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Gum Odina-A New Tablet Binder

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Abstract: Gum odina and various parts of the plant *Odina wodier*, Roxb., family, *Anacardiaceae*, is traditionally used in Indian folk medicine. Here an effort was made to investigate the efficacy of gum odina as tablet excipient, in particular as a tablet binder. The studies of toxicity and chemical compositions of the experimental gum and gum-experimental tablet excipient interactions using FTIR (Furrier transform infrared) spectrum ensured its safe use as a tablet binder. Tablets were manufactured with various quantities of gum odina as a tablet binding agent and a comparison was made against the tablets prepared with 5% starch paste as binder based on studying the standard parameters like hardness, thickness, friability, weight variation and disintegration time. Gum odina at a very low amount (1/20th of the starch paste used) was found to be effective as tablet binder. Thus this gum is a cheap, economic and easily available option of a tablet binder in the list of pharmaceutical excipients.

Key words: Gum odina, tablet binders, Odina wodier

Introduction

As a natural defense mechanism to prevent infection or dehydration many trees and shrubs are known to produce an aqueous thick exudation when the plants bark is injured (Whistler, 1993). Eventually the solution dries up in contract with sunlight and air and a hard transparent brown-tint glass like mass is formed. This solid exudation is commonly known as natural gum (Whistler, 1993; Phillips and Williams, 2001). Natural gum is normally neutral or slightly acidic complex of polysaccharides or partially acetylated polysaccharide or heterogeneous polysaccharide obtained as a mixed calcium, potassium and magnesium salts (De Paula et al., 2001; Verbeken et al., 2003). Odina wodier, Roxb., family Anacardiaceae is a large tall tree found in deciduous forest in India, Myanmar, Srilanka, China, Malaysia, Cambodia and Philippine Island (Chidanbarathanu, 1995). It is popularly known as Kashmala, Odimaram, Jiol in local languages and in English it is called Rhus olina (Kiritikar and Basu, 1935). Various parts of this plant have been used since the ages of Ayurveda. The leaves have been reported to use in Elephantiasis of the legs (Kiritikar and Basu, 1935). Juice of green branches is used as an emetic in case of coma or insensibility produced by narcotic. The dried and powdered bark is found to use as tooth powder by poor villagers (Chidanbarathanu, 1995). The bark extract has been reported to be useful in vaginal trouble, curing ulcer, heart diseases etc (Kiritikar and Basu, 1975).

In the present study an effort was made to evaluate the efficacy of Gum odina (obtained from *Odina wodier*, Roxb. Family *Anacardiaceae*) as a tablet binder and the potential binding capability of the gum has been evaluated with the standard starch paste as a tablet binder.

Materials and Methods

Chemicals used for tablet manufacturing were calcium carbonate (E. Merck (India) Ltd., Mumbai, India), starch purified (E. Merck (India) Ltd., Mumbai, India), lactose monohydrated pure (E. Merck (India) Ltd., Mumbai, India) and talc purified (E. Merck (India) Ltd., Mumbai, India). All other chemicals were used as such if not otherwise mentioned.

Collection of Gum Odina

Gum was collected from the tree *Odina wodier*, Roxb., family *Anacardiaceae* during Autumn in the month of August from the Mandal Ghat of Jalpaiguri District, West Bengal, India. The gum was the natural exudates on the bark of the tree and it was collected in a dry condition. The tree was identified by Dr. R.P. Nandi, Director, Cinchona, Mangpoo, Darjeeling, West Bengal, India and the voucher specimen has been kept with the Director of Cinchona, Mangpoo. After collection of the gum, the entire work was carried out in the department of Pharmaceutical Technology, Jadavpur University during last two years.

Chemical Analysis

For the detection of the presence of carbohydrates and reducing sugars, the standard tests Molisch's test for carbohydrates (Trease, 2002) and Reduction of Fehling's solution for reducing sugars (Trease, 2002) were done. In short, in Molisch's test, the gum was treated with α -naphthol and concentrated sulphuric acid which gave purple color. In case of the detection of reducing sugars, - to the preparation of gum odina equal quantity of Fehling's solutions A and B were added. After heating, brick red precipitate was obtained. Presence of tannin was tested upon treating the gum with Ferric Chloride solution. There was no black precipitation for tannin with ferric chloride solutions.

Presence of mucilage was tested by treating the gum with Ruthenium red solution (Trease, 2002) and Benzidine solution (Trease, 2002). No pink color with Ruthenium red solution and no blue color when treated with solution of Benzidine were detected. This indicates the absence of mucilage.

Gums like gum acacia contain peroxidase enzymes. Thus to know whether the gum odina contains the enzymes, it was treated with few drops of H_2O_2 , which gave no blue color (Trease, 2002).

Zeta Potential and Conductivity Measurement

Zeta potential and conductivity measurement was performed with the help of Zetasizer nano ZS (Malvern Instruments Ltd.,UK). One milliliter preparation of gum odina in warm water was taken in a Zeta Potential cell and kept inside the instrument and the lid was closed. Zeta Potential measurement was done by a combination of laser Doppler velocimetry and phase analysis light scattering technique.

Toxicity Study

To study the toxic effect (if any) of gum odina, the toxicity study was conducted on twelve male Swiss Albino Mice with an average weight 20.56±2.8 g. Animal experiments were conducted following the guideline of institutional animal ethics committee. The animals were housed in polypropylene cages at 22±0.5°C with a relative humidity 55% in a normal day and night photo-cycle. The animals were fasted for 12 h before the oral administration of the gum. The animals received gum odina (1 g kg⁻¹ body wt.) in viscous liquid condition by gavages and were monitored for 24 h. No death or abnormal behavior was observed. The animals then had free access to basal diet (Mukherjee *et al.*, 1998) mixed with gum odina (1:1) and water and they were observed for one month. No death or abnormal behavior was noticed.

FTIR Study

To study the gum and experimental tablet-excipient interaction, the pure gum odina, a mixture of the gum odina and the experimental tablet excipients and the tablet excipients without gum odina were mixed separately with IR grade KBr in the ratio 100:1. The well-ground and mixed powdered samples were compressed into pellets by applying 5.5 metric tons of pressure in a hydraulic press and the pellets were scanned over a wave number of 4000-400 cm⁻¹ in a Magna IR 750 series II (Nicolet, USA FTIR Instrument).

Formulation Development

Formulation was developed by conventional technique. In short, wet granulation was done by using sieve number 18. Then drying was done in hot air oven at 45°C for 30 min and air-dried granules were kept for two days. Again granules were sieved through sieve number 18. Talc (1.5%w/w) as lubricating agent was mixed with granules for the preparation of compressed tablets for each batch (Table 1).

Hardness

Hardness study was conducted by the following guidelines of the USP (The United State Pharmacopoeia, 1980). For this six tablets were taken and hardness of each tablet of each batch was measured by Monsanto Type Hardness Tester (Campbell Electronics Company, Mumbai, India).

Thickness Study

The study of the tablet thicknesses was conducted by the following USP guideline (The United State Pharmacopoeia, 1980). For these fifteen tablets were taken for each batch and thicknesses were measured by using Digimatic caliper, Mitutoyo Corporation, Japan.

Friability

Friability testing (The United State Pharmacopoeia, 1980) was done by using 6 tablets for each batch by using Friability Test Apparatus (Campbell Electronics, Mumbai, India.)

Weight Variation

Weight variation study was conducted by following guidelines of USP (The United State Pharmacopoeia, 1980). In short 20 tablets were taken and they were weighed together and individually. The individual weight variations were studied from the mean weight of each set. Four such sets were run.

Disintegration

Test for disintegration was done by taking 6 tablets in each batch by using USP tablet-disintegration testing apparatus, Electro Lab/ED-2L, by controlling the temperature 37.5°C by following USP guideline (The United State Pharmacopoeia, 1980).

Results and Discussion

Upon various chemical tests for carbohydrates the gum odina showed the presence of carbohydrate in it. Formation of brick red precipitate on reduction of Fehling's solution indicates that the gum contains reducing sugar. The presence of carbohydrate was further substantiated with the positive result (formation of purple color) upon Molisch's Test (Trease, 2002). Moreover, the gum was found to be devoid of tannin upon ferric chloride solution and mucilage upon ruthenium red solution and benzidine solution, respectively. The gum odina was also tested for the peroxidase

enzyme which is commonly present in some gums like gum acacia. But the gum odina showed the absence of the enzyme in it. Thus a chance of oxidative degradation due to gum odina as excipient is eliminated as compared to gum acacia. Again when the conductivity of 1 mL the preparation of gum odina in warm water was studied it was found that it had conductivity 2.777 (ms cm⁻¹), Mobility -1.851 (µm cm vs⁻¹) and Zeta-Potential -23.61 (mv) at 25°C temperature. The zeta potential helps us to understand and control colloidal suspension as it forms during the formation of gum paste. It was found that at acid pH (5.5-5.8) values the gum displayed delayed or hindered sedimentation. In such conditions, the electrophoretic mobility and zeta potentials were rather low. This negative zeta value indicates that in colloidal condition the repulsive force between the polymeric gum particles and the vehicle prevails, which helps the gum colloidal preparation not to settle down quickly (Gallardo *et al.*, 2005).

No death or abnormal behaviors were seen in animals both in short-term (24 h, with a dose of 1 g kg^{-1} body weight) and one month toxicity studies. Moreover, this gum as well as many parts of this tree has been being traditionally used by the native people without reporting any toxic manifestation. Thus it can be claimed that the gum is safe for use and in particular, the amount used here is very safe.

Chemical-chemical interactions are studied in various ways using various sophisticated instruments like FTIR, DSC etc. (Mukherjee *et al.*, 2005). In the present study interactions between the gum odina (natural gum) and the other experimental tablet excipients have been studied using FTIR spectra (Fig. 1-3). Figure 1 depicts the FTIR spectrum of gum odina, Fig. 2 shows the spectrum of the tablet excipients without the gum odina and Fig. 3 demonstrates the FTIR spectrum for tablet excipients along with gum odina. When the figures were compared it was found that there were no major physical and chemical interaction between gum odina and the other tablet excipients as there were no distinct changes in the available peaks with the corresponding wave numbers in the Fig. 2 and 3. However, there were some very minor changes in the wave numbers between 4000 and 2800 cm⁻¹ and between 1690 and 1620 cm⁻¹. Wave numbers between 4000 and 2800 cm⁻¹ are the stretching zone of C-H (alkenes) (3000-2850 cm⁻¹), C-H (Aromatic) (3100-3000 cm⁻¹), OH (Alcohol) (3700-3200 cm⁻¹), C-H (alkenes) (3100-3000 cm⁻¹), wave numbers between 1690 and 1620 are the stretching zone of C = N (1690-1620 cm⁻¹). These functional groups are present in the materials like starch, lactose and gum odina.

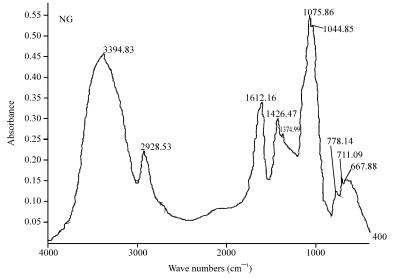


Fig. 1: FTIR spectrum of gum odina

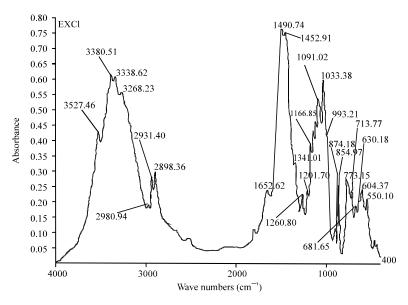


Fig. 2: The FTIR spectrum of the tablet excipients without the gum odina

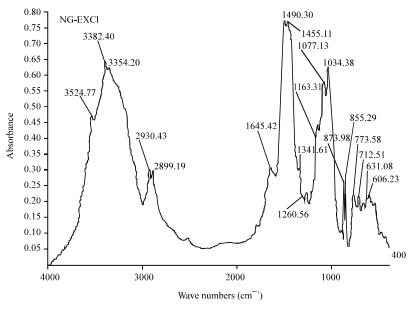


Fig. 3: The FTIR spectrum for tablet excipients along with gum odina

So, there is the possibility of formation of some weak bonding like hydrogen bonding, Vander-walls forces or dipole moment and these forces could help the molecules to adhere to each other and thereby, the gum odina may provide binding effect with the other excipients present in the tablet.

After studying the toxicity, possible chemical composition and chemical-chemical interaction the gum was selected as tablet binder and the tablets were formulated with the various percentages (Table 1) of this gum. The standard starch paste was also used as binder to another batch as standard control (Formulation IV).

Table 1: Experimental formulations with composition

	Starch IP (Disintegrating	Calcium carbonate	Lactose	Starch paste	Experimental gum (gum odina	
Formulation	agent)	(model drug)	(Diluents)	(binder)	as binder)	Remarks
I	1%	24%	50%	Nil	0.125%w/w	Test
II	1%	24%	50%	Nil	0.250%w/w	Test
III	1%	24%	50%	Nil	0.375%w/w	Test
IV	1%	24%	50%	5%	Nil	Control

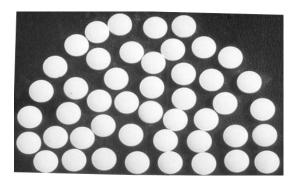


Fig. 4: Tablet formulations prepared with starch paste (as control preparation)

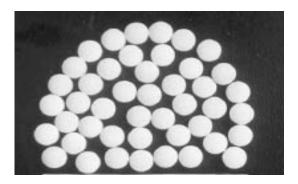


Fig. 5: Tablet formulations prepared with gum odina (0.125%w/w)

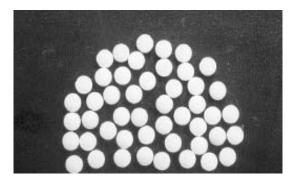


Fig. 6: Tablet formulations prepared with gum odina (0.25% $\mbox{w/w})$

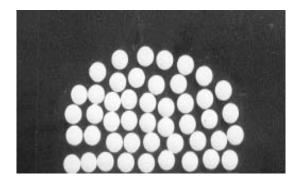


Fig. 7: Tablet formulations prepared with gum odina (0.375% w/w)

Table 2: Various experimental parameters of the formulations

		Test for	Mean	Mean		
	Mean	friability	hardness	thickness	Average	
	disintegration	(mean % weight	$(kg cm^{-2})$	testing (mm)	weight (g)	
Formulation	time $(n = 6)$	loss) (n = 6)	(n = 6)	(n = 15)	(n = 20)	Remarks
I	3 min	0.85	1.56 ± 0.2160	3.21±0.1909	0.16956 ± 0.011	Test
II	15 min	0.686	2.16 ± 0.2562	3.29 ± 0.2900	0.18149 ± 0.011	Test
IΠ	15 min	0.335	2.15 ± 0.1974	3.03 ± 0.0905	0.17093 ± 0.005	Test
IV	42 min	0.190	4.1±0.5609	3.37 ± 0.1071	0.20634 ± 0.0092	Control

Data show mean±SD

Hardness, thickness, friability, disintegration time, weight variation were compared amongst the various prepared formulations (Fig. 4-7) (Table 2).

It has been found that the hardness increased about 33% when the percentage of binder gum odina was increased from 0.125 to 0.25%. When this was further enhanced from 0.25 to 0.375% no further change of hardness was noticed. Similar trend of findings was noticed in case of the disintegration time (Table 2).

Formulation- I (Table 2) disintegrated in 3 min where as Formulation II required 15 min to disintegrate. When percentage of gum odina was enhanced (Formulation-III) (Table 1) no further change in disintegration time was noticed. When the findings were compared with the finding of Formulation-IV which contained 5% starch paste as binder, it was observed that disintegration time was more than the double in case of Formulation -IV (Table 2) as compared with Formulation II and III and the measures of hardness were about twice than those of Formulations II and III, respectively. Thus it is found that gum odina is capable of being used as a binder to provide desired hardness approximately 2 kg cm⁻² and disintegration time about 15 min using just 1/20th amount of starch paste. When the friability was considered, the maximum friability percentage of weight loss was detected in formulation containing 0.125% gum odina. This was followed by the Formulation -II and III and Formulation -IV (5% starch paste as binder), respectively. Increasing percentage of gum odina from 0.125 to 0.25% decreased friability and further increase of gum odina from 0.25 to 0.375% decreased the friability percentage half of the friability values of the Formulation II (0.25% gum odina). Average thickness did not vary much amongst the formulations. Again average weight variations in all the formulations were well within the Pharmacopoeial limits (The United State Pharmacopoeia, 1980). Thus it can be concluded that gum odina can be a suitable and cheaper option as a tablet excipient in particular, as a tablet binder. It is effective in a very low amount as compared to the standard tablet binders used. Moreover, as this plant is available chiefly in Asia and Africa, this could provide an economic means for the poor people.

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