Role of Superdisintegrants in Fast Dissolving Tablets

ABSTRACT

Oral disintegrating tablets are an emerging trend in novel drug delivery system and have received ever-increasing demand during the last few decades. Superdisintegrants are used to improve the efficacy of solid dosage forms. This is achieved by decreasing the disintegration time which in turn enhances drug dissolution rate. Disintegrants are substances or 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. In recent years, several newer agents have been developed known as Superdisintegrants. Diverse categories of Superdisintegrants such as synthetic, semi-synthetic, natural and coprocessed blends etc. have been employed to develop effectual mouth dissolving tablets and to overcome the limitations of conventional tablet dosage form. 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 all the information of Superdisintegrants including its types, mechanism, selection criteria, ideal properties, incorporation methods and advantages which are being used in the formulation to provide the safer, effective drug delivery with patient’s compliance.

Keywords: Superdisintegrants, Natural & Synthetic, FDT
INTRODUCTION

The oral route of administration still continues to be the most preferred route due to its diverse advantages including ease of administration, precise dosage, self-medication, versatility and most importantly patient compliance. Therefore, oral solid dosage forms are more popular. Fast dissolving tablets (FDT) are a solid single-unit dosage form that are placed in mouth, allowed to disperse/dissolve in the saliva without the need of water and provides a quick onset of action. Some drugs are absorbed from mouth, pharynx and oesophagus as the saliva passes down into the stomach. In such cases bioavailability of drug is significantly greater than those observed from conventional tablet dosage form [5]. United States Food and Drug Administration (FDA) defined FDT as “A solid dosage form containing medicinal substance or active ingredient which disintegrates rapidly usually within a matter of seconds when placed upon the tongue”. The disintegration time for FDTs generally ranges from several seconds to about a minute. The bioavailability of some drugs may be increased due to absorption of drugs in oral cavity and also due to pre-gastric absorption of saliva containing dispersed drugs that pass down into the stomach. Moreover, the amount of drug that is subjected to first pass metabolism is reduced as compared to standard tablets [1-7].

Disintegrants are agents added to tablet and some encapsulated formulations to promote the breakup of the tablet and capsule ‘slugs’ into smaller fragments in an aqueous environment thereby increasing the available surface area and promoting a more rapid release of the drug substance. They promote moisture penetration and dispersion of the tablet matrix. Tablet disintegration has received considerable attention as an essential step in obtaining fast drug release. The emphasis on the availability of drug highlights the importance of the relatively rapid disintegration of a tablet as a criterion for ensuring uninhibited drug dissolution behaviour. Number of factors affect the disintegration behaviour of tablets. The disintegrants have the major function to oppose the efficiency of the tablet binder and the physical forces that act under compression to form the tablet. The stronger the binder, the more effective must be the disintegrating agents in order for the tablet to release its medication. Ideally, it should cause the tablet to disrupt, not only into the granules from which it was compressed, but also into powder particles from which the granulation was prepared. Disintegrants are an essential component to tablet formulations. The ability to interact strongly with water is essential to disintegrate
function. Combinations of swelling and/or wicking and/or deformation are the mechanisms of disintegrant action. A disintegrant used in granulated formulation processes can be more effective if used both “intragranularly” and “extragranularly” thereby acting to break up the tablet into granules and having the granules further disintegrate to release the drug substance into solution. However, the portion of disintegrant added intragranularly (in wet granulation processes) is usually not as effective as that added extragranularly due to the fact that 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 disintegrant used intragranularly tends to retain good disintegration activity. There are three methods of incorporating disintegrating agents into the tablet: A. Internal Addition (Intragranular) B. External Addition (Extragranular) C. Partly Internal and External. In a direct compression process, drug is blended with a variety of excipients, subsequently lubricated and directly compressed into a tablet. A disintegrant used in this type of formulation, simply has to break the tablet apart to expose the drug substance for dissolution [8-9].

MECHANISM OF ACTION OF DISINTEGRANTS

- By swelling
- By Porosity and capillary action (Wicking)
- Because of heat of wetting
- Due to release of gases
- By enzymatic action
- Due to disintegrating particle/particle repulsive forces
- Due to deformation

Swelling: Perhaps 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.
Figure 1. Mechanism of superdisintegrant - wicking & swelling

**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.

**Due to disintegrating particle/particle repulsive forces:** Another mechanism of disintegration 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.
Figure 2. Mechanism of Superdisintigrant- Deformation & Repulsion

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 (Fig. 2). 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 [10].

By Enzymatic Reaction: Enzymes present in the body also act as disintegrants. These enzymes lack the binding action of binder and help in disintegration. Due to swelling, 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 [11].
SELECTION CRITERIA FOR SUPERDISINTEGRANTS

Although superdisintegrants primarily affect the rate of disintegration, but when used at high levels it can also affect mouth feel, tablet hardness and friability. Hence, various ideal factors to be considered while selecting an appropriate superdisintegrants for a particular formulation should:

- Proceed for rapid disintegration, when tablet comes in contact with saliva in the mouth/oral cavity.
- Be compactable enough to produce less friable tablets.
- Produce good mouth feel to the patients. Thus, small particle size is preferred to achieve patient compliance.
- Have good flow, since it improves the flow characteristics of total blend [12-13].

IDEAL PROPERTIES OF SUPERDISINTEGRANTS

Poor Solubility

Among the physical properties of accompanying particles that affect the effectiveness of a disintegrant, the solubility is considered of great importance. The solubility of the major component in a tablet formulation can affect both the rate and the mechanism of tablet disintegration. Water soluble materials tend to dissolve rather than disintegrate, while insoluble materials generally produce rapidly disintegrating tablets. Due to the presence of porous
morphology, liquid is drawn up or “wicked” into these pathways through capillary action and rupture the interparticulate bonds causing the tablet to break apart.

**Poor Gel Formation**

Disintegrants form gels when fully hydrated, particularly at high use levels required in some formulations to achieve desired tablet disintegration or drug dissolution. Gels can delay dissolution as the drug must first diffuse through the gel layer before being released into the body. Sodium starch glycolate is used as a superdisintegrant in tablet formulation at a concentration of 4-6%. Above 8%, disintegration time may actually increase due to gelling and its subsequent viscosity producing effects. Because polyplasdone does not form gel upon wetting, it maintains high disintegration efficiency, even after undergoing several wetting and drying cycles [14].

**Good Hydration Capacity**

Drugs or other excipients, which are hydrophobic and could be adsorbed on disintegrant surfaces, advertently influence the extent of hydration and the effectiveness of these disintegrants. Addition of fast disintegrants of high hydration capacity is reported to minimize this problem, and therefore, enhance dissolution [15].

**Good Compressibility and Flow Properties**

If the powders have 12-16% compressibility, they are said to be good flow powders. To achieve consistent tablet weights, the formula must be designed to flow consistently and to fill volumetrically. Thus, the powders in the formula must possess a consistent particle-size distribution and density to attain proper flow and achieve volume of fill. Crospovidone is significantly more compressible than other superdisintegrants, allowing for tablets with high breaking force and low friability. The breaking force of pure compacts of several disintegrants is tested at various compaction forces. The results report that Crospovidone provides significantly higher breaking force [16,17].
Complexation

An important formulation consideration is the potential interaction between drug actives and excipients. Anionic disintegrants like croscarmellose sodium and sodium starch glycolate may complex with cationic drug actives and slow dissolution. Crospovidone a non-ionic polymer does not interact with cationic drug actives to retard drug release [18]. The effects of superdisintegrants like croscarmellose sodium, sodium starch glycolate and polyplasdone XL on the dissolution behavior of several cationic drugs with varying water solubility reports that polyplasdone XL had a more rapid dissolution rate for the model cationic drugs, irrespective of their aqueous solubilities [19].

METHODS OF INCORPORATION OF SUPERDISINTEGRANTS

The incorporation of superdisintegrants in the dosage forms are mainly of three types:-

Intragranular or during granulation - In this process the superdisintegrants are blend with other powders and granulation is carried out. Thus the superdisintegrants are incorporated within the granules.

Extragranular or prior to compression - In this process, the superdisintegrants are mixed with prepared granules before compression.

Incorporation of superdisintegrants at intra and extra granulation steps- In this process part of superdisintegrants are added to intragranules and a part to extragranules. This method usually produces better results and more complete disintegration than type I and type- II [20].

TYPES OF SUPERDISINTEGRANTS

The Superdisintegrants can be classified into two categories on the basis of their availability:

- Natural Superdisintegrants
- Synthetic Superdisintegrants
Natural Superdisintegrants

These superdisintegrating agents are natural in origin and are preferred over synthetic substances because they are comparatively cheaper, abundantly available, non-irritating and nontoxic in nature. The natural materials like gums and mucilages have been extensively used in the field of drug delivery for their easy availability, cost effectiveness, Eco friendliness, emollient and non-irritant nature, non-toxicity, capable of multitude of chemical modifications, potentially degradable and compatible due to natural origin. There are several gums and mucilages are available which have super-disintegrating activity [21].

*Plantago ovata* Seed Mucilage (Isapgula) - Isapghula consists of dried seeds of the plant *Plantago ovata* and it contains mucilage which is present in the epidermis of the seeds. The seeds of *Plantago ovata* were soaked in distilled water for 48 hrs and then boiled for few minutes for complete release of mucilage into water. The material was squeezed through muslin cloth for filtering and separating out the marc. Then, an equal volume of acetone was added to the filtrate so as to precipitate the mucilage. The separated mucilage was dried in oven at temperature less than 60°C. The mucilage of *Plantago ovata* is a recent innovation for its superdisintegration property when compared with Crospovidone. It shows faster disintegration time than the superdisintegrant Crosspovidone [22-24].

*Lepidium sativum* Mucilage – *Lepidium sativum* (family: Cruciferae) is known as asaliyo and is widely used as herbal medicine in India. It is widely available in market and has very low cost. Parts used are leaves, root, oil, seeds etc. Seeds contain higher amount of mucilage, dimeric imidazole alkaloids lepidine B, C, D, E and F and two new monomeric imidazole alkaloids semilepidinoside A and B. Mucilage of *Lepidium sativum* has various characteristic like binding, disintegrating, gelling etc. [25].

*Gum karaya* - *Gum karaya* is a negative colloid and a complex polysaccharide of high molecular weight. On hydrolysis it yields galactose, rhamnose and galacturonic acid. *Gum karaya* occurs as a partially acetylated derivative. It is a dried exudation of *Sterculia urens* tree (Family-Sterculiaceae). Its synonyms are Karaya, sterculia, Indian tragacanth, Bassora tragacanth, kadaya, Kadira, katila. *Gum karaya* is compatible with other plant hydrocolloids as well as proteins and carbohydrates [26-28].

Fanugreek Seed Mucilage – *Trigonella foenum* graceum, commonly known as Fenugreek, is an herbaceous plant of the leguminous family. It has found wide applications as a food, a food additive, and as a traditional medicine. The leaves and both the ripe and unripe seeds of *Trigonella foenum* graceum are used as vegetables. Fenugreek has been used in treating colic flatulence, dysentery, diarrhoea, dyspepsia with loss of appetite, chronic cough, dropsy, enlargement of liver and spleen, rickets, gout, and diabetes. It is also used as gastro protective, antiurolithiatic, diuretic, antidandruff agent, Anti-inflammatory agent and as antioxidant. The seed is stated to be a tonic. It also is used in post-natal care and to increase lactation in nursing mothers. Fenugreek seeds contain a high percentage of mucilage (a natural gummy substance present in the coatings of many seeds). Although it does not dissolve in water, mucilage forms a viscous tacky mass when exposed to fluids. Like other mucilage-containing substances, fenugreek seeds swell up and become slick when they are exposed to fluids. The resulting soft mass is not absorbed by the body, but instead passes through the intestines and triggers intestinal muscle contractions [29,30].

**Table 1. Application of Various Mucilage**

<table>
<thead>
<tr>
<th>Mucilage</th>
<th>Drug</th>
<th>Approach Used</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Lepidium sativum</em></td>
<td>Nimesulide</td>
<td>Direct compression</td>
<td>Disintegration time of 17 sec. and mean dissolution time 5.27 sec. at 10% w/w concentration, found better than other synthetic disintegrants like Ac-di-sol and SSG.</td>
</tr>
<tr>
<td><em>Plantago ovata</em> mucilage</td>
<td>Prochlorperazine maleate</td>
<td>Direct compression</td>
<td>Dispersion time of 8 sec. at concentration of 8% w/w</td>
</tr>
<tr>
<td><em>Hibiscus rosa-sinensis</em></td>
<td>Aceclofenac</td>
<td>Direct compression</td>
<td>At concentration of 6% w/w showed disintegration time of 20 sec.</td>
</tr>
<tr>
<td>Linn. mucilage powder</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fenugreek seed mucilage</td>
<td>Metformin hydrochloride</td>
<td>Direct compression</td>
<td>It shows 15.6 sec. disintegration time and 100% drug release within 18</td>
</tr>
</tbody>
</table>
Guar gum - Guar gum is a galactomannan, commonly used in cosmetics, food products and in pharmaceutical formulations. Guar gum is mainly consisting of the high molecular weight (approximately 50,000-8,000,000) polysaccharides composed of galactomannans and is obtained from the endosperm of the seed of the guar plant, *Cyamopsis tetragonoloba* (L) Taub. (Synonym- *Cyamopsis psoraloides*). It is used as thickener, stabilizer and emulsifier, and approved in most areas of the world (e.g. EU, USA, Japan, and Australia) [31]. Its synonyms are Galactosol; guar flour; jaguar gum; meprogat; meyprodor. It has also been investigated in the preparation of sustained release matrix tablets in the place of cellulose derivatives such as methylcellulose. In pharmaceuticals, Guar gum is used in solid dosage forms as a binder and disintegrant, and in oral and topical products as a suspending, thickening, and stabilizing agent, and also as a controlled release carrier. Guar gum has also been examined for use in colonic drug delivery [32, 33].

**Cassia fistula gum** - Seeds of *Cassia fistula* gum obtained from *Cassia fistula* tree. Gum obtained from the seeds of *Cassia fistula* comprises β-(1→4) linked d-mannopyranose units with random distribution of α (1→6) linked d-galactopyranose units as side chain having mannose:galactose ratio of 3.0). Carboxymethylation as well as carbamoylethylcation 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 superdisintegrant in the formulation development of FDT [34].

**Locust bean gum** - Locust bean gum is extracted from the endosperm of the seeds of the carob tree *Ceretonia siliqua*, which grows in Mediterranean countries. It is also called Carob bean gum. Some other familiar polysaccharides are starch and cellulose, which are made up of long chains of the sugar glucose. In locust bean gum, the ratio of mannose to galactose is higher than in guar gum, giving it slightly different properties, and allowing the two gums to interact synergistically so that together they make a thicker gel than either one alone. It shows as a binder and as a disintegrant property at different concentration. Pharmaceutical application of locust bean gum is in various novel drug delivery systems. Locust bean gum has been widely used in food industry as a thickening and gelling agent. Locust bean gum has also been reported to have bioadhesive and solubility enhancement properties. There are various reports that Locust bean gum can be used in pharmaceutical and biotechnological purpose [35, 36].

**Hibiscus rosa-sinensis Linn Mucilage** - *Hibiscus rosa-sinensis* Linn of the Malvaceae family is also known as the shoe-flower plant, China rose, and Chinese hibiscus. The plant is available in India in large quantities and its mucilage has been found to act as a superdisintegrant. The plant contains cyclopropanoids, methyl sterculate, methyl-2-hydroxysterculate, 2-hydroxysterculate malvate and β-rosasterol. The leaves contain carotene (7.34 mg/100 g of fresh material) moisture, protein, fat, carbohydrate, fibres, calcium, and phosphorus. Mucilage of *Hibiscus rosa-sinensis* contains L-rhamnose, D-galactose, D-galactouronic acid, and D-glucuronic acid [37].

**Mango Peel Pectin** - Dried mango peel powder is used for extracting pectin. Rather mango peel pectin cannot be used for promising the behaviour of superdisintegrants, but due to its good swelling index and good solubility in biological fluids it can be used to prepare fast dispersible tablets [38].

Table 2. Biological source of some natural Superdisintegrants

<table>
<thead>
<tr>
<th>Natural Superdisintegrants</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plantago ovata Seed Mucilage</td>
<td>Seed of <em>Plantago ovata</em></td>
</tr>
<tr>
<td>Lapidium sativum mucilage</td>
<td>Seed of <em>Lapidium sativum</em></td>
</tr>
<tr>
<td>Gum karaya</td>
<td>Dried exudation of <em>Sterculia urens</em> tree.</td>
</tr>
<tr>
<td>Fanugreek Seed Mucilage</td>
<td>Seeds of Fenugreek, <em>Trigonella foenum graceum</em> L</td>
</tr>
<tr>
<td>Guar gum</td>
<td>Seed of the guar plant, <em>Cyamopsis tetragonaloba</em></td>
</tr>
<tr>
<td>Cassia fistula gum</td>
<td>Seed of <em>Cassia fistula</em> tree</td>
</tr>
<tr>
<td>Locust Bean Gum</td>
<td>Seed of Carob tree <em>Ceretonia siliqua</em></td>
</tr>
<tr>
<td>Hibiscus rosa-sinensis Linn Mucilage</td>
<td>Fresh Leaves of <em>Hibiscus rosa-sinensis</em> Linn</td>
</tr>
</tbody>
</table>

**SYNTHETIC SUPERDISINTEGRANTS**

A group of superdisintegrants including croscamelllose sodium (Ac-Di-Sol) sodium starch glycolate (Primojeland Explotab) and crospovidone (Polyplasdone XL) alleviate most of these problems. Use of the superdisintegrants in fast dispersible tablet is possible as tablet shows optimum physical properties [39].

**Advantages of Synthetic Superdisintegrants**

- Effective in lower concentrations than starch.
- Less effect on compressibility and flow ability.
- More effective intragranularly [40]

**Sodium Starch Glycolate: (Explotab, Primogel)** - Sodium starch glycolate is widely used in oral pharmaceuticals as a disintegrant in capsule and tablet formulations. It is recommended to use in tablets prepared by either direct-compression or wet-granulation processes. The recommended concentration in a formulation is 2-8%, with the optimum concentration about 4% although in many cases 2% is sufficient. Disintegration occurs by rapid uptake of water followed by rapid and enormous swelling. The disintegrant efficiency of sodium starch glycolate is unimpaired in the presence of hydrophobic excipients, such as lubricants unlike many other disintegrants. Increasing the tablet compression pressure also appears to have no effect on disintegration time. These are modified starches with dramatic disintegrating properties and are

available as explotab and primogel which are low substituted carboxy methyl starches. Explotab consists of granules that absorb water rapidly and swell. The mechanism by which this action takes place involves rapid absorption of water leading to an enormous increase in volume of granules result in rapid and uniform disintegration. The natural predried starches swell in water to the extent of 10-20 percent and the modified starches increase in volume by 200-300 percent in water [41].

**Cross-linked polyvinylpyrrolidone:** Crospovidone (crosopovidone, Polyplasdone XL, XL 10) quickly wicks saliva into the tablet to generate the volume expansion and hydrostatic pressures necessary to provide rapid disintegration in the mouth. Unlike other superdisintegrants, which rely principally on swelling for disintegration, Crospovidone superdisintegrants use a combination of swelling and wicking. When examined under a scanning electron microscope, crospovidone particles appear granular and highly porous. This unique, porous particle morphology facilitates wicking of liquid into the tablet and particles to generate rapid disintegration. Due to its high crosslink density, crospovidone swells rapidly in water without gelling. Other superdisintegrants have a lower crosslink density and, as a result, form gels when fully hydrated, particularly at the higher use levels in ODT formulations. Swells very little and returns to original size after compression but act by capillary action [42-44].

Unlike other superdisintegrants, which rely principally on swelling for disintegration, Polyplasdone disintegrants use a combination of mechanisms to provide rapid disintegration. Although Polyplasdone polymers swell by 95% to 120% upon contact with water, swelling is not the only mechanism for tablet disintegration. Swelling or swell volume is mainly a measure of the change in volume of the disintegrant after it is introduced to an aqueous solution and the system has reached equilibrium. However, swell volume does not measure the rate at which a disintegrant absorbs water and swells or the pressure generated by swelling. Polyplasdone polymers, with their porous particle morphology rapidly absorb water (wicking) via capillary action. As the deformed polyplasdone particles come in contact with water that is wicked into the tablet, the polyplasdone particles recover their normal structure and then swell, resulting in rapid volume expansion and high hydrostatic pressures that cause tablet disintegration [45].
Modified Cellulose (croscarmellose sodium, Ac-Di-Sol)

Croscarmellose sodium is described as a cross-linked polymer of carboxy methyl cellulose (CMC). This polymer is different in synthesis and structure as compare to Sodium starch glycolate. Most importantly, the degree of substitution using Williamson’s ether synthesis of croscarmellose sodium is higher than that of sodium starch glycolate, and the mechanism of cross linking is also different. The chemistry of SSG is different that of cross carmellose sodium as some of the carboxymethyl groups themselves are used to cross-link the cellulose chains. For example, the cross-linking in Primogel are phosphate ester rather than carboxyl ester links as compare to Croscarmellose sodium at concentrations up to 5% w/w may be used as a tablet disintegrant, although normally 2% w/w is used in tablets prepared by direct compression and 3% w/w in tablets prepared by a wet-granulation process [46-48].

Resins - Resins although insoluble, have great affinity for water and hence, act as disintegrant. Moreover, because of their smaller particle size the rate of swelling is high making them superdisintegrant. Like conventional disintegrant, they don’t lump but additionally impart strength to the tablets. The use of ion exchange resins into drug delivery systems have been encouraged because of their physicochemical stability, inert nature, uniform size, spherical shape assisting coating and equilibrium driven reproducible drug release in ionic environment. Ion exchange resins are insoluble polymers that contain acidic or basic functional groups and have the ability to exchange counter-ions within aqueous solutions surrounding them. Drug molecules attached to the resins are released by appropriate charged ions in the gastrointestinal tract, followed by diffusion of free drug molecules out of the resins as shown below.

\[
\text{Resin-Drug}^+ + \text{X}^+ \rightarrow \text{Resin}^- + \text{X}^+ + \text{Drug}^+ \quad (1)
\]
\[
\text{Resin}^+ + \text{Drug}^- + \text{X}^- \rightarrow \text{Resin}^- + \text{X}^- + \text{Drug}^+ \quad (2)
\]

Where, X and Y are ions in the gastrointestinal tract [49-50].
Table 3. Characteristic of synthetic superdisintegrant

<table>
<thead>
<tr>
<th>Synthetic superdisintegrant</th>
<th>Properties</th>
<th>Effective concentration for disintegrants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crospovidone</td>
<td>It is completely insoluble in water. Rapidly disperses and swells in water. Greatest rate of swelling compared to other disintegrants. Greater surface area to volume ratio than other disintegrants. Available in micronized grades if needed for improving state of dispersion in the powder blend. Swelling index- 58±1.5% v/v.</td>
<td>It is used in the range of 1-3% w/w.</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>It is insoluble in water, although it rapidly swells to 4-8 times its original volume on contact with water. Specific surface area- 0.81-0.83 m$^2$/g. Swelling index- 65±1.7% v/v.</td>
<td>It may be used as a tablet disintegrant at concentration up to 5% w/w, although normally 2% w/w is used in tablets prepared by direct compression and 3% w/w in tablets prepared by wet-granulation process.</td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>Absorbs water rapidly, resulting in swelling up to 6%. High concentration causes gelling and loss of disintegration. Swelling index- 52±1.2% v/v.</td>
<td>It is used in the range of 4-6%. Above 8%, disintegration times may actually increase due to gelling and its subsequent viscosity producing effects</td>
</tr>
<tr>
<td>Polacrilin Potassium</td>
<td>No lump formation after disintegration. High compatibility with excipients and common therapeutic</td>
<td>Used as a tablet disintegrant and as a taste masking agent for various drugs.</td>
</tr>
</tbody>
</table>
CONCLUSION

An oral solid dosage form should ideally disperse into the primary particles from which it was prepared. Tablets and capsules which need rapid disintegration, the inclusion of the right disintegrant is a prerequisite for optimal bioavailability. Superdisintegrants are used to improve the efficacy of solid dosage forms. This is achieved by decreasing the disintegration time which in turn enhances drug dissolution rate. Disintegrants are substances or mixture of substances added 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 superdisintegrants which are being used in the formulation to provide the safer, effective drug delivery with patient's compliance.

It was concluded from the above study that Natural and synthetic superdisintegrants both have better effects on fast dissolving tablets. Fast Dissolving tablets prepared by direct compression methods using natural superdisintegrants in different combination. Natural superdisintegrants are preferred over synthetic superdisintegrants as they are nontoxic, easily available at low cost used in low concentration and as they are naturally extracted provide nutritional supplement. The objectives behind addition of disintegrants are to increase surface area of the tablet fragments and to overcome cohesive forces that keep particles together in a tablet. Disintegrants expand and dissolve when wet causing the tablet to break apart in the digestive, releasing the active ingredients for absorption. They ensure that when the tablet is in contact with water, it rapidly breaks down into smaller fragments, thereby facilitating dissolution until fairly recently, starch was the only Excipient used as a disintegrant. Rapidly disintegrating dosage forms have been successfully commercialized by using various kinds of superdisintegrants.

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