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The physico-chemical and filler-binder-disintegrant properties of improved hydrophilic powder derived from the fibre of *Ipomoea batatas* tuber in paracetamol tablet

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ABSTRACT

Objectives: The physico-chemical and filler-binder-disintegrant properties of improved hydrophilic powder (HP) derived from the fibre of Ipomoea batatas tuber in a paracetamol tablet was studied.**Materials and Methods:** A 200 g of the powdered fibre was blended with 600 ml of 0.125 N NaOH and washed with deionized water until neutral, then stirred in 200 ml of 0.50 N HCl, washed until neutral. It was precipitated with 96 % v/v ethanol, dried in a desiccator, pulverized to 250 μm and coded as HP. It was characterized and applied as a filler-binder-disintegrant in paracetamol tablet by wet-granulation and direct- compression beside avicel® PH 101 for comparison as well as a plain natural fibre powder (NFP) as a control. **Results and Discussion:** The HP was amorphous with high hydration and swelling capacities. Tablets with uniform weight and acceptable mechanical strength were obtained. The tablets generally disintegrated in less than 30 sec, leading to dissolution efficiency of 78.65±0.02% and 81.44±0.01% of paracetamol for the HP in wet-granulation and direct-compression compared to 52.34±0.02% and 57.87±0.03% for avicel PH 101 in wet-granulation and direct-compression respectively. **Conclusion:** The HP exhibited good filler-binder-disintegrant properties in paracetamol tablet and was better than the avicel PH 101.

Keywords: Filler-binder-disintegrant, Ipomoea batatas, Hydrophilic-powder, Paracetamol-tablet

INTRODUCTION

The need for new excipients in the design of pharmaceutical products creates an increasing span of attention for the pharmaceutical industry. This is motivated by the rising need for more flexible excipients in terms of enhanced performance and the need to simplify the development of new drug delivery systems.[1] Excipients are materials added along with the active pharmaceutical ingredient (API) in the course of the formulation of a pharmaceutical dosage form[2,3] to ease the preparation of the product and its administration to the patient through the anticipated route to ensure enhanced dosing compliance, reliability and control of drug bioavailability, better drug product stability, etc.[4] Excipients are generally used in drug delivery systems[5] as fillers or bulking agents in the formulations that contain very potent active ingredients, making room for suitability, and accuracy of dosage. They are also relevant as disintegrants, binders, lubricants, glidants, etc. Excipients such as polymers are utilized in modified release dosage forms, protection of the API in enteric resistance dosage forms (e.g., Eudragit®). They are equally used in the coating of tablets, capsules, granules, or microspheres. Their usefulness has been extended in the formulation of orodispersible tablets in which tablets quickly disintegrate without chewing when placed on the tongue without the addition of water. Further, they are useful as viscosity enhancers in the formulation of solutions or suspensions and as wetting agents in the dispersion of hydrophobic APIs, etc.[4,6,7] Some pharmaceutical excipients are of natural origin, mainly the plant. Some of the naturally based excipients include starch, agar, alginates, guar gum, xanthan gum, gelatin, pectin, acacia, tragacanth, and cellulose-based excipients. Their advantages include being

of renewable source, low cost, biocompatibility, and eco-friendliness.[4,5]

Seeing that a good number of excipients are of plant origin,[8] the agro-biomass is made up mostly of cellulose, hemicellulose, and lignin. Cellulose is the highest available form of polysaccharide on earth and is a very systematic polymer of cellobiose. Renewable reserve-based biopolymers such as starch and other biodegradable polymeric materials make up to 85.0% of the total production bulk, the remaining amount is made up of the synthetic biopolymers.[9] Cellulose is a biological complex that is found in the cell wall of plants, some bacteria, and algae which add to lignin to give the strength for the cell wall of plants. It is found in numerous parts of several plants within our surroundings such as stem and bark of trees, leaves, fibrous roots, and tubers. Cotton linters and fast-growing plants are reported to be the highest sources of cellulose. Quite a lot of pharmaceutical excipients having manifold uses such as microcrystalline cellulose and methylcellulose are derivatives of cellulose.

Ipomoea batatas, a member of the family Convolvulaceae, is a significant arable food crop cultivated in the tropics, subtropics, and warm climate regions of the world due to its ability to provide tubers that are rich in starch, cellulose, etc. Up to 90.0% of the content of the sweet potato tuber constitutes carbohydrates and is mainly starch, cellulose, hemicellulose, sugars, and pectin.[10-12] Some excipients have been derived from the tubers of *I. batatas* and applied in some areas of pharmaceutical formulations. A novel hydrophilic biopolymer (*I-polygel*) derived from the tubers of the *I. batatas* has been processed, characterized, and evaluated as a suspending agent in sulfamethoxazole suspension. Its effect as a granulating agent in the paracetamol tablet formulation has also been reported.[13-15] A hydrophilic cellulose matrix has also been derived from the fiber obtained from *I. batatas* tuber. It was characterized and applied as a filler-disintegrant in piroxicam oral dispersible tablets.[16,17] The hydrophilic cellulose matrix was useful as a disintegrant in paracetamol tablet.[18]

Excipients have been employed in various applications in the solid dosage formulations such as the tablets and capsules. Tablets and capsules are ideal dosage forms since they can be accurately used in the management of ailments with good patient compliance. The technology employed in their preparation is simple and cost-effective. The high acceptance of tablets by patients coupled with an improved consideration of the physics of powder compression and manufacturing process variables have developed the production of tablets as science on its own.[19] Tablets could be prepared either by the wet granulation (WG), dry granulation, or direct compression (DC). The latter comprises the compression of a dry mixture of powders and drug. The simplicity and cost-effectiveness of the DC procedure have made it a preferable option than the WG technologies.[20] Although several excipients have been derived from the fiber of *I. batatas* tuber and applied in different areas of pharmaceutical formulations as reported in the literature,[13-18] these excipients demonstrated low powder flowability and compressibility. In the current study, an improved multifunctional hydrophilic powder (HP) was developed from the tuber of *I. batatas* by another procedure to enhance its flowability and compressibility. Its physicochemical properties and filler-binder-disintegrant effect in paracetamol tablet were evaluated using Avicel PH-101 as a standard and the plain natural fiber powder (NFP) as a control.

In this study, an improved multifunctional hydrophilic cellulose powder (HP) derived from the fiber obtained from *I. batatas* tuber is studied for its physicochemical properties and its filler-binder-disintegrant effect in the tableting of paracetamol is also evaluated applying the WG and DC methods alongside microcrystalline cellulose (avicel PH 101) for comparison.

MATERIALS AND METHODS

Materials

The following materials were used as procured; sodium hydroxide (Tianye Chemicals, China), ethanol (96% v/v), *n*- hexane (JHD), China), and hydrochloric acid (Loba Chemie, India).

Methods

Procurement, identification, and processing of HP

The *I. batatas* tubers were obtained in Port Harcourt, Nigeria and identified in the University of Port Harcourt central herbarium with a specimen voucher no: UPH/V/1263. A 35 kg of the tubers were peeled, washed, sliced, and milled into a wet paste which was washed through a muslin cloth to separate the starch from the fiber. The fiber was washed severally and dried at 60°C in an oven (Memmert, England). The dried fiber was pulverized and sized with a 250 µm stainless sieve (Retch, Germany). A 200 g of the pulverized fiber was blended at room temperature for 30 min in 600 ml of 0.125 N sodium hydroxide to delignify the fiber after which it was washed with deionized water till it as neutral. The wet mass was blended at room temperature for 30 min in 200 ml of a 0.5 N hydrochloric acid to hydrolyze it. It was washed with water until neutral. It was thrown into an ethanol (96% v/v) to precipitate the product which was pulverized, passed through a 250 µm stainless sieve and is referred to as the HP.

Characterization of HP

The HP was characterized as outlined below. Tests were repeated in triplicate. The mean and standard deviation (SD) were calculated as appropriate in each case.

Organoleptic, solubility, and pH tests

The color, odor, and texture of the HP were noted. Its solubility was evaluated in water and some organic solvents. The pH of a 2.0% w/v of its aqueous dispersion was determined with a pH meter (Corning, model 10, England).

Densities

The bulk and tapped densities of a 15 g of the HP were determined using a Stampfvolumeter (STAV 2003JEF, Germany). The particle density was evaluated through the displacement method using a 25 ml pycnometer and *n*-hexane as a non-solvent.[21] The weight of the pycnometer (w) was recorded (Mettler, Germany). On filling the pycnometer with *n*-hexane, the new weight (w_1) was noted. The weight of *n*-hexane (w_2) was obtained by subtracting w from w_1. A 0.5 g

(w_3) of the HP was introduced into the pycnometer holding *n*-hexane, the later weight being noted as w_4. The densities of the sample were calculated from equations 1-3.

$$Bulk\ density = Weight\ of\ powder/Bulk\ volume\ of\ powder \quad (1)$$

$$Tapped\ density = Weight\ of\ powder/Tapped\ volume\ of\ powder \quad (2)$$

$$Particle\ density = W_2 \times W_3\ V\ (W_3 - W_4 + W_2 + W) \quad (3)$$

Where V = Volume of pycnometer, 25 ml.

Flow properties

The funnel method[22] was used in determining the flow rate of the HP. The time for the complete outflow of 30 g of the powder positioned in the funnel was recorded. The angle of repose was determined using the fixed funnel method as reported by Zeleznik and Renak.[23] The funnel was clamped with its tip 3 cm above the horizontal base. The HP powder was poured through the funnel until the apex of the heap of the powder formed reached the tip of the funnel, thus, stopping the flow of the powder through the funnel. The mean diameter of the base of the powder heap was estimated. The flow rate and the angle of repose were calculated from equations 4 and 5, respectively.

$$Flow\ rate = Mass\ of\ Powder/Time \quad (4)$$

$$Angle\ of\ repose,\ \theta = tan^{-1}\ (2\ h/d) \quad (5)$$

Where h = the height of the powder heap, d = base diameter of the powder heap.

Other parameters such as the Hausner's ratio[24] and Carr's index[25] were calculated using equations 6 and 7.

$$Hausner's\ ratio = Tapped\ density/Bulk\ density \quad (6)$$

$$Carr's\ index = [(Tapped\ density - Bulk\ density)/Tapped\ density] \times 100 \quad (7)$$

The porosity was calculated using equation 8.

$$Porosity = [1-(bulk\ density/true\ density)] \times 100 \quad (8)$$

Scanning electron microscopy (SEM)

SEM of the HP was carried out using an SEM EVO MA-10 instrument (Carl Zeiss, Jena) at an acceleration voltage of 20Kv and probe current of 227Pa.

X-ray diffraction (XRD)

The XRD of the HP was established using the X-ray diffractometer, Thermo Scientific model ARL X'TRA (Walkman, Massachusetts, USA).

Moistures studies

Moisture content

The moisture content of the HP was determined using a digital moisture balance (Citizen, MB-50, China). With a 2 g of the powder weighed on the instrument, it was programmed to heat at 105°C. The device automatically switched off when the peak moisture contained in the powder has been evaporated by the heat generated from the halogen lamp. The moisture content was displayed digitally in percentage.

Moisture sorption capacity

A 50 ml of saturated solutions of magnesium nitrate, sodium chloride, magnesium chloride, and potassium sulfate, respectively, were prepared at ambient temperature to represent relative humidity (RH) of 52, 75, 84, and 96%, respectively.[26] These were held in air-tight desiccators serving as RH chambers. A 0.50 g of HP powder was weighed into crucibles in triplicate and placed in the respective RH chambers. The weight gained by the exposed HP after 5 days was recorded. The moisture sorption was calculated from the variation in weight expressed in percentage.

Hydration capacity

A 1 g of HP noted as *y* was placed in a 15 ml plastic centrifuge tube and submerged with 10 ml of deionized water and stoppered. The tube was agitated for 20 min, stood for 10 min, and ran in a centrifuge (PEC medicals, USA) at 3000 revolutions per minute (rpm) for 10 min. The supernatant water was poured out and the weight of the wet deposit due to uptake of water was noted as *x*.[27] The hydration capacity was calculated using equation 9.

$$Hydration\ capacity = x/y \quad (9)$$

Where: x is the weight of the wet HP after centrifugation and y is the weight of the dry HP.

Swelling index

A 5 g of HP in a 100 ml glass measuring cylinder was tapped to give a volume, *Vx*. It was then suspended in 85 ml of water and later made up to 100 ml and left for 24 h. The volume of the sediment, *Vv* was recorded.[28] The swelling index was calculated using equation 10.

$$Swelling\ index = Vv/Vx \quad (10)$$

Where *Vv* is the volume of sediment and *Vx* is the tapped volume occupied by 5 g of HP powder.

Ash contents and extractive values

The total, acid-insoluble, and water-soluble ashes, ethanol and water extractive values of the HP were determined using the procedures defined in the USP, 2007[29] and WHO Quality Control methods for herbal substances (1998).[30]

Total ash

A tarred nickel crucible was ignited to a constant weight at a dull red heat, cooled, and stored in a desiccator. A 2 g of the HP placed in the crucible was ignited at 550°C in a muffle furnace (Heraeus, D-2800, Bremen, Germany) until it was free from carbon. The dish was cooled in a desiccator and reweighed. The per cent total ash was calculated using equation 11.

$$\%\ Total\ ash = weight\ of\ ash/weight\ of\ original\ powder \times 100 \quad (11)$$

Acid insoluble ash

A 0.20 g of the ash obtained from the determination of the total ash was boiled with 25 ml of 2 N hydrochloric acid for 5 min. The insoluble residue was collected in a glass crucible, washed with hot water and ignited at 500°C for 20 min in a furnace. The percentage of acid-insoluble ash was calculated.

Water-soluble ash

A 0.20 g of the ash got from the total ash content was boiled with 25 ml of deionized water for 5 min. The insoluble residue was collected in a glass crucible and ignited at 500°C for 20 min in the furnace. The weight of the residue was subtracted from the weight of the ash and the difference was taken as water-soluble ash. The water-soluble ash was calculated in percentage.

Water extractive yield

A 2 g of the HP was left in a conical flask containing 100 ml of chloroform water for 24 h with intermittent agitation for 6 h and allowing to stand for 18 h. The mixture was filtered rapidly and 15 ml of the filtrate was evaporated to dryness in a beaker over a Bunsen burner. Drying the residue to a constant weight, the water extractive yield was calculated in percentage.

Ethanol extractive yield

A 2 g of the HP was placed in a conical flask containing 100 ml of ethanol (90% v/v) in a closed flask for 24 h with intermittent shaking for 6 h and allowed to stand for 18 h. It was filtered rapidly and 15 ml of the filtrate was evaporated to dryness over a water bath at 100°C. The residue was dried to a constant weight at 100°C and ethanol extractive value was calculated in percentage.

Formulation of paracetamol tablet

The DC and WG methods were adopted in the preparation of tablets containing 500 mg of paracetamol incorporating the HP as a filler-binder-disintegrant. The microcrystalline cellulose (avicel PH 101) (AVC) was employed as a standard. The tablet intended to weigh 600 mg containing 83.33% w/w (500 mg) of paracetamol, 0.25% w/w (1.50 mg) each of talc or magnesium stearate, and 16.17% w/w (97.02 mg) of HP or Avicel PH-101. Applying the DC method, paracetamol powder was blended with the HP or Avicel PH-101, respectively, and lubricated with a blend of talc and magnesium stearate before compression while in the case of WG blend of paracetamol and HP or Avicel PH-101 was moistened with water and kneaded until a good wet mass was achieved. This was passed through a 1.7 mm stainless steel sieve, dried at 60°C, and rescreened with a 1.0 mm sieve. To evaluate the effect of the treatment methods on the NFP got from the *I. batatas* tuber, compacts weighing 600 mg and containing no paracetamol were prepared by DC and WG to serve as a control. The respective batches of powders and granules were lubricated with talc and magnesium stearate and compressed at 1.5 ton using a 12.50 mm flat-faced punch fitted to an automatic single punch tablet press, model SSF3 (Cadmach, India).

Evaluation of tablet properties

The tablets were examined physically and their properties were evaluated using the methods outlined in the British Pharmacopoeia, 2012[31] after 24 h.

Uniformity of weight

Twenty tablets were used and the individual weight of each was determined on an analytical balance (Mettler, Germany).

Hardness and thickness

The respective hardness and thickness of ten tablets were determined using a diametrical digital tablet hardness tester (Veego, India) which digitally displays tablet weight, diameter, hardness, and thickness.

Friability

The friability of ten tablets was determined with a tablet friability (Erweka TAR 220, Germany).

Disintegration time

The disintegration time of six tablets was determined in a tablet disintegration apparatus (Erweka, ZT 122, Germany) in 900 ml of 0.10 N hydrochloric acid maintained at 37 ± 1°C.

Tensile strength

The tensile strength[32] of the tablets was calculated using equation 12.

$$T=2P/\varpi dt \quad (12)$$

Where: T = tensile strength, P = tablet hardness, t = tablet thickness, d = tablet diameter.

Dissolution rate studies

In the dissolution studies, the rotating paddle method (Apparatus 2) (Erweka DT 600, Germany)[29,31] containing 900 ml of phosphate buffer (pH 5.8) at 37 ± 0.5°C and paddle speed of 50 rpm was utilized for a 30 min procedure. Withdrawal of 5 ml sample of the dissolution medium was carried out at intervals of 5 min with a replacement of the dissolution medium each time. The absorbance of each sample was determined in a UV spectrophotometer (Jenway, model 6405, England) at a wavelength of 245 nm.

Statistical Analysis

The figures were presented as a mean ± SD. One-way analysis of variance was performed followed by Fisher's least significant difference *post hoc* test to determine the level of significance.

RESULTS AND DISCUSSION

Physicochemical Properties

General properties

The HP was an odorless, fairly coarse off-white powder which was insoluble in water and various organic solvents at low and elevated temperatures. It swells in the presence of water resulting in a gelatinous dispersion having a pH of 6.8 ± 0.01.

Table 1: The physicochemical properties of the hydrophilic powder

Parameter	Hydrophilic powder	AVC
pH	6.80±0.01	6.98±0.04
Particle size (μm)	185.00±0.15	62.15±0.11
Bulk density (g/ml)	0.36±0.01	0.33±0.01
Tapped density (g/ml)	0.46±0.01	0.44±0.01
Particle density (g/ml)	1.13±0.03	1.42±0.03
Flow rate (g/s)	15.62±0.39	No free flow
Angle of repose (deg)	29.51±0.23	37.04±0.82
Hausner's ratio	1.28±0.03	1.33±0.05
Carr's index (%)	21.77±0.02	25.00±0.01
Porosity (%)	68.07±0.10	69.01±0.31
Moisture content (%)	12.09±0.14	6.75±0.02
Hydration capacity	4.58±0.39	2.19±0.25
Swelling index (%)	406.67±0.24	21.51±0.01
Total ash (%)	1.13±0.03	NA
Acid insoluble ash (%)	0.68±0.03	NA
Water soluble ash (%)	0.42±0.02	NA
Water extractive yield (%)	10.75±0.04	NA
Ethanol extractive yield (%)	9.60±0.03	NA

NA: Not applicable

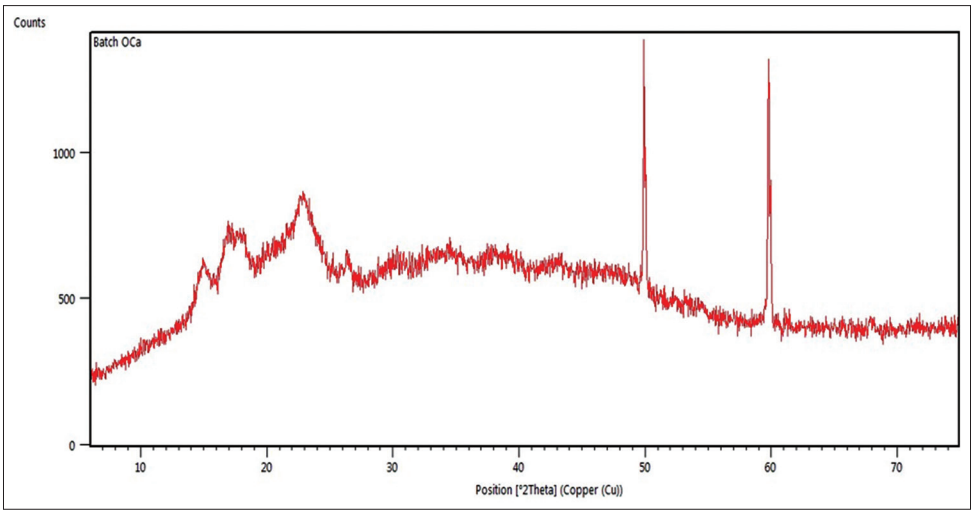

Figure 1: X-ray diffractogram of hydrophilic powder

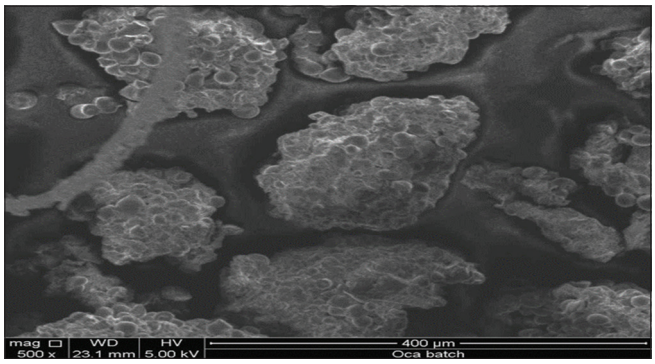

Figure 2: The scanning electron microscopy of hydrophilic powder

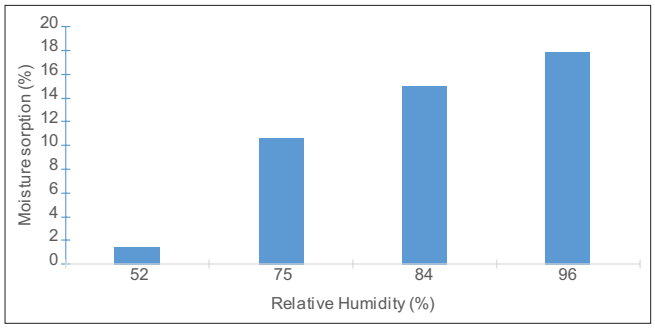

Figure 3: Moisture sorption pattern of hydrophilic powder at various relative humidity

The processing yield of HP was 46.83%, representing the amount obtained from the dry fiber which was modified to obtain HP.

Micromeritic properties

Further results of the physicochemical properties are presented in Table 1. The analysis of the bulk, tapped, and particle densities, as well as the porosity, along with the angle of repose, Carr's index, Hausner's ratio, and the flow rate shows that the HP has the ability to diminish in volume. It is compressible and exhibits good flowability which indicates a low level of interparticulate interaction.[24,25,29,31]

Morphology of HP

The results of the XRD [Figure 1] and SEM [Figure 2] show that the HP exhibits a low degree of crystallinity and is highly amorphous.

Moisture studies

The high moisture content, hydration capacity, swelling index [Table 1], and moisture sorption [Figure 3] show that HP has a high tendency for moisture uptake and retention. This could explain its ability to swell in contact with water forming a gelatinous dispersion. The moisture content of 12.09 ± 0.14% is higher than the official limit of 8% specified in the British Pharmacopoeia, 1993.[33] This is an indication that the HP may not be suitable as a bulking agent for the formulation of solid dosage forms containing a moisture-sensitive drug such as aspirin and ascorbic acid. Swelling is generally recognized as the indication of the tablet to disintegrate and this could be evaluated through the assessment of hydration capacity, swelling index, and moisture sorption studies. With a high value of the hydration capacity obtained [Table 1] the HP may be able to absorb and retain much water. Further, the swelling index reveals the increase in the volume of the HP after water sorption and with the value of 406.67 ± 0.24% recorded [Table 1], it indicates that only a little amount of the absorbed water infiltrated the individual particles triggering their swelling with the higher amount of the absorbed water probably in a "free" state between the particles. If HP was incorporated as a disintegrant in a tablet formulation, it may most likely produce tablet disintegration by two-way actions: Capillary or wicking due to interparticulate water, and swelling. Irrespective of the porosity of 68.07 ± 0.10% recorded for the HP, the exhibition of high hydration capacity and swelling index of the HP may be due to its high proportion of amorphous particles as shown in the XRD [Figure 1] and SEM [Figure 2]. Stamm[34] recognized that the amorphous portion is liable for the uptake and swelling of cellulose substances. The moisture sorption capability of powder is an

estimation of its moisture sensitivity. The moisture sorption capability of the HP increased proportionately with increasing RH [Figure 3]. It has been documented that the crystalline component of cellulose does not absorb water and that the degree of water uptake by cellulose ought to be relative to the amount of existent amorphous cellulose.[34] These results are suggestive of the high proportion of the amorphous particles possibly present in the HP and its possible suitability as a disintegrant.

Ash profiles

The quality of the ash content of an excipient of plant origin is a significant aspect to be evaluated in the quantitative assessment of processed substances which enables the understanding of the extent of its processing concerning value and clarity. Considering this, the total ash, acid-insoluble, and water-soluble ashes are considered to be the ash left after its combustion at various steps. The total ash may include carbonates, phosphates, silicates, and silica. When its value is high, it would probably indicate the presence of an impurity, showing that the sample was not properly processed. On the other hand, acid-insoluble ash shows the extent of such constituents as silica, earth, or sand while water-soluble ash indicates a portion of the total ash that is soluble in water, representing the measure of water-soluble salts existing in the sample.[35-37] Extractive values are mainly beneficial for the estimation of exhausted or contaminated drugs. They are equally important in the assessment of the chemical composition of the crude drug and assists in the approximation of precise components soluble in particular solvents.[38-40] Considering these, the total, acid-insoluble, and water-soluble ashes as well as the extractives of water and ethanol recorded for the HP were below the standard limits[35,41] and show that it was appropriately processed.

Tablet properties

The properties of the glossy and intact tablets prepared with HP or Avicel PH-101 are presented in Table 2. The properties of the plain compacts made with NFP are also shown.

Uniformity of tablet weight

The uniformity of weight of the respective batches of the tablets was within acceptable limit with the coefficient of variation of less than 0.1%, a lower value than 5.0% which is the limit for tablet weight coefficient of variation as specified in the British Pharmacopeia.[31] A similarity in tablet weights was observed for the batches containing HP, Avicel PH-101 or NFP prepared by the WG method and the DC ($P > 0.05$).

Disintegration time

The tablets disintegrated in less than 30 s across the batches with the batches prepared by DC disintegrating in less time than those of WG with the tablets containing HP generally taking the lead ($P < 0.05$). It was recorded that the compacts prepared from the NFP exhibited disintegration time much less than those containing HP [Table 2]. This result could be attributed to the fact that the NFP was poorly compressible and the compacts exhibited very low mechanical strength, thus, exposing them to an easy influx of water which causes their easy break-up. The tablet disintegration obtained based on the values of disintegration time obtained in the study could be described as superdisintegration prompted by wicking and swelling of the HP. For tablets formulated for the immediate release of their active ingredients, the British Pharmacopoeia (BP, 2012)[31] and the United States Pharmacopoeia (USP, 2007)[29] stipulated limit for tablet disintegration time of 15 min and 30 min, respectively. The early disintegration of the tablets prepared with HP was followed by the early release of paracetamol which is evidenced by the high level of drug dissolution efficiencies recorded for the tablets prepared with the HP [Table 2].

Tablet mechanical strength

Tablet friability above 1% was obtained amongst the batches produced by DC while the other batches prepared by WG exhibited percentage friability less than 1% ($P < 0.05$). For uncoated tablets, the British Pharmacopoeia[31] stipulated values less than 1% especially for tablets prepared by WG. It has been reported that the tablets produced by DC could exhibit values of friability above 1%.[42,43] Considering that paracetamol is a poorly compressible powder, the values of the friability obtained at large using the DC method could also be considered. In normal release tablets, values of tablet hardness between 4 and –0 kgf are acceptable.[44,45] In this study, tablet hardness varied. Tablets containing the HP prepared by the DC method exhibited lower values of hardness than those containing Avicel PH-101. However, when the tablets were prepared using the WG method, there was over 70% increase in tablet hardness of the batches containing HP ($P < 0.05$). However, the plain compacts prepared with NFP generally exhibited weakness in mechanical strength observed from their tablet hardness, friability, tensile strength, and

Table 2: Tablet properties

Parameter	HP (WG)	HP (DC)	AVC (WG)	AVC (DC)	NFP (DC)	NFP (WG)
Tablet weight (mg)	602.98±0.58	610.41±0.42	602.28±0.14	611.13±0.55	601.28±0.16	604.56±0.21
Total drug content (%)	99.56±0.05	98.91±0.06	99.75±0.09	98.72±0.07	Nil	Nil
Tablet thickness (mm)	3.31±0.01	3.70±0.01	3.22±0.01	3.41±0.01	3.42±0.11	3.52±0.21
Disintegration time (s)	15.43±0.11	12.12±0.03	23.50±0.02	20.25±0.04	5.20±0.24	7.25±0.34
Friability (%)	0.81±0.03	1.48±0.03	0.43±0.02	1.05±0.01	85.05±1.27	61.15±1.51
Hardness (kgf)	6.56±0.05	4.23±0.06	9.12±0.05	6.79±0.04	1.86±3.25	2.74±2.76
Tensile strength (kg/m^2)	100.10±0.03	58.25±0.02	144.4±0.02	101.46±0.02	0.03±1.34	0.04±1.23
Hardness-friability-ratio	8.10±0.02	2.86±0.02	21.21±0.04	6.47±0.03	0.02±1.23	2.38±1.12
Dissolution efficiency (%)	78.65±0.02	81.44±0.01	52.34±0.02	57.87±0.03	NA	NA

NA: Not applicable, HP: Hydrophilic powder, NFP: Natural fiber powder

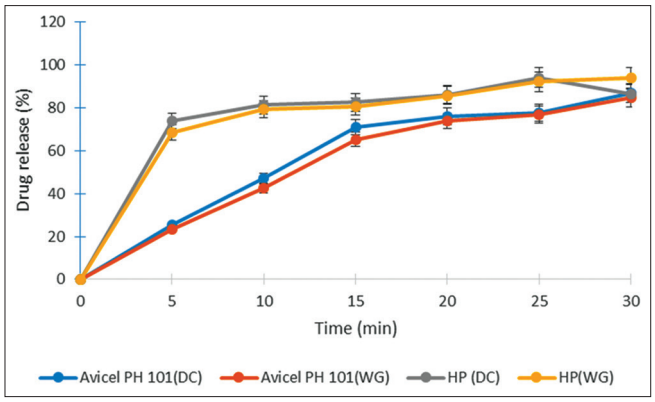

Figure 4: Drug release profiles for paracetamol tablets containing Avicel PH-101 or hydrophilic powder

hardness-friability-ratio (HFR). In considering, the general results got for tablet friability, hardness, tensile strength, and to some extent, HFR, the mechanical strength of batches of tablets could, therefore, be presented as Avicel PH-101(WG) > HP (WG) > Avicel PH-101(DC) > HP (DC) ($p < 0.05$).

Drug release studies

Considering the drug release studies [Figure 4], the release of paracetamol was faster from HP in both the methods of the WG and DC compared to Avicel PH-101 generally, releasing 50% of drug (T_{50}) in 3 min for the batch prepared by DC and 3.50 min for the batch prepared by WG. In the Avicel PH-101, a similar amount was released in 11.50 and 12.50 min for its DC and WG methods, respectively. Further, 80% of paracetamol (T_{80}) was released in 9.50 and 11.25 min, respectively, in the batches of HP prepared by the DC and WG, respectively, while in Avicel PH-101, it was achieved in 26.15 and 26.25 min for its DC and WG, respectively. The British Pharmacopoeia, 2012,[31] specified that for paracetamol tablet formulated for conventional release, not less than 80% of the drug content should be released within 30 min. From the above results, all the batches of tablets prepared with HP or Avicel PH-101 and by DC or WG released up to 80% of their paracetamol content in less than 30 min with those batches containing HP prepared by the DC taking the lead. With the aid of the dissolution efficiency [Table 2], the effectiveness of the release of paracetamol could be presented as HP (DC) > HP (WG) > Avicel PH-101(DC) > Avicel PH-101 (WG). This release pattern shown as noted from the dissolution efficiency imply that the administration of paracetamol tablet prepared with HP either by WG or DC will lead to a faster onset of action and higher paracetamol bioavailability in comparison to such tablet prepared with Avicel PH-101. The effectiveness of the HP to achieve this could be attributed to its enhanced hydrophilic property based on its high amorphous characteristics and low crystallinity attributable to the method of modification used in the treatment of the fiber obtained from the tuber of *I. batatas*. As earlier stated, Stamm[34] recognized that the amorphous portion is liable for the high uptake and swelling of cellulose-based powders since the crystalline component of cellulose does not absorb much water. This could explain the reasons for the lowest disintegration time got for the tablets containing HP against the Avicel PH-101 which led to the quick release of paracetamol and higher dissolution efficiency of the tablets prepared with HP. Avicel PH-101 is a crystalline powder[46] and could not have been more hydrophilic than the HP.

CONCLUSION

The method adopted in the modification of the fiber obtained from the tuber of *I. batatas* resulted in a new powder with enhanced hydrophilic properties. Its application as a filler-binder-disintegrant in the production of paracetamol tablets using the WG and DC methods yielded tablets with acceptable mechanical strength considering that paracetamol is poorly compressible. Tablet disintegration time occurring in less than 30 s across the entire batches exhibited a superdisintegrant action estimated to have occurred by wicking and swelling, leading to a quick release of paracetamol displayed by the high dissolution efficiency of 78.65 ± 0.02% for HP in the WG and 81.44 ± 0.01% in the DC compared to 52.34 ± 0.02% for Avicel PH-101 in the WG and 57.87 ± 0.03% in the DC. The authors, therefore, concluded that the improved HP derived from the fiber of *I. batatas* could serve simultaneously as a filler, binder, and superdisintegrant in the formulation of paracetamol tablets in both the WG and DC methods.

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