World Journal of Pharmaceutical Science and Research

www.wjpsronline.com

Review Article

ISSN: 2583-6579
SJIF Impact Factor: 6.916
Year - 2026
Volume: 5; Issue: 4
Page: 872-878

AN OVERVIEW OF FAST DISOLVING TABLETS- A NEW ERA IN NDDS

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Article Received: 2 March 2026 | | ***Article Revised: 24 March 2026*** | | ***Article Accepted: 13 April 2026***

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DOI: https://doi.org/10.5281/zenodo.19593583

How to cite this Article: Gopal Bharti, Dr. Gaurav Bhaduka, Dr. Dilip Agrawal (2026) AN OVERVIEW OF FAST DISOLVING TABLETS- A NEW ERA IN NDDS. World Journal of Pharmaceutical Science and Research, 5(4), 872-878.

ABSTRACT

Fast dissolving tablets emerge as one of the popular and widely accepted dosage forms, especially for paediatric patients because of incomplete development of the muscular and nervous system and a case of geriatric patients suffering from Parkinson's disorder or hand tremors. Few solid dosage forms like capsules and tablets are present days facing the problems like difficulty in swallowing (dysphagia), resulting in many incidences of non-compliance and making the therapy ineffective. Oral dosage form and oral route are the most preferred route of administration for various drugs have limitations like first-pass metabolism, psychiatric patients, bedridden and uncooperative patients. FDTs are disintegrating or dissolve quickly in the saliva without a need of water. The oral route is the most preferred route of administration due to its low cost, ease of administration, and patient compliance. Pharmaceutical technologists introduced the novel dosage forms known as oral disintegrating tablet (ODT), fast disintegrating tablet (FDT), and mouth dissolving tablet (MDT). Recently researchers have developed fast dissolving tablet (FDT) which dissolve or disintegrate rapidly in mouth saliva without intake of water. This novel drug delivery such as FDT or MDT (mouth dissolving tablet) have overcome many disadvantages like dysphagia or non-accessibility of water while travelling. When compared with conventional dosage form FDT can be a useful alternative as well. This review article contains different techniques used for preparing FDT, silent features, various patented technologies, mechanism of super disintegration etc.

KEYWORDS: Fast dissolving tablets, Paediatric patients, Oral route, Novel drug delivery, Dysphagia.

INTRODUCTION

Solid dose forms may be made into fast-dissolving tablets by crushing them into tiny grains, which dissolves rapidly in the cavity of the mouth. The disintegration period of a fast-dissolving tablet may range from a few seconds to over a

minute, which is determined by the formulation as well as the size of the tablet.

A solid dosage form termed as a rapid disintegrating system, capsule, or tablets may disintegrate/dissolve in the mouth in under 30 seconds without the need for water administration. You may use either "fast disintegrating tablets" or "fast dissolving tablets." They also make note of orodispersible pills, porous tablets, and rapimelts. They also discuss medications that dissolve in your tongue.

A drug delivery system (DDS) is a useful instrument for increasing product longevity, reaching more people, and opening up new prospects. The most recommended approach for systemic effects is oral administration since it is simple, painless, avoids side effects, is adaptable, and most importantly, that patients comply. Because they aren't required to be manufactured in a sterile environment, solid orally delivery systems also have a lower production cost.

Due to their high degree of precision in administration, ease of manufacture, and patient compliance, tablets are the solid dosage form of choice. There will be new possibilities for excipients and equipment if solid formulation technologies evolve in response to the tremendous improvements in drug development, including genomics. Tablets may not be the best option for next-gen drugs made mostly of proteins or peptides because of how difficult it is to give such a quantity. Until advanced auto injectors become available, patients usually lack the option to inject themselves.

Recent developments in biopharmaceutical investigation have primarily resulted in chemical compounds with low molecular weights, despite the fact that inhalation is an efficient alternative delivery strategy for many treatments.

Rapidly dissolved tablets, New oral protein delivery technologies has enormous potential for the delivery of peptides and proteins with large molecular weights, and these meds may be released orally in the form of tablets. The oral route remains the preferred method for therapeutic drug delivery due to its low production costs, high patient compliance, and ease of administration. Hard gelatin capsules and tablets are difficult for many individuals to swallow, which makes it difficult for them to take their prescription as prescribed. Roughly half of the nation might be affected.

The problem is that a lot of people don't follow the treatment plan, which leads to ineffective treatment. Solid forms of medication that are easy to chew, dissolve in mouth, or suspend in water are in great demand, especially among the paediatric along with geriatric sectors. Other patients who would rather have their medication in a more easily given form also have this requirement. The public's attention has been attracted to the significant problem of oral tablet delivery towards patients as a result of the mean human life duration expectancy along with the natural decline in swallowing abilities with age. To address this, it is possible to create dissolving or fast-acting oral formulations that do not need water for swallowing assistance. To take the dose forms orally, one must wait for them to disintegrate in saliva or spread out in the mouth before swallowing. They are sometimes meant to be fully absorbed when saliva passes via the buccal as well as esophageal mucosa on its way to the stomach. In the second case, rapid dispersion formulations of a medicine may have much greater bioavailability than more traditional dosing forms.

SALIENT FEATURES OF A DRUG DELIVERY SYSTEM IN THE FDDS

There should be no need to drink water when taking a mouth-dissolving tablet; the tab. would disintegrate/dissolve in the mouth within a few seconds. Have no fragility issues, be compatible with taste masking, and be portable feel pleasant when chewed. There is a slight to no aftertaste after oral use. Show little reaction time to changes in ambient conditions, such as temperature and humidity use common processing and packaging equipment to manufacture at a

low cost. Convenience for those who have difficulty swallowing tablets, including those with mental illness, small children, and the elderly.

Simplicity of administration and dosing accuracy are two advantages over liquids. Since water is not necessary to swallow the dose, this feature is especially useful for patients those were on journeys and may not have ready access to water. For young patients, in particular, MDDS's pleasant tongue feel might alleviate the stigma associated with the medication being a "bitter pill." A possible expedited onset of effect may be possible if the drug is rapidly absorbed and broken down.

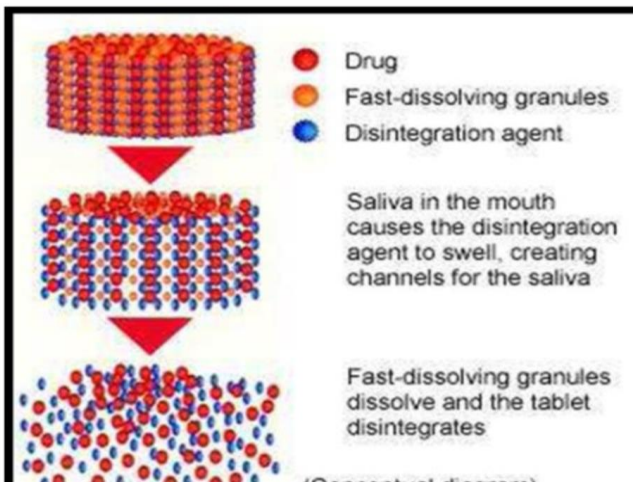
There are a number of drugs that are more bioavailable when taken orally because saliva is able to absorb them from the mouth, throat, and pharynx before they reach the stomach. Might be able to provide the advantages of a liquid medication in a solid form. An improvement in clinical effectiveness and a decrease in adverse effects might result from pre-gastric absorption, which increases bioavailability and allows for dose reduction.

PERFECT FAST DISSOLVING DELIVERY SYSTEM CHARACTERISTICS

Because of how crucial it is for patients to have a pleasant mouth-feel, it is imperative that they get a product that meets this need. It would be rather uncomfortable to feel the gritty texture caused by large pill pieces that either do not dissolve in mouth or disintegrate very slowly.

This issue may be resolved by ensuring that the majority of particles remain beneath the max limit of detectable size. A change in taste alone may occasionally enhance the product's mouth-feel perception, giving the impression that it is smoother and less gritty than it really is. A product's "dryness" may be reduced with the addition of effervescence, which helps with breakdown and enhances the mouth-feel. Moisture Retention - Many fast-dissolving dose forms become physically unstable when exposed to room temperature and humidity because they are hygroscopic. Specialised product packaging is therefore required to protect them from dampness.

The tablets used to make fast-dissolving medications are sometimes brittle as well challenging to work with since they are either formed of a highly porous either soft moulded matrix or crushed onto tablets with a very slight compression force. For this reason, customised peel-off blister packaging is often required. Wowtab by Yamanouchi- Shadlee & Dura Solve by CIMA laboratories are two examples of the stronger fast-dissolving tablet versions that some companies have developed to combat this problem.



Benefits of fast dissolving tablets

- Administered without water, anywhere, any time.
- Suitability for geriatric and paediatric patients, who experience difficulties in swallowing and for the other groups that may experience problems using conventional oral dosage form, due to being mentally ill, the developmentally disable and the patients who are un-cooperative, or are on reduced liquid intake plans or are nauseated.
- Beneficial in cases such as motion sickness, suede 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.

HYPOTHESIS OF FAST DISSOLVING TABLETS

A new kind of pharmaceutical dosage form, fast dissolving tabs. (FDTs) dissolve instantaneously in the mouth without the use of water. For patients who have trouble swallowing regular pills or liquids, these tablets provide a number of benefits, such as increased patient compliance, a quick start to action, and convenience of administration. The theory that underpins the creation and effectiveness of fast-dissolving tablets encompasses a multitude of elements and aspects.

Disintegration and Dissolution: The main idea is that the special composition of the fast-solving tablets allows them to dissolve and disintegrate quickly in the mouth.

When the tablets come into touch with saliva, they dissolve rapidly to form a thin suspension or solution that is easy to swallow.

Superdisintegrants (co-processed): The superdisintegrants croscarmellose sodium, crospovidone along with sodium starch glycolate are common ingredients in fast-solving tablets. Important for quick tablet disintegration, these chemicals quickly expand in the presence of saliva, causing the tablet to crumble into tiny particles.

Porous Structure: Because to their low density and porous texture, the tablets dissolve quickly. A large surface area is one of the goals of the formulation, which will facilitate the dissolving process and enable saliva to penetrate the substance quickly.

Wettability and Hydration: The working assumption is that the formulation of the tablets improves their wettability and water absorption, making it easier for saliva to pass through the tablet matrix. Because the tablet is more hydrated, the medicine and other excipients dissolve more easily.

Particle Size: For more rapid solubility, FDTs take the medication and excipient particle sizes into account. The surface area accessible for breakdown is raised by minimising particle size, leading to in speedier drug release.

Drug Stability: Analysing and determining how the fast-dissolving process affects medication stability is of the utmost importance. It is believed that the drug's chemical composition in addition with effectiveness are preserved throughout its production and formulation processes.

Taste Masking: The bitterness along with unpleasant flavour of several medications could influence their acceptance by patients. One possible explanation could be that FDTs have been engineered to use flavour-masking methods. This would allow the tablet to dissolve rapidly without affecting the way the taste is perceived.

Patient Acceptance and Compliance: Patients, particularly those with swallowing difficulties, such as children, the elderly, or those who are bedridden, may be more likely to accept and take their medication as prescribed when given FDTs due to their quick dissolving and easy administration.

Bioavailability: The bioavailability of fast-dissolving tablets should be similar to that of regular tablets. Optimising the drug's absorption into the circulation via the mouth as well as sublingual epithelium or the gut is the primary objective of the formulation and dissolving technique. Composition, dissolution profile, disintegration properties, patients acceptability, along with medicinal efficacy are often at the center of fast dissolving tablet hypotheses.

Techniques for Preparing Fast disolving Tablets

Many techniques have been reported for the formulation of Fast dissolving tablets or Oro-dispersible tablets.

1. Freeze drying / lyophilization
2. Tablet Moulding
3. Spray drying
4. Sublimation
5. Direct compression
6. Mass extrusion

Freeze-Drying or Lyophilization

Freeze drying is the process in which water is sublimed from the product after it is frozen. This technique creates an amorphous porous structure that can dissolve rapidly. A typical procedure involved in the manufacturing of ODT using this technique is mentioned here. The active drug is dissolved or dispersed in an aqueous solution of a carrier/polymer.

The mixture is done by weight and poured in the walls of the preformed blister packs. The trays holding the blister packs are passed through liquid nitrogen freezing tunnel to freeze the drug solution or dispersion. Then the frozen blister packs are placed in refrigerated cabinets to continue the freeze-drying. After freeze-drying the aluminum foil backing is applied on a blister-sealing machine. Finally the blisters are packaged and shipped. The freeze-drying technique has demonstrated improved absorption and increase in bioavailability. The major disadvantages of lyophillization technique are that it is expensive and time consuming; fragility makes conventional packaging unsuitable for these products and poor stability under stressed conditions.

Tablet Molding

Molding process is of two types i.e. solvent method and heat method. Solvent method involves moistening the powder blend with a hydro alcoholic solvent followed by compression at low pressures in molded plates to form a wetted mass (compression molding). The solvent is then removed by air-drying. The tablets manufactured in this manner are less compact than compressed tablets and posses a porous structure that hastens dissolution. The heat molding process involves preparation of a suspension that contains a drug, agar and sugar (e.g. mannitol or lactose) and pouring the suspension in the blister packaging wells, solidifying the agar at the room temperature to form a jelly and drying at

30○C under vacuum. The mechanical strength of molded tablets is a matter of great concern. Binding agents, which increase the mechanical strength of the tablets, need to be incorporated. Taste masking is an added problem to this technology.

Sublimation

To generate a porous matrix, volatile ingredients are incorporated in the formulation that is later subjected to a process of sublimation. Highly volatile ingredients like ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, naphthalene, urea, urethane and phthalic anhydride may be compressed along with other excipients into a tablet. This volatile material is then removed by sublimation leaving behind a highly porous matrix. Tablets manufactured by this technique have reported to usually disintegrate in 10-20 sec. Even solvents like cyclohexane; benzene can be used as pore forming agents.

Direct Compression

Direct compression represents the simplest and most cost effective tablet manufacturing technique. This technique can now be applied to preparation of ODT because of the availability of improved excipients especially superdisintegrants and sugar based excipients.

(a) Superdisintegrants: In many orally disintegrating tablet technologies based on direct compression, the addition of superdisintegrants principally affects the rate of disintegration and hence the dissolution. The presence of other formulation ingredients such as water-soluble excipients and effervescent agents further hastens the process of disintegration.

(b) Sugar Based Excipients: This is another approach to manufacture ODT by direct compression. The use of sugar based excipients especially bulking agents like dextrose, fructose, isomalt, lactilol, maltilol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose.

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