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Review Article

Super Disintegrants: An Overview

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ABSTRACT

Disintegrants play a crucial role as excipients in solid oral formulations. In immediate release and oral dispersible tablet formulations, super disintegrants like croscarmellose sodium, sodium starch glycolate, crospovidone, and polacrilin potassium are added in small quantities to counteract the effects of compression and binder after administration. The hygroscopic nature of these super disintegrants facilitates the penetration of water into the tablet matrix, while their cross-linkage reduces solubility in water. This article provides an overview of various factors that can influence the functionality of super disintegrants, including molecular and physicochemical factors (such as degree of cross-linkage and substitution, particle size, particle porosity, and impurities), formulation and process factors (such as solubility and hygroscopicity of fillers and binders, incompatibility, pH, lubricants, mode of disintegrant addition, granulation, mixer shear rate, compression pressure, and reworking), as well as aging and storage conditions.

INTRODUCTION

The oral administration of medication is the most favored method of delivering drugs, with a significant acceptance rate of approximately 50-60% among all available dosage forms. Solid dosage forms are particularly popular due to their ease of administration, precise dosing, ability for self-medication, avoidance of pain, and, most importantly, patient compliance.[1,2]The tablet is widely preferred among the various oral dosage forms due to its convenient preparation, easy administration, accurate dosing, and enhanced stability compared to oral liquids and capsules.[3] To achieve immediate release, a suitable pharmaceutically acceptable diluent or carrier can be utilized, which does not significantly delay the rate of drug release and/or absorption.[4] In the late 1970s, fast dissolving drug delivery systems were initially created as an alternative to traditional dosage forms specifically designed for pediatric and geriatric patients. The United States Food and Drug Administration (FDA) has defined fast dissolving tablets (FDTs) as solid dosage forms that contain medicinal elements or active

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ingredients capable of disintegrating or dissolving rapidly within seconds when placed on the tongue. These tablets are also referred to as mouth-dissolving tablets, rapid dissolving tablets, melt-in-mouth tablets, dispersible tablets, melts, porous tablets, quick dissolving tablets, quick melt tablets, and quick disintegrating tablets.[5,6] Tablets are commonly used for oral medication delivery, and their effectiveness relies on their ability to disintegrate and release the active ingredients in the gastrointestinal tract (GIT). The selection of an appropriate disintegrant and its consistent performance are crucial factors in the formulation development of these tablets. In recent years, there has been a growing interest in formulating tablets that not only dissolve and disintegrate rapidly when swallowed, but also orally disintegrating tablets that dissolve and disintegrate quickly in the mouth. Previous studies have mainly focused on the functional properties of super disintegrants, with a particular emphasis on establishing a correlation between these properties and the efficiency of disintegration and drug release rate. The rate at which water penetrates the tablet and the rate at which the tablet disintegrates are generally positively associated with the efficiency of the disintegrant in non-soluble matrices. However, it is important to note that there is not always a direct correlation between the disintegration time of the tablet and the rate at which the drug dissolves. [7]

Disintegration

Disintegration refers to the mechanical breakdown of a compressed tablet into small granules upon ingestion. It involves the disruption of the inter particulate bonds that were formed during the tablet compaction process. Disintegration also involves the interaction of the tablet with saliva and gastric fluids. The disintegrant must rapidly absorb saliva into the tablet, leading to volume expansion and the generation of hydrostatic pressures that facilitate rapid disintegration in the mouth. [8]

Disintegrants

Disintegrants are substances that are added to tablets and some encapsulated formulations in order to facilitate the fragmentation of the tablet and capsule into smaller particles when exposed to an aqueous environment. This process increases the surface area available for drug release and promotes a more rapid release of the active pharmaceutical ingredients. It is crucial for the drug to be released efficiently from the tablet in order to ensure its rapid action. Disintegrants play a role in breaking down the tablet matrix in an aqueous medium, as well as promoting moisture penetration and dispersion of the tablet matrix. In literature, tablet formulations containing various excipients for different actions are commonly classified, with one of them being disintegrants. Disintegrants such as maize and corn starch, partially pregelatinized starch, and low substituted hydroxypropyl cellulose are often used to aid in the breakdown of tablets into smaller particles, also known as disaggregation, to promote fast drug release. Additionally, clays, gums, resins, and finely divided microcrystalline cellulose can also serve as disintegrants. [9,10,11]

Super disintegrants

In recent times, a new type of disintegrant called super disintegrants has been introduced. These super disintegrants work faster than traditional disintegrants and require lower concentrations. They possess desirable properties that meet specific requirements and have a pleasing appearance. Super disintegrants can be considered as a modified version of super absorbing materials, with tailored swelling properties. Unlike traditional disintegrants, these materials do not absorb significant amounts of water or aqueous fluids. Instead, they rapidly swell when exposed to fluid. Super disintegrants utilize their structural weakening properties to aid in the breakup of

tablets. They are incorporated into formulations to assist in the disintegration of compressed tablets into primary particles, thereby facilitating the dissolution or release of the active ingredients when the tablet is placed in a fluid. Super disintegrants also promote moisture penetration and dispersion of the tablet matrix. The main function of disintegrants is to counteract the efficiency of the tablet binder and physical forces that occur during compression, which contribute to the tablet's structure. [12,13]

Criteria for choosing super disintegrants:

The selection of super disintegrants plays a crucial role in determining the rate of disintegration of tablets. However, it is important to note that these super disintegrants can also impact other factors such as tablet hardness, mouthfeel, and friability, especially when used in high doses. When choosing super disintegrants for a specific formulation, there are several key factors to consider:

- **Rapid Disintegration:**

The super disintegrants should facilitate rapid disintegration of the tablet when it comes into contact with saliva in the mouth or oral cavity.

- **Tablet Hardness:**

The chosen super disintegrants should contribute to the production of less friable tablets, ensuring that they maintain their structural integrity.

- **Pleasant Mouthfeel:**

To enhance patient experience, super disintegrants that provide a pleasant mouthfeel are preferred. This can be achieved by using super disintegrants with small particle sizes.

- **Flow Characteristics:**

Flow is an important aspect to consider as it improves the overall blend flow characteristics. Therefore, the selected super disintegrants should exhibit good flow properties.

By considering these factors, pharmaceutical formulators can make informed decisions when selecting super disintegrants for their formulations. [14,15]

Types of super disintegrants

A. Natural super disintegrants

B. Synthetic super disintegrants

A. Natural super disintegrants

Ispaghula Husk Mucilage (Plantago Ovata)

Ispaghula husk is derived from the dried seeds of the Plantago ovata plant. These seeds contain mucilage, which is present in the outer layer of the seeds. Prior to extraction, the Plantago ovata seeds were soaked in distilled water for 48 hours and then boiled briefly to release the mucilage into the water. The mucilage obtained from Plantago ovata possesses various properties, such as binding, dissolving, and maintaining qualities. It is considered a highly effective super disintegrating agent for the production of fast-dissolving tablets due to its exceptional swelling index (approximately 89±2.2 percent v/v) compared to other super disintegrants. To separate the residue, the mixture was filtered through muslin fabric. [16,17,18] The plant contains valuable sources of fibers and mucilage in its seeds and psyllium husk. Psyllium husk serves multiple purposes such as being used as a laxative, reducing the glycemic index, and aiding in the development of controlled-release formulations in the pharmaceutical industry. When exposed to water, psyllium husk can absorb water quickly and increase its weight up to 10 times. Psyllium husk consists of hydrocolloids, which make up 10-30% of its composition. These hydrocolloids are water-soluble polysaccharides that form mucilage layers when they come into contact with water. Through hydrolysis, the mucilage breaks down and various polysaccharides such as xylose, arabinose, galacturonic acid, rhamnose, and galactose are obtained. These compounds contribute to the disintegrative properties of psyllium husk and can be utilized as natural disintegrants in the manufacturing of drugs.[28] The filtrate was

supplemented with an equivalent amount of acetone to induce the precipitation of the mucilage. Subsequently, the isolated mucilage was subjected to drying in an oven at a temperature below 60°C. The mucilage derived from Plantago ovata is a novel advancement due to its exceptional disintegration capability, surpassing that of crospovidone. Notably, it exhibits a quicker disintegration time in comparison to crospovidone. [16,17,18]

Fig.1: Plantago ovata seed, Plantago ovata seed powder

Xanthan gum

Xanthan gum, derived from Xanthomonas campestris, is recognized as an official ingredient in the USP due to its notable hydrophilicity and minimal gelling propensity. This substance exhibits limited solubility in water but possesses remarkable swelling properties, facilitating rapid disintegration.[19] Xanthan Gum is produced through a fermentation process using the bacteria Xanthomonas campestris. It is known for its high hydrophilicity and low gelling tendency. The structure of Xanthan gum consists of a β-(1→4)-D-glucose backbone, with every second glucose unit attached to a trisaccharide made up of mannose, glucuronic acid, and mannose. The presence of negatively charged carboxylates from glucuronic acid allows Xanthan gum to form highly viscous fluids at the appropriate pH. Although it is not considered a gelling gum, it still generates a viscous medium due to its weak associations. While it is highly swellable, it can slow down the release of drugs in sustained release formulations. The modified xanthan gum obtained is biodegradable, directly compressible, and exhibits desirable swelling dynamics, making it suitable as a hydrophilic excipient for rapidly disintegrating tablets. The optimized formulation of rapidly disintegrating tablets containing roxithromycin consists of a lower level of modified xanthan gum and a higher level of MCC. This formulation showed a nine-fold reduction in lag time, remained stable for 12 months, and retained its rapid disintegration characteristics throughout the tested time period.[20]

Fig.2: Xanthan gum

Hibiscus Rosasinesis linn

Hibiscus rosa-sinensis Linn leaves are rich in mucilage, which can be utilized as an additive in pharmaceutical formulations. The tablets that were formulated underwent thorough evaluation of their pre and post compression parameters, including tablet hardness, thickness, % friability, and wetting time. These parameters were found to be within acceptable limits. The in vitro disintegration time of tablets containing 6% mucilage was determined to be 24 seconds, while tablets containing 4% crosspovidone had a

disintegration time of 42 seconds. Based on the in vitro disintegration time, drug release studies were conducted in phosphate buffer pH 6.8. The results revealed that the F3 formulation, which contained 6% mucilage, achieved 100% drug release within 12 minutes. Stability studies conducted on the F3 formulation demonstrated that the tablets remained stable for a period of 90 days, with no alteration in the in vitro drug release pattern.[22]

Fig.3: Hibiscus Rosasinesis linn

A study conducted by Gailute Draksiene et al. aimed to investigate the disintegrant property of Hibiscus rosasinensis mucilage using imipramine as a model drug. The research also focused on developing a fast-dissolving tablet of Imipramine using the natural disintegrant isolated from Hibiscus rosasinensis leaves. The effectiveness of this natural disintegrant was compared to a synthetic superdisintegrant called crosspovidone. The researchers isolated and characterized the Hibiscus rosasinensis mucilage to identify its chemical properties and micrometric properties. To formulate the fast-dissolving tablets of Imipramine, the direct compression method was employed using Hibiscus rosa-sinensis mucilage (2-8% w/w), Avicel PH 102 as diluents, mannitol to improve mouth feel and compressibility, and a sweetener.[21]

Gaur Gum

Guar gum is composed of a straight chain of D-mannose units linked by β-(1→4) bonds, with D-galactose attached to every other mannose unit through α-(1→6) linkages to create small side chains.[18] Despite not having the ability to gel on its own, guar gum exhibits a significant viscosity under low-shear conditions. Its nonionic nature allows it to remain unaffected by changes in ionic strength or pH.[24]

Fig.4: Guar gum seeds

Guar gum, a non-ionic polysaccharide obtained from the seeds of Cyamopsis tetragonolobus, which belongs to the Leguminosae family, is composed of linear chains of (1-4)- â -D-mannopyranosyl units with á-D-galactopyranosyl units connected through (16) linkages. Within the pharmaceutical industry, guar gum serves as a binder and disintegrant in solid dosage forms. Some studies have explored the utilization of guar gum as a hydrophilic matrix in the development of oral controlled release dosage forms.[22] Sunitha HS and her team conducted a study where they created a Captopril tablet using gaur gum as a super disintegrant. They then evaluated the tablet for pre-compression and post-compression parameters, ensuring that it met the official limits. Sunitha HS stated that out of all the formulations tested, the one containing 10 mg of guar gum exhibited the best disintegration and dissolution profile compared to the others. This formulation showed a drug release of 99.86±0.54% within 12 minutes and a disintegration time of 50.16±1.32 seconds.[22]

B. Synthetic Super disintegrants

Modified Starch (Sodium starch glycolate, Primojel)

Sodium starch glycolate is a carboxymethyl ether of starch that is in the form of its sodium salt. These modified starches are created by crosslinking potato starch, which gives them excellent disintegrating properties. The effectiveness of these materials as super disintegrants depends on the degree of cross-linking and substitution. Crosslinking reduces both the water-soluble fraction of the polymer and the viscosity of the dispersion in water. Natural pre-dried starches swell by 10-20 percent when exposed to water, while modified starches can increase in volume by 200-300 percent. This increase in volume is due to the rapid absorption of water, resulting in the rapid and uniform disintegration of the granules. This process is characterized by a significant increase in volume, as observed in studies. [23,25]

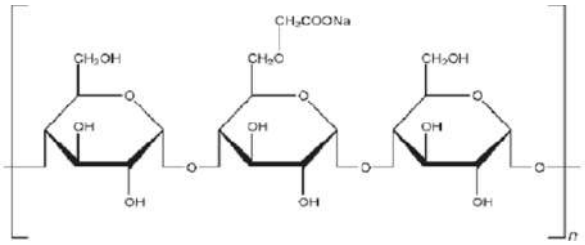

Fig.5: Sodium starch glycolate

Cross-linked Polyvinyl Pyrrolidone (Cross povidone)

Cross povidone efficiently absorbs saliva into the tablet, resulting in an increase in volume and hydrostatic pressure. This process enables the tablet to rapidly disintegrate in the mouth. When observed through a scanning electron microscope, cross povidone particles exhibit a granular and highly porous structure. This distinctive porous nature aids in the absorption of liquid into the dosage systems and promotes rapid disintegration. Unlike other super disintegrants like sodium starch glycolate and croscarmellose sodium, cross povidone does not tend to form gels, even at high ratios.[26]

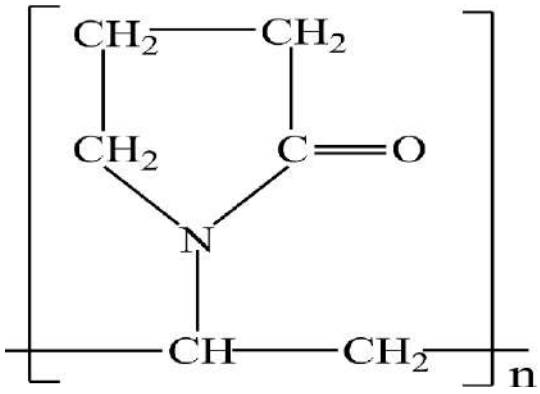

Fig.6: Polyvinylpyrrolidone

Cross povidones possess exceptional particle morphology, making them highly compressible materials. In various pharmaceutical manufacturing techniques such as direct compression, wet and dry granulation processes, Cross povidone serves as a super disintegrant, typically employed at low concentration levels ranging from 2% to 5%.[27]

Modified Celluloses (Croscarmellose Sodium)

It cannot be dissolved in water, but it quickly expands to 4-8 times its original size when it comes into contact with water. Its specific surface area is 0.81-0.83 m2/g and its swelling index is 65±1.7% v/v. Cross-linked sodium carboxymethylcellulose is a white, free-flowing powder with a high capacity for absorption. It has a strong ability to swell, which allows for rapid disintegration and dissolution of drugs at lower levels. Additionally, it has excellent water-wicking capabilities and its cross-linked chemical structure creates a hydrophilic, highly absorbent material that is insoluble, resulting in exceptional swelling properties. The recommended concentration for use is 0.5–2.0%35. Croscarmellose sodium is a cross-linked polymer of carboxymethylcellulose. There are several differences between starch and cellulose polymers, including the synthetic processes used to modify them. In tablet formulations, croscarmellose sodium can be used in both direct compression and wet-granulation processes. When used in wet-granulation, it is best to add croscarmellose

sodium during both the wet and dry stages of the process (intra- and extra-granularly) to fully utilize its wicking and swelling abilities.[28]

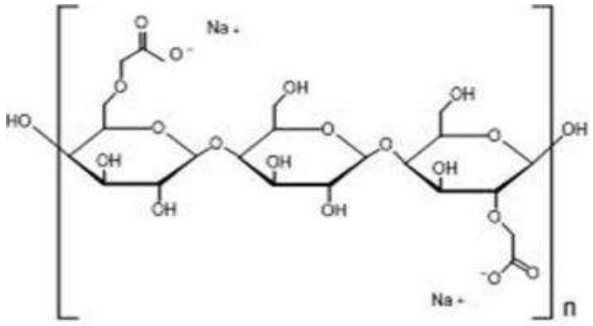

Fig.7: Croscarmellose sodium

Alginates

These substances are hydrophilic colloidal components that are naturally extracted from specific types of kelp or chemically enhanced from natural sources such as alginic acid or alginic acid salts. Alginic acid is a polymer derived from seaweeds, consisting of D-mannuronic and L-glucoronic units. Its ability to absorb water and high capacity for sorption make it an exceptional disintegrant. Alginic acid is utilized as a disintegrant at a concentration of 1-5%, while sodium alginate is used at a concentration of 2.5-10%. It can be effectively employed in combination with ascorbic acid and multivitamin formulations.[29]

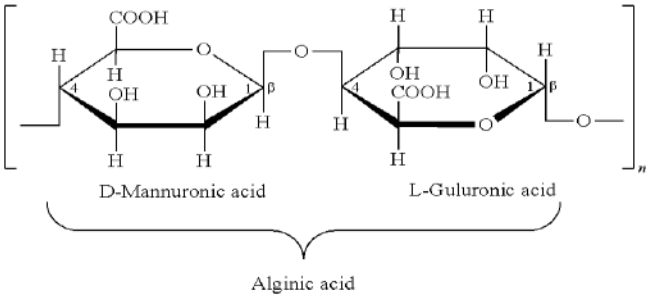

Fig.8: Alginate

Advantages and Disadvantages of super disintegrants:

Advantages

1. Disintegration does not lead to the formation of lumps.
2. Compatible with a wide range of therapeutic agents and excipients.
3. Effective in both hydrophilic and hydrophobic formulations.
4. Provides excellent mechanical strength to the tablet, facilitating easy packing and transportation.
5. Despite the existence of numerous super disintegrants that exhibit superior disintegration, researchers continue to search for new disintegrants and conduct experiments with modified natural products.[30]

Disadvantages

1. Costly.
2. Time-consuming and delicate.
3. More sensitive and hygroscopic in nature.[31]

Ideal Properties of Super-Disintegrants:

1. Good Compressibility and Flow Properties

When powders exhibit a compressibility range of 12-16%, they are classified as powders with good flow properties. In comparison to other super disintegrants, Cross povidones demonstrate significantly higher compressibility.[32]

2. Poor Solubility

The rate and mechanism of tablet disintegration can be influenced by the solubility of the main ingredient in a tablet formulation. Water-soluble substances tend to dissolve rather than disintegrate, whereas insoluble substances typically result in fast disintegrating tablets.[33]

3. Poor Gel Formation Capacity

Gels can slow down the dissolution because the drug need first diffuse through the gel layer before being released into the body. Primo gel is utilized as super disintegrant in tablet preparation at a concentration of 4-6%.[34]

4. Good Hydration Capacity

The efficacy of disintegrates can be influenced by drugs and other hydrophobic excipients that can be adsorbed on disintegrate surfaces. This, in turn, affects the degree of hydration. To address this issue, it is recommended to add rapid disintegrates with high hydration capacity, as it has been found

to decrease the problem and enhance dissolution.[35]

5. Complexation

Croscarmellose sodium and primo gel are examples of anionic disintegrants that can form complexes with cationic drug actives, leading to slow dissolution. However, cross povidone, a non-ionic polymer, does not interact with cationic drug actives and therefore does not hinder drug release. A study on the effects of super disintegrating agents such as croscarmellose sodium, primo gel, and polyplasdone XL on the dissolution of various cationic drugs with different water solubilities found that polyplasdone XL exhibited a faster dissolution rate for the model cationic drugs, regardless of their aqueous solubilities. [36,37]

Mechanism of action of super disintegrants:

A. Swelling.
B. Porosity and capillary action (wicking).
C. Heat of wetting.
D. Deformation.
E. Enzymatic reaction.
F. Electrostatic repulsion.
G. Chemical reaction.

A. Swelling

The process of swelling is widely acknowledged as a crucial mechanism and serves as the initial stage for tablet disintegration. During this process, specific disintegrating agents, such as starch, play a vital role in generating the desired disintegrating effect. However, tablets with high porosity tend to exhibit inadequate disintegration due to the absence of sufficient swelling force. When particles of disintegrants come into contact with water, they undergo swelling, which helps overcome the adhesiveness of other pharmaceutical ingredients present in the tablet, ultimately leading to its breakage. [38,39] The mechanism of disintegration through swelling is shown in figure:9

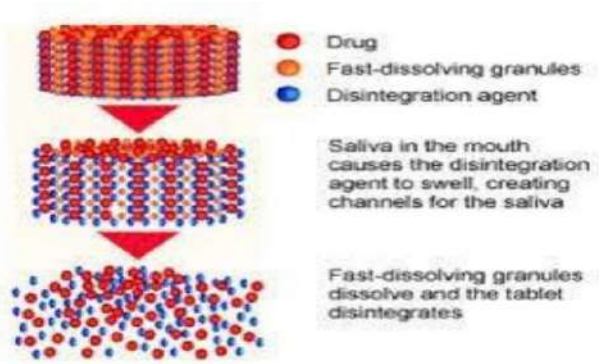

Fig. 9: Mechanism of Disintegration through Swelling Action

B. Capillary Action

Agents that disintegrate without swelling function through the mechanisms of porosity and capillary action. The tablet's porosity provides channels for fluid to penetrate into the tablet. The disintegrating particles, which possess low cohesiveness and compressibility, enhance porosity and create these channels within the tablet.[40] Capillary action draws liquid up or "wicks" it into these pathways, causing the inter-particle bonds to break and resulting in the tablet's fragmentation. Examples of such disintegrating agents include Crospovidone and Croscarmellose, as illustrated in Figure:10.

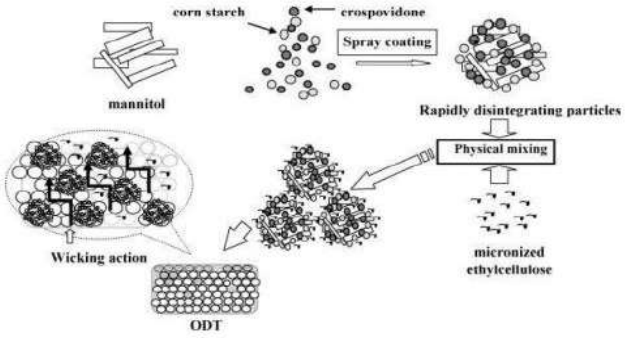

Fig. 10: Capillary action

C. Heat of wetting

The localized stress generated by capillary air expansion when wetted disintegrating agents with exothermic properties disintegrate, aids in tablet disintegration. This mechanism elucidates the action of certain disintegrants but is inadequate in describing the action of the majority of contemporary disintegrants.[41]

D. Deformation

During the compression process of tablets, the particles that have disintegrated undergo deformation. However, when these deformed particles come into contact with water, they regain their normal structure. This deformation leads to an improvement in the swelling capacity, ultimately resulting in the breakup of the tablets. Starch, such as potato starch and corn starch, is believed to possess elastic properties. However, when subjected to high compaction force during tableting, the grains of starch become deformed under pressure but return to their original shape once the pressure is released. When these tablets are exposed to an aqueous environment, the energy potential of the deformed starch grains is triggered, causing the tablets to disintegrate. [42,43] The mechanism of disintegration by deformation shown in figure:11.

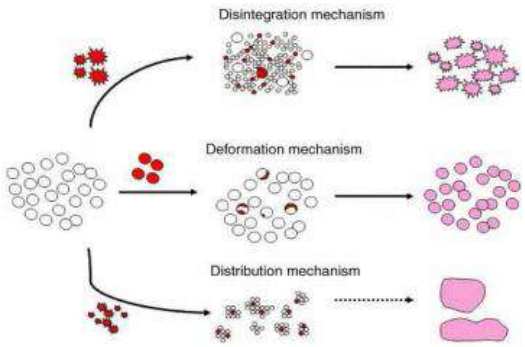

Fig. 11: Deformation

E. Enzymatic action

Enzymes present within the body also function as disintegrants. These enzymes work on the binding action of binders and aid in the process of disintegration. As a result of swelling, pressure is exerted outwardly, leading to the breakup or bursting of the tablet. The rapid absorption of water results in a significant expansion of the granules, facilitating disintegration. In other words, swelling applies pressure externally, causing the tablet to break and enhancing water absorption. [44,45] The enzymatic action is illustrated in figure:12.

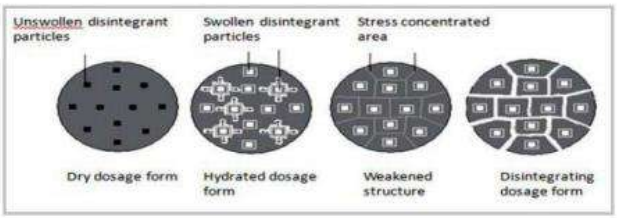

Fig. 12: Enzymatic action

F. Electrostatic Repulsion

This is an alternative disintegration mechanism that aims to elucidate the expansion of tablets composed of non-swellable disintegrants. Guyot-Hermann's theory suggests that particle-particle repulsion is responsible for the disintegration of tablets, even when the particles do not swell. The disintegration process is driven by electric repulsive forces between the particles, which necessitates the presence of water. Water infiltrates the spaces between starch grains due to its attraction to starch surfaces, consequently disrupting hydrogen bonds and other forces that maintain the tablet's integrity.[46] The electrostatic repulsion is illustrated in figure:13

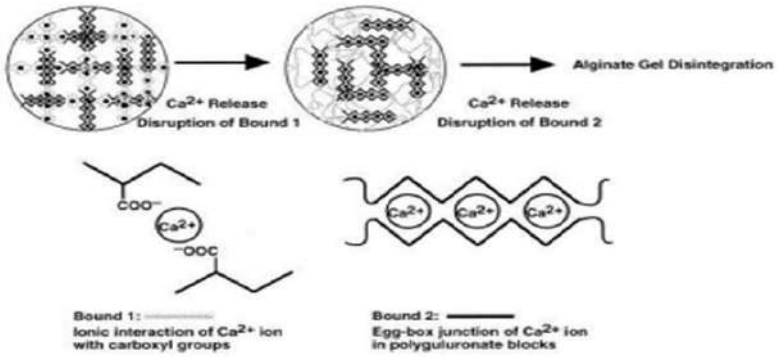

Fig. 13: Electrostatic Repulsion

G. Chemical reaction

The rapid fragmentation of water tablets occurs through the internal release of CO2, which is a result of the interaction between citric acid and tartaric acid (acids) with alkali metal bicarbonates or carbonates (bases) in the presence of water. This process leads to the disintegration of the tablet due to the generation of pressure within it. The release of carbon dioxide gas enhances the dissolution of active pharmaceutical ingredients (APIs) in water and also masks the taste. However, it is important to note that these disintegrating agents are highly sensitive to even minor changes in temperature and humidity levels. Therefore, strict environmental control is necessary during the tablet preparation process. The effervescent mixture can be added in two separate fractions of the formulation either before compression or rapidly.[47]

CONCLUSION:

Disintegrants are substances incorporated into tablets to aid in the fragmentation of the tablet into smaller particles when exposed to water, thereby increasing the surface area available for drug release. Recent advancements in fast disintegrating technology primarily focus on enhancing the disintegration properties of these delicate dosage forms without compromising their structural integrity. This is achieved by utilizing highly efficient super disintegrants, which exhibit superior disintegrating efficiency and mechanical strength even at low concentrations. Typically, super disintegrants are used in small quantities, ranging from 1-10% of the total weight of the tablet. Despite the availability of both natural and synthetic disintegrants in today's era, there is still a need to explore the potential of natural disintegrants that have not yet been investigated for their disintegration capabilities.

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