

Investigations of *Plantago ovata* husk Powder as a Disintegrating Agent for Development of Famotidine Tablets

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ABSTRACT

The main objective of this study is to explore development of pharmaceutical excipients from the husk obtained from the seeds of *Plantago ovata*. Husk shows very good swelling property in water due to the major part of mucilage in it. Since swelling is one of the mechanisms of action of some tablet disintegrants, it is thought that the husk powder of *Plantago ovata* would be able to act as a tablet disintegrant. The powder obtained from the *Plantago ovata* husk was characterized for micromeritcal properties, swelling capacity, hydration capacity, LOD, pH, particle size, foreign particles, ash value and microbial limit tests. Its disintegrant ability in comparison with maize starch was investigated by preparing famotidine tablets via the direct

compression method. It was also compared with three marketed tablets of famotidine. The *Plantago ovata* husk powder, however, showed superior flow, swelling capacity as well as water retention capacity than maize starch. The tablets were characterized for hardness, friability, weight variation, *in vitro* disintegration study and *in vitro* dissolution study. The optimized batch F2C comprising of 10% of the *Plantago ovata* husk powder showed a 15 seconds disintegration time, which was significantly less than tablets prepared from maize starch as well as all three market preparations. Tablets from batch F2C were submitted for short term stability studies and exhibited stable characteristics.

KEYWORDS: Plantago ovata husk; famotidine; disintegration time; maize starch BP; stability study.

Introduction

Among the oral solid dosage forms, the tablet is the most preferred form because of ease of administration, compactness, and flexibility in manufacturing. Disintegrant is the most important excipient in a tablet and facilitates the breakup of the tablet in a liquid environment into fine particles prior to dissolution of the active drug and its absorption from the gastro-intestinal tract (Shangraw et al., 1980; Kanig and Rudnic, 1984). Several mechanisms have been proposed to rationalize the action of disintegrants. These include porosity and capillary action, rate of water uptake into the tablet, swelling of disintegrant particles, gas release, melting and enzymatic action, and heat of wetting and lysis of physico-chemical bonds (Caramella et al., 1986; 1988).

Mucilage and gum have long been known as pharmaceutical aid agent. Nowadays these gums and mucilage are gaining importance in pharmaceutical industries as thickeners, suspending and emulsifying agents, binder and film formers. As these are vegetative in origin hence the demand of these substances is increasing and therefore new sources been searched. (Patel et al., 2007; Ravikumar et al., 2007)

Various scientists have contributed to explore the use of natural polymers as pharmaceutical excipients. Malayiva et al (2010) have studied the

superdisintegrating property of a mango peel and also compared the same with sodium starch glycolate. Ravikumar et al (2009) have evaluated the disintegrating properties of *Abelmoschus esculentus* mucilage for Aceclofenac tablets. Antony et al (1997) have worked in assessing disintegrating action from Gellan gum (*Pseudomonas elodea*).

Since swelling is one of the mechanisms of action of major tablet disintegrants it is thought that the powder of the *Plantago ovata* (Family – Plantaginaceae) husk would be able to act as a tablet disintegrant because of its swelling ability *Plantago ovata* (*P. ovata*) grows wildly in the Asian countries. It is known by various names in different parts of the world like ispaghula, ispagol, psyllium and plantago psyllium. It is widely used as herbal medicine in India and is available in market at low cost. Seeds are nontoxic, light brown and oval shaped. It contains a core portion covered by outer husk layer. Separated husk is fibrous in nature which consist of 34% insoluble fiber and 66% soluble fiber (which is in the form of polysaccharide). Psyllium husk contains about 30% mucilage, mainly xylose, arabinose and galacturonic acid. Mucilage of the *P. ovate* husk has various characteristic like binding, disintegrating, gelling and suspending (Baveja and Gupta, 1968; Washi et al., 1985; Kulkarni et al., 2002).

Famotidine is a highly selective H₂histamine 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 tablets leading to variable dissolution rates. Another limitation for famotidine is incomplete oral absorption and hence low (40%) bioavailability (Yeh et al., 2006).

Research on the isolated mucilage of the *P. ovate* husk and seed was carried out by various researchers (Khanna et al., 1988; Chakraborty et al., 2008; Shirsand et al., 2009; Deveswaran et al., 2010). Mucilage was isolated by various methods, some of which were quite lengthy and complex. Instead of isolating mucilage, direct use of husk powder was explored in the present study. The husk and husk powder were characterized before use and compared with maize starch.

The main objective of the present study was to explore the possible uses of the powder of the *P. ovata* husk as tablet disintegrant and to find its optimum concentration as disintegrant in the formulation of famotidine tablets. It was aimed to carry out comparative evaluation with maize starch as well as with market products of famotidine to find its suitability as a disintegrant.

Materials and Methods

Materials. Famotidine was received as a gift sample from Torrent Research Centre (Gandhinagar, India). Psyllium seed husk was purchased from the local market. Dicalcium phosphate, lactose monohydrate, microcrystalline cellulose, aerosil and purified talc were received from Suvik Pharmaceuticals and Chemicals (Gandhinagar, India). All other chemicals used were of analytical grade.

Preparation of *P. ovata* husk powder

Characterization of the *P. ovata* husk. The collected husk sample was evaluated for swelling factor, ash value and foreign particles according to Indian Pharmacopoeia 2007 herbal monograph for isabgol husk.

Preparation of *P. ovata* husk powder from the seeds. The *P. ovata* husk (98% pure grade) was collected from a local market. About 40 g of the husk was taken and checked for absence of foreign matter. Then it was crushed and sieved through 100# sieve. The sieved powder was collected and checked for absence of foreign particles. It was preserved in an air tight, dry container for further use.

Characterization of the *P. ovata* husk powder

1. Derived Properties. The flow property of the powder was investigated by measuring its angle of repose by fixed funnel method.

$$\theta = \tan^{-1} (h/r) \quad \dots(1)$$

where, h is height of conical powder heap, and r is radius of circular base.

Triplicate determinations were made and the mean angle of repose was calculated.

Compressibility index is a measure of the ability of a solid to get compressed. The powder (25 g) was placed inside a measuring cylinder of a tapped density apparatus and the bulk volume, V1, was recorded and subjected to 100 taps and the tapped volume, V2, was recorded. The bulk and tapped densities were computed as

$$\text{Bulk density} = \text{weight of powder}/V1 \quad \dots(2)$$

$$\text{Tapped density} = \text{weight of powder}/V2 \quad \dots(3)$$

The powder porosity was computed from the bulk density and true density (specific gravity) values using the equation below:

$$E = 1 - D_b/D_t \quad \dots(4)$$

Where, E is powder porosity, D_b and D_t are bulk and true densities, respectively.

2. Swelling capacity. The swelling capacity of the powder was estimated by a modification of the methods of Bowen and Vadino (Bowen et al., 1984) and Iwuagwu and Okoli (Iwuagwu et al., 1992). The tapped volume occupied by 1 g of the powder V_x, was noted. The powder was then dispersed in 85.0 ml of water and the volume made up to 100 ml with more water. After 24 hours of standing, the volume of the sediment, V_y, was estimated. The swelling capacity was computed as follows:

$$\text{Swelling capacity} = V_y/V_x \quad \dots(5)$$

The mean of the three determinations was calculated.

3. Hydration capacity. The hydration capacity (water retention capacity) was determined by the method of Ring (Ring, 1985). 1 g of powder was placed in a centrifuge tube and covered with 10 ml of water. The tube was shaken intermittently over a 2 hour period and left to stand for 30 minutes. This was then centrifuged for 10 minutes at 3000 rpm. With the supernatant decanted and the weight of the powder after water uptake and centrifugation, x was determined.

$$\text{Hydration capacity} = x/y \quad \dots(6)$$

Where x is the weight of moist powder after centrifugation and y is the weight of dry powder. The values of hydration capacity listed were the means of three determinations.

4. Loss on drying. The moisture present in the husk or mucilage influence the stability of the product. High moisture content contributes to the degradation of moisture sensitive drug as well as favor microbial contamination. The moisture content was determined by digital moisture balance (SARTORIUS, Germany). 1 g of sample was heated at 105°C in muffle furnace until constant weight was achieved. The % LOD was calculated by calculating a mean of three determinations.

5. **pH.** The pH of 1% aqueous dispersion was determined by an electronic pH meter (3020 pH meter, Jenway, UK)
6. **Particle size.** Particle size was microscopically estimated by placing a small quantity of the powder suspended in light liquid paraffin on a slide and covered with a cover slip. The eye-piece graticle was used to view the powder sample at the highest magnification of the microscope. Each division of the eye-piece graticle was calculated to 0.3 mm using the stage micrometer. The number of divisions for each fragment of the mycelia was noted and multiplied by 0.3 mm. The mean was taken. A camera lucida was used to measure the sizes.
7. **Foreign particles.** The powder was visually inspected for any foreign particles.
8. **Ash value.** It was carried out according to Indian Pharmacopoeia 2007. Acid-insoluble ash was also determined according to Indian Pharmacopoeia 2007.
9. **Microbiological limit test.** 1 g of *P. ovate* husk powder was dissolved in 9 ml of sterile distilled water. Serial dilutions were made and viability assessed using the pour plate method. For detection of fungal growth in sample, sodouraud dextrose agar medium was used. The plates were incubated at 27°C for 72 hours. For detection of bacteria growth casein digest agar medium was used. The plates were incubated at 37°C for 24 hours (Michael and Pelezar 1993; Ghule et al., 2006).

Preparation of Famotidine Tablet

The tablet of famotidine was prepared by the direct compression method. Various ratios of drug and excipients were studied as shown in Table 1. The drug, disintegrant and filler (dicalcium phosphate or lactose or microcrystalline cellulose) were passed through the #40 sieve. All the ingredients were mixed uniformly in a polybag. Talc and magnesium stearate were passed through #60 sieves and added to the polybag and mixed properly. The blend was compressed on a 12 station rotary punch tablet machine (Karnawati Engineering, Gujarat) using a 6 mm flat faced punch set. Prepared tablets were stored in well labeled glass jars in a humidity chamber containing dry silica gel and characterized after at least 72 hours of storage at ambient temperature.

TABLE 1

Formulations (all quantities are in mg).

INGREDIENT	FORMULATION/BATCH CODE															
	F1					F2					F3					S1
	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
FAMOTIDINE	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20
MCC (AVICEL 101)	101.8	104.6	101.8	99	96.2	N.A.					N.A.					N.A.
LACTOSE	N.A.					101.8	104.6	101.8	99	96.2	N.A.					101.8
DCP	N.A.					N.A.					101.8	104.6	101.8	99	96.2	N.A.
ISABGOL HUSK POW.	8.4	11.2	14	16.8	19.6	8.4	11.2	14	16.8	19.6	8.4	11.2	14	16.8	19.6	N.A.
STARCH BP	N.A.					N.A.					N.A.					14
TALC	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8
AEROSIL	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4

N.A. Not Applicable

Characterization of tablets

The weights of 20 tablets were individually determined using an electronic balance (Sartorius, CP-224S, Germany) and the mean weight was calculated. Friability was determined using a Roche friabilator (Erweka Apparatebau GmbH, Germany). Ten tablets per batch were weighed and caused to cascade in the drum of the friabilator which rotated at 25 rpm for 4 minutes. The tablets were dusted and reweighed. The loss in weight expressed as a percentage of the original weight of the ten tablets was calculated as the friability of the tablets. The crushing strength of each of ten tablets was determined using a motorized hardness tester (Model 2E/205, Schleuniger, Switzerland). The mean crushing strength was calculated.

In vitro Disintegration study. The test was carried out on six tablets using tablet disintegration tester ED-20 (Electrolab, Mumbai, India). Distilled water at 37°C ± 2°C was used as a disintegration media and the time in second taken for complete disintegration of the tablet with no palable mass remaining in the apparatus was measured in seconds (Lachman et al., 1987). The mean of three determinations was taken.

In Vitro Dissolution study. *In vitro* dissolution study was carried out using a USP type II dissolution test apparatus (Veego Model No DA- 6D, Ahmedabad) in 900 ml of pH 4.5 phosphate buffer at 37±0.5°C at 50 rpm. Aliquot were withdrawn at 5, 10, 15, 20, 25 and 30 minutes and were replaced immediately with the same volume of the fresh buffer. Aliquot were diluted suitably and assayed spectrometrically (Shimadzu Model 1800) at 265 nm as per USP-NF 2007.

Stability study

The tablets were charged for the accelerated stability studies as per ICH guidelines (40±2°C and 75±5% RH) for a period of 3 months in stability chambers (Thermolab, Mumbai, India). They were placed in flint vials and hermetically sealed with rubber plugs and aluminum caps. The samples were taken out at 15, 30, 60 and 90 days and evaluated for the drug content, disintegration time and pattern, cumulative drug release, microbial limit test and physical parameters like color change, friability and hardness.

FTIR spectroscopy

The pure drug famotidine, disintegrant *P. ovata* and physical mixture of famotidine-excipients (Batch F2C) were analyzed for determination of drug excipients compatibility by Fourier Transformed Infrared Spectroscopy (FTIR, 8400S, Shimadzu, Germany) studies. The IR spectra were done against the KBr background. Spectral scanning was done in the range between 4000–400 cm⁻¹.

Results and Discussion

The comparative study of the physicochemical characteristics of *P. ovata* husk powder and maize starch was carried out and the results obtained are listed in Table 2. The angle of repose of a powder provides an insight into the magnitude of the cohesiveness of the powder, and hence its flowability (Carli et al., 1981; Paronen et al., 1984). Mildly cohesive powders have angles of repose between 40° and 60° when measured by any of the standard methods as was done in this study (Bolhuis et al., 1982). *P. ovata* husk powder has an angle of repose of 26.5 ± 0.15 while maize starch has an angle of repose of 56.3 ± 0.2. It could be inferred that powder, being less cohesive, has superior flow properties. The Hausner's ratio (i.e. the ratio of tapped density to bulk density) previews the degree of densification which could occur during tableting. A high ratio indicates the greater the propensity of the powder to density. This phenomenon may cause tablets which lack uniformity of weight and content to be produced (Jones, 1968).

TABLE 2
Physicochemical characterization.

Characteristics	Maize starch BP	<i>P. ovate</i> husk powder
Angle of repose (θ)	56.3±0.2	26.5±0.15
True density (g/cm ³)	1.30±0.02	1.45±0.02
Bulk density (g/cm ³)	0.56±0.017	0.67±0.02
Tapped density (g/cm ³)	0.67±0.04	0.91±0.036
Hausner ratio	1.20	1.36
Porosity	0.57	0.63
Swelling capacity	1.33	33.3
Water retention capacity	1.49	9.17
pH (1% aqueous dispersion)	5.57	6.72
LOD (%)	9.2	7.8
Ash Value (%)	0.53	3.87
Average particle size (µm)	42.35	80.34

P. ovata husk powder densified more than maize starch; this could also be an indication of its superior flowability. The pH of the maize starch (5.57) is slightly acidic while that of *P. ovata* husk powder (6.72) is in the neutral range. This implies that if *P. ovata* husk powder is dispersed in an aqueous medium, an alkaline or acidic medium will not result, since this may encourage product instability via effects on the gastro-intestinal tract absorption of the active drug. The common feature of

disintegration theories is that penetration of water (or liquid medium) into the tablet must precede disintegration (Fukuoka et al., 1981, Van Kamp et al., 1986, Akbuga et al., 1989).

The swelling capacity and water retention capacity of the *P. ovata* husk powder were found higher than those of maize starch. These results may suggest that *P. ovata* husk powder may be a superior disintegrant to maize starch. The particles of *P. ovata* husk powder were larger (mean 80.34 µm) which implies that a powder bed of *P. ovata* husk powder may have a higher porosity.

All the tablets passed the I.P. uniformity of weight test. The weights of the tablets ranged from 135-145 mg. The highest value of standard deviation recorded was 4.5 mg, giving a relative standard deviation of 3.21%. Tablets containing *P. ovata* husk powder revealed retardation in crushing strength on increasing the concentration of disintegrant. The friability was increased on enhancing the concentration of *P. ovata* husk powder.

Among the batches prepared, the optimized batch was selected on the basis of disintegration time. Comparative study for disintegration time of all the batches as well as marketed products is shown in Table 3. Graphical presentation of disintegration time for all the batches are shown in Figure 1. Batch F2C and F3D showed the lowest disintegration time, but the dissolution profiles for batch F3D was poor compared to batch F2C. Hence, F2C was taken as optimized formulation and was further compared with tablets prepared using maize starch as disintegrant, and also with three marketed preparations. Results of comparative evaluation are shown in Table 4.

Due to high swelling capacity of the husk powder, the tablet burst quickly to give fast disintegration. The swelling of the disintegrating agent provides enough channels for the drug to release in the initial seconds. Trials were done for different concentrations (6%, 8%, 10%, 12% and 14%) of husk powder. Increase in husk powder concentration could be a decrease in disintegration time but higher concentration (>10%) again increased disintegration time. This may be due to the binding effect of the mucilage at higher concentrations. The microbial load characterization data exhibited absence of fungi and bacteria in the sample. The result shows *P. ovata* husk powder under microbial limit test.

The stability study data revealed the stable characteristics of the formulation. The disintegration time of the batch F2C after 3 months was found 16±2 seconds, which indicated an insignificant difference (t test, p<0.05). The disintegrating pattern was also almost similar. There was no remarkable change in color and no significant difference in hardness, friability and cumulative drug release for tablet submitted in stability study. There was no evidence of microbial growth in the *P. ovata* husk powder after three months.

FTIR

The region of IR spectrum of SO₂-NH₂ moiety exhibiting the NH₂ stretching modes is around 3377–3240 cm⁻¹. The very strong bands observed at 1639, 1600 and 1535 cm⁻¹ are assigned to NH₂ bending vibrations. The band observed at 963 cm⁻¹ is assigned to the n(N-S) stretching mode. The scissors and wagging vibrations of this group are observed at 607 and 543 cm⁻¹, respectively. The FTIR spectrum shows the characteristic peak of aromatic C-H stretching bands at 3103 cm⁻¹. The presence of amide group is proved by peak at 1600 for C=O and 1147 cm⁻¹ for C-N respectively. The characteristics peak of famotidine were also found in the FTIR spectrum of physical mixture of famotidine-

excipients, which indicates the stable characteristics of drug.

TABLE 3
Disintegration time (sec).

FORMULATION	A	B	C	D	E
F1	57±2*	55±2*	47±2	45±2*	49±2
F2	25±2	18±2	15±2	22±3	28±2
F3	29±3*	24±2*	15±3	18±2	31±3
M1	49±5				
M2	183±5				
M3	376±5				
S1	61±3				

*could not pass USP dissolution test limits (not less than 75% of the labeled amount of Famotidine in 30 min) M1, M2 and M3 are market preparations (each tablet containing Famotidine USP dose 20mg)

TABLE 4
Comparative evaluation.

FORMULATION	% DRUG DISSOLVED (in 30 min)	DISINTEGRATION TIME (sec)	% DRUG CONTENT	AVERAGE WEIGHT (mg)	% FRIABILITY	HARDNESS (kg/cm ²)
F2C	97.57	15±2	98.4	138.20	0.78	4.2
S1	95.4	61±3	97.8	135.3	0.72	4.1
M1	102.76	49±5	99.97	153.2	0.95	4.1
M2	97.41	183±5	99.53	83.4	0.81	4.3
M3	95.62	376±5	99.85	163.8	0.65	4.4

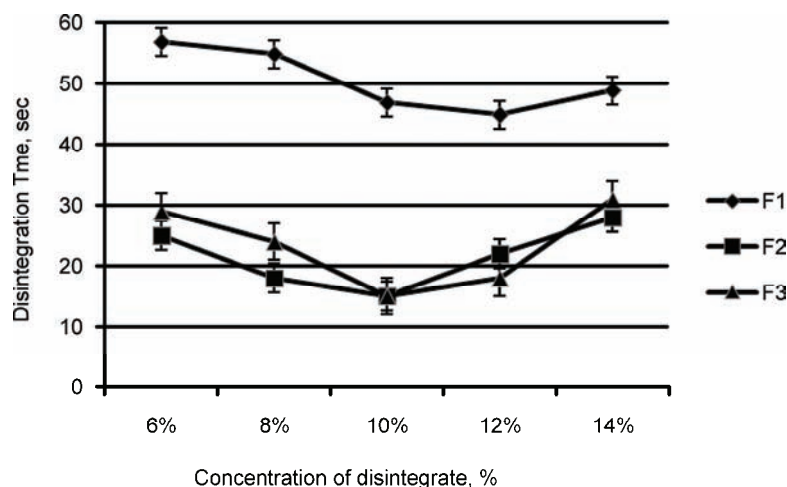


Fig. 1. Effect of disintegrant (husk powder) concentration on disintegration time.

Conclusion

This study evaluated main physical characteristics of *P. ovata* husk powder. Its disintegrant ability relative to that of maize starch has also been demonstrated in famotidine tablets. Psyllium powder was superior to maize starch as a disintegrant, particularly at the concentration 10% w/w. The disintegration time of famotidine tablets was lowered a lot by using husk powder as a disintegrant. Hence, it may improve dissolution of famotidine. From a comparative study, it was postulated that tablets prepared using *P. ovata* husk powder as disintegrant proved better than the standard disintegrant maize starch, as well as all three market preparations. It is suggested that *P. ovata* can act as a better disintegrant than other commonly used disintegrants.

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