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Swift Solutions: The Science and Innovation Behind Fast-Dissolving Tablets

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Abstract

Swift solutions in the context of fast-dissolving tablets (FDTs) represent an innovative breakthrough in pharmaceutical science, aiming to provide rapid and effective drug delivery for patients who face difficulty swallowing conventional dosage forms. The science and innovation behind FDTs are rooted in advanced formulation techniques, material science, and drug delivery mechanisms that prioritize speed, convenience, and patient compliance. These tablets are formulated to dissolve quickly in the mouth, removing the necessity for water and providing a quicker onset of effects. The development of FDTs relies heavily on the use of cutting-edge technologies, including the incorporation of super disintegrants, water-soluble excipients, and porous materials that facilitate immediate disintegration upon contact with saliva. Techniques, such as lyophilization, spray drying, and direct compression, are employed to create tablets that dissolve swiftly while maintaining mechanical strength and stability. Additionally, advancements in nanotechnology and polymer science have further enhanced the solubility and bioavailability of poorly water-soluble drugs, enabled faster absorption and improving therapeutic efficacy. Innovations in taste-masking are crucial for enhancing patient adherence, particularly among paediatric and geriatric groups. Furthermore, the integration of effervescent agents and other dissolution-enhancing systems has expanded the possibilities of FDTs, making them suitable for a wide range of therapeutic applications, including acute conditions that require rapid intervention. In conclusion, the science and innovation behind fast-dissolving tablets exemplify the growing trend toward patient-centered, rapid drug delivery systems. These swift solutions not only address the clinical challenges of traditional oral dosage forms but also provide enhanced convenience and efficacy, reshaping the future of pharmaceutical development and drug delivery systems.

Keywords: Fast dissolving tablets (FDTs), super disintegrants, drug delivery system, patented technologies, taste masking

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INTRODUCTION

Tablets are currently the most popular way to take medicine because they're easy for people to take on their own, are small, and simple to make. However, older adults, children, and those with mental illnesses often struggle to swallow regular tablets, which means they don't take their medication as prescribed. To solve this, scientists have created special mouth-dissolving/disintegrating tablets (MDTs) that are much easier to take. As stated in the European Pharmacopoeia, these advanced mouth-dissolving or disintegrating tablets (MDTs) are intended to dissolve or break apart in less than three minutes. This type of formulation is especially advantageous for patients who are confined to bed or struggle with swallowing. The key advantages of MDTs, which contribute to their popularity in the

current market, include improved patient compliance, a faster onset of action, enhanced bioavailability of the drug, and good stability [1–3].

Mouth-dissolving tablets are known by various terms, such as orodispersible tablets, fast disintegrating tablets, orally disintegrating tablets, quick disintegrating tablets, fast dissolving tablets, rapid dissolving tablets, porous tablets, quick melt tablets, and rapid melt tablets. The United States Pharmacopoeia (USP) officially refers to them as ODTs (Orally Disintegrating Tablets). The United States Food and Drug Administration (FDA) defines ODTs as "a solid dosage form containing medicinal substances or active ingredients that rapidly disintegrates within a few seconds when placed on the tongue" [4, 5].

Many dose forms are available to make administration easier, and the most popular commercial items are fast-dissolving tablets. The idea of fast-dissolving drug delivery systems arose from the need to offer patients a traditional method for taking their medication. Fast-dissolving tablets are particularly beneficial for patients who struggle with swallowing, notably the elderly and young children. A key requirement for these tablets is that they must dissolve in the saliva of the oral cavity within 15 to 60 seconds without needing water, and they should offer a pleasant taste. The introduction of fast-dissolving tablets aimed to enhance patient adherence to treatment. This review primarily aims to examine the ideal characteristics, benefits, conventional and patented technologies, available formulations of fast dissolving tablets, and methods for evaluating them [6–8].

However, it is important to note some drawbacks to this approach, and these drawbacks include difficulties in swallowing (known as dysphagia), limited bioavailability, and a delayed onset of action. Scientists have investigated addressing these issues through exploiting the – oral cavity. The drug's permeability and bioavailability increase. Because the keratinization of its keratinization is comparatively low, the buccal mucous membrane of the – oral region offers permeability that is good. Permeability is good for the "oral cavity". It is because of the fact that the buccal mucosa has a relatively low amount of keratinization. Tablets get absorbed through the oral canal; subsequently, they enter the bloodstream directly via the jugular vein, so this results in quick action onset. This method bypasses issues tied to metabolism during the first pass, drug breakdown in the gastrointestinal region, and enzymatic hydrolysis in the intestine (Figure 1) [9].

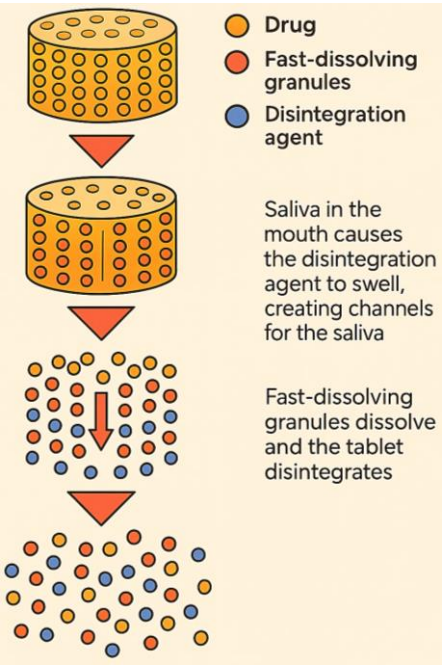

Figure 1. Conceptual diagram of FDTs.

SALIENT FEATURES OF FAST DISSOLVING DRUG DELIVERY SYSTEM

- Easy administration to patients who have difficulty swallowing, including elderly patients, stroke victims, bedridden patients, patients with renal failure, and those who refuse to swallow, including paediatric, geriatric, and mental health patients.
- By preventing physical obstruction during oral administration of a conventional formulation, the risk of choking or suffocation is reduced, improving safety.
- A fresh commercial opportunity, such as life cycle management, patent extensions, product promotion, and differentiation.
- Beneficial in circumstances, such as motion sickness, abrupt episodes of allergy attack or coughing, where an ultra-rapid beginning of action is required.
- A higher bioavailability because of these tablets' quick dissolving and disintegration, especially for insoluble and hydrophobic medications.
- Longer stability because the medication stays in solid dose form until it is taken. Thus, it combines the benefits of liquid dosage forms for bioavailability and solid dosage forms for stability [10].
- Simple administration for patients who have difficulty swallowing, including the elderly, stroke victims, bedridden patients, patients with renal failure, and patients who are mentally, paediatric, or elderly.
- The dose form can be swallowed without water, which is a very practical feature for patients who are on the go and do not always have access to water.
- The medicine will dissolve and absorb quickly, resulting in a prompt commencement of action [11].

TECHNOLOGIES UTILIZED IN MDT PRODUCTION

In recent times, significant strides have been made in developing advanced technologies for manufacturing mouth-dissolving tablets (MDTs). These innovations aim to achieve ideal characteristics such as very short disintegration times, a pleasant sensation in the mouth, effective taste masking, and the production of sugar-free options for diabetic patients. Broadly, the manufacturing technologies for MDTs fall into two main categories: patented and non-patented methods. Manufacturing methods for mouth dissolving tablets (MDTs) have advanced significantly in recent years. The goal of these modern technologies is to provide MDTs with better qualities, like faster disintegration, a delightful mouthfeel, efficient flavor masking, and the capacity to be sugar-free for diabetic patients. The methods used to produce MDTs are generally categorized into two main groups: patented technologies and non-patented technologies (Figure 2) [12].

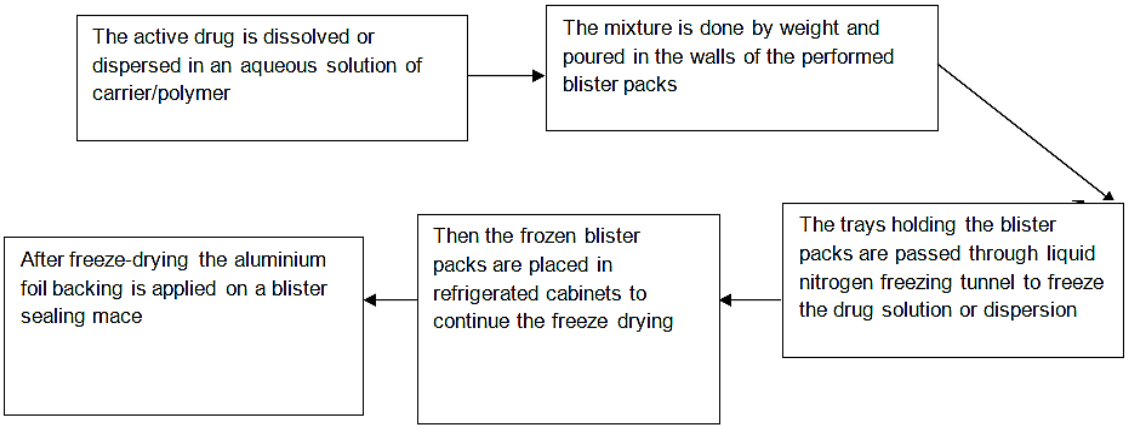

Figure 2. Step-by-step procedure of lyophilization for FDTs.

Freeze-Drying or Lyophilization

Freeze-drying, also known as lyophilization, is a pharmaceutical process that uses a vacuum to remove water through sublimation, allowing heat-sensitive biological and pharmaceutical products to be dried at low temperatures. In this method, the drug formulation (containing the drug and other

ingredients) is first frozen below –18°C. Then, the system's pressure is reduced to provide the necessary heat for sublimation, turning the ice directly into vapor.

Specifically for rapidly dissolving tablets, drugs are either dissolved or dispersed in a water-based solution, placed into pre-made blister packs, and then frozen using a nitrogen flush. The tablets are then dried in a refrigerator (presumably the freeze-drying step happens here, although "refrigerator" might be a simplification for the vacuum chamber). The resulting tablet contains the drug within a water-soluble, freeze-dried matrix, creating a highly porous structure with a large surface area. This porous nature allows saliva to quickly enter when the tablet is placed in the mouth, causing it to dissolve in less than 5 seconds.

Lyophilization is particularly advantageous for compounds that are sensitive to heat. It has been demonstrated that this freeze-drying method increases the drug's absorption and bioavailability. For this procedure, tasteless, water-insoluble drug candidates with particle sizes less than 50 μm are ideal. This freeze-drying technique is used in several patented technologies, including Zydis®, Lyoc®, and Quicksolv® [13, 14].

Spray Drying

Because it is straightforward and only requires one step, this method is frequently employed in the pharmaceutical sector. It is also readily controllable and scalable. It has been used to create microspheres, with the spray dryer's nozzle size affecting the size of the particles. The method produces fine, extremely porous powders that are appropriate for the creation of Fast-Melting Tablets (FMTs).

In this method, ingredients are blended with super-disintegrants like sodium starch glycolate, croscarmellose sodium, or crospovidone; gelatin (both hydrolyzed and non-hydrolyzed) as a structural support; mannitol as a bulking agent; and citric acid and/or sodium bicarbonate to aid in disintegration and dissolution through acid-base interaction. When the resulting dosage form contacts water, it rapidly disintegrates and dissolves – typically within 20 seconds. However, the resulting tablets tend to have low mechanical strength, and the process itself can be time-consuming and costly [15, 16].

Tablet Molding

Compression moulding is a technique used to produce tablets from water-soluble substances like sugars. The method involves pressing a moistened powder blend – typically using ethanol or water as the solvent – into mould plates to create a damp mass. Moulded tablets offer benefits such as fast disintegration and better taste, thanks to their sugar-based, water-soluble makeup. These advantages are amplified when the tablets have a porous structure or when the ingredients undergo physical changes during moulding. Compared to lyophilization, moulded tablets are more suitable for large-scale manufacturing. On the other hand, tablets made by direct compression dissolve more slowly but are less likely to become friable [17, 18].

Sublimation

To create fast disintegrating tablets (FDTs) characterized by high porosity, the employment of the sublimation process has indeed occurred. Volatile ingredients get compressed by this technique into tablets with excipients, and then they undergo sublimation. Solid inert components have been employed for this purpose. These components possess high volatility along with ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, hexamethylene-tetramine, naphthalene, phthalic anhydride, urea, and urethane. For the generation of porosity that is within the matrix, solvents, such as cyclohexane and benzene, have been recommended for use [19].

Nanonization

Nanomelt technology is a novel approach that reduces drug particles to the nanoscale using a specialized wet-milling process. The resulting drug nanocrystals are stabilized against clumping through surface adsorption onto selected stabilizers, and these stabilized particles are then incorporated

into fast-dissolving tablets (FDTs). This method is particularly beneficial for drugs with poor water solubility. Key advantages include rapid disintegration and dissolution of the nanoparticles, which can lead to lower required dosages, improved absorption and bioavailability, a cost-efficient production process, compatibility with standard packaging due to the tablets' high durability, and flexibility in dosing – supporting drug loads of up to 200 mg per tablet [20, 21].

Fast Dissolving Films

This method involves preparing a non-aqueous solution that contains a water-soluble film-forming polymer – such as pullulan, carboxymethylcellulose, hydroxypropyl methylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinylpyrrolidone, polyvinyl alcohol, or sodium alginate – along with the active drug and taste-masking agents. After the solvent evaporates, a thin film is formed. For bitter drugs, resin adsorbates or coated microparticles can be added to the film to help mask the taste. The film rapidly melts or dissolves in the mouth, releasing the medication in the form of a suspension or solution. Ultra-thin films (less than 2 x 2 inches), dissolving in about 5 seconds, quick medication administration, and a tasty aftertaste are some of this system's key features [22–24].

EXCIPIENTS USED IN FDT's PREPARATION

At least one super disintegrant, a diluent, a lubricant, and optionally a swelling agent, a permeabilizing agent, sweeteners, and flavorings are among the excipients utilized in FDTs.

Super Disintegrants

With the increasing demand for rapidly disintegrating drug formulations, there is a growing need for the development of more efficient disintegrants – specifically, super disintegrants. These agents are designed to work effectively even at low concentrations and offer superior disintegration performance. Super disintegrants primarily function through a swelling mechanism, where they absorb water and expand, creating outward or radial pressure. This action causes the tablet to break apart or allows it to absorb water rapidly, significantly increasing granule volume and promoting quick disintegration [25–27].

Bulking Materials

When making fast-dissolving tablets, bulking agents are crucial. They can be used as fillers, diluents, and inexpensive components, among other things. These agents improve the tablet's texture, promoting faster disintegration in the mouth, and also help dilute the active pharmaceutical ingredient. For this drug delivery system, sugar-based bulking agents are generally recommended. Typical examples include starch hydrolysate, mannitol, lactitol, polydextrose, and direct compressible lactose (DCL). Sugar-based therapies are used because of their greater water solubility and palatable sensory qualities. Among them, mannitol is unique because of its remarkable solubility and sensory benefits [28].

Lubricants

Although not essential, excipients can improve the taste and overall mouthfeel of tablets after they disintegrate. Lubricants make it easier for the medication to move from the mouth to the stomach by smoothing out any harsh textures [29].

Taste Making

Taste-masking materials are typically classified based on how they alter or suppress basic taste sensations. Flavoring and aromatic agents can come from either natural or synthetic origins. Natural options include fruit juices, essential oils like peppermint and lemon, herbs, spices, and their distilled forms. These come in a variety of forms, including syrups, spirits, alcoholic or water-based solutions, and concentrated extracts.

Beyond traditional agents, certain compounds have shown significant taste-masking abilities while also enhancing flavor. Among these are compounds such as alkaline hydroxides, alkaline earth hydroxides, and alkaline earth oxides. Another effective group consists of phosphorylated amino acids such as phosphotyrosine, phosphoserine, phosphothreonine, and their mixtures [30–33].

Emulsifying Agents

These agents are used in the formulation of tablets designed to dissolve rapidly, allowing for quick disintegration and drug release without the need for water, chewing, or swallowing. In addition to enhancing patient convenience, they can improve the bioavailability of the drug and stabilize formulations that may contain incompatible components. Such formulations often include a variety of emulsifying agents, such as lecithin, propylene glycol esters, alkyl sulfates, and sucrose esters [34].

ADVANTAGES OF FAST DISSOLVING TABLETS

Fast-dissolving tablets (FDTs) are particularly beneficial for individuals without access to water, as they dissolve within seconds in the buccal cavity, enhancing patient adherence. Since the drug is absorbed directly through the mouth, throat, and esophagus – bypassing first-pass metabolism – FDTs offer improved bioavailability. They are also convenient to carry, exhibit good physical and chemical stability, ensure accurate dosing, and are especially suitable for elderly and pediatric patients (Figure 3).

Due to their rapid dissolution and absorption in the mouth, FDTs provide quick therapeutic action during emergencies and pose minimal risk of choking. Additionally, they can be efficiently packaged in blister packs, supporting cost-effective manufacturing without requiring specialized equipment or processes [35–37].

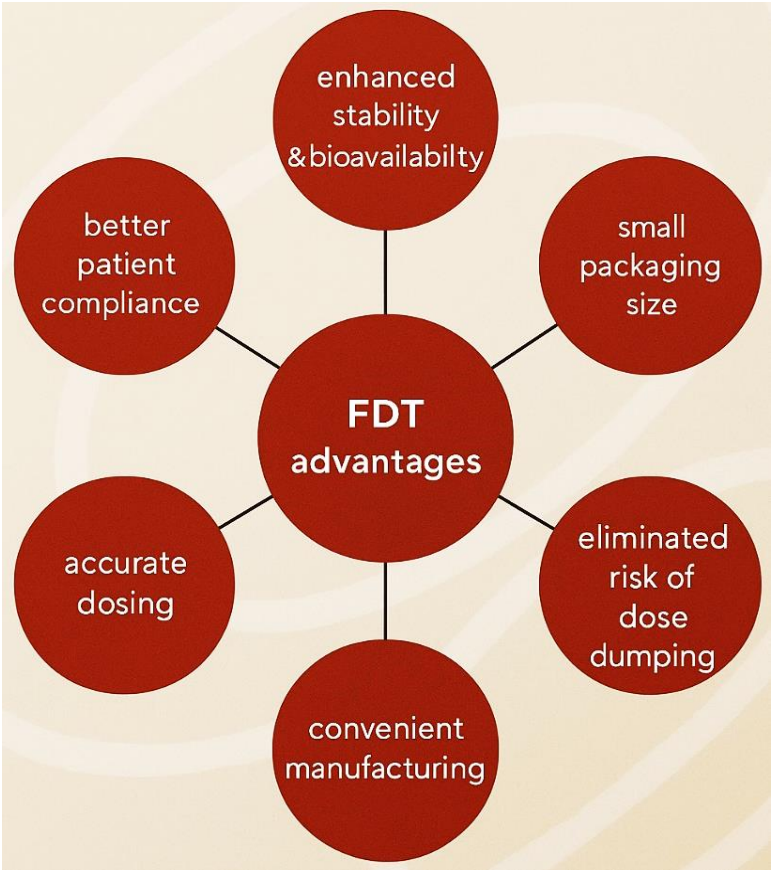

Figure 3. Advantages of FDTs.

DISADVANTAGES OF FAST DISSOLVING TABLETS

The primary drawbacks of fast-dissolving tablets (FDTs) include their high porosity, which makes them fragile and prone to crumbling. Their hygroscopic nature also affects their ability to maintain physical and structural stability. Additionally, FDTs are not suitable for individuals with dry mouth conditions, as adequate saliva is necessary for proper tablet dissolution [38].

CHALLENGES TO DEVELOP SWIFT SOLUTIONS (FDTs)

A number of issues must be resolved during the formulation and production stages of the development of fast-dissolving tablets (FDTs). Among the main difficulties are:

Drug Compatibility

It is essential to ensure that the active pharmaceutical ingredient (API) is compatible with the excipients used in the formulation. Certain drugs may degrade or react chemically when exposed to conditions involved in FDT production, such as elevated temperatures or moisture. Conducting compatibility studies is vital to identify and prevent such potential problems [39].

Taste Masking

Fast-dissolving tablets (FDTs) are formulated to dissolve quickly in the mouth, which directly exposes the drug to the taste buds. Since many drugs have a bitter or unpleasant taste, enhancing the palatability of the formulation is crucial for patient acceptance. To address this issue, various taste-masking strategies – such as incorporating sweeteners, flavoring agents, or using encapsulation techniques – are commonly employed [40].

Mechanical Strength

Fast-dissolving tablets (FDTs) must be durable enough to endure the processes of manufacturing, packaging, and transportation without breaking or crumbling excessively. It is essential to strike an appropriate balance between quick disintegration and sufficient mechanical strength to ensure the tablet stays intact until it is administered [41].

Formulation Stability

Fast-dissolving tablets (FDTs) frequently include drugs that are sensitive to moisture or chemically unstable, making it difficult to maintain their stability throughout the product's shelf life. Problems include drug degradation, moisture absorption, and formulation physical changes that might alter the medicine's release profile or reduce its effectiveness. Selecting appropriate excipients, using protective packing materials, and maintaining appropriate storage conditions are crucial for ensuring long-term stability [42].

Hygroscopicity

Under normal temperature and humidity conditions, many orally disintegrating dosage forms tend to absorb moisture and are unable to retain their structural integrity. As a result, these products must be protected from moisture, which calls for specialized packaging solutions [43].

EVALUATION OF FAST DISSOLVING TABLETS

By Weight Variation

To assess weight variation, 20 tablets are randomly selected from the batch and weighed individually. The results are then evaluated against the weight variation limits specified by the Indian Pharmacopoeia (I.P.) [44, 45].

Tablet Hardness

Tablet hardness measures the force needed to fracture a tablet along its diameter, reflecting its ability to withstand chipping, abrasion, or breakage during handling, transport, and storage. The hardness of each tablet formulation was determined using either a Monsanto or Pfizer hardness tester [46].

Uniformity of Weight

The Indian Pharmacopoeia (I.P.) weight uniformity protocol was adhered to. A digital balance was used to measure the weights of the twenty tablets that were chosen, both individually and collectively. From the overall weight, the average weight per tablet was determined. The weight variation test serves as an acceptable method to assess the uniform distribution of drug content. Additionally, the time taken for complete dispersion of the tablets was recorded.

Accelerated Stability Studies

Orally disintegrating tablets are placed in appropriate packaging and stored under specific conditions for a duration defined by ICH guidelines for accelerated stability studies.

i. 40 ± 1°C.
ii. 50 ± 1°C.
iii. 37±1°C and Relative Humidity= 75% ± 5%.

After 15 days, the tablets were removed from storage and examined for physical characteristics such as visual defects, hardness, friability, disintegration, dissolution, and drug content. The collected data were applied to first-order kinetic equations to evaluate the degradation rate. Accelerated stability results were then analyzed using the Arrhenius equation to estimate the product's shelf life at 25 °C.

Friability

The friability test assesses the effects of friction and mechanical stress that could cause tablets to chip, cap, or break. A Roche friabilator was used for this purpose. This instrument exposes tablets to both abrasion and impact by rotating a plastic drum at 25 rpm, causing the tablets to fall from a height of 6 inches with each rotation.

Wetting Time

Wetting time is strongly influenced by the internal structure of the tablet and the hydrophilic nature of the excipients used. Based on the equation proposed by Washburn E.W. (1921), the rate at which water penetrates a powder bed is directly proportional to the pore size and is significantly affected by the hydrophilicity of the powder materials.

dl/dt = r¡cosq/ (4hl)

Where l is the length of penetration,
r is the capillary radius,
¡ is the surface tension,
h is the liquid viscosity,
t is the time, and q is the contact angle.

Dissolution Test

The development of the dissolution methods of FDTs is somewhat similar to conventional tablets. Pharmacopoeial monographs provide a useful starting point for initial testing, especially when developing a bioequivalent ODT. Additional dissolution media, such as 0.1N HCl and buffers at pH 4.5 and 6.8, should also be tested, just as they are for conventional tablet formulations.

Disintegration Time

Six tablets were subjected to the disintegration test using the equipment outlined in the Indian Pharmacopoeia (I.P.) 1996. Distilled water maintained at 37 ± 2°C served as the disintegration medium. The time required for each tablet to completely disintegrate, leaving no visible residue in the apparatus, was recorded in seconds.

CONCLUSIONS

Fast-dissolving drug delivery systems have demonstrated enhanced patient compliance, improved therapeutic effectiveness, and better biopharmaceutical properties. FDTs developed using various technologies possess adequate mechanical strength and disintegrate or dissolve rapidly in the mouth. Traditional tablets often pose swallowing challenges for elderly and paediatric patients, resulting in poor compliance. To address this issue, scientists have created fast-dissolving tablets (FDTs), which allow easy administration without the need for water, offering significant benefits for both geriatric and paediatric populations.

Fast melt tablets (FMTs) are innovative dosage forms specifically designed to overcome challenges associated with traditional solid oral medications, particularly the difficulty of swallowing faced by elderly and paediatric patients. These tablets are formulated to dissolve or disintegrate in saliva within an average of 60 seconds. Compared to conventional oral dosage forms, FMTs offer greater patient compliance and acceptance, along with potential improvements in biopharmaceutical properties, bioavailability, therapeutic effectiveness, convenience, and safety.

Over the past decade, FMTs have gained significant popularity. They are especially helpful for patients who are elderly, children, bedridden, schizophrenic, or who don't have access to water or are constantly moving. The mechanical strength of FMT formulations – which are created using a variety of traditional and new techniques – is adequate to guarantee durability.

Fast-dissolving tablets (FDTs) are made especially to dissolve or break down quickly in saliva, usually in less than 60 seconds. Compared to traditional oral dose forms, these tablets provide more patient compliance and acceptance, which may result in better biopharmaceutical qualities, increased bioavailability, increased efficacy, user convenience, and improved safety. FDTs have been very popular in the last ten years.

They are particularly suited for patients who are psychotic, bedridden, elderly, paediatric, or for individuals who lack access to water or are frequently on the move. Both conventional and patented techniques are employed in the development of FDTs to ensure they have sufficient mechanical strength and can quickly disintegrate in the buccal cavity without the need for water.

A substantial surge in the development of fast-dissolving tablets (FDTs) is expected in the near future, driven by continuous advancements in scientific research and the introduction of innovative excipients. These developments are paving the way for a dynamic and highly competitive environment in the field of pharmaceutical drug delivery systems.

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