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Research Article

EVALUATION OF MUCILAGE OF *PROSOPIS JULIFLORA* AS TABLET BINDER

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ABSTRACT

The aim of the present study was to isolate the hydrophilic mucilage from the seeds of *Prosopis juliflora* (Mimosaceae) and study the potential of mucilage in tablet formulation as a binder. The DSC thermogram of the drug, drug-mucilage mixture indicates no chemical interactions. The tablet formulations of PJ I, PJ II, PJ III, PJ IV and PJ V were prepared by using 2%, 4%, 6%, 8% and 10% of mucilage, using lactose as diluents, Diclofenac sodium as a model drug and 2% of talc and magnesium stearate used as a glidant and lubricant respectively. The granules were prepared by wet granulation technique and evaluated the granules properties like flow rate, Carr index, Hausner ration and angle of repose were studied and compared with starch which was used as standard binder at 10% concentration. The tablets were compressed and evaluate the various parameters of weight variations, hardness, friability, disintegration and *in-vitro* dissolution. The result shows that the granules having the excellent flow property and tablet prepared using 8 and 10 % of mucilage shows drug release over a period of 5 h and it exhibits more hardness than other formulations.

Keywords: *Prosopis juliflora,* mucilage, binding property, Mimosaceae.

INTRODUCTION

Tablet is most widely used dosage form because of its convenience in terms of self administration, compactness and ease in manufacturing. The choice of the binding agent depends on the binding force required to form granules and its compatibility with the other ingredients particularly their active drug [1]. There are several reports about the successful use of hydrophilic polymers derived from plant, locust bean gum, karaya, guar and xanthin gum in pharmaceutical preparations [2].

Moringa oleifera gum has been evaluated for its binding properties [3], *plantago ovata* and *Trigonella foenum* graecum mucilage has been evaluated for its binding properties [4]. Guar gum has been investigated for its colon specific dosage forms gum of the tree *moringa oleifera* been reported to have gel forming potential for topical application [5]. Gum odina have been evaluated for its binding property [6]. *Plantago ovata* mucilage has been evaluated in fast disintegrating tablet [7]. *Cassia tora* have been evaluated as a binder [8]. The present work was carried out to study the binding property of *Prosopis juliflora* (PJ) mucilage in tablet formulation Diclofenac sodium was used as a model drug.

MATERIALS AND METHODS

The plant seeds of *Prosopis juliflora (SW) DC* were collected from surrounding area of Ramanathapuram District, Tamil Nadu, India. The collected plant was authenticated by Botanical survey of India, Coimbatore, Tamil Nadu, voucher specimen BSI/Sc/5/23/07-08/Tech-377. Diclofenac sodium was obtained from Microlabs, Houser, as a gifted sample, Lactose obtained from Moly chem, Mumbai. All other materials used in the study were of analytical grade.

Isolation of mucilage

The seeds of *Prosopis juliflora* (100 g) were soaked in distilled water for 24 h, boiled for 1 h and kept aside for 2 h to release mucilage in to water. The material was squeezed in a muslin bag to remove the marc from the filtrate. Then, equal volume of acetone was added to filtrate to precipitate the mucilage. The mucilage was separated, dried in oven at temperature less than 50°, powdered and passed through sieve number 80. The powder was stored in desiccator until further use [1, 9].

Differential scanning colorimetry

The DSC curve of Diclofenac sodium and mixture of mucilage/Diclofenac sodium were generated by differential scanning colorimeter (Mettler Toledo DSC 821, Switzerland.) at heating rate of 10°/min from 0 – 300 ° under nitrogen atmosphere.

Preparation of the granules

All the materials were passed through a mesh sieve with aperture of 250 µm before use. The tablets were prepared by wet granulation method. The compositions of tablets were given in table 1. Diclofenac sodium and lactose was thoroughly mixed and the solution of the mucilage of specified concentration was prepared by dispersing the mucilage in water. The mucilage solutions were used for moistening the powder mixture, for preparing tablets to evaluate the binding potential. The wet mass was then passed through sieve no. 16 and dried at temperature not exceeding 50° in a hot air oven for 30 min. The dried granules were rescreened through a sieve no 20. The same method was followed in the preparation of standard formulation (ST I) using starch mucilage 10% w/w concentration as a binder.

Table 1: Composition of Tablets Containing *Prosopis Juliflora* Mucilage as Binder

Ingredents	PJ I	PJ II	PJ III	PJ IV	PJ V	ST I
Diclofenac Sodium	50 mg	50 mg	50 mg	50 mg	50 mg	50 mg
P J mucilage	2%	4%	6%	8%	10%	_
Starch Mucilage	_	_	_	_	_	10%
Talc	2%	2%	2%	2%	2%	2%
Magnesium Stearate	2%	2%	2%	2%	2%	2%
Lactose	q.s	q.s	q.s	q.s	q.s	q.s
Total Weight	220mg	220mg	220 mg	220 mg	220mg	220mg

The granules were evaluated for their particle size, the particle size were estimated by sieving method, sieves were arranged in a nest with coarsest at the top a sample of 15 g of the granules were placed on the top sieve. The sieve set were fixed and shaken for a sudden

period of time (20 min) the granule retained on the each sieves were weighed. Frequently, the granules were assigned the mesh number of the screen through which it passed or on which it was retained. It was expressed in terms of arithmetic mean of the two sieves.The flow properties of granules evaluated by the flow rate through a funnel, the compressibility index and Hausner ratio was determined. Using the glass funnel specified in the European Pharmacopoeia III the flow rate (g/s) was calculated from the time needed for the entire sample (40 g) to empty from the funnel.

The bulk density was calculated by 15 g of granules were introduced in to a 100 ml measuring graduated cylinder. The cylinder was fixed on the bulk density apparatus and the timer knob was set for 100 tapings. Then noted the volume continued another 50 tapings and noted the final volume. This volume was noted as bulk volume. Based on the bulk and tap density both the Carr index (%) [(Tapped – Bulk) X 100/Tapped] and Hausner ratio (tapped/bulk) were calculated.

Angle of repose was determined by fixed funnel method [10]. Funnel with the end of the stem cut perpendicular to the axis of symmetry was secured with its tip at a given height (H) above a graph paper placed on a flat horizontal surface. The material was carefully poured through the funnel until at apex of the conical pile so formed just touches the tip of the funnel. The mean diameter (2R) of the base of the powder cone was determined and the tangent of the angle of repose is given by tan α = H/R, where α is the angle of repose. All the results were compared with the standard formulation (ST-I).

Production of tablets

The granules were lubricated with 2% w/w Talc and 2% w/w magnesium stearate and compressed to tablets of diameter of 6 mm weighing 220 mg using (Cadmach Single Punch machine)

Tablet properties

Twenty tablets were selected at random and weighed individually the individual weights are compared with the average weight for determination of weight variation. Hardness and friability of the tablet were determined by using Monsanto hardness tester and Roche Friabilator USP at 25 rpm for 4 min, respectively. The disintegration test was performed in disintegration apparatus (Model ED-2 Electro Lab, Mumbai) using water (900 ml as a medium at 37°. The disintegration times reported are average of six determinations.

***In-vitro* dissolution study**

In vitro release of Diclofenac sodium from the tablet formulation was carried out by basket method of dissolution described in U.S.P on USP XXI LAB INDIA eight spindle Dissolution Apparatus. Using 900 ml of phosphate buffer (pH 6.8) at a temperature of 37° ± 0.5° and basket rotation was set for 50 rpm. 5 ml of sample was withdrawn from the dissolution media at predetermined time interval (every 30 min) and same volume of fresh medium was replaced immediately over a period of 5 h. Collected samples were filtered and diluted with phosphate buffer pH 6.8 blank made up to 10 ml (2 fold), and the absorbance was measured at 276 nm by using ELICO SL 164 double beam spectrophotometer. Cumulative percentage release of the drug was calculated. The study was performed in triplicate. The standard error of the means of the triplicate points was determined.

Statistical analysis

The cumulative percentage releases of Diclofenac sodium from tablets were calculated their statistical significance was tested using student's t-test. A value of $p<0.05$ was considered statistically significant.

RESULTS AND DISCUSSION

DSC thermograms of Diclofenac Sodium and mixture are depicted in figs 1 and 2 respectively. The thermogram of the pure drug exhibited a sharp endothermic peak at 161.82° corresponding to its melting point, The DSC thermograms of drug mixture showed identical peaks corresponding to pure drug indicated the absence of well defined chemical interaction between the drug and the mucilage.

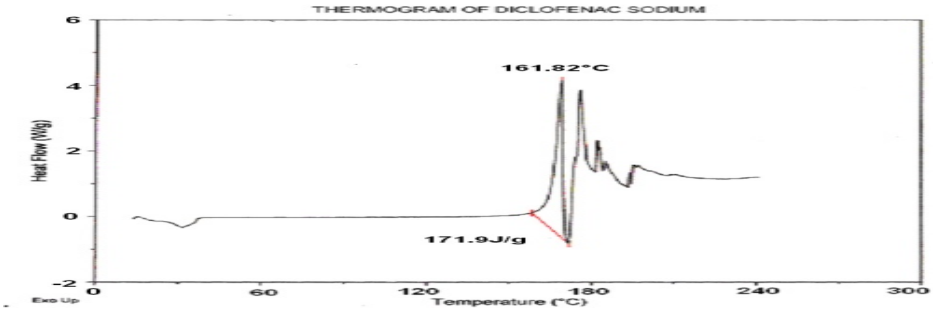

Fig. 1: DSC thermograms of Diclofenac sodium exhibiting a sharp endothermic peak at 161.82^0

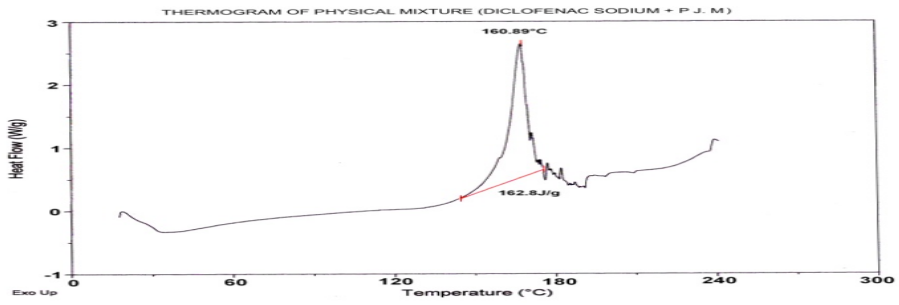

Fig. 2: DSC thermograms of physical mixture of Diclofenac sodium and *Prosopis juliflora* mucilage exhibiting a sharp endothermic peak at 160.89^0

The granules prepared were evaluated for mean particle size (µm), tapped bulk density, loose bulk density, flow rate, Carr index (%), Hausner ratio and angle of repose. Flow properties of the granules were determined as good flow ability is prerequisite for the preparation of the tablets with an acceptable weight variation. For all the formulations the flow rate of the granules between 6-8 g/s. all the formulations tested had a Carr index ranging between 11.7 and 12.9% while their Hausner ratio was below 1.25. The mean particle size was found to be satisfactory for preparation of tablets. The angle of repose was found to be between 20-23°. Hence, all granules exhibited good flow property. The results are shown in table 2.

Physical characteristics such as mean particle size, tapped bulk density, loose bulk density, flow rate, Carr index, Hausner ratio and angle of repose of prepared granules using different concentration of binder. Each value is mean of three observations.

Table 2: Evaluation of the granules

Properties	PJ I	PJ II	PJ III	PJ IV	PJ V	ST I
Mean particle size(µm)	359.5	356.81	362.56	360.21	355.67	380.74
Tapped bulk density g/cm^3	0.618	0.601	0.619	0.622	0.608	0.631
Loose bulk density g/cm^3	0.524	0.529	0.524	0.517	0.502	0.526
Flow rate (g/s)	7.2	7.9	6.7	7.4	7.6	7.1
Carr index (%)	12.3	11.8	12.8	11.7	12.7	12.9
Hausner ratio	1.16	1.08	1.14	1.07	1.09	1.08
Angle of repose	21°14’	20°17’	22°16’	20°26’	21°19’	22°24’

Six batches of tablets were prepared using mucilage at 5 different concentrations. Starch mucilage (10% concentration) was used as standard binder for comparison. The prepared tablets were evaluated for weight variation, hardness, friability, disintegration time and *in-vitro* dissolution profiles.

All the formulations had coefficient of variation values of less than 3% release to their mean weight. The hardness of the tablet varies between 3 – 7 kg/cm^2. The hardness of the tablets increased with increase in percentage of binding agent. The tablets prepared with 10% of starch mucilage (ST I) showed equal hardness when compared to formulation PJ IV and PJ V but the formulation PJ I, PJ II and PJ III have less hardness as compared to formulations (ST I) have enough hardness to withstand the mechanical shocks of handling in manufacturing by packing.

The friability values were decrease with increase binder concentration of isolated *Prosopis juliflora* seed mucilage. But overall friability values were less than specified limits. This demonstrated the effectiveness of the gum to use as binder. The disintegration time of the tablet varied between 2-4 min. The disintegration time increase the concentration of binder, but all the values were within the pharmacopeial limits. At 8% and 10% concentration, the disintegration time was higher for tablets prepared with 2%, 4% and 6% mucilage and equal to standard formulations as 10% starch mucilage used as a binder. The results are shown in table- 3.

Table 3: Evaluation of the granules

Formulations	Hardness	Friability (%)	Weight variation (%)	Disintegration time (min)
PJ I	3.79±0.1287	0.5108±0.03	221.85±2.41	2min, 45s
PJ II	4.83±0.1494	0.3630±0.06	221.35±2.81	3min, 23s
PJ III	5.48±0.1932	0.2289±0.04	219.15±1.89	3min, 33s
PJ IV	6.17±0.1494	0.2797±0.02	219.60±2.87	4min, 21s
PJ V	6.73±0.2163	0.2141±0.07	220.00±2.59	4min, 35s
ST I	6.57±0.1494	0.2092±0.03	220.37±2.42	4min, 14s

Physical characteristics such hardness, friability, weight variation and disintegration time of prepared tablets using different concentration of binder. Each value is mean of three observations.

The *in-vitro* dissolution profile is shown in fig -3. This study showed that the drug release was found to decrease with increase in concentration of mucilage. The formulation PJ IV and PJ V releases 90% of the drug over a period of 4 h but formulation PJ I, PJ II and PJ III releases 90% of drug over a period of 3 h. The release profile of PJ II and PJ III showed almost similar release profile as that of standard 10 % starch paste. The higher concentration mucilage retards the drug release by producing a sticky film of hydration on the surface.

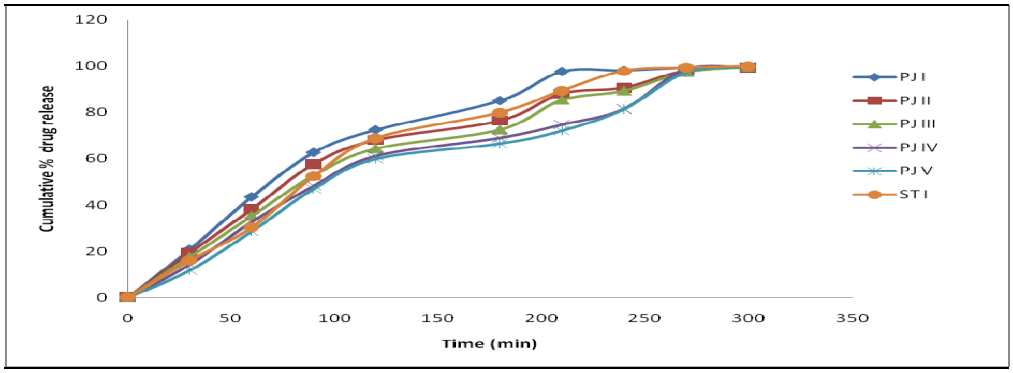

Fig. 3: Comparative *In-Vitro* dissolution study of *Prosopis juliflora* mucilage and 10% starch as a binder

Dissolution profile of Diclofenac sodium from Standard starch (ST I) and Natural gum formulations (PJ I, PJ II, PJIII, PJ IV, and PJ V) in phosphate buffer pH6.8. Each value is a mean of three determinations.

The mucilage used in the present study namely *Prosopis juliflora* exhibited good binding properties. For uncoated tablets 4 and 6% concentration can be used. Since the tablet produced a sticky film of hydration on the surface, which reduce the drug release rate. This mucilage can also be used for sustaining the drug release from tablets.

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