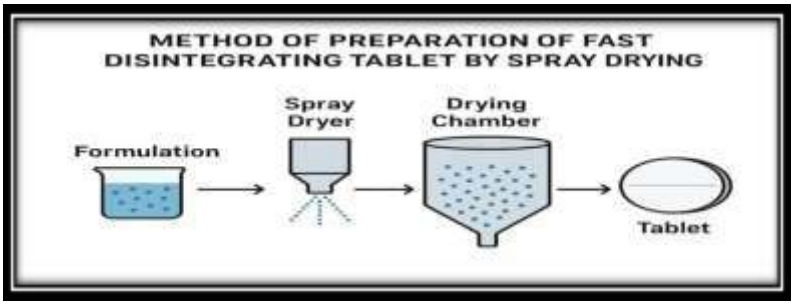

Figure 4: Spray Drying Method

6.6 Mass Extrusion

A soft mass of drug and excipients is extruded and cut into uniform segments. The method allows precise control of shape and uniformity (10,14).

6.7 Phase Transition Method

This approach involves using a combination of two sugar alcohols with different melting points; heating causes partial melting and recrystallization, enhancing strength while maintaining rapid disintegration (20).

6.8 Nanotechnology-Based Approaches

Recent developments include integrating drug nanocrystals or solid lipid nanoparticles into FDTs to improve dissolution and bioavailability of poorly soluble drugs (12,24).

7. Evaluation Parameters

Evaluation of FDTs is a crucial step to ensure product performance, quality, and compliance with pharmacopeial standards. The evaluation parameters are generally classified into pre-formulation and post-formulation studies(2,4,8,10,16,23).

7.1 Pre-Formulation Studies

(a) Flow Properties

Good flowability is necessary for uniform die filling during tablet compression. Flow properties are assessed through:

- Angle of repose (θ): Indicates the internal friction between particles. A lower angle (<30°) denotes good flow.

Table 1 : Angle of Repose as an identification of powder flow Properties

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

- **Bulk and tapped density:** Used to calculate **Carr's index** and **Hausner ratio**, which indicate compressibility.
- **Compressibility index:**

Carr's Index = (Tapped−Bulk)/Tapped×100

- Values below 15% suggest excellent flow(3,14,17).

Table 2: Relationship between % compressibility and flow ability

% Compressibility	Flow ability
5-12	Excellent
12-16	Good
18-21	Fair Passable
23-35	Poor
33-38	Very Poor
<40	Very Poor

(a) Compatibility Studies

Drug–excipient compatibility ensures chemical and physical stability. Common techniques include:

- **FTIR spectroscopy:** Identifies potential interactions through peak shifts.
- **Differential Scanning Calorimetry (DSC):** Detects changes in melting point or enthalpy.
- X-ray diffraction (XRD): Determines crystalline changes in the formulation(4,15,20).

7.2 Post-Formulation Studies

(a) Weight Variation

Twenty tablets are weighed individually, and the mean weight is compared with pharmacopeial limits (±5% for tablets >250 mg).

Table 3: Weight variation specification as per IP

Average Weight Of Tablet	% Deviation
80mg or less	±10
More than 80 mg but less than 250 mg	±7.5
250 mg or more	±5

(b) Thickness and Diameter

Measured using a vernier caliper to ensure uniformity and compatibility with packaging materials.

(c) Hardness

Determines the mechanical strength of tablets. Measured using a Monsanto or Pfizer hardness tester; ideal FDT hardness ranges between 2–4 skg/cm²(10,18).

(d) Friability

Evaluated using a Roche friabilator. A weight loss below 1% indicates adequate strength (2,11).

Figure 5: Friability Test Apparatus

(e) Wetting Time and Water Absorption Ratio

A tissue paper method is used to measure the time taken for water to reach the tablet surface. The water absorption ratio (R) is calculated as:

$$R = Wa - Wb / Wb \times 100$$

where, Wa and Wb are tablet weights before and after absorption.

(f) In-Vitro Disintegration Time

Measured in 900 mL of distilled water at 37°C ± 0.5°C using the disintegration apparatus. FDTs should disintegrate within 30 seconds to 3 minutes, depending on formulation(3,6,7).

(g) In-Vitro Dissolution Studies

Dissolution tests determine the rate and extent of drug release, typically performed usingUSP Type II (paddle) apparatus at 50–100 rpm in a suitable medium (9,13).

(h) Taste Evaluation and Mouthfeel

Performed using a trained human taste panel or electronic tongue technology. Criteria include taste, aftertaste, and mouthfeel(8,24).

(i) Stability Studies

Stability testing is conducted as per ICH Q1A (R2) guidelines at accelerated conditions (40°C ± 2°C and 75% RH ± 5%) for 6 months to evaluate any changes in appearance, disintegration time, or drug content (14,19).

4. Packaging of FDTs

Because of their porous structure and hygroscopic nature, FDTs are sensitive to environmental factors, especially moisture and temperature. Hence, specialized packaging is essential to maintain stability(2,5,6,11,21**).**

4.1 Moisture-Resistant Packaging

FDTs are commonly packed in:

- Blister packs: Provide individual protection against moisture and mechanical stress.
- Strip packs: Cost-effective alternative but offer less moisture protection compared to blisters.
- Alu-Alu packs: Provide superior moisture and light resistance, ideal for hygroscopic drugs(8,10).

4.2 Specialized Packaging Systems

Some FDT technologies utilize proprietary packaging, such as:

- Zydis® (Catalent Pharma): Uses peelable foil blister packs.
- OraSolv® and DuraSolv® (CIMA Labs): Employ moisture-resistant polymer blisters.

These packages prevent physical damage and ensure long-term stability under varying conditions (4,12,15).

5. Applications of FDTs

FDTs have gained widespread acceptance due to their broad therapeutic applicability and patient-friendly nature(3,7,9,18,24).

1. Pediatric Patients: Ideal for children who have difficulty swallowing conventional tablets.
2. Geriatric Population: Facilitates administration for elderly patients suffering from dysphagia or neurological disorders.
3. Psychiatric and Unconscious Patients: Enables rapid drug administration without water.
4. Emergency Situations: Useful for conditions requiring quick onset of action, such as allergic reactions, nausea, and migraine attacks.
5. Improved Bioavailability: Drugs absorbed in the oral cavity bypass first-pass metabolism, enhancing systemic availability (e.g., selegiline, propranolol).
6. Convenience for Traveling and On-the-Go Use: Portable, easy to self-administer **without water (10,14,17,19).**

6. Case Studies / Marketed Products

A number of FDT products have been successfully commercialized, showcasing the feasibility and benefits of this technology (6,8,13,22,25).

Table 4: Marketed Products

Product Name	Active Ingredient	Manufacturer	Indication
Claritin RediTabs®	Loratadine	Schering-Plough	Antihistamine
Feldene Melt®	Piroxicam	Pfizer	Analgesic
Zydis® Risperdal M-Tab®	Risperidone	Janssen Pharmaceuticals	Antipsychotic
Nimulid-MD®	Nimesulide	Panacea Biotec	Anti-inflammatory
Maxalt-MLT®	Rizatriptan benzoate	Merck & Co.	Antimigraine
Orapred ODT®	Prednisolone sodium phosphate	BioAlliance	Anti-inflammatory

Pepeid® ODT	Femotidene	Merck	Anti-ulcer
Zyperxa®	Olazepine	Eli Lilly	Psychotropic
Zofran® ODT	Olandansetron	Galaxo Smith kline	Antiemetic
Resperdal® M-TabTM	Resperidone	Janssen	Schizophrenia
ZubrinTM (Pet drug)	Tepoxelin	Scherig corporation	Canine NSAIDs
ZelaparTM	Selegiline	Elanl Amarin corporation	Parkinsons disease
Klonopin® wafer	Clonazepam	Roche	Sedation
Childrens Dimetapp® ND	Loratadine	Wyeth consumer Healthcare	Allergy
Imodium Istant Melts	Loperamide HCL	Jannsen	Antidiarrheal
Propulsid® Quicksolv ®	Cisapride Monohydrate	Jannsen	Gastrointestinal prokinetic Agent
Tempra Quicksolv®	Acetaminophen	Bristol-Mters squibb	Analgesic
Remeron® Soltab®	Mirtazapine	Organon Inc.	Anti-dipression
Triaminic® Softchews®	Various combination	Novartis consumer Health	Pediatric cold cough,Allergy
Zomig-ZMT® and Rapimelt®	Zolmitriptan	AstraZeneca Alavert® Loratadine Allergy	Anti-migraine AstraZeneca
DuraSolv® Alavert®	Loratadine	Wyeth Consumer Healthcare	Allergy
NuLev®	Hyoscyamine sulfate	Schwarz Pharma	Anti-ulcer

Kemstro™ Baclofen	Baclofen	Schwarz Pharma	Anti-spastic analgesic
Benadryl® Fastmelt®	Diphenhydramine citrate	Pfizer	sinus pressure relief
Nasea OD	Ramosetoron HCl	Yamanouchi	Anti-emetic
Gaster D	Famotidine	Yamanouchi	Anti-ulcer
Excedrin® QuickTabs	Acetaminophen	Bristol-Myers Squibb	Pain reliever

Key Insights from Marketed Formulations

- Freeze-dried formulations offer the fastest disintegration but require costly packaging.
- Direct compression-based products are more economical and robust.

- Taste masking through polymer coating or complexation remains critical for patient compliance.

11. Challenges in Formulation of FDTs

Despite their wide acceptance and advantages, FDTs present several formulation and manufacturing challenges that must be carefully addressed(2,7,8,14,20).

11.1 Mechanical Strength

Because of their porous and fragile structure, FDTs often exhibit low hardness and high friability. Achieving the right balance between fast disintegration and mechanical strength remains difficult. Optimizing compression force, binder concentration, and choice of excipients is critical.

11.2 Taste Masking

Many active pharmaceutical ingredients (APIs) have an inherently bitter taste, which negatively impacts patient compliance. Techniques such as microencapsulation, complexation with ion-exchange resins, and polymer coating are essential for effective taste masking (6,10,17).

11.3 Moisture Sensitivity

FDTs are hygroscopic due to the presence of superdisintegrants and porous excipients. Exposure to humidity may cause premature disintegration or structural damage, requiring specialized moisture-barrier packaging (3,11,23).

11.4Drug Loading Limitations

The dosage of drugs incorporated into FDTs is limited. Drugs requiring high doses (>500 mg) are challenging to formulate into FDTs due to size and disintegration constraints(13,15).

11.5Stability Issues

Lyophilized or moisture-sensitive formulations may exhibit reduced shelf life. Maintaining stability in varying climatic zones requires optimization of both formulation and packaging design(8,12,19).

12. Recent Advances in FDT Technology

FDT technology has rapidly evolved with the integration of modern pharmaceutical and nanotechnological innovations **(6,10,18,22,24).**

12.1Nanotechnology-Based FDTs

Nanoparticles and nanocrystals enhance solubility and dissolution of poorly water-soluble drugs.

Example: Nanonised aripiprazole FDTs exhibit faster onset of action and improved bioavailability.

12.23D Printing of FDTs

Three-dimensional printing (3DP) enables personalized dosage and complex geometries for controlled disintegration. The first FDA-approved 3D printed FDT, Spritam® (levetiracetam), set a milestone in 2015 for on-demand oral dosage fabrication (21).

12.3 Co-Processed Excipients

Modern excipient systems such as Ludiflash®, Prosolv® ODT G2, and Pharmaburst® 500enhance flowability, compressibility, and mouthfeel simultaneously(11,23).

12.4Superdisintegrant Synergism

Combining disintegrants like crospovidone + sodium starch glycolate results in superior wetting and capillary action compared to individual agents (4,9,18).

12.5 Sublimation and Foam Drying Innovations

Sublimation techniques using camphor, urea, or ammonium bicarbonate generate highly porous structures without compromising strength. Foam drying offers a rapid, solvent-free alternative for thermolabile drugs(20,24).

13. Regulatory Aspects

Regulatory guidance for FDTs is derived from general oral solid dosage form requirements with additional criteria for disintegration and stability(2,8,13,14,25).

13.1Definition and Acceptance

The USFDA classifies FDTs under "orally disintegrating tablets" (ODTs), which disintegrate within 30 seconds or less in the mouth without water (FDA Guidance, 2008).

13.2 Pharmacopoeial Specifications

- USP: FDTs should disintegrate within 30 seconds.
- European Pharmacopoeia (EP): Defines "orodispersible tablets" as tablets that disintegrate within 3 minutes.
- Indian Pharmacopoeia (IP): Adopts similar standards for disintegration, uniformity, and assay.

13.3 Labeling and Packaging

Labels must specify "orally disintegrating" and provide appropriate storage instructions (e.g., store in a dry place below 25°C). Packaging should ensure protection from light and moisture.

13.4 Bioequivalence Studies

In-vitro disintegration and dissolution studies, followed by in-vivo pharmacokinetic comparison, are mandatory to establish equivalence with reference products (12,19).

FUTURE PROSPECTS

The future of FDTs lies in integrating precision medicine, nanotechnology, and smart manufacturing to enhance therapeutic outcomes and patient convenience (3,10,17,20,21).

1. Personalized FDTs: 3D printing and AI-driven modeling will enable custom dose strengths and multi-drug combinations.
2. Fast-Onset Therapeutics: FDTs will expand into novel therapeutic areas like anti-epileptics, vaccines, and biologics through mucoadhesive and nano-enhanced systems.

3. Natural Polymer Utilization: Biopolymers such as chitosan, guar gum, and aloe vera gel are being explored as sustainable disintegrants and binders.
4. Regulatory Harmonization: Global guidelines are expected to standardize testing methods for ODTs/FDTs to facilitate international commercialization.
5. Smart Packaging: Intelligent blister packs with humidity sensors may soon be used to maintain stability during distribution and storage.

CONCLUSION

Fast Disintegrating Tablets (FDTs) represent a breakthrough in oral drug delivery, merging patient-centric design with technological innovation. They offer rapid onset of action, improved compliance, and enhanced bioavailability, particularly for pediatric and geriatric patients. Despite formulation challenges such as moisture sensitivity and mechanical fragility, advancements in superdisintegrants, 3D printing, and nanotechnology continue to refine this dosage form. Future research should focus on optimizing taste masking, stability, and scalability to achieve globally acceptable standards. FDTs will continue to evolve as a cornerstone of patient-friendly, effective, and smart oral drug delivery systems.

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