$Patil\ \mathcal{D}.\mathcal{N}^*$, Kulkarní $\mathcal{A}.\mathcal{R}^2$, Hatapakkí $\mathcal{B}.C$ and $Patil\ \mathcal{B}.S$

Corresponding Author dnpatilgadag@rediffmail.com

ABSTRACT

In the present work, we have formulated the oral tablets of paracetamol by using Aegle marmelos fruit gum as a binder. The four different tablet formulations were prepared by wet granulation method. The binder concentrations used in the formulation were 2, 4, 6 & 8 % w/w of cordia fruit gum; tablets were subjected for evaluation of hardness, friability, drug content uniformity. Preliminary evaluation of granules showed that, 0.71 to 0.77 mm granule size, 29.20 to 30.10° angles of repose and 22.1 to 12.7 % fines. Hardness was found to be in the range of 7.1 to 7.4 kg/cm², the percent friability was in the range of 1.50 to 0.75 %, and tablet showed 97.46 to 98.96 % of labeled amount of paracetamol indicating uniformity in drug content, 8 to 18 min disintegration time and more than 90% dissolution in 75 min. Tablets at 6 % w/w binder concentration showed more optimum results as tablet binder. The Aegle marmelos gum was found to be useful for the preparation of uncoated tablet dosage form.

KEY WORDS

Aegle marmelos gum, Binder, Paracetamol, Dissolution

INTRODUCTION

Gum is obtained from fruits of *Aegle marmelos* belonging to family Rutaceae is indigenous to India. This tree is generally found in the outer Himalayas, Shivaliks and South Indian plateau with altitudes

ranging from 250 to 1200 m. It prefers comparatively drier and sunny or warmer aspect of the hill slopes with well-drained loamy soil. It is found growing naturally in dry temperate region. Its natural habitat begins from Burma and extends to Afghanistan, and also the Deccan plateau. The ripen fruit pulp is red in colour with mucilaginous and astringent taste. The pulp contains

¹Department of Pharmacognosy & Phytochemistry, KLES's College of Pharmacy, Gadag-582101, Karnataka (India).

²Department of Pharmacology, KLES's College of Pharmacy, Belgaum-10, Karnataka.

carbohydrates, proteins, vitamin C, vitamin A, angelenine, marmeline, dictamine, O-methyl fordinol and isopentyl halfordinol. The neutral oligosaccharides were characterized as 3-0-beta-D-galactopyranosyl-L-5-0-beta-D-galactopyranosyl-L-arabinose, arabinose, and 3-0-beta-D-galactopyranosyl-D-galactose, and the acidic oligosaccharides ³. The plant extracts were used against multi-drug resistant Salmonella typhi⁹. During summer bael gives a very cool and cozy shade. It also improves the environment by utilizing carbon dioxide and exhaling oxygen. The screening was done of some plants of importance in the Ayurvedic system of traditional medicine used in India to treat various diseases and also as a nutrient. The various gums were used as a tablet binder in pharmaceutical dosage forms¹. In this present investigation A. marmelos gum has been evaluated as a suitable binder for paracetamol tablet.

MATERIALS AND METHODS

Paracetamol IP and Microcrystalline cellulose was received as a gift sample from Kem Well House, Bangalore. All other materials used in this study were of A.R.grade purchased from s.d.fine chemicals Mumbai. Fresh white gum of *Aegle marmelos* was collected from authenticated plant fruits in local area of Gadag district of Karnataka. This research work was conducted from Nov 2008 to Jul 2009.

Purification of Gum:

The well dried gum was powdered in mortar, passed through sieve no.80 and solublised in distilled water. The concentrated solution was precipitated in acetone. The precipitate was separated and dried at 60°C. The dried gum was powdered and stored in tightly closed container for further usages.

Standardization of Gum:

The Gum was standardized for following properties. Loss on drying: The 5 gm gum was dried at 105 ± 5 °C till the constant weight of gum was obtained. The loss on drying was found to be less than 8 % w/w. Ash value: 1gm of gum 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 of ash content was found to be less than 7 % w/w and 2 to 8 % w/w gum solutions have pH 6.0 to 6.5.

Preparation and evaluation of granules:

formulation The was developed Paracetamol IP as model drug by wet granulation method. Binder solution of gum in the concentration 2, 4, 6 and 8 % w/w were prepared in distilled water. 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 60 °C in oven and again received through number 16 mesh sieve. The granules were evaluated for percentage of particle size, angle of repose and fines. Granules were mixed with 4 % talc flow property^{2,5}. The tablet evaluated for formulation was developed for 600 mg tablet weight using 400 mg of Paracetamol (drug), 24 mg of talc powder (lubricant), 164-128 mg of microcrystalline cellulose (diluent) and 2-8 % w/v of A.marmelos gum (as tablet binder).

Preparation and Evaluation of Tablets:

The tablets were compressed by using 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 30

days. No evidence of chemical change was observed. The tablets were evaluated for content uniformity, hardness, friability, disintegration time and dissolution study^{4,7}. Dissolution study was carried out in 900ml 0.1 N HCL medium using paddle type Dissolution Test Apparatus. The dissolution was carried out at 37 \pm 1 $^{\circ}$

C and 60 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 Simadzu^{6,8}.

Table 1: Composition of Tablets Containing Aegle marmelos Gum as Binder

Ingredients	Variation of Binder Concentration by lowering the level of MCC				
	Batch I	Batch II	Batch III	Batch IV	
Paracetamol	400 mg	400 mg	400 mg	400 mg	
Microcrystalline Cellulose	164 mg	152 mg	140 mg	128 mg	
Binder	2 % w/v	4 % w/v	*6 % w/v	8 % w/v	
(A.marmelos gum) Talc	24 mg	24 mg	24 mg	24 mg	

^{*}Indicates good concentration of binding agent.

In the formula weight of one tablet (600 mg) is mentioned, but each batch was calculated and taken for 100 tablets.

RESULTS AND DISCUSSION

The binder gum is natural and have pH between 6.0 - 6.5. The prepared granules were evaluated for percentage of fines, particle size and flow properties. 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 29.20 to 30.10°. The increased percentage of fines reduces particle interlocking and friction, thus decreasing angle of repose from 22.1 to 12.7 %. All batches showed good flow property.

Granule size distributed between 0.71 to 0.77 mm Table 2. Four batches of tablets with variation of binder concentration were prepared and evaluated for content uniformity. hardness. friability disintegration time. All batches of tablets exhibited a good uniformity in content (97 to 98 %). The hardness of tablet increased with increase in percentage of binding agent (7.1 to 7.4 kg / cm²). The friability values decreased with increase in binder concentration (1.50 to 0.75 %). The disintegration time also increased with increase in binder concentration (8 to 18 min10 sec) Table 3. All the evaluation parameters were found to be within the pharmacopoeial limits at binder concentration 6-8 % w/w. Dissolution study

showed that the drug release from the tablets containing 2-8 % w/w binder was more than 90 % in 75 min. The drug release from tablets decreased with

increase in binder concentration. Tablets at 6 % w/w concentration shows more optimum results as tablet binder.

Table 2: Evaluation of Granules Prepared from Aegle marmelos Gum

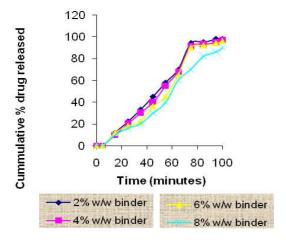
Characteristic	Binder concentration (%w/w)			
	2	4	6	8
Fines	22.1 %	19.5 %	16.2 %	12.7 %
Particle size	0.710 mm	0.722 mm	0.750 mm	0.772 mm
Angle of repose	29.20°	29.40°	29.65°	30.10°

Table 3: Evaluation of Tablets Prepared from Aegle marmelos Gum as Binder

Characteristic	Binder concentration (%w/w)				
	2	4	6	8	
Content					
Uniformity	97.46 %	98.96 %	98.96 %	98.94 %	
Hardness	7.1 kg/cm^2	7.3 kg/cm^2	7.0 kg/cm^2	7.4 kg/cm^2	
Friability	1.50 %	1.30 %	1.00 %	0.75 %	
Disintegration time	8 min	10 min 15 sec.	13 min 20 sec	18 min 10 sec	



Dissolution study of paracetmol



CONCLUSION

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

ACKNOWLEDGEMENT

We thank to KLE University Belgaum (India), for providing the facilities and financial support to carry out the research work.

REFERENCES

1. Antony, P.J. and N. M. Sanghavi, 1997, New binder for pharmaceutical dosage forms.Drug Dev. Ind. Pharm., 23 (4), 417-418.

- Bankar, G.S. and R.A. Neil, 1987, Theory and practice of industrial pharmacy.Lachman L, Liberman AH and Joseph LK; 3rd ed. Mumbai; Varghese publishers. 297-321.
- 3. Bhattacharya, S.B. and A.K. Mukherjee, 1976, The structure of degraded bael gum.Carbohydr Res, 50, 87-96.
- 4. Chukwu, A. and P. Okpalaezinne, 1989, Preliminary evaluation of cissus root gum as a binder in sodium salicylate tablet formulations. Drug Dev. Ind. Pharm., 15 (2), 325-330.
- 5. Gorden, R.E. and D.E. Fonner, 1999, Pharmaceutical dosage forms. New York. 12,245-335.
- 6. Indian Pharmacopoeia, 1996, Ministry of Health and Family Welfare, Govt. of India, Controller of Publications, New Dehli. 2, A100 A111.
- 7. Itiola, O.A., 2005, Characterization of khaya gum as a binder in Paracetamol tabletformulations. Drug Dev. Ind. Pharm., 28 (3), 329-337.
- 8. Kulkarni, G.T. and B. Suresh, 2002, Evaluation of binding properties of plantago ovateand trigonella gaecum mucilages. Indian Drugs., 39 (8), 422-425.
- 9. Phulan, R. and N. Khullar, 2004, Antimicrobial evaluation of some medicinal plants.Phytoterapy Research, 18 (8), 670-6.