



FAST DISSOLVING TABLETS: A NEW ERA IN NOVEL DRUG DELIVERY SYSTEM

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ABSTRACT

Fast dissolving tablets (FDTs) have received ever-increasing demand during the last decade and the field has become a rapidly growing area in the pharmaceutical industry. Fast dissolving tablets (FDTs) are those solid dosage forms when put on tongue, disintegrate or dissolve instantaneously, releasing the drug, within a few seconds without the need of water. Fast dissolving tablets (FDTs) aim for designing dosage forms, convenient to be manufactured and administered, free of side effects, offering immediate release and enhanced bioavailability, to achieve better patient compliance. Fast dissolving tablets have been formulated for pediatric, geriatric, and bedridden patients and for active patients who are busy and traveling and may not have access to water. Such formulations provide an opportunity for product life extension in the many elderly persons which have difficulty in taking conventional oral dosage form (viz., solutions, suspensions, tablets, and capsules) because of hand tremors and dysphagia. The current article is focused on ideal requirements, need for development of FDTs, challenges in formulation, suitability of drug candidates, superdisintegrants employed, various technologies developed for FDTs and evaluation methods.

Keywords: Fast disintegrating tablets (FDTs), Superdisintegrants, Enhanced bioavailability, Patients compliance, Patented technology.

INTRODUCTION

Solid dosage forms are popular because of low cost, ease of administration, accurate dosage self medication, pain avoidance and the most importantly the patient compliance. The most widely used solid dosage forms are being tablets and capsules. However, in case of dyspepsia of geriatric patients, the underdeveloped muscular and nervous system in young individuals and in case of uncooperative patient, many problems are occurring but swallowing is common phenomenon which leads to poor patient compliance. To improve these drawbacks fast dissolving tablets or orally disintegrating tablets has immersed as alternative oral dosage forms^{1,2,3}.

The FDT technology, which makes tablets dissolve or disintegrate in the mouth without additional water intake. The FDT formulation is defined by the Food and Drug Administration (FDA) as “a solid dosage form containing medical substances which disintegrates rapidly, usually within a seconds, when placed upon the tongue.” According to European Pharmacopoeia, “the FDT should disperse/disintegrate in less than three minutes. Fast dissolving tablets are also known as mouth-dissolving tablets, melt-in mouth tablets, Orodispersible tablets, rapid melts, porous tablets, quick dissolving etc. The basic approach in development of FDT is the use of super disintegrants, which provide instantaneous disintegration of tablet after putting on tongue, their by release the drug in saliva. The fast dissolving tablets are rapidly dissolved or disintegrate by the use of super disintegrants^{4,5,6}.

CRITERIA FOR SELECTION OF DRUG FOR FAST DISSOLVING TABLETS^{7,8,9}

- Drug should have to permeate through oral mucosal tissue.
- Fast dissolving tablets dose should be lower than 20mg.
- Drug should be partially nonionized at pH in oral cavity.
- Drug should possess log P>2.

MECHANISM OF SUPERDISINTEGRANTS¹⁰⁻¹³

There are four major mechanisms for tablets disintegration as follows (see Figure-1):

1. Swelling-: The most widely accepted general mechanism of action for tablet disintegration is swelling. Tablets with high porosity show poor disintegration due to lack of

adequate swelling force. On the other hand, sufficient swelling force is exerted in the tablet with low porosity. It is worthwhile to note that if the packing fraction is very high, fluid is unable to penetrate in the tablet and disintegration is again slows down.

2. Porosity and capillary action (Wicking)-: Disintegration by capillary action is always the first step. When we put the tablet into suitable aqueous medium, the medium penetrates into the tablet and replaces the air adsorbed on the particles, which weakens the intermolecular bond and breaks the tablet into fine particles. Water uptake by tablet depends upon hydrophilicity of the drug/excipient and on tableting conditions. For these types of disintegrants maintenance of porous structure and low interfacial tension towards aqueous fluid is necessary which helps in disintegration by creating a hydrophilic network around the drug particles. Water is pulled by disintegrant particles swell and breaks up and reduced the physical the matrix form within bonding force between particles.

3. Due to disintegrating particle/particle repulsive forces-: Another mechanism of disintegrating attempts to explain the swelling of tablet made with ‘non-swelling’ disintegrants. Guyot- Hermann has proposed a particle repulsion theory based on the observation that non-swelling particle also cause disintegration of tablets. The electric repulsive forces between particles are the mechanism of disintegration and water is required for it. Researchers found that repulsion is secondary to wicking.

4. Due to deformation: During tablet compression, disintegrated particles get deformed and these deformed particles get into their normal structure when they come in contact with aqueous media or water. Occasionally, the swelling capacity of starch was improved when granules were extensively deformed during compression. This increase in size of the deformed particles produces a breakup of the tablet. This may be a mechanism of starch and has only recently begun to be studied.

ADVANTAGES OF FAST DISINTEGRATING TABLETS¹⁴⁻¹⁷

FDTs has many advantages of solid dosage forms and liquid dosage forms along with special features which include:

- **Accurate dosing:** Being an solid dosage forms, provide luxury of accurate dosing, easy portability and manufacturing, good physical and chemical stability and an ideal alternative for pediatric and geriatric patients.
- **Enhanced bioavailability:** Bioavailability of drugs can be enhanced due to absorption from mouth, pharynx and esophagus,
- **Rapid action:** Fast onset of therapeutic action as tablet gets disintegrated rapidly along with quick dissolution and absorption in oral cavity.
- **Patient compliance:** No need of water to swallow the dosage form. Hence, it is convenient for patients who are traveling and do not have immediate access to water.
- **Ease of administration:** Convenient to administer specially for geriatric, pediatric, mentally disabled and bed ridden patients who have difficulty in swallowing.
- **Obstruction free:** No risk of suffocation in airways due to physical obstruction when swallowed, thus providing improved safety and compliance.
- **Enhanced palatability:** Good mouth feel, especially for pediatric patients as taste masking technique is used to avoid the bitter taste of drug.
- **Simple packaging:** No specific packaging required. It can be packaged in push through blisters.
- **Business avenue:** Provide new business opportunities in the form of product differentiation, line extension, uniqueness and life cycle management.
- **Cost effective:** Conventional processing and packaging equipments allow the manufacturing of tablets at low cost.

THE NEED FOR DEVELOPMENT OF FAST DISINTEGRATING TABLETS¹⁸

The need for non-invasive delivery systems persists due to patient's poor acceptance and compliance with existing delivery regimes, limited market size for drug companies and drug uses, coupled with high cost of disease management.

Patient factors

Fast disintegrating dosage forms are particularly suitable for patients who feel inconvenient to swallow traditional tablets and capsules with an 8-oz glass of water. These include the following:

- Geriatric patients mainly suffering from conditions like hand tremors and dysphasia.
- Pediatric patients who are unable to swallow easily because their central nervous system and internal muscles are not completely developed.
- Traveling patients suffering from motion sickness and diarrhea because they do not have easy access to water.
- Patients with persistent nausea for a long period of time are feel difficulty in swallowing. Especially cancer patients after taking their chemotherapy are too nauseous to swallow the H2 blockers, which are prescribed in order to avoid gastric ulceration.

Effectiveness factor

Increased bioavailability and faster onset of action are a major claim of these formulations. Dispersion in saliva in oral cavity causes pre-gastric absorption from some formulations in those cases where drug dissolves quickly. Buccal, pharyngeal and gastric regions are all areas of absorption for many drugs. Any pre-gastric absorption avoids first pass metabolism and can be a great advantage in drugs that undergo hepatic metabolism. Furthermore, safety profiles may be improved for drugs that produce significant amounts of toxic metabolites mediated by first-pass liver metabolism and gastric metabolism, and for drugs that have a substantial

fraction of absorption in the oral cavity and pre-gastric segments of GIT.^{18, 19}

Manufacturing and marketing factors

When drug approaches near to the end of its patent life, it is common for pharmaceutical manufacturers to develop a given drug entity in a new and improved dosage form. A new dosage form allows a manufacturer to extend market exclusivity, unique product differentiation, value-added product line extension, and extend patent protection, while offering its patient population a more convenient dosage form. This results in increased revenue, while also targeting underserved and undertreated patient populations.

CHALLENGES IN FORMULATION OF FAST DISINTEGRATING TABLETS (FDTs)

Mechanical strength and disintegration time:

It is obvious that increasing the mechanical strength will delay the disintegration time. So a good compromise between these two parameters is always essential. FDTs are formulated to obtain disintegration time usually less than a minute. While doing so, maintaining a good mechanical strength is a prime challenge²⁰.

Taste masking:

As most drugs are unpalatable, rapid disintegrating drug delivery systems usually contain the medicament in a taste-masked form. Delivery systems disintegrate or dissolve in patient's oral cavity, thus releasing the active ingredients which come in contact with the taste buds; hence, taste-masking of the drugs becomes critical to patient compliance²¹.

Aqueous solubility:

Water-soluble drugs pose various formulation challenges because they form eutectic mixtures, which result in freezing-point depression and the formation of a glassy solid that may collapse upon drying because of loss of supporting structure during the sublimation process. Such collapse sometimes can be prevented by using various matrix-forming excipients such as mannitol than can induce crystallinity and hence, impart rigidity to the amorphous composite.²²

Hygroscopicity: Several orally disintegrating dosage forms are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and humidity. Hence, they need protection from humidity which calls for specialized product packaging.²³

Amount of drug:

The application of technologies used for FDTs is limited by the amount of drug that can be incorporated into each unit dose. For lyophilized dosage forms, the drug dose must be lower than 400 mg for insoluble drugs and less than 60 mg for soluble drugs. This parameter is particularly challenging when formulating a fast-dissolving oral films or wafers.²⁴

Size of tablet: It has been reported that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle was larger than 8 mm. Therefore, the tablet size that is both easy to take and easy to handle is difficult to achieve.

Mouth feel:

FDTs should not disintegrate into larger particles in the oral cavity. The particles generated after disintegration of the FDTs should be as small as possible. Moreover addition of flavours and cooling agents like menthol improve the mouth feel.

Sensitivity to environmental conditions:

FDTs should exhibit low sensitivity to environment conditions such as humidity and temperature as most of the materials used in FDTs are meant to dissolve in minimum quantity of water.

DRUG CANDIDATES SUITABLE FOR FAST DISINTEGRATING TABLETS (FDTs)²⁵

The following factors must be considered while selecting an appropriate drug candidate for development of orally fast disintegrating dosage forms.

- Drugs which require controlled or sustained release are unsuitable candidates of fast dissolving oral dosage forms.
- Drugs which have bitter or unacceptable taste because taste masking cannot be achieved.
- Patients with Sjogren's syndrome or dryness of the mouth due to decreased saliva production may not be good candidates for FDT formulations.
- Drugs with a short half-life and frequent dosing. Patients who frequently take anticholinergic medications may not be the best candidates for these drugs.
- The drugs which have significantly different pharmacokinetic profiles compared with the same dose administered in a conventional dosage form. E.g. selegiline, apomorphine, buspirone etc. The drugs which produce a significant amount of toxic metabolites mediated by first pass liver metabolism and gastric metabolism and for drugs that have a substantial fraction of absorption in the oral cavity and segments of the pre-gastric GIT.
- Drugs which have the ability to diffuse and partition into the epithelium of the upper GIT (log P > 1, or preferable > 2); and those able to permeate oral mucosal tissue are considered ideal for FDT formulations.

EVALUATION OF FAST DISINTEGRATING TABLETS:²⁵

Tablets from different formulation are subjected to following quality control test.

General Appearance: The general appearance of a tablet, its visual identity and overall "elegance" is essential for consumer acceptance and tablet's size, shape, colour, presence or absence of an odour, taste, surface texture, physical flaws and consistency and legibility of any identifying marking.

Size and Shape: The size and shape of the tablet can be dimensionally described, monitored and controlled.

Tablet thickness: Tablet thickness is an important characteristic in reproducing appearance and also in counting by using filling equipment. Some filling equipment utilizes the uniform thickness of the tablets as a counting mechanism. Ten tablets are taken and their thickness is recorded using micrometer.

Weight variation: 20 tablets are selected randomly from the lot and are weighed individually to check for weight variation. Weight variation specification as per I.P. (see table-1).

Hardness: Hardness of tablet is defined as the force applied across the diameter of the tablet in the order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its hardness. Hardness of the tablet of each formulation is determined using Monsanto Hardness tester.

Friability (F): Friability of the tablet determined using Roche friabilator. This device subjects the tablet to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping a tablet at height of 6 inches in each revolution. Pre-weighted sample of tablets is placed in the friabilator and are subjected to the 100 revolutions. The friability (F) is given by the formula.

$$F = \frac{W_{\text{int.}} - W_{\text{fin.}}}{W_{\text{int.}}}$$

Where, $W_{\text{int.}}$ - Weight of tablets before friability.

$W_{\text{fin.}}$ - Weight of tablets after friability.

Wetting time: Wetting time of dosage form is related to the contact angle. It needs to be assessed to give an insight into the disintegration properties of the tablets; a lower wetting time implies a quicker disintegration of the tablet. For this purpose, a tablet is placed on a piece of tissue paper folded twice and kept in a small Petri dish (ID = 6.5 cm) containing 6 ml of water, and the time for complete wetting is measured.²⁶

Water absorption Ratio: A piece of tissue paper folded twice is placed in a small Petridish containing 6 ml of water. A tablet was put on the paper & the time required for complete wetting is measured. The wetted tablet is then weighed. Water absorption ratio, R, is determined using following equation,

$$R = 10 (w_a/w_b)$$

Where, w_a is weight of tablet before water absorption & w_b is weight of tablet after water absorption.

In vitro dispersion time: In vitro dispersion time is measured by dropping a tablet in a beaker containing 50 ml of Sorenson's buffer pH 6.8. Three tablets from each formulation are randomly selected and in vitro dispersion time is performed.

In vitro Dissolution test: The development of dissolution methods for FDTs is comparable to the approach taken for conventional tablets and is practically identical. Dissolution conditions for drugs which are listed in a pharmacopoeia monograph, is a good place to start with scouting runs for a bioequivalent FDT. Other media such as 0.1 M HCl and buffer (pH 4.5 and 6.8) should be evaluated for FDT much in the same way as their ordinary tablet counterparts. It has been suggested that USP 2 paddle apparatus is the most suitable and common choice for orally disintegrating tablets, with a paddle speed of 50 rpm commonly used.²⁷

Stability testing of drug (temperature dependent stability studies): The fast disintegrating tablets are packed in suitable packaging and stored under the following conditions for a period as prescribed by ICH guidelines for accelerated studies.

(1) $40 \pm 1^\circ\text{C}$

(2) $50 \pm 1^\circ\text{C}$

(3) $37 \pm 1^\circ\text{C}$ and RH $75\% \pm 5\%$

The tablets are withdrawn after a period of 15 days and analyzed for physical characterization (Visual defects, Hardness, Friability, Disintegrations and Dissolution etc.) and drug content. The data obtained is fitted into first order equations to determine the kinetics of degradation. Accelerated stability data are plotted according to Arrhenius equation to determine the shelf life at 25°C .

Packaging: Packing is one of the important aspects in manufacturing FDT. The products obtained by various technologies vary in some of the parameters especially in mechanical strength to a good extent. The products obtained from lyophilization process including various technologies such as Zydis, Lyoc, Quicksolv, and Nanocrystal are porous in nature, have less physical resistance, sensitive to moisture, and may degrade at higher humidity conditions. For the above reasons products obtained require special packing. Zydis units are generally packed with peelable backing foil. Paksolv is a special packaging unit, which has a dome-shaped blister, which prevents vertical movement of tablet within the depression and protect tablets from breaking during storage

and transport, which is used for Orasolv tablet. Some of the products obtained from Durasolv. WOW Tab, Pharmaburst oraquick, Ziplets, etc. technologies have sufficient mechanical strength to withstand transport and handling shock so they are generally packed in push through blisters or in bottles.²⁸

EXCIPIENTS COMMONLY USED FOR FDT PREPARATION²⁵

Mainly seen excipients in FDT are as follows at least one disintegrant, a diluent, a lubricant, and, optionally, a swelling agent, a permeabilizing agent, sweeteners, and flavorings.

1) Role of superdisintegrants in FDT²⁵

The main approach in development of Fast Dissolving Tablets is use of disintegrant. Disintegrant play a important role in the disintegration and dissolution of FDT. It is important to choose a suitable disintegrant, in an optimum concentration so as to ensure quick disintegration and high dissolution rates. Super disintegrant provide quick disintegration due to combined effect of swelling and water absorption by the formulation. Due to swelling of super disintegrant, the wetted surface of the carrier increases; this promotes the wettability and dispersibility of the system, thus enhancing the disintegration and dissolution. Care should be taken while selecting concentration of the super disintegrant. Super disintegrants are selected according to critical concentration of disintegrant. Below this concentration, the tablet disintegration time is inversely proportional to the concentration of the super disintegrant, whereas if concentration of super disintegrant is above critical concentration, the disintegration time remains almost constant or even increases. Common disintegrants used in this formulation are croscarmellose sodium (Vivasol, Ac]Di]Sol), crospovidone (Polyplasdone), carmellose (NS]300), carmellose calcium (ECG]505), sodium starch glycolate (SSG) etc. Recently few ion exchange resins (e.g. Indion 414) are found to have super]disintegrant property and are widely used in pharmaceutical industry. Swelling index of the superdisintegrants is commonly studied in simulated saliva. Volume occupied by the material at the end of 4 h should be noted and swelling index is calculated by the formula: $(\text{final volume}] \text{ initial volume} / \text{initial volume}) \times 1008$.

2) Role of binders in FDT

Main role of Binders is to keep the composition of these fast melting tablets together during the compression stage. Binders commonly used are cellulosic polymers, povidones, polyvinyl alcohols, and acrylic polymers. Among the cellulosic polymers it will be advantageous to select ethyl cellulose, hydroxypropylcellulose (HPC), and hydroxypropylmethylcellulose (HPMC), alone or in admixtures, and the most commonly acrylic polymers are used are the ammonio] methacrylate copolymer (Eudragit. RL and RS), polyacrylate (Eudragit. NE), and polymethacrylate (Eudragit. E). The right selection of a binder or combination of binders is essential to maintain the integrity and stability of the tablet. The temperature of the excipient should be preferably around 30-35 degree Celcius for faster melting properties. Further, its incorporation imparts smooth texture and disintegration characteristics to the system. Binders can either be liquid, semi solid, solid or mixtures of varying molecular weights such as polyethylene glycol. The choice of a binder is critical in a fast] dissolving formulation for achieving the desired sensory and melting characteristics, and for the faster release of active ingredient

3) Role of antistatic agent and diluents in FDT

The most common antistatic agents used are colloidal silica (Aerosil), precipitated silica (Sylod.FP244), micronized or non micronized talc, maltodextrins, .beta.-cyclodextrins, etc. Magnesium stearate, stearic acid, sodium stearyl fumarate, micronized polyoxyethylene glycol (micronized Macrogol 6000), leucine, sodium benzoate are used as lubricant⁴. An additional thickening agent, generating a stabilized suspension, is added to avoid settling of the particles and moreover provide a pleasant mouth feeling. Commonly used Diluents are most commonly selected from cellulose derivatives and preferably microcrystalline cellulose, starches, lactose, polyols, and, preferably, mannitol.

TECHNIQUES FOR PREPARING FAST DISSOLVING TABLETS^{26,27,28}

Various techniques have been reported for the formulation of Fast dissolving tablets or Orodispersible tablets.

1. Freeze-Drying or Lyophilization: Freeze drying is the process in which water is sublimed from the product after it is frozen. This technique produce an amorphous porous structure that can dissolve rapidly. A typical procedure involved in the manufacturing of FDT using this technique is mentioned here. The active drug is dissolved or dispersed in an aqueous solution of a carrier/polymer. The mixture is done by weight and poured in the walls of the preformed blister packs. The trays holding the blister packs are passed through liquid nitrogen freezing tunnel to freeze the drug solution or dispersion.

Then the frozen blister packs are placed in refrigerated cabinets to continue the freeze-drying. After freeze-drying the aluminum foil backing is applied on a blister-sealing machine. Finally the blisters are packaged and shipped. The freeze-drying technique has illustrated improved absorption and increase in bioavailability. The major disadvantages of lyophilization technique are that it is expensive and time consuming; fragility makes conventional packaging unsuitable for these products and poor stability under stressed conditions.

2. Tablet Molding-: Molding process is of two types i.e., solvent method and heat method. Solvent method involves moistening the powder blend with a hydro alcoholic solvent followed by compression at low pressures in molded plates to form a wetted mass (compression molding). The solvent is then removed by air-drying. The tablets manufactured in this manner are less compact than compressed tablets and posses a porous structure that hastens dissolution.

The heat molding process involves preparation of a suspension that contains a drug, agar and sugar (e.g. mannitol or lactose) and pouring the suspension in the blister packaging wells, solidifying the agar at the room temperature to form a jelly and drying at 30 degree Celcius under vacuum. The mechanical strength of molded tablets is a matter of great concern. Binding agents, which increase the mechanical strength of the tablets, need to be incorporated. Taste masking is an added problem to this technology. The taste masked drug particles were prepared by spray congealing a molten mixture of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethylene glycol and an active ingredient into a lactose based tablet triturate form. Compared to the lyophilization technique, tablets produced by the molding technique are easier to scale up for industrial manufacture.

3. Spray Drying: In this technique, gelatin can be used as a supporting agent and as a matrix, mannitol as a bulking agent and sodium starch glycolate or croscarmellose or

crosspovidone are used as superdisintegrants. Tablets manufactured from the spray-dried powder have been reported to disintegrate in less than 20 seconds in aqueous medium. The formulation contained bulking agent like mannitol and lactose, a superdisintegrant like sodium starch glycolate & croscarmellose sodium and acidic ingredient (citric acid) and/or alkaline ingredients (e.g. sodium bicarbonate). This spray-dried powder, which compressed into tablets showed rapid disintegration and enhanced dissolution.

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

5. Direct Compression: Direct compression represents the simplest and most cost effective tablet manufacturing technique. In this method, tablets are prepared directly by compression of the mixture of drug and excipients without any preliminary treatment. The mixture which is to be compressed must have good flow properties. This method complete within 3 steps i.e.

- a. Milling of drug and excipients
- b. Mixing of drug and excipients
- c. Tablet compression

6. Nanonization: A recently developed Nanomelt technology involves reduction in the particle size of drug to nanosize by milling the drug using a proprietary wet-milling technique. The nanocrystals of the drug are stabilized against agglomeration by surface adsorption on selected stabilizers, which are then incorporated into FDTs. This technique is especially advantageous for poorly water soluble drugs. Other advantages of this technology include fast disintegration/ dissolution of nanoparticles leading to increased absorption and hence higher bioavailability and reduction in dose, cost effective manufacturing process, conventional packaging due to exceptional durability and wide range of doses (up to 200 mg of drug per unit).

7. Fast Dissolving Films: In this technique, a non-aqueous solution is prepared containing water soluble film forming polymer (pullulan, carboxy methylcellulose, hydroxypropyl methylcellulose, hydroxyl ethylcellulose, hydroxyl propylcellulose, polyvinylpyrrolidone, polyvinyl alcohol or sodium alginate, etc.), drug and other taste masking ingredients, which is allowed to form a film after evaporation of solvent. In case of a bitter drug, resin adsorbate or coated microparticles of the drug can be incorporated into the film. This film, when placed in mouth, melts or dissolves rapidly, releasing the drug in solution or suspension form. The features of this system include paper thin films of size less than 2X2 inches, dissolution in 5 sec, instant drug delivery and flavored after taste.

CONCLUSION

Introduction of fast disintegrating dosage forms has solved some of the problems encountered in administration of drugs to the pediatric and elderly patient, which constitutes a large proportion of the world's population. Hence, patient demand and the availability of various technologies have increased the acceptance of Fast disintegrating tablets, which in turn

prolongs the patent life of a drug. Keeping in view of the advantages of the delivery system, fast disintegrating dosage forms have been successfully commercialized, and these dosage forms very well accepted at doctors as well as patient level.

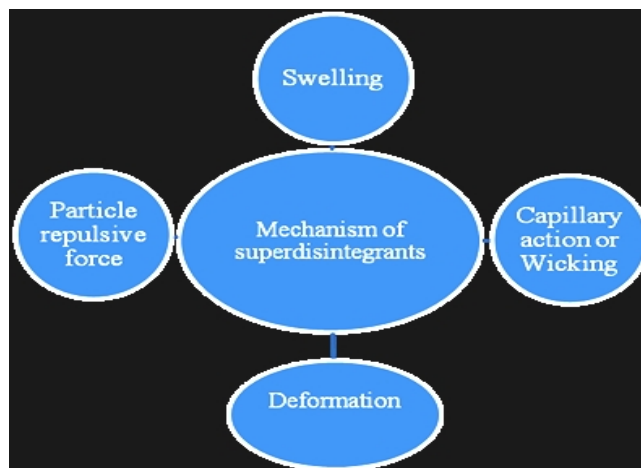


Figure 1:- Mechanism of super disintegrants

Table -1 : Weight variation table

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

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