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Review Article

Innovations In Fast Disintegrating Tablet Formulation: Harnessing The Power Of Super Disintegrants For Rapid Oral Dissolution- A Review

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ABSTRACT

This work looks into how to improve the oral dissolving qualities of fast disintegrating tablets (FDTs) by formulating and testing them using cutting-edge super disintegrants. Modern super disintegrants have the ability to dissolve and disintegrate quickly in FDTs, which could be advantageous for patient convenience and compliance. To maximize tablet disintegration times, a variety of super disintegrants were used, such as sodium starch glycolate, crospovidone, and croscarmellose sodium. Excipients such binders, diluents, and sweeteners were carefully chosen to ensure compatibility and maintain the overall integrity of the tablet matrix. Hardness, friability, and disintegration time—three physicochemical characteristics of FDTs—were methodically assessed in order to determine how various super disintegrants affected the quality of the tablets. To evaluate the drug release characteristics of FDTs, in vitro dissolution assays were carried out utilizing recognized dissolution media. When the results were compared to those of conventional tablets, the dissolution kinetics showed the enhanced performance ascribed to the addition of super disintegrants. Evaluations of stability under both fast and extended storage settings were carried out to guarantee the long-term resilience of the developed FDTs. A thorough examination looked into how the environment might affect the tablets' chemical and physical stability.

INTRODUCTION

Fast dissolving tablets (FDTs) are a novel dosage form that have gained popularity. They provide a patient-friendly substitute for those who have difficulty swallowing regular tablets or capsules. Fast-dissolving tablets (FDTs) have several benefits for different patient groups, such as young

patients, elderly patients, people who have trouble swallowing, and people who are always on the go. Super disintegrants are essential to the formulation of full-dose tablets (FDTs) because they help the tablet break quickly when it comes into contact with saliva, which promotes the active pharmaceutical ingredient's (API) speedy

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dissolution and absorption. Sodium starch glycolate, croscarmellose sodium, and crospovidone are common super disintegrants; they all have special qualities that help in effective tablet disintegration. The super disintegrant of choice and the amount of it in the formulation have a big impact on the FDT's disintegration time and overall performance. The purpose of this study is to investigate the complexities of formulation involved in the creation of FDTs with super disintegrants, taking into account the additive effects of super disintegrants, binding agents, and excipients on tablet characteristics. To guarantee the quality and integrity of the formed tablets, the evaluation procedure also includes a thorough assessment of physicochemical criteria like hardness, friability, and disintegration time. The findings of this study could have a substantial impact on the creation of effective, patient-centred pharmaceutical formulations that cater to the changing requirements of various patient populations.

ADVANTAGE OF FAST DISSOLVING TABLETS 1,2:

- The pill does not need to be swallowed with water.
- Patients with mental disabilities, the elderly, and children can all receive it with ease.
- As opposed to liquids, the dosing is precise.
- Quick start of action due to quick drug absorption and disintegration.
- The first pass's metabolism is lowered, improving bioavailability and lowering adverse effects.
- Permit heavy drug loading and economically efficient.
- Perfect for regulated and continuous release activity ,it keeps you safe from the risk of asphyxia from physical obstructions .
- Taste well and leave the mouth feeling wonderful and No need to chew.

- It is possible to increase medication bioavailability by oral, pharyngeal, and esophageal ingestion.
- Quick drug treatment intervention is feasible.
- Blisters may be pushed through; no special packaging is required

LIMITATIONS TO FDT [3,4]:

- Drugs with relatively large dosages are difficult to manufacture into fast-dissolving tablets.
- Patients who are concurrently receiving anticholinergic medications are not suitable candidates for fast-dissolving tablets.
- Tablets often have a weak mechanical strength. As a result, handling and packaging must be done carefully.
- Tablets that are not properly prepared may leave the tongue feeling gritty and unpleasant to chew.
- Medications that require regulated or sustained release, have a short half-life, and require frequent injection are not suitable candidates for tablets that disintegrate quickly.
- Drugs with unpleasant tastes are difficult to create into quickly dissolving tablets, hence extra caution should be used while creating such a medication.

Ideal properties of fast Dissolving Tablets [5,6]:

- It dissolves, disperses, and disintegrates into the mouth in a couple of seconds when taken orally and doesn't require water.
- It should be sufficiently hard to withstand rigors both during and after production procedures.
- It should also leave little to no residue in the mouth after disintegration.
- It ought to be less susceptible to external factors like humidity and temperature.
- It should be cost effective.



- Easily dissolve or crumble in salivary fluid in a matter of seconds.
- Be conveniently transportable and portable.
- The production process is simple and inexpensive.

Formulation Procedures for Creating Fast-Dissolving Tablets; [7,10]

variety of procedures can be employed to create tablets that dissolve quickly in the mouth with various techniques and the resulting ODTs differ in a number of ways, including:

1. The tablets' mechanical strength
2. Mouthfeel and taste
3. Ability to swallow
4. Salivary drug dissolution
5. The ability to absorb
6. Consistency

A number of techniques are used in the creation of ODTs, including as compaction, nanonization, mass extrusion, molding, spray drying, cotton candy, direct compression, freeze-drying, and fast-dissolving film processes. The simplest and most economical method of producing tablets is direct compression. Thanks to the development of better excipients, particularly sugar-based and super disintegrant excipients, this technology may now be used to prepare ODT.

The Need for Development of fast dissolving tablets [7,8]:

The patients' low acceptance and adherence to current delivery regimens is the reason why non-invasive delivery techniques are still needed. Since

both age groups found it difficult to take traditional pills, the paediatric and geriatric populations are the primary targets.

The following patient-related considerations played a role in the creation of fast-dissolving tablets:

1. Children and elderly individuals have difficulty swallowing or digesting solid food
2. The risk of suffocating from physical blockage was avoided with the oral administration of standard formulations, providing a higher level of safety.
3. Those who are really old and might not be able to swallow a daily dose of an antidepressant.
4. An eight-year-old with allergies wants a more convenient dosing form than antihistamines.
5. A middle-aged female having radiation treatment for breast cancer could find it too nauseating to swallow her H2 blocker.

EXCIPIENTS COMMONLY USED FOR FDTs PREPARATION[10] .

One super disintegrant, a diluent/bulking agent, a lubricant, and potentially swelling, permeabilizing, sweetening, and flavoring agents are the excipients utilized in FDTs.

Table No. 1: Names and weight percentage of various major excipients

Name of the excipients	Percentage used
Super disintegrants	1–15
Binder	5–10
Antistatic agent	0–10
Diluents	0–85

CHALLENGES IN FORMULATION OF FAST DISSOLVING TABLETS [11,12];

Table 2: Challenges in the Formulation of Fast Dissolving Tablets

Challenges	Description
Mechanical strength and disintegration time	FDTs are formulated to obtain disintegration time usually less than a minute. While doing so, maintaining a good mechanical strength is a prime challenge. Many MDTs are fragile and there are many chances that such fragile tablet will break during packing, transport or handling by the patients. It is very natural that increasing the mechanical strength will delay the disintegration time.
Taste masking	Many drugs are bitter in taste. So effective taste masking of the bitter drugs must be done so that the taste of the drug is not felt in the oral cavity.

Mouth feel	Tablets in the oral cavity should not disintegrate into larger particles. Particles generated after the FDTs have disintegrated should be as small as possible. After oral Administration, the tablet should leave minimal or no residue in the mouth.
Sensitivity to environment	Tablet will typically exhibit low sensitivity to environmental factors such as humidity and temperature, as most of the materials used in a tablet are intended to dissolve in limited water amounts.
Palatability	As most drugs are unpalatable, tablets should contain the medicament in a taste-masked form.
Aqueous solubility	Water-soluble drugs pose different formulation challenges because they form eutectic mixtures, resulting in freezing-point depression and the formation of a glassy solid that may collapse after drying due to the loss of supporting structure during the sublimation.
Size of tablet	It has been reported that the easiest size of the tablet to swallow is 7-8 mm while the easiest size to handle was one larger than 8 mm.
Fast Disintegration	FDTs should disintegrate in the mouth without additional water or with a very small amount (e.g., 1–2 ml) of water

Super disintegrants:

Ingredients that are commonly added to tablet formulations as disintegrating agents to break up the compacted. When it is placed in a fluid environment, the mass dissolves or releases the active chemicals more easily into the main particles. They support the tablet matrix's dispersion and penetration of moisture. Disintegrants' primary purpose is to counteract the tablet binder's effectiveness and the physical forces that work to shape the tablet when it is compressed. In an effort to enhance the disintegration processes, novel materials dubbed "super disintegrants" have recently been produced. A further variation are super disintegrants, producing very absorbent fabrics with customized swelling characteristics.¹³ These materials are intended to swell quickly rather than absorb large volumes of water or other aqueous fluids. The disintegrable solid dosage forms are structurally weakened by the use of super disintegrants. They are physically scattered throughout the dosage form's matrix and will enlarge when it comes into contact with a damp environment ¹⁴. These more recent materials have higher mechanical strength and disintegration efficiency at lower concentrations.¹⁹ In the solid dose form, super disintegrants are usually employed at modest

levels, approximately 1–10% by weight in relation to the total weight¹³. Their typically tiny and porous granules enable quick pill decomposition without leaving an uncomfortable mouthfeel behind from big particles or gelling. Additionally, the particles' compressibility increases the tablet's friability and hardness¹⁴

Selection of Super disintegrants [14,15].

Since super disintegrant is used as an excipient in the tablet formulation, it has to meet certain criteria other than its swelling properties. The ideal disintegrant should have –

1. Poor solubility.
2. Poor gel formation.
3. Good hydration capacity.
4. Good moulding and flow properties.
5. No tendency to form complexes with the drugs.
6. Good mouth feel.
7. It should also be compatible with the other excipients and have desirable tableting properties.

Techniques for Adding Disintegrants to Tablets [16]:

Two techniques exist for integrating dissolving ingredients into the pill in the manner mentioned below:

1. Internal Addition (Intragranular):

In this technique, additional powders are combined with the disintegrant before the powder mixes are wetted with the granulating fluid. The disintegrant is therefore integrated into the granules.

2. **External Addition (Extra granular)** –

In this procedure, the sized granulation is mixed with the disintegrant before compression, which is called an external addition.

3. **Partially Internal and External:**

This technique allows for the addition of disintegrant both internally and externally. As a result, the tablet is immediately disrupted into previously compressed granules, and further granule erosion back to the original powder particles is caused by the dissolving agent within the granules. Compared to the conventional approach of applying the disintegrant to the granulation surface alone, the two-step procedure often yields better and more thorough disintegration.

Super disintegrants' mechanism of action [17]:

Super disintegrants increase the effectiveness of stable dose forms. Many mechanisms work together to accomplish this. The following principles underpin the process by which the tablets break into tiny pieces and create a homogenous suspension:

1. Swelling
2. Wicking, porosity and capillary action
3. Wetness heat
4. chemical process: the acid-base reaction
5. Repelling forces between particles
6. Return to deformation
7. Enzymatic process

Swelling:

The most well recognized mode of action for tablets is likely swelling, even though water penetration is a need for disintegration breakers. When disintegrant particles come into touch with an appropriate liquid, they expand and a swelling force form, which causes the matrix to break apart.

High porosity tablets disintegrate poorly because there is insufficient swelling force. However, the tablet with limited porosity exerts a considerable swelling force. It is important to remember that a very high packing percentage prevents liquids from entering the tablet and causes the disintegration to slow down even more.

Porosity and capillary action (Wicking):

It is thought that disintegrants that are effective but do not swell transmit their disintegrating activity via porosity and capillary flow. Tablet porosity creates channels for liquid to seep into tablets. The tablet breaks into tiny particles and the intermolecular link is weakened when it is placed in an appropriate aqueous solution, which permeates the tablet and replaces the air that has been adsorbed on the particles. Tablet water absorption is dependent on tableting circumstances as well as the drug's or excipient's hydrophilicity. The preservation of a porous structure and low interfacial tension towards aqueous fluid are crucial for these disintegrants, since they aid in the disintegration process by forming a hydrophilic network around the drug particles.

Heat of wetting:

When exothermic disintegrants are wetted, capillary air expansion causes localized stress that promotes disintegration of a tablet. Nevertheless, the majority of contemporary disintegrating agents cannot be explained by this theory, which is restricted to a small number of disintegrant kinds.

Chemical reaction (Acid-Base reaction):

Tartaric acid and water interact to cause the tablet to rapidly break apart by internal CO₂ release acidic substances like citric acid combined with bases or carbonates of alkali metals in the presence of water. The production of pressure inside the pill causes it to dissolve. The active medicinal components dissolve more readily in water and have a stronger taste-masking action as a result of their release in CO₂ gas. Either the effervescent

mix is added right before compression, or it can be administered in two different formulation fractions. Another disintegration process called particle repulsive forces aims to explain why tablets constructed with non-swelling disintegrants swell. The particle-particle repulsion hypothesis of Guyot-Hermann states that water enters tablets through hydrophilic pores and forms a continuous network of starch that may transfer water from one particle to the next, producing a considerable hydrostatic pressure. Water then breaks hydrogen bonds and other factors keeping the tablet together by penetrating between the starch grains due to its attraction for starch surfaces.

Deformation Recovery:

According to deformation recovery theory, disintegrant particles undergo shape distortion during compression and then revert to their original form. The tablet breaks apart as a result of the distorted particles' increased size upon soaking and returning to their pre-compression configuration. This phenomenon might play a significant role in the mechanism of action of disintegrants that show little to no swelling, including starch and crospovidone.

Through Enzymatic Reaction:

The body's own enzymes serve as disintegrants as well. These enzymes aid in disintegration by preventing the binder's binding effect. Owing to swelling, pressure is applied externally, causing the tablet to rupture, or the rapid absorption of water results in a massive granule volume increase that aids in disintegration.

Synthetic Super disintegrants:

To increase the pace and extent of tablet disintegration and, consequently, the rate of drug release, synthetic super disintegrants are widely utilized in tablet formulations breakdown. The following is an illustration of the most popular synthetic super disintegrants.

Pyrrolidone cross-linked polyvinyl (Crospovidone):

Crospovidone has a different mechanism for disintegration than other super disintegrants, which mostly rely on swelling wicking and swelling combined. The reason crospovidone expands quickly in water without gelling is because of its high crosslink density. It has been discovered that the granular, extremely porous nature of crospovidone particles allows fluids to seep into the tablet and causes the particles to disintegrate quickly¹⁸. Particles with larger sizes disintegrate more quickly than those with smaller sizes¹⁹ Because of their distinct particle shape, crospovidone disintegrants are very compressible materials¹⁸. Another application for crospovidone is as a solubility enhancer. It comes in two different particle sizes: Polyplasdone XL and Polyplasdone XL-10.

Croscarmellose Sodium:

Croscarmellose Sodium is a polymer of carboxymethyl cellulose sodium that is cross-linked internally. Its large swelling capacity and low gelling time allow for quick dissolution number¹⁸. The wicking activity of croscarmellose particles is also attributed to their fibrous nature²¹. Both direct compression and wet granulation methods can be employed to include croscarmellose sodium into tablet formulations. In order to maximize the disintegrant's capacity for wicking and swelling, croscarmellose sodium should be administered intra- and extra-granularly throughout both the wet and dry stages of the process^{20,21}

Sodium Starch Glycolate:

This substance is the sodium salt of a starch carboxymethyl ether. These altered starches are created by the crosslinking of potato starch as it provides the highest dissolving qualities for the product²³. The degree of substitution and cross-linking has a significant role in how well these materials work as superdisintegrants²².



Crosslinking has the effect of lowering the polymer's water-soluble percentage as well as the dispersion's viscosity in water. The modified starches expand in volume by 200–300% in water, while the normal predried starches swell to a degree of 10–20 percent.

ADVANTAGES OF SUPERDISINTEGRANTS

1. It's suitable to use with common therapeutic agents and excipients.
2. It is biodegradable and does not stick to punches or dyes.
3. It is effective at lower concentration.
4. It is less effective on compressibility and flow ability.
5. It is more effective intergranular.

DISADVANTAGES OF SUPERDISINTEGRANTS

1. It can be used with a wide range of medicinal drugs and excipients.
2. It degrades quickly and does not cling to punches or dyes.
3. It works at lower concentrations.
4. It has a lower compressibility and flow ability.
5. Intergranular communication is more effective.

IDEAL PROPERTIES OF SUPERDISITGRANTS

1. It should disintegrate quickly.
2. It should be water insoluble.
3. It should have good moulding and flow properties.
4. It should have a good particle size, hydration capacity, and compressibility index.
5. It should produce compactable, less friable tablets

TABLE 3: CHARACTERISTICS OF SYNTHETIC SUPERDISINTEGRANTS EMPLOYED IN FORMULATION OF ODTs 17,18,20,24.

Synthetic Super disintegrants	Properties	Effective Concentration for disintegration
Crospovidone	It is completely insoluble in water. Rapidly disperses and swells in water. Greatest rate of swelling compared to other disintegrants. Greater surface area to volume ratio than other disintegrants. Available in micronized grades if needed for improving state of dispersion in the powder blend. Swelling index- 58±1.5% v/v.	It is used in the range of 1-3% w/w
Croscarmellose sodium	It is insoluble in water, although it rapidly swells to 4-8 times its original volume on contact with water. Specific surface area- 0.81- 0.83 m ² /g. Swelling index- 65±1.7% v/v.	It may be used as a tablet disintegrant at concentration upto 5% w/w, although normally 2 % w/w is used in tablets prepared by direct compression and 3 % w/w in tablets prepared by wet-granulation process.
Sodium starch glycolate	Absorbs water rapidly, resulting in swelling up to 6%. High concentration causes gelling and loss of disintegration. Swelling index- 52±1.2% v/v.	It is used in the range of 4-6%. Above 8%, disintegration times may actually increase due to gelling and its subsequent viscosity producing effects.

EVALUATION OF TABLETS

Tablet formulation consists of two types of evaluation i.e. pre-compression studies and post compression studies.



Pre-compression parameters [25-27]:

$$\theta = \tan^{-1}(h/r)$$

Angle of repose: The funnel technique was used to calculate the angle of repose. The height and radius of the granule heap that had developed were then used to determine the angle of repose.

Where, θ is the angle of repose and h is the height and r is the radius.

Table 4: Relation between Angle of repose and type of flow and type of powder

Angle of repose	Type of flow
< 25	Excellent
25-30	Good
30-40	passable
>40	Very poor

Bulk density:

It is the proportion of the powder's bulk volume to its overall mass. It is provided by and represented as g/ml.

$$D_b = M / V_b$$

Where, M is the mass of powder

V_b is the bulk volume of the powder.

Tapped density:

It is the proportion of the powder's total mass to its tapped volume. It is provided by and stated in g/ml.

$$D_t = M / V_t$$

Where, M is the mass of powder

V_t is the tapped volume of the powder.

Carr's compressibility index (%):

It indicates powder flow properties.

It is expressed in percentage

$$I = (D_t - D_b) / D_t \times 100$$

Where,

D_t is the tapped density of the powder.

D_b is the bulk density of the powder

Table 5: Relation between % Compressibility and Flowability

% compressibility	Flow property
15-12	Excellent
12-16	Good
18-21	Fairly passable
23-35	Poor
33-38	Very poor
<40	Very very poor

Hausner's Ratio:

An indirect measure of powder flow easiness is the Hausner ratio. This formula is used to compute it:

$$\text{Hausner Ratio} = \frac{\text{Tapped Bulk Density}}{\text{Loose Bulk Density}}$$

Hausner ratio	Type of flow
<1.25	Good
1.25-1.5	Moderate
>1.5	Poor



Post compression parameter: [28-32]**General appearance:**

Different formulations of tablets were chosen at random, and the organoleptic characteristics (color, odor, taste, and shape) were assessed.

Tablet thickness:

A digital screw gauge micrometer was used to measure the thickness of ten randomly selected tablets from each formulation. The values of the mean SD were computed

Tablet hardness:

The force necessary to shatter a tablet in a diametric compression is known as the tablet's crushing strength, and it was determined using a Monsanto tablet hardness tester. The unit of expression is kg/cm² and is influenced by the hydrophilicity of the powders, according to the following equation put forward by Washburn E.W. (1921).

$$dl/dt = r\gamma\cos q / (4hl)$$

Where

l is the length of penetration,

r is the capillary radius,

γ is the surface tension,

h is the liquid viscosity,

t is the time, and q is the contact angle.

Friability (f):

The Roche friabilator was used to test the tablet's friability. The tablet's weight decreases in the container as a result of the small particles being removed from the surface is known as friability.

$$F = \frac{Wt\ initial - Wt\ final}{Wt\ initial} \times 100$$

Variations in weight: To look for weight variation, 20 pills are chosen at random from the lot and given individual weights. Weight variation parameters according to I.P. Tablets that have been compressed shouldn't lose more than 1% of their initial weight.

Table 7: Weight variation specification as per I.P.

Average weight of the tablet	% Deviation
80 mg or less	±10
80 mg to 250 mg	±7.5
250 mg or more	±5

Uniformity of Weight:

Twenty pills were eaten in accordance with IP, and both the individual and collective weights of the tablets were measured on a computerized weighing balance. The average weight was compared with each individual weight in order to achieve weight variability.

Wetting time:

A tablet was placed on a piece of tissue paper that had been folded twice and placed in a tiny Petri dish (d = 5 cm) with 6 ml of water. Wetting time was defined as the amount of time it took for water to reach the tablet's top surface and completely wet it.

In vitro drug release:

The USP 2 Paddle device was used to measure the drug release in vitro at 37±0.5°C rpm (50 or 100) in accordance with the drug profile provided in IP.

A particular 900 ml of phosphate buffer was used in accordance with IP phosphate buffer.

Modified Disintegration test:

Very low disintegration periods are inappropriate for measurement, and the typical method for performing the disintegration test for these dose types has numerous limitations. Since disintegration without water is required, the FDT disintegration time needs to be adjusted. As a result, the test ought to replicate breakdown into saliva. For this reason, a 10 cm-diameter petri dish was filled.

Mechanical Strength:

Tablets ought to be strong enough to endure the mechanical shocks that come with handling, packing, and shipping. Two crucial factors to consider when assessing a tablet's mechanical strength are its friability and crushing strength.

Crushing Strength:

It is the force required to compress a tablet to split it in half radially; it is an important mouth formulation parameter that dissolves tablets due to their high resistance to crushing and greatly shortens the disintegration period.

Disintegration in the oral cavity: The six safe participants, who were given tablets of the ideal formulation, were asked to record how long it took for the tablets to dissolve fully in their mouths. Absorption of water Six milliliters of water and a piece of tissue paper that has been folded twice are placed in a tiny Petri dish. After placing the tablet on the paper, the amount of time needed for full soaking was measured. Next, the moist tablet was weighed.

Stability studies:

In accordance with ICH recommendations, the stability experiments were conducted at several temperature conditions: $25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ / $60\% \pm 5\%$ RH for real stability studies, and $40\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ / $75\% \text{RH} \pm 5\%$ for accelerated stability studies. The samples were taken out at various intervals: 0, 7days 15, 30, 60, and 90. Stability tests on the chosen formulation were conducted for three months. The color, thickness, hardness, drug content, friability, in vitro drug release tests, and in vitro disintegration time of the samples were assessed.

CONCLUSION

In conclusion, a crucial field of study with important ramifications for drug development is the formulation and assessment of fast-disintegrating tablets using superdisintegrants. The literature review highlights the complex properties of superdisintegrants, their many modes of action, and their vital function in improving the disintegration of tablets and the release of the medicine. This review offers formulators useful insights for creating the best possible fast-disintegrating tablet designs by thoroughly analyzing a variety of superdisintegrants and their

benefits, drawbacks, and combined effects. The significance of choosing the best superdisintegrant based on the unique qualities of the medication and the intended tablet features is highlighted by the essential examination of several evaluation metrics, including disintegration time, wetting time, and dissolving profiles. Furthermore, emphasis is placed on the effects of manufacturing methods, formulation factors, and regulatory considerations on the creation of fast-disintegrating tablets as a whole. Future efforts in this subject should concentrate on overcoming issues with scalability, flavor masking, and stability in order to improve the practical application of fast-disintegrating tablets in pharmaceutical practice. In summary, the present research highlights the importance of comprehending the complex interactions between superdisintegrants and formulation variables in order to attain optimal formulations.

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