Review Article

Natural Disintegrating Agents in Pharmaceutical Formulation and Development: Review

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Received: 10-02-2023; **Revised:** 20-04-2023; **Accepted:** 26-04-2023; **Published on:** 15-05-2023.

ABSTRACT

The development of new excipients for potential use as disintegrant agent in tablet formulations continues to be of interest. This is due to the fact that various disintegrating agents can be helpful in boosting moisture penetration & dispersion of tablet matrix, and disintegration of tablets has recently drawn significant attention as a necessary step in achieving rapid drug release. Natural disintegrants are substances added to tablets and also some encapsulated formulations to help break up tablet and capsule "slugs" into smaller pieces in an aqueous environment. This increases the surface area that is available and speeds up the release of the therapeutic component. Natural polymers including starches, gums, mucilage, & dried fruits are used as a binder, diluent, & disintegrants to speed up the disintegration of drugs that aren't very water-soluble, boost nutritional supplementation, and raise the solubility of the medicine. Natural disintegrants are more cost-effective and secure than synthetic ones. The advantages of natural excipients over semi-synthetic and synthetic excipients include their soothing effect, biocompatibility, availability, cheap cost, and non-irritating nature. They are also more readily available and less expensive. Therefore, in the present review, an attempt has been made to explore the various natural disintegrants which have been used in pharmaceutical formulation and development.

Keywords: Natural Excipients, Plant products, Natural Disintegrants, Natural superdisintegrants, Tablet formulation, Disintegrating tablets, Research articles.

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DOI:
10.47583/ijpsrr.2023.v80i01.005

DOI link: http://dx.doi.org/10.47583/ijpsrr.2023.v80i01.005

1. INTRODUCTION

The function of an API and the support for safety and efficacy are greatly influenced by the excipient. Excipients are generally used in historical indeterminate dosage forms like tablets, capsules, etc. as diluents, binders, disintegrants, adhesives, glidants, and sweeteners. Excipients work in conjunction with API to enhance the functionality and potency of a medicinally active molecules[1]. Excipients are used to improve the bulk, durability, stability, and absorption of active substances. Excipients play a crucial role in the variability of the final product. Excipients often make up three times as much of a pharmaceutical formulation as the therapeutically active ingredient[2].

The globe is now becoming more and more interested in natural medications and excipients. Natural excipients have attracted a lot of attention recently because of their numerous pharmacological uses as diluents, binders, lubricants, & disintegrants in tablets. Because of their absence of toxic effects, low cost, availability, calming effect, and non-irritating nature, these are preferred to semi-synthetic & synthetic excipients because they are biocompatible, affordable, and easily accessible[3].

This research review shows the use of various natural, plant based disintegrants in various pharmaceutical dosage formulation and development.

2. NATURAL EXCIPIENTS

Nature is rich in a variety of priceless elements that either directly or indirectly contribute to the wellbeing of living things. Natural excipients, including their derivatives, are widely distributed in plants, animals, and minerals. These excipients include binders, diluents, sweeteners, colorants, preservative, film formers, etc. Pharmaceutical firms are showing interest in using natural excipients to create novel medicine formulations, cosmetics, and food products since they are inert, biocompatible, and biodegradable with little harmful, as well as cost-effective[4]

Natural excipients have attracted a lot of attention lately because of their numerous medicinal uses. For instance, when creating and manufacturing medicinal dosage forms, natural polysaccharides polymers are used. They safeguard, support, or improve bioavailability, stability, or patient acceptance. Moreover, improve any aspect of the drug's overall safety, effectiveness, or delivery during storage and usage, or help identify the product[5].

2.1 Sources of natural excipients:

a) **Animal source**: -, Stearic acid Lactose, Bees wax, Honey Gelatin, Musk, Lanolin etc.

b) **Vegetable source**: - Starch, Peppermint,

Turmeric, Guar gum, Arginates, Acacia etc.

c) **Mineral source**: - Silica, Talc, Calamine Asbestos, Calcium phosphate, Kaolin, Paraffin, etc. [6].

2.2 Advantages of Natural Excipients over synthetic excipients:

1. Natural excipients, which are all derived from organic materials. They are hence secure and degradable. They have little impact on the surroundings.

2. These natural and herbal excipients are all naturally occurring carbohydrates. Natural excipients are therefore non-toxic substances.

3. Compared to synthetic excipients, natural excipients are less expensive and economical.

4. Because they are created from natural sources, natural excipients have no negative or side effects on people.

5. A variety of natural resources make it simple to find natural excipients [7].

2.3 Classification of natural excipients based on their functionality

Table 1: Classification of natural excipients according to their function

Fillers & Diluent	Gelatin Plant Cellulose, Lactose, , Sucrose Mannitol, Glucose[8]
Disintegrant	Gellan gum, Guar gum, Agar, Leucaena seed gum Silicon, Starch, pudica, Lepidium Sativum-seeds, Locust Bean gum, Mimosa Isapghula, Fenugreek, Banana powder, Mango peel pectin, husk/seeds, Agar and treated agar, Soy polysaccharide, Chitin and chitosan, Gum Karaya [9 10 8 11 12 13]
Emulsifiers& Suspending agents	Agar, Ghatti gum, Tragacanth gum, Bavchi mucilage, Acacia gum, Cashew gum, Neem gum, Asario mucilage, Xanthan gum, Guar gum, Leucaena seed gum, Karaya gum, Ispagol mucilage, Hibiscus mucilage, Pectin, Sodium alginate, Tamarind seed polysaccharide, Ocimum seed mucilage, Ski waxes, Tea saponins.[14 9 10 15 16 17 18]
Lubricants/ Glidants	Mineral oil, Paraffin oil, Castor oil, Vitamin D, Talc, Ispagol mucilage. [9 11]
Preservatives/ Antioxidents and Chelating agents	Cumin seeds, Onions, Neem oil, Cayenne pepper, Cinnamon, Clove oil, Coca Garlics, Turmeric, Clove oil, Chlorella, Brazil nuts. [9]
Flavouring agents, Perfumery and Fragrant agents	Raspberry, Lemon, Ginger, Orange, Menthol, Jasmine oil, Peppermint, Cardamom oil, Musk Rose oil, Sandal Wood Oil, [9]
Sweating agents	Glucose, Lactose, Honey[9]
solvents	Purified water, oils
Colouring agents	Caramel, Chlorophylls, Carotenoids, Red beetroot, Turmeric, Saffron[9]
Thickening, Viscosity imparting and Gelling agent	Neem gum, Tragacanth, Pectin, Agar, Carrageenan, Aloe mucilage, Fenugreek mucilage, Gelatin, Aloe mucilage, Gums, Carrageenan, Tragacanth, Xanthan.[11 9 17 12 15]
Demulcents /Emollient in cosmetics	Acacia gum, Fenugreek mucilage, Tragacanth gum, Ispagol mucilage[11 15]
Stabilizers	Carrageenan, Sodium alginate, Xanthan gum, Curdlan and Scleroglucan [11 12]

3. NATURAL DISINTEGRANTS

Fast dissolving pills are frequently made using natural disintegrants because they are inexpensive, widely available, chemically inert, environmentally benign, and non-harmful. Natural disintegrants thereby shorten the releasing period and provide patients with a positive outcome[19].

Disintegrating agents are compounds that are frequently added to tablet formulations to help break up the dense mass into the fundamental particles to make it easier for the active ingredients to dissolve or release when the tablet is placed in a fluid environment. They support the tablet matrix's penetration and dispersion by moisture. Disintegrants main job is to combat the physical forces that occur during compression to shape the tablet and the tablet binder's effectiveness. Superdisintegrants are new materials that have recently been developed to enhance disintegration processes. Another type of super-absorbing substance with specialised swelling capabilities is called a superdisintegrants. These substances are not intended to absorb a lot of water or other aqueous fluids; instead, they are intended to swell quickly. Superdisintegrants are used to decrease the disintegrable solid oral dosage forms' structural integrity. They are physically scattered throughout the dosage form's matrix and will enlarge when exposed to a moist environment[20].

3.1 Selection of disintegrants:

Superdisintegrant must satisfy a number of requirements in addition to having swelling qualities because it is utilised as an excipient in the formulation of tablets. The requirements for tablet superdisintegrant should be made very explicit.

1. Poor solubility. Disintegrants should have this property.

2. Ineffective gel formation

3. Strong capacity for hydration.

4. Good flow and moulding characteristics.

5. Lack of propensity to combine medicines in complexes.

6. Pleasant mouth feel

7. It should also have favourable tableting qualities and be compatible with the other excipients[21 14].

3.2 Methods involved in the addition of disintegrants:

- During granulation or Intragranular or internal addition.
- Prior to compression or Extragranular or External addition.
- Partially internal and external[13].

4. VARIOUS NATURAL DISITEGRANTS USED IN PHARMACEUTICAL FORMULATION AND DEVELOPMENT

These articles were focusing on research review of several natural disintegrating agents in pharmaceutical formulation and development**.**

Prashant L. Pingale, *et al.,* (2020) used Isapghula mucilage and Banana powder as natural superdisintegrant in the formulation of fast disintegrating tablet of atenolol. The tablets were made using a natural super disintegrant, microcrystalline cellulose as a diluent, and aspartame as a sweetener. Banana powder and Isapghula mucilage, two natural superdisintegrants, were used in this formulation at concentrations of 2%, 4%, 6%, and 8%. According to the results, the tablet formulation with 6% Isapghula mucilage & 8% banana powder had a quicker & higher drug release during in-vitro dissolution trial, 98.02% & 96.75%, respectively[22].

G. D Gupta, *et al.,* (2020) presented a research work on formulation and evaluation of Nimesulide dispersible tablets using natural super disintegrating agent. Natural substances like Plantago ovata seed husk, *Cassia tora* (Sickle Senna), and *Cassia nodata* at varying concentrations (5%, 10%, and 15%) were used as superdisintegrants in the formulation of dispersible tablets containing Nimesulide Formulations were evaluated for the standard dispersible tablets and were compared with marketed products. All of the formulations were found to be within the acceptable range of criteria needed for dispersible tablets. The study revealed that natural gums worked well as disintegrants at low concentrations (5%) [23].

Valéria C. Orsi1, *et al.,* (2019) used Bran of cassava starch flour and bran of cassava flour as natural disintegrant in venlafaxine hydrochloride tablet. Three venlafaxine hydrochloride tablet formulations with the excipients cassava flour, cassava starch flour, and Starch 1500® were proposed. The mechanical properties of the tablets, including their hardness and friability as well as their dissolubility, were assessed after they were made under two different pressures (98.5 MPa and 32.6 MPa). Both cassava flours have the potential to be employed as disintegrating agents in tablet manufacturing because the tablets they produced under greater pressures had similar physicochemical features and pre- and post-tablet evaluation parameters to those obtained with the excipient Starch1500®. [24]

Rita N. Wadetwar et al., (2017) performed research work on Development of Orodispersible Tablet using *Lepidium sativum* Seed Mucilage as Natural Super disintegrant. extraction of mucilage from *Lepidium sativum* Linn. seeds were investigated as a natural superdisintegrant in Orodispersible tablets using Promethazine HCl, as a model antiemetic drug. Mucilage was isolated from *Lepidium sativum* Linn. seeds and was evaluated for physicochemical characterization. Drug–excipient compatibility studies were performed by FT-IR and DSC. Promethazine HCl ODTs were prepared separately using different concentrations of (8%, 10%, 12% and 15%w/w) of isolated mucilage from *Lepidium sativum* Linn. seeds (natural) and Croscarmellose sodium (synthetic) as superdisintegrants by direct compression method. Different pre- and post-compression parameters were studied. The stability studies were performed on optimized formulation on b batch containg 12% of *Lepidium seed* mucilage. The characterization and in-vitro release profile of prepared ODTs showed that the formulated Promethazine HCL tablet containing 12% mucilage was effective, and suitable than marketed tablet because it has better dispersion time 29 sec and maximum % cumulative drug release i.e. 98.87%. this work revealed that isolated mucilage from *Lepidium sativum* Linn. seeds has a good potential to enhance in vitro dispersion time and in vitro drug release of ODT of Promethazine HCl. Also mucilage of *Lepidium sativum* Linn. seeds is better than synthetic superdisintegrants because of low cost, natural origin, less side-effect, bioacceptable, renewable source, local availability and better patient compliance.[25]

Kalpana Kaucha Chitwan, *et al.,* (2016) presented the research work on Formulation and evaluation of flurbiprofen fast disintegrating tablets using natural superdisintegrants. The primary goal of this study was to create flurbiprofen fast-dissolving tablets (FDTs) that included superdisintegrants that were isolated from natural sources such *Plantago ovata* (PO) seeds, *Lepidium sativum* (LS) seeds, & agar-agar (malt agar). For the natural superdisintegrants, the swelling index & hydration capacity were evaluated in order to assess their disintegration capacity. In order to create the tablet formulations, isolated natural superdisintegrants were used. Pre-compressional factors like angle of repose, bulk density, tapped density,

Car's index, and Hausner's ratio were assessed for the powder mixes. Direct compression was used to create FDTs. The post-compression properties of the compressed tablets were identified.

All formulations met the pharmacopoeial requirements for hardness, friability, weight fluctuation, and drug content. The in vitro disintegration time ranged from 59.2 to 221 seconds, and the in vitro drug release ranged from as low as LS1 - 11.80% to as high as PO4 - 98.99% within 4 minutes of investigation. The wetting time was 84 to 254 seconds. PO4 was the best-performing formulation overall, with a decent wetting time of 84 seconds, the quickest disintegration time of 59.2 seconds, the fastest dispersion time of 135 seconds, and a drug release rate of 98.99% in just 4 minutes. The development of flurbiprofen FDTs with isolated natural disintegrants was successful. The separated natural disintegrants displayed encouraging results and may work well in place of synthetic disintegrants [26].

M. Uday Kumar, *et a*l., (2014) performed research work on Design and evaluation of fast dissolving tablets containing diclofenac sodium using fenugreek gum as a natural superdisintegrant. superdisintegrant which also possess anti-inflammatory activity. The fenugreek gum was attempted to be extracted, and its various physicochemical characteristics were assessed. Fenugreek gum has a viscosity of 293.4 mpa and a swelling index of 221%, respectively. FDTs for diclofenac sodium were created utilizing the direct compression method and a range of concentrations (1%–6%, w/w) of fenugreek gum, a well-known natural superdisintegrant, in comparison to sodium starch glycolate and croscarmellose sodium, two well-known artificial superdisintegrants.

The tablets' physical properties, including weight fluctuation, friability, and hardness, were assessed, and the results were within acceptable ranges. First order kinetics were established for the release of drug from every formulation. The formulation F3, which contains fenugreek gum at a concentration of 6%, had the shortest disintegration time (21 seconds) and the highest drug release rate (93.74%) after 25 minutes. As a result, it was regarded as an optimal formulation. According to the findings, fenugreek gum functions well as a super dissolving agent and exhibits promising additive anti-inflammatory efficacy when combined with diclofenac sodium[27].

Arun Raj R, *et al.,* (2013) performed research on comparative evaluation of potato starch and banana powder as disintegrating agents in Aceclofenac tablet formulation. The physicochemical characteristics, such as solubility, iodine test, angle of repose, bulk density, tapped density, carr's index, Hausner's ratio, and melting point, of dehydrated banana powder and potato starch were assessed. Through FTIR spectroscopy, the interaction in between excipients & Aceclofenac was also investigated. Following the preparation of tablets utilising the direct compression method and several disintegrants, the disintegration time of the tablets developed was calculated. It was discovered that tablets containing potato starch and banana powder dissolve more quickly than those containing microcrystalline cellulose. The evaluation tests for weight fluctuation, hardness, friability, and content homogeneity were passed by the created formulations. Drug release from tablets was discovered to be caused by a non-Fikian, anomalous transport mechanism. Banana powder & potato starch could be employed as disintegrants in tablet formulation, according to the results of several tests..[28]

Mahaveer Pr. Khinchi, *et al*., (2010) performed research work on disintegration properties of seed powder, husk powder and mucilage of plantago ovata by formulation of orally disintegrating tablet. The work that is being presented focuses on the investigation of the mucilage, husk powder, & seed powder of Isapghula disintegrant properties. The direct compression method was used to create the Orodispersible tablets tablet of fexofenadine HCl (the model medicine) utilizing microcrystalline cellulose & mannitol as the direct compressible vehicle. These tablets underwent quality control tests to assess their organoleptic properties, weight fluctuation, hardness, friability, in vitro swelling time, in vitro disintegration time, and dissolving behavior. In order to compare the swelling behavior of Plantago ovata seed powder, husk powder & mucilage, swelling index was also looked into. Isapghula seed powder, husk powder, and Plantago ovata mucilage were reported to have swelling indices of 952.0, 881.7, and 721.5, respectively. All three excipients, husk, powder, and Isapghula seed [29]

Ravi Kumar, *et al.,* (2009) performed research work on Isolation and Evaluation of Disintegrant Properties of Fenugreek Seed Mucilage. In this study, the polysaccharide mucilage from the seeds of fenugreek, *Trigonella foenum*-graceum L (family Leguminosae), was evaluated for use in mouth-dispersing tablet formulations containing metformin hydrochloride. Fast disintegrating tablet (FDT) of metformin HCl was developed using different quantities (2, 4, 6 and 10% w/w) of a natural disintegrant, extracted mucilage of fenugreek seed, and synthetic superdisintegrants such croscarmellose sodium. In terms of weight, thickness, hardness, friability, disintegration time, wetting time, and dissolving investigations, the produced tablets were evaluated for consistency. The newly designed tablets featured better medication release characteristics and a better visual appeal than commercially available traditional tablets. Fenugreek mucilage is used in the most efficient formulation at a concentration of 4% because it shows 100% drug release in 18 minutes and has shorter half-life[30].

Kalidindi, Sanyasi R, et al., (2008) presented research work on Evaluation of Soy Polysaccharide as a Disintegrating Agent. Using lactose & Dicalcium Phosphate Dihydrate as fillers, soy polysaccharide from soy beans was tested as a disintegrant in tablets manufactured by direct compression. As a control, cross-linked sodium carboxymethyl cellulose & corn starch were used. Compressibility, friability, and disintegration times were studied parameters.

Hydrochlorothiazide tablets were used as a model medicine for the dissolution investigations because of its low water solubility. In direct compression formulations, soy polysaccharide performs admirably as a disintegrating agent, with results that are superior to maize starch at 8% and comparable to cross-linked CMC at 2%. Drug tablet dissolution rates were quick, especially at the 5% level, and weren't negatively impacted by ageing at room temperature[31] .

CONCLUSION

Natural disintegrants are cost-effective, eco-friendly, easy accessible, compared with synthetic disintegrates which prefers widely over synthetic disintegrates. These are widely employed in Pharmaceutical as well as food industry since they are safe and non-toxic to animals and human beings and are extracted from natural products such as plant exudates and seeds of land and marine sources. Natural disintegrates plays an important role in pharmaceutical formulations in many ways over synthetic disintegrates.

Several studies confirm that utilization of natural disintegrants is valuable with proven biocompatibility, safe, chemically inert and non-toxic. The higher availability of natural excipients impact on the development of pharmaceutical products with less cost effective. It is also environmental friendly processing and biodegradable.

ACKNOWLEDGEMENT

The author is thankful to all the contributors in compiling and preparing manuscript for this review article.

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Source of Support: The author(s) received no financial support for the research, authorship, and/or publication of this article.

Conflict of Interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.