Review on the Superdisintigrant

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***Abstract*- The 90% of medicine are taken orally in the form of tablets, Capsule Suspension, &Emulsion etc. Tablet is one of the most preferred dosage forms amongst these because of its ease of manufacturing, convenience in administration the formulation of tablet containing API and excipients. The role of API to produce therapeutics action and excipients are the additives used in tablet formulation to improve Dissolution rate, Disintegration, taste, color, flavors, bulkiness and bioavaibility of the drug. The Bioavaibility of drug is dependent on in vivo disintegration, dissolution and various others factors. Disintegrating agents is a Substances added to tablet to facilitate its break up. The therapeutic action is based on the amount of drug released from the tablet, these disintegrants produce rapid disaggregation of solid in to solution and absorption of the drug takes place number of conventional and in novel dosage form utilize the Disintegration agents this base create number of preparation like Fast Dissolving Tablet, Dispersible Tablet and Pulsatile Tablet etc. This review article focuses on various aspects of disintigrants like defination, Classification Characteristics, Methods and etc.**

***Index terms*- Disintegration, Superdisintigrants, classification, factors, Method**

INTRODUCTION

have the ease of administration, flexibility in formulation, and patient fulfillment. Tablets and capsules are amongst the list of solid oral dosage form.[1,2] it is the most popular dosage form and almost 70% of medicines are dispensed in tablet form and wide range advantages like a cost effective dosage Lowest cost among all other solid dosage form, dose precision, Tablets are single dosage form, it is suitable for manufacturing large size batches, it having less moisture content no chance microbial contamination, good chemical and ease of swallowing, least content variability and Ease of packing pain avoidance etc.

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 pediatric, 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 release1-5. 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 behavior 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-disintegrants6. 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 nonirritant nature. Further, they are eco-friendly, capable of multitude of chemical modifications, potentially degradable and compatible due to their natural origin.

DISINTIGRATION

Disintegration may be define as the mechanical break up of a compressed tablet into small granules upon ingestion and therefore it is characterized by the breakdown of the inter particulate bonds, which were forged during the compaction of the tablet. Also refer the process break down of tablet interaction with saliva and gastric fluids. The disintegrant must quickly wick saliva into the tablet to generate the volume expansion and hydrostatic pressures necessary to provide rapid disintegration in the mouth.

DISINTEGRANTS

Disintegrants are substances added to tablet and some encapsulated formulation to facilitate the breakup of the tablet and capsule into smaller particles in an aqueous environment thereby increasing the available surface area and promoting a more rapid release of the drug substance. The active pharmaceutical ingredients must be released from the tablet as efficiently as possible to allow its rapid action. Disintegrants bring about tablet matrix break-up in an aqueous medium and they promote moisture penetration and dispersion of the tablet matrix are commonly classified further in literature as tablet containing number of excipients for different action one is Disintegrants to help tablet for break down in to small particles also called a disaggregation to promote drug release fast on side of action generally utilize the Disintegrants like maize and corn starch, partially pregelatinized starch, and low substituted hydroxypropyl cellulose. Some clays, gums, resins, and finely divided, microcrystalline cellulose.

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 form9. 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

CLASSIFICATION OF THE SUPERDISINTEGRANTS

Superdisintegrants can be classified into.

1. Synthetic Superdisintegrants
   a. Modified starcheseg. Sodium Starch Glycolate
   b. Modified celluloseeg. Croscarmellose
   c. Cross-linked poly-vinyl pyrrolidoneeg. Crospovidone, polyvinyl-pyrrolidone
   d. Modified Resineg. Indion 414, Kyron 314
   e. Microcrystalline Celluloseeg. Avicel 102
   f. Cross-linked alginic acideg. Alginic acid NF
   g. L-substituted Hydroxypropyl derivatives.
2. Natural Superdisintegrants
   a. Gumseg. Guar Gum, Xanthan Gum, Locust Bean, Cassia Fistula Gum, Karaya Gum,
   b. Gellan Gum.
   c. AgaregGelidiumamansii
   d. Chitosanegβ (1, 4)2-amino-2-d-glucose
   e. Soy polysaccharide Emcosoy
3. Co-processed superdisintegrants
   a. EgStarlac (lactose and maize starch).

b. Starcap 1500 (corn starch and pregelatinized starch).
c. Ran Explo-C (microcrystalline cellulose, silica and crospovidone).
d. Ludipress (lactose monohydrate, polyvinylpyrrolidone and crospovidone).
e. PanExcea MH300G (microcrystalline cellulose, hydroxyl- propyl- methyl cellulose and crosspovidone).
f. Ran Explo-S (microcrystalline cellulose, silica and sodium starch glycolate).

VARIOUS PHYSICAL FACTORS OF DISINTEGRANTS AFFECTING DISINTEGRATION

a. Amount of disintegrants present in the formulation.
b. Proportion of disintegrants used.
c. Compatibility with other excipients.
d. Presence of surfactants.
e. Hardness of the tablets.
f. Nature of Drug substances.
g. Mixing and types of addition

IDEAL PROPERTIES OF DISINTEGRANTS

a. It should be Poor water solubility
b. It should be Poor gel formation
c. It should be Good hydration capacity
d. It should be Good flow properties
e. It should be No tendency to form complexes with the drugs
f. It should be Non-toxic and inert
g. It should be Good compressibility
h. It should be Requirement of least quantity
i. It should be Good Mouth feel effect

ADVANTAGES OF DISINTEGRANTS

a. Does not stick to the dyes and punches
b. No lumps formation at the time of granulation
c. Effective in fewer amounts than starch
d. More effective intragranularly
e. Low effect on flow ability and compressibility
f. Compactable with commonly used API and Additives
g. Work equally effective in hydrophilic and hydrophobic

SELECTION CRITERIA FOR SUPERDISINTEGRANT

Although superdisintegrants primarily affect the rate of disintegration, but when used at high levels it can also affect mouth feel, tablet hardness and friability. Hence, various ideal factors to be considered while selecting an appropriate superdisintegrants for a particular formulation should:

1. Proceed for rapid disintegration, when tablet comes in contact with saliva in the mouth/oral cavity.
2. Be compactable enough to produce less friable tablets.
3. Produce good mouth feel to the patients. Thus, small particle size is preferred to achieve patient compliance.
4. Have good flow, since it improves the flow characteristics of total blend.

MECHANISM OF ACTION OF DISINTEGRANTS

1. Capillary action (Wicking).
2. Swelling.
3. Heat of wetting.
4. Release of gases.
5. Enzymatic action.
6. Particle repulsive forces.
7. Deformation recovery.

1. Capillary action

Those are effectivedisintigrants that do not swell they produce means action through the porosity and capillary action. Porosity produce pathway for the penetration of fluid which weakens the intermolecular bond and breaks tablet into fine particles. And also rupture intra particles bonds and cause the disintegration.These types ofdisintegrants maintenance of porous structure and low interfacial tension towards aqueous fluid are necessarywhich helps in disintegration by creating a hydrophilic network around the drug particles.

2. Swelling

Water penetration is a necessary first step for disintegration swelling is most widely accepted mechanism of action for tablet disintegrants. Particles of disintegrants swellon coming in contact with suitable fluid and a swelling force develops which leads to break-up of the compact.Porosity and

swelling behaviors are inversely proportional to each other.

3. Heat of wetting.
Those disintigrants with exothermic characteristics get wetted localized stress is created due to capillary air expansion which facilities in disintegration of dosage form.

4. Release of gases.
Interaction between tartaric acid and citric acid (acids) with alkali metal carbonates or bicarbonates (bases)then liberation of CO2 in water which generates the pressure within the tablet and facilitate disintegration. As these disintegrants are highly sensitive to strict control on the humidity level and temperature is required during preparation of the tablets.

5. Enzymatic action
Enzymes available in the body also role performing as a disintegrants. These enzymes act on binding action of binder and helps in disintegration. Due to swelling, pressure is exerted in the outer direction that causes the tablet to break up Some examples of disintegrating enzymes are presented in table 1 along with the binders against which these are active.

Sr.No.	Enzymes	Disintegrting agent
1	Amylase	Starch
2	Protease	Gelatin
3	Cellulase	Cellulose and its derivatives
4	Invertase	Sucrose

Agent.

6. Particle repulsive forces
This mechanism is shown in compact made with non swellable disintegrant. Water penetrates into compact through hydrophilic pores and breaks the hydrogen bonds other forces.

7. Deformation recovery
The shape of disintigrants particles is change means distorted during compression the shape of particle is return at the time of wetting. This increase in size causes the tablet to break.

NATURAL SUPERDISINTEGRANTS

Lepidium sativum (family: Cruciferae) is known as asaliyo and 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 semilepidinoside A and B. Mucilage of Lepidium Sativum has various characteristic like binding, disintegrating, gelling etc.16 Hence a method is developed to isolate the mucilage from seeds and its use to develop the fast dissolving tablet in a study.

Hibiscus rosa-sinens: Hibiscus rosa-sinensis Linn of the Malvaceae family is also known as the shoe_flower plant, China rose, and Chinese hibiscus. The plant is available in India in large quantities and its mucilage has been found to act as a super disintegrant. The plant contains cyclopropanoids, methylsterculate, methyl_2_hydroxysterculate, 2_hydroxysterculate malvate and rosasterol. The leaves contain carotene (7.34 mg/100g of fresh material) moisture, protein, fat, carbohydrate, fibers, calcium, and phosphorus. Mucilage of Hibiscus rosa-sinensis contains Lrhamnose, Dgalactose, Dgalactouronic acid, and Dglucuronic acid. The percentage yield of mucilage is estimated as 17%. Other physicochemical parameters of mucilage are also evaluated. The results of swelling ratio, angle of repose, bulk density and compressibility index are observed as 9,26.5oC,0.65g/cc, 16% respectively.

Trigonella Foenum-graceum : It is commonly known as Fenugreek. Fenugreek is an herbaceous plant of the Leguminous family. 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. Hence, the study revealed that this natural disintegrant (fenugreek mucilage) showed better disintegrating property than the most widely used synthetic superdisintegrants like Ac-di-sol in the formulations of FDT's. Studies indicated that the extracted mucilage is a good pharmaceutical adjuvant, specifically a disintegrating agent.

Plantago ovata: It is also known as Isapghula Husk consists of dried seeds of the plant known as plantago ovata. The plant contains mucilage in the epidermis of the seeds. Mucilage of plantago ovata has various characteristics like binding, disintegrating and sustaining properties. Mucilage can be used as superdisintegrant to formulate fast dissolving tablets because it has very high percentage of swelling index (around 89±2.2%v/v) as compared to the other superdisintegrating agents. The rapid disintegration of the FDTs is due to the swelling of Superdisintegrants to create enough hydrodynamic pressure for quick and complete disintegration of the tablet. The rate at which swelling develops and significant force of swelling also determine its disintegrating efficiency.

Soy polysaccharide: It is a natural superdisintegrant that does not contain any starch or sugar so can be used in nutritional products. Khalidindi23 et al 1982 evaluated soy polysaccharide (a group of high molecular weight polysaccharides obtained from soy beans) as a disintegrant 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.

Agar: Agar is the dried gelatinous substance obtained from Gelidium amansii (Gelidanceae) and several other species of red algae like, Gracilaria (Gracilariaceae) and Pterocadia (Gelidaceae). Agar is yellowish gray or white to nearly colorless, odorless with mucilaginous taste and is accessible 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. It is a potential candidate to act as a disintegrant due to its high gel strength .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

Gellan gum: Gellan gum is a water-soluble polysaccharide produced by Pseudomonas elodea, a bacterium. Gellan gum is an anionic, high molecular weight, deacetylated exocellular polysaccharide gum produced as a fermentation product by a pure culture of Pseudomonas elodea2, with a tetrasaccharide repeating unit of one α-L-rhamnose, one β-D-glucuronic acid and two β-D-glucose residues. Antony et al 1997 studied the Gellan gum as a disintegrant and the efficiency of gum was compared with other conventional disintegrants such as dried corn starch, explotab, avicel (pH 10.2), Ac-di-sol. and Kollidon CL. 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. The complete disintegration of tablet was has proved itself as superior disintegrant.

Aloe vera: The genus, Aloe, belongs to the family, Liliaceae, and includes the species Aloe barbadensis Miller, commercially known as Aloe vera. Fast dissolving tablets offer the combined advantages of performance, convenience, rapid onset of action and patient compliance and allow administration of an oral solid dose form in the absence of water or fluid intake. When placed on the tongue, it disintegrates instantaneously, releasing the drug which dissolves or disperses in the saliva. They are prepared by techniques such as tablet molding, spray drying, lyophilization, sublimation, or addition of disintegrants. Pharmaceutical formulators often face the challenge of finding the right combination of formulation variables that will produce a product with optimum properties.

Locust bean gum: Locust bean gum also called as carob bean gum is a galactomannan Vegetable gum extracted from the seeds of the Carob tree (Ceretonia siliqua), mostly found in the mediterranean regions. 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 ioadhesive and solubility enhancement properties.30 Malik K et al carried out formulation and evaluation nimesulide orodispersible using locust bean gum as superdisintegrant. The gum was evaluated for powder flow properties, swelling index and loss on drying. Excellent powder flow properties were observed, swelling index was found to be 20 sec. which indicated appreciable capability of locust bean gum

to be used as superdisintegrant. The prepared tablets were evaluated against standard superdisintegrant i.e. crosscarmellose sodium. Disintegration time of tablets containing 10 % locust bean gum was found to be 13 second.

Cucurbita maxima pulp powder: Cucurbita maxima fruit was cleaned with water to remove dust from surface and further peel was removed. The seed was removed and pulp was put into juicer mixer to form highly viscous liquid. This 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. Study revealed that Cucurbita maxima pulp powder have comparable dissolution behaviour to that of sodium starch glycolate. It also has comparable hardness and friability thus the naturally obtained Cucurbita maxima pulp powder stands as a good candidate to act as disintegrant and it is possible to design promising Fast disintegrating tablet using this polymer.

Mangifera indica gum: Common name of mangifera indica is mango belongig to Anacardiaceae family. It is nontoxic and used as disintegrant, binder, suspending agent, emulsifying agent in different formulations. The gum is white to off white in colour to cream colour powder, the powder was soluble in water and practically insoluble in acetone chloroform, ether, methanol and ethanol it is easily available and gum is deviod of toxicity and each and every part of the tree has pharmacological activity like diuretic, astringent, diabetes, asthma, diahorrea, urethritis, and scabies.

SYNTHETIC SUPERDISINTEGRANTS

Synthetic superdisintegrants are frequently used in tablet formulations to improve the rate and extent of tablet disintegration thereby increasing the rate of drug dissolution. The most widely used synthetic superdisintegrants are illustrated below.

Sodium Starch Glycolate: Sodium starch glycolate is widely used in oral pharmaceuticals as a disintegrant in capsule and tablet formulations. It is recommended to use in tablets prepared by either direct-compression or wet-granulation processes. The recommended concentration in a formulation is 2-8%, with the optimum concentration about 4% although in many cases 2% is sufficient. Disintegration occurs by rapid uptake of water followed by rapid and enormous swelling. Thedisintegrant efficiency of sodium starch glycolate is unimpaired in the presence of hydrophobic excipients, such as lubricants unlike many other disintegrants. Increasing the tablet compression pressure also appears to have no effect on disintegration time. These are modified starches with dramatic disintegrating properties and are available as explotab and primogel which are low substituted carboxy methyl starches. Exploitable consisting of granules that absorb water rapidly and swell. The mechanism by which this action takes place involves rapid absorption of water leading to an enormous increase in volume of granules result in rapid and uniform disintegration. The natural predried starches swell in water to the extent of 10-20 percent and the modified starches increase in volume by 200-300 percent in water.

Low-substituted hydroxypropyl cellulose:
It is preferable in wet granulation and directly compressed tablets. Larger particle size and higher hydroxypropyl content show higher degree of swelling. It is useful to prevent capping. Now a day it is widely used as a super-disintegrate in fast dissolving tablets. Bi et al and Watanabe et al used microcrystalline cellulose and Low substituted hydroxy propyl cellulose (L-HPC) as disintegrant to prepare rapidly disintegrating tablets. Ratio of the MCC and L- HPC was in the range of 8: 2 – 9: 1 resulted in tablets with shortest disintegration time.
Resins Resins although insoluble, have great affinity for water and hence, act as disintegrant. Moreover, because of their smaller particle size the rate of swelling is high making them superdisintegrant. Like conventional disintegrant, they don‟t lump but additionally impart strength to the tablets. The use of ion exchange resins into drug delivery systems have been encouraged because of their physico-chemical stability, inert nature, uniform size, spherical shape assisting coating and equilibrium driven reproducible drug release in ionic environment. Ion exchange resins are insoluble polymers that contain acidic or basic functional groups and have the ability to

exchange counter-ions within aqueous solutions surrounding them.

Croscarmellose sodium: Swells 4-8 folds in < 10 seconds. Swelling and wicking both. High swelling capacity, effective at low concentration (0.5-2.0 can be used up to 5.0%) Croscarmellose sodium is described as a cross-linked polymer of carboxymethylcellulose. Apart from the differences between the starch and cellulose polymer backbones, there are Differences between the synthetic processes used to modify the polymer. Most importantly, the DS of croscarmellose sodium is higher than that of sodium starch glycolate, and the mechanism of cross-linking is different. The substitution is performed using Williamson's ether synthesis to give the sodium salt of carboxy-methylcellulose. A key difference from the chemistry of sodium starch glycolate is that some of the carboxy-methyl groups themselves are used to cross-link the cellulose chains, the process being accomplished by dehydration. Thus the cross-links are carboxyl ester links rather than phosphate ester links as in Primojel.

CONCLUSION

Disintegrants are substances added to tablet to facilitate the breakup of the tablet into smaller particles in an aqueous environment thereby increasing the available surface area and promoting a more rapid release of the drug substance.

Recent development in fast disintegrating technology mainly works to improve the disintegration quality of these delicate dosage forms without affecting their integrity by using suitablesuper disintigrant. Superdisntigrants are more effective at low concentration then disintigrants with greater disintegrating efficiency and mechanical strength it is use in low amount in tablet typically 1-10% by weight relative to the total weight of the dosage unit. In this era natural and synthetics disintigrtants are available still there is need search of natural disintigrants which is not explored for its disintegration action.

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