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Review article

Role of mucilage as pharmaceutical additives and cytoprotective agent

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Abstract

Now a days, a large number of pharmaceutical excipients are obtained from natural sources. Mucilages and their derivatives are a group of polymers extensively used in pharmaceutical dosage forms. On one hand, it acts as pharmaceutical adjuvants and on the other hand, mucilages of different sources act as cytoprotective agents. It has been reported that mucilage helps in the treatment of gastric ulcer. It may act by forming a protective layer with increase in mucous secretion from the superficial epithelial cells against the ulcer inducer and thus the necrotizing agent is prevented from penetrating into the gastric mucosa. The present review discusses the expansive sources of mucilage, its versatile excipient property as tablet binders, disintegrating, emulsifying, suspending, gelling, stabilizing, thickening and film forming agents along with the cytoprotective nature of mucilage obtained from certain plants which adds an antiulcer property to its uses.

Introduction

Drugs are converted into a suitable dosage form by using different type of excipients. Traditionally, excipients were used as inert vehicle and diluent in formulating a dosage form but in modern pharmaceutical dosage forms they often play different multi-functional roles. Pharmaceutical aid in drug formulations help to modify the drug release, improve stability of dosage form and bioavailability of the active pharmaceutical ingredient, enhance patient acceptability and ensure ease of manufacture. To meet the needs of advanced drug delivery system continuously new improved and modified excipients are developed[1, 2]. As natural materials are cost effective, nontoxic, stable, easily available with less regulatory issues, eco-friendly, capable of multiple chemical modifications, degradable and compatible due to their natural origin, so they have been gaining lot of importance in the field of drug delivery [3]. The synthetic excipients are continuously being replaced with natural ones as recent trend toward the use of the vegetable and nontoxic products has increased. Today, a large number of naturally obtained pharmaceutical excipients are available. Like other natural products application of mucilage is increasing in industry so it has become necessary to explore the newer source of plant mucilage for industrial demand.

Mucilages are polysaccharide hydrocolloids with sugar molecules linked with uronic acids. They are translucent amorphous substances and polymers of a monosaccharide or mixed monosaccharides combined with uronic acids. On hydrolysis they yield mixture of sugars and uronic acids. Since, they contain hydrophilic molecules so they combine with water to form viscous solution or gel. Mucilages are complexes polysaccharides which consist of arabinose, galactose, rhamnose and galacturonic acid and in solution form large molecular aggregates.

Mucilage present in plants help to store water and food and also play a role in seed germination and thickening membranes. The term mucilage in plants means "those substances which are soluble, or at least swell very perceptibly in water and which , upon addition of alcohol, are precipitated in a more or less amorphous or granular mass" [4]. They are similar to gums except that mucilages are generally normal products of metabolism, formed within the cell (intracellular formation) and/or are produced without injury to the plant. Mucilages of different sources and their derivatives represent a group of polymers widely used in pharmaceutical dosage forms. On one hand, it acts as pharmaceutical adjuvants and on the other hand, mucilages of different sources act as cytoprotective agents. It has been reported that mucilage helps in the treatment of gastric ulcer. It may act by forming a protective layer with increase in mucous secretion from the superficial epithelial cells against the ulcer inducer and thus prevent the penetration of necrotizing agent into the gastric mucosa [5].

This review gives an insight of mucilage, as a potent candidate to be used in various pharmaceutical formulations. It discusses the expansive sources of mucilage, its versatile excipient property as tablet binders, disintegrants, emulsifiers, suspending agents, gelling agents, stabilizing agents, thickening agents, film forming agents and the cytoprotective action of mucilage of certain plants which gives it an antiulcer property.

Extraction and isolation of mucilage

The fresh plant material containing mucilage is collected, cleaned with water to remove dirt, debris and then dried in shade. The drying of the plant material is carried out in shade to prevent the degradation of any thermolabile and photosensitive constituent present if any. The dried material is grinded to form powder; the powdered material is then immersed in distilled water and kept for six hours, boiled for half an hour, and then allowed to stand for an hour to allow all the mucilage to release into the water. In case of thermosensitivity, the mucilage is extracted by soaking the dried part with ten times its weight of distilled water and kept for 24 Hrs without boiling. The material is then passed through an eight fold muslin cloth and squeezed to separate the marc from the solution. After this, three volume of acetone is added to the filtrate to allow precipitation of mucilage. The precipitated mucilage is separated and washed thrice with acetone to remove the traces of water. It is then dried in an oven at a temperature less than 50˚C or in vacuum. The drying of the final product should be carried out with care. The dried powder is then passed through sieve no. 80 to obtain fine powder and stored in a desiccator so that any further moisture uptake and degradation of the product can be prevented [6,7].

Pharmaceutical applications of mucilage

Mostly, mucilages are used as pharmaceutical additives in different dosage formulations with wide range of applications such as thickening, binding, disintegrating agent, suspending and emulsifying agent in biphasic liquid dosage forms, stabilizing and gelling agents. Mucilages may also be used as an adjuvant in sustained as well as controlled release dosage form [8].

Binders

One of the most important adjuvant to be added in tablet dosage form is binder. It is used for binding powders and converting it into granules by a process called Granulation. Different mucilages from natural sources have been used as good binders as compared to many synthetic compounds. The mucilage extracted from the dried tubers of *Eulophia campestris* was used for preparing tablets containing paracetamol as the active pharmaceutical ingredient and the binding and granulating properties were evaluated. The binding properties of the extracted mucilage were compared with a standard binder. Here, starch at a concentration of 10%w/v was used as standard. The tablets prepared with the plant mucilage of *E. campestris* showed greater hardness than the tablets prepared with starch mucilage of same concentration [9]. The mucilage extracted from the fruits of *Ziziphus mauritiana* and *Aegle marmelos* was evaluated for their binding property taking the model drug as paracetamol. The binding properties of the extracted mucilage were compared with a standard binding agent i.e., starch at a concentration of 10%w/v. Tablets showed that on increasing the binder concentration, hardness and disintegration time also increased whereas there is decrease in the friability of tablets with increase in concentration of binder [10]. Another study was performed with *Hibiscus rosasinensis*. The mucilage was extracted from its flower petals and explored as a binder in Paracetamol tablets. The tablets formulated using 5% w/v of *H. rosasinensis* mucilage exhibits more hardness than starch (binder) at a concentration of 10%w/v. So *H. rosasinensis* mucilage at an optimum concentration could be considered as binder for tablet preparation [11]. The mucilage from the seed of *Trigonella foenum- graecum* L. was extracted and checked for binding efficiency in tablet using three different active pharmaceutical ingredients on the basis of solubility. The results showed that the extracted mucilage at 2.5% concentration compared well with the standard binder (starch) for properties studied. Fenugreek seeds mucilage can be used as a tablet binder and produces tablets with good hardness and friability [12]. Another study was carried out to extract mucilage from the fruits of *Artocarpus heterophyllus* and to compare its binding properties with starch. Different concentrations (4, 6 and 8%w/w) of the extracted mucilage were used to prepare tablets by wet granulation method. It was seen that on increasing the concentration of binder, friability of the tablets reduced and disintegration time of the tablets increased [13]. After isolation of mucilage from *Hibiscus esculentus* by ethyl alcohol, the percentage yield of mucilage was found 9.17%. It was observed from the study that the tablets formulated using *H. esculentus* mucilage has better hardness and lesser friability than the tablets prepared with starch [14]. The mucilage obtained from the roots of *Asparagus racemosus* and seeds of *Cassia sophera* exhibits better binding properties than the tablets prepared taking 10% starch mucilage [15]. A study was performed to find out the potentials of mucilage extracted from *Hibiscus cannabinus* as tablet binder. Different batches of tablet with varying concentration of mucilage was studied [16]. The granules prepared with Fenugreek seed husk has advantage over starch as binder as it could be used without heating whereas starch has to be heated [17]. In a study, water soluble mucilage was extracted from *Caesalpinia pulcherrima* seeds. The study showed that the tablets prepared with 8-10% concentration of isolated *C. pulcherrima* seeds mucilage exhibited disintegration time and hardness within the standard limit when compared with 10% starch binder formulation [18].

Disintegrating agent

Disintegrants are another important pharmaceutical adjuvants added in tablet formulation. They are substances that help in the breakdown of tablets into smaller particles as soon as it comes in contact with GI fluid. They help the tablet to disintegrate faster than tablets prepared without disintegrants. For faster release of drug from tablet, disintegration is considered as the rate limiting step. In formulating a tablet, disintegrating agent help the tablet to disintegrate more rapidly in aqueous system [19, 20].

Mucilages swell in water to a greater extent so they can be used as disintegrating agents. Mucilages extracted from several plants have already been evaluated for its disintegrant properties and the process is progressing. In a study, the mucilage extracted from *Trigonella foenum-graceum* L seeds also called fenugreek belonging to family Leguminosae exhibited disintegrating property in metformin hydrochloride mouth dissolving tablet formulation. The study showed better disintegrating property at 4%w/w concentration than the most common synthetic super disintegrants like cross carmellose sodium [21]. The mucilage present in *Salicornia fruticosa* was extracted from its aerial parts. This mucilage can be used as disintegrating agent at concentration of 5%w/w. Thus it can also be used as superdisintegrants in place of currently marketed synthetic super disintegrating agents [22]. *Hibiscus rosa sinensis* Linn leaves were used for isolation and extraction of mucilage. The mucilage was used in formulating fast dissolving tablets which showed better disintegrating property at a concentration of 6%w/w mucilage than widely used synthetic super disintegrants like crosspovidone [23]. *Plantago ovate* mucilage has been extracted and evaluated for its disintegrant [24,25] and superdisintegrant properties [26]. Similar study was performed with the mucilage extracted from the seeds of *Lepidium sativum* (Cruciferae). Fast disintegrating tablets were formulated using the mucilage and compared with tablets containing synthetic disintegrating agent such ac-disol and as sodium starch glycolate [27].

Suspending agent

Mucilages are also used as suspending agent and help to suspend insoluble solid substances in liquid formulations. They prevent immediate sedimentation and caking due to their colloidal character and high viscosity. Their high viscous nature makes mucilage a stabilizer of choice in suspension. The suspending property of mucilages is found to be similar to different gums, which have already been used in formulating pharmaceutical suspension. The mucilage extracted from *Coccinia indica* fruits was found to possess suspending ability at 2%w/v concentration. Studies show that the mucilage of *Coccinia indica* was found to be a comparable suspending agent with tragacanth and thus may be used as a pharmaceutical additive depending on its suspending ability and the stability [28]. The mucilage obtained from the fruits of *Abelmoschus esculentus* was isolated and act as suspending agent. The suspension formulated from the mucilage sedimented slowly and the sediment formed was readily redispersible in nature [29]. The extraction of mucilage from fenugreek seeds explored as suspending agent at 8% w/w concentration. The sedimentation volume of suspension formulated using fenugreek mucilage as suspending agent shows highest sedimentation volume than suspension prepared using tragacanth, acacia. Thus, it can be used as a stabilizer of choice in suspension and due to its high viscosity; it is desired especially in pharmaceutical, food and cosmetic industries [30]. In a study, *Chlorophytum borivilianum* mucilage showed good suspending properties when used for preparing suspension taking zinc oxide as model drug and thus can be used for preparing pharmaceutical suspension [31]. The mucilage present in the seeds of *Plantago ovata* was isolated, extracted and used for preparing suspension. The study showed that natural suspending agent can be used as an effective alternative for traditional suspending agents [32]. The suspending property of mucilage extracted from the leaves of *Hibiscus lobatus* was compared with suspensions prepared by using other suspending agents. The results indicate that Hibiscus mucilage at a low concentration of 2%w/v exhibits high viscosity, slightly basic pH and easily redispersible properties. Thus, it has the potential to be used as suspending agent [33].

Sustained release agent

A prolonged therapeutic effect can be achieved by designing sustained drug delivery system which continuously release medication over an extended period of time after its administration. This is achieved by formulating drug loaded matrix tablets using drug of choice, retardant material and suitable additives. Drug release can be modulated by incorporating polymeric materials in the matrix system. Various mucilages have been used as polymer to sustain the release of drug in formulations, out of which, hydrophilic polymers are the best candidate for retarding the release of drug. Thus there is growing interest in incorporating these natural polymers in sustained drug delivery system [34-36]. Mucilage from the seeds of *Mimosa pudica* was isolated, characterized and evaluated for sustained release properties using Diclofenac sodium as the model drug. The swelling and erosion studies revealed that as the concentration of mucilage in tablet was increased gradually, percent erosion of the tablets decreased and percent swelling of the tablets increased correspondingly [37]. The mucilage extracted from *Hibiscus rosa sinensis* leaves exhibits the potential to be used as matrix forming material for preparing sustained release matrix tablets[38]. Mucilage derived from the seeds of *Trigonella Foenum graceum* was studied for use in matrix formulations using propranolol hydrochloride as active pharmaceutical ingredient. In a study, Fenugreek seed mucilage exhibited better release retardant at a concentration of about 66%w/w as compared to hypomellose at equivalent content [39]. Mucilage extracted from the leaves of *Aloe barbadensis* Miller have been used as a pharmaceutical adjuvant in preparing sustained release matrix tablets. A similar study showed that mucilage obtained from the dried fruit of *Abelmoschus esculentus* possess the property to be used as a matrix forming material for preparing sustained release matrix tablets [40]. Since the natural mucilage acts as release retardant so it can be employed to sustain the release of drug from matrix tablet. Thus mucilages from natural sources proved to have good suspending properties.

Comparison of pharmaceutical properties of mucilages

It is becoming increasingly apparent that there is an important relationship between the properties of the excipients and the dosage forms containing them. All the properties are essential for preparing an ideal dosage form. The pharmaceutical properties of mucilages of various sources at concentration 10%w/v is compared with starch mucilage of same concentration and is illustrated in Table 1 (a) and 1 (b). *Hibiscus esculentus* mucilage and Fenugreek seed husk mucilage has low angle of repose which is less than 25°. Thus they have excellent flow property compared to the standard as well as other mucilages and can be used as excipient. When comparison is done in terms of friability, *Cassia sophera mucilage* and *Caesalpinia pulcherrima* mucilage is better than other mucilages as their percentage friability is least. The less is the percentage friability, the more is the binding property of the mucilages. It can be seen that granules prepared with mucilages have comparable properties with respect to starch granules for hardness, bulk, tap density and angle of repose. It was found that the tablets prepared using 10% concentration of isolated mucilage exhibited disintegration time below 15 minutes which is within the standard limit. Taking all the above parameters into consideration, the study has revealed a good potential of the mucilages as a binder for conventional tablet formulations. The binder prolongs the dissolution rate of aqueous soluble drugs. This effect may be related to the hydrophilic nature of the binders that compete with the active drug in water attraction. Various mucilages with their common names, biological sources, part of plant used for extraction of mucilage and their pharmaceutical applications are listed in Table 2.

Cytoprotective activity of mucilage

Apart from the application of mucilage as adjuvant, it has cytoprotective activity which helps to prevent as well as heal ulcer. The treatment with mucilage shows gastroprotective effect. The cytoprotective activity of the mucilage from different plants, their biological source and the part used is listed in Table 3.

The treatment with mucilage extracted from *Opuntia ficus indica* cladodes brought about a significant gastroprotective effect by decreasing the gastric hyperaemia and the number and severity of the lesions. This negatively charged polyelectrolyte obtained from cladodes of the plant is highly viscous in nature. Due to the negative charges strong intermolecular repulsion is caused, resulting in expansion of the molecules. The pH and Ca^{++} concentration influences the viscosity of the mucilage. The changes in the conformation of the molecule change the gelation properties in the gastric lumen. These changes on molecular shape and conformation could be the reason for protective activity of mucilage on gastric mucosa [5]. The mucilage averts the deep necrotic lesions and the extensive exfoliation of surface epithelium induced by ethanol by forming a protective layer. The mucilage prevents the necrotizing agent to penetrate into the gastric mucosa. Probably, the mucilage, a high molecular weight acid polysaccharide mainly formed by arabinogalactan and galacturonic acid can act synergetically with defense factors of gastric mucosa. This arabinogalactan protein has the potential to interact with macromolecules or small ligand of gastric mucosa [5].

The major components of *A. esculentus* mucilage are carbohydrate-containing polymers along with proteins and some minerals. The polysaccharides from *A. esculentus* mucilage probably may affect the regeneration of gastrointestinal mucosa or may form a protective covering on it. Ethanol lowers the level of tissue proteins, causes the gastric blood flow to come to standstill by tending to dissolve the components of mucous membrane of the stomach [43] but the damage due to ulcerogenic agent gets inhibited with pretreatment of *A. esculentus* aqueous extract. The regeneration process starting from the neck cells of the gland is a rapid process of migration of cells towards the luminal surface. The deposition on the area is stripped by ulcerogenic agent and thus plays a major role in healing ulcer. The acute attack on gastric mucosa by different types of necrotic agent can be protected by various mechanisms, out of which mucus production plays a vital role. This protection depends on a delicate balance of factors which control its synthesis and the protein, glycoprotein and lipid composition necessary to give it the right viscosity and its characteristic hydrophobicity [44]. The increase in mucous secretion from the superficial epithelial cells results in formation of a protective layer which may cause cytoprotection [45].

Table 1(a). Comparison of pharmaceutical properties of mucilages from various sources

Properties	Starch (10%w/v)	*Eulophia campestris* mucilage (10%w/v)	*Ziziphus mauritiana* mucilage (10%w/v)	*Aegle marmelos* mucilage (10%w/v)	*Hibiscus rosasinensis* mucilage (10%w/v)	*Hibiscus esculentus* Mucilage (10%w/v)
Angle of repose (°)	28	30	30	30	28.35	21.8
Percentage friability	0.2	0.5	0.5	0.3	0.497	0.32
Hardness	6.5	4	4	5.96	3.8	5
Disintegration time (s)	24	207	214	290	267	260

Table 1(b). Comparison of pharmaceutical properties of mucilages from various sources

Properties	*Asparagus racemosus mucilage* (10%w/v)	*Cassia sophera mucilage* (10%w/v)	*Hibiscus cannabinus mucilage* (10% w/v)	*Fenugreek seed husk mucilage* (10% w/v)	*Caesalpinia pulcherrima* mucilage (10% w/v)
Angle of repose (°)	28.3	27	26	20.3	25.59
Percentage friability	0.3	0.2	0.45	0.7	0.21
Hardness	6	6.5	6.2	6.7	6.63
Disintegration time (s)	166	196	612	300	295

Table 2. Different Pharmaceutical applications of mucilages from various sources [41,42].

Sl no.	Common Name	Botanical Name	Family	Parts used	Pharmaceutical applications
1	Amaltas	*Cassia fistula* Linn	Caesalpiniaceae	Seeds	Binding agent
2	Asario mucilage	*Lepidum sativum*	Cruciferae	Seeds	Suspending agent, emulsifying agent, controlled release agent
3	Banana peel mucilage	*Musa paradisiaca*	Musaceae	Peel of fruit	Binding and suspending agent
4	Bavchi mucilage	*Ocimum canum*	Labiatae	Seeds	Suspending agent, emulgent
5	Cactus mucilage	*Opuntia ficusindica*	Cactaceae	Cladodes	Gelling agent for sustained release drug delivery
6	Casia tora mucilage	*Cassia tora Linn*	Leguminoseae	Seeds	Binding agent
7	Cashew gum mucilage	Anacardium occidentale	Anacardiaceae	Plant	Binding, granulating agent
8	Cassia roxburghii mucilage	*Cassia roxburghii*	Fabaceae/ Leguminosae	Seed	Stabilizer and thickening agent in pharmaceutical suspension
9	Chlorophytum borivilianum mucilage	*Chlorophytum borivilianum*	Liliaceae	Tuber	Suspending and binding agent
10	Dika nut mucilage	*Irvingia gabonensis*	Irvingiaceae	Seed	Binding, emulsifying, suspending sustained release agent, lubricant, as suppository base, micro encapsulation, as a component of film coating .
11	Glasswort mucilage	*Salicornia fruticosa*	Chenopodiaceae	Aerial parts	Pharmaceutical adjuvant, disintegrating agent
12	Gulmohar mucilage	*Murraya paniculata*	Moraeceae	Seed	Suspending agent, stabilizer in biphasic liquid dosage forms
13	Ispagol mucilage	*Plantago ovate, P. psyllium*	Plantaginaceae	Seed husk	Lubricant, demulgent, suspending, sustained release agent, emulsifier, disintegrant
14	Jujube Mucilage	*Ziziphus mauritiana*	Rhamnaceae	Seeds of ripe fruit	Excipient in oral mucoadhesive tablet
15	Mimosa pudica mucilage	*Mimosa pudica*	Mimosaceae	Seeds	Binding and disintegrating agent, sustained release agent
16	Ocimum mucilage	*Ocimum gratissimum Linn*	Labiatae	Seed	Suspending, binding agent
17	Prosopis mucilage	*Prosopis juliflora*	Fabaceae	Seed	Binding, granulating agent, sustained release agent
18	Peacock Flower	*Caesalpinia pulcherrima*	Euphorbiaceae	Seeds	Binding, granulating agent
19	Phoenix mucilage	Phoenix dactylifera	Palmaceae	Dried fruit	Binding agent
20	Qodume mucilage	*Alyssum homolocarpum*	Cruciferae	Seed	Thickening agent
21	Sisi Leaves mucilage	*Cocculus hirsutus*	Menispermaceae	Leaves	Gelling agent, used topically as emollient and demulcent
22	Stavari mucilage	*Asparagus racemosus*	Apocynaceae	Root	Binding, suspending agent in tablets

Table 3. Cytoprotective activity of mucilages [5, 43-47]

Sl no	Scientific name	Family	Part used	Cytoprotective action
1	*Opuntia ficus indica*	Cactaceae	Cladodes	The mucilage from *Opuntia ficus indica* (L.) Mill. cladodes are used for the treatment of gastric ulcer.
2	*Abelmoschus esculentus*	Malvaceae	Seed	Seed mucilage is used for the treatment of gastric ulcer and duodenal ulcer.
3	*Linum usitatissimum*	Linaceae	Flax seed	The flaxseed mucilage have gastroprotective effect against gastric ulcers.
4	*Annona reticulata*	Annonaceae	Seed	Anti-ulcer effect of seed mucilage is evaluated
5	*Trigonella foenum-gracum*	Leguminosae	Seed	Aqueous extract of seeds have anti-ulcer effect
6	*Hibiscus rosa sinensis*	Malvaceae	Root	Oral administration shows antiulcer activity.

In another study, the mucilage extracted from flaxseed also produced a significant reduction in ulcer length and the severity of ulcer pathology and also to a lesser extent in ulcer number or incidence. Due to higher acid neutralizing capacity of flaxseed mucilage, it provides cytoprotective action. This suggests that the acid neutralizing action, in addition to the mechanical protection by mucilage, may contribute for its gastroprotective effect [46].

Preliminary photochemical screening shows the presence of only carbohydrate in *Annona reticulata* mucilage. The cytoprotective action may be due to the development of a protective layer of mucilage against the ulcer inducer.The presence of *Trigonella foenum-gracum* mucilage in the aqueous extract reduced the total acid significantly. The acid antisecretory and acid neutralizing action of the mucilage contribute for its gastroprotective effect [46]. The antiulcer activity is due to the presence of mucilage in the *Hibiscus rosasinensis* aqueous extract [47].

Mucilages have a wide range of applications in pharmaceutical formulations. Being a hydrophilic polymer, it is useful as tablet binding and disintegrating agent. In liquid dosage forms, it is used as emulsifying agent, suspending agents as well as gelling agents, stabilizing agents and thickening agents. In transdermal patches, periodontal films and buccal tablets, they act as film forming agents. They are used as sustaining agents in matrix tablets and coating agents in microcapsules as well as for protein delivery. Besides these, mucilages also provide cytoprotective activity and are used for the treatment of ulcer. Figure 1 shows the comparative study of the uses of mucilage in various fields.

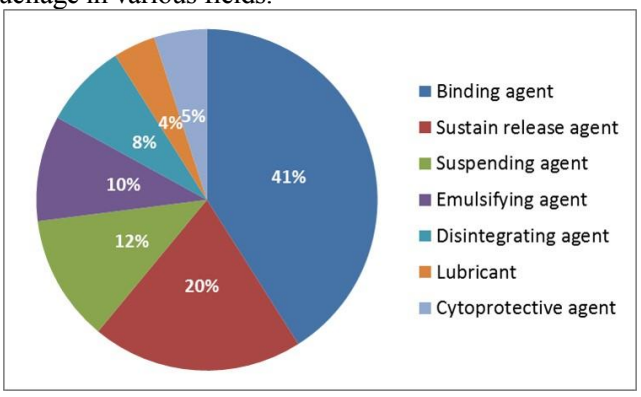

Figure 1. Comparative study of the uses of mucilage

Conclusion

It is concluded that mucilage obtained from natural sources can be used as a tablet binder and produce tablets with good hardness, low friability, disintegration time within limit and better dissolution rate. Thus it has versatile excipient property for conventional dosage forms. On the other hand, mucilages obtained from various sources act as antiulcer agents. The treatment with mucilage provides gastroprotective effect and thus helps to prevent as well as heal ulcer. So, it has become essential to explore out the new sources of plant mucilage for pharmaceutical demand.

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