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Original Article

Development and evaluation of sesbania grandiflora linn seed mucilage as a tablet binder

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Abstract

The aim of the present study was to isolate the hydrophilic mucilage from the seeds of *Sesbenia Grandiflora* (Leguminosae) 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 SG I, SG II, SG III, SG IV and SG 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 ratio 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: *Sesbenia Grandiflora,* Hydrophilic mucilage, Granulation technique, Starch

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1. Introduction

The most commonly used dosage form for pharmaceutical preparations is currently the tablet, available in various forms and administered orally. The advantages of this dosage form are manifold: tablets are cost effective to manufacture, convenient to dispense and store, and easy for the patient to administer. Release of drug from the tablet can be controlled by altering the design

and content of the formulation [1]. There are several reports about the successful use of hydrophilic polymers derived from plants, locust bean gum, karaya, guar and xanthin gum in pharmaceutical preparations [2].

Plantago ovate, Trigonella foenum graecum, and *Moringa oleifera* gum mucilage has been evaluated for its binding properties [3, 4]. Gum odina have been evaluated for its binding property [5]. 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 [6]. *Cassia tora* have been evaluated as a binder [7]. *Plantago ovata* mucilage has been evaluated in fast disintegrating tablet [8]. The present work was carried out to study the binding property of *Sesbenia grandiflora* mucilage in tablet formulation and Diclofenac sodium was used as a model drug.

2. Materials and Methods

Seed of *Sesbania grandiflora* was collected from Vaizapur, Dist. Aurangabad (M.S.), India in the month of November. Seeds were polished by ethanol. The collected seeds were authenticated by botanist, Mrs. Kalpana Vijay Wagh, Lecturer in Botany, Bhaskaracharya Science College, Renuka Mata Mandir, Beed-by-pass road, Satara parisar, Aurangabad (M.S.), India. Diclofenac sodium and Lactose obtained from Shreya Ltd., Aurangabad (M.S.), India. All other materials used in the study were of analytical grade.

Isolation of mucilage

The seeds of *Sesbenia grandiflora* (50g) 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 [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 10o/min from 0 – 300^{o} 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 50o 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 (STD) using starch mucilage 10% w/w concentration as a binder.

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Table No.1 Composition of tablets containing *Sesbania grandiflora* seeds mucilage as binder.

Sr. No.	Ingredients	SG1	SG2	SG3	SG4	SG5	STD
1	Diclofenac sodium	50	50	50	50	50	50
2	*Sesbenia grandiflora* Mucilage	2%	4%	6%	8%	10%	-
3	Starch Mucilage	-	-	-	-	-	10%
4	Magnesium stearate	2%	2%	2%	2%	2%	2%
5	Talc	2%	2%	2%	2%	2%	2%
6	Lactose	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
	TOTAL	250 mg	250 mg	250 mg	250 mg	250 mg	250 mg

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 also 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 and continued for another 50 tapings and noted the final volume. This volume was noted as bulk volume. Based on the bulk and tap density, the Carr index (%) [(Tapped – Bulk) X 100/Tapped] and Hausner ratio (tapped/bulk) were calculated.

Angle of repose was determined by fixed funnel method. 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 $\tan \alpha = H/R$, where α is the angle of repose. All the results were compared with the standard formulation (STD) [10].

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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 (Erweka single station tablet minipress).

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 TDT Electro Lab, Mumbai) using water (900 ml as a medium at 37^{o}C. 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 USP on six spindle Dissolution Apparatus. Using 900 ml of phosphate buffer (pH 6.8) at a temperature of 37^{o}C ± 0.5^{o}C and basket rotation was set for 50 rpm. The 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 U.V. 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.

3. Results and Discussion

DSC thermogram 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 o 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.

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 7.1-7.9 g/s. All the formulations tested had a Carr index ranging between 11.7 and 12.9 %, while their Hausner ratio was below 1.06. The mean particle size was found to be satisfactory for preparation of tablets. The angle of repose was found to be between 20^{0}16'-22^{o}24. Hence, all granules exhibited good flow property. The results are shown in Table No.2.

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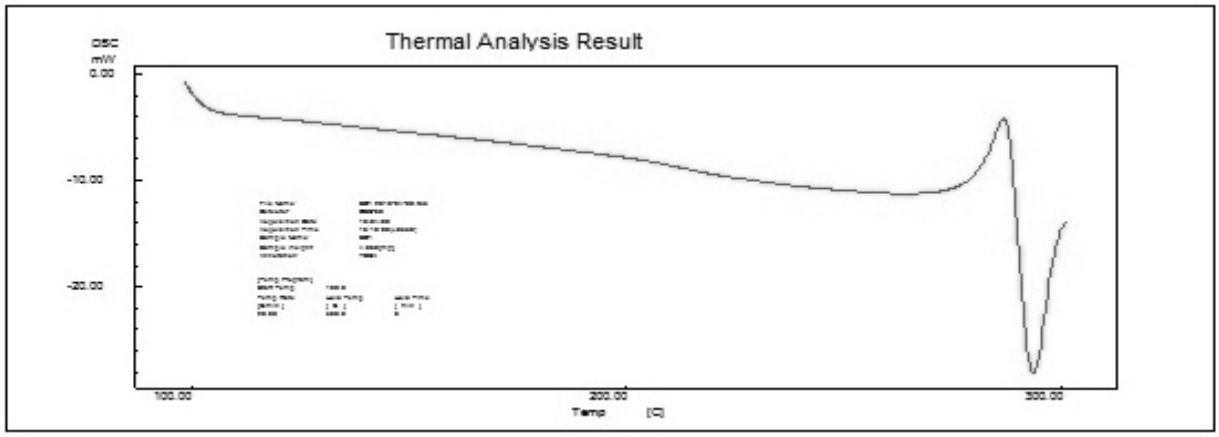

Figure No. 1: DSC thermograms of Diclofenac sodium exhibiting a sharp endothermic peak at 286-290^0 C.

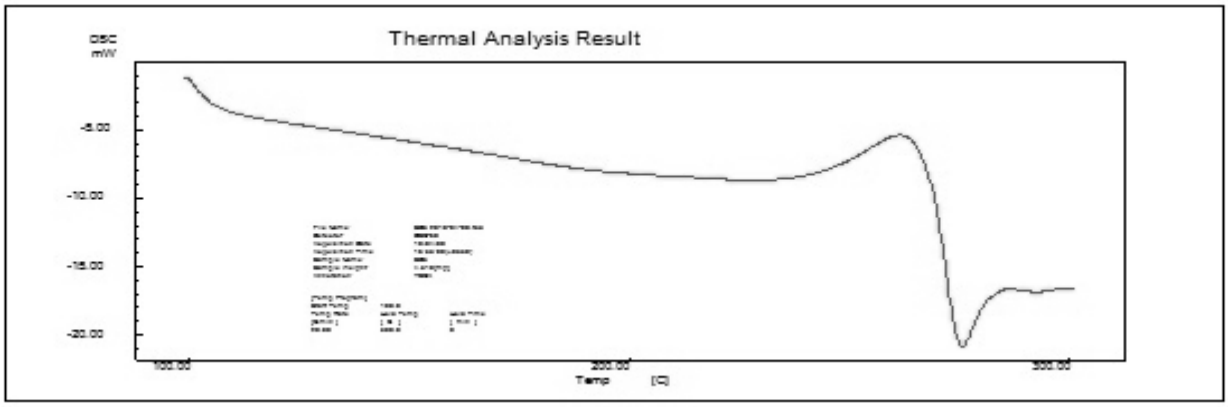

Figure No. 2: DSC thermogram of Diclofenac sodium + *Sesbania grandiflora* seed mucilage at 270-275^{0}C.

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, thickness, disintegration time and *in vitro* dissolution profiles. All the formulations had coefficient of weight variation values of less than 3% release to their mean weight. The hardness of the tablet varies between 3.56-7.33 kg/cm^2. The hardness of the tablets increased with increase in percentage of binding agent. The tablets prepared with 10% of starch (STD) showed equal hardness when compared to formulation SG4 and SG5 but the formulation SG1, SG2 and SG3 have less hardness as compared to formulations (STD) but 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 *Sesbania grandiflora* seed mucilage. But overall friability values were less than specified limits. This demonstrated the effectiveness of the gum to use as binder.

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Table No. 2: Evaluation of the granules

Properties	**SG1**	**SG2**	**SG3**	**SG4**	**SG5**	**STD**
Mean particle size(µm)	362.56	378.62	377.56	360.58	365.56	379.52
Tapped bulk density g/cm^3	0.617±0.223	0.603±0.275	0.618±0.314	0.621±0.227	0.607±0.286	0.631±0.364
Loose bulk density g/cm^3	0.523±0.224	0.527±0.277	0.529±0.265	0.503±0.220	0.518±0.221	0.526±0.342
Flow rate (g/s)	7.3	7.9	7.8	7.1	7.2	7.7
Carr index (%)	12.6±0.345	11.7±0.323	12.5±0.319	11.7±0.355	12.5±0.289	12.9±0.389
Hausner ratio	1.17±0.321	1.07±0.379	1.13±0.365	1.08±0.321	1.06±0.328	1.08±0.378
Angle of repose	21^{0}15'±0.321	20^{0}16'±0.319	22^{0}04'±0.334	21^{0}17'±0.322	20^{0}26'±0.321	22^{0}24'±0.432

Table No. 3: Evaluation of the tablets

Parameters / Batches	Weight variation	Hardness	Friability	Thickness	Disintegration time	Drug Content
SG1	250.56±2.32	3.56±0.124	0.53±0.02	4.8±0.29	2 min 58 sec	98.31±0.39
SG2	251.45±2.76	4.37±0.148	0.38±0.05	4.9±0.37	2 min 25 sec	97.47±0.46
SG3	250.43±1.86	5.32±0.192	0.30±0.04	4.0±0.49	3 min 45 sec	97.18±0.47
SG4	249.87±2.65	6.15±0.138	0.26±0.06	4.8±0.97	4 min 34 sec	96.54±0.65
SG5	250.32±2.65	7.33±0.189	0.21±0.08	4.7±0.51	4 min 56 sec	96.20±0.94
STD	220.37±2.42	6.57±0.149	0.20±0.03	4.6±0.42	4 min 26 sec	98.19±0.85

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The thickness of the tablets was within 4.0 to 4.8 mm. The overall thickness values of tablets were within the specified limits.

The disintegration time of the tablet varied between 2-4 min. The disintegration time increases with increase in 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 No. 3.

The *in vitro* dissolution profile is shown in figure No. 3. This study showed that the drug release was found to decrease with increase in concentration of mucilage. All the formulations i.e. SG1, SG2, SG3, SG4, and SG5 releases more than 90% of the drug over a period of 4 h. All the batches showed release of drug over 94 % over the period of 5h. The release profile of SG4 and SG5 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.

4. Conclusion

The mucilage used in the present study namely, *Sesbania grandiflora* seeds mucilagevexhibited good binding properties. For uncoated tablets 8 and 10 % concentration of mucilage 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.

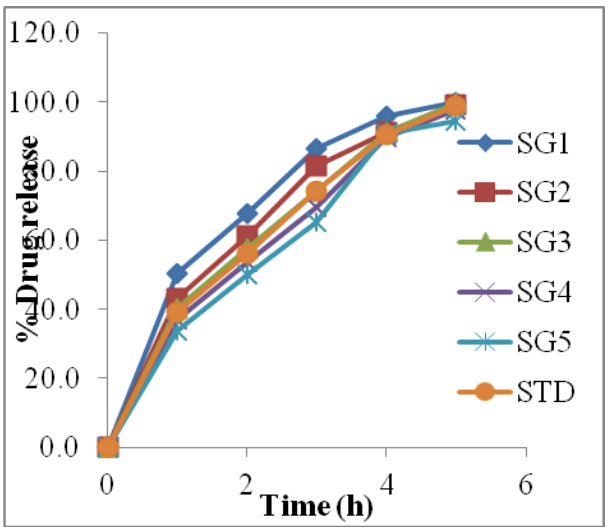

Figure No. 3: Comparative in vitro dissolution study of *Sesbania grandiflora* mucilage and 10 % starch as a binder.

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