Evaluation of Starch From New Sweet Potato Genotypes for use as A Pharmaceutical Diluent, Binder or Disintegrant

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ABSTRACT

Starches from four new sweet potato genotypes were evaluate for use as tablet diluents, binders and disintegrants; using a commercially available maize starch as reference. The pre-formulation studies established low pH (5.1 - 5.9) and moisture content (10.0 - 13.1%), but high bulk density (0.50 - 0.58), tapped density (0.75 - 0.82) and true density (1.15 - 1.18) for the sweet potato starches. Hardness and friability of tablets formulated with sweet potato starches as binder were significantly better (p = 0.001) than similar compacts containing maize starch. The sweet potato starches also caused significantly faster tablet disintegration and release of paracetamol (p = 0.005). The results established the sweet potato starches as stronger pharmaceutical diluents, binders and disintegrants, compared to the commercially available maize starch.

INTRODUCTION

Root and tuber crops have been a major source of food and nutrition for mankind since antiquity. In recent times, interest of researchers have been kindled by starches (either in their native or modified forms) from both staple and lesser known root crops like sweet potato; due to their versatility. These starches have been widely employed in the textile, paper, wood, petrochemical, food and beverage industries for various end uses (Graffham *et al*., 1998). The pharmaceutical industry however, finds use for such starch as excipient in the manufacture of solid oral dosage forms like tablets and capsules. They have been used as diluent, binder and or disintegrant in concentrations that depend on the quality and source of the starch (Manek *et al*., 2005). Pharmaceutical excipients refer to all materials other than the active drug or pro-drug essential to the manufacture and administration of the dosage form. Pharmaceutical diluents provide bulk and adjust weight of the dosage form; binders glue together powders of other excipients and the drug to form compacts while disintegrants help fragment

the dosage form into smaller particles for drug dissolution and absorption. Excipient use is carefully regulated due to their strong influence on drug products. The code of Good Manufacturing Practice (cGMP) stipulates manufacturing process validation before use of new excipients in a dosage form as it helps decrease the risks of processing problems, defect costs and regulatory noncompliance (Larsson *et al*., 1997). A successful validation is however contingent on the excipient data obtained from pre-formulation studies. We therefore investigated starches from the new sweet potato varieties for their acidity or alkalinity, loss upon drying, flow and bulk properties as a diluent, adhesive or binder quality as well as disintegrant and drug release capacity in order to facilitate their exploitation as pharmaceutical excipients. This study follows the development of new sweet potato varieties with high food value by the Crop Research Institute (CRI), Kumasi, subsequent to gene introgression into adapted Ghanaian germplasm (Dapaah *et al*., 2005). It is envisaged that, the genetic differences in the varieties would translate into physical and biochemical changes in the respective starch granules; which would ultimately influence their functional properties as pharmaceutical diluent, binder or disintegrant. Paracetamol was used as a model drug due to its poor flow and compressibility, as well as high capping and lamination tendency.

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MATERIALS AND METHODS

Materials

The Sweet potato starches were obtained from the fresh root tubers of four cultivars, viz. CRI-Sauti, CRI-Hi-starch (Fufu Santom), CRI-Ogyefo (Mugande) and CRI-Faara. The sweet potato varieties were authenticated by Dr. Ted Carrey of the International Potato Center (CIP), Kumasi. Maize starch BP, Mannitol BP, Povidone BP, Magnesium stearate BP and Paracetamol BP were all kindly supplied by the raw material stores of Tradewinds Chemist Limited, Kumasi. All reagents used were of analytical grade.

Methods
pH

The pH of the starches were determined potentiometrically with a pH meter (UD-95, Universal enterprises - India) according to the method described in the British Pharmacopoeia (BP, 2011).

Moisture Content

The moisture content of the starch samples was determined thermo-gravimetrically using a moisture analyser (MB-45, Ohaus – Switzerland). 1 g of starch powder was weighed and spread out on the pan. The samples were dried at 105 ^{o}C for 10 minutes. The weight difference due to loss of moisture was computed and expressed as the percent moisture content.

True density

The true density of the starches was determined by fluid displacement (Obitte and Chukwu, 2007). The weight of a 50 ml empty pycnometer bottle was recorded and subsequently filled with xylene.

The cover was replaced, excess fluid wiped off, and the weight of fluid that filled the bottle (W_3) noted. About 5 ml of the fluid was withdrawn from the bottle and 0.5 g of starch (W_2) transferred into it. With the fluid level restored, the density bottle was stoppered and the weight of fluid and starch (W_4) recorded. The true density was then calculated using the relation:

$$\text{True density (g/cm}^3) = \frac{W_2\,W_3}{50\,(W_2 - W_4 + W_3)}$$

Bulk density

A modified method simulating the bulk densitometer was used in the initial bulk density determination (Obitte and Chukwu, 2007). 10 g of starch powder was placed in a 25 ml measuring cylinder. The upper surface was carefully flattened out and the volume noted. Bulk density was calculated using the relation:

$$\text{Bulk density } (D_0)\ (\text{g/cm}^3) = \frac{\text{Weight of starch}}{\text{Bulk volume}}$$

Tapped density

The 10 g starch powder above was gently tapped 150 times on a padded bench and the final volume noted.

Tapped or final bulk density was calculated using the relation:

$$\text{Tapped density } (D_f)\ (\text{g/cm}^3) = \frac{\text{Weight of starch}}{\text{Tapped volume}}$$

Average diameter and size distribution of starch powders

A sieving method was used in analyzing particle size of the starch powders (Ohwoavworhua and Adelakun, 2005). Test sieves ranging from 250 µm to 75 µm were arranged in a descending order on the sieve shaker (AS 200 basic, Retsch - Germany). 20 g of starch powder was placed on the top sieve and the set-up shaken at amplitude 70 for 5 minutes. The weight of material retained on each sieve was determined. The average diameter was computed using the relation:

$$\text{Average diameter} = \frac{[\sum (\%\ \text{retained}) \times (\text{mean aperture})]}{100}$$

Powder flow properties

The angle of repose, Hausner's ratio and Carr's compressibility index were used in estimating the flow properties of the sweet potato starch powders (Ohwoavworhua and Adelakun, 2005).

Angle of repose

A funnel was clamped with its tip 2 cm above a 9 cm wide petri dish. The starch powders were allowed to flow through the funnel until the apex of the cone thus formed just touched the tip of the funnel. The mean diameter (D), of the base of the powder cone was determined and the tangent of the angle of repose (θ), calculated using the relation:

$$\text{Tan}\theta = \frac{2h}{D}$$
(Where; h is the height of the heap of powder)

Hausner's ratio

This was calculated as the ratio of tapped density to bulk density of the starches.

Carr's compressibility index

Carr's index was calculated from the bulk and tapped density data using the relation:

$$\text{Carr's index} = \frac{\{\text{Tapped density} - \text{Bulk density}\} \times 100}{\text{Tapped density}}$$

Evaluation of binder quality
Tablet formulations for evaluation of the binder quality of the starches

Granules for paracetamol tablets were formulated using paste from the various sweet potato starches as binder in four different concentrations (3%, 5%, 8% and 10% w/w) (Table 1). The starch pastes were prepared by dispersing appropriate quantities of starch powder in 10 ml of distilled water. 15 ml of boiling water was added to the suspension which was subsequently heated until the starch was fully gelatinized. The pastes obtained were used to wet the appropriate powder mixtures; adding more

water where necessary. The wet masses were screened with a 1700 µm mesh sieve and dried in a hot air oven at 60 °C to a moisture content of 1.20 ± 0.30 %.

The dried granules were then screened with an 1180 µm mesh sieve. Sodium starch glycolate and magnesium stearate were incorporated as extragranular disintegrant and lubricant, respectively, and thoroughly blended.

The paracetamol granules were then compressed into tablets using a single punch tableting machine (DP -30, Pharmao industries), fitted with 12 mm diameter concave punches and a fixed compression load of 11 kN. With a fill weight of 575 mg, formulations for investigational batches of 200 tablets were made in each case. A reference batch of paracetamol tablets were also compressed from a formulation containing 5 % w/w maize starch as binder.

Bulk and tapped density of paracetamol granules

The bulk and tapped densities of paracetamol granules were respectively determined as described for the starch powders above.

Tablet hardness

Tablet hardness was determined using a manually operated Monsanto hardness tester (VEEGO HT-01, Progressive Instruments). Ten (10) tablets were randomly selected from the different batches of tablets and each positioned vertically on the lower immovable anvil of the machine.

The upper anvil was gently moved down by rotating the head screw in anticlockwise direction, such that the two anvils just hold the tablet vertically. The main and follow pointers on the gauge were then set to zero and diametral load manually applied to the tablet by moving the head screw anticlockwise at a rate of 0.1 kg per turn. Hardness values of the paracetamol tablets were recorded on the gauge in kg/cm^2 (1 kg/cm^2 or kgf/cm^2 $\equiv$ 98066.5 N/m^2 or Pascal) by the follow pointer, while the main pointer went back to zero after the tablets cracked or crushed.

Tablet friability

The friability of fifteen tablets approximately weighing 6.5 g was determined in a friabilator (Erweka, TA 20, Germany). The drum was rotated at 25 rotations per minute (rpm) for 4 minutes. Percentage loss of tablet weight with respect to the initial weight was then calculated as degree of friability.

Evaluation of disintegrant quality
Tablet formulations for evaluation of the disintegrant quality of the starches

The sweet potato starches were each used as extra-granular disintegrant in four different concentrations (1%, 3%, 6% and 9% w/w) (Table 2). The Povidone K-30 was dissolved in 25 ml of distilled water and the solution used to wet and granulate the appropriate powder mixtures. The respective concentrations of sweet potato starch as disintegrant and magnesium stearate as

lubricant were incorporated into the resulting granules and thoroughly blended. The paracetamol tablets were then compressed to a fill weight of 575 mg, using formulations for investigational batches of 200 tablets in each case. Also a reference batch of paracetamol tablets was compressed from a formulation containing 3 % w/w maize starch as disintegrant.

Disintegration time

A disintegration apparatus (ZT 4, Erweka - Germany) was used to determine the disintegration time of tablets. A tablet was placed in each of the six tubes of the apparatus and the time taken for all tablets to completely disintegrate in distilled water maintained at 37 ± 2 °C were recorded.

Evaluation of diluent quality

Diluent quality of the starches was inferred from their bulk properties. The higher the density of a material the better its diluent power or quality (Aulton, 2001).

Influence of the starches as binder and disintegrant on *in-vitro* drug dissolution

Two sets of paracetamol tablets which respectively contained 5 %w/w of the different sweet potato starches as binder (Table 1) and 3 % w/w of the sweet potato starches as disintegrant (Table 2) were selected for these evaluations against paracetamol tablets containing similar concentrations of maize starch as reference.

Calibration of UV spectrophotometer

The UV spectrophotometer (Pharmaspec UV-1700, Shimadzu Corporation - Japan) was calibrated using appropriate quantities of paracetamol dissolved in 0.1M NaOH to produce 0.0001, 0.0002, 0.0004, 0.0008 and 0.001 % w/v solutions. The absorbances of these solutions were determined at 257 nm and a calibration curve ascertained. The resultant regression equation was subsequently used to estimate amount of drug released from the uncoated tablets.

Dissolution test

The method of the British Pharmacopoeia was used to assess the *in-vitro* dissolution of paracetamol from the tablets (BP, 2011). Graphs of percentage drug released over 60 minutes were used to elucidate the role of the starches as disintegrant and binder on drug release.

Statistical analysis

The results were expressed as Mean $\pm$ SD. Statistical analysis was done by One-way analysis of variance (ANOVA) with Newman-Keuls post test performed to determine differences between means. The statistical package GraphPad Prism version 5.01 for Windows (GraphPad Software Inc., San Diego - California) was used and the level of significance set at $p < 0.05$.

Table. 1: Formulations for the evaluation of the starches' binder quality.

Ingredients	Quantities per batch (mg)				
	B₁	B₂	B₃	B₄	B₅
Sweet potato starch	(3%w/w)	(5%w/w)	(8%w/w)	(10%w/w)	-----
(Paste binder)	17.25	28.75	46.00	57.50	
Maize starch	-----	-----	-----	-----	(5%w/w)
(Reference binder)					28.75
Paracetamol	500	500	500	500	500
Mannitol	50.05	38.55	21.30	9.80	38.55
Magnesium stearate	1.70	1.70	1.70	1.70	1.70
Na starch glycolate	6.00	6.00	6.00	6.00	6.00
Tablet weight	575	575	575	575	575

**Table. 2:** Formulations for the evaluation of the starches' disintegrant quality .

Ingredients	Quantities per batch (mg)				
	D₁	D₂	D₃	D₄	D₅
Sweet potato starch	(1% w/w)	(3% w/w)	(6% w/w)	(9% w/w)	-----
(As disintegrant)	5.75	17.25	34.50	51.75	
Maize starch	-----	-----	-----	-----	3 % w/w
(Reference disintegrant)					17.25
Paracetamol	500	500	500	500	500
Mannitol	50.30	38.80	21.55	4.30	38.80
Povidone K-30	17.25	17.25	17.25	17.25	17.25
Magnesium stearate	1.70	1.70	1.70	1.70	1.70
Tablet weight	575	575	575	575	575

Table. 3: Physicochemical and powder properties of the sweet potato starches.

Parameter	Starch				
	Hi-Starch	Sauti	Ogyefo	Faara	Maize
pH	5.9 ± 0.10^a	5.8 ± 0.05^a	5.1 ± 0.04^a	5.6 ± 0.04^a	5.2 ± 0.03^a
Moisture content	10.9 ± 0.21^a	12.8 ± 0.21^a	13.1 ± 0.31^a	10.0 ± 0.16^a	12.7 ± 0.23^a
Bulk properties:					
True density (g/cm³)	1.15 ± 0.02^a	1.16 ± 0.03^a	1.18 ± 0.02^a	1.16 ± 0.03^a	1.10 ± 0.03^b
Bulk density (g/cm³)	0.53 ± 0.00^a	0.50 ± 0.02^a	0.55 ± 0.01^a	0.58 ± 0.01^a	0.40 ± 0.01^b
Tapped density (g/cm³)	0.75 ± 0.01^a	0.79 ± 0.02^a	0.80 ± 0.01^a	0.82 ± 0.02^a	0.61 ± 0.00^b
Average diameter (µm)	86.2 ± 3.25^a	85.4 ± 5.00^a	83.0 ± 0.51^a	93.6 ± 3.92^a	86.4 ± 0.48^a
Flow properties:					
Angle of repose [NMT 40°]	40.4 ± 1.20^a	38.7 ± 1.45^a	37.6 ± 1.10^a	36.1 ± 0.80^a	36.9 ± 1.85^a
Hausner's ratio [NMT 1.25]	$1.42 \pm 0.09a$	$1.58 \pm 0.13a$	1.45 ± 0.18^a	1.41 ± 0.12^a	1.53 ± 0.10^a
Compressibility index [NMT 20%]	29.3 ± 0.18^a	$36.7 \pm 0.21a$	31.3 ± 0.19^a	29.3 ± 0.27^a	34.4 ± 0.32^a

Values followed by the same superscript in a row are not significantly different at $p<0.05$; and NMT means Not More Than.
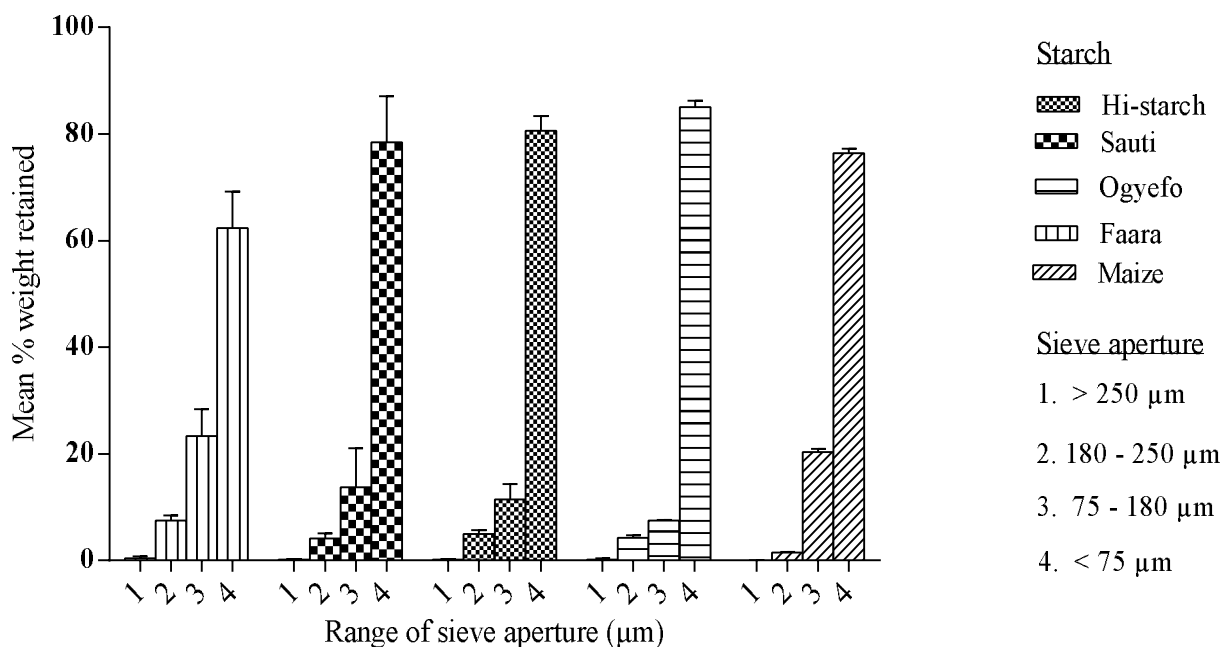
Fig. 1: particle size distribution of the dried pulverized starch.

RESULTS AND DISCUSSION

Physicochemical and powder properties of the sweet potato starches

The pH of the sweet potato starches (5.1 - 5.9) was acidic and similar to that of the commercial maize starch (5.2), hence should be used with caution in formulations of low dose alkaline drugs. The moisture content of all starches evaluated was within the limits (NMT 15%) recommended by the British Pharmacopoeia (Table 3) (BP, 2011).

The bulk properties describe the density, packing and flow of a powder mass. The sweet potato starch powders had higher true density (1.15 - 1.18), bulk density (0.50 - 0.58) and tapped density (0.75 - 0.82) compared to values of 1.10, 0.40 and 0.61, respectively, recorded for the commercial maize starch (Table 3). High density materials have high diluent power as they substantially reduce powder volume or bulk while improving consolidation and flow (Aulton, 2001). All the starch powders evaluated had similar mean particle size (83.0 - 93.6 µm) (Table 3) and size distribution (< 75 – 250 µm) (Fig. 1). Generally, fine powders (particle size < 75 µm) have poor flow which negatively affect uniformity of the dosage unit and limit their application in direct compressions.

The sweet potato starches like the commercial maize starch had high angle of repose (36.1-40.4), Hausner's ratio (1.41-1.58) and Carr's compressibility index (29.3-36.7) which confirmed their poor flow properties (Table 3). Therefore, their possible use as tablet excipients (either as diluent, binder or disintegrant) might be ideal for wet granulations, where improved granule flow allows for smooth tablet compression (Gilbert and Christopher, 2002).

Evaluation of binder quality of the sweet potato starches

The bulk and tapped densities of paracetamol granules prepared using the sweet potato starches as binder were significantly higher (p = 0.01) compared to that from Maize starch (Figs. 2a and 2b). Higher granule bulk density results when strongly adhesive binders agglomerate more particles of the drug. Narrow differences between granule bulk and tapped density signify enhanced consolidation and flow which ensures the compression of tablets with uniform weight (Aulton, 2001).
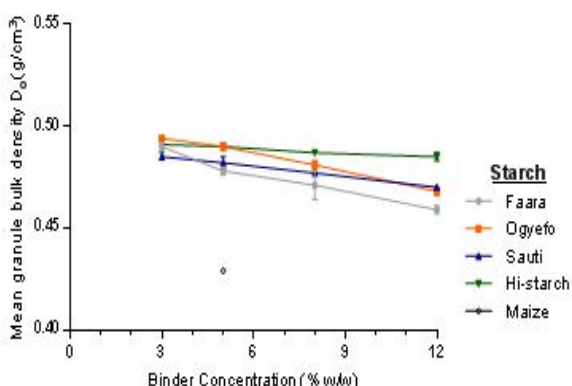

Fig. 2a: bulk density of paracetamol granules at different starch binder concentration
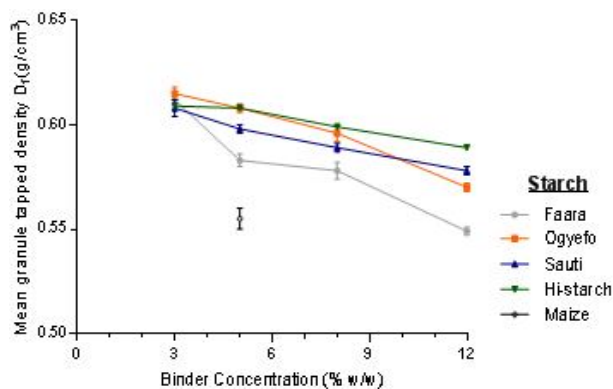

Fig. 2b: tapped density of paracrtamol granules at different starch binder concentration.
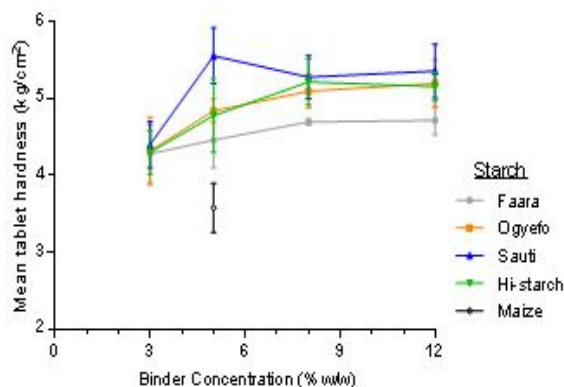

Fig. 3a: comparing hardness of paracetamol tablets at different starch binder concentrations.
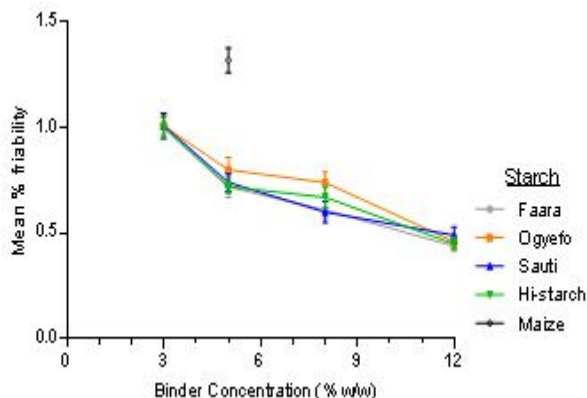

Fig. 3b: comparing friability of paracetamol tablets at different starch binder concentration.

Paracetamol tablets with the sweet potato starches as binder were significantly harder (4.46 - 5.56 kg/cm^2) and less friable (0.72 - 0.80 %) (p = 0.001) compared to similar compacts containing the commercial maize starch (3.58 kg/cm^2 and 1.32 %, respectively) (Figs. 3a and 3b). There was however no significant differences in tablet hardness and friability among compacts prepared using the different sweet potato starches as binder. The tensile strength and mechanical integrity of tablets are known to improve significantly when low density regions or voids are eliminated. Void elimination has been demonstrated to reduce incidences of tablet capping and lamination; and may be achieved at high compression loads or if the material has either high binding capacity (as was in

the case of the sweet potato starches) or if the quantity of binder is increased (Okor, 2005). In the latter instances, dense, uniform sized granules with good consolidation are produced. Conventional compressed tablets of acceptable hardness (4 - 6 kg/cm^2) and friability ($\leq$ 1 %) are essential for handling during packaging, transportation and administration (Gilbert and Christopher, 2002; Alfonso, 1990).

Evaluation of disintegrant quality of the sweet potato starches

The disintegration time of paracetamol tablets containing similar amounts of the sweet potato starches as disintegrant were similar, but generally, was marginally faster than compacts containing the commercial maize starch (Table 4). Starch granules as extra-granular disintegrant undergo deformation during high pressure tablet compression; and these swell maximally in aqueous fluids to cause tablet disintegration (Carter, 2002). However, the mannitol (a sugar alcohol) used as diluent could dissolve rather than aid tablet disintegration and cause an increase in viscosity of the penetrating fluid. This tends to reduce effectiveness of strongly swelling disintegrating agents like the sweet potato starches (Ribotta and Rosell, 2010). The British Pharmacopoeia recommends a disintegration time of not more than 15 minutes for immediate release tablets (BP, 2011).

Table. 4: Disintegration time profile of formulations with the sweet potato starches as disintegrant.

| Starch | Disintegration time for paracetamol tablets with different disintegrant (starch) concentrations (minutes) | | | |
| | (Mean $\pm$ SD) | | | |
	1 % w/w	3 % w/w	6 % w/w	9 % w/w
Faara	3.12 ± 0.03	0.62 ± 0.05	0.36 ± 0.03	0.30 ± 0.02
Ogyefo	3.21 ± 0.06	0.59 ± 0.04	0.32 ± 0.02	0.24 ± 0.01
Sauti	3.07 ± 0.05	0.60 ± 0.05	0.45 ± 0.02	0.32 ± 0.02
Hi-starch	2.54 ± 0.01	0.41 ± 0.02	0.36 ± 0.03	0.25 ± 0.02
Maize starch	-----	0.65 ± 0.05	-----	-----

Influence of the starches as binder and disintegrant on drug release

The drug release pattern amongst tablets containing starch from the sweet potato varieties either as binder or disintegrant was not significantly different. However, the paracetamol tablets containing the sweet potato starches as extra-granular disintegrant released more of the drug during the first 15 minutes of dissolution testing than those containing maize starch (Fig. 4). On the other hand, tablets containing the sweet potato starches as paste binder, released less of the drug during this period compared to tablets with maize starch binder (Fig. 5). Meanwhile, the percent drug release after 45 minutes was quite high (98.9 – 99.5%) and within acceptable limits in all the categories of tablets containing the potato starches; but was not significantly different from their counterparts with the commercial maize starch. The pattern of *in-vitro* dissolution and drug release seems to suggest that the paracetamol tablets with the potato

starches as disintegrant could exhibit a quicker onset of action than tablets with maize starch disintegrant (Ribotta and Rosell, 2010).

All in all, the sweet potato starches exhibited properties suitable for use as pharmaceutical excipients in oral tablet dosage forms. However, by virtue of superior yield, starch from the Hi-starch variety would be commercially viable as a substitute pharmaceutical diluent, binder or disintegrant in local drug manufacture. Although these sweet potato varieties and their starches are used in the food industry and their nutritional value well investigated, this is the first report of their suitability as excipients for use in the pharmaceutical industry and the possible commercial viability of the Hi-starch variety. It is also the first report of their superiority as binder and disintegrant compared to commercial maize starch in oral tablets.
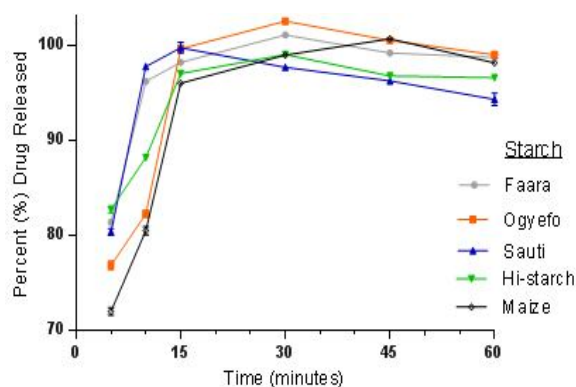

Fig. 4: the influence of the sweet potato starches as extra-granular disintegrant on in-vitro release of paracetamol.
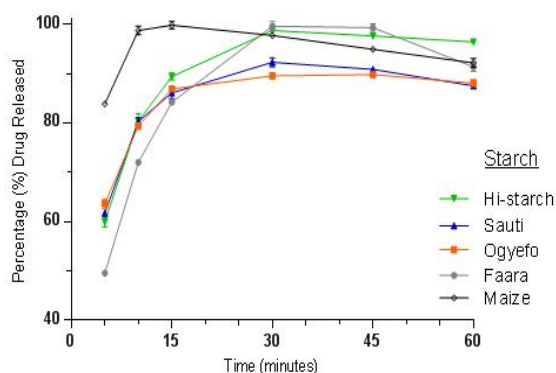

Fig. 5: the influence of the sweet potato starches as paste binder on in-vitro paracetamol release.

CONCLUSION

The sweet potato starches had superior bulk properties which could present them as possibly more robust and effective diluents compared to commercial maize starch. The sweet potato starches were superior to the commercial maize starch as tablet binder in concentrations of 3 - 8 % w/w. They also, demonstrated stronger disintegrant capacity in concentrations of 1 - 3 % w/w; with an *in-vitro* dissolution pattern in paracetamol tablets that suggests a quicker onset of action than tablets with maize starch disintegrant.

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