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FAST DISSOLVING TABLETS RECENT ADVANTAGES: A REVIEW

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ABSTRACT

Oral drug delivery remains the preferred route of drug delivery. Novel technologies with improved performance, patient compliance, and enhanced quality have emerged in the recent past. The fast dissolving drug delivery system started gaining popularity and acceptance as a new drug delivery system because they are easy to administer and lead to better patient compliance. Fast dissolving drug delivery system can be obtained by the various techniques i.e. direct compression, tablet molding, freeze drying, spray drying nanonization. Oral fast-dissolving tablets, are an examples of a few existing technologies with the potential to accommodate various physicochemical, pharmacokinetic and pharmacodynamic characteristic of drugs.

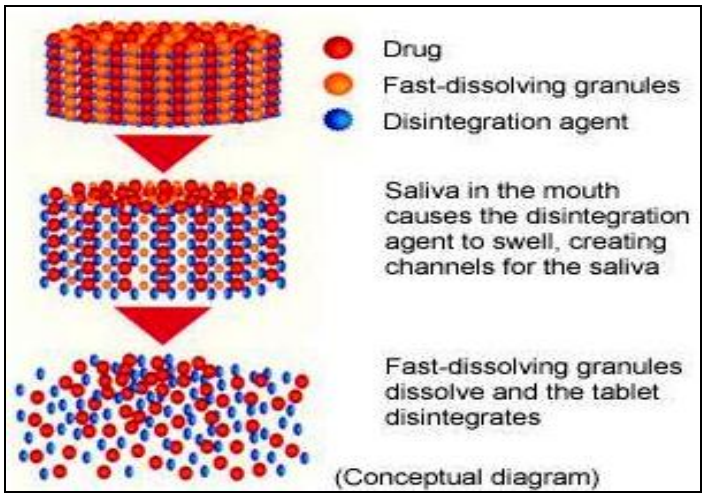
INTRODUCTION [1, 2, 3, 4, 18]: Solid dosage forms are popular because of low cost, ease of administration, accurate dosage self medication, pain avoidance and the most importantly the patient compliance. The most popular solid dosage forms are being tablets and capsules [1, 18]. However in case of dyspepsia of geriatric patients, the underdeveloped muscular and nervous system in young individuals and incase of uncooperative patient, many problems is occur 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 [2].

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 whish disintegrates rapidly, usually within a seconds, when placed upon the tongue[3]." According to European Pharmacopoeia, "the FDT should disperse/disintegrate in less than three minutes [1, 4]. Fast dissolving tablets are also called as mouth-dissolving tablets, melt-in mouth tablets, Orodispersible tablets, rapimelts, porous tablets, quick dissolving etc [1]. The basic approach in development of FDT is the use of superdisintegrants, which provide instantaneous disintegration of tablet after putting on tongue, their by release the drug in saliva [5]. The fast dissolving tablets are rapidly dissolved or disintegrate by the use of superdisintegrants.

Mechanism [6]: Bioavailability of a drug depends in absorption of the drug, which is affected by solubility of the drug in gastrointestinal fluid and permeability of the drug across gastrointestinal membrane. The solubility of a drug mainly depends on physiochemical properties of the drug. The rate of drug dissolution is greatly influenced by disintegration of the tablet.

Disintegrants are important excipient of the tablet formulation, they are always added to tablet to induce breakup of tablet when they are comes in contact with aqueous fluid and this process of desegregation of constituent particles before the drug dissolution occurs, is known as disintegration process and excipients which induce this process are known as disintegrants.

The objectives behind addition of disintegrants are to increase surface area of the tablet fragments and to overcome cohesive forces that keep particles together (**Fig. 1**).



Techniques for Preparing Fast dissolving Tablets [1, 2, 9]: 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 creates an amorphous porous structure that can dissolve rapidly. A typical procedure involved in the manufacturing of ODT using this technique is mentioned here. The active drug is dissolved or dispersed in an aqueous solution of a carrier/polymer. The mixture is done by weight and poured in the walls of the preformed blister packs. The trays holding the blister packs are passed through liquid nitrogen freezing tunnel to freeze the drug solution or dispersion.

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

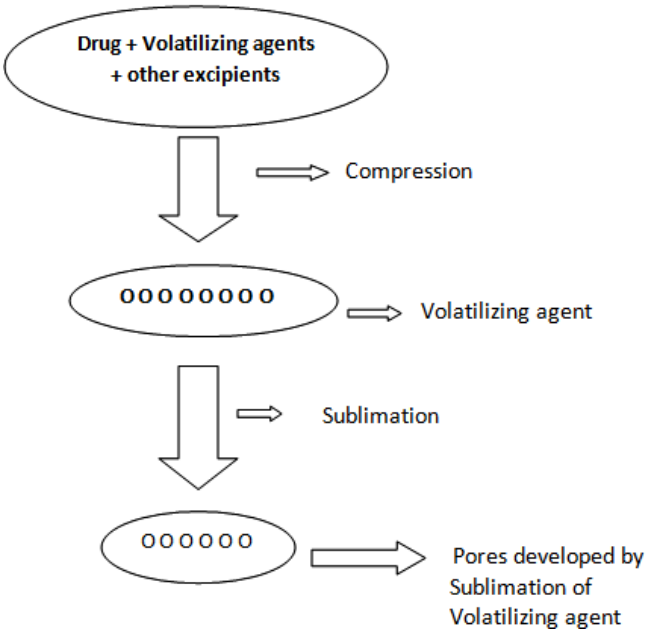
2. **Tablet Molding**-: Molding process is of two types i.e., solvent method and heat method. Solvent method involves moistening the powder blend with a hydro alcoholic solvent followed by compression at low pressures in molded plates to form a wetted mass (compression molding). The solvent is then removed 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^{o}C under vacuum. The mechanical strength of molded tablets is a matter of great concern. Binding agents, which increase the mechanical strength of the tablets, need to be incorporated.

   Taste masking is an added problem to this technology. 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 crosscarmellose 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. (**Fig. 2**)



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 (**Fig-3**). 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.

Patented technology for the formulation of FDT [1, 2, 10, 11, 17]:

1. **Zydis Technology** [19]: Zydis® was introduced *By R. P. Scherer Corporation* in 1986. The Zydis process requires the active ingredient to be dissolved or suspended in an aqueous solution of water-soluble structure forming additives then the mixture is poured into the preformed blister pockets of a laminate film and freeze-dried. This results in a tablet shaped dosage form that spontaneously disintegrates in mouth in seconds. The two most commonly used structural additives are gelatin and mannitol although some other (e.g., starches, gums, etc.) may be used depending on the

properties of the active ingredient. As a general rule, the best physical characteristics are achieved by using a mixture of a water-soluble polymer and a crystalline sugar alcohol or amino acid at a typical combined concentration of 10% w/w in the matrix solution. The polymer gives the strength and resilience while the crystalline component gives the hardness and texture.

2. **Orasolv Technology-:** *CIMA labs* have developed Orasolv Technology. In this system active medicament is taste masked. It also contains effervescent disintegrating agent. Tablets are made by direct compression technique at low compression force in order to minimize oral dissolution time. Conventional blenders and tablet machine is used to produce the tablets. The tablets produced are soft and friable.

3. **OraQuick**-: *KV Pharmaceutical* claims its microsphere technology, known as MicroMask, has superior mouthfeel over taste-masking alternatives. The taste masking process does not utilize solvents of any kind, and therefore leads to faster and more efficient production. Also, lower heat of production than alternative fast-dissolving/disintegrating technologies makes OraQuick appropriate for heat-sensitive drugs. KV Pharmaceutical also claims that the matrix that surrounds and protects the drug powder in microencapsulated particles is more pliable, meaning tablets can be compressed to achieve significant mechanical strength without disrupting taste masking.

   OraQuick claims quick dissolution in a matter of seconds, with good taste-masking. There are no products using the OraQuick technology currently on the market, but KV Pharmaceutical has products in development such as analgesics, scheduled drugs, cough and cold, psychotropics, and anti-infectives.

4. **Quick-Dis Technology:** *Lavipharm Laboratories Inc.* (Lavipharm) has invented an ideal intraoral fast-dissolving drug delivery system, which satisfies the unmet needs of the market. The novel intraoral drug delivery system, trademarked Quick- Dis™, is Lavipharm's proprietary patented technology and is a thin, flexible, and quick-dissolving film. The film is placed on the top or the floor of the tongue. It is retained at the site of application and rapidly releases the active agent for local and/or systemic absorption. The Quick-Dis™ drug delivery system can be provided in various packaging configurations, ranging from unit dose pouches to multiple-dose blister packages.

   The typical disintegration time, which is defined as the time at which the film begins to break when brought into contact with water, is only 5 to 10 seconds for the Quick-Dis™ film with a thickness of 2 mm. The dissolving time, which is defined as the time at which not less than 80% of the tested film is dissolved in aqueous media, is around 30 seconds for Quick Dis™ film with a thickness of 2 mm. The typical release profile of an active ingredient exhibited by a Quick-Dis™ drug delivery system is 50% released within 30 seconds and 95% within 1 minute.

5. **Durasolv Technology:** DuraSolv is *Cima's second-generation* fast-dissolving/ disintegrating tablet formulation. Produced in a fashion similar to OraSolv, DuraSolv has much higher mechanical strength than its predecessor due to the use of higher compaction pressures during tabletting.

   DuraSolv tablets are prepared by using conventional tabletting equipment and have good rigidity (friability less than that 2%). The DuraSolv product is thus produced in a faster and more costeffective manner. DuraSolv is so durable that it can be packaged in traditional blister packaging, pouches or vials. One disadvantage of DuraSolv is that the technology is not compatible with larger doses of active ingredients, because the formulation is subjected to such high pressures on compaction.

   Unlike OraSolv, the structural integrity of any taste masking may be compromised with high drug doses. The drug powder coating in DuraSolv may become fractured during compaction, exposing the bitter-tasting drug to a patient's taste buds. Therefore, the DuraSolv technology is best suited for formulations including relatively small doses of active compound.

6. **Flash Dose Technology:** By this technology sugar based matrix known as floss which made from combination of excipients either alone or in combination of drugs. Nurofen meltelt, a new form of ibuporfen is based on same technology.

7. **Flashtab technology:** *Prographarm* patented this technology in which tablet consists of active ingredients in form of microcrystals. Rest of all procedure is followed in conventional technology.

8. **Sheaform Technology:** This technology makes Sheaform matrix consisting of floss preparation. Floss is produced by subjecting to a feed shock containing a sugar to flash heat processing.

9. **Ceform Technology:** In this technology microspheres containing active ingredient are prepared. Basic requirement of this technology is placing dry powder containing either pure drug or special blend of drug and excipients. The microspheres then mixed and compressed into previously selected oral dosage form.

10. **Wowtab Technology:** Wowtab Technology is patented by *Yamanouchi Pharmaceutical Co.* WOW means "Without Water ". In this process, combination of low mouldability saccharides and high mouldability saccharides is used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low moldability saccharide and granulated with a high moldability saccharide and compressed into tablet.

11. **Lyoc tech:** This is patented technology of *Laboratories L. Lafon, Maisons Alfort* , France .It utilizes a freeze drying process but differ from Zydis in that the product is frozen on the freeze dryer shelves.

    To prevent inhomogeneity by sedimentation during this process, these formulations require a large proportion of undissolved inert filler (mannitol), to increase the viscosity of the inprocess suspension. The high proportion of filler reduces the potential porosity of the dried dosage form and results in denser tablets with disintegration rates that are comparable with the loosely compressed fast melt formulations.

12. **Pharmaburst technology:** Pharmaburst™ is a "Quick Dissolve" delivery system patented by *SPI Pharma.* Pharmaburst is a co-processed excipient system with specific excipients, which allows rapid disintegration and low adhesion to punch facesmouldablilty saccharides are used to obtain rapid melting strong tablet. The active ingredient mixes with low mouldablilty saccharides.

13. **Frosta technology:** *Akina* patents this technology. It utilizes the concept of formulating plastic granules and compressing them at low pressure to produce strong tablets with high porosity. Plastic granules composed of porous and plastic material, water penetration enhancer, and binder. The process involves mixing the porous plastic material with water penetration enhancer followed by granulating with binder. The tablets obtained have excellent hardness and rapid disintegration time ranging from 15 to 30 sec depending on size of tablet.

14. **Advatab:** AdvaTab tablets disintegrate rapidly in the mouth, typically in less than 30 seconds, to allow for convenient oral drug administration without water. These tablets are especially suited to those patients that experience difficulty in swallowing capsules and tablets. AdvaTab is distinct from other ODT technologies as it can be combined with Eurand's complimentary particle technologies like its world leading Microcaps® taste-masking technology and its Diffucaps®, controlled release technology.

    The pairing of AdvaTab with Microcaps creates products that offer the dual advantage of a patient preferred dosage form, together with a superior taste and smooth mouth feel. This is a critical advantage as the unpleasant taste of drugs is a significant restriction in the application of other ODT technologies.

TABLE 1: ADVANTAGES & DISADVANTAGES OF FAST DISSOLVING TABLETS [1, 7, 8]

Advantages	Disadvantages
No water needed	Fast dissolving tablet is hygroscopic in nature so must be keep in dry place.
No chewing needed	Some time it possesses mouth feeling
Improved stability	It is also show the fragile, effervescence granules property
Have a pleasing mouth feel.	FDT requires special packaging for properly stabilization & safety of stable product
Cost- effective	
Rapid dissolution and absorption of drug, which may produce rapid onset of action.	
Exhibit low sensitivity to environmental condition as humidity and temperature.	
Ease of administration to patients who refuse to swallow a tablet, such as pediatric and geriatric patients and psychiatric patients.	
Pregastric absorption can result in improved bioavailability and as a result of reduced dosage, improved clinical performance through a reduction.	
Ability to provide advantages of liquid medication in the form of solid preparation	

TABLE 2: ADVANCE MANUFACTURING TECHNOLOGIES

Conventional tablet processes with modifications		
Wowtab		Yamanaouchi Pharma Technologies,
a.	Orasolv	Cima Labs
b.	Efvdas	Elan Corp
c.	Flashtab	Prographarm
Freeze drying method		
a.	Zydis	R.P.Scherer
b.	Lyoc	Farmalyoc
c.	Quicksolv	Janseen Pharmaceutica
Floss Formation		
a.	Flashdose	Fuisz Technologies

Excipients used in the formulation of FDT [10, 12, 16]: Excipients balance the properties of the actives in fast-melting tablets. This demands a thorough understanding of the chemistry of these excipients to prevent interaction with the actives. Determining the cost of these ingredients is another issue that needs to be addressed by formulators. The role of excipients is important in the formulation of fast-melting tablets. These inactive food-grade ingredients, when incorporated in the formulation, impart the desired organoleptic properties and product efficacy. Excipients are general and can be used for a broad range of actives, except some actives that require masking agents.

a. Bulking agents: Bulking agents improve the textural characteristics that in turn enhance the disintegration in the mouth, besides; adding bulk also reduces the concentration of the active in the composition. The recommended bulking agents for this delivery system should be more sugar-based such as mannitol, polydextrose, lactitol, DCL (direct compressible lactose) and starch hydrolystate for higher aqueous solubility and good sensory perception. Mannitol in particular has high aqueous solubility and good sensory perception. Bulking agents are added in the range of 10 percent to about 90 percent by weight of the final composition.

b. Emulsifying Agents: Emulsifying agents are important excipients for formulating fast-melting tablets they aid in rapid disintegration and drug release without chewing, swallowing or drinking water. In addition, incorporating emulsifying agents is useful in stabilizing the immiscible blends and enhancing bioavailability. A wide range of emulsifiers is recommended for fast-

tablet formulation, including alkyl sulfates, propylene glycol esters, lecithin, sucrose esters and others. These agents can be incorporated in the range of 0.05 percent to about 15 percent by weight of the final composition.

c. **Lubricants:** They remove grittiness and assist in the drug transport mechanism from the mouth down into the stomach.

d. **Flavors and Sweeteners:** Flavors and taste-masking agents make the products more palatable and pleasing for patients. The addition of these ingredients assists in overcoming bitterness and undesirable tastes of some active ingredients. Both natural and synthetic flavors can be used to improve the organoleptic characteristic of fast-melting tablets. Formulators can choose from a wide range of sweeteners including sugar, dextrose and fructose, as well as non-nutritive sweeteners such as aspartame, sodium saccharin, sugar alcohols and sucralose. The addition of sweeteners contributes a pleasant taste as well as bulk to the composition.

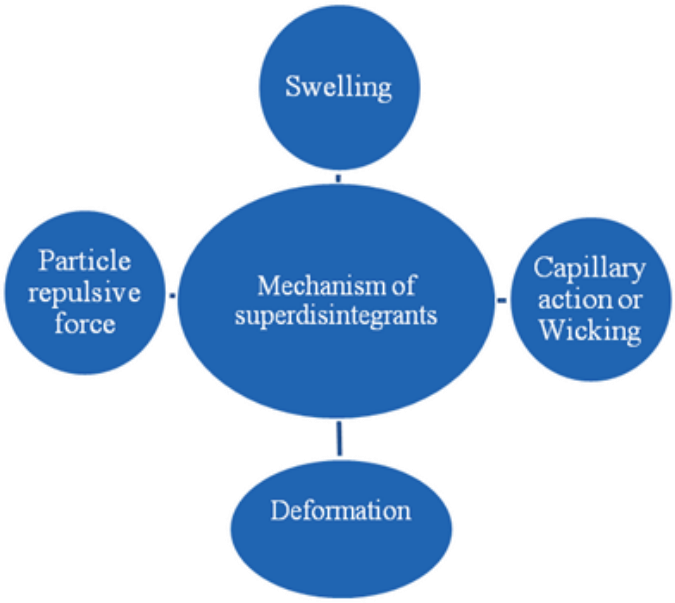
e. Gas producing disintegrants: Gas producing disintegrants are used especially where extra rapid disintegration or readily soluble formulation is required. They have also been found of value when poor disintegration characteristics have resisted other methods of improvement. Care should be taken during tab letting, particularly on moisture level. Composition is based upon the same principles as those used for effervescent tablets, the most common being mixtures of citric & tartaric acids plus carbonates or bicarbonates. In many instances lower concentration can be used with gas producing disintegrants than are required by other disintegrating agents. Certain peroxides that release oxygen have been tried, but they do not perform as well as those releasing carbon dioxide.

f. **Super disintegrants** [5]: Superdisintegrants are more effective at lower concentrations with greater disintegrating efficiency and mechanical strength. On contact with water the superdisintegrants swell, hydrate, change volume or form and produce a disruptive change in the tablet. Effective superdisintegrants provide improved compressibility, compatibility and have no negative impact on the mechanical strength of formulations containing high-dose drugs, some commonly used superdisintegrants are cross linked carboxymethyl cellulose (crosscarmellose), sodium starch glycolate, polyvinylpyrrolidone, sago starch, isphagula husk, calcium silicate, soy polysaccharides etc.

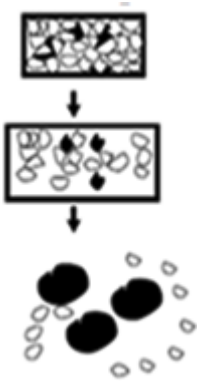
ADVANTAGES OF SUPERDISINTEGRANTS

Effective in lower concentrations
Compatible with commonly used therapeutical agents and excipients.
Less effect on compressibility and flowability
Remarkable tendency on wetting causing rapid disintegration
Work equally effective in hydrophilic and hydrophobic formulations.
More effective intragranularly
Does not stick to the punches and dyes.

Mechanism of Superdisintegrants [1, 5, 13, 20]: There are four major mechanisms for tablets disintegration as follows (**Fig. 4**).



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. (**Fig. 5**).



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 tabletting 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-swellable' 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.

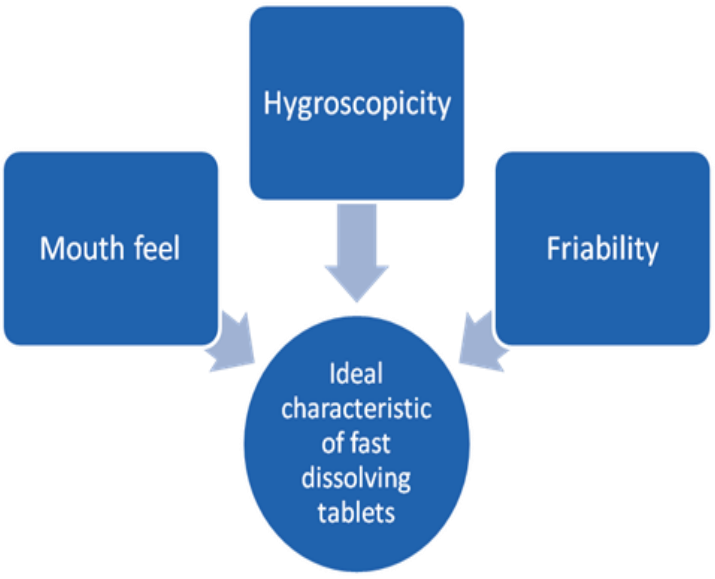
4. **Due to deformation:** During tablet compression, disintegrated particles get deformed and these deformed particles get into their normal structure when they come in contact with aqueous media or water. Occasionally, the swelling capacity of starch was improved when granules were extensively deformed during compression. This increase in size of the deformed particles produces a break**u**p of the tablet. This may be a mechanism of starch and has only recently begun to be studied (**Fig. 6**).

Disintegrating dosage form

Criteria for selection of drug for Fast Dissolving Tablets [2, 14]:

- 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 oralcavity.
- Drug should posses log P>2.

Ideal Characteristics of Fast Dissolving Delivery System (Fig. 7):



CONCLUSION: Due to the increasing demand of novel drug delivery, the fast disintegrating drug delivery system has become one of the mile stone in the novel drug delivery system. The introduction of fast dissolving drug delivery system has encountered the delivery of conventional dosage form.

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