



NATURAL DISINTEGRANTS: ROLE IN PHARMACEUTICAL FORMULATION

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ABSTRACT

Disintegrants are agents which are integrated to tablets and some encapsulated formulations in order to promote the breakup of the tablet and capsule “slugs” into more small fragments in an aqueous environment which thereafter increment the available surface area and promoting a more rapid release of the drug substance. The development of new excipients for potential use as disintegrant agent in tablet formulations continues to be of interest. This is because different disintegrant agents can be useful in promoting penetration of moisture and dispersion of the tablet matrix and disintegration of tablet has received considerable attention at present as an essential step in obtaining fast drug release. Natural polymers such as starches, gums, mucilage, and dried fruits utilized as binder, diluent, and disintegrants to increase the solubility of poorly water-soluble drug, decrease the disintegration time, and provide nutritional supplement. Natural disintegrants are safe and economical than synthetic disintegrants such as Polyvinylpyrrolidone (PVP). Therefore, in the present review, an attempt has been made to reveal the importance of the natural disintegrants in the pharmaceutical formulations.

KEYWORDS: Natural disintegrants, synthetic disintegrants, mucilages.

INTRODUCTION

Disintegrants are the formulation excipients added into the tablet to advance the breaking of the tablet into fine particles in an aqueous condition thereby expanding the accessible surface zone and advancing a faster release of the drug substance.^[1] The disintegration of the tablet has gotten impressive consideration as a basic advance in getting fast medication release. The accentuation on the accessibility of medication highlights the significance of the rapid disintegration of a tablet. While the oral route is the most convenient route of administration for various drugs. It is viewed as the most convenient, most secure, and economical route for patients. Fast disintegrating tablets are popular these days as they disintegrate in the mouth within a few seconds without the use of water. The burdens of regularly used medications in pediatric and geriatric patients have been overwhelmed by quick-dissolving tablets. Natural super disintegrants have been used for fast-dissolving tablets because they are biodegradable, chemically inert, nonharmful, more affordable, and generally accessible.^[2] Disintegrants are a basic part of the tablet formulation. Water plays an important factor in the dissolution and disintegration of the tablet. Mixes of swelling, as well as wicking and

additionally misshaping, are the systems of disintegrant activity.^[3]

Classification of Polymers

Based on pharmaceutical application

1. Polymers in conventional dosage form.
2. Polymers in sustain and controlled release form.
3. Polymers in pharmaceutical packaging.

Based on solubility

1. Water-soluble polymers
2. Water-insoluble polymers

Based on origin

1. Natural polymers
2. Synthetic polymers
3. Semi-synthetic polymers

Advantages of Super disintegrants

Biodegradable: Biodegradable as they are normally accessible, and they are created by all living life forms. The biodegradable polymer can be decomposed itself and does not cause pollution to the environment.^[4] Easy administration of film to the patients experiencing emesis, diarrhoea, and mental problems. Environmental-

accommodating handling: There are numerous sorts of natural polymers acquired from various plant sources which are generally used in the drug industry for production and manufacturing of new dosage forms^[5] Polymers provides good stability with API and does not react with them.

Selection of Disintegrants

Super disintegrant 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 super disintegrant 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.^[6,7]

Methods involved in the addition of disintegrants

- During granulation or Intragranular or internal addition.
- Prior to compression or Extra granular or External addition.
- Partially internal and external.^[8]

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.

Pingale, et al., (2020) used Isapgula mucilage and Banana powder as natural super disintegrant 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 Isapgula mucilage, two naturals super disintegrants, were used in this formulation at concentrations of 2%, 4%, 6%, and 8%. According to the results, the tablet formulation with 6% Isapgula mucilage & 8% banana powder had a quicker & higher drug release during in-vitro dissolution trial, 98.02% & 96.75%, respectively.^[9]

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* and *Cassia nodata* at varying concentrations 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%).^[10]

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 excipient's cassava flour, cassava starch flour, 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 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.^[11]

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 super disintegrant 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 super disintegrants by direct compression method. Different pre- and post-compression parameters were studied.^[12]

Kalpana Kaucha Chitwan, et al., (2016) presented the research work on Formulation and evaluation of flurbiprofen fast disintegrating tablets using natural super disintegrants. The primary goal of this study was to create flurbiprofen fast-dissolving tablets (FDTs) that included super disintegrants that were isolated from natural sources such Plantago ovata (PO) seeds, Lepidium sativum (LS) seeds, & agar-agar (malt agar). For the natural super disintegrants, the swelling index & hydration capacity were evaluated in order to assess their disintegration capacity. In order to create the tablet formulations, isolated natural super disintegrants were used. Pre-compressional factors like angle of repose, bulk density, tapped density.^[13]

M. Uday Kumar, et al., (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 super disintegrant, in comparison to sodium starch glycolate and croscarmellose sodium, two well-known artificial superdisintegrants.^[14]

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.^[15]

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 Orodispensible 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.^[16]

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 foenumgraceum* 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 super disintegrants such croscarmellose sodium. In terms of weight, thickness, hardness, friability, disintegration time, wetting time, and dissolving investigations.^[17]

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 environmentally friendly processing and biodegradable.

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