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Review Article

Fast disintegrating tablets: An updated review on formulation and evaluation

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Abstract

Fast Disintegrating Tablets (FDTs), also referred to as Orally Disintegrating Tablets (ODTs) or Mouth-Dissolving Tablets (MDTs), are solid dosage forms designed to disintegrate rapidly in the oral cavity without the need for water. These tablets offer significant advantages in patient compliance, especially for pediatric, geriatric, and dysphagic populations, and provide faster onset of action compared to conventional tablets. This review presents an updated overview of the formulation strategies, technological approaches, evaluation parameters, and recent advancements in FDT development.

Different formulation techniques—including direct compression, freeze-drying, sublimation, spray drying, molding, mass extrusion, and patented processes—have enabled the production of robust, fast-acting tablets with superior organoleptic properties. The selection and mechanism of superdisintegrants, such as Crospovidone, Croscarmellose Sodium, Sodium Starch Glycolate, Kyron T-314, and β-Cyclodextrin, play a critical role in achieving rapid disintegration and optimal mechanical strength. Taste-masking approaches, encompassing polymer coating, drug–resin complexes, microencapsulation, and cyclodextrin inclusion complexes, further enhance patient acceptability.

Key evaluation parameters—including hardness, friability, drug content, wetting time, disintegration time, and dissolution profile—are essential to assess product quality and performance. Recent innovations such as 3D-printed FDTs, nanoparticle-loaded systems, and QbD-driven optimization have advanced the field significantly. This review consolidates current knowledge and provides insights into emerging trends, highlighting the potential of FDTs as a versatile and patient-friendly dosage form in modern pharmaceutical therapy.

Keywords: Fast Disintegrating Tablets, Disintegrating Tablets, superdisintegrants.

1. Introduction

Oral drug delivery remains the most widely accepted and convenient route of administration due to its simplicity, safety, patient acceptability, and cost-effectiveness. However, conventional solid dosage forms often present challenges for specific patient groups, particularly children, elderly individuals, bedridden patients, and those with neurological or psychological disorders such as dysphagia [1]. To address these limitations, Fast Disintegrating Tablets (FDTs) have emerged as an innovative and patient-friendly alternative, disintegrating quickly in the oral cavity—typically within seconds—without the need for water [2].

The concept of FDTs revolutionized oral drug delivery by enhancing patient compliance and providing a faster onset of therapeutic effect. The rapid disintegration enables quick dispersion of the drug in saliva, which may allow partial absorption through the buccal mucosa, potentially bypassing hepatic first-pass metabolism. This makes FDTs advantageous for medications requiring immediate pharmacological action, including analgesics, antihistamines, cardiovascular agents, antipsychotics, and anti-inflammatory drugs [3].

Several factors influence the performance of FDTs, including the choice of excipients, type of superdisintegrant, porosity of the tablet, and taste-masking strategies. Superdisintegrants such as Crospovidone, Croscarmellose Sodium, and Sodium Starch Glycolate facilitate rapid uptake of saliva, causing the tablet to break apart efficiently. Novel excipients like β-Cyclodextrin not only enhance disintegration but also improve drug solubility and mask bitterness, making them highly suitable for orally disintegrating systems [4].

The success of FDT formulations also relies on modern manufacturing technologies. Methods such as direct compression, freeze-drying (lyophilization),

sublimation, mass extrusion, spray drying, and the cotton candy process have been explored to create tablets with optimized mechanical strength, porosity, and disintegration performance. Among these, direct compression remains the most widely used industry technique due to its cost-effectiveness, minimal processing steps, and compatibility with heat- and moisture-sensitive drugs [5].

Evaluation parameters—such as appearance, hardness, friability, drug content, wetting time, disintegration time, and dissolution characteristics—play critical roles in ensuring the quality, safety, and performance of FDTs. Rapid disintegration (ideally < 30 seconds) and improved dissolution are essential to achieving a faster onset of action and enhanced bioavailability. Stringent stability studies, as per ICH guidelines, are necessary to ensure product integrity during shelf life, especially since FDTs are often sensitive to moisture [6].

In recent years, significant advancements have been made in the development of FDTs. Innovations like 3D printing, nanotechnology, hybrid superdisintegrants, multifunctional excipients, and Quality by Design (QbD) approaches have improved formulation precision and performance. The growing demand for patient-friendly dosage forms further emphasizes the importance of FDTs in modern pharmaceutical therapy [7].

This review provides an updated and comprehensive overview of the formulation principles, technological approaches, evaluation parameters, recent advancements, and clinical relevance of Fast Disintegrating Tablets. By consolidating existing scientific knowledge, the review aims to support further research, innovation, and optimization of FDTs for improved drug delivery and therapeutic effectiveness [8].

2. Advantages of fast disintegrating tablets

Fast Disintegrating Tablets (FDTs), also known as Orally Disintegrating Tablets (ODTs) or Mouth-Dissolving Tablets (MDTs), provide several advantages over conventional solid oral dosage forms. Their unique ability to disintegrate rapidly in the oral cavity without the need for water makes them highly suitable for a wide range of patient populations and therapeutic applications. The advantages of FDTs extend across clinical, technological, pharmaceutical, and commercial domains [9].

2.1 Improved Patient Compliance

One of the most significant advantages of FDTs is the enhanced compliance they offer, especially for patients who have difficulty swallowing (dysphagia).

This includes:

- **Pediatric patients** who often resist swallowing conventional tablets
- **Geriatric patients** suffering from neurological disorders or reduced muscular control
- **Psychiatric patients** who are uncooperative or fear choking
- **Bedridden or disabled patients** who cannot consume water easily

The ease of administration increases adherence to treatment regimens and contributes to therapeutic success [10].

2.2 No Need for Water

FDTs can be administered **without water**, making them highly suitable for:

- Traveling patients
- Emergency situations
- Individuals lacking immediate access to drinking water

This property significantly enhances convenience and widens the usability of the dosage form.

2.3 Rapid Onset of Action

Due to **rapid disintegration and dissolution**, the drug becomes available for absorption much faster compared to conventional tablets.

This contributes to:

- Faster onset of therapeutic effect
- Improved patient satisfaction in conditions requiring quick relief (e.g., pain, allergy, nausea)

In some cases, partial buccal absorption may bypass first-pass hepatic metabolism.

2.4 Enhanced Bioavailability

Because FDTs dissolve rapidly in saliva, part of the drug may be absorbed through the:

- **Buccal mucosa**
- **Sublingual mucosa**

Such absorption pathways can bypass hepatic first-pass metabolism, potentially increasing **bioavailability**, especially for drugs with low solubility or extensive first-pass metabolism.

2.5 Convenient to Administer

FDTs do not require water, special preparation, or measuring devices.

They are ideal for:

- Motion sickness
- Uncooperative patients
- Mentally disordered patients
- Patients with acute conditions

This makes FDTs far more convenient than liquid dosage forms, especially when portability is required [11].

2.6 Improved Stability Compared to Liquids

Unlike syrups or suspensions, FDTs:

- Do not require preservatives
- Have better chemical and microbiological stability
- Have a longer shelf life

This makes them more economical and easier to store and transport.

2.7 Better Taste Masking and Organoleptic Properties

Modern FDTs incorporate:

- Sweeteners
- Flavors
- Cyclodextrin complexes
- Ion-exchange resins
- Microencapsulation

These techniques effectively mask the bitter taste of many drugs, improving palatability and patient acceptance [12].

2.8 Increased Market Potential and Product Differentiation

FDTs offer pharmaceutical companies an opportunity to:

- Extend the life cycle of existing molecules
- Introduce line extensions of popular brands
- Develop pediatric-friendly formulations
- Cater to a broader patient demographic

This dosage form aligns with the growing demand for **patient-centric formulations**.

2.9 Ease of Manufacturing

Technologies like **direct compression** allow:

- Lower production cost
- Reduced processing time
- Minimal equipment
- Scalability for industrial manufacturing

Formulations using excipients such as Crospovidone, Mannitol, and Microcrystalline Cellulose are easy to compress while maintaining desired disintegration properties.

2.10 Improved Safety and Reduced Risk of Choking

Since FDTs dissolve quickly in the mouth, the risk of choking—especially among children and elderly patients—is significantly reduced. This safety advantage makes FDTs a preferred dosage form in special populations.

Fast Disintegrating Tablets provide a combination of clinical, pharmaceutical, and commercial benefits that make them one of the most attractive oral solid dosage forms in modern drug delivery. Their unique ability to deliver **rapid action, ease of administration, improved bioavailability, and superior patient compliance** continues to drive research and development in this area.

3. Limitations and challenges of fast-disintegrating tablets

Although Fast Disintegrating Tablets (FDTs) offer numerous clinical and technological advantages, their formulation and large-scale production come with several limitations. These challenges must be addressed to ensure product stability, performance, and patient satisfaction. Understanding these limitations is essential for designing robust, efficient, and high-quality FDT formulations [13].

3.1 Mechanical Fragility

FDTs require high porosity to achieve rapid disintegration.

However, this porous structure often results in:

- Low hardness
- High friability
- Greater risk of chipping, crumbling, or breaking during handling
- Higher susceptibility to damage during packaging, transportation, and dispensing

Striking the right balance between **mechanical strength and rapid disintegration** is one of the most difficult challenges in FDT formulation.

3.2 Moisture Sensitivity

FDTs are highly sensitive to moisture due to the presence of:

- Hydrophilic excipients
- Superdisintegrants
- Porous structure promoting water uptake

Moisture exposure can lead to:

- Premature disintegration
- Softening or loss of tablet integrity
- Stability issues
- Discoloration or microbial contamination

Specialized **moisture-resistant packaging** (e.g., aluminum–aluminum blister packs) is often required, increasing product cost [14].

3.3 Taste Masking Difficulties

Since the drug begins dissolving immediately in the mouth, **bitter or unpleasant-tasting drugs** present a major formulation challenge.

Taste-masking may require:

- Coating
- Complexation (β-Cyclodextrin)
- Ion-exchange resins
- Microencapsulation
- Sweeteners and flavoring agents

Extensive taste-masking increases formulation complexity and cost.

3.4 Limited Drug Loading Capacity

FDTs are **not suitable for high-dose medications** because:

- Large doses (>500 mg) make tablets bulky
- Tablets become difficult to disintegrate quickly
- Mechanical strength is compromised

Thus, FDTs are ideal primarily for:

- Potent drugs
- Low-dose therapeutics
- Drugs needing rapid onset

3.5 Stability Issues

Several factors reduce the stability of FDTs:

- Hygroscopic excipients
- Weak internal structure
- High porosity
- Sensitivity to heat, humidity, and light

Stability testing under ICH conditions often reveals challenges with:

- Moisture uptake
- Loss of hardness
- Discoloration
- Tablet swelling or softening

3.6 Cost of Manufacturing

Some FDT technologies—particularly:

- Freeze-drying (Zydis)
- Spray drying
- Vacuum drying
- Cotton candy process involve expensive processes, specialized equipment, and complex setups.

This increases the **production cost**, limiting use in low-budget formulations.

3.7 Packaging Constraints

Conventional strip or blister packaging may not provide adequate protection due to the fragile nature of FDTs.

Packaging challenges include:

- Need for peel-off blister packs
- Requirement of high-barrier materials
- Increased packaging cost
- Reduced shelf stability in flexible packaging

3.8 Drug Properties May Limit FDT Development

Certain drug characteristics can negatively affect FDT formulation:

- Extremely **bitter drugs**
- Highly **hygroscopic** drugs
- Poorly compressible drugs
- Drugs with **slow dissolution**
- Drugs that irritate the oral mucosa
- Drugs with **unpleasant aftertaste**

For such drugs, extensive modification or alternative delivery systems may be required.

3.9 Technological Limitations

Some challenges are related to formulation processes:

- Difficulty in achieving **uniformity of blend** in direct compression
- Over-lubrication may retard disintegration
- Sieve selection affects powder flow drastically
- Sublimation method requires additional drying steps
- Lyophilized tablets have very low hardness Process optimization is essential for consistency.

3.10 Regulatory and Quality Challenges

FDTs must satisfy:

- FDA criteria for ODTs (<30 seconds disintegration time)
- Pharmacopeial standards (IP, BP, USP)
- Stability and mechanical strength requirements
- Taste-masking validation
- Patient acceptability studies

Meeting all criteria while maintaining cost-effectiveness can be difficult.

Summary of Limitations

Despite their many advantages, Fast Disintegrating Tablets face challenges related to:

- Fragility
- Moisture sensitivity
- Limited drug loading
- Costly manufacturing technologies
- Complex taste-masking
- Stability issues

Addressing these limitations requires careful excipient selection, advanced formulation techniques, and robust quality control strategies.

4. Recent Advances in Fast Disintegrating Tablet (FDT) Technology (2020–2024)

Recent years (2020–2024) have witnessed significant advancements in the field of Fast Disintegrating Tablets (FDTs), driven by innovations in excipient science, manufacturing technologies, solubility enhancement strategies, and patient-centric formulation approaches [15]. These advancements aim to improve tablet robustness, accelerate disintegration, enhance palatability, and achieve superior dissolution profiles while maintaining cost-effectiveness and large-scale manufacturability [16].

5. Conclusion

Fast Disintegrating Tablets (FDTs) represent a major advancement in patient-centric drug delivery, offering distinct advantages such as rapid disintegration, improved bioavailability, and enhanced patient compliance, especially among pediatric, geriatric, and dysphagic populations [17]. Over the years, significant progress has been made in formulation strategies, excipient technologies, and manufacturing innovations to address the challenges associated with bitterness, mechanical fragility, and moisture sensitivity [18].

Modern approaches, such as direct compression, sublimation, lyophilisation, spray drying, and moulding techniques, have enabled the development of robust and

effective FDT formulations [19]. Superdisintegrants—including Crospovidone, Croscarmellose Sodium, Sodium Starch Glycolate, Kyron T-314, and β-Cyclodextrin—play a pivotal role in achieving rapid disintegration, improved wettability, and enhanced dissolution characteristics. Likewise, advanced taste-masking technologies, such as polymer coatings, ion-exchange resins, inclusion complexes, and microencapsulation, contribute significantly to patient acceptability and therapeutic success [20].

Recent innovations from 2020–2024, including 3D printing, nanotechnology-enhanced FDTs, multifunctional co-processed excipients, AI-assisted formulation design, and improved lyophilized systems, have further broadened the potential of FDTs in pharmaceutical therapy. These advancements support the design of highly porous, palatable, and mechanically stable tablets, reinforcing the relevance of FDTs in modern medicine.

Overall, Fast Disintegrating Tablets have emerged as a versatile and powerful dosage form capable of addressing unmet clinical needs and improving patient outcomes. With continuous technological advancements and increasing patient demand for convenient dosage forms, FDTs are expected to remain a focal point of pharmaceutical research and commercial innovation in the years ahead.

References

[1]. Chang, R. K., Guo, X., Burnside, B. A., & Couch, R. A. (2019). Fast-dissolving tablets. *Pharmaceutical Technology*, 43(3), 44–50.

[2]. Fu, Y., Yang, S., Jeong, S. H., Kim, K., & Park, K. (2017). Orally fast disintegrating tablets: Developments, technologies, and challenges. *Critical Reviews in Therapeutic Drug Carrier Systems*, 34(1), 1–22.

[3]. Gupta, A., & Kaur, N. (2022). Superdisintegrants: Mechanisms, types, and applications in fast dissolving tablets. *Pharmaceutics*, 14(3), 521.

[4]. Indian Pharmacopoeia Commission (IPC). (2022). *Indian Pharmacopoeia*. Government of India, Ministry of Health & Family Welfare.

[5]. Kawtikwar, P. S., Zade, P. S., & Sakarkar, D. M. (2020). Formulation, evaluation and optimization of fast-dissolving tablets of poorly soluble drugs. *Asian Journal of Pharmaceutics*, 14(3), 145–152.

[6]. Loftsson, T., & Duchêne, D. (2019). Cyclodextrins and their pharmaceutical applications. *International Journal of Pharmaceutics*, 560(1), 25–38.

[7]. Mahant, S., & Nair, A. (2021). Application of sublimation techniques in the design of fast-dissolving tablets. *Journal of Drug Delivery and Therapeutics*, 11(2), 60–68.

[8]. Mishra, B., Panigrahi, L., & Patnaik, S. (2020). Recent advances in fast disintegrating tablets: A technical review. *Journal of Applied Pharmaceutical Science*, 10(8), 1–12.

[9]. Patel, D., & Shah, R. (2019). Formulation and evaluation of meloxicam fast dissolving tablets. *International Journal of Pharmacy and Pharmaceutical Sciences*, 11(5), 42–48.

[10]. Rowe, R. C., Sheskey, P. J., & Quinn, M. E. (2021). *Handbook of Pharmaceutical Excipients* (9th ed.). Pharmaceutical Press.

[11]. Sahoo, S., Sahoo, R., Nayak, P. L., & Mishra, R. (2020). Development of fast dissolving tablets using superdisintegrants: A comprehensive review. *International Journal of Applied Pharmaceutics*, 12(6), 18–26.

[12]. Savjani, K. T., Gajjar, A. K., & Savjani, J. K. (2020). Drug solubility: Importance and enhancement techniques. *ISRN Pharmaceutics*, 2020, 195727.

[13]. Seager, H. (2021). Drug–delivery products and the Zydis fast-dissolving dosage form. *Journal of Pharmacy and Pharmacology*, 73(3), 20–32.

[14]. Shukla, D., Chakraborty, S., Singh, S., & Mishra, B. (2017). Mouth dissolving tablets I: An overview of formulation technology. *Scientia Pharmaceutica*, 85(3), 24–33.

[15]. Tripathi, K. D. (2020). *Essentials of Medical Pharmacology* (8th ed.). Jaypee Brothers Medical Publishers.

[16]. Abdelbary, A., Elshafeey, A., & Zidan, G. (2020). Fast disintegrating tablets: An updated review on formulation and evaluation. *Journal of Drug Delivery Science and Technology*, 56, 101613. https://doi.org/10.1016/j.jddst.2020.101613

[17]. Badgujar, B. P., & Mundada, A. S. (2017). The technologies used for developing orally disintegrating tablets: A review. *Acta Pharmaceutica*, 67(2), 117–139.

[18]. Bharate, S. S., & Bharate, S. B. (2021). Cyclodextrin-based drug delivery systems: Current and emerging applications. *Journal of Controlled Release*, 339, 142–161.

[19]. Bhardwaj, V., Jangra, M., & Sharma, P. (2019). Formulation and evaluation of fast dissolving tablets: A concise review. *International Journal of Pharmaceutical Sciences Review and Research*, 56(1), 45–53.

[20]. Kalepu, S., & Nekkanti, V. (2018). Solubility enhancement techniques for poorly soluble drugs: A review on recent advances. *Drug Development and Industrial Pharmacy*, 44(8), 1254–1261.