

Note

Studies on *Ocimum gratissimum* seed mucilage: Evaluation of binding properties

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Received 30 June 2005; received in revised form 7 June 2006; accepted 21 June 2006

Available online 27 June 2006

Abstract

Mucilage extracted from *Ocimum gratissimum* seeds, inertness and safety parameters established by a previous study was subjected to pre-formulation trial to assess its suitability as a pharmaceutical binder. Properties of the granules prepared with calcium carbonate using different concentrations of ocimum and compared with acacia (5%, w/w), as standard. Ocimum at 2.3% (w/w) level was found to be comparable with 5% (w/w) of acacia. Effect on drug release studied with paracetamol indicated that ocimum mucilage could be an alternative to acacia.
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Keywords: Ocimum mucilage; Binding; Tablets; Paracetamol

There are growing concerns for the safety on pharmaceutical excipients derived from animal sources (Aoshima et al., 2005). Plant gums and exudates are getting screened for their use as pharmaceutical adjuvants. Mucilages are used for their binding, thickening, stabilizing and humidifying properties in medicine (Monif et al., 1992). Newer uses in cosmetics and textiles had hiked up demand (Verma and Razdan, 2002) and screening of gums had become a vital pharmaceutical interest (Baveja et al., 1998; Odeku and Itiola, 1998). However pharmaceutical adjuvants have stringent specifications, which few natural agents can fulfill. Our earlier study had shown that the mucilage extracted from *Ocimum gratissimum* passes the safety criteria (Anroop et al., 2005) and the present study investigates its binding property.

Paracetamol (SKPL Pvt. Ltd., Kolkata, India) was received as gratis sample. Calcium carbonate and other ingredients were purchased from market. Ocimum mucilages were extracted from the seeds obtained from the medicinal garden, Birla Institute of Technology, Ranchi, India.

For preliminary study, three batches of calcium carbonate granules were prepared using ocimum mucilage (1.0, 3.0 and

5% (w/v)). Granules formulated with 20% w/v acacia solution as binder is used for comparison. The granules prepared by standard moist granulation method (Keith M., 1991) were compressed on a single stroke tablet machine (Cadmach, Ahmedabad, India) using 1% (w/w) of magnesium stearate and talc. Similarly paracetamol tablets were prepared with 5% and 20% (w/v) of ocimum and acacia, respectively.

Granule properties (percentage of fines, tapped density, bulk density, porosity) and tablet properties (crushing strength, weight variation) were determined by standard procedure (Keith M., 1991).

Paracetamol was assayed spectrophotometrically (Systronics, India) as described in Indian Pharmacopoeia (1996). The *in vitro* release profiles of paracetamol from the tablets were also obtained in two medias; 0.1 M hydrochloric acid and phosphate buffer (pH 7.8) using dissolution tester USP XX model (Electro Lab, Mumbai, India) at 37 ± 0.5 °C and 50 rpm. All the data obtained for dissolution were evaluated statistically (Student's *t*-test).

The work has been carried out in two phases. Initial studies on ocimum mucilage using calcium carbonate (1, 3 and 5% (w/v)) resulted in granules containing 0.6, 1.5 and 2.3% (w/w) dry ocimum (Table 1). Granules with 20% (w/v) acacia (5% dry acacia) were used as standard (Rawlins, 1980). Comparison of the granule (Table 2) and tablet parameters (Table 3) indi-

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Table 1
Composition of formulated tablets of calcium carbonate and paracetamol

Ingredients	Batch					
	F ₁	F ₂	F ₃	F ₄	F ₅	F ₆
Calcium carbonate (mg)	500	500	500	500	–	–
Paracetamol (mg)	–	–	–	–	500	500
Starch (mg)	50	50	50	50	50	50
Acacia (% w/w)	–	–	–	5.00	–	4.80
Ocimum (% w/w)	0.60	1.50	2.30	–	2.10	–
Talc (mg)	5.50	5.50	5.50	5.50	5.50	5.50
Magnesium stearate (mg)	5.50	5.50	5.50	5.50	5.50	5.50

Table 2
Characteristics^a of calcium carbonate granules prepared with different concentration of ocimum and acacia

Granule properties	Calcium carbonate			
	Ocimum (0.6%, w/w)	Ocimum (1.5%, w/w)	Ocimum (2.3%, w/w)	Acacia (5%, w/w)
Percentage fine	12.03 ± 1.60	7.55 ± 1.07	5.60 ± 0.82	5.19 ± 0.80
Bulk density (g/cm ³)	0.74 ± 0.03	0.71 ± 0.01	0.67 ± 0.01	0.62 ± 0.01
Tapped density (g/cm ³)	0.80 ± 0.02	0.77 ± 0.01	0.71 ± 0.01	0.67 ± 0.02
Porosity (%)	7.40	7.10	6.60	6.25
Angle of repose	34.16 ± 0.59	32.98 ± 0.22	30.66 ± 0.12	29.12 ± 0.15

^a Each values are the mean ± S.E. (*n* = 3).

Table 3
Characteristics of calcium carbonate tablets prepared with different concentration of ocimum and acacia

Tablet properties	Calcium carbonate			
	Ocimum (0.6%, w/w)	Ocimum (1.5%, w/w)	Ocimum (2.3%, w/w)	Acacia (5%, w/w)
Hardness (kg/cm ²)	2.75 ± 0.38	3.58 ± 0.34	4.93 ± 0.41	4.78 ± 0.32
Friability (% w/w)	3.50 ± 0.33	1.86 ± 0.11	1.13 ± 0.09	1.01 ± 0.83
Uniformity of weight	564.60 ± 2.16	570.30 ± 1.44	574.60 ± 1.02	592.20 ± 1.04
Disintegration time (min)	4.14 ± 0.95	6.17 ± 1.01	9.48 ± 1.21	10.12 ± 1.33

Each values is the mean ± S.E. (*n* = 3).

icates that 2.3% (w/w) of ocimum and 5% (w/w) of acacia could contribute comparable properties to the calcium carbonate formulations.

Table 4 compares the binding properties of paracetamol tablets made with ocimum (2.1%, w/w) and acacia (4.8%, w/w). Here, ocimum bound tablets showed slightly higher friability, but were superior in terms of weight variation and disintegration time.

Comparative dissolution profiles (Figs. 1 and 2) show that in hydrochloric acid media ocimum tablets had a faster dissolution than that of acacia. At the 10th min, 75% release was obtained from ocimum where the value is 61% in acacia. Similar profile was also observed in phosphate buffer (pH 7.8). In both cases the release was almost complete within 30 min (91% and 97% respectively from acacia and ocimum) the *t*₅₀ being less than 10 min. However difference in the dissolution rate was insignificant (*P* > 0.005).

The release kinetics closely followed the cubic root law (regression coefficient –0.8978 to –0.9676) (Hayashi et al., 2005). It can be said that as the ocimum bound tablets underwent faster disintegration compared to acacia bound tablets, the drug more readily available from the former, causing the initial difference in the dissolution rate.

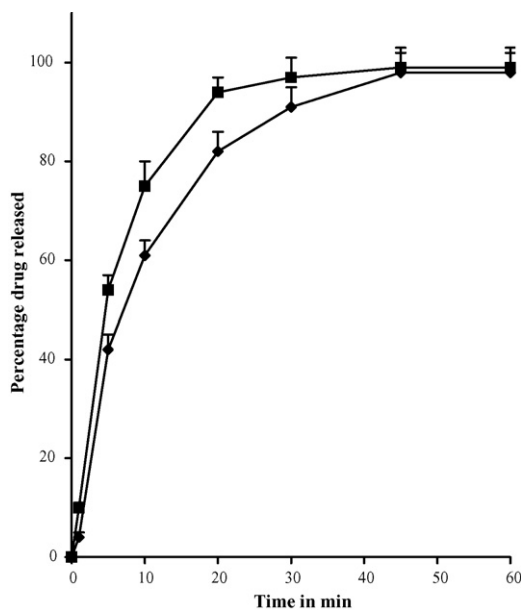


Fig. 1. Comparison of dissolution of paracetamol prepared with acacia and ocimum in 0.1 M HCl. Each data represents the mean ± S.E. of six experiments: (♦) acacia; (■) ocimum.

Table 4
Comparison of binding properties of acacia 4.8% (w/w) and ocimum (2.1% w/w) using paracetamol

Binders	Granule properties ^a				Tablet properties ^b				Assay (%)	
	Percentage fines	Bulk density (g/cm ³)	Tapped density (g/cm ³)	Angle of repose	Hardness (kg/cm ²)	Friability (% w/w)	Uniformity of weight	Disintegration time (min)	Granules	Tablets
Ocimum	5.21 ± 0.77	0.41 ± 0.02	0.46 ± 0.01	29.36 ± 0.17	4.90 ± 0.33	0.96 ± 0.06	573.10 ± 1.04	10.37 ± 1.07	100.67 ± 1.87	99.32 ± 2.16
Acacia	4.94 ± 0.74	0.43 ± 0.02	0.48 ± 0.01	28.8 ± 0.11	4.97 ± 0.23	0.81 ± 0.05	590.23 ± 1.52	12.16 ± 1.12	99.93 ± 2.39	99.12 ± 1.07

^a Each values are the mean ± S.E. (n = 3).

^b Each values are the mean ± S.E. (n = 6).

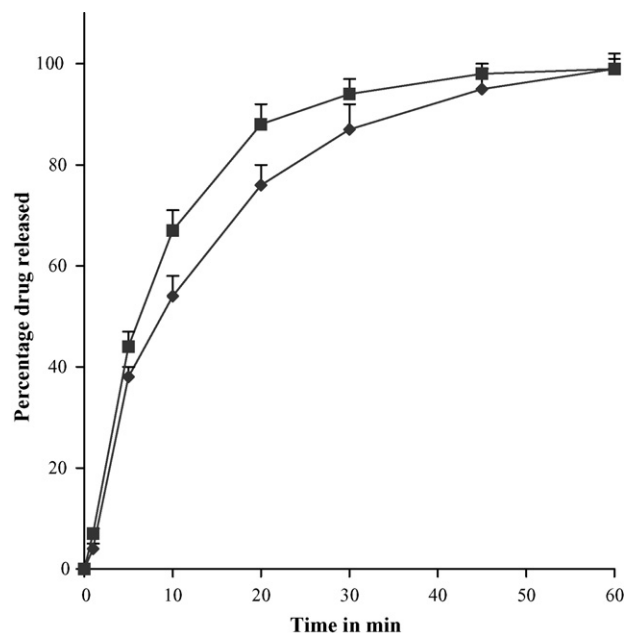


Fig. 2. Comparison of dissolution of paracetamol prepared with acacia and ocimum in phosphate buffer (pH 7.8). Each data represents the mean ± S.E. of six experiments: (◆) acacia; (■) ocimum.

In conclusion we can say that ocimum gum at a moderate formula weight of 2.1% (w/w) can exhibit good binding properties comparable to that of 5% (w/w) of acacia.

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