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Binder and Disintegrant Performance of Native and Thermally Modified *Dioscorea cayenensis* Starches in Paracetamol Tablet Formulations

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ABSTRACT

The versatility of starch as pharmaceutical excipient is gaining attention in the development of natural polymers for application in tablet formulations. In this study, we reported the binder and disintegrant properties of native and modified starches extracted from *Dioscorea cayenensis*. The extracted starch was modified by pregelatinization (PGS1) and ethanol dehydrated pregelatinization (PGS2) and was employed as binder and disintegrant in paracetamol tablet formulations via wet granulation. Two-way analysis of variance indicated significant differences between tablet properties, measured in terms of hardness, friability and disintegration time, with respect to the starch type and concentration. Multiple comparison computed using Bonferroni post-hoc analysis indicated higher values of tablet hardness in PGS2 than PGS1 and unmodified starch (UMS) (p<0.01). UMS had the highest friability implying poor mechanical quality (Friability >3%). At 2-7% concentrations, PGS1, PGS2 and UMS demonstrated acceptable United State Pharmacopoeial disintegration time profiles for uncoated tablets. Overall results demonstrated an improved quality of the modified starches compared to the UMS with the potential application of PSG1 as binder and disintegrant in different ratios for immediate release tablet formulation. PSG2 was shown to make a good binder when sustained-release of API is required.

Keywords: Natural polymers, *Dioscorea cayenensis* starch, Tablet Excipients, Pregelatinization; Binder, Disintegrant.

Introduction

Starch is a highly abundant polysaccharide with extensive pharmaceutical applications in tablet formulation.[1,2] It is commonly applied as an excipient in tablet compaction to provide mechanical bonding with other excipients and the active pharmaceutical ingredient (API) resulting in a coherent solid compact. It is in this context termed as a binder. Due to its intrinsic swelling and water imbibition tendencies, starch is applied as a disintegrant in tablet formulations to cause disaggregation of the tablets in the gastrointestinal tract for subsequent release and absorption of the therapeutic molecule into systemic circulation.[1]

The quest for natural materials as tableting excipients is tremendously increasing in the pharmaceutical sector for sustainable pharmaceutical manufacturing. Starch is a biopolymer exploited in the design and manufacture of numerous drug delivery systems due to its reliable availability and sustainable supply chain, affordability and biocompatibility.[3,4] *Dioscorea* species (yam) provide an excellent source of carbohydrate, and it is estimated that the tuber contains starch up to 75.6-84.3%.[5] Nigeria is among the world leading producers of yam. Commonly cultivated yam species include *D. rotundata* (white yam), *D. cayenensis* (yellow yam), *D. alata* (water yam), *D. dumetorum* (bitter yam), *D. esculenta* (lesser yam).[6] Unfortunately, unmodified starch is functionally deficient to suit tablet manufacturing due to its inherent poor tableting properties such as reduced binding and disintegration performance, poor die filling capacity and low mechanical properties.[7] Several physical and chemical modification strategies have been applied to produce starch with superior physicomechanical and biopharmaceutical indices to suit their application in tablet manufacturing.[8,9] Thermal pregelatinization has been employed as a means of starch modification resulting in irreversible granule swelling, loss of birefringence, and crystallinity with consequent improvement of flowability and compressibility. [9] The goal of this study is to evaluate the effect of thermal modification of starch derived from *Dioscorea cayenensis* (yellow yam) on tablet binding and disintegration using paracetamol as the model drug.

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Materials and Methods

Materials

D. cayenensis was obtained from Okpoga town in Okpokwu Local Government Area of Benue state, Nigeria. The tuber was identified at the Herbarium Unit of the Department of Biological Sciences (now

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Department of Biology), Ahmadu Bello University, Zaria. Pharmaceutical grade paracetamol powder, maize starch, talc, ethanol and magnesium stearate were sourced from BDH Chemicals (Poole, England). All other reagents used were of analytical grade.

Starch extraction from D. cayenensis

The skin was peeled off and weighed, grated into smaller pieces and size-reduced into fine pulp in a blender (Phillip cucina HR1757). The starch was extracted in accordance with reported procedures.[11] The extracted starch was dried at 40 °C in hot air oven and stored in air-tight plastic container. A portion of the starch was used in tablet formulation without any further modification. It is therefore labelled as unmodified starch (UMS) and represent the naturally occurring form. The other portion of the extracted starch was subjected to thermal modification as described below.

Thermal modification and ethanol dehydrated pregelatinization

Two pregelatinization methods were adopted; for pregelatinized starch (PGS1), 80 mL of cold distilled water was mixed with 320 g of the starch powder in a 12 L narrow base bowl. Hot distilled water (60°C) was added with stirring until the 4 L mark was reached. It was then heated on a hot plate with constant stirring until translucent mucilage was formed. The mucilage was poured onto 40 cm diameter stainless steel trays and dried in a hot air oven set at 40°C. The resulting dried flakes were milled to fine powder using blender and then passed through 180 µm mesh size sieve. It was weighed and stored in air tight container for further analysis. To prepare ethanol-dehydrated pregelatinized starch (PGS2), 40 mL distilled water was mixed with 160 g of the extracted starch powder followed by continuous stirring and simultaneous addition of hot distilled water (60°C) until 2 L was achieved. The slurry was heated with constant stirring on hot plate until translucent mucilage was formed. The mucilage was allowed to cool, and 4 L of ethanol was added with stirring as precipitate was formed. It was allowed to settle, and the precipitate was filtered. Another 3 L of ethanol was added to the precipitate, stirred and filtered. The final sediment was centrifuged and dried in the oven at 40°C. The PGS2 lumps were milled to fine powder, weighed and passed through 180 µm sieve. It was then stored in air tight container for further studies.

Determination of physicotechnical properties

Moisture content (M_{H_2O})

M_{H_2O} was determined using loss on drying method as the percentage weight loss of water content after drying a sample (1 g) of a known weight (W) over hot air oven at 105°C to a constant weight (W_o).[8]

$$M_{H_2O} = 100[\frac{W-W_o}{W}] \quad Equation\ 1$$

Moisture sorption (M_s)

Moisture sorption was determined as the weight of water absorbed when a weighed sample is exposed to water vapour in the upper compartment of a desiccator containing water (Relative humidity = 100%) in the lower compartment for a period of 5 days.[10]

$$M_s = 100[\frac{W_5 - W}{W_5}] \quad Equation\ 2$$

Where: W_5 : is the weight of material after 5 days exposure to water
W : Initial weight of the material

Swelling capacity (S_ϕ)

S_ϕ was derived from the expansion capacity of the aqueous dispersion of known samples of the starch. The sample was dispersed for 5 min in a graduated cylinder containing distilled water and the system was allowed to stand for 24 h.[7]

$$S_(\phi) = 100[\frac{V_2 - V_1}{V_2}] \quad Equation\ 3$$

Bulk density (d_b) and tapped density (d_t)

d_b and d_t were determined as the ratio of 5 g of powder samples to their loose and tapped volumes, respectively.[12]

$$d_b = \frac{Samle\ weight}{Loose\ volume} \quad Equation\ 4$$

$$d_t = \frac{Samle\ weight}{Tapped\ volume} \quad Equation\ 5$$

Hausner's ratio (HR) and Carr's Index (CI)

These are computed from the bulk and tapped density measurements.[13,14]

$$HR = \frac{d_t}{d_b} \quad Equation\ 6$$

$$CI = 100[(d_t - d_b)/d_t)] \quad Equation\ 7$$

Angle of repose ($\boldsymbol{\kappa}$)

Flow through funnel was used to measure angle of repose. The starch samples (5 g) were suspended in a glass funnel attached perpendicularly to a retort stand such that the tip is 10 cm away from the table surface. The angle (θ) formed after allowing the powder to flow under gravity was calculated as:

$$\boldsymbol{\kappa} = tan^{-1}\frac{(h)}{r} \quad Equation\ 8$$

Where: h: height of conical powder heap.

r: the radius of the circular base.

Powder flow

Flow rate was determined using Erweka flow meter (Type GDT, Germany) in which 50 g each, of the samples was allowed to pass through its orifice and the time taken was noted.

Particle size analysis

A nest of sieves (180, 150, 90 and 75 µm) containing 20 g of the test sample on the coarsest sieve were set at 10 min vibration. The mean particle size was calculated from plot of percentage of powder retained on each sieve against the corresponding particle diameter (sieve size).

Tablet formulation

The starches (UMS, PGS1, and PGS2) were employed as either binder (Table 1) or as disintegrant (Table 2) in paracetamol tablet formulations at different concentrations (2, 5, 7 and 10% w/w). Paracetamol, lactose and maize starch were weighed using electronic balance and sequentially mixed using doubling-up technique in a pestle and mortar. The binding solution was added continuously with simultaneous mixing until a homogenous moist mass was formed. The mass was passed through 1.7 µm sieve and dried under hot air oven at 40°C and further screened through 1.6 µm mesh size. In the second formula, the experimental starches were used as disintegrants while, gelatin was used as the binder. Extragranular excipients were included prior to tabletting. Paracetamol tablets were formed by compressing 650 mg of the granules using single punch tablet press (EKO type, Erweka AR 400 Germany). A total of 120 tablets were produced from each excipient.

Evaluation of binding and disintegration performance

The binding and disintegration performance were evaluated by analyzing the effect of different starch concentrations used either as binder or disintegrant in the formulation on tablet on tablet hardness, friability and *in-vitro* disintegration time.

Hardness test

Hardness of the tablets (n=5) was determined as the force required to cause the tablets to break using Monsanto Tablet Hardness Tester.

Friability test

To determine friability, weighed tablets (n=10) were placed in Erweka friabilator (Type TA3R Erweka, Germany) chamber and set into 25 revolutions per minutes and the percentage weight loss was calculated.

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Table 1: Formula for paracetamol granules using the experimental starches as binders.

Ingredients	Category	Functionality	Quantities (%w/w)
Paracetamol	Intragranular ingredients	Model drug	77.0
Lactose		Diluent	q.s
Maize starch		Disintegrant	7.8
UMS, PGS1, PGS2, Gelatin		Binder	2.0, 5.0, 7.0 &10.0
Maize starch	Extragranular excipients	Disintegrant	7.8
Talc		Lubricant	2.0
Magnesium stearate		Lubricant	0.2

UMS: Unmodified starch, PGS1: Pregelatinized starch, PGS2: Ethanol dehydrated pregelatinized starch, q.s: Sufficient quantity to produce 650 mg/tablet.

Table 2: Formula for paracetamol granules using the experimental starches as disintegrants.

Ingredients	**Category**	**Functionality**	**Quantities (%w/w)**
Paracetamol	Intragranular ingredients	Model drug	77.0
Lactose		Diluent	q.s
UMS, PGS1, PGS2		Disintegrant	2.0, 5.0, 7.0 &10.0
Gelatin		Binder	2.0
Maize starch	Extragranular excipients	Disintegrant	7.8
Talc		Lubricant	2.0
Magnesium stearate		Lubricant	0.2

UMS: Unmodified starch, PGS1: Pregelatinized starch, PGS2: Ethanol dehydrated pregelatinized starch, MSBP: maize starch BP, q.s: Sufficient quantity to produce 650 mg/tablet.

Disintegration time
To determine disintegration time, tablets (n=6) were picked at random from each batch and placed in each basket of USP disintegration apparatus with the water bath set at 37°C ± 0.5. The time for each tablet to disintegrate and passed through the mesh were recorded and mean of the six readings determined the disintegration time.

Statistical analysis
The differences between the means of measurements were analysed using two-way analysis of variance (two-way ANOVA) using GraphPad Prism 5.0. Multiple comparison was established using Bonferroni posthoc test. Differences were considered significant for $P<0.05$.

Results and Discussion

Physicotechnical properties of the starches
Wet granulation is a tablet production method that enables tableting via preliminary granulation of the ingredients which modify the physicotechnical properties of the powder ingredients prior to compression.[15-17] Granules thus have improved flowability and compressibility for efficient manufacturing in tablet press.[16] Together with other excipients, the *D. cayenensis* starches were employed as binders and disintegrants to form paracetamol granules. The properties of the granules shown in Table 3 and 4 influence the final tabletting performance indicated in subsequent sections.
Based on Carr's index and angle of repose values, all the starches demonstrated acceptable flow.[13,14] However, mass flow rate shows that MSBP had the highest fluidity followed by UMS, PGS1, and PGS2 (Table 3). The moisture content of the PGS1 and UMS was lower compared to maize starch B.P (MSBP). PGS2 had the lowest moisture content compared to PGS1, UMS and MSBP ($p<0.05$). Both modified and unmodified starches absorbed significant amount of moisture (>30%) which shows that water absorption capabilities of PGS2 is higher than other starches ($P<0.01$). Swelling of starches controls the water imbibition and disintegration properties of tablets.[1] The swelling power can be ranked in the order: PGS2>PGS1>UMS>MSBP.

Analysis of binder properties
Two-way analysis of variance indicated significant differences between tablet properties, measured in terms of hardness, friability and disintegration time, with respect to the starch type and concentration. Multiple comparison computed using Bonferroni post-hoc test compared the binder characteristics of UMS against PGS1, PGS2 and Gelatin/MSBP. The pregelatinized form of the starch, PGS2 and gelatin indicated higher values of tablet hardness ($P<0.01$) than PGS1 and unmodified starch (Table 5). The concentration of the binder significantly increase the binding strength resulting in higher values of hardness from 2-10% across all excipients types ($P<0.05$). The tablet hardness increases in the order Gelatin>PGS2>PGS1>UMS. Previous studies have reported increased binding performance when starch molecules are subjected to pregelatinization.[9,10]
Friability was also used as a factor to measure the mechanical strength of the tablets. At all concentrations, tablets formed using UMS and PGS1 were highly friable. Friability decreases significantly with pregelatinization and remarkable increase in binder concentration ($P<0.05$). The lowest friability value was achieved in PGS2 at 5%. Using the limit of the pharmacopoeial specification of 1%, it is implied that only PGS2 was able to form mechanically acceptable tablets. It has been reported that unmodified starches in their natural forms have poor tableting properties, especially poor powder flow and weak binding and dilution potentials resulting in high friability indices.[18]
In-vitro disintegration analysis indicated rapid disaggregation potential of the tablets. At all concentrations, PGS1, PGS2 and UMS demonstrated acceptable disintegration time for uncoated immediate release tablets specified by the United States Pharmacopoeia which stated time limit of <15 min.[19] There was no established differences in

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Table 3: Physicotechnical properties of thermally modified *D. cayenensis* starches used as binder in Paracetamol granules

Property	Binder concentration (%)	UMS	PGS1	PGS2	Gelatin
Bulk density (g/mL)	2	0.44[a] ± 0.01[b]	0.36 ± 0.02	0.40 ± 0.00	0.40 ± 0.02
	5	0.36 ± 0.01	0.38 ± 0.03	0.40 ± 0.02	0.46 ± 0.01
	7	0.36 ± 0.03	0.36 ± 0.01	0.44 ± 0.01	0.40 ± 0.04
	10	0.36 ± 0.02	0.36 ± 0.02	0.44 ± 0.02	0.40 ± 0.03
Tapped density (g/mL)	2	0.50 ± 0.02	0.47 ± 0.02	0.48 ± 0.00	0.48 ± 0.01
	5	0.46 ± 0.01	0.46 ± 0.01	0.49 ± 0.01	0.49 ± 0.03
	7	0.46 ± 0.03	0.46 ± 0.03	0.53 ± 0.01	0.48 ± 0.03
	10	0.46 ± 0.04	0.46 ± 0.02	0.54 ± 0.03	0.49 ± 0.01
Carr's index[c] (%)	2	12.22 ± 2.67	23.4 ± 1.00	16.67 ± 0.98	16.67 ± 3.00
	5	21.74 ± 3.23	17.39 ± 3.03	18.37 ± 1.09	6.12 ± 1.87
	7	21.74 ± 1.46	21.74 ± 2.89	16.98 ± 2.00	16.67 ± 1.07
	10	21.74 ± 2.22	21.74 ± 1.08	18.52 ± 0.98	18.37 ± 0.98
Angle of repose[d] (°)	2	33.21 ± 1.07	34.03 ± 2.22	32.33 ± 0.47	30.21 ± 3.01
	5	31.41 ± 0.98	32.33 ± 1.95	30.53 ± 1.00	32.07 ± 2.28
	7	31.94 ± 0.73	31.74 ± 1.21	34.21 ± 1.29	32.79 ± 0.89
	10	32.30 ± 0.19	30.65 ± 0.78	32.28 ± 2.06	30.85 ± 1.24
Flow rate (g/s)	2	5.23 ± 0.67	5.83 ± 0.28	6.13 ± 0.67	5.67 ± 0.32
	5	5.73 ± 0.34	6.03 ± 0.59	5.97 ± 0.44	5.90 ± 0.09
	7	6.24 ± 0.58	6.32 ± 0.47	5.99 ± 0.08	5.74 ± 0.71
	10	5.91 ± 0.09	6.09 ± 0.22	5.45 ± 0.73	5.62 ± 0.13
Moisture content (%)	2	1.50 ± 0.01	1.52 ± 0.07	1.23 ± 0.00	1.21 ± 0.02
	5	1.16 ± 0.02	1.21 ± 0.00	1.00 ± 0.04	1.00 ± 0.03
	7	1.31 ± 0.01	1.00 ± 0.02	1.00 ± 0.02	1.09 ± 0.04
	10	1.17 ± 0.02	0.81 ± 0.09	0.69 ± 0.03	0.65 ± 0.01
Particle size (µm)	2	198.62 ± 5.60	201.71 ± 6.00	202.46 ± 3.00	208.31 ± 3.41
	5	204.27 ± 7.80	203.31 ± 2.38	202.46 ± 1.28	208.31 ± 2.00
	7	209.59 ± 9.00	202.03 ± 3.87	200.43 ± 1.09	209.06 ± 5.38
	10	186.48 ± 5.00	162.63 ± 5.06	203.85 ± 3.48	212.36 ± 1.47

UMS: Unmodified starch, PGS1: Pregelatinized starch, PGS2: Ethanol dehydrated pregelatinized starch.
(a) Mean value (b) Standard deviation (c) Carr's index 11-15: Good, 16-20: Fair, 21-25: Passable (d) Angle of repose values between 31-35: Good flow [13,14]

terms of the disintegration behaviour between pregelatinized starches and the unmodified forms (P>0.05).

Analysis of disintegrant performance

For PSG2 and MSBP differences exist only at 7 and 10% (P<0.001), and at 7% (P<0.01), respectively indicating the binding superiority of the starches against UMS. Friability improved significantly with thermal pregelatinization at 2 and 5% for PGS1 (P<0.01) and at 2,5 and 7% for PGS2 (P<0.001). All the starches indicated acceptable disintegration time. PGS1 and PGS2 exhibited significant improvement in disintegration performance than MSBP and UMS (p<0.01).

As disintegrants, all the starches indicated acceptable hardness (> 5 KgF) (Table 6**)**. There was no statistically significant differences between the hardness value of UMS and PGS1 at all concentrations (P>0.05).

Conclusion

The two modified starches have shown improved quality compared to the UMS with the potential application of PSG1 as binder and disintegrant in different ratios for immediate release tablet formulations. PSG2 was shown to make a good binder when sustained-release of API is required.

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Table 4: Physicotechnical properties of thermally modified *D. cayenensis* starches used as disintegrant in Paracetamol granules

Property	Disintegrant concentration (%)	UMS	PGS1	PGS2	MSBP
Bulk density (g/mL)	2	0.43[a] ± 0.02[b]	0.39 ± 0.01	0.41 ± 0.04	0.47 ± 0.07
	5	0.39 ± 0.01	0.39 ± 0.00	0.40 ± 0.00	0.42 ± 0.03
	7	0.38 ± 0.04	0.38 ± 0.03	0.42 ± 0.02	0.44 ± 0.00
	10	0.40 ± 0.00	0.40 ± 0.01	0.41 ± 0.02	0.46 ± 0.02
Tapped density (g/mL)	2	0.48 ± 0.00	0.49 ± 0.01	0.48 ± 0.03	0.49 ± 0.00
	5	0.48 ± 0.02	0.48 ± 0.04	0.48 ± 0.01	0.51 ± 0.00
	7	0.48 ± 0.00	0.48 ± 0.03	0.50 ± 0.01	0.52 ± 0.00
	10	0.48 ± 0.01	0.48 ± 0.00	0.49 ± 0.03	0.48 ± 0.01
Carr's index (%)[c]	2	10.42 ± 1.40	20.41 ± 2.64	14.58 ± 1.42	16.00 ± 067
	5	18.75 ± 2.72	18.75 ± 1.90	16.65 ± 1.86	17.64 ± 0.70
	7	20.83 ± 2.20	20.83 ± 2.00	16.00 ± 1.00	15.38 ± 0.97
	10	16.67 ± 0.98	16.67 ± 1.80	16.33 ± 1.80	14.58 ± 0.90
Hausner's ratio	2	1.12 ± 0.00	1.26 ± 0.02	1.17 ± 0.01	1.04 ± 0.00
	5	1.23 ± 0.03	1.23 ± 0.02	1.20 ± 0.03	1.21 ± 0.00
	7	1.26 ± 0.00	1.26 ± 0.01	1.91 ± 0.00	1.18 ± 0.00
	10	1.20 ± 0.01	1.20 ± 0.00	1.20 ± 0.04	1.17 ± 0.00
Angle of repose[d] (°)	2	27.41 ± 2.33	29.9 ± 2.01	28.81 ± 2.00	40.2 ± 0.00
	5	30.53 ± 2.64	33.34 ± 1.92	31.64 ± 1.64	45.6 ± 0.00
	7	33.02 ± 2.04	32.66 ± 2.00	31.74 ± 1.00	42.0 ± 0.00
	10	32.33 ± 2.46	33.35 ± 3.08	32.66 ± 2.24	41.51 ± 2.00
Flow rate (g/s)	2	5.23 ± 0.03	4.92 ± 0.02	5.67 ± 0.05	5.33 ± 0.05
	5	5.89 ± 0.01	5.31 ± 0.00	5.50 ± 0.01	5.59 ± 0.31
	7	5.58 ± 0.00	5.60 ± 0.07	5.53 ± 0.04	5.70 ± 0.22
	10	5.62 ± 0.06	6.14 ± 0.05	5.58 ± 0.05	5.58 ± 0.05
Moisture content (%)	2	1.00 ± 0.00	1.00 ± 0.00	0.67 ± 0.02	2.00 ± 0.06
	5	1.00 ± 0.00	1.00 ± 0.02	0.67 ± 0.02	2.70 ± 0.07
	7	0.67 ± 0.01	1.00 ± 0.03	0.67 ± 0.01	2.46 ± 0.00
	10	1.00 ± 0.00	1.00 ± 0.00	1.00 ± 0.00	2.33 ± 0.00
Mean particle size (μm)	2	197.78 ± 6.80	194.04 ± 8.20	206.5 ± 12.20	223.00 ± 11.00
	5	209.7 ± 8.97	204.16 ± 10.00	209.06 ± 8.97	221.00 ± 12.00
	7	206.93 ± 9.00	214.81 ± 6.50	201.92 ± 5.05	206.00 ± 6.90
	10	202.14 ± 11.20	205.87 ± 7.40	212.79 ± 7.00	205.65 ± 8.80

UMS: Unmodified starch, PGS1: Pregelatinized starch, PGS2: Ethanol dehydrated pregelatinized starch. (a) Mean value (b) Standard deviation (c) Carr's index 11-15: Good, 16-20: Fair, 21-25: Passable (d)Angle of repose values between 31-35: Good flow [13,14]

Conflict of interest

The authors report no conflict of interest in this research.

Authors' declaration

The authors hereby declare that the work presented in this manuscript is original, and that any liability for claims relating to the content of this manuscript will be borne by them.

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Table 5: Tablet properties of thermally modified *D. cayenensis* starches used as disintegrant in Paracetamol granules

Tablet Property	Binder concentration (%)	UMS	PGS1	PGS2	Gelatin
Hardness (KgF)	2	5.70[a] ± 0.532[b]	8.00 ± 0.880	8.60 ± 1.27	7.9 ± 1.22
	5	6.30 ± 0.857	6.00 ± 0.345	11.10 ± 0.97	11.6 ± 2.01
	7	9.20 ± 1.028	6.00 ± 0.428	11.66 ± 2.02	12.0 ± 0.98
	10	9.56 ± 1.690	7.00 ± 0.970	12.40 ± 1.70	12.8 ± 1.47
Friability (%)	2	13.25 ± 1.27	5.00 ± 0.080	3.270 ± 0.60	2.87 ± 0.51
	5	4.01 ± 0.32	4.00 ± 0.000	2.52 ± 0.72	1.25 ± 0.00
	7	3.82 ± 0.99	3.00 ± 0.350	1.38 ± 0.00	0.76 ± 0.03
Disintegration time (min)	2	0.46 ± 0.070	0.54 ± 0.021	0.58 ± 0.000	2.38 ± 0.210
	5	0.50 ± 0.080	0.48 ± 0.000	0.63 ± 0.039	29.33 ± 2.430
	7	0.63 ± 0.050	0.63 ± 0.031	1.02 ± 0.091	32.26 ± 4.820
	10	0.60 ± 0.043	0.82 ± 0.002	1.61 ± 0.057	50.49 ± 1.970

(a) Mean value (b) Standard deviation, UMS: Unmodified starch, PGS1: Pregelatinized starch, PGS2: Ethanol dehydrated pregelatinized starch

Table 6: Tableting properties of different binder concentrations of thermally modified *D. cayenensis* starches

Tablet Property	Binder concentration (%)	UMS	PGS1	PGS2	Gelatin
Hardness (KgF)	2	5.70[a] ± 0.532[b]	8.00 ± 0.880	8.60 ± 1.27	7.9 ± 1.22
	5	6.30 ± 0.857	6.00 ± 0.345	11.10 ± 0.97	11.6 ± 2.01
	7	9.20 ± 1.028	6.00 ± 0.428	11.66 ± 2.02	12.0 ± 0.98
	10	9.56 ± 1.690	7.00 ± 0.970	12.40 ± 1.70	12.8 ± 1.47
Friability (%)	2	13.25 ± 1.27	5.00 ± 0.080	3.270 ± 0.60	2.87 ± 0.51
	5	4.01 ± 0.32	4.00 ± 0.000	2.52 ± 0.72	1.25 ± 0.00
	7	3.82 ± 0.99	3.00 ± 0.350	1.38 ± 0.00	0.76 ± 0.03
Disintegration time (min)	2	0.46 ± 0.070	0.54 ± 0.021	0.58 ± 0.000	2.38 ± 0.210
	5	0.50 ± 0.080	0.48 ± 0.000	0.63 ± 0.039	29.33 ± 2.430
	7	0.63 ± 0.050	0.63 ± 0.031	1.02 ± 0.091	32.26 ± 4.820
	10	0.60 ± 0.043	0.82 ± 0.002	1.61 ± 0.057	50.49 ± 1.970

(a) Mean value (b) Standard deviation, UMS: Unmodified starch, PGS1: Pregelatinized starch, PGS2: Ethanol dehydrated pregelatinized starch

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Table 7: Tableting properties of different disintegrant concentrations of thermally modified *D. cayenensis* starches.

Tablet property	Disintegrant concentration (%)	UMS	PGS1	PGS2	MSBP
Hardness (KgF)	2	5.92[a] ± 0.476[b]	7.0 ± 2.06	7.5 ± 1.22	8.55 ± 1.22
	5	6.70 ± 1.230	7.0 ± 1.45	9.3 ± 2.67	8.51 ± 1.09
	7	5.70 ± 0.789	6.0 ± 0.36	12.0 ± 0.89	9.69 ± 2.39
	10	6.96 ± 1.090	9.0 ± 1.00	12.0 ± 1.20	6.94 ± 0.89
	12	10.58 ± 2.330	10.0 ± 3.08	11.8 ± 3.33	8.67 ± 2.82
	15	11.40 ± 1.980	10.0 ± 0.78	8.9 ± 1.08	8.55 ± 0.89
	20	10.70 ± 2.010	8.0 ± 0.89	11.6 ± 1.92	7.99 ± 1.07
Friability (%)	2	14.07 ± 1.480	3.00 ± 0.33	2.72 ± 0.24	3.05 ± 0.99
	5	2.73 ± 0.460	6.00 ± 0.21	0.30 ± 0.02	2.99 ± 0.45
	7	3.12 ± 0.007	2.00 ± 0.11	1.48 ± 0.38	2.95 ± 0.00
	10	1.26 ± 0.910	1.00 ± 0.26	0.60 ± 0.07	0.98 ± 0.06
	12	1.80 ± 0.550	1.00 ± 0.00	0.92 ± 0.06	0.99 ± 0.03
	15	1.59 ± 0.68	1.00 ± 0.00	0.61 ± 0.02	0.97 ± 0.07
	20	2.11 ± 0.340	6.00 ± 0.88	1.58 ± 0.33	0.87 ± 0.41
Disintegration time (min)	2	2.97 ± 0.780	0.58 ± 0.07	0.48 ± 0.028	1.45 ± 0.780
	5	0.85 ± 0.030	0.87 ± 0.02	1.23 ± 0.310	1.38 ± 0.390
	7	0.59 ± 0.010	0.93 ± 0.02	5.81 ± 0.960	1.29 ± 0.452
	10	1.28 ± 0.330	1.75 ± 0.37	7.39 ± 0.980	1.28 ± 0.831
	12	2.35 ± 0.290	1.20 ± 0.49	1.97 ± 0.41	1.02 ± 0.9
	15	2.04 ± 0.001	1.18 ± 0.08	1.86 ± 0.17	1.01 ± 0.76
	20	2.02 ± 0.620	1.15 ± 0.06	1.14 ± 0.94	0.98 ± 0.38

(a) Mean value (b) Standard deviation, UMS: Unmodified starch, PGS1: Pregelatinized starch, PGS2: Ethanol dehydrated pregelatinized starch, MSBP: Maize starch BP.

References

1. Newman AW, Mueller RL, Vitez IM, Kiesnowski CC. Starch and starch derivatives. In: Encyclopaedia of Pharmaceutical Technology: Informa Healthcare; 2007. 3476-3482 p.
2. Kar M, Chourasiya Y, Maheshwari R, Tekade, RK. Current Developments in Excipient Science. Basic Fund Drug Deliv. 2019. 29–83 p.
3. Ingram JT and Lowenthal W. Mechanisms of action of starch as a tablet disintegrant III: Factors affecting starch grain damage and their effect on swelling of starch grains and disintegration of tablets at 37°. J Pharm Sci. 1968; 57(3):393-399.
4. Adedokun MO and Itiola OA. Material properties and compaction characteristics of natural and pregelatinized forms of four starches. Carbohyd Poly. 2010; 79:818–824.
5. Zhu F. Isolation, Composition, Structure, properties, modifications, and uses of yam starch. Compr Rev Food Sci Food Safety 2015; *5*14(4):357–386.
6. Obidiegwu JE and Matthew Akpabio EM. The geography of yam cultivation in southern Nigeria: Exploring its social meanings and cultural functions. J Ethnic Food. 2017; 4(1):28-35.
7. Salim I, Kehinde OA, Abdulsamad A, Khalid GM, Gwarzo MS. Physicomechanical behaviour of novel directly compressible Starch-MCC-Povidone composites and their application in ascorbic acid tablet formulation. Br J Pharm. 2018; 3(1):1-13.
8. Oluwatoyin AO and Picker-Freyer KM. Characterization of acid modified *Dioscorea* starches as direct compression excipient. Pharm Dev Technol. 2009; 14(3):259-270.
9. Adedokun MO and Itiola OA. Material properties and compaction characteristics of natural and pregelatinized forms of four starches. Carbohyd Poly. 2010; 79:818–824.
10. Khalid GM, Musa H, Olowosulu AK, Jatau AI, Ilyasu S, et al. Comparative FTIR, compaction and *in vitro* dissolution studies of *Plectranthus esculentus* modified starches in metronidazole tablet formulations by direct compression. Pharm Anal Acta. 2018: 9:577.
11. Olowosulu A, Oyi A, Isah A, Ibrahim M. Physicochemical characterization and tableting properties of StarAc 955 and StarAc 9010- New co-processed starch-based excipients. Nig J Pharm Sci. 2011; 10 (2):57-69.
12. The United States Pharmacopoeia (2014). Bulk and tapped densities of powders.
13. Carr R. Evaluation of Flow Properties of Solids. Chem Eng 1965; 72:163-168.
14. Aulton ME. Powder flow. In: Aulton ME, Taylor KM (Eds.). Aulton's Pharmaceutics: The Design and Manufacture of Medicines. London: Elsevier*;* 2013; 187-199.
15. Howard SA. Solids: Flow Properties. In: Swarbrick J (Eds.). *Encyclopaedia of Pharmaceutical Technology (*3rd ed., Vol. 5). Informa Healthcare USA, Inc; 2008. 3275-3296 p.
16. Alderborn G. Tablets and Compaction. In: Aulton ME, & Taylor KM(Eds.). Aulton's Pharmaceutics: The Design and manufacture of Medicines. (4th ed.). London: Elsevier Ltd; 2013. 504-549 p.
17. Aulton ME and Summers MP. Powder, granules and granulation. In: Aulton ME, & Taylor KM (Eds.). Aulton's Pharmaceutics: The Design and Manufacture of Medicines. London, United Kingdom: Elsevier; 2013. 465-486 p.
18. Tablet friability. USP 29-NF 24. 3046 p.
19. United States Pharmacopoeia (USP) General Chapters <711> Dissolution; 2011, <701> Disintegration; 2008.