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Study of *Ocimum basilicum* and *Plantago ovata* as Disintegrants in the Formulation of Dispersible Tablets

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Ibuprofen dispersible tablets using *Plantago ovata* mucilage powder, *Ocimum basilicum* mucilage powder, *Plantago ovata* husk powder and *Ocimum basilicum* seed powder as disintegrants were prepared and disintegrating property was studied. The swelling index of the above disintegrants was studied. Disintegrating property of the above disintegrants were evaluated by comparing with the formulations of starch powder as standard disintegrant. The study revealed that *Plantago ovata* seed powder and mucilage powder were effective in low concentrations (5%) as disintegrants compared to others .The study further revealed a poor relation between the swelling index and disintegrating efficiency.

Ispaghula husk consists of dried seeds of *Plantago ovata* (Ispaghula). Epidermis of the seeds contains mucilage[1-5]. Both husk and mucilage is found to be good binding and disintegrating agent for the preparation of compressed tablets[6]. *Plantago ovata* seed husk is found to have high swellability[7] and it has been used in the formulation of nimesulide dispersible tablets[8]. *Ocimum basilicum* (Basil) seeds contain mucilage[9] and these seeds can be substituted for ispaghula husk for their bulk laxative effect to treat constipation[10,11].

The present work was carried out to study the disintegrating properties of *Plantago ovata* mucilage powder, *Plantago ovata* husk powder, *Ocimum basilicum* mucilage powder and *Ocimum basilicum* seed powder by formulating dispersible tablets of ibuprofen. Disintegrant property of above disintegrants were evaluated by comparing with the formulations of starch powder as standard disintegrant. The swelling index of the above disintegrants were carried out.

MATERIALS AND METHODS

Ibuprofen, lactose, talc and magnesium stearate was obtained from M/S Roland Pharmaceuticals, Berhampur as gift samples. Ispaghula husk was procured from local market. The husk was dried at 50°, powdered and passed through sieve No. 100. *Ocimum basilicum* seeds were obtained from local market. These seeds were dried at 50° for 24 h, powdered and passed through sieve No.100. This seed powder was again dried at 40° for 24 h and passed through sieve No. 100. Other materials used in the formulation and evaluation were of pharmaceutical grade.

Mucilage extraction:

The mucilages of both *Plantago ovata* and *Ocimum basilicum* were extracted and precipitated separately using previously reported methods[12,13]. The precipitates collected were dried in an oven at 40° for 24 h, finely powdered, passed through sieve No.120 and kept in a dessicator.

Swelling index studies:

The swelling index is the volume in ml occupied by 1 g of drug; including any adhering mucilage after it has swollen in an aqueous liquid for 4 h[14]. Swelling index of *Plantago ovata* mucilage powder, *Plantago ovata* husk powder, *Ocimum basilicum* mucilage powder, and *Ocimum basilicum* seed powder were carried out using BP method[14]. One gram of each disintegrant was taken in a 25-ml ground glass stoppered cylinder graduated over a height of 120 to 130 mm in 0.5 ml divisions. About 25 ml of water was added and shaken vigorously every 10 min for 1 h and then allowed to stand for

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3 h. The volume occupied by the disintegrating agent including adhering mucilage was measured. The swelling index was calculated from the mean of three determinations.

Preparation of dispersible tablets:

Dispersible tablets of ibuprofen were prepared by conventional wet granulation method using the following disintegrants namely *Plantago ovata* husk powder (POH), *Ocimum basilicum* seed powder (OBS), *Plantago ovata* mucilage powder (POM), *Ocimum basilicum* mucilage powder (OBM) and starch powder (SSP) at a concentration of 5,10 and 15%. The composition of each formulation is given in Table 1. Starch paste (10%) was used as binder for all the formulations. The granules were prepared by passing the damp mass through sieve No. 22. The wet granules were dried at 50° in tray dryer for 1 h and later blended with other ingredients thoroughly by tumbling in a polythene bag. Prior to compression into tablets, tableting properties such as angle of repose, Carr's index and bulk density were determined for all the formulations and results are summarized in Table 2. The granules were compressed into tablets using a Cadmach single punch tableting machine using 10 mm biflat punches set at a hardness of 5-6 kg/cm^2.

Evaluation of dispersible tablets:

Dispersible tablets were evaluated for weight variation, hardness, friability, disintegration time, and uniformity of dispersion and drug content uniformity. Disintegration time was determined using USP tablet disintegration test apparatus and distilled water (900 ml) as medium. Uniformity of dispersion was tested as per official method[15], two tablets of each formulation was placed in 100 ml of water and stirred until completely dispersed. A smooth dispersion produced was passed through a sieve No. 22. The Pfizer hardness tester and the Roche friabilator were used to test hardness and friability respectively. Drug content was determined using an UV/Vis spectrophotometer (ELICO SL 159) at 264 nm[16]. Tablets were stored at room temperature for 30 d in

TABLE 1: FORMULATION OF DISPERSIBLE TABLETS.

Formulations	Ingredient (mg/tablet)						
	Ibuprofen	Lactose	POM	OBM	POH	OBS	SSP
POM_1	300	62.5	17.5	-	-	-	-
POM_2	300	45.0	35.0	-	-	-	-
POM_3	300	27.5	52.5	-	-	-	-
OBM_1	300	62.5	-	17.5	-	-	-
OBM_2	300	45.0	-	35.0	-	-	-
OBM_3	300	27.5	-	52.5	-	-	-
POH_1	300	62.5	-	-	17.5	-	-
POH_2	300	45.0	-	-	35.0	-	-
POH_3	300	27.5	-	-	52.5	-	-
OBS_1	300	62.5	-	-	-	17.5	-
OBS_2	300	45.0	-	-	-	35.0	-
OBS_3	300	27.5	-	-	-	52.5	-
SSP_1	300	62.5	-	-	-	-	17.5
SSP_2	300	45.0	-	-	-	-	35.0
SSP_3	300	27.5	-	-	-	-	52.5

POM is dispersible tablet (DT) with *Plantago ovata* mucilage powder, OBM is DT with *Ocimum basilicum* mucilage powder, POH is DT with *Plantago ovata* husk powder, OBS is DT with *Ocimum basilicum* seed powder and SSP is DT with starch powder.

TABLE 2: TABLETING PROPERTIES.

Formulations	Angle of Repose (°)	Carr's Index (%)	Bulk Density g/ml
POM_1	24.70±0.28	12.50±0.11	0.44±0.02
POM_2	23.20±0.23	11.20±0.24	0.42±0.00
POM_3	21.80±0.14	09.30±0.19	0.39±0.01
OBM_1	26.70±0.16	13.60±0.08	0.57±0.00
OBM_2	25.70±0.29	13.10±0.19	0.51±0.00
OBM_3	23.20±0.21	11.70±0.22	0.49±0.01
POH_1	21.30±0.27	09.89±0.07	0.39±0.02
POH_2	20.80±0.14	09.09±0.13	0.36±0.01
POH_3	19.40±0.22	08.31±0.11	0.31±0.01
OBS_1	25.00±0.22	15.80±0.17	0.47±0.00
OBS_2	22.20±0.17	15.00±0.03	0.43±0.01
OBS_3	22.10±0.21	14.10±0.12	0.41±0.00
SSP_1	19.20±0.11	09.70±0.13	0.51±0.03
SSP_2	22.40±0.29	10.20±0.08	0.57±0.01
SSP_3	24.80±0.18	12.40±0.07	0.61±0.00

Tableting properties of all the tablet formulations were determined in triplicate. Mean value ± SD.

tightly capped glass containers wrapped with aluminum foil and the disintegration time was determined.

RESULTS AND DISCUSSION

The swelling index of *Ocimum basilicum* seeds, *Plantago ovata* husk, *Ocimum basilicum* mucilage and *Plantago ovata* mucilage was found to be 23, 12, 17 and 15 ml, respectively. The disintegration time of all the formulations were within official requirements is less than 180 sec[17] except for SSP_1 and SSP_2. OBS_2 and OBS_3 failed in uniformity of dispersion test. It may be due to higher swellability of *Ocimum basilicum* seed powder by forming a gel structure that prevents the granules of disintegrated tablets to pass through sieve No. 22, which results in poor dispersion. The swelling index of *Ocimum basilicum* seeds was found to be twice that of *Plantago ovata* seeds while the swelling index of both the mucilages are almost equal. Initially *Ocimum basilicum* seed powder imparted oily spots on the tablets of OBS formulation. Hence the seed powder was pre-treated by drying at 40° for 24 h, after passing through sieve No.100. This resulted in oil free tablets. The black colour of *Ocimum basilicum* seed powder imparted its colour to the formulation OBS_1, OBS_2 and OBS_3. The hardness of mucilage formulations (POM and OBM) was high compared to other formulations (POH, OBS and SSP) which may be due to additional binding property of mucilage. The friability values of POM and SSP formulations were within official limits. Content uniformity of Ibuprofen was found to be 300 mg±15%

TABLE 3: EVALUATION DATA OF DISPERSIBLE TABLETS.

Formulations	Hardness (kg/cm^2) ±SD	Friability % ± SD	Weight Variation (%)	Disintegration time (s)	Disintegration time after one month at room temp. (s)
POM_1	5.6±0.01	0.5±0.00	2.0	45	48
POM_2	5.8±0.02	0.3±0.02	1.0	60	61
POM_3	5.2±0.01	0.8±0.03	4.0	60	63
OBM_1	4.8±0.09	1.0±0.02	4.0	47	75
OBM_2	4.2±0.02	1.5±0.03	4.5	60	82
OBM_3	4.6±0.02	1.8±0.02	4.0	75	102
POH_1	3.8±0.02	2.0±0.01	6.0	40	46
POH_2	3.9±0.11	1.5±0.01	3.0	45	48
POH_3	4.1±0.08	0.6±0.00	4.5	52	72
OBS_1	4.1±0.01	2.0±0.03	3.0	45	55
OBS_2	3.8±0.05	3.0±0.02	3.8	60	71

OBS_3	4.3±0.06	3.5±0.03	5.5	75	108
SSP_1	4.0±0.05	0.4±0.01	2.0	210	213
SSP_2	4.8±0.03	0.9±0.01	2.1	170	178
SSP_3	5.1±0.01	0.9±0.03	1.8	120	126

Prepared tablet formulations were evaluated for various quality control tests such as hardness, friability, weight variation, disintegration time and disintegration time after storage for one month. For hardness and friability determinations n=6. For tablet weight variation determination n=20.

for all the formulations. After storage for a month at room temperature formulations showed slight increment in disintegration time but are within the range, which may be due to absorption of moisture by the tablets. The study revealed that the flow properties of the granules of Ispaghula husk formulations were good enough and the tablets exhibited good disintegration and uniform dispersion characteristics necessary for the dispersible tablets compared to those of *Ocimum basilicum* formulations. There was a poor relation between the swelling index and disintegrating efficiency of above disintegrants. It is reported that not only extent of swelling but also the rate at which swelling develops and significant force of swelling determine the disintegrating efficiency of disintegrants[18]. The disintegrating efficiency were found to be in the order of POH>POM>OBS>OBM>SSP and all can be used as disintegrating agents.

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