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"Superdisintegrants used in Tablet"

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ABSTRACT:
One of the tablet excipients that are added to a pharmaceutical formulation to make it disintegrate is called a disintegrant. Disintegrants facilitate moisture penetration while allowing the tablet matrix in dispersing. Superdisintegrants are very effective disintegrants that, in contrast to disintegrants, allow quick disintegration at lower concentrations. They typically function by adsorbing water and swelling up. Tablets and capsules can both use superdisintegrants to provide the rapid disintegration. Combinations of swelling, wicking and deformation are among the mechanisms of superdisintegrant action. The present study comprises the various kinds of superdisintegrants which are being used in the various formulations and also describes factors which could affect the functionality of superdisintegrants such as molecular and physicochemical factors.

KEYWORDS: Superdisintegrant; Sodium starch glycolate; Croscarmellose sodium; Crospovidone; Disintegration dissolution; Wicking; Deformation

I. CHAPTER: I

INTRODUCTION:

Disintegrants are one of the tablet excipients that are added to a pharmaceutical preparation to make it disintegrate and thus release the active ingredient on contact with water. By doing this, the tablet will be broken into small particles that dissolve more quickly. Disintegrants help the tablet matrix dispersion and allow for moisture penetration[1,2].

The tablet is the most widely used dosage form now in use due to its ease of self-administration, compactness, and easy manufacture. Tablet disintegration has received a lot of interest as a necessary step for achieving rapid drug release. To overcome the challenges of patient compliance, many attempts have been undertaken to produce rapid disintegrating tablets. Over the past 10 years, there has been an increase in the need for more patient-friendly and compliant dosage forms. Superdisintegrants can be used in both tablets and capsules to produce the fast disintegration [3]. The mechanisms of disintegrant action include combinations of swelling, wicking and deformation[4].

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

1. Internal Addition (Intra-granular)
2. External Addition (Extra-granular)
3. Partly Internal and External.

In a procedure of direct compression, the drug is mixed with a number of excipients and disintegrants before being lubricated and directly compacted into a tablet. Superdisintegrants, which are very efficient disintegrants that generally work by adsorbing water and swelling up, are those compounds that, in comparison to disintegrants, allow rapid disintegration with smaller concentrations [5].

Due to the importance of disintegration in the production of solid orals, formulators are interested in selecting the appropriate disintegrants and superdisintegrants for dosage forms. The design characteristic of a fast-dissolving tablet can be achieved by selecting the appropriate formulation excipients and manufacturing technology. The primary purpose of the disintegrants is to counter the effectiveness of the tablet binder and the physical forces that work during compression to create the tablet [6].Thus, superdisintegrants must have the following characteristics:

- Able to stay hydrated
- Poor solubility
- Good hydration capacity
- Flow qualities are excellent.
- Good tableting consistency
- Ineffective gel formation
- Excellent mouth feel
- Good compressibility
- Non-toxic

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Synthetic superdisintegrants (Crosslinked PVP, Sodium starch Glycolate) are mainly used in tablet formulations. However, certain demerits of synthetic superdisintegrants are seen in some cases. Thus, natural superdisintegrants (Guar gum, Aloe vera mucilage) are commonly used.Thus, this article provides an overview of key factors affecting performances of superdisintegrants in the tablet formulations in pharmaceutical industry [7].

II. CHAPTER: II

Classification Of Superdisintegrants:

Superdisintegrants can be classified on the basis of their source of origin:

A. Synthetic superdisintegrants
B. Natural superdisintegrants
C. Co-processed superdisintegrants

Synthetic superdisintegrants:

Synthetic superdisintegrants are generally used in tablet formulations to accelerate up the rate of drugs disintegration. These superdisintegrants improve speed of the disintegration process, improve the dissolution and solubility. Crospovidone (crosslinked PVP), Crosslinked Cellulose (croscarmellose sodium), Soy Polysaccharides, Chitin and Chitosan and Sodium Starch Glycolate are some of the most commonly used synthetic superdisintegrants[8].

Natural superdisintegrants:

Biologically derived and widely utilized in tablet formulation, natural superdisintegrants accelerates tablets disintegration. The main purpose of these superdisintegrants is to overcome the disadvantages of synthetic superdisintegrants. Some commonly used Natural superdisintegrants are Plantagoovatahusk, Ocimumtenuiflorum, Aloe vera mucilage, Hibiscus rosa-sinensis, Lepidiumsativum, Mangifera indica pectin, guar gum etc[9].

Co-processed superdisintegrants:

To meet the specifications of industrial tablet manufacturing, new, enhanced superdisintegrants were being developed, that provide formulations with desired results. Some co-processed excipients blends were Ludipress, StarLac and Ludiflashetc[10].

Some of the commonly used super disintegrants are:

1. Modified Starches: Sodium Starch Glycolate

These are granular forms of low substituted carboxymethyl starches. However a wide variety of native starches can be used to manufacture sodium starch glycolate, potato starch has been produced since this resulting in a product with the best disintegration qualities. Rapid water absorption leads to a significant increase in granule volume, which allows them to disintegrate rapidly and uniformly. These superdisintegrants exhibit the disintegration of solid dosage form within two minutes when added in formulations. Superdisintegrants could have greater disintegration rates because of their quick breakdown and fine dispersal of generated particles. The massive hydrophilic carboxymethylgroup's inclusion has the effect of shattering the hydrogen bonds that are present inside the polymer structure. The polymer becomes soluble in cold water as a result of water to be allowed to penetrate the molecule. Both the polymer's hydrophilicity and the viscosity of its water dispersion are reduced as a result of cross-linking. Rapid water absorption by the polymer is facilitated by the best choice between the extent of substitution and the degree of cross-linking, which prevents the formation of a viscous gel that can obstruct disintegration[11, 12].

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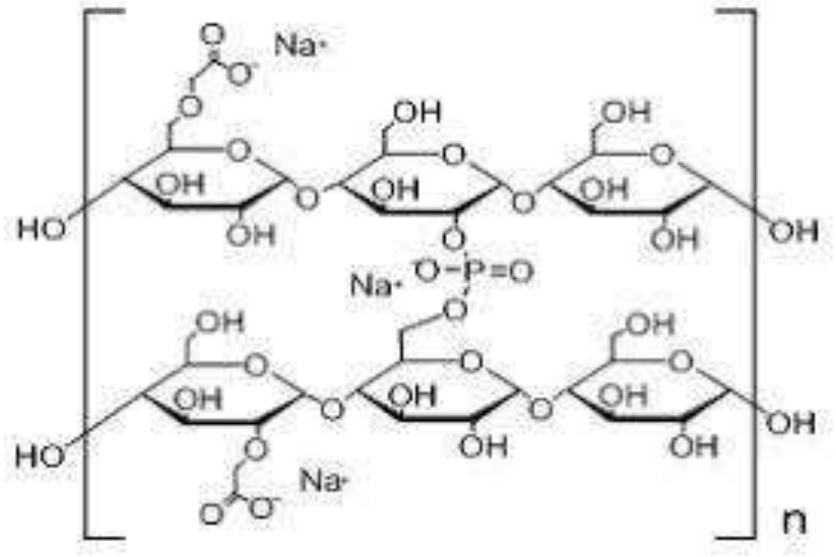

Fig. 2.1Structure of Sodium Starch Glycolate

2. Cross-linked Polyvinylpyrrolidone: Crospovidone

In order to achieve the volume expansion and hydrostatic pressures required for fast disintegrating in the mouth, crospovidone rapidly draws saliva into the tablet. Crospovidonesuperdisintegrants utilize a mixture of swelling and wicking, in compared to conventional superdisintegrants that mostly tend to focus on swelling for disintegration. Crospovidone particles appeared granular and very porous under a scanning of electron microscope. This characteristic, porous particle shape makes it simpler for liquid to wick into the tablet and allows the particles to quickly disintegrate. Even though crospovidone has a high crosslink density, it expands quickly in water without gelling. Other superdisintegrants, especially those used at greater concentrations in ODT preparations, have lower crosslink density and as a result, when fully hydrated form gels. Because of their specific particle size and shape, Crospovidonedisintegrants are very compressible materials as compared to other superdisintegrants, which are either incompressible or moderately compressible. Even at significant use levels, Crospovidonesuperdisintegrants show almost zero potential toward gel formation in comparison to sodium starch glycolate and croscarmellose sodium. Gelling disintegrants may lead ODT and chewable medications to have an undesirable gummy texture. The best high quality experience is delivered by crospovidonesuperdisintegrants that also offer quick disintegration and sturdy tablets[13].

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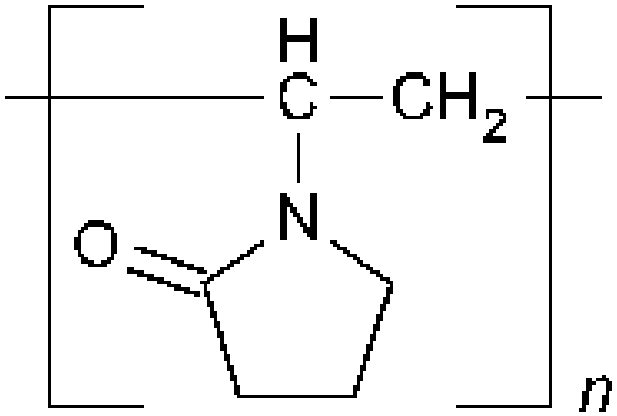

Fig. 2.2 Structure of Crospovidone

3. Modified Cellulose: Croscarmellose sodium

It is said that croscarmellose sodium is a cross-linked carboxymethylcellulose polymer. There are variations in the synthetic techniques utilized to change the polymer in addition to the differences between the starch and cellulose polymer backbones. Most significantly, croscarmellose sodium has a greater degree of substitution than sodium starch glycolate and uses a different cross-linking process. The sodium salt of carboxymethylcellulose is produced by the substituting using Williamson's ether synthesis. The fact that some of the carboxymethyl groups themselves are required to cross-link the cellulose chains, with the activity being performed by dehydration, represents a significant change from the chemistry of SSG. Therefore, rather than phosphate ester linkages as in Primojel, the cross-links are carboxyl ester links[14].

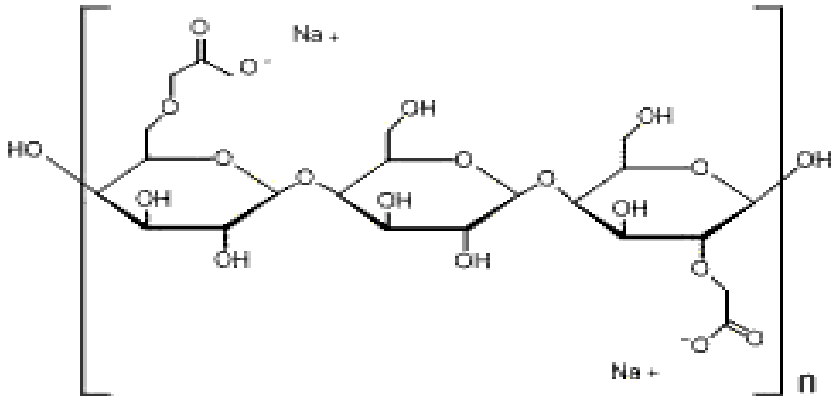

Fig. 2.3 Structure of Croscarmellose Sodium

4. Microcrystalline Cellulose: Avicel

Less than 10% of the Avicel content leads to a better disintegration. This process is based on water entering the tablet matrix through capillary openings, which disrupts the hydrogen bonds holding nearby bundles of cellulose microcrystal together. Due to quick capillary absorption and rapid dehydration of the tablet surface, oral disintegrating tablets, especially, have a tendency to adhere to the tongue when consumed under more concentratedconditions. Because Avicel quickly absorbs water, it performs very well and quickly disintegrates in ODT formulations when combined with starch. As per studies, MCC was used in the study as a disintegrating agent in the manufacturing of fast-releasing compressed propranol hydrochloride suppositories. In order to formulate fast-dissolving tablets, Watanabe

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used microcrystalline cellulose as a disintegrant, with low substituted hydroxypropyl cellulose[15].

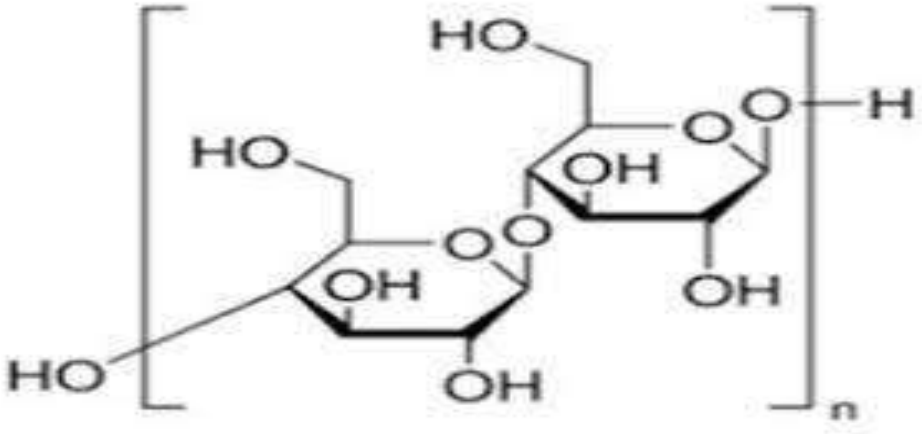

Fig. 2.4 Structure of Avicel

5. Soy polysaccharide:

Soy polysaccharides are the natural super disintegrant which does not compose of any starch or sugar so can be used in nutritional products.

6. Cross-linked alginic acid:

It is insoluble in water and disintegrates by swelling or wicking action.These are hydrophilic colloidal substances extracted naturally from certain species of Kelp or chemically modified from natural sources like alginic acid or salt of alginic acid. They are having higher affinity for water absorption and capable for an excellent disintegrants. It is also available in the form of salts of sodium and potassium. It can be successfully used with ascorbic acid, multivitamins formulation[16].

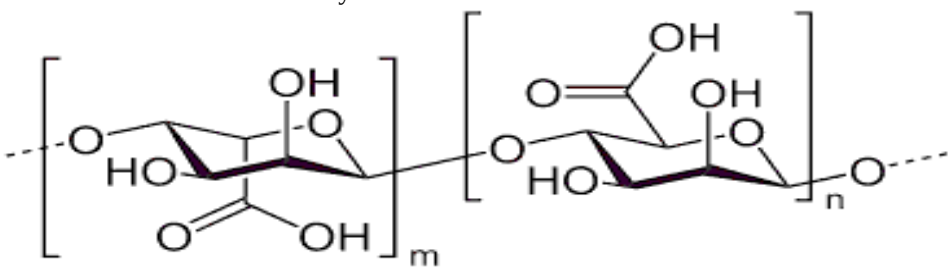

Fig. 2.5 Structure of Alginic Acid

7. Gellan gum:

It is a Pseudomonas elodea derived anionic polysaccharide of linear tetrasaccharides with excellent superdisintegrant properties like modified starch and celluloses.

8. Modified Polysaccharides: Agar and guar gum

Natural polysaccharides that have the superdisintegration characteristic are treated with water and then co-grinded with mannitol. They can be known to as C-TAG (co-grinded treated agar) and C-TGG (co-grinded treated guar gum), respectively, for these modified polysaccharides. They are readily compressible, biodegradable, and have suitable swelling dynamics. The mentioned modified polysaccharides were compared to tablets containing MCC and then utilized as superdisintegrants in Roxithromycin fast disintegrating tablets. Due to their porous nature, greater capability for absorbing water, and free-flowing properties, the C-TAG and C-TGG have exhibited improved disintegration than others. For the manufacturing of disintegrating tablets, karaya gum another natural polysaccharide changed by distilled water to provide superdisintegration properties. In comparison to synthetic superdisintegrants that are already on the market, this modified karaya gum (MKG) is simple to prepare, affordable, easily available, biodegradable and stable[17].

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9. Mucilage of Plantago ovate seed husk:Isapghula

When compared to Crospovidone, the mucilage from Plantagoovata has greater disintegration properties, considering it a recent discovery. Compared to Crospovidone, a superdisintegrant exhibits a quicker disintegration time[18].

10.Chitin/Chitosan:

One of the latest and most interesting categories of superdisintegrants is silicon dioxide co-precipitate chitin. Chitin is collected from the shell wastes of shrimp, crab, lobster, krill and squid and is utilized for the synthesis of Chitosan by a deacetylation reaction in alkaline media. It is the second most common polysaccharide found in nature after cellulose. However, when processing pharmaceutical mixtures on a large scale, both chitin and chitosan powders have low bulk density, which has a poor effect on flowability and compressibility.They may be co-precipitated with colloidal silicon dioxide to improve them to overcome this weakness. The Chitin-silica co-precipitate has greater disintegration and dissolution functionality, based on comparative studies of different superdisintegrants. Chitin-silica shows similar levels of particle rearrangement and plastic deformation as compared to Avicel. Chitin-silica may be allowed in direct compression applications because to its high compressibility and compact ability characteristics. Chitin-silica's hygroscopicity and excessive water capillary penetration serves as the catalyst for disintegration. Chitin-silica capacity to be used as filler in solid dosage forms with no limitations on the superdisintegrants concentration can provide further advantages in pharmaceutical applications[19].

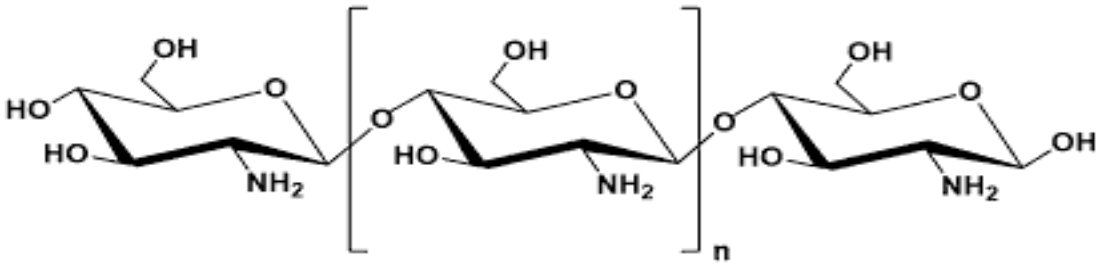

Fig. 2.6 Structure of Chitosan

III. CHAPTER: III

Mechanism Of Tablet Disintegration:

1. Swelling: Swelling is considered to be a technique by which some disintegrating substances (like starch) transfer the disintegrating effect, even though not all effective disintegrants swell in water exposure. The adhesiveness of other components in a tablet is countered by swelling when in contact with water, leading the tablet to break.

2. Porosity and Capillary Action (Wicking): Effective disintegrants are believed to transfer their disintegration effect through porosity and capillary action as they do not swell. Tablet porosity creates routes for fluids to enter tablets. The poor cohesion and compressibility of the disintegrant particles themselves act to improve porosity and provide these entryways into the tablet. By capillary action, liquid is drawn up into or wicked into these routes, where it disrupts the interparticulate linkages that bind the tablet together[20].

3. Deformation: In general, it is thought that starch granules have an "elastic" character, meaning that when pressure is applied, the grains will deform but will immediately return to their original shape. These grains, however, are claimed to be "energy rich" and to be permanently deformed due to the compression forces used in tableting. This energy is expected to be released upon exposure to water. In other words, "energy rich" starch grains have a higher capacity for swelling than do starch grains that have not suffered pressure-induced deformation. Instead, it is most likely the result of the interactions between these important mechanisms[21].

4. Due to disintegrating particle/particle repulsive forces: Another disintegration process allows an attempt to explain why a tablet manufactured with 'nonswellable' disintegrants swells. The mechanism of disintegration is the electric repulsive forces between particles and water is necessary for it. Researchers discovered that wicking comes second to repulsion.

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Superdisintegrants are a novel class of agents that have been discovered in recent years.These more recent compounds have higher mechanical strength and disintegration efficiency, resulting in greater effectiveness at lower concentrations. The superdisintegrants swell, hydrate, modify volume, or take on a different form when in contact with water, which creates a disruptive modification in the tablet. Effective superdisintegrants increase the compressibility and compatibility of formulations containing high-dose medications while having no adverse affects on their mechanical strength. Super disintegrants have material advantages over starch. Hygroscopicity might provide a difficulty in certain formulations. In order to produce disintegrants that are useful at low concentrations, have better disintegration efficiency, and are more effective intra-granularly, pharmacists must produce Superdisintegrants.And these superdisintegrants perform by swelling, which results in pressure being applied in the radial or outer directions, which causes tablets to break or speed up water absorption, which produces a huge rise in granule volume to facilitate disintegration. Three main classes of compounds have been produced that expand significantly when exposed to water while having no impact on viscosity.

IV. CHAPTER: IV

FACTORS AFFECTING THE SWELLING BEHAVIOUR OF SUPERDISINTEGRANTS:

There are various factors which influence the disintegration mechanism of superdisintegrants. The swelling behavior of superdisintegrants is mainly affected by these factors. Due to this, dissolution and bioavailability gets affected. These factors are as follows:

1. pH value: Ionisablegroups of superdisintegrants are mainly affected [22].

2.Binders: The enhancement of disintegration process depends when there is increase in concentration of binders in tablet formulation.

3.Insoluble diluents: The disintegration mechanism of tablets is enhanced when there is appearance of insoluble diluents in tablet formulation. For example, formulations made from spray-dried lactose (soluble filler) showed a slow disintegration mechanism. As a result, dissolution occurs slowly.

4.Mode of addition of superdisintegrants: Intra-granular and Extra-granular methods are used but sometime both the steps are brought in action. Intra-granular method results in the breaking of tablets into finer particles and also allows erosion of granules to fine particles[23].

5.Amount of superdisintegrant added: Adequate swelling of outer membrane is developed by addition of little quantity of superdisintegrant. One gram of superdisintegrants absorbs 10- 40 g of water or aqueous solution. To produce adequate swelling, sufficient amount of superdisintegrants is added[24,25].

FACTORS AFFECTING FUNCTIONALITIES OF SUPERDISINTEGRANTS:

Molecular and Physicochemical Factors:

1. Effect of Degree of Cross-Linkage and Substitution:

Functionalities of SSG and CCS are offered with the aid of using substitution of hydroxyl agencies with greater hydrophilic agencies and cross-linking of linear polymer chains. The diploma of cross-linkage and carboxymethylation (substitution) of SSG notably has an effect on its overall performance. Disintegration and dissolution performances of SSG turned into observed to be foremost in cross-linkage degree 33%-35% and substitution degree 0.28-0.29. For CCS, a brand with greater simple substitution (sodium salt) had large settling volume, better maximal water uptake and better swelling potential in neutral medium than any other brand with much less quantity of simple substitution though each had comparable particle length distribution and overall diploma of substitution. Yet, the results of various tiers of cross-linkage on performances of CP and PP have now no longer been stated[12].

2. Effect of Particle Size:

SSG, XPVP, and PP coarse particle fractions performed better during disintegration than small particle fractions. The effect of CCS's particle size on how well it disintegrates has not been properly evaluated. The particle size of this disintegrant, however, might be essential since bigger particles generate a stronger swelling force on tablet matrix than smaller particles because swelling is the main mechanism through which CCS triggers tablet disintegration[26,27].

3. Effect of Particle Porosity:

Large intra-particle porosities in a disintegrant will enhance the surface area for liquid medium interaction, leading to the rapid water absorption and swelling or shape restoration. The disintegration time (DT) of a brand of PP with a

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higher total porosity was found to be shorter than that of other brands with lower total porosities, and it also had a higher starting water uptake rate. Additionally, it was observed that intra-particle porosity was crucial for the fast disintegration of a model medication in tablets containing various CP grades in an insoluble filler system[28].

4. Effect of Impurities:

Superdisintegrant synthesis might produce by-product contaminants. Examples of reaction by-products created during the manufacture of SSG include sodium chloride, sodium glycolate, and sodium citrate. In official compendia, the quantities of these by-products in SSG are mentioned. In comparison to SSG compacts with greater percentages of impurities, those with lower percentages of total cold watersoluble fractions (impurities) showed greater water absorption and penetration rate. SSG with low percentages of impurities exhibited faster tablet DT than SSG with large percentages of impurities when used at 4% concentration in tablet formulations, though the difference is negligible. Disintegrants perform poorly when there are more salt impurities present because they compete with them for the same amount of water[29].

Formulation and Process Factors:

1. Effect of Water Solubility and Hygroscopicity of Components:

The rate and method of tablet disintegration are affected by a key ingredient's water solubility in tablet formulation. In contrast to insoluble ingredients, which result in rapidly disintegrating tablets, water-soluble compounds mainly dissolve as compared to disintegration. Components that are water soluble disintegrate and produce a viscous, saturated solution barrier surrounding the tablet matrix. This barrier prevents the entry of water to the disintegrants, delaying the breakdown of the tablet. However, it is stated that the effect of viscosity produced by water soluble fillers on the suppression of disintegration would be small. Instead, additional water molecules are held up by hydrated filler molecules, preventing them from interacting with disintegrants.Overall tablet hygroscopicity caused on by fillers has a severe effect on superdisintegrants abilities. For example, the rate of P-aminosalicylic acid dissolution from tablets containing sorbitol or naproxen sodium (hygroscopic substances) as filler was slowed down when superdisintegrants were present as compared to when they are absent. A hygroscopic excipient competes a superdisintegrant with water, which affects DT. Additionally, compared to insoluble binders, water soluble binders tend to extend tablet DT. This is explained by the insoluble nature of the binders and their low hydration potential[30].

2. Effect of pH:

Since CCS and SSG are anionic disintegrants, a medium pH may have an impact on their capacity to absorb water and swell. Studies on the effect of medium pH on tablet disintegration time (DT) and drug dissolution rate from formulations consisting SSG, CCS, and XPVP showed that CCS and SSG's disintegrating capabilities in acidic medium were significantly decreased compared to neutral medium. However, the non-ionic polymer XPVP's disintegration performance was hardly affected by medium pH. The conversion of the carboxymethyl sodium moiety to free acidic form, which has a lower capacity for hydration than the salt form, may be the cause of the low performances of CCS and SSG in acidic medium. The overall degree of substitution as well as the ratio of basic to acidic substituent has an effect on how much water uptake and swelling capacity of superdisintegrants are affected by medium pH. The functioning of PP may also be affected by an acidicpH since it is anionic disintegrant[31].

3. Effect of Incompatibility:

Drugs and excipients having different physicochemical qualities, such as weakly basic or weakly acidic characteristics, may be present in tablet formulations. There have been reports of incompatibilities between CCS and basic excipients. As the quantity of thiswater soluble polymer increases, a viscous barrier that prevents water from penetrating the tablet matrix may form, reducing the rate at which drugs dissolve. Drugs that are cationic interact with CCS and SSG in a way that affects how quickly they dissolve in vitro. Phenylpropanolamine HCl (a weakly basic drug) and CCS interacted in vitro, but the interaction had no effect on the drug's bioavailability. At physiological salt concentrations, the interaction between weakly basic drugs and anionic superdisintegrants eliminates. This shows that the ion exchange type determines how anionic superdisintegrantsand weakly basic drugs interact [32].

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V. CHAPTER: V

ADVANTAGES:

1.Remarkable tendency on wetting causing rapid disintegration
2.No lump formation on disintegration
3.Compatible with commonly used therapeutical agents and excipients.
4.Work equally effective in hydrophilic and hydrophobic formulations.
5.Provides good mechanical strength to the tablet facilitating easy packing and transportation.
6.Does not stick to the punches and dyes
7.Eco-friendly, cheaper and some are easily available
8.Patient compliance and provides onset action.
9.High consistency of drug content and surface area retention[32,33].

VI. CHAPTER: VI

APPLICATIONS:

Superdisintegration uses are widespread in applications of oral disintegration tablets, rapid dispersion tablets, capsules, mouth dissolving films, etc. Especially for ODT and quick dispersal tablets, are optimized according to their decay time [34]. ODTs should be broken down in the presence of saliva in the oral cavity within one minute. As a result, these formulations achieve better compliance of patients in all classes of pediatric to geriatric, bedridden and non-cooperative patients, including frequent travellers as there is requirement of water is less.

This synthesis article discusses the use of super-disintegrators in various formulations, listing the innovations already patented in this field as follows:

1.Pharmaceutical Superdisintegrants: Super disintegration that improves compressibility in relation to advanced superdisintegration.Superdisintegration includes a particle agglomeration of co-produced starch or cellulose and enough of an amplifying agent to increase the compact ability of the superdisintegrant.

2.Rapidly disintegrating enzyme-containing solid oral dosage compositions: The invention refers to the rapid disintegration of solid oral dosage forms having an efficient amount of an enzyme and superdisintegration.The lactase enzyme is claimed in the present patent in the case of solid oral preparations [35].

3.Fast disintegrating tablet: A fast disintegration tablet containing Nimesulide and one or more disintegrators. This research involves the use of croscarmellose cellulose, crospovidone and sodium starch glycolate[36].

4.Method of producing fast dissolving tablets: A method to produce a fast-melting tablet. There is no granulation in the process, which makes the process more energy efficient and economical. Rapid-dissolving sugar alcohol is chosen from a group that includes: mannitol; sorbitol; erythritol; xylitol; lactose; dextrose; and sucrose. The active component is appropriately supplied as a micro-particle or microcapsule with an average diameter of less than 125 microns.

5.Disintegrating loadable tablets: A decomposition product that is loadable in compressed form. A disintegrant or a mixture of disintegrants has 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[37].

6.Rapidly disintegrating tablet: The study focuses on rapid disintegration tablets for use as orodispersible tablets or dispersive tablets.Tablets consist of silicified microcrystalline cellulose. They are particularly suitable for antibiotics.It also describes tablets that disintegrate quickly and contain Amoxicillin and Clavulanic acid[38].

VII. CHAPTER: VII

CONCLUSION:

Disintegrants are one of the tablet excipients that are added to a pharmaceutical preparation to make it disintegrate. Disintegrants help the tablet matrix dispersion and allow for moisture penetration.Superdisintegrants, which are very efficient disintegrants that generally work by adsorbing water and swelling up, are those compounds that, in comparison to disintegrants, allow rapid disintegration with smaller concentrations.Superdisintegrants can be used in both tablets and capsules to produce the fast disintegration. The mechanisms of superdisintegrant action include combinations of swelling, wicking and deformation.

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