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Potentials of *Sterculia tragacantha* Lindl seed husk gum as a release modifier in matrix tablet formulation

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Abstract

Natural gums have been utilized severally in the design of matrix tablets, either in their native or modified forms. The primary objective of this work was the extraction, characterization and utilization of the seed husk gum from *Sterculia tragacantha* Lindl as a release modifier in theophylline matrix tablets.

Gum was extracted from the fresh seed husk of *Sterculia tragacantha* and tablet formulated via wet granulation. Drug-polymer compatibility was determined by FTIR and DSC while formulated tablets were evaluated for their *in vitro* dissolution release profile in two media, simulated gastric fluid (SGF) and simulated intestinal fluid (SIF) and compared with a commercial brand. Extracted gum powder presented a poor flow which improved on granulation, had a better swelling index and water holding capacity than tragacanth gum.

Formulated tablets passed standard tablets test and sustained theophylline release up to 90.97 % and 88.09 % in SGF and SIF respectively at the twelfth hour. Drug release kinetics was by zero order in SGF via non-fickian diffusion. *S. tragacantha* seed husk gum presented a promising potential as a release retarding agent.

Keywords: *Sterculia tragacantha; M*atrix tablet; Natural gums; Release retardant; Theophylline

1. Introduction

Sustained-release drug delivery systems (SRDDS) are targeted at prolonged temporal and/or spatial delivery of an active ingredient to the blood or tissue and drug release is primarily via diffusion, dissolution or diffusion-dissolution controlled mechanism. A release controlling agent is therefore necessary and polymers (natural, synthetic and semi-synthetic) are utilized for this role. Hydrophilic polymers have found a large acceptability for their release retarding attribute [1,2] and this acceptance has been majorly linked to certain advantages they possess over other types of polymers amongst which are cost effectiveness, eco-friendliness, bio-compatibility, biodegradability, etc. [3] . Natural gums are a major source of hydrophilic polymers utilized in the design of sustained-release matrix tablet; they tend to possess good swellability, erodibility, ease of manufacture, amenability to modification, drug release profile amongst other properties.

Sterculia tragacantha Lindl, also known as the African tragacanth is formerly of the family Sterculiaceae which consist of almost 200 species mainly indigenous to the tropics and subtropics. Amongst these species are *S. urens, S. foetida* and *S. africana* which are utilized in the drug industry [4]. The leaves and fruit pods of *S. tragacantha* are consumed as food by indigents and in tradomedical practices such as snake bite, diarrhoea, boils, fever, pains; some of these

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pharmacological claims have been investigated by various workers [5-13]. Phytochemical analysis elucidating the constituent composition of the plant parts were investigated by other workers [14,15]. The wide utilization of karaya gum exudate of *S. urens* as a release modifier in drug formulations led to the possibility of the usage of *S. tragacantha* as a release retardant in matrix tablet formulation for this study.

Theophylline is an alkaloid that occurs as a crystalline powder with a low aqueous solubility and a plasma half-life of about 4.5 hours. It is indicated majorly for managing respiratory conditions.

2. Materials and method

The fresh seed pods of *Sterculia tragacantha* were collected in Ibesikpo local government of Akwa Ibom state in the South-South region of Nigeria, West Africa in October when the fruiting commenced. Theophylline and other reagents utilized were obtained from local distributors, were of analytical grade and utilized without further purification. Tragacanth gum was characterized alongside the extracted gum powder and utilized as a release retardant in tablet formulation. A commercially available brand of theophylline prolonged release tablet was obtained for *in vitro* dissolution studies.

2.1. Extraction of *Sterculia tragacantha* gum

S. tragacantha pods (Figure 1) were deseeded (Figure 2) and the husk broken down into smaller pieces. To 500 g of the husk, 3 litres of boiling water was added, macerated for 3 hours with intermittent agitation every 30 minutes. The filtrate was collected and gum precipitated using a 1:1 mixture of ethanol to acetone at 2:1 (solvent mixture to filtrate) severally until precipitate appeared light brown in colour. The gum was dried at 50 ^{o}C for one hour in a laboratory oven (Techmel Techmel, USA). Gum was size-reduced, screened with a mesh sieve, weighed and stored in an airtight container. Extract was used without any further purification for the study.

Figure 1 Fresh seed pods of *S. tragacantha*

Figure 2 Popped seed pod of *S. tragacantha*

2.2. Gum Characterization

Organoleptic, confirmatory and pH test: Extracted gum was observed for colour, smell, taste and texture and confirmatory tests, Ruthenium and Molisch tests were done as described in a previous study [16]. Gum pH was also measured using a pH meter in a 1 %w/v solution; test was in triplicate.

Solubility test: Gum solubility was investigated in various solvents – chloroform, petroleum ether, methanol, water. 10 mL of solvent was added to a test tube containing a small quantity of the gum, shaken, allowed to stand for about 2 minutes and observed.

Viscosity test: A 1 and 2 % w/v solutions of the gum was prepared with distilled water, stirred for 2 minutes with a Silverson mixer, allowed to stand for another 2 hours before stirring again. Mixture was left to stand on a laboratory bench to allow for escape of any air bubbles before measurement with a Brookfield digital viscometer (ND5-5S, China) at 60 rpm using spindle 2.

Swelling test: 3mg of the extracted gum was placed in a 100 mL measuring cylinder, volume noted (Vo), water added, stirred and made up to the 50ml mark. The cylinder was covered with aluminum foil and allowed to stand for 24 hours. The new volume of gum in the cylinder after 24 hours was measured (Vt). Swelling index (equation 1) was calculated as

$$\text{Swelling index (\%)} = \left(\frac{Vt-Vo}{Vo}\right)x\ 100 \quad - - - \quad (1)$$

Water and Oil-holding Capacity: these parameters are presented as the weight of liquid in grams withheld by 1g of the gum and the method of Monrroy and co-workers [17] was utilized with some modifications. To 10 mL of either distilled water or olive oil in a test tube, 200mg of the gum was mixed using a vortex mixer (Stuart Vortex Mixer XH-C, China) for 2 minutes, centrifuged (at 2500 rpm for 25 minutes), supernatant decanted and sediment measured. The difference between the initial volume of the solvent and the decanted supernatant was equivalent to the withheld volume.

Flow properties: Polymers were characterized for their flow properties using methods described in earlier works [18] Parameters tested were bulk density, tapped density, flow rate, and true density while angle of repose, Hausner's ratio, Carr's index and porosity were derived from the generated data using the following equations 2 and 3

$$\text{H.R} = \frac{Tapped\ density}{Bulk\ density} \quad - - - - - \quad (2)$$

$$\text{C.I} = \left(\frac{Tapped\ density - bulk\ density}{Tapped\ density}\right) \text{x } 100 \quad - - - \quad (3)$$

2.3. Granule Preparation and evaluation

Table 1 presents the formula utilized in the formulation of theophylline granules via wet granulation using previously established methods [16]. Granule flow attributes were evaluated as with the polymer powders. Granule density and packing fraction were determined using the equations 4 and 5.

$$\text{Granule density} = \frac{ds(Ws)}{Ws-(W2-W1)} \quad - - - - - \quad (4)$$

Where ds is density of solvent (xylene)used in the pycnometer, ws is weight of solid sample, w_1 is the weight of pycnometer + xylene, and w_2 is weight of pycnometer +xylene+ granule sample

$$\text{Packing fraction} = \frac{bulk\ density}{granule\ density} \quad - - - - - \quad (5)$$

Table 1 Theophylline matrix tablet formula

INGREDIENTS	BATCH I	BATCH II
Theophylline	50 %	50%
Sterculia tragacantha gum	20 %	-
Tragacanth gum	-	20%
Talc	1 %	1%
Magnesium Stearate	1 %	1%
Microcrystalline cellulose	qs	qs

2.4. Drug-Polymer Compatibility

A selection of a thermal (Differential Scanning Calorimetry, DSC) and non-thermal (Fourier Transform Infrared, FTIR) methods were utilized, The DSC (model DSC2, (Mettler Toledo, USA) thermogram of the pure drug, polymer and drug-polymer (1:1) mixtures were generated when a small sample size was weighed and transferred to the DSC crucible, heated under nitrogen and scanned at a temperature range of 0 to 260 ^{0}C. The generated thermogram was noted for any thermal incompatibility.

The FTIR (Agilent Technologies FTIR machine model Cary 360, USA) spectra of the pure drug, polymer and drug-polymer (1:1) mixtures were carried out. A small amount of a sample was prepared, mounted on a hydrostatic press and scanned at a frequency range of 4000 – 650 cm^{-1} to generate the spectra which were noted for any chemical incompatibility.

2.5. Tablet compression and evaluation

Matrix tablets of 400 mg target weight were compressed with a single punch tableting machine (Cadmach, Ahmedabad, India) with an upper punch pressure of 38kN and 15 kN lower punch pressure fitted with a 12.5 mm flat-faced punch. Tablets were allowed to relax for 24 hours before evaluation for weight uniformity, diameter, thickness, hardness, friability using already established methods from previous works [16]. Tablet porosity was calculated using the formula (equation 6)

$$\text{Tablet porosity} = 100\left[1 - \frac{4w}{\rho\pi d^2 h}\right] \quad - \quad - \quad - \quad - \quad (6)$$

Where w = tablet mean weight, ρ = granule density, d = average diameter h = average thickness of the tablet

Content uniformity was determined in two media, SGF and SIF, after crushing 10 randomly selected tablets. The weight equivalent of one tablet was taken, mixed with the media in use via a vortex mixer for 5 minutes, filtered, diluted and its absorbance with UV spectrophotometer at 271 nm determined. The calibration curve for theophylline was generated using a dilution range of 0 to 12 µg/ml to obtain a linear plot with slope 0.0664 and a regression co-efficient of 0.9929.

Tablet swelling test was done using a modification of the method of Ramana and co-workers [19] employing three media – distilled water, phosphate buffer (7.8) and 0.1N HCl. About 5 mL of the medium was placed in in a petri dish and the pre-weighed tablet on a pre-weighed mesh sheet placed in it. Tablet was removed at intervals, blotted to remove excess fluid and reweighed. Percentage tablet swelling was calculated using equation 7. This test was done in triplicates and for a duration of 8 hours.

$$\text{Swelling (\%)} = \left(\frac{Wt - Wo}{Wt}\right) x\ 100 \quad - \quad - \quad - \quad - \quad (7)$$

2.6. *In vitro* release Profile

The USP basket dissolution apparatus (RCZ-6C3 Type Medicine Dissolving Instrument, China) was utilized, Test was carried out in 900 mL of two different media, SGF and SIF with temperature maintained at 37 ± 2 ^{o}C at 250 rpm for 12 hours. A 5mL aliquot was withdrawn at 30 minutes intervals, filtered and assayed with a UV spectrophotometer at 271 nm. To maintain sink condition, medium was replaced with a fresh 5 mL portion after each withdrawal.

3. Results and discussion

Extracted gum yield was 2.25 %w/w and dried gum powder (Figure 3) was light brown in colour, tasteless, coarse to touch and had a characteristic smell. This yield is similar to that reportedly obtained from the leaves of *Corchorus olitorius* [16]. Confirmatory tests on the powder were positive for a carbohydrate and gum. In water, the extracted gum formed a gel while tragacanth gum was soluble. This attribute could define the basis for the plant use as an antidiarrheal locally and this study of its potential as a release retardant. In chloroform, the extracted gum appeared to form a colloid but tragacanth gum a mucilage while both polymers were insoluble in in methanol. Variation in pH can lead to changes in viscosity, solubility and emulsifying properties of a gum [20] . Upon testing, *S. tragacantha* gum had a pH of 7.0 (neutral) while tragacanth gum, 6.37 (slightly acidic). Natural gums have been reported with more than one pH value and this variability is mainly due to factors like topography, harvest season, stage of maturity, etc. For instance, Karaya gum (from *Sterculia urens*) variants with pH ranges from 6.7 to 7.3 have been reported [20] and consequently ranges in viscosity presented while another study found a pH of 4.26 [21].

Figure 3 Extracted gum powder of *S. tragacantha* seed husk

Aside pH, other factors that could affect the viscosity of a natural gum include, concentration of gum dispersion, climate, storage condition, shelf life and harvest time. At a 1 %w/v concentration, *S. tragacantha* gum had a viscosity value (27.84 mPas) over five times the value of tragacanth gum (4.43 mPas). On increase to 2 %w/v, this value (133.60 mPas) increased to over twenty times that of tragacanth gum (6.57 mPas). Upon long storage, natural gum powders tend to lose viscosity and their gel forming behaviour. Formation of stable gels by natural gums on contact with water has been linked to the presence of highly branched polysaccharides which possess a restricted number of interaction points unlike when there is a high linearity. On addition of water, *S. tragacantha* gum formed a gel which showed no signs of separation after standing for 24 hours; rather continuous swelling was observed and a calculated swelling index of 616.67 %. The WHC and OHC values for *S. tragacantha* gum were 14.08 and 4.51 g/g of sample respectively; when compared to the WHC of tragacanth gum (8.65 g/g of sample) and OHC 1.95 g/g of sample from a previous study [22].

A fair prediction of any powder flow in a drug formulation process allows for production of efficiency and characterization results for *S. tragacantha* and tragacanth gum is presented in Table 2. Evaluated parameters showed a poor flow attribute. The coarse texture of *S. tragacantha* gum presented the relatively higher porosity value with a Carr's index of poor flow while TG presented with a fair flow. However, powder flow can be improved by various techniques such as the addition of flow aids or granulation. Evaluation of the polymer granules (Table 3) showed an improvement in flow in both batches sufficient for compressibility efficiency of the tablets. Porosity is a contributory factor to the deformation process during tablet compression, moisture ingress in matrix tablets, the shelf life, pharmacokinetic behaviour and bioavailability of solid dosage forms. In a matrix tablet, the uptake of fluid is an important step in API dissolution and subsequent bioavailability over a period. The extent of fluid channelling into tablet matrix is partly dependent on granule pores present and translocation of API from tablet matrix into the biosystem will be through the same pores after dissolution, hence influencing bioavailability.

Table 2 Flow properties of powders

Parameter	***S.tragacantha* gum**	**Tragacanth gum**
Bulk density(g/cm3)	0.50 ± 0.00	0.56 ± 0.00
Tapped density(g/cm3)	0.61 ± 0.00	0.68 ± 0.33
Angle of repose (^{o})	45.33	22.96
Flow rate (g/s)	6.58	2.73
Carr's index (%)	18.33	18.44
Hausner's ratio	1.23	1.23
True density	1.01	1.11
Porosity (%)	61.37	50.35

Table 3 Flow properties of tablet granules

Parameter	***S.tragacantha* gum**	**Tragacanth gum**
Bulk density(g/cm^3)	0.31 ± 0.00	0.34 ± 0.17
Tapped density(g/cm^3)	0.42 ± 0.00	0.37 ± 0.17
Angle of repose (^{o})	23.37	14.79
Flow rate (g/s)	4.98	4.29
Carr's index (%)	26.92	6.82
Hausner's ratio	1.33	1.07
Granule density (g/ml)	1.01	1.21
Packing fraction	0.31	0.28
Porosity (%)	69.06	71.83

Compatibility studies in drug development are designed towards the identification, measurement and prediction of the impact of any interaction(s) that may occur between an API and excipient present on the manufacturability of a formulation and its quality. Such investigations are established in the early stages of development especially where a novel substance is utilized. On close inspection, FTIR spectrum of the physical mixture of theophylline and *S. tragacantha* gum (Figure 4) presented new peaks at 1997.9 and 2001.6 cm^{-1} aside the slight shifts in peak position and intensity due to merging of closely placed peaks. The new peaks indicated the possibility of products of interaction and will require further investigation to confirm so. The DSC thermogram (Figure 5) of the same physical mixture presented with a disappeared exotherm between 218.37 and 225.03 ^{o}C and a shallow endotherm between 193.39 to 197.80 ^{o}C found on the *S. tragacantha* gum thermogram. As seen on the FTIR spectrum, the possibility of an interaction may account for this and further runs are recommended.

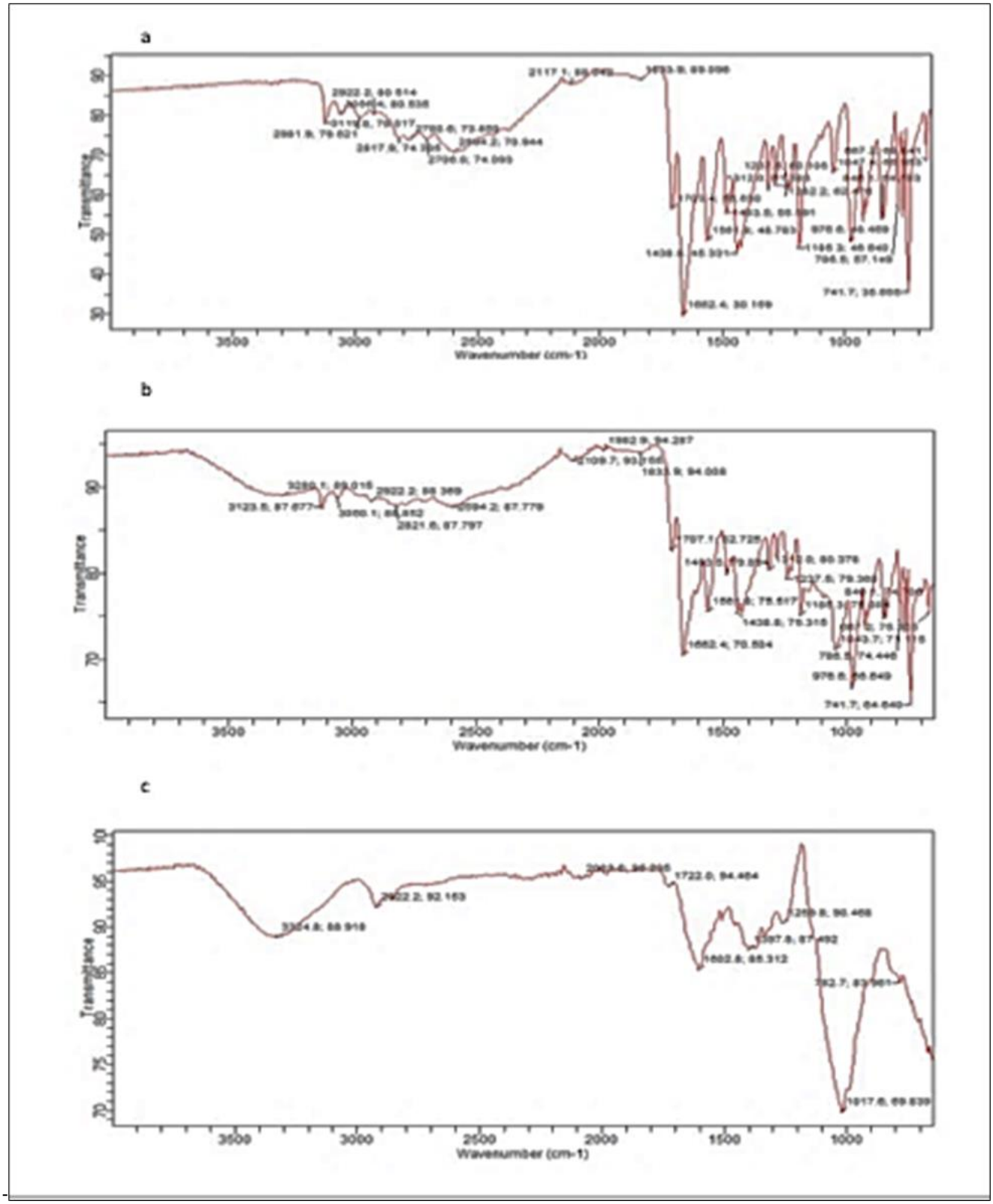

Figure 4 FTIR of (a) theophylline (b) physical mixture of theophylline and *S. tragacantha* gum (c) *S. tragacantha* gum

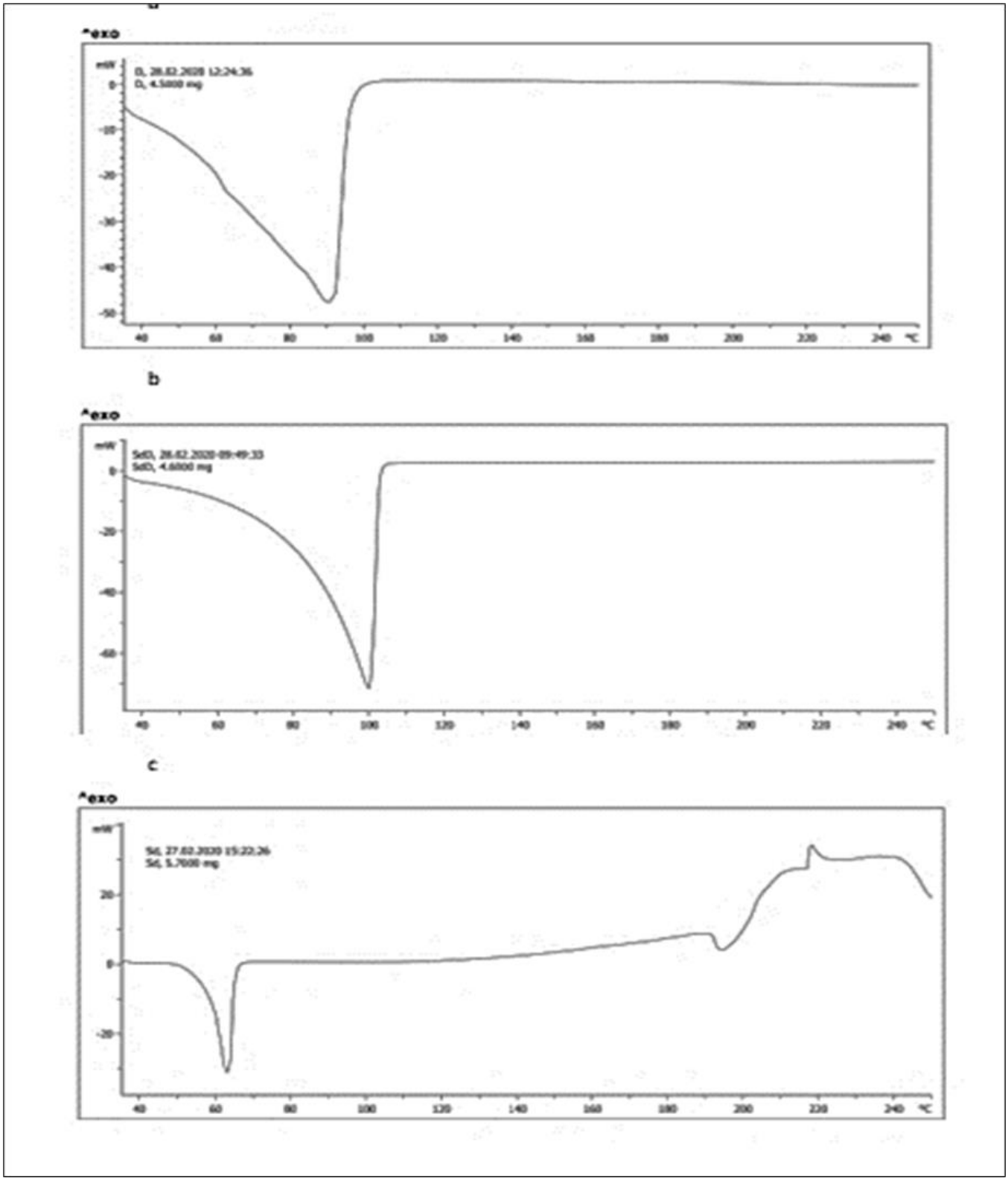

Figure 5 DSC thermogram of theophylline (top) physical mixture of theophylline and *S. tragacantha* gum (middle) *S. tragacantha* gum (bottom)

Formulated tablets appeared to be of good integrity with no observable signs of chipping, cracking, lamination or mottling; tablet batch with *S. tragacantha* gum (STU) appeared to have a sheen on its surface and were firm to touch. Tablet weight fell within acceptable limit with no significant difference in weight between the batches (Table 4). Tablet diameter, hardness and friability all fell within acceptable limits with no significant differences between batches. Tablet batch containing STU failed tablet thickness test and this deviation may be related to the high percentage composition

of polymer in the tablet. Uniformity in drug distribution within a tablet formulation ensures dosing accuracy since formulation processes could be challenged by powder blending problems. Content uniformity in both tablet batches fell within the acceptable limits (85 – 115 % w/w) in both media.

Table 4 Formulated tablet evaluation values

Parameter	**Batch STU**	**Batch TG**
Colour	Light brown	White
Shape	Round	Round
Weight uniformity (mg)	413.25 ± 2.44	422.15 ± 5.27
Diameter (mm)	12.56 ± 0.00	12.63 ± 0.00
Thickness (mm)	2.61 ± 0.01	2.50 ± 0.01
Hardness (KgF)	6.00 ± 0.00	7.60 ± 0.40
Friability (%)	1.01	0.90
Tablet porosity (%)	26.59	11.45
Content uniformity ((SIF)	102.04	85.75
Content Uniformity (SGF)	92.32	107.43

Key: Batch STU – matrix tablet formulation containing *S. tragacantha* gum; Batch TG - matrix tablet formulation containing tragacantha gum

On contact with an aqueous medium, hydrophilic polymers form a hydrated gel network which act as a barrier to drug release and impede further water absorption into the tablet core. The rate of drug release will be dependent mainly on drug and polymer characteristics (eg swelling property, viscosity and pH) amongst other factors [23, 24]. Amongst the various media at room temperature (Figure 6), STU presented with the highest percentage swelling within the initial 30 minutes (450.13 % in distilled water, 313.37 % in HCl and 394.39 % in phosphate buffer); TG was at the fifth hour in distilled water (112.47 %), second hour in HCl (54.26 %) and first hour in phosphate buffer (53.98 %) while the commercial brand (CB) was at the sixth hour in all the media (104.9 %, 95.29 % and 101.23 % in distilled water, HCl and phosphate buffer respectively). All the polymers gave highest value of swelling in distilled water although at different times, indicating their hydrophyllic make-up. STU absorbed the most volume of water rather rapidly and presented with erosion onset within the first hour especially in distilled water where highest erosion was observed at the eighth hour. CB and TRAG presented similar profiles; however, erosion onset was more delayed and the tablets appeared to maintain some integrity even at the eighth hour.

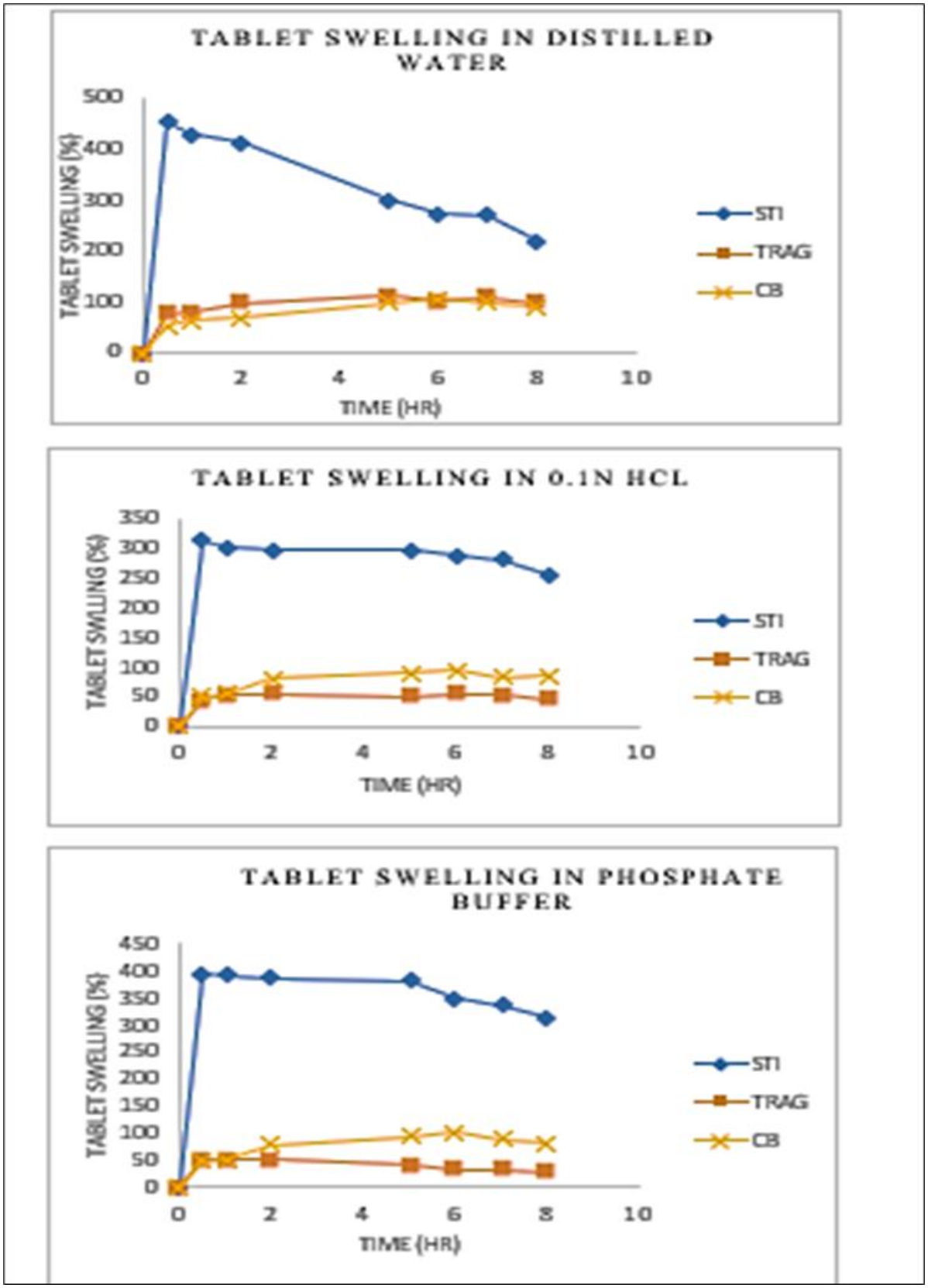

Figure 6 Percentage swelling profiles of tablets against time

Key: STU– matrix tablet formulation containing *S. tragacantha* gum; TRAG - matrix tablet formulation containing tragacantha gum; CB – commercial brand

Upon study of the in vitro release profiles of the formulations and CB in SIF and SGF (Figure 7) for twelve hours, STU successfully retarded the drug release from the formulation up to the final hour alongside TRAG formulation and CB. While it is desirable to sustain drug release in matrix tablets, it is also imperative that sufficient concentration of the API to elicit a therapeutic action is released initially to avoid delayed onset of action. In SIF, initial releases within the first 30 minutes were 23.46, 18.4 and 14.42 % in CB, STU and TRAG respectively; 25 % was attained at the first hour for CB and STU. At the twelfth hour, release was 90.36 (CB), 88.09 (STU) and 67.71 % (TRAG).

In SGF, 25% release was attained within 30 minutes by CB while STU and TRAG after the second and sixth hour respectively. At the twelfth hour, drug release was 100.20, 90.79 and 55.34 % for CB, STU and TRAG respectively. The STU and TRAG formulations sustained the drug longer than the CB in the SGF and followed a zero order kinetic.Table 5 summarizes the release kinetics and mechanisms of the formulations in both media.

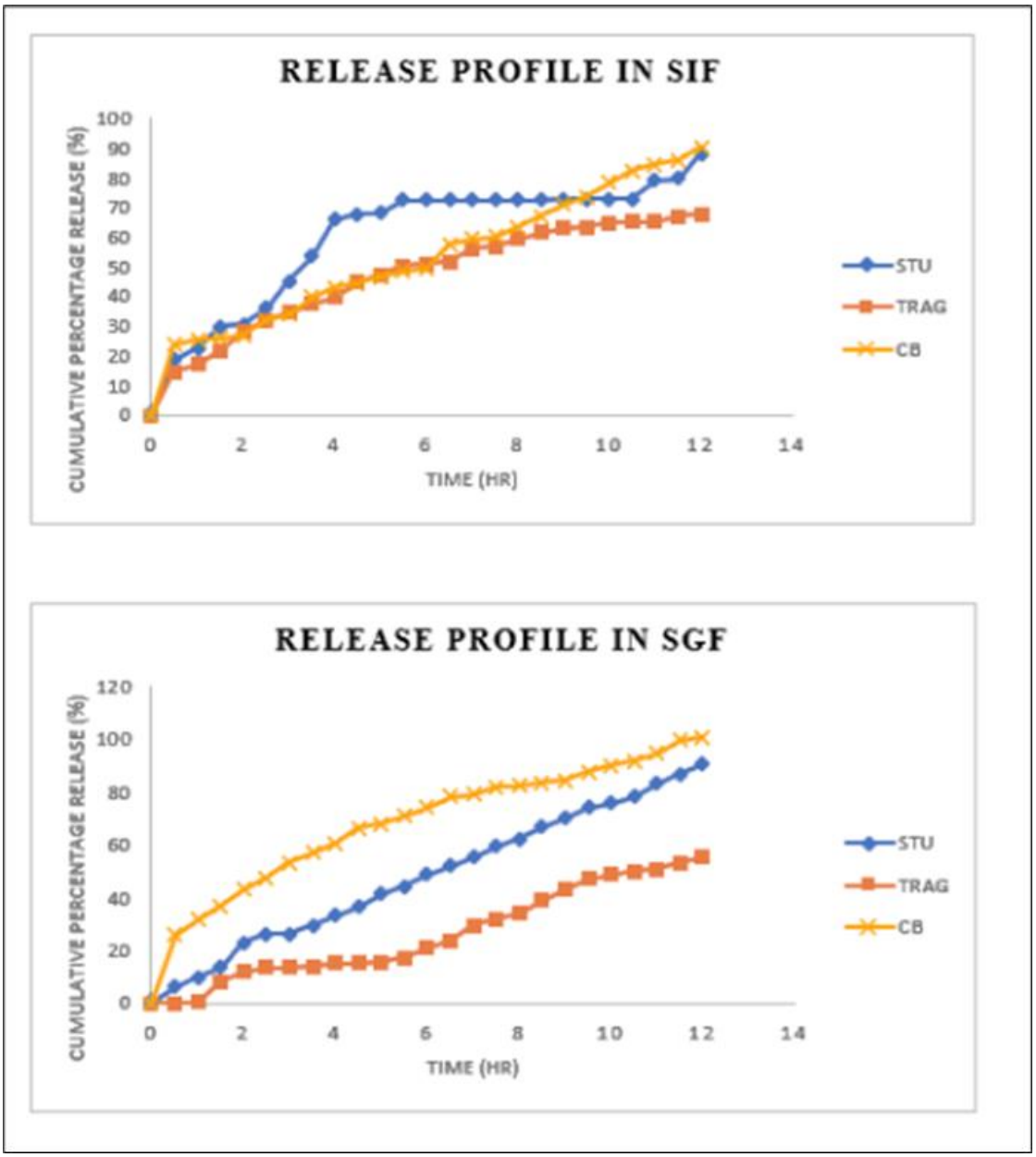

Figure 7 I*n vitro* dissolution profile of matrix tablet formulation

Key: STU – matrix tablet formulation containing *S. tragacantha* gum; TRAG - matrix tablet formulation containing tragacantha gum; CB – commercial brand

Table 5 Release kinetics and mechanisms of theophylline matrix tablets

SIF			**SGF**	
Formulation	**Release kinetics**	**Release mechanism**	**Release kinetics**	**Release mechanism**
STU	Korsemeyer Peppas R^2 = 0.8664 n-value = 0.49	Non-Fickian diffusion	Zero order R^2 = 0.9959 n-value = 0.855	Non- Fickian Diffusion
TRAG	Higuchi R^2 = 0.9890 n-value = 0.53	Non-Fickian diffusion and erosion	Zero order R^2 = 0.9601 n-value = 1.6	Non- Fickian Diffusion
CB	Zero order R^2 = 0.9762 n-value = 0.75	Non-Fickian diffusion	Higuchi R^2 =0.9942 n-value = 0.74	Non- Fickian

Key: STU – matrix tablet formulation containing *S. tragacantha* gum; TRAG - matrix tablet formulation containing tragacantha gum; CB – commercial brand

4. Conclusion

Sterculia tragacantha seed husk gum sustained theophylline release from the formulated matrix tablet for over 12 hours with a maintained release rate between the fourth to eleventh hour in SIF before a decline while a steady release gradient was observed on SGF till the twelfth hour with no observed decline. The physiochemical properties of the extracted gum powder of *S. tragacantha* compared favourably with tragacanth gum and indicate a potential for other pharmaceutical excipient role.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declare there is no conflict of interest in this study.

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