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FAST DISSOLVING TABLETS: BRIDGING GAP IN PATIENT COMPLIANCE - A REVIEW

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ABSTRACT

Fast-dissolving tablets have become widely accepted and popular, especially among older patients with Parkinson's illness or tremors in hand and juvenile patients with underdeveloped muscles and neurological systems.[1] In contemporary times, certain forms of solid dosage, such as capsules and tablet forms, are confronted with challenges like trouble swallowing, which makes it difficult for the patients to follow their prescribed course of action and reduces the effectiveness of the treatment. Although oral dose and oral administration continue to be the most effective ways to take different medications, they have drawbacks, including the first-pass metabolism and limited application to patients with mental illness, immobile patients, and uncooperative patients. Fast-dissolving tablets can disintegrate or break down quickly in saliva without Water. They prepare them for rapid dissolution, often achieving this within a few seconds (usually less than 60 seconds), which earns them the title of proper FDTs. Super disintegrating agents enhance the tablet's breakdown in the buccal cavity. These tablets provide a viable alternative for older and younger patients because of their portability, ease of manufacture, accurate dosing, and robust physical and chemical stability. Fast-dissolving tablets disintegrate rapidly, leading to faster absorption and an improvement in vitro drug release time, ultimately enhancing the bioavailability of drugs in this dosage form.[2] FDT formulations combine the advantage of liquid dosage and traditional tablet formulations. Researchers and pharmaceutical companies have developed numerous conventional and patented technologies for manufacturing fast-dissolving tablets, including spray drying, sublimation, direct compression, and freeze-drying (lyophilization). This

Article briefly introduces fast-dissolving tablets, including their purpose, benefits and the criteria they meet. It also highlights some prominent features, limitations, and challenges in their development and an overview of many formulations of FDTs now available in the market.

KEYWORDS: Fast dissolving tablets (FDTs), Super disintegrants, drug delivery system, patented technologies, taste masking.

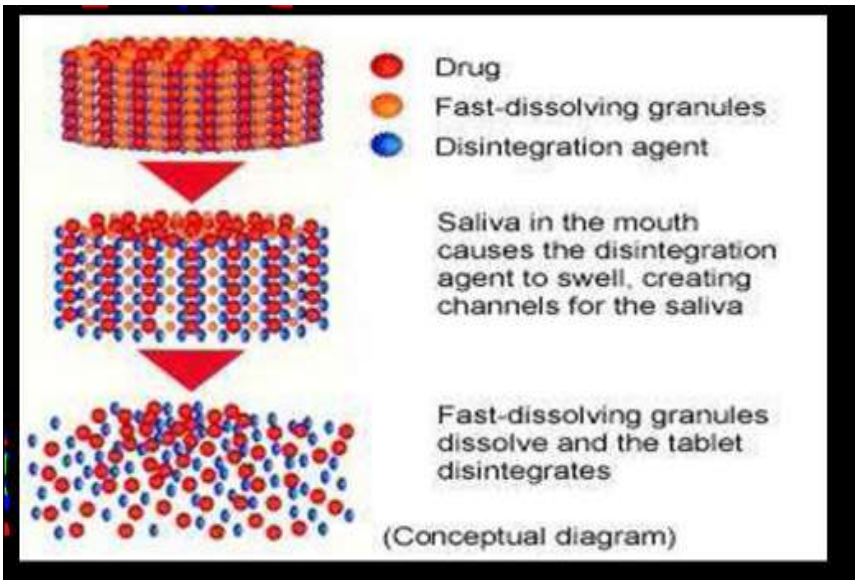
1. INTRODUCTION

Traditional drug delivery methods have long been the pioneers in drug administration. Oral administration is the most generally accepted and often used method. Individuals prefer it due to its compact size, convenience of self-administration, and relatively simple manufacturing process compared to other dosage forms.[3] However, it is essential to note some drawbacks of this approach, including difficulties in swallowing (known as dysphagia), limited bioavailability, and a delayed onset of action. Scientists have looked into addressing these issues by exploiting the “oral cavity” to increase the drug’s bioavailability and permeability. Because of its comparatively low keratinization, the buccal mucous membrane of the “oral region” offers good permeability. The "oral cavity" offers favourable permeability due to the relatively low keratinization of the buccal mucosa. Tablets that undergo absorption through the oral canal enter the bloodstream directly via a jugular vein, resulting in a quick onset of action. This approach avoids the problems related to metabolism during the first pass, the breakdown of drugs in the gastrointestinal area and enzymatic-mediated hydrolysis in the intestine.

Quick dissolving, mouth-dissolving, orodispersible and rapid dissolving are some names for Fast-dissolving tablets. Pharmaceutical companies manufacture tablets to dissolve or disintegrate rapidly in saliva, typically in less than 60 seconds. The Food and Drug Administration defines a fast-dissolving tablet as “a solid dosage form containing a medicinal substance or active ingredient that rapidly disintegrates, typically within seconds, when placed on the tongue”. According to the European pharmacopoeia, “The FDT should disperse/disintegrate in less than three minutes."[4]

There are two types of fast-dissolving tablets. The first tablet formulation allows consumption without Water and dissolves quickly in the tongue. On the other hand, the second type of tablet readily dissolves in Water to form a water-easy-to-consume

dispersion.[5] Fast-dissolving medication delivery systems are tablets that dissolve or disintegrate in the oral cavity without Water or chewing.



2. BENEFITS OF FDTs

1. Patients who have trouble swallowing the tablet, such as young children, older adults, people with mental disabilities, and bedridden patients, can easily administer it.

2. Unlike traditional dose forms, Water is not required to consume fast-dissolving tablets (FDTs). It makes taking medication easier for patients who are travelling or may not have access to Water, which ensures patients' adherence to treatment plans.[6]

3. Beneficial in situations where a swift beginning of action is needed, such as nausea from travelling, abrupt episodes of allergic reaction, or coughing.

4. It allows high drug loading and is cost-effective.

5. Pregastric absorption can decrease the side effects by requiring a smaller dosage, enhancing absorption and therapeutic efficacy.[7]

6. A quicker start of action could result from a drug's faster solubility and absorption.

7. Rapid drug therapy intervention is possible.

8. A quicker start of action could be the outcome of a drug that is absorbed more quickly through the mouth, throat and oesophagus.

3. FDTs LIMITATIONS

1. Several fast-dissolving tablets (FDTs) exhibit hygroscopic properties and cannot retain their physical integrity under typical humidity conditions, necessitating specialized packaging.

2. These tablets require greater mechanical strength, thus requiring careful Handling.

3. An incorrect medication development may result in the tongue feeling gritty and experiencing an unpleasant taste.

4. These tablet forms might not be appropriate for people who experience dry mouth from decreased salivation.

5. It can be challenging to manufacture drugs with comparatively higher dosages into FDTs.[8]

6. Medications that require frequent intake, have a short duration of action or necessitate controlled or sustained release are not suitable for fast-dissolving tablets.

7. Fast-dissolving tablets (FDTs) are highly porous. Low amounts of compression during moulding or compression cause the tablets to break easily and become brittle, making them difficult to handle.

4. REQUIREMENTS FOR FAST-DISSOLVING TABLETS

1. It should break down or dissolve in the oral cavity in seconds and does not require Water to be Water in.

2. It should give a pleasant feel to the area of the mouth.

3. It should be compatible with taste masking techniques.[9]

4. It should be more rigid and less brittle.

5. It should be less sensitive to changes in the temperature and humidity in the surroundings.

5. CHALLENGES IN FAST DISSOLVING TABLET FORMULATION (FDTs)

5.1. PALATABILITY

Because most medications have an unpleasant taste, fast-dissolving tablets (FDTs) incorporate the medication to conceal its taste. Following delivery, the active components in FDT dissolve or disintegrate in the patient's oral cavity, interacting with their taste buds. For this reason, medication flavour masking is essential to guarantee patient compliance.

5.2. HYGROSCOPICITY

Under typical temperature and humidity conditions, many orally disintegrating dosage forms show hygroscopic characteristics and cannot maintain structural integrity.[10] Therefore, products require safeguarding against moisture, necessitating specialized product packaging.

5.3. MECHANICAL STRENGTH

The tablet must possess suitable mechanical strength in proportion to the added ingredients, avoiding easy breakage or fragility. This challenge arises because the drug must disintegrate rapidly in the oral cavity while retaining sufficient mechanical durability.

5.4. WATER SOLUBILITY

A medication's ability to dissolve in Water becomes material when it is highly lipophilic or hydrophobic. The API might not break down or dissolve in the mouth in these situations, resulting in grittiness and residue.

5.5. MOUTH FEEL

Fast-dissolving tablets (FDTs) should maintain their disintegrated state as small Particles in the oral cavity and avoid forming larger fragments.[11] Furthermore, incorporating flavours and cooling agents such as menthol enhances the sensation experienced in the mouth.

5.6. AMOUNT OF DRUG

The maximum quantity of drugs included in each dose constraints the utilization of technologies employed for Fast dissolving tablets. The drug dosage must remain below 400mg for insoluble, while for soluble drugs in lyophilized dosage forms, it should not exceed 60mg. This criterion poses a particular challenge in developing fast-dissolving oral films or wafers.

5.7. SENSITIVITY TO ENVIRONMENTAL CONDITIONS

Fast-dissolving tablets (FDTs) are designed to dissolve with as little Water as possible. Therefore, they should be less sensitive to variables like temperature and humidity.

6. TECHNIQUES FOR THE PREPARATION OF FAST-DISSOLVING TABLETS

TRADITIONAL TECHNIQUES

6.1. Tablet molding

6.2. Spray drying

6.3. Lyophilization/freeze-drying

6.4. Sublimation

6.5. Direct compression

6.6. Mass extrusion

6.1. Tablet molding

Tablet moulding distinguished two types of moulding processes: the solvent method and the heat approach. The solvent approach yields less compact tablets with a porous structure that facilitates faster dissolution than compression tablets.[12] Binding agents can assist with ensuring the mechanical strength of moulded tablets, which is a significant problem. Furthermore, this technology raises an additional challenge in the taste masking process. To accomplish this, we create concealed drug particles by spraying a molten blend comprising sodium bicarbonate, Lecithin, Cottonseed Oil, Hydrogenated Polyethylene (PEG) and active ingredients. The moulding method yields more suitable tablets for large-scale industrial production than lyophilization.

6.2. Spray Drying

Spray drying can generate finely powdered substances with high porosity, facilitating rapid dissolution. These formulations contain the following components: Sodium starch glycolate acts as a disintegrating agent, mannitol as a bulking agent, hydrolyzed and non-hydrolyzed gelatins as supportive and either an acidic substance(such as citric acid) or an alkaline substance(like sodium bicarbonate) to enhance both disintegration and dissolution. When exposed to an aqueous medium, tablets compressed from spray-dried powder disintegrate within 20 seconds.

6.3. Freeze drying

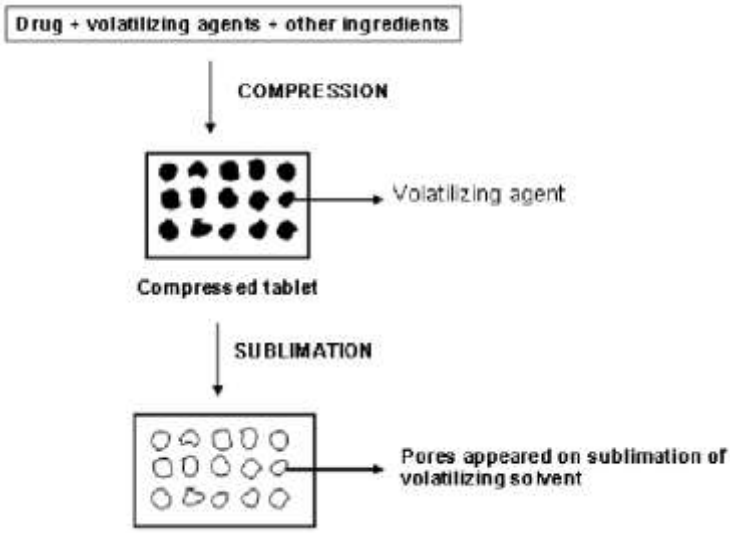
Freeze-drying involves removing Water from Water through sublimation after freezing it. This technology creates an amorphous and porous structure that enables rapid dissolution. Below is a typical procedure for formulating fast-dissolving tablets using this technique

1. The active drug, including a carrier or polymer, is either dissolved or distributed within an aqueous solution.
2. The mixture is carefully measured and poured into performed blister packs.
3. Liquid nitrogen cools a freezing tunnel to transport the blister packs and solidify the drug solution or dispersion.
4. the frozen blisters are laced in a refrigerated cabinet to continue the freeze-drying process.
5. After the freeze dryer, A blister sealing machine applies the aluminium foil backing.
6. The blisters are then sealed and prepared for shipping.

The Freeze-drying technique has demonstrated improved absorption and enhanced bioavailability.[13] However, it has significant drawbacks, including being costly and time-consuming—additionally, conventional susceptibility to stability issues under pressure.

6.4. Sublimation

The formulation includes volatile ingredients later subjected to a sublimation process to create a porous matrix. Highly flammable substances such as camphor, benzoic acid, naphthalene, urea, urethane, ammonium bicarbonate, and ammonium carbonate can be combined with other additives to form a tablet.[14] Sublimation eliminates these volatile components, leaving behind a highly porous matrix. Tablets produced through this method have reported average disintegration times ranging from 10 to 2 seconds. Solvents like cyclohexane and benzene can also serve as pore-forming agents in this content.



6.5. Direct compression method

The direct compression method has been considered the most efficient tablet manufacturing technique. This approach produces tablets directly by compressing a blend of drugs and additives without any preliminary treatment. The compressed medicine must exhibit good flow properties. This method is completed in three steps, i.e.

A. Milling of drugs and additives

B. Mixing of drugs and additives

C. Tablet compression.

Direct compression is applied to prepare disintegrating tablets (ODT) orally due to advancements in excipients, especially disintegrants and sugar-based excipients.

A.Superdisintegrants influence fast-dissolving tablet disintegration and subsequent dissolution, especially when using direct compression techniques. Adding other components, such as water-soluble excipients and effervescent agents, further hastens the disintegration process.

B.Sugar-based: This represents an alternative approach for manufacturing orodispersible tablets through direct compression.[15] It involves the utilization of sugar-based excipients, particularly bulking agents such as dextrose, fructose, isomalt, maltol, mannitol, sorbitol, polydextrose, and xylitol. These excipients are characterized by their high aqueous solubility and sweetness, contributing to taste-masking properties and an enjoyable mouth feel.

Mizummito et al. have categorized sugar-based excipients into two types based on their moulding and dissolution rates.

Type 1 saccharides (like lactose and mannitol) exhibit low moldability but have a high dissolution rate.

Type 2 saccharides (such as maltose and maltitol) possess high moldability but a lower dissolution rate.

6. Mass-extrusion

This method makes the active blend more pliable using a solvent mixture of water-soluble polyethene glycol and methanol. The softened mass is then pushed through the extruder or syringe to create a cylindrical product, which is then divided into even segments using a heated blade to produce tablets. Furthermore, we can use the dried cylinder to coat granules, especially for bitter-tasting drugs, to achieve taste masking.

7. PATENTED TECHNOLOGIES FOR FORMULATING FAST-DISSOLVING TABLETS.

7.1. Zydis formulation

The Zydis formulation is a distinctive freeze-dried tablet where the drug is either physically enclosed or dissolved within a swiftly dissolving carrier material matrix.[16] When placing Zydis units in the mouth, the freeze-dried structure rapidly breaks down, allowing for swallowing without needing Water. This ZWatermatrix comprises various materials chosen to achieve specific objectives. Polymers like gelatin, dextran, or alginates are incorporated to provide strength and durability during Handling, forming a sleek, non-crystalline structure that adds robustness. We integrate saccharides like mannitol and sorbitol to achieve crystalline quality, sophistication, and hardness. Water plays a role in the production process,

ensuring the creation of porous units for rapid disintegration. Simultaneously, we use various gums to prevent the settling of drug particles dispersed during manufacturing. Collapse protectants like glycine safeguard Zydis units against shrinking during freeze-drying or extended storage periods.[17] Zydis products are packaged in blister packs to shield the formulation from moisture in the surrounding environment.

2. Orasolv Technology

CLMA labs have pioneered the resolve technology, a system designed to address various aspects of medication delivery.[18] This innovative approach involves masking the active medicament's taste and incorporating an effervescent disintegration agent. We meticulously craft tablets using a low compression force direct compression technique, a method we choose to minimize the time it takes for oral dissolution. We employ Standard blending and tablet manufacturing equipment in production.[19] The resulting tablets have a soft and easily crumbled texture, and we package them using a specifically designed pick-and-place system.

3. Wow Tab Technology

Yamanounchi Pharmaceutical Co. has secured a patent for its innovative WOW tab technology, where WOW stands for "Without water." This method employs a blend of saccharides with varying levels of moldability to create a fast-dissolving, robust tablet. The active ingredient is combined with a saccharide possessing low moldability, such as lactose, glucose, or mannitol, and then granulated alongside a saccharide with high moldability, like maltose or oligosaccharides.[20] Then, we compress these components to create tablets.

4. Flashtab technology

The flashtab technology represents another formulation for rapidly dissolving and disintegrating tablets. Pragrapham Laboratories has obtained a patent for this innovative approach. It shares many of the same excipients commonly found in traditional compressed tablets. In this particular formulation, a blend of a disintegrating agent and a swelling agent is employed with coated drug particles to develop a pill that rapidly disintegrates inside the oral cavity, usually in less than one minute.

5. Advatab Technology

Advatab tablets rapidly disintegrate within the oral cavity, typically in less than 30 seconds, facilitating easy medication administration without Water. These Waterts are particularly

beneficial for individuals who encounter challenges swallowing capsules or conventional tablets.

8. Marketed products of fast-dissolving tablets.

S.No	Trade Name	Active drug	Manufacturer
1	Benadryl Fastmelt	Diphenhydramine	Warner-Lambert, NY, USA
2	Domperidone Ebb	Domperidone	Ebb Medical, Sweden
3	Imodium Instant Melts	Loperamide HCL	Janssen, UK
4	Zyprexa	Olanzapine	Eli Lilly, Indianapolis, USA
5	Nausea OD	Ramosetoron HCl	Yamanouchi
6	Zofran ODT	Ondansetron	Glaxo Wellcome, Middlesex, U.K.
7	U.Koming ZMT	Zolmitriptan	AstraZeneca, Wilmington, USA
8	Zeplar TM	Selegiline	Amarin Corp., London, UK
9	Tempra Quicklets	Acetaminophen	Bristol Myers Squibb, NY, USA
10	Febrectol	Paracetamol	Prographarm, Chateauneuf, France

9. CONCLUSION

As per design, fast-dissolving tablets dissolve or disintegrate quickly in saliva, typically in less than 60 seconds. Compared to standard oral dose forms, these tablets offer improved patient compliance and acceptance, which may result in improved biopharmaceutical qualities, increased bioavailability, increased efficacy, convenience and enhanced safety. Fast-dissolving tablets(FDTs) have become more popular during the past ten years. Formulators are required to prepare FDTs for patients who are psychotic, bedridden, elderly, or pediatric, as well as patients who might not have access to Water or who are Waterousy travelling. We employ traditional and proprietary methods to develop these formulations to guarantee that FDTs possess the necessary mechanical strength and can dissolve or disintegrate rapidly in the buccal cavity without needing Water. Grown Waterpularity.[21]

We anticipate a significant acceleration in the growth of fast-dissolving tablets (FDTs) soon. It is attributed to the ongoing progress in scientific research and the discovery of novel excipients, setting the stage for a dynamic and competitive landscape in pharmaceutical drug delivery systems.

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