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Disintegrant properties of banana starch obtained from the unripe fruits of *Musa sapientum* L

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ABSTRACT

Banana starch obtained from unripe fruits of *Musa sapientium L.* has been evaluated as disintegrant in comparison with official corn starch. The physicochemical and material properties of the starches were evaluated and the properties of paracetamol tablet prepared by wet granulation using the starches as endo-disintegrants were determined. The results indicated that the physicochemical and material properties of banana starch varied considerably from corn starch. Scanning electron microscopy showed that banana starch granules were oval or ellipsoidal in shape while corn starch granules were angular or polyhedral in shape. The crushing strength (CS) of paracetamol tablets increased with disintegrant concentration while friability decreased. Tablets containing banana starch exhibited higher CS but lower friability than those containing corn starch. Paracetamol tablets containing banana starch had longer disintegration times than those containing corn starch although there were no significant ($p > 0.05$) differences in the disintegration time of tablets. The results showed that banana starch compared well with corn starch as disintegrant.

INTRODUCTION

Disintegrants are one of the essential excipients added to tablet formulations to enhance the breakup of the tablet into smaller fragments in aqueous environment thereby facilitating and promoting more rapid release of the drug substances (Itiola and Pilpel, 1991). They usually promote moisture penetration and dispersion of the tablet matrix to facilitate tablet disintegration which is frequently a prerequisite for dissolution and release of the active drug from the tablet. Starch is one of the multifunctional excipient used in tablet formulations as disintegrant. They are incorporated to the powder mixture before granulation (internal or endo-disintegrant) or as a dry powder to the prepared granules (external or exo-disintegrant) or both internally and externally (Pilpel *et al.,* 1978; Odeku and Akinwande, 2011). There are several plants in the tropical countries that grow in abundance with little or no artificial inputs that contain starch as one of their main constituents that could be useful as excipients in pharmaceutical tablets. One of such plants is the unripe fruits of *Musa sapientium* L, family Musaceae, which is the largest herbaceous plant in the world grown abundantly in many developing countries. The fruit is often available throughout the year and is commonly used as nutritional supplement (Cordenunsi and Lajolo, 1995). Banana is rich in carbohydrate with starch being the principal component of green banana accounting for about 70 to 80% dry weight basis (Hung *et al.,* 2013). The starch undergoes important changes during ripening and the average starch content drops in the pre-climacteric (prior to starch breakdown) period to less than 1% at the end of the climacteric period, when sugars, mainly sucrose, accumulate to more than 10% of the fresh weight of the fruit (Marriott *et al.,* 1981; Zhang *et al.,* 2005).

Banana starch have been reported to be resistant to α-amylase and glucoamylase hydrolysis, and has been shown to possess health benefits similar to dietary fiber. They have been shown to prevent colorectal cancer, lower the risk of heart disease, and influence metabolic and inflammatory bowel diseases such as diabetes and diverticulitis (Englyst and Cummings, 1986). The high amount of sugar in the fruit when ripe makes it highly perishable and large quantities of the fruits are discarded yearly. Conversion of the fruit into flour and starch will minimize loss and improve the economic value of the plant and eliminate the large environmental problem presented by banana waste (Zhang *et al.,* 2005). Recent

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studies has reported the binding properties of banana starch obtained from the unripe fruit of *Musa sapientum* in comparison with official corn starch (Odeku *et al.,* 2009). Banana starch was found to compare favorably with corn starch as the binding agent in tablet formulations although the tablets produced had lower crushing strength and faster disintegration time, suggesting its potential usefulness when fast tablet disintegration is desired. However, no work has been done to evaluate the physicochemical and material properties of banana starch to determine their functional properties and their usefulness. Moreover, the disintegrant properties of the starch has remained largely uninvestigated. Thus in the present study, the physicochemical and material properties of banana starch has been evaluated in comparison with corn starch and the disintegrant properties of the starch in paracetamol tablets has been determined.

MATERIALS AND METHODS

Materials

The materials used were corn starch BP, lactose BP, polyvinylpyrrolidone, PVP, MW 40,000 (all gifts from Bond Pharmaceutical Company, Awe, Nigeria), paracetamol BP (from Olly Chemists Ltd., Ibadan, Nigeria) and banana starch obtained from the unripe fruit of *Musa sapientum* L., (purchased from a local market in Ibadan, Nigeria). The starch was extracted using established procedures (Young, 1984).

Methods

Proximate composition

The ash, crude fat and crude fibre contents were determined using the AOAC methods (2000). The protein content was calculated from the nitrogen content determined by elemental analysis using a conversion factor of 6.25 (Gebre-Mariam and Schmidt, 1998). The amylose content was determined using a colorimetric method as described by William et al. (1970). All determinations were done in triplicate and results are given as mean and standard deviation

Swelling power and solubility

The swelling power at room temperature (24 ± 2 ˚C) and in hot water (80 ± 2 ˚C) was determined using the method described by Leach et al. (1959), the solubility was determined using the method described by Bowen and Vadino (1984), while the water binding capacity was determined using the method of Ring (1985). All determinations were done in triplicates.

X-ray powder diffraction pattern

The X-ray diffraction pattern was recorded with a copper anode x-ray tube (Cu-K$\acute{a}_1$ radiation) using a STOE STADI-MP diffractometer (Stoe and Cie GmbH, Darmstadt, Germany). The starch powders were packed tightly in sample holders and each sample was exposed to the X-ray beam at an accelerating voltage of 40 kV and 30 mA. The scanning region of the diffraction angle (2θ) was 3-50^o. The total run time was 100 minutes.

Scanning electron microscopy

The starch powders were sputtered with gold and analyzed in a scanning electron microscope (ESEM 30, Philips, Kassel, Germany) at an accelerating voltage of 2kV.

Moisture content

The percentage moisture loss of the starches was determined using TGA (Pyris 1 Thermogravimetric Analyzer TGA 7 Perkin Elmer Instruments, U.S.A.). The sample was placed in ceramic pans and heated at the rate of 10^{o}C/min from 60^{0}C to 300^{0}C.

Density measurements

The particle densities of the starches were determined by the ultrapycnometer method using helium gas (Ultrapycnometer 1000 version 2.12. Quantachrome Corporation Florida, U.S.A).

The bulk density of the starch powders at zero pressure (loose density) was determined by pouring 30g of the powder at an angle of 45^o through a funnel into a glass measuring cylinder with a diameter of 21mm and a volume of 50ml (Itiola, 1991).

The tap density was measured by applying 100 taps to 30g of each starch sample in a graduated cylinder using a mechanical tapper (Erweka GmbH Type SVM 22, Model D-63150 Heusenstamm/ Germany) at a standardized rate of 38 taps per minute.

Powder flowability

The flowability of the starches was assessed using the Hausner ratio and the Carr index (Carr, 1965). The Hausner`s ratio was determined as the ratio of the initial bulk volume to the tapped volume. The Carr index (% compressibility) was calculated as followings:

Carr index = (tap density – bulk density)/ tap density X 100.

Preparation of granules

Batches (200g) of a basic formulation of paracetamol (70%w/w) and lactose (30%w/w) were dry-mixed for 5min in a planetary mixer (Kenwood Corp., Tokyo, Japan) and then moistened with appropriate quantities of 2%w/v polyvinylpyrrolidone as binder. Banana and corn starches were incorporated intragranularly at concentration of 5 to 20%w/w. The wet mass was passed manually through a number 12 mesh sieve (1400µm). The granules were dried in a hot air oven for about 24 hours at 50ºC. The dried granules were then re-sieved through a number 16 mesh sieve (1000µm) and stored in an air-tight container till required.

Tabletting

Tablets of 500mg ± 10mg were prepared from granule size fraction 500 - 1000µm with a 10.5mm diameter die, in combination with flat faced upper and lower punches using a Carver hydraulic hand press (Model C, Carver Inc. Menomonee Falls, Wisconsin, USA). Before each compression, the die and

punches were lubricated with a 2% w/w dispersion of magnesium stearate in ethanol- ether (1:1). The materials were compressed for thirty seconds with pre-determined pressures and the tablets ejected carefully. Tablets were stored in air- tight containers for 24 hours prior to measuring their dimensions and weight, to allow for elastic recovery and hardening and to prevent falsely low yield values.

Tablet properties

The crushing strength of the tablets was determined at room temperature by diametral compression (Fell and Newton, 1970), using a hardness tester (Ketan Scientific and Chemicals, Ahmadabad, India). The percent friability of the tablets was determined using a Veego friability test apparatus (Veego Scientific devices, Mumbai, India) operated at 25 rpm for 4 min. The disintegration time, DT, of the tablet was determined in distilled water at 37 ± 0.5°C using a Veego disintegration tester (Veego Scientific devices, Mumbai, India).

Statistical Analysis

Statistical analysis to compare the disintegrants properties of the starches in paracetamol tablets was done using the Analysis of Variance (ANOVA) on a computer software GraphPad Prism® 4 (GraphPad Software Inc. San Diego, USA). Tukey-Kramer multiple comparison tests was used to compare the individual differences between the starches. At 95% confidence interval, *p* values less than or equal to 0.05 were considered significant.

RESULTS AND DISCUSSION

Proximate composition

The proximate compositions of starches have been shown to affect functional performance such as pasting and gelling behaviour and have been shown to vary with the botanical source of the starch (Peroni *et al.*, 2006; Zakpaa *et al.*, 2010). The proximate compositions of the starches are presented in Table 1. The results showed that the starches exhibited low levels of protein, fat and crude fibre (≤ 1%) indicating a high level purity of the starches. Banana starch had higher amount of non-starch constituent than corn starch although there were no significant difference (p>0.05) constituents.

Table 1: Proximate composition of banana and corn starches (mean ±SD,n = 3)

Chemical composition	Banana (%)	Corn (%)
Crude protein	0.45±0.04	0.13±0.01
Crude fat	0.45±0.01	0.39±0.03
Crude fibre	1.02±0.04	0.69±0.01
Total ash	1.02±0.03	1.05±0.03
Moisture content	10.05±0.05	8.97±0.02
Amylose	20.78±0.03	26.60±0.04

The result showed that banana starch contain 20.78% amylose which is lower than the value obtained for corn starch. Higher amylose contents have been reported for starches from *Musa var. valery* (Waliszewski *et al.*, 2003), criollo (Bello-Perez *et al.*, 1999) and Vietnamese variety of banana (Hung *et al.*, 2013). However, the amylose contents is comparable to the value reported for cavendish (Ling *et al.*, 1982) and macho banana starches (Bello-Perez *et al.*, 1999). Therefore, amylose/amylopectin content of banana starch appeared to vary depending on the varieties and the climatic conditions (Hung *et al.*, 2013). The difference in amylose content from different botanical sources have been shown to be responsible for the difference in the physicochemical and functional properties of starches.

Physicochemical properties

The results of the water binding capacity as well as the swelling power and solubility of the starches in cold (24˚C) and hot (80˚C) water and water binding capacity of the starches are presented in Table 2. The result showed that corn starch exhibited higher swelling capacity and solubility at both temperatures than banana starch. On the other hand, banana starch had a higher water binding capacity than corn starch.

Table 2: Swelling and solubility properties of banana and corn starches (mean ± SD, n = 4).

Starch	Solubility (%)		Swelling power (v/v)		Water Binding Capacity
	24°C	80°C	24°C	80°C	(g/g)
Banana	0.54±0.04	5.0±0.03	1.02±0.03	10.75±0.05	2.16±0.02
Corn	1.20±0.01	9.07±0.02	1.25±0.04	12.01±0.02	0.98 ±0.03

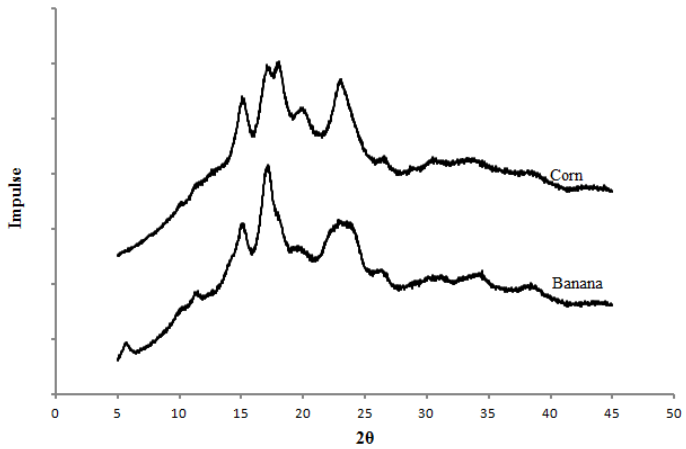

Fig. 1: X-ray diffraction pattern of banana and corn starches.

The swelling and water binding capacity of starches have been attributed to the intensities of molecular association forces inside the granules (Odeku and Picker-Freyer, 2007) which is governed by factors such as the amylose/amylopectin content, molecular weight, molecular conformation, degree of polymerization and degree of branching of amylopectin (Melo *et al.*, 2003). Generally, the intrinsic swelling power and water binding capacity have been recognized as qualitative assessments of disintegrant properties of starches but may not be an absolute indices of disintegrant efficiency (Adebayo and Itiola, 1998).

The X-ray powder diffraction patterns which is used to characterize the crystal packing in starch granules for banana and

corn starches are presented in Figure 1. Banana starch showed the C-type crystalline structures with strong peaks at 2θ of 5.2°, 15.8°, 18° and 24° while corn starch showed A-type crystalline structure (Hung *et al.*, 2013). This diffraction pattern is associated with a slight increase in the crystalline region and loss in the amorphous fraction . Thus the corn starch appear to be more crystalline in nature than the banana starch.

Material properties

The SEM of the starches is presented in Figure 2. Banana starch granules showed an oval-ellipsoidal shape with irregular sizes which is consistent with the results obtained for starches from other varieties of banana (Lii et al. 1982; Ling, 1982). On the other hand, corn starch granules were angular or polyhedral in shape. Particle shape has been shown to influence particle rearrangement at the initial stages of the compaction process (Wray, 1992). Furthermore, particle size and specific surface area have been shown to influence polymer dispersion and hydration. Starches with finer particles tend to have higher number of particles per unit weight which is indicative of a higher potential of achieving homogeneity during mixing (Odeku and Picker-Freyer, 2007).

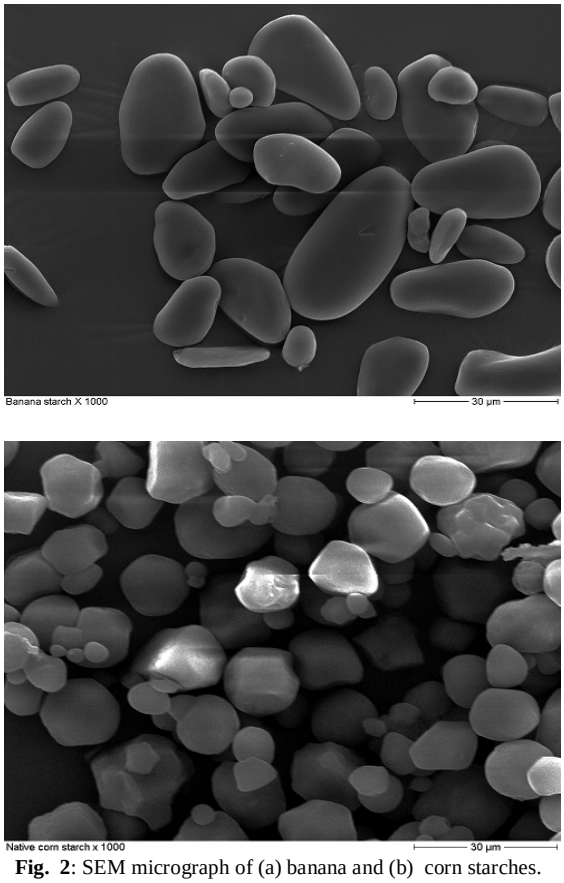

Fig. 2: SEM micrograph of (a) banana and (b) corn starches.

Moisture content of pharmaceutical powders has been shown to affect the flow and mechanical properties of starches and can lead to microbial spoilage and subsequent deterioration in starch quality. The maximum moisture content prescribed for safe storage of starches is 13 % w/w (Radley, 1976). The moisture content obtained by thermogravimetric analysis for banana and for corn starches falls within acceptable range for good quality starch. The particle and bulk densities of the banana starch was generally higher than that of the corn starch. High bulk density value has been shown to be indicative of denser particles. The Carr's index for banana starch was characteristic of fairly free flowing material and was significantly ($p<0.05$) lower than corn starch. The lower the Carr index of a material, the better the flowability, but the poorer the compressibility (Carr, 1965). This result is confirmed by the Hausner ratio which was generally lower than 1.25 for banana but higher for corn starch.

Table 3: Material properties of banana and corn starches (mean ± SD, n=4)

	Banana	Corn
Particle density (g.cm^3)	1.51 ±0.01	1.49±0.01
Bulk density (g.cm^3)	0.58 ±0.06	0.47±0.04
Carr's index	15.00±0.01	30.88±1.40
Hausner's ratio	1.17 ±0.02	1.45±0.01

Tablet properties

The crushing strength (CS) and friability (F) of pharmaceutical tablets have been used to quantify the mechanical properties of the tablets (Odeku, 2005). Plots of CS and friability for paracetamol tablets containing 10%w/w banana and corn starches as disintegrant are presented in Figure 3 and 4 respectively, while the values of the parameters at compression pressure of 113.23MPa are shown in Table 4. The result showed that CS generally increased with increase in compression pressure and disintegrant concentration while friability decreased. The crushing strength-friability ratio (CSFR) which has also been used as a measure of the mechanical strength of tablets generally increased with increase in the concentration of starch disintegrant (Table 4). This could be due to the fact that there were more particle-particle contact points, particularly with the particles of the starches which help create more solid bonds, resulting in tablets with higher CSFR values at high starch concentrations. The CSFR of banana was generally higher than that of corn.

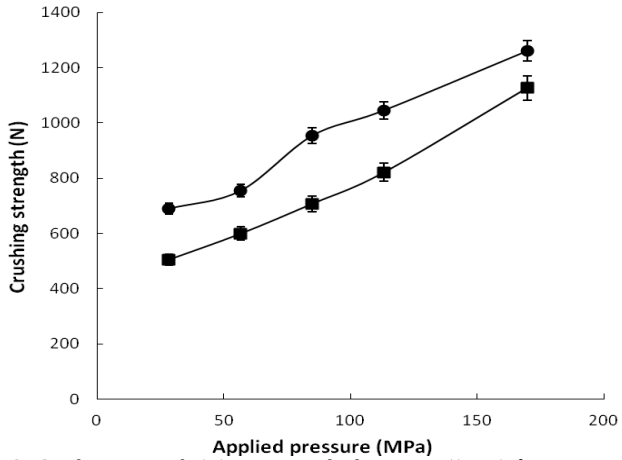

Fig. 3: Crushing strength (N) versus applied pressure ((MPa) for paracetamol tablets containing 10%w/w starch disintegrant: •, banana starch; ■, corn starch.

Table 4: Properties of paracetamol tablet at compression pressure of 113.23 MPa (mean ± SD, n = 3).

Starch	Disintegrant conc. (% w/w)	Crushing strength (N)	Friability (%)	DT (min)	CSFR	DER
Banana	5	900.30±10.20	0.93±0.04	1.46±0.02	7.32	5.01
	10	1045.90±13.20	0.61±0.02	1.30±0.23	12.89	9.91
	15	1041.30±9.04	0.54±0.03	1.93±0.03	14.54	7.53
	20	913.50±10.34	0.26±0.01	1.76±0.08	26.54	15.07
Corn	5	821.30±8.40	1.00±0.10	1.59±0.04	6.26	3.93
	10	937.90±14.20	0.97±0.02	1.51±0.08	11.58	7.66
	15	966.80±22.01	0.65±0.09	1.38±0.11	13.63	9.87
	20	964.70±6.90	0.18±0.02	1.54±0.14	28.46	18.48

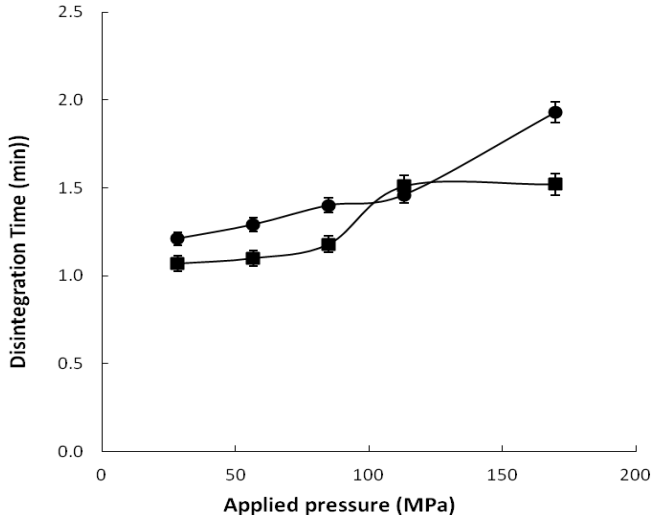

Fig. 4: Disintegration time (min) versus applied pressure (MPa) for paracetamol tablets containing 10%w/w starch disintegrant: •, banana starch; ■, corn starch

Plots of disintegration time (DT) versus compression pressure are shown in *Figure 5* while the disintegraton time at compression pressure of 113.23MPa are also shown in Table 4. The disintegration time of paracetamol tablets generally increased with compression pressure but generally decreased with increase in the concentration of starch disintegrant. This increase in disintegration time could be as a result of the starch migrating to the surface of the granules to form solid films during drying which would readily undergo plastic deformation during compression (Rumpf, 1962). Tablets containing banana starch generally showed higher disintegration time than those containing corn starch disintegrant. Statistical analysis showed that there were no significant ($p > 0.05$) differences in the disintegration time for tablets containing the various starch disintegrants. Furthermore, all the tablets conformed to official requirements for uncoated tablets on disintegration, i.e. disintegration within 15 min.

The disintegrant efficiency ratio (DER) which is defined as a ratio of CSFR and DT has been suggested as a better index of measuring tablet quality because in addition to measuring tablet strength (crushing) and weakness (friability), it simultaneously evaluates all negative effects of these parameters on disintegration time (Luangtanan-Anan and Fell, 1990). In general, high values of the DER indicate a better balance between binding and disintegration properties while a low value implies that the disintegration time have unduly high effect on the system. The value of DER shown in Table 4 indicates there appeared to be a better balance between binding and disintegration properties of the tablets containing the two starches. Furthermore, tablets containing banana starch disintegrant was lower than that of formulations containing corn starch although statistical analysis showed that there were no significant ($p > 0.05$) differences in the DER of paracetamol tablets containing the two starch disintegrants. The results show that the two starches compared favorably as disintegrants in paracetamol tablet formulations.

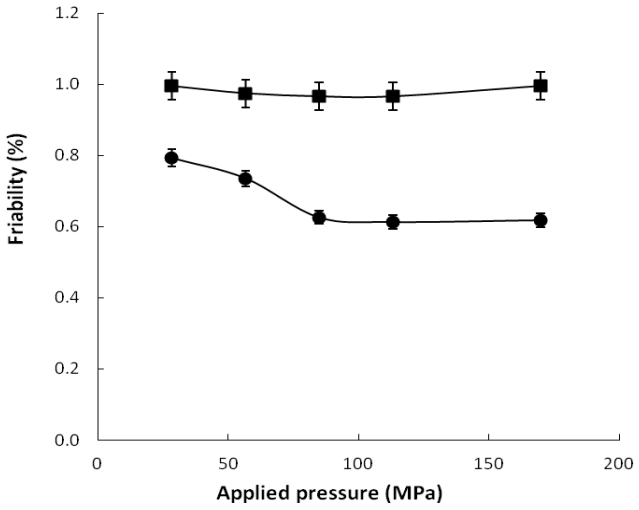

Fig. 5: Friability versus applied pressure (MPa) for paracetamol tablets containing 10% of the starch disintegrant: • banana starch; ■, corn starch

CONCLUSION

The results obtained indicate that the physicochemical and material tablet properties of the banana and corn starches varied considerably. When used as disintegrant in paracetamol tablet formulations, banana starch had longer disintegration times than those containing corn starch although there were no significant ($p > 0.05$) differences in the disintegration time and DER of paracetamol tablets containing the two starch disintegrants. The results showed that banana starch compared well with corn starch B.P as disintegrant in paracetamol tablet formulation.

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Conflict of interest

The authors declare no conflict of interest

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