

Evaluation of Binding Properties of Aegle marmelos fruit Mucilages.

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Abstract:

The objective of present investigation was to evaluate fruit mucilages of *Aegle marmelos* (Bael) as a binder for pharmaceutical dosage forms. Natural gums are economic, easily available and found useful as tablet binder. No significant work has been reported on fruit mucilages of *Aegle marmelos* to use it as a tablet binder. Tablets were prepared with fruit mucilages of *Aegle marmelos* and evaluated for tablet characteristics. Wet granulation technique was used for the preparation of Paracetamol granules. The binder concentrations used in the formulation were 2, 4, 6 & 8 % w/w. The evaluation of granules showed 0.43 to 0.71 mm granule size, 26.15 to 30.15 ° angles of repose and 20.1 to 12.3 % fines. Tablets were compressed to hardness at about 5.1 to 6.5 kg/cm2. The evaluation of tablet showed 1.25 to 0.5 % friability, 11 to 15 min disintegration time and more than 90% dissolution in 80 min. Tablets at 6% w/w binder concentration showed more optimum results as tablet binder. The fruit mucilages of *Aegle marmelos* was found to be useful for the preparation of uncoated tablet dosage form.

Key words: Aegle marmelos fruit mucilages, Binder, Paracetamol and Dissolution.

Introduction:

Mucilages are most commonly used adjuvants in pharmaceutical preparation. They possess a variety of pharmaceutical properties, which include binding, disintegrating, suspending, emulsifying and sustaining properties. The usefulness of gums and mucilages as emulsifying and suspending agents has been used in tablet formulation as binding agents and also to sustain the drug release. Natural mucilages are preferred to synthetic materials due to their non-toxicity, low cost, free availability, emollient and nonirritating nature. The tree *Aegle marmelos* (Rutaceae) commonly known as Bael is indigenous to India and found wild all over the Sub-Himalayan forests, in Central, and South India. It is a rich source of coumarins, vitamin C, and riboflavin. The bark as well as fruit is reputed to be a valuable Ayurvedic medicine for dysentery and various intestinal complaints^{1,2,3}. Hence, in the present study, selected mucilages *Aegle marmelos* have been evaluated for their binding properties.

Materials and Methods:

Plant Collection and authentication

The fruits of *Aegle marmelos* (Rutaceae) were collected from Ramling Mudgad Dist.-Latur (Maharashtra); and authenticated by Botanical Survey of India, Pune (Maharashtra). A voucher specimen has been deposited at the herbarium of BHISOFIR2. *Isolation of Mucilages* For the isolation of mucilages, the fruits of *Aegle marmelos* was used. The fruits was cut and soaked in water 24 hrs. boiled for 1 hrs and kept aside for 2 hrs for release in a mucilages into water. The material was squeezed in a muslin bag to remove the mark from the filtrate. Then. Equal volume of acetone was added to precipitate the mucilage. The mucilage was separated, dried in oven at temperature less than 50 °C, powdered and passed through sieve number 100. The powder was stored in desiccators until further use (Yields: 20%)⁴.

Microbiological Properties and pH

The isolation mucilage was evaluated for microbial load after storage for 2 months. The number of colony forming units (CFU) per gram of mucilage was determined by a procedure described in Indian Pharmacopoeia. The pH of mucilages was determined by using digital pH meter.

Standardization of mucilage powder

The mucilage powder was standardized for following properties. Loss on drying: The 5 gm mucilage powder was dried at 100 + 5 °C till the constant weight of mucilage powder was obtained. The loss on drying was found to be less than 8 % w/w Ash value: 2 gm of mucilage powder was accurately weighed and evenly distributed it in the crucible. It was dried at 105 °C for one hour and ignited in muffle furnace at 600 + 25 °C. Percentage ash content was found to be less than 3.5% w/w. pH: mucilage powder was analysed for 2 to 8% w/w mucilage solutions with pH found to be in the range of 5.9- 5.1.

Preparation and evaluation of granules:

Wet granulation method was used to prepare granules of drug. The formulation was developed by using Paracetamol IP as model drug. Binder solution was prepared by dissolving it in distilled water. The binder concentrations used were 2, 4, 6, 8 % w/w in solution. Binder level was adjusted by lowering the level of MCC in the formula. All ingredients were dry mixed manually in mortar. Binder solution was slowly added into mixture. The wet mass was granulated by passing them manually through a number 12 mesh sieve. Granules were dried at 50 °C in oven and again resieved through number 16 mesh sieve. The granules were evaluated for percentage of fines and particle size. Granules were mixed with 3% talc and evaluated for flow property ^{5,6}. The tablet formulation was developed for 600mg tablet weight as shown in Table No.1

Ingredients	Quantity (%w/w)
Paracetamol	80
Microcrystalline Cellulose	11
Binder (Aegle marmelos mucilage)	06
Talc	03

Table 1 Formulation containing 6% w/w fruit mucilages of Aegle marmelos binder

Preparation and Evaluation of Tablets

The tablets were compressed by using Cadmach single punch tablet machine fitted with flat faced punches. 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 content uniformity, hardness, friability, and disintegration time and dissolution study.

Dissolution study was carried out in 900ml 0.1 N HCL medium using paddle type Dissolution Test Apparatus (Electrolab). The dissolution was carried out at $37 + 1 \circ C$ and 50 rpm paddle speed. The 10 ml samples were withdrawn at 10 min intervals. 10 ml dissolution medium was added into dissolution chamber as a replacement for sampling after each interval. Absorbance was measured at 243 nm using UV spectrometer (Chemito 2600)⁷⁻⁹.

Results and Discussion:

The binder mucilage is natural and have pH between 5.9- 5.1. The prepared granules were evaluated for percentage of fines, particle size and flow properties. The results are shown in Table No.2. It was observed that the percentage of fines was reduced as the concentration of binder was increased. The flow property of granules was determined by angle of repose and it was found that values were between 26.15-30.15°. The increased percentage of fines reduces particle interlocking and friction, thus decreasing angle of repose. All batches showed good flow property. Granule size distributed between 0.43-0.71 mm.

Characteristic	Binder concentration (%w/w)				
	2	4	6	8	
Percentage of fines	20.1	18.6	14.2	12.3	
Particle size (mm)	0.43	0. 52	0.67	0.71	
Angle of repose (°)	26.15	27.20	28.07	30.15	

Table 2 Evaluation of granules prepared from fruit mucilages of Aegle marmelos.

Table 3 Evaluation of tablets

Characteristic	Binder concentration (%w/w)				
	2	4	6	8	
Content Uniformity (%)	96.60	97.20	98.50	97.96	
Hardness kg/cm2	5.1	5.3	6.0	6.5	
Friability (%)	1.25	1.15	1.01	0.5	
Disintegration time	11 min	12min 20	13 min 20	15 min	
		sec	sec		

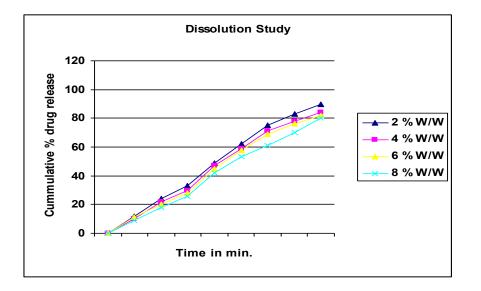


Figure 1: Dissolution study

Three batches of tablets of each binder concentration were prepared. The prepared tablets were evaluated for content uniformity, hardness, friability and Disintegration time. The results are indicated in table No. 3. All batches of tablets exhibited a good uniformity in content. The hardness of tablet increased with increase in percentage of binding agent. The friability values decreased with increase in binder concentration. The disintegration time also increased with increase in binder concentration. All the evaluation parameters were found to be within the pharmacopoeial limits at binder concentrations 6-8 % w/w. Increase in binder concentration therefore resulted in a corresponding decrease in friability and increase in disintegration time. In vitro dissolution profile is given in Figure No. 1. Dissolution study showed that the drug release from the tablets containing 2-8 % w/w binder was more than 90 % in 65 min. Tablets at 6% w/w concentration shows more optimum results as tablet binder. The drug release from tablets decreased with increase in binder concentration.

Conclusion:

The fruit mucilages of *Aegle marmelos* exhibited good binding properties for uncoated tablets. The increased concentration of gum showed small retardation in drug release from tablet.

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