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Review TDD

Rapid-on-Tongue Delivery: A Review of ODT Technologies, Taste Masking, and Compliance

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Abstract

Orodispersible Tablets (ODTs), another name for Fast Dissolving Drug Delivery Systems (FDDS), are innovative drugs that dissolve in the mouth rapidly without requiring water. These will be especially helpful for kids, the elderly, and others who have difficulty swallowing ordinary tablets or capsules. Superdisintegrants are used in these pills to break down quickly in the mouth, while flavorings or sweeteners are used to cover up any harsh or unpleasant taste. Because they dissolve on the tongue, which accelerates the medication's action, they offer comfort more rapidly. ODTs are commonly used to treat mental illnesses like depression or schizophrenia, cardiovascular conditions like high blood pressure, and acute symptoms like motion sickness or allergies. Most of these tablets are made by direct compression, which is a simple and affordable method, while additional methods like mold, freeze, or spray drying are also used. Since they are simple to take, act quickly, and don't require water, they improve patient compliance, comfort, and safety. Due to ongoing research and development, MDDS are becoming increasingly important in modern, patient-focused healthcare systems.

Keywords: Rapid-on-Tongue delivery, drug delivery, fast-dissolving medication delivery system, fast dissolving tablets, Over-the-Counter (OTC) medications

INTRODUCTION

Oral medicine administration is the most common and advised method because it is easy, safe, and comfortable for most patients. However, normal oral dosage forms like tablets and capsules may be challenging for youngsters (pediatric patients) and the elderly (geriatric patients), who often suffer from a disorder called dysphagia (difficulty in swallowing). This problem may cause patients to forget to take their medications, which could lead to poor treatment compliance. To solve this issue, a novel type of medication delivery system called the Fast-Dissolving Medication Delivery System (FDDS) was created. Other terms for Oro dispersible tablets (ODTs), mouth-melting tablets, these special tablets, often referred to as fast-dissolving tablets, are made to dissolve or break down quickly in the mouth, usually within 5 to 30 seconds, without requiring chewing or drinking. Because they simply need to dissolve in the mouth's saliva, they are more practical and patient-friendly. Effective taste masking is crucial to the development of FDDS since the pill dissolves in the mouth. To do this, sweeteners, sugar, or taste-masking coatings are typically utilized. Another important formulation component is the use of super disintegrants, which hasten pill disintegration and enhance bioavailability. These disintegrants can be integrated using one of three methods: intragranular (within the granules), extragranular (outside the granules), or a combination of the two. FDDS can be produced in several ways, such as tablet molding, solid dispersion, and wet granulation. However, because of its ease of use, affordability,

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and suitability for large-scale production, direct compression is the most extensively used technique. The comfort and compliance of the patients are greatly enhanced by this novel technique [1].

Beyond their ease of use and rapid breakdown, fast dissolving tablets (FDTs) offer several noteworthy advantages. These tablets are very portable and useful because they don't require water or other special circumstances to be taken. As a result, they are ideal for patients who need medication while traveling or in situations where water sources are limited. FDTs are very helpful for people who have difficulty swallowing, such as those with Parkinson's disease, arthritis, or cognitive impairments. Any medical treatment's effectiveness depends on patient compliance, which MDTs can significantly boost by offering a more practical and easily accessible dosage form. FDT is used in several therapy fields. Originally developed for over-the-counter (OTC) medications such as analgesics and antacids, they are now often used for a variety of prescription medicines. These are medicines, including ones that help with mental health problems like depression or anxiety. depression and schizophrenia as well as treatments for heart disease, allergies, and other chronic ailments. The flexibility of FDT formulation allows for the incorporation of a wide range of active pharmaceutical components, from small molecule drugs to more complex biologic compounds. FDTs are a fantastic option for developing patient-centred drug delivery systems that enhance user convenience and therapeutic outcomes due to their adaptability (Figure 1).

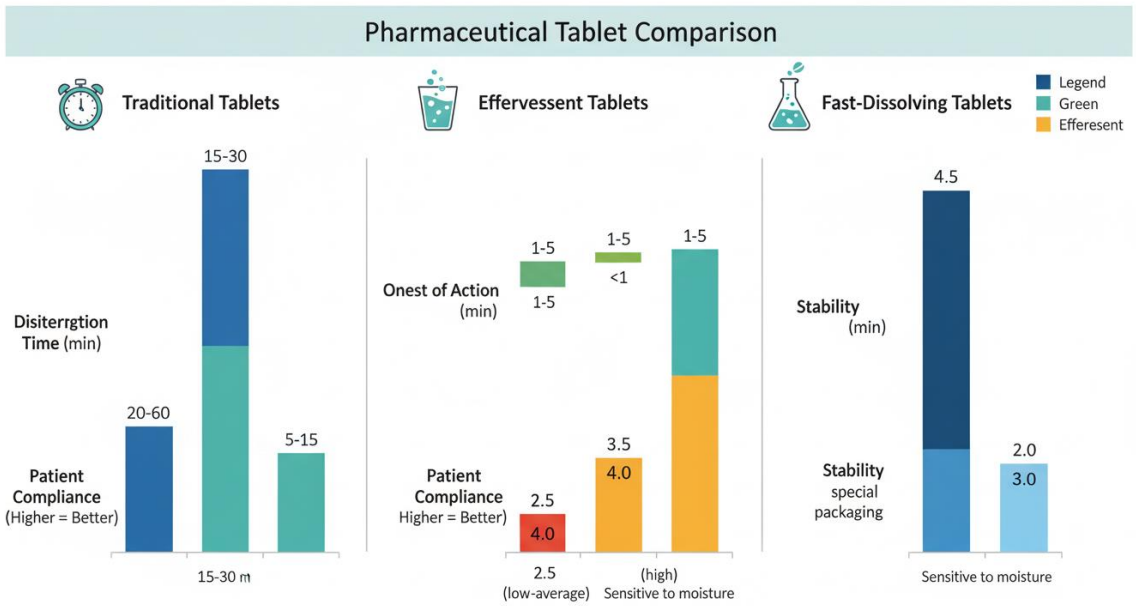

Figure 1. Bar chart comparing traditional tablets, effervescent tablets, and fast-dissolving tablets based on parameters such as disintegration time, onset of action, patient compliance, and stability.

IDEAL CHARACTERISTICS OF FDTs

A Fast-Dissolving Tablet (FDT) should have the following crucial features: It should dissolve or disintegrate quickly in the oral cavity following placed on the tongue, typically within a few seconds. It shouldn't require water or any other liquid to begin operating. The patient should have a smooth and pleasurable experience as it dissolves without leaving any residue or particles in their tongue. The formulation should have a fair price for widespread use and accessibility. It should be stable and continue to function well in a range of environmental conditions, such as temperature and humidity, for a longer shelf life and dependable performance [2].

ADVANTAGES OF FAST DISSOLVING TABLETS (FDTs)

Fast- dissolving tablets are perfect for a variety of patient demographics and clinical settings because of their many important advantages. Easy for patients who struggle to take traditional tablets, like young

children, the elderly, those who are unconscious, or those with mental problems. Since they don't need water, they are quite useful when traveling or in locations where water is difficult to obtain. The rapid breakdown and dissolution regarding the tablet in the oral cavity lead to a quicker beginning of action, which is very useful in acute or emergency conditions. 3improved patient compliance, especially for individuals who are bedridden, busy, or disabled and may not have access to water while taking their prescription drugs. The pleasant mouthfeel of bitter drugs and their capacity to mask taste help boost pharmaceutical acceptability, particularly in young patients (Figure 2).

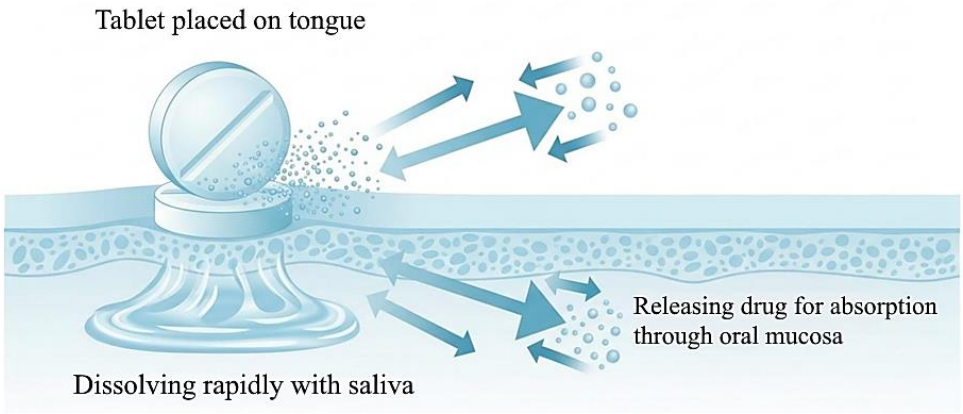

Figure 2. Infographic showing the concept of fast-dissolving oral tablets (FDTs).

SALIENT FEATURES OF FAST DISSOLVING TABLETS (FDTs)

They have several important features that enhance their effectiveness, usefulness, and patient compliance: Easy administration for children (pediatric), older patients (geriatric), and adults with mental health conditions (psychiatric) who have difficulty swallowing or refuse to do so [3]. Since they don't need water, they're perfect for patients who are constantly on the road or in locations with limited water supplies. The oral cavity's quick breakdown and absorption of medication allow for a rapid onset of effect, which is helpful in situations where immediate relief is required. Pre-gastric absorption, in which the drug is taken up through the mouth's mucous membranes and throat, can lead to higher bioavailability than traditional oral dosing forms [4].

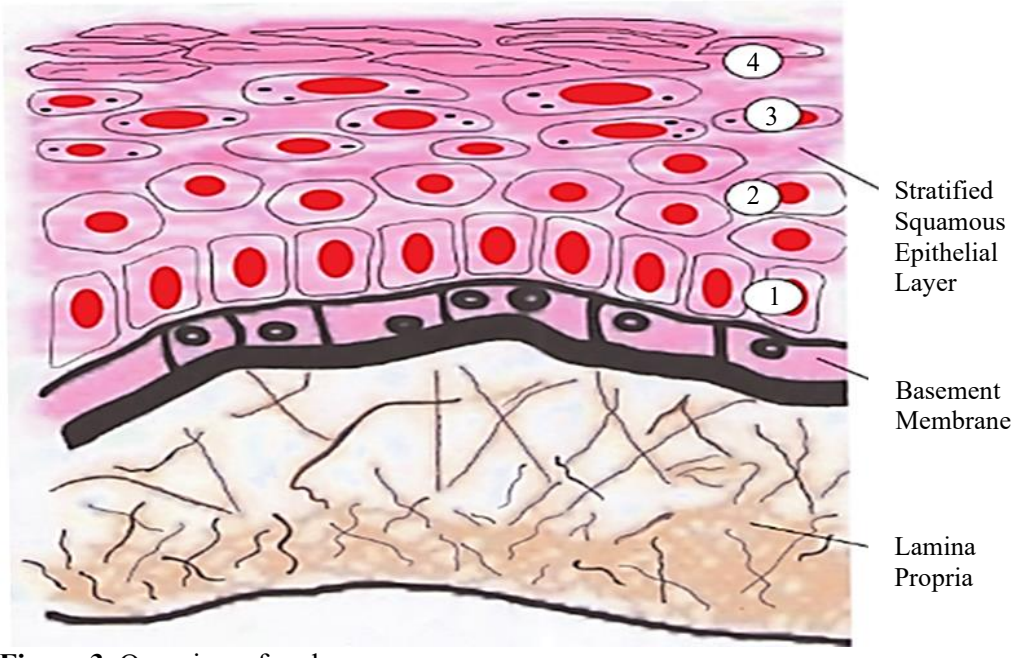

Figure 3. Overview of oral mucosa.

OVERVIEW OF ORAL MUCOSA

The oral mucosa, the moist tissue lining the inside of the mouth, is vital for protecting underlying structures and sustaining several oral functions. It consists of several distinct layers: The outermost layer, the stratified squamous epithelium, acts as a protective barrier. Below this is the foundation membrane, which is followed by the lamina propria, a layer of connective tissue, and the submucosa, the deepest layer, which contains glands, blood vessels, and nerves. The stratified squamous epithelium found in other body parts is like the epithelial layer of the oral mucosa. Its bottom layer of basal cells is mitotically active, meaning that new cells are constantly being created. During their maturation, these cells differentiate and ascend through intermediary layers to the surface. New cells constantly arise from under the surface to replace the old cells that are shed there. As a result of its layers, the oral mucosa can act as an effective barrier, encourage absorption in particular areas, and maintain overall oral health (Figure 3).

INGREDIENTS USED IN FAST DISSOLVING TABLETS (FDTs)

Fast dissolving tablets are formulated with a mixture of ingredients to improve drug release, flavour, and stability while speeding up the tablet's breakdown in the oral cavity. These excipients work best at temperatures between 30 and 35°C. 1.

Superdisintegrants [5]

The kind and concentration of the tablet determine its effectiveness; superdisintegrants aid in the rapid dissolution of tablets in the oral cavity. Microcrystalline cellulose (MCC), crospovidone, are a few examples.

Binders [6]

Ensure tablet integrity during manufacturing and handling, give the tablet mechanical strength, and hold the ingredients together. Polyvinyl pyrrolidone (PVP), hydroxypropyl methylcellulose (HPMC), and maltodextrin are a few examples.

Flavouring Agents

Improve the taste and texture of the tablet. This is important for patient compliance, especially when oral formulations are being used. Examples include peppermint oil, menthol, aspartame, and citric acid.

Sweeteners

Enhance flavor and palatability while concealing the harshness of the active component. Examples include aspartame, stevia, xylitol, and sucrase.

Lubricants

reduce friction during tablet compression and aid in the tablets' ejection from the press. Enhance the formulation's flow characteristics. Examples include talc, magnesium stearate, and stearic acid.

Diluents and Fillers

Increase the tablet's weight, particularly for medications with modest dosages, and give it a consistent size and shape. Examples include microcrystalline cellulose (MCC), lactose, mannitol, and sorbitol.

FORMULATION AND CONSIDERATION OF MDTs (MOUTH DISSOLVING TABLETS)

Criteria for Drug Selection

When selecting a drug to create mouth dissolving tablets (MDTs), the following considerations should be made:

- *Palatability:* The drug shouldn't have an unpleasant or bitter taste.
- *Dosage:* A dosage of less than 20 mg is advised for a medicine to be successfully included in MDTs.
- *Molecular Weight:* The drug should have a moderate or low molecular weight to facilitate rapid absorption.

- *Solubility:* The drug should dissolve and absorb quickly in the oral cavity by being soluble in both water and saliva.
- *First-Pass Metabolism:* Drugs with high first-pass metabolism are suitable for MDTs due of their ability to go around the liver's pathway by allowing absorption through the oral mucosa [4].

Technologies Used in the Formulation of Fast Dissolving Tablets (FDTs) [6]

Non-Patented (Conventional) Technologies

These are open-access, commonly utilized techniques that do not require special licensing or intellectual property rights.

- *Freeze Drying (Lyophilization):* Removes moisture by freezing and then drying under vacuum, resulting in a porous, fast-dissolving tablet.
- *Tablet Molding:* Uses heat and pressure to shape the drug into a mold, improving taste and solubility.
- *Spray Drying:* Converts liquid formulations into dry powder, enhancing solubility and uniformity.
- *Mass Extrusion:* Mixes the drug with a polymer to form granules, improving flow and compressibility.
- *Sublimation:* Uses a volatile ingredient that sublimates, creating pores in the tablet for quick disintegration.
- *Cotton Candy Process:* Spun sugar-like fibers are compressed into tablets, making them highly porous.
- *Direct Compression:* A simple and cost-effective method using directly compressible excipients.
- *Melt Granulation:* Uses molten binders to agglomerate particles, improving tablet cohesion.
- *Phase Transition Process:* Involves heating and cooling steps to form a stable, quick-dissolving matrix.

Patented (Proprietary) Technologies

These are advanced, company-specific technology that is covered by intellectual property laws.

- *Zydus Technology:* Developed by Zydus Cadila for rapid disintegration.
- *Orasolv Technology:* Uses effervescent agents to aid quick tablet breakdown.
- *Durasolv Technology:* Offers durable tablets that dissolve quickly in the mouth.
- *Wowtab Technology:* Combines water-soluble and water-insoluble components for fast melt.
- *Dispersible Tablet Technology:* Designed to disperse easily in the mouth or water.
- *Fastab Technology:* Produces tablets that disintegrate within seconds.
- *OraQuick Technology:* Ensures high mechanical strength with fast dissolution.
- *Lyoc Technology:* Freeze-dried porous tablets with high stability.
- *Quick Solv Technology:* Produces thin, fast-dissolving oral films or tablets.
- *Nanocrystal Technology:* Reduces particle size to enhance dissolution rate.

Non-Patented Technologies for Fast Dissolving Tablets (FDTs)

Molding Method

Molded tablets dissolve or disintegrate quickly when taken because they are made of water-soluble ingredients. They are created by mixing a hydroalcoholic solvent – a concoction of alcohol and water – with the powdered ingredients to form a wet substance. After that, this mass is molded into tablets using light pressure, which is less than what is required for the traditional tablet compression. After molding, the tablets are dried using air to remove the solvent. This process creates a structure of the tablet's pores, which makes it simpler to dissolve in the mouth or physiological fluids. Binders like polyvinylpyrrolidone (PVP K30), sucrose, or acacia can be added during the formulation process to lessen breakage and increase the mechanical strength (hardness) of the tablets [7].

Sublimation Method (Fast Dissolving Tablets)

In order to mixture and inside the tablet structure that accelerate the tablet's disintegration and allow it to dissolve quickly in the presence of saliva, the sublimation technique involves adding a volatile

ingredient (such as a volatile salt) to the tablet formulation, mixing it with other ingredients to create a homogenous mixture, and then heating or vacuuming the mixture to remove the volatile ingredient. In this process, ammonium bicarbonate, urea, camphor, and naphthalene are often utilized volatile agents.

Spray Drying Method (Fast Dissolving Tablets)

To create thin, porous particles, a liquid formulation is sprayed into a stream of heated air, which accelerates the solvent's evaporation. A very porous powder is produced by spray-drying the mixture. mixing this powder with the active pharmaceutical ingredient (API). compressing the final mixture to create tablets. Important Features: Tablets made using this method disintegrate in less than 20 seconds. Blister packs shield products like those made by Zydus from moisture and external factors.

The Direct Compression Method

The direct compression method is a simple and efficient way to make fast-dissolving tablets (FDTs). Because it requires fewer processing steps, has lower production costs, and can result in a greater final tablet weight, it can enable larger dosages of medication than other methods. Tablets made via direct compression require the breakdown and dissolution of disintegrants, water-soluble excipients, and effervescent agents. The effectiveness of disintegrants is influenced by the size and hardness of tablets. To ensure rapid breakdown, it is essential to maintain a moderate or low pill weight, low hardness, and minimal physical resistance. Selecting the appropriate type and concentration of disintegrant is necessary to achieve high drug release and quick tablet breakdown. Superdisintegrant are very effective due to the combined actions of swelling and water absorption since they increase the wetted surface area of the formulation, improving tablet wettability and accelerating dispersion. However, the concentration of the superdisintegrant must be optimized. Below the threshold concentration, a higher superdisintegrant content reduces disintegration time; but, above this point, disintegration time may remain unchanged or even grow without any further benefit.

Patented Technologies

Zydus technology, Lyco, Quick Solv, Nanocrystal technology, Flashtab technology.

PATENTED TECHNOLOGIES FOR FAST DISSOLVING TABLETS (FDTs)

Zydus Technology

Using Zydus Technology, the medication is physically contained within a matrix made of a polymer and a sugar (saccharide). Common polymers include alginates, polyvinyl alcohol, polyvinylpyrrolidone (PVP), partially hydrolysed gelatine, hydrolysed dextran, dextrin, and acacia. The drug and matrix ingredients in blister packs are prepared as a solution or dispersion. These are then rapidly frozen using liquid nitrogen. After freezing, the solvent is removed by sublimation, commonly referred to as freeze-drying, creating porous wafers that disintegrate quickly in the mouth. The medicine must be stable chemically, insoluble in water, and have a particle size of less than 50 microns, according to Zydus Technology's main requirements. Medication that dissolves in water should not be taken more than 60 mg.

Lyoc's Technology

Blister packs containing the oil-in-water emulsion utilized in Pharmalyoc's Lyoc are then freeze-dried. Using an inert filler prevents uneven drying throughout the process by increasing viscosity and inhibiting sedimentation. On the other hand, lowering porosity by overuse of filler could prevent the tablet from dissolving.

Quicksolve Technology

This process, which is patented by Janssen Pharmaceuticals, uses a dual-solvent technique to produce a matrix that dissolves rapidly. The matrix components are spread or dissolved in water and then frozen. The water is subsequently extracted via solvent extraction using the excess alcohol. This method creates a tablet with sufficient mechanics and constant porosity that dissolves rapidly.

Nanocrystal Technology

Technology of Nanocrystals Elan (King of Prussia) is the patent holder of this technology, which involves lyophilizing (freeze-drying) a colloidal dispersion containing the medication and water-soluble excipients. Then, without the need for conventional processes like granulation, mixing, and tableting, the formulation is loaded straight into blister packs. It is suitable for formulations with modest quantities of medication since it also reduces drug loss.

Flashtab Technology

Ethypharm (France) developed Flashtab Technology, which involves compressing the tablets after granulating excipients (such as carboxymethylcellulose and cross-linked polyvinylpyrrolidone). The resultant tablets are useful for quick drug delivery since they dissolve in less than a minute and have strong mechanical strength.

Several emerging technologies for fast-dissolving tablets (FDTs) are attracting increased attention from pharmaceutical research.

3D Printing Technology

Custom mouth-dissolving tablet technology that can be 3D printed with precise drug dosages and complex shapes. permits controlled release patterns and multi-drug combinations in personalized therapy. Improved patient compliance, rapid prototyping, and personalized dosing are among the advantages [8].

Hot-Melt Extrusion, or HME [9]

without the use of solvents, melting and forming drug and polymer mixtures into tablets. makes tablets with improved solubility and bioavailability, especially for drugs that don't dissolve well in water. Benefits include continuous manufacturing, scalability, and improved drug dispersion.

Electrospinning [10]

The drug molecules that are electrospun into extremely thin, fibrous mats disintegrate rapidly in saliva. provides a large surface area, rapid dissolution, and taste concealment. Improved drug loading, rapid dissolution, and creative drug delivery methods are among the advantages.

Microneedle-Integrated Mouth Dissolving Tablets [11]

By piercing the oral mucosa, tiny microneedles are used in mouth dissolving tablets with integrated microneedles to enhance drug absorption. blends rapid disintegration with improved systemic administration. Benefits include its rapid onset, non-invasive nature, as well as avoiding first-pass metabolism [12–24].

CONCLUSION AND FUTURE PROSPECT

Fast Dissolving Drug Delivery Systems (FDDS), also called Orodispersible Tablets (ODTs), offer a convenient and effective alternative to conventional tablets and capsules that are often difficult to swallow, especially for pediatric, geriatric, and dysphagic patients. these tablets break down quickly in the mouth, in just seconds without requiring water, improving patient compliance and comfort. FDTs are suitable for an extensive selection of medications and medicinal areas, including psychiatric, cardiovascular, and acute conditions like motion sickness and allergies. In conclusion, MDDS effectively address the challenges of swallowing difficulties and delayed drug action associated with traditional oral dosage forms, providing a rapid, safe, and patient-friendly option. Their fast onset of action through pre-gastric absorption, pleasant taste, and reduced choking risk make them especially valuable for vulnerable patient groups and emergency treatments. With ongoing advances in pharmaceutical technologies and excipient innovation, mouth Tablets that dissolve are ready to work to play an increasingly important role in enhancing medication adherence, improving therapeutic outcomes, and offering personalized drug delivery solutions in modern healthcare.

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