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Research Article

Evaluation of *Mimosa pudica* Seed Mucilage as Sustained-Release Excipient

Kuldeep Singh,[1] Ashok Kumar,[1] Naresh Langyan,[2] and Munish Ahuja[1,3]

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Abstract. The present study was conducted to investigate the sustained-release properties of *Mimosa pudica* seed mucilage. Matrix tablets of diclofenac sodium containing different proportions of mucilage and dibasic calcium phosphate as diluent were formulated by wet granulation method. The tablets had uniform physical appearance, average weight, drug content, and adequate hardness. The results of *in vitro* release conducted using USP type II dissolution rate apparatus, in a dissolution media comprising of 900 mL of 0.1 N HCl for 2 h followed by phosphate buffer (pH 6.8) for 24 h at 37°C and 50 rpm, revealed that as the proportion of mucilage in the matrix was increased there was a corresponding decrease in the release of drug. Further, the matrix tablets were found to release the drug following Higuchi square root release kinetics, with the mechanism of release being diffusion for tablets containing higher proportion of mucilage and a combination of matrix erosion and diffusion for tablets containing smaller proportion of mucilage. The swelling and erosion studies revealed that, as the proportion of mucilage in tablets was increased, there was a corresponding increase in percent swelling and a decrease in percent erosion of tablets. The SEM photomicrographs showed gelling structures in tablets containing higher percentage of mucilage, while both pores and gelling structures were present on the surface of tablets containing smaller proportion of mucilage and commercial formulation. On comparative evaluation, the dissolution profile from formulation containing mucilage to drug in the proportion of 1:40 was found to be similar to the commercial sustained-release formulation of diclofenac.

KEY WORDS: diclofenac sodium; Higuchi's square root; *Mimosa pudica* mucilage; sustained release.

INTRODUCTION

Natural gums and mucilages have been widely explored as emulsifying (1,2), suspending (3), binding (4,5), and disintegrating agent (6) and as sustained-release matrix (7–9) by the pharmaceutical industry. These natural polymers are preferred over the synthetic and semisynthetic polymers because they are cheap and easily available, nonirritant, biodegradable, biocompatible, and ecofriendly. Mucilages are naturally occurring, high molecular weight (approximately 200,000) polyuronides consisting of sugar and uronic acid units (10). They are regarded as normal physiological product of metabolism, formed within the cell or deposited on it in layers. Mucilages serve as food reserve and membrane thickener and aid in water storage and seed germination.

Mimosa pudica (family Mimosaceae), commonly known as sensitive plant, is a diffuse undershrub found widely in the tropical and subtropical parts of India. Seeds of *M. pudica* yield mucilage, which is composed of *d*-xylose and *d*-glucuronic acid (11). *Mimosa* seed mucilage hydrates and swells rapidly on coming in contact with water. During earlier study in our laboratory, the disintegrating and binding properties of *Mimosa* seed mucilage were evaluated (12). In the present work, we have isolated and characterized *Mimosa* seed mucilage and evaluated its sustained-release properties employing diclofenac sodium (DS) as a model drug. The matrix tablet of DS was formulated using wet granulation method and evaluated for appearance, weight variation, hardness, friability, *in vitro* drug release, swelling, and erosion behavior.

MATERIALS AND METHODS

Materials

M. pudica seeds were procured from the local market (Hisar, India) and authenticated by taxonomists of Forest Research Institute (Dehradun, India), and a sample was submitted in the Department of Pharmaceutical Sciences (authentication voucher no. Pcog/2007/65). DS (purity 98.58%) was obtained as gift sample from Dabur Research Foundation (Ghaziabad, India). All other chemicals used were of reagent grade.

Isolation of Mucilage

M. pudica seeds were soaked in sufficient quantity of water for 10 h; the hydrated mucilage along with seeds was

[1] Drug Delivery Research Laboratory, Department of Pharmaceutical Sciences, Guru Jambheshwar University of Science and Technology, Hisar, Haryana 125 001, India.
[2] Johnson & Johnson Ltd., Jharmajri, Baddi, Dist. Solan, Himachal Pradesh 173 205, India.
[3] To whom correspondence should be addressed. (e-mail: munishahuja17@yahoo.co.in)

spread in a thin layer on the stainless steel tray and dried in an oven at 50°C for 4–5 h. The dried mucilage was scraped from the tray by blade and separated from the seeds by passing through a no. 18 mesh. The mucilage was further purified by winnowing to separate seed husk.

Characterization of Mucilage

The isolated mucilage was characterized for swelling index, total ash value, acid-insoluble ash, water-soluble ash, loss on drying, limit test, solubility, melting point, bulk density, tapped density, Carr's index, Hausner ratio, and compression characteristics as per the standard procedures (13–15).

Preparation of Diclofenac Sodium Matrix Tablet

Matrix tablets of DS were prepared by wet granulation method as per formula given in Table I. Calculated amount of DS was dry blended with required quantity of mucilage and granulated using distilled water. The wet mass was passed through no. 8 mesh. The wet granules were dried at 50°C for 3 h. The dried granules were blended with magnesium stearate (1%, wt/wt) as lubricant and compressed using 8-mm biconvex punches and dies in a single-station, hand-operated, R and D tableting machine (Konark Instruments, Ambala, India).

Characterization of Granules

The granules of matrix tablet were prepared as per formula (Table I) and characterized for angle of repose, moisture content, bulk density, tapped density, Carr's index (%), and Hausner ratio (14).

Characterization of Tablets

The prepared DS matrix tablets were evaluated for thickness, weight variation, content uniformity, hardness, and friability as per the standard procedures (14,15).

Thickness and Diameter. Thickness and diameter of ten tablets were measured using Vernier caliper (Aerospace, China), and the average was calculated.

Weight Variation. Twenty tablets of each batch were weighed individually using electronic balance (AND, Japan), and standard deviation was calculated.

Table I. Composition of *Mimosa* Mucilage Matrix Tablet Formulations

	Quantity/tablet (mg)					
Ingredients	F1	F2	F3	F4	F5	F6
Diclofenac sodium	100	100	100	100	100	100
Mucilage	2.5	5	10	20	30	100
Dibasic calcium phosphate	97.5	95	90	80	70	–
Magnesium stearate	2	2	2	2	2	2
Total	202	202	202	202	202	202

Content Uniformity. Twenty tablets were weighed individually and powdered in pestle mortar, and an amount equivalent to 100 mg of DS was extracted with 100 mL of phosphate buffer (pH 6.8) and sonicated for 10 min. The solution was filtered through a 0.45-μm syringe filter, and the content of DS in the solution was determined by measuring absorbance at 276 nm after suitable dilution.

Hardness. Ten tablets of each batch were tested for hardness using Monsanto hardness tester (Perfit, Ambala).

Friability. Ten tablets of each batch were weighed and placed in a friabilator (Campbell Electronics, Mumbai, India) and subjected to 100 rotations in 4 min. The tablets were then dedusted, collected, and reweighed. The friability was calculated as the percentage weight loss.

In Vitro Release Study (16)

The *in vitro* release studies were conducted using USP type II apparatus (TDT-08 L, Electrolab, Mumbai, India); the dissolution media is comprised of 0.1 N hydrochloric acid for the first 2 h and the phosphate buffer (pH 6.8) until 24 h (900 mL) kept at 37.0±0.5°C and 50 rpm. An aliquot of 5 mL sample was withdrawn and replaced with another 5 mL of fresh dissolution medium at various time intervals. The contents of DS in sample were determined by measuring absorbance at 276 nm in a UV-Visible spectrophotometer (Cary 5000, Varian Australia). The release study was performed in triplicate.

Release Kinetics

To determine the order and mechanism of DS release from matrix tablet, the release rate data were fitted to zero-order, first-order, and Higuchi square root equation (17,18). The value of k (the release rate constant) for different model was determined. However, these equations fail to explain the drug release mechanism from matrices that undergo swelling and/or erosion during dissolution. Therefore, the dissolution data were fitted to the Korsmeyer–Peppas equation, which is often used to describe the drug release mechanism from polymeric systems.

$$\log(M_t/M_f) = \log k + n \log t \quad (1)$$

Where M_t is the amount of drug released at time t; M_f is the amount of drug released after infinite time, and k is the release rate constant incorporating structural and geometric characteristics of the tablets, and n is the diffusion exponent indicative of the release mechanism. To determine the release exponent, n for different batches of matrix tablets, the log value of percentage drug dissolved was plotted against log time for each batch, according to Eq. 1. For determination of exponent n, only the initial portion of release curve ($M_t/M_f<0.6$) was used. A value of $n=0.45$ indicates Fickian (case I) release; the rate of drug release is much less than that of polymer relaxation (erosion). Thus, the release of drug is primarily by diffusion through the matrix. A value of n ($0.45<n<0.89$) indicates non-Fickian (anomalous) release; the release of the drug occurs by combined effect of drug diffusion and polymer relaxation. The value of $n>0.89$

indicates super case II type of release. Case II generally refers to the erosion of the polymeric matrix.

One of the model-independent approaches to compare dissolution data is similarity factor (f_2) and difference factor (f_1) (19). Similarity factor is the logarithmic reciprocal square root transformation of one plus the mean squared (the average sum of squares) differences of drug percent dissolved between the test and the reference products. Difference factor measures the percent error between two curves over all time points. Equations 2 and 3 show both of the independent methods.

$$f_2 = 50 \times \log\left\{\left[1 + (1/n)\sum_{j=1}^{n}\left|R_j - T_j\right|^2\right]^{-0.5} \times 100\right\} \quad (2)$$

$$f_1 \frac{\sum_{j=1}^{n}\left|R_j - T_j\right|}{\sum_{j=1}^{n} R_j} \times 100 \quad (3)$$

Where n is the number of time points and R_j and T_j the dissolution of reference and test samples at time t. In order to consider the similar dissolution profiles, the f_1 value should be close to 0 (f_1<15) and f_2 value nearer to 100 (f_2>50).

Swelling and Erosion Studies (20)

Matrix tablet was introduced into dissolution apparatus under the standard conditions specified earlier in *in vitro* drug release study. The tablets were removed using a small basket, and swollen weight of each tablet was determined. To assess the matrix erosion, swollen tablets were kept in a vacuum oven at 40°C for 48 h, and then the tablets were removed and weighed. The percent swelling and percent erosion were calculated according to the following formula:

$$\%\ Swelling = \frac{S}{R} \times 100 \quad (4)$$

$$\%\ Erosion = \frac{(T - R)}{T} \times 100 \quad (5)$$

where S is the weight of the matrix after swelling, and R is the weight of eroded matrix, and T is the initial weight of the matrix. The surface morphology of batch of matrix tablets providing the dissolution profile most similar to the commercial tablet was observed before and after the swelling and erosion study with the help of scanning electron microscopy (Model 268D, Fei-Philips Morgagni, scanning electron microscope) at 15 kV.

RESULTS AND DISCUSSION

Characterization of *Mimosa* Mucilage

Mimosa mucilage comprises of yellowish-brown and odorless flakes, which hydrate rapidly on contact with water to swell but is sparingly soluble in water. The pH of 1% (wt/vol) aqueous dispersion of the mucilage was found to be 6.0–6.5. The swelling index of mucilage was found to be 81.77% (vol/vol). The mucilage showed a loss on drying of 6.8% (wt/wt) and yielded 0.106% (wt/wt) of water-soluble extractive; the total ash contents were found to be 86.75% (wt/wt); water-soluble ash and acid-insoluble ash were 61% and 7.5% (wt/wt), respectively. The bulk density, tapped density, Carr's index, and Hausner ratio of the mucilage were 0.1679 g/cm^3, 0.2356 g/cm^3, 40.6, and 1.406, respectively. The mucilage passed the limit test for chlorides and heavy metals. The viscosity of 0.5% (wt/vol) dispersion of the mucilage was found to be 50,000 cps at 25°C as determined by Brookfield viscometer (RVDVE 230) using spindle no. 7. Further, the mucilage showed plastic compression characteristics.

Characterization of Granules

Table II presents the results of characterization of granules of DS matrix tablets prepared according to the composition given in the Table I. The angle of repose of the prepared granules remained between 28 and 30°, indicating satisfactory flow properties. As the moisture content of granules is less than 2%, the granules are optimally dried. The other parameters for granules were also calculated and found to be within the acceptable limits.

Physical Characterization of Tablets

The physical appearance, hardness, friability, weight variation, and drug content of all the tablet formulations were found to be satisfactory and reproducible (Table III). It can be observed from results that the increase in the concentration of mucilage in the tablet resulted in a corresponding decrease in the hardness of tablets, which may be attributed to the plastic nature of mucilage. The results are consistent with friability studies, which indicated slight increase with increase in the concentration of mucilage

Table II. Physical Characteristics of Various Batches of Diclofenac Sodium Granules

Batch	Angle of repose[a]	Moisture content (%)	Bulk density (g/cm^3)	Tapped density (g/cm^3)	Carr's index (%)	Hausner ratio
F1	31.83±1.2	1.2	0.471	0.6104	20.05	1.289
F2	31.75±0.9	1.3	0.468	0.5940	19.6	1.282
F3	29.53±1.6	1.2	0.468	0.576	18.75	1.230
F4	29.74±1.3	1.4	0.461	0.566	18.5	1.227
F5	28.45±1.8	1.5	0.458	0.545	15.9	1.189
F6	28.01±1.1	1.8	0.447	0.517	13.53	1.156

[a] Values are mean ± SD (n=3)

Table III. Evaluation of Matrix Tablets of Diclofenac Sodium

Batch	Thickness (mm; n=10)	Diameter (mm; n=10)	Average weight (mg; n=20)	Hardness (kg/cm^2; n=10)	Content uniformity (%; n=20)	Friability (%, wt/wt; n=10)
F1	4.02±0.03	8.02±0.02	0.202±0.005	13±0.90	97.1±0.4	0.42±0.098
F2	4.02±0.02	8.02±0.02	0.202±0.005	13±0.90	99.8±0.5	0.42±0.028
F3	4.02±0.01	8.03±0.01	0.204±0.002	11±0.90	98.3±0.3	0.46±0.064
F4	4.03±0.02	8.05±0.01	0.205±0.002	10±0.90	97.2±0.8	0.76±0.062
F5	4.02±0.03	8.05±0.04	0.203±0.002	8.75±0.41	98.9±0.4	0.80±0.061
F6	4.07±0.02	8.07±0.01	0.202±0.004	7.5±0.57	99.5±0.6	0.89±0.022

in tablets. The content uniformity among different batches of tablets was found to be good and was found to be more than 97%.

In Vitro Release

The release rate pattern of DS from various batches of formulated tablets is illustrated in Fig. 1. The results show that <1% of the drug dissolved during the first 2 h in 0.1 N HCl. DS is a weakly acidic drug with pK_a of 4.2; as a result, it is practically insoluble in acidic solution (21). Thus, the lower solubility of DS in 0.1 N HCl accounted for <1% release of the drug. It can be observed from the results that, as the proportion of mucilage in tablets was increased from the mucilage to drug ratio of 1:40 (F1) to 1:1 (F6), there was a decrease in the release rate, and release of DS was extended with 101% and 58% of the DS getting released from the tablets of batches F1 and F6, respectively. The commercial sustained-release tablet of DS (Voveran SR) released almost 100% of the drug in 22 h. Earlier studies have also reported the decrease in the release rate of drug with increase in the proportion of matrix polymer (22,23). The decrease in the release rate of drug from the matrix tablets with increase in the mucilage proportion can be attributed to increase in the gel strength and to the formation of gel layer with longer path of diffusion, resulting in reduction of diffusion coefficient of the drug.

Further, to compare the dissolution profile of various batches of formulated matrix tablets, the dissolution data were treated for calculation of similarity factor f_2 and dissimilarity factor f_1. The values of f_1<15 and f_2>50 are indicative of the similarity of dissolution profiles. The results of the comparison of dissolution profile of batch F1 and Voveran SR were similar with f_1 value of 13.29 and f_2 value of 56.03, while in case of all other formulations, the f_1 value was >15 and f_2 value was <50, indicating dissimilarity of dissolution profiles. Further, on comparison between the different batches of formulated tablets, it was observed that the dissolution profile of tablets of batch F3 and F4 was similar with f_1 value of 5.66 and f_2 value of 80.90.

To determine the mechanism of drug release, the release rate was fitted into various kinetic models. Table IV shows the result of modeling and drug release kinetics of various batches of DS matrix tablet. It can be observed from the results that the release rate data of all the batches of DS matrix tablets formulated using mucilage as the matrix fitted to the Higuchi's square root release kinetics, as indicated by highest value of r^2, while the release rate of commercial tablets fitted best to zero-order release kinetics. Further, the results of n, the release exponent of Korsmeyer–Peppas equation, show that the DS is released by a combination of diffusion and erosion mechanisms (0.45<n<0.89) in the case of batch F1 (n=0.688), F2 (n=0.640), and F3 (n=0.453), while diffusion (n<0.45) is the mechanism of drug release from tablets of batch F4 (n=0.388), F5 (n=0.382), and F6 (n=0.361). The commercial product (n=0.458) releases the drug by a combination of both diffusion and erosion.

Swelling and Erosion Study

The results of swelling (Fig. 2) and erosion (Fig. 3) studies show that, as the proportion of mucilage in the tablets was increased, the percent swelling increased, and the percent erosion decreased. Similar results were earlier reported for mucilage of *Hibiscus rosasinensis*; matrix tablets formulated using pure mucilage showed greater swelling and lesser erosion as compared with the matrix tablets containing mucilage and drug (9). The release of drug from hydrophilic matrices occurs as a result of complex interaction between diffusion, dissolution, and erosion mechanisms. On coming in contact with water, hydrophilic matrices undergo gel formation,

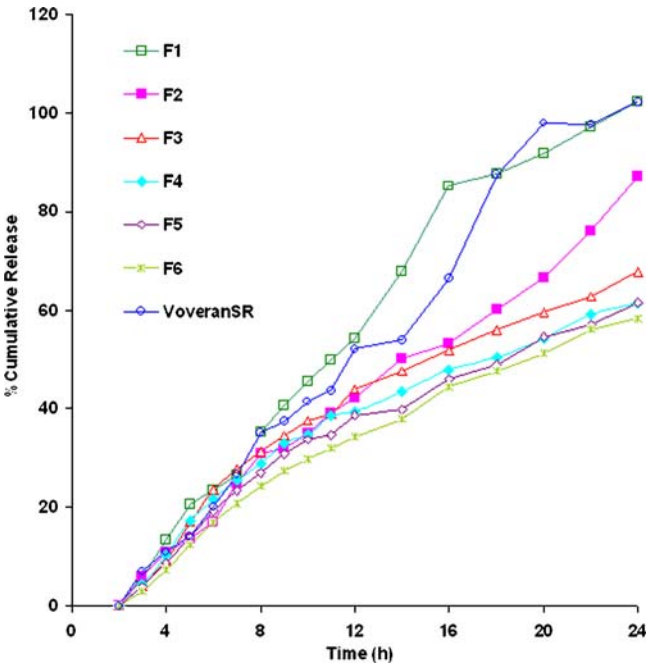

Fig. 1. Comparative drug release profile from different batches of mucilage matrix tablet and commercial tablet (Voveran SR)

Table IV. Modeling and Release Kinetics of Diclofenac from Matrix Tablets of *Mimosa* Seed Mucilage and Commercial Tablet (Voveran SR)

Kinetic model		F1	F2	F3	F4	F5	F6	Voveran SR
Zero order	r^2	0.977	0.989	0.941	0.938	0.955	0.970	0.985
	K (% h^{-1})	4.878	3.671	2.940	2.648	2.677	2.633	4.880
First order	r^2	0.801	0.839	0.68	0.690	0.716	0.721	0.863
	K (h^{-1})	0.111	0.104	0.095	0.089	0.096	0.104	0.114
Higuchi	r^2	0.984	0.983	0.984	0.984	0.993	0.997	0.968
	K (% $h^{-0.5}$)	31.70	23.72	19.53	17.61	17.69	17.31	31.35
Korsmeyer–Peppas	r^2	0.679	0.727	0.933	0.947	0.928	0.917	0.861
	K (% h^{-n})	1.829	2.359	2.218	2.179	2.183	2.179	2.223
	n	0.688	0.6406	0.453	0.388	0.382	0.361	0.498

and progressive phase transition from glassy to rubbery state takes place. This results in solvation of individual polymer chains. As the swelling continues, the swollen matrix retains more water until the shear forces in the dissolution medium disentangle the individual polymer chains from the matrix (24). The solubility of the additives also influences the dissolution of the matrix. Matrices containing additives of low solubility release the drug by matrix erosion, while matrices containing the additives of higher solubility release the drug by diffusion (25,26). In the present study, dibasic calcium phosphate, a water-insoluble additive, was employed, with the formulation F1 containing the highest proportion of dibasic calcium phosphate and F6 containing none. The formulation F1 showed the least percent swelling and highest percent erosion, while the formulation F6 showed the least percent erosion and highest percent swelling. The commercial formulation showed percent swelling similar to the formulation F6, while percent erosion was found to be slightly less than F1. Thus, the matrix formed by the higher proportion of mucilage will provide more gel strength and longer diffusion path length as compared with the matrix formed with smaller proportion of mucilage. Thus, the findings of swelling and erosion studies are consistent with the kinetic studies. The formulation F1 which contains lesser amount of mucilage showed the higher value of n (n=0.688), indicating both swelling and erosion mechanisms, while the formulation F6 (higher proportion of mucilage) showed the value of n (n= 0.361) indicating diffusion as the release mechanism.

Figure 4a–f displays the scanning electron photomicrographs of tablets of batch F1, F6, and commercial tablets. The photomicrographs show the surface morphology of tablets after 0 and 24 h of dissolution study. The surface of tablets of batch F1 after 24-h study shows the presence of both gelling structures and pores on the surface, while the tablets of batch F6 show the presence of large number of swollen gelling structures. The surface of commercial diclofenac tablets shows the presence of both pores and gelling structures similar to the tablets of batch F1. Thus, the presence of both pores and gelling structure indicates the combination of diffusion and erosion mechanism in the release of DS from the matrix tablet of batch F1 and commercial tablet formulation.

CONCLUSION

The present study provided an insight into the evaluation of *M. pudica* seed mucilage as sustained-release matrix excipient using DS as a model drug. The results of the present study demonstrated that *Mimosa* mucilage sustained the drug release. Drug release from *Mimosa* matrix formulations was dependent on the mucilage to drug ratio. As the

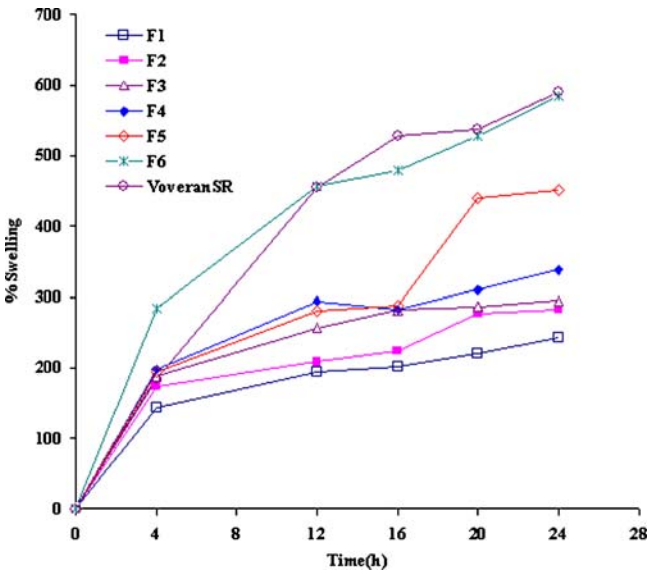

Fig. 2. Swelling behavior of different batches of DS, *Mimosa* matrix tablet, and commercial tablet (Voveran SR)

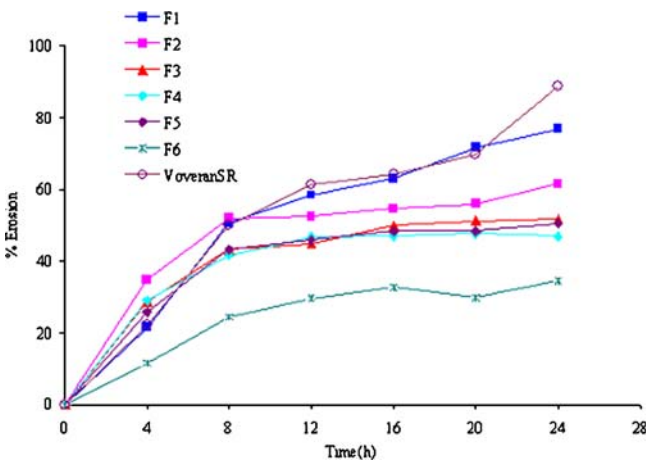

Fig. 3. Erosion behavior of different batches of DS, *Mimosa* matrix tablet, and commercial tablet (Voveran SR)

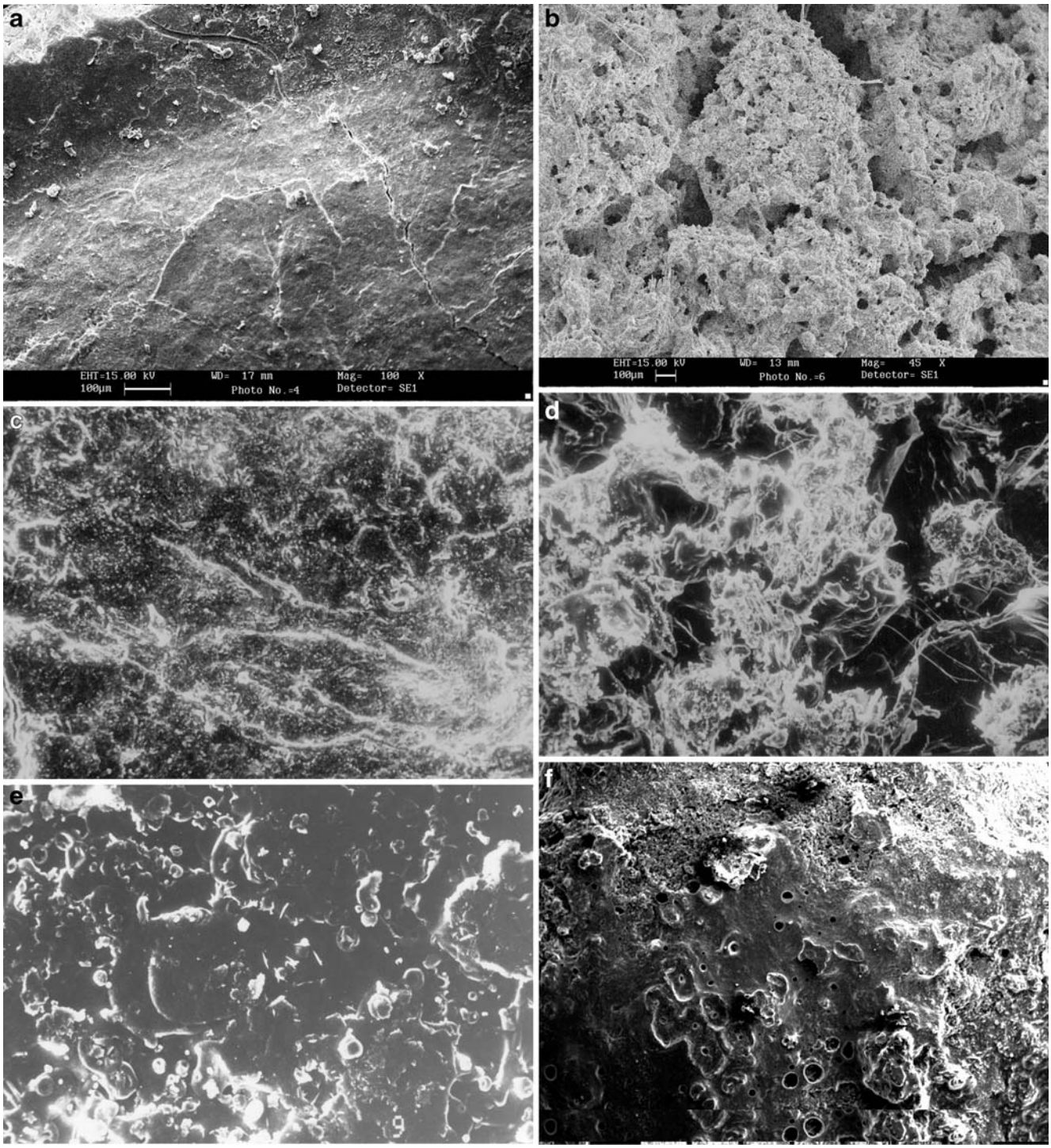

Fig. 4. SEM photomicrographs of matrix tablets showing surface morphology of batch F1 at **a** 0 h and **b** after 24 h; batch F6 at **c** 0 h and **d** after 24 h; for commercial product at **e** 0 h and **f** after 24 h of dissolution study

concentration of mucilage increased, drug release is retarded due to increase in the gel strength and to the formation of gel layer with longer path of diffusion, resulting in reduction in diffusion coefficient of the drug. The matrix was found to release the drug following Higuchi square root kinetics. The results of swelling and erosion studies were consistent with the kinetic study; the formulations containing lower proportion of mucilage (1:40 to 1:10) released the drug by combination of diffusion through the matrix and matrix erosion, while the formulation containing higher proportion of mucilage (1:5 to 1:1) released the drug by diffusion through the swollen matrix. Application of model-independent methods to release data like similarity factor and difference factor showed that optimal formulation, which showed similar dissolution profile as that of commercial reference tablet (Voveran SR), contained *Mimosa* mucilage in the proportion of mucilage to drug ratio of 1:40. So,

it can be concluded that *Mimosa* mucilage can be used as matrix-forming agent for sustained drug delivery in tablet formulations.

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