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Research Article

EVALUATION OF *TRIGONELLA FOENUM- GRAECUM* SEEDS GUM AS A NOVEL TABLET BINDER

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ABSTRACT

A binder holds powders together to form granules and also provides the cohesiveness required for the binding of the granules under compression to form a tablet. Since Fenugreek seeds produce high viscosity mucilage at low concentration levels, the objective of the present investigation was to evaluate the binder effects of this mucilage in tableting. The mucilage of *Trigonella foenum- graecum L.* seed was extracted and evaluated as a tablet binder in three different model drugs in term of solubility. Calcium acetate (CA), theophylline (TH) and ibuprofen (IB) were chosen as models of freely soluble, slightly soluble and practically water insoluble, respectively. Granules containing 0.1-2.5% of the mucilage were prepared and pressed using Kilian KS single punch tableting machine. Corn starch and polyvinylpyrrolidone (PVP K30) were selected as standard binders. The physical properties of the granules (bulk density, flow-ability and granule strength) and the tablets were assessed. The results showed that a 2.5% concentration of the new binder compared well with standard binders at least for properties studied herein. At this concentration level, CA tablets showed the highest mean value in tablet hardness but prolonged disintegration times and dissolution rate. Also, the binder prolonged the disintegration time and dissolution rate of TH tablets. However, IB tablets showed the least mean value in tablet friability and moderate disintegration time-dissolution rate. The binder of *Fenugreek* seeds mucilage sustains the dissolution rate of water soluble drugs.

Keywords: Mucilage, *Trigonella foenum- graecum*, Binder, Tablets.

INTRODUCTION

Trigonella foenum-graecum L. (Fenugreek) belongs to the Leguminosae family. It is an annual grassy plant and is one of the most important of 32 species of Iranian *Trigonella* species cultivated in several areas of the country [1]. Fenugreek seeds have been widely used in food as a flavour component and seasoning and in Iranian folk medicine as a tonic [2,3].

In clinical, pharmacological and biological tests, extracts and fractions of Fenugreek seeds are reported to have glucose and lipid-lowering properties and antioxidant and antiphlogistic effects. Phytochemical studies on *T. foenum-graecum* revealed that carbohydrates and mucilages (mainly galactomannans), proteins, fixed oils, flavonoids and saponins were the main components of the seeds [3, 4].

Since Fenugreek seeds produce high viscosity mucilage at low concentration levels, the objective of the present investigation was to evaluate the binder effects of this mucilage in tableting.

A binder holds powders together to form granules and also provides the cohesiveness required for the binding of the granules under compression to form a tablet [5]. The properties of the wet granules and the resulting tablets are influenced by the type and amount of binders.

The aim of this study was to investigate the possibility of using Fenugreek mucilage as a tablet binder in wet granulation process. Since water solubility of a drug candidate can influence over uniform binder distribution throughout the wet mass during tablet granulation [6] three different model drugs were examined in terms of water-solubility.

Calcium acetate (CA), theophylline (TH) and ibuprofen (IB) were selected as freely soluble, slightly soluble and practically water-insoluble, respectively [7]. The physical characteristics of the granules and tablets were evaluated and compared with those prepared using corn starch and polyvinylpyrrolidon (PVP K30) as standard binding agents.

MATERIALS AND METHODS

Trigonella foenum-graecum L. seeds were obtained from a research farm in Roshan Dasht, Isfahan, Iran, at an altitude of ca. 1700 m in September 2000. The plant material was authenticated by Dr. Iraj Mehregan in the Biology Department of Tehran Azad University, Tehran, Iran. CA (Merck, Germany), TH (Amin Pharmaceutical Company, Iran) and IB (Shasun, India) were used as model drugs. Avicel PH101 (FMC, USA), Starch (Gesellschaft GmbH, Austria), Lactose, Magnesium stearate, PEG6000, Na CMC, Aerosil, PVP (all from Merck, Germany), all solvents and other reagents were of high purity grade and all from (Merck, Germany).

Extraction of seed mucilage

Extraction of seed powder was carried out by a mixture of water and chloroform (2.5 ml chloroform in 1 lit of water), under low rate shaking and followed by filtration. The filtrate was gently mixed with acidified acetone (2.5 ml HCl/1 lit) to ensure complete precipitation [8].

Characterization of Fenugreek seed binder

The extracted seed mucilage was characterized for properties such as pH, specific gravity, surface tension, water content, ash percent [9, 10]. The swelling index of the pulverized plant seeds was also determined. It is the volume (ml) taken up by the swelling of 1 g of plant material under specified conditions [9]. To determine the swelling index of Fenugreek seeds powder, 1 g accurately weighted of the plant material was introduced into a 25 ml glass measuring cylinder. Then 25 ml of water was added and shaken thoroughly for 1 hour and allowed to stand for 3 hours at room temperature. The volume (ml) occupied by the plant material including any sticky mucilage was assessed [9].

The yield value of Fenugreek binder was undertaken according to British Pharmacopoeia (BP) and compared to standard binder, starch paste [10]. The measuring device consists of two square shaped flat glass plates with thickness of 3 mm and two dimensions each 100 mm. The plates were placed in a water bath until their temperature reaches 25°C and quickly dried. Then a sample of 1 g of the dispersion was poured in four points of the lower plate and second plate was being carefully placed on. The appropriate weight equivalent to 100 g was then applied on and allowed to remain for 10 minutes. After removing the upper plate, the diameter of four regions was measured and the average diameter, d (cm) was placed on the following formula to obtain yield value, τ (N/m^2) of the binder [10]:

$$\tau = \frac{2.943 \times 10^3}{d^3} \quad \text{eq. [1]}$$

Preparation and characterization of granules

Granules of lactose, CA, TH and IB containing binders (Fenugreek 0.1-2.5%w/w, PVP 22% and starch 12.5%) were prepared using wet granulation method, dried at 50°C in a hot air drier and characterized for their micromeretic and mechanical properties as well.

Bulk and Tapped density

The bulk density (V_b) was determined by filling 50 g granules into a graduated cylinder and calculating the ratio of the sample weight to sample volume. The tapped density (V_t) was determined as the ratio of the sample weight to the final sample volume [11].

Carr's and Hausner ratio

Carr's Index (I), the parameter representing the packing arrangement, was expressed as shown by the following equation [12].

$I = [1-V_b/V_t] \times 100$ eq. [2]

Interpretation of Carr's index is shown in Table 1.

Table 1: Interpretation of carr's index for powder and granule flow (12)

Carr's index	Flow
5-15	Excellent
12-16	Good
18-21	Fair to passable
23-35	Poor
33-38	Very poor
> 40	Very very poor

A similar index has been defined by Hausner that is calculated as the ratio of bulk density to tapped density. The Hausner ratio values less than 1.25 indicate good flow, while the values greater than 1.5 will show poor flow. The values between 1.25 and 1.5 affirm that adding glidant will improve flow-ability [12].

Angle of repose

The flowability of the granules was simply measured by determination of the angle of repose (θ) using fixed funnel method [12]. The granules were allowed to flow through the funnel onto the graph paper. The radius (r) and the height (h) of the cone formed on the paper permitted the determination of the angle of repose using eq. 3 [11, 12].

$$\text{Tan } \Phi = h/r \text{ eq. [3]}$$

The values given in Table 2 may be used as the guide [12].

Table 2: Relationship between angle of repose (θ) and powder flow (12)

θ	Flow
<25	Excellent
25-30	Good
30-40	Passable
> 40	Very poor

Granule strength

The granule strength was determined by friability test using the Roche friabilator (Erweka T.A.P, Germany). A sample of 10 g (W_A) granules from the 250-850 µm sieve fraction was poured in friability testing machine. After the drum movement stopped, the granules were sieved through a 60-mesh sieve and the residue remaining on the sieve was weighed (W_B). The granule strength was calculated using the following equation [13]:

$F (\%) = (W_A - W_B / W_A) \times 100$ eq. [4]

Preparation and evaluation of the tablets

The tablets containing lactose (as a control), CA (350 mg), TH (100 mg) and IB (150 mg) were separately prepared by wet granulation method using various binders; starch paste 12.5%, PVP 22% and Fenugreek binder 2.5% (Table 3).

Table 3: Composition of selected tablet formulations for model drugs prepared by fenugreek binder

Ingredients(mg)	Model drugs		
	Calcium acetate	Theophylline	Ibuprofen
Calcium acetate	350	-	-
Theophylline	-	100	-
Ibuprofen	-	-	150
Lactose	150	90	20
Corn starch	25	20	18
Magnesium stearate	5	-	2
PEG 6000	-	10	-
Avicel	-	-	96
Fenugreek binder	q.s	q.s	q.s

The resultant granules were lubricated and compressed using a single punch press machine (Kilian Co, KS 43373-202, Germany). The tablets were evaluated for weight variation, hardness, friability and disintegration time according to the USP 29 requirements [14]. Tablet dissolution behaviour was carried out using a dissolution tester (Pharmatest PTWS3, Germany). The settings of dissolution test for different tablets are summarized in Table 4.

Table 4: The setting of dissolution test for tablets prepared from drug models

Condition	Model drugs		
	Calcium acetate	Theophylline	Ibsprofere
Apparatus	Paddle	Paddle	Basket
Medium type	HCl 0.1 N	Distilled water	Phosphate buffer (pH=7.2)
Volume of Medium	500 ml	900 ml	900 ml
rpm	75	50	150
Temperature	37°C ± 0.5	37°C ± 0.5	37°C ± 0.5
Procedure	Atomic absorption (λ=422.9 nm)	UV (λ=273 nm)	UV (λ=221 nm)

RESULTS AND DISCUSSION

The amount of mucilage extracted from Fenugreek seed was 23.86% w/w. Table 5 shows the results of physicochemical properties of Fenugreek binder. In Table 5, The yield value of binder determined according to BP Pharmacopoeia [10] was 63.5±7.08 (N/m^2) and 4892±988 (N/m^2) for Fenugreek and starch binders respectively. In this experiment, the equivalent average diameter related to Fenugreek and starch binders was 3.6±0.14 cm and 0.85±0.05 cm respectively; indicating binder extracted from Fenugreek spreads more easily than starch paste in the powder mass.

In Table 6, the effect of various Fenugreek concentrations and standard binders (PVP and Starch) used to prepare lactose granules are shown.

Table 7 shows the physical characteristics of lactose granules and those of prepared tablets.

As table 7 shows the Carr's index and angle of repose of all formulations prepared by Fenugreek binder were lower than 15 and 25, respectively. Therefore, the granules were fallen in acceptable range for flow-ability properties [12]. A similar index has

been defined by Hausner that is calculated as the ratio of bulk density to tapped density. The Hausner ratio values less than 1.25 indicate good flow, while the values greater than 1.5 will show poor flow. The values between 1.25 and 1.5 affirm that adding glidant will improve flow-ability [12].

Considering the results shown in Tables 6 and 7, Fenugreek binder in concentration of 2.5% was selected to prepare tablets containing the model drugs by wet granulation process. Physical characteristics of granules prepared from the model drugs and their pharmacopoeial properties have been shown in Table 8.

Table 5: Characteristics of fenugreek seed mucilage (n=3)

pH (1% solution)	6.23 ± 0.2
Specific gravity (0.01% solution) g/ml	1.0005 ± 2.3×10^{-4}
Surface tension (0.1% solution) dym/cm	42 ± 0.1
Water content (%)	71 ± 5.2
Percent of total ash	0.967 ± 0.015
Percent of water soluble ash	0.847 ± 0.015
Percent of acid insoluble ash	0.01 ± 0.005
Swelling index (ml)	8 ± 0.2

Table 6: Type and percent of binders used to prepare lactose granules

Type & percent of binder									
	Fenugreek							**PVP**	**Starch**
Percent(W/W)	0.1	0.3	0.5	1	1.5	2	2.5	22	12.5
Amount (g)/ 100g lactose granule	24.4	19.5	17.7	17.5	16.5	16.4	12	14.1	27.1

Table 7: Physical characteristics of granules and tablets prepared from lactose

Properties	**Fenugreek**							**PVP**	**Starch**
	0.1%	**0.3%**	**0.5%**	**1%**	**1.5%**	**2%**	**2.5%**	**22%**	**12.5%**
Bulk density (g/ml)	0.57± 0.006	0.54± 0.008	0.58± 0.006	0.53± 0.008	0.56± 0.003	0.50± 0.007	0.56± 0.006	0.52± 0.009	0.49± 0.005
Tapped density (g/ml)	0.64± 0.008	0.70± 0.014	0.63± 0.008	0.62± 0.011	0.63± 0.008	0.53± 0.009	0.62± 0.008	0.62± 0.013	0.56± 0.006
Carr's index	10.35± 0.11	22.0± 1.005	9.2± 0.12	14.7± 2.98	10.1± 0.67	7.9± 0.15	11.1± 0.12	15.5± 0.32	11.8± 0.13
Hausner ratio	1.11± 0.001	1.28± 0.017	1.10± 0.001	1.17± 0.041	1.11± 0.008	1.09± 0.002	1.13± 0.017	1.25± 0.016	1.13± 0.005
Flow rate (g/sec)	30.6± 1.06	31.8± 0.05	33.3± 0.00	33.3± 0.00	30.2± 1.06	31.3± 0.00	33.3± 0.00	33.3± 0.00	32.1± 1.57
Angle of repose	17.9± 0.29	23.9± 2.12	14.7± 0.65	17.6± 0.64	18.3± 0.13	22.7± 0.00	18.9± 0.59	21.9± 0.00	24.4± 0.58
Granule straight	66.6± 1.39	85.9± 2.52	87.03± 0.47	92.3± 1.56	92.67± 0.09	93.9± 1.00	97.1± 0.54	97.9± 1.01	97.5± 1.89
Hardness(N)	58.2± 17.7	69± 19.94	80.1± 41.2	56.3± 13.8	57.9± 14.15	83.8± 12.14	72.5± 15.14	91.5± 28.85	81.7± 13.56
Friability	0.88± 0.19	1.12± 0.19	0.76± 0.2	0.88± 0.17	0.87± 0.005	0.60± 0.1	0.58± 0.09	0.80± 0.05	0.83± 0.1
Disintegration time (s)	67.5± 10.37	82.5± 4.18	86.67± 8.16	83.3± 2.58	72.5± 7.58	87.5± 7.58	112.5± 7.58	173.3± 19.92	214.7± 25.38

Table 8: Physical characteristics of granules and tablets prepared from model drugs

Properties	**Calcium acetate**			**Theophylline**			**Ibuprofen**		
	Fenugreek	**PVP**	**Starch**	**Fenugreek**	**PVP**	**Starch**	**Fenugreek**	**PVP**	**Starch**
Bulk density (g/ml)	0.51± 0.005	0.54± 0.005	0.48± 0.004	0.44± 0.007	0.48± 0.004	0.41± 0.006	0.38± 0.003	0.35± 0.003	0.36± 0.003
Tapped density (g/ml)	0.58± 0.006	0.62± 0.007	0.54± 0.005	0.48± 0.009	0.51± 0.003	0.48± 0.00	0.44± 0.002	0.38± 0.001	0.41± 0.008
Carr's index	13.1± 012	11.9± 0.18	12.3± 0.06	8.6± 0.17	5.98± 1.36	13.72± 1.19	14.7± 0.32	9.4± 0.71	11.9± 1.23
Hausner ratio	1.15± 0.002	1.14± 0.002	1.14± 0.001	1.09± 0.00	1.06± 0.015	1.16± 0.015	1.17± 0.005	1.10± 0.008	1.14± 0.016
Flow rate (g/sec)	31.3± 0.00	33.3± 0.00	33.3± 0.00	33.3± 0.00	33.3± 0.00	33.3± 0.00	27.4± 2.3	14.3± 0.4	21.2± 1.39
Angle of repose	20.1± 0.41	18.9± 0.51	23.3± 0.49	24.1± 0.38	23.23± 0.43	26.98± 0.42	24.5± 0.42	25.7± 0.45	23.2± 0.43
Granule strength	93.1± 3.04	96.6± 0.53	95.5± 0.54	94.50± 0.29	97.54± 0.04	85.52± 0.83	95.7± 0.06	97.3± 0.56	77.5± 1.46
Hardness (N)	89.5± 6.43	82.0± 6.15	76.7± 6.69	80.95± 8.7	82± 9.92	75.1± 5.22	75.5± 9.56	92.9± 5.29	71.2± 7.19
Friability	0.91± 0.002	0.90± 0.05	0.91± 0.004	0.48± 0.081	0.79± 0.11	0.90± 0.008	0.66± 0.006	0.32± 0.005	1.004± 0.005
Disintegration time (min)	20.5± 3.74	18.1± 1.04	13.3± 1.08	11.14± 3.14	3.32± 0.44	1.1± 0.30	7.7± 1.39	26.2± 3.1	2.3± 0.59

Tablet hardness of CA formulated by Fenugreek was more than those tablets formulated by standard binders, PVP and Starch. However, in case of IB and TH, tablets prepared by PVP had the highest hardness (Table 8). Moreover, an increase in Fenugreek concentration between 0.1 to 0.5 percent of binder usually increased the hardness and disintegration time and decreased friability values of the tablets. This finding may be attributed to gel forming property of Fenugreek in the tablet matrix as reported by Onunkwo and Mba [15]. They have formulated sodium salicylate tablets by Okra gum as a binder and investigated the effectiveness of gum on tablet properties.

Antony and Sanghavi [16] have also reported similar behaviour for a biodegradable polysaccharide, gellan gum when they compared gellan with several standard binders such as starch, acacia, gelatine, PVP and PVA. Gellan gum and PVP produced tablets with the highest level of hardness and the least friability[16].

More recently, Jani et al. [17] have reviewed the versatile role of natural gums and musilages in pharmaceutical formulations including their functions as tablet binder, disintegrant, coating agent and sustained release matrix.

Drug dissolution profiles of tablets prepared from CA, TH and IB are shown in figures 1, 2 and 3 respectively. To compare the release of drug from tablets, two main parameters, $t_{50\%}$, the time required for 50% of drug release and dissolution efficiency, $DE_{90}\%$ were calculated [18].

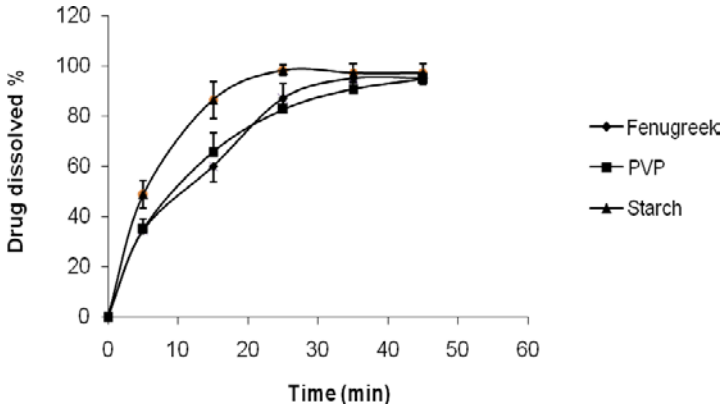

Fig. 1: Effect of binder type on drug release from calcium acetate tablets in HCl 0.1 N

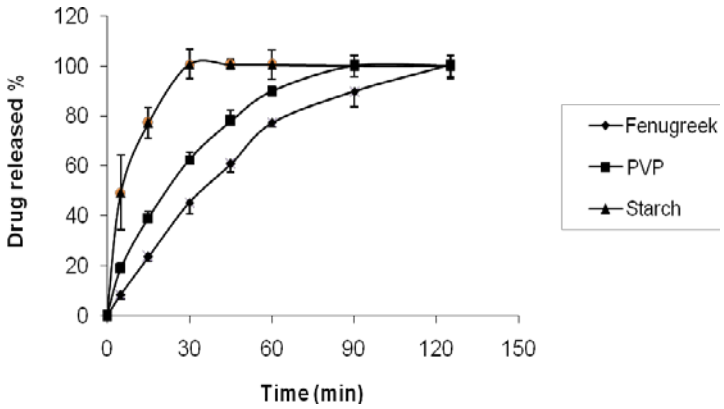

Fig. 2: Effect of binder type on drug release from theophylline tablets in distilled water

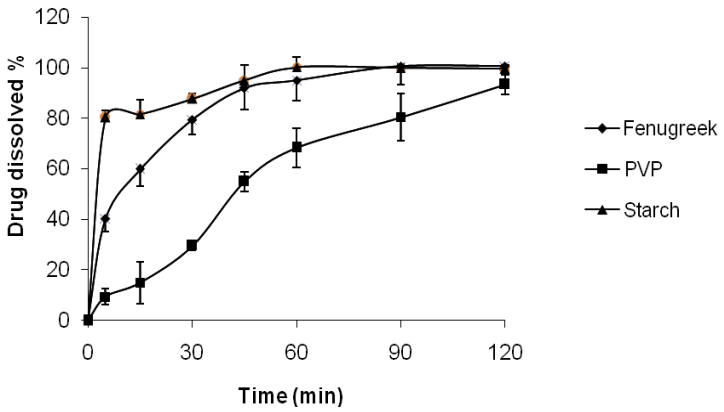

Fig. 3: Effect of binder type on drug release from ibuprofen tablets in phosphate buffer.

Table 9: Dissolution parameters of tablets prepared from model drugs by fenugreek and standard binders

Dissolution parameter	Calcium acetate			Theophylline			Ibuprofen		
	Fenugreek	PVP	Starch	Fenugreek	PVP	Starch	Fenugreek	PVP	Starch
$T_{50\%}$(min)	11.03± 2.08	9.63± 1.78	5.27± 0.99	34.41± 4.1	21.94± 1.67	5.18± 2.56	9.96± 2.23	42.07± 2.11	3.11± 0.09
DE_{90}(%)	48.86± 7.53	59.55±14.4	28.01± 6.46	60.6± 10.7	34.92± 7.8	20± 1.1	26.31± 11.5	89.35± 27.5	24.17± 5.13

As illustrated in Table 9, the time need to release 50% of drug from tablets prepared by Fenugreek binder is 11.03±2.08 min, 34.41±4.1 min and 9.96±2.23 min for CA, TH and IB, respectively. Comparison of both DE_{90}% and $t_{50\%}$ for TH tablets prepared by three different binders shows a significant difference among them ($P<0.05$) with highest values for Fenugreek. However, for IB tablets it seems Fenugreek binder is similar to PVP in term of DE_{90}%.

CA tablets formulated by PVP and Fenugreek have similar dissolution profiles (Figure 1). Furthermore, after 30 minutes of drug release, the profile of IB tablets formulated by Fenugreek looks alike to those tablets prepared by starch paste (Figure 3). Nevertheless, fenugreek binder shows a sustained effect on drug release from TH tablets (Figure 2). A similar behaviour for the impact of binder sort on drug release has previously reported by Baveja and et al [19]. They evaluated twelve natural binders for their ability to retard drug release from matrix tablets and found mucilages extracted of *Hibiscus esculenta* and *Linum usitatissimum* had superior retarding characteristics than even commonly used synthetic polymers such as HPMC [19].

Tavakoli et al. [20] have also evaluated the effectiveness of Okra gum as binder for tableting of Ibuprofen. They reported that Okra had a retarding effect on drug release from these tablets. Mucilage of Prosopis *juliflora* [21] and Cydonia *vulgaris* pers. seeds [22] are amoung the other plant mucilages reported as the useful binders in tablet production.

Similar results have reported by Sumathi and Ray [23] those who evaluated tamarind seed polysaccharide, a hydrophilic polymer isolated from seed kernel of *Tamarindus indica* for sustained release behaviour of both water soluble and water insoluble model drugs.

It is concluded that Fenugreek seeds mucilage can be used as a tablet binder and produces tablets with good hardness, friability, disintegration time and dissolution rate. The binder sustains the dissolution rate of water soluble drugs such as TH. This effect may be related to the hydrophilic nature of the binders that compete with the active drug in water attraction. However, in the case of CA, high water solubility of drug may overcome the hydrophilicity of the binder.

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