

A REVIEW ON FAST DISSOLVING DRUG DELIVERY SYSTEM

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ABSTRACT

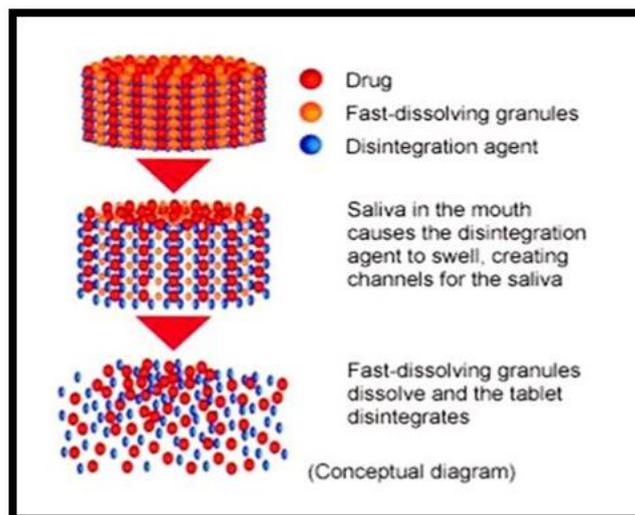
Fast Dissolving Drug Delivery Systems (FDDDS) signify a remarkable innovation in pharmaceutical technology, promoting improved patient compliance and a rapid onset of therapeutic effects. These systems are designed to disintegrate or dissolve rapidly in the oral cavity without the need for water, making them especially appropriate for pediatric, geriatric, and dysphagic patients. FDDDS encompass various dosage forms, including fast dissolving tablets, oral disintegrating films, and lyophilized wafers, which are developed using super disintegrants, taste-masking agents, and advanced manufacturing techniques such as direct compression, lyophilization, and 3D printing. The primary advantage of these systems lies in their ability to enhance bioavailability and bypass first-pass metabolism in certain cases. However,

challenges persist, including mechanical strength, moisture sensitivity, and limited drug loading capacity. This review provides a comprehensive analysis of the formulation strategies, mechanisms, evaluation criteria, and recent advancements in FDDDS. It also highlights marketed products and future prospects, emphasizing the growing significance of these systems in improving therapeutic outcomes and patient-centered drug delivery.

KEYWORDS: Pediatric, Geriatric, Bioavailability, Rapidly dissolving, Oral films, Methodology, Drug Delivery, Suspending Agent, Formulation Technology.

INTRODUCTION

FDDDS were initially launched in 1970 as a substitute for tablets, syrups, and capsules intended for pediatric and geriatric patients. They quickly disintegrate and dissolve in saliva, facilitating easy swallowing without requiring water, which offers a considerable benefit compared to conventional dosage forms. Rapidly dissolving drug delivery systems have become increasingly important in the pharmaceutical industry owing to their unique features and advantages, including a greater surface area that promotes rapid disintegration and dissolution in the oral cavity, no need for water, accurate dosing, quick onset of action, ease of transport, simple handling, a pleasant flavor, and improved patient adherence, especially among pediatric and geriatric populations. A fast-dissolving drug delivery system is generally a tablet that disintegrates or dissolves in the oral cavity without the need for water or chewing in most instances. To ensure palatability, fast-dissolving delivery system films must include agents that mask the taste of the active ingredient. The patient subsequently swallows this masked active ingredient with their saliva, along with both soluble and insoluble excipients. These formulations are also known as melt-in-mouth tablets, regimens, porous tablets, oro-dispersible tablets, quick-dissolving tablets, or rapid disintegrating tablets. The Fast Dissolving Drug Delivery System concept emerged from the necessity to provide patients with a conventional method for administering their medication. Due to physiological changes, especially in the elderly and pediatric populations, many individuals face difficulties with swallowing [Dysphasia]; however, this challenge is common across all age groups. Solid dosage forms that can disintegrate, dissolve, or suspend in saliva within the mouth make swallowing easier, offering significant benefits to pediatric and geriatric patients, as well as others who prefer the convenience of easily swallowable forms. This tablet disintegrates instantly upon contact with the tongue, releasing the drug that dissolves or disperses in saliva. The fast disintegrating drug delivery system (FDDTS) represents a new generation of formulations that combine the advantages of both liquid and traditional tablet forms, while also offering additional benefits over conventional dosage forms. They provide the convenience associated with tablet formulations and facilitate ease of swallowing similar to liquid formulations. This category of formulation is specifically designed for patients who have difficulty swallowing, including those with dysphagia, geriatric patients, pediatric patients, travelers, and individuals with psychotic conditions who are either unable to swallow or refuse to take conventional oral formulations. Dysphagia, or difficulty in swallowing, is prevalent across all age group. The FDT is also referred to as fast melting, fast dispersing or Dispersible tablet, rapid dissolve, and rapid melt tablet.



A. Fast dissolving Tablets

Fast dissolving tablets (FDTs), which are also known as fast disintegrating or melting tablets, as well as dispersible tablets, rapimelts, and porous tablets, dissolve or disintegrate within 60 seconds when placed in the mouth without requiring drinking or chewing. The psychological apprehension related to swallowing, chewing, or choking, combined with the high costs associated with packaging for low-pressure molded tablets produced through various manufacturing methods, presents considerable challenges. Furthermore, fast-dissolving tablets (FDTs) frequently lack sufficient mechanical strength, which necessitates careful handling. To protect the dosage form and tackle these challenges, a novel technology has been introduced in the form of fast dissolving oral films.

B. Fast dissolving oral films

Fast dissolving oral films (FDOFs) are the most sophisticated form of oral solid dosage, offering improved flexibility and comfort. They increase drug efficacy by dissolving within minutes in the oral cavity upon contact with saliva, thus eliminating the necessity for chewing or water for administration. Moreover, they are useful for local applications, such as local anesthetics for toothaches, oral ulcers, cold sores, or teething. Fast dissolving oral films employ technology derived from transdermal patches. The films closely resemble postage stamps in shape, size, and thickness. Occasionally, taste masking agents are added to disguise the flavor of the active ingredient.

Table 1: Comparison between Fast Dissolving, Tablets and Films.

Fast Dissolving Tablet	Fast Dissolving Film
It is a tablet	It is a film
Lesser dissolution due to less surface area	Greater dissolution due to larger surface area
Less durable as compared with oral films	Better durable than oral disintegrating tablets
Less patient compliance than films	More patient compliance
High dose can be incorporated	Low dose can only be incorporated

Salient Feature of Fast Dissolving Drug Delivery System

- ❖ The process of administering medication is made easier for patients who cannot swallow tablets, including those who are pediatric, geriatric, or psychiatric.
- ❖ The ease of administration and accurate dosing is superior to that of liquid forms.
- ❖ The removal of the requirement for water to take the dosage is a significant advantage for patients traveling without immediate access to water.
- ❖ The rapid dissolution and absorption of the medication can result in a swift onset of action.
- ❖ Assisting in the administration for patients who are unstable, disabled
- ❖ And uncooperative.
- ❖ There is no need for water from the patient.
- ❖ It must guarantee quick disintegration of fast-dissolving formulations.
- ❖ Mitigate the unpleasant taste of the medication.

ADVANTAGES

- i. Rapid dissolution and absorption of the medication.
- ii. Prevention of first-pass metabolism.^[11]
- iii. Simplified administration for patients who have difficulty swallowing tablets, including geriatric and psychiatric patients.^[12]
- iv. No need for water
- v. Improved stability.
- vi. Cost-effective^[13,14]

DISADVANTAGES

- i. They exhibit fragility and brittleness.
- ii. FDTs should be kept in a dry environment because of their hygroscopic properties.

- iii. Specialized packaging is required to provide protection during both storage and transportation.
- iv. The tablet generally shows insufficient mechanical strength, which requires careful handling during the manufacturing process.
- v. If not formulated properly, the tablet may lead to an unpleasant taste and/or grittiness in the oral cavity.

CHARACTERISTICS OF FAST DISSOLVING DRUG DELIVERY SYSTEM

Ease of Administration

Fast Dissolving Delivery Systems are easy to administer and manage, thereby improving patient compliance. Generally, elderly individuals encounter difficulties in swallowing conventional dosage forms (such as tablets, capsules, solutions, and suspensions) due to tremors in their extremities and dysphagia. Fast Dissolving Delivery Systems may offer a practical solution to these challenges.^[10]

Taste of the medicament

A mouth-dissolving delivery system generally includes the medication in a format that masks its taste. The taste-masking process is essential for developing an acceptable fast dissolving drug delivery technology (FDDT). Traditional tablet formulations often neglect the importance of taste masking, under the assumption that the dosage form will not dissolve until it has moved past the oral cavity.

Hygroscopicity

Many fast-dissolving dosage forms display hygroscopic characteristics and cannot maintain their physical integrity in standard humidity conditions, which requires specialized packaging for the products.^[5]

Friability

To aid in the disintegration of fast-dissolving tablets in the mouth, they are made from either highly porous and soft-moulded matrices or are compressed into tablets using a very low compression force. This results in tablets that are friable and/or brittle, which makes them difficult to handle, often requiring the use of specialized peel-off blister packaging.

IDEAL FAST DISSOLVING DRUG DELIVERY SYSTEMS

Orally disintegrating drug delivery System should possess following Characteristics:

- No water is required for oral administration.
- Dissolves, disperses, or disintegrates in the mouth within seconds.
- Provides a pleasant mouthfeel and effectively masks taste.
- Exhibits low friability and possesses adequate hardness.
- Leaves little to no residue in the mouth following administration.
- Produced using traditional manufacturing techniques.

DRUGS USED IN FAST DISSOLVING DRUG DELIVERY SYSTEM

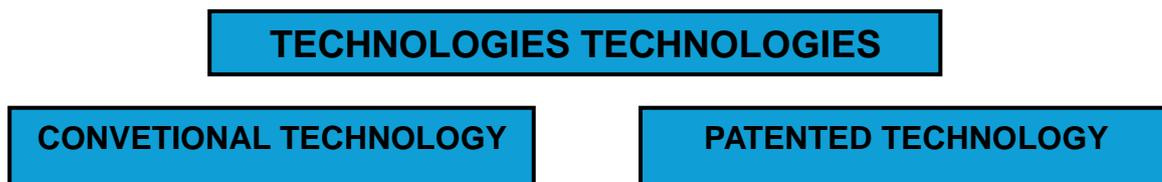
Example of some drug candidates best for FDT

- 1) **Andante -inflammatory Agents:** Ibuprofen, Proxicam, Mefenamic Acid
- 2) **Anti-bacteria Agent:** Erythromycin, Tetracycline, Doxycycline, Rifampicin
- 3) **Anti-fungal Agents:** Griseofulvin, Miconazole
- 4) **Anti-Malarials:** Chloroquine, Amodiaquine
- 5) **Anti-Gout Agent:** Allopurinol, probenecid
- 6) **Anti-Hypertensive :** Amlodipine, Nefidipine
- 7) **Anti-Coagulants:** Glipizide, Tolbutamide
- 8) **Anti-Protozoal Agents:** Benznidazole, Tinidazole
- 9) **Anti-Thyroidagent:** carbimazole
- 10) **Cardiac Inotropic Agent:** Digitoxin, Digoxis
- 11) **Gastro-Intestinal Agents:** Omeprazole, Ranitidine, Fomatidine
- 12) **Nutritional Agents:** Vitamin A, Vitamin B, Vitamin D, etc.

APPROACHES FOR FAST DISSOLVING TABLET:

The tablet dissolves rapidly because of the quick absorption of water into its matrix, resulting in its fast disintegration.

Technologies involved

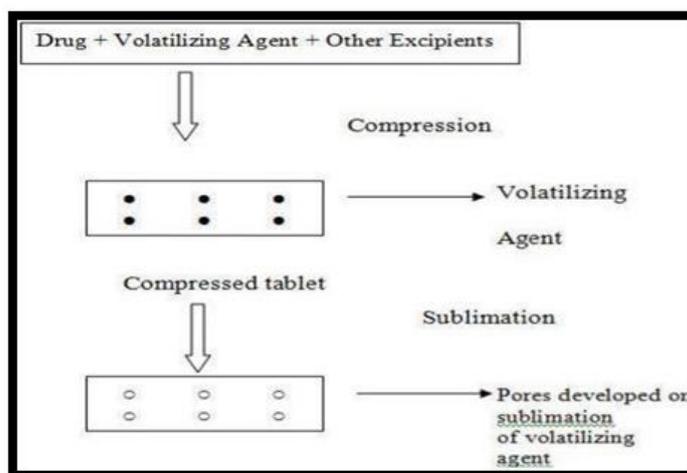


Conventional technology

1. Sublimation
2. Freeze drying or Lyophilization
3. Moulding
4. Spray drying
5. Direct compression
6. Mass extrusion

Sublimation technique

Inert solid components (e.g., urea, urethane, camphor, ammonium carbonate, naphthalene) are combined with other tablet excipients, and the resulting mixture is compressed into a tablet. The process of removing volatile substances via sublimation results in a porous structure. The tablet dissolves within 20 seconds and exhibits adequate mechanical strength. Traditional compressed tablets that include highly water-soluble ingredients frequently face challenges due to the low porosity of the matrix.



Freeze – drying (Lyophilisation technologies)

In this process, water is sublimated from the product following its freezing. Lyophilization is a pharmaceutical technique that allows for the drying of heat-sensitive drugs and biological materials at low temperatures under conditions that promote the removal of water via sublimation. The lyophilization process results in preparations that possess a very high specific surface area and are highly porous, which facilitates rapid dissolution and enhances absorption and bioavailability.

Molding method

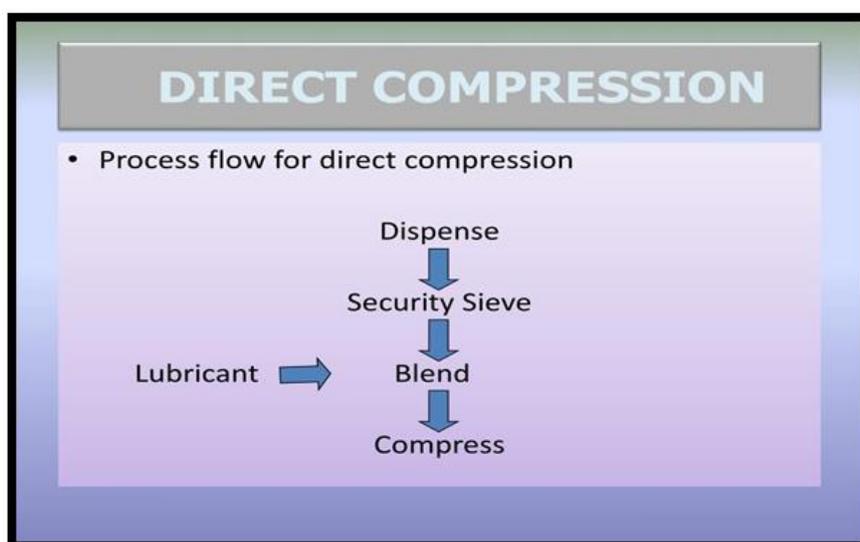
The Moulded tablets are produced using water-soluble ingredients to guarantee that the tablets dissolve or disintegrate rapidly and completely. The powder is moistened with a hydroalcoholic solvent and then formed into tablets under lower pressure compared to conventional methods. These tablets possess porous structures that aid in easy dissolution. The addition of sucrose, acacia, or PVP K30 can improve the mechanical strength of the tablet, thus facilitating easier dissolution.

Spray drying technique

Spray drying can produce highly porous and fine powders that dissolve rapidly. The formulations include hydrolyzed and non-hydrolyzed mannitol as a supporting agent, Sodium starch glycolate or croscarmellose sodium as a disintegrating agent, along with an acidic Substance (like citric acid) and/or an alkaline substance (such as sodium bicarbonate) to Improve disintegration and dissolution.

Direct compression Technique

The tablet formulation represents the most straightforward approach, utilizing standard equipment, easily accessible excipients, and a limited number of processing steps, with direct compression being utilized. Large doses can be accommodated, and the final weight of the tablet may exceed that produced by alternative methods. The disintegration and solubilization of directly compressed tablets depend on the individual or synergistic effects of the integrated ingredients, effervescent agents, and water-soluble components employed.



Mass Extrusion

This procedure involves the softening of the active blend through the use of a solvent mixture made up of water-soluble polyethylene glycol and methanol. Subsequently, the softened mass is extracted using a syringe to form a cylinder of the product, which is then divided into uniform segments with the aid of a heated blade to create tablets.

Patented technology

1. Zydis Technology
2. Durasolv Technology
3. Orasolv Technology
4. Flash Dose Technology
5. Wow tab Technology
6. Quick –Dis Technology

Zydis Technology

The Zydis formulation is a unique freeze-dried tablet where the drug is either physically encapsulated or dissolved within a matrix of quickly dissolving carrier material. When Zydis units are placed in the mouth, the freeze-dried structure disintegrates instantly and does not require water to aid in swallowing.

Durasolv Technology

Durasolv signifies the patented technology created by CIMA Labs. The tablets generated through this technology consist of a drug, a filler, and a lubricant. These tablets are produced utilizing standard tableting equipment and demonstrate good rigidity. They can be packaged using traditional packaging systems such as blisters.

Orasolv Technology

CIMA Labs has developed Orasolv Technology. This system incorporates a taste-masked active ingredient. Furthermore, it contains an effervescent disintegrating agent. The tablets are manufactured using a direct compression technique at a low compression force to minimize oral dissolution time.

Flash Dose Technology

Prographarm Laboratories has obtained a patent for the Flash tab technology. The tablets created by this system incorporate an active ingredient in the form of microcrystals. Drug

microgranules can be produced using conventional methods such as coacervation, microencapsulation, and extrusion spheronization. All processing utilizes standard tableting technology.

Wow tab Technology

The patented Wow tab technology has been developed by Yamanouchi Pharmaceutical Co. The acronym WOW signifies “Without Water.” This innovative method employs a blend of low mouldability saccharides and high mouldability saccharides to produce a tablet that dissolves rapidly while maintaining durability. The active ingredient is mixed with a low mouldability saccharide (such as lactose, glucose, or mannitol) and granulated using a high mouldability saccharide (such as maltose or oligosaccharides) prior to being compressed into a tablet.

Quick –Dis Technology

Lavipharm Laboratories Inc. (Lavipharm) has created an effective intraoral fast-dissolving drug delivery system that meets the unfulfilled needs of the market. The film is placed on the upper surface or the base of the tongue. It stays at the site of application and rapidly releases the active ingredient for local and/or systemic absorption. The QuickDis™ drug delivery system is offered in a variety of packaging configurations, including unit-dose pouches and multiple-dose blister packages.

EVALUATION OF TABLETS

General Appearance

The general appearances of a tablet include Size, shape, colour, taste, odour, surface Texture.

Size, Shape, Thickness and diameter

The size and shape of the tablet can be described, observed, and controlled. The thickness of tablets is a vital characteristic for their visual appeal and also influences the counting process when utilizing filling equipment. Some filling machines use the uniform thickness of the tablets as a means of counting.

Uniformity of weight

In the Indian Pharmacopoeia, the procedure for assessing weight uniformity involved the selection of either ten or twenty tablets, with their weights evaluated both separately and

collectively using a digital weighing balance. The average weight of a single tablet was calculated by determining the total weight.

Hardness of Tablets

The hardness of a tablet is defined as the force exerted across its diameter in order to fracture the tablet. The tablet's resistance to chipping, abrasion, or breakage during storage, transformation, and handling prior to use is contingent upon its hardness. The hardness of each tablet formulation was assessed using the Monsanto hardness tester.

Friability of tablets

The fribrater consists of a plastic chamber that rotates at a rate of 25 revolutions per minute, releasing the tablets from a height of 6 inches with each rotation. The tablets were subjected to rotation in the fribrater for a minimum period of 4 minutes.

Wetting time

In this process, the wetting duration of the tablet is assessed. A straightforward piece of tissue paper (12 cm X 10.75 cm), folded in half twice, was placed in a small petri dish (ID = 6.5 cm) that held 6 ml Of Sorenson's buffer at pH 6.8. A tablet was positioned on the paper, and the time taken for Complete wetting was noted.

In Vitro Disintegration test

The In Vitro disintegration time was evaluated by immersing a tablet in a beaker containing 50 ml of Sorenson's buffer at pH 6.8 Three tablets from each formulation were randomly selected, and the In Vitro dispersion time was performed.

In Vivo Disintegration test

The test was conducted on 2 or 3 tablets. The tablets were placed in the mouth, and the time taken for complete disintegration was measured in a few seconds.

EXCIPIENTS USED TO PREPARE FDDT'S

Super disintegrants

Crosspovidone, microcrystalline cellulose, sodium starch glycolate, sodium carboxymethyl Cellulose, pregelatinized starch, calcium carboxymethyl cellulose, and modified corn starch. Sodium starch glycolate demonstrates better flowability than crosscarmellose sodium. Crosspovidone has a fibrous structure and is very compressible.

Flavours

The flavor of peppermint offers a refreshing taste, complemented by various oils and aromatic flavoring agents, such as peppermint oil, clove oil, hay oil, anise oil, eucalyptus oil, thyme oil, and bitter almond oil. Flavoring components include essences of vanilla, citrus, and bun.

Sweetners

Aspartame, Sugars derivatives.

Surface active agents

Sodium dodecyl sulfate, sodium lauryl sulfate, polyoxyethylene sorbitan fatty acid esters (commonly referred to as Tweens), sorbitan fatty acid esters (known as Spans), and polyoxyethylene stearates.

Binder

Polyvinylpyrrolidone(PVP), Polyvinylalcohol(PVA), Hydroxypropyl methylcellulose(HPMC).

Colour

Sunset yellow, Amaranth etc.

Lubricants

Stearic acid, magnesium stearate, zinc state, calcium state, talc, polyethylene glycol, liquid Paraffin, magnesium lauryl sulfate, colloidal silicon dioxide.

MECHANISM OF SUPERDISINTEGRANTS**Swelling**

The primary mechanism acknowledged for the disintegration of tablets is swelling. Tablets characterized by high porosity often demonstrate insufficient disintegration due to a lack of adequate swelling force. Conversely, tablets with low porosity produce a sufficient swelling force.

Porosity and capillary action (Wicking)

Disintegration via capillary action is consistently the first stage. When the tablet is placed in a suitable aqueous medium, the medium permeates the tablet and replaces the air that is adsorbed on the particles, thus diminishing the intermolecular bonds and leading to the

tablet's fragmentation into fine particles. The degree of water absorption by the tablet is affected by the tablet's hydrophilicity and the conditions present during the tableting process.

Due to disintegrating particle/particle repulsive forces

Another mechanism of disintegration aims to clarify the expansion of tablets made with 'nonswellable' disintegrants. Guyot-Hermann has proposed a particle repulsion theory, which rests on the observation that particles that do not swell also aid in the disintegration of tablets. The electric repulsive forces that act between particles function as the mechanism for disintegration, with water being an essential element for this process.

Due to Deformation

During the tablet compression process, disintegrant particles experience deformation, and these modified particles return to their original structure when they come into contact with aqueous media or water. In certain cases, the swelling ability of starch is increased when granules undergo considerable deformation during compression.

CONCLUSION

Rapidly dissolving drug delivery systems improve patient adherence and may offer enhanced biopharmaceutical characteristics, greater effectiveness, and improved safety compared to conventional oral dosage forms. At present, fast disintegrating tablets are increasingly available as over-the-counter solutions for treating allergies, as well as symptoms associated with colds and flu. The future prospects for these products appear positive due to the advent of new technologies, alongside strong market acceptance and patient demand. The potential for progress in rapid disintegration and drug delivery is promising; however, the technology is still in its early stages. Continuous research is ongoing, and more products need to be brought to market to fully capitalize on this technology. Mouth dissolving films are intended for application in the oral cavity and represent a novel and promising dosage form, especially advantageous for pediatric and geriatric patients. These films provide several benefits over traditional dosage forms and fast dissolving tablets

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