



## ROLE OF PSYLLIUM AS PHARMACEUTICAL ADDITIVES

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### ABSTRACT

Psyllium or psyllium is a seed grade natural polysaccharide obtained from psyllium and its mucilage is calm of natural arabinoxylan (arabinose 22.6% and xylose 74.6%). Psyllium mucilage is extracted from psyllium husk. Graft copolymerization is one of the best methods for modifying psyllium, which impart certain functional properties to psyllium without destroying its basic properties. The grafting is initiated through the formation of the free radical centers on the polymer backbone. Psyllium has wide application in many health problems, particularly cholesterol control, colon cancer prevention, high sugar levels in blood and widely used as a laxative.

**Keyword:** *Plantago ovata, Natural carbohydrate, Mucilage, Chemical modification, Excipient.*

### 1. INTRODUCTION

Psyllium husk is obtained from the seed of the *Plantago ovata* plant. Psyllium is also recognized as ispaghula and isabgol widely used as a laxative. Isabgol comes from the Persian words as band ghoul, meaning “horse flower” which is descriptive of the shape of the seed [1-6]. The plant of isabgol is generally 10 to 18 inches in height, with numerous small and white flowers are shown in (Figures 1 and 2). Normally, psyllium is cultured for its mucilage content, which is a white fibrous material with hydrophilic characteristic. The mucilage can be obtained by mechanical milling/grinding, and is usually referred to as husk [7]. Psyllium is the commonly used word for more than 200 species of the plant genus *Plantago* which are used commercial manufacturing of mucilage. *Plantago psyllium* and *Plantago ovata* are shaped commercially in many European countries, the former Soviet Union and various region of middle Asia. *Plantago* seeds popular as black, Spanish or French in trade market. Psyllium is obtained from *Plantago psyllium* and *Plantago arenaria* [8,9]. Psyllium was an indigenous plant of Persia, currently grown in the western states of India. Gujarat, Rajasthan, Madhya Pradesh, Haryana is main crop psyllium producing states in India. Currently, India is the chief producer as well as exporter of Isabgol husk and Psyllium husk in world. The crop of psyllium is mainly cultivated in Gujarat, Madhya Pradesh and Rajasthan. Among these states, Gujarat is the main center for the production as well as processing, because the environmental conditions of the Gujarat. Rajasthan also has similar status for cultivation and production as the environmental conditions are very conducive for harvesting of these crops. Gujarat and Rajasthan are collectively reported to have an area of about 61,000 hectares under its cultivation [10,11]. 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.

### 2. HISTORY

Blonde psyllium (*Plantago ovata*) is a low herbaceous annual plant native to Iran and India, extensively cultivated there and in other countries, including Pakistan. Black psyllium of the *P. afra* species is native to the western Mediterranean region, Northern Africa, and Western Asia, now cultivated in Southern France and Spain. Black psyllium of the *P. indica* species is native to Southeastern Europe and Asia. In commerce, blonde psyllium is obtained mainly from India, Pakistan, and Iran. Black psyllium is obtained mainly from southern France. Psyllium has a long history of medical use in both conventional and traditional systems of medicine throughout Asia, Europe and North America. Blonde psyllium is official in the National Pharmacopoeias of France, Germany, Great Britain, and the United States. Psyllium monographs also appear in the Ayurvedic Pharmacopoeia, British Herbal Pharmacopoeia, British Herbal Compendium, ESCOP Monographs, Commission E Monographs, and the German Standard License

Monographs. The World Health Organization (WHO) has published a monograph on psyllium seed covering *P. afra*, *P. indica*, *P. ovata*, and *P. asiatica* (WHO, 1999). Asian psyllium seed (*P. asiatica* Linn or *P. depressa* Willd.) is official in the National pharmacopeias of China and Japan.



fig no:1 Isabgol

#### **PLANT PROFILE:**

**Family:** Plantaginaceae

**English name:** Blond psyllium , Spogel seeds

**Indian name:** Snigdhajibah, Snigdhajirakah (Sanskrit) Isabgol, Isabgul (Hindi) Iskol, Isphogol (Tamil)

**Species:** *Plantago ovata* P. psyllium

**Distribution:** India, West Asia, Pakistan, Persia, Mexico, Mediterranean Regions

#### **CULTIVATION:**

##### **Land preparation and sowing:**

- The land is brought to fine tilth and laid out into beds of convenient sizes of Irrigation.
- It is preferable to add 15 tonnes of FYM/ha during the preparation of land and Mix it well.
- The seeds are sown in rows at 15 cm apart or broadcasted during the month of October. About 3 kg seeds required for one acre.
- After sowing they are covered thinly by raking the soil.

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### **3. USE OF PSYLLIUM IN PHARMACEUTICAL FIELD**

*Plantago psyllium* mucilage or *Plantago psyllium ovata* is a food grade polysaccharide. It has soluble fiber component. Psyllium has wide application in many health problems. Manresearchers have investigated amazing health benefits of psyllium mucilage particularly cholesterol control, preparation for colonoscopy procedure, increasing absorption of water during ingestion subsequent to relaxed stools and reduced pain associated with hemorrhoids, colon cancer prevention, high sugar levels in blood, obesity and weight loss, inflammatory bowel disease, and widely used as laxativ.

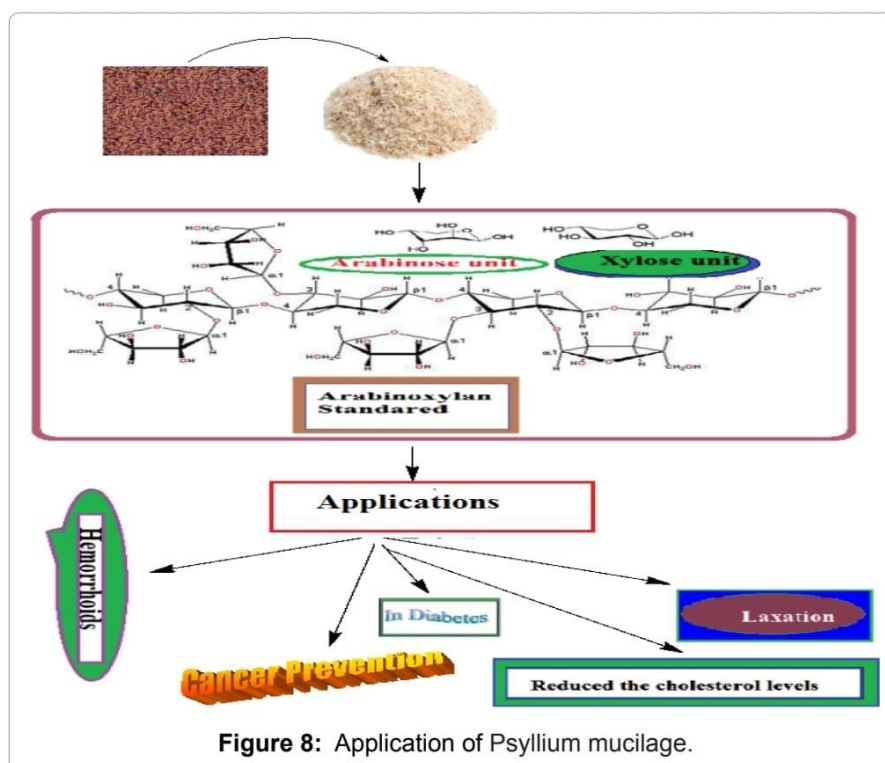


Figure 8: Application of Psyllium mucilage.

#### **CONSTIPATION:**

Psyllium has been shown to have the paradoxical property of both improving constipation by increasing stool weight and ameliorating chronic diarrhea. Several studies suggest that psyllium may provide benefits for treating constipation. There is a scientific basis for psyllium working as a mild laxative. First-line treatment for patients complaining of chronic constipation may involve the use of osmotic laxatives, lubricating agents, dietary fiber, bulk-forming agents or rectal evacuants the choice depends on whether the clinical context is suggestive of slow transit or evacuation disorders<sup>9</sup>

#### **DIARRHOEA:**

Wenzl and co-workers have concluded that the normal intestine delivers stools that defer widely in quantity but maintain percent fecal water within a narrow range. Stools looseness in diarrhea is determined by the ratio of fecal water to water holding capacity of insoluble solids. Psyllium increases the number of normal stools and decreases the number of liquid stools. A combination of psyllium and calcium seems to be cheap and effective alternative to conventional treatment of chronic diarrhea. Fecal consistency was markedly different in psyllium calves as compared with control.

#### **DIABETES:**

Psyllium has been proposed as a possible treatment for high blood sugar levels. Studies in humans suggest moderate reductions in blood sugar levels after a single dose of psyllium, with unclear long-term effects. Water-soluble dietary fibers decrease postprandial glucose concentrations and decrease serum cholesterol concentrations to men with type 2 diabetes. Early or uncontrolled studies suggested that psyllium improved glycemic and lipid control in individuals with type-2 diabetes. The ability of soluble fibers to reduce the postprandial glucose response to meals eaten several hours after fiber ingestion (second meal effect) was shown previously in non-diabetic individuals.

#### **CHOLESTEROL LOWERING:**

It has been observed that there is a positive association with plasma LDL cholesterol levels and coronary heart disease risk. Intake of dietary fibers known to lower the concentration of LDL in plasma is considered to be highly beneficial. Psyllium intake has consistently shown significant reductions in plasma LDL cholesterol levels ranging from 10 to 24%. Reports of the use of psyllium, largely in hypercholesterolemia men, have suggested that it lowers serum cholesterol as a result of the binding of bile acids in the intestinal lumen and reduced risk of coronary heart disease. The mechanism of action of psyllium's hypercholesterolemia effects has not been fully elucidated. Psyllium was shown to stimulate bile acid synthesis by increasing the hydroxylase activity in animals.

#### **LAXATION:**

Many researchers have investigated that psyllium is widely used as a laxative. In many years, psyllium has been used as an effective action towards irritable bowel disease due to its laxative effect. They also study has been conducted to measure the effectiveness of psyllium, and the results were seen to be combined. Kumar et al. Studied, similar effect of psyllium on ameliorating bad-tempered bowel syndrome. They observed that the optimum dosage of psyllium for this treatment using three different doses: 10 g, 20 g and 30 g daily. The observation was divided into two parts. In part first,

patients were administered 10 g psyllium every day for 17 days, and then the dosage increased to 20 g for the subsequent 17 days and finally, 30 g psyllium were given to patients daily for the last 17 days. In part II, to avoid the potential spill over from single dose to the next one, three different dosages of psyllium were administered in a random order and a one-week washout period was included between the two dosages [17]. By clinical assessments of irritable bowel syndrome in patients, a dosage of 20 g psyllium per day was postulated to be the optimum dosage. The laxative effect of psyllium was considered to be mainly due to its water soluble and gelforming capacity.

#### **SIDE-EFFECTS OF PSYLLIUM:**

Many researchers have investigated that a daily dose of 15 g of psyllium was well tolerated as well as the majority of unpleasant events recorded were minor, for minimum and either unconnected or perhaps related to the study behavior. They were also observed that psyllium husk could be used with self-assurance for treatment of mild-to-moderate hypercholesterolemia. U.S. Food and Drug Administration now authorized the use of health claims on food products from psyllium that state that they were connected with a decreased danger of coronary heart disease. The addition of isabgol to traditional nourishment for people with diabetes is safe, is well tolerated, and improves glycemic and Lipid control in men with type diabetes and hypercholesterolemia.

#### **CHARACTERIZATION OF PSYLLIUM:**

FT-IR spectroscopy Kaith and Kumar [22] investigated that the spectra of Psyllium has broad absorption band at 3401 cm<sup>-1</sup> which can be credited to –OH stretching of alcohol (Figure 5). A peak seeming at 2926 cm<sup>-1</sup> is due to C-C stretching of alkanes, while the peak at 1050 cm<sup>-1</sup> credited to C-O-C stretch of ether. The peaks showing at 896, 714 and 613 cm<sup>-1</sup> may be due to polymer chain bending. Scanning electron microscopy Sen et al. [23] studied the surface morphology of psyllium they were analyzed in scanning electron microscopy (SEM) in powdered form (Model: JSM-6390LV, Jeol, Japan). the Surface morphology of psyllium they were analyzed in scanning electron microscopy (SEM) they were found psyllium has smooth and homogenous structure shown in Figure 6.

Thermo-gravimetric analysis and differential thermal analysis Thermo gravimetric analysis of Psyllium in different conditions was carried-out as a function of percent weight loss versus temperature

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## **4. PHYSICOCHEMICAL CHARACTERIZATION OF ISAPGHULA**

### **a) Identification of Mucilage**

Powdered mucilage was treated with ruthenium red dye solution and observed pink color passing the test for mucilage.

### **b) Organoleptic Evaluation**

The polysaccharide was characterized by various organoleptic properties such as color, odor, taste, shape, touch and texture.

### **c) Phytochemical screening of the powder**

The basic Phytochemical screening tests for carbohydrates, alkaloids, steroids, flavonoids saponins, tannins and phenols were carried out

### **d) Solubility Profile of powder**

The solubility profile of the powder was found to as shown in Table 5. The powders were insoluble in acetone, alcohol, ether, chloroform. It was found to form a gel in Hot water.

### **e) Thermal Stability**

Thermal stability study was established and the mucilage withstands to temperature up to Type1 =140°C and Type 2 =135°C showing high thermal stability.

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## **5. FLOW PROPERTIES OF PSYLLIUM POWDER**

### **a) Particle Shape Distribution**

Particle shape was Rough and irregular on microscopic evaluation. The microscopic picture of Psyllium powder Micromeritics Properties of psyllium Powder The derived properties such as bulk density, tapped density, compressibility index, Hausner's ratio and angle of repose which depend mainly on particle size distribution, particle shape and tendency of the particles to adhere together results. The values of bulk density, compressibility index and Hausner's ratio infer that the psyllium polysaccharide powder has excellent flow properties and compressibility.

### **b) Micromeritics Properties of psyllium Powder**

The derived properties such as bulk density, tapped density, compressibility index, Hausner's ratio and angle of repose which depend mainly on particle size distribution, particle shape and tendency of the particles to adhere together. The values of bulk density, compressibility index and Hausner's ratio infer that psyllium polysaccharide powder has excellent flow properties and compressibility.

#### **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 thermo sensitivity, 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].

#### **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.

#### **DISINTEGRANT:**

Superdisintegrants are substances added to Tablets to assist the breakup of compacted mass into Particles, so as to facilitate the discharge of active Ingredient and drug dissolution, when it approaches

The fluid surroundings. Plantago ovata is used as a Superdisintegrant owing to swelling characteristics of its mucilage. The paramount step of disintegration is appropriate media permeation. When media Penetrates the tablet, disintegrant swells upon interaction with it and a swelling force develops, which Brings about disintegration of tablet. Fast disintegrating tablets (FDTs) are novel type of tablets that Disintegrate/disperse or dissolve in saliva and are Used by pediatrics, geriatrics, bed ridden, mentally Disabled patients who have dysphagia and also by Those having nausea, allergy, coughing and motion Sickness. Great many studies have been performed On superdisintegrant properties of Plantago ovata in Comparison with other natural and synthetic super-Disintegrant for various FDTs. Taste masked FDTs of lisinopril were prepared By direct compression method with an objective to Compare the effect of three natural superdisintegrants (isolated mucilage of Plantago ovata, Hibiscus rosasinesis, and Aloe vera) in different concentrations on lisinopril oral formulation. The Lisinopril oral tablet with maximum concentration of Plantago ovata mucilage showed better disintegration time of  $9 \pm 0.26$  s and increased dissolution rate As compared to other two disintegrants due to its Swelling property (19). Similarly, in another study Fexofenadine FDTs were prepared by using seed Powder, husk powder and mucilage of Plantago Ovata as a super disintegrant and emphasis was Given to their disintegrating property. Disintegrants Were used in concentration of 5% w/w Plantago Ovata.

## 6. SYNTHESIS OF PSYLLIUM BASED POLYMER MATRIX

Psyllium based polymeric networks were synthesized by chemically induced polymerization through free radical mechanism. In the presence of crosslinker NN-MBAAm ( $\text{CH}_2\text{CHCONHCH}_2\text{NHCOCH}_2\text{CH}_2$ ), because of its poly functionality, a new macro-radical get formed that has four reactive sites and these sites can be linked both with the radical on the psyllium and the monomers. This will result into the formation of three-dimensional networks, which were used to study the in vitro release of the model drugs. Reaction was carried out with definite amount of psyllium husk, APS, monomer and N,N- MBAAm in the aqueous reaction system at 65°C temperature for 2 h. Polymers thus formed were stirred for 2 h in distilled water and for 2 h in ethanol to remove the soluble fraction and then were dried in air oven at 40°C. Psyllium cross linked poly (N-hydroxymethylacrylamide) [Psy-cl-poly (HMAAm)] and psyllium crosslinked poly (acrylamide) [Psy-cl-poly (AAm)] (based hydro gels have been prepared by above mentioned method).

- **Drug loading to the Psyllium based polymeric:** matrix The loading of a drug onto hydrogels was carried out by swelling equilibrium method. The hydrogel was allowed to swell in the drug solution of known concentration for 24 h at 37°C and then dried to obtain the release device. The concentration of the rejected solution was measured to calculate percent entrapment of the drug in polymer matrix.
- **Drug release from polymer matrix In vitro:** release studies of the drug were carried out by placing dried and loaded sample in definite volume of releasing medium at 37°C temperature. The drug release was measured after fixed interval of time and release dynamics of model drugs were calculated.

### DIFFERENT TESTS CARRIED OUT TO ASSURE THE QUALITY OF PROCESSED PSYLLIUM:

#### **Swelling index:**

It is the measurement of the ability of the isabgol to absorb water and soil. It is defined as the volume in ml occupied by the swelling of 1 gm of isabgol including mucilage after it has swollen in water or any other specified liquid under specified conditions. Weight 1 gm of isabgol seeds and transfer it in a measuring cylinder of 25 ml. Add 20 ml water in measuring cylinder containing isabgol. Close the measuring cylinder, shake it occasionally and keep aside for 24 hrs. for complete swelling. After 24 hr the seeds absorb water and volume occupied by the seed in the measuring cylinder increases. Quantitative swelling of seeds is due to presence of mucilage. Measure the volume occupied by the seeds before and after swelling. This value gives the swelling index. Swelling index checks the purity of isabgol and this value ranges between 10-14 for isabgol. Microscopic examination: The material will adjust to the accompanying depiction:

Prolonged polygonal cells, 90 to 120 micron long, 18 to 27 micron wide, cellulose walled, thickened by auxiliary store

## 7. CONCLUSION

Psyllium is a natural polysaccharide obtained from *Plantago psyllium* and its mucilage is composed of natural arabinoxylan (arabinose 22.6%, xylose 74.6%). Mucilage is a non-toxic biomaterial, and abundantly found in nature. It has a typical combination of biological activity with mechanical and physical properties, chemical effects of psyllium. Many researchers have investigated that a daily dose of 15 g of psyllium was well tolerated as well as the majority of unpleasant events recorded were minor, for minimum and either unconnected or perhaps related to the study behavior. They were also observed that psyllium husk could be used with self-assurance for treatment of mild-to-moderate hypercholesterolemia. U.S. Food and Drug Administration now authorized the use of health claims on food products from psyllium that state that they were connected with a decreased danger of coronary heart disease. The addition of isabgol to traditional nourishment for people with diabetes is safe, is well tolerated, and improves glycemic and Lipid control in men with type diabetes and hypercholesterolemia [45]. Among the techniques for improve natural polymers mostly polysaccharides. Graft/ crosslinked copolymerization is an effective method to incorporate desired properties in the available polymer backbone, and these are useful in many applications in diverse fields. This unique characteristic makes them an important bio material for biochemical and pharmaceutical additives.

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