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Evaluation of the binding and disintegrating properties of gum obtained from the stem bark of *Cinnamomum zeylanicum*

Excipients are the various ingredients, apart from the active pharmaceutical ingredients, which are added to pharmaceutical formulations. Excipients obtained from natural sources are preferred over those from synthetic sources because they are cheap, biocompatible and readily available. Gums are made up of carbohydrate units which are linked by glycosidic bonds. This study was aimed at evaluating the potential binding and disintegrating properties of gum obtained from the bark of *Cinnamomum zeylanicum*, which was obtained from Effiduase in the Ashanti region of Ghana. The gum was extracted using 96% ethanol and the moisture content, Fourier transform infrared spectroscopy spectra, water holding capacity, swelling index and flow properties of the gum were determined. The gum was used to formulate tablets at different concentrations (10% $^{w}/_{v}$, 15% $^{w}/_{v}$ and 20% $^{w}/_{v}$) as binder with acacia as the standard. The gum was also used to formulate tablets at different concentrations (5% $^{w}/_{v}$, 7.5% $^{w}/_{v}$ and 10% $^{w}/_{v}$) as disintegrant with starch as the standard. Quality control tests were then conducted on all formulated tablets. The gum exhibited good flow and physicochemical properties. All formulated tablets passed the uniformity of weight test, friability test, disintegration test, hardness test, uniformity of dimensions test and drug content. All batches of tablets, except Batch 7, passed the dissolution test. Based on the study carried out, *C. zeylanicum* gum can be used as an alternative excipient to acacia and starch as a binder and a disintegrant, respectively.

Significance:

- A natural polysaccharide (gum) from the bark of *Cinnamomum zeylanicum* tree can be harnessed and commodified as a pharmaceutical excipient (binder and disintegrant) in the production of immediate release tablets.

Introduction

Pharmaceutical excipients constitute about 90% of dosage forms and can be defined as any substance added to the active pharmaceutical ingredient(s) during the process of pharmaceutical manufacturing.[1] In pharmaceutical formulations, excipients may be employed as binders and disintegrants in immediate release tablets. In formulating immediate release tablets, binders promote the cohesiveness of powder mixtures, improving the flow of granules and the strength of the resulting tablet.[2] Disintegrants are included in the formulation of tablets to facilitate their break-up into smaller fragments in an aqueous medium. Binders and disintegrants may be from natural, synthetic or semi-synthetic sources. The quest for natural excipients has increased tremendously over the past decade. Pharmaceutical excipients obtained from natural origin are known to be economical, biodegradable, safe and relatively abundant.[3] In pharmaceutical industries, natural polysaccharides like mucilages, starches and gums are used as fillers, binders and disintegrants.[4]

Gums are pathological products of plants resulting from the breakdown of cell walls as a result of plant injury or unfavourable environmental conditions. They are hydrophilic, amorphous, colloidal and sticky in nature with uronic and sugar units. They may be natural, synthetic or semi-synthetic in nature. Gums from okra, khaya, acacia and gellen, which are naturally occurring, have been commonly used as binders in tablet formulation.[5] The bark of *Cinnamomum zeylanicum* (Family: Lauraceae), aside from its medicinal properties as an anthelmintic and anti-inflammatory agent, has not been widely researched as a potential excipient in solid dosage forms.[6,7] *C. zeylanicum,* or Ceylon cinnamon tree, is readily available in the tropics and subtropics with Ghana being no exception. Gum obtained from the bark of the plant can be locally harnessed and investigated as a potential excipient in tablets. In this study, gum obtained from the bark of *C. zeylanicum* was investigated for its potential as both a binder and disintegrant in the formulation of oral immediate release tablets.

Materials and methods

Materials

The bark of *C. zeylanicum* was obtained from Effiduase in the Ashanti region, Ghana, and authenticated at the Department of Herbal Medicine, Faculty of Pharmacy and Pharmaceutical Sciences, Kwame Nkrumah University of Science and Technology (Kumasi, Ghana) by a botanist. It was given a specimen voucher number of KNUST/HM1/2018/SB002. Diethyl ether, ethanol (96%), paracetamol powder, acacia powder, starch powder, talc, magnesium stearate and lactose were obtained from UK Chemicals, Kumasi. All other reagents used were of analytical grade.

Extraction of gum from Cinnamomum zeylanicum *bark*

Distilled water (7 L) was added to 200 g *C. zeylanicum* powdered bark and allowed to stand for 24 h at room temperature (27 °C). The mixture was then boiled for 15 min, allowed to cool and filtered with a calico strainer to remove any debris to obtain the gum. Ethanol (96%) was used in purifying the gum obtained via precipitation. The precipitated gum was filtered, washed with diethyl ether and dried in a hot air oven at 60 °C for 12 h.[8] The dried gum was milled, passed through a sieve with an aperture size 180 μm and appropriately stored for use.

Determination of moisture content

A mass of 1 g of the gum was transferred into a dried crucible of known weight and placed in an oven at 105 °C for 5 h. The crucible containing the gum was removed and allowed to cool at room temperature and weighed.[9]

Swelling index and water holding capacity of Cinnamomum zeylanicum *gum*

An amount of 0.5 g *C. zeylanicum* gum (CZG) was transferred into a measuring cylinder, tapped and its volume recorded as V_0. It was then dispersed in 10 mL of distilled water and allowed to stand for 24 h. The volume occupied by the gum was observed after 24 h (V_{24}) and calculated as:

$$\text{Swelling index} = \frac{V_{24} - V_0}{V_0} \times 100$$

Contents in the measuring cylinder used for determination of the swelling index were also used to determine the water holding capacity as described by Ofori-Kwakye's group.[10]

Determination of the pH of CZG

Cinnamomum zeylanicum gum (0.1 g) was dispersed in 10 mL of water and stirred for complete dissolution. The pH was then checked with a pH meter (MW101, Milwaukee Instruments, Rocky Mount, NC, USA).[11] This was done in triplicate.

Compatibility studies on formulated granules

Paracetamol powder, CZG and formulated granules were individually scanned using a Fourier transform infrared spectrophotometer (Bruker Alpha II, Germany) over 500–3500 cm^{-1} wavelengths. Their spectra were then superimposed to assess the presence or absence of principal bands of paracetamol in the formulated tablets.

Determination of the flow property of CZG

Cinnamomum zeylanicum gum (30 g) was weighed (M) and transferred into a 100-mL measuring cylinder and the initial volume (V_0) recorded. The measuring cylinder was tapped on a bench until a constant volume (V_f) of the gum was obtained. The bulk density, tapped density, Carr's index and Hausner ratio were calculated as:

$$\text{Bulk density} = \frac{M}{V_0}$$

$$\text{Tapped density} = \frac{M}{V_f}$$

$$\text{Carr's index} = \frac{(\text{Tapped density} - \text{bulk density})}{\text{Tapped density}} \times 100$$

$$\text{Hausner ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

The fixed height method was also used in the angle of repose determination. The gum was allowed to freely flow through a clamped funnel to form a heap. The height (h) and diameter (d) of the heap were determined. Using the equation below, the angle of repose (α) was calculated:

$$\tan(\alpha) = h/(0.5\ d)$$

Formulation of tablets

The wet method of granulation and the technique of doubling the bulk were employed in preparing 12 batches of paracetamol granules. CZG was used as a binder (10% w/v, 15% w/v and 20% w/v) for Batches 1–3 (B1–B3) and as a disintegrant (5% w/w, 7.5% w/w and 10% w/w) for B7–B9. Acacia gum and starch were used as a standard binder and disintegrant, respectively, at the same concentrations stated above for B4–B6 and B10–B12, respectively. All ingredients except talc and magnesium stearate were accurately weighed and mixed together with water as the granulating fluid to form a damp mass. This was then screened with a mesh (2360 μm) and dried at 60 °C for 2 h in an oven. The dried granules were screened with a 1180 μm sieve, mixed with magnesium stearate and talc and compressed into tablets using a single punch tableting machine (TDP 5, Herun, China). Sixty (60) tablets were compressed from each batch to cater for all quality control tests. The constituents of the formulated tablets are given in Table 1.

Table 1: Constituents (mg) of formulated tablets

Ingredients	Formulation codes											
	B1	B2	B3	B4	B5	B6	B7	B8	B9	B10	B11	B12
Paracetamol	500	500	500	500	500	500	500	500	500	500	500	500
Cinnamomum zeylanicum gum	30	52	64	–	–	–	30	45	60	–	–	–
Starch	30	30	30	30	30	30	–	–	–	30	45	60
Acacia	–	–	–	30	52	64	–	–	–	–	–	–
Hydroxypropyl methylcellulose	–	–	–	–	–	–	1.4	1.4	1.6	1.4	1.4	1.6
Talc	3.2	3.3	3.3	3.2	3.3	3.3	3.0	3.0	3.0	3.0	3.0	3.0
Magnesium stearate	6.2	6.3	6.3	6.2	6.3	6.3	6.0	6.0	6.0	6.0	6.0	6.0
Lactose	70	70	70	70	70	70	70	55	40	70	55	40

Flow properties of granules

The flow properties of the granules were determined before compression into tablets. The angle of repose was determined using the fixed height method whereas the Carr's index and Hausner ratio were determined using the bulk and tapped densities of the granules.[12,13]

Evaluation of tablets

Weight uniformity test

Twenty tablets were randomly selected from each batch and individually weighed to calculate average weight. The average weight and percentage deviation of each tablet were determined as described in the British Pharmacopoeia.[14]

Friability test

Ten tablets from each batch were randomly selected and weighed. They were then placed in a friabilator (EF-2W, Roche, Switzerland) regulated at 4 min at a speed of 25 rpm (revolutions per minute). Afterwards, the tablets were removed from the friabilator, dedusted and reweighed.[15] The percentage friability was calculated as:

$$\text{Friability (\%)} = \frac{W_0 - W}{W_0} x100$$

where W is the final weight and W_0 is initial weight.

Disintegration test

Six tablets from a batch were selected at random and each tablet placed in a tube of the basket-rack assembly in an Erweka disintegration apparatus (ZT 320 series, Germany). The basket rack was placed in a water bath regulated thermostatically at 37±2 °C and observed until all the tablets had disintegrated completely.[12] This procedure was repeated for all batches.

Uniformity of dimension and hardness test of tablets

Ten tablets were randomly selected from each batch. Their diameters and thickness were determined using vernier calipers. The hardness of ten randomly selected tablets from each batch was determined with a Veego hardness tester (DIGITAB-SPV, India). The tensile strength was calculated as:

$$\text{Tensile strength} = \frac{2F}{\pi Dt}$$

where D is the diameter, t is the tablet thickness and F is the diametrical break force of the tablet.

Uniformity of drug content

Ten tablets from each batch were randomly selected. Each tablet was crushed, dissolved in 50 mL of HCL (0.1 M) and the mixture topped up to 100 mL using 0.1 M HCL. The mixture was filtered and its absorbance determined at 245 nm using a UV spectrophotometer (DU-8800R, Drawell, Shanghai). A standard calibration curve was used to calculate the average drug content for three determinations.

In vitro dissolution studies

In vitro drug release of the tablets was determined using the USP II dissolution apparatus (DT6, Erweka, Germany) at 50 revolutions per minute. Six (6) tablets each for all batches were evaluated. A tablet was put in each vessel containing 900 mL of the dissolution medium, HCL (0.1 M), at 37±0.5 °C. A volume of the medium (10 mL) was drawn at time intervals (5, 15, 30, 45 and 60 min) and filtered using Whatman filter paper number 5 with a pore size of 2.5 μm. The volumes taken were replaced to maintain sink conditions. A UV-visible spectrophotometer (Alpha II, Bruker, Germany) was used to check the absorbance of the filtrates at a wavelength of 245 nm. The average drug release profile for three determinations was carried out using a standard calibration curve.[16] The various batches of tablets which passed the dissolution profile were analysed for their similarity factor (f2) using the equation:

$$\text{Similarity factor (f2)} = 50 x \log [\{1 + (1/n) \sum t=1^{n} (Rt - Tt)^2\}^{-0.5} x 100]$$

where n = dissolution time points, Rt = dissolution value for reference at time t, and Tt = dissolution value at time t.

Statistical analysis

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS v.20, IBM). Differences between means were analysed using t-tests; $p<0.05$ was considered statistically significant.

Results and discussion

Physicochemical properties of CZG

The yield obtained from the extractive process was 2.31%. Different solvent systems can affect the percentage yield of gums.[17] According to Vani and Reddy[8] who used an acetone precipitation method, percentage yield obtained for CZG was 1.6%, which is less than the yield obtained in this study (Table 2). Comparing percentage yield obtained from work done by Kolhe et al.[18] using microwave assisted extraction, a higher gum yield of 33.4% was obtained. This could be due to the geographical location of the plant, time or season of harvesting of the plant, and the difference in extraction methods employed.[19] The aqueous method of extraction was used in this study due to its low cost and economic viability. The moisture content of the gum plays a vital role in its flow properties and microbial stability. The moisture content of the extracted gum was 0.63%, which fell within specification (<15% w/w)[20] (Table 2). Gums with moisture content above 15% w/w are likely to stick together, support microbial growth and deteriorate over time. This results in a reduction in shelf life and quality.[21] Therefore, the low moisture content (0.63%) reported for the extracted CZG enhances its suitability as a potential pharmaceutical excipient.

The swelling index of gums contributes to bioadhesion in tablet formulation, which is a determinant of drug release during dissolution. Gums reported to have swelling indices between 31.8% and 180% are said to have good disintegrating properties.[22] The extracted gum exhibited good swelling and water holding capacities (Table 2), which could be attributed to the presence of hydrophilic functional groups. The swelling and water holding capacities of the extracted gum could also be attributed to shorter chain molecules as gums with longer chain polymers are known to have longer hydration time and vice versa.[15,18,19,22] Hence tablets formulated with CZG will potentially exhibit good disintegration and drug release profiles.

The suitability of a natural polymer as an excipient in a formulation can be influenced by its pH. CZG had a neutral pH (Table 2), which indicates its suitability to be incorporated in a pharmaceutical formulation as the stability and physiological activity of the active pharmaceutical ingredient will not be altered.[23]

Table 2: Physicochemical characteristics of *Cinnamomum zeylanicum* gum

Yield (%)	Moisture content (%)	Swelling index (%)	Water-holding capacity (%)	pH
2.31	0.63 ± 0.04	175 ± 0.14	98 ± 0.05	6.92 ± 0.08

Fourier transform infrared spectroscopy analysis

The spectra of the pure powder of paracetamol, CZG only, and formulated granules revealed the compatibility and stability of the gum and other excipients with the active pharmaceutical ingredients. All principal peaks of the various functional groups for paracetamol (3322.03 cm^{-1}, 3159.39 cm^{-1} (hydroxyl group, O-H stretching) and 1561.11 cm^{-1}, 1504.98 cm^{-1} (amide II band))[14] were intact in the formulated granules, indicating the absence of interactions between the active ingredients and the excipients (Figure 1).

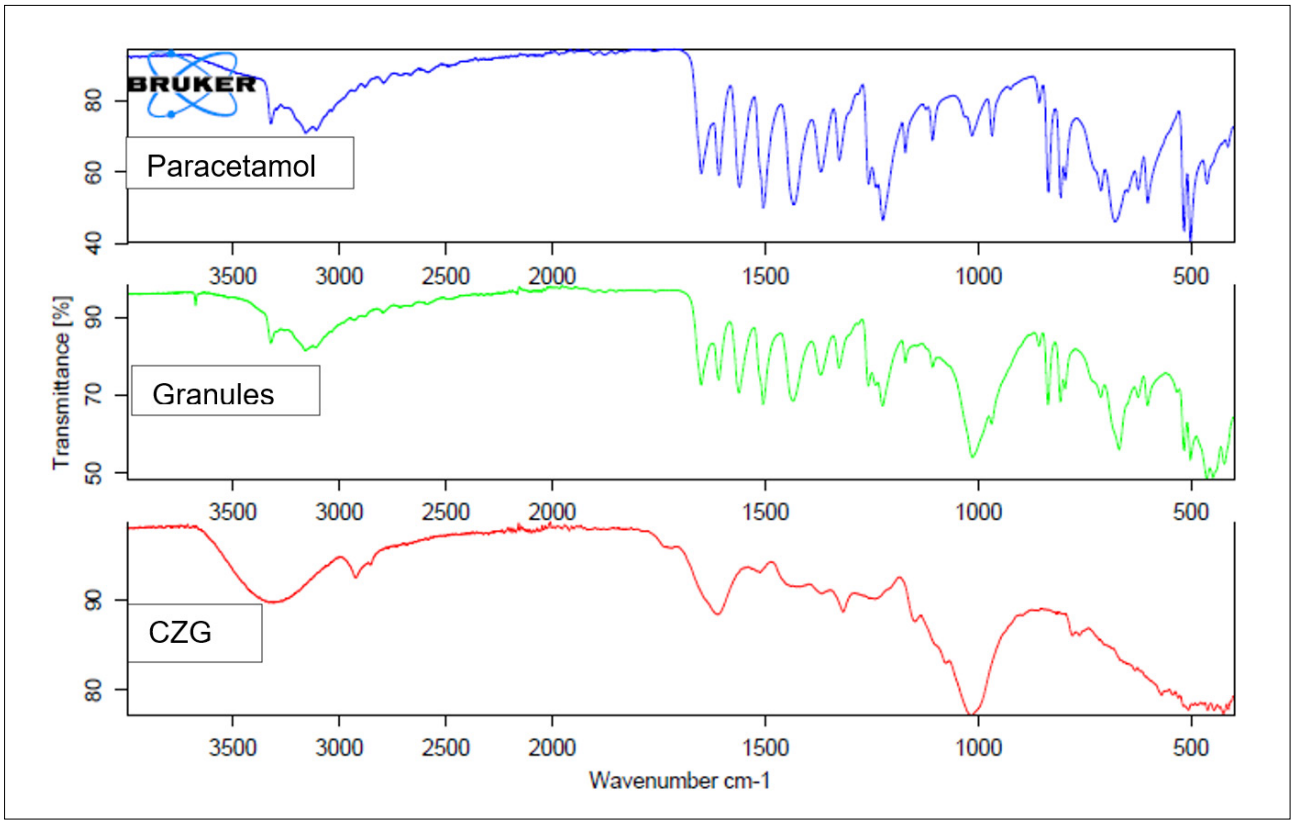

Figure 1: Fourier transform infrared spectroscopy spectra of *Cinnamomum zeylanicum* gum (CZG), paracetamol and paracetamol granules with CZG.

Evaluation of formulated tablets

Granules formulated for all batches exhibited good flow with angle of repose, Carr's index and Hausner ratio within the acceptable limits indicating suitability for compression into tablets. This will ensure uniformity in the filling of dies during tablet compression, resulting in weight uniformity, which was evident in the weight uniformity test (Table 3). All formulated tablets exhibited uniformity in diameter and thickness (Table 3), which was within the acceptable limit.[20]

The ability of a tablet to withstand breakage during handling, storage and transportation is affected by its tensile strength and hardness. All formulated tablets had hardness and friability within the specifications of 4–8 kg/f and less than 1%, respectively.[20] Disintegration and drug release of tablets is dependent on the amount and nature of binder and disintegrant used during the granulation process and the compression force applied.[1,5,13] Harder tablets are formed when the concentration of binders is increased with a corresponding extension in the tablet disintegration time.[14,20] On the other hand, the disintegration time of tablets is reduced with an increase in concentration of disintegrants, which was evident in the formulated tablets (Table 3). All the formulated tablets passed the disintegration test (disintegration time less than 15 min) (Table 3). When comparing CZG as a binder and disintegrant to the standard binder (acacia) and standard disintegrant (starch) in immediate release tablets, statistical analysis revealed a significant difference in disintegration time. This indicates that variations in disintegration time between CZG and the standard binder and disintegrant can affect other parameters such as dissolution (Figure 2). There was no significant difference in the friability and hardness profile of formulated tablets for all batches with CZG as binder (B2–B6) and disintegrant (B7–B12) when compared to that of acacia and starch with the exception of B1 and B4 (Figures 3 and 4). Increasing concentration of CZG as binder resulted in tablet with better friability profile, which were comparable to that of the standard binder (Figure 3).

The effectiveness of a dosage form in the gastrointestinal tract and its systemic absorption depends on dissolution and disintegration.[24] At 45 minutes, the amount of drug released should not be less than 70%.[20] A longer disintegration time may result in slower drug release during dissolution which could account for B7 failing the dissolution profile test (Figure 5). B1 and B3 had similar dissolution profiles to that of the standard binder, with only B9 having a similar dissolution profile to that of the standard disintegrant (Table 4). Thus, formulations containing the same active ingredient with similar dissolution profiles are expected to be bioequivalent with similar effects in vivo. CZG can serve as a substitute for acacia and starch for use in the pharmaceutical industry.

Conclusion

Cinnamomum zeylanicum gum exhibited good disintegrating and binding properties at varying concentrations and it can be used as an alternative to starch and acacia as a disintegrant and a binder, respectively, in immediate release tablets.

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Competing interests

We have no competing interests to declare.

Authors' contributions

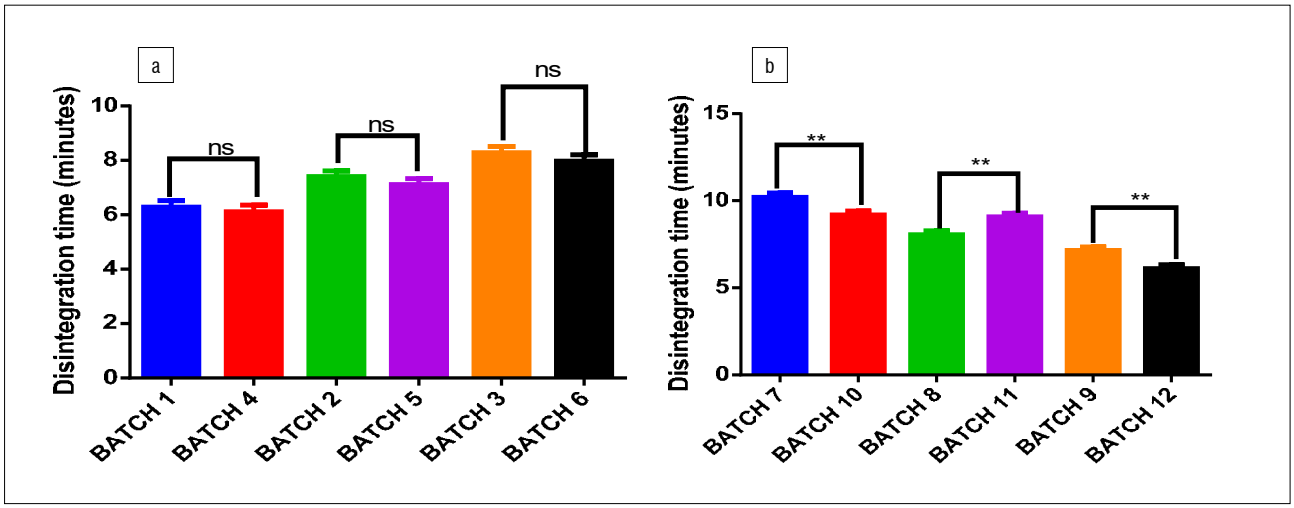
L.C.S.: Methodology, data collection, data analysis, writing – initial draft. P.E.: Conceptualisation, methodology, data collection, data analysis, writing – initial draft, writing – revisions. F.W.A.O.: Methodology, data analysis, writing – revisions. M.E.B.-G.: Conceptualisation, project leadership, project management, methodology, data analysis, writing – revisions. M.T.B. and K.O.-K.: Conceptualisation, project management, methodology, writing – initial draft, writing – revisions.

Table 3: Properties of *Cinnamomum zeylanicum* gum (CZG), formulated granules and tablets

Parameters	CZG	B1	B2	B3	B4	B5	B6	B7	B8	B9	B10	B11	B12
Hausner ratio	1.30±0.03	1.17±0.02	1.16±0.03	1.11±0.02	1.18±0.03	1.18±0.05	1.14±0.04	1.09±0.04	1.20±0.05	1.15±0.04	1.16±0.03	1.25±0.02	1.18±0.03
Carr's index	23.01±0.02	14.380±0.04	14.070±0.02	10.62±0.03	15.38±0.05	15.75±0.02	12.630±0.04	8.40±0.04	17.09±0.02	13.710±0.03	14.080±0.05	20.540±0.02	15.95±0.03
Angle of repose (α)	30.69±0.02	29.510±0.02	27.120±0.03	28.17±0.02	21.48±0.04	26.28±0.03	30.960±0.02	27.34±0.03	27.50±0.02	26.950±0.04	25.160±0.02	30.830±0.03	28.23±0.02
Tablet diameter (mm)	–	12.56±0.03	12.58±0.05	12.61±0.10	12.58±0.06	12.51±0.02	12.39±0.22	12.57±0.07	12.55±0.03	12.55±0.01	12.50±0.11	12.56±0.04	12.47±0.08
Tablet thickness (mm)	–	3.21±0.04	3.29±0.10	3.52±0.12	3.56±0.07	3.34±0.15	3.37±0.03	3.31±0.14	3.43±0.08	3.47±0.04	3.62±0.06	3.96±0.14	3.69±0.16
Hardness (kg/f)	–	4.38±0.07	4.26±0.02	7.16±0.11	4.26±0.06	4.62±0.08	6.62±0.01	4.38±0.15	4.38±0.03	4.34±0.01	4.42±0.04	4.48±0.11	4.60±0.05
Friability (%)	–	0.01±0.17	0.01±0.01	0.01±0.13	0.16±0.05	0.01±0.19	0.01±0.04	0.07±0.10	0.01±0.11	0.05±0.02	0.12±06	0.03±0.01	0.04±0.09
Disintegration time (min)	–	6.17±0.01	7.24±0.05	8.17±0.03	6.07±0.01	7.07±0.04	7.58±0.02	10.13±0.02	8.03±0.07	7.09±0.03	9.12±0.06	9.05±0.04	6.07±0.02
Weight uniformity (g)	–	0.62±0.007	0.62±0.004	0.61±0.002	0.62±0.003	0.61±0.001	0.62±0.004	0.61±0.003	0.61±0.002	0.62±0.001	0.62±0.005	0.62±0.001	0.62±0.004

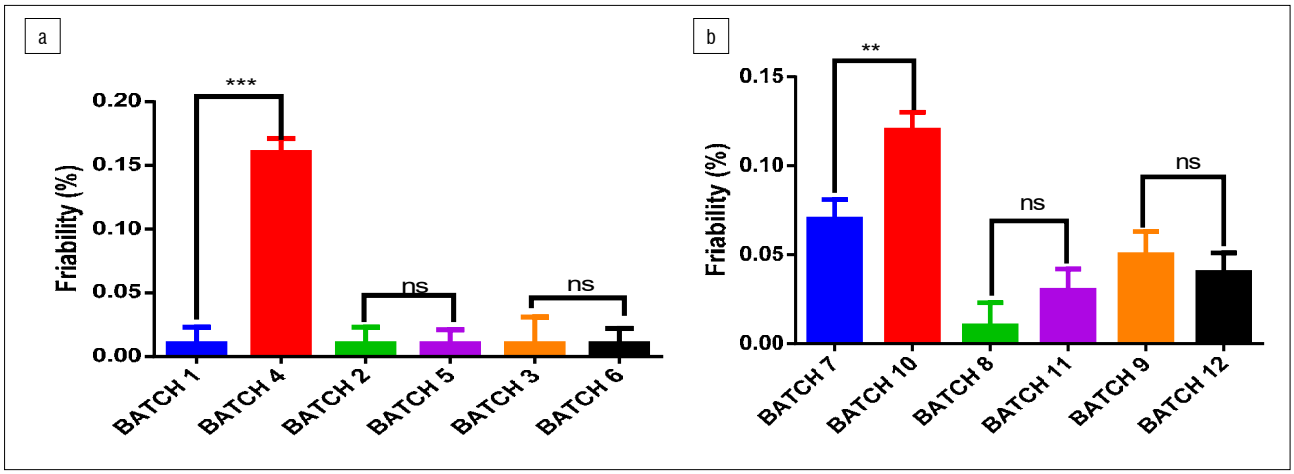
Table 4: Similarity factor analysis of formulated *Cinnamomum zeylanicum* gum tablets in comparison with starch or acacia formulations

Formulation	Similarity factor (*f2*)	Comment
B1	63.50	Similar
B2	38.08	Dissimilar
B3	60.54	Similar
B7	34.51	Dissimilar
B8	33.24	Dissimilar
B9	53.10	Similar



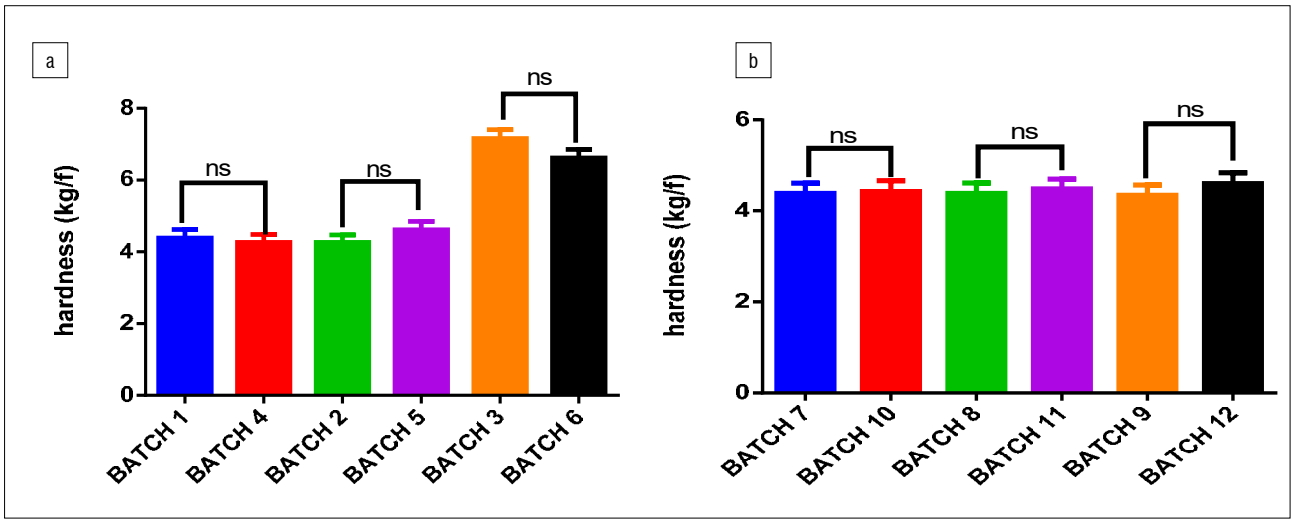
**p≤*0.01; ns, not significant; Student's two-tailed t-test*

Figure 2: Statistical analysis of the disintegration time of paracetamol tablets with (a) *Cinnamomum zeylanicum* gum (B1–B3) or acacia gum (B4–B6) as binders and (b) *Cinnamomum zeylanicum* gum (B7–B9) or starch (B10–B12) as disintegrants.



***p≤0.001; ns, not significant; Student's two-tailed t-test

Figure 3: Statistical analysis of the friability index of paracetamol tablets with (a) *Cinnamomum zeylanicum* gum (B1–B3) or acacia gum (B4–B6) as binders and (b) *Cinnamomum zeylanicum* gum (B7–B9) or starch (B10–B12) as disintegrants.



**p≤0.01; ns, not significant; Student's two-tailed t-test

Figure 4: Statistical analysis of the hardness of paracetamol tablets with (a) *Cinnamomum zeylanicum* gum (B1–B3) or acacia gum (B4–B6) as binders and (b) *Cinnamomum zeylanicum* gum (B7–B9) or starch (B10–B12) as disintegrants.

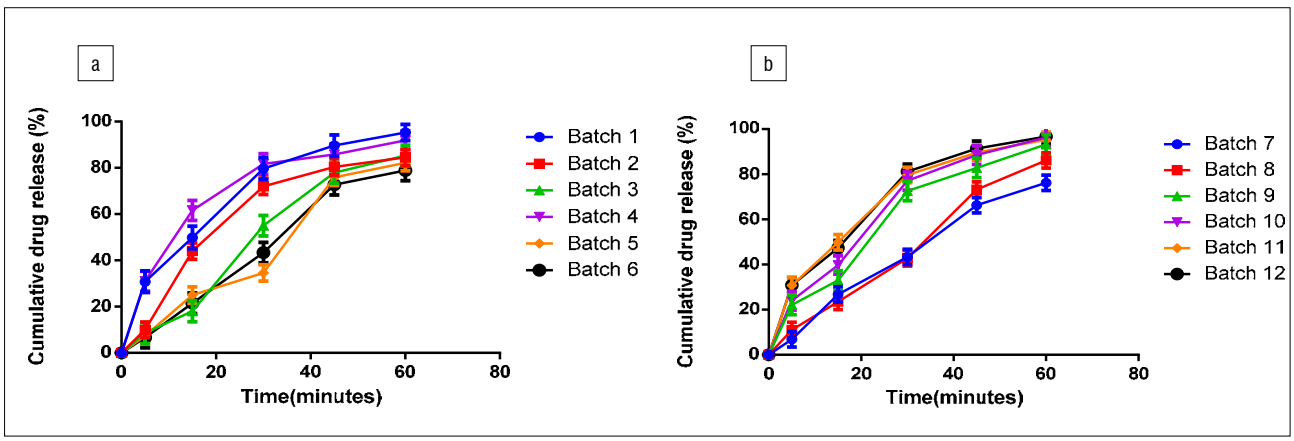


Figure 5: Dissolution profiles of (a) Batches 1–6 and (b) Batches 7–12.

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