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Review Article

EMERGENCE OF NATURAL SUPER-DISINTEGRNATS IN ORO-DISPERSIBLE TABLETS: AN OVERVIEW

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ABSTRACT
Orally disintegrating tablets (ODTs) are an emerging trend in novel drug delivery system and have received ever-increasing demand during the last few decades. ODTs are solid unit dosage forms, which disintegrates or dissolves rapidly in the mouth without chewing and water. This type of property in dosage form can be attained by addition of different excipients, in which disintegrants are the key adjuvant. In recent years, several newer agents have been developed known as super-disintegrants. Super-disintegrants are used to improve the efficacy of solid dosage form and influence the release rate of dosage form. Diverse categories of super-disintegrants are such as synthetic, semi-synthetic, natural and co-processed blends etc. These have been employed to develop effectual ODTs and to overcome the limitations of conventional tablet dosage forms. The plant derived natural super disintegrants comply with many requirements of pharmaceutical excipients as they are non-toxic, stable, easily available, associated with less regulatory issues as compared to their synthetic counterpart and inexpensive; also these can be easily modified into more polar form. This review discuss about the development of various kind of natural super-disintegrating agents, along with their role in the tablet disintegration and as potent candidate to be used in ODTs, which are being used in the formulation to provide the safer, effective drug delivery with patient compliance.
Keywords: Oral-disintegrants tablets, gums, mucilages.

INTRODUCTION

Recent development in novel drug delivery system aims to improve safety and by the formulating a convenient dosage form for administration to achieve the better patient compliance. One such approach is formulation of (ODTs); these are useful for paediatric, geriatric and also dysphasic patients, leading to enhanced patient compliance. These dosage forms dissolve or disintegrate rapidly in the oral cavity within a matter of seconds without the need of water. Tablet disintegration has been considered as the rate determining step in faster drug release[1-5]. Developers these days are looking for a new, safe and effective disintegrating agents which can disintegrate tablets rapidly even at a tablet crushing strength of greater than 3.5 Kg. On analyzing the behaviour of disintegration time in the oral cavity as well as wetting time by surface free energy we came to know, that for a faster wetting a molecule should have high polar component of surface free energy and the agents which meet these special requirements are called as super-disintegrants[6]. Natural gums and mucilages have been widely explored as pharmaceutical excipients. These are preferred over semi-synthetic and synthetic excipients in the field of drug delivery because they are cheap and easily available, have soothing action and non irritant nature. Further, they are eco-friendly, capable of multitude of chemical modifications, potentially degradable and compatible due to their natural origin[7,8].

Super disintegrants

The term super-disintegrants refer to substances which achieve disintegration faster than the substances conventionally used. A tablet or a capsule content breaks up or disintegrates into smaller particle that dissolve more rapidly than in the case of absence of such disintegrates. Super-disintegrants are granules used at low level in the solid dosage form, typically from 1 to 10 % of the total weight of a given unit dosage form[9]. The disintegration of dosage forms are depends upon various physical factors of disintegrants / super-disintegrants. They are as follow:

- Percentage of disintegrants present in the formulation
- Proportion of disintegrants used
- Compatibility with other excipients
- Presence of surfactants
- Hardness of the tablets
- Nature of drug substances
- Mixing and types of addition

They all should possess the following characteristics

- Poor water solubility with good hydration capacity
- Poor gel formation
- Good flow properties
- Good compressibility
- Inert, non-toxic
- Requirement of least quantity
- Complexation[10]

Mechanism of Disintegration by super-disintegrants

There are five major mechanisms for tablet disintegration as follows:-

- Swelling
- Porosity and capillary action (wicking)
- Deformation
- Enzymatic reaction
- Due to disintegration particle / particle repulsive force[11]

By Swelling Action

In this mechanism, super-disintegrants swell when they come in contact with water (e.g. starch).

By Capillary (Wicking)

In this mechanism, the disintegrants that do not swell facilitate disintegration by their physical nature of low cohesiveness and low compressibility. Thus they provide porosity and capillary action for the penetration of liquid into the bulk, rupture intra particulate bonds and cause the disintegration.

Deformation

In case of starch (such as potato starch and corn starch) are believed to be elastic in nature, but due to high compaction force in case of tableting the elasticity deformed to plasticity with energy rich potential. When these tablets are exposed to aqueous environment, the energy potential of deformed starch grain will be triggered to cause disintegration[10].

Due to Disintegrating Particle / Particle Repulsive Force

Another mechanism of disintegration attempts to explain the swelling of tablet made with "nonswellable'' disintegrants. Researchers have 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[12].

By 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[13].

Natural Super-Disintegrants

Now days, we have a number of plant-based pharmaceutical excipients and various researchers have explored the utility of some of these plant-based materials as pharmaceutical super-disintegrants[14]. These super-disintegrating agents are natural in origin and are alternative over synthetic substances because they are comparatively cheaper, easily available, non-irritating and nontoxic in nature. Therefore natural gums and mucilages have been extensively used in the field of novel drug delivery for their easy availability, cost effectiveness, Eco friendliness, emollient and non-irritant nature and 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 property. Some natural substances like gum karaya, modified starch and agar have been used in the formulation of ODTs[15].

Mucilage as Disintegrants

Mucilage is glutinous substance which mainly consists of polysaccharides, proteins and uranides. Dried up mucilage or the concentrated mucilage is called as Gum. The main difference between them is that mucilage does not dissolve in water whereas gum dissolves in water. Mucilage is formed in the normal growth of plant by mucilage secreting glands. Naturally the demand of these substances is increasing and new sources are tapped. India due to geographical and environmental positioning has traditionally been a good source for such products[16,17].

***Plantago ovata* Seed Mucilage**

Psyllium or Ispaghula is the common name, whose seeds are used commercially for the production of mucilage.[1] The seeds of *Plantago ovata* were soaked in distilled water for 48 hours 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°. [18] Mucilage of *Plantago ovata* has various characteristics like disintegrating, binding and sustaining properties. Mucilage of *Plantago ovata* can be used as super-disintegrant to formulate ODTs because it has very high percentage of swelling index (around 89 ± 2.2 % v / v) as compared to the other natural or synthetic super-disintegrating agents[19].

***Hibiscus rosa-sinensis* Mucilage**

Hibiscus rosa-sinensis is commonly known as the shoe-flower plant, China rose and Chinese hibiscus. The plant is found in India in large quantities and its mucilage has been found to act as a super-disintegrant in the ODTs formulations. The plant contains various chemical substances like, cyclopropanoids, methyl sterculate, methyl_2_hydroxysterculate, 2_hydroxysterculate malvateandrosasterol. Mucilage of *Hibiscus rosa-sinensis* contains L_rhamnose, D_galactose, D_galactouronic acid and D_glucuronic acid[20].

***Cucurbita maxima* Pulp Powder**

Cucurbita maxima fruit was cleaned with water to remove dust and impurities from surface and further peel was removed. The seed was removed and pulp was put into juicer mixer to form highly viscous liquid. Viscous liquid was further lyophilized to get solid porous mass. Size reduction was done and powder was collected. The collected powder was passed through 80 # sieve and stored for further study. It also has comparable hardness and friability thus the naturally obtained *Cucurbita maxima* pulp powder serves as a good candidate to act as super-disintegrant and it is possible to design promising ODTs using this polymer[21].

Trigonella Foenum-graceum

It is commonly known as Fenugreek. It is one of the oldest cultivated plants; it has been found wide applications as a food, a food additive and as a traditional medicine in every region. Fenugreek seeds contain a high percentage of mucilage which can be used as a disintegrants for use in ODTs formulation. Although it does not dissolve in water, but quickly dissolve in warm water forms a viscous colloidal solution. Like other mucilage-containing substances, fenugreek seeds swell up and become slick when they are exposed to fluids. So due to their high swelling property it serves as a better super-disintegrants for ODTs formulation[17].

***Lepidium sativum* Seed Mucilage**

Lepidium sativum is commonly known as asaliyo and has wide application in pharmaceutical field as disintegrating agent and as herbal medicine in India because of its low cost. Various 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 semilepidinoside A and B. Mucilage of *Lepidium sativium* has various characteristic like binding, disintegrating, gelling[22].

Chitosan

Chitosan is a natural polymer obtained by deacetylation of chitin which is the second most abundant polysaccharides in nature after cellulose. Super-disintegrant property of chitosan has been utilized to develop ODTs. Similar to the other super-disintegrants chitosan has the high swelling property when in contact with aqueous media and burst due to the pressure exerted by their capillary action thereby impart instantaneous disintegration of the dosage form and resulting

in formation of a uniform dispersion in the surrounding media which behave like a true suspension formed inside the body leading to rapid and complete absorption of drug[23].

Table 1: Biological Source of Some Natural Super-disintegrants

Natural Super-disintegrants	Source
Plantago Ovata Seed Mucilage	Seed of Plantago ovata[18]
Lapidium Sativum mucilage	Seed of Lapidum Sativum[21]
Gum Karaya	Dried exudation of sterculia urens tree[24]
Fanugreek Seed Mucilage	Seed of fenugreek, TrigonellafoenumgraceumL[20]
Guar gum	Seed of theguar plant, Cyamopsistetragonaloba[25]
Cassia Fistula gum	Seed of Cassia fistula tree[26]
Locust Bean Gum	Seed ofCarob tree Ceretonia Siliqua[16]
Hibiscus rosa-sinensis Linn Mucilage	Fresh leaves of Hibiscus rosa-sinensis[27]

Table 2: Literature Review on Application of Various Mucilages

Mucilages	Drug	Approaches used	Results
Lepidium *sativium*	Nimesulide	Direct compression	Disintegration time of 17 sec. and mean dissolution time 5.27 sec. at 10 % w/w concentration, found better than other synthetic disintegrants like Ac-di-sol and SSG[30].
Hibiscus rosa-sinensis mucilage powder	Aceclofenac	Direct compression	At concentration of 6 % w/w showed disintegration time of 20 sec. (20, 27)
Plantago ovata mucilage	Prochlorperazine maleate	Direct compression	Dispersion time of 8 sec. at concentration of 8 % w/w[19,28,29]
Cucurbita maxima pulp powder	Diclofenac sodium	Wet granulation	Disintegration time of 7.23 minutes at the concentration of 2.5 % w/w[21]
Ocimum gratissimum mucilage powder and seed powder	Metformin Hcl	Direct compression	Mucilage powder and seed powder both at concentrations of 5 % w/w showed disintegration time
Chitosan	Cinnarizine	Wet granulation	Good mouth feel and disintegration time of 60sec. at the level of 3 % w/w[23].

Gum as Disintegrants

Gums have been used as disintegrants because of their tendency to swell in water. They can have the good disintegration property (2-10 % w/w of tablet weight) and the amount of gum must be carefully titrated to determine the optimum level for the tablet. Gums, which are commonly used as disintegrants consist of karaya, guar gums, gellan, agar, pectin and tragacanth[31].

Gellan Gum

Gellan gum is produced by the microbe *Pseudomonos elodea*. It is a linear anionic polysaccharide, biodegradable polymer consisting of a linear tetrasaccharide repeat structure and used as a tablet disintegrants. Gellan polymer consists of monosaccharide α-L-rhamnose, β-D-glucuronic acid and β-D-glucose in molar ratio of 1:1:2 linked together to form a linear primary structure. The disintegration of tablet might be due to the instantaneous swelling characteristics of gellan gum when it comes into contact with water and owing to its high hydrophilic nature. Study revealed that the complete disintegration of tablet was observed within 4 minutes with gellan gum concentration of 4 % w/w and 90 % of drug dissolved within 23 minutes[32].

Gum Karaya

Gum Karaya is a natural gum produced as an exudates by trees. Chemically, it is an acid polysaccharide composed of the 13 % D- galactose, 15 % L- rhamnose and 43 % D-galacturonic acid. It absorbs water and swells to 60-100 times their original volume. The high viscosity nature of gum limits its uses as binder and disintegrants in the development of conventional dosage form. It can be used as an alternative super-disintegrants to commonly available synthetic and semi synthetic super-disintegrants due to their low cost, biocompatibility as well as easily availability[33,34].

Guar Gum

Guar gum is naturally occurring guar seed extract, containing about 80 % of galactomannan (guaran), 10 % moisture, 5-7 % protein and trace amounts of heavy metals and ash. It is used as thickener, stabilizer and emulsifier, it is naturally occurring gum (marketed under the trade name jaguar). It is free flowing; completely soluble, neutral polymer composed of sugar units and is approved for use in food. It is not sensitive to pH, moisture contents or solubility of the tablet. As a disintegrants, guar gum has been found to be superior to some common disintegrants such as corn starch, celluloses, alginates and magnesium aluminium silicate. Particle size can affect disintegration, with finer particle sizes having greater disintegrating capabilities[33].

Locust Bean Gum

Locust bean gum is extracted from the endosperm of the seeds of the carob tree. 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. Application of locust bean gum is done in various novel drug delivery systems. It 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[35,16].

Cassia fistula Gum

Seeds of *Cassia fistula* gum obtained from *Cassia fistula* tree. Gum obtained from the seeds of *Cassia fistula* comprises β-(1→4) linked d-mannopyranose units with random

distribution of _α (1→6) linked d-galactopyranose units as side chain having mannose: galactose ratio of 3.0). Carboxymethylation as well as carbamoylethylation of Cassia gum is reported to improve cold water solubility, improve viscosity and increase microbial resistance as compared to native gum. Therefore, an attempt was made to incorporate calcium or sodium salts of carboxymethylated or carbamoylethylated *Cassia fistula* gum as super-disintegrants in the formulation development of ODTs[26].

Mango Peels Pectin

Mango peel which constitutes 20–25 % of the mango processing waste was found to be a good source for the extraction of pectin of good quality, suitable for the preparation of film and acceptable jelly. Pectin is a complex hetro-polysacharides which is a hydrophilic colloid. Rather mango peel pectin cannot be used for promising the behaviour of super-disintegrants, but due to its good swelling index and good solubility in biological fluids it can be used to prepare oral dispersible tablets[36-38].

Agar

Agar is yellowish gray or white to nearly colourless, odourless with mucilaginous taste and is available in the form of strips, sheet flakes or coarse powder. Agar consists of two polysaccharides as agarose and agaropectin. Agarose is responsible for gel strength and Agaropectin is responsible for the viscosity of agar solutions. High gel strength of agar makes it a potential candidate as a disintegrant in the formulation of ODTs. Gums are used in concentration from 1 to 10 %. However, these are not as good disintegrating agents as others because capacity development is relatively low.

Other Traditional Natural Disintegrants

Starch

Starch is the oldest and probably the most widely used disintegrant in the pharmaceutical industry. The mode of action of starch is that the disintegrant forms pathways throughout the tablet matrix that enable water to draw into the structure by capillary action, thus leading to disruption of tablet 24. Regular cornstarch USP has certain limitation and has been replaced to some extent by modified starches with specialized characteristics to serve specific functions[40].

Pregelatinized Starch (Starch 1500)

Pregelatinized starch is a modified starch prepared from potato starch and is used as disintegrant in dispersible tablets due to its superior swelling capacity. It is a directly compressible form of starch consisting of intact and partially hydrolyzed ruptured starch grains. As it has been chemically or mechanically processed to rupture all or part of the granules in water, it has multiple uses in formulations as a binder, filler and disintegrant. As a disintegrant, its effective use concentration is between 5-10 %. Its major mechanism of action as a disintegrant is thought to be through swelling[41].

Celluloses

Cellulose such as purified cellulose, methylcellulose and carboxy methylcellulose are used as disintegrants to some extent depending on their ability to swell on contact with water.

Microcrystalline Cellulose

Microcrystalline cellulose is purified, partially depolymerized cellulose that occurs as a white, odourless, tasteless, crystalline powder composed of porous particles. It contains very good disintegrant property when present in a concentration of between 10-20 %. It functions by allowing water to enter the tablet matrix by means of capillary pores, which break the hydrogen bonding between adjacent bundles of cellulose microcrystals[42].

Alginates

Alginates are hydrophilic colloidal substances extracted from certain species of Kelp. Chemically they are available as alginic acid or sodium salt of alginic acid. Alginic acid is a polymer derived from seaweeds comprising D-mannuronic and L-glucoronic units. Its affinity for water absorption and high sorption capacity make it an excellent disintegrant. Alginic acid is used as disintegrant at 1-5 % concentration while sodium alginate at 2.5-10 % concentration. It can be successfully used with ascorbic acid, multivitamins preparation[43].

Chitin

These are obtained from marine sources. Chitin, a structural constituent in the shells of crustacean and insects, has an acylated polyamine, which is biodegradable and non toxic. It is the most abundant natural polymer after cellulose. Chitin shows faster disintegration and better dissolution. Moisture sorption and water uptake was found the major mechanism of disintegration while dissolution related to swelling capacity[44,45].

Soy Polysaccharide

It is a natural super-disintegrant that does not contain any starch or sugar so can be used in nutritional products. It concluded that soy polysaccharide (a group of high molecular weight polysaccharides obtained from soy beans) as a disintegrants in tablets made by direct compression using lactose and dicalcium phosphate dihydrate as fillers. A cross-linked sodium carboxy-methyl cellulose and corn starch were used as control disintegrants. Soy polysacchardie performs well as a disintegrating agent in direct compression formulations with results paralleling those of cross-linked CMC[46,47].

CONCLUSION

The orally disintegrating drug delivery system has become one of the mile stone in novel drug delivery system. The ease of availability of these agents and the simplicity in the direct compression process suggest that their use would be a more economic alternative in the preparation of ODTs than the sophisticated and patented techniques. Although, there are many super-disintegrants, the search for newer disintegrating agents is ongoing and researchers are experimenting with modified natural products like formalin casein, chitin, chitosan, polymerized agar acrylamide, xylan, smecta, key-jo-clay, cross linked carboxymethyl guar, mango peel pectin, *Cassia tora* and modified tapioca starch etc. Studies have suggested that the water insoluble super-disintegrants show better disintegration property than the slightly water soluble agents. Thus the natural super-disintegrant can be effectively used as disintegrants in tablet formulations.

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