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Studies on the Disintegrant properties of Mucilage and Seed Powder of *Plantago ovata*

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ABSTRACT: Tablet disintegration has received considerable attention as an essential step in obtaining fast drug release. 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 study of binder, suspending agent and thickening agent property of seeds and mucilage powder of plantago ovata has already being studied. The present work emphasis on the study of disintegrant property of mucilage and seed powder of Isapghula by formulating dispersible tablets of famotidine. Hardness of the tablets was found to be in the range of 4.0 kg/cm^2 for all formulations. The wetting time decreased with the increase in concentration of seed and mucilage powder. The tablets showed 96.1-99.3% of the labeled amount of drug, indicating uniformity in drug content. The mucilage powder was found to have better disintegrating property compared to the seed powder. All the formulations were found to be within the acceptable limits of official weight variation test and they exhibited good friability. The results of uniformity of dispersion showed that no particles were retained on sieve no. 22 and the *in-vitro* dissolution profile exhibited maximum drug release from all the formulations.

KEYWORDS : Dispersible tablet, Famotidine, *Plantago ovata*, mucilage, seed powder.

INTRODUCTION

Tablet is the most widely used dosage form because of its convenience in terms of self-administration, compactness and ease in manufacturing. But paediatric and geriatric patients may encounter inconvenience in swallowing it[1]. To overcome this problem, in recent years increasing attention has been focused in formulating fast dissolving and dispersible tablets that are intended to dissolve or disintegrate rapidly in the mouth[2]. Tablet disintegration has been considered as the rate limiting step in faster drug release. Disintegrants are substances that are added to drug formulation that facilitate the breakup or disintegration of tablet content into smaller particles that dissolve more rapidly in aqueous environment[3,4]. The various disintegrants includes synthetic derivatives such as sodium carboxy methyl cellulose, cross povidone, sodium starch glycollate, cross carmellose sodium, and natural derivatives such as alginates, cellulose, agar, locust bean, pectin, tragacanth, chitosan and gum karaya. Isapghula consists of dried seeds of the plant plantago ovata and it contains mucilage which is present in the epidermis of the seeds[5]. Famotidine is a highly selective H_2 receptor antagonist with properties of inhibiting gastric acid secretion and healing gastric & duodenal ulcers[6]. In the present study, an attempt was made to develop dispersible tablets of famotidine using the seed and mucilage powder of the *Plantago ovata.*

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

Method

Preparation of seed powder of Isapghula

The dried Isapghula seeds were comminuted and sieved through mesh No.80 and stored in a desiccator.

Isolation of mucilage from Isapghula seed

The seeds 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[7].

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* seed and mucilage powder as disintegrants, dicalcium phosphate as a diluent, PVP as 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[8] (Rimek, RSB-4 mini press Cadmach, Ahmedabad, India).

Evaluation of the tablets

Drug-Excipient interaction studies

The pure drug sample, isolated mucilage powder and seed powder of plantago ovata, and the physical mixture of drug to excipient 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 were measured using a Monsanto hardness tester. Six tablets from each formulation batch were tested randomly and the average reading noted.

Friability

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,

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)**.**

Drug content

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 estimated for the drug content at 265nm 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[9]. Three tablets from each formulation were randomly selected and the average wetting time was noted.

Uniformity of dispersion

Three tablets were randomly selected and dispersed in 100ml of water. The resulting dispersion was passed through sieve No.22.

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 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 30% of mucilage powder from the seeds of *plantago ovata*. The compatibility between the drug with seed powder and isolated mucilage powder was found to be good by the I.R spectral studies which are indicated in

(Fig.1-5). The formulations were prepared using seed powder and isolated mucilage powder as disintegrants in different ratio and compressed into tablets with processing variables such as compression force and hardness maintained constant through out the studies. Table 2 shows the results of all the formulated tablets. The hardness was maintained between 4 - 4.5Kg/cm^2 for all the formulations and the inclusion of seed and

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 increased concentration of both the seed powder and the isolated mucilage powder. Moreover the isolated mucilage powder was found to have better disintegrating property compared to the seed powder. The least average wetting time and disintegration time of formulation F4 proved the superior disintegrant property of the isolated mucilage. The results of uniformity of dispersion showed that no particles are retained on mesh no. 22, weight variation and the drug estimation 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.6) indicated a faster and maximum of 99.4% drug release from formulation F4 proving the disintegrant property of isolated mucilage of *plantago ovata*.

CONCLUSION

In the present study the disintegrating properties of the seed and mucilage powder of *Plantago ovata* had been studied. Both the mucilage and seed powder exhibited potentially as a rapidly disintegrating agent for faster drug dissolution and improved bioavailability, thereby helping in effective therapy and improving patient compliance.

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Table 1: Composition of different batches of dispersible tablets of famotidine

Ingredients	**F1 (mg)**	**F2 (mg)**	**F3 (mg)**	**F4 (mg)**
Famotidine	20	20	20	20
Dicalcium phosphate	187.5	175	187.5	175
Seed powder	12.5	25	--	--
Mucilage powder	--	--	12.5	25
Poly vinyl pyrollidone	20	20	20	20
Talc	3	3	3	3
Aspartame	5	5	5	5
Aerosil	2	2	2	2

Table 2: Evaluation of dispersible tablets of Famotidine

Formulation	**Weight Variation (mg)**	**Drug content (%)**	**Hardness^{+} (Kg/cm^2)**	**Friability (%)**	***In vitro* Disintegration time* (sec)**	**Wetting time $^{+}$ (sec)**
F1	252 ± 4	98.4	4.5±0.2	0.69	145±3	27±2
F2	253 ± 2	99.3	4.4±0.2	0.65	124±6	22±1
F3	251 ± 5	96.1	4.4±0.2	0.52	90±5	20±2
F4	248 ± 3	98.7	4.5±0.1	0.49	82±3	16±1

*Average of six determinations
+Average of three determinations

Fig. 1 I.R Spectra of pure drug Famotidine

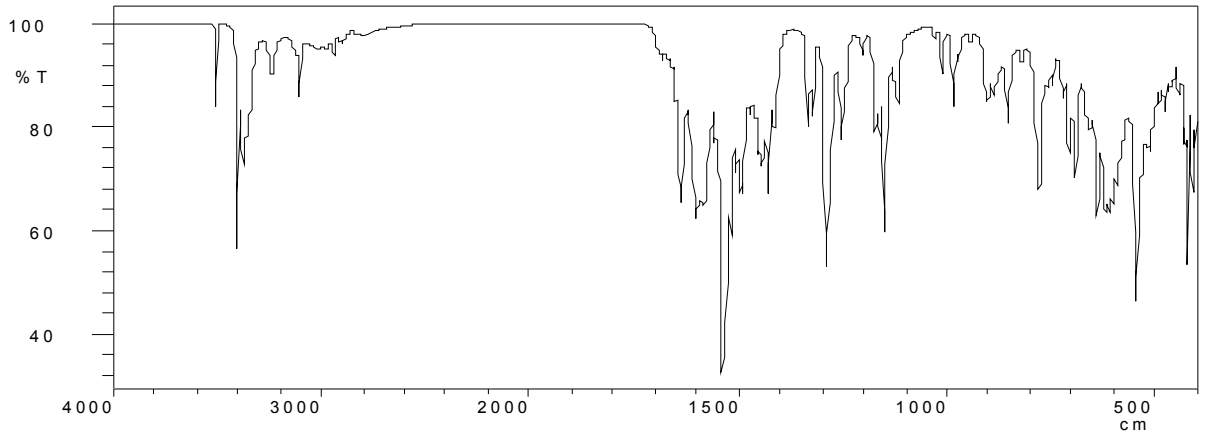


Fig. 2 I.R Spectra of Isapghula pure seed powder

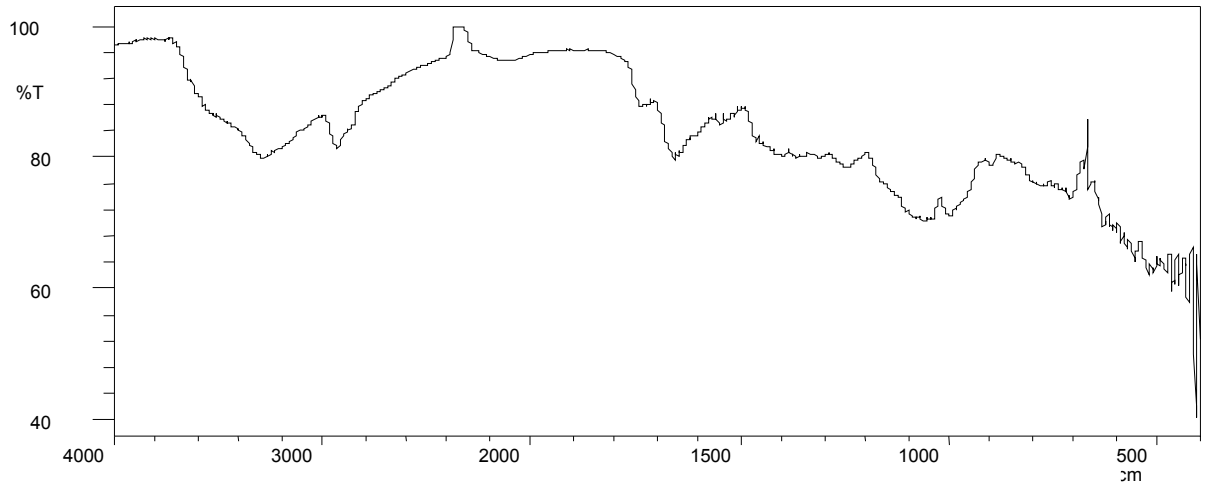


Fig. 3 I.R Spectra of Isapghula pure mucilage powder

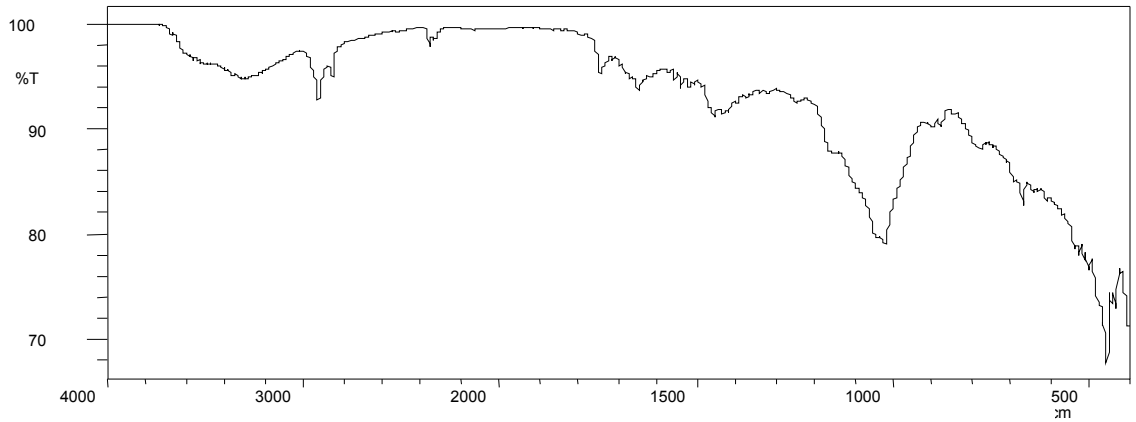


Fig. 4 I.R Spectra of the physical mixture of the Isapghula seed powder and drug

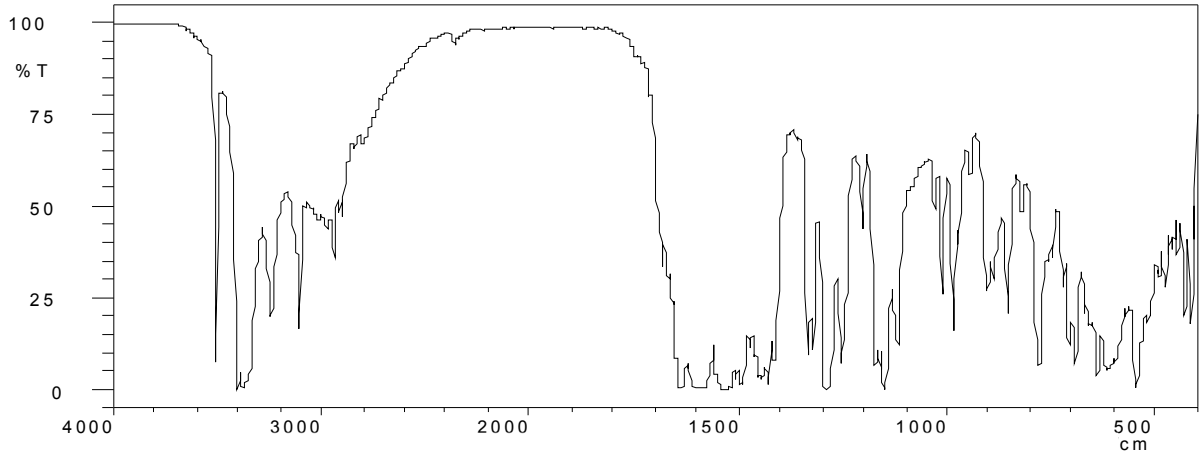


Fig. 5 I.R Spectra of the physical mixture of the mucilage powder and drug

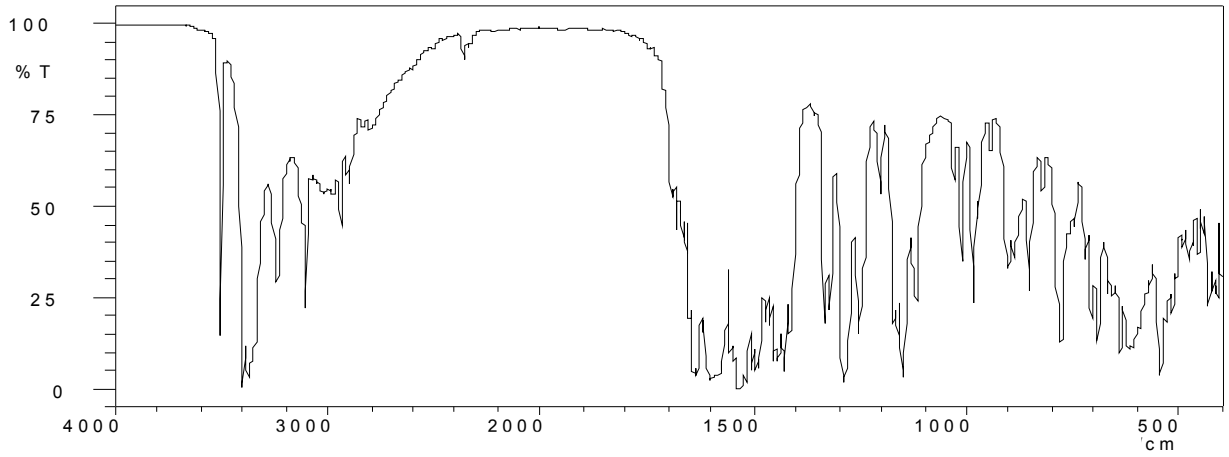
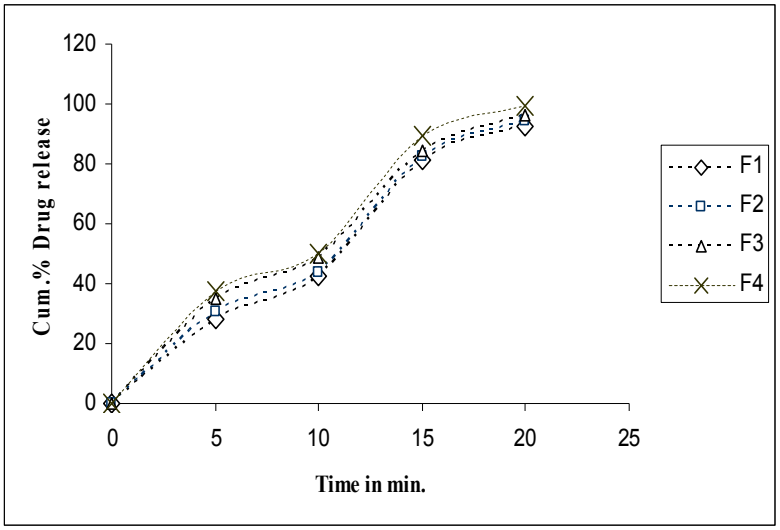


Fig. 6: In vitro release profile of famotidine from tablet formulations



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