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AN OVERVIEW ON FDA-APPROVED NATURAL SUPER DISINTEGRANTS EFFICACY IN A FAST DISSOLVING DRUG DELIVERY SYSTEM

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ABSTRACT

FDTs are defined by the United States Food and Drug Administration (FDA) as a solid dosage form containing the therapeutic substance or when applied on the tongue, the active ingredient disintegrates quickly, usually within seconds. The goal of this study is to create a fast-dissolving tablet that uses natural disintegrants. Fast dissolving tablets have grown in popularity in the pharmaceutical industry in recent years. They have a quick disintegration activity that dissolves with saliva without the use of water when placed within the mouth. Furthermore, FDT aims to provide quick medication absorption, reduced toxicity, and higher drug bioavailability, and it is especially popular among geriatric and paediatric patients. Natural disintegrants, which are obtained from natural sources, have a number of advantages, including low cost, nontoxicity, biodegradability, environmental friendliness, and less adverse effects. As a result, it has been established that natural disintegrants are often safer than synthetic disintegrants. Natural disintegrants includes Chitin and chitosan, Guar gum, Gum karaya, Agar and treated agar, Fenugreek seed mucilage, Soy polysaccharide, Gellan gum, Mango peel pectin, *Lepidium sativum* mucilage, *Plantago* seed mucilage, *Agele marmelos* gum, *Locust bean* gum, *Mangifera indica* gum, *Hibiscus rosa sinensis* mucilage, Dehydrated banana powder.

INTRODUCTION

Fast dissolving tablets are a novel drug delivery method which dissolves, disintegrates, or disperses drugs in saliva in a matter of seconds, with or without water [1]. Because they are uncoated, they quickly disintegrate, releasing the active pharmaceutical ingredients and allowing for rapid therapeutic

effect [2]. The fundamental benefit of fabricating fast-dissolving tablets is that it increases the bioavailability of poorly soluble drugs, which benefits both juvenile and elderly patients [3]. Fast dissolving tablets (FDTs) are made using a variety of techniques, including direct compression, freeze-drying, spray drying, sublimation, and wet granulation [4]. Natural disintegrants are

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commonly used to prepare fast dissolving tablets as they are environmentally safe, chemical inert, non-harmful, affordable and generally accessible. Natural disintegrants hence decrease the release amount of time and give well-being conclusion to the patients [5].

Different natural polymers play vital roles in the formulation of fast dissolving tablets:

1. Chitin and Chitosan

Chitin (β -(14)-N-acetyl-D-glucosamine) is a naturally occurring polymer found in crab and shrimp shells. It has an amino group that is covalently bonded to an acetyl group, unlike chitosan [6]. The crab shell yielded 36.7 percent chitosan with a degree of deacetylation of 62.7 percent for usage as a superdisintegrant in metronidazole tablets, according to E.O.Olorunsola et al. There was also no evidence of a detrimental interaction between chitosan and metronidazole, according to the researchers. Disintegration times for tablets containing 2, 4, and 8% chitosan were 12.2, 10.4, and 9.3 respectively [7].

2. Guar gum

Galactomannans, which have a considerable molecular weight (about 50,000–8,000,000), make up the majority of guar gum. It's legal in almost every country and is used as a thickener, stabiliser, and emulsifier (e.g., EU, USA, Japan, and Australia). It's a gum that's found in nature. It is a natural polymer contains of sugar units that is free flowing and consummately soluble, and it is permitted for use in food. It is unaffected by pH, moisture content, or tablet matrix solubility. It is not always pure white in alkaline tablets and can range in colour from off-white to tan. It also has a tendency to tarnish over time [8]. The pre and post compression properties of a captopril tablet using guar gum as a superdisintegrant were examined and confirmed to be within official limits. Sunitha H S et al. evaluated his formulations and found that the guar gum 10 mg formulation (F4) had the best disintegration and dissolving profile, with a drug release rate of 99.86% after 12 minutes and a disintegration time of 50.16 seconds [9].

3. Agar and treated agar

Agar is made from *Gelidium amansii* (Gelidaceae) and other red algae species like *Gracilaria* (Gracilariaceae) and *Pterocadia* (Pterocadiaceae) (Gelidaceae). Agar is a mucilaginous substance that occurs in strips, sheet flakes, or coarse powder. It is yellowish grey or white to practically colourless, has no odour,

and has a mucilaginous taste. Agarose and agarpectin are two polysaccharides found in agar. Agarose is in charge of gel strength, while Agarpectin is in charge of agar solution viscosity. Agar's high gel strength makes it a viable disintegrant option [10]. The goal of the study is to use agar as a natural super disintegrant in metformin hydrochloride orodispersible tablets to improve bioavailability, disintegration time, dissolve efficacy, and patient compliance. B Pankaj et al found that the formulation of nine batches, including batch F5 with 6% super disintegrant, generated superior results than other formulations. After passing the friability test with only 0.4 percent loss, the F5 batch was evaluated for disintegration and found to have 11.03 seconds and in-vitro dispersion was determined to be 15 sec in simulated saliva fluid, with a percentage drug release of 98.5 percent in less than 30 minutes. As a result, because the F5 batch had 6% treated agar, it was deemed superior. It demonstrates that animal models can be used in the future [11].

4. Mango Peel Pectin

Mango peel has been revealed to be an excellent source for extracting high-quality pectin that may be utilized to manufacture film and acceptable jelly, accounting for 20-25 percent of mango manufacturing waste. Pectin is a complex heteropolysaccharide-based hydrophilic colloid. Due to its high swelling index and high solubility in biological fluids, mango peel pectin, on the other hand, cannot be used to anticipate the behavior of super disintegrants, but it can be used to manufacture oral dispersible tablets [12]. Mango peel pectin was discovered to be a good candidate for acting as a superdisintegrant by M Rishabha et al. Although it is not as powerful as synthetic sodium starch glycolate, Because of its superior solubility and improved swelling index, it can be used to make rapid dissolving tablets [13].

5. Fenugreek seed

Seed mucilage from fenugreek *Fenugreek*, also known as *Trigonella foenum-graceum*, is a leguminous herbaceous plant. Fenugreek seeds contain a lot of mucilage (a natural gummy substance present in the coatings of many seeds). Despite the fact that mucilage does not dissolve in water, it forms a thick sticky mass when exposed to fluids. When exposed to liquids, fenugreek seeds swell and become slick, just as other mucilage-containing compounds. As a consequence of the research, it was observed that this natural disintegrant (fenugreek mucilage) has a better disintegration property than the most often used

synthetic superdisintegrants in FDT formulations, such as Ac-di-sol. The extracted mucilage is an effective pharmacological adjuvant and, more precisely, a disintegrating agent, according to research [8]. The superdisintegrant capability of Fenugreek seeds was investigated in the current work by M Sumathi et al. When fenugreek was employed as a superdisintegrant, the pills disintegrated significantly faster and more consistently than when plantago ovate and cross carmellose sodium were utilized. Fenugreek seeds could be employed as a natural superdisintegrant in the formulation of fast-dissolving tablets, according to the findings [14].

6. Locust bean gum

Carob bean gum, also known as locust bean gum, is a galactomannan vegetable gum extract made from the seeds of the Mediterranean tree *Ceretonia siliqua*. It's commonly used as a thickening and gelling ingredient in the food sector. It also has an adhesive and solubility-enhancing characteristic, according to reports [15]. This study looked into the capacity of locust bean gum to super disintegrate. The natural material's extensive swelling, porosity, and wicking action in the orodispersible tablet formulation were discovered to be contributing to its superdisintegrant action. When locust bean gum was employed as a superdisintegrant instead of cross carmellose sodium, the tablets disintegrated faster and more reliably. Locust bean gum and modified locust bean gum could be employed in a variety of tablet dosage forms and could be investigated as a high functionality excipient in the future [16].

7. *Hibiscus rosasinensis* linn

Hibiscus rosasinensis Linn, often known as China rose, is a powerful medicinal plant that belongs to the Malvaceae family. Mucilage from the leaf has anti-inflammatory qualities and has been reported to have hypoglycaemic, antioxidant, and antihypertensive characteristics. Hibiscus extracts have also been shown to protect against the development of cancer [17]. The disintegrant property of *Hibiscus rosasinensis* mucilage was investigated using imipramine as a model drug, and work was done to develop a fast-dissolving tablet of Imipramine using a natural disintegrant isolated from *Hibiscus rosasinensis* leaves, and its efficiency was compared to that of synthetic superdisintegrants such as crosspovidone. R Balaet et al. revealed that fast-dissolving Imipramine tablets were produced with *Hibiscus rosasinensis* mucilage (2-8 percent w/w), Avicel pH 102 as diluents, and mannitol to improve mouth feel and

compressibility, as well as mannitol as a sweetener, utilizing a direct compression approach. The pre- and post-compression properties of the formed tablets, such as tablet hardness, thickness, percent friability, and wetting time, were all found to be within acceptable ranges.

The in vitro disintegration time for tablet formulations containing 6% mucilage was found to be 24 seconds and 42 seconds for tablet formulations containing 4% crosspovidone. In vitro drug release tests in phosphate buffer pH 6.8 based on in vitro disintegration time found that the F3 formulation with 6% mucilage released 100% of the medication in 12 minutes. The F3 formulation's stability testing demonstrated that the manufactured tablets remained stable for 90 days and that the in vitro drug release pattern did not alter [18].

8. *Plantago ovata* seed mucilage

Psyllium, often known as ispaghula, is the common term for a number of *Plantago* species whose seeds are commercially utilized to manufacture mucilage. *Plantago ovata* mucilage has a variety of capabilities, including binding, dissolving, and sustaining properties. In a study, different amounts of *Plantago ovata* mucilage were used as natural superdisintegrants in the production of fast dissolving tablets containing amlodipine besylate [19]. Using a direct compression process, varying amounts of plantago ovata mucilage as a natural superdisintegrant were used to make quick disintegrating tablets of Amlodipine Besylate. According to FT-IR studies, there was no physicochemical interaction between amlodipine besylate and other excipients. Each formulation was evaluated for weight variation, hardness, friability, disintegration time, drug content, and solubility. *Plantago ovata*-based formulations have a faster in vitro disintegration time of 11.69 seconds and a faster in vitro dissolving time of 16 minutes. As a result, we determined that dried isabgol mucilage can be used as a superdisintegrant in the formulation of rapid dissolving tablets [20].

9. Dehydrated Banana Powder

Banana is also known as plantain. Dehydrated banana powder is derived from the banana variants Ethan and nenthran, which belong to the Musaceae family (*Nenthra vazha*). It is used to heal stomach ulcers and diarrhoea since it contains vitamin A. Vitamin B6 is also included, which aids in the alleviation of stress and anxiety. It is abundant in carbohydrate and contains potassium, which is needed for more predominant brain activity.

It is also a good source of energy [19]. The goal is to use Banana powder and SSG in varied concentrations to make multiple batches of Telmisartan oral disintegrating tablets. The tablets were also evaluated for precompression parameters such as bulk density, compressibility, angle of repose, and hardness, as well as post compression factors such as hardness, weight variation, friability, disintegration time, and in-vitro dissolution profiles. Within 15 seconds, tablets containing banana powder as a disintegrating agent distributed fast, resulting in 92.09 percent drug release in 15 minutes. As a result, banana powder can be employed as a natural disintegrant in the creation and manufacturing of Fast dissolving tablets [21].

10. *Aegle marmelos* gum (AMG)

It's manufactured from the fruits of the *Aegle marmelos* tree, a Rutaceae family tree endemic to India. The ripe fruit pulp is reddish-brown in colour and has a mucilaginous, astringent flavor. The pulp contains carbohydrate, protein, vitamins C and A, angelenine, marmeline, dictamine, O-methyl fordinol, and isopentyl halfordinol [22]. *Aegle marmelos* gum was used to change the formulation of acefenac for quick dissolving tablets. Acefenac is a poorly water-soluble medication with low bioavailability when taken orally. The solubility of acefenac increases as the concentration of AMG increases, and modified AMG could be employed as a carrier to improve the solubility and dissolution rate of poorly soluble drugs. The solubility of water insoluble drugs is improved by AMG and modified AMG's increased dispersibility, surface area, wettability, and solubilization action [23].

11. *Lepidium sativum* linn

Halim or Garden (*Lepidium sativum* linn) belongs to the Brassicaceae (cabbage family) and is locally known as 'Hab el Rashaad'. *Lepidium sativum* is widely dispersed in Egypt's cultivated area, particularly in the Nile Delta and the Oases. The seeds of the *Lepidium sativum* plant are used in medicine to cure a variety of ailments, including leprosy and other skin conditions. Brown seeds, 300 x 3100 μm in size, are oval in shape. Many researchers have looked at the seeds, which are primarily made up of protein (27%), lipids (14%-26%), carbs (35%-54%), and crude fiber (almost 8%). Natural antioxidants found in *Lepidium sativum* seeds include carotenoids, alkaloids, lepidine, monomeric alkaloids, imidazole, and others. The seeds absorb water and create a huge amount of mucilaginous material, which is a rich source of high molecular weight hydrocolloids

(*Lepidium sativum*). These extracted seeds are believed to have antioxidant, antibacterial, antifungal, anticancer, and anti-inflammatory properties [24]. Formulated Nimesulide tablets that dissolve quickly utilizing *Lepidium sativum* as a natural polymer as a disintegrating agent. Tablet dissolving is higher with 10% mucilage concentration and 10% mannitol concentration. The time it takes to disintegrate is 17 seconds, while the time it takes to dissolve is 5-27 seconds. When compared to Ac-Di-Sol and SSG, *Lepidium sativum* mucilage has a faster drug release rate [25].

12. *Ocimum sanctum* seeds

Ocimum sanctum is said to have a number of medicinal qualities. Different components of the plant, such as leaves, flowers, stems, roots, and seeds, have been utilized as anti-diabetic, anti-fertility, hepatoprotective, hypotensive, hypolipidemic, expectorant, analgesic, anticancer, anti-asthmatic, antiemetic, diaphoretic, and stress agents in the past. Fever, bronchitis, arthritis, convulsions, and other ailments have all been treated using *ocimum*. It was determined that the swelling index was 1600. The natural substance has a significant impact on tablet hardness and friability. The results of in vitro disintegration matched those of in vivo disintegration. In comparison to Nimuslide (MD), the values of *Ocimum sanctum* were 95.90 and 93.65, respectively that have been analyzed by M Karan et al [26]. The purpose of this study was to develop a fast-acting pill using *Ocimum sanctum* as a natural superdisintegrant. Paracetamol was used as a model drug in this formulation. Paracetamol is a regularly prescribed antipyretic and analgesic drug for persons of all ages.

Tablets, dispersible tablets, suspensions, syrups, and FDTs are all examples of paracetamol products available on the market. The preformulating qualities of the tablet blend demonstrate that it has good flow properties. Six formulations were prepared, and post compression properties revealed that formulation F2 was the best, releasing 99.6% of the drug after 10 minutes and dissolving in 180.01 seconds. For one month, it was submitted to accelerated stability tests at RH 75 percent and 400 C. As a result, it may be stated that *Ocimum sanctum* can also be employed to make fast-acting pills [27].

13. Gum karyya

Gum karaya is a vegetable gum generated as an exudate by trees of the genus Sterculia. Because of its high viscosity, gum cannot

be utilised as a binder or disintegrant in typical dosage forms. Gum karaya's potential as a tablet disintegrant has been investigated. Modified gum karaya, according to various studies, causes tablets to disintegrate quickly. Gum karaya can be employed as an alternative superdisintegrant to commercially available synthetic and semisynthetic superdisintegrants because of its low cost, biocompatibility, and simplicity of availability [8]. Gum Karaya is a negative colloid and a complex polysaccharide with a high molecular weight. When galactose, rhamnose, and galacturonic acid are hydrolyzed, they yield galactose, rhamnose and galacturonic acid. Gum Karaya is a partly acetylated derivative of guar gum. It's the dried exudate of the Sterculia Uren tree (Family- Sterculiaceae). Karaya, sterculia, Indian tragacanth, Bassora tragacanth, kadaya, Kadira, and katila are some of its synonyms. Gum Karaya is compatible with other plant hydrocolloids, as well as proteins and carbohydrates [28].

14. Gellan gum

Gellan gum (GG) is a biodegradable linear anionic polysaccharide derived from *Pseudomonas elodea* and used as a food ingredient. It's made up of linear tetra saccharide repeats. *Gelidium amansii* (Gelidanceae) and other red algae species such as *Gracilaria* (Gracilariaceae) and *Pterocadia* (Pterocadiaceae) are used to make agar (AG) (Gelidaceae) [29]. Antony et al. studied Gellan gum as a superdisintegrant and compared it to typical disintegrants including dried corn starch, explotab, avicel (pH 102), Ac-di-sol, and Kollidon CL, among others. Complete disintegration of the tablet occurs within 4 minutes with a gellan gum concentration in the formulation of 4% w/w and 90 percent of the drug dissolved within 23 minutes due to the instantaneous swelling characteristics of gellan gum when it comes into contact with water and its high hydrophilic nature. The disintegration patterns and in vitro dissolving rates of Ac-di-sol and Kollidone CL are strikingly similar the same concentration formulation with explotab took 36 minutes to release 90% of the medication, while the same concentration formulation with starch took 220 minutes. As a result, the study's conclusion was that gellan gum has been proven to be a superdisintegrant [30].

15. Soy polysaccharides

It's a starch-free, sugar-free natural superdisintegrant that can be utilised in nutritious products. Soy polysaccharide (a class of high molecular weight polysaccharides obtained from soy

beans) was tested as a disintegrant in direct compression tablets using lactose and dicalcium phosphate dihydrate as fillers. Cross-linked sodium carboxymethyl cellulose and maize starch were utilised as control disintegrants. Soy polysaccharide works effectively as a disintegrating agent in direct compression formulations, with results comparable to cross-linked CMC [19]. Orodispersible tablet formulas with Emcosoy as superdisintegrant and Pullulan as diluent had the quickest wetting and disintegration periods (20 and 35 seconds, respectively), the fastest water absorption rate (82), and the highest dissolving rate (100 percent after 20 minutes). To summarise, orodispersible tablets containing simvastatin-hydroxy butyl-cyclodextrin and produced using Emcosoy as a superdisintegrant and pullulan as a diluent are the best choice for improving water solubility and hence bioavailability [31].

CONCLUSION

Individuals such as Geriatric and pediatrics patients, require a drug's action to begin within a few seconds or minutes. To address these issues, FDTs were developed, which come into touch with saliva after delivery, allowing medications to be absorbed as the saliva flows downhill into the stomach, resulting in an immediate response. Natural disintegrant can be utilized to make FDTs since they are non-toxic, inexpensive, can be employed in low concentrations, and can be extracted organically.

Faster medication dissolving, increased bioavailability, and greater patient compliance are among advantages of these commonly used natural disintegrates. As a result, it can be concluded that FDA approved natural disintegrates can be utilized in the preparation of FDTs and are widely recognized in the market.

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Nil

CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTION

Darshan Pradhan, Prodipta Chakraborty and Sudip Halder designed the work and made necessary corrections and revisions in the manuscript. Darshan Pradhan and Arnab Bagchi collected the content and performed the literature review and also contributed in drafting the manuscript. All the authors framed the final manuscript.

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