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Evaluation of Disintegrant Properties of Plantago Ovata Mucilage in Comparison with other Superdisintegrants

R.Deveswaran*, Sharon Furtado, S.Bharath, Sindhu Abraham, B.V.Basavaraj, V.Madhavan

M.S.Ramaiah College of Pharmacy, M.S.R.Nagar, MSRIT Post, Bangalore -560 054.

Abstract: Dispersible tablets are intended to dissolve or disintegrate rapidly in the mouth for which various natural and synthetic disintegrants are included in the formulation. The disintegrant property of isolated mucilage powder of Isapghula was studied by formulating dispersible tablets of famotidine and comparing its efficiency with other commercially available super disintegrants. Hardness of the tablets was found to be in the range of 4-5kg/cm^2 for all formulations. The wetting time was found to be 18 seconds for the tablet formulation prepared with isolated mucilage powder. The tablets showed 98.9-99.4% of the labeled amount of drug, indicating uniformity in drug content. All the formulations were found to be within the acceptable limits of official weight variation test and they exhibited good friability. The *in-vitro* dissolution profile exhibited maximum drug release from all the formulations. The results of weight variation, content uniformity, disintegration time, hardness, friability and wetting time of the formulations prepared with isolated mucilage powder from plantago ovata are similar to that of those formulations prepared using other superdisintegrants. Thus the isolated mucilage powder can be effectively used as disintegrant in tablet formulations.

Key words: Isapgol mucilage powder, Famotidine, Disintegrant.

INTRODUCTION

Excipients play an important role in dosage forms such as tablet, capsule, lotions, suspensions, syrups and ointments[1]. Recent trends towards the use of the vegetable and nontoxic products demand the replacement of synthetic excipients with natural ones. Mucilage as excipient is preferred for its non-toxic, low cost and free availability. They are utilized in manufacturing of different pharmaceutical dosage forms. They possess a variety of pharmaceutical properties, which includes binding, disintegrating, suspending, emulsifying and sustaining properties at different proportion in different pharmaceutical dosage forms. Isapghula mucilage consists of epidermis of the dried seeds of Plantago ovata. Recent advances in novel drug delivery systems (NDDS) aim to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for administration and to achieve better patient compliance. One such approach is fast disintegrating tablets.[2, 3] Famotidine is a highly selective H_2 receptor antagonist with properties of inhibiting gastric acid secretion and healing gastric & duodenal ulcers. Since the aqueous solubility of the drug is 0.1%w/v at 20°C, it gives rise to difficulties in the formulation of dosage forms leading to variable dissolution rates. In the present work, an attempt was made to evaluate the disintegrant property of mucilage powder of the Plantago ovata and comparing its disintegrant property with other common superdisintegrants by formulating fast disintegrating tablets of Famotidine.

MATERIALS AND METHODS

Materials:

Famotidine was obtained as a gift sample from Tonira Pharmaceuticals, Ankhleshwar and aerosil from Kemwell Ltd.Bangalore. Isapghula seeds were purchased from the local market. Dicalcium phosphate, Microcrystalline cellulose, Sodium starch glycollate,

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Crospovidone, polyvinyl pyrrolidone, aspartame and purified talc were purchased from S.D. Fine Chemicals, Mumbai, India.

Method:

Isolation of mucilage from Isapghula seed:

The dried seeds of Isapghula were soaked in distilled water for 48 hours and then boiled for 10 minutes. The resulting mass was squeezed through muslin cloth. To the filtrate an equal volume of acetone was added to precipitate the mucilage. The isolated mucilage was dried in an oven at 40^0C for 2 hours, powdered, passed through sieve No. 80 and stored in a dessicator[4].

Formulation of dispersible tablets:

The dispersible tablets of famotidine were prepared by non-aqueous wet granulation method using absolute alcohol as the solvent. *Plantago ovata* mucilage powder, microcrystalline cellulose, sodium starch glycollate, crospovidone was used as disintegrants, dicalcium phosphate as a diluent, PVP as a binder, aspartame as sweetener, purified talc as lubricant and aerosil as glidant (Table 1). The drug and other ingredients with half the quantity of disintegrant (intragranular disintegrant) were mixed together, sufficient quantity of alcohol was added and mixed to form a coherent mass. The wet mass was granulated using sieve No.12 and the granules formed were dried in a tray dryer (Tempo instruments and equipments, Mumbai) at 40^0C for 20 minutes and regranulated through sieve no. 18. The granules were further blended with the remaining quantity of the disintegrant (extragranular disintegrant), purified talc, aerosil and compressed into tablets using a 8mm round concave punches in a rotary tablet machine[5] (Rimek, RSB-4 mini press Cadmach, Ahmedabad, India).

Evaluation of the tablets:

Drug-Excipient interaction studies:

The physical mixture of pure drug sample and isolated mucilage powder in the ratio 1:1 were subjected to I.R spectral studies using FTIR spectrophotometer (FTIR 8400 S, Shimadzu,Japan).

Hardness:

The crushing strength of the tablets was measured using a Monsanto hardness tester. Six tablets from each formulation batch were tested randomly and the average reading noted.

Table 1: Composition of different batches of Famotidine tablets

Ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)
Famotidine	20	20	20	20
Dicalcium phosphate	175	175	175	175
Isapghula mucilage powder	25	X	X	X
Microcrystalline cellulose	X	25	X	X
Crosspovidone	X	X	25	X
Sodium Starch Glycollate	X	X	X	25
Poly vinyl pyrrolidone	20	20	20	20
Purified talc	3	3	3	3
Aspartame	5	5	5	5
Aerosil	2	2	2	2

Friability: [6]

Twenty tablets were weighed and placed in a Roche friabilator and rotated at 25 rpm for 4 min. The tablets were taken out, dedusted and reweighed. The percentage friability of the tablets was calculated by the formula,

$$\text{Percentage friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Weight Variation:

Randomly twenty tablets were selected after compression and the mean weight was

determined. The sample tablets were weighed individually and the deviation from the mean weight was calculated (USP XXVII).

Twenty tablets were weighed and powdered. An amount of the powder equivalent to 20mg of famotidine was dissolved in 100ml of pH 6.8 phosphate buffer, filtered, diluted suitably and

Drug content:

Formulation	Weight Variation (mg)	Drug content (%)	Hardness* (Kg/cm^2)	Friability (%)	*In vitro* Disintegration time* (sec)	Wetting time* (sec)
F1	253 ± 1	99.0	4.5 ± 0.1	0.45	82±3	18±2
F2	249 ± 3	99.1	5.0 ± 0.1	0.53	76±3	20±1
F3	251 ± 3	98.9	4.1 ± 0.2	0.54	60±2	16±2
F4	252 ± 1	99.2	5.0 ± 0.2	0.49	85±3	17±1

Table 2: Evaluation of Famotidine Tablets

*Average of six determinations

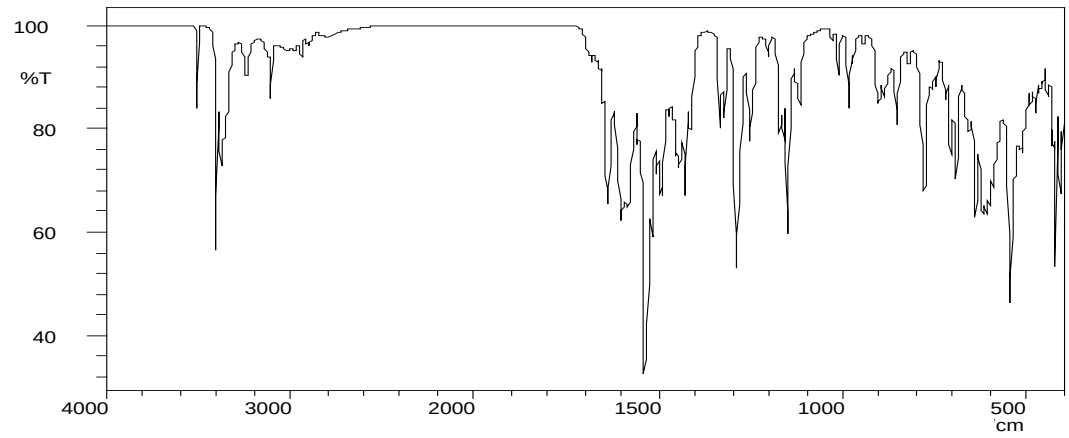

Fig. 1 I.R Spectra of pure drug Famotidine

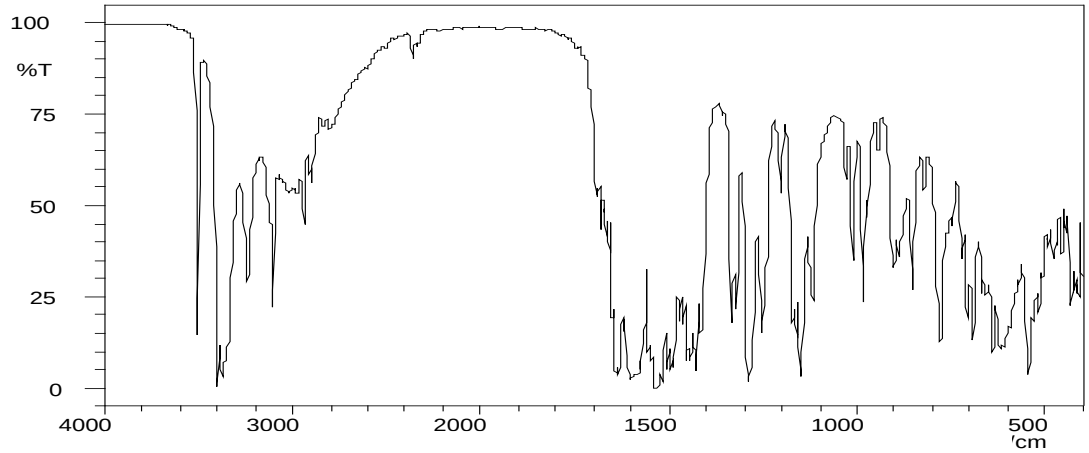

Fig. 2 I.R Spectra of the physical mixture of the mucilage powder and drug

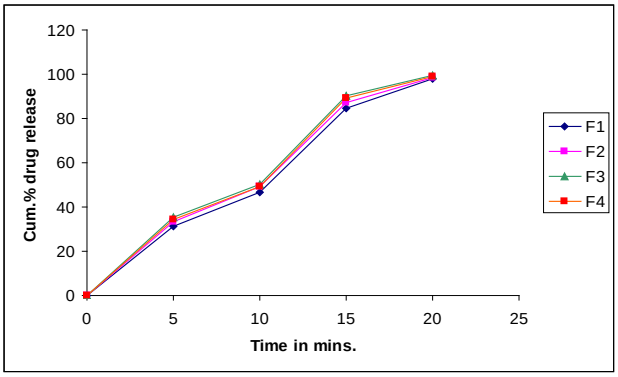

Fig. 3: In vitro release profile of famotidine from tablet formulations

estimated for the drug content at 265nm[7] using UV-Visible spectrophotometer (UV 160-Shimadzu, Japan).

Wetting time:

A piece of tissue paper (12cmx10.75cm) folded twice was placed in a petri dish containing 6ml of water. A tablet was placed on the paper and the time taken for complete wetting of tablet was noted[8]. Three tablets from each formulation were randomly selected and the average wetting time was noted.

***In- vitro* disintegration time:**

In vitro disintegration time was measured by placing a tablet in 100ml water maintained at 25°C. The time taken for the tablet to disintegrate completely was noted.

Dissolution studies:

In- vitro drug release studies of all the formulations were carried out using multi basket tablet dissolution test apparatus (USP TDT 06 PL, Electrolab, Mumbai) at 50rpm. Phosphate buffer pH6.8 was used as the dissolution media with temperature maintained at 37±1ºC. Samples were withdrawn at different time intervals, diluted suitably and analyzed at 265nm for cumulative drug release using Shimadzu UV-Visible spectrophotometer. The sample after each withdrawal was replaced with same volume of fresh media and the test was conducted in triplicate.

RESULTS AND DISCUSSION

The isolation method yielded 25% of mucilage powder from the seeds of plantago ovata. The compatibility between the drug and isolated mucilage powder was found to be stable by the I.R spectral studies which are indicated in (Fig.1-2). The formulations of famotidine were prepared using the isolated mucilage powder of Isapghula as disintegrating agent and other commercially available super disintegrants in different ratio and compressed into tablets. Table 2 shows the results of all the formulated batches of tablets. The hardness was maintained between 4 – 5 Kg/cm^2 for all the formulations and the inclusion of mucilage powder improved the tablet properties with respect to wetting time and *in- vitro* disintegration time. The *in- vitro* disintegration time of the tablets was found to be decreased with the inclusion of isolated mucilage powder. The isolated mucilage powder was found to have similar disintegrating property compared to other superdisintegrants. Weight variation and the drug content proved that all the tablets had good uniformity in the drug content. The prepared tablets exhibited good friability values indicating that they can withstand the pressure during transportation and handling. The *in-vitro* dissolution profile (Fig.4) indicated a faster and maximum of drug release from all the formulations proving the disintegrant property of isolated mucilage from plantago ovata. The results of evaluation tests that are carried out in the formulations prepared with isolated mucilage powder are similar to that of those formulations prepared using superdisintegrants.

CONCLUSION

In the present study the disintegrating properties of the mucilage powder of

Plantago ovata had been studied in comparison with other commercially available super disintegrants. The isolated natural disintegrant exhibits faster drug dissolution in comparison to the other super disintegrants thereby helping in effective therapy and improved patient compliance. Thus the isolated mucilage powder can be effectively used as disintegrants in tablet formulations.

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