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Preliminary studies on Hausa potato starch I: The disintegrant properties

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ABSTRACT

The present study is aimed at extracting and characterising a tablet excipient from local source Hausa potato tubers, which is used locally as food because of its high carbohydrate content. Maize starch BP was used as reference standard. The disintegrating properties of Hausa potato starch were studied in paracetamol tablets produced by wet granulation method of massing and screening and compared with Maize starch BP. The disintegrating property was assessed by disintegration time and dissolution time tests. The results showed that, Hausa potato starch and Maize starch BP were insoluble in water, alcohol and gave positive result on test with iodine solution. The two starches had acceptable limits of Hausner's ratio, Carr's index, angle of repose, Hydration capacity and swelling power. There were similarities in both disintegration and dissolution times of both the starches. Hausa potato starch can be used as an alternative disintegrant to maize starch BP.

Key words: Hausa Potato, Disintegrant, Starch, Paracetamol, Tablet

INTRODUCTION

Hausa potato *Solenostemon rotundifolius*, is perennial, semi-succulent, aromatic herb believed to have originated in the savannah region between Togo and Guinea and spread through tropical Africa. Although Hausa potato is not widely cultivated food crop in Africa, it is still popular in Nigeria especially in Jos plateau, Kaduna, Borno and Adamawa states. The plants are small, usually between 20cm to 30cm high (Aniedu and Agugo, 2010). The crops produce ovoid tubers up to 4cm to 8 cm long. The tubers contain 75% water, 1.45 protein, 0.5% fats, 21% carbohydrate, 0.75 fibres, 1% ash, 17mg 100g-1 thiamine, 0.02 mg 100-I riboflavin, 1mg 100-1 niacin and 1mg 100 g-1 ascorbic acid (Jadda et al 2007). The tasty tubers of Hausa potato are eaten as a relish with a starchy staple food, but occasionally they constitute the staple food. They are cooked with spices in various combinations with other foods such as beans and cooked vegetables.

Starch is an irregular, angular, white mass or fine powder. It is composed of very small spherical or elliptical granules. It is colourless, odourless with slight characteristic taste, insoluble in water and alcohol. In pharmaceutical manufacture, starch is an important excipient that has been commonly employed because of its versatility and cheapness. Freshly prepared starch paste has been widely used as binder for the preparation of granules for tablet and capsule dosage forms.

Disintegrant aids in breaking of tablet in to smaller fragments in a fluid environment prior to dissolution of active drug and its absorption from gastro intestinal, examples are starch, cellulose etc.

The aim of this work is to investigate disintegrating property of Hausa potato starch in paracetamol tablet formulations.

MATERIALS AND METHODS

Hausa potato was purchased from Biu market, Borno state, Nigeria, and identified by Professor S.S Sanusi, a Taxonomist from the Department of Biological Sciences, University of Maiduguri. Paracetamol powder (Royal Ingredients Group B.V, Holland), Magnesium stearate (BDH chemicals, Poole, England), Talc (BDH chemicals, Poole, England), Lactose (India), Maize starch B.P. (BDH chemicals, Poole, England), were all purchased from commercial source.

Extraction of starch from Hausa potato tubers

The method of Muazu *et al*, 2011 was adopted, external materials and some rotten potato tubers were removed and the tubers were peeled and washed and weighed. The peeled potato was grinded using local grinding machined and the pulp was passed through 180 µm sieve. The filtrate was allowed to settle down and 0.1N sodium hydroxide was added in order to deproteinate and neutralise the slight acidity. Excess distilled water was added in order to remove the excess sodium hydroxide. The supernatant fluid was poured away and the settled starch was collected on a tray and air dried at room temperature. Final weight of the starch was taken. Dried starch was ground using pestle and mortar, then passed through 180 µm sieve and fine powder was stored in airtight container.

Preparation of paracetamol granules

The paracetamol granules were prepared by the wet granulation method with batch size of 100 tablets. The wet granulation method of massing and screening was used in preparing all batches of paracetamol granules. The paracetamol powder, lactose powder and intra-disintegrates maize starch or Hausa potato of concentration between 2.5% - 10% depending on the batches where dry mixed in a mortar for 5 min. Appropriate quantity of freshly prepared starch mucilage (5%w/v) was added to each of the batches to produce granules. The wet mass was passed through sieve, the granules were dried at 45 ^{0}C in oven], then screened through sieve mesh.

Characterization of Starch Powders

Organoleptic properties

The colour, odour, taste of Hausa potato starch (HPS) compared to maize starch (MS) BP were determined physically using sense organs and the observation noted.

Determination of percentage yield

The method of Musa *et al*, (2011) was used. The percentage yield of Hausa potato was determined from the weight of pilled tubers used which was noted as w_o and the final starch obtained from the procedure noted as w_1.Quantities of Hausa potato starch before and after extraction were noted as W_0 and W_1 respectively. Percentage yield X was then calculated as,

$$X = \frac{W_0 - W_1}{W_0} \times 100$$

Acidity test, pH, Iodine test and solubility of the starches were determined using standard methods (Muazu et al, 2011).

Determination of starch hydration capacity

The method of Isah et al,*(2009)* was adopted. One gram of each starch was placed in each of the four 15ml plastic centrifuge tube and 10ml distilled water added and then stoppered. The content

was shaken for 2minutes and then allowed to stand for 10 min and immediately centrifuge at 1000rpm for 10 min. The supernatant water was decanted and the sediment was weighed. The hydration capacity was determined using the equation below.

$$Hydration\ capacity = \frac{weight\ of\ sediment}{weight\ of\ dry\ sample}$$

Determination of moisture content

A 3g weight of each starch was weighed and placed on the pan of moisture analyser (Sartorius, Germany) set at 130^0 C. The test repeated three times and the mean recorded.

Determination of swelling power

The method of Muazu, (2011) was adopted, 5g of each starch was tapped with a measuring cylinder, the volume occupied was noted. The starch was then dispersed in 85ml of distilled water and the volume made up to 100ml with distilled water. This was allowed to stand for 18hours, then the volume of the sediment was determined and the swelling capacity calculated from the volume differences.

Microscopic examination of starch

Small quantity of each of the starches was mounted in a drop of glycerol on a glass slid and covered with a slip. The size and shape of starch particles were determined with microscope (Carizeiss Jenna; Germany) equipped with a micrometres using 40 x magnification [8].

Determination of flow properties of starch

Angle of repose: a funnel mounted on a retort stand at a height of 10cm from the laboratory bench. A 50g weight of each of starches was poured into a funnel with closed tip. The tip-plug was removed and the starch was allowed to pass through the orifice, the height and diameter of starch were measured. The angle of repose was calculated by the following equation.

$$Tan\theta = \frac{h}{r}$$

Where h is size of conical powder heap, Where r is radius of circular base

Bulk and tapped density: A 50g weight of starches was measured and poured into a measuring cylinder and the bulk volume was noted. The cylinder was then tapped on laboratory bench 100 times from a height of 2 cm and the tapped volume was recoded. The bulk and tapped densities where then calculated using the formula:

$$Density = \frac{m}{v}$$

Where m is mass and v is volume

Hausner ratio: The ratio of tapped density to bulk density of starches was determined using the below formula

$$Hausner\ ratio = \frac{tapped\ density}{bulk\ density}$$

Carr's index: Carr's index was calculated with formula

$$Carr's\ density = \frac{tapped\ density - bulk\ density}{tapped\ density} \times 100$$

Compression of granules into tablets

The granules were mixed with extra-granular excipients, magnesium stearate and talc. The granules were then compressed in a single punch tabletting machine (Manesty, England) at a compression pressure of 6.5 metric tonnes. The tablets were kept in airtight container for 24 hours to allow for recovery.

Quality control test on tablets produced

Crushing strength test: the crushing strength of tablet was measured using a hardness tester (Erweka TBH100, Germany). Six tablets from each of the formulation batches were tested randomly and the average readings were noted.

Friability test: Ten tablets per batch were randomly selected, weighed and placed in friabiliator (Erweka, Germany) the equipment was rotated at 25 rpm for 4 minutes. The tablets were taken out, dedusted and reweighed. The percentage friability of the tablets was then calculated.

$$\text{Percentage friability} = \frac{\text{initial weight- final weight}}{\text{Initial weight}} \times 100$$

Disintegration time: The disintegration time of tablets were determined according to the method described in BP (2008), six tablets selected at random from each batch were individually determined using BP specification disintegration machine (Erweka Z31, Germany), with distilled water thermostatically maintained at 37 ± 1^0C as the medium. The time it took the tablets to pass through the mesh of the apparatus was taken as the disintegration time.

Dissolution time test: The dissolution of compressed tablet was determined using BP paddle dissolution test apparatus (Erweka DT36R, Germany). For paracetamol tablet, the test conditions were: 900ml buffer pH 5.8 at 37 ± 0.5^0C and the Peddle speed were 50 rpm. Samples (20ml) were withdrawn at 30 min, the withdrawn sample was filtered in to a labelled conical flask and diluted with 0.1M sodium hydroxide to about 0.00075%w/v. The absorbance of the resultant solution was determined spectrophotometrically (Jenway 6405UV/VIS, UK), at 275 nm. The amount of paracetamol was calculated taking 715 as value of A (1%, 1cm) at the maximum at 257nm.

Results and Discussion

The percentage yield of starch extracted from Hausa potato tubers was 10. 26% as shown in table 1, this was low yield. This could be due to loss of some starch during processing and high water content (75%) of the tubers. The physicochemical properties of HPS and MS are also presented in table 1. The results indicated that, the extracted starch of Hausa potato was off-white in colour with sweetish flavoured smell. Microscopic observation shows HPS particles were spherical in shape. The maize starch is white in colour with angular shape. This could be as a result of bleaching that the maize starch had under gone prior to marketing (Muazu et al, 2011). The flavoured smell of HPS might help in masking of unpleasant taste of some drug(s). The two starches were practically insoluble in water, ethanol (95%) at room temperature and turn blue-black on addition of iodine reagent. The result showed Hausa potato complied with BP standard of starch identification test. Table 1 further shows HPS was more acidic than maize starch BP. Although both starches were within the acceptable limit of 4.5 - 8.0 (Ohwoavworhuao and Adelakun, 2005), but neutral P^H is better in order to avoid drug excipient interaction. The hydration capacity studies demonstrated that all starches have similar hydration capacity. Hydration capacity is very important parameter in assessing new disintegrant because of a strict

relationship between water absorption and drug release mechanism (Mannur et al, 2010). The moisture content of maize starch BP was slightly higher than Hausa potato starch as shown on table 2. Although the moisture content of both starches were within official limit 4 to 30% (Olayemi et al, 2008). Low content of moisture in starch is of great importance. This will help in increasing tablets stability, especially moisture sensitive drugs. High moisture may lead to activation of enzymes and proliferation of microorganisms (Petal et al, 2011). The swelling capacity reflects increase in volume of starch following water absorption. The result (table 1) also indicated the starches both swelled. Thus, if starches were incorporated in tablet formulation as disintegrant, it would probably produces disintegration by capillary or wicking, due to inter particulate water and swelling in order of it swelling ability (Achor et al, 2010).

Table 1: Physicochemical properties of Hausa potato starch compared with maize starch BP.

PARAMETERS	HPS	MS
Yield	10.26	-
Odour	Flavoured	Odourless
Colour	Off-white	White
Angle of repose (^{0})	31.47	31.66
Bulk density (g/ml)	0.50	0.48
Tapped density (g/ml)	0.67	0.60
Hausner ratio	1.34	1.25
Carr's index (%)	25.37	20.00
Solubility	Insoluble	Insoluble
P^H	5.19	6.31
Iodine test	Positive	Positive
Swelling power	0.50	0.20
Hydration capacity	2.50	1.74
Moisture content	16.04	10.36
Microscopic observation	Spherical	Angular

The flow properties of powders are essential in determining its suitability as direct compression excipients. The angle of repose of starch provides an insight into the magnitude of the cohesive and flow-ability of the powder. For must pharmaceutical powders, the value ranges between 25^o - 45^0 (Musa et al, 2011). The value obtained shows that both starches were within the range, but HPS showed slightly higher value than MS.

The Hausner ratio which is the ratio of tapped density to bulk density, gives an insight to the degree of densification which could occur during tableting .The higher the ratio, the greater the propensity of the powder to densify. Carr's index shows the aptitude of material to diminish in value. As the value of indices increase the flow of powder decreases. In general, however, Hausner ratio greater than 1.25 indicates poor flow, and Carr's index between 16% to 35% indicates good flow of powder (Ohwoavworhuao and Adelakun, 2005) . The values of Carr's

index and Hausner ratio of both starches were within limit. This implies both starches flow better during tableting.

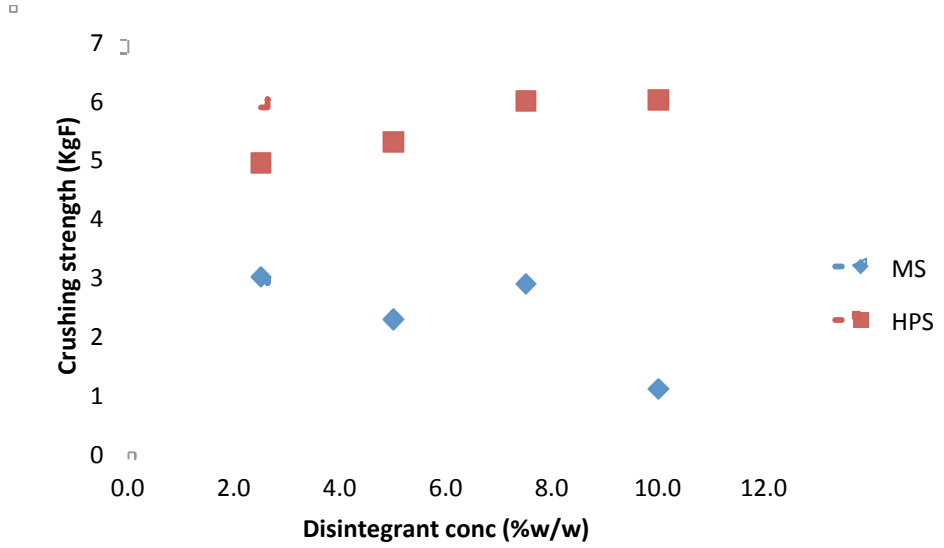

Fig 1: Graphs of crushing strength of tablets produced with different disintegrants and at varying concentrations

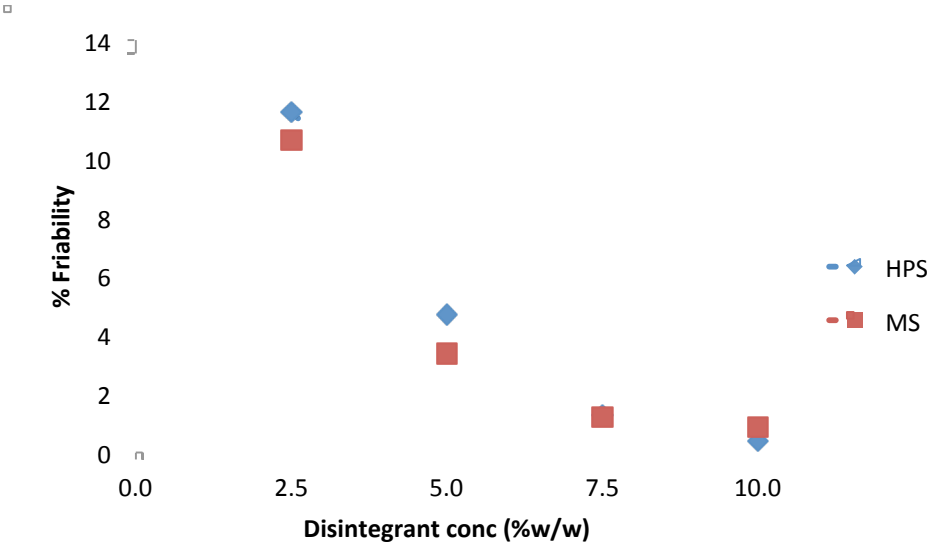

Fig 2: Effects of disintegrant concentrations on friability profile of paracetamol tablets

Fig 1 shows slight increase in tablet crushing strength with increase in concentration of disintegrant followed by decrease in tablet strength. The initial increase in strength was as a result of part of the starch being wetted the binder hence acting as additional binder while the decrease was as a result of over saturation of the binder i.e. there was no more binder to wet the

starch. Tablets produced with Hausa potato starch as disintegrant have ability to withstand stress during packaging storage and shipment.

Friability test is design to evaluate the ability of tablets to withstand abrasion during packaging, handling and shipping. Conventionally compressed tablet that lost less than 1% weight, are generally consider acceptable (Ali et al, 2011). The results of friability test obtained (fig 2) show that tablets at concentration 7.5 and 10% as disintegrant met the official requirement. The pattern was similar for both starches

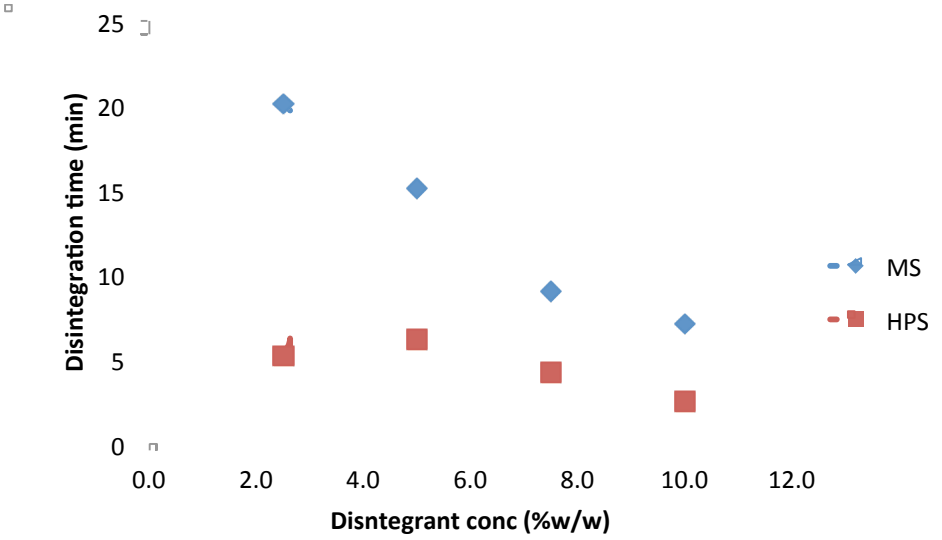

Figure 3: Effects of disintegrant concentration on disintegration time of paracetamol tablet formulations

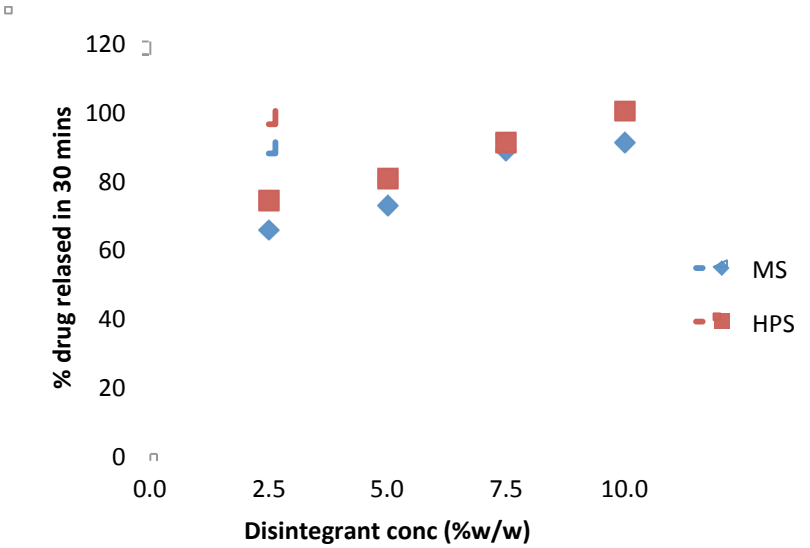

Figure 4: percentage of drug released in 30mins from different disintegrants

The disintegration time of the tablets containing HPS as disintegrant indicates better disintegration than maize starch BP as shown in fig 3, although both starches were within official limit of 15min (BP, 2008). The results indicated that, as concentration of disintegrant increases the disintegration time decreases. The superiority of HPS as a disintegrant might be as a result of higher swelling power and hydration capacity (table 1).

The decrease in disintegrant time with increase in disintegrant concentration could be as result of enhanced water penetration by capillary force since it has low swelling power, into the tablet to Couse the swelling of some component in the tablet to break apart.

Dissolution test measures amount of time require for certain percentage of drug substance in a tablet to into solution under specified set of condition. The results of dissolution test as shown in fig 4 indicates that tablets made with varying concentration of MS dissolved better than tablets made with varying concentration of HPS. Suitable dissolution characteristics are important property for a satisfactory tablet. The dissolution profile followed that of disintegration.

Conclusion

The study showed HPS have good flow properties for tableting, produced hard tablets with similar disintegrating time and dissolution time to MS. And can therefore, be used as an alternative disintegrant in paracetamol tablet formulations.

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