Preliminary investigations of banana (*Musa paradisiaca*) starch mucilage as binder in metformin tablet formulation

Sylvester Okhuelegbe Eraga*, Matthew Ikhuoria Arhewoh, Janet Olamiposi Agboola and Magnus Amara Iwuagwu
Department of Pharmaceutics and Pharmaceutical Technology, Faculty of Pharmacy, University of Benin, PMB, Benin City, Nigeria

Abstract: The binding properties of banana (*Musa paradisiaca*) starchwas investigated using maize starch BP and polyvinylpyrrolidone (PVP) as standards in the formulation of metformin tablets. Starch from unripe banana fruits was extracted with distilled water. Mucilages of the banana and maize starches and solutions of PVP at 5 and 10 %w/v were used to produce metformin granules by wet granulation and compressed into tablets. Granules and tablets properties were evaluated. Compatibility studies using differential scanning calorimetry (DSC) and Fourier transform infrared spectroscopy (FTIR) were also carried out. Granules flow properties was of the order: PVP >banana starch > maize starch. DSC and FTIR analysis reveals no interaction between excipients and metformin. Increase in concentration of banana starch mucilage from 5-10% w/v led to an increase in hardness, disintegration time and decrease in friability of the tablets. Tablets of banana starch mucilages were comparable in tablet properties with those of maize starch mucilages and PVP solutions with no significant differences ($p<0.05$). The tablets exhibited crushing strength, friability and disintegration time values ranging from 6.75-12.00 kp, 0.82-1.50 % and 11.04-14.51 min, respectively. The tablet parameters met compendial requirements at binder concentrations studied except friability values for tablets of PVP. Results revealed that banana starch could be used as a binding agent in metformin tablet formulation due to its comparable binding property with maize starch BP and PVP.

Keywords: Banana starch, characterisation, mucilage, metformin, tablets.

INTRODUCTION

One of the most frequently and commonly used binders in the tablet manufacturing process are starches. Starches of various sources used as binder in its mucilage or dry powdered form have been studied and successfully evaluated (Olayemi *et al*., 2008; Eraga *et al*., 2014). Maize starch is the most common of the starches and despite its extensive use, researchers are still in search of other sources of botanical starches for use as tablet excipients (Olayemi *et al*., 2008; Oyi *et al*., 2009; Eraga *et al*., 2014).

Initial official and unofficial screening and evaluation of these starches from newer sources have shown that they possess some of the desirable properties of good excipients (Adebayo and Itiola, 1998). Various starches have been studied in these preliminary evaluations, examples includes; *Dioscorea rotundata* starch, studied for its binding and disintegrant activity (Iwuagwu *et al*., 1986) as well as its compressional properties (Itiola *et al.*, 2006) in tablet formulations. The compressional, mechanical and disintegration properties of starches from pigeon pea and plantain have also been evaluated in paracetamol tablets (Kunle *et al*., 2006) and the binding effect of ginger starch in acetaminophen tablets (Ibezim *et al*., 2008).

**Corresponding author:* e-mail: eragaso@uniben.edu

The cohesiveness of granules for tableting is usually imparted by binders as they promote improved flow properties of the granules by the formulation of granules of desired hardness and size as well as intact tablets after compression. Certain criteria must be considered in the selection of any binder intended for use in tablet formulation and these includes; a good knowledge of the properties of the binder and also of the interactions between the various materials constituting a tablet (Mattsson, 2000).

Banana belongs to the family Musaceae and there are probably over 30 well known species within the genus Musa and more than 700 varieties (De la Torre-Gutierrez *et al*., 2008).

It is a popular fruit that is highly nutritious and delicious. It can be eaten either raw as a daily fruit, as a dessert, or cooked as a tasty tropical dish. Usually, ripe bananas are soft and sweet, and are consumed raw while unripe bananas contain lots of starch and fibre.

Banana starch forms colourless viscous mucilage. It is extracted from the fruits of banana (*Musa paradisiaca*), which grows well in Nigeria and employed as food item (Onyenekwe *et al*., 2013). Although reports have shown that starches extracted from other locally available cereals and tubers can be employed in tablet formulation, little information exist on the use of banana starch as a tablet excipient.

This study was designed to evaluate the binding properties of banana (*Musa paradisiaca*) starch mucilage in comparison to maize starch mucilage and polyvinylpyrrolidone in metformin hydrochloride tablets.

MATERIALS AND METHODS

Materials

Banana (*Musa paradisiaca*) was purchased from a local market in Okeigbo town, Ondo State, Nigeria and the starch was extracted by maceration in distilled water. Other reagents include metformin hydrochloride (Spring Nigeria Enterprises, Lagos, Nigeria), poly-vinylpyrrolidone K 30 (PVP) (ISP Technologies Incorporated, NJ, USA), maize starch BP (Roquette Freres, France), lactose (May and Baker, Nigeria), sodium hypochlorite (Reckitt and Coleman Nig. Ltd), microcrystalline cellulose (Avicel®) and talc (BDH. Laboratories, UK) and magnesium stearate (Hopkin and Williams, UK) were all utilized as obtained.

Methods

Extraction of banana starch

The method described previously by Kayisu *et al*., 1981 was employed. The unripe green banana was peeled and sliced into pieces using a kitchen knife. The sliced pieces were grinded 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 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 2 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 micronized into fine powders using a ball mill. The powder was passed through an 850 µm sieve (No. 18, BSS Endecott) and further dried in an oven at 60ºC for 6h. The percentage starch yield from the extraction process was determined using Equation 1, where Wm is the weight of banana starch after drying and Wt is the total weight of banana used for the extraction.

$$Yield\ (\%) = \frac{Wm}{Wt} \times 100 \qquad (1)$$

Characterization of starch powders

Organoleptic properties

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

Solubility

Starch powder (100mg) 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 (KERRO BL3002, England) and the difference in weight was used as a measure of solubility of the starch powder (Eraga *et al*., 2015a).

Chemical test

A 5 ml of the starch suspension was 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 5g of the starch powder with a tapped volume (V_i) in a 100ml 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 (Vm) noted. The swelling capacity was computed with Equation 2.

$$Swelling\ capacity\ (\%) = \frac{[Vm - Vi]}{Vi} \times 100 \qquad (2)$$

Microscopy

The starch powder was thinly spread over a glass slide and viewed under a light microscope (Labo Microsystems GmbH, Germany) via a calibrated eyepiece and the sizes and shape of the particles were recorded at a magnification of ×40 (MICAM 1.4, ScopeImage 9.0).

Preparation of binder solutions

A 5 and 10% w/v solutions of *Musa paradisiaca* starch was prepared by dissolving 5g and 10g of the starch powder in two separate beakers with 10ml of distilled water and stirred to form a dispersion. Boiling water was immediately poured into the mixture to gel with continuous stirring. The boiled water was used to make the mucilage up to 100ml volume (Odeku and Itiola, 2002, Karr *et al*, 1990). Similar procedures were repeated for maize starch BP and polyvinylpyrrolidone.

Preparation of metformin granules

The formula used in preparing the metformin granules using the wet granulation method are shown in table 1. Six batches were prepared, consisting of two batches of *M. paradisiaca* starch (R1, R2), two batches of maize starch BP (R3, R4) and two batches of polyvinylpyrrolidone (R5, R6). Fifty grams of metformin powder, 5g of lactose and 1.25g of microcrystalline cellulose were weighed and mixed intimately in a mixer for 5min. Sufficient quantity of the binders (*M. paradisiaca* starch or maize starch or polyvinylpyrrolidone) was added to the mixture with continuous mixing to produce a wet mass. The wet mass was passed through a 2.80mm aperture sieve and the resulting granules dried in an oven (Gallenkamp, UK) at 60ºC for 30 min. The granules were rescreened through a 710µm aperture sieve and further dried for 30min. The other half of the disintegrant, glidant and lubricant 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.

Table 1: Formula of prepared metformin granules and tablets

Ingredients	Quantities/tablet	Quantities/batch
Metformin	500 mg	50g
Lactose	50 mg	5g
Microcrystalline cellulose	25 mg	2.5g
Binder solution*	q.s	q.s
Magnesium stearate	1 %w/w	1 %w/w
Talc	1 %w/w	1 %w/w

*Binder solution, *Musa. paradisiaca* starch or maize starch BP or polyvinylpyrrolidone (5 and 10 %w/w)

Table 2: Some physical properties of *Musa paradisiaca* starch

Properties	*Musa paradisiaca* starch
Appearance	White
Taste	Tasteless
Odour	Odourless
Texture	Rough
Solubility (30 °C)	Insoluble
Size range (μm)	30 - 130
Form	Polyhedral/Elliptical
Hilum	Elongated cleft
Striations	Striations
Swelling capacity (%)	52
Yield (%)	22.9

Table 3: The micromeritic properties of granules prepared

Binder	Batch	Binder concentration (% w/v)	Bulk density (g/ml)	Tapped density (g/ml)	Flow rate (g/s)	Angle of repose (°)	Hausner ratio	Carr's index (%)
M. paradisiaca starch	R1	5	0.61	0.71	2.61	29.05	1.18	15.2
	R2	10	0.54	0.67	3.14	30.41	1.23	18.91
Maize starch	R3	5	0.61	0.77	2.04	30.25	1.26	21.2
	R4	10	0.57	0.74	2.77	31.18	1.29	22.8
Polyvinyl pyrrolidone	R5	5	0.63	0.74	4.10	27.23	1.16	12.91
	R6	10	0.59	0.71	5.30	30.3	1.20	17.65

Table 4: Some physicochemical characteristics of the metformin tablet

Binder	Batch	Binder concentration (% w/v)	Mean Weight (g)	Crushing strength (kp)	Friability (%)	Disintegration Time (min)
M. paradisiaca starch	R1	5	0.5885 (0.009)	9.25 (0.23)	1.00	11.55 (0.81)
	R2	10	0.5805 (0.008)	11.60 (0.70)	0.82	14.18 (1.25)
Maize starch	R3	5	0.5865 (0.011)	7.55 (0.05)	0.98	11.29 (1.17)
	R4	10	0.5810 (0.011)	12.00 (0.84)	0.83	14.51 (0.70)
Polyvinyl pyrrolidone	R5	5	0.5830 (0.011)	6.75 (0.79)	1.50	11.04 (1.91)
	R6	10	0.5790 (0.011)	7.25 (0.01)	1.35	13.16 (0.68)

Standard deviation values are listed in parenthesis

Differential scanning calorimetry (DSC) characterization

DSC analysis was carried out on the banana starch sample using the Netzsch DSC 204F1 Phoenix apparatus (Netzsch Germany). Four milligrams of the sample was weighed into an aluminium pan. The seal was pierced and calibration of the calorimeter was done with indium. Heating of the sample was carried out at the rate of 10°C per min from 30 to 350°C under nitrogen at a flow rate of 70 ml/min.

Fourier transform infra-red (FTIR) characterization

The analysis of the samples was done using an FTIR Spectrophotometer (Spectrum BX, Perkin Elmer, England) and the potassium bromide tablet method was used. Five milligrams of the sample was blended with potassium bromide to 200mg. The powder was compressed using a sigma potassium bromide press into a tablet shape. The tablet was placed in the sample compartment and the IR scan was carried out at a range of 4000-1000cm^{-1}.

Analysis of granules

Pre-compression analyses were carried out on the granules using standard procedures; bulk density, tapped density, Carr's (Compressibility) index, Hausner's quotient or ratio, flow rate and angle of repose (Eraga *et al*., 2015b)

Flow rate

Thirty grams of the metformin granules was allowed to pass through the orifice of an Erweka flow tester and the time taken was recorded. The mean time of three determinations was reported.

Angle of repose

The hollow cylinder method was used. A hollow cylinder of 3 cm in diameter fixed to a flat surface was filled with granules. The cylinder was slowly pulled up allowing granules to form a cone-like heap on the flat surface. The height of the heap was measured and the angle of repose, θ, was calculated using Equation 3.

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

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

Compatibility studies

DSC and FTIR compatibility studies were carried out on the metformin granules and pure metformin powder.

Compression of granules

Compression of the granules into tablets was carried out with a single punch tableting machine (F-3 Manesty Machines, UK) at compression pressure of 23 arbitrary units (AU). Die volume was adjusted to compress tablets of uniform weight by using granules weighing 580mg. The tablets made were then kept in air tight containers and stored in a desiccator until evaluation.

Tablet evaluation

Post compression evaluations carried out on the compressed tablets includes; tablet weight uniformity, crushing strength, friability, disintegration time and dissolution rate (BP, 2009).

Weight uniformity

Twenty tablets from each batch were used for the test. The weight of each tablet was determined and the mean or average weight and standard deviation was computed.

Crushing strength

Using a motorized tablet hardness tester (Campbell Electronics, Model HT-30/50, India), the crushing strength of ten individual tablets per batch was determined by diametric compression. The mean and standard deviation values were calculated.

Friability test

Pre-weighed tablets (10) were placed in the drum of a friabilator (Erweka GmbH, Germany) revolving at 25 rpm. After 4 min, the tablets were brought out, de-dusted and reweighed. Their percentage loss in weight value was calculated. Triplicate determination was carried out and the mean and standard deviation were reported.

Disintegration time

The time taken for six tablets per batch to disintegrate in distilled water at 37±2.0°C were determined using the BP disintegration tester (MK IV, Manesty Machines, UK). The mean or average time and standard deviation was calculated.

Dissolution studies

The *in vitro* dissolution analyses of the various batches of the metformin tablets were carried out using the BP paddle method. A dissolution apparatus (Caleva ST7, UK) containing 900 ml of phosphate buffer pH 6.8 solution thermo stated at 37±0.5°C with a revolution speed of 50 rpm was used. Aliquot samples (5ml) were withdrawn from the dissolution fluid at specific time intervals for 60min and replaced with an equivalent volume maintained at the same temperature (37±0.5°C). The samples withdrawn were filtered and diluted appropriately with the phosphate buffer solution. The resulting solutions were subjected to spectrophotometric analysis at λmax of 233nm (T70, PG Instruments Ltd). The concentration and percentage of metformin released at the various time interval was computed from the equation of the standard calibration plot of the pure metformin powder. Triplicate determinations was carried out.

STATISTICAL ANALYSIS

The data from the tablet batches were subjected to statistical analysis using the student's t-test at the 5 % level of significance with GraphPad InStat software version 3.10.

RESULTS

Starch powder properties

Some of the physical properties of the starch powders are shown in table 2. The starch powder of *Musa paradisiaca* was white, odourless and tasteless with a rough texture. It is insoluble in water and give blue black colouration with iodine solution. Microscopic examination of the starch

particles showed a range of shapes from polyhedral to oval or elliptically shaped particles with a large particle size range (fig. 1). The swelling capacity of 52% would indicate that *M. paradisiaca* could be a good disintegrant. The percentage starch yield obtained from the extraction was 22.9%. This is similar to the range of 21-26% reported by Jaffe *et al*., 1963 and Marriott and Lancaster, 1983, for green plantains. The DSC characterization of the starch powder reveals a powder that is amorphous in nature with a wide melting point temperature range of 79-85°C and a glass transition temperature of 82.5°C (fig. 2 (a)) while the FTIR analysis shows some characteristic absorption bands: -OH or -NH (3400-3550cm^{-1}), CH (2924 cm^{-1}), C=O (1730cm^{-1}), H-O-H (1648 cm^{-1}), C=O with aromatic ring (1634cm^{-1}) and CH_2 (1430 cm^{-1}) (fig. 3 (a)).

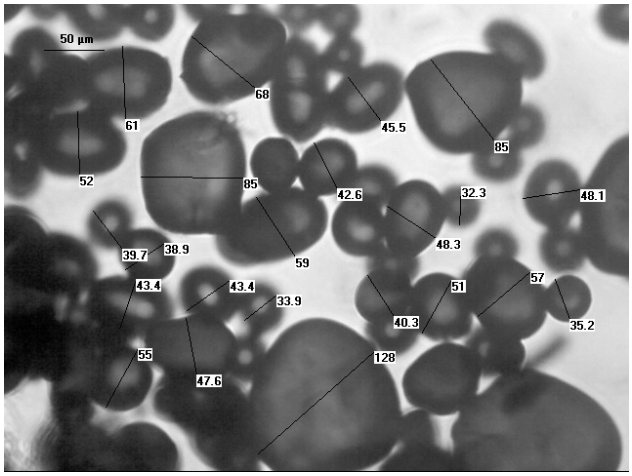


Fig. 1: Microscopy of banana (*M. paradisiaca*) starch Magnification: X40

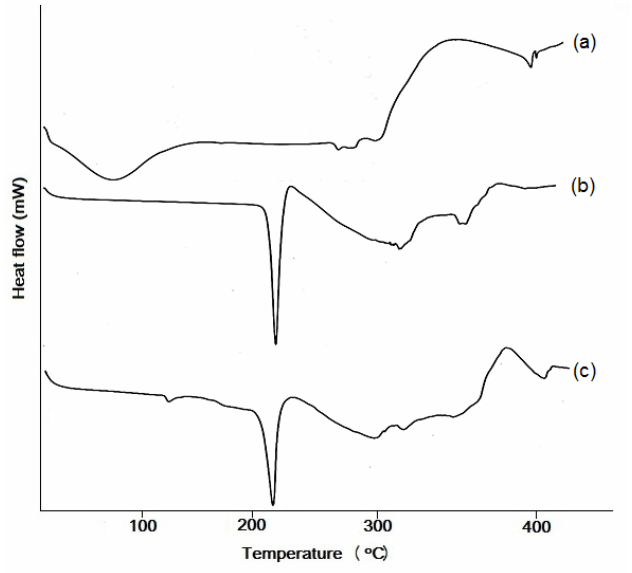


Fig. 2: DSC of (a) banana (*M. paradisiaca*) starch, (b) metformin powder and (c) metformin granules prepared with banana (*M. paradisiaca*) starch

Granule properties

The results of the flow properties of the granules are presented in table 3. The bulk and tapped densities of the metformin granules produced using *Musa paradisiaca* starch mucilage (R1 and R2), maize starch mucilage (R3 and R4) and polyvinylpyrrolidone (R5 and R6) did not show any significant difference, i.e. $p>0.05$. The R1, R5 and R6 batches of granules exhibited better Hausner ratios and Carr's indices. All the granules exhibited satisfactory angle of repose (≤34) at all binder concentrations. There was a decrease in flow rate with increasing binder concentration, this could be as a result of increased bonding and cohesiveness between particles leading to reduction in the flow of granules (Abdulsamad *et al*., 2008). Overall, the granule flow properties is of the rank order; polyvinylpyrrolidone > banana starch > maize starch.

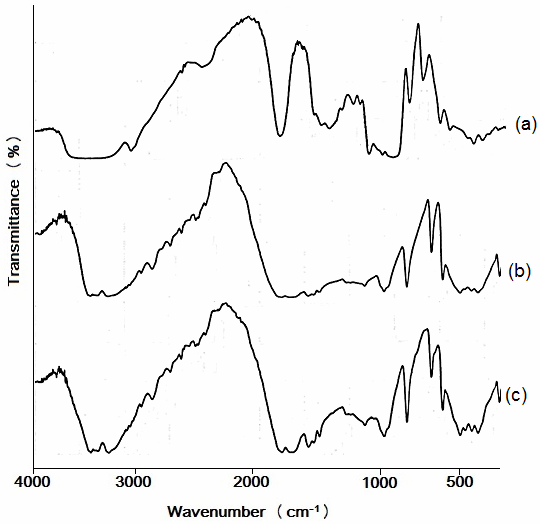
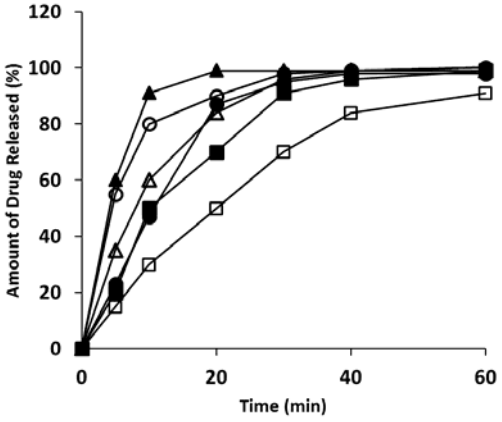


Fig. 3: FTIR of (a) banana (*M. paradisiaca*) starch, (b) metformin powder and (c) metformin granules prepared with banana (*M. paradisiaca*) starch



M. paradisiaca starch: 5% (■), 10% (□); Maize starch BP: 5% (▲), 10% (Δ); PVP: 5% (●), 10% (○)

Fig. 4: Dissolution profile of metformin tablets using varying amounts (w/w) of *M. paradisiaca* starch, maize starch BP and polyvinylpyrrolidone (PVP)

Compatibility studies

Thermal analysis

Fig. 2(b) and (c) shows the DSC thermograms of pure metformin powder and the granules. Metformin thermogram shows a sharp endothermic peak, corresponding to its melting point (225°C). This sharp peak which appears as a spike is indicative of the purity and crystallinity of metformin. On the other hand, the thermogram of the granules containing excipients and metformin together showed the characteristic peak of pure metformin at the middle.

FTIR

The FTIR spectrum of pure metformin powder showed characteristic peaks at 1058.85, 1625.99, 3172.90 and 3369.64cm^{-1} (fig.3(b)). These peaks observed for metformin remained unchanged when compared with the spectral data of the granules (fig. 3(c)). This observation indicate the absence of chemical interaction and complex formation between metformin and excipients during the mixing process.

Tablet properties

Table 4 shows some properties of the metformin tablets formulated. There were no significant differences ($p > 0.05$) among the weights of the tablets irrespective of the type and concentration of binder used and hence conformed to pharmacopeia specification that states not more than two of the individual weights of the 20 tablets should deviate from the average weight by more than ±5 % and none should deviate by more than ±10% (BP, 2009). There were significant differences ($p<0.05$) in the tablet hardness amongst the binders with tablets prepared with *M. paradisiaca* starch showing higher values. Also, there was increase in tablet crushing strength (hardness) with increase in binder concentrations. The friability values of the tablets decreased with increasing concentrations of the binder. However, all the tablets did not met the BP specification of a 0.8-1.0% maximum loss of the weight of tablets tested (BP, 2009). All the formulated tablets did not disintegrate within 15 min as specified by BP for uncoated tablets, but the results showed an increase in the disintegration time with increase in the binder concentration. Results from the dissolution studies (fig. 4) show that the dissolution rate decreased with increase in concentration of binder except in the case of polyvinylpyrrolidone, which is probably due to the fact that dissolution correlates with or is directly proportional to disintegration. However, all the tablets formulated passed the BP dissolution test for tablets which specifies that at least 75 % of the drug should be in solution after 45 min (BP, 2009).

DISCUSSION

The binding ability of *M. paradisiaca* starch in comparison with maize starch BP and poly-vinylpyrollidone have been evaluated in this study. The starch of *M. paradisiaca* exhibited a wide size range of its particles which would facilitate the smaller particles filling the void spaces created by larger ones. This is in line with Newman, 1967, who showed that consolidation of powder particles results from low densities where there is none filling of void spaces by the smaller particles and this is a feature of maize starch. The improvement in the flow properties of the granules with increasing binder concentration is consistent with the formation of granules that are larger in sizes as the concentration of binders increased leading to larger voids in between the larger granules. This increase in particle sizes would also lead to a faster flow of the granules as a result of their reduced surface free energy and frictional forces between the particles (Iwuagwu *et al*., 1986).

All the tablets gave good crushing strength values above 5 kp. Hardness values greater than or equal to 4kp are considered optimal and acceptable (Rudnic and Schwartz, 2000). Increase in the binder's concentrations caused a corresponding increase in tablets hardness and a decrease in friability. This increase in hardness could be attributed to the binder's adhesiveness, leading to increased bonding among the granules as a result of asperity melting and the plastic and elastic deformation of the granule particles during compaction (Musa *et al*., 2008). Plastic deformation of particles by binders has also been implicated in increasing the area of contact for interparticulate bonding (Uhumwangho *et al*., 2006) and consequently promoting solid bond formations in the tablet. The mechanical strength of a tablet (hardness and friability) is majorly due to inter-particulate bonding which could be Van Dar Waal's forces, mechanical interlocking or the formation of solid bridges via the binder.

The dissolution pattern agreed with the disintegration-dissolution theory, which indicates that the disintegration process is primordial to dissolution since it determines to a considerable extent, the contact area between the liquid and solid (Odeku and Itiola, 2003). That is to say that tablets would have to disintegrate before the drug is released maximally into solution. Some authors further explained that disintegration and dissolution times are correlated as particle size of a tablet's primary particles and the total surface area exposed upon the tablet's disintegration, strongly influence the dissolution time of the drug in the tablet formulation (Rubeinstein and Wells, 1997; Iwuagwu *et al*., 2001). At 60min, only the tablets formulated with 10% w/v of the *M. paradisiaca* starch did not release 100% of the drug, which goes to support that a 5% w/v of the starch concentration is optimum for *M. paradisiaca* starch powder as a binder.

CONCLUSION

From this study, it can be concluded that *Musa paradisiaca* starch mucilage could be effectively used as a

binding agent in metformin tablet formulation. This starch mucilage has proven to be a useful substitute for the standard binders (maize starch mucilage and polyvinylpyrrolidone) due to its remarkable binding property. Commercial production of *Musa paradisiaca* starch would be easier because it is readily available and affordable. In addition, extraction is easy and cost effective although the yield is not very high. It may therefore be a worthy venture for the pharmaceutical industry to invest in the large scale production of *Musa paradisiaca* starch.

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