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PHYSICOCHEMICAL EVALUATION OF α-CELLULOSE OBTAINED FROM DESTARCHED WHITE AND YELLOW MAIZE CHAFF II: DISINTEGRANT PROPERTIES

***Eraga, S.O., Mbong, D.E. and Iwuagwu, M.A.**

Department of Pharmaceutics and Pharmaceutical Technology, Faculty of Pharmacy, University of Benin, PMB 1154, Benin City, Nigeria

*eragaso@uniben.edu; eijonoehi@yahoo.com; magnus.iwuagwu@uniben.edu

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ABSTRACT

The disintegrant property of cellulose extracted from destarched white and yellow maize chaff in comparison with microcrystalline cellulose (MCC) and maize starch in paracetamol tablet formulations has been investigated. Alpha-cellulose powders were extracted from dried white and yellow maize chaff by acid delignification. At varying concentrations (25-75 %w/w), the α-cellulose was used as a filler to formulate paracetamol tablets by direct compression. Also, at different disintegrant concentrations (2.5-10 %w/w) and volumes of granulating fluid (7.5 and 10 ml), the α-cellulose, MCC and maize starch were used to formulate a set of paracetamol tablets by wet granulation method. Various tablets' parameters (tablet weight, hardness, friability, disintegration time and dissolution) were evaluated for the formulated tablets. Drug-excipient interaction was investigated using Fourier transform infrared (FTIR) and differential scanning calorimetry (DSC). Results from the evaluation of tablets showed that the tablets had uniform weight, hardness > 4.0 kp and friability < 1.0%. The tablets exhibited excellent disintegration times of < 60 seconds except those formulated by wet granulation at disintegrant concentration of 2.5%w/w. The tablets passed the BP dissolution test for tablets except those formulated by direct compression at 25%w/w and wet granulation at 2.5%w/w disintegrant concentrations. Granulation fluid volume did not affect the tablet parameters except hardness which increased with increased fluid volume. FTIR and DSC analyses revealed no interaction between paracetamol and the excipients. The cellulose powders had disintegrant ability which compared favourably with maize starch but inferior to microcrystalline cellulose. The powders may prove a useful substitute for maize starch as tablet disintegrant at concentrations greater than 5%w/w.

1. INTRODUCTION

The bioavailability of a drug in a solid dosage form intended for oral administration depends on the dissolution of the drug in the intestinal fluids for absorption to take place. However, the dissolution process depends very much on the break down or disintegration of the drug formulation into fine particles (Eraga et al., 2014). This process of disintegration is normally achieved with the aid of a disintegrant. Disintegrants are substances or mixture of substances added to the drug formulation to facilitate the breakup or disintegration of tablet or capsule content into smaller particles that dissolve more rapidly than in the absence of disintegrants (Eraga et al., 2014; Jackson et al., 2015).

The compression process in tablet manufacturing involves the compaction of powders or granules into a solid mass. The surface area of the powders or granules is reduced in the solid mass leading to low porosity and difficulty in fluid penetration. Disintegrants help in alleviating this problem and facilitates the breakdown of solid tablet compacts into their primary particles thereby increasing the surface area of the particles and easy penetration of fluid (Ordu and Ocheme, 2011). It has been proposed that disintegrants cause tablet breakdown by two mechanisms - wicking and swelling (Gupta and Gaud, 2000). Through the wicking process, hydrophilic pathways are formed allowing access of fluids into the tablet structure. This process also allows the disintegrant to swell, resulting in built up pressure within the tablet and subsequent rupture of the tablets inter-particulate bonds (Rygnestad et al., 2000). The important role of disintegrants in tablet formulations has initiated a search for new and improved compounds as disintegrants from both synthetic and natural sources (Kottke et al., 1992). The newer compounds are expected to be of better quality with regards to their disintegrant efficiency, availability, cost effectiveness, biocompatibility and degradability (Uwaezuoke et al., 2014).

The polymer, α-cellulose has shown potentials in tablet formulations as a disintegrant and as a direct compression excipient because of its hydration and swelling ability (Okhamafe et al., 1991; Azubuike et al., 2012). This study seeks to evaluate the disintegrant property of cellulose extracted from destarched white and yellow maize chaff in comparison with microcrystalline cellulose (MCC) and maize starch BP in immediate release paracetamol tablets.

2. MATERIALS AND METHODS

2.1. Materials

Paracetamol powder, maize starch BP, talc and magnesium stearate (William Ransom and Son PLC, Hitchin Hertfordshire, England), microcrystalline cellulose (Avicel® PH 101) (FMC Biopolymer, USA). Maize (*Zea mays* L) chaffs of white and yellow varieties were collected as harvest wastes from the farms of the Faculty of Agriculture, University of Benin, Benin City, Nigeria.

2.2. Methods

2.2.1 Extraction of α-cellulose

Using the method of Ohwoavworhua et al. (2007), the collected maize chaff was sun-dried for 48 h and then micronized in a Fitz mill (Manesty Machines UK) into fine powders. Four hundred grams of the powder was treated for 2 h in a stainless steel vessel maintained at 90 °C with 4 litres of 3.5 % nitric acid containing 40 mg of sodium nitrite to remove lignin in the form of nitrolignin. The sample was washed thoroughly, filtered with a sieve (No. 18) and digested with a 4 litres solution containing 2.0 % w/v each of sodium hydroxide and sodium sulphite at a temperature of 50 °C for 1 h. The sample was washed thoroughly with distilled water, filtered and bleached with 1 litre of diluted aqueous solution of 3.85 %w/v sodium hypochlorite 40 °C for 1.5 h. The bleached sample (holo-cellulose) was thoroughly washed with distilled water, filtered and subsequently treated with 2 litres of 17.5 % w/v sodium hydroxide solution at 80 °C for 30 min. The resulting material was again washed thoroughly with distilled water, filtered and then bleached with 2 litres of diluted aqueous solution of 3.85 %w/v sodium hypochlorite at 40 °C for 1.5 h. The product (alpha-cellulose) was washed with more distilled water and air dried for 24 h and further oven dried (Kottermann, Germany) for 1 h at 60 °C. The alpha cellulose was milled in a blender (Moulinex, France) and screened through a 212 µm sieve, weighed and the percentage yield calculated before being stored in an air tight container.

2.2.2. Preparation of paracetamol powder blends and tablets

Using the formula shown in Table 1, the dry granulation method was used to prepare nine (9) batches of paracetamol powder blends containing varying amounts (25, 50 and 75 %w/w) of the α-cellulose powders (white and yellow maize chaff) and MCC. Each batch was prepared by dry mixing the required quantities of paracetamol and the cellulose powder in a mixer (Moulinex, France) for 10 min and compressed into tablets using a single punch tableting machine (Koln Niehi, Germany) at compression pressure of 8.0 MPa. The die volume was adjusted to compress tablets of uniform weight by using powders weighing 250, 300 and 350 mg for batches ADG, BEH and CFI respectively. The tablets made were then kept in air tight containers and stored in a desiccator until evaluation.

2.2.3. Preparation of paracetamol granules and tablets

Using only the α-cellulose powders from white maize chaff, the wet granulation method was employed in preparing twenty four (24) batches of paracetamol granules and tablets containing varying amounts of the disintegrants and wet massed with different volumes of the binder solution with the formula in Table 2.

Each batch was prepared by blending the required quantities of paracetamol and lactose in a mixer for 10 min. The powder mix was granulated with a specific quantity of 4 %w/v acacia solution (binder) and the wet mass was passed through a 1.4 mm sieve and then dried at 60 ºC for 30 min in a hot air oven (Gallenkamp, UK). The dry mass was passed through an 850 µm sieve and further dried for 30 min. Thereafter, the required amounts of the disintegrant and glidant (magnesium stearate) were intimately mixed with the dry granules in geometric proportion in readiness for compression. Granules sufficient to produce 40 tablets per batch

was prepared and compressed into tablets at 8.3 MPa using granules weighing 560 mg in order to achieve tablets equivalent to 500 mg paracetamol. The tablets made were then kept in air tight containers and stored in a desiccator until evaluation.

Table 1: Formula for preparing paracetamol powder blends and tablets

Ingredients (mg)	Batches								
	A	B	C	D	E	F	G	H	I
Paracetamol	200	200	200	200	200	200	200	200	200
α-cellulose (white maize)	50	100	150	0	0	0	0	0	0
α-cellulose (yellow maize)	0	0	0	50	100	150	0	0	0
Microcrystalline cellulose	0	0	0	0	0	0	50	100	150

Table 2: Formula for preparing paracetamol granules and tablets

Ingredients	Quantities/tablet
Paracetamol	500 mg
Lactose	42.5, 30, 17.5, 5 mg
Disintegrant*	12.5, 25, 37.5, 50 mg
Binder solution^{+} (4.0 %w/v acacia powder)	7.5, 10 ml
Magnesium stearate	5 mg

*Disintegrant: α-cellulose of maize chaff or microcrystalline cellulose or maize starch BP
$^{+}$Binder solution: volume used to prepared a total of 40 tablets

2.2.4. Drug-excipient compatibility studies

FTIR and DSC compatibility studies were carried out on the tablet granules and paracetamol powder. The FTIR analysis was carried out using FTIR-4100 Spectrophotometer (Shimadzu Co. Japan). Using the potassium bromide (KBr) tablet method, 5 mg of the sample was blended with potassium bromide to give a 200 mg weight powder. The powder was compressed using a Sigma KBr press into a tablet, and then placed in the sample compartment of the spectrophotometer and scanned at a range of 4000 - 1000 cm^{-1} (Lokshina et al., 2015) while the DSC analysis was carried out using the Netzsch DSC 204F1 Phoenix apparatus (Netzsch, Germany). Four milligrams of the sample was weighed into an aluminium pan. The seal of the pan was pierced and placed in the calorimeter previously calibrated with indium and nitrogen as the purge gas. 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.

2.2.5. Evaluation of tablets

The following post-compression tests were carried out on the compressed tablets using standard procedures: uniformity of tablet weight, crushing strength (hardness), friability, disintegration time and dissolution studies (British Pharmacopeia, 2009).

2.2.5.1. *Weight uniformity and friability*

Twenty tablets from each batch were used for the weight uniformity test. The weight of each tablet was determined and the mean weight and standard deviation were computed. Ten weighed tablets were then placed in the drum of a friabilator (Erweka GmbH, Germany) operated at 25 rpm for 4 min. The tablets were taken out, de-dusted and reweighed. Their

percentage loss in weight value was calculated as friability. Triplicate determinations were carried out and the mean and standard deviation were reported (British Pharmacopeia, 2009).

2.2.5.2. ***Crushing and tensile strengths***

Using a motorized tablet hardness tester (Campbell Electronics, Model HT-30/50, India), the crushing strength of each of ten tablets per batch was determined. The mean hardness value and standard deviation were calculated and used in determining the tensile strength of the tablets (British Pharmacopeia, 2009).

2.2.5.3. ***Disintegration time***

The time taken for each of six tablets per batch to disintegrate in distilled water at 37 ± 0.5 °C was determined using a disintegration tester (MK IV, Manesty Machines, UK). The mean time and standard deviation were calculated (British Pharmacopeia, 2009).

2.2.5.4. ***Dissolution test***

The *in vitro* dissolution analyses of the various batches of the paracetamol tablets were carried out using the BP paddle method. A dissolution apparatus (Caleva ST7, UK) containing 900 ml of 0.1 M HCl solution maintained at 37 ± 0.5 °C with a revolution speed of 50 rpm was used. Samples (5 ml) were withdrawn from the dissolution fluid at 10 min intervals over a period of 60 min and replaced with an equivalent volume maintained at same temperature (37 ± 0.5 °C). The withdrawn samples were filtered and diluted appropriately with 0.1 M HCl solution. The resulting solutions were subjected to spectrophotometric analysis at λ_{max} of 244 nm (T70, PG Instruments Ltd). The amount and the percentage of drug released at each time interval were calculated using the equation from the standard calibration plot obtained from pure paracetamol powder (British Pharmacopeia, 2009).

2.2.5.5. ***Statistical analysis***

Statistical difference in the tablet parameters of the various batches were subjected to student's t-test at 5 % level of significance using GraphPad InStat 3.10.

3. RESULTS AND DISCUSSION

3.1. Compatibility Studies

The FTIR spectrum of pure paracetamol (Figure 1 (a)) powder showed characteristic peaks at 1567.00, 1650.42 and 3171.00 cm^{-1} attributed to the –NH, C=O and –OH functional groups of paracetamol (Mallah et al., 2015). These peaks observed for paracetamol remained unchanged when compared with the spectral data of the granules (Figure 1 (b)). This observation ruled out the possibility of chemical interaction and complex formation between paracetamol and the excipients during the mixing process (Eraga et al., 2015).

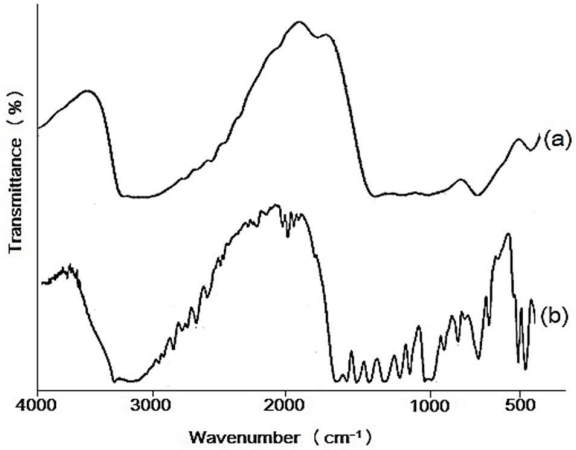

Figure 1: FTIR spectra of paracetamol powder (a) and the paracetamol granules (b) prepared by wet granulation

Figure 2 shows the DSC thermograms of pure paracetamol powder (a) and the paracetamol granules (b). Paracetamol thermogram shows a sharp endothermic peak, corresponding to its melting point (169 °C) and a semi-broad endothermic peak (310 °C), corresponding to the melting point of the decomposition product of paracetamol. The paracetamol sharp peak which appears as a spike is indicative of its purity and crystallinity (Schnitzler et al., 2002). On the other hand, the thermogram of the granules (b) showed one sharp and one broad endothermic peaks with the characteristic peak of pure paracetamol. The broader trough manifested by the granules could be the result of decomposition of the paracetamol and other ingredients used in the formulation (Eraga et al., 2015).

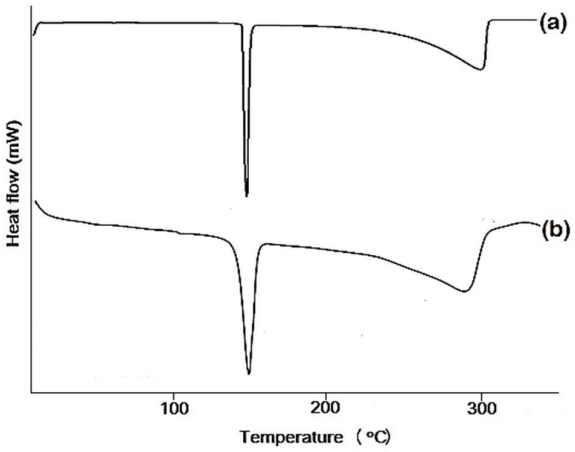

Figure 2: DSC thermograms of paracetamol powder (a) and the paracetamol granules (b) prepared by wet granulation

3.2. Tablet Properties

The post-compression parameters of the paracetamol tablets formulated by direct compression and wet granulation are presented in Tables 3 and 4 respectively. The weights of

the tablets within the various batches satisfied the British Pharmacopoeia (2009) specification for uniformity of weights, which states that not more than two of the individual weights of the 20 tablets tested should deviate from the average weight by more than ±5 % and none should deviate by more than ±10 %. All the tablets exhibited good tablet hardness with crushing strength values above 4.0 kp (Rudnic and Schwartz, 2000).

Table 3: Some physicochemical characteristics of the paracetamol tablets prepared by direct compression

Cellulose	Batch	Weight (g)	Dimensions (cm)		Crushing strength (kp)	Tensile strength (Nm/s^2)	Disintegration time (sec)
			Diameter	Thickness			
White maize	A	0.26(0.02)	1.25 (0.03)	0.20 (0.01)	4.14(0.26)	2.47 (0.15)	9.17 (2.16)
	B	0.31 (0.01)	1.25 (0.02)	0.21 (0.03)	4.33 (0.16)	2.83 (0.12)	4.83 (6.60)
	C	0.35 (0.02)	1.25 (0.09)	0.22 (0.03)	4.58 (0.34)	2.90 (0.10)	4.67 (2.10)
Yellow maize	D	0.25 (0.03)	1.25 (0.01)	0.21 (0.04)	3.58 (0.38)	3.23 (0.02)	8.83 (1.60)
	E	0.30 (0.01)	1.25 (0.02)	0.21 (0.03)	4.75 (0.16)	3.73 (0.12)	4.92 (0.59)
	F	0.35 (0.02)	1.26 (0.09)	0.22 (0.03)	5.00 (0.34)	3.83 (0.10)	4.33 (1.60)
Microcrystalline cellulose	G	0.26 (0.03)	1.25 (0.01)	0.21 (0.04)	4.16 (0.44)	10.09(0.02)	11.00 (2.40)
	H	0.33 (0.01)	1.25 (0.03)	0.21 (0.01)	7.17 (0.40)	17.38 (0.25)	12.41 (1.26)
	I	0.35 (0.01)	1.26 (0.03)	0.22 (0.02)	8.40 (0.32)	18.56 (0.04)	17.67 (1.25)

*Standard deviation in parenthesis

Table 4: Some physicochemical characteristics of the paracetamol tablets prepared by wet granulation

Disintegrant	Disintegrant Concentration (% w/w)	Weight (g)		Crushing strength (kp)		Friability (%)		Disintegration time (sec)	
		7.5 ml	10 ml	7.5 ml	10 ml	7.5 ml	10 ml	7.5 ml	10 ml
α-cellulose	2.5	0.56 (0.02)	0.56 (0.01)	4.75 (0.26)	4.80 (0.73)	0.44 (0.15)	0.34 (0.10)	559.30 (5.16)	660.00 (1.22)
	5	0.56 (0.01)	0.56 (0.02)	5.74 (0.44)	6.34 (0.16)	0.50 (0.12)	0.40 (0.12)	30.51 (6.60)	35.20 (2.20)
	7.5	0.56 (0.02)	0.56 (0.01)	5.50 (0.34)	7.04 (0.22)	0.72 (0.10)	0.61 (0.15)	15.32 (2.10)	20.50 (4.50)
	10	0.57 (0.03)	0.56 (0.01)	5.84 (0.28)	8.60 (0.38)	0.83 (0.02)	0.74 (0.12)	12.59 (1.60)	20.00 (1.32)
Micro-crystalline cellulose	2.5	0.56 (0.01)	0.56 (0.01)	5.41 (0.16)	6.45 (0.24)	0.34 (0.22)	0.34 (0.12)	540.12 (2.50)	600.00 (3.10)
	5	0.56 (0.02)	0.56 (0.02)	5.50 (0.34)	7.33 (0.23)	0.36 (0.20)	0.39 (0.10)	15.34 (1.60)	18.15 (1.82)
	7.5	0.56 (0.03)	0.56 (0.03)	5.91 (0.43)	7.78 (0.44)	0.46 (0.10)	0.44 (0.02)	10.14 (2.40)	15.45 (2.10)
	10	0.56 (0.01)	0.56 (0.01)	6.50 (0.30)	8.89 (0.40)	0.70 (0.25)	0.65 (0.10)	6.45 (1.30)	10.00 (1.84)
Maize starch BP	2.5	0.55 (0.01)	0.55 (0.01)	4.25 (0.16)	4.70 (0.26)	0.64 (0.12)	0.64 (0.30)	1200.0 (4.59)	1410.00 (5.40)
	5	0.56 (0.02)	0.55 (0.02)	4.43 (0.10)	4.90 (0.34)	0.65 (0.10)	0.69 (0.13)	25.34 (1.60)	29.17 (1.52)
	7.5	0.56 (0.03)	0.56 (0.03)	5.44 (0.42)	6.97 (0.44)	0.86 (0.02)	0.83 (0.02)	14.16 (1.45)	20.83 (2.35)

	10	0.57 (0.01)	0.56 (0.01)	5.58 (0.86)	8.19 (0.40)	0.91 (0.25)	0.97 (0.50)	10.41 (1.26)	20.00 (1.40)

*Standard deviation in parenthesis

All the tablets met the BP specification for tablet friability, of a maximum loss of 0.8 - 1.0 % of the weight of tablets tested (British Pharmacopoeia, 2009). There were observed increase in the tablets' friability, crushing and tensile strength with increase in disintegrant concentrations. The increase in hardness may be attributed to the increased bond formation between the granules as a result of plastic and elastic deformation of the particles during compaction (Musa et al., 2008).

The volume of granulating fluid did not significantly affect the weights and friability of tablets formulated by wet granulation (Table 4), but there was increase in the hardness values of the tablets with increase in fluid volume. Tablets containing 2.5 %w/w of the disintegrants, irrespective of the granulating fluid volume, disintegrated outside the British Pharmacopeia limit of 15 min. Since the disintegrants were incorporated extra-granularly, this may suggest that the disintegrants were not effective as exo-disintegrants at that concentration. Above that concentration, all the tablets disintegrated within 60 seconds. This observation is in agreement with previous works (Ponchel and Duchene 1990; Onyishi et al., 2013) in which it was demonstrated that for optimal tablet disintegration, there exists a critical concentration of disintegrant below which disintegration is very slow and improves dramatically as it approaches this critical value. Above this critical value disintegration times may continue to decrease slowly or remain fairly constant at its lowest value. With starches, this disintegration time may increase again when the amount of disintegrant is above this critical value. It has been reported that a sufficiently continuous hydrophilic network around other particle components of a tablet such as the filler or diluent, the active drug, etc., is necessary in order to effect tablet disintegration (Carter, 2002; Goran, 2002). An equation which expresses the optimal quantity of disintegrant powder necessary to obtain a continuous disintegrant network composed of a single layer of disintegrant particles in a tablet has been proposed by Ringard and Guyot-Herman (1988).

$$Q = \frac{d_1}{d_2} \times \left[\left(\frac{D_1}{D_2} + 1 \right)^3 - 1 \right] \times 100 \quad (1)$$

Where Q is the theoretical disintegrant quantity, d_1 and d_2 are the true densities of the disintegrant and diluent respectively and D_1 and D_2 are the particle sizes of the disintegrant and diluent respectively. Based on Equation (1), the theoretical disintegrant quantity was computed to be 4.47 %. This value is in close concordance with the results shown in Table 4 obtained from the disintegration test of wet granulation tablets, where the α-cellulose was used as a disintegrant. Also from Table 4, the α-cellulose from the white maize chaff yielded comparable disintegration times with maize starch BP at all concentrations of the disintegrant, which implies that it can successfully replace maize starch BP as disintegrant of choice. At all the concentrations investigated, microcrystalline cellulose yielded tablets with shorter disintegration times, making it superior to the maize chaff α-cellulose.

The dissolution data obtained from the dissolution studies of the tablets formulated via direct compression and wet granulation are shown in Tables 5 and 6 respectively. For the direct compression tablets, where the α-cellulose was used as a filler/diluent, the 25 %w/w α-cellulose tablets achieved a complete drug release (m_∞, i.e. maximum drug release) within 60 min with $t_{70\%}$ (time for 70 % drug release) of 42.0, 44.0 and 31.5 min for white and yellow maize chaff cellulose and microcrystalline cellulose respectively as shown in Table 5. At higher concentrations of the α-cellulose (50 and 75 %w/w), complete dissolution occurred from all the compacts within 5 min irrespective of the filler/diluent used. For the wet granulation tablets, Table 6 shows that irrespective of the granulating fluid volume, none of the tablets formulated with 2.5 %w/w of α-cellulose as disintegrant achieved complete drug release within the 60 min of testing with their $t_{70\%}$ greater than 45 minutes. Whereas, at disintegrant concentrations of 5 %w/w and above, all the tablets met the British Pharmacopeia standard on tablet dissolution that specifies a 70 % drug release within 45 min of profiling (British Pharmacopeia 2009).

Table 5: A comparison of the empirical dissolution data of paracetamol tablets prepared by direct compression

Filler/Diluent concentration (%w/w)	White maize chaff α-cellulose		Yellow maize chaff α-cellulose		Microcrystalline cellulose	
	m_∞ (%)	$t_{70\%}$ (min)	m_∞ (%)	$t_{70\%}$ (min)	m_∞ (%)	$t_{70\%}$ (min)
25	99	42.0	98	44.0	100	31.5
50	100	5.0	100	5.2	100	4.7
75	100	4.5	100	5.0	100	4.2

Table 6: A comparison of the empirical dissolution data of paracetamol tablets prepared by wet granulation

Disintegrant concentration (% w/w)	Parameter evaluated	White maize chaff α-cellulose		Microcrystalline cellulose		Maize starch BP	
		7.5 ml	10 ml	7.5 ml	10 ml	7.5 ml	10 ml
2.5	m_∞ (%)	45	46	56	55	45	45
	$t_{70\%}$ (min)	-	-	-	-	-	-
5.0	m_∞ (%)	98	95	100	100	99	98
	$t_{70\%}$ (min)	44	45	10	8.0	42	46
7.5	m_∞ (%)	100	100	100	100	100	100
	$t_{70\%}$ (min)	10.0	10.0	5.0	5.0	10.0	10.0
10	m_∞ (%)	100	100	100	100	100	100
	$t_{70\%}$ (min)	5.0	5.0	5.0	5.0	5.0	5.0

4. CONCLUSION

This investigation has established the potentials of the cellulose obtained from both white and yellow maize chaff as a filler or diluent or bulking agent and as a disintegrant in tablet formulation by direct compression or wet granulation. The extracted celluloses have disintegrant ability which compared favourably with maize starch BP but inferior to microcrystalline cellulose. Their disintegrant efficiency may be significantly improved to obtain comparable results with microcrystalline cellulose if the various stages of the extraction

process are optimized. Lastly, the extracted cellulose may therefore prove a useful substitute for maize starch BP as disintegrant at concentrations greater than 5 %w/w.

5. ACKNOWLEDGMENT

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6. CONFLICT OF INTEREST

There is no conflict of interest associated with this work.

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