



**International Journal of Biology, Pharmacy
and Allied Sciences (IJBPAS)**

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

UTILIZATION OF NATURAL SUPERDISINTEGRANT IN FAST DISSOLVING TABLET: A SIMPLIFIED REVIEW

BIDKAR S*, KADAM M, BIDKAR J, MANTRY S AND DAMA G

SGMSPM'S Sharadchandra Pawar College of Pharmacy, Dumbarwadi, Otur, Maharashtra
410504, India

*Corresponding Author: Shital Bidkar; E Mail: shitalbidkar@yahoo.com

Received 3rd Oct. 2021; Revised 11th Nov. 2021; Accepted 20th Dec. 2021; Available online 25th Jan. 2022

<https://doi.org/10.31032/ijbpas/2022/11.1.2058>

ABSTRACT

To achieve increased palatability in orally delivered products, numerous formulations with improved performance and acceptability have been developed. Fast dissolving tablets are a new trend in unique medication delivery systems that have seen an increase in demand over the last few decades. Disintegration of tablets is an essential step in achieving rapid drug release. Fast dissolving, quick melting, chewable and orally dissolving or disintegrating tablets are unit solid dosage form indefinite quantity that disintegrate rapidly and dissolve within the mouth without need of water. This type of feature in a dosage form is obtained through the addition of several excipients, the most important of which is the disintegrant. The fundamental issue in developing fast dissolving tablet formulations is to ensure that they disintegrate quickly, have a good tongue feel, and have a high breaking force for tablet strength. The disintegration of dosage forms is influenced by a variety of physical factors of superdisintegrants, including the percentage of disintegrants used in formulation, the proportion of disintegrants used, compatibility with other excipients and the presence of surfactants, tablet hardness, nature of drug substance mixing, and types of alternative excipient addition. Natural superdisintegrants includes chitin and chitosan, Guar gum, Locust Bean Gum, *Lepidium sativum*, *Plantago ovata*, Mango Peel Pectin, Dehydrated Banana Powder (DBP), Agar, *Hibiscus Rosasinensis linn* Mucilage, Gum karaya, Fenugreek Seed Mucilage, Gellan gum (kicogel) etc. The focus of this review is on the various types of natural superdisintegrants used in MDT, as well as their mechanisms and applications.

Keywords: Superdistintegrants, Tablets, Formulations, Excipients

INTRODUCTION

Many patients, especially the elderly and children, find it difficult to take medications. As a result, in order to address this issue, this Formulation is being carried out in order to improve patient compliance, formulate a new dosage form that is convenient for use by geriatric, pediatric and dysphagia patients, Reduce the cost of medication for those patients who cannot afford it, as well as improve existing products on the market, such as a new indefinite quantity kind, and lower the price of medications already on the market.¹ FDTs are a brand-new form of tablet that dissolves, disintegrates, and disperses in spit at short intervals. FDDDS (fast dissolving drug delivery systems) are an entirely new class of formulations that include the benefits of both liquid and traditional tablet formulations while also giving additional benefits over both previous dose forms.² The faster a medicine dissolves in a solution, the faster it

is absorbed and clinical results appear. Because of pregastric absorption of drug from saliva that passes down into the stomach, bioavailability of some drugs may improve medicine absorption in the oral cavity³. Natural gums and mucilages are preferred over semi-synthetic and synthetic excipients in the field of medication delivery because they are less expensive and more readily available, have a calming effect, and are non-irritant. Furthermore, because of their natural origin, they are environmentally friendly, capable of a wide range of chemical alterations, and likely degradable and compatible.⁴

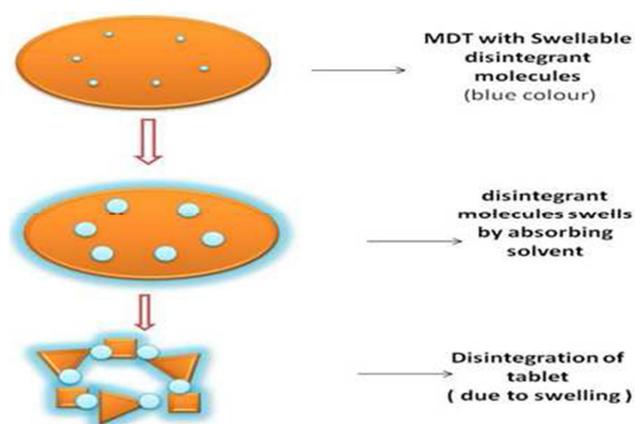


Figure 1: Mechanism of fast dissolving tablet

Selection criteria for Superdisintegrant : ^{5, 6}

Disintegration of tablets has attracted a lot of attention as a crucial step in achieving rapid medication release. Apart from its swelling capabilities, superdisintegrant is employed as an excipient in the tablet formulation to meet bound parameters. The tablet disintegrant's need should be explicitly established. should be present in the optimal disintegrate.

1. Poor solubility.
2. Poor gel formation.

3. Good hydration capacity.
4. Good moulding and flow properties.
5. No tendency to form complexes with the drugs.
6. Good mouth feel.
7. It must be compatible with the other excipients and provide excellent tableting properties.

Despite the fact that some are superior than others, the currently marketed superdisintegrants have the best mix of qualities.

Table 1: Ideal properties of FDT

Suitable for Conventional tablet process and packaging	Affirmative	Yes
Portable Dosage kind		Yes
Fragility Concern		No
Good Mouth Feel for taste		Yes
Sensitive to Environmental factors (humidity, temperature)		No
Toxic		No
Water needed for swallowing		No
Patient Compliance		Yes
Economic value		Yes
Leave Residue in oral cavity/Grittiness		No
Well suited with Taste Masking		Yes

Different method of preparation for fast dissolving tablet:^{7, 8, 9}

Several techniques have been developed on the basis of different principles as below:

1. Disintegrant addition
2. Freeze drying / lyophilization
3. Moulding
4. Sublimation
5. Spray drying
6. Mass extrusion
7. Direct compression
8. Taste masking

1-Disintegrant addition -entails adding superdisintegrants to the formulation at the correct concentration to achieve rapid disintegration/dissolution. Galanthamine HBr contains crosspovidone. In the formulation of prochlorperazine maleate, crosspovidone (3 percent w/w) and crosscarmellose Na (5 percent w/w) are utilised. Similar to traditional tablets, but with a higher percentage of disintegrants, a lesser hardness, and a higher percentage of friability.

2-Freeze Drying or lyophilisation - The medication is dissolved or dispersed in a carrier-associate solution. The mixture is poured into the pre-formed blister packs' wells. To freeze the medicine solution, the trays containing the blister packs are run through a liquid nitrogen freezing tunnel. The frozen blister packs are then placed in cool cupboards to finish the freeze-drying process. The blisters are then pre-packaged and sent. Characteristics: The formulations are exceptionally porous, have a large specific area, dissolve quickly, and have increased absorption and bioavailability as a result.

3- Moulding -water-soluble chemicals are combined with a hydro-alcoholic solvent and moulded into tablets at a lower pressure than in traditional tablet compression. Molded tablets are less compact than compressed tablets due to their porous structure, which increases disintegration/dissolution and, as a result, absorption rate.

4- Sublimation - Rapidly volatilizing inert solid components (urea, camphor ammonium carbonate, ammonium bicarbonate, hexamethylenetetramine) were added to the other tablet ingredients and compacted into tablets. Sublimation was used to eliminate the volatile components, resulting in a porous structure. Characteristics: porous structure that aids dissolution by utilising volatile materials or solvents such as cyclohexane, benzene, and other similar substances.

5-Spray-Drying – Supported by hydrolyzed and non-hydrolyzed gelatins, mannitol as a bulking agent, sodium starch glycolate or crosscarmellose sodium as a superdisintegrating agent, sodium starch glycolate or crosscarmellose sodium, and an acidic (e.g. citric acid)alkali material (e.g.sodium bicarbonate) to promote disintegration/dissolution When immersed in an aqueous media, the produced tablet disintegrates in a matter of seconds.

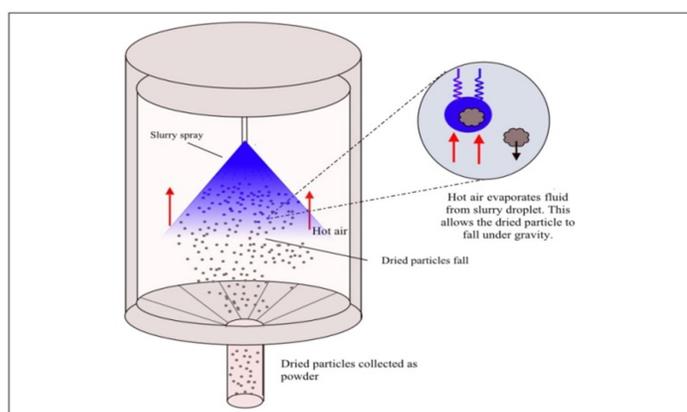


Figure 2: Spray-Drying Method for Preparation of Fast dissolving tablet

6-Mass-Extrusion – Softening the active mix, combining it with a solvent mixture of water soluble polythene glycol and methano, and then extruding or syringing the softened mass to induce a cylindrical form of the product into even segments using a hot blade to manufacture tablets. Characteristics: The dried product will cover bitter-tasting medication granules, concealing their bitter flavour.

7-Direct Compression - Direct compression employs standard instrumentation,

widelyavailable excipients, and a small number of process phases. Features: It is the most cost-effective tablet. The 8-Cotton candy method entails the synchronised action of flash melting and spinning to generate a polysaccharide matrix. After re-crystallization, the candy floss matrix is milled and combined with active substances and excipients before being compressed to FDT. It has greater mechanical strength and can accommodate large doses of medication.

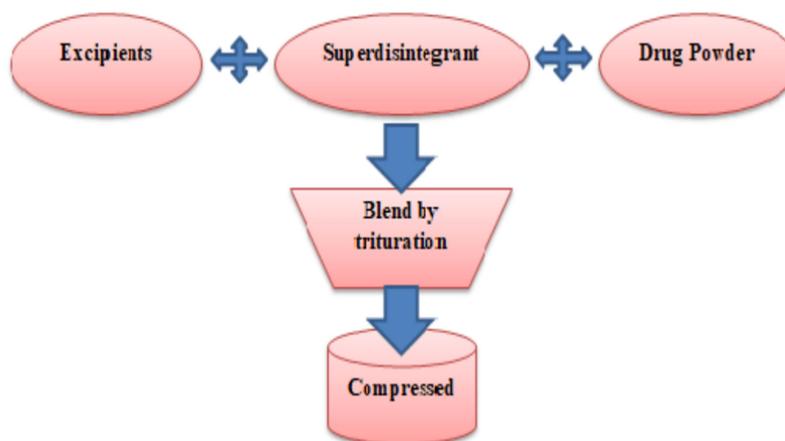


Figure 3: Direct Compression Method for Preparation of Fast dissolving tablet

8- Taste masking :

For industrial success, taste masking is a critical need for quick dissolving tablets. A variety of approaches are used to conceal the taste of the active substances. Microencapsulation of medicine with an unfavourable bitter taste in pH-sensitive acrylic polymers. Solvent evaporation and

solvent extraction procedures are used to microencapsulate cefuroxime axetil in a variety of acrylic polymers (e.g., Eudragit E, Eudragit L-55, and Eudragit RL). These compound tiny spheres demonstrated cost-effective Taste masking and total dissolving in a very short time. The bitter taste of sparfloxacin was disguised by fine granules

of drug and disintegrant (e.g. low substituted hydroxypropyl cellulose) coated with a water insoluble substance (e.g. ethyl cellulose). The addition of a low substituted hydroxypropyl polysaccharide as a disintegrant to the medication in cores resulted in a twofold increase in the rate of disintegration.

Salient Features of Fast Dissolving Drug Delivery System :¹⁰

1. The solid dose kind does not require water to ingest.
2. The dosage type disintegrates and dissolves quickly.
3. Because the medication goes down into the abdomen, it is absorbed through the mouth, tubular cavity, and muscle system. Because of the quick disintegration and dissolving of those pills, bioavailability of the drug is increased associate degree exaggerated bioavailability, particularly in circumstances of insoluble and hydrophobic medication.
4. The risk of choking or suffocation is reduced during oral administration of the conventional formulation due to physical obstruction, resulting in increased safety.
5. The ability to provide liquid pharmaceutical blessings in a variety of solid preparations.

6. flexible and compatible with existing processing and packaging machinery
7. Useful in situations where associate degree ultra-rapid onset of action is required, such as nausea, severe allergic reactions, or coughing.
8. New business opportunities such as product diversification, advertising, and patent extensions, as well as life cycle management.

Superdisintegrant :¹¹

Mouth dissolving tablets are prepared by numerous technologies with the help of superdisintegrants. Disintegrating agents are substances habitually included in the tablet formulations to help in the breakup of the compacted mass once it's place into a fluid surroundings. They help the tablet matrix to absorb moisture and disperse. Many novel agents known as "Superdisintegrants" have been developed in recent years. These novel chemicals have higher dissolving potency and mechanical strength, making them more effective at lower concentrations. When superdisintegrants come into touch with water, they swell, hydrate, alter volume or form, and cause a disruption in the tablet.

Mechanisms of superdisintegrants :^{12 13 14}

1. **Swelling:** Swelling is perhaps the most well understood overall mode of action for tablet disintegration. Due to

a lack of sufficient swelling force, tablets with a high consistency disintegrate poorly. On the other hand, a significant amount of swelling force is exerted within the pill, despite its low consistency. It's worth noting that if the packing fraction is exceedingly high, fluid cannot penetrate the tablet, and disintegration slows down again.

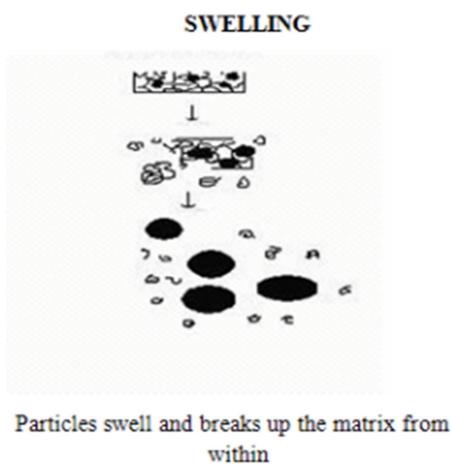


Figure 4: Mechanism of superdisintegrant (Swelling).

2. Porosity and Capillary Action

(Wicking): Porosity and Capillary Action play a role in the disintegration of some superdisintegrants. The disintegrated particles act to boost consistency that conveys ways that for the permeation of fluid into tablets. Afterward via wicking action, the liquid is tired up, this leads to inter particulate bonds

breakdown and ultimately tablet disintegration. e.g. Crosspovidone, Crosscarmellose.

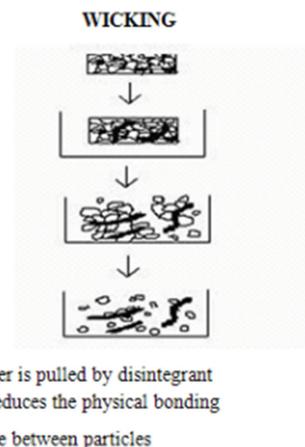


Figure 5: Mechanism of superdisintegrant (Wicking).

3. Deformation: once the pressure applied to the starch grains they deformed and once pressure removed they will inherit original form. however once they compressed into tablets they deformed permanently which release their energy once coming back in contact with water

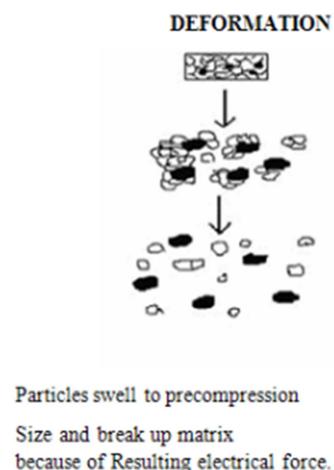


Figure 6: Mechanism of superdisintegrant (Deforming).

4. Due to disintegrating particle/particle repulsive forces:

Another mechanism for disintegration tries to explain why tablets constructed with 'nonswellable' disintegrants swell. Guyot-Hermann proposed a particle repulsion theory to explain why nonswelling particles are also responsible for tablet disintegration. The mechanism of disintegration is electric repelling interactions between particles, and water is required. Researchers discovered that wicking comes second to repulsion. Many novel agents known as "Superdisintegrants" have been developed in recent years. These novel chemicals are easier to work with at lower concentrations and have greater dissolving potency and mechanical strength. When superdisintegrants come into touch with water, they expand, hydrate, change volume or form, and generate an amendment within the tablet. Effective superdisintegrants improve compressibility and compatibility while having no negative impact on the mechanical strength of high-dose medication formulations. Super disintegrants provide important enhancements over starch. however hygroscopicity could also be a retardant in some formulations. As time passes, the desire for faster dissolving

formulations grows. As a result, health professionals must develop disintegrants, such as Superdisintegrants, that are effective at low concentrations, have a higher disintegration potency, and are easier to administer intragranularly. And because of the swelling pressure imposed in the outer or radial direction, when a tablet bursts or water absorbs more quickly, the volume of granules explodes, accelerating disintegration. The development of large groups of chemicals that swell to several times their original size when introduced in water while producing minor consistency consequences is underway.

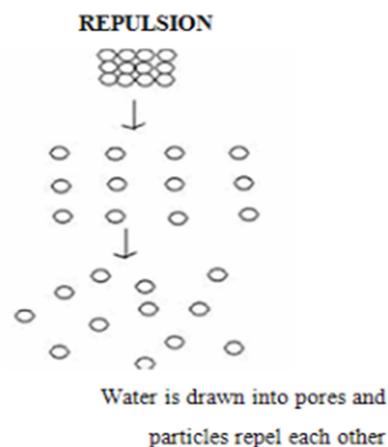


Figure 7: Mechanism of superdisintegrant (Repulsion) Disintegrants in Tablets: Methods of Incorporation:¹⁵

As shown below, there are three techniques for introducing dissolving agents into the tablet:

1. Internal Addition (Intragranular) - In this procedure, the disintegrant is mixed with alternate powders before the granulating fluid is applied to the powder mixes. As a result, the disintegrant is integrated into the granules at regular intervals.

2. External Addition (Extragranular) - In external addition, the disintegrant is combined with the sized granulation prior to compression.

3. Partly Internal and Partly External- During this methodology, a portion of the disintegrant is internal and a portion is external. This causes the tablet to be immediately disintegrated into previously compressed granules, while the disintegrating agent at intervals between the granules causes additional erosion of the granules to the initial powder particles. When compared to the traditional method of applying the disintegrant to the granulation surface, this method often generates higher and more complete disintegration.

Polymers used in the Fast Dissolving Tablet are classified as follows:¹⁶

- (1) Natural compound
- (2) artificial compound
- (3) Semi-synthetic compound

Natural compound :

These are measurements of a variety of plant-based products. Because of the following

reasons, plant-based material is a viable alternative to synthetic materials:

- (i) native accessibility
- (ii) Eco-friendliness
- (iii) Bio-acceptability
- (iv) It has a low value and a renewable supply as compared to artificial products.

Natural superdisintegrants have the following advantages:¹⁷

The following are the several sorts of natural plant-based materials.

1. Biodegradable: perishable since they are found in nature and are produced by all living species.

2. Non-toxic and biocompatible: fundamentally, all of those plant elements are sugar polysaccharides.

3. Low cost: they are less expensive to use than natural resources. When compared to artificial materials, the cost of production is lower. Agricultural is a big deal in Asia and a lot of other emerging countries, and there's a lot of money invested in agriculture.

4. Environmentally friendly processing: It contains a wide range of natural chemicals derived from various plant sources that are widely employed in the pharmaceutical industry and purchased in large quantities due to the simple manufacturing techniques involved.

5. native convenience (especially in developing countries): The government promotes the assembly of plants as pharmaceutical excipients in Asian countries and undiversified developing countries, but it does not provide facilities for bulk production, such as gum and mucilage, have a wide range of industrial applications.

6. Patient tolerance as well as public acceptance: natural materials are less likely to cause unpleasant effects than manufactured materials.

Sources of natural Superdisintegrants :¹⁸

They are natural in origin and are preferred over synthetic drugs since they are less expensive, easier to obtain, non-irritating, and non-toxic in nature. Natural materials such as gums and mucilages are widely used in the fields of drug delivery and availability, cost effectiveness, environmental friendliness, emollient and non-irritant nature, non-toxicity, ability to undergo a wide range of chemical modifications, and are unquestionably degradable and compatible due to their natural origin. There are numerous superdisintegrating gums and mucilages available.

Chitin and chitosan¹⁹

There are two types of chitin. Chitin (-(14)-N-acetyl-D-glucosamine) may be a naturally occurring carbohydrate found in crab and

shrimp shells. In contrast to the liberate amino in chitosan, it has an amino that is covalently attached to the acetyl. However, as wetting time passes, the DT remains in the mouth.

Gellan gum (kicogel)²⁰

It's an anionic polyose of linear characin fish saccharides produced from the *Pseudomonas liliopsis* species, with clever superdisintegrants properties similar to starch and celluloses. Anthony et colleagues investigated the disintegration capabilities of gellan gum, comparing its potency to that of other common disintegrants such as maize starch, explotab, avicel, Ac-di-sol, and Kollidon.

Agar²¹

Agar is a dried gelatin like substance derived from *Gelidium amansii* (Gelidanceae) and a variety of other algal species such as *Gracilaria* (Gracilariaceae) and *Pterocadia* (Pterocadiaceae) (Gelidaceae). Agar comes in the form of strips, sheet flakes, or coarse powder and is chromatic grey or white to nearly colourless, odourless, and viscous. Agarose and agarpectin are two polysaccharides found in agar. Agarose is responsible for gel strength, while Agarpectin is responsible for agar solution consistency. Because of its high gel strength, it has the potential to operate as a

disintegrant. Gums are used in concentrations ranging from one to one hundred percent. However, as a result of capability development, these don't appear to be nearly as good disintegration agents as others.

Locust Bean Gum²²

Algarroba bean gum is the name given to it. It's a galactomannan vegetable gum derived from the seeds of the Mediterranean carob bean tree (*Ceretonia siliqual*). Locust bean gum is used as a gelling and thickening ingredient in the food industry, as well as as a bio glue, and it improves solubility. The gum could be an odourless white to yellowish-white powder. Most organic solvents, as well as grain alcohol, are insoluble in it. It's part soluble in water at room temperature and part soluble in a mixture, and complete solubility necessitates heating to 850°F for 10 minutes.

Mango Peel cellulose²¹

Mangifera indica, also known as mango, is a member of the *Anacardiaceae* family. It is non-toxic and is used as a superdisintegrant, binder, suspending agent, and emulsifying agent in a range of formulations. Mango peel was discovered to be a consistent supply of high-quality cellulose, appropriate for filmmaking, and passable jelly, accounting for 20 to 25 percent of the waste generated by mango processing. Pectin is a hydrophilic

cellulose colloid that is a heteropolysaccharide with involutes. Over a given time period, the produced tablets exhibited nearly lower drug arrival than sodium starch glycolate. In this case, mango strip gelatin cannot be used as a prospective superdisintegrant. yet, due to its good financial condition in natural liquid and larger swelling list, it tends to be used.

Hibiscus genus *Rosa sinensis* linn Mucilage²⁰

Rosa sinensis linn. Hibiscus genus Hibiscus is a member of the dilleniid dicot family and is also known as the shoe flower plant, China rose, and hibiscus. The plant's mucilage has been discovered to act as a superdisintegrant, and it's widely available in India. The plant contains cyclopropanoids, methyl group sterculate, methyl-2-hydroxysterculate, 2-hydroxysterculate malvate, and -rosasterol. Shah et al. used direct compression and mallow to make Acelofenac orally disintegrating tablets.

Dehydrated Banana Powder (DBP)¹⁹

Plantain and banana are two different names for the same thing. DBP is made from the Ethan banana variety, while Nenthran (*Nenthravarsha*) is a monocot plant, as shown in Figure eight. It's a binder, diluent, and superdisintegrant all in one. It contains vitamin A, thus it's used to cure gastric ulcers

and bowel movability. It also contains vitamin B6, which aids in the reduction of stress and anxiety. Because of the high macromolecule content, it's a very smart source of energy, plus it contains metal, which aids in brain function. The natural superdisintegrants banana powder and soy polyose were utilised, as well as the chemical superdisintegrant crospovidone. It was formerly thought that tablets prepared with the inclusion of a natural superdisintegrant would have a faster disintegration time, more water absorption, and more drug release. Banana powder was thought to have a wonderful superdisintegrant property that may be used for growing orally breaking down tablets. In a quarter-hour, tablets containing banana powder as a disintegrating agent were dispersed quickly over fifteen seconds and revealed 92.09 percent drug release.

Gum karaya²⁰

Gum karaya could be a negative combination and a high-molecular-weight posh polyose. It produces brain sugar, rhamnase, and galacturonic acid in a chemical process. Gum karaya is a partially acetylated by-product of gum production. It's the dried exudation of the urens tree, a flowering tree (Family- Sterculiaceae). Karaya, sterculia, Indian gum, Bassora gum, kadaya, Kadira, and katila are

some of its synonyms. Gum karaya works well with a variety of plant hydrocolloids, as well as proteins and carbohydrates.

Fanugreek Seed Mucilage²³

Fenugreek, or *Trigonella foenum graceum*, is a herbaceous plant belonging to the herbaceous plant family. It has numerous uses as a food, a food additive, and a conventional pharmaceutical. *Trigonella foenum graceum* leaves and seeds, both ripe and unripe, are consumed as vegetables. Fenugreek has been used to treat painful flatulence, dysentery, diarrhoea, appetite loss, chronic cough, dropsy, liver and spleen enlargement, rickets, gout, and polygenic disease. It's employed as a gastroprotectant, antiurolithiatic, diuretic, antidandruff agent, pharmaceutical agent, and inhibitor, among other things. The seed declares itself to be a tonic. It's also used in post-natal care and to help nursing moms lengthen their lactation. Mucilage (a natural viscous substance found within the coats of many seeds) is abundant in fenugreek seeds. Mucilage creates a thick tacky mass when exposed to fluids, despite the fact that it does not dissolve in water. Fenugreek seeds, like other mucilage-containing compounds, expand and become slippery when exposed to liquids. The soft mass that results is not absorbed by the body,

but instead travels through the intestines, causing enteric muscular contractions.

Lepidium Sativum²⁴

Lepidium sativum (family: Cruciferae) is commonly used as a herbal medicine in India and is known as asaliyo. It is readily available and very inexpensive on the market. Other resources such as leaves, roots, oil, seeds, and other components are used. Seeds include higher levels of mucilage, dimeric imidazole alkaloids lepidine B, C, D, E, and F, as well as two new monomeric imidazole alkaloids semilepidinoside A and B. *Lepidium sativum* mucilage has a wide range of characteristics, including binding, dissolving, and gelling.

Plantago Ovata²⁵

The dried seeds of the *plantago ovata* are used to make Isapghula Husk. Mucilage from the plant is found on the seeds' skin. Mucilage from *Plantago ovata* has a wide range of properties, including binding, dissolving, and retaining properties. Mucilage is used as a superdisintegrant in the formulation of quick dissolving tablets because of its extraordinarily high proportion of swelling index (about 892.2 percent v/v) compared to the opposite super disintegrating property.

Guar gum²⁶

Guar gum is made up primarily of galactomannan polysaccharides with a high relative molecular mass (about 50,000–8,000,000). It's used as a thickener, stabiliser, and surfactant, and it's legal in almost every country (e.g., EU, USA, Japan, and Australia). It's gum that's on the market right now. It's a free-flowing, completely soluble chemical compound made up of sugar units that has been approved for use in food. It is unaffected by hydrogen ion concentration, wet contents, or tablet matrix solubility. It isn't always immaculate white and can range from off-white to tan in hue, and it tends to discolour over time in alkalescent tablets.

Current Regulatory Status of These Polymers²⁷

The Food and Drug Administration of the United States of America has authorised all of these polymers (FDA). These polymers, such as chitosan, guar gum, Locust gum, and bean gum, are GAS (Generally Recognized as Safe) according to the Code of Federal Regulations (CFR 21). Gum karaya satisfies all of the requirements listed in the Food Chemicals Codex and can be safely used in foods, according to the Federal Register (21 CFR). Gellan gum has been authorised as an addition by the World Organization under the number E 418, with the ADI (acceptable daily intake) verifying its safety. The Gellan

gumfood grade fully meets the standards and also the purity criteria issued in numerous regions of the planet or internationally, like the Food Chemicals Codex and JECFA, the U.S.A. Pharmacopoeia/National Formulary, and the European Directives. As a result, these polymers are safe and can be utilised safely.

CONCLUSION-

With the growing demand for innovative medicine delivery systems, the rapid disintegrating drug delivery device has been a major milestone in gift research. Despite this, multiple studies have found that natural disintegrant has a greater impact on quick-dissolving tablets than artificial disintegrant. Natural disintegrant is preferred over artificial disintegrant since it's non-toxic, readily available at a reasonable cost, used in low concentrations, and is naturally extracted, according to the literature review. Natural superdisintegrants have a faster rate of medication dissolution and a higher bioavailability, resulting in more effective medical care and better patient compliance. As a result, the natural superdisintegrant will be able to be used efficiently as a disintegrant in mouth dissolving tablet formulations.

Acknowledgement-

The authors express their heartfelt gratitude to Sharadchandra Pawar College of

Pharmacy, Dumbarwadi, Otur, the college library, and all other sources for their cooperation and guidance in writing this review article.

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