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Fast Dissolving Tablets: A Comprehensive Overview of Formulation and Manufacturing

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Abstract

Despite a number of drawbacks, the oral drug delivery system is still the recommended method of medication delivery since it is easier to administer and improves patient compliance. By creating "fast dissolving tablets" (FDTs), which dissolve or disintegrate quickly without water in the mouth in a matter of seconds because of the action of a superdisintegrants or by optimising the pore structure in the formulation. Fast Dissolving Tablets (FDTs) represent an innovative drug delivery system. This article provides a comprehensive review of FDTs, covering different components used in the formulation, manufacturing technologies along with their advantages, limitations and clinical applications.

Key words: fast dissolving tablets, superdisintegrants, oral drug delivery system, manufacturing technologies.

Introduction

Fast-dissolving tablets (FDTs) are innovative oral dosage forms designed to dissolve or disintegrate quickly in the mouth without the need for water. These tablets are especially beneficial for patients who experience difficulty swallowing (dysphagia), such as children, the elderly, or those with neurological conditions. They offer convenience, improved patient compliance, and rapid onset of action, making them suitable for acute conditions. [1]

FDTs are formulated using superdisintegrants and techniques like freeze-drying, direct compression, or spray drying. When placed on the tongue, the tablet absorbs saliva, breaks apart, and releases the active drug for absorption. Commonly used in medications for allergies, pain relief and nausea. FDTs are also ideal for improving bioavailability in certain drugs. Their portable and water-free administration enhances user convenience, particularly in emergency or travel settings. [2,3]

❖ Key Characteristics of FDTs

Disintegration Time: Typically disintegrate within 30 seconds to 3 minutes in the oral cavity.

Drug Release: It provide systemic or local effects through buccal absorption or gastrointestinal absorption.

Palatability: Taste masking is critical for patient acceptance, especially for bitter drugs. [4,5]

❖ Formulation Components

a) Superdisintegrants

Accelerate the breakdown of the tablet into smaller fragments for rapid disintegration.

Work by swelling, wicking, or deformation recovery when in contact with saliva.

Examples: Croscarmellose sodium (e.g., Ac-Di-Sol, Sodium starch glycolate, Crospovidone (Polyplasdone)

b) Fillers (Diluents)

Add bulk to the formulation and improve mouthfeel.

Should dissolve readily in saliva and contribute to a pleasant taste.

Examples: Mannitol, Lactose, Microcrystalline cellulose. [6]

c) Binders

Provide mechanical strength and integrity to the tablet.

Examples: Polyvinylpyrrolidone (PVP), Hydroxypropyl methylcellulose (HPMC)

d) Lubricants

Reduce friction during tablet compression and ejection.

Examples: Magnesium stearate, Talc, Stearic acid.[7]

e) Flavoring Agents

Mask unpleasant tastes and enhance palatability.

Examples: Natural Flavors: Orange, lemon, mint, strawberry.

Artificial Flavors: Synthetic fruit or sweet flavors.

f) Sweeteners

Enhance taste and mask bitterness of APIs.

Examples: Aspartame, Sucralose, Saccharin.

g) Wetting Agents

Improve the wettability of the tablet, facilitating rapid saliva penetration.

Examples: Sodium lauryl sulfate (SLS), Polysorbates (e.g., Tween 80.

h) Effervescent Agents

Generate carbon dioxide in the presence of saliva, aiding disintegration.

Examples: Citric acid and sodium bicarbonate. [8]

❖ **Technologies for FDT Manufacturing**

1. Direct Compression

The simplest and most economical method of producing tablets is direct compression. This method may now be used to prepare Fast Dissolving Tablets due to the availability of better excipients, particularly superdisintegrants and sugar-based excipients.

Advantages:

- Economical and requires fewer processing steps.
- Suitable for heat-sensitive APIs due to the absence of heat or solvents.
- Easily scalable for large-scale production.

Limitations:

- Limited mechanical strength of tablets, requiring careful packaging.
- Uniformity issues with APIs present in very low doses.[9]

2. Lyophilization (Freeze-Drying)

Lyophilization is the process of drying at a low temperature while removing water by sublimation. A very porous structure is produced by freeze-drying a drug in a water-soluble matrix. When put in the oral cavity, the lyophilization-prepared tablets dissolve quickly in less than five seconds because saliva quickly enters the pores. Drugs that are heat sensitive, or thermolabile, benefit from lyophilization.

Advantages:

- Extremely fast disintegration due to high porosity.
- Suitable for heat-sensitive drugs as it uses low temperatures.
- Creates elegant and light-weight tablets.

Limitations:

- Expensive and time-consuming process.
- Tablets are fragile and require specialized packaging to prevent breakage.
- Limited drug-loading capacity. [10,11]

3. Sublimation

Inert solid components that volatilise quickly, such as urea, camphor ammonium carbonate, ammonium bicarbonate, and hexamethylene-tetramine, are incorporated into porous material to achieve fast disintegration and dissolution.

They were crushed after being combined with other substances. Reduced pressure and a little amount of warmth are used to develop the volatile substance, leaving the bulk in a porous state. The sublimation method's properties include its porous nature and the use of solvents such as benzene and cyclohexane. [12]

Advantages:

- Produces highly porous tablets for rapid disintegration.
- Suitable for APIs that require quick onset of action.

Limitations:

- Requires controlled environmental conditions for sublimation.
- Additional manufacturing steps increase costs.

4. Spray Drying

Spray drying may create tiny, extremely porous powders that dissolve quickly. This method is based on a particulate support matrix, which is made into a fine, extremely porous powder by spray drying an aqueous composition that contains the support matrix and other ingredients. After that, it was combined with the active components and compacted to create tablets. Hydrolysed and non-hydrolyzed gelatins are used as supporting agents, mannitol is used as a bulking agent, sodium starch glycolate or crosscarmellose sodium is used as a disintegrating agent, and an acidic substance (like citric acid) or alkali substance (like sodium bicarbonate) is added to improve dissolution and disintegration. When submerged in an aqueous media, the tablet that was crushed from the spray-dried powder dissolved in 20 seconds. [13]

Advantages:

- Produces fine particles with improved solubility and disintegration properties.
- Allows for encapsulation of bitter-tasting drugs.

Limitations:

- Requires specialized equipment and expertise.
- Not suitable for heat-sensitive drugs. [14]

5. Molding

With this approach, water-soluble materials are used to make moulded tablets, which dissolve quickly and completely. A hydroalcoholic solvent is used to wet the powder mixture, which is then moulded into tablets at a pressure lower than that required for traditional tablet compression. After that, the solvent is eliminated by air drying. Compared to compressed tablets, moulded tablets are much less compact. Because of their porous nature, they dissolve more readily.

Advantages:

- Simple and cost-effective.
- Creates tablets with a smooth and palatable texture.

Limitations:

- Limited mechanical strength.
- Requires controlled humidity to avoid rewetting during storage.

6. Cotton Candy Process

This procedure gets its name from the fact that it creates a crystalline structure that resembles floss using a special spinning mechanism, much like cotton candy. In the cotton candy method, flash melting and spinning are done simultaneously to create a matrix of polysaccharides or saccharides. The resulting matrix undergoes partial recrystallization to enhance its compressibility and flow characteristics. After being ground and combined with excipients and active substances, this candy floss matrix is compressed to FDTs. Nevertheless, at 30–40% lower temperatures than sucrose, other polysaccharides, such as polydextrose and polymaltodextrins, can also be converted into fibers. The tablets produced with this method have a very pleasing mouthfeel because the sugars dissolve quickly in the

presence of saliva and are highly porous in nature. [15,16]

Advantages:

- Produces tablets with excellent mouthfeel and fast disintegration.
- Highly palatable, ideal for pediatric formulations.

Limitations:

- Requires specialized equipment for floss production.
- Moisture-sensitive process and products. [17]

7. Mass Extrusion

This method uses a solvent mixture of water-soluble polyethylene glycol and methanol to soften a blend of active drug and other ingredients. The resulting softened mass is then extruded through a syringe or extruder to create a cylinder of product, which is then cut into even segments using heated blades to create tablets. The granules of bitter-tasting medications can be coated with the dried cylinder to cover up their bitter flavor.

Advantages:

- Uniform drug content in the extruded segments.
- Suitable for small-scale production.

Limitations:

- Time-consuming process.
- Requires additional shaping steps.

8. 3D Printing (Emerging Technology)

The design, shape, and drug release profiles of tablets can be precisely customized thanks to 3D printing, an emerging technology in FDT manufacture. A digital model is used to create tablets layer by layer, enabling controlled release and customized dosage. Stable versions of APIs and cellulose derivatives are examples of printable excipients. Significant benefits of this technology include on-demand manufacturing, tailored medication, and the capacity to create intricate drug-release mechanisms. However, there are difficulties due to limited regulatory frameworks, expensive starting expenses, and sophisticated technology. Nevertheless, 3D printing is poised to transform the pharmaceutical sector by improving drug delivery's accuracy and adaptability.

Advantages:

- Customizable dosing and release profiles.
- Potential for personalized medicine.

Limitations:

- High initial costs and technological barriers.
- Limited regulatory guidance for widespread use.

9. Nanoionization

The medicine is ground using a patented wet-milling approach to reduce the drug's particle size to nano size in a freshly developed nanomelt technology. Surface adsorption on specific stabilizers prevents the drug's nanocrystals from clumping together, and these stabilizers are then integrated into FDTs. This method works particularly well for medications that aren't very soluble in water. Additional benefits of this technology include a cost-effective manufacturing process, conventional packaging because of its remarkable durability, a wide range of doses (up to 200 mg drug per unit), and the rapid disintegration/dissolution of nanoparticles, which increases absorption and, consequently, increases bioavailability and reduces dosage.

Advantages:

- Overcomes solubility issues of poorly soluble drugs.
- Provides faster onset of action.

Limitations:

- Complex and expensive manufacturing.
- Regulatory challenges. [18,19]

❖ **Applications of Fast Dissolving Tablets (FDTs)**

➢ **Pain Management:**

For rapid relief in acute pain conditions like migraines and headaches (e.g., ibuprofen, rizatriptan).

- **Antiemetics:**

Effective in managing nausea and vomiting, especially in chemotherapy-induced or motion sickness cases (e.g., ondansetron, metoclopramide).

- **Allergies:**

Used for rapid symptom relief in allergic rhinitis and seasonal allergies (e.g., loratadine, cetirizine).

- **Central Nervous System Disorders**:

Ideal for anxiety, schizophrenia, and depression due to improved compliance (e.g., alprazolam, mirtazapine).

- **Cardiovascular Conditions:**

Quick relief in angina and heart attack emergencies (e.g., nitroglycerin, aspirin).

- **Pediatrics and Geriatrics:**

Convenient for children and elderly patients with swallowing difficulties (e.g., paracetamol, multivitamins).

- **Motion Sickness:**

Provides fast relief from nausea and dizziness during travel (e.g., dimenhydrinate, meclizine).

- **Cough and Cold Remedies:**

Over-the-counter solutions for symptoms like nasal congestion and allergies (e.g., phenylephrine).

- **Seizures and Emergency Use:**

Immediate action in conditions like seizures (e.g., midazolam) or angina attacks.

- **Nutraceuticals:**

Used for dietary supplements, including multivitamins and probiotics, to enhance patient convenience. [20,21]

Conclusion

Fast Dissolving Tablets are a promising drug delivery system with significant potential to improve therapeutic outcomes and patient compliance. While challenges such as fragility and drug loading remain, advancements in technology and materials continue to drive innovation in FDT development. Future research should focus on overcoming current limitations and expanding the applications of FDTs across various therapeutic areas.

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