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Review Article

POLYMERS IN FAST DISINTEGRATING TABLETS – A REVIEW

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ABSTRACT

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 focus on the safer, effective drug delivery with patient's compliance.
Key words: superdisintegrants, polymers, crospovidone, crosscarmellose sodium.

INTRODUCTION

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 there by 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 behavior. Number of factors affects the disintegration behavior 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 disintegrate action. A disintegrate used in granulated formulation processes can be more effective if used both "intragranularly" and "extragranularly" thereby acting to break the tablet up into granules and having the granules further disintegrate to release the drug substance into solution. However, the portion of disintegrate 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 disintegrate. Since a compaction process does not involve its exposure to wetting and drying, the disintegrate used intragranularly tends to retain good disintegration activity. [1,2]

Mode of addition

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

A. Internal addition (Intragranular)

B. External addition (Extragranular)

C. Partly internal and external.

Properties of superdisintegrants with special emphasis on correlating these functional properties to disintegrate efficiency and drug release rate. Water penetration rate and rate of disintegration force development are generally positively related to disintegrate efficiency in nonsoluble matrix in a direct compression process, drug is blended with a variety of excipients, subsequently lubricated and directly compressed into a tablet. A disintegrate used in this type of formulation, simply has to break the tablet apart to expose the drug substance for dissolution. Most common tablets are those intended to be swallowed whole and to disintegrate and release their medicaments rapidly in the gastrointestinal tract (GIT). The proper choice of disintegrate and its consistency of performance are of critical importance to the formulation development of such tablets. In more recent years, increasing attention has been paid to formulating not only fast dissolving and/or disintegrating tablets that are swallowed, but also orally disintegrating tablets that are intended to dissolve and/or disintegrate rapidly in the mouth. Most prior studies have focused on the function related tries. However, such a positive correlation is not always observed between tablet disintegration time and drug dissolution rate. [3,4]

Mechanism of tablet disintegration [5, 6]

There are four major mechanisms for tablets disintegration as follow:

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.

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 'nonswellable' disintegrants. Guyot-Hermann has proposed a particle repulsion theory based on the observation that nonswelling particle also cause disintegration of tablets.[7] the electric repulsive forces between particles are the mechanism of disintegration and water is required for it.

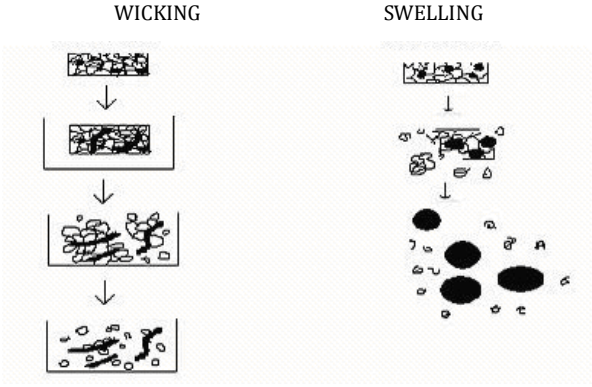


Fig. 1: Steps involved in wicking and swelling

Due to deformation.

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

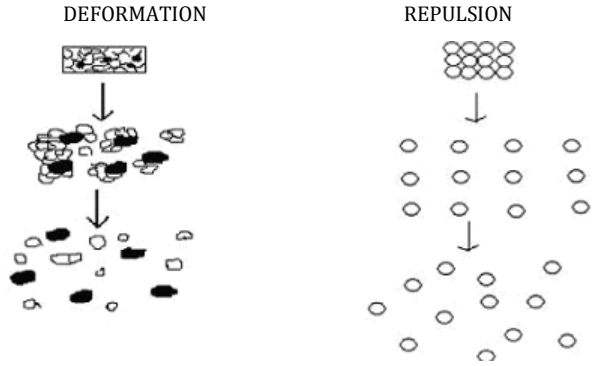


Fig. 2: Steps involved in repulsion and deformation.

Chemical reaction (Acid-Base reaction)

The tablet is quickly broken apart by internal liberation of CO_2 in water due to interaction between tartaric acid and citric acid (acids) with alkali metal carbonates or bicarbonates (bases) in presence of water. The tablet disintegrates due to generation of pressure within the tablet. Due to liberation in CO_2 gas, the dissolution of active pharmaceutical ingredients in water as well as taste masking effect is enhanced. As these disintegrants are highly sensitive to small changes in humidity level and temperature, strict control of environment is required during preparation of the tablets. The effervescent blend is either added immediately prior to compression or can be added in two separate fraction of formulation resulting electrical force.

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, 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.[8]

Factors Affecting Action of Disintegrants [9, 10]

1. Percentage of disintegrate present in the tablets
2. Type of excipients present in the tablets
3. Combination of disintegrants
4. Presence of surfactant
5. Hardness of tablet
6. Nature of drug substance
7. Mixing and Screening

Table 1: Some Examples of Enzymes as a Disintegranting Agent

Enzyme	Binder
Amylase	Starch
Protease	Gelatine
Cellulase	Cellulose and its derivative
	Sucrose
Invertase	

Types of superdisintegrant

- ✓ Natural
- ✓ Synthetic
- ✓ Co-processed

Natural

These are various plant based material. Plant based material serve as an alternative to synthetic products because of following reasons

- ✓ Local accessibility
- ✓ Eco-friendly
- ✓ Bio-acceptable
- ✓ Renewable source and low price as compared to synthetic products

1. Lepidus sativum

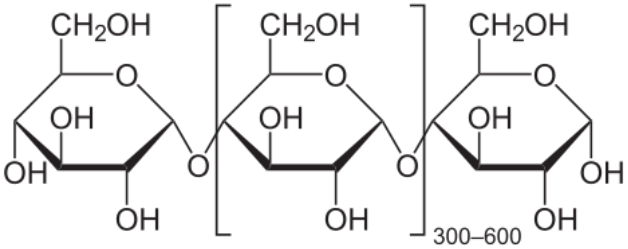
K.Metha *et al* developed fast dissolving tablets of Nimesulide using natural *Lepidium sativum* (family: Cruciferae) known as asaliyo and widely used as herbal medicine and pharmaceutical excipient as disintegrating agent. The mucilage was extracted from seeds of *Lepidium sativum* and was used to develop the fast dissolving tablet of Nimesulide. The extracted mucilage was characterized for weight loss on drying, particle size, pH of solution, swelling ratio, bulk and tapped density, compressibility index, viscosity and angle of repose. The disintegration property of extracted mucilage in FDTs was compared with widely used superdisintegrants like Sodium starch glycolate (SSG), kyron T314, Ac Di Sol. The prepared FDTs were evaluated for Uniformity of weight, Hardness, Tablet thickness, percentage friability, Wetting time, *Invitro* disintegration time and *Invitro* dissolution. From the study, it was concluded that higher dissolution of tablet could be obtained when mucilage concentration is 10% and also the mannitol concentration was 10 %. Promising batch (M5) exhibited better drug dissolution (79.9%) after 30 min than the other tablets. The disintegration and mean dissolution time for batch M5 was 17 sec and 5.27 sec respectively is better than other tablet prepared from other synthetic disintegrating agent.[11, 12]

2. Locust bean gum

M.O.A- swelling and capillary action

Locust bean gum also called as carob bean gum is a galactomannan vegetable gum extracted from the seeds of the Carob tree (*Ceretonia siliqua*), mostly found in the mediterranean regions. 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.[13]

Malik K *et al* carried out formulation and evaluation nimesulide



orodispersible using locust bean gum as superdisintegrant.The gum

was evaluated for powder flow properties, swelling index and loss on drying. Excellent powder flow properties were observed, swelling index was found to be 20 sec. which indicated appreciable capability of locust bean gum to be used as superdisintegrant. The prepared tablets were evaluated against standard superdisintegrant i.e. cross-carmellose sodium. Disintegration time of tablets containing 10 % locust bean gum was found to be 13 second.[14]

3. Isapghula Husk (Plantago ovata)

M.O.A-*Swelling*

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. mucilage of *Plantago ovata* at a concentration of 2 %, is also a good disintegrate having the additional advantage of being natural.[15]

Khinchi *et al* prepared the Orally disintegrating tablet of Fexofenadine HCl (as model drug) by direct compression method using microcrystalline cellulose and mannitol as direct compressible vehicle. These tablets were evaluated for quality control tests like organoleptic characteristics, weight variation, hardness, friability, *in-vitro* disintegration time, *in-vitro* swelling time, drug content and dissolution behavior. Swelling index was also investigated with an aim to compare the swelling property of seed powder, husk powder and mucilage of *Plantago ovata*. Among all the superdisintegrants, *Plantago ovata* mucilage showed the highest swelling index. Hence, the present study revealed that this natural superdisintegrant (*Plantago ovata* mucilage)[16]

Gupta *et al* has investigated the disintegrating property of the *Isapghula husk, Cassia tora* and *Cassia nodsa* and the formulations were evaluated for the standard of dispersible tablets and were compared with the marketed products. The study showed that the natural gums as disintegrants were effective in low (5 %) concenterations. (17)

4. Hibiscus rosa sinesis linn. Mucilage

Hibisicus rosa – sinensis linn. of the *Malvaceae* family is also known as the shoe flower plant, china rose, Chinese hibiscus. The plant is available in Indian in large quantities and its mucilage has been found to act as superdisintegrant. The plant contains cyclopropanoids, methyl sterculate, methyl-2-hydroxysterculate, 2-hydroxysterculate malvate and β-rosasterol. Shah *et al.* prepared orally disintegrating tablets of Acelofenac by direct compression method using mucilage of Hibisicus rosa–sinensis linn.with 6 % w/w concentration, which showed disintegration time of 20 sec. (18,19)

5. Fenugreek seed mucilage

Trigonella foenumgraceum (family Leguminosae), commonly known as fenugreek, is an herbaceous plant of the leguminous in mouth dissolving tablet formulations. Ravi Kumar *et al* prepared fast dissolving tablets of metformin HCL using different concentration of (2 – 10 % w/w) natural disintegrate viz; isolated mucilage of fenugreek seed and synthetic superdisintegrant like croscarmellose sodium and were compared. Fenugreek mucilage in concentration of 4 % give shorter disintegration time of 15 sec. studies indicated that the extracted mucilage is a good Pharmaceutical adjuvant, specifically a disintegrating agent.[20]

6. Cucurbita maxima pulp powder

Malviya Rishabha *et al* carried out preparation and evaluation of disintegrating properties of cucurbita maxima pulp powder. Dispersible tablets of Diclofenac sodium were prepared with different concentrations viz; 2.5, 5, 7.5 and 10 % (w/w) of cucurbita maxima pulp powder and sodium starch glycolate, and evaluated for physical parameters such as thickness, hardness, friability, weight variation, drug content, disintegration time and drug dissolution. The formulated tablets had good appearance and better drug release properties. Studies indicated that the cucurbita maxima pulp powder is a good pharmaceutical adjuvant, specifically a disintegrating agent.[21]

7. Ocimum americanum seed mucilage

Patel *et al* studied seed mucilage from *Ocimum americanum* linn. as disintegrate in tablets using propranolol hydrochloride as a model drug .The separated mucilage was evaluated for its performance as disintegrate in tablets at various concentrations (2, 4, 6, 8, 10, 12%w/w) and the optimum concentration found was 10%w/w. Its performance was compared with starch at optimum concentration and it was found better than starch in tablet formulations with less disintegration time (154 s) compared to that of starch (269 s). The hardness, friability and drug content were within limits. There was no effect of mucilage on drug release from tablets as all the formulations showed more than 90 % drug release at 30 min.[22]

8.Gellan gum (kicogel)

It is an anionic polysaccharide of linear tetra saccharides, derived from *Pseudomonas elodea* having good superdisintegrant property similar to the modified starch and celluloses.

Antony *et al* studied the disintegrate properties of gellan gum and the efficiency of gum was compared with the other conventional disintegrants such as corn starch, explotab, avicel,Ac-di-sol and Kollidon CL.[23]

9. Xanthan gum (Grindsted, xanthansm)

Xanthan Gum derived from *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. [24]

10. Soy polysaccharide (Emcosoy®)

It is a natural super disintegrate that does not contain any starch or sugar so can be used in nutritional products.

11. Chitosan gum Arabic

Rishabha M *et al* investigated the use of Chitosan–Gum Arabic Coacervates as excipient in Fast Dissolving Dosage Form. The aim of present research was to synthesize coacervates of two natural polymers viz. chitosan and gum Arabic, and further coacervates was characterized and evaluated as an excipient in the fast disintegrating dosage form for treatment of chronic epileptic attack. Coacervates were synthesized by mixing of separately prepared solution of chitosan and gum Arabic at controlled temperature. After vacuum drying, coacervates were used as pharmaceutical excipient; moreover they were used in varying ratios to formulate six batches of tablets and evaluated for pre-compression and post compression parameters. The physicochemical evaluation results demonstrate that coacervates had good potential to be used as pharmaceutical excipient. Thus, coacervates may have wide range of applications as polymer in different dosage form. The fast disintegrating tablet dosage forms can be formulated using such coacervates on commercial scale. [25]

Synthetic

Advantages of Synthetic Superdisintegrants [26]:

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

Limitations

- Hygroscopic (may be a problem with moisture sensitive drugs)
- Some are anionic and may cause some slight *in-vitro* binding with cationic drugs (not a problem *in-vivo*).
- An acidic medium significantly reduces the liquid uptake rate and capacity of sodium starch glycol ate and croscarmellose sodium, but not crospovidone.
- The degree of swelling of primojel1 (sodium starch glycol ate) and polyplasdone xl101 (crospovidone) is minimized following wet granulation formulation. Finally, the medium ionic strength was found to have an

adverse effect on the swelling capacity of croscarmellose [27, 28]

1. **Sodium starch glycol ate (primo gel, explotab, tablo, vivastar)**

M.O.A-Swells 7-12 folds in < 30 seconds.

Absorbs water rapidly, resulting in swelling which leads to rapid disintegration of tablets and granules. Recommended concentration 1.0-4 % but may need to use up to 6.0 %. Gels on prolonged exposure to water. High concentration causes gelling and loss of disintegration. It is possible to synthesize sodium starch glycolate from a wide range of native starches, but in practice potato starch is used as it gives the product with the best disintegrating properties. After selection of the appropriate starch source the second step is the cross linking of the potato starch. This is typically carried out using an FDA approved starch esterifying agent such as sodium trimetaphosphate or phosphorus oxychloride in alkaline suspension. The effect of introduction of the large hydrophilic carboxymethyl groups is to disrupt the hydrogen bonding within the polymer structure. This allows water to penetrate the molecule and the polymer becomes cold water soluble. The effect of the cross linking is to reduce both the water soluble fraction of the polymer and the viscosity of dispersion in water. The optimum balance between the degree of substitution and the extent of cross-linking allows for rapid water uptake by the polymer without the formation of a viscous gel that might impede dissolution.[29]

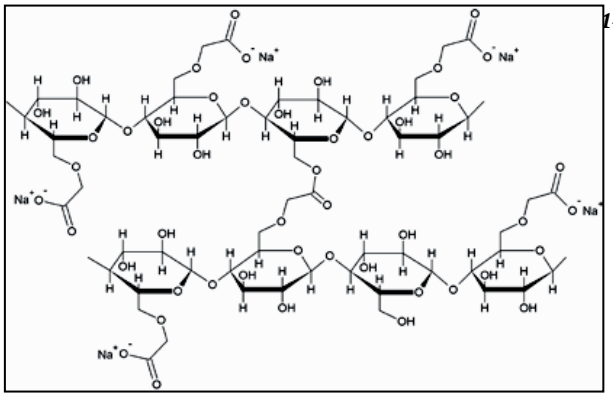
2. Croscarmellose sodium (AC-Di-Sol, nymce ZSX, primellose, vivasol, solutab)

M.O.A- Swells 4-8 folds in < 10 seconds. Swelling and wicking both.

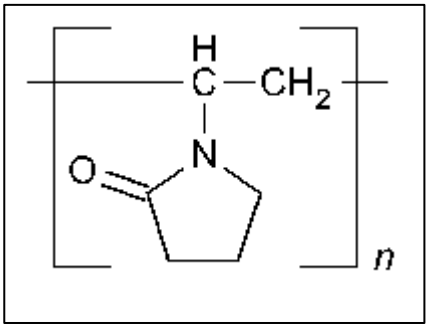
High swelling capacity, effective at low concentration (0.5-2.0 can be used up to 5.0%) Croscarmellose sodium is described as a cross-linked polymer of carboxymethylcellulose. Apart from the differences between the starch and cellulose polymer backbones, there are Differences between the synthetic processes used to modify the polymer. Most importantly, the DS of croscarmellose sodium is higher than that of sodium starch glycolate, and the mechanism of cross-linking is different. The substitution is performed using Williamson's ether synthesis to give the sodium salt of carboxy-methylcellulose. A key difference from the chemistry of sodium starch glycolate is that some of the carboxy-methyl groups themselves are used to cross-link the cellulose chains, the process being accomplished by dehydration. Thus the cross-links are carboxyl ester links rather than phosphate ester links as in Primojel. [30]

3. Cross-linked polyvinylpyrrolidone (crospovidone, polyplasdone XL, polyplasdone XL 10, kollidon CL)

M.O.A- Swells very little and returns to original size after compression but act by capillary action. Recommended concentration 1 to 3%. Available in micronized grades if needed to improve uniform dispersion in the powder blend. Crospovidone 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 superdisintegrant 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 orally disintegrating tablet formulations. Unlike other superdisintegrants which are either poorly compressible or non-compressible, crospovidone disintegrants are highly compressible materials as a result of their unique particle morphology. In contrast to sodium starch glycolate and croscarmellose sodium, crospovidone superdisintegrant exhibit virtually no tendency toward gel formation, even at high use levels. Disintegrants that gel can result in orally disintegrating tablet and chewable products with an



unpleasant, gummy texture. Crospovidone superdisintegrant provide the best overall sensory experience as well as rapid disintegration and robust tablets.[31]



4. Micro crystalline cellulose MCC (Avicel 102)

M.O.A- allowing water to enter the tablet matrix by means of capillary pores, which break the hydrogen bonding between adjacent bundles of cellulose microcrystals and exhibit very good disintegrant property.

Microcrystalline cellulose is partially depolymerised cellulose prepared from alpha cellulose. Microcrystalline cellulose for direct compression tabletting comes in a number of grades like PH101 (original product) & PH 102 (more agglomerated, large particle size with better fluidity).When compressed, the MCC particles are deformed plastically due to the presence of slip planes & dislocation. A strong compact is formed due to the extremely large number of clean surfaces brought in contact during plastic deformation & the strength of hydrogen bonds formed. Here Avicel 102 used as diluent cum disintegrant. The mechanism of Avicel 102 is interlocking .The particle size of Avicel 102 is small. The decrease in particle size increases binding strength and decreases disintegration time so here we used Avicel 102. MCC is found in the concentration of 10-25 % as a filler, binder, disintegrant. The MCC is effective as a binder in direct compression. Its binding advantages in granulation decrease with an increase in water addition. MCC is useful as a disintigrant when used in proportion of at least 5-15%. The disintegration time of tablets of cation exchange resin was reduced significantly in the presence of MCC.[32]

5. Low-substituted hydroxypropyl cellulose (L-HPC)

It is preferable in wet granulation and directly compressed tablets. Larger particle size and higher hydroxypropyl content show higher degree of swelling. It is useful to prevent capping. Now a day it is widely used as a super-disintegrate in fast dissolving tablets. Bi *et al* and Watanabe *et al* used microcrystalline cellulose and Low substituted hydroxy propyl cellulose (L-HPC) as disintegrant to prepare rapidly disintegrating tablets. Ratio of the MCC and L- HPC was in the range of 8: 2 – 9: 1 resulted in tablets with shortest disintegration time. (33, 34)

6. Partially Pregelatinized Starch (PPG Starch,Starch 1500, Colorcon)

Pregelatinized starch is a directly compressible form of starch consisting of intact and partially hydrolyzed ruptured starch grains. Pregelatinized starch has multiple uses in formulations as a binder, filler and disintegrant. As a disintegrant, its effective concentration is

between 5-10%. Its major mechanism of action as disintegrant is thought to be through swelling. The PPG starch improved the tablet's physical properties and dissolution properties with fewer processing steps, leading to a less complex formulation and dramatically lower costs. The PPG starch based formula produce more robust tablets, with higher hardness and with lower friability. The PPG Starch based formula produced a more rapid release of the drug. In addition, the PPG starch formula produced a lower vessel to vessel variation in the percent of drug released.

Amylose has a straight-chain molecular structure, which exhibits a very strong intermolecular bonding capability. Amylose swells significantly when wetted, giving it excellent disintegrating characteristics.[35]

7. Cross-linked alginic acid (Alginic acid NF)

M.O.A - Rapid swelling in aqueous medium or wicking action.

It is insoluble in water and disintegrates by swelling or wicking action. It is a hydrophilic colloidal substance, which has high sorption capacity. It is also available as salts of sodium and potassium.

8. Calcium Silicate

M.O.A - Wicking action.

It is a highly porous, light weight superdisintegrant, which acts by wicking action.

9. Ion exchange resins (indion 414, Tulsion 339, Amberlite IRP 88)

M.O.A-Swelling action

The INDION 414 has been used as a superdisintegrant for ODT. It is chemically cross-linked polyacrylic, with a functional group of – COO – and the standard ionic form is K^+. It has a high water uptake capacity. It is a high purity pharmaceutical grade weak acid cation exchange resin supplied as a dry powder. It is an extremely effective tablet disintegrant which provides the necessary hardness and chemical stability to the tablet. The product swells up to a very great extend when in contact with water or gastrointestinal fluids causing rapid disintegration without the formation of lumps. It is a high molecular weight polymer, therefore it is not absorbed by the human tissues and totally safe for human consumption.

10. Chitin and Chitosan

M.O.A-Swelling

Moisture absorption and water uptake was found the major mechanism of disintegration while dissolution related to swelling capacity. [36, 37]

Co-processed superdisintegrants

Co-processing is based on the novel concept of two or more excipients interacting at the sub particle level, the objective of which is to provide a synergy of functionality improvement as well as masking the undesirable properties of individual5. Co-processing excipients lead to the formulation of excipient granules with superior properties, compared with physical mixtures of components or individual components, like improved flow properties, improved compressibility, better dilution potential, fill weight uniformity, and reduced lubricant sensitivity. Several co-processed superdisintegrants are commercially available: (38)

- ✓ 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)
- ✓ Ludiflast (mannitol, crospovidon, and polyvinyl acetate)

M C Gohel *et al* carried out preparation and assessment of novel co processed superdisintegrants containing crospovidone and sodium starch glycolate. The use of co processing is a totally unexplored avenue in disintegrants. The widely used superdisintegrants are sodium starch glycolate, crospovidone, and croscarmellose sodium. Like diluents, each superdisintegrant has strengths and weaknesses. In the present investigation, the preparation and evaluation of co processed disintegrate containing crospovidone and sodium starch glycolate was explored. Moreover, the rate and extent of liquid uptake and swelling of crospovidone (Polyplasdone XL 10) are not reduced in 0.1 N hydrochloric acid when compared with aqueous medium. The aqueous medium (water) represents disintegration medium and 0.1 N HCl represents gastric environment. Sodium starch glycolate was chosen because of its high swelling capacity. Moreover, the disintegrate efficiency of sodium starch glycolate is unimpaired by the presence of hydrophobic excipients such as lubricants. Sodium starch glycolate exhibits good flow (angle of repose <36º). The bulk density of crospovidone and sodium starch glycolate is 0.4 and 0.756 g/cm^3, respectively. Hence, if a physical mixture of superdisintegrants is used in high-speed tableting, the problem of segregation of the disintegrants may be encountered. One of the reasons for preparing the co processed superdisintegrant was to avoid the problem of segregation. A blend of swelling and wicking types of excipient may also prove to be efficient because the medium (usually water) required for swelling will be brought into the tablet more easily if a wicking (hydrophilic) type of superdisintegrant is also present.[39]

Shirsand *et al* carried out preparation and evaluation fast dissolving tablets of metaclopramide using novel co-processed superdisintegrant**.** In the present study, novel co-processed superdisintegrants were developed by 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.[40]

Selecting the superdisintegrant

Although the superdisintegrant primarily affects the rate of disintegration, when used at high levels it can also affect mouth feel, tablet hardness, and friability. Thus, several factors must be considered when selecting a superdisintegrant.

Disintegration. The disintegrant must quickly wick saliva into the tablet to generate the volume expansion and hydrostatic pressures necessary to provide rapid disintegration in the mouth.

Compact ability. When manufacturing an ODT, it is desirable to have tablets with acceptable hardness at a given compression force to produce robust tablets that avoid the need to use specialized packaging while maximizing production speed. Thus, a more compactable disintegrant will produce stronger, less-friable tablets.

Mouth feel. To achieve patient compliance, ODTs must provide a palatable experience to the patient. Large particles can result in a gritty feeling in the mouth. Thus, small particles are preferred. If the tablet forms a gel-like consistency on contact with water, however, it produces a gummy texture that many consumers find objectionable.

Flow. As with all direct compression tablet formulations, attaining good flow and content uniformity is important to achieving the required dosage per unit. In typical tablet formulations, superdisintegrants are used at 2–5 % weight of the tablet formulation. With ODT formulations, disintegrant levels can be significantly higher. At these higher use levels, the flow properties of the disintegrant are more important because it makes a greater contribution to the flow characteristics of the total blend each formulation batch.

CONCLUSION

Disintegrants, an important excipient of the tablet formulation, are always added to tablet to induce breakup of tablet when it 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 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. To be effective, corn starch has to be used in concentrations of between 5-10 %. Below 5 %, there is insufficient "channels" available for wicking (and subsequent swelling) to take place. Above 10%, the incompressibility of starch makes it difficult to compress tablets of sufficient hardness. Although the connection between bioavailability of drug and tablet disintegration took some time to become appreciated, it is now accepted that the role of the disintegrant is extremely important.

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