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Gum cordia – A new tablet binder and emulsifier

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Abstract

The ripe fruits of *Cordia obliqua,* willed family, *Boraginaceae*, are traditionally eat by local Tribes and raw fruits are used as pickle. The fruit mucilage is used as a gum for pasting sheets of paper and board, etc. Here an effort was made to investigate the efficacy of cordia obliqua fruit mucilage as pharmaceutical excipient in particular as tablet binder and emulsifier. The study of toxicity and chemical compositions of the experimental gum and gum-experimental tablet excipient interactions using FTIR (Fourier transform infrared) spectrum ensured its safe use as a tablet binder. Tablets were manufactured with various quantities of cordia obliqua fruit mucilage as 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 cordia at a very low amount (1/25th of the starch paste used) was found to be effective as tablet binder. For emulsifying activity study, castor oil was taken as a model drug and emulsified with cordia obliqua fruit mucilage. The comparative stability studies were done with that of the emulsion prepared by taking gum acacia as standard emulsifying agent and it was found that the emulsion prepared with 1.5%w/v of gum cordia is more effective in comparison to that of the emulsion prepared by using 10%w/v of gum acacia. Thus this gum will be a non-toxic, bio-degradable, cheap, economic and easily available option as tablet binder and emulsifier in the list of pharmaceutical excipients.

Key words: Gum cordia, tablet binder, emulsifier, *Cordia obliqua, Boraginaceae.*

Introduction

The raw fruits of *Cordia Obliqua*, willd are used as fruit and as good pickle. The mucilaginous substance of the fruit used as a gum for pasting sheets of paper and cardboard etc, can be used as an expectorant and are effective in treating the disease of the lungs and the raw gum can be used beneficially in gonorrhea (Parmar et al. 1982).

The fruits are useful in treating coughs, the diseases of the chest and chronic fever and also effective in treating disease of the spleen (Kirtikar and Basu 1938). The fruits are used as a demulcent in southern Iran (Parmar et al. 1982). The ripe and unripe fruit mucilage found to be having decreased rabbit arterial blood pressure without affecting the respiratory rate (Abou-Shaaban et al. 1989). The constituents of the seeds of cordia obliqua are having potential anti-inflammatory activity (Agnihotri et al. 1989). Cardia abliqua willed, is a medium-sized tree found scattered through out Koraput District of Orissa as well as mid-Himalayas. The tree is very vigorous. There are two forms of trees are available, major difference between two is size of fruits, which is small in one case and large in the other. The present study performed on large fruit type which is commoner.

In the present study an effort was made to evaluate the efficacy of cordia obliqua fruit mucilage (obtained from *Cordia obliqua*, willed. Family *Boraginaceae*) as a tablet binder and emulsifier.

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The potential binding capability of mucilage was evaluated with standard starch paste as a tablet binder. The emulsifying characteristics of gum cordia was evaluated and compared with that of the emulsion prepared by using gum acacia as standard emulsifying agent (Dluzewska et al. 2004, Chanamai et al. 2002, Coia et al. 1987, Quintana et al. 2002, Acedo-Carrillo et al. 2006).

Material and Methods

Materials

Chemicals used for tablet manufacturing and emulsification are calcium carbonate, lactose monohydrate, starch, magnesium stearate and gum acacia obtained from E. Merck (India) Ltd., Mumbai, India. Diclofenac sodium was procured from Macleods Pharma Ltd., Mumbai, India as gift sample.

Methods

Extraction of mucilage from Cordia obliqua

The flowering starts during the first week of February and fruits are available in the month of April to May. The fruits were collected from the tree *Cordia Obliqua,* willed., family Boraginaceae (Figure 7) in the month of April 2006 from Borigumma, Village of Koraput District (Orissa), India. The mucilage was expressed from fruit by tincture press. The tree was identified by Dr. M. S. Mondal, Joint Director Botonical Survey of India, Govt. of India, Central National Herbarium, Botanical Garden, Howrah, West Bengal, India. 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 carbohydrate (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 sulpheric acid, which gave violet ring at the junction of two layers. In case of the detection of reducing sugars to the cordia obliqua fruit mucilage, equal quantity of Fehling's solution A and B were added. After heating yellow colour precipitate was obtained (Whistler et al. 1993). The presence of tannin was tested upon treating the gum with ferric chloride solution. There was no black precipitation for tannin with ferric chloride solution.

The presence of mucilage was tested by treating the mucilage with ruthenium red solution and Banzidine solution (Trease 2002), formation of pink colour with Ruthenium red and blue colour with Benzidine solution indicate the presence of mucilage. To know whether the cordia obliqua mucilage contains the enzymes, it was treated with few drops of hydrogen peroxide, no blue colour formation (Trease 2002), indicate the absence of enzymes.

Determination of viscosity

The viscosity of the expressed mucilage was done by Brooke field viscometer (Martin et al. 1994) (Brook Field Engineering Labs. Inc. USA).

The viscosity found to be 489 cp or 4.89 poise. The solid content found to be 1% w/v of expressed mucilage (precipitated with 1% Hydrochloric acid or Ethanol.)

Emulsifying Characteristics

To study the emulsifying characteristics, 2ml of the gum (expressed liquid obtained from unripe fruit) was taken in a clean and dry mortar and pestle. The emulsification of castor oil, tried by wet gum method (Martin et al. 1987).

The oil was added to the gum drop by drop with continuous triturating until a white primary emulsion with clicking sound results. The addition of oil continued till a white cream was obtained. From the study it was found that the primary emulsion results at the oil: gum ratio of 1.5 : 1 v/v. Now the primary emulsion diluted to 20ml with distilled water and kept in a clean and tightly closed container for stability study for 6 months. No creaming or settling of emulsion results during 6 months of storage period at room

temperature, which indicate that the gum is very effective as emulsifying agent at low concentration in comparison to other gums.

Stability Studies of Emulsions

To standardize the emulsifying characteristics and stability of gum cordia with that of the gum acacia as standard emulsifier (Dluzewska et al. 2004, Chanamai et al. 2002) an aqueous emulsifier solution was prepared by dispersing 10% w/v of gum acacia (as standard) and stirred for 6h to ensure complete dissolution. A 10% v/v of castor oil (as model drug) in water emulsion was prepared by weighing 20ml castor oil and 200ml emulsifier solution into 1000cm^3 glass beaker and homogenized with the high speed mixer (Remi Type: RQ-122, Remi Motors, Mumbai, India) for 15 min with the velocity of 4000 rpm.

Similarly an aqueous emulsifier solution of gum cordia (1.5% w/v, as test) and a 10% v/v of castor oil – in – water emulsion was prepared by weighing 20ml castor oil and 200ml emulsifier solution into 1000cm^3 glass beaker and homogenized with the high speed mixer (Remi Type: RQ-122, Remi Motors, Mumbai, India) for 15 min with the velocity of 4000 rpm.

Micromeritic measurements of emulsion stability (Chanamai et al. 2002, Quintana et al. 2002)

The particle size distribution of the emulsions was measured using a laser light scattering instrument (Master Sizer, 2000, Malvern Instruments Ltd., Malvern, U.K.). The emulsions were diluted with distilled water prior to analysis so that the droplet concentration was less than about 0.02% w/v. The dilute emulsions were placed into the measurement cell of the instrument and each sample was analyzed 3 times and the data are presented as the average (Figure 1).

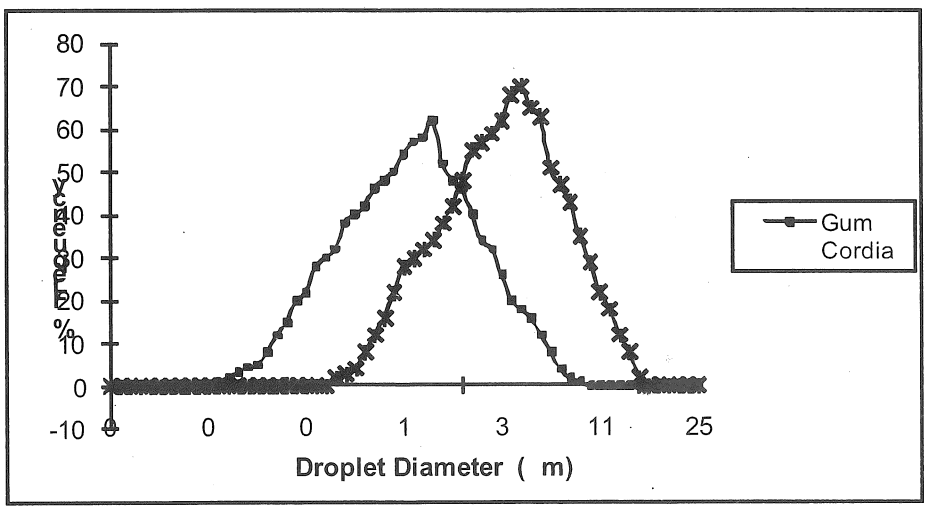

Figure 1. Droplet size distribution of emulsions stabilized by Gum cordia and Gum acacia

Zeta Potential measurements (Chanamai et al. 2002, Acedo-Carrillo et al. 2006)

The oil-in-water emulsions (0.01%v/v) were injected directly into the measurement chamber of particle electrophoresis instrument (Zetamaster, Malvern Ltd, U.K.) capable of measuring the zeta-potential of emulsion droplets of both castor oil emulsion prepared by using gum acacia(as standard for reference) and gum cordia (as test) as emulsifier. The zeta-potential measurements are reported as the average of 3 separate injections with 3 readings made per injection. The zeta potential of emulsion prepared by using 10% w/v of gum acacia is found to be -22.16 and the emulsion prepared by using 1.5%w/v of gum cordia is found to be -28.57.

Centrifugal method of evaluating emulsion stability (Dluzewska et al. 2004)

The samples of emulsion were placed in the test tube of centrifuge (Remi, C-24BL, Remi Instruments Ltd., Mumbai, India)controlled to temperature at 37 ^{0}C for 10 min with 3500 rpm.

The emulsion stability 'S' was determined from the formula: $S = [(V_0-V)/V_0] \times 100\%$. Where: S - emulsion stability %, V_0 – volume of emulsion undergo centrifugation cm^3, V- volume of the phase given off cm^3. No phase separation was observed in both cases of formulation, indicating 100% stability after centrifugation.

Viscosity measurement of emulsion stability (Coia et al. 1987, Quintana et al. 2002, Dluzewska et al. 2004 and Pravin et al. 2006)

The emulsions were stored at 37 ^{0}C for 12 week and the viscosity of the emulsions were measured by using Brook field viscometer (Brook field - DV-E, Viscometer, U.S.A.) at the interval of 0, 6 and 12 weeks (Table 1).

Turbidity measurement of emulsion stability (Dluzewska et al. 2004, and Pravin et al. 2006)

Every emulsion was diluted 1 part to 1000, prior to the absorbance measurements. The absorbance was taken at 400nm and 800nm, using U.V.- Vis Spectrophotometer (U-V-1700, Shimadzu, Japan). From the absorbance values the opacity was determined and the ratio of the absorbance at 800 to 400nm, the size index (R) and stability were predicted (Table 1).

Table 1. Stability Parameters of Emulsions.

Parameter		Emulsion with Gum Acacia			Emulsion with Gum Cordia		
Ratio		Oil : Gum : Water 10 : 10 : 100			Oil : Gum : Water 1.5 : 10 : 100		
Particulars		Day in weeks					
		Immediate	After 6 week	After 12 week	Immediate	After 6 week	After 12 week
Viscosity in CP		10.33 ± 0.57	10.66 ± 0.57	11.33 ± 0.57	8.0 ± 0.00	8.33 ± 0.57	9.33 ± 0.57
Turbidity of 1 in 1000 dilution	At 400 nm	0.450 ± 0.0010	0.462 ± 0.0011	0.476 ± 0.0010	0.430 ± 0.0010	0.436 ± 0.0010	0.443 ± 0.0012
	At 800 nm	0.170 ± 0.0010	0.178 ± 0.0010	0.185 ± 0.0010	0.160 ± 0.0016	0.175 ± 0.0012	0.177 ± 0.0012
Six index		0.376	0.385	0.388	0.371	0.401	0.399

Mean ± SD: Average of three readings.

Toxicity Study

To study the toxic effect (if any) of cordia obliqua mucilage, the toxicity study was conducted on 12 male Swiss Albino Rat with an average weight of 89–58gms. The animal experiments were conducted following the guideline of institutional animal ethics committee. The animals were housed in polypropylene cages at 25° ± 2°C / 60% relative humidity in normal day and night photo cycle. The animals were fastened for 12 h before oral administration of the solution. The animals were given 5 ml of mucilage orally and were monitored for 24 h (Mukherjee et al. 2006). The animals are then had free access to basal diet (Mukherjee et al. 1998) and continued administration of 5ml mucilage orally daily for 7 days and were observed for one month. No death or abnormal behavior was noticed.

FTIR Study

To study the gum and experimental tablet excipient interaction (Mukherjee, et al. 2005), the pure gum cordia oblique, a mixture of the gum cordia and experimental tablet excipients and the tablet excipients without gum cordia was mixed separately with IR grade KBR in the ration 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 pellets were scanned over a wave number of 4000 to 400 cm^{-1} in a FTIR instrument (Scimadzu Corporation, Kyoto, Japan). When spectrums were compared, it was found that there were no distinct changes in the available peaks of diclofenac sodium, excipients and gum cordia oblique. The distinct peaks of diclofenac sodium in Figure 4 (3255.95 cm^{-1}, 2538.41 cm^{-1}, 767.69 cm^{-1} and764.48 cm^{-1}) were retained in the spectrum of the physical mixture. The distinct peaks of excipient Fig. 3 (2920.32 cm^{-1}, 2850.88 cm^{-1}, 2511.4 cm^{-1}, 1795-79 cm^{-1}, 1537.32 cm^{-1}, 1471.74 cm^{-1} and 1168.9 cm^{-1}) were retained in the spectrum of physical mixture. Similarly on peak to peak matching in the region of 1700-

750 cm^{-1} of the spectrum of gum cordia obliqua (Figure 2 and Figure 5). It was concluded that there is no interaction between the drug, excipient and gum cordia obliqua.

However, there were some very minor changes in the wave numbers between 4000 and 2800cm^{-1} and between 1690-1620 cm^{-1}. Wave numbers between 4000 cm^{-1} and 2800 cm^{-1} are the stretching zone of C-H(alkanes) (3000-2850 cm^{-1}), C-H (Aromatic) (3100-3000 cm^{-1}), -OH (alcohol) (3720-3200 cm^{-1}), C-H (alkenes) (3100-3000 cm^{-1}), wave numbers between 1700-1850 cm^{-1} corresponds to stretching zone of C= O (carbonyl).

These functional groups are present in the materials like carbohydrates, starch, lactose and gum cordia. So there are possibilities of formation of some weak bonding like hydrogen bonding, Vander walls forces or dipole-dipole moment and these forces could help the molecules to adhere to each other and thereby, the gum cordia may provide binding effect with the other excipients present in the tablet.

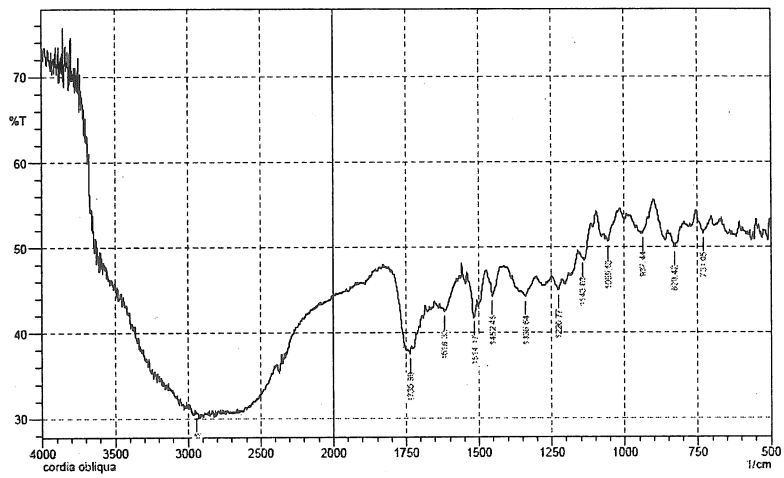

Figure 2. FTIR spectrum of *Gum cordial.*

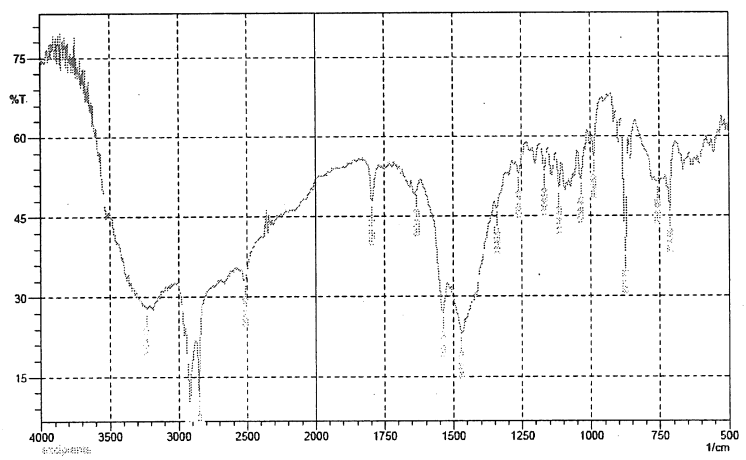

Figure 3. FTIR spectrum of excipients without *Gum cordial.*

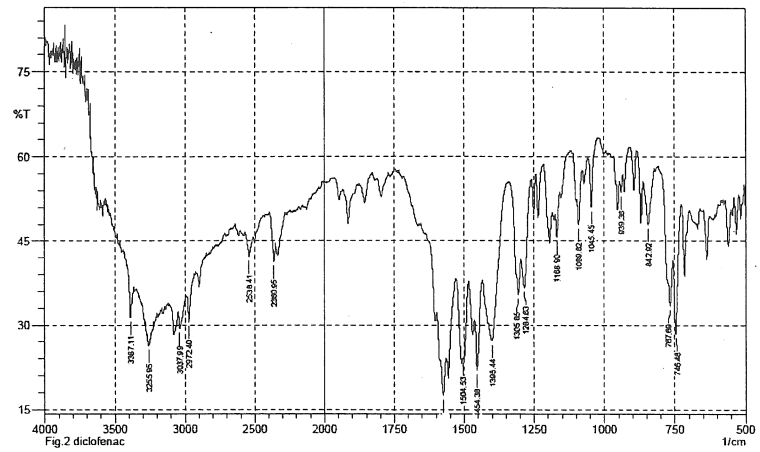

Figure 4. FTIR Spectrum of diclofenac sodium.

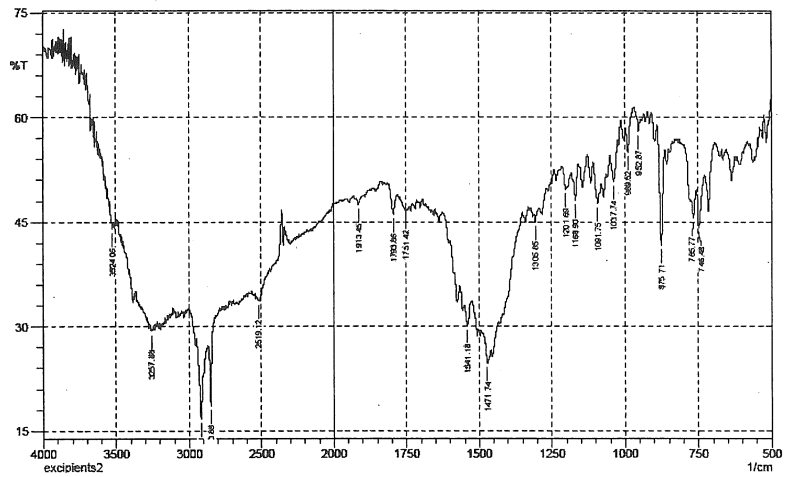

Figure 5. FTIR spectrum of Tablets excipients, *Gum cordia* along with diclofenac sodium.

Tablet formulation Development

Various tablet formulations were done by conventional technique using different concentrations of gum cordia. In short, wet granulation was done by using sieve No. 16. 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 no.16. Magnesium stearate (2% w/w) was mixed as lubricant. The tablets were compressed on a single punch (Cad Mack Ltd. Mumbai, India) tablet machine for each batch (Table 2, Figure 6)

Table 2. Experimental Tablet Formulations of With Composition.

Formulation	Starch I.P. (Dis-integrant)	Diclofenac Sodium (model drug)	Calcium carbonate (diluent)	Lactose (diluent)	Mag. Stearate (Lubricant)	Starch Paste (Binder)	Experimental cordia obliqua mucilage as binder	Remarks
F_0	1%	25%	25%	50%	2%	5%	--	Control
F_1	1%	25%	25%	50%	2%	--	0.1% v/w	Test
F_2	1%	25%	25%	50%	2%	--	0.2% v/w	Test
F_3	1%	25%	25%	50%	2%	--	0.3% v/w	Test
F_4	1%	25%	25%	50%	2%	--	0.5% v/w	Test

Hardness

Hardness study was conducted by following the guidelines of the USP-NF, 2002[18]. 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

The study of the tablet thickness was conducted by the following USP guidelines[18] (The USP-NF, 2002). For these fifteen tablets were taken for each batch and thickness were measured by using Digimatic caliper, Mitutoyo Corporation, Japan.

Friability

Friability testing (The USP-NF, 2002) 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 (USP-NF, 2002). 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 at 37±0.5°C by following USP guidelines[18] (The USP-NF, 2002).

Table 3. Various experimental parameters of the tablet formulations.

Formulation	Mean disintegration time (n = 6)	Test for friability (mean % weight loss) (n = 6)	Mean hardness (kg cm^{-2}) (n = 6)	Mean thickness testing (nm) (n = 10)	Average weight (gm) n = 20	Remarks
F_0	3 min	0.21	3.01 ± 0.04	5.30 ± 0.004	0.490 ± 0.009	Control
F_1	1 min	0.41	1.57 ± 0.12	5.35 ± 0.004	0.481 ± 0.007	Test
F_2	6 min	0.40	2.32 ± 0.30	5.30 ± 0.006	0.481 ± 0.005	Test
F_3	25 min	0.10	2.83 ± 0.12	5.29 ± 0.004	0.486 ± 0.008	Test
F_4	40 min	0.10	3.01 ± 0.04	5.24 ± 0.008	0.484 ± 0.007	Test

Data shown; mean ± SD (Standard deviation), n = no. of observations.

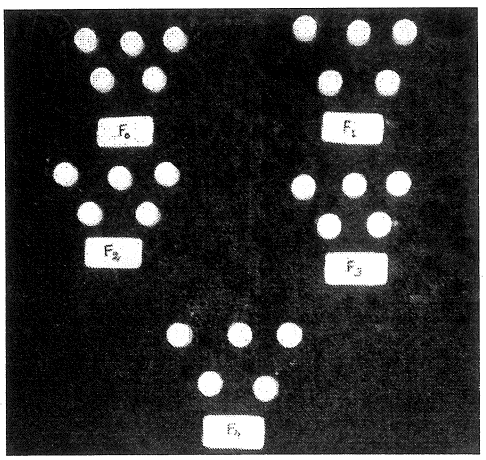

Figure 6. Tablets with different concentration of gum cordia and starch paste.

F_0 = Control, 5% starch paste, F_1 = Test, 0.1% v/w Gum Cordia, F_2 = Test, 0.1% v/w Gum Cordia, F_3 = Test, 0.5% v/w Gum Cordia, F_4 = Test, 0.5% v/w Gum Cordia

Results and Discussion

Upon various chemical tests for carbohydrate, the gum cordia showed the presence of carbohydrate in it. Formation of yellow colour precipitate on reduction of Fehling's solution indicate that the gum contains reducing sugar. The presence of carbohydrate was further substantiated with the positive result (formation of violet ring at the junction of α-naphthol in alcohol and concentrated sulfuric acid 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 cordia was also tested for the peroxidase enzyme which is commonly present in some gums like gum acacia. But the gum cordia showed the absence of the enzyme in it. Thus a chance of oxidative degradation due to gum cordia as excipient is eliminated as compared to gum acacia. Again the viscosity of the freshly expressed mucilage is found to be 489 cp or 4.89poise indicate that the mucilage is colloidal in nature following non-Newtonian bodies (Martin et al. 1994), which do not settle down quickly. The particle size distribution (Figure 1) indicate that both the emulsions stabilized by using gum acacia and gum cordia are within 1 to 10 μm ranges (Chanamai et al. 2002, Quintana et al. 2002).

The emulsion prepared by gum cordia results very fine particle size distribution in comparison to gum acacia and results in stable emulsion because of fine particle size. The zeta potential of the emulsion prepared by 1.5% w/v of gum cordia (test) and 10% w/v of gum acacia (standard for reference) are found to be – 28.57mv and – 22.16mv respectively. The – ve zeta potential indicate the electrostatic interactions between the droplets i.e. stearic repulsion resulting droplet dis-aggregation and formation of stable emulsion (Chanamai et al. 2002, Acedo-Carrillo et al. 2006).

The results of emulsion stability by centrifugal method indicate that there is no phase separation result even if with high rpm (3500) at 37^{0}C and the %ge stability was found to be 100% in both the cases indicating the formation of stable emulsion (Dluzewska et al. 2004). The stability parameters such as viscosity, turbidity and size index of both the emulsion stored at 37 ^{0}C for 12 week (Table 1) results that both the emulsions are stable because there is no such changes in their viscosity and turbidity found after 12 weeks (Coia et al. 1987, Quintana et al. 2002, Dluzewska et al. 2004 and Pravin et al. 2006). The emulsions prepared with 1.5%w/v of gum cordia (test) is more stable in comparison to that of the emulsion prepared by using 10%w/v of gum acacia (standard)

No death or abnormal behaviors were seen in animals both in short term (24 h, with a dose of 1gm kg^{-1} body weight) and one month toxicity studies. Moreover, this fruit has been traditionally used by the native people without reporting any toxic manifestations. 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 using sophisticated instrument like FTIR Spectroscope (Mukherjee et al. 2005).

In the present study, interactions between the gum cordia (natural gum) the other experimental tablet excipients and a model drug diclofenac sodium have been studied using FTIR spectra (Figure 5). Figure 1, depicts the FTIR spectrum of gum cordia, Figure 3, shows the spectrum of the tablet excipients without the gum cordia and Figure 4, and shows the spectrum of model drug diclofenac sodium. Figure 5, demonstrates the FTIR spectrum for tablet excipients along with gum cordia and model drug diclofenac sodium. After studying the toxicity, possible chemical composition and chemical-chemical interaction the gum was selected as tablet binder and tablets were formulated with various percentages (Table 2, Figure 6) of this gum. The standard starch paste was also used as binder to another batch as standard control (formulation

F_0). Formulation F_1 : (Table 3) disintegrated in one min, where as formulation F_2, F_3 and F_4 required 6 min, 25 min and 40 min respectively to disintegrate, which indicate that the concentration of gum increases, increase in disintegration time. When the findings were compared with the findings of formulation F_0, which contains 5% starch paste as binder, it was observed that the gum cordia has many folds binding capabilities in comparison to starch paste and gum cordia is capable of being used as a binder to provide desired hardness of 2.5 kg cm^{-2} and disintegration time about 6 min using just $1/25^{th}$ amount of starch paste. When the friability was considered, the maximum friability percentage of weight loss was detected in formulation F_1 containing 0.1% gum cordia. This was followed by the formulation F_2, F_3, F_4 and formulation F_0 (5% starch paste as binder), respectively.

Increasing percentage of gum cordia from 0.2% to 0.5% decreased the friability percentage. Average thickness did not vary much amongst the formulations. Again average weight variations in all the formulations were well within the pharmacopoeial limits 0f USP-2002. Thus it can be concluded that gum cordia can be a suitable and cheaper option as a tablet excipient in particular, as a tablet binder and emulsifier to provide a stable emulsion.

Conclusion

From the above experimental study it has been found that the gum cordia obtained from the fruit mucilage of the plant cordia obliqua is having a potential binding effect. It is effective in a very low concentration as compared to that of the standard binder (starch paste) used. While comparing the stability characteristics of emulsions prepared by gum cordia and that of the gum acacia it has been found that the emulsion prepared with 1.5%w/v of gum cordia is more effective in comparison to that of the emulsion prepared by using 10%w/v of gum acacia. The FTIR Spectroscopic study and toxicity study in animals says that the gum is non toxic and safe to use internally. Moreover as this plant is widely distributed in nature, fruits are eaten by the local tribes, available chiefly in India and many other countries and easily available option without destroying the natural sources as compared to that of the other available natural option will be one of the suitable options to utilize as pharmaceutical excipient.

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