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Evaluation of acacia catechu gum as a binder in tablet formulations

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ABSTRACT

The aim of present study was to examine the suitability of acacia catechu gum as a binder in tablet formulation. Tablets were prepared by using acacia catechu gum as a binder and diclofenac sodium as model drug. Concentration of binder was varied from 2 to 12% w/w in tablet formulation and was compared with starch paste (10% w/v) as a standard binder. The granules and tablets were evaluated for: angle of repose, bulk and taped density, compressibility index % fine, friability, hardness, disintegrating time, maximum drug release and dissolution time. Granules sowed good flow characteristics. However concentration of binder affects the flow characteristics. It also increased the disintegration time and dissolution time. Friability was decreased wit increased concentration of gum. Nevertheless it could be a good candidate for evaluation as a binder or hydrophilic polymer in sustained release tablet formulation.

Keywords: Binder; acacia catechu; natural gum; diclofenac; granules; tablet.

INTRODUCTION

Excipients are additives used to convert the active pharmaceutical ingredients into dosage forms suitable for administration. (Patel, D.M., *et.al*, 2007). Excipients of natural origin are of great interest to us for reasons of reliability, sustainability, and avoiding reliance upon materials derived from fossil fuels (Liu, M.,et al., 2007). Natural gums obtained from the plants have diverse applications in drug delivery as disintegrant, emulsifying, suspending agents and as a binder. They have also been found useful in formulation of immediate and sustained release preparations (Tekade Bharat W., Patil Vijay R., 2011; Jiangyang Fan, *et al.*, 2008; Sinha, V.R., Kumria, R., 2002; Ibrahim, M.A., *et al.*, 2002; Nasipuri, R.N.*et al.*, 1999; Nasipuri, R.N. 1999).

The present work was aimed to compare the effectiveness of acacia catechu gum as a binder in tablet formulation with starch as a standard binder. Diclofenac sodium was used as a model drug for present study.

MATERIALS AND METHODS

Acacia catechu gum was collected from the forest region of Faizpur. Diclofenac sodium was obtained as gift sample from Curex Pharmaceuticals Ltd., Jalgaon. Lactose, starch and all other chemical and reagents used were purchased from local market.

Purification of gum

The gum was collected from the neem tree in the Faizpur region. The collected gum was dried and powdered in mortar and passed through the sieve no. 100. Powdered gum was then solublised in distilled water. The concentrated solution was then precipitated in ethanol. The precipitate was separated and dried at 60°C. The dried gum was powdered and stored in air tight container and used for present study (Gangurde A.B. *et al.*, 2008)

Characterization of gum

Solubility test

The gum was evaluated for solubility in water, acetone, chloroform and ethanol in accordance with the pharmacopoeia specifications (India Pharmacopeia, 2007).

Swelling index

1.0g each of the sample was placed in each centrifuge tubes and the volume occupied was noted. 10 ml of distilled water was added from a 10 ml measuring cylinder and stoppered. The contents were mixed on a mixer 2 min. The mixture was allowed to stand for 10 min and immediately centrifuged at 1000 rpm for 10 min on a bench centrifuge. The supernatant was carefully decanted and the volume of sediment measured. The swelling index was computed using the equation (Ohwoavworhua F.O., Adelakun T.A, 2005):

S = V2/V1

Where; S = Swelling index

V1 = Volume occupied by the gum prior to hydration

V2 = Volume occupied by the gum after hydration

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Loss on drying

The Loss on drying was determined as per the method A given in I.P. The % moisture content was then determined as the ratio of weight of moisture loss to weight of sample and expressed as a percentage (%) (India Pharmacopeia, 2007).

pH determination

This was done by shaking a 1% w/v dispersion of the sample in water for 5 min and the pH determined using a pH meter (Emeje Martins, *et al.*, 2009).

Angle of repose

The static angle of repose was measured according to the fixed funnel and free standing cone method. A funnel was clamped with its tip 2 cm above a graph paper placed on a flat horizontal surface. The powders were carefully poured through the funnel until the apex of the cone thus formed just reached the tip of the funnel. The heights (h), of the powder cones and the mean diameters (D), of the base of the powder cones were determined and the tangent of the angle of repose calculated using the equation (Alfred Martin, 2006):

$$Tan \theta = 2h/D$$

Bulk and tap densities

Required quantity of the powder sample was placed in a 10 ml measuring cylinder and the volume (Vo), occupied by each of the samples without tapping was noted. After 100 taps on the table, the occupied volume V_{100} was read. The bulk and tap densities were calculated as the ratio of weight to volume (Vo and V_{100} respectively) (Alfred Martin, 2006).

Bulk Density -	Weight of sample					
Durk Density –	Volume	occupied	by the sample (V $_{\rm o}$)			
TappedDensity =	Weight of sample					
	Volume occupied by the sample after $100 \tan (V_{100})$					

Viscosity

Viscosity was of 1% gum solution was determined by using Brookfield viscometer (Chang L.W., Heng P.W.S, 2005).

Table 1: Characterization of ac	cacia catechu gum
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Sr. No.	Parameter	Result	
1	Swelling index	1.9	
2	Loss on Drying	2.6 % w/w	
3	Bulk density	0.84 g/ml	
4	Tapped density	1.02 g/ml	
5	Compressibility index	18.05	
6	Angle of Repose	35.17°	
7	рН	6.8	
8	Viscosity (1% w/v)	4.5 cp	

Compressibility index

This was calculated using the equation (Eugene F. Fiese, Timothy A Hagen, 1987)

Compressibility= (Tapped density- bulk density)/Tapped density x 100.

Findings of characterizations of gum are given in table no 1.

Preparation and evaluation of granules

Granules were prepared by using wet granulation method. Formulation was developed for diclofenac sodium as model drug. Gum was dissolved in distilled water to produce binder solution. Binder solution was prepared in different concentration as 2, 4, 6, 8, 10 and 12 % w/w. All other ingredients were dried and mixed in mortar. Binder solution was added slowly to dry powder mixture with continuous mixing till it forms a cohesive mass. This cohesive mass was shifted manually through the sieve no. 12 to produce the granules. These granules were dried at 50°C in hot air oven. These dried granules were then pass through sieve no16 (Banker G.S., Neil R.A, 1987)

Evaluation of granules

The granules were evaluated for various physical properties like percent fine, angle of repose, bulk density, tapped density, compressibility index, % porosity, friability etc as given in table no 2. (Alfred Martin, 2006; Eugene F. Fiese, Timothy A Hagen, 1987; Jens, T. C., 2008)

Preparation and evaluation of tablets

Tablets were compressed by using Jaguar Rotary tablet machine with flat faced punches of 8 mm size.

Evaluation of Tablet (India Pharmacopeia 2007; Banker G.S. and Neil R.A., 1987; United States Pharmacopeia, 2000)

Prepared tablets were evaluated for following parameters and results are summarized in table no3.

Hardness

The hardness of tablet of each formulation was measured by using Monsanto hardness tester.

Friability

Twenty tablets were weighed and placed in the Roche friability test apparatus that revolves at 25 rpm dropping the tablet through a distance of Six inches with each revolution. After four minutes the tablets were removed from the apparatus and weighed. The percentage loss in tablet weight was determined by following formula

% loss = (Initial weight of tablet-final weight of tablet/ Initial weight of tablet) X 100

		Concentration of binder							
Sr. No.	Parameter	Acacia catechu						Storeb (10%)	
		2%	4%	6%	8%	10%	12%	Starch (10%)	
1	Angle of repose	34.17	34.54	33.66	33.16	32.49	32.15	30.32	
2	Bulk Density	0.4125	0.4085	0.4013	0.3975	0.3994	0.3864	0.4237	
3	Tapped density	0.4798	0.4717	0.4699	0.4613	0.4562	0.4496	0.4780	
4	Compressibility index	14.03	13.40	14.60	13.83	12.45	14.06	11.36	
6	% Fine	13.26	13.1	12.85	12.47	12.1	11.8	11.85	
7	Friability	3.8	3.7	3.65	2.45	2.12	2.08	2.64	

Table 2: Evaluation of granules

Table 3: Evaluation of tablets

C		Concentration of binder							
Sr.	Parameter	Acacia catechu							
NO.		2%	4%	6%	8%	10%	12%	(10%)	
1	Hardness	3.8	3.8	4.2	4.2	4.4	4.6	4.8	
2	Disintegration	110	119	130	155	190	205	180	
	time (<u>+</u> S.D.)	<u>+</u> 0.74	<u>+</u> 0.84	<u>+</u> 0.58	<u>+</u> 0.68	<u>+</u> 0.61	<u>+</u> 0.46	<u>+</u> 0.39	
3	Content un- iformity	99.34	99.24	99.31	99.15	99.28	99.45	99.13	
4	Friability	0.87	0.74	0.58	0.52	0.45	0.42	0.65	
5	Maximum Drug released (<u>+</u> S.D.)	98.12 <u>+</u> 0.47	97.95 <u>+</u> 0.87	97.76 <u>+</u> 0.75	98.05 <u>+</u> 0.64	97.45 <u>+</u> 0.58	96.12 <u>+</u> 0.49	97.66 <u>+</u> 0.46	

Table 4: Drug release study

Sr.	Time	Concentration of binder							
		Acacia catechu							
NO.	(11111)	2%	4%	4% 6%		10%	12%	(10%)	
1	0	0	0	0	0	0	0	0	
2	10	62.36+0.99	57.60+0.75	50.97+0.75	43.57+0.62	32.95+0.95	27.85+0.84	51.08+0.76	
3	20	76.99 <u>+</u> 0.83	63.59 <u>+</u> 0.53	56.04 <u>+</u> 0.53	50.69 <u>+</u> 0.42	38.75 <u>+</u> 0.60	32.58 <u>+</u> 0.89	54.79 <u>+</u> 0.57	
4	30	88.21 <u>+</u> 0.75	68.80 <u>+</u> 0.38	63.29 <u>+</u> 0.42	56.94 <u>+</u> 0.54	43.43 <u>+</u> 0.95	37.52 <u>+</u> 0.76	60.56 <u>+</u> 0.35	
5	40	94.27 <u>+</u> 0.76	75.58 <u>+</u> 0.45	69.67 <u>+</u> 0.50	64.45 <u>+</u> 0.46	49.17 <u>+</u> 0.75	42.52 <u>+</u> 0.74	68.13 <u>+</u> 0.55	
6	50	99.80 <u>+</u> 0.71	85.41 <u>+</u> 0.46	76.12 <u>+</u> 0.44	69.73 <u>+</u> 0.34	54.55 <u>+</u> 0.70	46.98 <u>+</u> 0.66	78.08 <u>+</u> 0.55	
7	60		93.13 <u>+</u> 0.45	84.76 <u>+</u> 0.63	77.28 <u>+0</u> .62	59.73 <u>+</u> 0.69	53.61 <u>+</u> 0.75	83.92 <u>+</u> 0.91	
8	70		99.30 <u>+</u> 0.60	88.72 <u>+</u> 0.43	81.08 <u>+</u> 0.60	64.70 <u>+</u> 0.97	58.17 <u>+</u> 0.78	88.35 <u>+</u> 0.77	
9	80			96.29 <u>+</u> 0.54	85.93 <u>+</u> 0.46	69.64 <u>+</u> 0.60	62.02 <u>+</u> 0.63	92.36 <u>+</u> 0.51	
10	90			98.91+0.44	92.02+0.74	75.38+0.73	65.82+0.64	94.98+0.49	
11	100				97.66+0.53	81.27+0.74	70.84+0.77	97.66+0.36	
12	110					87.13 <u>+</u> 0.76	74.89 <u>+</u> 0.56		
13	120					92.88 <u>+</u> 0.88	78.64 <u>+</u> 0.86		
14	130					96.98 <u>+</u> 0.86	83.70 <u>+</u> 0.96		
15	140						88.89 <u>+</u> 0.72		
16	150						95.82 <u>+</u> 0.79		

n=6

Disintegration time

Tablets were placed in six tubes of disintegration test apparatus (Electrloab). The apparatus was run to observe the time required to complete disintegrate the tablet. Test was repeated for each formulation.

Content uniformity

Content uniformity was determined for each formulation. Content uniformity of tablets were determined as per IP monograph m using spectrophotometer (LabIndia UV 3000+)

Dissolution study

In vitro dissolution study of prepared formulations was carried out by using 8-basket USP dissolution test apparatus (Electro lab TDT 08L) type I. Tablets were placed in the basket filled with 0.1 N HCl. The test was carried out at $37\pm1^{\circ}$ C at 50 rpm. Sample was withdrawn at time interval of 10 min. 10 ml of fresh disso-



Figure 1: In vitro drug release profile

lution medium was added into dissolution chamber as replacement for sampling after each interval. Absorbance was measured at 285 nm using UV spectrophotometer (LabIndia UV 3000+) (United States Pharmacopeia, 2000).

CONCLUSION

The results obtained in this study established for the first time. The present investigation is a primary platform to indicate the suitability of acacia catechu gum as a binding agent. It performs better in better in 6 to 8 % w/w concentration as a binder. At this concentration the granules strength (friability) was found good, although as the concentration of gum increased, the friability of granules was decreased. Hardness of tablet was increased with increased concentration of gum and disintegration time was also increased and friability was decreased. At the same time wit increase in concentration of gum the dissolution time was increased to significant level. Increased concentration of gum prolongs the disintegration time of tablet and simultaneously the dissolution time. Hence the gum may be good candidate for evaluation as hydrophilic polymer in sustained released tablet formulation.

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