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AN OVERVIEW ON NATURAL SUPER DISINTEGRANTS USED IN FAST DISSOLVING TABLET AND THEIR EFFECTS

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ABSTRACT

Fast dissolving tablets are an emerging trend in novel drug delivery system and have increasing demand during the last few decades. Superdisintegrants are used in orally disintegrating tablet to improve the disintegration and efficacy of solid dosage forms. This is achieved by decreasing the disintegration time which in turn enhance drug dissolution rate. Disintegrates are substances which are used in formulations to promote the break down of the tablet (and capsule "slugs') into smaller fragments in an aqueous environment thereby increasing the available surface area and promoting a rapid release of the drug substance. Natural superdisintegrants remain an attractive role in orally disintegrating tablet because they are natural products of plants, readily available, inexpensive, biocompatible and capable of multitude of chemical modification. In recent years, some newer substances have been developed known as Superdisintegrants. Natural superdisintegrants are obtained from the natural origin and having a numbers of advantages like they are cost efficacious, nontoxic, biodegradable, eco-friendly, devoid of any side effect, renewable and also provide nutritional supplement. It is proved from variuos studies that natural polymers are more effective and safe than the synthetic polymers. The aim of the present article is to study the natural polymers utilized and their action in fast dissolving tablet.

KEYWORLDS: Fast Dissolving Tablet, Disintegrants, Natural Superdisintegrants, Natural Polymer, Biodegradable, Non-toxic.

INTRODUCTION

Fast dissolving tablets are novel drug delivery system that dissolves, disintegrate or disperse the medicine in saliva within few seconds with or without intake of water. In orally administration formulation superdisintegrants play a important role for disintegration and dissolution of tablet so the field has become a rapidly growing area in the pharmaceutical industry and become more popular due to ease of administration and better patient compliance in geriatric and pediatric patients. In case of mouth dissolving tablets fast disintegration is an essential step for faster drug release and quick action, thus superdisintegrants are added to facilitate faster disintegration hence disintegrating agents are added in the solid dosage forms. They are added in less concentration of 1-10% by weight relative to total weight of dosage units. The faster the dissolution of drug into the solution, quicker is the absorption and onset of clinical effect of drug. The bioavailability and therapeutic effect of some drugs may also increased due to absorption of drugs in oral cavity or also due to pregastric absorption of drug from saliva that pass down into the stomach.

Classification of Superdisintegrants

Based on their source of origin, superdisintegrants can be classified in following categories

A) Natural

B) Synthetic

C) Semi-synthetic

Natural Superdisintegrant

These are various plant based materials which serves as an alternative to synthetic products because they are

- Biodegradable:
- Biocompatible
- non-toxic
- Local accessible
- Patient tolerance as well as public acceptance.
- Eco-friendly and Bio-acceptable
- Low price as compared to synthetic and renewable source.

Mucilage of Lepidum Sativum (Asaliyo)

Lepidum sativum (family: Cruciferae) is commonly known as asaliyo and widely used as herbal medicine from a long time in India. it is easily available in local market and has very low cost. Parts used are leaves, root, oil, seeds etc. Seeds contain higher amount of mucilage containing 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 properties like binding, disintegrating, gelling etc. Hence isolated the mucilage from seeds and its used into develop the fast dissolving tablet in a study.[1] The super disintegrants obtained from mucilage of Lepidium sativum posses good physiochemical properties and Swelling index of the mucilage and Husk obtained from Lepidium sativum were found to be 27 and 25 respectively. The swelling factor is related to the disintegration of tablets rapid water uptake and rapid swelling leads to rapid disintegration of tablets.[2] The LOD value is within prescribe limit as specified in official. The compressibility index and angle of repose value indicates that the mucilage and the husk powder have good flow characteristics with moderate compressibility. Different batches were formulated using different ratio of drug, mucilage and husk of the seeds of Lepidium sativum by direct compression technique. Other excipients such as sucrose, microcrystalline cellulose, talc and magnesium stearate were incorporated in the formulation. Coarser grade of Microcrystalline cellulose (PH102) was selected as diluent as it facilitate the flow property of the blend from the hopper.[3]

Lovleen kaur et.al. prepared a fast dissolving tablet of aceclofenac using Mucilage of Lepidum sativum and find that Formulation D5 was selected by the design expert software which is exhibit DT 15.5 sec., WT 18.94 sec., and invitro drug release (100%) with in 15 min.[4]

Locust bean

Locust bean gum also called as carob bean gum is a galactomannan vegetable gum extracte which is extracted from the seeds of the Carob tree (Ceretonia siliqua), mostly found in the Mediterranean regions. It has been widely used in food industry as a thickening and gelling agent. It has also been reported to having a ioadhesive and solubility enhancement properties.[5] Malik K et al carried out formulation and evaluation nimesulide orodispersible using locust bean gum as superdisintegrant. The gum of Locust bean was evaluated for powder flow properties, swelling index and loss on drying and it show Excellent powder flow properties, swelling index was found to be 20 sec. which indicated appreciable capability of

locust bean gum to be used as superdisintegrant in fast dissolving tablet. The prepared tablets were evaluated against standard superdisintegrant i.e. crosscarmellose sodium. Disintegration time of tablets containing 10 % locust bean gum as superdisintegrant was found to be 13 second.[6]

Isapghula Husk (Plantago ovata)

Pantago ovata belongs to the family of Plantaginaceae. The seeds and psyllium husk are valuable sources of fibers and mucilage of this plant. Psyllium husk is used as a laxative, to lower the glycemic index, and for the development of controlled-release formulations in the pharmaceutical industry. Psyllium husk increase its weight of increases up to 10 times due to quick water absorption. Hydrocolloids make up 10–30% of psyllium husk; these are water soluble polysaccharides that form mucilage layers when exposed to water. During hydrolysis, mucilage splits and the variuos polysaccharides, including xylose, arabinose, galacturonic acid, rhamnose, and galactose, are obtained. These compounds are responsible for the disintegrative properties of psyllium husk and could be applied as natural disintegrants in drug manufacturing.[7] The disintegrating property of Plantago ovata mucilage was evaluated by Prajapati et al. prepared dispersible tablet of Nimesulide with wet granulation technique and found that the mucilage was effective at low concentration as superdisintegrant. Further, the results revealed that disintegrant property of isabgol mucilage was equivalent to Ac-Di-Sol and superior to sodium starch glycolate.[8] Chakraborty S et al. carried out a comparative study of natural superdisintegrant over the synthetic counterpart and obtained the similar results. They prepared fast dissolving tablets of aceclofenac by direct compression method employing microcrystalline cellulose used as a diluent and isabgol or Ac-Di-Sol or sodium starch glycolate as the disintegrant. The study attributed the better disintegrating property of isabgol mucilage over the Ac-Di-Sol and sodium starch glycolate and also to the higher swelling index of isabgol mucilage as compared to the Ac-Di-Sol and sodium starch glycolate.[9]

Hibiscus rosa sinesis linn

Leaves of Hibiscus rosa- sinensis Linn (family: Malvaceae) contains high proportion of mucilage which can be used as additives in pharmaceutical formulations. Gailute Draksiene et al. was carried out to study the disintergant property of Hibiscus rosa-sinensis mucilage using imipramine as a model drug and the work was carried out to develop fast dissolving tablet of Imipramine using natural disintegrant which is isolated from Hibiscus rosasinensis

leaves and its efficiency was compared with synthetic superdisintegrant like crosspovidone. Hibiscus rosasinensis mucilage was isolated and characterised for its identification by chemical test and micrometric properties. Fast dissolving tablets of Imipramine were formulated by direct compression method using Hibiscus rosa-sinensis mucilage (2-8% w/w), Avicel PH 102 as diluents, mannitol to enhance mouth feel and compressibility, as sweetener. The formulated tablets were evaluated for their pre and post compression parameters like tablet hardness, thickness, % friability, wetting time which was found to be in permissible limits. The in vitro disintegration time of tablet formulations containing 6% of mucilage was found to be 24 sec and that of tablet containing 4% of crosspovidone was 42secs. Based upon in vitro disintegration time in vitro drug release studies were carried out in phosphate buffer p H 6.8 which showed 100% drug release in 12 minutes of F3 formulation containing 6% of mucilage. Stability studies performed on F3 formulation indicated that the prepared tablets remain stable for the period of 90 days and showed no change in in vitro drug release pattern.[10]

Gellangum

Gellan gum is a linear anionic polysaccharide biodegradable polymer obtained from Pseudomonos elodea consisting of a linear tetrasaccharide repeat structure.[11] Antony et al. studied that the Gellan gum as a superdisintegrant and the efficiency of gum is compared with conventional disintegrants such as dried corn starch, explotab, avicel (pH 102), Ac-di-sol and Kollidon CL etc. The instantaneous swelling characteristics of gellan gum when it comes into contact with water and owing to its high hydrophilic nature the disintegration of tablet take place and complete disintegration of tablet is observed within 4 minutes with gellan gum concentration in the formulation of 4 percent w/w and 90 percent of drug dissolved within 23 minutes. Ac-di-sol and Kollidone CL shows very similar pattern of disintegration and in vitro dissolution rates. The same concentration formulation with explotab show 36 minutes for 90% of drug release and with starch show 220 minutes. Hence the conclusion of study were that gellan gum has been proved itself as a superdisintegrants.[12]

Xanthan gum

Xanthan Gum produced by a fermentation process using the bacteria Xanthomonas campestris it show high hydrophilicity and low gelling tendency. The xanthan gum has low water solubility and extensive swelling properties for faster disintegration. Xanthan gum has

a β-(1→4)-D-glucose backbone where every second glucose unit is attached to a trisaccharide consisting of mannose, glucuronic acid, and mannose. The negatively charged carboxylates from glucuronic acid allow it to form highly viscous fluids at appropriate pH. Although it is considered a nongelling gum, it generates a viscous medium due to its tenuous associations. Although it is highly swellable, it slows drug release in sustained release formulations**.** Modified xanthan gum obtained was biodegradable, directly compressible and exhibited desirable swelling dynamics to be used as a hydrophilic excipient for rapidly disintegrating tablets. The rapidly disintegrating tablets of roxithromycin formulated with lower level of modified xanthan gum and higher level of MCC was selected as the optimized formulation that displayed nine fold reductions in lag time, was stable for a period of 12 months and retained the rapid disintegration characteristics till the end of tested time period.[13]

Soy polysaccharide

The high fibrous soy polysaccharide material generally comprises high relative molecular mass carbohydrate polymers primarily contained in soybeans, like arabinose, galactose, xylose and mannose. It is normally employed as a collective term to explain the fibrous carbohydrate material obtained from the cell membrane structural components of soybeans that include soy flakes, flour, or meal.[14] Antony et.al. was carried out to study the disintergant property of soy polysaccharide using as a model drug Sildenafil citrate (SC) sublingual formulae containing the superdisintegrant component (Emcosoy or Explotab) were acceptable and their behavior in touch with water was excellent as indicated by the short wetting time that ranged between 25 seconds and 40 seconds, high water absorption ratio that ranged between 41 and 60, and short in vitro dispersion time that ranged between 55 seconds and 74 seconds. While the formulae prepared without superdisintegrant (F11,F12) showed long wetting and dispersion time, formulae F2 and F4 that contained superdisintegrant during a great deal (20 mg) were excellent in their wetting and dispersion behavior in comparison with same formulae prepared with little amount of (10 mg) superdisintegrant. This indicated that the presence of superdisintegrant within the sublingual tablet formula with optimum concentration is an important factor for achieving a suitable level of dispersion of the tablets. The tablet containing 8% soy polysaccharide as a superdisintegrant and it provided a wetting time of 25 seconds, and in vitro dispersion times of 55 seconds. The drug release was found to be 95.6%. The prepared SC sublingual tablet also exhibited a rapid onset of action, and its bioavailability was enhanced by 1.68-fold in the compariasion with the marketed tablets. It can be concluded that SC sublingual tablet is a promising formulation that results in higher

solubility, faster dispersion and onset of action, higher release rate, and higher systemic bioavailability.[15]

Mango peel pectin

Mucilage and pectin is most commonly used as adjuvant in the manufacture of different pharmaceutical dosage form. They possess a spread of pharmaceutical properties, which include binding, disintegrating, suspending, emulsifying and sustaining properties at different proportion in several pharmaceutical dosage form the synthetic polymer used as excipients suffer from any disadvantages such as high cost, toxicity, nonbiodegradability and environmental pollution caused during their synthesis. Natural mucilage, pectin, pulps are preferred over semi-synthetic and synthetic materials, due to their non-toxic, low cost, free availability, emollient and non-irritating nature. Magnifera indica contains 16% to twenty tannin, namely protocatechuic acid, kinic acid and catechin. it also contains mangiferine, alanine, shikimic acid and astringent and contains resinous gum, it is used as a vermifuges and astringents used in treatment of rheumatism.[16] Pectin of natural origin is preferred over semi-synthetic and artificial substances because pectin is relatively cheaper, abundantly available, non-irritating and nontoxic. European Pharmacopoeia defines oro-dispersible tablets as "uncovered tablet for buccal cavity, where it disperses before ingestion". Active moiety can rapidly dissolve in saliva and so absorbed through buccal mucosa. Freeze drying, sublimation, moulding or direct compression are techniques wont to prepare this sort of tablets. Rishabh malviya et.al. prepared a fast dispersible tablets of a model drug using mango peel pectin (MPP) and it was extracted by simple wet granulation method to develop, Diclofenac sodium, and effect of MPP as superdisintegrant was compared with synthetic superdisintegrant like sodium starch glycolate (SSG). Diclofenac is a non-steroidal anti-inflammatory so Naturally obtained MPP stands as an honest candidate to used as superdisintegrant though, not as stronger as synthetic sodium starch glycolate but although thanks to its good solubility and better swelling index, it's going to be utilized in formulation of fast dispersible formulations.[17]

Agar and treated agar

It is the dried gelatinous substance obtained from various species of family: Gelidanceae like *Gelidium amansii* and several other species of red algae like *Gracilaria* and *Pterocladia*. Agar is yellowish-gray or white to proximately colorless, inodorate with mucilaginous taste and is out there within the sort of divests, sheet flakes, or coarse powder. Agar consists of two

polysaccharides, agarose and agar pectin. Agarose is responsible for gel vigor and agar pectin is responsible for the viscosity of agar solutions. High gel vigor of agar makes it a potential candidate as a disintegrants. P. Bhardwaj et.al.prepare orodispersible tablets of metformin hydrochloride using agar as natural super disintegrant and the objective of the work is to improve bioavailability, disintegration time, dissolution efficacy and patient compliance. Formulation of nine batches out of which batch F5 with 6% super disintegrant was found to have better results in compare to other formulations, the F5 batch was passed with friability test and found negligible loss (0.4%), Then the batch was further evaluated for disintegration test and found to have 11.03 sec and *in-vitro* dispersion was found to be 15 sec in simulated saliva fluid and percentage drug release was evaluated to be 98.5% in less than 30 min. Hence, F5 batch was found to be better as it contain 6% treated agar. It shows further potential to carry animal model.[18]

Gaur gum

Guar gum consists of a linear chain of β-(1→4)-linked D-mannose units with D-galactose attached by α-(1→6) linkages to every other mannose unit to form short side chains.[19] Though not sel.f-gelling, guar gum has a high low-shear viscosity. Because it is nonionic, it is not affected by ionic strength or pH.[20] Guar gum is a nonionic polysaccharide derived from the seeds of Cyam.opsis tetragonolobus, family Leguminosae. It consists of linear chains of (1?4)- â -D-man..nopyranosyl units with á-D-galactopyranosyl units attached by (1?6) linkages. In pharmaceuticals, guar gum is used in solid dosage forms as a binder and disintegrant.[21-23] A few reports appear on the use of guar gum, as a hydrophilic matrix, for designing oral controlled release dosage forms.[24-27] Sunitha HS. et al. developed Captopril tablet using gaur gum as superdisintegrant and evaluated for pre compression and post compression parameters which complied official limits. Among all the formulations, formulation F4 containing guar gum 10 mg gives best disintegration and dissolution profile compared with other formulations, showed drug release of 99.86±0.54 % with 12 min and disintegration time 50.16±1.32 sec.[28]

Chitin and Chitosan

Chitin (β-(1→4)-N-acetyl-Dglucosamine) is a natural polysaccharide obtained from crab and shrimp shells. It possesses amino group covalently linked to acetyl group as compared to liberate amino group in chitosan. Chitosan is commercially produced by deacetylation process of chitin, which is the structural element in the exoskeleton of crustaceans (such as

crabs and shrimp) and cell walls of fungi. A high proportion of chitin in the powder mixtures results in tablets with a lower crushing strength and higher friability. At a low level of lubrication (0.1%), the combination of chitin with MCC (Avicel® PH 102) is more beneficial than with SDLC (Cellactose®) in terms of flowability of the powder mass and mechanical strength of the tablets. At a higher level of lubrication (0.5%), the tablets compressed are weaker and more friable irrespective the composition used. Consequently, due to its sensitivity to the presence of magnesium stearate, and this incompatibility there was one limitation of using chitin as a co-diluent in direct compression is should be taken into account in the formulation of chitin-based tablets. In conclusion, if tablet lubrication is properly selected, fractioned chitin of crustacean origin can be used in small proportions as a direct-compression co-diluent with MCC to improve the pharmaceutical quality of the tablets.[29] Olorunsola et al evaluate callinectes chitosan as a superdisintegrant in metronidazole tablet yield of 36.7% chitosan having degree of deacetylation of 62.7% was obtained from the crab shell. Fourier Transform Infrared absorption bands at 1495 and 3240 cm-1 typical of N-H bending and stretching respectively; and endothermic peak of 159 °C typical of melting of chitosan were obtained. There was no adverse interaction between the chitosan and metronidazole observed. The disintegration times of tablets containing 2, 4 and 8% chitosan were found 12.2, 10.4 and 9.3 min respectively.[30]

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