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Review Article

Fast Dissolving Tablets: An Overview

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ABSTRACT

The oral route is now the industry standard for drug delivery as it is recognized as the safest, least expensive, and most convenient method of achieving patient compliance. Rapidly dissolving tablets, a new idea for oral administration, is widely used and now accepted. These are solid dosage forms that dissolve and release the active ingredient when placed in the mouth without water for a short period of time. Geriatric, paediatric and bedridden patients are particularly favoured for the use of these FDTs because of dysphagia. Rapid absorption, quick onset of action and less drug loss properties are the main advantages of FDTs. Since disintegration is a critical step for any solid dosage form to exert its pharmacological effects, FDTs use super disintegrants to accelerate disintegration and increase bioavailability. This overview focuses on the overall development of ODTs and mainly highlights super disintegrants: selection, advantages, modes of addition, mode of action and types.

INTRODUCTION

The most popular and practical approach, with good stability and compact container size, is oral administration [1,2]. As a delivery method, the orally disintegrating tablet (ODT) requires no additional water because it quickly disintegrates in the mouth when it comes into touch with saliva. It can be absorbed through the pregastric mucosa. Other names for this kind of dosage forms have been mouth dissolving/disintegrating tablets (MDTs), quick disintegrating tablets, fast/rapid dissolving or disintegrating tablets (FDTs), quick/rapid melt tablets, orodispersible tablets and porous tablets [3,4]. Rapid action, disintegration and patient compliance are required, particularly for paediatric, elderly, psychotic, crippled and immobile patients leading to the emergence of ODTs in the 1980s [5].

Requirement for fast-acting tablets

There are numerous prerequisites for quickly eroding tablets, including, without water intake, the tablet must break down and spread throughout the oral cavity. It has a large drug capacity. It should have the most sensational effect and be compatible with excipients and flavour masking agents. They leave scant to no residue after administration. It should be able to stay intact

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during formulation procedures to its fullest potential. At the range of temperature and humidity, it ought to be steady. It should be flexible and compatible with current processing and packaging equipment. Low-cost manufacturing is required [6,7].

The best characteristics of fast-dissolving tablets

1. When put in the mouth, they ought to fall apart immediately.
2. Water shouldn't be necessary for them to disintegrate.
3. They ought to give precise dosing because they are unit dosage forms.
4. Rapid absorption and dissolution within the oral cavity.
5. Simple to convey.
6. Tablets are produced at an inexpensive cost using traditional machinery.
7. Less susceptible to changes in temperature and humidity.
8. They should have reduced fragility and keep their hardness [8].

Benefits of fast-dispersing tablets

1. Useful for paediatric and geriatric patients.
2. Enables high drug loading.
3. Ease of administration to patients having difficulty swallowing.
4. ODTs provide fast drug delivery hence there is a large surface area contact with the oral cavity.
5. Because fast-dissolving tablets have few leaves and completely dissolve in the tongue without leaving any trace, they provide users with a satisfying mouthfeel.
6. Fast-dissolving tablets are particularly stable because they are less susceptible to environmental changes.
7. Since fast-dissolving pills are packaged in straightforward blister packaging and don't require any specialized or expensive packaging.
8. These are economical.
9. Since they are a solid dosage form that is less sensitive to external conditions and does not require water to be swallowed, they are easily portable [9,10].

Drugs that are suitable for tablets that quickly dissolve:

When choosing the drug, excipients and formulation processes for a particular drug, numerous considerations should be made in order to construct FDT. Here are some of them,

1) Drug should have the ability to permeate the oral mucosa.
2) At least partially non-ionized at the oral cavity pH.
3) Have the ability to diffuse into the epithelium of the upper cavity.
4) Short half-life and frequent dosing drugs are unsuitable for fast-dissolving tablets.
5) Drugs should have good stability in saliva and water.
6) Drugs have very bitter or unacceptable taste and odour is unsuitable for orodispersible tablets.
7) The therapeutic dose must not exceed more than 20mg.
8) Small to moderate molecular weight [11].

FDT development issues

Edibility

The majority of medications are unpleasant taste, FDTs typically contain the medication in taste - masked form. FDTs release their active ingredients into patient's oral cavity after administration, coming into contact with their taste buds. This concealing the taste of the medications is essential for ensuring patient compliance [11,12].

Mechanical efficiency and duration of disintegration

In order to allow for oral disintegration, FDTs are either, are of a very porous, soft-moulded matrix or compressed into tablets with a very low compression force. As a result, the tablets are often

friable and/or brittle, difficult to handle, and frequently require specialised peel-off blister packaging, which may increase the cost [11,12]. Only the wow tab and Durasolv technologies can create tablets that are robust and rigid enough to be wrapped in several-dose bottles [11].

Hygroscopicity

Several orally dissolving dosage formulations are hygroscopic and unable to preserve their physical integrity in the presence of ambient temperature and humidity [11,12]. They must therefore be protected from damp, which necessitates the use of specialist product packaging [11].

Drug dosage

The amount of medication that can be included in each unit dose place restriction on how FDTs can be utilised. The medication dose must be less than 400mg for insoluble pharmaceuticals and 60mg for soluble drugs for lyophilized dosage forms [11,12].

Water solubility

Water-soluble medications present a number of formulation difficulties because they produce eutectic mixtures that lower the freezing point and lead to the formation of a glassy solid that may crumble when dried due to the loss of supporting structure during the sublimation process [11,12,13]. The use of different matrix forming excipients, like mannitol, which can induce crystallization, can sometimes prevent such collapse.

Size of tablet

A tablets size affects how easily it may be administered. According to reports, the tablets with a diameter of 7-8 mm are the simplest to swallow. Any size bigger than 8mm was the easiest to manage. The easy-to-take any easy-to-handle tablet size is therefore challenging to obtain [11,13].

Sensation in the mouth

FDTs shouldn't break up into larger pieces in the mouth. It is to be expected that FDT will break down into smaller particles upon administration. In addition, the addition of flavours and fresheners such as menthol improves tongue feel [13].

Sensitivity to environmental conditions

Since most materials used in FDTs are moisture and temperature resistant, they should be relatively insensitive to these factors and designed to dissolve in as little water as follows [13].

TECHNIQUES FOR THE PRODUCTION OF DISPERSIBLE ORAL TABLETS

Various techniques are currently used to produce rapidly disintegrating and dissolving tablets [14]

1) Freeze-drying and Lyophilization

Once the product is frozen, the water is removed in a process called freeze drying. This process creates an easily soluble amorphous porous structure. The base drug is dissolved in a solution consisting of a carrier/polymer. The suspension is poured into the prepared blister walls by weight. To freeze a drug solution or dispersion, the blister trays are removed through a liquid nitrogen tunnel freezer. To continue the freezer-drying process the frozen blisters are then placed in refrigerators. The aluminium foil carrier is then applied with a blister sealer after freeze-drying. In the end, the blisters are packed and shipped. Improved absorption and increased bioavailability could be demonstrated with the freeze-drying method [14].

2) Tablet Moulding

There are two main methods of stamping, namely the solvent method and the hot method. The powder mixture is moistened with hydroalcoholic solvent in the solvent process and then compacted at low pressure to form a moist mass (compression moulding). Drying is used to remove the solvent. The tablets produced by this method are more porous and less dense than compressed tablets, which accelerates dissolution. A suspension consists of drug, agar and a sugar (e.g., mannitol or lactose) is prepared for the hot stamping process and then poured into bubble cavities where the agar solidifies on drying at 30°C under vacuum and becomes a jelly at room temperature. Compared to

the freeze-drying method, the tablet forming method is easier to adapt to industrial production [14].

3) Spray Drying

In this method, sodium starch glycolate, croscarmellose, or crospovidone are used as superdisintegrants, while gelatin can be used as a matrix and a adjuvant. Mannitol acts as a filler. The mixture containing bulking agents such as mannitol and lactose, strong disintegrants such as sodium starch glycolate and croscarmellose sodium, as acidic (citric acid) and /or basic (sodium bicarbonate) substances. This spray-dried powder ground into tablets showed accelerated dissolution [14].

4) Sublimation

Volatile components are added to the formulation, which then undergoes a sublimation process to create a porous matrix. Volatile ingredients such as ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, naphthalene, urea, urethane and phthalic anhydride can be compressed into a tablet with other excipients. Tablets made with this technique usually disintegrate within 10-20 seconds. Solvents such as benzene and cyclohexane can also be used as blowing agents [14].

5) Direct Compression

It is an economical method with easy steps for formulating tablets. This technique can be used for the production of ODT as improved excipients are available, especially superdisintegrants and sugar-based excipients [14],

a) Superdisintegrants: In many ODT technologies based on direct compression, the inclusion of superdisintegrants mainly influences the rate of decay and hence resolution. The disintegration is further accelerated by the addition of additional formulation ingredients such as effervescent and water-soluble excipients.

b) Sugar- based Excipients:

This is another way to create an ODT using direct compression. When using sugar-based excipients, especially fillers such as dextrose, fructose, isomalt, lactitol, maltilol and maltose, xylitol, mannitol, sorbitol, starch hydrolysate, polydextrose and others, they are characterized by good water solubility and sweet taste that gives them taste making properties and a pleasant mouthfeel. Based on the formation and dissolution rate, Mizumito et al. have divided sugar-based excipients into two categories-

Type 1 saccharides (lactose and mannitol) show low plasticity but high dissolution rate.

Type 2 saccharides (maltose and mannitol) show high moldability and low dissolution rate.

6) Mass Extrusion

With this technology, the active blend is softened using a solvent solution of methanol and water-soluble polyethylene glycol, and the softened mass is then expelled through the extruder or syringe to divide a product cylinder into uniform segments using heated blade to form tablet. To mask the taste of bitter drugs, the dried cylinder can also be used to coat the granules [14].

PATENTED TECHNOLOGIES FOR DEVELOPING FAST DISSOLVING TABLETS

Some of patented techniques used in manufacturing of ODTs [15]:

1) Zydis Technology

It was patented by Zydis. Zydis formulation is original freeze-dried tablet where the drug is physically entrapped within the matrix of fast-dissolving carrier. When Zydis units are placed in the moth, the freeze-dried structure instantly dissolves and does not need water to help with in swallowing [15].

2) Durasolv Technology

Durasolv is a CIMA labs patentable technology. This method produces tablets that are composed of a medication, a filler, and a lubricant. Typical tableting apparatus is used to create tablets.

Durasolv is suitable technology for products that only need small amounts of active chemicals [15].

3) Orasolv Technology:

This innovation comes from CIMA labs. The flavour of the active medication is hidden in this system. Additionally, it has an effervescent disintegration agent. The oral dissolving time of the tablet is reduced by using a direct compression approach with a modest compression force [15].

4) Flash Dose Technology

It was patented by FUISZ. This technology produces tablets consisting of a self-binding shear form matrix called "floss" prepared by a flash heating process [15].

5) Wow tab Technology

Yamanouchi Pharmaceutical Co. has patented the Wow tab technology. WOW is short for "without water". To create a rapidly melting, robust tablet, a combination of high moulding and low moulding saccharides are used in this procedure. The active component is combined with a high mould-ability saccharide (such as maltose, or oligosaccharides) and then granulated with a low mould-ability saccharide (such as lactose, glucose and mannitol) before being compacted into tablet form [15].

6) Flash tab Technology

It is the patent of prographarm laboratories. This technology creates tablets with an active component in the form of tiny crystals. The traditional methods of coacervation, microencapsulation, and other methods can be used to create drug micro granules. Conventional tabletting technology was used throughout the entire processing [15].

EXCIPIENTS USED IN FAST DISSOLVING TABLETS

The excipient chosen must not interact in any way with the active ingredient or any other excipient. Table 1 shows the listed excipients which are widely used in the formulation of fast-dissolving tablets with their range, role and functions [16,17].

Table 1: List of excipients used in the development of ODTs [16,17]

Name	Range	Role	Example
Super-disintegrants	1-10%	Helps in the quick disintegration of the tablet which results in fast disintegration	Croscarmellose sodium (Ac-Di-Sol), Crospovidone, sodium starch glycolate (SSG)
Diluent/Bulking agent/Filler	10-90%	Increases the bulk of the tablet	Mannitol, Polydextrose, Lactitol, DCL (direct compressible lactose) and starch hydrolysate
Lubricant	1-5%	Reduces the friction between the surface of the die wall and the tablet and thus preventing sticking and picking	Talc, Waxes and Oils, PEG, Stearic acid and derivatives, leucine, sodium benzoate, magnesium lauryl sulphate, liquid paraffin
Sweeteners and Sugar based excipients	-	Good mouth feels and pleasant taste hence enhancing patient's compliance	Sugar, Dextrose and fructose, Aspartame, Sodium saccharin, Sugar alcohols and Sucralose
Flavouring agent	-	To impart flavour to the tablet	Peppermint flavour, clove oil, anise oil, eucalyptus oil
Emulsifying agent	-	Stabilize the immiscible blends and enhance bioavailability	Alkyl sulphates, Propylene glycol esters, Lecithin, Sucrose esters

SUPERDISINTEGRANTS

The superdisintegrants play a key role, in orally administered preparation for dissolution and disintegration of tablets, due to their benefits of better conformity in children and aged people they are widely used in formulation [18].

Selection criteria for superdisintegrants

1) Particle size should be small.

2) Should be non-toxic.
3) Compatible with other excipients and drug.
4) Good hydration capacity.
5) Good flow property.
6) Good mouthfeel.
7) Effective in less quantity [19,20].

Advantages of superdisintegrants

1) Required in less concentration.
2) Compatible with large number of drug and excipients.
3) Does not affect compressibility and flowability [21].

Disadvantages of superdisintegrants

1) Sensitive to moisture leading to instability [21].

Modes of addition of superdisintegrants

The superdisintegrants can be incorporated into the formulation by following methods [22,23],

1) Internal addition (Intragranular)
2) External addition (Extra granular)
3) Partly internal and external

Superdisintegrants mechanism:

To facilitate the rapid disintegration of tablets into small fragments, leading to faster dissolution and rapid onset of action, superdisintegrants use a mechanism called,

1) Swelling

Swelling is the most common tablet disintegration mechanism in natural and synthetic superdisintegrants. The necessary first step of this mechanism is the contact of the tablet with water, followed by the swelling of the disintegrating particle, leading to the formation of the swelling force that leads to tablet disintegration [24].

2) Wicking

Tablet disintegration occurs by penetration of medium into the tablet replacing the adsorbed air on the particles results in weaking of intermolecular bond and break down of tablets into its fine particles [25].

3) Heat of wetting

When disintegrating agents with exothermic properties becomes wetted, capillary air expansion generates localized stress, which helps in tablet disintegration. This mechanism of action explains the functioning of different types of disintegrators and cannot describe the functioning of most modern disintegrators [26].

4) Chemical reaction

Tablet disintegrates primarily due to pressure build-up within the tablet due to the release of carbon dioxide from water, which is produced when tartaric or citric acid reacts with bicarbonate or alkali metal carbonates. In this case, the effervescent mixtures are added before pressing. Dissolution of active ingredients and taste masking are also enhanced by the release of carbon dioxide [27].

5) Repulsive force of particles

This mechanism is used to explain the swelling of tablets from non-sweeling explosive. Guyot-Hemann proposed a theory of particle -particle repulsion based on the observation that non-swellable particles also lead to tablet disintegration. The decay mechanism is repulsive electrical forces between the particles, and water is required for this [28].

6) Deformation recovery

The disintegrated particles get deformed during tablet compression and these deformed particles regain their normal structure when they come in contact with water. The swelling capacity was improved during deformation which results in breakup of tablets [29].

7) Enzymatic reaction

Tablets disintegrate under the influence of certain enzymes present in our body These enzymes act as disintegrants and reduce the binding ability of the binder. The swelling creates outward pressure, the tablet ruptures, or increases water absorption, resulting in excessive tablet volume, which promotes tablet disintegration. The list of enzymes in our body that help to breakdown pills are amylase, protease, cellulase and invertase [30].

8) Combination action

Disintegration of tablet occur by a disintegrant which shows a combination action of both swelling and wicking. Example: Crospovidone [31]

Superdisintegrants types

Based on origin and availability, superdisintegrants are divided into [18]

1) Natural,
2) Synthetic,
3) Co-processed.

Natural Super disintegrant

These are several plant-based substances which serves as an alternative to synthetic products as they are,

i. Biodegradable
ii. Biocompatible
iii. Non-toxic
iv. Local accessible
v. Patient tolerance as well as public tolerance
vi. Eco-friendly and Bio-acceptable
vii. Low price as compared to synthetic and renewable source [32].

Below Table 2 shows the list of natural superdisintegrants used in developing ODTs, its source and mechanism involved,

Table 2: Natural superdisintegrants list, source and its mechanism of action [32]

Natural Super disintegrant	Source	Mechanism
Lepidium Sativum	Mucilage was obtained from the seeds of Lepidus sativum	Swelling
Chitin and chitosan	Chitin is derived from a natural polysaccharide extracted from crab and shrimp shells	Swelling
Locust bean gum	Obtained from seeds of locust bean	Swelling and capillarity
Guar gum	Isolated from guar gum seed	Swelling
Agar and processed agar	Dried gelatinous substance derived from gelidium amansii and several other species of red algae	High gelling property
Xanthoma gum	Obtained from Xanthomonas compestris	Swelling
Soy Polysaccharide	High molecular weight polysaccharides derived from soybeans.	Swelling
Ispaghula shells (Plantago ovata)	From the ispaghula seeds	Swelling
Hibiscus rosa sinesis Linn	Hibiscus rosa sinesis mucilage	Swelling
Gellan gum	Obtained from Pseudomonas elodea	Swelling
Mango peel pectin	Mango peel extract accounting for 20-25% of the mango processing	Swelling
Fenugreek seed mucilage	Fenugreek seed slime	High gelling power

Synthetic superdisintegrants

They are commonly used to facilitates tablet disintegration. Advantages of synthetic superdisintegrants.

i. Effective at low concentration compared to starch.
ii. They have the little influence on compressibility and flow.
iii. More efficient intragranular [32,33].

Synthetic superdisintegrants used in formulating ODTs their nature, properties, mechanism followed and the brands available are given below in the Table 3 below,

Table 3: Synthetic superdisintegrants [32,33]

Synthetic Super disintegrant	Nature	Mechanism	Properties	Brands available

Sodium starch glycolate/sodium carboxymethyl starch	Modified starch and cross-linked starch	Absorbs water quickly results in swelling, swells 7-12 folds within 30 seconds	Swells in 3 dimensions and acts as sustained release matrix	Vivastar, Explotab, Tablo, Primo gel
Crospovidone	Cross linked PVP	Combination of swelling and wicking	Water insoluble, spongy in nature	M Kollidon Polyplasdone
Croscarmellose Sodium	Modified cellulose	Swelling and wicking within 20 seconds, swells up to 4-8 folds	Swells in 2 dimensions	Ac-Di-Sol Nymce ZSX Primellose Solutab Vivasol L-HPC
Crosslinked Alginic acid	-	Rapid swelling and wicking	Promotes disintegration in both dry and wet granulation	Alginic acid NF
Calcium Silicate	-	Absorbing effect	Very porous and light weight	-
Ion exchange resins	Cross- linked polyacrylate	Swelling	Has high water absorbency and high purity weak acid, pharmaceutical grade cation resin that is supplied in dry.	Indion 414 Tulsion 339 Amberlite IRP88
Chitin and Chitosan	-	Swelling	-	-

Co-processed Superdisintegrants

These are the new and improved version of superdisintegrants developed to meet the needs of advanced tablet manufacturing [34,35]. Co-processed excipients provide best properties compared to physical mixture of individual excipient mixture Table 4 below shows the list of co-processed superdisintegrants and the list of components it contains,

Table 4: List of Co-processed superdisintegrants [34,35]

Co-processed superdisintegrants	Consists of
Ludipress	Lactose monohydrate, poly vinyl pyrrolidone and crospovidone
Starlac	Lactose and maize starch
Starcap 1500	Corn starch and pregelatinized starch
Ran-Explo-C	Microcrystalline cellulose, silica and crospovidone
Pan Excea MH300G	Microcrystalline cellulose, Hydroxy-propyl methyl cellulose and crospovidone
Ludiflast	Mannitol, crospovidone and polyvinyl acetate

EVALUATION OF RAPID DISSOLVING TABLETS

Quality control testing of ODTs [36,37].

1) **Size and shape**

The size and shape of the tablet can be dimensionally defined, monitered and controlled.

2) Tablet thickness

It is an important factor in repetitive appearance and calculation using filling apparatus. Some filling apparatus use to measure the identical thickness of tablets in a calculation method. Ten tablets were taken, and their intensity was recorded using micrometer.

3) Weight variation

The 20 tablets were randomly selected and weighed individually to test for weight loss. Specification of weight difference as specified in I.P. is given in the below table;

Table 5: Specification as per I.P. [36]

Average Weight of Tablet	%Deviation
80mg or less	±10
80mg to 250 mg	±7.5
250mg or more	±5

4) Tablet hardness

The force applied across the diameter of the tablet in order to break the tablet is defined as its hardness. The hardness of a tablet is determined using a Monsanto Hardness tester.

5) Friability

It is performed to measure the mechanical strength of tablets. Friability is measured by using Roche friability. A pre-weighed tablet was placed in the friabilator that revolves at 25rpm, dropping those tablets at a distance of 6 inches with each revolution. The tablets were placed in the friabilator and rotated for at least 4 minutes. In the end, tablets were dusted and reweighed, and the loss in the weight of a tablet is measured.

%Friability = loss in weight/initial weight×100

6) Wetting time

A piece of tissue paper(12cm×10.57cm) folded twice was placed in a small petridish (ID=6.5) containing 6ml of Sorenson's buffer pH 6.8. The time taken for complete wetting of a tablet was measured by placing on a paper. Three trails for each and the standard deviation was also determined.

7) *In- vitro* disintegration test

This test is performed on 6 tablets using the method described in I.P. Specified equipment at a temperature of 37±2^{0}C in a disintegrating medium and the time required for the tablets to completely disintegrate without leaving any residue remaining in the apparatus was measured in seconds.

8*) In- vitro* dispersion time

In vitro dispersion time was measured by placing a tablet in a beaker containing 50 ml of Sorenson's buffer, pH 6.8. Three tablets were randomly selected from each formulation and the dispersion time measured.

CONCLUSION

Fast dissolving drug delivery system have emerged as a key development in current research due to the rising demand for innovative drug delivery. Superdisintegrants makes tablets with a quicker medication release rate and shorter breakdown times. There are several materials that can be used to create dispersible tablets, however despite the development of synthetic superdisintegrants, natural superdisintegrants are still being actively researched for their ability to quickly dissolve tablet structure. Natural superdisintegrants have been increasingly popular recent years due to their accessibility in nature, affordability, origin and ease of in vivo disintegration, lack of toxicity, and potential for chemical customization. Therefore, many ODTs may be developed for most of the available drugs by using several natural superdisintegrants in future.

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