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APPLICATIONS, ISOLATION AND CHARACTERIZATION OF FENUGREEK SEED GUM AS PHARMACEUTICAL EXCIPIENT

Ajay Kumar Shukla*, Ajay Yadav, Ravi Kant Vishwakarma, Santosh Kumar Mishra

Institute of Technology and Management GIDA, Gorakhpur, India

Correspondence
Ajay Kumar Shukla*
Department of P'ceutical Chemistry, Institute of Technology and Management GIDA, Gorakhpur, 273209, India
✉ ashukla1007@gmail.com

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ABSTRACT
Fenugreek seed gum (FSG) is a polysaccharide having galactomannans as chemical constituents, and it is isolated from the seeds of *Trigonellafoenum guaiacum* (Family Leguminosae). Generally, polysaccharides play vital roles such as emulsifying, hydrating, thickening, gelling, and suspending agents in the pharmaceutical formulations. The objective of this research work was to investigate the film coating potential of FSG, using paracetamol as a model drug. Aqueous coating solution consists of 2% FSG hydroxy propyl methyl cellulose (HPMC) (2% w/v), and sodium alginate (1% w/v) were prepared and used to coat the tablets by dip coating technique. The coated tablets showed lower friability; increased disintegration time (14 min) as compared to the core tablet (3 min), with improved hardness, and drug release profile. FSG film coated batches showed drug release profile up to 8 hrs and HPMC coated batches showed drug release up to 12 hrs. The results of drug release rate of FSG film is very closed to HPMC release profile. Thus FSG have good film formers properties. FSG is a promising natural, biodegradable, economical and eco-friendly film former, mainly when masking of taste or objectionable odor in a solid dosage formulation is desired. It can be used as carrier in sustained release formulation.

INTRODUCTION
The most significant role of film coating unit operation in the pharmaceutical industry.[1] Film coatings are used for many reasons like for development of visual qualities of dosage forms, masking disagreeable taste or odor, easing digestion, improving stability, and modifying the release characteristics of the drug. [2-3] Film coating process applies to a variety of pharmaceutical products like as tablets, beads, pellets, granules, capsules, and drug crystals. Film layer can be formed from both aqueous polymeric dispersion (commonly known latex) and polymeric solution (organic solvent or aqueous based). It is the chief ingredient in the greater part of film-coated formulations, and it made from diverse origins (natural, synthetic or semisynthetic), including cellulosic, acrylics, vinyl, and combination polymers has been used for different soluble drugs. [4, 5, 6] The fenugreek natural gum is a natural polymer isolated from the seed of *Trigonellafoenum graecum* (Family Leguminosae). The natural polymers have advantages over synthetic and semi synthetic polymers, because they are cheap and easily available, nonirritant, biodegradable, biocompatible, eco-friendly, traditionally fenugreek seeds used in the treatment of diabetic diseases [7]. It is cultivated in northern Africa, the Mediterranean, western Asia, northern India, and in Canada. The sustain release formulation usually preferred over conventional dosage form to attain constant therapeutic affect for extended period of time. The key advantages of this formulation are decrease frequency of administration, maintained plasma drug level, devoid of dose dumping effect and lesser side effects. In literature various utilizations of fenugreek seed gum have been reported like as oral drug release retardant [7, 8, 9], binder, mucoadhesive, emulsifiers, as gelling agent and formulation of nanoparticles. To date there is no published research work on the film coating

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potential of FSG. The objective of this research paper is to investigation of the film coating potential of fenugreek gum with paracetamol tablets as the model drug. [10]

MATERIALS AND METHODS

Materials

Paracetamol tablets (Nestor pharmaceuticals Ltd, were obtain from a government pharmacy shop B.N. PTTT-143, Hydroxypropylmethylcellulose E5 LV (Methocel® E5 LV premium Loba chem., India) all other chemicals were used analytical grade or Pharmacopeia standards, Fresh fenugreek seed and paracetamol tablets were obtained from the Gorakhpur GIDA, UP, India local market, India.

Methods

Extraction of fenugreek gum

The seeds of fenugreek were washed in water and powdered coarsely with grinder. In addition coarse powder was soaked in distilled water for 10 h, and the gum was filtered out from the bulk material by using muslin cloth. The filtrate was precipitated with ethanol several times to complete the extraction process. The gum was air dried at 60 ^{0}C, powdered, and packaged into polythene container for further use [11].

EVALUATION OF PHYSICOCHEMICAL PROPERTIES OF FENUGREEK GUM POWDER

Organoleptic evaluation:

Organoleptic properties like as color, odor, taste, fracture, and texture, these properties were determined.

Qualitative tests

Preliminary tests were conducted to verify the properties of mucilage obtained. The qualitative chemical tests that were conducted are: test for carbohydrates as Molisch's test, test for tannins as Ferric chloride test, test for proteins as Ninhydrin test, test for alkaloids as Wagner's test, test for glycosides as Keller-Killaini test, test for mucilage as Ruthenium red test, test for flavonoid as Shinoda test, and test for reducing sugar as Felhing's test. [12]

Determination of purity of Gum

To determine the purity or chemical nature of gum, tests for alkaloids, carbohydrates, flavonoids, steroids, amino acids, terpins, saponins, oils, fats, tannins and phenols were carried out.

Percentage yield

10 gm of fenugreek seed was extracted and isolated. The isolated gum was then dried well and percentage yield was calculated by following formula.

% Yield = Practical Yield x 100 /Theoretical Yield

Solubility

One part of dry gum powder was shaken with different solvents and the solubility was determined. [13]

Swelling index

Accurately weighed amount (1g) of the fine powder of FSG gum was introduced into a 25 ml glass-stoppered measuring cylinder, added 25 ml of water, and was well shaken continuously at every 10 min for 1 h. It was then stay free for 3 h at room temperature. Then measured the volume were occupied by the gum. The same procedure was repeated three times and the mean value was calculated, by applying the following formula**.**

$$\textbf{Swelling index} = (W_2 - W_1) \times 100/W_2,$$

Where W1 is the initial weight of tablet and W_2 is the weight of hydrated tablet.

Bulk density, Tapped density

The density of FSG was determined by using FSG powder (10 g) was accurately weighed into a 100 ml measuring cylinder and without distressing the cylinder, the volume of powder was read to give the bulk volume. Then the volume of the powder was reading noted, after at every 50 taps till the volume of powder was constant obtained. This represents the tapped volume of the powder. The bulk density and tapped density was calculated with equation 1 and 2 respectively. [14]

Eq 1 Bulk density (ρ) = $\frac{\text{Weight of sample}}{\text{Tapped volume}}$

Eq 2 Tapped density (ρ_b) = $\frac{\text{Weight of sample}}{\text{Bulk volume}}$

Hausner quotient

Hausner ratio or quotient was calculated as the ratio of tapped to bulk densities (Equation 3)

Hausner'squotient (ratio) = $\frac{\textbf{Tapped density}}{\textbf{Bulk density}}$

Angle of repose

Angle of repose measured the flow characteristics. Improper flow of powder is due to frictional forces between the particles. Angle of repose quantifies these frictional forces. It can be calculated by following formula:

$$\textbf{Tan } \theta = h/r \textbf{ or } \theta = \tan^{-1} h/r$$

Where, h= height of pile; r= radius of the pile base θ = angle of repose.

A dry and clean funnel was fixed on to a burette stand at height (2-3 cm). Firstly a graph paper taken and was placed on the well flat surface and taken sufficient quantity of the powder (10 g). It was allowed to flow slowly through the funnel until the heap near touched the tip of the funnel. The circumference of the pile was drawn through the pencil and the midpoint was located and its radius was calculated. The experiment was performed three times and the average height and radius

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was calculated. The angle of repose was calculated using this formula. [15]

Powder compressibility (Carr's consolidation index)

Powder compressibility was determined by using gum powder (5 g) and was transferred into a 10 ml measuring cylinder with the help of a funnel and the measuring cylinder was placed on the bulk density apparatus. The initial volume occupied by the powder was noted down (fluff volume, V0). The measuring cylinder was then tapped until a constant volume was obtained. After completing the tapping the final volume was noted (tapped volume, Vt) and the compressibility was calculated using the below formula: [16]

Consolidation Index = [(Tapped density – Fluff density)/Tapped density] × 100

Moisture content (MC) %

An evaporated dish containing 10 g of FSG was heated to 105ºC in hot air oven, till a constant weight was obtained. The average for three readings was obtained

$$MC\ (\%) = \frac{Wf - Wi}{W_i} \times 100 \quad \ldots\ldots (5)$$

Where Wf is the final weight sample and Wi initial weight of sample.

pH of gum

Sample (5g) was weighed and taken, triplicate form in separate beaker, and were mixed with 20 ml of distilled water, the resulting suspension stirred for 5 minutes and the pH was measured using a calibrated digital pH meter

Ash content %

Accurately weighed gum (3 g) was taken in a crucible of silica, which was previously ignited and weighed. The powder was spread as a fine, even layer at the bottom of the crucible. The crucible was gradually heating by using heating mental to make it red hot until free from carbon. When sample completely free from carbon then the crucible was cooled and weight noted down. The procedure was repeated in thrice to get constant weight. The percentage of total ash was determined with reference to air-dried drug. [17]

Viscosity

Viscosity of gum was determined, by preparing different concentration of gum suspension, initially 0.4%, 0.8%, and 1% w/v concentration were prepared at 25ºC. The viscosity of the prepared suspension was investigated in 1st day and next day, using Brookfield Rheometer (Model No. R/S- PI).

FTIR Study

100mg of the gum powder was added with potassium bromide (400 mg) and was compressed in a hydraulic press to form a tablet at 15 tons pressure. The tablet was scanned over the range of 4000 to 400 cm^{-1} in a Perkin Elmer FTIR spectrophotometer. [18]

X-ray diffraction analysis (XRD)

An X-ray diffraction spectrum was recorded on an X-ray diffraction spectrometer (Bruker, AXS/8, Berlin, Germany). The dry gum powder was pressed into tablet. The X-ray diffraction spectra were recorded using Cu-ka radiation (40 kV, 60 mA). The X-ray diffraction grams were run at a scanning speed of2°/min and chart speed of2°/2 cm per 2<j>.)

Preparation of coating suspension

2 % w/v fenugreek gum and 1% sodium alginates were dispersed in distill water at 40-50ºC with continuous stirring on a magnetic stirrer, and allowed to mix, up to 2 h. Similarly, HPMC coating suspension was also prepared using 2% w/v HPMC.

Viscosity of coating suspension

The viscosity of optimized coating suspensions of gum was determined by using Brookfield LVDV-IV+ digital rheometer at 100 RPM by using spindle 4. [19-20]

PREPARATION CORE TABLET OF PROPRANOLOL HYDROCHLORIDE FOR FILM COATED TABLET FORMULATION

Core tablets of propranolol hydrochloride were prepared by using different polymers ratio by direct compression method, as specified in the formulation table. Accurately weighed quantities of the drug, polymer mixture were passed through sieve no #80 and mixed well for 10 minutes. Satisfactory quantities of the diluents (lactose) were used to raise the total bulk of the tablets to a weight of 400mg each. The resultant powder blend was compressed on single punch tablet press using 8 mm round punches to the hardness of 6-8 kg/cm^2. [21]

Preparation of coated tablets

The purchased paracetamol tablets were dipped into prepared coating suspension of FSG for 5min, and then coated tablets were dispersed 5% solution of $CaCl_2$ for 5min. The film coated tablets were dried in hot air oven. Similarly, HPMC coated tablets were also prepared. [22]

EVALUATION OF CORE AND FILM COATED TABLETS

Weight uniformity

The evaluation of weight uniformity of tablets was determined, and was 20 tablets selected randomly and their individual weights were taken by using analytical balance (Shimadzu, EL 300, USA).

Friability

Friability of the tablets was estimated using Roche Friabilator apparatus. This tool subjects the tablets to the

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joint effect of abrasion and shock in a plastic cavity revolving at 25 rpm and dropping the tablets at a height of 6 inches in per revolution. Pre weighed sample of tablets, place in the friabilator cavity and were subjected to 100 revolutions times or 4 minutes, and will then e-dusted with a soft muslin cloth and reweighed. [23-24]

The friability (f) is given by the formula.

$$\% \text{ Friability} = \frac{(w1-w2)}{w1} \times 100$$

Where'W1 'is weight of the tablets before the test and 'W2' is the weight of the tablet after the test. Limit: It should be not more than 1%.

Hardness test

The resistance of tablets to breakage under the circumstances of storage, transportations and handling prior to usage depends on its hardness. The hardness of prepared tablet, were measured by using Pfizer hardness tester. The hardness was measured in terms of Kg/cm^2.

Disintegration test

The disintegration time test was determined according to USP method in 0.1N HCl.

Dimensions

The diameter and the thickness of tablets were determined with vernier caliper. [25]

EVALUATION OF COATED TABLETS

The physicochemical properties of the coated tablets such as weight uniformity, hardness, friability, and disintegration time were evaluated as described above for uncoated tablets.

Dissolution studies

The in vitro release of FSG, and HPMC film coated tablets was studied, using eight station (USP) Type II dissolution apparatus at 37 ± 0.5°C and at 50 rpm speed in 0.1 N HCL as dissolution media for 2hrs. From the dissolution medium 5 mL of the sample was withdrawn at the specific time intervals and replaced with an equal volume of fresh medium (5mL) to preserve constant media volume. After filtration, each sample was analyzed by using double beam UV visible spectrophotometer at selected 249 nm max. This study was performed in triplicate for each batch, and after 2hrs dissolution media were replaced by phosphate buffer pH 7.2 [26-28].

RESULTS AND DISCUSSIONS

The isolation of FSG gum by using hot water extraction and ethanol treatment, Fenugreek seeds yielded 25% w/w gum. The isolated gum was subjected to identification tests using ruthenium red, and by dissolving them in hot distilled water. With ruthenium red, the particles stained pink and a gelatinous mass was formed. All others tests indicated that the isolated gum were polysaccharide in nature. The results of purity tests of FSG exhibited the presence of carbohydrates. Other phytoconstituents were absent in the isolated powder. This indicates the purity of the isolated gum. Results was shown in Table1

Further characterization of isolated gum was identified by organoleptic properties test as color, odor, taste, fracture and texture. The color of FSG was found to be yellowish in color, characteristics bitter in taste. The fracture was rough and texture was irregular for the isolated FSG gum. Result was shown in Table 2.

The solubility of FSG was determined, by using warm water, organic solvents are ethanol, benzene, butanol, chloroform, and ether. The FSG formed viscous colloidal dispersions with warm water, and were insoluble in organic solvents such as ethanol, benzene, butanol, chloroform, and ether. The result was shown in Table 3.

Results of evaluated physicochemical properties of fenugreek gum were showed in table 4. All these values found within the limits, as per the reference values of natural gum. Isolated FSG have ash values of 5.98, pH 6.7, moisture content 21.40%, melting point 248-256^{0}C, bulk density 0.667, tapped density 0.809, cars index 17.55, H.R 1.246 and was angle of repose 27.85.

The pH values of 2% solution of the FSG were found to be a little acidic or near neutral, which indicated that the FSG is non-irritating to the mucous membrane of buccal cavity and gastrointestinal tract, and can be used for the development of buccal and oral drug delivery systems.

The swelling index of FSG were found 10.2 ml, which is an indication of good water absorption, and hence, it forms a hydrated three-dimensional network from which drug can efficiently releases through diffusion.

The absorption of moisture by any substance represents hygroscopic nature of the substance. If excipient is hygroscopic, it can alter many properties of the dosage forms. Hence, it is necessary to determine the hygroscopic nature of the excipient and the amount of moisture that can be absorbed by the excipient. The result of the present study indicated that the FSG were hygroscopic and need to be stored in air-tight containers.

The FSP exhibited poor to passable flow. Hence, to improve the flow, it needs addition of glidants. Viscosity of isolated FSG was found to 33cp, 34cp, 43cp at concentration 0.4, 0.8, and 1% respectively on 1st day

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and on next day viscosity was found to 33cp, 35cp, 45cp at concentration 0.4, 0.8, and 1% respectively. It indicated that as the concentration increased, drug released rate will be reduced due to swelling or gelling property of FSG.

The FTIR spectra of the FSG were given in Fig 1, which indicated that the FSG were carbohydrates in nature. These spectra can be used as standard spectra for quality control and determination of the purity of the FSG range of peak shown in Table 6.

The FTIR spectrum of sharp peak at 1700–1800 cm-1 represented there was no any carboxyl group. While another hand, the presence of peak at 1000–1200 cm-1revealed the presence of alcoholic group mostly secondary alcohols. These peaks of FTIR proved that where no esters in the structure. The range of wave numbers 800 to 1200 cm-1 represents carbohydrates nature.

To study the surface characteristics of FSG, by using XRD of the powder was taken. The XRD of FSG exhibited rough surface with pores and crevices on it, (Fig 2). Earlier, it has been mentioned that the drug release from the dosage form depends on surface characteristics of excipient. The rough surface of gum represented it having good quality for drug release retarded property. The rough surface of gums entrapment drug particles in their pores and crevices, consequently, FSG and TSG capable to sustain the drug release. It is confirmed that by XRD report and was also evident that the particle size of the gum powders was not homogeneous and the size distribution was not within a narrow range. The gum powder consists larger to ultra-fine particles. This capacity be the reason for the 'heavy' nature of the powders. The powders exhibit a 'closet' packing arrangement, in which, the minor particles fill the voids between larger particles and reduce the bulkiness. The low porosity values also indicate this packing arrangement. The close packing can also be responsible for poor flow properties of FSG.

Viscosities of coating suspensions were found to be 237cp and 202 cp, for FSG and HPMC respectively. Results are shown in table 7.

The evaluations results of film coated paracetamol tablets were shown in Table 8.

The physiochemical properties of film coated tablets with FSG and HPMC was found satisfactory as per official guideline. The dissolution drug release profile results shown in Figure 3,

All the formulations had a low friability profile <1% [17]. The coated paracetamol tablets with HPMC had superior hardness property compared to those coated with fenugreek gum, and the disintegration time of core tablets amplified from 3 min (core) to 12.33 min after coating with FSG. The order of disintegration time of formulation was found: HPMC>fenugreek gum >core. [18-21]. The dissolution profile of the coated tablets is shown in Figure 3. In FSG and HPMC film coated tablets, 95% drug was released into dissolution medium in 8 hrs, and 12 hrs respectively. Hence drug release rate of FSG film coated tablets was sustained as compare to core tablets. So FSG can be used for sustained release of drugs from tablets.

Table 1: Phytochemical properties of FSG gum powder

Test	Results
Test for mucilage (Ruthenium red test)	+
Monosaccharide Test	-
Test for Tannins (Ferric chloride test)	-
Test for proteins (Ninhydrin test)	-
Test for alkaloids (Wagner's test)	-
Test for glycosides (Keller – Killaini test)	-
Test for Carbohydrates (Molisch's test)	+
Test for flavonoid (Shinoda test)	-
Test for reducing sugar (Felhing's test)	-

Table 2: Organoleptic properties of isolated FSG powder

Gums	Colour	Odour	Taste	Fracture
FSG	Yellow	Characteristics	Bitter	Irregular

Table 3: Solubility profile of isolated FSG powder

Solvents	Results
Cold water	Slightly soluble
Hot water	Viscous colloidal dispersion
Ethanol	Insoluble
Benzene	Insoluble
Acetone	Insoluble

Table 4: Some physicochemical properties of FSG powder

Parameters	Results
Percentage yield	25%
Solubility	Slightly soluble
Swelling Index	10.2ml
Bulk Density	0.667
Tapped Density	0.809
Angle of repose	27.85
Carr's index	17.55%
H.R	1.246
Moisture Content%	21.40
pH of mucilage	6.7
Ash content%	5.98
Melting point	248-256^{0}C

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Table 5: Determination of viscosity of isolated FSG (spindle 4 speed 100rpm) powder

S.N.	Days	0.4% FSG	0.8% FSG	1% FSG
A	1	33cp	34 cp	43 cp
B	2	33 cp	35 cp	45 cp

Table 6: FTIR Interpretation of isolated FSG powder

FTIR Range of peak	Presence of functional groups FSG
1036 cm^{-1}	C-O-C ether group
1637-1655 cm^{-1}	CH OH stretching vibration
2924 cm^{-1}	C-H aliphatic Stretching
3356 cm^{-1}	O-H, Glucan backbone
1053 cm^{-1}	CH stretching vibration

Table 7. Viscosity of coating suspension

Coating suspensions	Viscosity(cP)	RPM Spindle-4
Fenugreek gum	237	100
HPMC	202	100

Table: 8. Composition of propranolol hydrochloride for film coated tablet formulation

Ingredient	Quantity
Drug	80 mg
PVP	10mg
MCC	285 mg
Mg. Stearate	Q. S. mg

Table 9: Evaluation of film coated paracetamol tablets

Description	Core	FSG	HPMC
Hardness kg/cm^2	$7kg/cm^2$	$12kg/cm^2$	13 kg/cm^2
Friability (%)	5.23	.71	.69
Disintegration time (min)	3.1	12.33	15.16
Diameter (mm)	10.9	11.5	11.4
Thickness (mm)	2.5	2.64	2.63

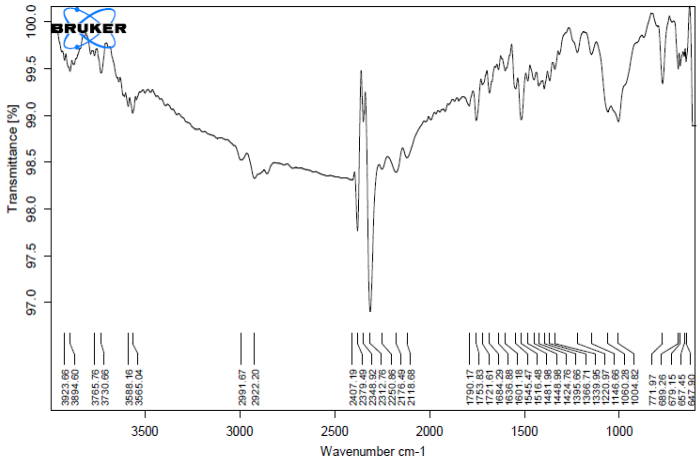

Figure 1. FTIR spectra of FSG

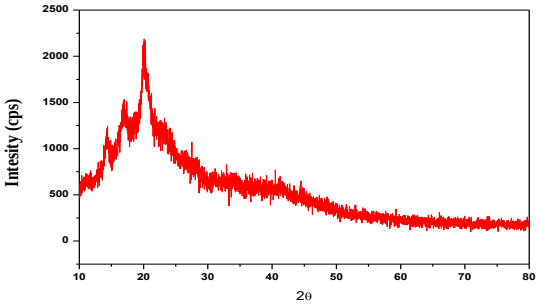

Figure 2. Xrd spectra of FSG

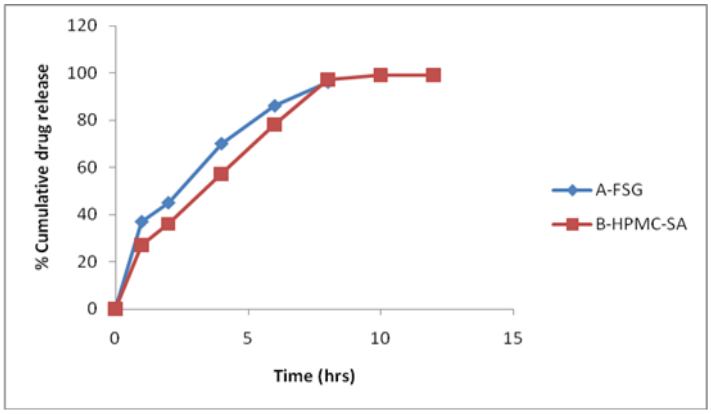

Figure 3: Dissolution profile of paracetamol coated tablets

CONCLUSION

The potential of fenugreek gum as a film-coating agent or polymer was investigated, with paracetamol tablets as model drug. The tablets were evaluated for diverse parameters such as uniformity of weight, friability, disintegration time, and dissolution profiles. Fenugreek seed gum can be used for development of visual qualities of dosage forms, masking disagreeable taste or odor, easing digestion, improving stability, and modifying the drug release characteristics of the drug.

Future perception

FSG has been successfully isolated from water extraction procedure, and could be used as pharmaceutical excipients in the formulation of different drug delivery dosage forms. FSG has been used as release retarding agent in matrix tablet formulation with water soluble and insoluble drugs. Water soluble drug release rate can be better controlled by cross-linking derivative of FSG. The extent of release can be varied by controlling the degree of cross-linking. Natural cross-linking derivative can play significant role for the development of sustained release dosage with water

soluble drug. So, additional research required in development of novel cross-linked derivative of FSG.

Conflict of Interest: None declared.

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