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Review Article

Comparative study of natural disintegrants, selection criteria for superdisintegrants

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ABSTRACT

Natural super disintegrants have been used for fast dissolving tablets because they are biodegradable, chemically inert, non-harmful, more affordable and widely available. The natural polymer improves the properties of the tablet as it is commonly used as diluents and binders. Super explosives are those substances that promote rapid decomposition in a lesser amount compared to explosives. Super disintegrants are the vehicles added to the tablet formulation to promote the breakdown of tablets and capsules into small microparticles in aqueous media, leading to an increase in surface area and promoting rapid drug release. Some research is going to develop safe and effective medication with super disintegrating agents that can be dissolved rapidly to treat the disease.

Key words: Natural Disintegrants, Superdisintegrants, ODT, FDT and Disintegration process.

INTRODUCTION

Disintegrants are substances or mixtures of substances added to pharmaceutical preparations that help collapse or disintegrate the contents of tablets or capsules into smaller particles. New materials called superdisintegrants have been developed to improve the disintegration process [1]. The plan features of fast disintegrating tablets can be obtained by selecting appropriate dosage forms and support materials and production technology [2].

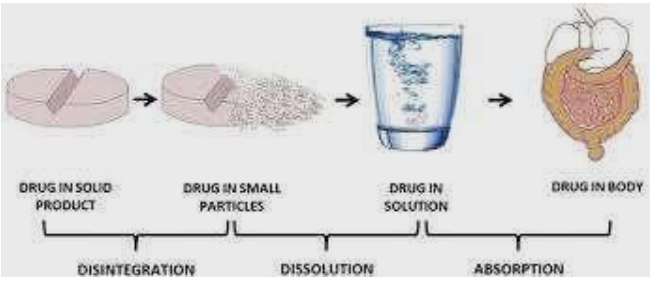

Figure 1: Disintegration of tablet

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The main function of disintegrants is to influence the effectiveness of tablet binders and the physical forces acting on compression to form tablets. In solid dosage forms, the amount of superdisintegrants is usually small and typically amounts to 1-10% of the total weight of the dosage unit. Natural disintegrants such as karaya gum, psyllium husk, agar, and modified starch, are used in the formulation of instant tablets [3]. Due to its many advantages, such as simplicity of administration, dose accuracy, self-medication, adaptability and, above all, patient compliance, the oral route of administration remains the preferred method of administration. Most recommended. Therefore, oral solid formulations are increasingly used1. Fast Dissolving Tablets (FDT) are solid single unit dosage forms that are placed in the mouth and allowed to disperse/dissolve in saliva without the need for water resulting in a rapid onset of action. The bioavailability of some drugs may be enhanced due to absorption of the drug in the oral cavity as well as pregastric absorption of saliva containing dispersed drugs that travel down the stomach [4,5] .

Disintegration Phenomena:

The disintegration process is an integral step in ensuring, if not maximizing, the API bioavailability of most solid dosage forms. With the exception of controlled diffusion matrix systems, the wetting and subsequent disintegration of the powder compact into the tablets is the first step towards releasing the API from the dosage form. Without disintegration, only the API close to the surface of the tablet would be able to dissolve and thus reproducible and complete disintegration of the tablet after exposure to the dissolution medium is of critical importance to obtain reliable clinical performance of the dosage form.[6,7]

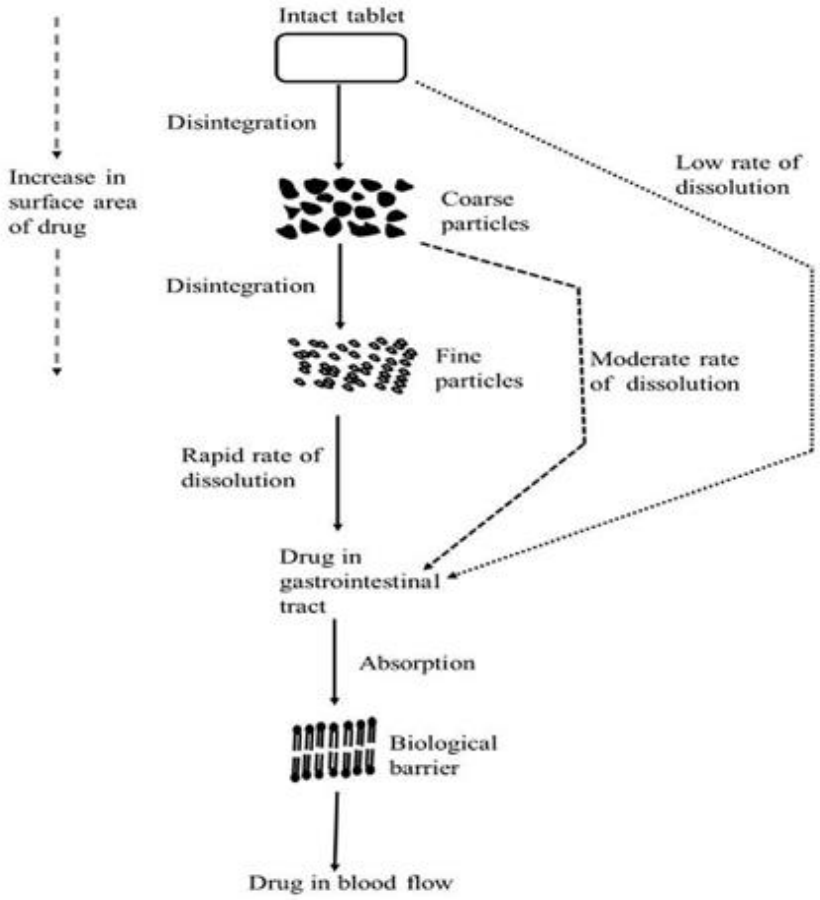

Figure 2: Disintegration process

SELECTION CRITERIA FORSUPERDISINTEGRANT

Because superdisintegrants are used as fillers in tablet form, they must meet certain criteria in addition to their swell ability. Requirements for disintegrating tablets should be clearly defined. An ideal digester should have-

- When the tablet comes into touch with saliva in the mouth/oral cavity, proceed to fast breakdown.

- Be small enough to make tablets that are less friable.
- Provide patients with a pleasant mouth sensation. To promote patient compliance, tiny particle size is desirable.
- Have good flow since it increases the whole blend's flow qualities.[7,8,9]

Mechanism action of disintegrant:

One or more of the mechanisms indicated below split the tablet into fundamental particles.

- **By capillary action-** replaces the air deposited on the particles, deteriorating and breaking the tablet into fine trash particles.
- **By swelling-** Perhaps the most well accepted general mechanism action for tablet into disintegrant is swelling, which causes pressure, which causes disintegrants.
- **Due to release of gases-**Due to the development of pressure within the tablet, the tablet disintegrants.
- **Due to repulsion-**The mechanism of disintegration is electric repelling interactions between particles, and water is necessary.[10]

Advantages and disadvantages of natural-disintegrants:

Advantages-

- Effective in lower concentrations than starch.
- Less effect on compressibility and flow ability.
- Beneficial in cases such as motion sickness, coughing, where an ultra-rapid onset of action required.

Disadvantages-

- More hygroscopic may be problem with moisture sensitive drugs.
- Some are anionic and may cause some slight invitro binding with cationic drug.[11]

Natural Superdisintegrants

Natural superdisintegrants are added in dosages form that promotes the drug release in the systemic circulation. They are increased the water wicking into the sludge, that are promoted to degradation of the plug particle Adding of the natural disintegrants a tablet or capsule etc. Formulation does facilitate the release of drug, thus they make the formulation more rugged to the inevitable variation in excipients properties.

Table: 1 Name of Natural disintegrants with Application

S. No.	Natural Disintegrants	Pharmaceutical Application
1.	Gum agar	Suspending agent, sustained release agent, disintegrants, bacterial culture media.[12]
2.	Gellan gum	Disintegrating agent, ophthalmic drug delivery, beads, floating in situ gel. [13-16]
3.	Leucaena seed gum	Disintegrating agent, suspending agent, emulsifier. [17-45]
4.	Mimosa pudica	Binder, disintegrants agent.[18-19]
5.	Kyaha gum	Binder.[20]
6.	Locust beam gum	Controlled release agent. [21-22]
7.	Guar gum	Disintegrant agent, binder, thicker, laxative,
8.	Pullulan	Emulsifier. [23-29]Insulin preservation.[30]
9.	Acacia gum	Suspending agent, emulsifier, binder, demulcent, osmotic drug delivery system. [31-33]
10.	Tamarind gum	Binder, mucoadhesive drug delivery, emulsifier. [34-35]

Table: 2 Common Names of Natural Disintegrants with use [36-47]

S. N	Vernacular Name	Botanical Name	Family	Chemical Constituents	Uses	Reference	Figure
1-	Agar	*Gelidiumamansii*	*Gelidaceae*	Agaropectin Agarose D-galactose L-galactose	Laxative Pargative	Solunke A, (2018)	
2-	Hibiscus	*Hibiscus rosa-sinensis*	*Malvaceae*	Anthocyanins Polyphen Quercetin	Dry Cough Skin Affliction Gallblader Attack	**Khristi**Vincenta,etal., (2017)	
3-	Aloevera	*Aloe barbadensis Miller*	*Liliaceae*	Lignin Saponins Salicylic Acid Vitamin	Remove Acne Heals burn Moisture Skin	**Gupta**BrijMohan, etal., (2017)	
4-	Mango	*Mangiferaindica*	*Malvaceae*	Malic Acid Citric Acid	Prevent Diabetes Heart Health Eye Health	**YahiaElhadiM.,et al.,(2019)**	
5-	Psyllium Plant	*Plantagoovata*	*Plantains*	Anvertyn Tanin Vitamin C	Irritable Bowel Syndrome IBS Diarrhea Hemorrhoids	Katke S. D.,etal.,(2020)	
6-	Garden cress	*Lepidiumsativam*	*Cruciferae*	Cardia Glycoside Coumarin Sinapic Acid Triterpine	Asthama Bronchitis Cough	Abdelaleem M. A.,etal.,(2019)	
7-	Neem	*AzadirachtaIndica*	*Meliaceae*	Arabinose Xylose Glucosamine Arabinose	Leprosy Bloody Nose Intestinal worms Diabeties Birth control	**GiriRudra Prasad, et al.,(2019)**	
8-	Banana	*Musa acuminata*	*Bananas*	Pantothenic acid Pyridoxine Choline Vitamins C	Diabetese Hypotension Cancer	SarahMathew,et al.,(2017)	
9-	Karaya	*SterculiaurensRoxb.*	*Malvaceae*	Galactose Rhamnose Galacturoni Acid	Anti-inflamatry Laxative Adhesive Aphrodisiac	Vineet Kumar,et al.,(2020)	

10 -	Fenugreek	*Trigonellafoenum-graecum*	*Fabaceae*	Alkaloids Aminoacid Steroidal flavinoids	Diabities Sexual hormone	Kumar Pradyuman,et al.,(2018)	

Prospective on ODT Dosage Forms' Current and Future Challenges and Opportunities

ODTs are a dosage form that can create high levels of patient compliance, as mention in the preceding sections. As a result, formulation scientists continue to be captivated by the formulation of ODT dosage forms. The obstacles, clinical opportunities, and future potential of ODT dosage forms.

Table: 3 Challenges, clinical opportunities, and future of ODTs

Challenges	Clinical Opportunities	Future of ODTs
When formulated as ODTs, novel medications or APIs (active pharmaceutical ingredients) with limited or very poor water solubility may provide major hurdles.	For marketed medications that do not currently have a Commercially viable ODT dose form (particularly for Paediatric and geriatric patients), ODTs can be shaped	3D printing technology advancements will advance the creation of personalized or patient specific ODTs
Because of their essential instability and disintegration in the hostile environment of the GI tract, ODTs of complex biological substances (proteins, peptides, etc.) would needto be overcome by inventing ODT matrices that protect the drug.	ODT dose forms are ideal for acute and chronic pain because of their quick beginning of action.	liberate that is either controlled or continuous ODTs give a one-of-a-kind opening to expand the therapeutic effect of ODTs.
	Patients can save money by using drug combination ODTs (bilayer ODTs), which also have the benefit of being Individualized therapy.	There will be added examine into (a) the use of innovative materials for taste masking and (b)more relevant testing of ODT disintegration times and Disintegration media.

Future Prospects

The rapid dissolution tablets have a number of biopharmaceutical advantages, including greater efficiency than traditional dose forms. Tablet hardness, friability and stability can all be improved to the point that packing multiple tablets in standard bottles is becoming commonplace. There may be no miracle, but a more effective use of existing taste masking technologies to alleviate taste masking issues. Creating FDTs with controlled release qualities is key to the future of FDTs. Despite developments in FDT technologies, the formulation of hydrophobic drugs remains a problem, especially when the amount of drugs is high. Low dose medications, such as loratadine (10mg), are no problem, but as the dose increases, the formulation loses its ability to dissolve quickly. A new method has been developed to enable the incorporation of larger doses of hydrophobic drugs without negatively affecting the fast disintegration property. A rupture would be this FDT formulation so fewer excipients with respect to the drug itself.

Drugs in orodispersible pill dosage shape have the equal protection and effectiveness profile as the ones in traditional pill dosage shape. New approaches, which include Zydis, Wow Tab, Flash tab technology, and others, are evolved primarily based totally on conventional procedures, ensuing in a patent and a brand-new market place method for orodispersible tablets. This dosage kind is growing market place proportion each day and is turning into a greater suited option.

Extraction of Mucilage

The seeds were on the ground with a pestle and a mortar, and 100g of the powder was extracted with ESANO using a Soxhlet apparatus to eliminate lipophilic chemicals. The resulting solution was

combined with the equivalent volume of 96% ethanol and cooled for 4 hours. Centrifugation was used to separate the precipitated mucilage (5000g). To remove chloride ions and other contaminants, the recovered mucilage was suspended in distilled water, stirred for 20 minutes, and then precipitated again. Finally, the residue was washed with diethyl ether and acetone before being dried at 45° overnight, obtaining a whitish powder.[48-51]

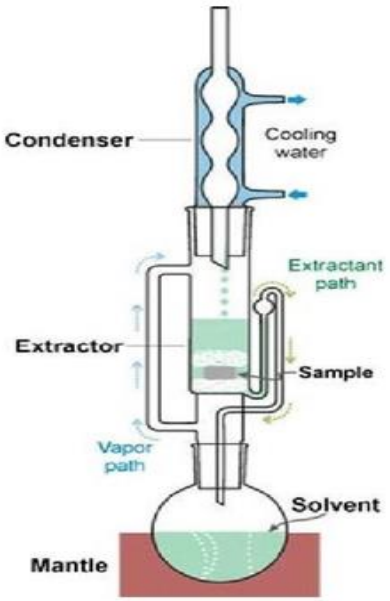

Figure 3: Soxhlet Apparatus

Conclusion

With the increasing demand for new drugs, the fast-dissolving drug delivery system has become an important stage of research. Although there are many super disintegrants, researchers are experimenting with modified natural products such as casein formalin, chitin, chitosan, polymerized acrylamide agar, xylan, smecta, keyjoclay, cross-linked carboxymethyl guar , mango skin pectin, cassia tora, cassia nodosa, modified Tapioca starch and modified Tapiocal According to studies, water-insoluble super-disintegrants have a greater disintegration property than sparingly soluble agents. Water because they do not swell. Due to the establishment of a viscous barrier, super disintegrants which tend to swell have a slight delay in disintegration.
Natural excipients offer a number of advantages over synthetic and semi-synthetic excipients. As a result, these excipients are gaining popularity day by day. Their potential property claimed the scientist in formulating more effective formulations. However, whether or not you work with these. Experiments and studies with natural excipients should be conducted in order to find the safest and most acceptable ones for pharmaceutical use.

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