



Fast Dissolving Tablets: A Review Of Formulation And Evaluation Strategies

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Abstract

Fast dissolving tablets (FDTs) gained significant attention in the pharmaceutical industry due to their numerous advantage such as rapid disintegration, ease of administration, enhanced patient compliance, and suitability for pediatric and geriatric populations. This comprehensive review explores various aspects of FDTs including formulation strategies, manufacturing techniques, evaluation parameters, and recent advancement. Different methods employed for the preparation of FDTs, including direct compression, freeze-drying, and sublimation, are discussed along with their advantages and limitations. The key factors influencing the disintegration and dissolution of FDTs such as choice of excipients, superdisintegrants and disintegration agents are highlighted. Furthermore, recent innovations in the field such as orally disintegrating films and 3D printing for FDT manufacturing are also discussed. Additionally challenges associated with FDT formulation and regulatory considerations are addressed. This review aims to provide valuable insights for researchers and pharmaceutical professionals involved in the development of fast dissolving tablets.

Keywords: Fast dissolving tablet, oral route, superdisintegrants, mouth dissolving tablet

INTRODUCTION

Drug formulations is essential for modern medicine. This dose is a method of delivering drugs to the body. There are various dosage forms available, including pills, syrups, suspensions, injections, transdermal patches, each with its own drug delivery mechanism. Traditional and current dose formulations have both advantages and downsides. Developing an effective medicine delivery system is a significant challenge for pharmacists in the present situation. To achieve the desired effect, the medicine should be administered to the site of action at a pace and concentration that maximizes therapeutic impact while minimizing side effects. A comprehensive investigation into the physiochemical principles governing a particular medication formulation should be conducted in order to develop an appropriate dose form¹.

Up to 50-60% of all dosage forms are administered orally. This indicates widespread acceptability of this method. Solid dosage forms are widely used due to their patient compliance, convenience of administration, precise dosage, ability to self-medicine, ability to avoid pain, and most importantly, these factors. Tablets and capsules are the most often used solid dose forms; nevertheless, some patients may find these to be difficult to

swallow. Water consumption is crucial for the effective ingestion of oral dose forms. People frequently have difficulty swallowing traditional dosage forms, such as tablets, when water is scarce, when they have motion sickness (kinetosis), or when they suddenly start coughing during a common cold, an allergy or bronchitis. For these reasons, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention².

The inability to swallow is a typical occurrence in elderly patients because of dysphagia, hand tremors, and choking fear. It is also common in younger people because of immature muscles and neural systems, and in patients with schizophrenia because it impairs patient compliance. Swallowing issues affect about one-third of the population, primarily the young and old. This causes poor adherence to oral tablet medication therapy, which lowers the efficacy of therapy as a whole. Because of this, there has been a lot of interest in tablets that can quickly dissolve or disintegrate in the oral cavity³.

The United States Food and Drug Administration (USFDA) defined a fast-dissolving tablet (FDT) as “a solid dosage form containing a medicinal substance or active ingredient which disintegrates rapidly usually within a matter of seconds when placed upon the tongue”³.

In order to provide paediatric and elderly patients with an alternative to traditional dose forms, fast-dissolving drug delivery devices were originally created in the late 1970s. These tablets are made to dissolve or break down quickly in saliva—typically in less than 60 seconds⁵. Pharmaceutical technologies have created new oral dosage forms called immediate release tablets that dissolve quickly in saliva, typically in a matter of seconds, without the need of water, to meet these medical needs. These tablets are known as mouth melting tablets (MMTs), mouth dissolving tablets (MDTs), or fast disintegrating tablets (FDTs).

Certain medications may have a higher bioavailability because of oral drug absorption and pre-gastric saliva that contains scattered medication that travels down into the stomach. Additionally, compared to conventional tablets there is a decrease in the amount of medication that is susceptible to first pass metabolism⁵.

Criteria for fast dissolving tablets^{47, 48, 49}

Fast-dissolving tablets (FDTs) are designed to disintegrate and dissolve rapidly in the mouth without need of water. The key criteria for formulating FDTs include:

- 1) **Disintegration Time:** The tablet should disintegrate quickly in the oral cavity, typically within seconds to a minute. This ensures rapid drug release and absorption.
- 2) **Mechanical strength:** Despite rapid disintegration, the tablet should still possess adequate mechanical strength to withstand handling during manufacturing, packaging, and transportation.
- 3) **Uniformity of dose:** The formulation should ensure uniform distribution of the active pharmaceutical ingredients (API) to guarantee consistent dosage delivery in each tablet.
- 4) **Taste masking:** FDTs often contain bitter or unpleasant tasting drugs. Effective taste-masking strategies, such as coating or flavouring, are crucial to enhance patient acceptability and compliance.
- 5) **Drug compatibility:** The excipients used in FDT formulations should be compatible with the API to maintain stability and prevent degradation.
- 6) **Wettability:** The tablet surface should have good wettability to facilitate rapid dispersion and dissolution upon contact with saliva.
- 7) **Manufacturability:** the manufacturing process should be scalable and cost-effective to provide FDTs on a commercial scale.

Advantages of fast dissolving tablets^{6, 7, 8, 9}

Fast dissolving tablets (FDTs) offer several advantages over conventional oral dosage forms, making them a preferred choice for many patients and healthcare providers. Here are some advantages mentioned below:

- 1) **Enhanced patient compliance:** FDTs are particularly beneficial for patients who have difficulty in swallowing traditional tablets or capsules, such as geriatric, paediatric, and dysphasic patients. This can lead to improved medication adherence and therapeutic outcomes⁶.

- 2) **Rapid onset of action:** FDTs dissolve or disintegrate quickly upon contact with saliva, allowing for rapid drug release and absorption. This can be advantageous for drugs requiring fast onset of action, such as analgesic and antiemetic⁷.
- 3) **Improved bioavailability:** The rapid dissolution of FDTs in the oral cavity can lead to enhanced drug absorption and bioavailability compared to conventional dosage forms, which may be affected by factors such as geriatric emptying and first-pass metabolism⁸.
- 4) **Convenience and portability:** FDTs are easy to administer and do not require water for swallowing, making them convenient for patients on the go or in situations where access to water is limited⁹.
- 5) **Reduced risk of choking:** For patients prone to choking or aspiration, such as the elderly or individual with neurological disorders, FDTs offer a safer alternative to conventional solid dosage forms¹².

Limitations of fast dissolving tablet

- The tablets usually have insufficient mechanical strength. Hence, careful handling is required.
- The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly.

Salient features of fast dissolving tablet^{3, 4, 11}

- Suitable for administering to patients who cannot swallow, including the elderly stroke victims, bedridden patients, those with renal failure, and those who refuse to swallow (e.g., paediatric, and geriatric)⁶.
- There is no need for water to ingest the dosage form, which is very useful feature for patients who are travelling and do not have immediate access to water.
- This medicine is rapidly dissolved and absorbed, resulting in a quick commencement of effect.
- Some medications are absorbed by the mouth, pharynx, and oesophagus as saliva enters the stomach. In these circumstances, the drug bioavailability increases.
- Pre-gastric absorption can improve bioavailability and minimize dosage; Improve clinical performance by reducing undesired side effects.
- The good mouthfeel feature helps to modify the perception of medication as a bitter pill, especially in paediatric patients.
- Prevents choking or suffocating during oral administration of traditional formulations, improving safety.
- New business opportunities include product diversification, advertising, patient extension, and life cycle management.
- Helpful in situations where an extremely quick beginning of action is needed, such as motion sickness, abrupt episodes of allergic reaction, or coughing.
- A higher bioavailability as a result of tablets quick dissolving and disintegration, especially for insoluble and hydrophobic medications. Stability for an extended period of time since the medication is administered in a solid dose form until it is used. Thus, it combines the benefits of liquid dosage form for bioavailability with solid dosage form for stability.
- It is cost-effective, flexible, and compatible with current processing and packaging equipment. It also allows for high drug loading.

Challenges to develop fast dissolving tablets^{3, 10}

Palatability

Since most medications are unpleasant, FDTs typically include the medication in a form that masks its taste. FDTs dissolve or disintegrate in the patient's mouth cavity following ingestion, releasing the active components that come into contact with the taste buds. Thus, it becomes essential to taste-mask the medications in order to ensure patient compliance^{3, 11}.

Mechanical strength and disintegration time

FDTs are either made of a very porous and soft-moulded matrix or compressed into tablets with very low compression force, which makes the tablets brittle and/or friable, difficult to handle, and frequently requiring specialized peel-off blister packing that could increase the cost. This allows the tablets to disintegrate in the oral cavity^{3, 11}. The only tablet technologies that can make tablets hard and robust enough to be packed in multi-dose bottles and Wow Tab and Durasov³.

Hygroscopicity

Oral disintegrating dosage forms are prone to hygroscopicity, causing them to lose physical integrity under typical temperature and humidity settings^{3, 11}. To protect against humidity, appropriate product packaging is necessary³.

Amount of drug

The amount of medicine that can be added to each unit dose restricts the applicability of technologies used as FDTs. Drug dosage for lyophilized dosage forms must be less than 400mg for insoluble substances and 60 mg for lipid substances^{3, 11}. When creating oral films of wafers that dissolve quickly, this parameter is a very difficult to work with³.

Aqueous solubility

The creation of eutectic mixes, which cause freezing-point depression and the formation of a glassy solid that may collapse upon drying due to loss of supporting structure during the sublimation process, is one of the formulation problems associated with water soluble pharmaceuticals^{3, 5, 11}. In a certain cases, such collapse can be avoided by employing different matrix forming excipients, including mannitol, which can cause crystallinity and give the amorphous composite stiffness³.

Size of tablet

A tablet's size affect how it is to take. According to reports, tablets with a size of 7-8 mm are the simplest to swallow, while tablets larger than 8mm are the easiest to handle. As a result, it is challenging to create a tablet size is both manageable and easy to consume^{3, 5}.

Mouth feel

In the mouth, FDTs should not break down into bigger particles. Particles formed following the FDTs disintegration ought to be as little as feasible. Additionally, adding flavours and cooling ingredients like menthol enhances the mouthfeel⁵.

Sensitivity to environmental conditions

FDTs materials are designed to dissolve in a small amount of water, making them less sensitive to environment factors like humidity and temperature⁵.

Regulatory challenges

Meeting regulatory requirements for product quality, safety, and efficacy. Conducting stability studies to support shelf life determination. Demonstrating bioequivalence with conventional dosage forms for generic FDTs¹³.

Techniques for preparing fast dissolving tablet

Many techniques have reported for the formulations of Fast dissolving tablets. Here we have discussed six major techniques which are widely used for the formulation of these tablets^{14, 15}.

- 1) Freeze drying/ Lyophilization
- 2) Tablet moulding
- 3) Spray drying
- 4) Direct compression
- 5) Sublimation
- 6) Mass extrusion

1) Freeze drying/ Lyophilization

Freeze drying is the technique of removing water from a product after it has been frozen. This approach produces an amorphous porous structure that dissolves rapidly. A typical approach used in the production of ODT utilizing this technique is described below¹⁶. The active medication is dissolved or disseminated in an aqueous solution including a carrier or polymer. The substance is weighted and then put into the prefabricated blister pack walls. The trays containing the blister packs are run through a liquid nitrogen freezing tunnel to freeze the medication solution or dispersion. The frozen blister packs are then stored in chilled cabinets to continue to freeze dry. Following freeze-drying, the aluminium foil backing is added using a blister-sealing machine. The blisters are then packed and sent. The process of freeze-drying has shown to boost bioavailability and improve absorption. The primary drawbacks of the lyophilisation process are its high cost and duration; also; these items fragility renders traditional packaging inappropriate for them, and their poor stability in pressured circumstances^{17, 18}.

2) Tablet moulding

There two types of moulding processes: solvent method and heat method. Solvent-produced tablets have a porous structure that speeds up dissolution and are less compact than compacted tablets. One major issue is the mechanical strength of tablets that have been moulded. It is necessary to include binding agents, which increase the tablets mechanical strength¹⁹. The preparation of the masked drug particles involves spray-congealing a molten mixture of hydrogenated polyethylene glycol, cottonseed oil, lecithin, and sodium carbonate, an active component, into a lactose- based tablet triturate form. Masking of flavour is an additional issue with this approach. Compared to the lyophilisation approach, the moulding technique produces tablets that are easier for industrial manufacturers to scale up²⁰.

- a) Solvent method: In this method moisten the drug powder blend with hydro alcoholic solvent. Then compress the powder at low pressure in moulded plates to form a wetted mass (compression moulding). Now the solvent is removed by the air drying. And then tablets are packed.
- b) Heat method: In this method prepare a suspension that contains a drug, agar and sugar (e.g. mannitol or lactose). Then pour the suspension in the blister packaging wells. Then solidify the agar at the room temperature to form jelly at 30 degree

3) Spray drying

This method involves use of superdisintegrants such as croscopolvidone, sodium starch glycollate, and croscarmellose sodium, as well as mannitol as a bulking agent and matrix. In an aqueous media, it has been observed that tablets made from spray-dried powder including bulking agent, superdisintegrant, acidic component (citric acid), and/or alkaline ingredients (sodium bicarbonate) dissolve in less than 20 seconds. When this spray-dried powder was compacted into tablets, it disintegrated quickly and dissolved better²¹.

4) Sublimation

Sublimation is the procedure used when volatile chemicals are added to create a porous combination. It is possible to compress highly volatile substances such as urea, phthalic anhydride, camphor, naphthalene, ammonium carbonate, and urethane along with other excipients to create a tablet. This volatile substance is subsequently eliminated by sublimation, leaving behind the very porous matrix. It has been claimed that tablets made using this method often dissolve in 10-20 seconds. Pore-forming substances include solvents such as cyclohexane and benzene²². In this method drug, volatile agents, and excipients are blended well. Then the blend is subjected to direct compression. These tablets are subjected to sublimation then the volatile agents leaves the tablet upon sublimation, making the tablet porous and higher to disintegrate²².

5) Direct compression

The simplest and most economical method of producing tablets is direct compression. This method can now be used to prepare fast-dissolving tablets since better excipients-superdisintegrants and sugar excipients in particular are more readily available²³.

a) Superdisintegrants

Superdisintegrants play a key role in the disintegration and dissolution of fast dissolving tablets, particularly when compressed directly. The addition of water soluble excipients and effervescent agents accelerates the disintegration process.

There is another way to go about using the direct compression method. The use of sugar-based excipients, particularly bulking agents with high aqueous solubility and sweetness, such as lactitol, dextrose, fructose, isomalt, maltitol, maltose, mannitol, sorbitol, polydextrose, xylitol, and starch hydroxylase, which provide taste masking properties and a pleasing mouthfeel. Sugar-based excipients have been divided into two groups by Mizumoto et al. according to the rates of molding and dissolving.

Type 1 saccharides (mannitol and lactose) exhibit low mould-ability but high dissolution rate.

Type 2 saccharides (maltitol and maltose) exhibit high mould-ability and low dissolution rate²⁴

6) Mass-Extrusion

Using a solvent mixture of water-soluble methanol and polyethylene glycol, the active blend is softened in this method. The softened mass is then expelled through an extruder or syringe to create a cylinder product, which is then cut into even segments using a hot blade to make a tablet. To provide taste masking, the dried cylinder can be utilized to cover bitter medication granules²⁵. In this mass extrusion method drug and excipients are blended well. Then the blend is softened using solvent mixture (e.g., water soluble polyethylene glycol, methanol). The softened mass is then extruded via an extruder or syringe. These extrude are cut into even segments via heated blades to obtain tablets. And then tablets are coated to taste mask the bitter taste and packaged.

7) Granulation methods

- a) **Dry granulation:** When tablet ingredients are sensitive to moisture or are unable to withstand elevated temperature during drying, and when the tablet ingredients have sufficient inherent binding or cohesive properties, slugging may be used to form granules. This method is referred to as dry granulation, precompression, or double compression.
- b) **Wet granulation:** The technique of adding a liquid to powder in a vessel with any kind of agitation to create granule or agglomeration is known as wet granulation. When compared to the original drug-containing powder blend, wet granulation is a frequently utilized approach that produces granulate that has improved flowability, homogeneity, and compressibility, hence improving the tableting process. The pharmaceutical business produces granules using a variety of techniques, the most popular of which being high shear. Wet granulation, like other pharmaceutical processes, is a complicated one in which a variety of parameters, including binder type and processing conditions, will affect the final granules physical characteristics.
- c) **Melt granulation:** A mixture of an active ingredient and a water-soluble carrier that has been heated to a melting point is called melt granulation. In an ice bath, the melts is quickly consolidated while being vigorously stirred, ground, and sieved. Due to the drugs super saturation caused by the solute molecules becoming trapped in the solvent matrix by fast solidification, rapid congealing is preferred. Stainless steel plates connected to a cooling system for quick heat loss can be used to accomplish the solidification process. The melt granulation method has two benefits: since no solvents are used, it is easy to use and inexpensive.

Patented technologies for fast dissolving tablets

1) Zydis technology

Zydis formulation is a special method for making tablets that dissolve quickly. The medication ingredients are physically entrapped or dissolved within the matrix of quickly dissolving carrier polymers in this freeze-dried technique. Water is not necessary for swallowing because the freeze-dried structure quickly disintegrates in the mouth when the "zydis unit" is placed there. Zydis material is made up of wide variety of materials to accomplish certain goals²⁶. Alginate and gelatin are added to polymers like dextran to provide strength during handling. Good elegance, hardness, and crystallinity are achieved by including saccharides, such as sorbitol

or mannitol. In freeze-drying or long-term storage, glycine is typically employed as a collapse protectant to stop “zydis unit” from shrinking. To protect the formulation from the moisture it should be packed in a blister²⁷.

2) Durasov technology

It is based on direct compression technology, which is patented by CIMA LAB (US patent no. 6,024,981). It makes use of appropriate excipients with increased qualities, particularly superdisintegrants, which speed up the rate of disintegration and, consequently, dissolution⁵¹. This approach is based on the use of traditional non-direct compression fillers, which dissolve fast and don't leave the moth feeling sandpaper or gritty. Examples of these fillers are dextrose, mannitol, and sorbitol. It is also possible to employ effervescent and water-soluble chemicals to speed up the disintegration process. Blisters can be packed with Durasolv technology, which is intended to provide stronger tablets without the need for extra packaging measures. The tablet used in this technology is made up of fillers, lubricants²⁸.

3) Orasolv Technology^{29, 40}

Orasolv technology refers to a patented oral disintegration tablet (ODT) technology developed by the pharmaceutical company AstraZeneca. These tablets are designed to dissolve rapidly in the mouth without the need of water, making them convenient for patients who have difficulty swallowing pills or for situations where water may not be readily available. Orasolv tablet typically contain a mixture of active ingredients (APIs), disintegrants, sweeteners, and other excipients. The formulation is compressed into a tablet from using conventional tableting techniques. The key feature of Orasolv tablets is their ability to disintegrate quickly upon contact with saliva, allowing for rapid absorption of the drug into the bloodstream

The technology involves several advantage:

- a) Patient convenience: Orasolv tablets provide a convenient dosing option for patient a convenient dosing option for patients who have difficulty swallowing traditional tablets or capsules.
- b) Rapid onset of action: The fast disintegration of Orasolv tablets facilitates rapid absorption of the drug, leading to a quicker onset of action compared to conventional oral dosage forms.
- c) Improved compliance: The ease of administration and pleasant taste of Orasolv tablet may improve patient compliance, particularly in populations such as children or the elderly.
- d) Versatility: Orasolv technology can be applied to wide range of drugs, making it suitable for various therapeutic areas.

4) Wow technology

It is patented by Yamanouchi Pharmaceutical corporation where wow tends for “without water”. In this process high mouldability saccharide like oligosaccharide, mannitol is mixed with low mouldability saccharide like glucose, lactose, and mannitol to obtain rapidly melting strong tablet³⁰.

5) Shearform technology

The preparation of floss forms the basis of this technology. The method of flash heating feed stock including sugar carrier yields floss. A mixture of sucrose, mannitol, or dextrose, and surfactant is thoroughly combined. This is the main mixture of floss. During the flash heat process, the floss is flung concurrently with the carrier materials under centrifugal force. The carrier materials exhibit an intended flow state that is heat induced and exists via a spinning head. The floss created in the previous method has longer fibres, which are then further diced in a high shear mixer granulator to create smaller particles. The process of recrystallization involves treating floss with 1% ethanol, spraying it out, and then letting it evaporate, which improves the cohesive and flow characteristics. After being recrystallized, this matrix is compressed and combined with medications and other excipients. When sugar comes into touch with saliva, the procedure produces tablets that are immediately soluble in it, have a good tongue feel, and are very porous³¹.

6) Flashdose technology

This technique, like cotton candy, uses a unique spinning mechanism to create a crystalline floss structure. The medicine can then be mixed with this crystalline sugar and crushed into a tablet. Such a product has a large surface area for dissolution, dissolves quickly on the tongue, and is easily dispersed. The flash dosage pills are composed of self-binding shear from matrix known as “floss”³².

7) Ceform technology

This procedure involves spinning a dry powder comprising pure drugs and excipients. The ceform machine uses centrifugal force to combine dry medication powder via a small, heated hole at high speed. This pharmacological blend liquefies to form a sphere as a result of microburst of heat produced by precisely controlled temperature. This has no effect on drug's stability. These microspheres are mixed and/or crushed to fit the predetermined oral dosage format³³.

8) Flashtab technology

The goal of this method is to provide effervescent microencapsulated drugs with quick release in the gastrointestinal tract and easily flash-dispersible tablets. Eudragit is often the polymer used for fast release. This technology follows the traditional method of compression with a wet/dry granulation methodology. Drug formulation involves the use of taste masking agents, dissolving agents, swelling agents, and drug microgranules³⁴. These tablets exhibit strong physical resistance and strongly recommended for use with hygroscopic materials for blister packing. This is because materials such as aluminium foils and polyvinyl chloride provide superior moisture protection as compared to traditional polyvinyl chloride to polypropylene foils.

9) Nanocrystal technology

The technique improves dissolving rates by reducing particle size and increasing surface area. Nano-crystal particles (less than 100 nm in diameter) are created by grinding medicinal substances using weight-based approach. Nanocrystal quick dissolving technology allows for a wide range of dosages (up to 200 mg of API per unit) and is based on exclusive and patent-protected technology aspects, making goods easily categorized. Improved pharmacokinetics of oral drugs. The use of non-moisture-sensitive actives is economical and cost-effective. Drug Nano crystal colloidal dispersions and water-soluble GRAS components are combined, put into blisters, and lyophilized to make product wafers. They are extremely durable, yet dissolve in very little amounts of water in seconds, which is convenient for working with highly potent or hazardous chemicals reduction procedures such as granulation, blending, and tableting. This method allows for the conversion of modest quantities of pharmaceuticals into fast-dissolving tablet with minimal manufacturing process³⁵.

10) Advantol 200

Specifically created for use in nutraceuticals with its “soft-Melt” capability, Advantol 200 is a directly compressible excipient system that doesn't require any specialized manufacturing tools or equipment. Standard rotary tablet presses with standard tooling and typical tableting temperature and humidity levels are needed to produce sturdy “softmelt” tablets.

11) Advatab technology

Kyowa Hakka Kogyo (Tokyo, Japan) created and patented the Advatab™ technology (Eurand), which makes orally dissolving tablets using a proprietary tablet composition. Each tablet is lubricated with a spray during the manufacturing process. Advatab™ is made with 10-30 times less hydrophobic lubricant and can be 30-40% stronger than traditional tablets³⁶.

This results in tablet being:

- Hard and durable, yet allows easy wetting upon contact with saliva
- High drug loading
- Coated drug particles for better mouth feel
- Not require special packaging, and can be packed in conventional packaging systems (push-through blisters and bottles)

- Unique as it can be paired with Eurand's technologies like Microcaps (taste-masking) and Diffucaps (controlled release)

12) Frosta technology

This technology produces robust tablets with great porosity by compressing highly plastic granules under low pressures, resulting in a fast melting tablet. These plastic granules are divided into three types: porous and plastic materials, water penetration enhancers, and binders. A porous plastic substance is water soluble or dispersible. Plastic deformations of powders promote inter-particle interactions, which are necessary for the creation of bonds. If a porous and plastic substance is polymer. Avoid forming a viscous film on the tablet surface when in contact with watery liquids. One method for creating such tablets is to combine porous, plastic material with a water penetration enhancer as specific ratios. To prevent a viscous coating on the tablet surface, water-penetration-enhancing particles separate porous and plastic particles. Depending on the tablet size, the generates FDTs with the appropriate hardness and quick disintegration time (2 to 30 seconds)³⁷.

13) Ora-quick technology

KV Pharmaceuticals says that its microsphere technology, known as Micro Mask, uses a unique patented taste masking technique. It does not utilize any solvents, which allows for faster and more efficient tablet manufacture. It also produces less heat, which is ideal for thermally sensitive medications. This technique promises speedier dissolution and improved flavour masking for tablets. Except for KV medicine, no other items made using this technique are accessible on the market. This technique assesses absorption and dissolution rates, mouth feel, taste, physical strength, bioavailability, and stability³⁸.

14) Pharmaburst technology

SOI Pharma, New castle, patents this technology. It utilizes the coprocessor excipients, dissolving within 30-40 seconds. This technology incorporates, dry blending of drug, flavour, and lubricant followed by compression in tablets. Tablets obtained have sufficient strength so they can be packed in blister pack bottles³⁹.

15) Lyoc

Farmyoc has patented technology called Lyoc. The technique attempts to create a solid and porous galenic of oil-in-water inside the blister alveolus through lyophilisation. The bulk medication of drug micro particles contained in this emulsion paste are subsequently frozen in blisters. Because of its porosity, the locomotive product has a good disintegration rate but a low mechanical strength. One such product is Farmyoc Phlorogluconol Hydrate. Similar to Zydis, Lyoc uses a freeze-drying method, except their product is frozen on the shelves of the freeze-dryer. These formulations need to add a significant amount of undissolved inert filler (mannitol) to increase the viscosity of the in-process suspension in order to prevent inhomogeneity by sedimentation during this procedure. By directly compressing a powdered combination with an external lubricant, tablet are produces⁴⁸.

Mechanism of superdisintegrants

Superdisintegrants are excipients commonly used in pharmaceutical formulations to promote the rapid disintegration of tablets and facilitate drug dissolution. They enhance the dissolution rate and bioavailability of poorly soluble drugs, making them more effective. There are several mechanisms through which superdisintegrants work:

1) Swelling

Superdisintegrants which act by this mechanism work on the fundamental of "swell" and "burst". When the superdisintegrants comes in contact with the water/saliva, the aqueous phase exerts more adhesive force upon the superdisintegrants as compared to other excipients and drug resulting in swelling and thrust or breaking apart of the tablet⁴¹. Superdisintegrants such as cross-linked polymers like croscopolidone (PVPP), and croscarmellose sodium (CCS), swell rapidly upon contact with water. This swelling exerts pressure on the tablet matrix, leading to its fragmentation and disintegration.

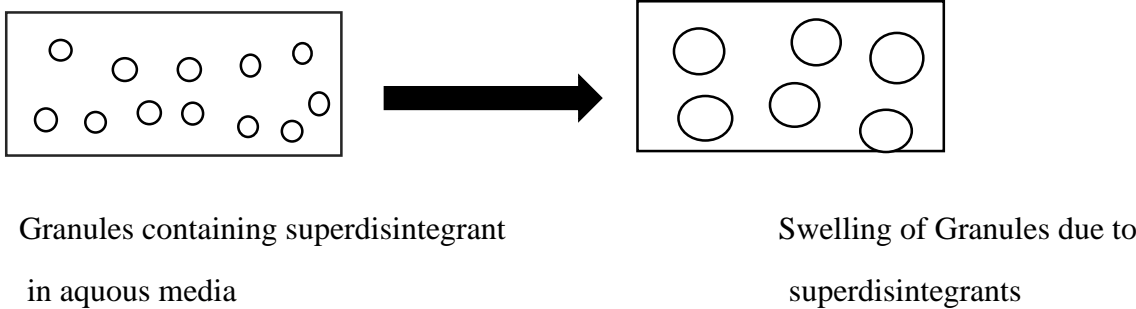


Figure 1 Diagrammatic Depiction of Mechanism of Swelling

2) Porosity and Capillary Action (wicking)

This mechanism suggests that primarily all particles of the tablet are surface wetted in the given aqueous media. Water then penetrates into the core of the tablet, reducing the inter-particle bond thus aiding in breaking of the tablet. Thus it is termed as capillary action or wicking as slowly, the wetting rises in the tablet is of the utmost importance as it is the fundamental requirement for easy and quick wetting/water uptake. The more porous the material the greater the rate of wetting and disintegration time less. Some superdisintegrants have capillary action properties, allowing them to draw water into tablet matrix. This influx of water helps in breaking the inter particle bonds, leading to faster disintegration.

3) Particle/Particle Repulsive Forces

Guyot-Hermann presented a particle repulsion theory. According to this view, the swelling is caused by tablets containing “non-swelling” disintegrants. This works on the basis of the electric repulsive force that causes particles to reject each other, resulting in tablet disintegration⁴². This technique employs biological enzymes as disintegrants. The tablet contains a binder that can be easily broken down by salivary enzymes. When these binders come into touch with saliva, they are catalysed, and the tablet dissolves. This method also combines the swelling and burst, releasing medication as granules. Amylase breaks down binder starch. Invertase breaks down sucrose, hemicellulose breaks down gums, and Carragenase breaks down alginates.

4) Deformation

Certain disintegrants possess a high degree of elasticity. Upon exposure to water, they deform and create channels within the tablet, facilitating water penetration and disintegration. Starch grains are considered “elastic” meaning they can distort under pressure but return to their original shape once the pressure is released. Tableting causes permanent deformation of grains, resulting in “energy rich” starch granules have a greater ability to swell than starch grains that have not been distorted under pressure⁴³.

5) Hydration

Superdisintegrants with hydrophilic properties absorb water rapidly, leading to their swelling and subsequent rupture of the tablet matrix.

6) Gas formation

Some superdisintegrants, like sodium bicarbonate, generate gas upon contact with water. This gas production creates internal pressure within the tablet, leading to its disintegration.

Table 1: List of superdisintegrants^{5, 46}

Sr no	Superdisintegrants	Mechanism of action	Specific properties
1	Croscarmellose sodium	Swells 4-8 folds in <10s. Swelling and wicking action	Effective in concentration (0.5-2%), high swelling capacity, cross linking of the carboxyl ester groups
2	Crospovidone	Combination of swelling and wicking action. Swells 7-12 folds <30 s.	The effective concentration in 1-3%. Rapidly disperse 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 tetra saccharides, good superdisintegrants property similar to the modified starch and celluloses.
5	Sodium starch glycollate	Strong swelling properties upon contact with water. Swells 7-12 folds in <30a.	Rapid absorption of water results in swelling up to 6%, high concentration causes gelling.
6	Xanthan gum	Extensive swelling properties for faster disintegration	High hydrophilicity and low tendency, low water solubility.
7	Soy polysaccharide	Rapid dissolving	Does not contain starch or sugars so can be used in products meant for diabetics

Evaluation Parameters:

It is important to evaluate the formulated drugs in order to determine the quality of the tablet. Given below are the fundamental evaluation parameters^{44, 45}.

Table 2: Evaluation parameters of FDT

Parameters	Criteria
Weight Variation	Weight variation tests are carried out according to either USP, IP, BP
Hardness	Hardness of the tablet should be lesser than conventional tablet falling in the range of 3-4kg/cm ²
Mechanical Strength	Should possess adequate mechanical strength to absorb transportation shock and avoid breakage of tablet
Tablet Porosity	Tablet porosity is conducted (as per ICH guideline)
Wetting time and water absorption	Use of simulated saliva to check the wetting time of tablet as well as water absorption
In-vitro Dispersion time	At optimum and fixed pH and temperature, time taken for dispersion of tablet in media is determined

Disintegration Studies	The time period at which the tablet starts to disintegrate in given aqueous medium
Dissolution Studies	Dissolution studies carried out according to USP, IP, BP.
Stability Studies	Stability studies (including Accelerated stability studies) are conducted according to the ICH guidelines
Content Uniformity	Content uniformity according to either USP, IP, BP
Friability test	Friability test carried out on 20 tablet. It should be not less than 1%

Conclusion

Fast-dissolving tablets are novel dosage forms that were created with the purpose to address some of the issue associated with traditional solid dosage forms, such as difficulties swallowing the tablet in patients who are elderly or young. Fast-dissolving tablets are made to dissolve or break down in saliva in less than 60 seconds on average (with a range of 5 to 60 seconds). Compared to standard oral dose forms, fast-dissolving tablets offer higher patient compliance and acceptance, and they may also have improved biopharmaceutical characteristics, bioavailability, efficacy, convenience, and safety. In the past ten years, FDTs have become incredibly popular. FDTs must be developed for patients who are psychotic, bedridden, elderly, or paediatric, as well as for patients who might have access to water or who are occupied with travel. Some of these conventional and patent technologies have been used to make FDTs, and these formulations have enough mechanical strength and dissolve quickly in the buccal cavity without the need of water. The FDTs are formulated using more recent technology, which offer more advantageous and minimally disadvantageous dose forms

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