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OVERVIEW ON NATURAL SUPERDISINTEGRANTS

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ABSTRACT

Recent improvements in innovative drug delivery systems (NDDS) aim to improve patient compliance by enhancing safety and producing a convenient dosage form for administration. Formulation of orally disintegrating tablets, which are useful for paediatric, geriatric, and dysphasic patients and lead to greater patient compliance, is one such. These dose forms dissolve or disintegrate quickly in the oral cavity without the use of water in a matter of seconds. Orally disintegrating drug delivery is currently the gold standard in the pharmaceutical industry, where it is recognised as the quickest, most convenient, safest, and most cost-effective way of drug delivery, with the best patient compliance and preference over traditional tablets. The purpose of this research is to learn about the different forms of natural disintegrants, as well as their mechanisms, benefits, and drawbacks.

KEYWORDS: NDDS, ODT, Natural Superdisintegrant.

INTRODUCTION

Oral Drug Delivery System

Because of its non-invasive nature, ease of use, cost-effectiveness, and the highly absorptive qualities of the gastrointestinal (GI) tract, oral drug delivery is by far the most well-known and frequently selected method of drug administration.[1] Oral administration refers to the process of administering a drug through the mouth. Many medications are taken orally because they are meant to have a systemic effect, meaning they will travel throughout the body via the bloodstream.[2] Disintegrants are chemicals that are added to tablet and capsule formulations to help break up the "slugs" of the tablets and capsules into smaller fragments in an aqueous environment, increasing the accessible surface area and encouraging faster drug release. They help the tablet matrix to absorb moisture and disperse. Disintegration of tablets has attracted a lot of attention as a crucial step in achieving rapid medication release. The emphasis on drug availability emphasises the significance of a tablet's comparatively quick disintegration as a criterion for determining unrestricted drug dissolving behaviour. Disintegrants are an important part in tablet manufacturing. To dissolve, the capacity to interact vigorously with water is required. Disintegrant activity is mediated by a combination of swelling, wicking, and deformation. Disintegration and replacement of tablets are influenced by a number of factors. The main purpose of the disintegrants is to counteract the tablet binder's efficiency and the physical forces that act under compression to form the tablet. The disintegrating agents must be more effective than the binder in order for the tablet to release its medicament. It should, in theory, shatter the tablet, not just into the granules from which it was compacted, but also into the powder particles from which the granulation was created. A disintegrant used in granulated formulation methods can be more effective if it is used both "intra granularly" and "extra granularly," breaking the tablet into granules and then dissolving the granules to release the medication component into solution.

However, the amount of disintegrant integrated intra granularly (in wet granulation procedures) is often less effective than that integrated extra granularly since it is subjected to wetting and drying (as part of the granulation process), reducing the disintegrant's activity. Since a compaction process does not involve its exposure to wetting and drying, the disintegrant used intra granularly inclines to retain good disintegration activity.[3,4]

ADVANTAGES AND DISADVANTAGES OF ORAL DRUG DELIVER SYSYTEM

Advantages of Oral Drug Delivery System

1. It is the simplest, most convenient, and safest means of drug administration.
2. It is convenient for repeated and prolonged use.
3. It can be self-administered and pain-free.
4. It is economical since it does not involve the patient in extra cost. Where the drug is a solid e.g., tablet and capsule, the patient needs just one or two cups of water, which in most cases is freely available. If the drug is in liquid form, nothing is needed except a

measuring tool that comes with the drug in most cases.
5. No sterile precautions needed.
6. Danger of acute drug reaction is minimal.
7. Neither special knowledge nor special supplies (syringes, needles) is required for its use.

DISADVANTAGES OF ORAL DRUG DELIVERY SYSTEM

1. It is not suitable for emergency as onset of action of orally administered drugs is relatively slow.
2. It can only be used in conscious patients and those patients who can swallow.
3. It requires patient's cooperation or compliance, especially outpatients.
4. It is not suitable for:

a. Unpalatable and highly irritant drugs
b. Drugs that are destroyed by gastric acid and digestive juices (e.g., insulin)
c. Drugs with extensive first-pass metabolism (e.g. lignocaine, imipramine)
d. Patients with severe vomiting and diarrhea.

5. Oral route of drug administration is sometimes inefficient as absorption is in most cases irregular and incomplete.
6. Changes in drug solubility can result from reactions with other materials present in the gastrointestinal tract e.g., the interference of absorption of tetracyclines through the formation of insoluble complexes with calcium, which can be available from dairy products or formulation additives.

NATURAL SUPER DISINTEGRANT

Disintegrates are compounds or mixtures of substances that are added to tablet formulations to accelerate the break-up of tablets (and capsule "slugs") into smaller pieces in an aqueous environment, increasing the accessible surface area and facilitating a more rapid release of the medicinal component. Disintegration of tablets has attracted a lot of attention as a crucial step in achieving quicker medication release. The focus on drug availability emphasises the significance of a tablet's relatively quick disintegration as a criteria for assuring unrestricted drug dissolving behaviour. Tablet disintegration is influenced by a number of factors.[7] The role of disintegrants can be considered while making quick dissolving or disintegrating tablets. Super disintegrants, which are chemically modified disintegrants, have recently been produced to improve disintegration processes. The design feature of a fast disintegrating tablet can be achieved by using the right formulation excipients and manufacturing technologies. The main purpose of the disintegrants is to counteract the tablet binder's efficiency and the physical forces that act under compression to form the tablet. The disintegration agents must be more effective the stronger the binder is in order for the tablet to release its medicament. It should ideally disrupt the tablet, not only into the granules from which it is compressed, but also into the powder particles from which the granulation is made.[8] The proper choice of a disintegrant or a super disintegrant and its consist performance are of critical importance to the formulation development of such tablets. Drug release from a solid dosage form can be enhanced by addition of suitable disintegrants. In more recent years, increasing attention has been paid to formulating not only fast dissolving and/or disintegrating tablets[9,10] that are swallowed, but also orally disintegrating tablets.[11-13]

Table1: Natural Disintegrants Used in marketed formulations.

Sr no	Natural Disintegrants	Marketed Drug	Disintegration Time
1	Chitin and chitosan	Cinnarizine	60 sec
2	Guar gum	Glipizide	30 sec
3	Gum Karaya	Amlodipine, granisetron hydrochloride	17.10 sec
4	Agar and treated agar	Theophylline	20 sec
5	Fenugreek seed mucilage	Metformin hydrochloride	15.6 sec
6	Soy polysaccharide	Lornoxicam	12 sec
7	Gellan gum	Metronidazole	155 sec
8	Mango peel pectin	Aceclofenac	8 – 18 min
9	Lepidium sativum mucilage	Nimesulide	13 sec
10	Plantago ovata seed mucilage	Granisetron HCL	17 sec
11	Aegle marmelos gum	Aceclofenac	8 – 18 min
12	Locust bean gum	Metformin HCL, Paracetamol	13 min
13	Lepidium sativum	Nimesulide	17 sec
14	Mangifera indica gum	Aceclofenac	3 - 8 sec
15	Hibiscus rosa - sinenisis mucilage	Aceclofenac	20 sec
16	Dehydrated banana powder	Ondansetron HCL/ propranolol, gabapentin	15 – 36 sec

SELECTION OF SUPER DISINTEGRANTS

Since super disintegrant is used as an excipient in the tablet formulation, it has to meet certain criteria other than its swelling properties. The requirement placed on the tablet disintegrant should be clearly defined.

The ideal disintegrant should have

- Poor solubility.
- Poor gel formation.
- Good hydration capacity.
- Good moulding and flow properties.
- No tendency to form complexes with drugs.
- Good mouth feel.
- It should also be compatible with the other excipients and have desirable tableting properties.

MECHANISM OF DISINTEGRANTION BY SUPER DISINTEGRANTS

There are five major mechanisms for tablet disintegrations follows:

1. Swelling.
2. Porosity and capillary action (Wicking).
3. Deformation.
4. Particle repulsive forces.
5. Heat of wetting.
6. Due to release of gases.
7. Enzymatic reaction.
8. Combination.

1. Swelling

Swelling is believed to be a mechanism in which certain disintegrating agents (such as starch) impact the disintegrating effect. By swelling in contact with water, the adhesiveness of other ingredients in a tablet is over come causing the tablet to fall apart. Sodium starch glycolate, PlatagoOvata.

Figure 1: Swelling.

2. Porosity and capillary action (Wicking)

Effective disintegrants that do not swell are believed to impart their disintegrating action through porosity and capillary action. Tablet porosity provides pathways for the penetration of fluid into tablets. The disintegrants particles (with low cohesiveness and compressibility) themselves act to enhance porosity and provide these pathways into the tablets. Liquid is drawn up or "Wicked" into these pathways through capillary action and rupture the inter particulate bonds causing the tablet to break apart as shown in figure.1. Crospovidones are synthetic, insoluble, crosslinked homopolymers of N-vinyl-2-pyrrolidone. Crospovidone quickly wicks saliva into the tablet to generate the volume expansion and hydrostatic pressures necessary to provide rapid disintegration. Unlike other super disintegrants which rely principally on swelling for disintegration, Crospovidones uses a combination of swelling, wicking and deformation[19,20] formulated fast dissolving Efavirenz formulation by using three different super disintegrants such as cross carmellose sodium (CCS), sodium starch glycolate (SSG) and crospovidon (CP). It is concluded that CP is able to release the drug faster than the two disintegrants.

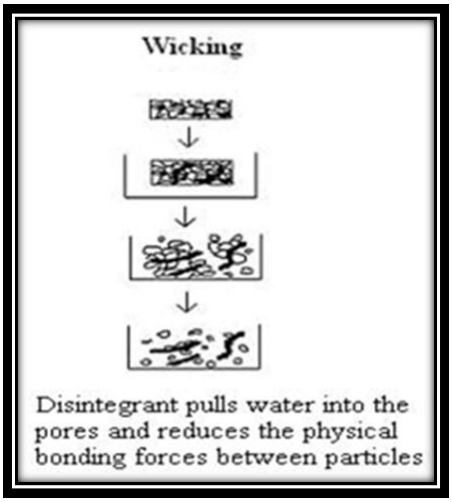

Figure 2: Wicking.

3. Deformation

Hess had proved that during tablet compression, disintegrated particles get deformed and these 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. (fig.3).[21,22]

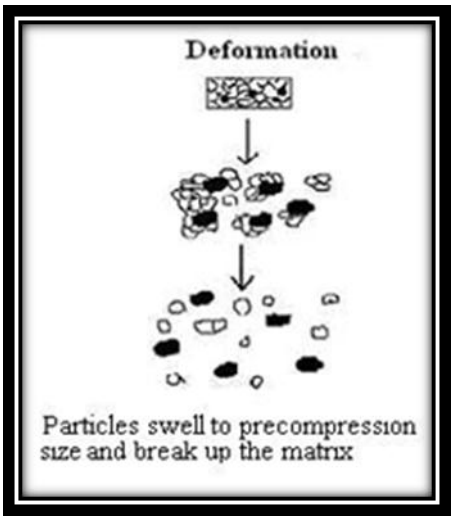

Figure 3: Deformation.

4. Due to disintegrating particle / particle repulsive force

Another mechanism of disintegration attempts to explain the swelling of tablet made with ''non swellable'' disintegrants. Guyot-Hermann has proposed a particle repulsion theory based on the observation that non swelling particle also cause disintegration of tablets. The electric repulsive forces between particles are the mechanism of disintegration and water is required for it. Researchers found that repulsion is secondary to wicking. It is believed that no single mechanism is responsible for the action of most disintegrants. But rather, it is more likely the result of inter-relationships between these major mechanisms.[23]

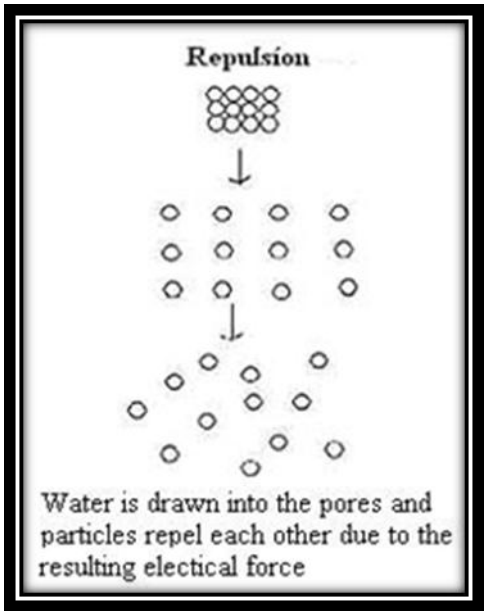

Figure 4: Repulsive force.

5. Heat of wetting

When disintegrants with exothermic properties get wetted, localized stress is created due to capillary air expansion, which aids in disintegration of tablet. This explanation, however, is limited to only a few types of disintegrants and cannot describe the action of most modern disintegrating agents.

6. Due to release of gases

Carbon dioxide released within tablets on wetting due to interaction between bicarbonate and carbonate with citric acid or tartaric acid. The tablet disintegrates due to generation of pressure within the tablet. This effervescent mixture is used when pharmacist needs to formulate very rapidly dissolving tablets or fast disintegrating tablet. As these disintegrants are highly sensitive to small changes in humidity level and temperature, strict control of environment is required during manufacturing of the tablets. The effervescent blend is either added immediately prior to compression or can be added in to two separate fraction of formulation.[24]

7. Combination

In this mechanism, the combination of both wicking and swelling action facilitate disintegration. E.g. Crosspovidone.

8. 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.

Natural Super disintegrants

These super disintegrating agents are natural in origin and are preferred over synthetic substances because they are comparatively cheaper, abundantly available, non-irritating and nontoxic in nature. The natural materials like gums and mucilages have been extensively used in the field of drug delivery for their easy availability, cost effectiveness, Eco friendliness, emollient and non-irritant nature, non -toxicity, capable of multitude of chemical modifications, potentially degradable and compatible due to natural origin. There are several gums and mucilages are available which have super-disintegrating activity.[25]

Lepidium sativum mucilage

Lepidium sativum (family: Cruciferae) is known as asaliyo and is widely used as herbal medicine in India. It is widely available in market and has very low cost. Parts used are leaves, root, oil, seeds etc. Seeds contain higher amount of mucilage, dimeric imidazole alkaloids lepidine B, C, D, E and F and two new monomeric imidazole alkaloids Semilepid inoside A and B. Mucilage of Lepidium sativum has various characteristic like binding, disintegrating, gelling.[26]

Plantago Ovata Seed Mucilage (Isapgula)

Isapghula consists of dried seeds of the plant plantagoovata and it contains mucilage which is present in the epidermis of the seeds. The seeds of Plantagoovata were soaked in distilled water for 48 hrs and then boiled for few minutes for complete release of mucilage into water. The material was squeezed through muslin cloth for filtering and separating out the marc. Then, an equal volume of acetone was added to the filtrate so as to precipitate the mucilage. The separated mucilage was dried in oven at temperature less than 60°C.The mucilage of plantagoovatais a recent innovation for its super disintegration property when compared with Crospovidone. It shows faster disintegration time than the super disintegrant, Crosspovidone.[27,28]

GumKaraya

Gum Karaya is a negative colloid and a complex polysaccharide of high molecular weight. On hydrolysis it yields galactose, rhamnose and galacturonic acid. Gum Karaya occurs as a partially acetylated derivative. It is a dried exudation of sterculia Urenstree (Family-

Sterculiaceae). Its synonyms are Karaya, sterculia, Indian tragacanth, Bassora tragacanth, kadaya, Kadira, katila. Gum Karaya is compatible with other plant hydrocolloids as well as proteins and carbohydrates.[29,30,31]

Guargum

Guar gum is a galactomannan, commonly used in cosmetics, food products and in pharmaceutical formulations. Guar gum is mainly consisting of the high molecular weight (approximately 50,000-8,000,000) polysaccharides composed of galactomannans and is obtained from the endosperm of the seed of the guar plant, It is used as thickener, stabilizer and emulsifier, and approved in most areas of the world (e.g. EU, USA, Japan, and Australia)[32]. Its synonyms are Galactosol; guar flour; jaguar gum; meprogat; meyprodor. It has also been investigated in the preparation of sustained release matrix tablets in the place of cellulose derivatives such as methylcellulose. In pharmaceuticals, guar gum is used in solid-dosage forms as a binder and disintegrant, and in oral and topical products as a suspending, thickening, and stabilizing agent, and also as a controlled-release carrier. Guar gum has also been examined for use in colonic drug delivery.[33, 34]

Fenugreek Seed Mucilage

Trigonella Foenum-graceum, commonly known as Fenugreek, is an herbaceous plant of the leguminous family. It has found wide applications as a food, a food additive, and as a traditional medicine. The leaves and both the ripe and unripe seeds of Trigonella Foenum-graceumare used as vegetables. Fenugreek has been used in treating colic flatulence, dysentery, diarrhoea, dyspepsia with loss of appetite, chronic cough, dropsy, enlargement of liver and spleen, rickets, gout, and diabetes. It is also used as gastro protective, antiurolithiatic, diuretic, antidandruff agent, Anti-inflammatory agent and as antioxidant. The seed is stated to be a tonic. It also is used in post-natal care and to increase lactation in nursing mothers. Fenugreek seeds contain a high percentage of mucilage (a natural gummy substance present in the coatings of many seeds). Although it does not dissolve in water, mucilage forms a viscous tacky mass when exposed to fluids. Like other mucilage-containing substances, fenugreek seeds swell up and become slick when they are exposed to fluids. The resulting soft mass is not absorbed by the body, but instead passes through the intestines and triggers intestinal muscle contractions.[35,36]

Locust Beangum

Locust bean gum is extracted from the endosperm of the seeds of the carob Tree Ceretoniasiliqua, which grows in Mediterranean countries. It is also called Carob bean gum. Some other familiar polysacharides are starch and cellulose, which are made of long chains of the sugar glucose. in locust bean gum, the ratio of mannose to galactose is higher than in guar gum, giving it slightly different properties, and allowing the two gums to interact synergistically so that together they make a thicker gel than either one alone. It shows as a binder and as a disintegrant property at different concentration. Pharmaceutical application of locust bean gum in various novel drug delivery systems. Locust bean gum has been widely used in food industry as a thickening and gelling agent. Locust bean gum has also been reported to have bio adhesive and solubility enhancement properties. There are various reports that Locust bean gum can be used in pharmaceutical and biotechnological purpose.[37,38]

CONCLUSION

Synthetic polymers have fewer impacts than natural Super disintegrants.Natural polymers, which are used as a binder super disintegrant and diluent, increased the drug release rate from the tablet while decreasing the dissolving and disintegration time. Natural polymers are chosen over synthetic polymers because they are nontoxic, easy to get at a low cost, may be used in low concentrations, and can be extracted naturally to offer nutritional supplements. Plantago ovata, Lepidium sativum, gum karaya, Guar gum, Fenugreek seed mucilage, mango peel pectin, and other natural super disintegrants have all been investigated in comparison to manufactured super disintegrants. As a result, natural super disintegrants have a faster medication dissolving rate and higher bioavailability, resulting in more effective therapy and better patient compliance. As a result, the natural super disintegrant can be effectively used as disintegrant in tablet formulation.

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