ISSN:0975-542X

Cassia Roxburghii Seed Galactomannan-A Potential Binding Agent in the Tablet Formulation

M.R.Shivalingam*[1] K.S.G.Arul Kumaran[2], D.Jeslin[2],Y.V.Kishore Reddy[1], M.Tejaswini[1], Ch.MadhusudhanaRao[1], V.Tejopavan[1]

Department of Pharmaceutics, Victoria College of Pharmacy, Guntur, AndhraPradesh[1]

K.M.C.H.College of pharmacy, Coimbatore [2]

Abstract:

The present study involves isolation of gum from the seed of plant Cassia roxburghii by filteration and hot continuous percolation method then evaluated for its binding properties in the formulation of Paracetamol tablet containing 8%, 10% and 12% binding concentration. The binding properties of gum was evaluated in relation to conventional binder like guar gum, gelatin, Sod.CMC at different parameter like percentage of fines, tablet hardness, disintegration time, dissolution and friability and found that 8% binding concentration of both gum shows superior binding properties when compared to the other binders. Further study shows that increase in binding concentration of filtered and defatted ***C. roxburghii*** gum from 8% to 12%; decrease the percentage of fine, increase the hardness, increase the disintegration time, decrease the percentage of friability and decrease % cumulative release. The binder-excipients interaction study was also carried out by using FTIR i.e. by KBr pellet method which showed that *C. roxburghii* gum is compatible with drug and all excipients in the formulation. Results indicate that Paracetamol tablets prepared with 8 % of mucilage were found to be ideal for the preparation of uncoated tablet formulation.

Key words: Cassia roxburghii, Binding concentration, Conventional binders, Precompression

Introduction: [1, 5]

Plant gums and mucilage widely have been used in various industries like paper, textile, food, ink, cosmetics, petroleum and frequently used in pharmaceuticals as thickening, binding, emulsifying, suspending, stabilizing agents and coating materials in micro encapsulation. In view of importance of binders in pharmaceuticals for the manufacture of tablets and capsules, ***Cassia.roxburghii*** seed gum was undertaken to evaluate its binding properties through assessment of various parameters essential for pharmaceutical formulation.

Materials and Methods:

Collection of seeds

C. roxburghii seeds, *M.oleifera* gum were collected from Tamil University, Thanjavur, and the same was authenticated by G. V. S. Moorthy, Botanical Survey of India (BSI), Southern circle, Coimbatore, Tamil Nadu.

Collection of Drug

Paracetamol was received as gift sample from Tablets India Ltd, Chennai. All other ingredients used were of analytical grade.

Isolation of seed gum [6, 7]

The seeds of *C. roxburghii* were coarsely powdered, defatted by soxhlet extraction using petroleum ether (60-80^0 C).Then extracted mucilage was precipitated with acetone and freeze dried to get fine gum powder. Yield was found to be 24%.

Filtered gum

C. roxburghii seed powder was soaked in sufficient water kept over boiling water bath for 30 min. with occasional stirring, left overnight and filter using muslin cloth and precipitated with acetone. Then the mucilage obtained was freeze dried to get gum powder. Yield was found to be 26%.

Preparation of standard calibration curve for Paracetamol

A Stock solution of 1mg/ml of Paracetamol was prepared by dissolving 100mg of drug in 100ml of phosphate buffer (pH 7.4) and working standard namely 10, 20, 30, 40, 50 microgram/ml were prepared by appropriate dilution and y max of Paracetamol solutions were obtained in UV region. The absorbances of solutions were measured at respective y max and a calibration curve was developed by plotting concentration on x axis and absorbance on y axis. The absorbance of the different diluted solutions were measured in a UV spectrophotometer at 257nm (Fig 1)

Table-1: **Precompression parameters**

Binding Concentration									
PARAMETERS	**8%**			**10%**			**12%**		
Formulation	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Bulk Density (g/cc)	0.41	0.42	0.44	0.47	0.46	0.47	0.47	0.47	0.46
Tapped Density (g/cc)	0.40	0.48	0.42	0.57	0.54	0.56	0.52	0.53	0.52
Angle of Repose (θ)	20.22	25.10	24.89	23.79	23.52	24.90	22.86	26.22	23.7

Table-3: Formulations

F1	Paracetamol formulation with 8% *C. rox*. Filtered seed gum.
F2	Paracetamol formulation with 8% *C. rox*. Defatted seed gum.
F3	Paracetamol formulation with 8% Gelatin.
F4	Paracetamol formulation with 8% Guar gum.
F5	Paracetamol formulation with 8% SCMC
F6	Paracetamol formulation with 10% *C. rox*. Filtered seed gum.
F7	Paracetamol formulation with 10% *C. rox*. Defatted seed gum
F8	Paracetamol formulation with 12% *C. rox*. Filtered seed gum.
F9	Paracetamol formulation with 12% *C. rox*. Defatted seed gum.

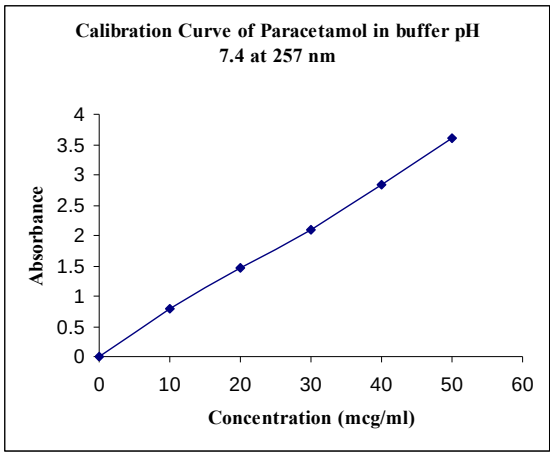

Fig 1: **Calibration curve for Paracetamol**

Precompression parameters of the Paracetamol formulations[3, 4]

Bulk Density, Tapped density, Angle of repose, was determined for Paracetamol granules prepared by using various binders with different binding concentrations**.** (Table 1)

Bulk Density (Db)

25 gm of granules were introduced into a clean, dry 100 ml measuring cylinder and

Table-4: Post formulation study of Paracetamol formulations

Parameters	F1	F2	F3	F4	F5	F6	F7	F8	F9
% of Fines	6.12	6.22	6.18	6.54	6.43	5.7	5.82	5.6	5.80
Hardness (kg/cm2)	5.98	5.73	5.92	5.16	5.3	6.5	6.13	6.50	6.23
Friability %	0.66	0.82	0.71	0.91	0.96	0.4	0.57	0.3	0.40
Weight variation(mg)	604±3.89	607±4.76	608±3.10	607±2.67	605±3.56	607±3.99	510±5.76	507±4.76	515±3.76
Thickness (mm)	4.2	4.3	4.1	4.2	4.4	4.2	4.2	4.2	4.1
Disintegrations (min.)	12.20	11.98	12.08	9.34	9.02	13.92	13.05	14.45	13.50

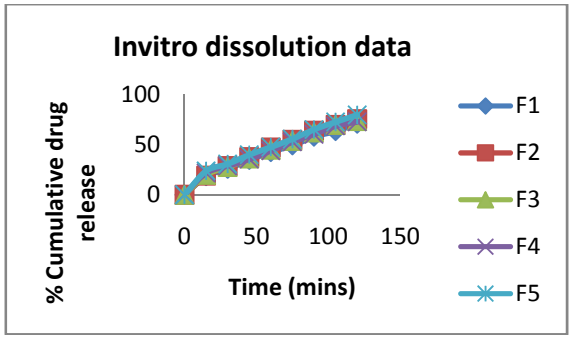

Fig-2: Invitro dissolution graphs for Paracetamol formulations

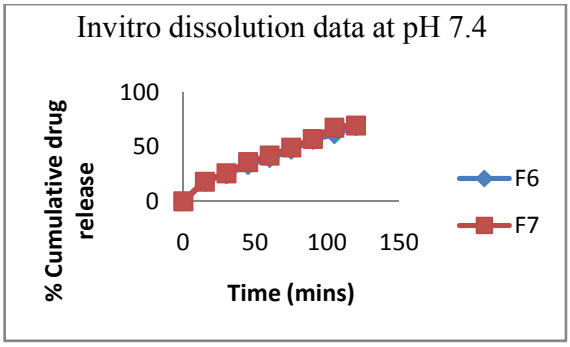

Fig-3

the volume was recorded. It is expressed in gm/ml and is given by, Db = M/Vo
Where M is the mass of the powder.
Vo is the bulk volume of the powder

Tapped density (Dt)

25 gm of granules were introduced into a clean, dry 100 ml measuring cylinder. The cylinder was then tapped 2500 times from a constant height and the tapped volume was read. It is expressed in gm/ml and is given by Dt = M/Vt
Where, M is the mass of the powder.
Vt is the tapped volume of the powder.

Angle of repose

The fixed funnel method was employed for determining the angle of repose. The granules were poured carefully until the apex of the conical pile just touches the tip of the stem of the funnel. The angle of repose was calculated using the equation,
$\theta = \tan^{-1}$ (h/r)
Where, θ is the angle of repose, h is the height of the pile in cm, r is the radius of the base of the conical pile.

Method of formulation [8]

Paracetamol tablets (500mg) were prepared by wet granulation method, by using *C. Roxburghii* filtered gum, *and C.rox* defatted gum**,** Sod.CMC, Guar gum**,** Gelatin**,** as binding agents**.** The Compression process was performed by using twelth station rotary tablet punching machine (punch size 12/32). Various formulations are mentioned in (Table 2)

Post formulation study of Paracetamol formulations [2, 3, 4]

The formulated tablets were evaluated for the following parameter such as % fines, hardness test, friability, weight variation, thickness, disintegration. (Table 3)

Invitro dissolution studies[9]

This study was crried out by USP XIX Dissolution rate test apparatus which is rotated at a speed of 50 rpm with medium 900 ml Phosphate buffer (pH 7.4) maintained at temperature 37±0.5°C. Samples (1ml) were withdrawn at pre determined time interval and the same volume was replaced immediately to maintain sink condition. The study was run for 2 hours with the above fixed parameters. The withdrawn samples were suitably diluted and the absorbance of the solution was determined at specified wavelength of 257nm. and results were recorded.(Fig 2 -4)

Characterization of Paracetamol formulation by Fourier transfer Infrared spectroscopy *(FTIR)* [10]

Fourier transform IR spectra were recorded on FT/IR-4100 type A. The spectra were recorded for Paracetamol, C. *roxburghii* gum and Paracetamol formulation made with the same gum. Samples were prepared in KBr disc (2 mg sample in 200 mg KBr).The scanning range was 400-4000 cm-1, resolution was 4 cm-1**.** (Fig 5-7)

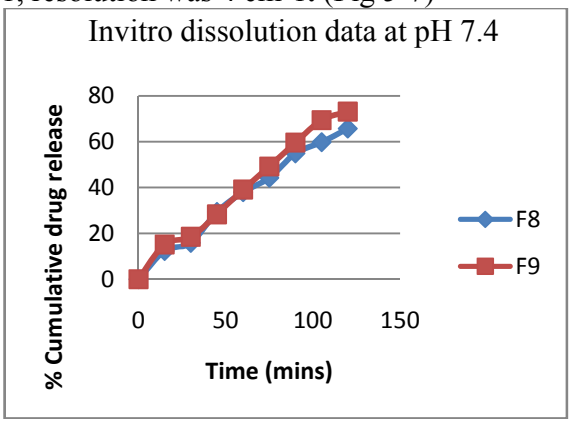

Fig-4

Results and Discussion:

The precompression parameters like Bulk density, Tapped density, Angle of repose were performed and results showed that all the formulations were well with in the official limits.

Different batches of 500mg conventional Paracetamol tablets having 8% of binders like *C. roxburghii* defatted gum,*C. roxburghii* filtered seed gum, sodium carboxy methyl cellulose, guar gum, gelatin were prepared by wet granulation method. Tablets prepared were evaluated for % of fines, weight variation, hardness, friability,

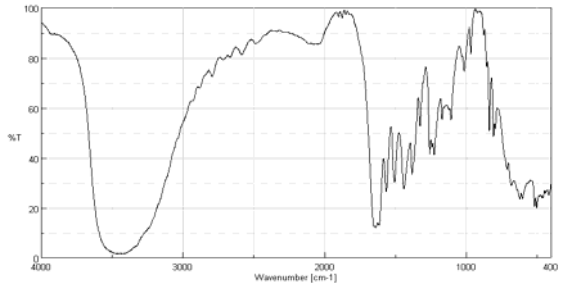

Fig 5: FTIR Spectra for Paracetamol

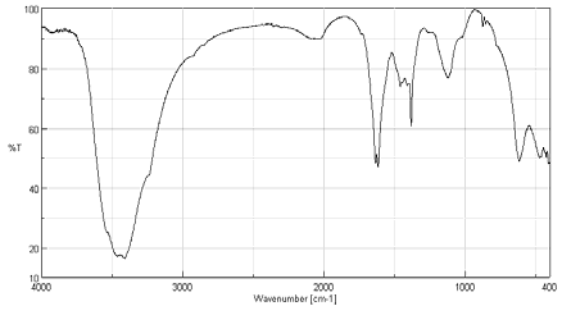

Fig 6: Spectra for *C.Rox* Gum

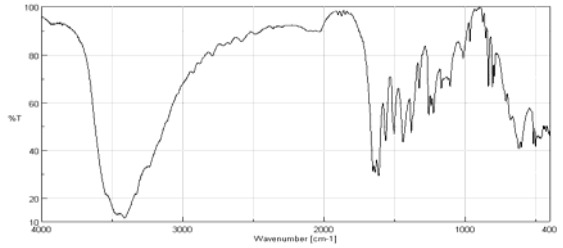

Fig 7: FTIR Spectra for formulation with *c.rox* gum

thickness, disintegration time. Based on preformulation, post formulation studies F1 was selected and taken to study the effect of increasing binding concentration on Paracetamol tablet formulation. It has been observed that increase in the concentration of binders from 8% to 12% effectively changes the binding characteristic of the tablets. Results obtained from the dissolution study of Paracetamol tablets using 8% of all binders like *C. roxburghii* filtered gum, defatted *C. roxburghii* gum, gelatin, SCMC, and guar gum, drug release post 2 hour were shown in the Fig 1. Filtered *C. roxburghii* gum, as a binder shows less release as compared to the other binders. Increase in the concentration from 8% to 12% of *C.rox* filtered, *C. roxburghii* defatted gum, decreases the drug release. There was no observation of extra peak in FTIR spectra (Fig 3). It showed that there was no physical interaction of the excipients with active ingredient

Summary and Conclusion:

From the present study it can be concluded that *Cassia roxburghii* seed gum (8%) may be used as a binding agent in the conventional tablet formulation when high mechanical strength is more essential. From the *invitro* release study it can be concluded that *C.rox* gum can also be used to formulate sustained release by increasing the binding concentration of the formulation. Since *C.rox* gum displayed good tabletting characteristics have greater potentialities to become the new source of gums and could also be exploited for the commercial production of gums.

References:

[1] Mahesh V.Chaubal, Excipient development for Pharmaceutical, Biotechnology and
[2] Drug delivery system, Edited by Ashok Katdare, 2006, p. 109-124
[3] Mehta, R.M., Text book of Pharmaceutics. P.226-253.
[4] Leon, L., Liberman, H. A., and Kanig, J.L., The Theory and Practice of Industrial
[5] Pharmacy. 3rd Edition: p.293-345.
[6] Liberman, H. A., Leon, L., and Joseph, B. S., Text book of Pharmaceutical Dosage forms : Tablets., 2nd Edition., Vol. 1, p. 75-130
[7] Wade, A., and Walker, P.J., Handbook of Pharmaceutical excipient, 2nd Edition. London., 1994: p. 51-72
[8] Tausif M., Malhotra, A.K., and Kapoor, V.P., I J Pharma sci., 1992; 54(6): p. 234-240
[9] Kulkarni, G.T., Gowthamarajan, K., Brahmaji, G., and Suresh, B., Evaluation of binding properties of selected natural macilages., J. scientific & industrial research., ISSN 0022-4456 CODEN JSIRAC: 2002, vol. 61: p. 529-532
[10] Kohli, D.P.S., and Shah, D.H., 3rd Edition. Drug formulations manual. p. 78.
[11] Indian Pharmacopoeia 1985., Vol II., 734-736., A 80-82
[12] Areevath, J., Munday, L.D., Cox, J.P., and Khan. A.K., Release characteristic of Diclofenac sodium from encapsulated natural gum mini matrix formulation; Int J Pharmaceutics., 1996: Vol.139: (1-2), p. 53-62.