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# Design and evaluation of fast dissolving tablets containing diclofenac sodium using fenugreek gum as a natural superdisintegrant

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## ARTICLE INFO

## Peer reviewer

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## Comments

The paper is well written and interesting for reading. The topic of the manuscript is quite interesting and results are hesitating. I believe that this manuscript could contribute to the knowledge in terms of design and evaluation of fast dissolving tablets containing diclofenac sodium in combination with fenugreek gum, as a natural superdisintegrant.

Details on Page S334

## ABSTRACT

**Objective:** To formulate diclofenac sodium as fast dissolving tablets (FDTs) using fenugreek gum as a natural superdisintegrant which also possess anti-inflammatory activity.

**Methods:** An attempt was made to extract the fenugreek gum and evaluated it for various physicochemical characterizations. The swelling index and viscosity of fenugreek gum was 221% and 293.4 mpa-s respectively. FDTs of diclofenac sodium was formulated by direct compression technique using different concentrations (1%–6%, w/w) of fenugreek gum as a natural superdisintegrant and compared with renowned synthetic superdisintegrants like sodium starch glycolate and croscarmellose sodium. The anti-inflammatory activity of a formulation was evaluated with carrageenan induced experimental rats.

**Results:** The formulated tablets were evaluated for various physical tests like weight variation, friability, hardness and results complied with the limits. The drug release from all the formulations ascertained first order kinetics. Among all the formulations F3 containing fenugreek gum with the concentration of 6% produced least disintegrating time 21 seconds resulting in higher drug release rate 93.74% at the end of 25 min. Hence, it was considered as optimized formulation. The present study revealed that the fenugreek gum as a natural superdisintegrant showed better disintegrating property than the most widely used synthetic superdisintegrants like sodium starch glycolate and croscarmellose sodium in the formulations of FDTs.

**Conclusions:** The results suggested that the fenugreek gum act as a good super disintegrating agent and it showed promising additive anti-inflammatory activity with diclofenac sodium.

## KEYWORDS

Diclofenac sodium, Fenugreek gum, Superdisintegrant, Anti-inflammatory activity, Sodium starch glycolate, Croscarmellose sodium, Direct compression, Quick pain relief

## 1. Introduction

Oral route is the most preferable and convenient route of administration as it offers advantages like ease of administration, highly versatile, patient compliance and accurate dosing<sup>[1]</sup>. The most popular solid dosage forms are being tablets and capsules. One important drawback of these dosage forms for some patients, is the difficulty to swallow and readily access to water for easy swallowing dosage<sup>[2]</sup>. Difficulty in swallowing (dysphasia) is also a common problem of all age groups, especially the elderly and paediatrics, because of physiological changes

associated with these groups<sup>[3]</sup>. Fast dissolving drug delivery is rapidly gaining acceptance as an important new drug delivery technology which aims to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for administration and to achieve better patient compliance<sup>[4]</sup>. The fast dissolving tablet (FDT) has remarkable disintegration properties and it can rapidly disintegrate without water in the mouth within few seconds. When an FDT is placed in the oral cavity, saliva quickly penetrates into the pores causing rapid disintegration<sup>[5]</sup>. Based on the absolute bioavailability of diclofenac sodium<sup>[6]</sup>, tablet is about 50–60%. The half-life is 2 h and highly protein

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bound (>99%). In the bioavailability classification system, diclofenac is classified as a class II drug, because of its low water solubility and high permeability. The bioavailability of drug is significantly greater than those observed from conventional tablet dosage form. Usually, superdisintegrants are added to a drug formulation to facilitate the break-up or disintegration of tablet or capsule content into smaller particles that can dissolve more rapidly than drugs in the absence of disintegrates. Many superdisintegrants like cross povidone, croscarmellose sodium (Ac-di-sol) and sodium starch glycolate (SSG) have been used in the formulations of FDTs. In the present study it was proposed to formulate an oral drug delivery, in the form of FDTs by using direct compression method<sup>[7]</sup>. The purpose of the present study was to extract the fenugreek gum, evaluate its powder flow properties (bulk density, tapped density, angle of repose, Carr's index and hausner ratio), swelling index and loss on drying and to compare disintegration efficiency of fenugreek gum with widely used synthetic superdisintegrants *i.e.* SSG and croscarmellose sodium in the formulation of FDTs. All the superdisintegrants were used in optimized concentration levels to assess their efficiency. The tablets were evaluated in various physical tests. The formulation of a FDTs, thus containing diclofenac sodium and fenugreek gum, produces additive anti-inflammatory activity resulting in reduction in a dose of diclofenac sodium and thereby its dose related side effects.

## 2. Materials and methods

### 2.1. Materials

Fenugreek seeds, diclofenac sodium (Harman Finocem Ltd, Mumbai), microcrystalline cellulose (SD Fine Chemicals), SSG (SD Fine Chemicals), croscarmellose sodium (Arrow Chem. Product., Mumbai), hexane (SD Fine Chemicals) and all other ingredients used throughout the study were of analytical grades.

### 2.2. Methods

#### 2.2.1. Extraction and purification of fenugreek gum

Fenugreek seed (100 g) were ground to 100 mesh using a laboratory mill. The fine powder was extracted with boiling hexane in Soxhlet apparatus for 80 min. The obtained extract was treated with 95% ethanol (maintaining its boiling point) for 130 min in a conical flask to remove the unwanted saponin. Further enzyme deactivated was initiated by refluxing the extract with 70% ethanol for 180 min. The resulting mixture was repeatedly treated with ethanol to remove undissolved traces if necessary. The residue was filtered through sintered glass at room temperature. The filtered residue was subjected to mechanical stirring at 700 r/min with addition of water for 8 h. The obtained mixture was centrifuged at 5000 r/min for 12 min at 10 °C.

The supernatant contained crude fenugreek gum, which was decanted and precipitated by adding of ethanol (70%). Thus the gum precipitate was washed with acetone, diethyl ether and water. The pure fenugreek gum was oven dried<sup>[8]</sup>.

#### 2.2.2. Physicochemical characterization of gum

The purified and dried extracted gum powder was evaluated for its micromeritic properties, viscosity, solubility studies, swelling index and loss on drying.

##### 2.2.2.1. Swelling index

The study was carried out by using a 100 mL stoppered graduated cylinder. The initial bulk volume of 1 g of fenugreek gum was noted. Water was added in sufficient quantity to ensure 25 mL of uniform dispersion by vigorously shaking every 10 min for 1 h and then allowed to stand for 24 h. The dispersion was stored at room temperature and the sediment volume of the swollen mass was measured after 24 h<sup>[9]</sup>.

$$\text{Swelling index} = 100 \times (V_2 - V_1 / V_1)$$

Where,  $V_1$  = Initial volume of material before hydration;  $V_2$  = Volume of hydrated material.

##### 2.2.2.2. Viscosity

One gram of fenugreek gum powder was suspended in 75 mL of distilled water for 4 h. Distilled water was added up to 100 mL to produce the concentration of 1%. The mixture was homogenized by mechanical stirrer for 2 h and its viscosity was determined by using Brookfield viscometer, spindle SC4-18 (Brookfield Viscometer, DV-2+LV) at 5 r/min<sup>[10]</sup>.

##### 2.2.2.3. Loss on drying

Loss on drying technique is used to determine high levels of moisture or solvents present in the sample. The material sample was weighed ( $W_1$ ) and heated in an oven for 2 h. It was cooled in the dry atmosphere of desiccators and then finally weighed ( $W_2$ ).

$$\% \text{ Loss on drying} = [(W_1 - W_2) / W_1] \times 100$$

Where,  $W_1$  = Initial weight of the powder;  $W_2$  = Final weight of the powder.

#### 2.2.3. Characterization of drug and excipients

##### 2.2.3.1. Drug-excipient compatibility studies

The physicochemical compatibility between diclofenac sodium and fenugreek gum used in the research were assessed by subjecting to infrared spectral studies. The samples were scanned under diffuse reflectance mode and the graph was plotted by KBr pellet method. Its spectra were recorded in the wavelength region between 4000  $\text{cm}^{-1}$  to 400  $\text{cm}^{-1}$ . The spectra of diclofenac sodium, fenugreek gum and physical mixtures of diclofenac sodium and fenugreek gum were compared.

#### 2.2.4. Formulation of FDTs

FDTs containing 50 mg diclofenac sodium were prepared by direct compression method and the formulae used in

the study are shown in Table 1. The formulation containing varying proportions (for optimization) of fenugreek gum along with the microcrystalline cellulose as direct compressible diluent and mannitol as sweetening agent. To compare disintegration efficiency of fenugreek gum with widely used synthetic superdisintegrants *i.e.* SSG and croscarmellose sodium. All the ingredients were passed through # 60 separately to attain uniformity and mixed thoroughly. The blended mixture was directly compressible into tablets with 9 mm punch using 16-station rotary tableting machine (Table 1).

**Table 1**

Formula of different formulations of Diclofenac Sodium FDTs (mg).

Composition	F1	F2	F3	F4	F5	F6	F7	F8	F9
Diclofenac sodium	50	50	50	–	–	–	–	–	–
Fenugreek gum	4	8	12	–	–	–	–	–	–
Sodium starch glycolate	–	–	–	4	8	12	–	–	–
Croscarmellose sodium	–	–	–	–	–	–	4	8	12
Microcrystalline cellulose	90	86	82	90	86	82	90	86	82
Mannitol	50	50	50	50	50	50	50	50	50
Talc	3	3	3	3	3	3	3	3	3
Magnesium stearate	3	3	3	3	3	3	3	3	3
Total	200	200	200	200	200	200	200	200	200

### 2.2.5. Evaluation of tablets

All the tablets were evaluated for different physical parameters as weight variation, hardness, friability, disintegration time, wetting time, drug content and *in vitro* dissolution study<sup>[11–13]</sup>.

#### 2.2.5.1. Thickness

The thicknesses of the formulated tablets were measured by using Vernier callipers.

#### 2.2.5.2. Weight variation

The formulated tablets were tested for weight uniformity. For this 20 tablets were weighed collectively and individually. From the collective weight, average weight was calculated. Each tablet's weight was then compared with average weight to ascertain whether it was within permissible limits or not.

$$\% \text{ Weight variation} = \frac{\text{Average weight} - \text{Individual weight}}{\text{Average weight}} \times 100$$

#### 2.2.5.3. Hardness

Hardness of tablets was measured using Pfizer type hardness tester. Three tablets were selected from each formulation randomly and their hardness was measured. The mean±SD of hardness values were calculated.

#### 2.2.5.4. Friability

Friability of the tablets was determined by using Roche friabilator. The weight of 20 tablets (initial weight) was subjected to friabilator at 25 revolutions per 4 min. Tablets were then dedusted, reweighed (final weight) and percentage loss was calculated. Friability is obtained by the following formula:

$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

#### 2.2.5.5. Wetting time and water absorption ratio

A double folded tissue paper was placed in a Petri dish. 6 mL of water containing a water-soluble dye (eosin) was added to the Petri dish. A tablet (pre-weighed) was carefully placed on the surface of tissue paper. The time required for water to reach the upper surface of the tablet was noted as the wetting time. The wetted tablet was then weighed and the water absorption ratio (R) was determined by using the equation:

$$R = 100 (W_b - W_a) / W_b$$

Where  $W_a$  and  $W_b$  are the weights of tablet before (dry weight) and after water absorption (wet weight) respectively.

#### 2.2.5.6. Drug content

Twenty tablets were weighed and powdered. The quantity of powder equivalent to 50 mg of diclofenac sodium was dissolved in phosphate buffer pH 6.8 diluted to 100 mL with the same and the solution was filtered and suitably diluted. The drug content was estimated spectrometrically at 276 nm.

#### 2.2.5.7. *In vitro* disintegration test

*In vitro* disintegration time was determined by using disintegration test apparatus (Electrolab, USP model ED-2L, Mumbai) without disk for six tablets. The disintegration medium was 900 mL of distilled water kept at (37.0±0.5) °C and stirred at a rate of (30±2) r/min. The time was measured in seconds for complete disintegration of the tablet with no palpable mass remaining in the apparatus. The test was carried out in triplicate.

#### 2.2.5.8. *In vitro* dissolution studies

Dissolution rate was studied by using USP type II paddle dissolution apparatus, in 900 mL of phosphate buffer pH 6.8 at (37.0±0.5) °C at 75 r/min. Aliquot of dissolution medium was withdrawn at regular time intervals and the same volume of pre-warmed (37±0.5) °C fresh dissolution medium was replaced. The samples were filtered and drug content of diclofenac sodium in each sample was analyzed after suitable dilution by Shimadzu UV-spectrophotometer at 276 nm.

### 2.2.6. Pharmacodynamic studies

Pharmacodynamic study was carried out in adult male Wistar rats weighing 180–260 g obtained from the Animal House of Bapatla College of Pharmacy (1032/ac/07/CPCSEA), Bapatla<sup>[14]</sup>. The experiment protocol (IAEC/IV-9/BCOP/2012) was approved by the Institutional Animal Ethical Committee of Bapatla College of Pharmacy. Inflammation was induced in rats using Lambda carrageenan (1%) suspension. A dose of the tablets equivalent to human's body weight was dissolved in normal saline and administered orally to the rats. After 4 h the percentage of inhibition of paw volume was measured.

To study the additive anti-inflammatory activity of diclofenac sodium and the extract of fenugreek gum powder, Wistar rats (180–260 g) were divided into 4 groups, each with

six rats and were fasted for 18 h with free access to water. To Group I normal saline was administered and used as the negative control. For Group II, 5 mg/kg of diclofenac sodium was administered. For Group III, a physical mixture of 5 mg/kg of diclofenac sodium and 1.1 mg/kg of fenugreek gum powder was administered. Group IV received a 1.1 mg/kg fenugreek gum.

After 30 min, oedema was induced by injecting 0.1 mL of 1% carageenan suspension into the sub planter region of right hind paw rats in all groups. The volume changes in the rat paw were measured by Plethysmographic technique. The mercury volume displaced in the Plethysmographic (the paw volume) was measured at the end of 4 h.

The anti-inflammatory activity (percentage inhibition) was calculated by using the formula:

$$(A-B)/A \times 100$$

Where, A=Mean paw volume of control (left leg); B=Mean paw volume of drug treated animals (right leg).

### 3. Results

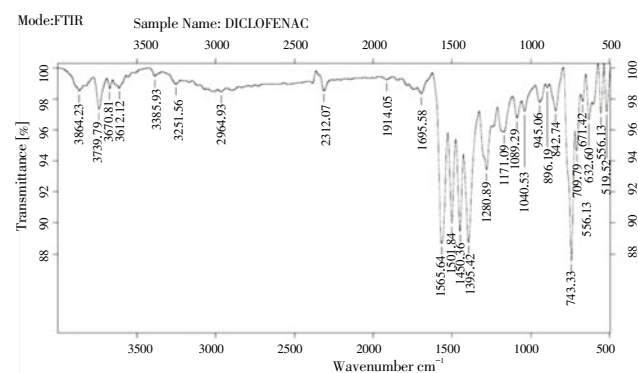
The fenugreek gum was extracted and evaluated for the physicochemical characterization as shown in Table 2. Compatibility study of diclofenac sodium and fenugreek gum were conducted by employing infrared spectral studies as shown in Figures 1–3. The swelling index and viscosity of fenugreek gum was 221% and 293.4 mpa.s respectively. The percent of loss on drying was observed within limit. In case of micromeritic studies such as bulk density was found to be 0.396 g/cm<sup>3</sup> and tapped density was 0.413 g/cm<sup>3</sup>. From density data percentage of Carr's index was calculated as 14.11%. Angle of repose was found to be 22.4°. Hausner's ratio was

found below 1.12% indicating well acceptable limits.

**Table 2**

Physicochemical characterization of fenugreek gum.

Parameters	Results
pH (1%, w/v)	6.2
Loss on drying	7.54%
Swelling index	221%
Solubility	Slightly soluble in cold water, But moderately dissolves in warm water, forms viscous solution, insoluble in organic solvents.
Percentage yield	26.4
Bulk density	0.396 g/cm <sup>3</sup>
Tapped density	0.413 g/cm <sup>3</sup>
Compressibility index	14.11%
Hausner's ratio	1.042
Angle of repose	22.4°



**Figure 1.** FT-IR studies of diclofenac sodium.

The different formulations of diclofenac sodium FDTs were prepared by direct compression method using fenugreek gum as a natural superdisintegrants, and were compared

**Table 3**

Physical evaluation of FDTs diclofenac sodium.

Formulation	Weight variation (%)	Hardness (kg/cm <sup>2</sup> )	Thickness (mm)	Friability (%)	Drug content (%)	Wetting time (second)	Water absorption test (%)	Disintegration time (second)	<i>In vitro</i> dissolution (cumulative % release)
F1	2.92±0.02	5.8±0.24	4.1±0.17	0.61±0.09	99.48±0.18	35	83.91±0.26	42	82.20±0.03
F2	2.93±0.02	5.6±0.08	4.1±0.29	0.66±0.03	99.46±0.16	27	88.91±0.92	33	88.80±0.03
F3	3.44±0.07	6.4±0.14	4.2±0.13	0.61±0.02	99.78±0.10	17	92.48±1.98	21	93.74±0.04
F4	2.55±0.10	6.3±0.20	4.0±0.04	0.7±0.13	99.74±0.04	51	71.20±0.19	57	73.23±0.09
F5	3.23±0.12	5.7±0.12	3.9±0.16	0.61±0.02	99.53±0.03	36	73.02±1.36	46	80.87±0.02
F6	3.16±0.09	5.8±0.16	3.9±0.04	0.63±0.10	99.82±0.02	25	81.12±0.96	34	84.93±0.01
F7	2.47±0.34	5.7±0.20	4.2±0.09	0.68±0.03	99.89±0.08	44	82.09±1.01	49	79.53±0.02
F8	2.62±0.12	5.8±0.25	4.0±0.04	0.59±0.01	99.71±0.01	31	84.18±0.88	37	85.89±0.01
F9	2.93±0.03	5.9±0.28	4.3±0.08	0.63±0.02	99.28±0.03	21	89.92±0.81	28	88.75±0.02

All values are expressed as mean±SD (n=3).

**Table 4**

Effect of anti inflammatory activity of diclofenac sodium and fenugreek gum on carageenan induced rat paw oedema.

Groups	Treatments	1st h	2nd h	3rd h	4th h	% Inhibition
Group-I	Control (normal saline)	0.380±0.160	0.410±0.021	0.500±0.018	0.460±0.090	–
Group-II	Diclofenac sodium (5 mg/kg)	0.150±0.130	0.110±0.110	0.150±0.021	0.080±0.140	65
Group-III	Diclofenac sodium (5 mg/kg)+fenugreek gum (1.1 mg/kg)	0.090±0.120	0.110±0.260	0.150±0.090	0.080±0.280	85
Group-IV	Fenugreek gum (1.1 mg/kg)	0.270±0.080	0.320±0.130	0.420±0.090	0.350±0.060	23

Data are expressed as mean±SEM.

with various standard synthetic superdisintegrants like SSG, croscarmellose sodium. All the superdisintegrants were used in optimised concentration. The tablets were prepared and evaluated. Results were shown in Table 3 and Figure 4. And the results of additive anti-inflammatory activity of diclofenac sodium and the extract of fenugreek gum powder is shown in Table 4.

#### 4. Discussion

The method employed for the production of the fenugreek gum from fenugreek seeds was found to be reproducible. The characteristic peaks in the physical mixture of diclofenac sodium and fenugreek gum indicated that the gum did not interfere the peaks of drug confirming its compatibility. The physicochemical characterization adopted for the gum powder revealed that it possessed good swelling ratio in the distilled water. The rheological studies indicated that 1% w/v gum dispersion in water had a gel like consistency exhibiting pseudoplastic behaviour. The flow properties of the powder attribute to the uniform mass of the tablets which is essential prior to compression to tablets. The micromeritic properties of gum powder such as bulk density and tapped density indicated good packing characteristics. Further the Carr's index, Hausner's ratio and angle of repose were found to be 14.11%, 1.042 and 22.40° respectively indicating the desirable flow properties. The formulated FDTs were subjected to evaluation. The weight variation of all the tablet formulations complied with the pharmacopeial limits. The hardness of the FDTs was between 5.6 to 6.4 kg/cm<sup>2</sup> and the thickness was 3.8 to 4.3 mm. Hardness and thickness studies indicated the mechanical strength of the tablet. The percent friability was well within prescribed limits revealing the physical integrity of the tablet. The percent of drug content in all the formulated tablets was in the range of 99.28% to 99.89%, ensuring the uniformity of drug content in all the tablets. The wetting time of all the formulated tablets (F1 to F9) were found to be 17 to 51 seconds. These results suggested that the wetting process of the tablets were closely related to the inner structure of the tablets, especially pore size, which affects water penetration into the tablets. Of all the formulations, the tablets formulated with fenugreek gum (F3) showed the least wetting time of 17 seconds, which had a direct impact on high water absorption ratio (92.48±1.98)%. It was observed that the increased concentration of fenugreek gum decreased the disintegration time and optimized the drug release. Fenugreek gum in the concentration of 6% acts as a eminent superdisintegrant and disintegrates the tablet within 21 seconds fulfilling the criteria of FDT. Further the higher dissolution rate of the F3 formulation 93.74% at the end of 25 min indicated that fenugreek gum had a better choice among the renowned synthetic super disintegrating agents like SSG and croscarmellose sodium. From the data of *in vivo* studies, it was assumed that Group III formulation containing 5 mg/kg diclofenac sodium and 1.1 mg/kg fenugreek gum exhibited more significant inhibition comparing with the other groups include the control. This significant anti-inflammatory activity may be due to the synergistic action of diclofenac sodium and fenugreek gum resulting in the better suppression of various inflammatory mediators in prostaglandin synthesis, cytokinins production and leucocytes migration. Hence, it can be concluded that the fenugreek gum acts as a good superdisintegrating agent

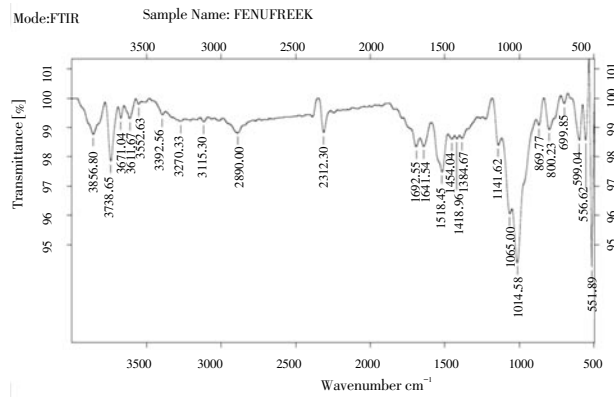


Figure 2. FT-IR studies of fenugreek gum.

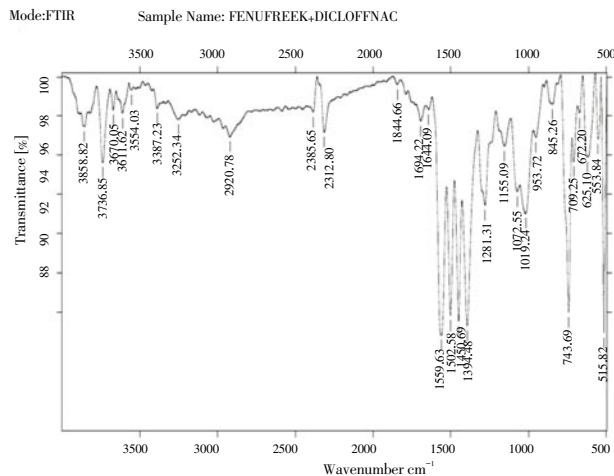


Figure 3. FT-IR Studies of physical mixture of diclofenac sodium and fenugreek gum.

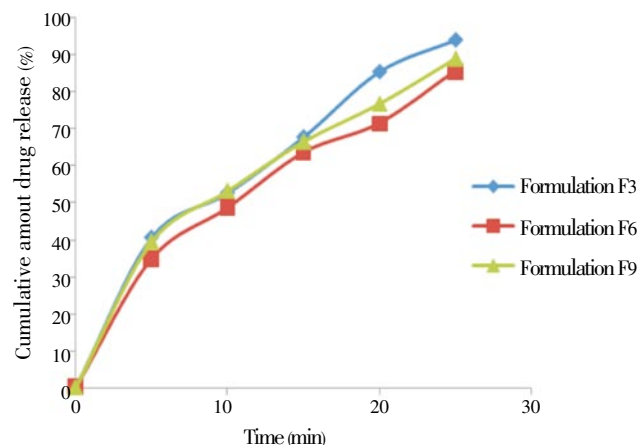


Figure 4. Comparative dissolution profiles of optimized formulation with renewed superdisintegrants. F3-Fenugreek gum; F6-Sodium starch glycolate; F9-Croscarmellose sodium.

and shows promising additive anti-inflammatory activity with diclofenac sodium in quick relief of pain.

### Conflict of interest statement

We declare that we have no conflict of interest.

### Acknowledgements

The authors are thankful to the management of Bapatla Education Society, Bapatla for providing the adequate laboratories facilities in the execution of this work.

### Comments

#### Background

The purpose of this manuscript was to extract the fenugreek gum and evaluate for powder flow properties (bulk density, tapped density, angle of repose, Carr's index, and hausner ratio), swelling index and loss on drying and to compare disintegration efficiency of fenugreek gum with widely used synthetic superdisintegrants *i.e.* SSG, croscarmellose sodium in the formulation of FDTs. All the superdisintegrants were used at optimized concentration levels to assess their efficiency. The tablets were evaluated for various physical tests.

#### Research frontiers

The formulation of a FDT containing diclofenac sodium and fenugreek gum produces additive anti-inflammatory activity resulting in reduction in dose of diclofenac sodium and thereby its dose related side effects.

#### Related reports

I did a search of Pub Med and I found out that there were not many publications on this topic, in total. Thus, this particular manuscript is of importance.

#### Innovations and breakthroughs

As was stated in conclusion that the fenugreek gum acted as a good super disintegrating agent and showed promising additive anti-inflammatory activity with diclofenac sodium in quick relief of pain, it is a finding of potential importance.

#### Applications

This finding could have potential use in clinical practice.

#### Peer review

The paper is well written and interesting for reading. The topic of the manuscript is quite interesting and

results are hesitating. I believe that this manuscrit could contribute to the knowledge in terms of design and evaluation of fast dissolving tablets containing diclofenac sodium in combination with fenugreek gum, as a natural superdisintegrant.

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