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Fast dissolving tablet

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Abstract

Fast dissolving tablets have emerged as a popular dosage form, particularly beneficial for pediatric and geriatric patients facing challenges such as dysphagia or hand tremors. These tablets dissolve quickly in saliva without needing water, enhancing compliance and effectiveness of therapy. They offer advantages like easy portability, accurate dosing, and improved bioavailability. Various technologies, including spray drying and melt granulation, have been developed for their manufacturing. This review provides comprehensive information on fast dissolving tablets, covering their definition, advantages, limitations, challenges, and available formulations. The design of an oral drug delivery system prioritizes convenience in administration and improved patient compliance, making it the preferred route of drug delivery despite certain drawbacks. Over the last decade, there has been a growing demand for Fast Disintegrating Tablets (FDTS), turning this field into a rapidly expanding area within the pharmaceutical industry. The formulation's popularity and effectiveness have led to the development of various FDT technologies. These technologies aim to achieve rapid tablet disintegration and mouth dissolution within five seconds, eliminating the need for chewing or water intake. This characteristic is particularly advantageous for populations such as pediatrics, geriatrics, and patients facing difficulties in swallowing conventional tablets and capsules. The formulation of an easily administrable dosage form, considering challenges like swallowing difficulties and low patient compliance, has driven the creation of orally disintegrating tablets. Traditional preparation methods include spray drying, freeze drying, direct compression, molding, and sublimation. In addition, new technologies have been devised to enhance the production of orodispersible tablets.

Keywords: Fast dissolving tablets; FDTS; Superdisintegrants; Mouth dissolving tablets; Fast melting

1. Introduction

Despite the tremendous advancements in drug delivery, the oral route remains the preferred method for administering therapeutic agents due to its advantages, including accurate dosage, cost-effectiveness, self-medication, non-invasiveness, and ease of administration, resulting in high patient compliance. Pediatric patients may face ingestion challenges due to underdeveloped muscular and nervous control. Additionally, patients traveling with limited access to water may find the utility of orally administered conventional tablets or capsules1, 2, 3 restricted. Extensive pharmaceutical research is focused on developing new dosage forms, primarily targeting the formulation of novel drug delivery systems or enhancing patient compliance. Fast dissolving tablets (FDTS) are among the most widely preferred commercial products. While tablets and capsules are the most popular dosage forms, a notable drawback is the difficulty in swallowing, especially for individuals with dysphagia associated with conditions like stroke, Parkinson's disease, AIDS, head and neck radiation therapy, and other neurological disorders, including cerebral palsy. FDTS offer significant advantages, such as not requiring water for administration, rapid onset of action, reduced risk of suffocation, and avoidance of hepatic first-pass metabolism. However, a significant challenge with FDTS is the bitterness of the drug

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exposed to taste buds as the tablet breaks apart in the oral cavity. Skillful taste-masking techniques, including the formation of inclusion complexes, polymer coating, and resin complexes, are essential to address this issue. Recognizing the benefits of the oral cavity, Oral Dispersible Tablets, commonly known as Fast Dissolving Tablets, are widely accepted formulations. According to the European Pharmacopoeia, Oral Dispersible Tablets should disperse or disintegrate in less than 3 minutes when placed on the tongue. The concept of Fast Dissolving Drug Delivery Systems (FDDDS) represents a newer approach combining the advantages of both liquid and solid formulations while offering benefits over traditional dosage forms.7-10 The benefits of Fast Dissolving Tablets include improved patient compliance, rapid onset of action, increased bioavailability, and good stability, making them a popular choice in the current market 11-13. This review provides concise information about Fast Dissolving Tablets (FDTS). Formulating drugs into a presentable form is crucial in today's context, as it serves as the means of drug delivery to the body. There exist various dosage forms such as tablets, syrups, suspensions, suppositories, injections, transdermal patches, each with distinct drug delivery mechanisms. Developing an ideal drug delivery system poses a significant challenge to pharmacists, necessitating a thorough understanding of physicochemical principles governing specific drug formulations. Oral routes of drug administration are widely accepted, constituting up to 50-60% of total dosage forms. Solid dosage forms like tablets and capsules are popular due to ease of administration, accurate dosage, and patient compliance. However, some patients face difficulties swallowing conventional dosage forms, particularly in scenarios like motion sickness or sudden coughing episodes.

2. Characteristics of FDTS

A rapid-breakdown or fast-disintegrating tablet, designed to undergo disaggregation in the mouth upon contact with saliva in less than 60 seconds, preferably within 40 seconds, forming a suspension that is easy to swallow. Commonly referred to as 'orodispersible tablets,' these tablets address the challenge faced by approximately 50% of the population, who encounter difficulties in swallowing traditional tablets or capsules. This issue often leads to non-compliance with prescribed medications, significantly impacting treatment efficacy. Orodispersible tablets offer a convenient administration method for individuals with deglutition problems or those who prefer taking their treatment without simultaneous liquid ingestion.Recent advancements in Novel Drug Delivery Systems (NDDS) aim to enhance the safety and efficacy of drug molecules by developing convenient dosage forms for ease of administration, ultimately improving patient compliance. Oral Disintegrating Tablets (ODTs) represent one such approach. ODTs are solid unit dosage forms that rapidly disintegrate or dissolve in the mouth, eliminating the need for swallowing, chewing, or water intake. The design of ODTs focuses on meeting patient needs without compromising efficacy, particularly addressing the difficulty in swallowing conventional tablets or capsules.

The fundamental properties of ODTs are summarized in the following table:

Table 1 The fundamental properties of ODTs

Properties	**Yes/No**
Suitable for Conventional tablet processing and packaging	Yes
Portable	Yes
Fragility Concern	No
Good Mouth Feel	Yes
Sensitive to Environmental factors (humidity, temperature)	No
Water required for swallowing	No
Patient Compliance	Yes
Economic	Yes
Leave Residue in oral cavity/Grittiness	No
Compatible with Taste Masking	Yes

2.1. Ideal properties of FDA

2.1.1. Fast dissolving tablets

(FDTS) address these challenges, designed to disintegrate rapidly in saliva, typically within seconds, without the need for water. They offer advantages for pediatric, geriatric, and other patient populations with swallowing difficulties, leading to improved therapy effectiveness. These tablets are formulated using super disintegrants or by maximizing pore structure through techniques like freeze drying or vacuum drying, with direct compression being the preferred method due to its simplicity and cost-effectiveness.Additionally, FDTS may enhance drug bioavailability by promoting drug absorption in the oral cavity and reducing first-pass metabolism, thereby offering potential therapeutic benefits compared to standard tablets.

2.1.2. Patient Considerations

Fast dissolving tablets are beneficial for patients, particularly pediatric and geriatric individuals, who struggle with swallowing traditional tablets and capsules without water. This includes:Patients facing difficulty in swallowing or chewing solid dosage forms Patients with compliance issues due to fear of choking.Elderly patients experiencing depression who may have difficulty swallowing solid dosage forms.Children with allergies who prefer a more convenient dosage form over antihistamine syrup.Individuals undergoing radiation therapy or experiencing nausea, who find it challenging to swallow conventional tablets.

2.1.3. Effectiveness Factors

Fast dissolving tablets offer increased bioavailability and faster onset of action. They allow pre-gastric absorption, bypassing first-pass metabolism, which can be advantageous for drugs undergoing hepatic metabolism. This can improve safety profiles, particularly for drugs producing toxic metabolites.

2.1.4. Manufacturing and Marketing Considerations

Pharmaceutical manufacturers often develop new dosage forms near the end of a drug's patent life to extend market exclusivity and patent protection. For example, Eisai Inc. launched Aricept FDT in response to a generic challenge, extending the product's market presence

2.2. Advantages of Fast Dissolving Tablets

- No need for water for administration.
- Suitable for pediatric, elderly, and mentally disabled patients.
- Accurate dosing compared to liquids.
- Rapid dissolution and absorption for faster onset of action.
- Increased bioavailability, especially for drugs absorbed through saliva.
- Convenient administration and transportation compared to liquid medications.
- Reduced first-pass metabolism, leading to improved safety and potentially lower side effects.
- Suitable for sustained/controlled release formulations and high drug loading.

2.3. Challenges to develop FDTS

Challenges to develop FDTS include palatability, mechanical strength and disintegration time, hygroscopicity, limited drug amount, aqueous solubility, tablet size, mouthfeel, and sensitivity to environmental conditions. Criteria for excipients used in FDT formulations include quick disintegration, no interaction with drug or other excipients, integrity and stability of the product, melting point within 30-35 °C, no interferenc with efficacy and organoleptic properties, and various forms of binders. Excipients in FDT preparation typically include super disintegrants, diluents, lubricants, and optionally swelling agents, permeabilizing agents, sweeteners, and flavoring agents.

2.3.1. Superdisintegrants.

Play a crucial role in formulating fast-dissolving tablets due to the increasing demand for rapid disintegration. These super disintegrants, such as croscarmellose sodium and crospovidone, exhibit high swelling capacities and effectively promote tablet disintegration. Factors for selecting super disintegrants include their ability to quickly absorb saliva, compactibility, mouthfeel, and flow properties. Bulking materials, essential for fast-dissolving tablet development, serve as diluents, fillers, and cost reducers. Common bulking agents like mannitol and starch hydrolysate contribute to texture enhancement and sensory perception. Emulsifying agents, lubricants, flavors, and sweeteners further enhance the

palatability and bioavailability of fast-dissolving tablets. Various conventional manufacturing techniques are employed for formulating fast dissolving tablets.

2.3.2. Freeze-drying

Freeze-drying or lyophilization is a method employed in pharmaceuticals to dehydrate heat-sensitive drugs and biological substances at low temperatures under vacuum conditions, thereby removing water through sublimation. The process involves dissolving or dispersing drugs in an aqueous carrier solution, transferring them to preformed blister packs, subjecting them to a nitrogen flush to induce freezing, and finally placing them in a refrigerator to complete the drying process. Lyophilization techniques are characterized by their high porosity and specific surface area, facilitating rapid dissolution in the mouth and enhancing drug bioavailability. However, this method is associated with drawbacks such as high costs, time-consuming procedures, and fragility, rendering conventional packaging unsuitable and leading to stability issues under stress conditions.Advantages of lyophilization include the production of tablets with minimal disintegration time and a pleasant mouthfeel due to rapid melting.The molding method involves designing tablets using hydrophilic ingredients to achieve maximum drug dissolution. Powder masses are wetted with a hydroalcoholic solvent, compressed into dosage forms, and then allowed to evaporate. Taste enhancement is achieved by spray-congealing a mixture of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethylene glycol, and the active ingredient into a lactose-based tablet triturate. This method results in porous tablets that promote rapid dissolution.

2.3.3. Spray-drying

Spray-drying is a method used to combine ingredients such as hydrolyzed and nonhydrolyzed gelatins, mannitol, sodium starch glycolate or crosscarmellose sodium, and acidic or alkali materials to enhance disintegration and dissolution, resulting in rapid dissolution within 20 seconds upon contact with water.Phase transition processes utilize sugar alcohols like erythritol, xylitol, trehalose, and mannitol to disintegrate fast-dissolving tablets (FDTS). Tablet hardness increases after heating due to the phase transition of lower melting point sugar alcohol.

2.3.4. Nanoionization

Nanoionization involves reducing drug particle size to nano size using wet-milling, stabilizing nanocrystals with selected stabilizers, and incorporating them into MDTs. This method is advantageous for poorly water-soluble drugs, offering increased absorption, bioavailability, and cost-effective manufacturing.

2.3.5. Oral disintegrating:

Oral disintegrating or fast-dissolving thin films provide a convenient means of medication intake. A non-aqueous solution containing water-soluble film-forming polymers, drugs, and taste masking ingredients forms a film upon solvent evaporation. These films dissolve rapidly in the mouth, releasing the drug.

2.3.6. Zydis technology

Zydis technology utilizes a unique freeze-dried tablet matrix for fast dissolving tablets. It incorporates polymers like gelatin, dextran, or alginates for strength and resilience. Limitations include drug incorporation amounts and particle size restrictions, while advantages include absorption across various regions without first-pass metabolism.

2.3.7. Orasolv Technology

Developed by CIMA labs, Orasolv masks the taste of active ingredients with effervescent disintegrating agents. Tablets are made using low compression force to minimize dissolution time, with packaging designed for soft tablets

2.3.8. Molding

Molded tablets are prepared using water-soluble ingredients to ensure complete and rapid dissolution. The powder blend is moistened with a hydroalcoholic solvent and molded into tablets under lower pressure than conventional tablet compression. Air-drying removes the solvent, resulting in tablets with a less compact and porous structure that enhances dissolution.

2.3.9. Tablet Molding Types

Solvent Method: Tablets are less compact and possess a porous structure that aids dissolution. Mechanical strength is a concern, requiring the incorporation of binding agents.

Heat Method: Involves spray congealing a molten mixture of hydrogenated polyethylene glycol, cottonseed oil, lecithin, sodium carbonate, and an active ingredient into a lactose-based tablet triturate form. Masking the taste is addressed by this method

2.3.10. Mass Extrusion

In this method, a blend of the active drug and other ingredients is softened using a solvent mixture of water-soluble polyethylene glycol, usually methanol. The softened mass is extruded through an extruder or syringe to form a cylinder, which is then cut Into even segments with heated blades to obtain tablets. The dried cylinder can be used to coat granules of bitter-tasting drugs, masking their bitter taste.

3. Evaluation of fast dissolving tablets

- Organoleptic Characteristics: The tablet's size and shape can be dimensionally described, monitored, and controlled. Tablet thickness plays a crucial role in reproducing appearance and serves as a counting mechanism in some filling equipment. To ensure uniformity, ten tablets were selected, and their thickness was recorded using a micrometer.
- Hardness: Achieving significant hardness in Orodispersible Tablets (ODTs) is challenging due to specialized processes and ingredients. The ODT's hardness limit is intentionally kept in a lower range to facilitate rapid disintegration in the mouth. Tablet hardness can be measured using conventional hardness testers.
- Friability: Maintaining % friability within specified limits poses a challenge for formulators, as various ODT manufacturing methods tend to increase % friability values. Evaluation of this parameter is essential, and the results should fall within defined limits (0.1-0.9%).
- Wetting Time: The wetting time of the tablet was measured following the method reported by Yunixia et al. A folded tissue paper (12 cm X 10.75 cm) was placed in a small petri dish (ID = 6.5 cm) containing 6 ml of Sorenson's buffer pH 6.8. A tablet was positioned on the paper, and the time for complete wetting was measured. Three trials were conducted for each batch, and the standard deviation was determined.
- In-Vivo Disintegration Test:The test involved six tablets using the apparatus specified in I.P.-1996. Distilled water at 37°C ± 2°C served as the disintegration media, and the time In seconds required for complete tablet disintegration, with no palatable mass remaining in the apparatus, was measured.

Table 2 Challenges of the formulation of FDTS

Challenges	Description
Mechanical strength and disintegration time	MDTs are formulated to obtain disintegration time usually less than a minute. While doing so, maintaining a good mechanical strength is a prime challenge. Many MDTs are fragile and there are many chances that such fragile tablet will break during packing, transport or handling by the patients.. It is very natural that increasing the mechanical strength will delay the disintegration time
Taste masking	Many drugs are bitter in taste. So effective taste masking of the bitter drugs must be done so that the taste of the drug is not felt in the oral cavity.
Mouth feel	Tablet should not disintegrate into larger particles in the oral cavity. The particles generated after disintegration of the Tablet should be as small as possible. Tablet should leave minimal or no residue in mouth after oral administration.
Sensitivity to environment	Tablet generally should exhibit low sensitivity to environment conditions such as humidity and temperature as most of the materials used in a Tablet are meant to dissolve in minimum quantity of water.
Palatability	As most drugs are unpalatable, tablets should contain the medicament in a taste-masked form.
Mechanical strength	In order to allow ODTs to disintegrate in the oral cavity, they are made of either very porous and soft-molded matrices or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle, difficult to handle, and often requiring specialized peel-off blister packing that may add to the cost.

Hygroscopic property	Several orally disintegrating dosage forms are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and humidity. Hence, they need protection from humidity which calls for specialized product packaging.
Aqueous solubility	Water-soluble drugs pose various formulation challenges because they form eutectic mixtures, which result in freezing-point depression and the formation of a glassy solid that may collapse upon drying because of loss of supporting structure during the sublimation process.
Size of tablet	It has been reported that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle was one larger than 8 mm.
Fast Disintegration	FDTS should disintegrate in the mouth without additional water or with a very small amount (e.g., 1–2 mL) of water.

4. Conclusion

Fast Dissolving Tablets (FDTS) are designed to rapidly dissolve or disintegrate in saliva, typically within a few seconds. They offer numerous advantages over traditional dosage forms, including enhanced efficacy, increased bioavailability, rapid onset of action, and improved patient compliance. Notably, FDTS are particularly beneficial for pediatric and geriatric patients, providing increased comfort.L Various methods can be employed for FDT preparation, contingent on the specific drug and additives used. While FDTS generally possess lower mechanical strength, advancements in technology and the incorporation of additives can yield formulations with sufficient mechanical strength.The foundational principle in fast-dissolving tablet development is maximizing pore structure. Researchers have explored techniques such as vacuum drying and freeze drying to achieve this goal. Freeze drying, although effective, can result in a fragile and hygroscopic product. In this context, the present investigation adopted a vacuum-drying technique after incorporating a subliming agent to enhance tablet porosity.Even bitter-tasting drugs can be integrated into FDTS through the use of taste-masking agents. Ongoing research in the field of FDTS indicates a continuous quest for innovation. FDTS not only demonstrate significant market potential but also contribute to a wide marketing reach, establishing the dosage form's success in the market. The formulation of many drugs as FDTS is anticipated in the future, given their promising market prospects. Fast dissolving tablets represent an innovative solution to address challenges associated with conventional solid dosage forms, particularly in patients with swallowing difficulties such as the geriatric and pediatric populations. These tablets are designed to rapidly dissolve or disintegrate in saliva, typically within 60 seconds, offering improved patient compliance and acceptance. Additionally, they have the potential to enhance biopharmaceutical properties, bioavailability, efficacy, convenience, and safety compared to traditional oral dosage forms. The increasing popularity of fast dissolving tablets over the past decade underscores their significance in catering to diverse patient needs, including those with psychiatric conditions, bedridden individuals, and travelers. Formulated using a combination of conventional and patented technologies, fast dissolving tablets exhibit adequate mechanical strength and rapid disintegration without the need for water. Ongoing advancements in formulation technologies continue to refine these dosage forms, offering even greater benefits with minimal drawbacks.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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