International Journal for Pharmaceutical Research Scholars (IJPRS)
ISSN No: 2277-7873
RESEARCH ARTICLE
V-1, I-4, 2012

Formulation and Evaluation of Okra Fruit Mucilage as a Binder in Paracetamol and Ibuprofen Tablet

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Manuscript No: IJPRS/V1/I4/00213, Received On: 25/12/2012, Accepted On: 08/01/2013

ABSTRACT

The purpose of this study is to search for cheap and effective natural excipients that can be used as an effective alternative for the formulation of pharmaceutical dosage form. The mucilage from the Okra Fruit (*Abelmoschus esculentus*) was subjected to Preformulation study for evaluation of its safety and suitability for use as binding agent. The mucilage extracted is devoid of toxicity. Tablets of Lactose were prepared as a control and with 1-5% w/v concentrations of *Abelmoschus esculentus* mucilage and compared paracetamol, Ibuprofen tablet. The tablets were evaluated for weight variation, hardness,friability and disintegration time according to the USP. Studies indicate that the mucilage of *Abelmoschus esculentus* may be used as a pharmaceutical adjuvant and as a binding agent at 4 to 5% w/v, depending on its binding ability and the stability of the resulting tablets.

KEYWORDS

Abelmoschus esculentus, binding agents, weight variation, hardness, friability and disintegration time.

INTRODUCTION

Binders are agents employed to impart cohesiveness to the granules. This ensures the tablet remains intact after compression. The development of new excipients for potential use as binding agent in tablet formulations continues to be of interest. This is because different binding agents can be useful in achieving various tablet mechanical strength and drug release properties for different pharmaceutical purpose. Natural polysaccharides are widely used in the pharmaceutical and food industry as excipients and additives due to their low toxicity, biodegradable, availability and low cost. Natural binders like different starches, gums, mucilages dried fruits possess binding capacity as well as some other properties like disintegrant, filler, sustain release, and these natural polymers are much safer and economical than polymers like PVP. Different starches like rice, potato, maize, corn, wheat, tapioca starch and gums like ferula gummosa boiss, gum olibanum, beilschmiedia seed gum, okro gum, aegle marmelod gum, gum cordial, okra gum and cassia roxburghii seeds gum and plant fruit like date palm fruit and orange peel pectin shows good potency as a binding agent[1-4].

Gums are widely employed in the pharmacy as thickeners, suspending agents, emulsifying agents, binders and film formers. With the increase in demand for natural gums, it has been necessary to explore the newer sources of gums to meet the industrial demands. India, due to its geographical and environmental positioning has traditionally been a good source for such products among the Asian countries[5]. There are reports about the successful use of Ferula gummosa Boiss, Gum Olibanum,

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Beilschemiedia mannii and Aegle marmelos fruit gum as binding agent[6-9].

The fresh fruits of *Abelmoschus esculentus* (L.) are a common component of Indian diet. In addition, the plant has been used medicinally in treatment of several disorders[11-12]. Anti-cancer, antimicrobial and hypoglycemic activities of plant are reported[13-14]. The anti-ulcer activity of fresh fruits is recently reported[15]. This is a coarse, erect, branched, more or less hairy, annual herb 0.6 to 1.5 meters in height, which is grown widely in India. The only published work so for on the potential application of this gum as a binder in tablet formulation was on sodium salicylates, a highly water soluble drug that is no longer in therapeutic usage. The present work is an attempt to extract and investigate the pharmaceutical properties of the gum to assess its suitability as a binding agent in the pharmaceutical formulation. Binding ability was used as the basis for evaluating the performance of *Abelmoschus esculentus* mucilage as binding agent.

MATERIAL AND METHODS

Paracetamol (Sunij Pharmaceuticals, Ahmedabad), Gum tragacanth, sodium CMC (Loba Chemie, Mumbai), was procured from the open market. All the other solvents, reagents used were of Pharmacopoeial and analytical grade. *Abelmoschus esculentus* fruits were purchased from local market. Immature pod were selected because they contain more content of mucilage compared to matured fruits.

Extraction of the Mucilage[18,19]

About 2kg of fresh immature fruit of *Abelmoschus esculentus* were purchased from a local market. After removal of the seeds, the fresh immature fruits were sliced, homogenized and extracted with cold water containing 1% (w/v) sodium metabisulphate. The crude mucilage was centrifuged at 3000 rpm for 5 min and the gum was precipitated from the supernatant with acetone. The precipitated gum was washed several times with acetone; the obtained cream coloured product was dried under vacuum in a desiccator. A light brown coloured powder was obtained after complete removal of moisture. The dried gum was pulverized using end runner mill and screened through a 0.25 mm stainless steel sieve. This was stored in a well closed amber colored specimen bottle till ready for use. The yield of crude *Abelmoschus esculentus* mucilage was 10 g/kg immature fruits. The physicochemical studies of gum and mucilage is tabulated in Table no.1.

Table 1: Physicochemical parameter of Okra gum

Parameter	Practical value
Total Ash(%)	7.56
Water soluble ash (%)	6.24
Acid insoluble ash (%)	0.52
Sp.gravity 0.01% solution	0.997gm/ml
Surface tension 0.1% solution	51.2dyn/cm
P^H of 1% solution	Alkaline

Phytochemical Examination

Preliminary tests were performed to confirm the nature of mucilage obtained. The chemical tests that were conducted are: Ruthenium red test, Molisch test, test for reducing sugars and Ninhydrin test[16].

Toxicity Studies

Toxicity studies were carried out according to the method of Knudsen and Curtis[17]. The animals used in the toxicity studies were sanctioned by the Institute animal Ethics Committee. The male albino rats of Wistar strain weighing 160-200 gm were divided into different groups comprising of six animals each. The control group received normal saline 20ml/kg i.p. The other groups received 500, 1000, 2000, 3000 and 4000 mg/kg of gum suspension in normal saline orally[20]. The

animals were observed continuously for the behavioural changes for the first 4 hours and then observed for mortality if any for 48 hours. Since no mortality, no toxic manifestations were observed and behavioural pattern was unaffected. In chronic toxicity studies, 12 animals were used, divided in to two groups, 6 as control and 16 as test animals. In the test group a dose of 250 mg/kg was administered daily for a period of 30 days. Body weights were recorded for both the groups at an interval of 10days and at the end; haematological parameters were studied in both the groups.

Preparation and Evaluation of Tablets

The tablets containing lactose (as a control), Paracetamol (300 mg) and Ibuprofen (150 mg) were separately prepared by wet granulation method using various binders (starch paste, PVP and Okra gum). The resultant granules were lubricated and compressed using a Killian single punch press machine. The tablets were evaluated for weight variation, hardness, friability and disintegration time according to the USP. Tablet dissolution behavior was carried out using a PTWS3 Pharmatest dissolution tester. The settings of dissolution test for different tablets were summarized in Table no. 4.

RESULTS AND DISCUSSION

Okra gum is a natural polysaccharide composed of d-galactose, L-rhamnose and L-galacturonic acid. It is soluble in cold water and used in the food industry as an emulsifying and foam-stabilizing agent [12].Addition of diluted lead acetate to the gum produces a white precipitation resemble to acacia gum [8]. The results of physicochemical properties of Okra gum are shown in Table1.

The effect of different concentrations of Okra gum on the lactose granules are listed in Table 3. The Carr's index and angle of repose of resultant granules were lower than 15 and 25, respectively. That is acceptable in the range for flow properties (10). Based on Table 3, Okra gum at concentrations of 3 and 4 % (w/w) could produce suitable lactose granules. Therefore, concentration of 3% for Okra gum was chosen as the optimum level to produce granules. However, based on our preliminary studies the 5% concentration of binder was preferred for granulation of the poor compressible (Paracetamol) and high dosage (Ibuprofen) drugs. The effect of Okra gum concentration on physicochemical characteristics of lactose tablets are shown in Table no.2 and Fig.1 (a-c).

Table 3: Physicochemical characteristics of Lactose granules prepared by different concentrations of *Okra* gum

Parameter	Concentration of Okra gum (%)				
	1	2	3	4	5
Bulk density (gm/ml)	0.43	0.47	0.49	0.53	0.55
Tapped density (gm/ml)	0.50	0.55	0.57	0.60	0.65
Carr's index	13.3	14.1	11.7	11.2	13.5
Strength of granules (%)	14	16.8	17.5	18.1	18.3
Angle of repose	22.9	23.5	20.2	19.6	23.4

Table 2: Physicochemical properties of 5%binder concentration (w/w) in different model tablets formulated by *Okra* gum

Parameter	Lactose	PCM	Ibuprofen
Friability (%)	0.2	0.92	0.68
Hardness (N)	52	29.6	53
Disintegration time (min)	35.8	40.5	32.4

Table 4: The setting of dissolution test for tablets

	Paracetamol	Ibuprofen
Apparatus	paddle	Basket
Medium	Buffer (P^H=5.4)	Buffer (P^H=7.2)
Volume	900ml	900ml
RPM	50	150
Temperature	37^0c ± 0.5	37^0c ± 0.5
Absorbance (nm)	242nm	221nm

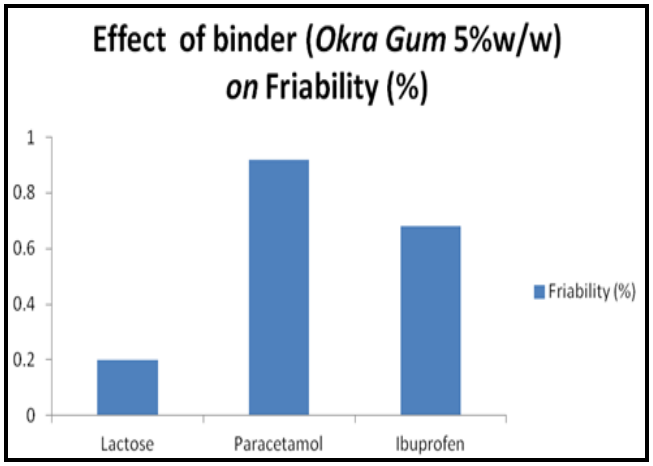

Figure 1(a): Effect of binder on friability

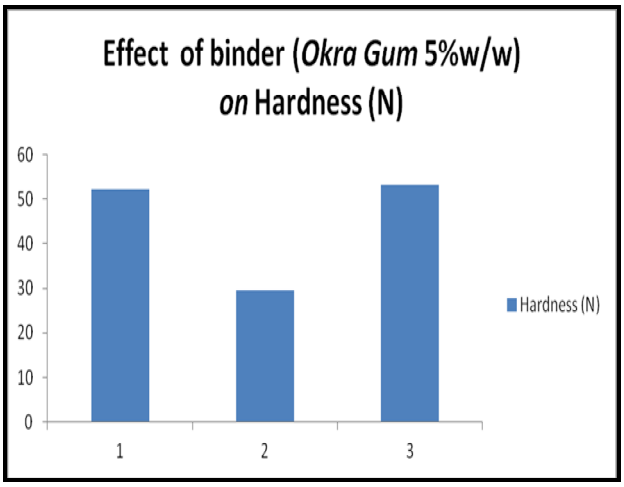

Figure 1(b): Effect of binder on Hardness

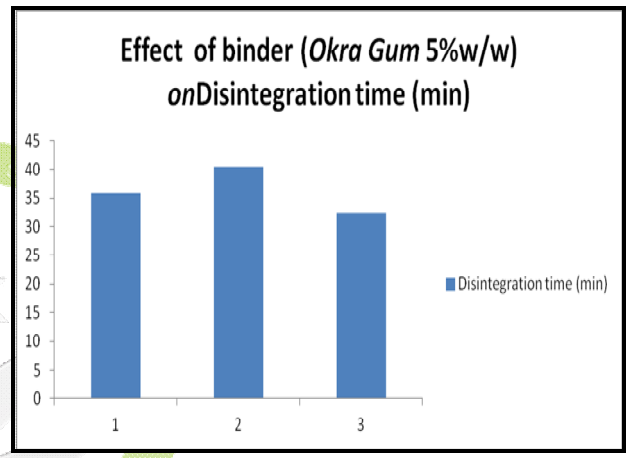

Figure 1(C): Effect of binder on Disintegration time

An increase in binder concentration increased the hardness and disintegration time and decreased friability values of the tablets. Table 2 compares the physicochemical properties of lactose tablets (control) and the tablets prepared of model drugs, Paracetamol and Ibuprofen. The dissolution profiles of the Ibuprofen tablets are shown in Fig. 2. It shows the influence of Okra gum binder on the release of a slightly soluble drug, Ibuprofen. This effect in turn may lead to reduction of side effects, notably gastrointestinal adverse reaction of Ibuprofen[14]. Paracetamol tablets formulated by However, comparison of drug release from Ibuprofen tablets prepared by Okra gum indicated that Okra had a retarding effect on drug release from the tablets.

CONCLUSION

Okra gum as a binder produces some tablet formulations with good hardness, friability, disintegration time and dissolution rate. However, this binder prolongs the dissolution rate of slightly soluble drugs.

ACKNOWLEDGEMENTS

Authors are thankful to principal, director and president of GHB Pharmacy College, Aniyad for kind support.

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