



A comparative investigation of the disintegrant efficiency of *Musa paradisiaca* L. and *Musa sapientum* L. starches in paracetamol tablet formulations

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Abstract

The disintegrant properties of unripe banana (*Musa paradisiaca*) and plantain (*Musa sapientum*) starches in comparison with maize starch BP in paracetamol tablet formulation was investigated. Starch from the unripe fruits was extracted with distilled water. The starch powder properties were evaluated. Paracetamol granules and tablets were formulated with the starches as endo- and exo-disintegrants at concentrations of 5 and 10 %w/w using wet granulation. Granules and tablet properties were evaluated. Compatibility studies using differential scanning calorimetry (DSC) and Fourier transform infrared spectroscopy (FTIR) were also carried out. The flow properties of the granules rank in the order: banana starch > maize starch BP > plantain starch. DSC and FTIR analyses revealed no interaction between the starches and paracetamol. Increase in concentration of starch disintegrants led to an increase in hardness and a decrease in disintegration time and friability of the tablets. Tablets containing banana and plantain starches when compared with those made with maize starch BP produced comparable tablet properties with no significant differences ($p > 0.05$). All tablet parameters met compendial requirements at 10 % w/w disintegrant concentration. Results revealed that banana and plantain starches were comparable with maize starch BP and these starches can be used as substitutes to maize starch BP as disintegrant in tablet formulation.

Keywords: Banana; Plantain; Starch; Characterisation; Tablets

INTRODUCTION

Starch or amyllum is a carbohydrate consisting of a large number of glucose units joined by glycosidic bonds. This polysaccharide is produced by most green plants as an energy store. It is the most common carbohydrate in human diets and is contained in large amounts in such staple foods as potatoes, wheat, maize (corn), rice, and cassava. Starch is used extensively in pharmaceutical industries as excipient in tablet formulation as disintegrants, binders or

lubricants. Maize starch is the most common of the starches used, however some authors have studied the use of starches from other sources (Iwuagwu *et al.*, 1986; Adane *et al.*, 2006; Ibezim *et al.*, 2008). The important role of starch in tablet formulations has initiated a search for new and improved starch compounds from natural sources (Kottke, *et al.*, 1992).

Banana and plantain starches on preliminary evaluations have shown that they possess some of the desirable features of good

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excipients (Adebayo and Itiola, 1998; Kunle, et al., 2006. Arun, 2013; Babalola and Odeku, 2014).

Disintegrants are agents employed in tablet formulations to induce breakup of the tablet when in contact with intestinal fluids in the gastrointestinal tract. This process of de-aggregation of a tablet constituent particles will facilitate the dissolution of the drug incorporated in the tablet formulation. Since the rate of dissolution of any drug is a determinant of its absorption from the intestines and bioavailability of such drug in the systemic circulation, the importance of disintegrant in a solid dosage form intended for oral administration cannot be over emphasized. The choice of a suitable disintegrant for a tablet formulation requires extensive knowledge of the disintegrating properties of the disintegrant for inducing break-up of the tablet and also of the interactions between the various materials constituting a tablet (Mattsson, 2000).

Banana and plantain belong to the family Musaceae, and there are probably over 30 well known species within the genus *Musa* and more than 700 varieties (De laTorre-Gutierrez, et al., 2008). They are popular fruits that are highly nutritious and delicious. They can be eaten either raw as a daily fruit, as a dessert, or cooked as a tasty tropical dish. Usually, their ripe forms are soft and sweet and are consumed raw while their unripe forms contain lots of starch and fibre. They grow well in Nigeria where they are employed as food item (Onyenekwe, et al., 2013). Starch powder extracted from the unripe fruits is white and odourless. Although there are extensive reports on starches extracted from other locally available cereals and tubers being employed in tablet formulation, little work appears to have been reported on the use of banana and plantain starches as tablet excipient.

This study was designed to evaluate the disintegrant ability of unripe banana

(*Musa paradisiaca*) and plantain (*Musa sapientum*) starches in comparison with maize starch BP in paracetamol tablet formulation.

EXPERIMENTAL

Materials. Banana (*Musa paradisiaca*) and plantain (*Musa sapientum*) were purchased from a local market in Okeigbo town, Ondo State, Nigeria and their starches were extracted by maceration in distilled water. Other reagents include paracetamol powder BP (BDH Chemical Ltd., Poole, England), lactose (Sigma Chemicals, St. Louis, USA), maize starch BP (Roquette Frères, France), 3.5 % w/v sodium hypochlorite (Reckitt and Coleman Nig. Ltd), magnesium stearate (AHA International Co. Ltd, China), hydroxypropylmethyl cellulose (HPMC) (Qualikems Pvt Ltd, Delhi, India). Water was double distilled.

Methods

Extraction of starch. Using the method of Kayisu, et al. (1981), the unripe fruits of banana or plantain were peeled and sliced into pieces using a kitchen knife. The sliced pieces were ground into a paste using an electric grinder (Moulinex, France). The paste was mixed with sufficient water and then strained through a muslin cloth. The suspension obtained was allowed to settle overnight after the addition of 3.5 % w/v sodium hypochlorite solution. Thereafter, the supernatant layer was decanted and the starch sediment washed several times to remove any water soluble impurities by mixing with sufficient water, stirring and allowing to settle for 3 h and then decanting the supernatant. This process was repeated several times until a clear supernatant was obtained. The starch sediment was sun-dried and the percentage yield of the extraction process calculated. The dried sediment was micronized into fine powders using a ball mill and the powders passed through a 750 µm sieve (Gallenkamp, UK). The fine powder was further dried in an

oven (Gallenkamp, UK) at 60 °C for 6 h and stored in an airtight plastic container.

Characterization of starch powder

Organoleptic properties. The taste, odour and colour of the starches were recorded by five different individuals and a score sheet was assigned to which each assessor indicated their respective impression. The average score was computed.

Solubility. Starch powder (100 mg) was placed in 2 ml of water in a test-tube at 30 °C and shaken. The dispersion was filtered and the residue air dried. The dried residue and the filter paper was weighed using a sensitive balance (KERRO BL3002, England) and the difference in weight was used as a measure of solubility of the starch powder.

Chemical test. A 5 ml dispersion of the starches were prepared and boiled for a minute and a few drops of 0.01 M iodine solution were added. The resulting colour change was recorded.

Swelling capacity. About 5 g of the starch powder with a tapped volume (V_i) in a 100 ml measuring cylinder was dispersed with 85 ml of distilled water and thereafter made up to volume with more water. The dispersion was allowed to stand for 24 h and the volume of the sediment (V_m) noted. The swelling capacity was computed with Equation 1.

$$\text{Swelling capacity}(\%) = \frac{[V_m - V_i]}{V_i} \times 100 \dots (1)$$

Microscopy. The starch powder samples were thinly spread over a glass slide and viewed under a microscope (Labo Microsystems GmbH, Germany) via a calibrated eye piece. The sizes and shapes of the starch particles were measured at a magnification of $\times 40$ (MICAM 1.4, ScopeImage 9.0).

Bulk and tapped densities, Hausner's ratio and Carr's index. Starch powder (20 g) was weighed and poured gently into a 100 ml measuring cylinder. The volume occupied by

the powder was recorded as the bulk volume. The cylinder was tapped mechanically on a flat surface for about a 100 times to a constant volume which was recorded as the tapped volume. Triplicate determinations were carried out and the average values generated were used to calculate the bulk and tapped densities, Hausner's ratio and the Carr's index.

True density. A 25 ml specific gravity bottle (glass pycnometer) was filled with liquid paraffin, cleaned of any residual liquid paraffin and weighed (a). The bottle was emptied, rinsed with acetone and dried. About 1 g (b) of the starch was poured into the bottle and then filled with liquid paraffin. It was weighed (c) after cleaning off the residual paraffin from the bottle. The various weights recorded were used to calculate the true density of the starch powder using Equation 2 (Irwin, *et al.*, 2002, Eichie, *et al.*, 2005, Ohwoavworhua, *et al.*, 2007). The tests were carried out for all the starches in replicates.

$$\rho = b/[(a+b)-c]S \dots (2)$$

Where ρ is the particle density of the starch and S is the specific gravity of liquid paraffin

Preparation of granules. The values shown in Table 1 were used in the preparation of all the batches of paracetamol granules using the wet granulation method. Six batches were prepared, consisting of two batches of *M. paradisiaca* starch (M1, M2), two batches of *M. sapientum* starch (M3, M4) and two batches of maize starch BP (M5, M6). To prepare a batch of 100 tablets, fifty grams of paracetamol powder, 5 g of lactose and half of the quantity of the test starches required for that batch, were weighed and mixed intimately in a mixer for 5 min. Sufficient quantity of the binder solution (5 % w/v HPMC) was added to the mixture with continuous mixing to produce a wet mass. The wet mass was passed through a 2.80 mm aperture sieve and the resulting granules dried in an oven (Gallenkamp, UK) at 60°C for 30 min. The granules were rescreened through a

710 μm aperture sieve and further dried for 30 min. The other half of the test starches, and magnesium stearate previously weighed and mixed in a mortar was added in geometric proportion and mixed with the dry granules. The granules were kept in an airtight container until analyses and compression.

Granule analysis

Compatibility studies. DSC and FTIR compatibility studies were carried out on the granules of *M. paradisiaca* and *M. sapientum* starches and paracetamol powder. The DSC analysis was carried out using a Netzsch DSC 204F1 Phoenix apparatus (Netzsch Germany). The sample (4 mg) was weighed into an aluminium pan. The seal was pierced and calibration of the calorimeter was carried out with indium. Heating of the sample was carried out at the rate of 10 $^{\circ}\text{C}$ per min from 30 to 350 $^{\circ}\text{C}$ under nitrogen at a flow rate of 70 ml/min. FTIR analysis of the sample was done using Fourier Transform Infrared Spectrophotometer (Spectrum BX, Perkin Elmer, England). The potassium bromide (KBr) tablet method was used. The sample (5 mg) was blended with KBr to 200 mg. The powder was compressed using a Sigma KBr press into a tablet shape. The tablet was placed in the sample compartment and the IR scan was carried out at a range of 4000 - 1000 cm^{-1} .

Bulk and tapped densities, Hausner's ratio and Carr's index. Similar methods used in determining these parameters for the starch powders were employed for the paracetamol granules.

Flow rate. The time taken for 20 g of the paracetamol granules to pass through the orifice of an Erweka flow tester (Model: GT, GmbH, Germany) was recorded. This was carried out in triplicates and the mean values recorded (Musa, et al., 2010).

Angle of repose. The hollow tube method was used. A short hollow tube of 3 cm in internal

diameter sitting on a circular horizontal surface of same diameter was filled with granules. The tube was withdrawn vertically and excess granules allowed to fall off the edge of the circular horizontal surface. The height of the heap was measured. The angle of repose, θ , was calculated using Equation 3.

$$\theta = \tan^{-1} (h/r) \quad \dots (3)$$

Where h is the height of the heap of granules and r is the radius of the circular base

Compression of granules. Batches of the granules were compressed into tablets using a single punch tableting machine (F-3 Manesty Machines, UK) at a compression pressure of 31 arbitrary units (AU). The die volume was adjusted to compress tablets of uniform weight by using granules weighing 600 mg. The tablets made were then kept in air tight containers and stored in a desiccator until evaluation.

Tablet evaluations. The following tests were carried out on the compressed tablets using standard procedures: tablet weight, hardness, friability and disintegration time (BP, 2003).

Tablet weight and dimensions. The weight of each of 20 tablets was determined from each batch using an electronic balance and the mean weights computed while the thickness and diameter of 10 tablets from each of the batches were estimated using the Gallenkamp micrometre screw gauge and their mean values recorded.

Hardness. The hardness of each of ten tablets per batch was determined by diametral compression using a digital tablet hardness tester (Vdigitab-VI, India). The mean hardness was calculated.

Friability. The weight of ten tablets was determined on the electronic balance. The tablets were then placed in the drum of a Roche friabilator (Erweka-ZT4 Heusenstamm, Germany) revolving at 25 rpm. After 4 min, the tablets were brought out and reweighed. The weight was then recorded

and friability calculated as percentage loss in weight.

Disintegration time. The BP tablet disintegration unit apparatus (Type MK IV, Manesty Machines Ltd, Liverpool, England) was used. The disintegration times of six tablets per batch of the tablets were determined in distilled water at 37 ± 0.5 °C. The time taken for the tablets to break into its primary particles, which passed through the mesh of the apparatus was recorded and their average times computed.

Dissolution test. The dissolution profiles of the paracetamol tablets were determined using the BP paddle method for the various batches of the tablets (Erweka-DT Heusenstamm, Germany). A dissolution medium of 900 ml of 0.1 N HCl solution maintained at 37 ± 0.5 °C with a revolution of 50 rpm was used. A 5 ml volume of the dissolution fluid was withdrawn at various intervals (5, 10, 20, 30, 40, 50, 60 min) and replaced with an equivalent volume maintained at same temperature (37 ± 0.5 °C). The samples were filtered and diluted appropriately with 0.1 N HCl solution and their absorbances measured at λ_{max} of 245 nm with a UV-Vis spectrophotometer (Shimadzu, Germany). Triplicate determinations were carried out and their mean values recorded. The concentration and the percentage of drug released at each time interval was determined using the equation from the standard calibration plot obtained from paracetamol powder.

Statistical analysis. Statistical difference in the tablet parameters of the batches were subjected to student's t-test at 5 % level of significance using GraphPad InStat 3.10.

RESULTS

Starch powder properties. Some of the physical properties of the starch powders are shown in Table 2. The starch powders of *M. paradisiaca* and *M. sapientum* was white, odourless and tasteless with a smooth texture.

They were insoluble in water and gave a blue black colouration with iodine solution. Microscopic examination of the starch particles showed a range of shapes from polyhedral to oval or pear shaped particles with a medium particle size range, as against the large particle size range of maize starch BP. The swelling capacities of *M. paradisiaca* and *M. sapientum* starches were 52 and 50 % respectively, as against the 33 % of maize starch BP. The percentage starch yield obtained from the extraction was 23.0 % for *M. paradisiaca* and 24.9 % for *M. sapientum*. Also, the starches of *M. paradisiaca* and *M. sapientum* exhibited comparable but higher densities than maize starch BP.

Granule properties. The results of the flow properties of the granules are presented in Table 3. The results show a direct proportionality between granule flow and disintegrant concentration. There was a general improvement in the flow properties of the granules with increasing disintegrant concentration. There was increase in the flow rate and a decrease in the angle of repose, Carr's index and the Hausner's ratio with increase in the concentrations of the disintegrant. Generally, the granule flow properties rank in the order: maize starch BP > *M. paradisiaca* starch > *M. sapientum* starch.

Compatibility studies

Thermal analysis. Figure 1 (a), (b) and (c) showed the DSC thermograms of pure paracetamol powder and the granules prepared with *M. paradisiaca* and *M. sapientum* starches respectively. Paracetamol thermogram showed a sharp endothermic peak, corresponding to its melting point (196 °C). This sharp peak which appeared as a spike is indicative of its purity and crystallinity. On the other hand, the thermogram of the granules containing the starches as excipients and paracetamol

together showed the characteristic peak of pure paracetamol at the middle.

FTIR. The FTIR spectrum of pure paracetamol [Figure 2 (a)] powder showed characteristic peaks at 1227.00, 1636.42 and 3171.00 cm^{-1} . These peaks observed for paracetamol remained unchanged when compared with the spectral data of the granules of *M. paradisiaca* [Figure 2 (b)] and *M. sapientum* [Figure 2 (c)] starches. This observation ruled out the possibility of chemical interaction and complex formation between paracetamol and the starches during the mixing process.

Tablet properties. Table 4 shows the mean weight of the paracetamol tablets prepared with the various test starches. The weights of all the tablets met the British Pharmacopoeia, 2003 specification, i.e., that not more than two of the individual weights should deviate

from the average weight by more than $\pm 5\%$ and none should deviate by more than $\pm 10\%$. Also Table 4 shows results from the hardness test of the tablets. It reveals satisfactory hardness values > 4 kp for all tablets of the test starches at the different concentrations tested as a minimum hardness of 4 kp is desirable or acceptable for tablets (Rudnic and Schwartz, 2000). There were no significant differences ($p > 0.05$) in the tablet hardness amongst the batches. The friability values of less than 1.0 % for all the tablets produced were also satisfactory (Table 4). All the formulated tablets disintegrated within 15 min as specified by BP for uncoated tablets (BP, 2003), but the results showed a decrease in the disintegration time with increase in the disintegrant concentration. Results from the dissolution studies showed an increased in dissolution rate with increase in concentration of disintegrant (Figure 3).

Table 1: Formula of prepared paracetamol granules and tablets

Ingredients	Quantities/tablet
Paracetamol	500 mg
Lactose	50 mg
Disintegrant*	25 or 50 mg
Binder solution (5 % w/v HPMC)	q.s
Magnesium stearate	1 % w/w

*Disintegrant; *M. paradisiaca* or *M. sapientum* starches or maize starch BP

Table 2: Some physical properties of the starches studied

Properties	Maize starch BP	<i>M. paradisiaca</i> Starch	<i>M. sapientum</i> Starch
Organoleptic	Appearance	White	White
	Taste	Tasteless	Tasteless
	Odour	Odourless	Odourless
	Texture	Smooth	Smooth
	Solubility (30 °C)	Insoluble	Insoluble
Microscopy	Size range (μm)	10 – 25	8 – 15
	Form	Polyhedral	Oval or pear-shaped
	Hilum	Central and triangular	Elongated cleft
	Striations	No striations	Striations present
Powder parameters	Bulk density (g/cm^3)	0.41	0.43
	Tapped density (g/cm^3)	0.46	0.47
	Hausner's ratio	1.14	1.14
	Carr's index (%)	5.85	12.46
	True density (g/cm^3)	0.51	0.36
	Swelling Capacity (%)	33	52
	Test for starch	Blue black	Blue black

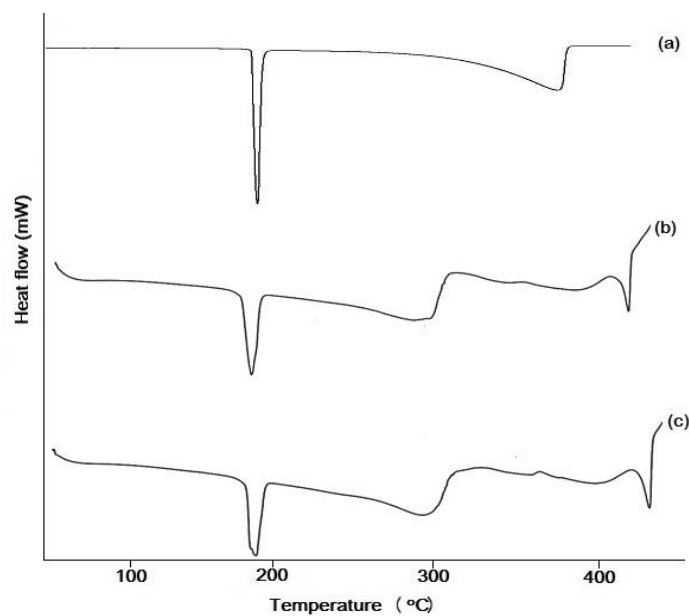
Table 3: Some physicochemical properties of the paracetamol granules

Starch	Batch	Disintegrant concentration (% w/w)	Bulk density (g/cm ³)	Tapped density (g/cm ³)	Carr's index (%)	Hausner's ratio	Angle of repose (°)	Flow rate (g/sec)
<i>Musa paradisiaca</i>	M1	5	0.45	0.48	15.25	1.18	35	3.88
	M2	10	0.44	0.50	8.00	1.09	26	4.85
<i>Musa sapientum</i>	M3	5	0.39	0.53	26.38	1.27	38	3.68
	M4	10	0.45	0.57	15.42	1.17	28	4.37
Maize	M5	5	0.44	0.52	12.00	1.14	24	3.85
	M6	10	0.43	0.47	6.54	1.07	20	4.61

Table 4: Some physicochemical characteristics of the paracetamol tablet

Starch	Batch	Weight* (g)	Dimensions (mm)		Hardness (kp)	Friability (%)	Disintegration time* (min)
			Diameter*	Thickness*			
<i>Musa paradisiaca</i>	M1	0.60 (0.02)	12.34 (0.03)	4.14 (0.01)	4.75	0.52	5.55 (1.26)
	M2	0.60 (0.01)	12.30 (0.02)	4.42 (0.03)	4.86	0.74	2.93 (1.31)
<i>Musa sapientum</i>	M3	0.60 (0.02)	12.31 (0.09)	4.43 (0.03)	4.64	0.50	5.68 (1.54)
	M4	0.59 (0.03)	12.29 (0.01)	4.42 (0.04)	4.95	0.94	3.45 (1.22)
Maize	M5	0.59 (0.01)	12.38 (0.03)	4.42 (0.01)	4.55	0.33	5.41 (1.26)
	M6	0.61 (0.01)	12.31 (0.03)	4.35 (0.02)	4.94	0.38	2.43 (0.35)

*Standard deviation in parenthesis

**Figure 1:** DSC of paracetamol powder (a), and paracetamol granules prepared with *M. paradisiaca* (b) and *M. sapientum* (c) starches.

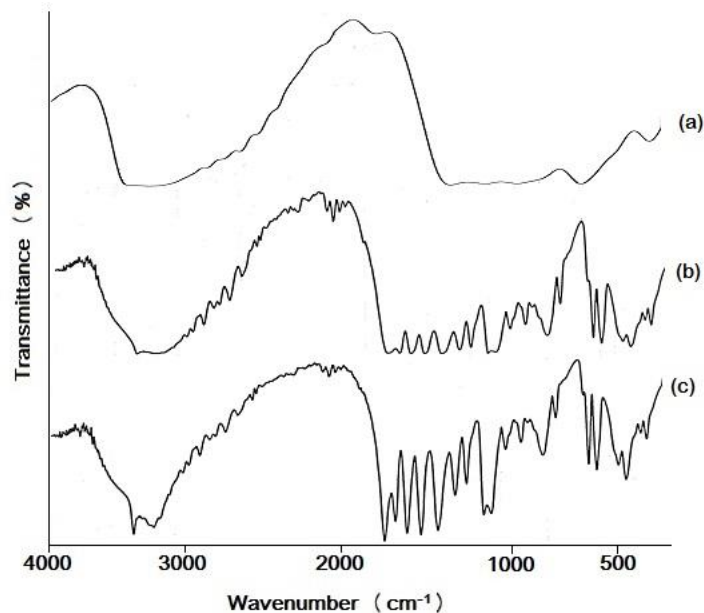


Figure 2: FTIR of paracetamol powder (a), and paracetamol granules prepared with *M. paradisiaca* (b) and *M. sapientum* (c) starches.

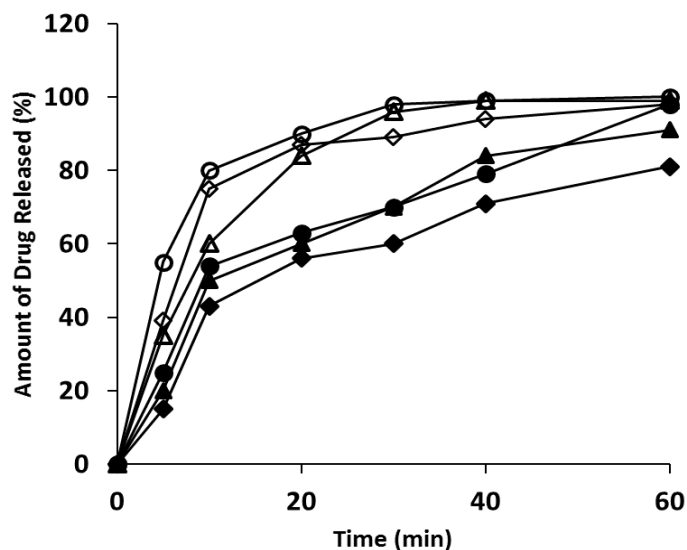


Figure 3: Dissolution profile of paracetamol tablets using varying amounts (w/w) of *M. paradisiaca* and *M. sapientum* starches and maize starch BP
M. paradisiaca starch: 5 % (◆), 10 % (◇); *M. sapientum* starch: 5 % (▲), 10 % (△);
 Maize starch BP: 5 % (●), 10 % (○)

However, all the batches of the tablets formulated with the test starches did not pass the BP 2003 dissolution test for tablets which specifies that at least 70 % of the drug should be in solution after 30 min.

DISCUSSION

The disintegrant ability of *M. paradisiaca* and *M. sapientum* starches in comparison with maize starch BP was evaluated. The percentage yield of 23 % for and 24.9 % from the extraction process

though small agrees with the range of 21 - 26 % reported by Jaffe, *et al.* (1963) for banana and Marriott and Lancaster (1983) for green plantains. The densities of the starch powders were high when compared with maize starch BP. It was expected that with the starches' low to medium particle size range, their densities should be lower than that of maize starch but the results could be as a result of their particle shapes and not their particle size range. Also, their low true density values confirm that the particle shapes of the starches may have caused uneven packing resulting in a lot of void spaces. The swelling capacity of the test starches was almost twice the swelling ability of maize starch; this superior swelling ability indicates a good candidate as a disintegrant. Some workers reported a higher swelling and water absorption ratios with *M. paradisiaca* and *M. sapientum* starches when compared with maize starch (Rajeevkumar, *et al.*, 2010; Babalola and Odeku, 2014).

The paracetamol granules formulated from the test starches showed good micromeritic properties indicating good flow properties, and their increase with increased disintegrant concentration is consistent with the formation of larger granules as the concentration of disintegrant increased. This increase in particle sizes would also lead to decrease in surface free energy of the granule particles and decrease in frictional forces between the granules leading to faster flow (Iwuagwu, *et al.*, 1986). The compatibility studies showed that paracetamol is stable in the formulations with the starches.

The properties of the tablets prepared from the test starches met official compendial specifications with regard to tablet weight, hardness, friability and disintegration time. However, the dissolution studies revealed that tablets formulated with 5 %w/w of the test starches did not release up to 70 % of drug within 30 min. This is probably due to the fact that dissolution is a subject of disintegration. Although these tablets disintegrated within

the official specified time, their longer disintegration times may have reduced the rate of dissolution as some authors have maintained that disintegration and dissolution times are correlated. (Rubeinstein and Wells, 1997; Iwuagwu, *et al.*, 2001). At 60 min, the tablets formulated with 10 %w/w of the test starches released almost 100 % of the drug, which supports that this concentration is optimum for disintegration using the starches.

Conclusion. This study has shown that the test starches, locally sourced from banana (*Musa paradisiaca*) and plantain (*Musa sapientum*) have significant disintegrant effect. The results obtained for the banana and plantain starches showed that they are comparable with maize starch BP and as such can be used as a substitute disintegrant in tablet formulation.

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