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Characterization and Evaluation of Disintegrant Property of Pre-gelatinized Tigernut Starch in Paracetamol Tablet

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Abstract

Starch had been used as pharmaceutical excipient in the production of tablets. Studies on the use of starch both as binder and disintegrant had been reported. Several studies revealed that Tigernuts (*Cyperus esculentus*) served as a source of starch. However, the study of pregelatinized tigernut starch as disintegrant in solid dosage form has not been reported. The study aimed at extraction, modification and characterization of starch from tiger nut as well as evaluating the disintegrant properties of the modified starch. The starch was extracted using standard method and has undergone pregelatinization to obtain pregelatinized starch. The modified starch was characterized and used as disintegrant in formulation of tablet. The hardness/weakness of the tablets were assessed using crushing strength test and friability value while the release profile were assessed using disintegration and dissolution times of the tablet.

The result of hydration and swelling capacity shows that the pre-gelatinized starch has high value of 0.36 and 2.67 as compared with native starch of 0.24 and 2.38, and corn starch of 0.20 and 2.10 respectively. The tablets formed at optimized concentration (5% w/w) with pre-gelatinized tigernut starch (PGS) disintegrated at 5.51 min while the native tigernut starch (CES) disintegrated at 10.12 min, and the corn starch at 36.58 min respectively.

Pre-gelatinized tigernut starch has shown good disintegrant property as such can be used as a pharmaceutical excipient in paracetamol tablet formulation.

Keywords: *Cyperus esculentus*, Paracetamol tablet, Corn starch, Disintegration time

Introduction

Tablets are solid dosage preparations each containing a single dose of one or more active substance and are usually obtained by compressing uniform volumes of particles Okoye *et al.*, (2010). Tablets are manufactured by the process of granulation. Granulation is the process in which primary powder particle are made to adhere to form larger, multi particle entities called granules. Granulation method can be broadly classified into wet granulation which utilizes some

fluids to bind the primary particles and the dry method which do not utilize any liquid.

Tablet is formed with active ingredient together with excipient. These Excipients play an important role in formulating a dosage. They can act as protective or bulking agents, and can also be used to improve bioavailability of drugs in some instances. Disintegrants are excipients added to a tablet formulation to facilitate its breakage or disintegration when in contact with GI fluid or water. E.g. starch.

Starch is one of the abundant carbohydrate reserves in plant and is found in leaves, flowers, fruits, seed, and different types of stem and roots Meirles *et al.*, (2015). Starch is rarely used pharmaceutically in its native form. Most native starches are limited in their direct application because of their low activity compared to modified starch.

Modifications of starch include physical, chemical and enzymatic methods Krithika *et al.*, (2019). Physical methods involve the use of heat and moisture while chemical modifications introduce functional groups into the starch molecule using derivatization reaction. Pre-gelatinized starch is starch that has undergone a cooking process until complete gelatinization and a simultaneous (or subsequent) drying process.

Generally, there are three methods involved in the disintegration of tablet which include swelling, wicking and strain recovery Parind *et al.*, (2016). Among these, swelling is considered as the mechanism of action for starch based disintegrant.

This study is aimed at extraction, modification and characterization of starch from tiger nut as well as evaluating the disintegrant properties of the modified starch in a tablet formulation.

Materials and Methods:

Chemical and Reagents: *Cyperus esculentus* starch, Paracetamol powder B. P, Talc, Maize starch B P, Lactose, Magnesium stearate, Ethanol, N-Hexane, Distilled water, and Xylene.

Machines and equipments: Digital weighing balance (metra-2000,UK), Friability Tester (India,IEC-2), Hardness tester (ErwekaTBH 100,Germany), Dissolution Tester (Erweka

ZT-71 Germany), Disintegration Tester (Erweka,ZT-71 Germany), UV Spectrophotometer (UV7652(D) USA), Vanier Caliper (OE M/6,Switzerland), Centrifuge machine (80-2, shanghai India), Oven Electronic thermostable Drying Box(GZX-DH 400-11, India), Oakton pH meter (pH series, singapore), AG moisture balance (Sartorius AG 16P6,Germany), Tabulating Machine (Type F3 England).

Collection and identification: *Cyperus esculentus* tubers were collected from samaru market, Zaria Local government of Kaduna state, Nigeria and identified at the Department of Biological Science, Faculty of Science, University of Maiduguri.

Extraction of *Cyperus esculentus* starch

Three (3) kg quantity of the tigernut was washed and dried in a hot air oven set at 50 °C for 2 h. It was then pulverized into coarse particles of large multiparticulate sizes (>1 mm) and boiled in ethanol before treating with several portions of n-hexane. The defatted granules were thereafter soaked in 6 L of 0.075% (w/v) sodium metabisulphite for 24 h.

The hydrated mass of the coarse granules were milled into a homogenous fine pulp which was dispersed in 12 L of sodium metabisulphite solution (0.075%, w/v) and filtered through a muslin cloth of 150 µm pore size. The suspension was allowed to stand for 24 h for complete sedimentation of the starch granules before the supernatant was decanted. The starch layer was repeatedly washed with distilled water and recovered by centrifugation at 3,000 rpm for 10 min. The resulting starch cake was dried for 5 h at 50 °C in the hot air oven and pulverized to a fine powder. It was then

passed through a 250 -µm mesh and stored in a dry airtight container until used.

Starch modification

A starch slurry was made by dispersing 100 g of starch sample in 500 ml beaker containing 150 ml distilled water. The mixture was stirred for 2 min, placed on water bath and heated to the gelatinization temperature of the starch (67 °C). The gel was spread out on stainless steel tray and dried for 3 h at 50 °C in the hot air oven. The dry starch was thereafter pulverized to a fine powder, passed through a 250-µm mesh and stored in a dry airtight container.

Physicochemical evaluation of the Powder

Iodine Test

To a 2 ml solution of starch in a test tube, 2 drops of iodine was added and agitated for 1 min. The mixture was then warmed for some times and allowed to cool. Observation made was recorded.

Organoleptic Properties

The colour, odour, taste, and texture of each sample starch powders were observed and recorded.

pH

The pH of 1 g in 30 ml slurry of each of the sample starch powders was determined using a pH meter and the result recorded. This was done in triplicate for each of the samples.

Hydration Capacity

A 1 g weight of each sample starch powder was poured into a centrifuge bottle. 10 ml of distilled water was then added and mixed for two minutes. The mixture was then centrifuged for 10 min at 1000 rpm. The supernatant obtained was decanted and the sediment weight. The hydration capacity was determined using the equation below;

$$\text{Hydration capacity} = \frac{\text{WS}}{\text{WD}} \dots \dots \dots \text{eq1}$$

Where WS and WD represent the weight of the sediment formed and weight of the dry sample respectively.

Swelling Capacity

A 2 g of each sample starch powder was weighed and transferred into measuring cylinder, it was then tapped 50 times and the result was recorded. 10 ml of distilled water was added to the powder and the volume occupied by the powder was recorded. Swelling capacity was calculate as; $F_v - I_v \dots \dots \dots \text{eq2}$

Where F_v is the final volume and I_v is the initial volume

Gelatinization Temperature

The method used by Muazu *et al.*, (2014) was adopted. One (1) gram of the powdered sample was poured into a 20 ml beaker and 10 ml distilled water added. The dispersion was heated using hot plate. Temperature at which the mixture gels was read using thermometer placed in the slurry.

Solubility

Two gram of various sample starch powders were poured into a test tube containing 5 ml of cold distilled water and 5ml ethanol separately and the solubility of each starch sample observed and recorded.

Angle of Repose

Using a glass funnel clamped on a retort stand which was 10 cm away from the flat surface of a bench, 50 g of each sample starch powder was placed into the funnel and allowed to flow freely forming a conical heap. The angle of repose was calculated from the heap of each sample starch powder using equation 2 $\text{Angle of repose, } \tan \theta = \frac{h}{r} \dots \dots \dots \text{eq 3}$

Where h = height and r = radius of the circular heap

Bulk and Tapped Density

Ten (10) g quantity of the powder sample was placed in a 20 ml measuring cylinder and the volume V_0 occupied by the sample without tapping noted. After 500 manual taps, volume occupied V_{500} was determined. The bulk densities were calculated as the weight to volume (V_0 and V_{500} respectively).

Carr's index

The Carr's index was calculated using the following formula presented in equation 3

$$CI = \frac{(TD-BD)}{TD} \times 100 \dots \dots \dots eq 4$$

Where CI is carr's index, TD = Tapped density and BD= bulk density

Hausners Ratio

Hausners ratio was calculated using the following formula presented in equation 1

$$\text{Hausner's ratio} = \frac{TD}{BD} \dots \dots \dots eq5$$

Where TD = Tapped density and BD = Bulk density

True Density

The method used by Bayor *et al.*, 2013 was adopted. The true density of the starch was determined by fluid displacement. The weight of a 50 ml empty pncnometer 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 5ml 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.

$$\text{True Density (g/cm}^3\text{)} = \frac{W_2 W_3}{W_4 - W_2 - W_3} \dots \dots \dots eq6$$

Powder Porosity

This was calculated using the outcomes of both true and bulk densities similar to Ohwoavworhwa *et al.*, (2005).

$$e = \frac{1 - \frac{Bb}{Dt}}{\dots \dots \dots} \times 100 \dots \dots \dots eq7$$

Where Bb is the bulk density, Dt , is the true density and e is the porosity

Moisture Content

Using a Sigmum test AG moisture balance (Sartorius AG, Germany), 3 g of each sample starch was poured unto the moisture balance and evenly distributed on the tray. The machine was then set at 115 °c to determine the moisture content. The result was recorded when the machine automatically stops after fifteen (15) minutes.

Flow rate

A 20 g weight of the starch powder was poured into a funnel of the flow rate machine. The time taken by the sample to completely pass through the funnel was recorded.

Moisture Sorption Capacity

Starch sample (2) g was kept in a desiccator containing distilled water (Relative humidity 100%) for five days after which it was reweighed daily. The moisture sorption capacity was calculated as the ratio of change in weight to the initial weight.

Tableting Procedure

The materials used were corn starch, *Cyperus esculentus* starch, pregelatinized *Cyperus esculentus* starch, lactose powder, Talc, magnesium stearate and paracetamol powder. Below is the working formula for the tablet produced.

Table 1: Formula for production of paracetamol tablet

Exipient	A(CST,CEST and PCEST) (mg)	B(CST,CEST and PCEST) (mg)	C(CST,CEST and PCEST) (mg)	D(CST,CEST and PCEST) (mg)
Paracetamol (77%)	500	500	500	500
Starch Disintegrant	16.25	32.5	48.75	65
Corn starch (7.7%) Binder	49.66	49.66	49.66	49.66
Magnesium stearate (0.3 %)	1.26	1.26	1.26	1.26
Talk (2.5 %)	12.6	12.6	12.6	12.6
Lactose	65.23	48.98	32.73	16.48
Total (mg)	645	645	645	645

Key: where A is 2.5 %, B= 5%, C=7.5%, and D=10%, CET=corn starch tablet, CEST= Cyperus esculentus starch Tablet, and PCEST= pregelatinized Cyperus esculentus starch Tablet.

Production of Paracetamol Granules

For the production of 70 tablets containing 2.5 %, 5 %, 7.5 % and 10 % disintegrant, 7.7 % w/v corn starch was heated in a hot plate to form a binder solution. A 35 g of paracetamol powder together with 1.14 g, 2.28 g, 3.41 g, and 4.55 g of *Cyperus esculentus* starch (As disintegrant) with their respective 4.57g, 3.43g, 2.29g, and 1.15 g of lactose were weighed in a porcelain mortar and mixed.

The mixed powders were wet massed with the binder solution and screened through a sieve of 4 mm mesh screen. The screened wet granules were spread as a thin layer on a tray and dried in an oven (tray drier) at a controlled temperature of 40 °c for 20 min and screened through a sieve of 5 mm mesh

and bottled. The granules were tabulated after adding 882 mg of talc as glidant while magnesium stearate was used to lubricate the machine. The same procedure was repeated using corn starch and pregelatinized *Cyperus esculentus* starch as disintegrant.

Evaluation of Granules

Determination of moisture content, bulk and tapped density, Carr's index, and angle of repose were carried out using same method as of the starch powders.

Evaluation of Tablet

The following tests were carried out on each batch of the tablets obtained.

Weight Variation

Ten tablets were picked and weighed on an analytical balance (Toledo, Japan). The tablets were then individually weighed and recorded. The mean weight and percentage variation were then computed.

Variation (%) = $\frac{\text{weight of tablet} - \text{Average weight of tablet}}{\text{Average weight of tablet}} \times 100$...eq8

Disintegration Time

Using Erweka Disintegration tester, the temperature of the water bath and beaker were thermostatically maintained at $37 \pm 1^\circ\text{C}$ for all batches of tablet. The disintegration time of each of the 6 tablets was determined and their mean was calculated and recorded.

Hardness Test

Using the Erweka digital hardness tester, the crushing strength of 5 tablets from each batch was determined. The results were recorded and the respective mean hardness of the tablet was determined.

Friability Test

Twenty 20 tablets were weighed on analytical balance and the weight was recorded, they were then placed in the friabilator that was set to rotate at 25 rpm for 4 min. The tablets were gently redusted and weighed. Percentage weight loss and hence friability was calculated and the result were recorded for each batch.

% weight loss = $\frac{W_1 - W_2}{W_1} \times 100$eq9

Where W_1 = Initial weight and W_2 = Final weight

Thickness and Diameter

The vernier caliper was used to measure the thickness and diameter of 10 tablets from each sample. The mean value of 10 determinations was recorded in each case.

Dissolution Test

The calibration curve was constructed using standard paracetamol powder and 0.1M NaOH as dissolving medium. 27.89 mg of the standard paracetamol powder was weighed and serially diluted to obtain a stock solution of 0.0046 mg/ml (44.62 µg/ml). 0.5, 1.0, 1.5, 2.0, 2.5 ml of the stock was then re-diluted in 10 ml volumetric flask to give 2.2, 4.4, 6.6, 8.9 and 11 µg/ml concentrations respectively. The absorbance of the different concentrations was spectrophotometrically determined at 257 nm wavelength and a graph of absorbance against concentration was plotted.

900 ml of the medium (0.1N NaOH) was poured into a glass jar and suspended in a water bath thermostatically maintained at $37 \pm 0.5^\circ\text{C}$. The paddle was set at 50 rpm and 25 mm away from the base of the glass jar. One tablet was placed in each glass jar. 5 ml sample of the dissolution medium was withdrawn from each glass jar at an interval of 5, 10, 15, 30, 45, and 60 minutes and replaced with 5 ml of the medium. The sample was spectrophotometrically analysed for paracetamol at 257 nm. The absorbance were recorded and used to obtain the concentrations using the calibration curve.

Results

Percentage yield

The percentage yield of starch obtained from *Cyperus esculentus* starch was 19.15 % w/w.

Table 2 Starch identification and organoleptic test

Parameter	CS	CES	PCES
Iodine test	+	+	+
Colour	White	White	White
Odour	Odourless	Odourless	Odourless
Texture	Fine	Fine	Fine
Taste	Tasteless	Tasteless	Tasteless

KEY: CS = Corn starch, CES = *Cyperus esculentus* starch and PCES = Pregelatinised *Cyperus esculentus* starch, + = positive, and - = Negative

Table 3 Material properties of the starch powders studied

Sample	pH \pm SD	Hydration capacity \pm SD	Swelling Capacity \pm SD	Gelatinization Temperature \pm SD
CS	9.62 \pm 0.15	2.10 \pm 0.12	0.20 \pm 0.02	69.00 \pm 1.41
CES	7.20 \pm 0.06	2.38 \pm 0.07	0.24 \pm 0.05	76.00 \pm 1.41
PCES	7.40 \pm 0.06	2.67 \pm 0.16	0.36 \pm 0.13	78.50 \pm 0.70

KEY: CS=Corn starch, CES= *Cyperus esculentus* starch and PCES= pre-gelatinized *Cyperus esculentus* starch

Table 4 Physicochemical properties of the starch powders studied

Properties	CS	CES	PCES
Solubility in cold Water	Insoluble	Insoluble	Insoluble
Solubility in 95 % Ethanol	Insoluble	Insoluble	Insoluble
Angle of Repose ($^{\circ}$) \pm SD	29.36 \pm 2.24	32.8 \pm 0.83	34.40 \pm 2.52
Bulk Density (g/ml) \pm SD	0.34 \pm 0.02	0.41 \pm 0.03	0.49 \pm 0.01
Tapped Density (g/ml) \pm SD	1.10 \pm 0.17	0.86 \pm 0.05	0.62 \pm 0.03
Carr's Index (%) \pm SD	68.33 \pm 5.69	52.09 \pm 3.38	20.77 \pm 2.20
Hausner's ratio	1.06 \pm 0.02	0.79 \pm 0.02	0.48 \pm 0.03
True Density (g/ml) \pm SD	2.25 \pm 0.09	2.025 \pm 0.16	1.97 \pm 0.13
Powder porosity (%) \pm SD	2.94 \pm 0.13	3.27 \pm 0.27	3.37 \pm 0.23
Moisture content (%) \pm SD	10.72 \pm 0.84	11.18 \pm 0.18	8.97 \pm 0.25
Flow rate (m/s) \pm SD	1.20 \pm 0.82	0.97 \pm 0.32	3.26 \pm 0.21

Key: CS=Corn starch, CES= *Cyperus esculentus* starch and PCES= pre-gelatinized *Cyperus esculentus* starch.

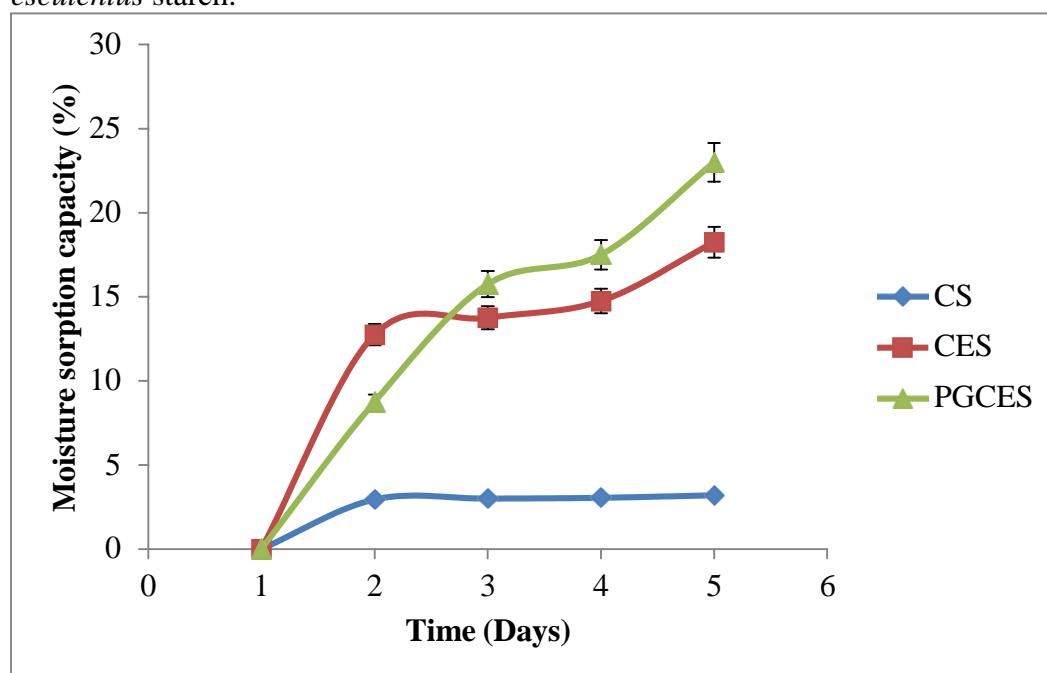


Figure 1 shows the result for CS, CES, and PCES respectively. Where CS=Corn starch, CES= *Cyperus esculentus* starch and PCES= pre-gelatinized *Cyperus esculentus* starch.

Table 5: Physicochemical Properties of the Paracetamol granules formulated

Sample code	Bulk density \pm SD	Tapped Density \pm SD	Angle of Repose \pm SD	Moisture content \pm SD
CSGa	0.35 ± 0.01	0.43 ± 0.01	25.9	1.71 ± 0.03
CSGb	0.36 ± 0.01	0.43 ± 0.01	27.06	1.87 ± 0.03
CSGc	0.34 ± 0.01	0.41 ± 0.01	25.24	1.15 ± 0.11
CSGd	0.33 ± 0.01	0.38 ± 0.01	27.06	1.36 ± 0.29
CESGa	0.30 ± 0.01	0.39 ± 0.02	23.20	2.15 ± 0.08
CESGb	0.30 ± 0.01	0.37 ± 0.01	22.48	1.39 ± 0.06
CESGTc	0.29 ± 0.01	0.37 ± 0.01	22.50	1.53 ± 0.53
CESGd	0.29 ± 0.01	0.35 ± 0.05	23.44	1.25 ± 0.13
PCESGa	0.33 ± 0.01	0.42 ± 0.00	20.85	1.61 ± 0.63
PCESGb	0.31 ± 0.01	0.4 ± 0.02	25.24	1.45 ± 2.43
PCESGc	0.38 ± 0.01	0.43 ± 0.01	23.75	1.5 ± 4.15
PCESGd	0.33 ± 0.01	0.42 ± 0.01	23.82	1.47 ± 6.02

Key: CSG = Corn starch Granulest CESG = *Cyperus esculentus* starch granule and PCESG = Pregelatinised *Cyperus esculentus* starch granules while a, b, c and d represents 2.5, 5, 7.5 and 10 % w/w disintegrant concentrations respectively.

Table 6: Quality assessment of the tablets formulated

Sample code	Diameter (mm) ± SD	Thickness (mm) ± SD	Weight Uniformity (g) ± SD	Crushing Strength (kgf) ± SD	Friability (%)	Disintegration time (Min.) ± SD
CSTa	5.66 ± 0.18	12.93 ±0.04	0.660 ± 0.01	14.08 ± 1.16	± 1.32	48.19 ± 2.05
CSTb	5.67 ± 0.16	12.92 ±0.04	0.653 ± 0.01	8.19 ± 0.78	± 1.45	36.58 ± 2.93
CSTc	5.76 ± 0.13	12.91 ±0.06	0.661 ± 0.01	7.44 ± 0.53	± 1.08	23.57 ± 2.59
CSTd	6.14 ± 0.14	12.91 ±0.05	0.652 ± 0.02	10.28 ± 0.81	± 1.205	11.05 ± 4.83
CESTa	5.61± 0.07	12.82 ±0.08	0.645 ± 0.01	8.68 ± 1.29	± 2.1	36.77 ± 3.48
CESTb	5.44 ± 0.06	12.92 ±0.05	0.634 ± 0.01	5.80 ± 0.52	± 1.35	10.12 ± 1.58
CESTc	5.58± 0.14	12.86 ±0.03	0.660 ± 0.01	5.15 ± 0.54	± 2.1	5.15 ± 0.54
CESTd	5.52 ± 0.08	12.90 ± 0.06	0.644 ± 0.01	3.98 ± 0.46	± 2.56	2.64 ± 0.40
PCESTa	5.76 ± 0.15	12.90 ±0.06	0.656 ± 0.02	6.58 ± 1.11	± 2.45	27.56 ± 1.37
PCESTb	5.55 ± 0.10	12.91 ±0.07	0.655± 0.01	6.87 ± 0.94	± 1.28	5.51± 0.64
PCESTc	5.44 ± 0.14	12.94 ±0.04	0.659 ± 0.01	5.71 ± 0.67	± 1.44	4.62 ± 0.67
PCESTd	5.73 ± 0.17	12.84 ±0.07	0.662 ± 0.01	4.7 ± 0.21	1.11	1.26 ± 0.38

Key: CST = Corn starch tablet CEST = *Cyperus esculentus* starch tablet and PCEST = Pregelatinised *Cyperus esculentus* starch tablet and a, b, c and d represents 2.5, 5, 7.5 and 10 %w/w disintegrant concentration respectively.

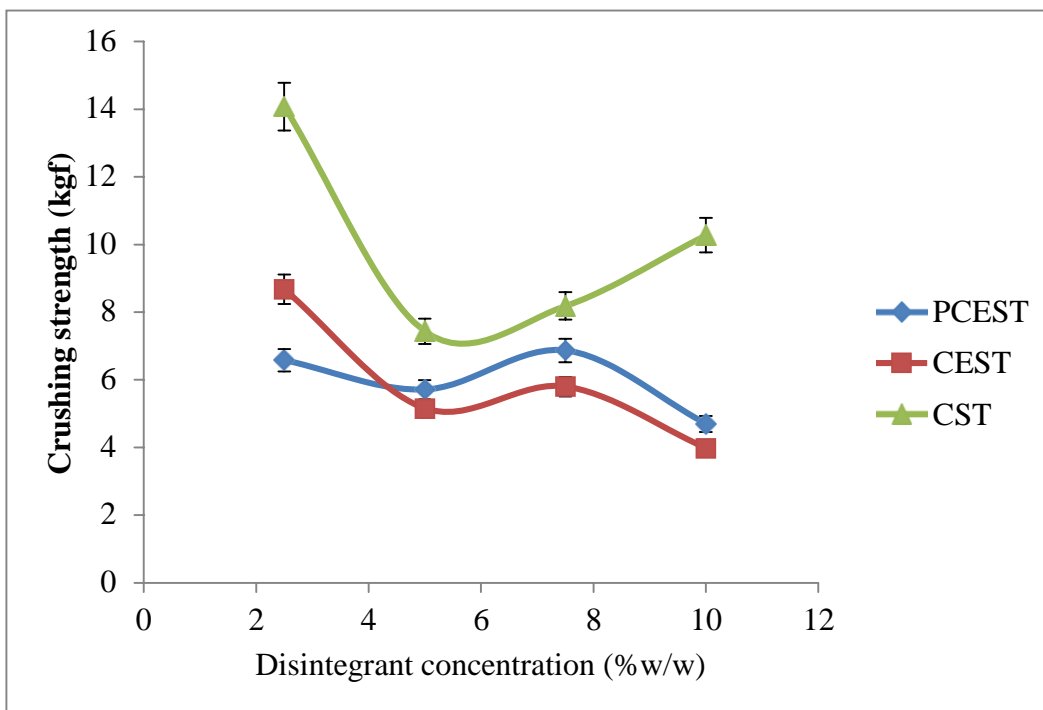


Figure 2 shows the crushing strengths of CST, CEST, and PCEST where CST=Corn starch Tablet, CEST= *Cyperus esculentus* starch Tablet and PCET= pre-gelatinized *Cyperus esculentus* starch Tablet

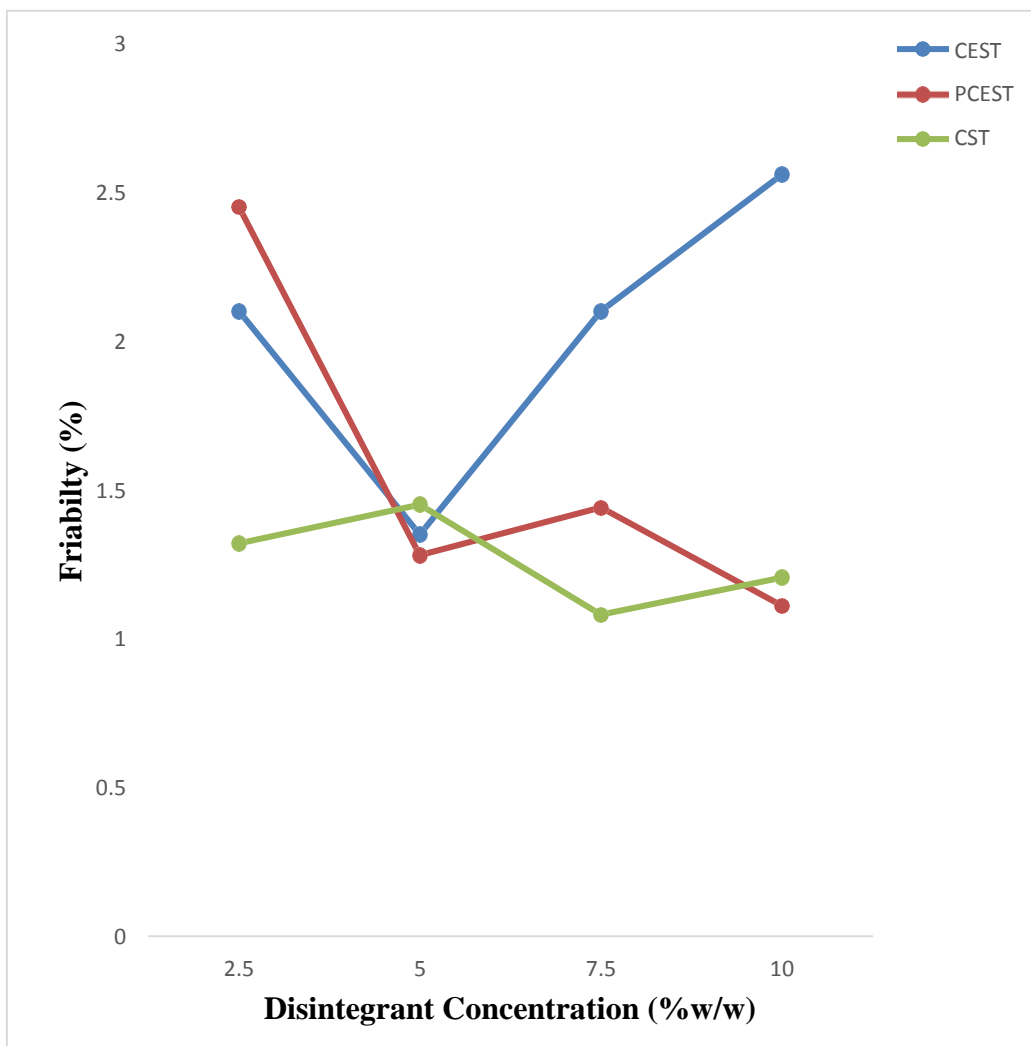


Figure 3 shows the friability profile of CST, CEST and PCEST where CST=Corn starch Tablet, CEST= *Cyperus esculentus* starch tablet and PCET= pre-gelatinized *Cyperus esculentus* starch Tablet

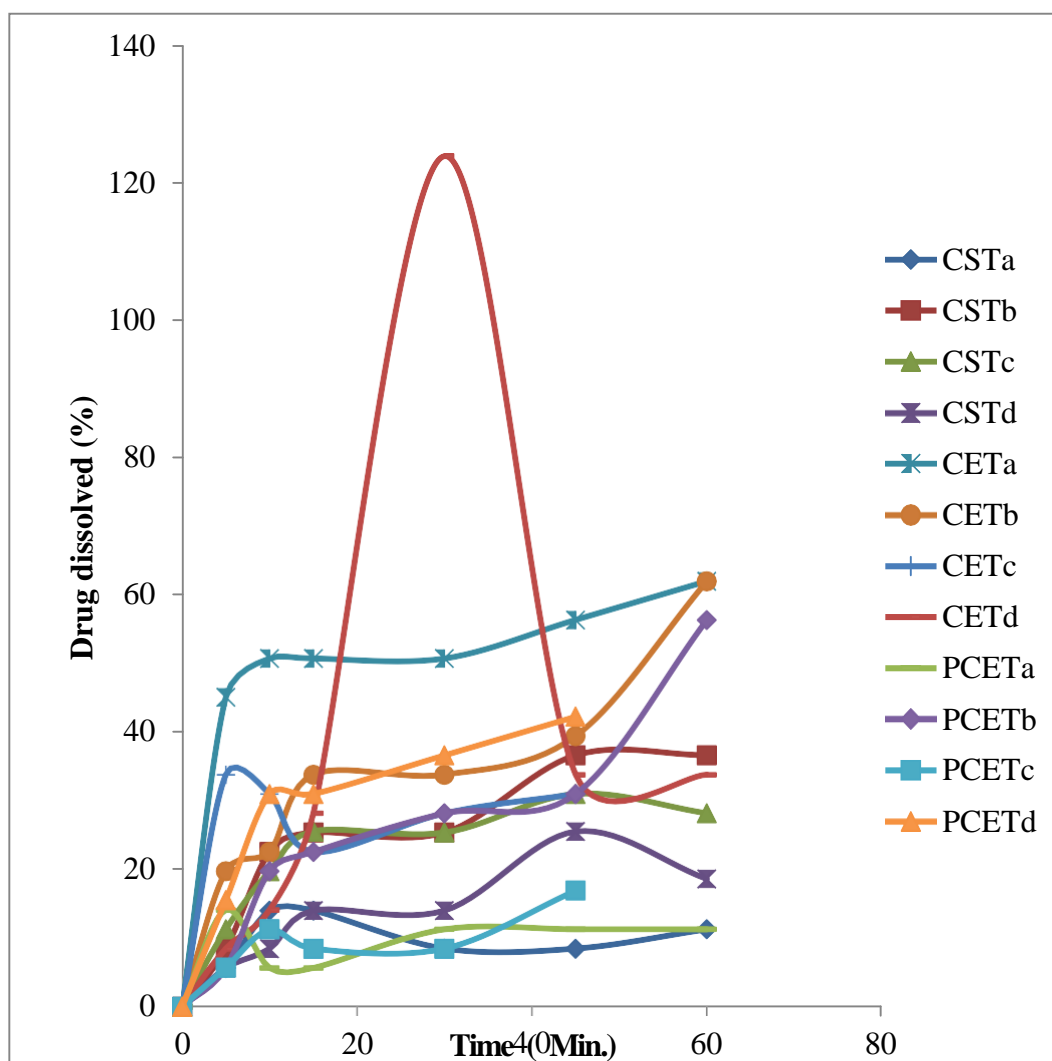


Fig 4 shows the Dissolution rate of CSTa, CSTb, CSTc, CSTd, CETa, CETb, CETc, CETd, PCESTa, PCESTb, PCESTc, and PCESTd, Where CST = Corn starch tablet CEST = *Cyperus esculentus* starch tablet and PCEST = Pregelatinised *Cyperus esculentus* starch tablet and a, b, c and d represents 2.5, 5, 7.5 and 10 % w/w disintegrant concentration respectively.

Discussion

The percentage yield of starch obtained from *Cyperus esculentus* tuber was 19.5% w/w. This was less than the finding of Builders *et al.*, (2013) and Rahul *et al.*, (2012). The variation may be attributed to specie from which the starch was extracted, materials used in the extraction process, environmental condition, soil nutrient, or other important

factors involved in the synthesis of starch in plant.

The iodine test is a confirmatory test for starch. Organoleptic and material properties of the starch samples were presented in Table 2 and 3 respectively. The organoleptic properties agree with the findings of Okorie *et al.*, (2016).

The pH of starch powders which is the measure of its acidity or alkalinity varies depending on the source of the starch. The value obtained for all the three samples were higher than the finding of Rahul *et al.*, (2012) which can be attributed to the different method of the starch extraction employed.

Powder with high hydration and swelling capacities when employed in solid dosage (tablet) formulation as Disintegrants will be expected to rapidly disintegrate muazu *et al.*, (2014). This implies that tablets formed with PCES will be expected to have higher disintegration power than batches made with CES and CE respectively.

Starch gelatinization is associated with disruption of granular structure causing starch molecules to disperse in water. PCES and CES possess higher values which correspond to the finding of Wajira *et al.*, (2006) while CS had the lowest value which can be attributed to the source from which the starch was obtained.

Solubility test is the determination of percentage amount of starch that leached out in to the supernatant Signh *et al.*, (2005). All the three samples were insoluble in both water and 95 % ethanol. This indicates that pre-gelatinization does not change the solubility of starch.

Powders with good flow properties tend to have an angle of repose of $\leq 30^\circ$ while powders with poor flow tend to have angle of repose of $\leq 40^\circ$ Emenike *et al.*, (2017). The Flow property of CS corresponds to good flow while CES and PCES correspond to passable. Value of CES also corresponds to the finding of Builders *et al.*, (2013).

Carr's index and hausner's ratio are used in pharmaceutics to indicate flowability of a powder. Low carr's index (less than 15) indicate excellent or free flow and Carr's index greater than 35 is termed poor flow, Rakhi *et al.*, (2008). CS and CES tend to have poor floor while the PCES correspond to fair to passable flow.

All the samples tend to have high true density which reduces from CS, CES to PCES. High density materials have high diluent power as they substantially reduce powder volume or bulk while improving consolidation and flow Bayor *et al.*, 2013.

Porosity determines the swelling capacity of starch, the higher the porosity of a starch, the more inter particulate spaces where more water could be absorbed Achor *et al.*, (2015). This signifies that PCES has more tendency of swelling than CES and CS.

Regulation of moisture content in a formulation is essential as high moisture content can interfere with active ingredient Muazu *et al.*, (2014). The maximum moisture content prescribed for safe storage by most starch producing countries is 13 %w/w Emenike *et al.*, (2017). All the three samples are within the specified limit and are therefore less prone to microbial contamination.

PCES has higher flow rate than CS and CES which signifies that the two samples have better flowability than PCES. This can be attributed to the change in particles size and shape caused by the pregelatinization.

Moisture sorption capacity is a measure of the moisture sensitivity of a material Ohwoavworhwa *et al.*, (2005). The higher value for PCES indicates its higher

susceptibility to microbial contamination than CES and CS.

Tablets should have uniform Thickness and diameter to enable their efficient packaging. Tablets of same weight may have difference in thickness and diameter depending on the granules particle size and compression force of the tabulating machine. Both thickness and diameter are non- pharmacopeia test and should be controlled with ± 5 % of a standard value *kumar et al.*, (2016). All the tablet batches were found to be within the specified limit.

(BP 2009) specifies that not more than two of the individual weight of tablets deviating from the average weight by more than ± 5 % and none should deviate by more than ± 10 % *Eraga et al.*, (2017). This implies that all the tablet batches were expected to have same concentration of ingredients while CSTd are more prone to variation in content. This result agrees with the finding of *Teklu et al.*, (2014).

The BP 2014 specifies 4-10 kg F as hardness for a conventional tablet *kuevi et al.*, (2019). Batch CSTa and CSTd were above the specified limit and are therefore more prone to have higher disintegration time while all the remaining batches were within the acceptable range. It was observed that crushing strength decreases from CST to CEST and finally to PCEST.

In a batch of tablet, friability of less than 1 % is considered acceptable. *Teklu et al.*, (2014). All the tablet batches had a friability above 1 % which implies that these tablets have less tendency of withstanding pressure when exposed to mechanical shock or attrition.

The BP specifies limit for disintegration of uncoated tablet is less than 15 min. *Teklu et*

al., (2014). Batch A tablets had the highest disintegration time whereas batch D possess the lowest. This shows that disintegration time is inversely proportional to the concentration of the disintegrant. The disintegration time also decreases abruptly from CS, CES and to PCEST.

The BP specifies 90-110 % of paracetamol tablet should be released in 30 minute *Teklu et al.*, (2014). Batch CESA was able to release over 90% of its concentration at 30min and therefore is the only batch that passed. This failure may be attributed to the disintegration time of the tablets, particle size of the granules, compression force, or temperature of the medium.

From this study, it can be concluded that the yield of tiger nut starch is good and the pre gelatinized tiger nut starch possess higher disintegration property than the native while the Native starch itself possess higher Disintegration properties than the corn starch. Thus, Tiger nut starch can successfully be used for large scale production.

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