Original Article

Formulation and Evaluation of *Phanera variegata* Linn. Mucilage as a Pharmaceutical Binder in Solid Dosage Form

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ABSTRACT

Objectives: The present study is aimed to isolate, evaluate the mucilage obtained from the leaves of Kachnar (*Phanera variegata*) and to compare the binding efficacy of the isolated mucilage with acacia gum. **Methods:** Extraction and isolation of mucilages from the leaves of *Phanera variegata* were carried out by the maceration method. The isolated mucilage was analyzed for phytochemical, microbial andvarious physico-chemical properties for acceptability as a novel excipient for the formulation of tablets. Uncoated paracetamol tablets of different batches (F1–F4) were prepared by preparing granules (different concentrations) of isolated mucilage (3%, 5%, 10% and 15% w/v respectively) using wet granulation technique.The formulated tablets were evaluated: pre-compression (Micromeritics properties) and post-compression parameters (size, hardness, friability, weight uniformity, content uniformity, disintegration and *in vitro* dissolution profile.) For comparison purposes, acacia gum was used as a binder and different batches of tablets (A1 – A4) were prepared similarly and evaluated for pre-compression and post-compression parameters. **Results:** The formulated tablets using isolated mucilage had a good appearance, on increasing the concentration of binder hardness of tablets were also increased, all the formulations fall within the limit for friability and disintegration according to official standards, *in vitro* dissolution profile of optimized formulation F2 showed 98.28% drug release within 20 min. **Conclusion:** According to the observation, isolated mucilage can opt as an alternative natural excipient (binding agent) for the formulation of uncoated tablets. *Phanera variegata* is a novel plant with less or almost no reported data.

Key words: Paracetamol, *Phanera variegata*, Mucilage, Maceration, Formulation, *in vitro* dissolution.

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INTRODUCTION

In recent years, Polymers derived from plants have invoked great interest as they have valuable advantages over synthetic polymers and these plant-derived polymers (excipients) have diverse pharmaceuticals applications in all dosage forms like for solid dosage form as binders, diluents, disintegrants, in liquid dosage form as a viscosity enhancer, thickening agents and as a base in semisolid dosage forms.[1,2] They also have applications in packaging industries, cosmetics and inedible films.[3,4] Pharmaceutical excipients are non-active substances that are used to make a compatible, patient-friendly, physically and chemically stable dosage form.[5] Plant origin mucilages and gums have broad applications in pharmaceutical industries as they have several merits over synthetic because they are widely available, low cost and biocompatible.[6] Even semi-synthetic mucilages and gums are also preferred because of low cost readily availability, non-toxicity.[7,8] Mucilages are polysaccharides that are composed of sugar and uronic acid (uronic acids are carboxylic acids derived from sugars) units. Chemically mucilages are not well defined, but they have hydrophilic

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as well as water trapping capacity (to form gels), on exposure to water mucilage swells to many times to the volume of water it absorb.[9] Conventionally mucilage is used as disintegrants, binders, emulsifiers, suspending agents and it has also been reported for the control drug release from tablets.[10,11]

Modification of plant origin mucilages and gums can also be done to meet some requirements of modified drug delivery systems and compete with synthetic gums that are available in the market.[12] Okra gum obtained from *Abelmoschus esculentus*,[13] Albizia gum from *Albiziazygia*,[14] Tamarind gum from *Tamarindus indica*,[15] Fenugreek mucilage obtained from *Trigonella foenum-graceum*,[16] Hibiscus mucilage from *Hibiscus rosasinensis*,[17] Aloe mucilage from *Aloe barbadensis*,[18] *Cassia tora* mucilage from *Cassia tora*,[19] are some mucilages and gums whose characterization and applications on pharmaceutical formulations have been reported. Due to environment and geometrical conditions, India has been reported for a significant contributor tothe availability of natural mucilages and gums.

Linn. plant (leaves) has been taken for investigation. It is species of flowering plant in the legume family *Fabaceae* and its scientific synonym is *Bauhinia variegata*, other common names are Kachnar, Mountain ebony, Kandan, Arbe de saint, Bwechin, Ayata, Orchid tree, Camel toe tree etc.[20] Kachnar is a medium-sized deciduous tree, fast-growing, sun-loving having a short, dark brown trunk, large fragment flowers of either white or purplish color (bright pink) or hairy branches. The leaves are obcordate (heart-shaped attached by the pointed end) shape having lobes at the base and apex. In India, it is widely distributed in sub-Himalayan and outer Himalayan, Sikkim, Punjab, Rajasthan, Uttar Pradesh, extending from Burma to China, all over in South East Asia including Bangladesh and Malaysia.[21] Some pharmacological properties *Phanera variegata* has been reported, like Antibacterial, Hepatoprotective, Anti-inflammatory, Anti-diabetic, Anti-ulcer activity, Antimicrobial, and Haematinic. Kachnar is also used as a source of food in various parts across the country.[22]

In the present study, we aimed to characterize the various physicochemical properties and to observe the characterization of mucilage isolated from *Phanera variegata* as binding or granulating agents for the formulation of the conventional solid dosage form (tablets). *Phanera variegata* mucilage is a novel polysaccharide gum with little to almost no published information on its characterization and application as pharmaceutical excipients. The following characterization was done. (i) Phytochemical properties of crude mucilage, (ii) Microbiological studies, (iii) Physico Chemical properties of crude mucilage, (iv) Drug – Excipient compatibility, (v) Micromeritics Studies of prepared granules, (vi) Evaluation of prepared tablets, (vii) *in vitro* dissolution studies.

MATERIALS AND METHODS

The leaves of *Phanera variegata* Linn. were collected locally from the campus of GLA University, Mathura, U.P., India. The plant was authenticated by Dr. Sunita Garg, CSIR- NISCAIR, New Delhi, India. Ref. No.- NISCAIR/RHMD/Consult/2018/3230-31.

Paracetamol was procured from Yarrow chem. Products, Mumbai. Lactose, Corn starch, Acacia gum, Talc and Magnesium stearate from Central drug house (P) Ltd. New Delhi and other chemicals from Thermo Fisher Scientific India Pvt. Ltd., Mumbai (AR grade).

Isolation of the Mucilage

The fresh leaves of *Phanera variegata* Linn. were collected and cleaned with water properly to remove debris and dirt and then kept for drying. After drying, they were crushed in a grinder to make a fine powder. Then the powder was soaked (homogenize) in water (x 4) for 2-3 hr (homogenization) after that slurry was boiled for 15-20 min. at 70°C and kept undisturbed for around 1 h for release of mucilage into water. The slurry was passed by eight folds of muslin cloth for separation of the marc and the solution. Acetone in the ratio of 1:3 to the volume of the filtrate was added to the filtrate to precipitate the mucilage. The mucilage was filtered, dried in an oven at a temperature not exceeding 50°C. The dried material was then collected, crushed and passed by mesh 80. The resultant fine powdered was stored for further use in the desiccator. Deionized water was used to conduct all experiments. All chemicals were used as received of analytical grades without further purification.[23] The total percentage yield of isolated mucilage from *Phanera variegata* Linn. was found to be 10.2 %. Isolated mucilage is shown in (Figure 1).

Phytochemical Properties of Mucilage

The isolated mucilage was qualitatively examined for phytochemical properties. Presence of carbohydrates, mucilage, proteins, flavonoids, alkaloids, glycosides, resins, saponins, steroids and tannins.[24,25]

Microbiological Properties

The microbial load of the isolated mucilage of *P. variegata* was analyzed for fungal as well as for bacteria by using Sabouroud's dextrose agar media and Nutrient agar media, respectively. All the ingredients of both the media were boiled in separate vessels and autoclaved

at 121°C for 15 min, the medium transferred to Petri plates in the sterile chamber and left to solidify; finally, the previously incubated samples of each isolated material were transferred on the media by strike method and plates to both the media for fungal and bacterial growth were allow to incubate at 27°C for 72 hr and at 37°C for 24 hr respectively.[26-28]

Physico- Chemical Properties of Crude Mucilage

Solubility

The solubility of isolated mucilage was done by doing qualitative analysis; 10 mg of isolated mucilage of kachnar was dissolved in 10 ml of different solvents.

pH

pH of isolated mucilage of Kachnar was examined by preparing its 1% w/v solution and analyzed by immersing the digital pH meter (Labtronics LT – 11, India) in the prepared solution.

Total Ash Value

Total Ash Value of isolated mucilage was analyzed by incinerating 2 gmof grounded isolated mucilage in a tare silica dish at a temperature not exceeding 450°Cuntil free from carbon; it was allowed to cool and then weighed.[29]

$$\text{Total Ash Value} = \frac{\text{Total Weight of ash formed}}{\text{Total weight is taken}} \text{ X } 100$$

Acid insoluble ash

Acid insoluble ash of isolated mucilage was studied by using ash procured from total ash and was washed with 25 ml of dil. HCl. The ash filtered through an ashless filter paper. Filter paper, along with residue, was placed in pre weighted silica crucible and was allowed to heat until vapors ceased; it was then allowed to cool. The residue was weighed andinsoluble acid ash was calculated using following formula.[29]

$$\text{Acid insoluble ash value} = \frac{\text{Weight of residue}}{\text{Total weight is taken}} \text{ X } 100$$

Water-soluble ash

Water-soluble ash of the isolated mucilage was determined the same as acid-insoluble ash by using 25 ml of water in place of diluted HCl.

Viscosity

The viscosity of isolated mucilage of kachnar was determined by using a viscometer (Brookfield DV - E) and LT spindle 63. The viscosity was analyzed by preparing 3% and 5 % w/v solution of mucilage.

Loss on drying

1 gm of isolated mucilage was weighed and transferred in weighing bottle, which was previously heated at 105 ± 2°C. Sample was distributed evenly in the bottle and kept for drying at 105 ± 2°C in an oven for 3 hr. Then it was kept in a desiccator and allowed to cool till room temperature. Loss on drying was calculated by following equation.[30]

$$\text{Loss on Drying \%} = \frac{(W_1\text{-}W_2)}{(W_1\text{-}W)} \text{ X } 100$$

Where, W = Weight of empty weighing bottle, W_1 = Weight of weighing bottle with the sample, W_2 = Weight of weighing bottle with sample after drying.

Swelling Index

The swelling behavior of mucilage was experimented according to reported experiment. 0.1g of Kachnar mucilage powders were poured in 10 ml of graduated measuring cylinders separately and the initial volumes of dry mucilage were recorded as (V_0) separately. Then the volume was made up by distilling water and the cylinder was kept aside for 24 h. Finally, the volume of swelled mucilage of cylinder was recorded as (V_1) after 24 h and swelling index (SI) was calculated as.[31]

$SI = V_1/V_0$

Drug Excipient Compatibility Study

Fourier-transform infrared spectroscopy (FTIR) of a mixture of isolated mucilage with drug and the pure drug was analyzed separately. To check theinteraction between pure drug and mucilage, a mixture of both were taken and kept in a desiccator for 3 months and analyzed, all the spectra were recorded on an FT-IR spectrometer (IRAffinity, Shimadzu, Japan). Each of the samples was pulverized and blended with Kbr and transfer to the sample holder and all the spectra were obtained individually between 4000-4001/cm. Multiple spectra were recorded and the ones with clearest peaks were chosen for each sample.

Compatibility study of isolated mucilage (*Phanera variegata*) and drug (PCM) was also analyzed by UV spectrophotometer (UV-1800 spectrophotometer, Shimadzu, Japan). The mixture of PCM/Mucilage of 1:1 ratio is kept for 3 months and then scanned in the wavelength range of 400 – 200. The peak at 242 nm was monitored for any wavelength shift.

Thermal analysis (DSC) of the pure drug was analyzed separately and compared with a mixture of the drug (PCM) and isolated mucilage in the ratio of 1:1 to analyze the physicochemical interaction between them.

Preparation of Tablets

Tablets of isolated mucilage of *Phanera variegata* was prepared by granulation method (wet granulation), mucilage isolated was used as a binder, Paracetamol (PCM) as a model drug, Lactose as a diluent, Corn Starch as a disintegrating agent, Talc as a glidant, Magnesium Stearate asa lubricant and distilled water as granulating liquid. Different batches of paracetamol tablets were formulated using 3%, 5%, 10% and 15% w/v. PCM, lactose were weighed according to the composition table (Table 1) and transferred in the mortar,and required % w/v solution of isolated mucilage as a binder was added dropwise in the mixture to form a dough. Corn starch was divided into two parts and added intra granularly and extra granularly (during granulation and after sieving drying of granules, respectively). The dough was screened through sieve no. 22 and the granules were kept for drying at 60°C until completely dried. Dried granules were passed through sieve no. 44. Finally, weighed quantity of talc and magnesium stearate was added before compression and 650 mg tablets were prepared.[32] The compression was done using a 12 mm concave face round tooling on an automatic tablet compression machine.

For comparison purposes, four batches of paracetamol tablets (i.e., 3 %, 5%, 10% and 15 %w/v binder) were prepared by using Acacia gum as a standard binder in place of *Phanera variegata* mucilage and all other ingredients are same accordingly. Tablets were prepared using the same method. Acacia gum is a frequently used excipient as a binding agent for uncoated conventional tablets. The weight of each compressed tablet was 650 mg. Formulation A1-A4 of acacia gum as a binder containing the same concentration as of F1–F4.

Evaluation of Dried Granules (Micromeritics Studies)

The prepared dried granules of kachnar mucilage were evaluated for Particle size distribution and Flow properties (Bulk density, Tapped density, Carss's Compressibility Index, Hausner's ratio and Angle of repose).[33,34]

Micromeritics studies of dried granules prepared by acacia gum were also evaluated for flow properties.

Determination of Particle size distribution

Determination of the particle size distribution of the prepared granules of isolated mucilage was done by mechanical sieving (mesh analysis) method. A stack of sieves (#60, #80 and #100) was taken and 35 gm of prepared granules of each batch waskept on the topmost sieve and allow to shaken mechanically for 10 min. The quantity on each sieve was weighed individually and particle size distribution was determined.

Evaluation of Flow properties

Determination of flow properties of prepared granules is important as it directly affecting the preparation of tablets, so the prepared granules of isolated mucilage were evaluated for the flow properties. 20 gm of prepared, isolated mucilage granules were transferred in a pre-weighed 50 ml graduated measuring cylinder. The volume obtained before and after tapping (by ROLEX, Bulk density apparatus) was determined for each batch. The volume before tapping and volume after tapping was used to determine the bulk and tapped density, respectively. Hausner's ratio and Carr's compressibility index were determined by tapped and bulk density.

Bulk density = Mass of granules taken / Bulk volume

Tapped density = Mass of granules taken / Tapped volume

Haunser's ration = Tapped density / Bulk density

$$\text{Carr's compressibility index} = \frac{\text{Tapped density} - \text{bulk density}}{\text{Tapped density}} \text{X100}$$

The angle of repose determines the flow characteristics of granules directly. The angle of repose was evaluated by calculating tan Q by using funnel hanged withstand

Table 1: Composition table [All the values were in percentage (%)].

Ingredients	Application in formulation	3% F1	5% F2	10% F3	15% F4	3% A1	5% A2	10% A3	15% A4
Paracetamol	API	76.9	76.9	76.9	76.9	76.9	76.9	76.9	76.9
Lactose	Diluents	13.1	11.1	6.1	1.1	13.1	11.1	6.1	1.1
Phanera variegata Mucilage	Binder	3.0	5.0	10.0	15.0	-	-	-	-
Acacia Gum	Binder	-	-	-	-	3.0	5.0	10.0	15.0
Corn Starch	Disintegrants	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
Talc	Glidant	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Magnesium Stearate	Lubricant	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0

at 5 cm above the base. Prepared granules were allowed to pass through the funnel to form a pile; the height of the pile, as well as diameter, was taken to calculate the angle of repose by the equation below.

$$\text{Angle of repose (Q)} = \text{Tan} \frac{\text{Height of pile (h)}}{\text{Radius of pile (r)}}$$

Evaluation of Prepared Tablets

Non–official and official evaluation parameters of prepared tablets using kachnar mucilage were determined to check the quality of the batches with different concentrations of the isolated binder.

Paracetamol tablets prepared by using different concentrations of acacia gum were also evaluated for all official and non-official parameters. Post compression tests were performed according to Indian Pharmacopoeia (IP) 2014 including dissolutions profile.[35]

Diameter and thickness of prepared tablets

Prepared tablets were observed for thickness and diameter by Vernier Caliper of randomly selected prepared tablets.

Uniformity of weight of tablets

Weight variation or uniformity weight of the prepared tablets of isolated mucilage was done. Twenty tablets were selected randomly of each batch; all were assessed gravimetrically individually and compared accordingly to the IP.

Hardness of tablets

Hardness test of tablets is non-official test, but it's done to check the crushing strength of tablets to resist pressure during transportation (handling) till consumption. Hardness test for each batch prepared using different concentrations of isolated mucilage was done by using Monsanto type hardness tester by which the average force required to break tablets completely was obtained.

Friability test of tablets

Random ten tablets were taken, dusted, weighed. Tablets are kept in a friabilator and rotated mechanically at 25 rpm for 4 min. Then again, tablets are dusted and reweighed and the % friability was evaluated by the given equation.

$$\text{Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \text{ X } 100$$

Disintegration test of tablets

The disintegration was examined by using tablet disintegration apparatus and the test was done by placing one tablet in each tube of apparatus which carried out by using distilled water as a medium, the temperature was maintained at 37 ± 2°C with a dip speed of 30 dips/min. All the measurements were performed in triplicate.

Uniformity of content

Twenty tablets of formulations were weighed and powdered in a mortar. The quantity of powder equivalent to 0.15 g PCM was added with methanol in a 100 ml volumetric flask. The flask was shaken for 15 min, dilution was made and absorbance was observed at 242 nm and the concentration of PCM was determined.

In-vitro Dissolution Study

Prepared tablets from the isolated mucilage of kachnar studied for *in vitro* drug release profile using USP type 2 apparatus (Paddle type). The dissolution medium taken was 900 ml of .1N HCl at 37°C to provide gastric conditions where uncoated prepared tablets will disintegrate. All the different batches of prepared tablets were examined; 5 ml of sample was withdrawn at a regular interval (5 min) and was replaced by fresh buffer so as to maintained sink condition. Then samples were filtered and analyzed on UV – spectrophotometer at 242 nm for determining the drug release profile. The drug concentrations in samples were determined from the prepared standard curve and the drug release percentage was analyzed and calculated.

In vitro drug release profile of paracetamol tablets prepared from the different concentrations of acacia gum was analyzed by using the same procedure mentioned above.

RESULTS AND DISCUSSION

Phytochemical Properties of Mucilage

Mucilages are polysaccharides hydrocolloids, which are commonly found in plants; these types of polysaccharides reduce the release of drugs from the dosage form.[36] The isolated mucilage from the leave of *Phanera variegata* was examined for various phytochemical constituents present in it. The isolated mucilage confirms polysaccharide in nature. (Table 2) shows data of other phytoconstituents of isolated mucilage.

Microbiological Properties

The microbiological properties of isolated mucilage of *P. variegata* were analyzed andthe results of microbial load are determined in (Table 3). After 72 hr, no growth was found in any of the media.

Physico Chemical Properties of Crude Mucilage

The various physicochemical properties of isolated mucilage from the leaves of *Phanera variegata* have

Figure 1: Isolated mucilage of *Phanera variegata* Linn.

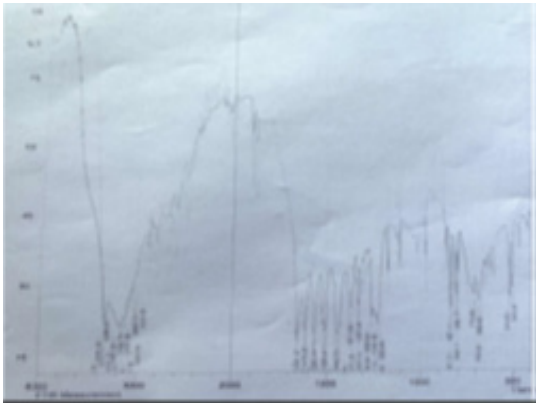

Figure 2: IR spectra of 1:1 mixture of drug (paracetamol) and mucilage (*Phanera variegata*).

been characterized under the specification as per Pharmacopoeial guidelines. The mucilage was freely soluble in hot distilled water, formed colloidal solution in the cold distilled water.

Insoluble in acetone, ethanol and chloroform. The pH was found to be 6.2; pH shows that natural mucilage might not irritate the mucus membrane of the oral cavity and it is suitable for uncoated tablets.[37,38] Viscosity of kachnar mucilage of 3% and 5% w/v solution was found to be 1323 cP and 1562 cP, respectively. All the other physicochemical parameters results are shown in (Table 4) and these parameters conferred as per Pharmacopoeia guidelines.

Drug Excipient Compatibility Study

The drug-mucilage compatibility study was done by FTIR, UV-spectroscopy and differential scanning calorimeter (DSC) so as to investigate the physicochemical changes between isolated mucilage and drug.

The IR spectra suggested no interaction in the mixture of drug-mucilage in comparison with the peaks of the pure drug (PCM). (Figure 2) shows the 1:1 mixture spectra of drug and isolated mucilage. The strong peak at 3325.28 cm^{-1} can be of the

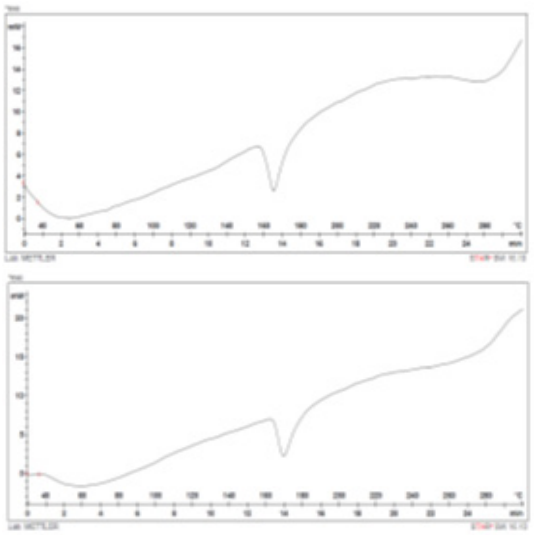

Figure 3: A) DSC thermogram of pure drug (paracetamol); B) DSC thermogram of 1:1 mixture of drug (paracetamol) and mucilage (*Phanera variegata*).

characteristic strong bond of p-substituted phenol. The peak at 3292.49 cm^{-1} showing secondary amino group stretching. The peak at 1651.07 cm^{-1} is of C=O amide keto. Peaks at 1371.39 cm^{-1} and 1435.04 cm^{-1} were due to a strong band of stretching phenolic C –O and peaks at 837.11 cm^{-1} and 686.66 cm^{-1} concurred the p substituted benzene.

The UV spectroscopy analysis suggested no physico chemical interaction between drug and isolated mucilage as there was no change in the λ_{max} (242 nm) of drug when the 1:1 mixture spectra of drug and isolated mucilage was analyzed on UV – spectrophotometer.

The DSC of drug (PCM) and 1:1 mixture of drug and mucilage showed no change in the thermogram as shown in the (Figure 3A and 3B).

Evaluation of Dried Granules (Micromeritics Studies)

Particle Size distribution

The study of the particle size distribution of granules is essential as it has a great impact on flowability, compression, uniformity of weight, uniformity of content, disintegration as well as on drug release.[39,40] Large particle size and small particle distribution have great flowability, but larger particle leads to less hardness of tablets as large particle have lesser surface area than small particles. So an average particle and its size distribution are required to get an optimized tablet of good hardness.[41] The particle size of the prepared granules of paracetamol and isolated mucilage increase as the concentration of binder increased. The particle size distributions of prepared granules from Kachnar

Table 2:Phytochemical properties of isolated mucilage from *Phanera variegata.*

Active Constituent	Test	Result
Carbohydrates	Molisch's test	Positive
Mucilage	Ruthenium red test	Positive
Proteins	Biuret test	Negative
Flavonoids	Shinoda test	Positive
Alkaloids	Mayer's reagent test	Negative
Glycosides	Baljet's test	Positive
Saponin	Forth formation test	Negative
Steroids	Salkowski test	Negative
Tannins	Ferric chloride test	Negative
Resin	Resin test	Negative

Table 3: Microbiological properties of isolated mucilage from *Phanera variegata.*

Parameters	Fungal	Bacterial
Growth media	Sabouroud's dextrose agar media	Nutrient agar media
Temp. during incubation	27°C	37°C
Observed after 24 hr	No growth	No growth
Observed after 72 hr	No growth	No growth

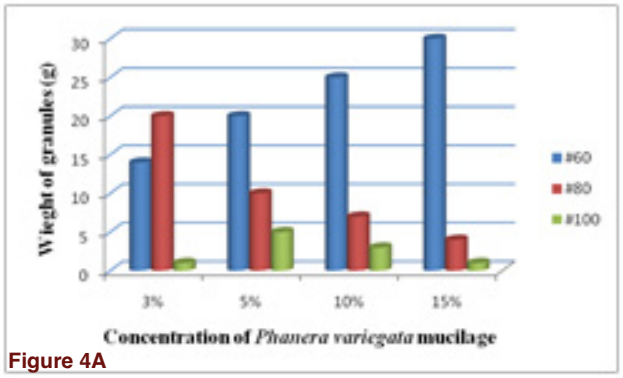

Figure 4A

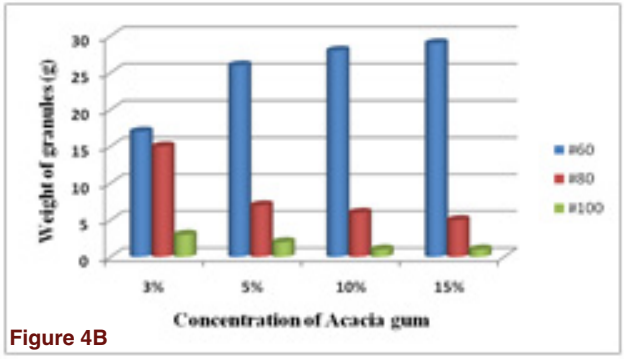

Figure 4B

Figure 4: A) Particle size distribution of granules prepared by *P. variegata* mucilage; B) Particle size distribution of granules prepared by Acacia gum.

Table 4: Physico chemical parameters of isolated mucilage from *Phanera variegata*

The values are mean ± S. D. for *n* = 3.	Observation
Solubility in water	Freely soluble in hot water, Colloidal solution formed in cold water. Insoluble in acetone, ethanol and chloroform
pH (1% w/v solution)	6.2
Total Ash value (%) ± S. D.	9.5 ± 0.11
Acid insoluble ash (%) ± S. D	1.5± 0.16
Water soluble ash (%)± S. D	7.25 ± 0.12
Viscosity (3% and 5% w/v solution)	1323 cP and 1562 cP respectively
Loss on drying (%)	2.73
Swelling Index	6

mucilage and acacia gum are shown in (Figure 4A and 4B).

Flow properties

The flow properties of prepared granules using isolated mucilage were evaluated under which bulk and tapped density, Carr's compressibility index, Hausner's ratio and Angle of repose were parameters were tested and the results are shown in the (Table 5). The compressibility index of the granules is an important parameter as it determines the ability of granules to compact during compression so as to increase the hardness of the table, which can withstand pressure. When the compressibility index is below 15 %, the granules have good flow properties while above 25 % show poor flow properties.[42,43] Average compressibility index of the granules of all concentration prepared by isolated mucilage of *Phanera variegata* were under 15%, which shows good flow property of granules.

Granules having hausner ratio below 1.8 and an angle of repose below 30°C indicate good flow properties. *Phanera variegata* mucilage granules exhibited hausner ratio andangle of repose for 2% and 5% concentration below 1.0 and 30° respectively which indicated good flow properties of both concentrations.[44]

The granules containing isolated mucilage of kachnar shows very similar results when compared with granules containing acacia gum.

Evaluation of prepared tablets

Non-official and official evaluation parameters of prepared tablets were determined to check the quality of the batches with different concentrations of the isolated binder.

Table 5: Flow properties characterization of isolated mucilage from *Phanera variegata*								
All the values are mean ± S. D. for *n* = 3.	**Kachnar Mucilage**				**Acacia Gum**			
	F1	**F2**	**F3**	**F4**	**A1**	**A2**	**A3**	**A4**
Bulk Density (g/ml) ±S.D.	0.55± 0.05	0.50± 0.03	0.47± 0.03	0.45± 0.03	0.65± 0.02	0.58± 0.05	0.51± 0.05	0.45± 0.03
Tapped Density (g/ml) ±S.D.	0.62± 0.02	0.58± 0.01	0.55± 0.02	0.52± 0.03	0.72± 0.02	0.65± 0.02	0.58± 0.05	0.53± 0.04
Carr's Compressibility Index (%) ±S.D.	11.2± 0.25	13.7± 0.36	14.5± 0.42	13.4± 0.32	9.7± 0.22	10.7± 0.24	12.06± 0.35	15.09± 0.42
Hausner Ratio ±S.D.	1.08± 0.05	1.07± 0.04	1.08± 0.05	1.1± 0.07	1.10± 0.05	1.12± 0.05	1.13± 0.07	1.17± 0.07
Angle Of Repose (°) ±S.D.	29.74± 0.78	28.02± 0.74	31.66± 0.9	32.61± 0.95	29.02± 0.8	31.27± 0.85	31.56± 0.9	32.25± 0.9

Table 6: Official and Non-official test of all prepared formulation								
All the values are mean ± S. D. for *n* = 3.	**Kachnar Mucilage**				**Acacia Gum**			
Parameters	2% F1	5% F2	10% F3	**15% F4**	**2% A1**	**5% A2**	**10% A3**	**15% A4**
Diameter (mm) ± S. D	12.7 ± 0.11	12.5 ± 0.10	12.4 ± 0.12	12.4 ± 0.11	12.4 ± 0.12	12.7 ± 0.11	12.5 ± 0.12	12.7 ± 0.12
Thickness (mm) ± S. D	5.5 ± 0.05	5.6 ± 0.06	5.6 ± 0.05	5.5 ± 0.06	5.6 ± 0.05	5.7 ± 0.07	5.6 ± 0.05	5.8 ± 0.07
Hardness (kg/cm²) ± S. D	3.00 ± 0.41	5.5 ± 0.31	5.7 ± 0.32	6.5 ± 0.45	3.5 ± 0.43	4.9 ± 0.3	5.5 ± 0.41	7.1 ± 0.5
Uniformity of weight (mg) ± S. D	649.5 ± 0.008	649.9 ± 0.014	650.3 ± 0.010	650.4 ± .011	649.1 ± 0.01	649.8 ± 0.09	650.8 ± 0.01	651.1 ± 0.01
Disintegration time (minutes) ± S. D.	1.0 ± 0.02	2.1 ± 0.06	3.45 ± 0.1	3.5 ± 0.12	2.2 ± 0.06	2.9 ± 0.08	3.4 ± 0.1	3.7 ± 0.15
Drug content (%) ± S. D	99.8 ± 0.4	92.5 ± 0.4	98.4 ± 0.5	97.8 ± 0.5	95.6 ± 0.5	97.3 ± 0.5	93.8 ± 0.4	97.9 ± 0.5
Friability (%) ± S. D.	Less than 1% in all formulations							

Four batches of uncoated tablets carrying PCM as a model drug were prepared by using different proportions of isolated mucilage of kachnar, which was used as a binding agent by conventional wet granulation method. The results of various official and nonofficial properties of prepared tablets from the different concentration of the mucilage of *P. variegata* are shown in (Table 6). Non-official test of prepared tablets was evaluated like thickness, diameter and hardness, the thickness of all formulations F1 to F4 was between 5.5 mm to 5.6 mm, the diameter was in the range of 12.4 mm to 12.7 mm. The uncoated tablet should attain 4 kg/cm^2 of minimum hardness.[45] All three formulations except F1 were in the range of 5-7 kg/cm^2. Official parameters of prepared tablets were evaluated like percentage friability, uniformity of weight, disintegration, uniformity of content.

Friability is one of the mechanical strength properties of tablets with compendia (IP, 1996) specification of less than 1%. Friability is done to check the surface deformation of tablets; more the rougher surface of the tablet more will be its friability.[46] The percentage friability of all formulations was found to be less than 1%. According to the pharmacopoeial standard for uniformity of weight of uncoated tablets, if the avg. weight of tablets is more than 250 mg, than not more than two tablets should deviate from the 5 % average weight of the tablets. All the batches of tablets containing different concentrations of isolated binders met the pharmacopoeial specification.

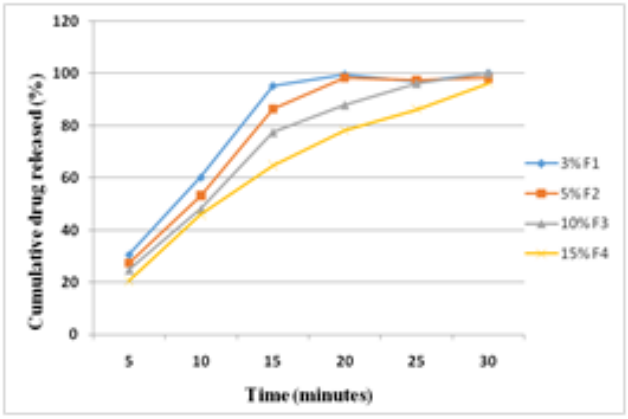

Figure 5A

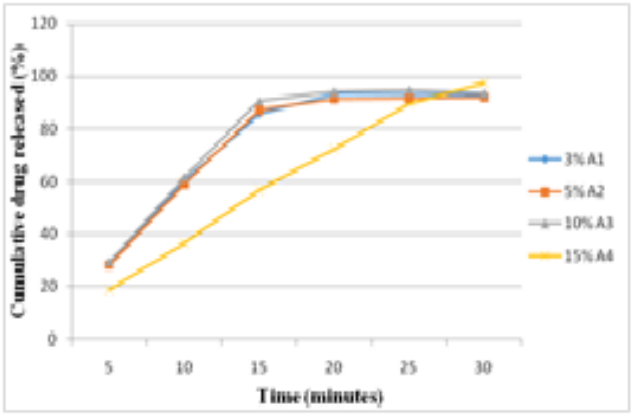

Figure 5B

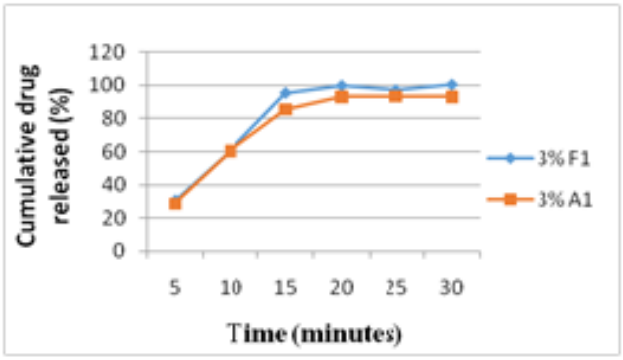

Figure 5C

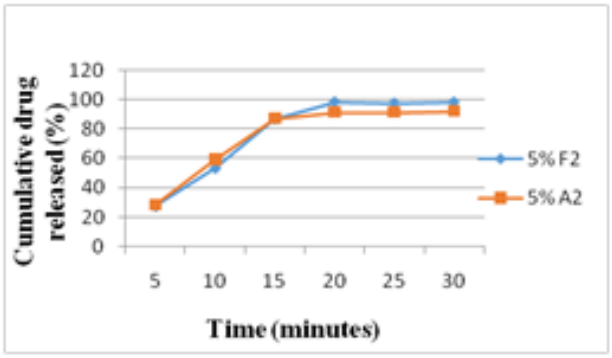

Figure 5D

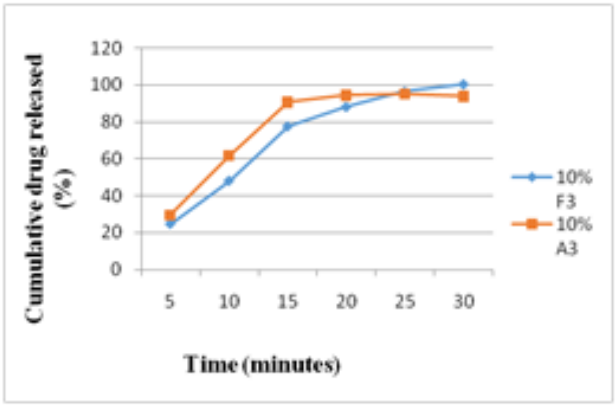

Figure 5E

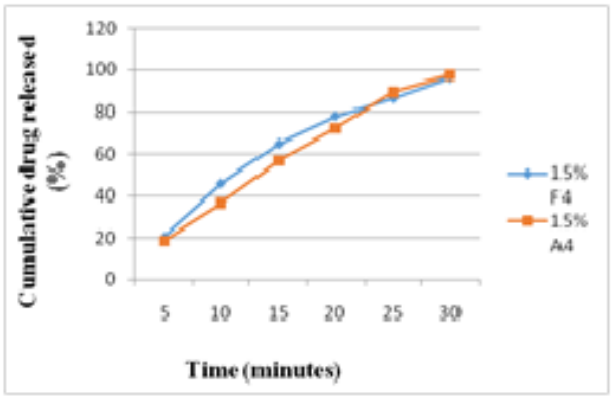

Figure 5F

Figure 5: A) Percentage cumulative drug released profile of paracetamol tablets with *P. variegata* mucilage as a binder (F1 – F4); B) Percentage cumulative drug released profile of paracetamol tablets with acacia gum as a binder (A1 – A4); C) Comparative drug released profile of 3 % w/v of binders (between F1 and A1); D) Comparative drug released profile of 5 % w/v of binders (between F2 and A2); E) Comparative drug released profile of 10 % w/v of binders (between F3 and A3); F) Comparative drug released profile of 15 % w/v of binders (between F4 and A4).

Disintegration is a rate determining step in case of uncoated tablets as the release of drug in the medium is dependent on the disintegration the tablet. As per the pharmacopoeial standards uncoated tablet must be disintegrate till 15 min. All the batches of tablets were made by using corn starch as a disintegrating agent which was used in the formulation as intra and extra granular. The result of disintegration shows that all four F1, F2, F3 and F4 formulation using different concentration of isolated mucilage passed the quality control limit as per pharmacopoeia, as disintegration time of all four batches were less than 4 min. Percentage drug content or drug assay test is performed to ensure the label claim of the formulation. The percentage of drug content of all the formulations F1 to F4 was in the range of 97.8 to 99.8 %. On the basis of all the official and non-official

evaluation parameters (Uniformity of weight, Hardness, Friability, Disintegration, Percentage drug content) F2 and F3 were found to be the optimized formulation and on comparing tablets formulated using different concentrations of acacia gum as a binder A1 – A4 the results obtained were almost similar.

In vitro Dissolution Study

In vitro dissolution release study was performed to evaluate the drug release pattern in all formulations. The batches prepared with kachnar mucilage were compared with those of acacia gum to analyze the drug release pattern. The dissolution profile of all formulations is represented in (Figure 5A to 5F). According to USP and BP percentage, the drug release of paracetamol should not be less than 85% within 30 min.

According to IP drug release should follow the respective pattern as 25-30 % should release in the first cut of the whole time, not less than 50 % in second and more than 80 % in the third cut of time. Results showed that tablets prepared by kachnar mucilage had given a decreased rate of release as the concentration of isolated mucilage increases, which is similar to the release pattern of tablets prepared by using acacia gum. The cumulative drug release of kachnar mucilage F1 formulation was 99 % in 20 min and F4 formulation was 96 % in 30 min. In comparison to kachnar mucilage, the cumulative drug release of acacia gum was 93 % in 20 min and 97 % in 30 min of formulation A1 and A4, respectively. All the batches of isolated mucilage of kachnar complied with the specification and showed a linear drug release profile. From the dissolution profile of isolated mucilage, it could be concluded that the drug release solely depends upon the binder concentration.

CONCLUSION

The main aim of the study was to extract and isolate mucilage from the leaves of *Phanera variegata* and to evaluate various properties for its suitability as an ideal natural excipient for uncoated tablet dosage form as *P. variegata* is a novel polysaccharide gum with no published information on its use as an excipient. Being natural *P. variegata* mucilage is non-toxic, biodegradable and biocompatible and can be used as a binding agent for conventional tablet dosage form. The granules prepared from *P. variegata* mucilage pass flow properties and showed an excellent compressibility index, which leads to less variation in weight. Paracetamol tablets formulated using isolated mucilage showed promising results for hardness, friability, DT and drug content when compared with acacia gum. *In vitro* dissolution, drug profile showed that lesser concentration of isolated mucilage had optimum % drug release, which concludes that tablets prepared from *P. variegata* mucilage are better compared to acacia gum.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interests.

ABBREVIATIONS

HCl: Hydrochloric acid; **FT-IR:** Fourier-transform infrared spectroscopy; **UV:** Ultraviolet–visible spectroscopy; **DSC:** Differential scanning calorimetry; **PCM:** Paracetamol; **IP:** Indian Pharmacopoeia; ***P. variegata:*** *Phanera variegata.*

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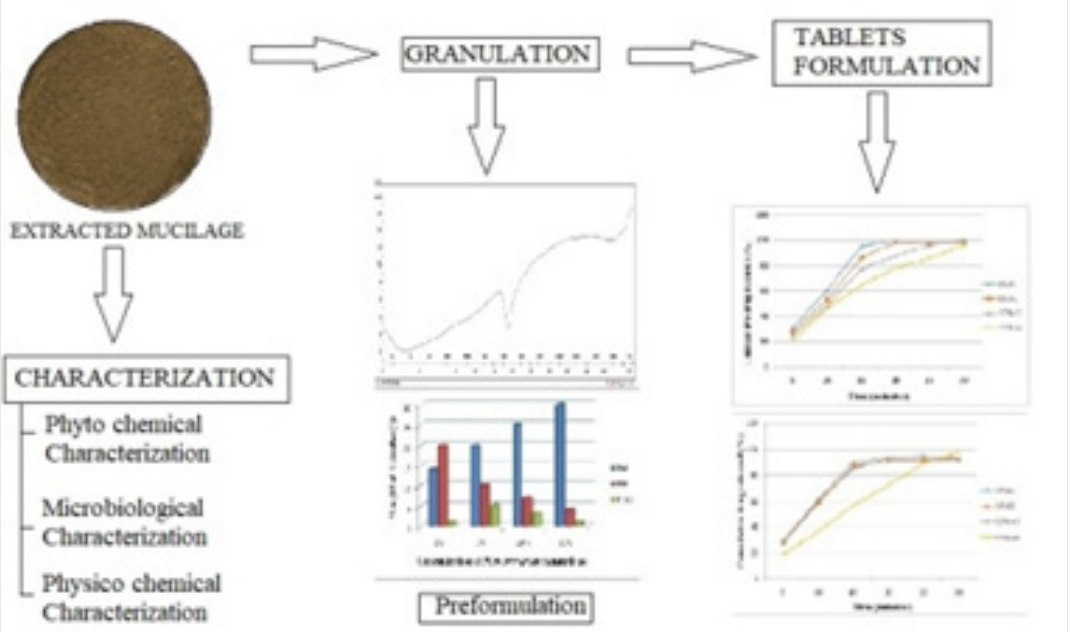
PICTORIAL ABSTRACT



SUMMARY

- *Phanera variegata* Linn. isolated mucilage is a novel polysaccharide gum with little to almost no published data on characterization as well as on its formulation.
- In the present study, the mucilage from the leaves of Phanera variegata plants was isolated and characterized for its Phyto chemical screening, microbiological properties and various physico chemical properties like selling index, viscosity, total ash value and pH.
- Further, granules were prepared by wet granulation technique using isolated mucilage as a binding agent and paracetamol as a model drug with other excipients.
- Preformulation characterization of the prepared granules were done like drug-mucilage compatibility, particle size distribution and flow properties of granules.
- Uncoated conventional tablets were formulated using prepared granules and all the post compression studies were performed like official and non – official test.
- To compare the binding efficiency of the isolated mucilage, granules using acacia gum were also prepared followed by formulation of tablets by same procedure and comparison was done by pre compression and post compression parameters
- Finally, the obtained results showed that isolated mucilage from the leaves of Phanera variegata is suitability for an ideal natural excipient for uncoated tablet dosage form.

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