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ANALYSIS OF *BORASSUS AETHIOPUM* SHOOT STARCH AS A BINDER IN A TABLET FORMULATION

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ABSTRACT
Binders are incorporated into granules to impart cohesiveness and also to ensure that a compressed tablet remains intact after compression. The binding properties of starch extracted from *Borassus aethiopum* shoot (Muruchi) was extracted and compared with maize starch BP. The properties considered included bulk density, tapped density, moisture content, Hausner's ratio, Carr's index, angle of repose of the sample starch powders and paracetamol granules produced. The tablets produced were also analyzed for quality. The outcome showed that Muruchi starch employed as mucilage (Binder) at 2.5, 5, 7.5 and 10 % concentrations respectively produced tablets comparable in friability, crushing strength, disintegration and dissolution time to tablets produced with maize starch BP binder. Therefore, it can be established that *Borassus aethiopum* shoot starch can be employed as an alternative binder to maize starch BP in the formulation of paracetamol tablets.

KEY WORDS: *Borassus aethiopum* shoot, Starch, Tablet binder and Tablet formulation.

INTRODUTION

The plant *Borassus aethiopum* mart (family Aracaceae) has been described as a palm tree with huge fan shaped leaves (Mann *et al*., 2007). The young germinating shoot of the plant called "Muruchi" in hausa is only known in northern Nigeria and the people consume it as an aphrodisiac. Fruits and shoot of the plants are the major constituents of traditional medicine in northern Nigeria and they also provide the cheapest means of providing supplies of carbohydrates fats, protein and minerals to the people (Mann *et al*., 2007).

Agents employed to impart cohesiveness to granules are referred to as binders (Mattson, 2000). They ensure the tablet remains intact after compression as well as improving the flow qualities by the formulation of granules of derived hardness and size. The choice of a suitable binder for a tablet formulation requires extensive knowledge of the relative importance of binder properties for enhancing the strength of the tablet and also of the interactions between the various materials constituting a tablet (Mattsson, 2000). The choice of a particular binding agent depends on the binding force required to form granules and its compatibility with other ingredients particularly the active drug (Gardon *et al.*, 1990).

Starch is one of the most widely used excipients in the manufacture of solid dosage form. Starches from different sources have been evaluated and used as a binder (in either mucilage or in dry powdered form), a disintegrant, a diluent or as a glidant. (Adebayo *et al.*, 1998). Although maize starch BP is the most frequently used excipient in tabletting, many researchers have tried to develop botanical starches for use as tablet excipients (Adebayo *et al.*, 1998). Preliminary evaluation of these starches following official and unofficial protocols showed that they possess some of the desirable features of good excipients (Adebayo *et al.*, 1998).

Starches from different sources have been evaluated and used as excellent binders in either mucilage or the dry powdered form (Iwuagwu *et al.*, 1991). However, to the best of our knowledge the binding property of starch from the shoot of *Borassus aethiopum* has not been assessed in these environs. Therefore, this study is aimed at determining the binding property of *Borassus aethiopum* shoot starch compared to official maize starch BP.

MATERIALS AND METHODS

Collection and identification of *Borassus aethiopum* shoot (muruchi)

The *Borassus aethiopum* shoot were obtained from the Monday Market in Maiduguri, Borno State and subsequently authenticated by plant a taxonomist from the Department of Biological Science, University of Maiduguri, Nigeria.

Extraction of starch from fresh *Borassus aethiopum* shoots

The process used by Muazu *et al*., (2014) was adopted. The fresh *Borassus aethiopum* shoots were washed and peeled using a stainless steel knife. The *Borassus aethiopum* shoots were then washed with distilled water two times and then allowed for some time for the water to drain. The *Borassus aethiopum* shoots were then reduced to small sizes prior to pulverization in a mill (TYPE YC100L-4, China).

The pulverized sample was then passed through a sieve of diameter 150µm and the slurry allowed to sediment for three hours. After sedimentation, the supernatant water was then decanted while the sediment (starch) treated with 0.1N NaOH in order to precipitate the protein content of the starch. The starch was then washed with distilled water two times with a minimum interval of an hour after each washing to allow the starch to sediment. The starch extracted was then air dried, size reduced using porcelain pestle and mortar, weighed and the percentage yield of the *Borassus aethiopum* shoot (Muruchi) starch determined (23.00 %).

Physicochemical characters of starch powders and paracetamol granules produced

Organoleptic properties

The colour, odour, texture, and taste of the *Borassus aethiopum* shoot and maize starch BP were observed and the observations recorded.

Solubility

Two gram weight of each starch powder was poured into a test tube containing 3 ml of 99 % ethanol and cold distilled water separately, observations were then recorded.

Iodine test

Two drops of iodine was added in 2ml solution of starch in a test tube and shaken. The mixture was then warmed for some minutes and allowed to cool. Observations made were then recorded.

p.H

Similar to the method used by Ohwoavworhua *et al.*, (2005), the pH of 20% w/v slurry of each of the sample starch powder was determined using a pH meter (Mettler Toledo, UK) and the result recorded.

Moisture content

A 3 g weight of each sample starch powder and the granules produced were poured unto the balance of a moisture analyzer (Sartorius, Germany) and evenly distributed. The machine was then set at 130 ± 1 °C. The readings were noted when the machine automatically stops.

Angle of repose

The angle of repose of each sample starch powder and the granules produced were determined using a glass funnel clamped on a retort stand which is 10cm away from the flat surface of a bench. 50 g of each sample starch powder was placed into the funnel and allowed to flow freely forming a conical heap.

Bulk and tapped density

These were carried out by measuring the volume occupied by a 50 g weight of each sample starch powder and granules produced in a dry measuring cylinder. The measuring cylinder was then tapped 50 times on a wooden table from a height of 2cm.

Determination of Carr's index

Carr's index was calculated from the outcomes obtained from bulk and tapped densities above.

Determination of Hausner's ratio

Hausner's ratio was determined using the data/results obtained from both bulk and tapped density.

Hydration capacity

A 1 g weight of each sample starch powder was weighed and poured in to centrifuge tubes. 10ml of distilled water was then added and mixed for 2 min. The mixture was then centrifuged for 10 minutes at 1000 rpm. The supernatant obtained was decanted and the sediment weighed.

Swelling capacity

Similar to the method used by Muazu *et al*., (2014) the swelling capacity was determined by weighing 5g of each sample starch powder into a measuring cylinder and then tapped 50 times on a wooden bench from the height of about 2 cm and the tapped volume recorded. The starch was then dispersed in 100ml of distilled water and allowed to stand for 18 hours. The volume of the sediment formed was noted.

Ash value

The method used by Muazu *et al*., (2014) was adopted. A 2 g weight of each sample starch powder was poured into a nickel Crucible which was initially heated at 105°C to a constant weight and allowed to cool. The crucible with its content was then gently heated until it was moisture free and completely charred. Subsequently, the heat was increased gradually until most of the carbon vapourised. The sample was finally heated strongly until the residue is free from carbon (i.e. almost white). The crucible with its content was allowed to cool and weighed. The heating and cooling step was then repeated until the residue (ash) was constant.

Preparation of paracetamol granules

Maize starch BP and *Borassus aethiopum shoot* starch were employed at concentration level of 2.5, 5, 7.5 and 10 %w/v respectively as binder. Weighed quantities of paracetamol powder and intra-granular disintegrant were dry mixed in a porcelain pestle and mortar for five minutes. Subsequently, lactose was added separately after five minutes of trituration. Calculated concentration

of maize starch BP / *Borassus aethiopum shoot* starch mucilage was then added and mixed to form a damp coherent mass.

The Coherent mass formed was passed through number 5 stainless steel sieve to produce granules. The wet granules were air dried and passed through number 8 stainless steel sieve in order to produce uniformly sized granules.

Compression of granules into tablets

The granules produced were mixed thoroughly with extra granular excipients (lubricants and glidants) prior to compression in a single punch tableting machine (Manesty type F_3, England) at a compression pressure of 7.5 metric tones. The tablets were kept in an air tight container for 24 hours preceding quality control tests. This is to allow for recovery. (Emeje *et al.*, 2008).

Quality control tests on the formulated tablets

Uniformity of thickness and diameter.

The vernier caliper was used to measure the diameter and thickness of the tablets. The mean value of five determinations was recorded in each case.

Uniformity of weight test

Ten tablets were randomly selected from each batch and weighed individually. The mean weight of the tablets was then calculated and the standard deviation determined.

Crushing strength

The Erweka hardness tester (TBH 100, Germany) was used in measuring the crushing strength of the tablets. Three (3) tablets were randomly selected from each batch and placed between the anvil and the spindle of the Erweka hardness tester. They were then subjected to an increasing pressure by turning the knurled knob in a clockwise direction at constant rate until the tablet was crushed. The value of the pressure applied at this point gives a measure of the tablet hardness in KgF. The mean of the three determinations was taken for each batch.

Friability test

Ten (10) tablets were randomly picked from each batch and weighed accurately. They were then placed inside the drum of Erweka friabilator (D-63150, Germany) and operated for four (4) minutes at a speed of 25 rpm. Thereafter, the intact tablets were removed from the drum, dusted and weighed. The percentage loss of weight was calculated and recorded as friability value for that batch.

Disintegration test

The British Pharmacopoeia, (2009) method was used. Six tablets were randomly selected from each batch and placed individually in the six tubes of the rack. The rack was then raised and lowered at constant rate in distilled water contained in a glass jar suspended in a water bath whose temperature was thermostatically maintained at 37 ± 1 °C the time taken for the last tablet or its fragment to pass through the 2mm mesh into the disintegrating medium (distilled water) was recorded for each batch.

Procedure for dissolution rate test

The Erweka dissolution test apparatus (Model DT 700, Germany) was used to determine the dissolution rate of the paracetamol tablets from the different batches using the procedure as stated by the British Pharmacopoeia (B.P., 2009).

The dissolution medium used was 900ml 0.1 M HCl, thermostatically maintained at 37 ± 0.5 °C. The paddle which was adjusted 25 mm away from the base of the glass jar was set to rotate at 50 rpm. One tablet was placed into each glass jar. Samples of the dissolution medium (5ml) were withdrawn at specified time interval of 5, 15, 30, 45, and 60 min respectively and spectrophotometrically (Barlowond scientific, U.K.) analysed for paracetamol at 245.3 nm. After each withdrawal of the sample, same volume of the dissolution medium was replaced.

RESULTS

Characterization of starch powder

Table 1: Organoleptic assessment *Borassus aethiopum* shoot starch and maize starch BP

Parameters	Maize starch B.P	Borassus aethiopum shoot starch
Colour	White	White
Odour	Odourless	Odourless
Taste	Tasteless	Tasteless
Texture	Fine	Very fine

Table 2: Physicochemical properties of the different starch powders

Parameters	Maize starch BP	*Borassus aethiopum* shoot starch
Solubility in 99% ethanol and cold water	Insoluble	Insoluble
Iodine test	Positive	Positive
pH	5.50	5.22
Moisture content (%)	9.67	11.26
Angle of repose (^{o})	27.89	20.8
Bulk density (g/ml)	0.48	0.69
Tapped density(g/ml)	0.63	0.86
Carr's index (%)	23.81	19.77
Hausner's ratio	1.31	1.25
Hydration capacity	2.00	2.30
Swelling capacity	1.12	1.50
Ash value	0.10	0.43

Evaluation of tablets

Table 3: Physicochemical properties of tablets produced

PARAMETERS	MS 2.5%	MS 5%	MS 7.5%	MS 10%	BASS 2.5%	BASS 5%	BASS 7.5%	BASS 10%
Thickness (mm) ± SD	4.70±0.06	5.00±0.00	4.30±0.06	5.30±0.06	4.70±0.06	5.30±0.06	4.70±0.06	5.30±0.06
Diameter (mm) ± SD	13.70±0.58	14.00±0.00	13.30±0.58	14.00±0.00	13.70±0.06	13.3±0.06	14.00±0.00	13.70±0.06
Crushing strength (KgF) ± SD	4.23±0.10	5.05±0.67	5.24±0.19	5.60±0.50	3.72±0.55	4.62±0.10	5.09±0.78	5.87±0.15
Friability test (%) ± SD	1.44±0.27	1.20±0.10	1.08±0.04	1.07±0.06	1.24±0.05	1.15±0.04	1.07±0.04	1.03±0.04
Weight (g) ± SD	536±3.20	540±10.20	584±5.30	593±7.60	556±7.20	586±17.40	601±3.51	619±3.60
Disintegration time (min) ± SD	1.20±0.40	2.63±2.40	10.08±2.28	7.62±2.10	2.26±0.81	6.10±0.63	4.57±1.07	4.41±1.72

Key: **MS =** Maize starch, **BASS =** *Borassus aethiopum* shoot starch and **SD =** Standard deviation

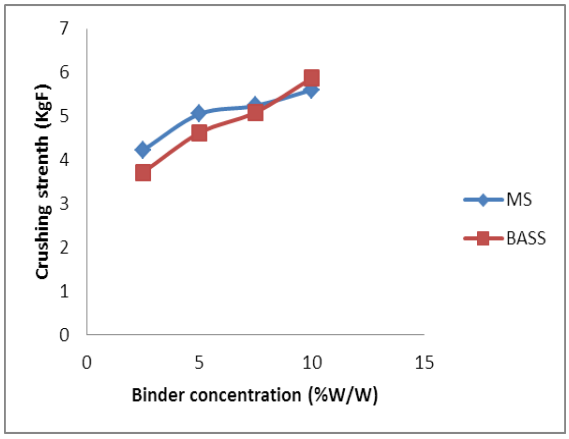

Figure 1: Effect of binder concentration on the crushing strength of the paracetamol tablets formulated

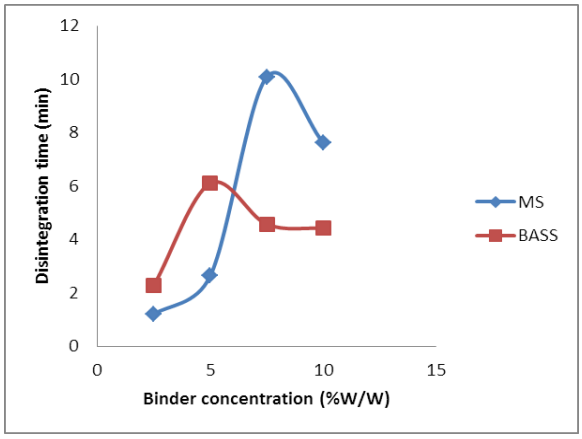

Figure 3: Effect of binder Concentration on Disintegration Time of Paracetamol Tablet formulated

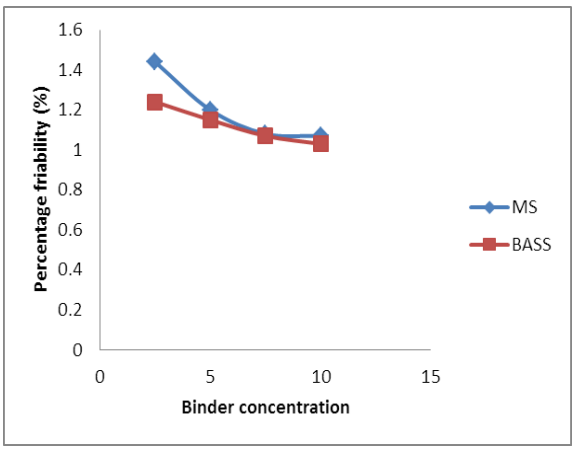

Figure 2: Effect of binder Concentration on Friability of the paracetamol tablets formulated

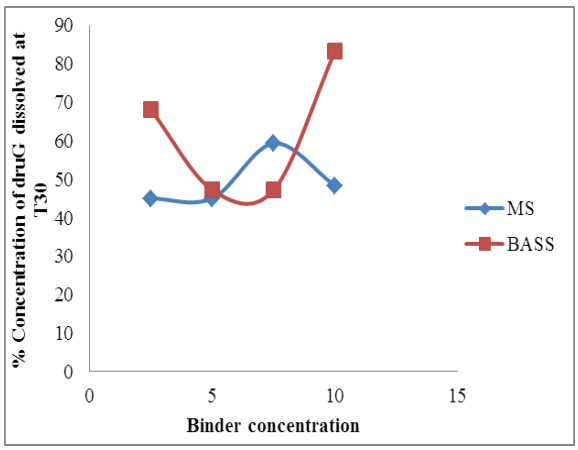

Figure 4: Percentage concentration of drug dissolved at thirty minutes (T_{30})

DISCUSSION

Starch yielded from the fresh shoot of *Borassus aethiopum* was 23%. The yield of this study is below what was reported by Muazu *et al*., (2014). This might be as a result of loss of some starch during processing Muazu et al., (2012) or probably varieties of *Borassus aethiopum* exist which can account for the difference in composition.

The Organoleptic characters (colour, odour, texture and taste), solubility of the sample starch powders in both 99% ethanol and cold water, iodine test for identification of starch and pH of both sample starch powders complied with BP, (2009) specifications for maize starch BP (Table 1 and 2). The moisture content for maize starch BP and fresh shoot of *Borassus aethiopum* starch are shown in table 2. The later has high moisture content compared to the former similar to the findings of Muazu *et al*., (2014) and these outcomes are also within acceptable limits.

Borassus aethiopum starch proved to have a better flow property compared to maize starch BP following the analyses as shown in table two. This finding is similar to that of Muazu *et al*., (2014) and also supported by the definition of flow property by Staniforth and Aulton, (2007) that powders with angles of repose greater than 50° have unsatisfactory flow properties, whereas minimum angles close to 25° correspond to very good flow properties. However, it is difficult to judge the flow property of powders using one parameter. Carr's index is used to indicate the measure of flow property of powders using small quantities of powders. Our findings demonstrate that maize starch BP had poor flow property while *Borassus aethiopum* shoot starch had a fair to passable flow that may be improved by glidant. Similar index also exist that supports this interpretation known to as Hausner ratio.

According to Ohwoavworhua *et al*., (2005) it is assumed that the hydration of a starch powder represents the water absorbed by the granule. This implies that the powders with high hydration and swelling capacity when incorporated to a tablet as disintegrant are expected to disintegrate rapidly when swelling as a mechanism of disintegration is considered. Table 2 shows that the fresh shoot of *Borassus aethiopum* starch has a higher hydration and swelling capacity compared to the maize starch BP.

The ash values of maize starch BP, and fresh shoot of *Borassus aethiopum* starches as shown in table 3 designates presence of organic salts e.g. organic salts like calcium oxalate found naturally in drugs as well as inorganic matter derived from the external sources according to Kar, (2005). Therefore, it's of great importance in the examination of the purity of powdered drugs.

Tablet thickness and diameter are not only important in producing tablets identical in appearance but also to ensure that every production lot will be usable with selected packaging components. Tablet thickness is also important in counting tablets using filling equipment. Our findings demonstrated a uniform diameter and thickness since the values of their standard deviation was low, indicating that the values for uniformity of diameter and thickness were close (Table 3).

Table 3 shows that compressed tablets formulated using *Borassus aethiopum* shoot starch as binder have binder concentration dependent increase in crushing strength comparable to those formulated using maize starch BP and both falling within acceptable limits of 3-6KgF (Gupta, 2004). This is in concordance with the report of Musa *et al*., (2008) who also noted binder concentration dependent increase in crushing strength (Figure 1).

As shown in Table 3 and figure two, friability characteristic decreases with an increase in binder concentration as a result of firmer and less friable tablets produced with cumulative binder concentration. Both samples produced tablets at the varying binder concentration with friability value slightly above the acceptable limit of 1% weight loss as stipulated by the USP, 2008.

Our findings as demonstrated in Table three and figure three specifies that tablets produced from the different sample starch powders disintegrated within the stipulated time for uncoated tablets (i.e less than 15 minutes) BP 2009. However, it is worthy of note that as binder concentration is increased, the disintegration time increases for tablets produced with maize starch BP binder while the increase in disintegration time was not consistent in the case of *Borassus aethiopum* shoot starch.

The rate of dissolution determines the rate and extent of absorption and subsequent therapeutic outcome of a drug. The factors that affect dissolution include type and concentration of binder, hardness, surface area, distance of diffusion, solubility of the drug, manufacturing process (wet granulation or direct compression) and diluents. (Ngwuluka *et al.*, 2010).

Figure four illustrates the percentage concentration of drug dissolved at 30 minutes. Tablets produced from *Borassus aethiopum* shoot starch had significant concentration of the drug in solution compared to maize starch BP. It should however be noted that only tablets produced from *Borassus aethiopum* shoot starch with 10 % binder concentration had active medicament above 70 %. The findings from the dissolution is not however consistent with the disintegration data thus, supporting the report of Musa *et al*., (2008) that tablets may disintegrate into hard coarse particles from which dissolution may be slow.

CONCLUSION

Based on the outcome of these studies, *Borassus aethiopum* shoot starch exhibited quality character as a novel starch and analogous binding properties to maize starch BP. Therefore, it can be established that *Borassus aethiopum* shoot starch can be employed as an alternative binder to maize starch BP in the formulation of paracetamol tablets.

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