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EVALUATION OF *AEGLE MARMELLOS* FRUIT MUCILAGE FOR BINDING PROPERTIES

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ABSTRACT

Plant products served as an alternative to synthetic products because of local accessibility, eco friendly nature and lower prices. Natural gums and mucilages are widely explored as pharmaceutical excipients. The present study was undertaken to separate mucilage from unripe fruits of *Aegle marmelos* (L) Corr. and explore its use as binder in tablets. The binding properties at different concentrations of mucilage were evaluated using Paracetamol as model drug. Mucilage at 3%w/w was found to be comparable with 10%w/w of starch paste. The drug release studies indicated that *Aegle marmelos* mucilage could be considered as a potential binding agent.

INTRODUCTION: Mucilages are polysaccharide macro molecules that dissolve more or less upon contact with water and form colloidal solutions¹. Mucilages are widely used in pharmaceutical industries as thickeners, water retention agents, suspending agents, binders and film formers². Apart from its use in finished medicines, newer uses have been found in the preparation of cosmetics, textiles and paint paper³. Vast application of plant mucilages and gums in various industries is because of low cost, ready availability and important properties which they confer on products. So screening of gums and mucilages has become a vital pharmaceutical interest^{4, 5}. The objective of present work was to isolate mucilage from the unripe fruit of *Aegle marmelos* (L) Corr. and explore its use as a binder in tablets.

Paracetamol (Helios pharmaceuticals, Ahmadabad) was received as gift sample. Lactose, starch, talc, magnesium stearate were purchased from Loba chemical, Mumbai. The fruits of *Aegle marmelos* were collected from local crude drug market, Mumbai. It

was authenticated by Agharkar Research Institute, Pune, India and a Voucher specimen AHMA F – 154 was assigned. The mucilage was isolated from freshly, dried and coarsely powdered fruits of *Aegle marmelos*.

Mucilage when subjected to acute oral toxicity studies in rats according to OECD guidelines (no.423) showed a median lethal dose (LD50) greater than 2000 mg/kg, p.o. Permission from Animal Ethics Committee was obtained for the studies done. The mucilage was also subjected to physicochemical characterization for solubility, swelling index, loss on drying, ash value, pH, viscosity, microbial load, density, compressibility index and angle of repose⁶. The evaluation was carried as per the procedures described in Indian Pharmacopoeia 1996⁷.

Paracetamol was used as model drug to formulate granules with lactose as diluents and starch as disintegrant. Three batches of paracetamol granules were prepared using *Aegle marmelos* mucilage (3, 4, 5 % w/w) labeled as A₁, A₂ and A₃ respectively. Granules

formulated with 10%w/w starch paste as binder labeled as A₄ was used for comparison (**Table 1**). The granules prepared by standard moist granulation method were compressed on a single stroke tablet machine using talc and magnesium stearate as anti-adherent and lubricant respectively⁸. Granule properties (percentage of fines, tapped density, bulk density, Hausner's ratio, compressibility index) and tablet properties (hardness, weight variation) were determined by standard procedure⁸.

TABLE 1: COMPOSITION OF FORMULATED TABLETS OF PARACETAMOL

Ingredients	Batch			
	A ₁	A ₂	A ₃	A ₄
Paracetamol (mg)	500	500	500	500
Lactose (mg)	52.6	46	39.5	7
Starch (mg)	65	65	65	65
Mucilage (mg)	19.5	26	32.5	-
Starch paste (mg)	-	-	-	65
Talc (mg)	6.5	6.5	6.5	6.5
Magnesium stearate (mg)	6.5	6.5	6.5	6.5

Paracetamol was assayed spectrophotometrically as described in Indian Pharmacopeia (1996). The *in vitro* release profiles of paracetamol from the tablets were also obtained in two medias; 0.1M hydrochloric acid and phosphate buffer (7.8) using dissolution test

TABLE 3: CHARACTERISTICS OF PARACETAMOL TABLETS PREPARED WITH DIFFERENT CONCENTRATIONS OF AEGLE MARMELLOS MUCILAGE AND STARCH

Granules properties	Batch			
	A ₁	A ₂	A ₃	A ₄
Hardness kg/cm ²	4.55 ± 0.08	4.85 ± 0.09	5.35 ± 0.88	5.10 ± 0.075
Friability (% w/w)	0.84 ± 0.04	0.73 ± 0.026	0.66 ± 0.02	0.720 ± 0.03
Disintegration time (sec)	140 ± 10	180 ± 15	300 ± 12	290 ± 10
Assay (% w/w)	98.85 ± 1.56	97.67 ± 1.35	97.90 ± 1.3	97.65 ± 1.65
Weight variation (% w/w)	Passes	Passes	Passes	Passes
Drug release at 30 min	92.29 ± 1.29	81.57 ± 1.59	68.86 ± 1.5	75.27 ± 1.56

Comparative dissolution profile (**Fig. 1**) shows that in hydrochloric acid media, mucilage tablets had a faster dissolution than that of starch paste. At the end of 30 minutes 93.97%, 84.28% and 71.95% drug release was obtained for A₁, A₂ and A₄ formulations respectively. Similar profile was also obtained in phosphate buffer (pH 6.8) (**Fig. 2**) where the formulations A₁, A₂ had a best dissolution release profile with 92.29% and 81.57% at the end of 30 minutes. (Indian

apparatus (electro lab, Mumbai, India) at 37°C and 50 rpm

Table 2 compares the binding properties of paracetamol tablets made with different concentrations of mucilage and starch paste. It was observed that percentage of fines decreased as concentration of binder increased. The compressibility index (Carr' index) between 5-15 % indicated that granules had excellent flowability with good bridge strength and stability.

TABLE 2: CHARACTERISTICS OF PARACETAMOL GRANULES PREPARED WITH DIFFERENT CONCENTRATIONS OF AEGLE MARMELLOS MUCILAGE AND STARCH

Granules properties	Batch			
	A ₁	A ₂	A ₃	A ₄
Bulk density (g/cc)	0.357	0.370	0.384	0.416
Tapped density (g/cc)	0.400	0.434	0.454	0.476
Carr's index (%)	10.75	14.70	15.40	12.66
Hausner ratio	1.120	1.172	1.182	1.144
Angle of repose (deg.)	20.44	24.91	27.19	26.56
Percentage of fines	21.29	21.29	14.54	11.53

In **Table 3**, which compares the tablet properties of paracetamol, A1 formulation containing 3%w/w of mucilage showed slightly higher friability but was superior in terms of disintegration time and assay.

Pharmacopeia limit: 80% release and above at the end of 30min).

Moore and Flanner proposed, model independent mathematical approach was used to compare the dissolution profile using two factors, f₁ and f₂⁹

$$f_1 = \{[\sum_{t=1}^n |R_t - T_t|] / [\sum_{t=1}^n R_t]\} \cdot 100$$

$$f_2 = 50 \cdot \log \{[1 + (1/n) \sum_{t=1}^n (R_t - T_t)^2]^{-0.5} \cdot 100\}$$

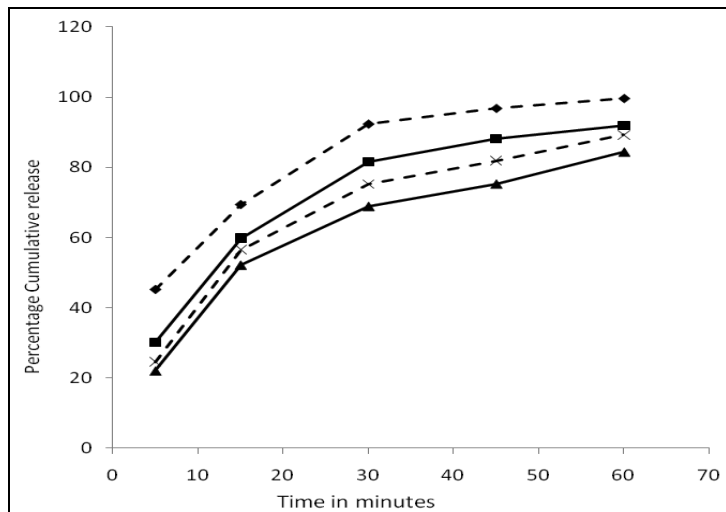


FIGURE 1: COMPARISON OF DISSOLUTION OF PARACETAMOL TABLETS PREPARED WITH STARCH AND AM MUCILAGE IN 0.1 M HCl

LEGENDS: ◆ A1, ■ A2, ▲ A3, X A4

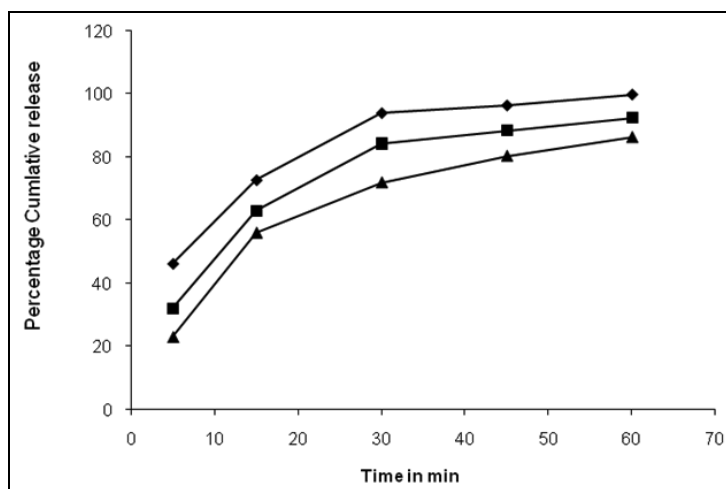


FIGURE 2: COMPARISON OF DISSOLUTION OF PARACETAMOL TABLETS PREPARED WITH STARCH AND AM MUCILAGE IN PHOSPHATE BUFFER (pH 7.8)

LEGENDS: ◆ A1, ■ A2, ▲ A4

Where, R_t and T_t are the cumulative percentage dissolved at each of the selected n time points of the reference and test product respectively. When the dissolution profiles, in hydrochloric acid media of formulations A1, A2 and A3 were compared with A4

standard formulation, the similarity profile f_2 was 26.14, 52.15 and 55.91 respectively. According to FDA f_2 value between 50-100 indicates similarity between two dissolution profiles. Thus it may be said that A1 formulation was better than A4, whereas A2 and A3 were similar to A4.

In conclusion we can say that, tablets containing *Aegle marmelos* mucilage at concentration of 3% w/w can be used as binding agent for preparation of conventional tablet as the hardness, disintegration time, drug content and dissolution profile were as per the prescribed limits of Indian pharmacopeia when Paracetamol was used as model drug.

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