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Studies on Preparation and Evaluation of Modified Form of Gum Karaya

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Effect of temperature and time of heating on viscosity and swelling characteristics of gum karaya was investigated with an aim to prepare modified form of gum karaya. It was found that heating of gum karaya for 2 h at 120° produced modified form of gum karaya with low viscosity and comparable swelling capacity with that of parent gum karaya. The selected modified form of gum karaya further characterized for its physicochemical properties in comparison with gum karaya and evaluated as disintegrant in the preparation of tablets. Theophylline was selected as model drug. Formulations containing modified form of gum karaya showed faster disintegration time than those of formulations containing gum karaya. Optimum disintegration time and dissolution of tablet were obtained with 10% w/w levels of modified form of gum karaya in the formulation. It was found that dissolution efficiency of theophylline was significantly improved in the presence of modified form of gum karaya.

Identification of new uses for the existing excipients is a relatively inexpensive and less involving process as compared to an entirely new development. In developing the new grades of existing excipients, the physical characteristics of the materials are to be modified while, the chemical nature is preserved to a large extent[1]. The development of these types of excipients is economically beneficial, because the detailed toxicity and safety studies are not required. Gum karaya (GK) is a natural gum exudate, obtained from the trees *Sterculia urens* belonging to the family Sterculiaceae[2]. Chemically the gum is an anionic polysaccharide, contains 43% D-galacturonic acid, 13% D-galactose and 15% L-rhamnose[3]. GK has high acetyl value ranging from 13.4 to 22.7 and has greater solvation due to acid groups, which attracts and immobilizes large amount of water[2]. The high viscosity nature of gum limits its usage as binder and disintegrant in the development of oral conventional dosage forms.

The present investigation was aimed to prepare modified gum karaya (MGK) and evaluate its suitability as disintegrant in the development of oral conventional dosage forms. Modified form of gum was prepared by application of heating. Theophylline (TH) was selected as a model drug. Tabletting characteristics and dissolution rate studies were performed to explain the results.

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MATERIALS AND METHODS

Gum karaya (viscosity of 1% w/v solution is 1800 cps.) was bought from M/s. Girijan Co-operative Corporation Ltd., Visakhapatnam. Theophyline (anhydrous) was supplied by M/s. Natco Pharma Ltd., Hyderabad as a gift sample. Lactose, microcrystalline cellulose, talc and magnesium stearate used were of USP grade. All other chemicals used were of Analytical Reagent Grade.

Preparation and preliminary characterization of modified forms of GK:

The tears of gum were pulverized, sieved through mesh no. 100. Ten grams of powdered GK was taken in a porcelain bowl and subjected to heating using a sand bath for different time periods at different temperatures as shown in Table 1. The viscosity studies of 1% w/v aqueous solution of each sample of gum was measured according to the USP XXII at 37° using Rheomat 115, MS-DIN 145 and module 4/

TABLE 1: PRELIMINARY CHARACTERIZATION OF MODIFIED FORMS OF GK.

Sample	Temp (°)	Time of exposure (h)	Yield (%)	Color	Swelling property (ml) Mean ± s.d.	Viscosity (cps) Mean ± s.d.
GK	-	-	-	White	37.3±3.1	1800±56
Modified GK	60	0.5	98.8	White	37.1±2.6	1620±10
		1.0	98.5	White	36.9±2.3	1526±24
		1.5	98.0	White	36.9±1.9	1440±13
		2.0	97.3	White	36.8±1.3	1203±19
	80	0.5	98.3	White	37.0±2.7	1510±21
		1.0	98.0	White	36.9±2.6	1320±20
		1.5	97.6	White	36.8±2.3	1106±11
		2.0	96.9	White	36.7±1.5	995±10
	100	0.5	98.2	White	36.9±2.3	1239±24
		1.0	98.0	White	36.8±1.2	1025±16
		1.5	97.3	White	36.8±2.6	974±17
		2.0	96.8	White	36.7±3.1	859±12
	120	0.5	98.1	White	36.7±2.6	1106±22
		1.0	97.9	White	36.6±1.2	789±19
		1.5	97.2	White	36.6±1.3	629±26
		2.0	96.8	White	36.5±2.1	550±35
	140	0.5	98.1	Brown	36.7±1.8	946±15
		1.0	97.5	Brown	36.6±2.1	710±16
		1.5	97.7	Brown	36.6±2.5	574±23
		2.0	96.7	Brown	36.5±1.3	545±26

Weighed samples of gum were taken in porcelain bowl and subjected for heating on sand bath for different time periods at different temperatures and the obtained modified forms evaluated for its swelling and viscosity properties.

3. Swelling capacity of modified forms of GK were determined by using a slightly modified method reported by Gauthami and Bhat[4]. One gram of GK powder was accurately weighed and transferred to a 100 ml stoppered measuring cylinder and was made up to volume with distilled water. It was kept aside for 24 h or until constant swelling was observed. Then the volume to which the gum was swollen was noted.

Characterization of selected modified form of GK in comparison with parent GK:

The SEM photographs of GK and selected modified form were obtained using a Scanning Electron Microscope (Jeol, JSM - 840 A, Japan) with 20 kV accelerating voltage. The size distribution of the GK particles was measured using a calibrated eyepiece micrometer. True density of GK powder was determined by liquid displacement method. The bulk density of this polysaccharide was determined by the three tap method[5]. The percent compressibility index (I)[6] was also calculated. The angle of repose of the GK and MGK was determined by the Funnel method[7]. The pH of the 1% w/v solution of the samples was measured using pH meter (Systronics, model no. 361). Moisture content was detected by the method of loss on drying. Volatile acidity of GK was determined by the method reported by Jacob[8]. Water retention capacity of samples was determined by the method reported by Gauthami and Bhat[4].

Preparation of tablets:

Tablets were prepared as per the formulae given in Table

less than that of GK. This is because of evaporation of free and bound water present in the GK during heating. The pH of MGK was found to be slightly more due to loss of volatile acetyl content on heating.

The results of the hardness, friability, uniformity of weight, drug content, and D.T. of the tablets containing TH are given in Table 4. All the batches of tablets prepared fulfilled the official (IP) requirements for uniformity of weight. All the tablets prepared were found to contain the medicament within 100±5% of labeled claim. Hardness of the tablets in all the batches was found to be in the range of 3.5 to 5 kg/sq. cm and was satisfactory. The percent weight loss in the friability test from all formulations was found to be within the IP limits.

The DT of all the formulations containing GK were found higher than that of the formulations containing MGK. The DT of all formulations containing MGK decreased as the proportion of disintegrant increased upto 10% w/w level and remained constant on further increase, where as the DT of the formulations containing GK increased in contrast with MGK as the proportion of disintegrant increased. The increase in the concentration of GK (above 2.5% w/w) in the formulations prevented the fast disintegration of tablets due to its high viscosity in the microenvironment and the formulations containing MGK absorbs water readily and disintegrates rapidly due to its low viscosity and high swelling properties.

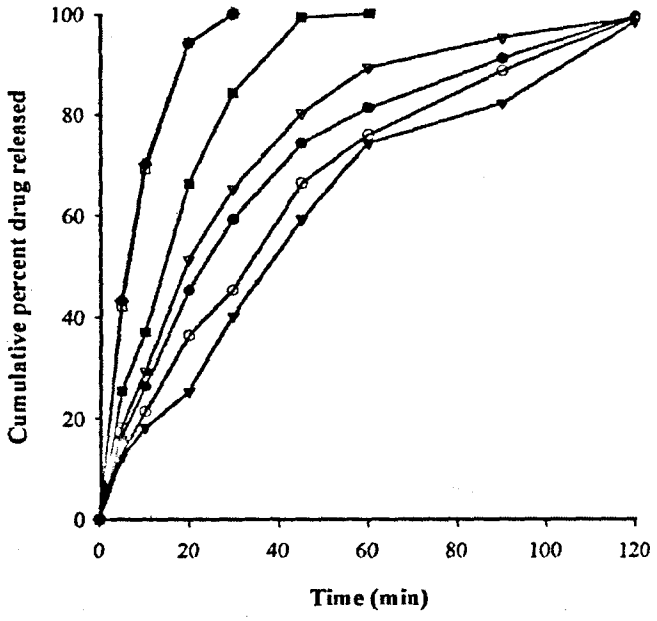

Fig. 2: Release profiles of theophylline from prepared tablets.

***In vitro* dissolution profiles of theophylline from tablets containing GK as disintegrant (T1 (-●-), T2 (-○-), T3 (-▼-)) and MGK as disintegrant (T4 (-▽-), T5 (-■-), T6 (-□-) and T7 (-◆-)) were studied in phosphate buffer (pH 7.2), samples drawn at regular time intervals and theophylline content was measured spectrophotometrically at 271 nm.**

TABLE 4: TABLETTING CHARACTERISTICS OF PREPARED TABLETS.

Tablet	Weight[a] (mg)	Drug Content[a] (%)	Hardness[a] (kg/cm²)	Friability[b] (%)	D.T.[c] (min)	D.E. 30[c] (%)
T1	119.3 ± 1.81	98.36±2.57	4.26 ± 0.34	0.69	13.5	34.26
T2	119.9 ± 1.22	98.99± 1.45	4.59 ± 0.26	0.46	17	27.21
T3	120.6 ± 1.32	99.53 ± 1.09	5.26 ± 0.16	0.35	22	21.78
T4	119.3 ± 1.75	99.18 ± 1.89	4.03 ± 0.69	0.66	7.0	38.41
T5	119.9 ± 1.25	99.69 ± 1.36	4.29 ± 0.29	0.52	5.0	49.59
T6	120.2 ± 1.69	99.36 ± 2.01	4.59 ± 0.48	0.46	3.5	72.41
T7	119.2 ± 1.26	98.23 ± 1.01	4.23 ± 0.33	0.47	3.5	72.84

Tablets prepared as per the formulae given in Table 3 were evaluated for various tabletting charactristics. The dissolution studies were performed in 900 ml of phosphate buffer (pH 7.2) using USP dissolution test apparatus II. Samples were withdrawn at predetermined time intervals and assayed spectrophotometrically at 271 nm. a, Mean ± S.D. n=10 tablets, b, n=10 tablets and c, n=6 tablets.

The dissolution profiles of TH from tablets formulated are shown in fig. 2. Tablets formulated employing MGK gave rapid dissolution of the drug, when compared to the corresponding tablets formulated with GK. High dissolution efficiency values of tablets prepared with MGK as shown in Table 4, indicating rapid and high dissolution rate of the drug from the tablets formulated using MGK when compared to the tablets formulated with GK. It was found that dissolution efficiency increased as the MGK concentration increased in contrast to decreased values for formulations containing GK.

In conclusion, GK can be suitably modified by heating it at 120° for 2 h. The selected modified form of GK has excellent disintegration property when compared to GK. It can be used as disintegrant in place of currently existing disintegrants, as it is cheap, biocompatible, biodegradable and can be prepared easily.

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