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A REVIEW ON SUPERDISINTEGRANTS FOR THE DEVELOPMENT OF ORALLY DISINTEGRATING TABLETS

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ABSTRACT

In recent decades, oral disintegrating tablets have become increasingly popular as a novel drug delivery method. Disintegrants are chemicals, or mixtures of chemicals, that are added to a medicinal formulation to help break up or disintegrate the content of tablets or capsules into tiny pieces that dissolve faster than they would otherwise. current years have seen the development of a number of more modern substances referred to as "Superdisintegrants." This can be used to decrease the disintegration time and improve the efficacy of solid dosage forms. It can be classified into Natural, synthetic, semi-synthetic and co-processed. Natural superdisintegrants are of gum karaya, fenugreek seed and gum of locust bean, chitin and chitosan, gellan, agar, alginates, soy polysaccharide, Cassia fistula, xanthan, Cucurbita maxima pulp powder, Hibiscus rosa-sinensis Linn. Synthetic includes croscarmellose sodium, sodium starch glycolate, crospovidone and ion exchange resin.Current research covers every aspect of superdisintegrants, including their types, benefits, selection criteria, integration techniques, optimum features, and mechanism. These are employed in formulations to deliver drugs in a safer, more efficient manner while ensuring patient compliance.

Key words: Croscarmellose sodium, Crospovidone, Hibiscus rosa, Mango peel pectin Superdisintegrants, Sodium starch glycolate.

I. INTRODUCTION

In terms of drug distribution, the oral route is the most convenient method of the several dosage forms, the most often used is the oral tablet due to its exact dosing, convenience of administration, ease of preparation, oral liquid stability, and greater resistance to tampering than capsules [1]. Disintegrants are substances or mixtures of ingredients added to pharmaceutical formulations to break down or disperse the contents of tablets and capsules into tiny particles for quick dissolution. When they come into contact with water in the gastrointestinal tract, they may function by sucking water into the tablet, which causes it to expand and break into tiny fragments. Tablet fragmentation could prevent the medication from dissolving eventually and completing a reasonable drug bioavailability [2].

A number of more contemporary substances known as "Superdisintegrants" have been created in recent years. These more recent compounds have higher mechanical strength and disintegration efficiency and work better at lower concentrations. In non-soluble matrices, disintegrant efficiency is often strongly correlated with the rate of water penetration and the rate at which disintegration force develops. But this kind of favourable relationship between tablet disintegration time and medication dissolving rate cannot always be seen [3].

Selection of Superdisintegrants

As an excipient in the tablet formulation, superdisintegrants need to fulfill certain requirements in addition to their capacity to swell. Thus, the following characteristics are required of superdisintegrants [4]:

1. Able to stay hydrated
2. Poor solubility
3. Good tablet consistency
4. Moulding and flow qualities
5. Excellent mouth feel.

1.1.Ideal Characteristics of Superdisintegrants

- ✓ **Excellent compressibility and flow characteristics**
  Good flow powders are defined as those having a compressibility of 12% to 16%. Crospovidone compressible and are much greater. [5]
- ✓ **Insufficiency in solubility**
  In tablet formulation, the solubility of the important component can influence the rate and mechanism of tablet disintegration. Water-soluble substances are more likely to dissolve than to break down, while insoluble elements typically produce tablets that dissolve quickly. [6]
- ✓ **Inadequate Gel Forming Capacity**
  Gels can slow down disintegration because the medication must first diffuse through the gel layer before entering the body. Primo gel is utilized as a superdisnitegrants in tablet manufacturing at a concentration of 4-6 percent. [7]
- ✓ **Complexation**
  Croscarmellose sodium and primo gel are examples of anionic disintegrants that can slow down the dissolving of cationic medication actives by forming complexes with them. Crospovidone is a non-ionic polymer that doesn't interfere with the release of cationic medication actives. Super disintegrating drugs such as polyplasdone XL, primo gel, and croscarmellose sodium have an impact on Polyplasdone XL exhibited a quicker rate of dissolution for the model cationic pharmaceuticals, irrespective of their aqueous solubilities, according to the dissolving activities of several cationic medications with varying water solubility. [8]

1.2.Classification of superdisintegrants

Based on the source of origin, superdisintegrants can be classified into:
A. Natural superdisintegrants
B. Synthetic superdisintegrants
C. Semi synthetic superdisnitegrants
D. Co-processed superdisnitegrants

A. Natural superdisntegrants

These diverse plant-based materials can be used as a substitute for synthetic products due to their biodegradability:
a. Biocompatible
b. Non-toxic
c. Available locally
d. Both public and patient acceptance is important.

1. Hibscus rosa sines is linn

Linn’s hibiscus rose Mucilage, which is abundant in Hibiscus rosa-sinensis Linn (family: Malvaceous) leaves, can be added to pharmacological compositions. In order to create a fast-dissolving tablet of imipramine using a natural disintegrant that was isolated from Hibiscus sassiness, Gailute Draksiene et al. studied the disintegrant property of Hibiscus rosa-sinensis mucilage using imipramine as a model drug.Its effectiveness was contrasted with that of synthetic superdisintegrants such as crospovidone. The mucilage of Hibiscus rosasinensis was separated and identified using a chemical test and micrometric characteristics. utilizing Hibiscus rosa-sinensis mucilage (2–8% w/w), Avicel PH 102 as a diluent, mannitol to improve mouthfeel and compressibility, and sweetener, fast-dissolving imipramine tablets were created utilizing the direct compression method. The pre and post compression properties of the prepared tablets, such as tablet thickness, hardness, percentage friability, and wetting time, were assessed and determined to be within acceptable bounds [9].

2. Mango peel pectin

The most prevalent adjuvants utilized in the production of various pharmacological dosage forms are mucilage and pectin. They have a variety of pharmaceutical qualities, such as the ability to bind, disintegrate, suspend, emulsify, and sustain at varying proportions in a number of pharmaceutical dosage forms. However, the synthetic polymers used as excipients have drawbacks, including high cost, toxicity, nonbiodegradability, and environmental pollution during synthesis. Because they are non-toxic, inexpensive, readily available, emollient, and non-irritating, natural mucilage, pectin, and pulps are chosen over semi-synthetic and synthetic components. Protocatechuic acid, kinic acid, and catechin make up 16% to 20% of Mangifera Indica’s tannin composition**.**

In order to develop Diclofenac sodium, Rishabh Malviya et al. used mango peel pectin (MPP) to create fast dispersible tablets of synthetic superdisintegrants such as sodium starch glycolate (SSG). Since diclofenac is a non-steroidal anti-inflammatory, naturally occurring MPP is a good option to use as a superdisnitegrants. It isn't as effective as synthetic sodium starch glycolate, but it will be used in the creation of formulations that dissolve quickly because of its high solubility and superior swelling index [10]

3. Guar gum

Guar gum is made up of a linear chain of D-mannose units connected by β-(1→4) linkages, to which D-galactose is joined by α-(1→6) connections to each other mannose unit to create brief side chains. Guar gum is utilized in medicines as a disintegrant and binder in solid dosage forms. Guar gum is used as a hydrophilic matrix in a few papers on the construction of oral controlled release dosage forms. Using gaur gum as a superdisnitegrants, Sunitha HS. et al. created the Captopril tablet and assessed its pre- and post-compression properties, ensuring that they met official limitations. When compared to other formulations, formulation F4, which contains 10 mg of guar gum, had the best disintegration and dissolving profile. It demonstrated a drug release of 99.86±0.54% after 12 minutes and a disintegration time of 50.16±1.32 seconds [11].

Table 1: List of natural super disintegrants

Superdisintegrants	source	mechanism
Hibiscus rosa	Sinesis linn mucilage of hibiscus rosa sinesis	swelling
Mango peel pectin	Pectin from Mangifera Indica's	swelling
Guar gum	Isolated from endosperm seed of the guar gum Cyamopsis	tetragon Loba

B. Synthetic superdisintegrants:

1. Sodium starch glycolate

Sodium starch glycolate is the carboxymethyl ether starch's Na+ derivative. These modified starches are created by cross-linking potato starch and have excellent disintegration properties. The degree of cross-linking and substitution are important factors for the super disintegrating effect. The polymer's water-soluble percentage and water dispersion viscosity are both reduced by cross linking. The natural pre-dried starches swell by 10–20% in water, but the volume of the modified starches rises by 200–300%. This process is brought on by the granules' rapid, even breakdown and significant mass growth due to the rapid absorption of water.The low substituted carboxymethyl starches Primo gel and Explotab are examples of them. The addition of large water-loving carboxymethyl groups breaks the H+ bonds within the polymer structure, making the polymer soluble in cold water and allowing water to enter the molecule.[12]

2. Croscarmellose sodium

Croscarmellose sodium is a linked carboxymethyl cellulose polymer, according to certain hypotheses. This polymer's structure and synthesis are different from those of sodium starch glycolate. When employing Williamson's ether synthesis, croscarmellose sodium undergoes a greater degree of substitutions than sodium starch glycolate, and the crosslinking procedure is distinct. The chemistry of sodium starch glycolate is different from that of croscarmellose sodium because some of its carboxymethyl groups are utilized to crosslink the cellulose chains.

For example, primo gel cross-links via phosphate ester connections rather than carboxyl ester linkages, unlike croscarmellose sodium.

Tablet disintegrants can contain up to 5% w/w of croscarmellose sodium, 2% w/w in tablets made by direct compression, and 3% w/w in tablets made by the wet granulation procedure. There is internal cross-linking in this CMC sodium polymer. Its low gelling and high swelling capacity cause it to break down rapidly. Croscarmellose particles also have wicking action due to their fibrous structure. Croscarmellose sodium can

be used in direct compression as well as wet granulation. Croscarmellose sodium can be used in both intragranular and extra granular processes due to its wicking and swelling characteristics. [13,14]

3. Crospovidone

In order to create the volume expansion and hydrostatic pressure required for fast disintegration in the mouth, crospovidone rapidly wicks saliva into the tablet. Under a scanning electron microscope, the crospovidone particles appear to be very porous and granular. This special porous quality promotes quick disintegration and makes it easier for liquid to wick into the dosing systems. Even at high ratios, crospovidone shows almost little propensity to gel, in contrast to other superdisintegrants such sodium starch glycolate and croscarmellose sodium.

The unique particle shape of crospovidone makes them extremely compressible materials. Wet and dry granulation methods, as well as direct compression, use crospovidone as a superdisnitegrants at low concentrations (2–5%). [15].

4. Alginates

Alginic acid or alginic acid salts are examples of natural sources from which these hydrophilic colloidal components are chemically enhanced or naturally derived from specific species of kelp. Alginic acid is a seaweed-derived polymer made up of L-glucuronic and D-mannuronic units. Because of its strong sorption capacity and affinity for water absorption, it is a great disintegrant. As a disintegrant, alginic acid is utilized at concentrations of 1–5% and sodium alginate at 2.5–10%. It works well with formulations of multivitamins and ascorbic acid.[16]

5. Ion exchange resin

INDION 414 is a chemically bound polyacrylic with an amino group of -COO-, and its usual ionic form is K+. It has a large water-absorbing capacity. It is used in oral dissolving pills as a superdisnitegrant. A mild acid cation exchange resin is this dry powder. It provides the necessary hardness and chemical stability to the tablet by an effective disintegration action. Dosage forms expand significantly and disintegrate rapidly without lumping when they come into contact with water or gastrointestinal fluids. This high molecular mass polymer is safe for ingestion by humans since it cannot be absorbed by human tissues.
[17].

Table 2: List of synthetic superdisintegrants

S.no	Superdisintegrants Name	Brand	Mechanism
1.	Sodium starch Glycolate	Explotab Primo gel	Absorb quickly
2.	Crospovidone	Polyplasdone	Combination of swelling and wicking
3.	Croscarmellose Sodium	Ac-Di-Sol Nymce ZSX Primellose Solutab Vivasol L-HPC	Swelling and wicking Within 10 seconds, swells up to 4-8 folds
4.	Alginates	Alginic acid NF	Rapid swelling

C. semi synthetic superdisintegrants

A product that is mostly produced by organic materials, and it was slightly modified chemically to enhance its disintegration properties in Drug formulations are referred to as semisynthetic superdisintegrants. These substances are suitable for a range of dosage forms in which rapid dissolution and disruption are essential since they blended the advantages of natural materials with specially designed qualities accomplished through chemical.

D. Co-processed super disintegrants

An additive of a particular type used in pharmaceutical preparations, particularly in solid oral dose forms. For instance, tablets and capsules are referred to as co-processed superdisintegrants Instead of being made from a single component, processed superdisintegrants are made by combining two or more distinct excipients using a specific manufacturing process to enhance their disintegrant performance and functionality. Together, co-processed excipients function to raise patient compliance by increasing the rates at which tablets dissolve and disintegrate. as well as drug bioavailability.[18]

1.3.Methods of incorporation of superdisintegrants

The three techniques for adding dissolving agents to the tablet are as follows:

1. Internal Addition (Intragranular):

This technique involves combining the disintegrant with additional powders and then soaking the powder mixtures with the granulating fluid. The disintegrant is therefore integrated into the granules.

2. External addition (extra granular):

Before compression, the disintegrant is mixed into the sized granulation using the external addition method.

3. Partly Internal and External:

This technique allows for the addition of disintegrant both internally and externally. The tablet is immediately broken up into previously compressed granules as a result, and the granules' dissolving agent causes further erosion of the granules to their original powder.

Compared to the conventional way of applying the disintegrant solely to the granulation surface, the two-step procedure typically yields better and more thorough disintegration. [19,20]

1.4.Mechanism of action of superdisintegrants

Superdisintegrants are used to increase solid dose forms' effectiveness. This is accomplished through a number of methods. The process that splits the tablets into tiny fragments and creates a uniform suspension is predicated on:

1) Swelling
2) Capillary action and porosity (Wicking)
3) Wetting heat
4) Acid-based chemical reaction
5) Repulsive forces of particles
6) Deformation
7) The enzymatic process

1. Swelling: A commonly known mechanism, swelling is necessarily the initial stage of pill disintegration. It is a method where the disintegrating effect is produced by specific disintegrating chemicals, like starch. High porosity tablets disintegrate poorly because they don't have enough swelling force. When disintegrant particles come into touch with water, they swell, which can override the adhesiveness of other pharmaceutical substances in a tablet and cause it to break.[21]

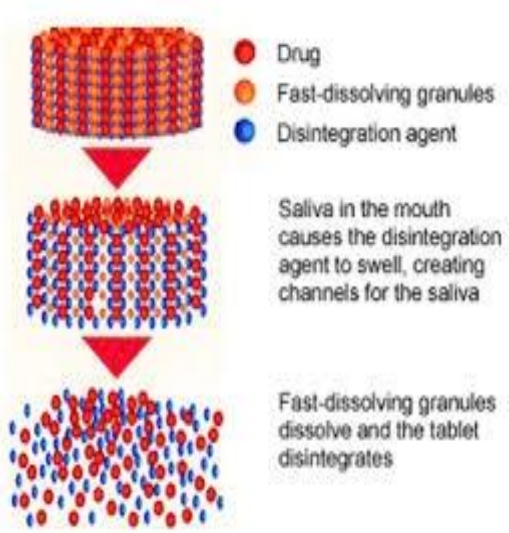

Fig 1: Mechanism of disintegration through swelling

2. **Capillary action and porosity (Wicking):** Porosity and capillary action are thought to be the mechanisms by which effective disintegrants that do not swell convey their disintegrating action. The porosity of tablets creates channels for liquids to enter them. The disintegrant particles, which have low compressibility and cohesiveness, work to increase porosity and provide these channels into the tablet. The tablet disintegrates when the fluid is pulled up, or "wicked," into these routes by capillary action and breaks the interparticle connections. For example, Crospovidone and Croscarmellose.

Combination action

Wicking and swelling action work together in this mechanism to cause disintegration. The way that wicking causes tablet breakdown [22]

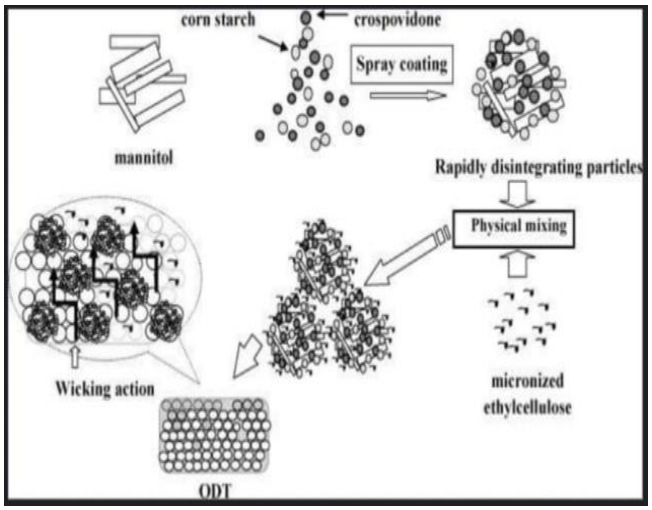

***Fig 2*:** wicking mechanism

3.Wetting heat: Tablet disintegration is facilitated by the creation of localized tension caused by capillary air expansion when exothermic disintegrants are wetted. However, this explanation only covers a small number of disintegrant types and is unable to explain how the majority of contemporary disintegrating agents work [23].

4. Acid base chemical reaction: When alkali metal carbonates or bicarbonates (bases) combine with tartaric acid and citric acid (acids) in the presence of water, the tablet is rapidly broken apart by the internal release of CO2 in the water. The pressure that builds up inside the tablet causes it to dissolve. The release of CO2 gas improves the flavor masking effect and the solubility of active medicinal substances in water. Strict environmental control is necessary during tablet manufacturing since these disintegrants are extremely sensitive to even little variations in temperature and humidity. Either the effervescent blend is added right before compression, or it can be added in two different formulation fractions [24].

5. Repulsive force of particles:A different method of disintegration aims to clarify why the tablet made with "nonswellable" disintegrants swells. Given that "non-swelling particles also induce tablet disintegration," Guyot-Hermann proposed the particle repulsion theory. Water is required, and electrostatic repelling interactions between particles are the mechanism of disintegration. Researchers found that repulsion comes first, followed by wicking [25].

6. Deformation: It is a process by which earlier elastic starches, like maize or potato starch, turn plastic when subjected to high compaction pressure during tableting. These pills disintegrate when they come into contact with water because it activates the starch granules' potential energy.[26]

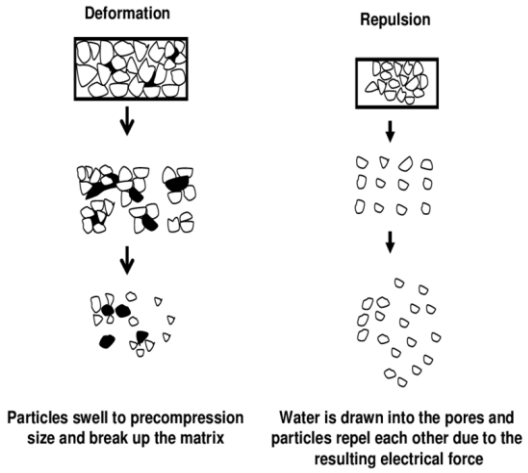

Fig3: Deformation and repulsive mechanism

7. Enyzmatic process: The body has own natural enzymes that also serve as disintegrants. These enzymes aid in breakdown and strengthen the binder's binding effect. Either the tablet bursts due to external pressure caused by swelling, or the granule volume drastically increases due to rapid water absorption, which encourages disintegration.[27]

2.1.Advantages of superdisintegrating agents [28]

1. A noticeable tendency toward moisture that causes rapid decomposition.
2. Upon disintegration, there is no lumping.
3. Compatible with commonly used medicinal agents and excipients.
4. They do not adhere to the dyes and punches.
5. Propensity to function at lower concentrations.
6. Less influence on compressibility and flow capacity.
7. Enhanced intragranular efficiency.
8. Some of them may partially bind to cationic drugs in vitro due to their anionic nature.
9. They decompose naturally.

1.6. Disadvantages of super disintegrating agents [29]

1. Expensive
2. Time consuming.
3. Hypersensitive

1.7. Applications

A variety of recently identified superdisnitegrants excipient types are essential to the disintegration process. The goal of developments in fast-dissolving tablet formulation is to decrease the disintegration time while simultaneously enhancing the performance of the dosage form. There are a lot of superdisintegrants on the market, and researchers are constantly looking for more disintegrating agents. Numerous multifunctional superdisintegrants, including polyplasdone Superdry, collidine CL-F, starch 1500, and others, are being tested by researchers. The following are some examples of developments that have already been patented and the use of superdisintegrants in various formulations [30,31]:

1.Pharmaceutical superdisnitegrants:

superdisintegrants that are more permeable than those from the previous generation. Particulate accumulations of coprocessed cellulose or starch with an enough quantity of an enhancing chemical to boost the superdisintegrants compatibility are examples of superdisintegrants.

2. Rapidly disintegrating enzyme-containing solid oral dosage compositions:

The development involves solid oral dosage forms that dissolve quickly and contain a sufficient quantity of a superdisnitegrants and an enzyme. This patent covers solid oral preparations of the enzyme lactase.

3. Fast disintegrating tablets:

A pill that dissolves quickly and contains nemsulide and one or more disintegrants. Superdisintegrants such as sodium starch glycolate, crospovidone, and croscarmellose cellulose are employed in this study.

4. Method of producing fast dissolving tablets:

A way of making a tablet that melts quickly. Granulation is not a phase in the process, which makes it more economical and energy efficient. The fast-dissolving sugar alcohol is chosen from the category that includes lactose, dextrose, sucrose, erythritol, sorbitol, mannitol, and xylitol. Microparticles or microcapsules with an average diameter of fewer than 125 microns are well suited to offer the active ingredient**.**

5. Disintegrating loadable tablets:

A compacted dose form of a dissolving loadable tablet product. The porosity of a disintegrant or a mixture of disintegrants is 45% v/v or above. b) a minimum hardness of 20 newtons, and c) the capacity to load at least 30% of a liquid.[32]

6. Rapidly disintegrating tablet:

The rapidly disintegrating tablets were the subject of research studies. Additionally, microcrystalline cellulose was employed. In this study, the antibiotics clavulanic acid and amoxicillin were utilized.[33]

Superdisintegrants are being used more often in mouth-dissolving films, pills, and capsules. In particular, rapid dispersible tablets and oral dispersible tablets (ODTs) have optimal disintegration times. When saliva is present, ODTs must dissolve in a minute. 46 Because of this, these formulations enhance patient compliance across all age groups, from young children to elderly people. Data and patent counts for a number of superdisintegrants are displayed in Table 3. The information comes from both the US Patent and Trademark Office and the National Institute of Standards and Technology (NIC).[34]

3. CONCLUSION

The results of the study show that both synthetic and natural superdisintegrants work better on tablets that dissolve quickly. Natural polymers were employed as binder superdisintegrants and diluents in order to speed up the release of medication from tablets and shorten the time it took for them to dissolve and disintegrate. Because they are naturally derived, they are inexpensive, widely accessible, and utilized in little amounts to provide nutritional supplements. Although tablets and capsules have become the most widely used therapeutic dose forms for oral delivery, they have certain disadvantages for patients with dysphagia and chemotherapy. Since the disintegration time and drug delivery percentage are significantly higher than those of conventional dose forms, mouth dissolving tablets containing guar gum and xanthan gum should be regarded as an appropriate detailing and delivery framework to improve patient uniformity.

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