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## Novel Natural Superdisintegrants: An Updated Review



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### ABSTRACT

In dosage forms, solid dosage forms gain maximum popularities, about 85%, because of many advantages over others. Disintegration plays a major role in improving drug activity and hence increases patient compatibility. The therapeutic activity of the formulations is obtained by disintegration followed by dissolution. The inclusion of right disintegrants is a prerequisite to get optimal bioavailability in tablets and capsules. Disintegrants are substances or a mixture of substances added to the drug formulation that facilitates the breakup or disintegration of tablet or capsule content into smaller particles that dissolve more rapidly than in the absence of disintegrants. Superdisintegrants are generally used at a low level in the solid dosage form, typically 1-10 % by weight relative to the total weight of the dosage unit. The present study comprises the various kinds of super disintegrants which are being used in the formulation to provide safer, effective drug delivery with patient's compliance. In this review article, more emphasis is given on the application and usage of various natural super disintegrants comparing with other disintegrants about available scientific studies.

## INTRODUCTION

The oral route for drug delivery is the most attractive route for the delivery of drugs. Different kinds of dosage forms administered orally, the tablet is the most desired dosage form among them. For of its ease of preparation, ease in administration, correct dosing, and stability related to oral liquids and because it is more tamper-proof than capsules. The small volume of saliva is usually sufficient to result in tablet disintegration in the oral cavity. The medication can then be absorbed partially or entirely into the systemic circulation from blood vessels in the sublingual mucosa, or it can be swallowed as a solution to be absorbed from the gastrointestinal tract. Tablet disintegration has received considerable attention as an essential step in obtaining faster drug release<sup>1</sup>. The oral route of administration is central for the delivery of a large number of the important drug in the various therapeutic area, many patients prefer standard oral dosage form as well as advanced oral drug delivery system over other dosage form<sup>2</sup>.

### **Superdisintegrants:**

The term super-disintegrants refer to substances which achieve disintegration faster than the substances conventionally used. A tablet or a capsule content breaks up or disintegrates into a smaller particle that dissolves more rapidly than in the case of the absence of such disintegrates. Super-disintegrants are granules used at a low level in the solid dosage form, typically from 1 to 10 % of the total weight of a given unit dosage form<sup>3</sup>.

### **Selection of SuperDisintegrants:<sup>1</sup>**

Many factors are considered in the selection of Superdisintegrants.

1. Quantity of disintegrates present in preparation.
2. Tablet hardness.
3. Kind of addition and mixing.
4. Drug nature.
5. Good flowability.
6. The occurrence of surface-active agents.

7. Compactable to formulate less friable tablets.
8. Good mouth feels produce to the patient.

## **METHOD OF ADDITION OF SUPERDISINTEGRANTS**

There are three methods of incorporating disintegrating agents into the tablet.

### **Internal Addition**

In the wet granulation method, the disintegrant is added to other excipients before wetting the powder with the granulating fluid. Thereby, the disintegrant is incorporated within the granules. In a dry granulation method, the disintegrant is added to other excipients before compressing the powder between the rollers. In a computer-optimized experiment, the study shows the effect of incorporating a disintegrant, croscarmellose sodium, intragranular, extra granularly or distributed equally between the two phases of a tablet in which a poorly soluble drug constituted at least 92.5% of the formulation. The results analyzed using a general quadratic response surface model suggest that, tablets with the same total concentration of croscarmellose sodium dissolve at a faster rate when the super disintegrant is included intragranular. Tablet friability is not affected by the method of disintegrant incorporation [9].

### **External Addition**

In both wet and dry granulation method, the super disintegrants are added to the granules during dry mixing before compression. The effect of mode of incorporation of super disintegrants (croscarmellose sodium, sodium starch glycolate, and crospovidone) on the dissolution of three model drugs with varying aqueous solubility (carbamazepine, acetaminophen, and cetirizine HCl) from their respective tablet formulations by wet granulation was studied. It is proved that crospovidone is effective in improving the dissolution of the drugs in an extra granular mode of addition seems to be the best mode of incorporation, irrespective of the solubility of the main tablet component.

### **Internal and External Addition**

In this method, the disintegrant is divided into two portions. One portion is added before granule formation (intra) and the remaining portion is added to granules (extra) with mixing before compression. This method can be more effective. If both intragranular and

extragranular methods are used, extra-granular portion breaks the tablet into granules and the granules further disintegrate by intra-granular portion to release the drug substance into solution. However, the portion of intra-granular disintegrant (in wet granulation processes) is usually not as effective as that of extra-granular because it is exposed to wetting and drying (as part of the granulation process) which reduces the activity of the disintegrant. Since a compaction process does not involve its exposure to wetting and drying, the intragranular disintegrant tends to retain good disintegration activity.

### Mechanism of disintegrations by superdisintegrants

There are five major mechanisms for tablet disintegration as follows:

#### Swelling:

Swelling is believed to be a mechanism in which certain disintegrating agents (such as starch) impart the disintegrating effect. By swelling in contact with water, the adhesiveness of other ingredients in a tablet is overcome causing the tablet to fall apart. E.g. Sodium starch glycolate, Plantago Ovata<sup>1</sup>.

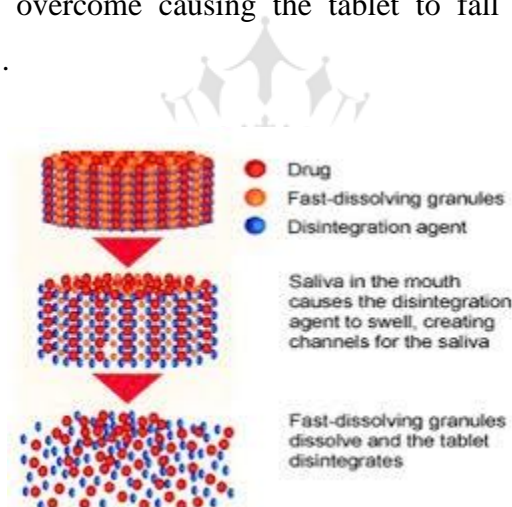


Figure No. 1: Swelling

#### Capillary Action / Wicking:

In this mechanism, the disintegrants that do not swell facilitate disintegration by their physical nature of low cohesiveness and compressibility. The disintegrant particles (with low cohesiveness and compressibility) themselves act to enhance porosity and provide these pathways into the tablet. The liquid is drawn up or "wicked" into these pathways through capillary action and ruptures the inter particulate bonds causing the tablet to break apart<sup>4</sup>.

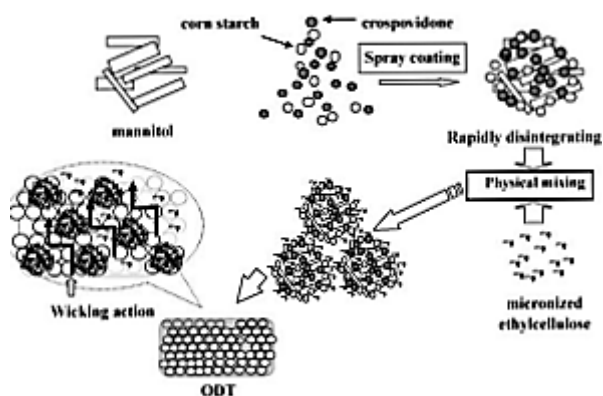


Figure No. 2: Wicking Action

**Disintegrating particle/particle repulsive forces:**

Another mechanism of disintegration attempts to explain the swelling of the tablet made with “nonswellable” disintegrants. Guyot-Hermann has proposed a particle repulsion theory based on the observation that nonswelling particles also cause the 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. It is believed that no single mechanism is responsible for the action of most disintegrants. But rather, it is more likely the result of inter-relationships between these major mechanisms<sup>1</sup>.

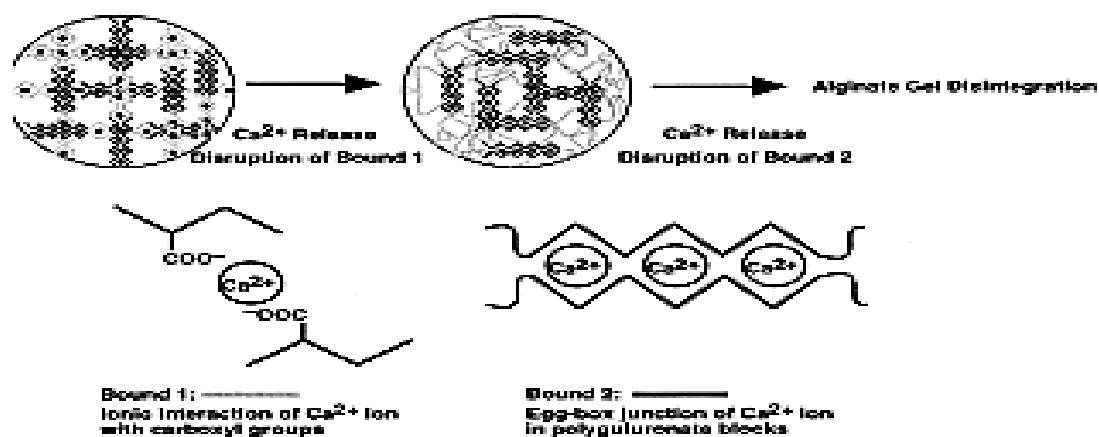


Figure No. 3: Electrostatic repulsion

### Deformation:

Hess had proved that 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<sup>1</sup>.

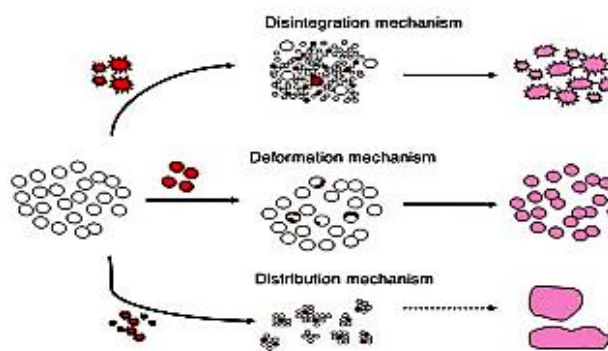


Figure No. 4: Deformation

### The heat of wetting:

When disintegrants with another microproperties get wetted, localized stress is created due to capillary air expansion, which aids in the disintegration of the tablet. This explanation, however, is limited to only a few types of disintegrants and cannot describe the action of most modern disintegrating agents<sup>1</sup>.

### Due to release of gases:

Carbon dioxide released within tablets on wetting due to interaction between bicarbonate and carbonate with citric acid or tartaric acid. The tablet disintegrates due to the generation of pressure within the tablet. This effervescent mixture is used when a pharmacist needs to formulate very rapidly dissolving tablets or fast disintegrating tablets. As these disintegrants are highly sensitive to small changes in humidity level and temperature, strict control of the environment is required during the manufacturing of the tablets. The effervescent blend is either added immediately before compression or can be added into two separate fractions of formulation<sup>1</sup>.

### **Combination action:**

In this mechanism, the combination of both wicking and swelling action facilitates disintegration. E.g. Crosspovidone<sup>1</sup>.

### **Enzymatic Reaction:**

Enzymes present in the body also act as disintegrants. These enzymes dearth the binding action of binder and helps in disintegration. Due to swelling, the pressure is exerted in the outer direction that causes the tablet to burst or the accelerated absorption of water leads to an enormous increase in the volume of granules to promote disintegration. Some examples of disintegrating enzymes are presented in table 1 along with the binders against which these are active<sup>1</sup>.

#### **ENZYMES    BINDER**

Amylase	Starch
Protease	Gelatin
Cellulase	Cellulose and its derivatives
Invertase	Sucrose



#### **TYPES OF SUPERDISINTEGRANTS<sup>1</sup>**

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

#### **Synthetic Superdisintegrants:**

These are the most commonly used disintegrants in oral disintegrating tablets to improve the rate and extent of tablet disintegration, therefore, increases tablet dissolution.

**Advantages:**

1. Effective in low concentrations
2. More effective intragranular
3. Less effect on compressibility and flowability

**Limitations:**

1. Sensitive to moisture

**Crospovidone:**

It is also known as cross-linked povidone, polyvinyl pyrrolidone, and polyplasdone. These are synthetic, insoluble, cross-linked homopolymers of N-vinyl -2-pyrrolidone. It is freely soluble on acids, chloroform, ethanol (95%), ketones, methanol, and water<sup>5</sup>. Crospovidone act by the combination of mechanisms to provide rapid disintegration. Although Crospovidone polymers swell by 95% to 120% upon contact with water, swelling is not the only mechanism for tablet disintegration. Their porous particle morphology rapidly absorbs water (wicking) via capillary action. Also, during tablet compaction, the highly compressible. At low concentration levels (2-5%) crospovidone is used as super disintegrant in direct compression, wet and dry granulation process<sup>1</sup>. Formulation with this super disintegrant had a concentration of 1-3% as it is dispersed uniformly due to its micro graded particles. It quickly wicks saliva and performs rapid disintegration by hydrostatic pressures and volume expansion<sup>6</sup>. It is generally regarded as a non-toxic and non-irritating excipient<sup>5</sup>.

**Croscarmellose sodium:**

It has a high swelling capacity and effective at low concentration. It is a crosslinked polymer of carboxymethyl cellulose<sup>5</sup>. This follows the mechanism of action of both swelling and wicking then disintegrates less than the time of 10sec. high swelling capacity and fast disintegration when used at 5.0%. Here in this, the type of synthesis plays a crucial role in the arrangement of crosslinks<sup>6</sup>.<sup>5</sup>it may be used in both direct compression and wet granulation. The disintegration action of croscarmellose sodium is higher than that of sodium starch glycolate and the mechanism of cross-linking is different<sup>5</sup>.



### **Microcrystalline cellulose:**

It is purified cellulose that occurs as a white, odorless, tasteless, crystalline powder composed of porous particles<sup>3</sup>. It is also known as Avicel. Its mechanism of action generally involves entry of water using capillary pores results in the breakdown of hydrogen bonds present between adjacent bundles of cellulose microcrystals and exhibits effective disintegration. It acts as a disintegrant in the concentration range of 5-15%<sup>5</sup>. This is partially depolymerized synthesized from alpha-cellulose. This is mainly used for the direct compression method. Here advice 102 is used as a diluent as well as disintegrant with its mechanism of interlocking as it is small size has advantages like rapid disintegration and increased binding strength<sup>6</sup>.

### **Low Substituted Hydroxy Methyl Cellulose:**

It has a high degree of swelling due to its large particle size and used to prevent capping. It is widely used now a day in the wet granulation method and directly compressible method. Here the combination of microcrystalline cellulose and low hydroxyl propyl cellulose are used for rapidly disintegrating the tablet. As the ratio of these both of 8:2 and 9:1 to get rapid disintegration<sup>6</sup>.

### **Sodium starch glycolate:**

It is also known as carboxymethyl starch sodium salt, exploited, primojel, and Viva-star P. it is white to white-off, freely flowing and practically tasteless, odorless powder. It consists of an oval or spherical granules 30-100µm in diameter. It is sparingly soluble in ethanol and practically insoluble in water and settles in the form of a highly hydrated layer. Tablets that are prepared by using sodium starch glycolate have good storage life<sup>5</sup>. Mostly in formulations, the concentrations used are nearly about 1.0-4.0% but are increased up to 6.0% which may lead to the formation of gel as completion of after its mechanism of action swelling. To disrupt the hydrogen bonding within the molecules large hydrophilic carboxy methylcellulose groups are added to increase the penetration of water into the molecule to increase the water-soluble fraction of polymer. So the cross-linking becomes less and rapid uptake of water and quick dispersion is allowed<sup>6</sup>.

### **Starch Partially Pre-Gelatinized:**

This is synthesized directly from starch grains in a directly compressed method with intact and partially hydrolyzed property and a pharmaceutical aid like a binder, filter, and disintegrant here the concentration mainly used is nearly about 5-10% and swelling is the main mechanism of action here. The ppg starches improved the tablet physical properties with few steps leading to a complex formation and dramatically lower costs. It has its chemical formula with rapid drug release<sup>6</sup>.

### **Calcium Silicate:**

It is light in weight disintegrates with the mechanism of action of wicking. When used in a concentration of 5%<sup>1</sup>.

### **Cross-linked alginic acid:**

Alginates are hydrophilic colloidal substances extracted from certain species of Kelp. Chemically they are available as alginic acid or sodium salt of alginic acid<sup>3</sup>. It is insoluble in water and disintegrates by swelling or wicking action. It is a hydrophilic colloidal substance, which has high sorption capacity<sup>1</sup>. Alginic acid is used as a disintegrant at 1-5 % concentration while sodium alginate at 2.5-10 % concentration<sup>3</sup>.

### **Soy Polysaccharide:**

It is a natural super-disintegrant that does not contain any starch or sugar. It as a disintegrant in tablets made by direct compression using lactose and dicalcium phosphate dihydrate as fillers with results paralleling those of cross-linked CMC. A cross-linked sodium carboxymethyl cellulose and corn starch were used as control disintegrants<sup>3</sup>.

### **NATURAL SUPERDISINTEGRANTS:**

Nowadays, we have several plant-based pharmaceutical excipients and various researchers have explored the utility of some of these plant-based materials as pharmaceutical super-disintegrants. These super-disintegrating agents are natural in origin and are alternative over synthetic substances because they are comparatively cheaper, easily available, non-irritating and nontoxic in nature<sup>3</sup>.

### **Ispaghula husk:**

Ispaghula husk mucilage is obtained from the seeds of *Plantago ovata*. The plant contains mucilage in the epidermis of the seed. This mucilage contains a variety of properties like binding, suspending and easily dispersible agents in the pharmaceutical industry. Extracted mucilage also used as a matrix for entrapment and delivery of various drugs, proteins, and cell<sup>5</sup>. Mucilage of *Plantago ovata* can be used as super-disintegrant to formulate ODTs due it has a very high percentage of the swelling index (around  $89 \pm 2.2$  % v/ v) as compared to the other natural or synthetic super- disintegrating agents. The seeds of *Plantago ovata* were soaked in distilled water for 48 hours and then boiled for few minutes for the complete release of mucilage into water. The material was squeezed through muslin cloth for filtering and separating the marc. Then, an equal volume of acetone was added to the filtrate to precipitate the mucilage. The separated mucilage was dried in an oven at a temperature of less than  $60^{\circ}\text{C}$ . 2% of the solution acts as good disintegrating agent<sup>6</sup>.

### **Fenugreek Seed Mucilage:**

*Trigonella foenumgraceum* is known as fenugreek the fast mouth disintegrating agent coming under Leguminosae family<sup>6</sup>. Mucilage is an off-white cream-yellow color amorphous powder that quickly dissolves in warm water to form viscous colloidal solution<sup>5</sup>. Fenugreek seeds contain a high percentage of mucilage which can be used as a disintegrant for use in ODTs formulation. Although it does not dissolve in water, quickly dissolve in warm water forms a viscous colloidal solution. Like other mucilage-containing substances, fenugreek seeds swell up and become slick when they are exposed to fluids. So due to their high swelling property, it serves as a better super-disintegrants for ODTs formulation<sup>3</sup>. 4% is rapid in disintegration and acts good pharmaceutical adjuvant and good disintegrating agent<sup>6</sup>. The disintegration and swelling properties of FDT were compared with widely used super disintegrant like Ac-di-sol<sup>7</sup>.

### **Lepidium sativum Seed Mucilage:**

*Lepidium sativum* also known as saliyo belongs to the family Cruciferae. The mucilage can be extracted from the seeds by different procedures and its yield varies from 14% to 22%. Mucilage has various properties like binding, disintegrating, gelling, etc. Extracted mucilage was used to develop fast-dissolving tablets. Mucilage is found to be a brownish-white powder which decomposes above  $200^{\circ}\text{C}$  and has a characteristic odor<sup>5</sup>.<sup>6</sup>The *Lepidus sativum* shows

less disintegration at 10% mucilage and 10% mannitol at 5.27 sec and other preparation of nimesulide at 17 sec. It also acts as herbal medicine and pharmaceutical excipient<sup>6</sup>.

### **Gellan Gum (Kicogel):**

Gellan gum is produced by the microbe *Pseudomonas elodea*. It is a linear anionic polysaccharide, a biodegradable polymer consisting of a linear tetrasaccharide repeat structure and used as a tablet disintegrants. The disintegration of tablets might be due to the instantaneous swelling characteristics of gellan gum when it comes into contact with water and owing to its high hydrophilic nature. The complete disintegration of the tablet is observed within 4 minutes with a gellan gum concentration of 4 % w/w and 90 percent of drug dissolved within 23 minutes. Ac-di-sol and Kollidone CL shows a very similar pattern of disintegration and in vitro dissolution rates. With the same concentration tablet with exploited show 36 minutes for 90% of drug release and with starch show 220 minutes. From this result, gellan gum has been proved as a superdisintegrant<sup>1</sup>.

### **Locust Bean gum:**

It is obtained from Seed of Carob tree *Ceratonia Siliqua*<sup>3</sup>. Locust bean gum is extracted from the endosperm of the seeds of the carob tree found meditation region. It is also called Carob bean gum. In the food industry, it is widely used as a thickening and gelling agent. It has also been reported to have bioadhesive and solubility enhancement properties<sup>1</sup>. It is with a mechanism of action with swelling and capillary action<sup>6</sup>. The swelling index was found to be 2000 which points towards good swelling competency of locust bean gum<sup>5</sup>. Swelling is observed with less than 20sec and got the appreciable capability of super disintegrant, compared with standards super disintegrants like carmellose sodium. Disintegration time of 13 sec is least that containing 105 of locust bean gum is used<sup>6</sup>. It shows as a binder and disintegrant at different concentrations<sup>5</sup>.

### ***Hibiscus Rosa Sinesis Linn* Mucilage:**

*Hibiscus rosa-Sinensis* is commonly known as the shoe-flower plant, China rose and Chinese hibiscus and belongs to the family Malvaceae. The plant is found in India in large quantities and its mucilage has been found to act as a super-disintegrant in the ODTs formulations<sup>3</sup>. Mucilages are utilized as thickeners, suspending agent, water retention agent, and disintegrants. The plant is facilely available and its leaves contain mucilage and are present in

mucilage L-rhamnose, D-galactose, D-galacturonic acid, and D-glucuronic acid<sup>1</sup>. Shah et al prepared aceclofenac oral disintegrating tablets by direct compression method using hibiscus *Rosa Sinensis* linn mucilage and shows the disintegration of the tablet within less than the time of 20 sec<sup>6</sup>.

### **Guar Gum:**

It is a high molecular weight polysaccharide extracted from the seeds of *Cyamopsis tetragonaloba* which has thickening and stabilizing properties used in the food and industrial application<sup>5</sup>. It is a high molecular weight polysaccharide extracted from the seeds of *Cyamopsis tetragonaloba* which has thickening and stabilizing properties used in the food and industrial application. Particle size can affect disintegration, with finer particle sizes having greater disintegrating capabilities<sup>3</sup>. In pharmaceutical applications, it is widely used as binder and disintegrant and also been investigated in the preparation of sustained-release matrix tablets in the place of cellulose derivatives such as methylcellulose<sup>5</sup>.

### **Gum Karaya:**

It is also known as gum sterculia or Indian gum tragacanth is a vegetable gum obtained as an exudate by the trees of the *Astragalus gummier* (Leguminosae). Chemically, gum karaya is an acid polysaccharide composed of the sugar galactose, rhamnose, and galacturonic acid. Due to its viscous nature, it is used as a binder and disintegrant in the development of conventional dosage form<sup>5</sup>. Gum karaya has been investigated for its potential as a tablet disintegrant. Different results showed that modified gum karaya produces rapid disintegration of tablets. Gum karaya can be utilized as an alternative super disintegrant to commonly available synthetic and semisynthetic super disintegrants due to its low cost, biocompatibility as well as facile availability<sup>1</sup>.<sup>3</sup>It absorbs water and swells to 60-100 times their original volume<sup>3</sup>.

### **Mango Peel Pectin:**

Mango peel contains 20-25% of mango processing waste used as a good source for the extraction of pectin of good quality used for the preparation of film and jelly. Pectin is a heteropolysaccharide which as a hydrophilic colloid. Naturally obtained mango peel pectin stands as a good candidate to act as a super disintegrant. Due to its good solubility and higher swelling index it may be used in the formulation of the fast disintegrating formulation<sup>5</sup>.

### **Plantago ovata Seed Mucilage:**

Psyllium or Ispaghula is the common name, whose seeds are used commercially for the production of mucilage. The seeds of *Plantago ovata* were soaked in distilled water for 48 hours and then boiled for few minutes for the complete release of mucilage into water. The material was squeezed through muslin cloth for filtering and separating the marc. Then, an equal volume of acetone was added to the filtrate to precipitate the mucilage. The separated mucilage was dried in an oven at a temperature of less than 60°. Mucilage of *Plantago ovata* has various characteristics like disintegrating, binding and sustaining properties. Mucilage of *Plantago ovata* can be used as super-disintegrant to formulate ODTs because it has a very high percentage of the swelling index (around  $89 \pm 2.2$  % v/v) as compared to the other natural or synthetic super- disintegrating agents<sup>3</sup>. All formulations were evaluated for weight variation, hardness, friability, disintegration time, drug content, and dissolution. The optimized formulation shows a less in vitro disintegration time of 11.69 seconds with rapid in vitro dissolution within 16 minutes. In-vitro disintegration time decreases with an increase in the concentration of natural superdisintegrant<sup>1</sup>.

### **Agar and treated agar:**

It is the dried gelatinous substances obtained from *delirium amansii* (gelidanceae) and several other species of red algae like *Gracilaria* and *Pterocladia*. Agar is a yellowish-gray or white with mucilaginous taste and is available in the form of divests, sheet flakes, or coarse powder. Agar consists of two polysaccharides agarose and agaropectin<sup>5</sup>. Agarose is responsible for gel strength and Agaropectin is responsible for the viscosity of agar solutions. The high gel strength of agar makes it a potential candidate as a disintegrant in the formulation of ODTs. Gums are used in a concentration from 1 to 10 %. However, these are not as good disintegrating agents as others because capacity development is relatively low<sup>3</sup>.

### **Aegle marmelos Gum (AMG):**

It is obtained from the fruits of *Aegle marmelos* belonging to the disintegrated faster and consistently than the croscarmellose sodium. The ripened fruit pulp is red with a mucilaginous and astringent taste. The pulp contains carbohydrates, proteins, vitamin C, vitamin A, Angeline, marceline, dictamen, O-methyl ordinal, and isopentyl halfordinol. AMG is prepared by the heat treatment technique. It increases the solubility of poorly soluble drugs. It increases glucose level and glycosylated hemoglobin in diabetic patients decreases plasma

insulin and liver glycogen in a diabetic patient, decreases lipid peroxidation, stimulates macrophage functioning, and causes significant deviation in the GSH (glutathione) concentration in liver, kidney, stomach, and intestine. Purified, bael gum polysaccharide contains D-galactose (71%), D-galacturonic acid (7%), L-Rhamnose (6.5%), and L-arabinose (12.5%)<sup>1</sup>.

#### ***Cucurbita Maximum Pulp Powder:***

It is commonly known as pumpkin, belongs to the family Cucurbitaceae<sup>5</sup>. *Cucurbita maxima* fruit was cleaned with water to remove dust and impurities from the surface and further peel was removed. The seed was removed and pulp was put into juicer mixer to form a highly viscous liquid. Viscous liquid was further lyophilized to get solid porous mass. Size reduction was done and the powder was collected. The collected powder was passed through 80 # sieve and stored for further study. It also has a comparable hardness and friability thus the naturally obtained *Cucurbita maxima* pulp powder serves as a good candidate to act as super-disintegrant and it is possible to design promising ODTs using this polymer<sup>3</sup>. Pulp Powder Malviya et al., carried of the evaluation of *Cucurbita* with diclofenac sodium and prepared various concentrations of 2.5, 5, 7.5,10% and these also sent for various tested like friability drug content, drug disintegration time, and this study also proves that this is a good pharmaceutical adjuvant and disintegrating agent<sup>1</sup>.

#### ***Mangifera indica Gum (MIG):***

The mundane name of *Mangifera indica* is mango, and it belongs to the Anacardiaceae family. It is nontoxic and utilized as a disintegrant, binder, suspending agent, and emulsifying agent in different formulations. The gum powder is white to off white, and the powder was soluble in water and virtually insoluble in acetone chloroform, ether, methanol, and ethanol. It is facilely available, and gum is devoid of toxicity, and every component of the tree has pharmacological activity like a diuretic, astringent, diabetes, asthma, diarrhea, urethritis, and scabies<sup>1</sup>.

#### ***Ficus Indica Fruit Mucilage:***

The mucilage of *ficus indica* fruit is utilized as a super disintegrant which is obtained from the pulp of fruit *ficus indica*. *Ficus India* is an astronomically immense tree up to 3 meters and very fast-growing with spread branches and aerial roots. The fruits of *ficus indica* are of

the size of a cherry. It has nutritional as well as medicinal value. The dried and uncooked ficus indica fruit gives 230 kcal (963 KJ) of energy per 100 gm or 3.5 oz. (ounce). It is utilized in assuaging fever, pain, inflammation, wound rejuvenating, blood quandaries, and urinary quandaries<sup>1</sup>.

#### **Dehydrated Banana Powder (DBP):**

Banana is additionally called plantain. DBP is yare from the variety of banana called Ethan and nenthran (nenthra vazha) and belongs to the family Musaceae. It contains vitamin A, so it is utilized in the treatment of gastric ulcer and diarrhea. It withal contains vitamin B6, which avails in reducing the stress and solicitousness. It is a very good source of energy due to high carbohydrate content, and it contains potassium, which is responsible for more preponderant brain functioning<sup>1,5</sup>. Banana powder is made from processed bananas and it is rich in dietary fiber. Studies showed that the disintegrant property of banana powder in the formulation of mouth dissolving tablet has shown the best results. The disintegration time obtained by tablets with banana powder was comparable to that obtained with other commonly used disintegrants; hence it can be used very effectively in the formulation of fast dissolving tablets. It is used as a potential pharmaceutical excipient in various solid dosage forms especially in fast-dissolving tablets<sup>5</sup>.

#### ***Cassia fistula* gum:**

*Cassia fistula* is commonly known as the golden rain tree belongs to the family Fabaceae. The gum obtained from the seeds of *Cassia fistula* containing  $\beta$ -(1,4) linked d-mannopyranose units with a random distribution of  $\alpha$ -(1,6) linked d-galactopyranose units as side chain having mannose galactose ratio of 3.0. Carboxymethylation of *cassia fistula* seed showed better swelling properties than that of crude gums. It is further used as a disintegrant, diluent and drug release controlling agent in the pharmaceutical industry<sup>5,1</sup>. Carboxymethylation, as well as carbamoylethylation of Cassia gum, is reported to improve cold-water solubility, improve viscosity and increase microbial resistance as compared to native gum, Therefore, an attempt was made to incorporate calcium or sodium salts of carboxymethylated or carbamoylethylated C. fistula gum as super disintegrant in the formulation development of FDT<sup>1</sup>.



### **Xanthum gum:**

It is produced by the bacteria *Xanthomonas campestris* is official in USP with high hydrophilicity and low gelling tendency. It has low water solubility and extensive swelling properties for faster disintegration. It is a heteropolysaccharide consisting of repeated pentasaccharide units formed by 2 glucose units, 2 mannose units, and one glucuronic acid units<sup>5</sup>.

### ***Ocimum americanum*:**

Seed Mucilage, Patel et al prepared the propranolol hydrochloride tablets using *Ocimum americanum* seed mucilage using various concentrations like 2, 4, 6, 8, 10% the optimum concentration of mucilage for rapid dissolution is shown at 10% and the same concentration with starch and propranolol hydrochloride is prepared and shows disintegration time of 269 seconds while *Ocimum* shows the disintegration in 154 seconds. The hardness friability drug content is within limit<sup>1</sup>.

### **Chitin and Chitosan:**

Chitin ( $\beta$ -(1 $\rightarrow$ 4)-N-acetyl-D-glucosamine) is a natural polysaccharide obtained from crab and shrimp shells. It possesses an amino group covalently linked to the acetyl group as compared to the liberate amino group in chitosan. Chitosan is produced commercially by deacetylation of chitin, which is the structural element in the exoskeleton of crustaceans (such as crabs and shrimp) and cell walls of fungi. Bruscato and Danti, 1978, reported that when chitin was included in the conventional tablets, the tablets disintegrated within 5 to 10 minutes irrespective of solubility of the drug. The disintegration time in the oral cavity, as well as wetting time, could be analyzed by surface free energy. Chitosan is the best known natural polysaccharide utilized for its multifarious applications in the pharmaceutical industry<sup>1</sup>.

### ***Portulaca oleraceae* mucilage:**

It is commonly known as red root and pursely. It belongs to the family Portulacaceae. The leaf contains omega-3-fatty acids and dietary minerals. It is used as a natural disintegrant in the formulation of fast dissolving tablets; studies revealed that the results obtained from the *portulaca oleraceae* mucilage are better than those of conventional commercial formulations<sup>5</sup>.

**Arachis hypogaea shell powder (AHSP):**

The peanut also is known as groundnut, goober or monkey nut and taxonomically classified as *Arachis hypogaea* belonging to the family Fabaceae (Leguminosae). Peanuts grow best in light, sandy loam soil with pH 5.9-7. It contains polyphenols, polyunsaturated and monosaturated fats, phytosterols and dietary fiber. Peanut skins contain resveratrol. The preparation of AHSP includes the washing of Peanut Shells with water to remove the soil then sundried for 1 day. After that shells are separated and placed in a hot air oven for 30 minutes at 100°C then shells are crushed in a grinder and then passed through # 60 mesh. The tablets were prepared by direct compression method by using AHSP in various concentrations. The disintegration time is in between 9-22 seconds and the AHSP has significant super disintegrant potential<sup>12</sup>.

**List of super disintegrants:**

Sr. No.	Name of the super disintegrant	Mechanism of action	Concentration	Time
1	Crosslinked PVP	Swells 7-12 folds in <30 seconds Swell very little and returns to original size after compression but act by capillary action	5%	14s
2	Croscarmellose	Swells 4-8 folds in <10 seconds. Swelling and wicking both	5%	35s
3	Cross-linked Alginic acid	Rapid swelling in aqueous medium or wicking action	1-5%	15s
4	Crosslinked Starch	Swelling	5 – 10% 1 – 6%	40s
5	Sodium starch glycolate	Swells 7-12 folds in <30 seconds	2-8%	42s
6	Locust bean gum	Swelling & capillary	5% & 10%	13s
7	Isaphghulla Husk	Swelling	10%	46-75s
8	<i>Hibiscus rosa sinensis</i> Linn.	Swelling	4-6%	20s
9	Fenugreek seed mucilage	Swelling	4%	15s
10	Soy polysaccharides	Swelling	8%	12s
11	Xanthum Gum	Swelling	10%	24.2s
12	Gallen Gum	Swelling	4%	155s
13	Ion Exchange Resin	Swelling	1-2%	60s

14	Calcium Silicate	Wicking action	7.5%	30s
15	<i>Lepidium sativium</i>	Swelling	5-15%	17s
16	<i>Ocimum gratissimm</i> mucilage	Swelling	5%	43s
17	Chitin and Chitosan	Swelling	3%	60s
18	<i>Cucurbita maxima</i> pulp power	Swelling& wicking	2.5%	7.23m
19	<i>Plantago ovate</i> mucilage	Swelling	5%	17.10s
20	<i>Aegle marmelos</i> gum	Swelling	6%	8-18m
21	<i>Mangifera indica</i> gum	Swelling	6%	3-8m
22	Guar gum	Swelling	1%	30s
23	Banana powder	Swelling	6%	15-36s
24	Agar and treated agar	High strength gelling	1-2%	20s
25	<i>Gum karaya</i>	Swelling	4%	17s
26	Mango peel pectin	Swelling	0.1-4%	12s
27	<i>Arachis hypogaea</i> shell powder		3-10%	9-22s

#### Co-processed super disintegrants:

This is based on the novel concept that 2-3 excipients interact at particle level, the objective of which is used to provide a synergy of functionality development as well as masking the undesired properties of individuals. Co-processing excipients lead to the formation of excipient granules with superior properties. Compared with physical mixtures of components like improved flow property and compressibility. Better dilution potential full uniformity and reduced lubricant sensitivity<sup>6</sup>.

- Ludipress (lactose monohydrate, polyvinylpyrrolidone, and crospovidone).
- Starlac (lactose and maize starch). Starcap 1500 (corn starch and pregelatinized starch).
- Ran Explo-C (microcrystalline cellulose, silica and crospovidone).
- Ran Explo-S (microcrystalline cellulose, silica and sodium starch glycolate).
- PanExcea MH300G (microcrystalline cellulose, hydroxyl-propyl-methyl cellulose, and Crospovidone).
- Ludiflash (mannitol, crospovidone, and polyvinyl acetate)<sup>1</sup>.

### **Co-processed blend of Excipients:**

It involves the mixture blend of more than two excipients to satisfy the required quality using a different technique like spray drying and freeze-drying etc<sup>1</sup>.

### **Ludiflash:**

Ludiflash is an innovative, unique co-processed blend of Mannitol (95%), crospovidone (5%) and polyvinyl acetate (5%) manufactured in a validated patented process. It disintegrates rapidly within seconds with a soft, creamy consistency. It is specially designed for direct compression on standard high-speed tablet machines for the hard tablet with very low friability. It gives an extremely fast release rate<sup>1</sup>.

### **F-melt:**

F-MELT® is a spray-dried excipient used in orally disintegrating tablets that contain saccharides, disintegrating agents, and inorganic excipient. F-MELT exhibits excellent tableting properties and facilitates rapid water-penetration for a fast disintegration time<sup>1</sup>.

### **Pharmaburst:**

Pharmaburst is a Quick Dissolving delivery system in which there is an addition of active drug in a dry blend with Pharmaburst excipients and compresses by tablet machine. Pharmaburst is a co-processed excipient system with specific excipients, which allows rapid disintegration and low adhesion to punches<sup>1</sup>.

### **Mannogem EZ:**

Mannogem EZ is spraying dried Mannitol, specially designed for a direct compression tablet. It has advantages of highly compatible, non-hygroscopic, chemically inert, narrow particle size distribution and mainly rapid disintegration property benefits quick dissolve application. It is highly stable and inert to many of the chemical reactions which are problematic with lactose, microcrystalline cellulose, or starch<sup>1</sup>.

### **Modified Chitosan with silicon dioxide:**

This is the new excipients based on co-precipitation of Chitosan and silica. The physical interaction between Chitosan and silica creates an insoluble, hydrophilic highly absorbent

material, resulting in superiority in water uptake, water saturation for gelling formation. Studies have shown that Chitosan–silica delivers superior performance in wet granulation formulations and is the only disintegrant that is effective at all concentrations in tablet formulation<sup>1</sup>.

### **Modified Resins**

#### **Polacrilin Potassium (Tulsion 339):**

It is a crosslinked polymer of methacrylic acid and divinylbenzene supplied as the potassium salt. Polacrilin potassium is a weakly acidic cation exchange resin. On wetting, the resin swells by approximately 150 %, thereby causing the tablet to disintegrate. Tablet disintegration property is due to its extremely large swelling capacity in aqueous solutions. Water can exert force between particles within tablet pores, but this force is low. This is used effectively at 1-2% of solid dosage forms. It is biocompatible and non-toxic. It is available in various grades i.e., tulsion-335, tulsio-344, tulsion-345 and tulsion-412<sup>1</sup>.

### **Modified Mannitol**

#### **Pearlitol 200 SD:**

These are the granulated Mannitol white, odorless, slightly sweet-tasting, crystalline powder. It has a unique blend of exceptional physical and chemical stability, with great organoleptic, non-carcinogenic, sugar-free properties. Together with its versatile powder properties, it can be used in different processes wet or dry granulation, direct compression, and compaction or freeze-drying. It has properties like flowability, excellent compressibility, non-hygroscopic and excellent chemical stability. Pearlitol SD dissolves very rapidly because of its porous crystalline particles<sup>1</sup>.

### **Modified sugars**

#### **Glucidex IT:**

Glucidex IT is obtained by moderate hydrolysis of starch. It is micro granulated form enables almost instantaneous dispersal and dissolution in water. Different range of Glucidex IT products is available. All co-processed and modified excipients are playing a vital role in the development of easy dosage forms that are resistant to the atmosphere. The improved

physical, chemical and mechanical properties of such excipients as compared to existing excipients, have helped in solving formulation problems such as flowability, compressibility, hygroscopicity, palatability, dissolution, disintegration, sticking, and dust generation<sup>1</sup>.

### **Applications:**

Superdisintegrants are used in different types of formulation. These are as follows:

a) Mouth dissolving tablet; Khalidindi et al 1982 evaluated soy polysaccharide (a group of high molecular weight polysaccharides obtained from soybeans) as a disintegrant in tablets made by direct compression using lactose and dicalcium phosphate dihydrate as fillers.

b) Fast disintegrating tablet; Shirsand et al carried out preparation and evaluation fast dissolving tablets of metoclopramide using novel co-processed super disintegrant. In the present study, novel co-processed superdisintegrants were developed by a solvent evaporation method using crospovidone and sodium starch glycolate in different ratios (1:1, 1:2 & 1:3) for use in the fast dissolving tablet formulations.

c) Rapidly disintegrating tablet; Sandeep B. Patil et al prepared Olanzapine, quick dispersing tablets by direct compression method. Effect of super disintegrant crospovidone on wetting time, disintegration time, and drug content and in vitro release has been studied.

d) Pharmaceutical super disintegrant: Superdisintegrants which provide improved compressibility compared to prior art super disintegrants. The superdisintegrants include a particulate agglomerate of co-processed starch or cellulose and a sufficient amount of an augmenting agent to increase the compatibility of the super disintegrant.

e) Rapidly disintegrating enzyme-containing solid oral dosage compositions: Invention relates to rapidly disintegrating solid oral dosage forms having an effective amount of an enzyme and a super disintegrant. The enzyme lactase is claimed in this patent for solid oral formulations.

f) Fast disintegrating tablets: A fast disintegrating tablet comprising Nimesulide and one or more disintegrants. In this research superdisintegrants used are croscarmellose cellulose, crospovidone, and sodium starch glycolate.

g) Method of producing fast dissolving tablets: A method of producing a fast-melt tablet. The

process does not involve any granulation step, thereby making the process more energy-efficient and cost-effective. The fast-dissolving sugar alcohol is selected from the group comprising: mannitol; sorbitol; erythritol; xylitol; lactose; dextrose; and sucrose. The active component is suitably provided in the form of microparticles or microcapsules having an average diameter of fewer than 125 microns.

h) Disintegrating Loadable Tablets: A disintegrating loadable tablet product in compressed form. A disintegrant or a mixture of disintegrants have a) porosity of 45% v/v or more, b) a hardness of at least 20 Newton, and c) a loading capacity of at least 30% of a liquid.

i) Rapidly disintegrating tablet: The study relates to rapidly disintegrating tablets intended to be used as orodispersible tablets or dispersible tablets. The tablets include silicified microcrystalline cellulose. They are especially suitable for antibiotics. Rapidly disintegrating tablets which contain amoxicillin and clavulanic acid are also described.

j) Development and Evaluation of orodispersible tablet using a natural polysaccharide isolated from Cassia tora seeds: Orodispersible OF FDT dissolve or disintegrate immediately on the patient tongue or buccal mucosa.

k) Taste masked microsphere of ofloxacin: Solvent evaporation technique as a method for preparation of microsphere.

l) Enhancement of Loperamide Dissolution rate by Liquisold Compact technique: Enhance the dissolution of Loperamide at Ph values that stimulate the gastric condition so to improve gastric absorption.

m) Sublingual Fast dissolving liposomal films for enhanced bioavailability and prolonged effect of metoprolol tartrate: Fast dissolving liposomal could be a promising delivery system to enhance the bioavailability and prolong the therapeutic effect of metoprolol tablet<sup>1</sup>.

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