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Review Article

Fast Dissolving Tablet: An Overview

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ABSTRACT

Oral delivery is the preferred route of drug delivery in the pharmaceutical industry because to its safety, convenience, and cost-effectiveness, with high patient compliance. Fast dissolving tablets have become a prevalent and widely recognized dose form, particularly for young patients due to the insufficient development of their muscular and neural systems, as well as for senior individuals experiencing Parkinson's disease or hand tremors. Nowadays, a small number of solid dosage forms, such as tablets and capsules, have issues such dysphagia, which makes it difficult to swallow. This leads to a high rate of non-compliance and renders the treatment ineffective. Fast dissolving. Tablets dissolve easily in saliva, eliminating the need for water. Fast-dissolving pills dissolve quickly in saliva, often within seconds. Fast dissolving tablet formulations offer advantages over conventional tablet and liquid dosing formats. Various techniques, including spray drying, sublimation, melt granulation, direct compression, freeze-drying/lyophilization, and mass extrusion, have been developed for producing fast dissolving tablets. This review examines the needs, benefits, constraints, and technology used for quick dissolving tablets, as well as evaluation methodologies.

INTRODUCTION

Solid dosage forms remain the preferred method for administering therapeutic agents due to their accuracy, ease of self-administration, pain avoidance, patient compliance, and low cost when compared to other forms. [1,3] Tablets and capsules are the most often used solid dose forms. However, some patients, particularly the elderly and children, may struggle to swallow them (Dysphagia). Drinking water is crucial for ingesting oral medications. When water is not available, patients may struggle to swallow traditional dosage forms, such as during motion sickness (kinetosis) or coughing due to colds, allergies, or bronchitis. Tablets that dissolve quickly in the mouth have received significant attention.[2] Fast disintegration tablets are gaining popularity and acceptability as a new medication administration technique. They are easy to

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administer and improve patient compliance, ensuring drug safety. [4] The US Food and Drug Administration (USFDA) defines a fast dissolving tablet (FDT) as "a solid dosage form containing a medicinal substance or active ingredient that disintegrates rapidly usually within a matter of seconds when placed on the tongue" [3]. The European Pharmacopoeia now uses the term "Oro Dispersible Tablet" to refer to uncovered tablets that disperse in the buccal cavity prior to consumption. [5] Fast dissolving medication delivery systems were developed in the late 1970s as an alternative to traditional dose forms for juvenile and geriatric patients. The pills dissolve quickly in saliva, often within 60 seconds [5]. Pharmaceutical technologists have created new oral dosage forms, such as orally disintegrating tablets (ODTs), fast disintegrating tablets (FDTs), mouth melting tablets (MMTs), and mouth dissolving tablets (MDTs), that dissolve quickly in saliva without the need for water. Some medications may have higher bioavailability due to oral absorption and pregastric absorption of dispersed pharmaceuticals in saliva that enters the stomach. Additionally, the amount of medication susceptible to first-pass metabolism is reduced compared to normal tablets [5].

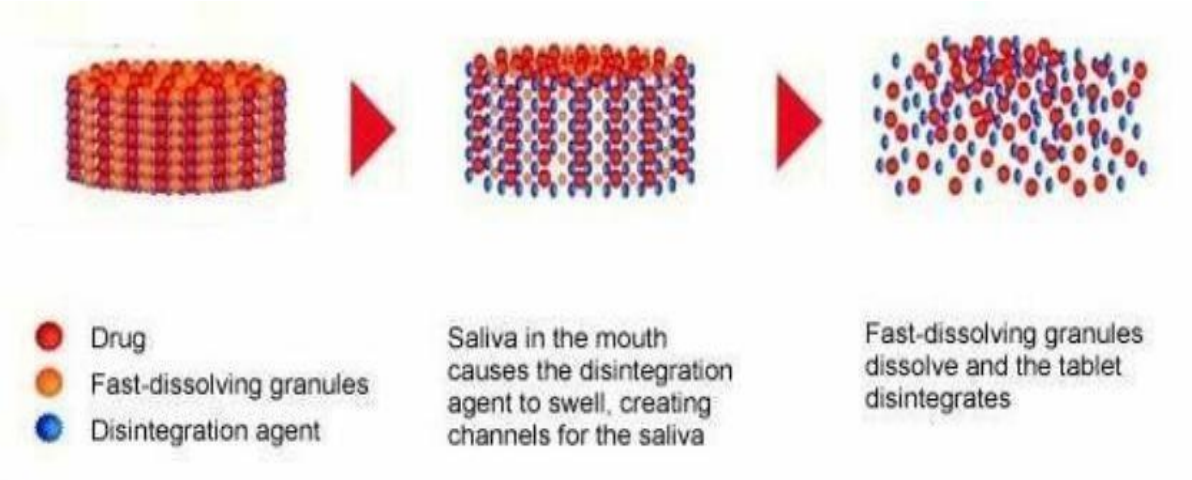

Fig. Conceptual diagram of FDTs Requirements of fast dissolving tablets:

Patient factor [5]

Fast dissolving dosage forms are ideal for pediatric and geriatric patients who cannot swallow regular tablets or capsules with an 8-oz glass of water. This includes the following:

- Very elderly patients of depression who may not be able to Swallow the solid dosage forms.
- Patient who has fear of choking.
- Patients who have difficulty in swallowing and chewing solid dosage form.
- A patient with persistent nausea, who may be a journey, or has Little or no access to water.

Manufacturing and marketing factors [11]

As a drug's patent expires, producers often design a new and superior dosage form. Introducing a new dosage form can help manufacturers gain market exclusivity, differentiate their products, and protect their patents. Eisai Inc. launched Aricept FDT, an extension of donepezil for Alzheimer's disease, in Japan in 2004 and the US in 2005 in response to Ranbaxy's generic challenge.

Effectiveness factor

These formulations claim to have increased bioavailability and faster onset of effect. Saliva dispersion in the oral cavity can lead to pre-gastric

absorption of some formulation ions, particularly when the medication dissolves fast. Many medications are absorbed through the buccal, pharyngeal, and stomach regions. Pre-gastric absorption is beneficial for medications that require hepatic metabolism as it avoids first-pass metabolism. Drugs with high levels of hazardous metabolites produced by first-pass liver and stomach metabolism, as well as those with significant absorption in the oral cavity and pre-gastric regions, may have enhanced safety profiles.

METHODS:

There are many methods for the preparation of fast dissolving tablets described as follows:

Freeze drying / Lyophilization

Freeze drying involves removing water from a substance using sublimation. Freeze-dried goods dissolve faster than other solids. Lyophilization creates a consistent structure for the bulking agent and drug, improving dissolving properties. [11]

Spray Drying

This technique involves using gelatin as a matrix and supporting agent, mannitol as a bulking agent, and superdisintegrants such as crosscarmellose, sodium starch glycolate, or crospovidone. Spray-dried powder tablets containing a bulking agent, superdisintegrant, acidic ingredient (citric acid), and alkaline ingredient (e.g. sodium bicarbonate) dissolve in 20 seconds in water. The spraydried powder was crushed into tablets with rapid disintegration and excellent dissolving. [14]

Tablet moulding

Molding can be done using two methods: solvent or heat. Solvent-made tablets are less compact than compressed tablets and have a permeable structure, allowing for faster dissolving. The mechanical strength of moulded tablets is a significant concern. Tablets should include binding agents to improve mechanical strength. [12] Taste masking is an additional issue with this technology and the medicine it masks. Particles are created by spray-congealing a mixture of hydrogenated polyethylene glycol, cottonseed oil, lecithin, and sodium carbonate into a lactosebased tablet triturate. Molded tablets are easier for artificial manufacturers to measure than lyophilized tablets. [13]

Sublimation

FDTs are created by combining porous materials with volatile solids such as urea, camphor ammonium carbonate, ammonium bicarbonate, and hexamethylene-tetramine. Tablets can contain volatile substances such as benzoic acid, ammonium bicarbonate, ammonium carbonate, camphor, naphthalene, urea, and urethane. Sublimation removes volatile material and creates a porous matrix. Tablets made with this approach typically dissolve in 10-20 seconds. Solvents like benzene and cyclohexane can act as pore-forming agents.

Direct compression

Direct compression is the recommended method for tablet manufacturing. The tablet size and hardness significantly impact disintegrant effectiveness. Tablets that are hard or large take longer to disintegrate. Soft and tiny tablets have a poor mechanical strength. To achieve rapid disintegration and high dissolution rates, select the right disintegrant kind and concentration.

Milling Sieving Mixing Compression

Mass extrusion

In this procedure, the active blend is softened with a solvent mixture of methanol and polyethylene

glycol, then expelled using a syringe to form a cylinder. The cylinder is then cut into even pieces using a heated blade to produce tablets. The dried cylinder can be used to cover harsh medicine grains and disguise their taste.

Principle Of Fast Dissolving Tablet:

The basic principle of fast dissolving tablets (FDTs) is to design a tablet that dissolves quickly in the mouth, usually within a minute, without the need for water. This is achieved through the use of superdisintegrants, which are ingredients that help break down the tablet quickly [1]. The basic principle of fast dissolving tablets (FDTs) is to design a tablet that dissolves quickly in the mouth, usually within a minute, without the need for water. This is achieved through the use of superdisintegrants, which are ingredients that help break down the tablet quickly.

The principle involves several key factors:

Rapid Disintegration: FDTs are formulated to disintegrate quickly, releasing the active pharmaceutical ingredient (API) into the mouth.

High Porosity: FDTs have high porosity, allowing saliva to penetrate and facilitate rapid disintegration.

Low Density: FDTs typically have low density, enabling them to dissolve quickly.

Super disintegrants: FDTs often contain super disintegrants, such as crospovidone or sodium starch glycolate, which rapidly absorb water and swell, facilitating disintegration. By combining these factors, FDTs can provide rapid release of the API, improving bioavailability and patient compliance

Mechanism Of Action:

The mechanism of action of fast dissolving tablets, also known as orally disintegrating tablets (ODTs), primarily relies on the rapid uptake of water into the tablet matrix due to its high porosity, causing the tablet to quickly disintegrate and release the active drug when placed on the tongue, facilitated by the use of specific excipients like superdisintegrants that swell upon contact with saliva, effectively breaking down the tablet structure.

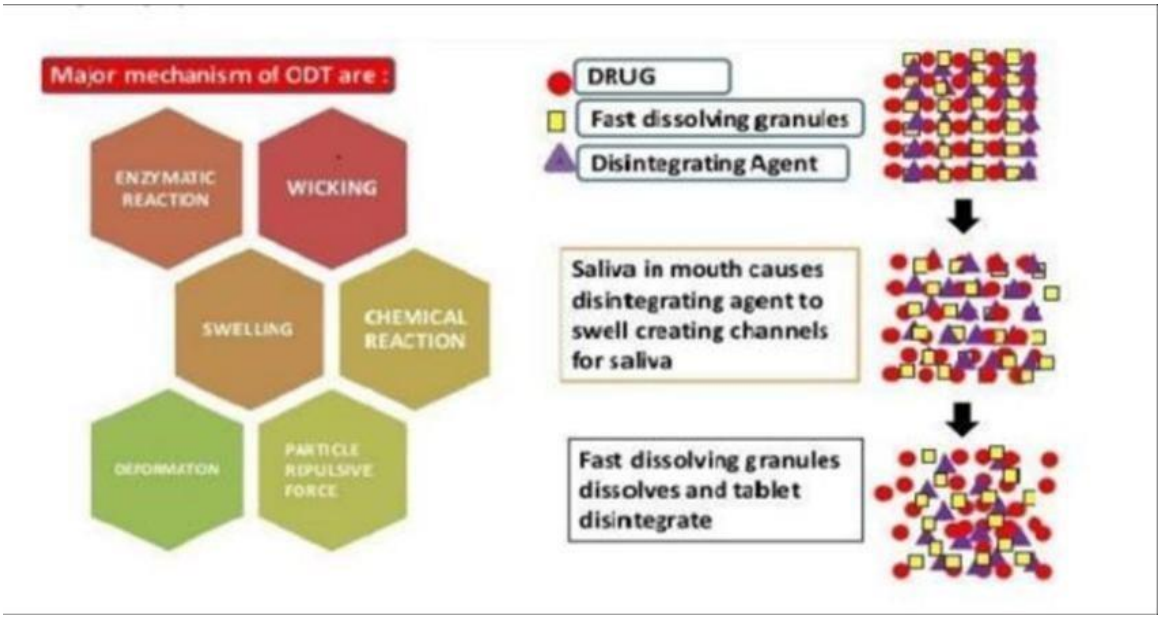

Fig.2 Mechanism of Action of Fast Dissolving Tablet

ADVANTAGES:

1. No need of water.
2. Improved patient compliance.
3. No chewing needed.
4. Improved stability
5. Cost effective.
6. Have adequate taste and pleasant mouth feeling.
7. Suitable for controlled/sustained release actives.
8. Allows high drug loading.

DISADVANTAGES:

1.Dryness of the mouth due to decreased saliva production may not Be good candidates for these tablet formulations.

2.FDT may leave unpleasant taste or grittiness in Mouth if not formulated properly.

3.Insufficient mechanical strength, Hence, careful Handling is required.

4.Drug with relatively large dose are difficult to Formulate into FDT.

Polymers Used In Fast Dissolving Tablet:

List of super disintegrants

Super disintegrants	Mechanism of action	Specific properties
1.Crosscarmellose Sodium	Swells 4–8 folds in<10 s. Swelling and wicking action	Effective in low concentration (0.5–2.0%), high swelling capacity, cross-linking of the carboxyl ester groups.
2.Crospovidone	Combination of swelling and wicking action. Swells 7–12 folds in<30 s.	The effective concentration is 1–3%. Rapidly disperses and swells in water, available in micronized grades.
3. Cross-linked alginic acid	Hydrophilic colloidal substance which has high sorption capacity	The combination of swelling and wicking action causes disintegration
4. Gellan gum	Strong swelling properties upon contact with water.	Anionic polysaccharide of linear tetrasaccharides, good superdisintegrants property similar to the modified starch and celluloses.
5. Sodium starch glycolate	Strong swelling properties upon contact with water. Swells 7–12 folds in<30s.	Rapid absorption of water results in swelling up to 6%, high concentration causes gelling.
6. Soy polysaccharide	Rapid dissolving	Does not contain starch or sugar so can be used in products meant for diabetics.
7.Xanthum gum	Extensive swelling properties for faster disintegration	High hydrophilicity and low gelling tendency, low water solubility.

Factors Affecting:

Solubility:

Highly soluble drugs are ideal for fast dissolving tablets as they readily dissolve in saliva.

Particle size:

Smaller drug particles have larger surface area leading to faster dissolution.

Super disintegrants:

These excipients rapidly absorb water and cause the tablet to fall apart quickly,crucial for fast dissolving tablets.

Crystal morphology:

Crystal structure can influence dissolution rate.

Hygroscopicity:

Highly hygroscopic drugs may affect tablet stability in humid environment.

Pre-Formulation Parameters:

Angle of repose :

The funnel method was used to determine the angle of repose for powder. Powder was measured accurately and placed in a funnel. The funnel's height was adjusted so that the angle contacted the powder's tip. The powder blend was free to flow through the funnel and reach the surface.

The powder cone's diameter was measured and the angle of repose determined using the equation given as follows:

Tan θ= h/r

Bulk density:

Bulk density was determined by placing preseived drug excipients blend into a graduated cylinder And measuring the volume .

Bulk density= Mass / Bulk volume

Tapped density:

The measuring cylinder containing a known mass of blend was tapped for a 100 time. The minimum volume occupied in the cylinder and the weight of the blend was measured. The tapped density was Calculated using following formula.

Tapped density= Mass / Tapped volume

Compressibility index:

Compressibility index (CI) / Carr's index was Calculated by using the following formula. % Carr's index = (Tapped density – Bulk density / Tapped density) × 100

Hausner's ratio:

Hausner's ratio is Measured by ratio of tapped density to bulk density. It is used to measure floawability of powder.

Hausner's ratio = (Tapped density / Bulk Density)

Evaluation Parameters:

Uniformity of weight:

To determine the average weight, 20 tablets were randomly selected and weighed. Individual weights must not depart from the average by more than the percentage, and none should deviate by more than twice that percentage.

Uniformity of thickness:

The thickness was measured using a Vernier caliper and the results will be recorded .

Friability test:

This test was performed using Roche friabilator. Ten tablets were weighed and placed in the friabilator that Revolves at a speed of 25 rpm,

dropping those tablets at a distance of 6 inches with each revolution. The tablets were rotated in the friabilator for at least 4 minutes.Friability is calculated by using following formula:

Percentage friability= (initial weight-final Weight/initial weight) ×100

Drug content:

Five tablets were chosen at random and weighed correctly. The average weight per tablet was computed. Each tablet was reduced to a fine powder. Weigh the tablet accurately and transfer the powder to a 100 mL volumetric flask. Fill to the mark with 0.1 N HCl: Methanol (1:9) solution.

After filtering, discard the first few milliliters of filtrate. To analyze 1 ml of filtrate was diluted in 0.1 N HCl: Methanol (1:9) and measured spectrophotometrically at 250 and 282 nm, respectively.

Disintegration test:

The tablet's in-vitro disintegration time was measured using an Electro Lab ED-2L instrument (Mumbai). Place one tablet in each of the basket's six tubes. Place a disc in each tube and run the device with 0.1 N HCl (pH 1.2) at 37 ± 2 °C as the immersion liquid.

Dissolution test:

In-vitro release tests were conducted utilizing a tablet USP type II dissolution test instrument (Electro Lab TDT-06 T, Mumbai). Tablets were added to 900 ml of 0.1N HCl (pH 1.2) at 37°C ± 0.5°C and swirled with a rotating paddle at 75 rpm. Samples (2 ml) were taken at specified intervals, replaced with equal volume of new medium, and examined using a UV-visible spectrophotometer at 250 and 282 nm wavelengths.

CONCLUSION:

Fast-dissolving tablets have considerably reduced non-compliance in pediatrics and geriatrics, primarily due to dysphagia. FDTs are distinguished by their rapid disintegration and dissolving in the mouth with saliva.FDTs were developed to address challenges with traditional dosage forms. FDTs may improve efficacy, bioavailability, and patient compliance by allowing for rapid absorption from the mouth.Formulating hydrophobic medications remains challenging, especially for large amounts. FDTs, when combined with other technologies like modified release and microencapsulation, can offer significant commercial and clinical benefits. Advancements in FDT technology will enable more efficient delivery of medicinal agents.

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