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Evaluation of *Malva sylvestris* and *Pedalium murex* Mucilage as Suspending Agent

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ABSTRACT: Natural plant drugs and excipients have gained importance over synthetic materials because they are non toxic, less expensive and freely available. The purpose of this study is to search for a cheap and effective natural excipient that can be used as an effective alternative for the formulation of pharmaceutical suspensions. The suspending properties of *Malva sylvestris* and *Pedalium murex* mucilage were evaluated comparatively with *Acacia* at concentrations of 0.5, 1, 1.5, and 2% w/v in calcium carbonate suspension. Characterization tests were carried out on purified *Malva sylvestris* and *Pedalium murex* mucilage. Sedimentation profile, redispersibility, rheology, particle size analysis were employed as an evaluation parameters. The values obtained were used as basis for comparison of the suspending agents studied. The results suggested that, *Malva sylvestris* and *Pedalium murex* mucilage could be used as a suspending agent. They have low rate of sedimentation, high viscosity, slightly basic pH and are easily redispersible.
KEYWORDS: *Malva sylvestris*, *Pedalium murex*, suspending agent, Calcium carbonate.

INTRODUCTION

A pharmaceutical suspension, is thermodynamically unstable, thus, making it necessary to include in the dosage form, a stabilizer or suspending agent which reduces the rate of settling and permits easy redispersion of any settled particulate matter both by protective colloidal action and by increasing the consistency of the suspending medium.[1-3] Suspending agents are (i) inorganic materials, (ii) synthetic compounds, or (iii) polysaccharides. Natural gums like *Acacia*, *Malva sylvestris* and *Pedalium murex* belong to the last group.[4]

Mucilages are widely used in pharmaceutical industries as thickeners, water retention agents, emulsion stabilizers, suspending agents, binders and film formers. Apart from its use in finished medicines, newer uses have been found in the preparation of cosmetics, textiles and paint paper.[5] Hence the demand for these substances is increasing and new sources are getting tapped. India due to geographical and environmental positioning has traditionally been a good source for such products.

Malva sylvestris is species of mallow belong to family of Malvaceae known as common mallow. It is an annual or perennial herb, growing to a height of four feet, which is grown widely in India. The high mucilage content of *Malva sylvestris* makes it an excellent demulcent that can be used for many applications. In the digestive tract the fruit mucilage can be used to heal and soothe inflammations such as gastritis, peptic ulcers, enteritis, and colitis.

Pedalium murex (Family Pedaliaceae) is a succulent, musk-scented annual herb, growing to a height of 60 cm, with four sided spiny fruits. The plant has been used medicinally in treatment of several disorders. Anti-hyperlipidemic, anti-microbial and anti-cancer activities of fruits and roots of the plant are reported [6-8]. The present work is an attempt to investigate these mucilages as a suspending agent in pharmaceutical formulations.

MATERIALS AND METHODS

The materials used include Calcium carbonate, *Acacia* gum powder, benzoic acid (loba chemical). All solvents used were of analytical grade.

The fruits of *Malva sylvestris* and *Pedalium murex* were collected from local crude drug market, Mumbai. It was authenticated by Agharkar Research Institute, Pune, India. Voucher specimen AHMA F – 124 and AHMA F – 125 have been deposited for *Malva sylvestris* and *Pedalium murex* respectively.

Extraction of mucilage

The mucilage was isolated from freshly dried & coarsely powdered fruits of *Malva sylvestris* and *Pedalium murex*. The materials were homogenized with water in the ratio of 1:5 and kept aside to release mucilage into water. The material was squeezed through muslin cloth to remove the marc from the filtrate. Mucilage was precipitated from water using acetone. Precipitated mucilage was dried in a vacuum oven at temperature of 45ºC & passed through sieve no.80. The powdered mucilage was stored in desiccator until further use.[9]

Acute toxicity study

The *Pedalium murex* and *Malva sylvestris* mucilage were subjected to acute oral toxicity studies in rats according to OECD guidelines (no.423) to evaluate its toxicity and median lethal dose (LD_{50}). The albino rats of wistar strain (160-200 gms, either sex) were taken and dose of 2000 mg/kg, p.o. was administered to them. Test and control rats were observed for behavioral changes, toxicity and mortality up to 48 hrs. Permission from Animal Ethics Committee was obtained for the studies done.[10, 11]

Physicochemical characterization of mucilage

The physicochemical parameters studied were the flow properties[12], swelling ratio, loss on drying, ash values (total ash, acid insoluble ash) and pH of 1% solution.[13]

Preparation and evaluation of suspensions

Suspensions of 2% $CaCO_3$ in water were made using 0.5% to 2% of suspending agents like *Acacia*, *Malva sylvestris* and *Pedalium murex* mucilage. For the preparation of suspensions, $CaCO_3$ was first levigated with glycerin (1:1). Then a weighed amount of these suspending agents were added and triturated and finally the volume was made up with distilled water. The suspension contained 0.1% w/v benzoic acid as a preservative. The test suspensions were evaluated using the parameters like, sedimentation volume, viscosity, pH, particle size analysis and redispersibility and it was compared with *Acacia*.[14]

Sedimentation volume -: The sedimentation volume is ratio of the ultimate height (Hu) of the sediment to the initial height (Ho) of the total suspension as the suspension settles in a cylinder under standard conditions. It was determined by keeping a measured volume of the suspension in a graduated cylinder in an undisturbed state for a certain period of time and note the volume of the sediment, which is expressed as ultimate height (Hu).[14]

Redispersibility -: Redispersibility can be estimated by shaking the suspension with the help of a mechanical device which simulates motion of human arm during shaking. Fixed volume (50 ml) of the each suspension was kept in calibrated tubes which were then stored at room temperature for various time intervals (5, 15, 25 days). At regular interval of 5 day, one tube was removed and shaken vigorously to redistribute the sediment and the presence of deposit if any is recorded.[14]

Rheology -: The time required for each suspension sample to flow through a 10 ml pipette was determined and the apparent viscosity (η_α in ml^{-1}) was calculated using the equation: [16]

$$\text{Flow rate} = \eta_\alpha = \frac{\text{Volume of pipette (ml)}}{\text{Flow time (seconds)}}$$

The viscosity (in poise) of the samples was determined at 25 ^{0}C using Brookfield viscometer at 50 rpm by using spindle no.3. All determinations were made in at least triplicate and the results obtained are expressed as the mean values.[14]

pH -: The pH of the suspensions were determined at intervals of one week for 21 days using pH meter.

Particle size analysis -: After shaking, 10 ml of each sample was separately transferred into 200 ml cylinder. Distilled water (150 ml) was then added, mixed and 10 ml aliquot was removed at a distance of 10 cm below the surface of the mixture at 1, 5, 10, 15, 20, 25 and 30 min. This was transferred into an evaporating dish and evaporated to dryness in an oven at 105 ^{o}C and the residue weighed. The particle diameter (d in cm) was then calculated using the Stoke's equation.

$$d = \frac{18\,\eta h}{(\rho s - \rho 0)}\,gt$$

Where, h is the distance of fall of the particle (cm), t is the time in (s), η is the viscosity of dispersion medium (poise), Ps – Po is the density between dispersed particles and the liquid ($g/cm^{3)}$, g is the gravitational constant (cm/s^2).[15]

RESULTS AND DISCUSSION

The average yield of dried mucilage obtained *from Malva sylvestris* and *Pedalium murex* fruit was found to be 4.2 % and 5 % respectively. The mucilages obtained were subjected to physicochemical characterization, the results of which are summarized in Table 1.

Acute toxicity study of both mucilage showed no manifestations of toxic syndromes. The *Malva sylvestris* and *Pedalium murex* mucilage have been found to be safe. (LD_{50} > 2000 mg /kg, p.o.).

A $CaCO_3$ suspension formulation was prepared in different batches containing *Pedalium murex* mucilage, *Malva sylvestris* mucilage or *Acacia* in the concentration range of 0.5 to 2 %. The preparations were evaluated based on their sedimentation profile, redispersibility, rheology, pH and particle size analysis. The sedimentation volume profile and viscosity of the suspensions prepared with *Malva sylvestris* and *Pedalium murex* mucilage increased with increasing concentration of the suspending agent (Table 2 and 3). The reverse was the case for flow rate (Table 3). The dispersed particle of $CaCO_3$ prepared using *Pedalium murex* mucilage was found to settle at. lower rate than those prepared with *Acacia*. All the formulations prepared were observed to obey the Stoke's law when subjected to particle size analysis.

Since the suspension produces sediment on storage it must readily be dispersible so as to ensure the uniformity of the dose. The redispersing ability of the suspendants were in the order of *Pedalium murex* > *Malva sylvestris* > *Acacia* (Table 4). The pH of the suspensions was found to be slightly basic (Table 4). Suspension prepared using 1% *Pedalium murex* and *Malva sylvestris* showed a redispersibility cycle of 6 and 7 respectively as compared to 13 of *Acacia*. From the parameters of sedimentation volume, flow rate, redispersibility abilities, it was observed that suspension prepared using *Pedalium murex* mucilage showed better suspendability of all the materials investigated followed by the suspension prepared using *Malva sylvestris*. Thus, it can be concluded that the extracted mucilage from fruits of *Pedalium murex* and *Malva sylvestris* has the potential of a suspending agent even at low concentration and can be used as a pharmaceutical adjuvant.

Table 1: Results of physicochemical characterization of mucilage

Test	***Pedalium murex***	***Malva sylvestris***
Swelling ratio (ml) In 0.1 N hydrochloric acid	7.00	10.30
In phosphate buffer pH 7.4	6.50	9.43
In distilled water	8.00	10.66
Loss on drying (%w/w)	5.33	6.70
Total ash (%w/w)	18.50	26.50
Acid insoluble ash (%w/w)	1.00	1.16
pH of 1% solution	7.04	6.81
Bulk density (gm/ml)	0.565	0.6944
Tapped density (gm/ml)	0.710	0.8615
Compressibility index %	20.42	19.39
Angle of repose	29.355	31.53

Table 2: Determination of Sedimentation volume (%)using different concentration of suspending agents

Suspending Agent	Concentration w/v	Sedimentation Volume%						
		Time (Min.)						
		0	5	10	15	20	25	30
Pedalium murex	0.0	100	24	24	24	24	24	24
	0.5	100	96	93	91	88	86	83
	1.0	100	97	95	93	91	89	88
	1.5	100	99	99	98	97	96	96
	2.0	100	99	99	98	98	98	97
Malva sylvestris	0.5	100	94	91	89	86	84	81
	1.0	100	96	93	90	88	85	83
	1.5	100	97	95	92	89	88	85
	2.0	100	99	98	97	95	94	92
Acacia	0.5	100	95	91	88	86	83	81
	1.0	100	96	94	91	89	86	84
	1.5	100	98	97	95	92	90	87
	2.0	100	99	98	98	97	96	95

Table 3: Determination of flow rate and viscosity of suspensions

Suspending Agent	Concentration w/v	Flow Rate ml/sec	Viscosity (Poise)
Pedalium murex	0.5	0.97	1.00
	1.0	0.84	1.10
	1.5	0.73	1.20
	2.0	0.61	1.45
Malva sylvestris	0.5	1.10	0.85
	1.0	0.91	0.95
	1.5	0.78	1.10
	2.0	0.69	1.25
Acacia	0.5	1.16	1.10
	1.0	0.94	1.25
	1.5	0.80	1.35
	2.0	0.66	1.50

Table 4: Determination of redispersibility and pH

Suspending Agent	Concentration w/v	Rate of Redispersibility (cycles)			pH after Storage for			
		5 Days	15 Days	25 Days	0th Day	7th Day	14th Day	21st Day
Pedalium murex	0.5	4	6	7	8.55	8.48	8.36	8.20
	1.0	3	5	6	8.18	8.02	7.95	7.88
	1.5	2	4	5	7.68	7.58	7.45	7.31
	2.0	2	4	4	7.46	7.28	7.20	7.10
Malva sylvestris	0.5	4	6	8	8.97	8.77	8.61	8.53
	1.0	4	6	7	8.36	8.22	8.10	7.96
	1.5	3	5	7	7.91	7.79	7.67	7.56
	2.0	3	4	6	7.6	7.48	7.34	7.20
Acacia	0.5	8	12	15	9.2	8.92	8.79	8.62
	1.0	8	9	13	8.7	8.53	8.41	8.28
	1.5	5	6	9	8.37	8.22	8.09	7.94
	2.0	4	5	8	7.96	7.83	7.70	7.55

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