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A Review On Fast Disintegrating Tablet

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Abstract

Over the past ten years, the demand for fast disintegrating tablets (FDTs) has grown steadily, and the field is now one of the fastest-growing segments of the pharmaceutical industry. For many medications, oral drug delivery is still the preferred method of administration. Scientists have created FDTs that are more patient-friendly and convenient as a result of recent technological advancements. These tablets dissolve or disintegrate in the mouth when placed there without the need of water to be added, making it simple to take in the active pharmaceutical ingredients. The formulation's acceptance and usefulness led to the creation of several FDT technologies.

The various formulations and methods described in this review were created to facilitate the rapid dissolution/dispersion of tablets in the oral cavity. This review focuses on lyophilization, molding, sublimation, and compaction-based FDT technologies as well as methods for increasing the FDT features such spray-drying, moisture treatment, sintering, and the use of sugar-based disintegrants.

Keywords Fast Disintegrating Tablets, Bioavailability, Humidity, Superdisintegrents, Fragmented

Introduction

Fast Dissolving Drug Delivery System originated as an approach to give patients access to traditional drug administration methods. Dysphagia, an inability to swallow due to physiological changes linked with, particularly, ageing, and pediatric patients, is an issue that affects individuals of all ages. (Chang et al.,2020) The pediatric and geriatric populations, as well as those patients who prefer the ease of easily swallowable dosage forms, can benefit greatly from solid dosage forms that can be fragmented, dissolved, or suspended by saliva in the mouth. When placed on the tongue, this tablet instantly dissolves, releasing the medication that dissolves or disperses in the saliva. Pharmaceutical treatments for elderly individuals have recently been investigated to increase their treatment compliance and quality of life. Rapidly disintegrating tablets are a desirable dose form and pharmaceutical product that is patient-focused. (Siddiqui et al., 2010) They can quickly dissolve in saliva. Many researchers are interested in the mouth-dissolving tablets. Tablets, pills, and powders can be challenging to swallow for many older individuals. These tablets are designed to dissolve or disintegrate in the mouth without the need for water to remedy this issue. Saliva aids in the disintegrating mass's smooth descent via the esophagus, enabling even those who have trouble chewing or swallowing to ingest it without difficulty. (Masih et al.,2017) Distinguishing between the two types of dispersible tablets is necessary because one dosage form instantly dissolves in the mouth and can be swallowed without the use of water, while the other tablet formulation easily dissolves in water to create a dispersion that is simple for the patient to consume. (Valleri et al., 2004)

Definition

FDTs are solid unit dose forms that disintegrate or dissolve quickly in the mouth without the need for chewing or water. (Rahane et al.,2018) FDTs, or orally disintegrating tablets, are especially useful for pediatric and geriatric populations who have trouble swallowing traditional pills and capsules.

Characteristics of Fast disintegrating Drug Delivery System (Sharma et al., 2011)

The tablets should,

- It does not need to be swallowed with water, but it should dissolve or disintegrate in the mouth within seconds.
- Be tolerant of flavor masking.
- Be portable without regard for fragility.
- Have lovely taste in your tongue.
- After oral administration, leave little or no residue in the mouth.
- Low sensitivity to external conditions such as temperature and humidity.
- Allow for the low-cost production of tablets utilizing normal processing and packaging equipment.

Concept of Fast Disintegrating tablets

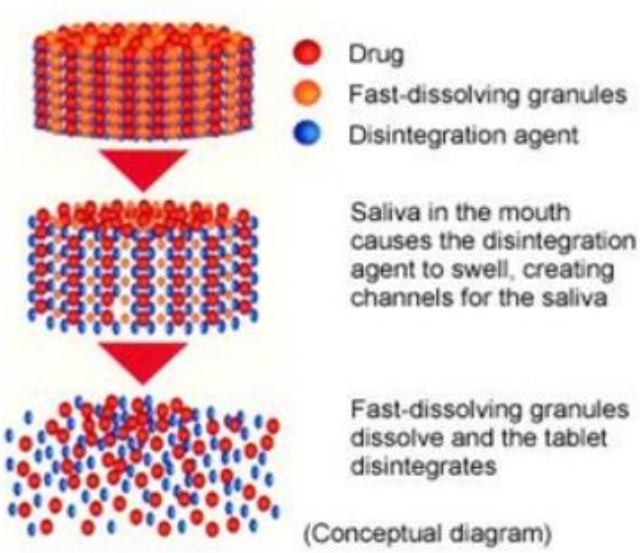

Figure 1 Concept of Fast Disintegrating Tablet

Salient features of fast disintegrating tablet (Reddy et al., 2002)

- Ease of administration for patients who are unable to swallow, such as the elderly, stroke victims, bedridden patients, patients suffering from renal failure, and patients who refuse to swallow, such as pediatric, geriatric, and psychiatric patients.
- There is no need for water to consume the dosage form, which is a very useful feature for people who are travelling and do not have easy access to water.
- Rapid medication solubility and absorption, resulting in a rapid start of action.
- Some medications are absorbed from the mouth, pharynx, and esophagus as saliva flows down into the stomach, increasing drug bioavailability.
- The risk of chocking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.
- Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra-rapid on set of action required.
- An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
- Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.

Applications of fast disintegrating tablets (Lalla et al., 2004)

- There is no need for water to consume the tablet.
- FDTs are simple to deliver to pediatric, geriatric, and intellectually challenged patients.
- When contrast to liquids, accurate dosing is possible.
- The medicine dissolves and absorbs quickly, providing a quick onset of effect.

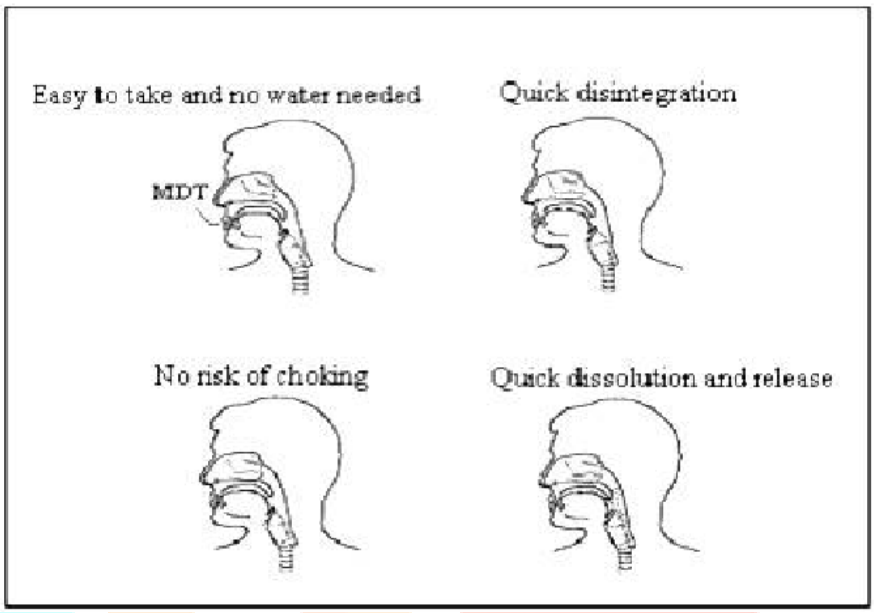

Figure 2Advantages of Fast Disintegrating Tablets

Challenges to be faced during development of Fast Disintegrating Tablets

- **Palatability**
  Because most medications are unpleasant to swallow, FDTs usually contain the medication in a flavor-masked form. FDTs breakdown or dissolve in the patient's oral cavity, releasing active chemicals that encounter the taste buds. As a result, disguising the taste of the medications becomes crucial to patient compliance. (Prajapati et al.,2009)
- **Mechanical strength and disintegration time**
  To allow FDTs to disintegrate in the oral cavity, they are either made of a very porous and soft-molded matrix or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle, difficult to handle, and frequently necessitating specialized peel-off blister packing, which may increase the cost. Only wow tab and dorsal technologies can create tablets that are hard and robust enough to be put in multi-dose bottles. (Arya et al.,2010)
- **Hygroscopicity**
  Several orally disintegrating dosage formulations are hygroscopic and lose physical integrity under typical temperature and humidity conditions. As a result, they require humidity protection, which necessitates specialized product packaging. (Rane et al.,2012)
- **Amount of drug**
  The amount of medicine that can be included into each unit dose limits the application of FDT technologies. The drug dose for lyophilized dosage forms must be less than 400 mg for insoluble pharmaceuticals and 60 mg for soluble drugs. This value is especially difficult to calculate when creating fast-dissolving oral films or wafers.
- **Aqueous solubility**
  Water-soluble pharmaceuticals provide several formulation issues due to the production of eutectic mixtures, which results in freezing-point depression and the formation of a glassy solid, which may collapse upon drying due to loss of supporting structure during the sublimation process. Such collapse can occasionally be avoided by

employing matrix-forming excipients like mannitol, which can promote crystallinity and so impart stiffness to the amorphous composite.

- **Size of tablet**
  The size of a pill influences its ease of administration. The easiest size of tablet to swallow is 7-8 mm, whereas the easiest size to handle is one larger than 8 mm. As a result, it is challenging to obtain a tablet size that is both portable and easy to manage.
- **Mouth feel**
  In the oral cavity, FDTs should not break into larger particles. The particles formed following FDT disintegration should be as tiny as possible. Furthermore, the inclusion of tastes and cooling substances such as menthol improves the tongue feel.
- **Sensitivity to environmental conditions**
  FDTs should be resistant to environmental conditions such as humidity and temperature because most of the materials used in FDTs are designed to dissolve in a small amount of water. (Kumar et al., 2014)

Limitations of mouth dissolving film of tablets

- The mechanical strength of the tablets is frequently insufficient. As a result, extreme caution is essential.
- If the tablets are not properly formed, they may leave an unpleasant taste and/or grittiness in the mouth. (Masih et al., 2017)

Excipients used in Fast Disintegrating tablets

Sr.no	Name of the excipient	%Used
1	Superdisintegrents	1 to 15%
2	Binders	5to10%
3	Antistatic Agent	0 to 10%
4	Diluents	10 to 85%

Table 1Excipient used in Fast Disintegrating Tablets

Superdisintegrents

A solid dose form containing medical drugs or active ingredients that degrades quickly when placed on the tongue. Following are the examples of Superdisintegrents used in formulation of fast disintegrating tablets. (Pahwa et al.,2011)

Sr.no	Superdisintegrents	Mechanism of Action	Specific Properties
1	Croscarmellose Sodium	Sewells 4-to 8folds in <10S	Effective in low concentrations (.5to 2.0)
2	Crospovidone	Combination of swelling and wicking action	The effective concentration is 1-3%.
3	Cross-linked alginic acid	Hydrophilic colloidal substance having high sorption capacity	The combination of swelling and wicking actions causes disintegration
4	Gellan gum	Strong selling properties upon contact with water.	Anionic polysaccharide of linear tetra saccharides, good Superdisintegrents

			property similar to modified starch and cellulose.
5	Sodium starch glycolate	Strong swelling properties upon contact with water swells7-12 folds in <30s	Rapid absorption of water results in swelling up to 6% high concentration causes gelling

Table 2 Super disintegrants and their mechanism of action and properties

Bulking materials

Bulking elements are essential in the creation of rapid dissolving tablets. They serve as a diluent, filler, and cost-cutting agent. Bulking agents improve the texture of the tablets, which improves disintegration in the mouth, in addition to adding volume and lowering the concentration of the active in the formulation. For better aqueous solubility and sensory perception, the bulking agents for this dosage form should be more sugar-based, such as mannitol, polydextrose, lactose derivatives such as directly compressible lactose (DCL), and starch hydrolysate. Mannitol, has great aqueous solubility and superior sensory perception due to its negative heat of solution. Bulking agents are added in amounts ranging from 10% to approximately 90% by weight of the final composition.

Excipients are classified in descending order of brittleness as follows: microcrystalline cellulose>alpha lactose monohydrate>spray-dried lactose>anhydrous beta lactose>anhydrous alpha lactose>dicalcium phosphate dihydrate.

The most common sugar-based excipients are bulking agents (such as dextrose, fructose, lactitol, maltitol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose, and xylitol) with high aqueous solubility and sweetness, which contribute taste masking and a pleasant mouth feel.

Sugar-based excipients can be classified according to their molding and dissolving rate:

Type 1 saccharides Lactose and mannitol are examples, which have a low moldability but a high dissolving rate.

Type 2 saccharides (maltose and maltitol) are highly moldable but dissolve slowly. (Panigrahi et al.,2010)

Emulsifying agents

Emulsifying agents are important in the formulation of rapid dissolving tablets because they aid in drug release without the need for chewing, swallowing, or drinking water. Emulsifying chemicals can help to keep immiscible mixtures stable and boost bioavailability. Alkyl sulphates, propylene glycol esters, lecithin, sucrose esters, and other emulsifying agents are used in rapid dissolving tablet formulations. These can be added in amounts ranging from 0.05% to 15% by weight of the final product.

Lubricants

Though not required excipients, these can help make the tablets more appealing once they dissolve in the mouth. Lubricants help with drug transit from the mouth to the stomach by reducing grittiness.

Flavors and Sweeteners

Flavorings and taste masking chemicals make the items more appealing to patients. The incorporation of these compounds' aids in the reduction of bitterness and unpleasant tastes associated with some actives. Natural and synthetic flavors can be utilized to improve the organoleptic properties of quick dissolving tablets. There is a vast variety of sweeteners available, including sugar, dextrose, and fructose, as well as non-nutritive sweeteners like aspartame, sodium saccharin, sugar alcohols, and sucralose. Sweeteners provide a pleasant taste as well as weight to the composition.

Technologies used in preparation of fast dissolving Tablets

- **Freeze-drying**
  The freeze-drying process is used to improve the dissolution rate and oral bioavailability of medications that have low solubility but high permeability (biopharmaceutical classification system Class II pharmaceuticals). Freeze drying (Lyophilization) is the process of removing water from a product after it has been frozen. This process can be carried out in a variety of ways to produce the same product, for example, I) the drug is physically trapped in a water-soluble matrix (a water-soluble mixture of saccharide and polymer formulated to provide rapid dispersion and physical strength), which is freeze dried to produce a product that dissolves quickly when placed in the mouth. A chemically stable and water-insoluble medication with particle size less than 50 m is required for such formulations.[8,34] II) Porous solid form obtained by freezing an aqueous dispersion or solution of the active-containing matrix and removing the water with an excess of alcohol (solvent extraction), with the advantage that thermolabile drugs can be formulated at non-elevated temperatures, thereby eliminating adverse thermal effects, and stored in a dry state with few shelf-life stability problems III) A porous solid galenic form of an oil-in-water emulsion is lyophilized and deposited directly in the blister alveolus. The fundamental downside of these dose forms is their lack of physical resistance in ordinary blister packs, as well as their limited capacity to integrate higher amounts of active medication. Steps involved in freeze drying process. (Siddiqui et al., 2010)

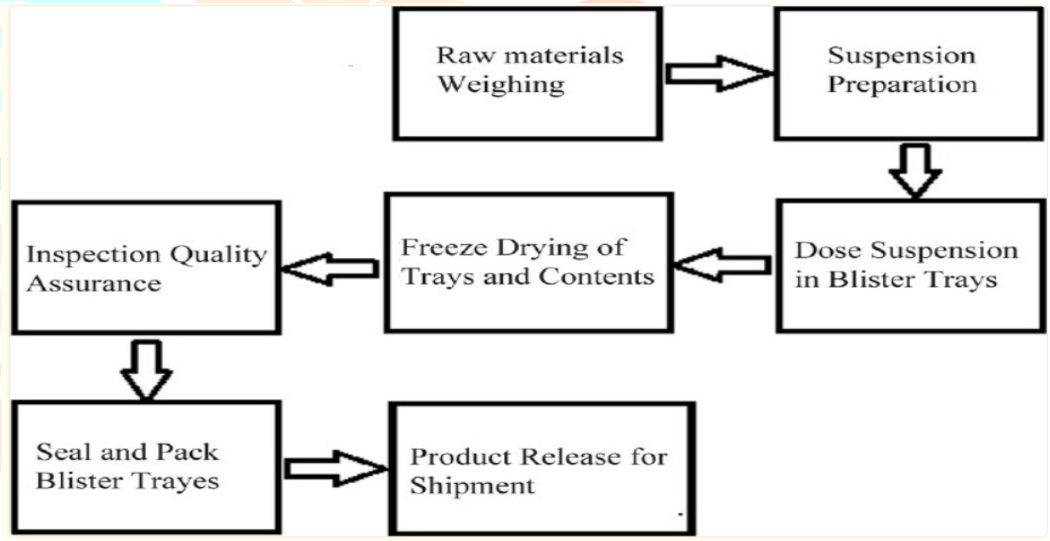

Figure 3Steps involved in Freeze Drying Process

- **Zydis technology**
  Zydis technology (ZT) is a trademarked method. ZT uses a proprietary freeze-drying technique to create completed dose units that differ greatly from standard oral systems. In this technology, a drug solution or suspension in water is poured into preformed blisters (giving the tablet shape) and then frozen in a specially designed cryogenic freezing process to control the size of ice crystals, ensuring that the tablet has a porous matrix for rapid disintegration. The frozen units are then transferred to large-scale freeze dryers for the sublimation process, in which most of the remaining moisture from the tablets is evaporated and open blisters are sealed using a heat seal method.

- **Lyoc**
  Lyoc is a porous and solid galenic form created by lyophilizing an oil-in-water emulsion that has been deposited directly in the blister alveolus. Freezing a thicker (paste-like) emulsion containing the active as bulk or coated microparticles is the method of preparation. This product can withstand a high dose and disintegrates quickly however it has low mechanical strength.

- **Quicksolv**
  Quicksolv porous solid dosage forms are created by freezing an aqueous dispersion/solution of the drug-containing matrix and then drying it by solvent extraction to remove the water. The final form disintegrates quickly, but it has a low drug content and can only be utilized for medicines that are insoluble in the extraction solvent. The optimum drug properties for this method include low water solubility, tiny particle size of 50 m, and strong aqueous stability in suspension.

- **Molding**
  Tablets are made with hydrophilic components to achieve optimum medication dissolution. The powder bulk is soaked in a hydroalcoholic solvent before being compacted into a dosage form. After then, the solvent system is allowed to evaporate. Spray congealing a molten combination of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethene glycol, and an active component into lactose-based tablet triturate produces the taste of medication particles. The molding procedure is particularly porous since solvents are eliminated by drying, producing a porous aggregate that favors quick disintegration.

- **Compaction**
  Attempts were made to reduce the disintegration time of RDT prepared by direct compression with adequate hardness. Bi and Watanabe prepared RDT by direct compression using microcrystalline cellulose (MCC) and low-substituted hydroxypropyl cellulose (L-HPC) as disintegrants. According to the authors, MCC/L-HPC ratios ranging from 8:2 to 9:1 resulted in tablets with the quickest disintegration times. Bi and Sinada and Bi, on the other hand, utilized a wet compression method in which wet granules of -lactose monohydrate was crushed and then dried at 60°C and maintained in a desiccator for 12 hours at room temperature.
  Direct compression is the most basic and cost-effective tablet manufacturing technique for Mouth Dissolving Tablets (MDT) because it can be done with standard tablet manufacturing and packaging machinery are also because tableting excipients with improved flow, compressibility, and disintegration properties are available.

- **Flashtab**
  Flashtab is a patented method, although the tablets are compressed directly. Flashtab comprises drug-coated crystals and microgranules, as well as disintegrants. This method employs two types of disintegrants: a dissolving agent with a high swelling force and a swelling agent with a low swelling force. (Sharma et al.,2011)
- **Direct compression**
  It is a most preferred technique for manufacturing of Fast disintegrating tablets because having certain advantages. High doses can be accommodated, and the final tablet weight can be greater than that of other methods.
  - The simplest method of producing tablets.
  - Standard equipment and readily available excipients are employed.
  - There are only a few processing stages involved.
  - Financial viability.

Figure 4 Direct Compression Process

- **Cotton candy process**
  This method is named after a unique spinning mechanism that produces a floss-like crystalline structure that resembles cotton candy. The cotton candy technique utilizes the simultaneous action of flash melting and spinning to generate a matrix of polysaccharides or saccharides. The resulting matrix is partially recrystallized to increase

flow and compressibility. After milling and blending with active ingredients and excipients, the candy floss matrix is compacted into FDTs.

- **Spray-drying**
  Ingredients are integrated using hydrolyzed and nonhydrolyzed gelatins as supporting agents, mannitol as a bulking agent, sodium starch glycolate or croscarmellose sodium as a disintegrating agent, and an acidic (e. g. citric acid) or alkali (e. g. sodium bicarbonate) material to improve disintegration and dissolution. The spray-drying process provides quick disintegration (within 20 seconds) when the dosage form meets the aqueous medium.

- **Phase transition process**
  This procedure uses erythritol (melting point 122 °C), xylitol (93-95 °C), trehalose (97 °C), and mannitol (166 °C) to disintegrate FDTs via phase transition of sugar alcohols. Compressing a powder comprising two sugar alcohols with high and low melting points and then heating at a temperature between their melting points resulted in tablets. Because of their low compatibility, the tablets lack appropriate hardness prior to heating. (Masih et al ., 2017)

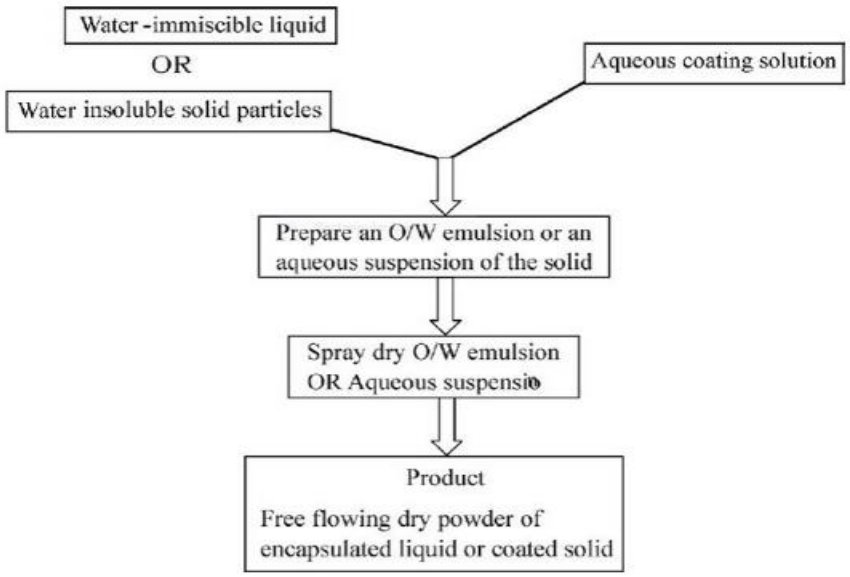

Figure 5Flow chart for coating liquid and solid particles using spray-drying process

Conclusion

Fast dissolving tablets are novel dosage forms that were created and specifically created to address some of the issues with conventional solid dosage forms, such as the difficulty in swallowing the pill in elderly and young patients. Fast-dissolving pills are made to dissolve or disintegrate in the saliva in a matter of seconds, usually between 5 and 60. When compared to traditional oral dose forms, fast-dissolving tablets offer higher patient compliance and acceptance. They may also have better biopharmaceutical characteristics, bioavailability, improved efficacy, convenience, and safety. Over the past ten years, FDTs have become incredibly more popular. For patients who are psychotic, bedridden, elderly, or young, for those who might not have access to water, or for patients who are actively travelling, FDTs must be developed. FDT formulations created using some of these conventional and patented technologies have adequate mechanical strength and quickly dissolve in the mouth without the use of water. The development of FDTs using improved technologies results in dosage forms that are more efficient and have fewer drawbacks.

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