



Fast Dissolving Tablet; A Review

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ABSTRACT

Fast Dissolving Tablets (FDTs) are oral drug formulations designed to rapidly disintegrate and dissolve in saliva without water, improving ease of use and patient compliance—especially for children and the elderly with swallowing difficulties (dysphagia). FDTs use super disintegrants and offer benefits such as portability, accurate dosing, improved bioavailability, faster onset of action, and enhanced chemical and physical stability.

The Review covers:

- Key advantages and limitations of FDTs
- Suitable drug types and formulation challenges
- Evaluation methods and marketed examples

Fast Dissolving Tablets (FDTs) are an effective oral dosage form designed to improve patient compliance, particularly in pediatric and geriatric populations with swallowing difficulties. They rapidly dissolve in saliva without water, aided by super disintegrants. FDTs offer benefits such as ease of administration, portability, accurate dosing, good stability, and enhanced bioavailability. The review highlights their definition, advantages, limitations, formulation challenges, and manufacturing methods like spray drying and lyophilization, along with examples of marketed products.

I. Introduction

The formulation of drugs into proper dosage forms is essential for effective drug delivery and therapy. While oral dosage forms like tablets



and capsules are widely used due to their ease of use and patient compliance, a major limitation is difficulty in swallowing, especially among geriatric, pediatric, and mentally ill patients. This issue often leads to non-compliance and reduced treatment effectiveness. Swallowing difficulties are further aggravated when water is not available, or during episodes of illness like vomiting, coughing, or motion sickness.

To address this, Fast Dissolving Tablets (FDTs)—also known as Orally Disintegrating Tablets (ODTs) or Mouth Dissolving Tablets (MDTs)—have been developed. These tablets disintegrate quickly in the mouth (usually within 60 seconds) without the need for water, improving patient convenience and adherence.

The USFDA defines FDTs as solid dosage forms that dissolve rapidly in the mouth. These tablets are especially beneficial in situations where swallowing is difficult or water is not available.

FDTs are typically formulated using:

- Superdisintegrants (e.g., Crospovidone, Sodium starch glycolate) Pore structure enhancement through freeze-drying or vacuum drying. Direct compression is also a preferred method due to its simplicity and cost-effectiveness.

The fundamental role of formulating drugs into suitable dosage forms to ensure efficient drug delivery and therapeutic efficacy. Various dosage forms like tablets, syrups, suspensions, injections, and patches exist, each with its advantages and disadvantages. Among them, oral solid dosage forms—particularly tablets and capsules—are the most widely accepted, accounting for 50-60% of drug administration due to ease of use, accurate dosing, and high patient compliance.

However, a significant drawback of traditional tablet is the difficulty in swallowing, particularly in geriatric and pediatric patient as well as those with condition like dysphagia, parkinson disease or mental illness. This leads to poor compliance, reduced therapeutic effectiveness and treatment failure. Swallowing difficulties are further aggravated when water is not available or during episodes of illness like vomiting, coughing or motion sickness.

To overcome these limitations, Fast Dissolving Tablets (FDTs) or Mouth Dissolving Tablets (MDTs) were developed in the late 1970s, designed to disintegrate quickly in the mouth (within 60 seconds) without the need for water. These tablets are particularly useful for patients who cannot swallow conventional tablets and have since

gained significant attention in pharmaceutical development.

Criteria

Not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds.

Be compatible with taste masking.

Be portable without fragility concern.

Have a pleasant mouth feel.

Leave minimum or no residue in the mouth after oral administration.

Exhibit low sensitive to environmental condition as temperature and humidity.

Improved compliance/Added convenience

Better taste

Suitable for control as well as fast release activity

cost effective

Salient Features

Does not require water for oral administration.

Have sufficient strength to withstand the rigors of the manufacturing process and post manufacturing handling.

Allow high drug loading..

Insensitive to environmental conditions such as humidity and temperature.

Adaptable and amenable to existing processing and packaging machinaries

Have a pleasant mouth feel

Limitation

Generally have low mechanical strength, requiring careful handling May cause unpleasant taste or gritty sensation if formulation is not optimized

Technologies Used For Manufacturing Of MDT's

New advanced technologies have been developed for manufacturing Mouth Dissolving Tablets (MDTs).

These technologies aim to achieve ideal features like:

Faster disintegration time

Pleasant mouthfeel

Effective taste masking

Sugar-free formulations for diabetic patients

MDT manufacturing technologies are broadly classified into:

Patented technologies

Non-patented technologies

1. Lyophilization/Freeze Drying

Freeze-drying (lyophilization) is used to create porous structures in MDTs. The process involves



removing solvent from a frozen drug solution containing structure-forming additives. This results in a glossy, amorphous, porous, and lightweight tablet. Tablets disintegrate and dissolve rapidly on the tongue, releasing the drug instantly. Limitations of lyophilized MDTs include:

- Low mechanical strength
- Poor stability under high temperature and humidity conditions.

2. Molding

Molded tablets are made using water-soluble ingredients for quick and complete dissolution. The powder mixture is moistened with a hydro-alcoholic solvent. Tablets are formed using lower pressure compared to conventional tablet compression. The solvent is removed by air-drying. Molded tablets are less compact and have a porous structure. The porous nature enhances the dissolution rate.

3. Cotton Candy

Named for its use of a spinning mechanism that creates a floss-like, cotton candy-like crystalline structure. Involves flash melting and spinning of polysaccharides or saccharides to form a matrix. The matrix is partially re-crystallized to enhance flow and compressibility. This candy floss matrix is then milled and mixed with the drug and other excipients. The final blend is compressed into Mouth Dissolving Tablets (MDTs).

4. Spray Drying

This technique produces highly porous and fine powders by evaporating the processing solvent. Ingredients used include: Hydrolyzed and non-hydrolyzed gelatin (supporting matrix) Mannitol (bulking agent) Sodium starch glycolate or croscarmellose sodium (superdisintegrants) Disintegration and dissolution are enhanced by adding: Citric acid (acidic substance) Sodium bicarbonate (alkaline substance) Results in a porous formulation with a disintegration time of less than 20 seconds.

5. Melt Granulation

In this process, MDTs can be prepared by incorporating a hydrophilic waxy binder, Super Polystate (PEG-6-stearate). Super Polystate is a waxy material with a melting point of 33–37°C and a hydrophilic-lipophilic balance (HLB) of 9. It not only functions as a binder, enhancing the physical resistance of the tablets, but also facilitates rapid disintegration. Upon administration, it melts in the mouth and solubilizes quickly, leaving no residue behind.

Super Polystate is incorporated into the MDT formulation using the melt granulation method, wherein granules are formed from its molten state. This technique ensures uniform drug distribution and improves tablet integrity while maintaining fast disintegration properties.

6. Phase Transition Process

Tablets were produced by compressing a powder containing two sugar alcohols with high and low melting points and subsequent heating at a temperature between their melting points. Before heating process, the tablets do not have sufficient hardness because of low compatibility. The tablet hardness was increased after heating process, due to the increase of inter particle bonds or the bonding surface area in tablets induced by phase transition of lower melting point sugar alcohol.

7. Sublimation

The presence of a highly porous structure within the tablet matrix is a crucial factor for the rapid disintegration of mouth-dissolving tablets (MDTs). Although conventional tablets may contain highly water-soluble ingredients, they often fail to disintegrate quickly due to low porosity. To enhance porosity, volatile substances such as camphor can be incorporated during the tableting process. These substances are later sublimated, leaving behind a porous matrix.

In one approach, MDTs were developed using camphor as a subliming agent. Tablets were prepared from a mixture of mannitol and camphor, then subjected to vacuum sublimation at 80°C for 30 minutes. This process effectively removed camphor from the compressed tablets, resulting in a highly porous structure that facilitated rapid tablet disintegration.

8. Direct Compression Method

This technique offers a simple and cost-effective approach to formulate mouth-dissolving tablets (MDTs), owing to the limited number of processing steps and low manufacturing cost. Additionally, it is suitable for high-dose formulations, as the final tablet weight can easily exceed that of tablets produced by other methods.

The disintegration and dissolution of directly compressed tablets depend on the individual or combined effects of disintegrants, water-soluble excipients, and effervescent agents. The efficacy of disintegrants is significantly influenced by tablet size and hardness. Optimal disintegration is generally achieved with medium to small tablet sizes, low hardness, and low physical resistance.

It is essential to select a suitable type and optimum concentration of disintegrant to ensure rapid



disintegration and high dissolution rates. The inclusion of water-soluble excipients or effervescent agents can further enhance the disintegration and dissolution profiles.

Superdisintegrants are particularly effective due to their dual mechanism of swelling and water absorption. The swelling action increases the wetted surface area of the carrier, which improves wettability and dispersibility of the formulation, thereby promoting faster disintegration and dissolution.

The optimal concentration of a superdisintegrant should be determined based on its critical concentration. Below this threshold, disintegration time is inversely proportional to the superdisintegrant concentration. However, once the concentration exceeds the critical level, the disintegration time plateaus or may even increase.

EVALUATION

1. size and shape:

The size and shape of a tablet can be precisely described, monitored, and controlled using dimensional parameters. during manufacturing to ensure consistency, quality, and compliance with pharmacopoeial standards.

2. tablet thickness:

Tablet thickness is an important physical parameter, as it plays a key role in ensuring uniform appearance and is also critical in automated tablet counting processes. Certain filling equipment rely on the consistent thickness of tablets as a basis for counting mechanisms. In this study, ten tablets were randomly selected, and their thickness was measured using a micrometer to assess dimensional uniformity.

3. Uniformity of weight;

The Indian Pharmacopoeia (I.P.) : procedure for uniformity of weight was followed. A total of twenty tablets were randomly selected, and their individual and collective weights were determined using a digital weighing balance. The average weight of a single tablet was calculated from the collective weight. The weight variation test serves as a reliable and preliminary method for assessing drug content uniformity, particularly in formulations where the active ingredient is uniformly distributed.

Average weight of tablet(mg)	Maximum percentage difference allowed
130 or less	10
130-324	7.5

Morethan 324	5
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4. tablet hardness:

Tablet hardness is defined as the force required to break a tablet diametrically, and it serves as an indicator of the tablet's mechanical strength. The resistance to chipping, abrasion, or breakage during storage, transportation, and handling is directly influenced by the hardness of the tablet. In this study, the hardness of tablets from each formulation was measured using a Monsanto Hardness Tester.

5. Friability:

Friability is a measure of the mechanical strength of tablets, indicating their ability to withstand abrasion or breakage during handling, packaging, and transportation. The Roche Friabilator was used to determine the friability of the tablets according to standard procedures.

A pre-weighed sample of tablets was placed in the friabilator, which consists of a plastic chamber rotating at 25 rpm, causing the tablets to fall from a height of 6 inches during each revolution. The test was conducted for 4 minutes (equivalent to 100 revolutions). After the test, the tablets were removed, dusted, and reweighed.

The percentage friability was calculated using the following formula:

$$\% \text{friability} = \frac{\text{loss in weight}}{\text{initial weight}} \times 100$$

6. in vivo disintegration test:

The disintegration test was performed on six tablets using the apparatus specified in the Indian Pharmacopoeia (I.P.) 1996. Distilled water maintained at $37 \pm 2^\circ\text{C}$ was used as the disintegration medium. The time required for complete disintegration of each tablet—defined as the point at which no palpable mass remained in the apparatus—was recorded in seconds

7. wetting time:

The wetting time of tablets was measured following the method reported by Yunxia et al. A piece of tissue paper (12 cm × 10.75 cm), folded twice, was placed in a petridish (internal diameter = 6.5 cm) containing 6 mL of Sorenson's buffer (pH 6.8). A tablet was carefully placed on the folded tissue, and the time taken for complete wetting of the tablet was recorded. The test was performed in triplicate for each batch, and the mean wetting time and standard deviation were calculated

8. in vitro dispersion time:

In vitro dispersion time was determined by placing a tablet in a beaker containing 50 mL of Sorenson's buffer (pH 6.8) maintained at room temperature.



Three tablets from each formulation were randomly selected, and the dispersion time was recorded as the time taken for the tablet to completely disperse in the medium. The test was conducted in triplicate, and the results were averaged to assess the dispersibility of each formulation.

II. CONCLUSION

The MDTs have potential advantages over conventional dosage forms, with their improved patient compliance, convenience, bioavailability and rapid onset of action had drawn the attention of many manufactures over a decade. MDTs formulations obtained by some of these technologies have sufficient mechanical strength, quick disintegration/dissolution in the mouth without water. These MDTs can be used easily in children who have lost their primary teeth and in geriatric patients who have lost their teeth permanently. They remain solid during storage, which aid in stability of dosage forms and transform into liquid form within few seconds after its administration. As they have significant advantages as both solid and liquid dosage forms, MDTs may be developed for most of the available drugs in near future.

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