Pharmaceutical evaluation of plantain peel pectin as a disintegrant in conventional tablets

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Plantain peels are a potential source of raw materials for the pharmaceutical industry. In Ghana, most of the pharmaceutical excipients used by local companies are synthetically produced and imported from developed countries. One such excipient is pectin, a polysaccharide used as a disintegrating agent in solid-oral-dosage forms. In this study, we assessed the pharmaceutical potential of pectin extracted from two popular plantain varieties, Apem (M) and Apantu (T), at various ripening stages (matured-green (G), half-ripe (H) and full-ripe (R)), for use as a disintegrant in immediate-release tablets. Acid (D) and alkaline (L) extraction methods were used. The suitability of the extracted pectins for pharmaceutical use was evaluated by preparing paracetamol granules using the wet granulation method and assessing their flow properties. Post-compression tests, including friability, hardness, disintegration, uniformity of weight, assay and dissolution, were conducted. All the tablets met the uniformity of weight requirement, with no deviation beyond ±5%. The hardness of all the tablets ranged between 5.57±0.15 kgF and 11.96±0.75 kgF, while the friability for all tablets was below 1%. The drug content ranged from 99.9% to 103%. Pectin from both varieties demonstrated good disintegrating properties (DT < 15 min) at concentrations of 5%w/w, 7.5%w/w and 10%w/w, with the exception of TGL, THD, TRD and TRL at all concentrations. As a result, all tablet batches met the dissolution test requirement (Diss, Q > 75%), except for those that failed the disintegration test. In conclusion, pectins derived from plantain peels have potential commercial value as pharmaceutical disintegrants at various concentrations in immediate-release tablets.

Significance:

This study highlights the significant potential of plantain peels, a common by-product of plantain processing in Ghana, as a source of pectin for use as a disintegrant in immediate-release tablets. The research demonstrates that pectin extracted from two popular Ghanaian plantain varieties at various ripening stages can meet the pharmaceutical standards for tablet production. This could reduce the reliance on imported, synthetically produced excipients, support local industries and promote sustainability. The findings open up new possibilities for the commercial exploitation of plantain peels, contributing to waste reduction and economic growth.

Introduction

Medicines are complex systems that include a variety of excipients in addition to the active pharmaceutical ingredients. These excipients are often combined with active pharmaceutical ingredients to enhance, support or improve the stability of the formulation.[1,2] Excipients are key in shaping the quality of the final pharmaceutical dosage forms. They are engineered to improve the pharmacokinetic and pharmacodynamic properties of the drug. They also significantly influence the physical characteristics of medicinal products, such as solubility, texture, weight, volume and drug release, which are essential for delivering an adequate dose of the active drug in a specific dosage form.[3] Hence, the biological, chemical and physical properties of the drug product are directly affected by the type of excipients used, their amounts and their interactions.[4,5]

In Ghana, most pharmaceutical excipients are synthetically made and imported, leading to high prices due to the materials cost, shipping and tax expenses.[6,7] While these excipients must meet certain functional and safety standards[8,9], many synthetic ones used in various pharmaceutical formulations have shown undesirable side effects[10,11]. Hence, there's a growing interest in natural excipients with fewer side effects.[12]

Plant-based substances have been a foundation for various medicinal and pharmaceutical formulations.[13] Pectin, a naturally occurring polysaccharide, has seen a surge in significance recently due to its biocompatibility.[14-16] Pectins, chemically, are a collection of heteropolysaccharides, primarily made up of α-1-4-D galacturonic acid units, predominantly found in the cell walls and middle lamella of higher plants. Currently, commercial pectins are largely sourced from citrus peel or apple pomace, both by-products of juice production.[17] However, due to their lengthy maturation periods and the unsuitability of apple cultivation in Africa, there has been a shift towards alternative, faster-maturing (14–20 months) pectin sources readily available in Africa for local pharmaceutical use. Some explored alternatives include mango waste and cocoa pods, whose pharmaceutical applications have been assessed.[18,19]

Plantains, a staple in tropical regions, are nutritionally and economically valuable. In Ghana, the main varieties, 'Apantu' and 'Apem', are used differently depending on ripening stages.[20] Plantain peels, which make up 30–40% of the fruit's weight, pose a pollution problem after processing.[21] However, the growing interest in agricultural bio-based materials and waste reuse presents an opportunity. Extracting pectin from these peels could transform this waste into a valuable resource.

Otu et al.[22,23] have studied the physicochemical and binding properties of plantain peel pectin (PPP). They evaluated the effect of the extraction method on the physicochemical properties of the pectin derived from plantain peel waste at different ripening stages. The potential of PPP in pharmaceuticals could address pollution from plantain

processing and boost the economy. In this study, we aimed to evaluate the disintegrating properties of pectin from plantain peels at different ripening stages, contributing to our understanding of pectin's potential as a disintegrant. The ultimate goal is to assess the commercial viability of PPP as a pharmaceutical disintegrant.

Methodology

Materials

Pectin was obtained from two plantain (*Musa paradisiaca* L.) varieties, namely Apem (M) and Apantu (T), at different ripening stages (matured-green (G), half-ripe (H), and full-ripe (R)), extracted at each ripening stage using acidic (D) and alkaline (L) methods. The pectin extracts were coded (MGD, MGL, MHD, MHL, MRD, MRL, TGD, TGL, THD, THL, TRD and TRL) to represent the variety used, ripeness stage and method of extraction. Paracetamol powder (Ernest Chemist Ltd, Ghana), tragacanth gum powder BP (Sigma-Aldrich, USA), maize starch BP (UK Chemicals, Ghana), talc and lactose (Xi'an Rongsheng Biotechnology) were used in the study.

Methods

Preparation of paracetamol granules and tablets

Pectin derived from Apem and Apantu plantain peels at different ripening stages was used to prepare 39 batches of paracetamol granules through the wet granulation technique using 20%w/w tragacanth as a binder. The required quantity of PPP was incorporated into the formulations at different concentrations (5%, 7.5% and 10%). The damp mass was screened through mesh 8 (2360 μm) and subsequently dried using a hot air oven at 60 °C for 1 hour. The dry granules were screened through mesh 16 (1180 μm). Talc was added as an extra-granular lubricant. The standard disintegrant used in the formulations was maize starch BP at the same concentration as the test formulations. Quantities of 650 mg granules were compressed using a Saimach 11/37 (Saimach Pharmatech Pvt Ltd., India) at a compression force of 10–15 kN.

Evaluation of the pre-compression properties of the granules

Parameters including angle of repose, bulk and tapped density, Hausner's ratio and percentage compressibility were assessed for the granules. The assessment was carried out using the methods reported by Fosu et al.[24] and Bayor et al.[25]

Evaluation of disintegrant properties

Physicomechanical properties

Uniformity of weight

Weight variation was assessed for all produced tablets, in accordance with the USP XXIV monograph. For each batch, 20 random tablets were selected to evaluate the variation in weight, and the mean ± standard deviation was computed.[26]

Tablet dimensions

The Mitutoyo CD-8-CSX digital vernier calliper was used to measure the thickness and diameter of the tablets. The results are presented as the average values of six measurements along with their standard deviations.[24]

Determination of crushing strength and tensile strength

The crushing strength (*Cs*) of each batch using 10 tablets was determined using a Copley hardness tester (TH3). Triplicate testing was performed for every batch, following the USP XXIV monograph guidelines for conventional tablets.[26] The tensile strength (T_s) was calculated using Equation 1:

$$T_s = \frac{2C_s}{\pi dt} \quad \text{Equation 1}$$

where *t* and *d* are the thickness and diameter, respectively.

Friability test

The friability was assessed for tablets from all batches, following the guidelines of the USP XXIV monograph. The initial and final weights were denoted by I_w and F_w. The friability tests were conducted using an Erweka (TA-20, Germany) friabilator, with measurements done in triplicate.[26] The friability (%) was computed using Equation 2:

$$Friability\ (\%) = \frac{Iw - Fw}{Iw} \times 100 \quad \text{Equation 2}$$

Disintegration time determination

The time for the tablets to disintegrate was recorded using the Erweka (ZT-4, Germany) disintegration apparatus. Each of the apparatus's six tubes was filled with a tablet, and the duration taken to fully disintegrate in distilled water, kept at a temperature of 37±2 °C, was noted.[26,27]

Determination of the disintegration efficiency ratio

The disintegration efficiency ratio (DER) was evaluated using Equation 3:

$$DER = \frac{C_s/F}{D} \quad \text{Equation 3}$$

where *D*, C_s and *F* refer to the disintegration time, crushing strength and friability, respectively.

The dimensionless parameter DER_c was computed using Equation 4:

$$DER_c = \frac{DER_{test}}{DER_{standard}} \quad \text{Equation 4}$$

DER_{test} refers to the DER of a tablet that contains an experimental disintegrant (PPP extract) at a specific concentration. $DER_{standard}$ is the DER of a tablet that contains the standard disintegrant also at the same concentration.[28]

Drug content

A weight equivalent to a dose was weighed from 10 crushed tablets. A volume of 75 mL of phosphate buffer (pH 6.8) was used to dissolve the crushed tablets, and then diluted further to 100 mL and filtered. Serial dilutions were then obtained, and the absorbances and drug content evaluated using the previously calculated maximum wavelength and the calibration curve.[27,29] This was replicated for each batch.

Dissolution test

The in vitro dissolution test was performed using the 708-DS dissolution machine (Agilent Technologies, USA) and USP dissolution apparatus II at a revolution speed of 50 rpm. Six random tablets were selected from each batch and placed individually in each vessel containing 900 mL of phosphate buffer (pH 6.8) at a temperature of 37±0.5 °C. A sampling volume of 10 mL was taken and subsequently filtered at specific time intervals (5, 15, 30, 45 and 60 min). Following this, a quantity of 0.50 mL was pipetted from each filtrate and subsequently diluted with phosphate buffer to 50 mL. The resulting solution was later analysed using spectrophotometry at a wavelength of 245 nm. The quantity of paracetamol was calculated by employing the calibration curve. The dissolution profile of paracetamol from each batch was determined by constructing a graph that illustrates the percentage of medication released as a function of time.[30,31]

Data analysis

The model-independent comparison procedure, as reported by Adeleye et al.[31], was used to evaluate the difference (f1) and similarity (f2) factors between the dissolution profiles. Statistical analysis was performed to assess the quality of PPP as a disintegrant using an analysis of variance by employing GraphPad Prism software version 8 (GraphPad, San Diego, California, USA). The mean ± standard deviation was calculated for each data set. Tukey's post-hoc multiple comparison test was used

to compare the individual differences of the samples. A *p*-value set at ≤0.05 (5%) indicates a level of significance.

Results and discussion

Flow properties of granules and drug excipient compatibility

The evaluation of granule properties, including bulk and tapped densities, angle of repose, Carr's Index and the Hausner ratio, revealed excellent flow properties, as shown in Supplementary table 1. The angle of repose was found to be lower than 50 and closer to 25 for all samples, indicating excellent flow due to the physical combination of the ingredients.[32]

The compressibility of granules, which is crucial for producing strong tablets that can withstand pressure and abrasion, was also evaluated. The Hausner ratio and Carr's Index, which are indicative of the flow properties and cohesiveness of granules, showed good flow for all batches (Table 1). The near spherical granules, granulation process and the excipients added could account for the excellent flow of the granules observed. This suggests that the physical blend of the powders with the pectin samples conferred good flow properties on the powder mix, which is important due to its effect on the weight variation of tablets.[33]

Post-compression analysis

Uniformity of weight/dimensions

The *British Pharmacopoeia's* weight uniformity test stipulates that the weights of no more than two individual tablets should deviate from the average weight by more than ±5%, and no tablet should deviate by more than twice the percentage.[27] Minimising the risk of overdosing or underdosing is crucial, as any weight variations will inevitably influence the active pharmaceutical ingredient's consistency.[30,34] As shown in Table 1, all the tablets formulated at different concentrations adhered to the weight uniformity standards.

All the formulations had consistent and comparable thickness and diameter, with an average thickness and diameter ranging from 4.44 ± 0.01 to 4.77 ± 0.00 and 11.89 ± 0.00 to 12.02 ± 0.00, respectively (Table 1). These results can be linked to the consistent compressional force used and the similarities in the fluff and consolidated densities of the granules, leading to optimal flow properties of the granules.[35]

Friability and crushing strength-friability ratio

An increase in PPP concentration did not produce any specific effect on tablet friability, and there were no significant differences ($p > 0.05$)

Table 1: Weight variation, friability, dimension, drug content and disintegration time of the compressed tablets

Pectin type	Pectin concentrations (%w/w)	Weight variation (g) $n = 20$	Hardness (kgF) $n = 6$	Friability (%)	Tablet thickness (mm) $n = 6$	Tablet diameter (mm) $n = 6$	Drug content (%)	Disintegration time (min)
Control	5	646.3 ± 4.79	7.86 ± 0.00	0.51 ± 0.01	4.64 ± 0.00	11.97 ± 0.00	103 ± 0.0.00	10.15 ± 0.00
	7.5	648.3 ± 4.45	8.16 ± 0.00	0.71 ± 0.01	4.60 ± 0.00	11.89 ± 0.00	101.6 ± 0.00	8.14 ± 0.00
	10	647.5 ± 4.36	6.80 ± 0.00	0.81 ± 0.01	4.77 ± 0.00	12.02 ± 0.00	102.7 ± 0.00	5.15 ± 0.00
MGD	5	652.4 ± 6.09	8.57 ± 0.06	0.41 ± 0.01	4.51 ± 0.14	11.92 ± 0.05	101.7 ± 0.60	18.26 ± 0.05
	7.5	650.1 ± 6.28	7.95 ± 0.05	0.21 ± 0.01	4.57 ± 0.07	11.96 ± 0.02	100.4 ± 0.65	11.20 ± 0.08
	10	648.8 ± 4.09	8.43 ± 0.15	0.41 ± 0.01	4.61 ± 0.10	11.98 ± 0.03	100.6 ± 0.68	6.48 ± 0.07
MGL	5	652.0 ± 5.87	8.00 ± 0.04	0.41 ± 0.01	4.51 ± 0.14	11.90 ± 0.03	100.6 ± 0.38	9.49 ± 0.05
	7.5	651.9 ± 3.32	8.73 ± 0.07	0.41 ± 0.01	4.56 ± 0.19	11.94 ± 0.06	101.3 ± 1.50	7.08 ± 0.02
	10	652.2 ± 6.25	10.61 ± 0.08	0.31 ± 0.01	4.53 ± 0.16	11.92 ± 0.05	101.8 ± 1.12	4.51 ± 0.03
MHD	5	651.4 ± 3.45	8.63 ± 0.21	0.51 ± 0.01	4.44 ± 0.01	11.96 ± 0.07	101.9 ± 0.99	14.28 ± 0.14
	7.5	652.4 ± 5.65	7.61 ± 0.10	0.22 ± 0.01	4.49 ± 0.15	11.94 ± 0.06	101.4 ± 1.40	9.37 ± 0.37
	10	650.4 ± 2.6	5.57 ± 0.15	0.21 ± 0.01	4.61 ± 0.18	11.94 ± 0.07	101.9 ± 1.00	5.22 ± 0.03
MHL	5	647.2 ± 3.78	10.70 ± 0.1	0.11 ± 0.01	4.47 ± 0.08	11.93 ± 0.06	101.2 ± 1.00	13.63 ± 0.15
	7.5	648.7 ± 5.05	6.63 ± 0.15	0.31 ± 0.01	4.56 ± 0.08	11.93 ± 0.05	101.6 ± 1.01	8.40 ± 0.02
	10	651.1 ± 5.7	6.33 ± 0.12	0.81 ± 0.01	4.73 ± 0.02	11.95 ± 0.05	100.7 ± 0.49	4.14 ± 0.03
MRD	5	652.1 ± 5.51	7.99 ± 0.03	0.31 ± 0.01	4.68 ± 0.03	11.96 ± 0.06	100.8 ± 0.89	10.25 ± 0.04
	7.5	648.7 ± 5.05	6.95 ± 0.04	0.21 ± 0.01	4.56 ± 0.13	11.96 ± 0.08	101.3 ± 1.51	8.45 ± 0.01
	10	650.3 ± 5.13	9.14 ± 0.02	0.21 ± 0.01	4.44 ± 0.01	11.93 ± 0.06	101.2 ± 0.38	5.15 ± 0.03
MRL	5	648.3 ± 2.9	7.67 ± 0.12	0.31 ± 0.01	4.44 ± 0.17	11.92 ± 0.04	101.9 ± 1.58	6.48 ± 0.03
	7.5	648.3 ± 2.9	6.80 ± 0.10	0.41 ± 0.01	4.50 ± 0.17	11.99 ± 0.01	101.3 ± 1.10	6.12 ± 0.03
	10	653 ± 5.92	8.69 ± 0.02	0.41 ± 0.01	4.47 ± 0.08	11.94 ± 0.07	101.6 ± 1.12	9.49 ± 0.05
TGD	5	650.5 ± 6.56	8.03 ± 0.01	0.31 ± 0.01	4.51 ± 0.04	11.95 ± 0.07	100.2 ± 0.10	11.43 ± 0.02
	7.5	651.3 ± 4.64	7.27 ± 0.15	0.21 ± 0.01	4.73 ± 0.02	11.97 ± 0.06	101.6 ± 0.78	13.38 ± 0.06
	10	653 ± 2.89	8.48 ± 0.06	0.31 ± 0.01	4.53 ± 0.07	11.93 ± 0.04	100.8 ± 0.57	7.57 ± 0.02

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Table 1 continued...

Pectin type	Pectin concentrations (%w/w)	Weight variation (g) $n = 20$	Hardness (kgF) $n = 6$	Friability (%)	Tablet thickness (mm) $n = 6$	Tablet diameter (mm) $n = 6$	Drug content (%)	Disintegration time (min)
TGL	5	649.8 ± 4.54	7.35 ± 0.05	0.31 ± 0.01	4.53 ± 0.01	11.96 ± 0.08	100.4 ± 0.71	25.4 ± 0.04
	7.5	652.9 ± 3.82	8.29 ± 0.06	0.19 ± 0.01	4.62 ± 0.22	11.94 ± 0.07	100.8 ± 0.77	22.22 ± 0.07
	10	654.5 ± 5.77	8.80 ± 0.10	0.21 ± 0.01	4.60 ± 0.17	11.93 ± 0.05	101.7 ± 1.42	30.22 ± 0.00
THD	5	651.5 ± 5.05	7.41 ± 0.03	0.11 ± 0.01	4.70 ± 0.14	11.98 ± 0.08	101.2 ± 0.06	30.50 ± 0.34
	7.5	653.8 ± 2.55	9.71 ± 0.03	0.21 ± 0.01	4.59 ± 0.05	11.93 ± 0.04	100.5 ± 0.53	25.35 ± 0.04
	10	655.1 ± 4.52	9.08 ± 0.03	0.04 ± 0.01	4.57 ± 0.07	12.00 ± 0.02	101.4 ± 1.11	23.48 ± 0.06
THL	5	649.8 ± 4.54	5.70 ± 0.03	0.11 ± 0.01	4.61 ± 0.09	11.96 ± 0.06	101.0 ± 0.77	14.40 ± 0.34
	7.5	652.9 ± 3.82	8.10 ± 0.02	0.21 ± 0.01	4.66 ± 0.18	11.95 ± 0.05	100.1 ± 0.21	11.49 ± 0.05
	10	655.2 ± 8.31	7.96 ± 0.05	0.21 ± 0.01	4.55 ± 0.04	11.95 ± 0.07	101.2 ± 0.43	8.32 ± 0.03
TRD	5	650.9 ± 4.9	7.69 ± 0.02	0.61 ± 0.01	4.62 ± 0.22	11.94 ± 0.07	101.7 ± 1.42	26.16 ± 0.04
	7.5	653.5 ± 4.69	9.29 ± 0.57	0.21 ± 0.01	4.49 ± 0.03	11.91 ± 0.03	101.2 ± 0.06	25.15 ± 0.05
	10	651.7 ± 4.88	8.53 ± 0.06	0.21 ± 0.01	4.57 ± 0.07	11.98 ± 0.04	99.9 ± 0.13	36.44 ± 0.04
TRL	5	652.9 ± 8.07	11.96 ± 0.06	0.41 ± 0.01	4.70 ± 0.15	11.99 ± 0.07	101.3 ± 0.88	24.63 ± 0.23
	7.5	653.5 ± 4.69	8.70 ± 0.03	0.21 ± 0.01	4.65 ± 0.13	11.94 ± 0.05	101.7 ± 0.93	25.14 ± 0.04
	10	654.3 ± 5.52	8.53 ± 0.15	0.21 ± 0.01	4.58 ± 0.06	12.00 ± 0.02	100.2 ± 0.10	41.53 ± 0.23

Variety: Apem (M), Apantu (T); ripening stage: matured-green (G), half-ripe (H), and full-ripe (R); extraction method: acidic (D), alkaline (L)

between the friability of tablets which contained PPP and those containing maize starch BP. As per the *British Pharmacopoeia*, 1% loss of tablet during transportation is permissible. The result showed that all batches had a friability within the range of 0.11% to 0.81% (BP, 2013) (Table 1).

The crushing strength-friability ratio (CSFR) provides another means of measuring tablet strength. Table 1 shows a general drop in CSFR values as the disintegrant concentration increases. This is because an increase in disintegrant concentration reduces the tablet's hardness and increases friability. The type of disintegrant can also influence the CSFR, as different disintegrants have different mechanisms of action, swelling properties and particle sizes.[10] Marais et al.[36] studied the effect of three types of disintegrants on the CSFR of paracetamol tablets. The results obtained were attributed to the higher swelling capacity and lower particle sizes of the disintegrant, which enhanced disintegration and reduced the friability of the tablets.

Crushing strength and tensile strength

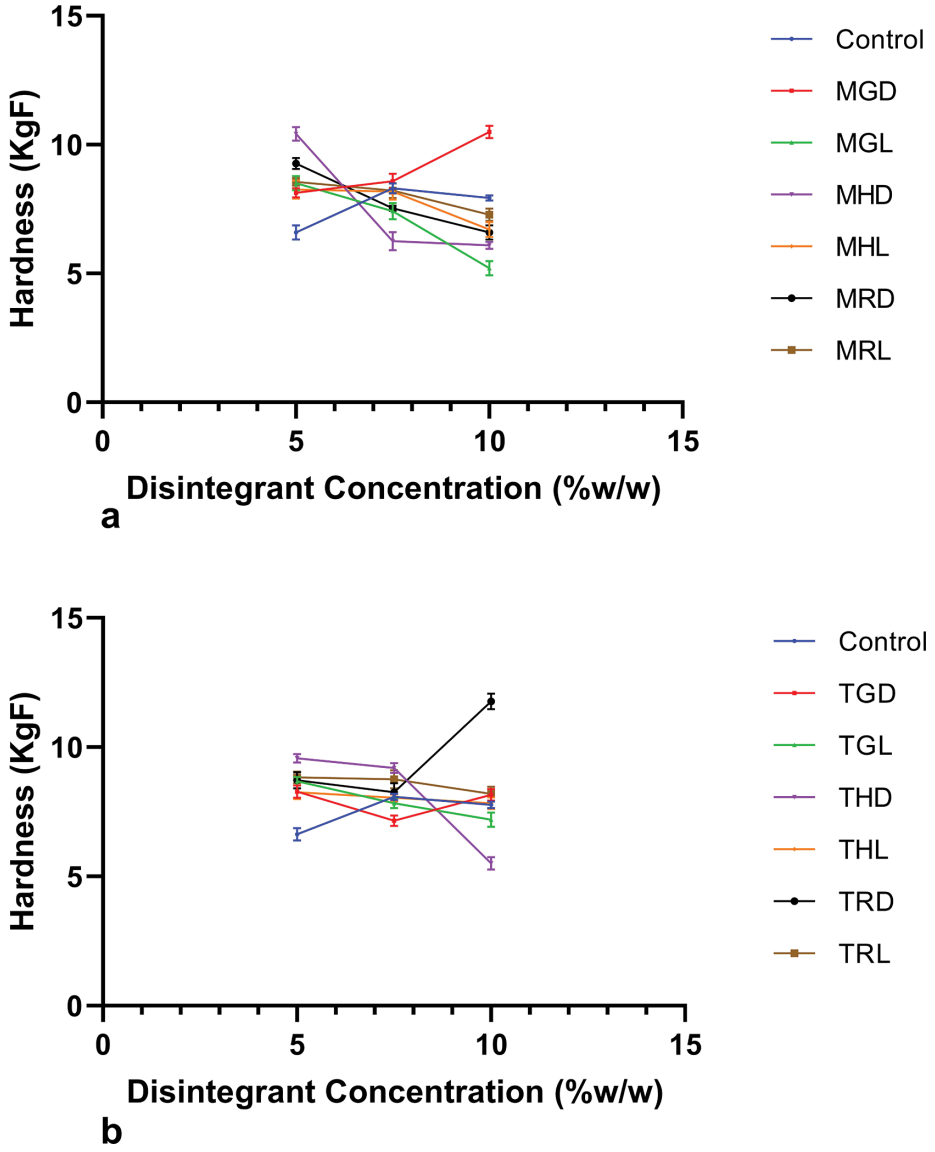
Chavan et al.[37] showed that crushing strength is a measure that assesses a tablet's resistance to permanent deformation. An increase in disintegrant concentration may reduce the tablet hardness (Table 1). However, Figure 1 shows that MDG and TRD pectin deviated from this observation. The results could be attributed to the function of the disintegrant which can act as an intra-granular and extra-granular agent that creates pores and weakens the bonds between the particles. Hence, larger particles lead to weak tablets as a result of a lower surface area for bond formation. Therefore, adding more disintegrant may increase the particle size and decrease the ability of the granules to be compressed.[38]

The tensile strength of the formulated tablets from both varieties ranged between 6.44 ± 1.12 and 11.29 ± 0.06 kN/cm^2 for all formulated batches using both varieties of pectin (Table 2). The tensile strength of the tablets decreased from 5% to 10% for both control and test samples. The effect of increasing disintegrant concentration on the tensile strength of a tablet can vary depending on the type of disintegrant used and the compression force applied during tablet formation.[39] An increase in the disintegrant concentration can potentially decrease the tensile strength of the tablet by reducing the disintegration time.[36]

Disintegration time, DER and DERc

Disintegrants are excipients that promote the rapid disintegration of tablets into small particles. Disintegrants have different mechanisms of action, such as strain recovery, swelling, wicking, interruption of particle–particle bonds and heat of interaction. These mechanisms are not independent and may work synergistically.[40] Table 1 shows the disintegration time of the various batches. The disintegration time ranged from 4.14 ± 0.03 min to 30.22 ± 0.00 min for all formulated batches. The disintegration time of a tablet is influenced by the concentration of the disintegrant. At the same compression force, disintegration time decreases as the disintegrant concentration increases.[36] Figure 2 shows the relation between increasing disintegrant concentration and disintegration time. All the formulated batches were observed to have a shorter disintegration time with an increase in disintegrant concentration, except for 10% concentrations of MRL, TRL, TGL and TRD. Significantly, the percolation threshold of the disintegrant invariably affects the disintegration time. The percolation threshold is the critical concentration at which a disintegrant forms a continuous network throughout the tablet.[41] For disintegrants, once their concentration in the tablet formulation exceeds the percolation threshold, they can rapidly absorb water, swell and exert a disintegrating force, leading to a decrease in the disintegration time.[42] However, there is a limit to this effect. When the disintegrant continues to increase beyond a certain point, it may not lead to a further decrease in disintegration time. This is because the tablet may already be saturated with the disintegrant and additional disintegrant may not contribute to further water uptake or swelling.[41] Moreover, all the batches formulated with pectin from both varieties showed significant differences ($p < 0.05$) in disintegration time to the control, except for the use of 5% and 10% MRD, 7.5% MHL and 10% MHD as disintegrants (Supplementary figures 1 and 2).

The DER is a key parameter in the evaluation of the balance between the binding and disintegration properties of a tablet as it is able to predict the balance between the hardness of the tablet and its ability to disintegrate. From the results obtained, the DER of the batches formulated with pectin as a disintegrant generally increased from the 5% through to the 10% concentration (Table 2). This finding was also observed by Akin-Ajani et al.[28] who reported that, as the concentration of the disintegrant



Ripening stage: matured-green (G), half-ripe (H) and full-ripe (R); extraction method: acidic (D), alkaline (L)

Figure 1: Effect of disintegrant concentration on tablet hardness using (a) Apem (M) and (b) Apantu (T) at concentrations of 5%w/w, 7.5%w/w and 10%w/w.

increases, the disintegration time of the tablet typically decreases, therefore increasing the ratio.

The results of the DERc are presented in Table 2. When the DERc>1, the DER of the test sample is considered to have superior disintegrant action compared with the standard disintegrant.[43] The results show a general increase in the DERc with an increase in the disintegrant concentration for the Apem variant, while the opposite holds true for the Apantu variant. Akin-Ajani et al.[28] reported the same observation, that is, an increase in disintegrant concentration led to a general decrease in the DERc. This indicates that the Apem PPP was efficient at higher concentrations, while the Apantu PPP was more efficient at lower concentrations. The DERc values of tablets containing Apem PPP were higher relative to the Apantu variant. The results obtained imply that the disintegrant quality of the PPP exceeded that of the standard disintegrant at all concentrations, except for MHD, TGL, THL, TRD and TRL at 10%w/w.

Assay

The *British Pharmacopoeia*[27] requirement for immediate-release paracetamol tablets indicates that a minimum of 95% and a maximum of 105% of pure paracetamol is present (Table 1). The assay test was successfully passed by all the batches. It is noteworthy to observe that the paracetamol concentration in all the formed tablets exhibited a rather consistent level, as indicated by the low estimated standard deviations.

In vitro drug release

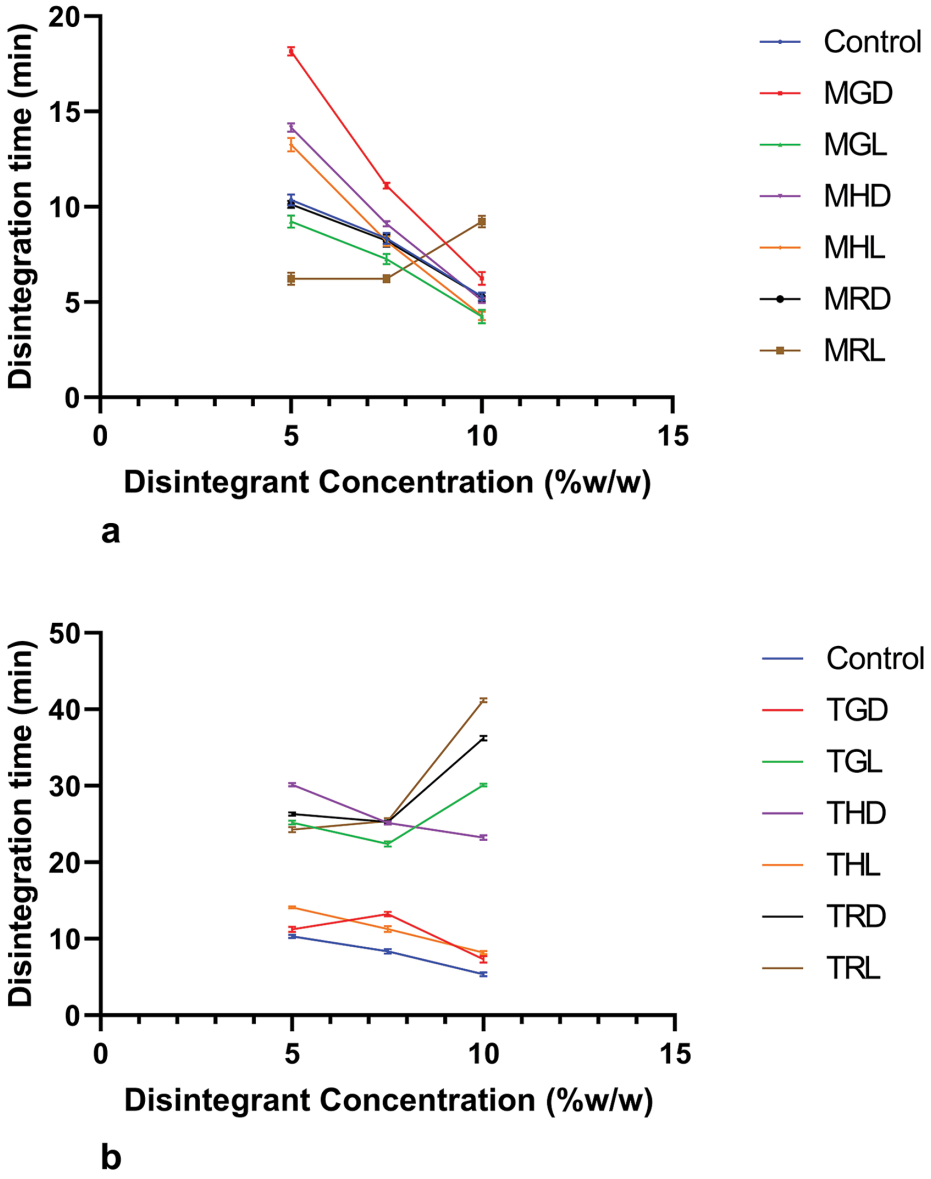
The dissolution test provides crucial data regarding the pharmacokinetics of a drug and the uniformity of products across different batches.[44] The in vitro dissolving behaviour of a dosage form is the most frequently employed physicochemical attribute. It is crucial to develop a drug release methodology that can accurately anticipate the behaviour of the drug product in the body.[45]

Tablet batches formulated with pectins MGD, TGL, THD, TRD and TRL at 5%w/w, TGL, THD, TRD and TRL at 7.5 w/w, and TGL, THD, TRD and TRL at 10%w/w as disintegrants failed the test (D_{iss}, $Q < 75\%$)[27] (Figure 3). These same batches failed the disintegration test ($D_T > 15$ min). The particle size of the disintegrant can significantly affect its performance. Generally, smaller particles provide a larger surface area for water absorption, leading to faster disintegration. Additionally, a combination of disintegrants could be used. Using a combination of two or more disintegrants can sometimes improve the disintegration properties of a formulation. This is because different disintegrants may use different mechanisms of disintegration, and these mechanisms can complement each other.[42]

Table 2: Crushing strength-friability ratio (CSFR), disintegration efficiency ratio (DER), dimensionless parameter (DERc) and tensile strength of paracetamol tablets

Pectin type	Pectin concentrations (%w/w)	Tensile strength (kN/cm²)	CSFR	DER	DERc
Control	5	7.55 ± 0.00	8.40 ± 0.00	0.83 ± 0.00	–
	7.5	9.50 ± 0.00	11.49 ± 0.00	1.41 ± 0.00	–
	10	9.01 ± 0.00	15.41 ± 0.00	2.99 ± 0.00	–
MGD	5	9.50 ± 0.61	19.52 ± 0.04	1.07 ± 0.05	1.29
	7.5	10.21 ± 0.66	21.3 ± 0.07	1.90 ± 0.08	1.35
	10	12.50 ± 0.69	34.23 ± 0.08	5.28 ± 0.07	1.76
MGL	5	10.35 ± 0.39	16.93 ± 0.21	1.78 ± 0.05	2.16
	7.5	9.04 ± 1.51	34.60 ± 0.1	4.88 ± 0.02	3.46
	10	6.44 ± 1.12	26.51 ± 0.15	5.87 ± 0.03	1.96
MHD	5	12.78 ± 0.99	97.27 ± 0.1	6.81 ± 0.15	8.24
	7.5	7.76 ± 1.41	21.4 ± 0.15	2.28 ± 0.38	1.62
	10	7.14 ± 1.01	7.82 ± 0.12	1.50 ± 0.04	0.50
MHL	5	10.15 ± 1.01	20.90 ± 0.06	1.53 ± 0.15	1.85
	7.5	9.08 ± 1.01	25.76 ± 0.03	3.07 ± 0.03	2.17
	10	8.11 ± 0.49	33.11 ± 0.04	7.99 ± 0.03	2.67
MRD	5	10.98 ± 0.89	43.54 ± 0.02	4.25 ± 0.04	1.85
	7.5	9.22 ± 1.51	24.73 ± 0.12	2.93 ± 0.02	2.07
	10	8.03 ± 0.39	16.59 ± 0.1	3.22 ± 0.03	1.08
MRL	5	10.36 ± 1.59	21.2 ± 0.02	3.27 ± 0.03	5.14
	7.5	9.48 ± 1.11	25.89 ± 0.01	4.23 ± 0.03	3.00
	10	8.18 ± 1.12	34.6 ± 0.15	3.65 ± 0.06	1.22
TGD	5	10.00 ± 0.11	27.36 ± 0.06	2.39 ± 0.03	3.95
	7.5	8.64 ± 0.78	23.70 ± 0.05	1.77 ± 0.07	1.25
	10	9.57 ± 0.57	43.65 ± 0.06	5.76 ± 0.02	1.92
TGL	5	10.21 ± 0.71	41.90 ± 0.1	1.65 ± 0.04	2.89
	7.5	9.25 ± 0.77	37.84 ± 0.05	1.70 ± 0.08	1.21
	10	8.38 ± 1.42	67.39 ± 0.03	2.23 ± 0.01	0.75
THD	5	11.29 ± 0.06	46.22 ± 0.03	1.52 ± 0.35	1.99
	7.5	10.54 ± 0.54	227.08 ± 0.03	8.96 ± 0.05	1.21
	10	6.58 ± 1.12	51.85 ± 0.03	2.21 ± 0.06	0.74
THL	5	9.25 ± 0.78	38.56 ± 0.02	2.68 ± 0.35	1.83
	7.5	9.31 ± 0.22	37.90 ± 0.05	3.3 ± 0.05	6.34
	10	8.87 ± 0.44	12.60 ± 0.02	1.51 ± 0.03	0.51
TRD	5	11.05 ± 1.42	44.24 ± 0.57	1.69 ± 0.04	3.24
	7.5	9.93 ± 0.06	40.63 ± 0.06	1.62 ± 0.05	2.34
	10	13.51 ± 0.14	29.17 ± 0.06	0.8 ± 0.04	0.27
TRL	5	9.97 ± 0.89	41.44 ± 0.03	1.68 ± 0.23	2.04
	7.5	9.89 ± 0.94	40.63 ± 0.15	1.62 ± 0.04	1.14
	10	9.72 ± 0.1	20.57 ± 0.15	0.5 ± 0.23	0.17

Variety: Apem (M), Apantu (T); ripening stage: matured-green (G), half-ripe (H), and full-ripe (R); extraction method: acidic (D), alkaline (L)



Ripening stage: matured-green (G), half-ripe (H), and full-ripe (R); extraction method: acidic (D), alkaline (L)

Figure 2: Effect of disintegrant concentration on disintegration time using (a) Apem (M) and (b) Apantu (T) at concentrations of 5%w/w, 7.5%w/w and 10%w/w.

Model independent comparison of dissolution profiles

The similarity and difference factors are shown in Supplementary table 2. The results show that the tablet batches formulated with pectin MHD and TGD at concentrations of both 5%w/w and 7.5%w/w, and MRD at a concentration of 5%w/w as disintegrants deviated from the release profile of the reference disintegrant used and hence are dissimilar.[23] This shows that plantain peel pectin extracted from different ripening stages could be used as an alternative disintegrant to maize starch BP when formulating immediate-release tablets. Given the ease of access to these varieties of plantains in Ghana, their pectin can be utilised to develop products at a lower expense than imported maize starch BP.

Conclusion

This study revealed that the pectin extracts yielded paracetamol granules with excellent flow characteristics and tablets with physical properties comparable to those of maize starch BP. The friability of the test samples was comparable to that of the standard formulations. However, as the concentration of PPP increased, there was a noticeable decrease in tensile and crushing strength. The disintegration time typically decreases with an increase in PPP concentration. The high DER values of the test formulations suggest that PPP could create a more balanced relationship between the mechanical and disintegrating properties of the tablets. The use of the dimensionless parameter was instrumental in verifying the dependence of the disintegrant activity on the disintegration mode. Thus, PPP compared well with maize starch BP and could be useful for conventional tablet formulations. Exploring the use of PPP in various formulations will help identify the most suitable applications and concentration for different pharmaceutical needs, helping in the reduction of food waste and improving the economic outlook of plantain peels.

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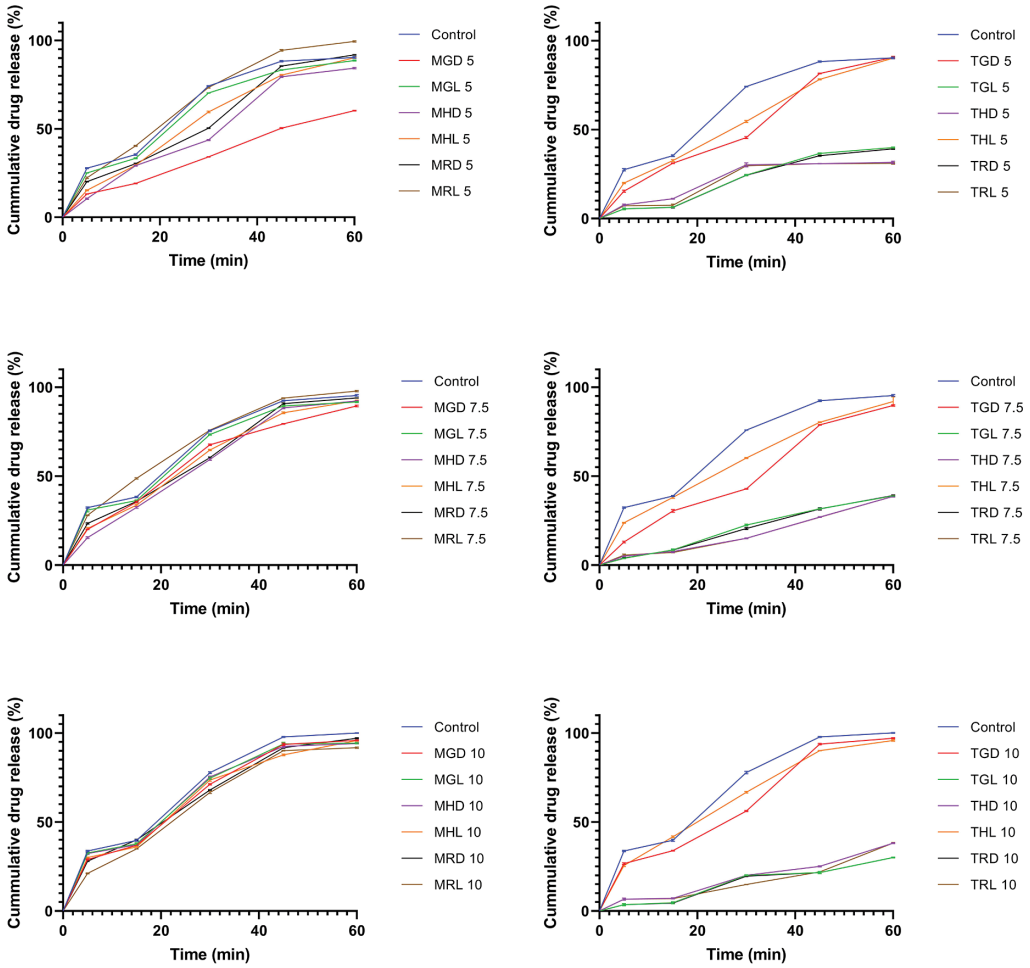
Data availability

All the data supporting the results of this study are included in the article itself.

Declarations

We have no competing interests to declare. We have no AI or LLM use to declare.



Ripening stage: matured-green (G), half-ripe (H) and full-ripe (R); extraction method: acidic (D), alkaline (L)

Figure 3: Dissolution profiles of tablets formulated with plantain peel pectin derived from Apem (M) and Apantu (T) at concentrations of 5%w/w, 7.5%w/w and 10%w/w respectively, and a standard disintegrant (control). Values shown are mean±SD, $n = 6$.

Authors' contributions

D.A.B.O: Conceptualisation, methodology, data collection, writing – initial and final drafts, visualisation, investigation, data analysis. F.W.A.O.: Conceptualisation, writing – reviewing and editing. M.E.B-G.: Conceptualisation, visualisation, writing – final draft, reviewing and editing. R.J.: Writing – final draft, reviewing and editing, validation, supervision. M.T.B.: Supervision, writing – final draft, reviewing and editing. P.G.J.A.: Visualisation, formal analysis, investigation. Y.E-A.: Investigation, methodology, writing – initial draft. M-A.A: Visualisation, methodology, data collection.

References

1. Manzoor A. Sodium starch glycolate as a superdisintegrant. J Contemp Pharm. 2021;5(1):33–39. https://doi.org/10.56770/jcp2021515
2. Singh P, Mahmood T, Shameem A, Bagga P, Ahmad N. A review on herbal excipients and their pharmaceutical applications. Sch Acad J Pharm. 2016;5(3):53–57.
3. Amiri MS, Mohammadzadeh V, Yazdi MET, Barani M, Rahdar A, Kyzas GZ. Plant-based gums and mucilages applications in pharmacology and nanomedicine: A review. Molecules. 2021;26, Art. #1770. https://doi.org/10.3390/molecules26061770
4. Twinomuhwezi H, Godswill AC, Kahunde D. Extraction and characterization of pectin from orange (*Citrus sinensis*), lemon (*Citrus limon*) and tangerine (*Citrus tangerina*). Am J Phys Sci. 2020;1(1):17–30. https://doi.org/10.47604/ajps.1049
5. Goswami S, Naik S. Natural gums and its pharmaceutical application. J Sci Innov Res JSIR. 2014;3(31):112–121. https://doi.org/10.31254/jsir.2014.3118
6. Barton I, Avanceña ALV, Gounden N, Anupindi R. Unintended consequences and hidden obstacles in medicine access in sub-Saharan Africa. Front Public Health. 2019;7, Art. #342. https://doi.org/10.3389/fpubh.2019.00342
7. Ghanaian Ministry of Health. Ghana national medicines policy. 3rd ed. Accra: Ghana National Drugs Programme, Ministry of Health; 2017.
8. Verma S, Baghotia A, Singh J, Saroha K, Kumar S, Kumar D. Pharmaceutical excipients: A regulatory aspect. Pharma Innov J. 2016;5(5):124–127.
9. Osterberg RE, DeMerlis CC, Hobson DW, McGovern TJ. Trends in excipient safety evaluation. Int J Toxicol. 2012;30(6):600–610. https://doi.org/10.1177/1091581811423582
10. Vlad R-A, Pintea C, Chirteş D-A, Antonoaea P, Rédai EM, Todoran N, et al. The influence of the intergranular superdisintegrant performance on new drotaverine orodispersible tablet formulations. Pharmaceutics. 2023;15(8), Art. #2147. https://doi.org/10.3390/pharmaceutics15082147
11. Akin-Ajani DO, Okunlola A. Pharmaceutical applications of pectin. In: Masuelli M, editor. Pectins – The new-old polysaccharides. London: IntechOpen; 2022. p. 87–132. https://doi.org/10.5772/intechopen.100152
12. Rouaz K, Chiclana-Rodríguez B, Nardi-Ricart A, Suñé-Pou M, Mercadé-Frutos D, Suñé-Negre JM, et al. Excipients in the paediatric population: A review. Pharmaceutics. 2021;13(3), Art. #387. https://doi.org/10.3390/pharmaceutics13030387
13. Babalola OC, Odeku OA. Disintegrant properties of banana starch obtained from the unripe fruits of *Musa sapientum* L. J Appl Pharm Sci. 2014;4(9):83–88. https://doi.org/10.7324/JAPS.2014.40915
14. Saha T, Masum ZU, Mondal SK, Hossain MS, Jobaer MA, Shahin RI, et al. Application of natural polymers as pharmaceutical excipients. Glob J Life Sci Biol Res. 2018;4(1):1–11.

15. Nayak A, Olatunji O, Bhusan Das D, Vladisavljević G. Pharmaceutical applications of natural polymers. In: Olatunji O, editor. Natural polymers. Cham: Springer; 2016. p. 263–313. https://doi.org/10.1007/978-3-319-26414-1_9

16. Pramanik D, Ganguly M. Formulation and evaluation of a pectin based controlled drug delivery system containing metronidazole. Res J Life Sci Bioinform Pharm Chem Sci. 2017;3(4):16–25. https://doi.org/10.26479/2017.0304.02

17. Srivastava P, Malviya R. Sources of pectin, extraction and its applications in pharmaceutical industry: An overview. Indian J Nat Prod Resour. 2014;2(1):10–18.

18. Girma E, Worku T. Extraction and characterization of pectin from selected fruit peel waste. Int J Sci Res Publ. 2016;6(2):447–454.

19. Adi-Dako O, Ofori-Kwakye K, Manso SF, Boakye-Gyasi MEL, Sasu C, Pobee M. Physicochemical and antimicrobial properties of cocoa pod husk pectin intended as a versatile pharmaceutical excipient and nutraceutical. J Pharm. 2016;2016, Art. #7608693 https://doi.org/10.1155/2016/7608693

20. Adeyeye EI, Adesina AJ, Olagboye SA, Olatunya MA. Effects of use and re-use of selected vegetable oils on the proximate, minerals, mineral ratios and mineral safety index of raw and fried plantain chips: Note I. J Agric Chem Environ. 2019;08(02):92–106. https://doi.org/10.4236/jacen.2019.82008

21. Oyawaluya AA, Oiseoghaede JO, Odukoya OA, Aluko TE. Extraction and estimation of pectins from unripe, ripe and overripe banana (*Musa acuminata* L.) and plantain (*Musa paradisiaca* L.) peels and their antioxidant activities. Niger J Pharm Appl Sci Res. 2020;16(1):87–96. https://doi.org/10.4314/njpr.v16i1.10

22. Otu DAB, Owusu FWA, Acquah PGJ, Boakye-gyasi M EI, Edzor-Agbo Y, Johnson R, et al. Effect of ripening and extraction method on the physicochemical properties of pectin extracted from peels of Apem and Apantu plantain cultivars in Ghana. J Chem. 2024;2024, Art. #6677179. https://doi.org/10.1155/2024/6677179

23. Otu DAB, Owusu FWA, Boakye-Gyasi MEI, Johnson R, Acquah PGJ, Edzor-Agbo Y, et al. Biogenic waste from two varieties of plantain in Ghana contain pectin with potential binding properties in conventional tablets. Sci World J. 2024;2024(1), Art. #5461358. https://doi.org/10.1155/2024/5461358

24. Fosu M-A, Ofori-Kwakye K, Kuntworbe N, Bonsu MA. Investigation of blends of cashew and xanthan gums as a potential carrier for colonic delivery of ibuprofen. Int J PharmTech Res. 2016;9(7):369–380.

25. Bayor MT, Tuffour E, Lambon PS. Evaluation of starch from new sweet potato genotypes for use as a pharmaceutical diluent, binder or disintegrant. J Appl Pharm Sci. 2013;3(8 SUPPL 1):S17–S23. https://doi.org/10.7324/JAPS.2013.38.S4

26. United States Pharmacopeial Convention (USP). US pharmacopeia. 37th edition. Rockville, MD: USP; 2014. Available from: https://www.usp.org/sites/default/files/usp/document/harmonization/gen-method/stage_6_monograph_25_feb_2011.pdf.

27. British Pharmacopoeia Commission. British pharmacopoeia. London: Her Majesty's Stationary Office; 2013.

28. Akin-Ajani OD, Itiola OA, Odeku OA. Evaluation of the disintegrant properties of native and modified forms of fonio and sweet potato starches. Starch/Staerke. 2016;68(1–2):169–174. https://doi.org/10.1002/star.201500188

29. Nyol S, Gupta MM. Immediate drug release dosage form: A review. J Drug Deliv Ther. 2013;3(2):155–161. https://doi.org/10.22270/jddt.v3i2.457

30. Adjei FK, Osei YA, Kuntworbe N, Ofori-Kwakye K. Evaluation of the disintegrant properties of native starches of five new cassava varieties in paracetamol tablet formulations. J Pharm. 2017;2017:1–9. https://doi.org/10.1155/2017/2326912

31. Kassaye L, Genete G. Evaluation and comparison of in-vitro dissolution profiles for different brands of amoxicillin capsules. Afr Health Sci. 2013;13(2):369–375. https://doi.org/10.4314/ahs.v13i2.25

32. Desta KH, Tadese E, Molla F. Physicochemical characterization and evaluation of the binding effect of *Acacia etbaica* Schweinf gum in granule and tablet formulations. Biomed Res Int. 2021;2021, Art. #5571507 https://doi.org/10.1155/2021/5571507

33. Yahoum MM, Lefnaoui S, Moulai-Mostefa N. Design and evaluation of sustained release hydrophilic matrix tablets of piroxicam based on carboxymethyl xanthan derivatives. Soft Mater. 2020;19(2):178–191. https://doi.org/10.1080/1539445X.2020.1789994

34. Taylor KMG, Aulton ME. Aulton's pharmaceutics: The design and manufacture of medicines. 2nd ed. London: Churchill Livingstone; 2011.

35. Nnamani DN, Eraga S. Evaluation of the compression properties of co-processed paracetamol, gelatin and microcrystalline cellulose formulation prepared via melt-in agglomeration. Trends Pharm Sci. 2022;8(4):243–252. https://doi.org/10.30476/tips.2022.96659.1168

36. Marais AF, Song M, De Villiers MM. Effect of compression force, humidity and disintegrant concentration on the disintegration and dissolution of directly compressed furosemide tablets using croscarmellose sodium as disintegrant. Trop J Pharm Res. 2003;2(1):125–135. https://doi.org/10.4314/tjpr.v2i1.14577

37. Chavan H, Chhabra G, Gujarathi N, Jadhav A. Comparative study of in-process and finished products quality control test for tablet and capsules according to pharmacopoeias. Asian J Pharm Res Dev. 2018;6(3):60–68. https://doi.org/10.22270/ajprd.v6i3.370

38. Khule NR, Mahale NB, Shelar DS, Rokade MM, Chaudhari SR. Extraction of pectin from citrus fruit peel and use as natural binder in paracetamol tablet. Der Pharm Lett. 2012;4(2):558–564.

39. Quodbach J, Moussavi A, Tammer R, Frahm J, Kleinebudde P. Assessment of disintegrant efficacy with fractal dimensions from real-time MRI. Int J Pharm. 2014;475(1–2):605–612. https://doi.org/10.1016/j.ijpharm.2014.09.021

40. Desai PM, Liew CV, Heng PWS. Review of disintegrants and the disintegration phenomena. J Pharm Sci. 2016;105(9):2545–2555. https://doi.org/10.1016/j.xphs.2015.12.019

41. Tonglairoum P, Ngawhirunpat T, Akkaramongkolporn P, Opanasopit P, Nattapulwat N. Effect of particle size and diluent type on critical parameters for disintegration of tablets containing croscarmellose sodium as a disintegrant. Trop J Pharm Res. 2017;16(6):1215–1221. https://doi.org/10.4314/tjpr.v16i6.2

42. Markl D, Zeitler JA. A review of disintegration mechanisms and measurement techniques. Pharm Res. 2017;34:890–917. https://doi.org/10.1007/s11095-017-2129-z

43. Adeoye O, Alebiowu G. Dimensionless quantities in the evaluation of novel composite disintegrants. J Drug Deliv Sci Technol. 2014;24(2):222–228. https://doi.org/10.1016/S1773-2247(14)50036-6

44. Kar AK, Kar B. In-vitro comparative dissolution study of commercially available paracetamol tablet. J Drug Deliv Ther. 2020;10(1):18–23. https://doi.org/10.22270/jddt.v10i1.3817

45. Parojčić J, Durić Z, Jovanović M, Ibrić S, Jovanović D. Influence of dissolution media composition on drug release and in-vitro/in-vivo correlation for paracetamol matrix tablets prepared with novel carbomer polymers. J Pharm Pharmacol. 2004;56(6):735–741. https://doi.org/10.1211/0022357023583