

Preliminary investigation of patchaippasali mucilage (*Basella alba*) as tablet binder

G. Ramu, G. Krishna Mohan¹, K. N. Jayaveera²

Department of Phytochemistry, S.A.C. College of Pharmacy, B. G. Nagar, Mandya, Karnataka, ¹Department of Pharmacognosy, J. N. T. University of Pharmaceutical Sciences, Hyderabad, ²Department of Chemistry, J. N. T. University, Anantapur, Andhra Pradesh, India

Basella alba leaf mucilage was investigated as a binder in paracetamol tablets prepared by wet granulation method. Mucilage at four levels (concentrations of mucilage binders: 4, i.e., 2.5, 5, 7.5 and 10% w/w) were studied. No significant work has been reported to use it as a tablet binder. The evaluation of granules showed 0.62 to 0.76 mm granule size, 28°47' to 30°27' angle of repose and 31.57 to 23.45% fines. Moisture content of the different granulations was less than 1%. The tablets were prepared and evaluated for average weight and weight variation, thickness, content uniformity, hardness, friability, disintegration time and *in vitro* dissolution profiles. All the batches of tablets exhibited good uniformity in content. The hardness was within the range of 4.5 to 5.5 kg/cm². The hardness was increased and friability decreased with the increasing concentration of binding agent. The disintegration time also increased with increasing binder concentrations. The evaluation of tablet showed 0.434 to 0.410% friability, 9 to 18 minutes disintegration time and the drug release was more than 70% in 60 minutes. Tablets at 7.5% w/w binder concentration showed more optimum results as tablet binder. The *B. alba* mucilage was found to be good as a binder to paracetamol tablets.

Key words: *Basella alba*, binder, mucilage, paracetamol, patchaippasali

INTRODUCTION

Most powders cannot be compressed directly into tablets, even after the addition of an appropriate lubricant, mainly because they lack the proper characteristics of binding or bonding together into a compact entity.

Binders are the adhesives that hold particles together in the production of tablets and granules. The role of binders is to assist size enlargement by imparting cohesiveness to the powders, thereby producing granules and tablets with the necessary binding strength.^[1] Binders increase cohesiveness under both wet and dry conditions such that sufficient strength is achieved to resist the destructive forces created during the processing and subsequent handling. Binder efficiency depends on its type, concentration and the method of incorporation. It also depends on the type of solvent. Although binders could be added in the solid state to the powder mix and the mixture wetted with

water, yet in practice, solutions of binders are usually used in tablet production.

Mucilages are polysaccharide complexes formed from sugar and uronic acid units.^[2] They are usually formed from the cell wall or deposited on it in successive layers. They are insoluble in alcohol but dissolve or swell in water forming a gel. Mucilages find diverse applications in pharmacy. These hydrophilic polymers has been well documented as tablet disintegrants, emulsifiers, suspending agents, gelling agents, stabilising agents and thickening agents. Some of the mucilages have also been used in tablet formulations as binding agents and also to sustain the drug release.^[3]

Basella alba is called as Patchaippasali in Tamil (Green Spinach). It belongs to Basellaceae family. Stem, petiole, leaf and peduncles are green in colour. The perianth tube is greenish white in the basal and pink in apical regions. *B. alba* is a fast-growing, soft-stemmed vine, reaching 10 m in length. Its thick, semi-succulent, heart-shaped leaves have a mild flavour and mucilaginous texture.^[4]

Typical of leaf vegetables, Malabar spinach is high in vitamin A, vitamin C, iron and calcium. It is low in calories by volume, but high in protein per calorie. The succulent mucilage is a particularly rich source of soluble fibre.

The purplish sap from the fruit is used as a food

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Address for correspondence: Dr. G. Ramu, Department of Phytochemistry, Sri Adichunchanagiri College of Pharmacy, B. G. Nagar-571 448, Nagmangala Taluk, Mandya District, Karnataka, India. E-mail: ramupharmu@yahoo.co.in

Received: 12-11-2010; **Accepted:** 26-11-2010

colouring in pastries and sweets. The flowers are used as an antidote to poisons. A paste of the root is applied to swellings and is also used as a rubefacient. The plant is febrifuge, its juice is a safe aperient for pregnant women and a decoction has been used to alleviate labour. The leaf juice is used in Nepal to treat dysentery, catarrh and applied externally to treat boils. The mucilaginous qualities of the plant make it an excellent thickening agent in soups, stews, etc, where it can be used as a substitute for okra, *Abelmoschus esculentus*.^[5] Hence, the present work was attempted to evaluate binding properties of mucilage isolated from leaves of *B. alba*.

MATERIALS AND METHODS

Materials

Paracetamol was obtained from Paxmy specialty chemicals. Maize starch BP, microcrystalline cellulose, magnesium stearate and corn starch were procured from SD Fine Chemicals Ltd., Mumbai. All other materials used were of pharmaceutical grade. *B. alba* leaves were purchased from local sellers, B.G. Nagar of Mandya District and identified at the herbarium by the Ethnobotanist at the Department of Pharmacognosy and Phytochemistry, Sri Adichunchanagiri College of Pharmacy, B.G. Nagar, Mandya District, Karnataka.

Methods

Isolation of mucilage

B. alba leaves (50 g) were powdered in a mechanical blender and soaked in distilled water (300 ml) for 24 hours in a round bottomed flask. It was boiled for 1 hour under reflux with occasional stirring and kept aside for 2 hours for the release of mucilage into water. The material was filtered through a muslin bag and hot distilled water (50 ml) was added through the sides of the marc and squeezed well in order to remove the mucilage completely. Equal volume of ethanol was added to the filtrate in order to precipitate the mucilage and kept aside a refrigerator for one day for effective settling. It was filtered and dried completely in an incubator at 37°C, powdered and weighed. It was subjected to chemical tests to confirm its identity.^[6]

Characterisation of mucilage

Phytochemical examination

Preliminary tests were performed to confirm the nature of mucilage obtained. The chemical tests that were conducted are Ruthenium red test, Molisch's test, test for reducing sugars and Ninhydrin test.

pH and viscosity

This was done by shaking a 1% w/v dispersion of the sample in water for 5 minutes and the pH determined using a digital pH meter (Merck, Mumbai). A Brookfield

Viscometer^[7] (Engineering labs, INC, Middlebord, USA) was used to determine the intrinsic viscosity of 5% w/v mucilage at 28°C.

Swelling capacity

Swelling capacity was determined using the method of Leach, McCowen and Schoch.^[8] One gram of mucilage was dissolved in 10 ml distilled water in a centrifuge tube and heated for 30 minutes with continuous shaking at 80°C. Thereafter, the suspension was centrifuged at 1000 rpm for 15 minutes, supernatant was decanted and the paste weight was noted. The swelling power was calculated by the ratio between the weight of paste and weight of dry mucilage.

Preparation of binder solution

Aqueous solutions of mucilage in the concentrations 2.5, 5.0, 7.5 and 10.0% w/w were prepared with the aid of heat.

Preparation and evaluation of granules

Wet granulation method^[9] was used to prepare granules of paracetamol IP as model drug. Binder level was adjusted by lowering the level of microcrystalline cellulose in the formula. Paracetamol was mixed manually with microcrystalline cellulose and corn starch (10% w/w as a disintegrant). Binder solution was slowly added into mixture. The wet mass was passed through sieve number 16 and granules were dried at 60°C for 1 hour (to moisture level <1%). Aerosil 0.5% w/w and magnesium stearate 1% w/w were finally mixed. The granules were evaluated for percentage of fines, flow property, particle size and moisture content.^[10] The formula for paracetamol tablets is shown in Table 1.

Preparation and evaluation of tablets

Rotary punching machine was used to prepare tablets.^[11] Lubrication of punches and die was done with 1% w/v dispersion of magnesium stearate in chloroform. After ejection, the tablets were stored over silica gel for 24 hours to allow for elastic recovery and hardening. The tablets contain 375 mg using microcrystalline cellulose as diluent, magnesium stearate as lubricant and corn starch as disintegrant. The batch size prepared was of 100 tablets. The prepared tablets were stored in closed container for 15 days. No evidence of chemical change was observed. The tablets were evaluated for average weight and weight variation, thickness, content uniformity, hardness, friability and disintegration time.^[12]

Table 1: Formula for paracetamol tablet

Ingredients	Amount per tablet (mg)
Paracetamol	250
Corn starch (10% w/w)	37.5
Mucilage in water (2.5-10 % w/w)	Variable (9.375-37.5)
Microcrystalline cellulose	Variable (44.25-72.5)

In vitro dissolution testing

The rate of dissolution of paracetamol from the tablets was studied in a paddle type apparatus, model TDT-06T (Electro lab, Mumbai, India) operated at rpm. 900 ml of 0.1N HCl with pH 5.8 was the dissolution medium and test temperature was maintained at $37 \pm 0.5^\circ\text{C}$. 10 ml of samples were withdrawn at 10 minutes intervals and immediately replaced with 10 ml of dissolution medium maintained at the same temperature. The amount of paracetamol in each sample was analysed spectrophotometrically at 249 nm with a 160A UV-Vis spectrophotometer.^[13]

RESULTS AND DISCUSSION

The standard procedure was used to isolate mucilage and where purified by using water as solvent and alcohol (90% v/v) as non-solvent. *B. alba* leaves have been reported to contain $9 \pm 2.0\%$ w/w mucilage.

The identification of isolated mucilages was confirmed by colour reaction with ruthenium red, where the mucilage showed pink colour, confirming the obtained product as mucilage. A gelatinous mass of mucilage was obtained by heating and cooling. A violet ring was formed at the junction of two liquids on reaction with Molisch's reagent, indicating the presence of carbohydrates. Mucilage could not reduce Fehling's solution, so the sugars present were non-reducing sugars. It reduced Fehling's solution after hydrolysis for 1 hour with concentrated sulphuric acid under reflux. Mucilage gave purple colouration on treating with ninhydrin reagent indicating the presence of amino acids. The mucilage has pH between 6.0 to 5.5 and viscosity of 2.120 cps.

Wet granulation was used in the present study. Physical properties of the granules such as percentage of fines, flow property, particle size and moisture content were evaluated. The results are shown in Tables 2 and 3. It was observed that as the concentration of mucilage was increased, the percentage of fines were decreased which reduces particle interlocking and friction, thus decreasing angle of repose. The flow property of granules was determined by angle of repose, which was found to be 28° to 30° .

All batches showed good flow property. Granule size

distributed between 0.62 and 0.76 mm. Moisture content of the different granulations was less than 1%.

The physicochemical parameters observed support the applicability of the selected excipient as tablet binder.

The formulated granules were compressed into tablets on a 10 station rotary tablet machine. The prepared tablets were evaluated for average weight and weight variation, content uniformity, thickness, hardness, friability and disintegration time. The results are given in Table 4.

The weights of the tablets ranged from 374 to 376 mg. All the batches showed uniform thickness. The average percentage deviation of 20 tablets of each formula was less than $\pm 5\%$ and good uniformity in drug content was found among the different batches.

Increase in concentration of the binder resulted in increase in the hardness. All the formulated batches have acceptable hardness which can withstand the abrasion during the transit.

The friabilities of the prepared tablets are less than 0.5% for all batches, indicating that it is within the prescribed limits. Increase in concentration of the binder resulted in decrease in the friability values.

Table 2: Percentage of fines of batches with different binder concentration

Binder	Concentration of binder (%)	Retained on sieve 44 (g)	Passed through sieve 44 (g)	% of fines
<i>Basella alba</i>	2.5	22.8	7.2	31.57
	5.0	23.0	7.0	30.43
	7.5	23.7	6.3	26.58
	10.0	24.7	5.7	23.45

Table 3: Granular properties of batches using *Basella alba* mucilage

Parameters	Binder concentration (%)			
	2.5	5.0	7.5	10.0
Particle size (mm)	0.621	0.678	0.684	0.76
Angle of repose ($^\circ$)	$30^\circ 27'$	$28^\circ 68'$	$28^\circ 49'$	$28^\circ 47'$
Moisture content (%)	0.89	0.75	0.81	0.93

Table 4: Tablet properties of batches using *Basella alba* mucilage

Parameters	Binder concentration (%)			
	2.5	5.0	7.5	10.0
Average wt and wt variation	374.28 (1.47)	374.31 (1.33)	373.24 (1.65)	376.26 (1.55)
Content uniformity	98.63	98.35	98.94	98.44
Thickness (mm)	3.97	3.98	3.97	3.97
Hardness (kg/cm ²)	4.5	5.0	4.5	5.5
Friability (%)	0.434	0.426	0.417	0.410
Disintegration time (min)	9 minutes 18 seconds	12 minutes 26 seconds	14 minutes 26 seconds	18 minutes 10 seconds

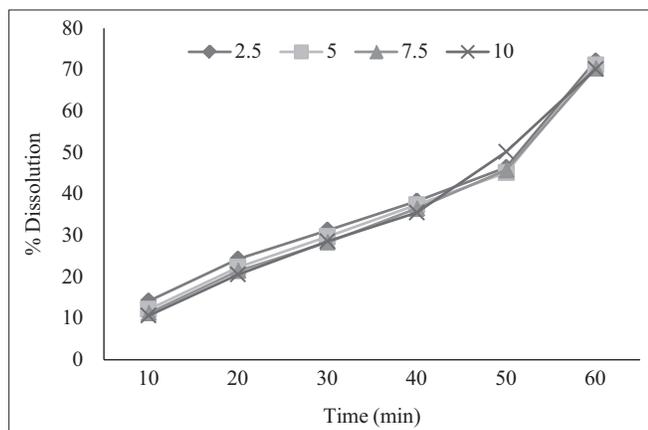


Figure 1: Formula for paracetamol tablet

An increase was observed in disintegration time with increase in the binder concentration for all the formulations. All the evaluation parameters were found to be within the pharmacopoeial limits at binder concentration 7.5% w/w.

In vitro dissolution profile is given in Figure 1. Drug release from the tablets containing 2.5 to 10.0% was more than 70% in 60 minutes. Tablets at 7.5 % w/w concentration show more optimum results as tablet binder. The drug release from tablets showed slight decrease with increase in binder concentration

CONCLUSION

The objective of the work was to evaluate the binding property of *B. alba* mucilage. Paracetamol was selected as a model drug to formulate the tablets, using corn starch as the disintegrant. Results suggest that *B. alba* exhibit good binding properties for uncoated tablets. The increased concentration of mucilage showed small retardation in drug release from tablet.

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Source of Support: Nil, Conflict of Interest: None declared.

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