



Formulation and Evaluation of Tablets Containing Fenugreek Extract Using Sodium Starch Glycolate as Super Disintegrant

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Author's contribution

The sole author designed, analysed, interpreted and prepared the manuscript.

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ABSTRACT

The present work is aimed to formulate the tablets containing fenugreek extract as drug by wet granulation method. Further the effect of Sodium Starch Glycolate as super disintegrant on disintegration and drug release was studied. Fenugreek extract contains mucilage which retards the disintegration of tablets and hence shows slower drug release. Hence in order to improve disintegration and thereby *in vitro* drug release, Sodium Starch Glycolate was used as super disintegrant.

Tablet formulations were prepared without the SSG (Conventional-F1) and also with sodium starch glycolate (F2-F4) by wet granulation method. Assessment of flow properties of granules, physicochemical characterization of tablet formulations was carried out. Fenugreek is widely used for its antidiabetic activity which is attributed to mainly to the presence of an alkaloid Trigonelline. Hence *in vitro* release study of trigonelline was carried out which showed that the percentage release from F1 and F2 was found to be 58.12 ± 4.49 and 99.08 ± 0.01 respectively after 6 hrs. This study concludes that tablet formulation of fenugreek seed extracts with super disintegrants will be more desirable, advantageous and therapeutically more beneficial than incorporating the direct plant materials for the treatment of diabetes for faster onset of action.

Keywords: Tablet; sodium starch glycolate; fenugreek.

1. INTRODUCTION

Tablets are the most popular oral formulations available in the market and preferred by the patients and physicians alike. Plant products serve as an alternative to synthetic products because of local accessibility, environment friendly nature and lower prices compared to imported synthetic products. Various authors reported the formulation of herbal extracts into the conventional tablet dosage forms for immediate release few of which include ethanolic extract of leaves of *Hiptage benghalensis* [1], aqueous root extract of *Ervatamia. Heyneana* [2], ethanolic extract stem bark of *Alstonia boonei* [3], methanolic extracts of root of *Rhinacanthus nasutus* [4], ethanolic extract of *Peumus boldus* [5], ethanol extract of *Croton membranaceus* root [6].

Trigonella foenum-graecum (Fenugreek) belonging to the family Leguminosae is one of the oldest medicinal plants, dating back to the ancient Egyptians, Greeks and Romans, who used it as a culinary and medicinal herb. Fenugreek is an annual herb with long velvety erect stalk. Leaves are 5cm long, stipules triangular, lanceolate; Leaflets are 2-2.5cm long, obovate to oblanceolate in shape. Flowers are 1-2 in number, axillary, sessile, raceme, and whitish yellow in colour. Pods are 5-7.5cm long, with a long persistent beak, often falcate, 10-20 quadrilateral seeded, without transverse reticulations. Seeds are small hard, flattened with characteristic rhomboidal outline and brownish yellow in colour [7,8]. Fenugreek contains different constituents such as alkaloids, saponins, 4-hydroxyisoleucine and coumarins are found to be responsible for antidiabetic effect [9]. Hence crude extracts of fenugreek were chosen for formulation of oral tablet dosage forms than the isolated compound. In crude extracts, pure chemical components are unstable plant products. The development of appropriate formulations is necessary to increase their stability, efficiency and to make them suitable for oral use.

Disintegration has received considerable attention as an essential step in obtaining faster drug release. The emphasis on the availability of the drug highlights the importance of disintegrating tablets. Recently chemically modified disintegrants termed as super disintegrants have been developed to improve

the disintegration processes. Super disintegrants are the agents added to the tablet and some encapsulated formulations to promote the breakup of tablet and capsules "slugs" into smaller fragments in an aqueous environment thereby increasing the available surface area and promoting a more rapid release of the drug substance. They are generally used at low levels in solid dosage form, typically 2-5% by weight relative to the total weight of the dosage unit. Many synthetic substances like Sodium Starch Glycolate, Ac-di-Sol, Crosspovidone, and Kyron T314 have been used as a super disintegrating agent in the tablet formulation in order to modify the drug release from conventional dosage forms [10]. Vijaya S *et al* reported that addition super disintegrants improved the drug release from tablet dosage forms containing high amount of polyherbal dry extract which has longer disintegration and dissolution parameters in conventional formula [11]. Superdisintegrants will break up the tablet into small particle that can rapidly dissolve. Hence in the current study, formulation of tablet dosage form of fenugreek extracts were done and their drug release was improved with the incorporation of SSG as super disintegrants.

2. MATERIALS AND METHODS

2.1 Plant Material

Seeds of *Trigonella foenum-graecum* were collected from local market and authenticated by Dr. Nagalaxmi, Botany Department, St. Aloysius College Mangalore.

2.2 Preparation of Extract

Coarsely powdered seed powder was subjected to exhaustive soxhlation using ethanol as solvent for 72hrs. After extraction period, solution was filtered and concentrated using rotary vacuum evaporator to get extract.

2.3 Preliminary Phytochemical Screening

Preliminary phytochemical analysis of ethanolic fenugreek extract was carried out in order to identify the presence of different phytoconstituents such as alkaloids, proteins, phenolic compounds, carbohydrates, steroids etc [12,13].

2.4 Estimation of Trigonelline by UV-Spectrophotometric Method

Ultraviolet spectrophotometric method was carried out using phosphate buffer (pH 6.8) as solvent media and trigonelline hydrochloride as standard as per reported method with slight modification [14]. Standard trigonelline hydrochloride and fenugreek extract solution in phosphate buffer (pH 6.8) was scanned between UV-Visible range for obtaining absorbance maxima. Then the absorbance of the different serial diluted samples of standard was measured at the λ max using a UV spectrophotometer (V-630, Jasco) and a standard calibration curve was plotted with concentration against absorbance which is shown in figure.

2.5 Preparation of Tablet Formulation Containing Fenugreek Extract

Conventional tablets (F1) were prepared by wet granulation method. Dried extract (500mg) was mixed with lactose till it produces coherent mass. Then required quantity of starch powder (5%) was added and then powder blend was passed through # 12 to produce granules. Granules were gently spread and dried at temperature below 60°C. Dry granules were weighed and their weight was recorded. Further dry granules were regranulated by passing through # 16 placed on oversize # 44 to get uniform sized granules. Granules retained on # 44 were collected and weighed. Fines which passed through # 44 were also weighed. Fines equivalent to 15% of the weight of granules were mixed with granules and other ingredients such as starch powder, talc and magnesium stearate were added in required quantities. Tablets were prepared by compressing granules in rotary tablet machine (MT Rimek -rotary tablet machine) using 9mm flat surface punches. Conventional tablet formulation was modified by addition of Sodium

Starch Glycolate (2-5%) as super disintegrant and increasing the percentage of starch powder to 15% (F2-F4). The incorporation of superdisintegrants i.e Sodium Starch Glycolate (5%) in the dosage forms is done prior to compression.

In vitro dissolution study of conventional tablets containing fenugreek extract were done which did not show satisfactory drug release, hence an attempt was made in order to enhance drug release by incorporating the super disintegrants. Conventional tablet formulation was modified by addition of Sodium Starch Glycolate (2-5%) as super disintegrant and increasing the percentage of starch powder to 15% (F2- F4) which is shown in Table 1.

2.6 Evaluation of Fenugreek Granules and Tablet Formulation

The flow property of powder ready to compress was evaluated by measuring bulk density, tapped density, Hausner ratio, Carr's index, angle of repose, bulkiness [15,16].The prepared tablets were evaluated for appearance, thickness, hardness, weight variation, friability, disintegration time were performed by following the official method [17]. Tablet thickness was measured using Vernier callipers.

2.7 Test for Weight Variation

Twenty tablets were selected randomly from each batch and weighed individually on electronic balance (Shimadzu). The individual weight is then compared with average weight for the weight variations. The limit is 1200 mg \pm 5 %. No more than two tablets deviate from this range and none deviates by more than double this limit. The percentage of friability of the tablets was determined using Roche tablet friabilator operated at 25 rpm for 4 min.

Table 1. Formulation of tablets

Ingredients	Quantity/ Tablet (mg)			
	F1	F2	F3	F4
Fenugreek extract	500	500	500	500
Lactose monohydrate	340	270	260	240
Starch powder	100	150	150	150
Talc (3%)	30	30	30	30
Magnesium stearate (3%)	30	30	30	30
Sodium Starch Glycolate	----	20	30	50

2.8 Determination of Disintegration Time

Disintegration time for fenugreek tablets were determined by disintegration apparatus. Six tablets were placed in six tubes of the basket and the apparatus was operated using water as the immersion fluid maintained at $37 \pm 2^\circ\text{C}$. The tablets were observed and the time taken for complete disintegration of all tablets was determined.

2.9 *In vitro* Dissolution Studies of Conventional Fenugreek Tablet

Dissolution rate was studied using USP type II paddle dissolution apparatus using 900 ml phosphate buffer pH 6.8 at 100 rpm. An aliquot amount of the sample was withdrawn at regular time intervals and the same volume of pre warmed ($37 \pm 0.5^\circ\text{C}$) fresh dissolution medium was replaced. The samples were filtered, suitably diluted and trigonelline in each sample was analysed by using Shimadzu UV-spectrophotometer at 265 nm and results are shown in Table 4.

3. RESULTS AND DISCUSSION

3.1 Extraction of Fenugreek Seeds and Preliminary Phytochemical Analysis of the Extract

Yield of the fenugreek extracts obtained was 12%. The preliminary phytochemical analysis of fenugreek extracts showed the presence of alkaloids, phenols, flavonoids, tannins, steroids, carbohydrates, proteins and amino acids.

3.2 Estimation of Trigonelline by UV-Spectrophotometric Method

Amount of trigonelline in fenugreek extracts were estimated by UV-spectrophotometric method. UV

spectrum of standard trigonelline solution showed maximum absorption at wavelength of 265 nm and hence λ_{max} of 265 nm was selected and utilized for the estimation of trigonelline. UV spectrum of fenugreek extract also showed the peak for trigonelline at wavelength of 265 nm which showed that absorption peak of trigonelline in fenugreek extract match with the absorption peak of standard trigonelline.

For preparation of standard plot, different concentration of standard trigonelline solution was prepared in phosphate buffer of pH (6.8) and absorbance was measured at 265 nm. Trigonelline showed good linearity with Regression coefficient 0.998 at the concentration range of 6-18 $\mu\text{g/ml}$ which indicated that Beer's law was obeyed in this concentration range (Fig. 1). Amount of trigonelline in fenugreek extract was calculated from calibration curve equation $Y = 0.023x + 0.001$ which was found to be 250 mg /g of the extract.

3.3 Preparation and Evaluation of Granules of Fenugreek

Fenugreek granules were subjected to preformulation studies and results of which is shown in Table 2. There was no significant difference in bulk densities, tapped densities of prepared granules. Hausner ratio was found in the range of 1.07-1.18. Since Hausner ratios were below 1.24 indicates good flow property of granules. Granules of almost all the formulations gave a compressibility index ranged from 6.57-15.85% and angle of repose in the range of $22.2^\circ - 30.4^\circ$. A compressibility index of greater than 25% is considered to be an indication of poor flowability and below 15% an indication of excellent flowability of granules. Since all the formulations had a Carr's index below 15% and angle of repose below 30° granules possess good flow property.

Table 2. Evaluation of fenugreek granules

Formulation Code	Evaluation parameters					
	Bulk density (g/ml)	Tapped density (g/ml)	Hausner ratio	Carr's index (%)	Angle of repose ($^\circ$)	Bulkiness
F1	0.70 \pm 0.01	0.76 \pm 0.02	1.08 \pm 0.06	7.57 \pm 0.07	30.4 \pm 0.05	1.41 \pm 0.03
F2	0.73 \pm 0.03	0.79 \pm 0.01	1.08 \pm 0.02	7.59 \pm 0.05	22.2 \pm 0.01	1.36 \pm 0.01
F3	0.70 \pm 0.01	0.81 \pm 0.03	1.15 \pm 0.01	13.58 \pm 0.01	23.3 \pm 0.05	1.42 \pm 0.01
F4	0.69 \pm 0.02	0.82 \pm 0.01	1.18 \pm 0.01	15.85 \pm 0.03	23.5 \pm 0.03	1.44 \pm 0.04

All values are expressed as mean \pm SD, n=3

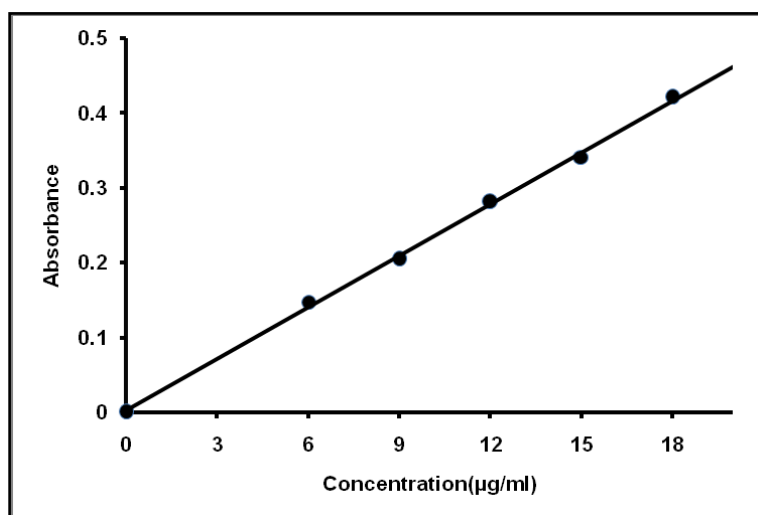


Fig. 1. Standard plot of trigonelline hydrochloride in phosphate buffer at 265 nm

3.4 Formulation and Evaluation of Fenugreek Tablets

The prepared tablets were spherical brown colour with smooth surface having acceptable elegance. The hardness of the tablets was within the acceptable range of 3.6-4.5 kg/cm². The friability value of all the formulations was below 1.0% indicating tablet resistance towards fracture and abrasion. Disintegration time is an important parameter of tablet. An ideal tablet should disintegrate within 15min. Disintegration of tablet was found to be 13min. Hence tablets were found to have good quality with regard to hardness, friability, weight variation and disintegration.

3.5 In vitro Dissolution Study of Tablet Formulations

In vitro dissolution study was carried out in order to determine the rate and extent of release of trigonelline from tablet formulations of fenugreek and results are shown in Table 4.

The tablet formulation F1 which do not contain super disintegrant showed 78.06 % release of trigonelline at the end of 6hrs. Since the drug release was incomplete, the dissolution study was continued for 12hrs to get 92% trigonelline release. The high percentage of mucilage (natural gummy substance in the coating of seed) produces a viscous tacky mass on exposure to dissolution fluids thereby causing slower and incompletes trigonelline release. Mucilage derived from the seeds of fenugreek find its application as binding agent, suspending agent, gelling agent and release retardant material in solid dosage forms [18-21]. In order to improve drug release, three tablet formulations F2, F3, F4 were prepared with the incorporation of 2%, 3% and 5% SSG as super disintegrant respectively. Dissolution profile of tablet formulations F2, F3, F4 showed more than 90% drug release after 6 hrs. Rate and extent of drug release were increased with the increase in concentration of SSG. SSG act as super disintegrant by rapid absorption of water and swelling leading to an enormous increase in volume of granules which result in rapid and uniform disintegration.

Table 3. Physical characterisation of fenugreek tablets

Formulation Code	Evaluation parameters					
	Hardness (kg/cm ²)	Friability (%)	Thickness (mm)	Weight variation (mg)	Trigonelline content (%)	Disintegration time (mins)
F1	3.6±0.15	0.35 ± 0.05	5.3± 0.05	986±0.4	87.80±0.1	15±0.3
F2	3.3±0.11	0.39± 0.07	5.2± 0.1	982±0.3	86.85±0.5	10±0.1
F3	3.1±0.09	0.36± 0.05	5.2± 0.1	984±0.4	87.41±0.3	9±0.4
F4	3.0±0.12	0.37± 0.06	5.3± 0.1	980±0.2	89.06±0.3	7±0.4

All values are expressed as mean ±SD, n=3

Table 4. Release profile of trigonelline from tablets

Time (minutes)	Cumulative drug release (%)			
	F1	F2	F3	F4
5	5.55±0.02	11.25±0.03	15.32±0.01	18.71±0.03
15	13.26±0.01	15.25±0.02	30.06±0.05	39.22±0.05
30	21.49±0.05	29.7±0.03	45.51±0.02	51.24±0.02
60	29.79±0.03	50.05±0.01	66.67±0.01	74.29±0.09
120	38.44±0.01	63.2±0.05	76.89±0.02	89.80±0.08
240	56.22±0.02	74.86±0.03	86.86±0.03	96.04±0.03
360	78.06±0.02	90.86±0.02	95.46±0.05	99.08±0.01
480	83.15±0.05	---	---	---
720	92.5±0.01	---	----	---

4. CONCLUSION

Fenugreek extracts are known to have the antidiabetic effect. In order to improve the patient compliance, the extract can be made into oral tablet dosage form. Addition of super disintegrants to the tablet formulations makes the immediate and complete release of antidiabetic constituent (Trigonelline) within short period of time which is necessary for producing faster onset of antidiabetic effect.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

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COMPETING INTERESTS

Author has declared that no competing interests exist.

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