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The Compaction, Mechanical and Disintegration Properties of Modified *Pennisetum glaucum* (Poaceae) Starch in Directly Compressed Chloroquine Tablet Formulations

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ABSTRACT

Pennisetum glaucum L (Millet) starch is a potential source of direct-compression excipient for use in tableting but has not been commercially explored. The aim of this study was to investigate the compaction properties of pregelatinized freeze (PFDMS) and oven-dried (PODMS) millet starch in directly compressed Chloroquine tablet formulation and compare with the native starch (NMS) and Avicel®. Tablets were directly compressed using the starch in drug-diluent ratios of 1:2, 1:4 and 1:9 and evaluated by compaction, mechanical and disintegration properties. The result showed that PFDMS and PODMS starch samples had higher flow properties in comparison to the native starch and PFDMS also gave the fastest onset of plastic deformation. Tablets formulated with PFDMS and PODMS showed acceptable mechanical and disintegration properties comparable with Avicel® in the order Avicel® > PFDMS > PODMS > NMS. The pregelatinized starch samples can be substituted for Avicel® for direct compression.

INTRODUCTION

The need for locally sourced raw material for pharmaceutical manufacturing cannot be over-emphasized as it lowers manufacturing costs, creates jobs in multiple areas like planting, harvesting, crop storage and boosts national image (Emeje *et al*., 2008).

Starch is one of the earliest excipients to be used for pharmaceutical dosage forms and has been used as a diluent, disintegrant or binder. Starches are of great economic importance being the major source of carbohydrates in human diet (Adebowale *et al*., 2005). It has been known to produce products with low cost, low toxicity, they are biodegradable and stable in biological systems (Musa *et al*., 2010). The inherent properties of native starches can be boosted by chemical and physical modification to obtain simplified starches having varied functional properties (Odeku and Picker-Freyer, 2009). Previous studies showed that chemical and physical adjustments usually improve the compaction properties of native starches (Okunlola and Odeku, 2009; Adedokun and Itiola, 2010). The molecular arrangement in a starch granule can be altered by various physical treatments like pregelatinisation, moisture adjustment and particle size changes (Adebowale *et al*., 2005). Starches from potato and yam have been thermally modified and exposed to different drying methods in past researches (Herman *et al*., 1989; Odeku *et al*., 2008). Gelatinisation of starch leads to noticeable changes in the chemical and physical nature of granular starch due to the rearrangement of intra- and intermolecular hydrogen bonding which occurs between the water and starch molecules. (Musa *et al*., 2010). Millet (*Pennisetum glaucum* L) starch is another potential source that could be used in the food, pharmaceutical or printing industries and is yet to be commercially explored. *Pennisetum glaucum* L is a forage plant of the family Poaceae commonly known as "Pearl millet" in English, "gero" in Hausa and "emeye" in Yoruba. Millet has high content (53-59 $\%^{w}/_{w}$) of starch on dry basis (Hoover *et al*., 2006). The disintegrant properties of the native and modified forms of millet starch has been studied (Odeku and Alabi, 2007), but work has not been done on the direct compression properties of its pregelatinised forms exposed to oven and freeze drying methods.

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Direct compression itself has several advantages including economy, time saving and selectivity for high and low dosage preparations. The objective of the present study was to investigate the compaction, mechanical and disintegration properties of millet starch modified by pre-gelatinisation, exposed to either freeze or oven drying and used as a directly compressible excipient in chloroquine tablet formulation.

MATERIALS AND METHODS

Materials

The materials used were *Pennisetum glaucum L.* seeds obtained from a local market in Ibadan, South Western part of Nigeria and extracted according to established procedures (Akin-Ajani *et al.*, 2005). Chloroquine phosphate BP (BDH chemicals Ltd., Poole, UK) and Avicel® (PH-102 FPC Biopolymer, USA).

Pregelatinisation of starch

The starch sample was pregelatinized using established method (Odeku *et al*., 2008). Aqueous starch slurry (20 % $^{w}/_{v}$) was heated at 100 ^{O}C in a water bath with constant stirring for 15 min. A portion was dried in the oven (Gallenkamp moisture extraction oven), at 40 ^{O}C for two days and the rest was freeze-dried at -84 ^{O}C and pressure of -0.375 bar for 24 hours using a freeze dryer (Christ GMBH, Osterode, Germany). The starches were coded using the following abbreviations: NMS (native millet starch), PFDMS (pregelatinized freeze-dried millet starch) and PODMS (pregelatinized oven-dried millet starch).

Density measurements

The loose bulk volume and density of each starch and the powder mix for direct compression was determined by pouring 30g of powder at an angle of 45^{o} through a funnel into a 50mL glass measuring cylinder. The height at which the powder reached was measured and the volume and density calculated (Mohammadi and Harnby, 1997). The tapped volume and density was measured by applying 100 taps to 30g of each starch in a graduated glass cylinder at a standardized rate of 38 taps per minute (Reus-Medina *et al*., 2004). The particle density was measured using a 50 mL pycnometer with xylene as the displacement fluid (Itiola, 1991).

Hausner's ratio, Carr's index and angle of repose determinations

The Hausner's ratio was determined as the ratio of the initial bulk volume to the tapped volume (Herman *et al*., 1989). Carr's index (Schwartz *et al*., 1975) was calculated from the results obtained from the bulk and tapped densities by using the equation below:

Carr's index (%) = (Tapped density – Bulk density)/tapped density x 100 Eq. 1

Angle of repose (Reus-Medina *et al*., 2004) was determined using an open ended cylinder of fixed diameter which was placed on a base with similar diameter. Thirty grammes of the starch were allowed to flow through a funnel under the force of gravity to form a conical heap. The angle of repose was calculated from:

Angle of repose (Tan Θ) = h/r …Eq.2

Where h is the height of powder and r is the radius of the base of the cone.

Water absorption capacity

The water absorption capacity (WAC) was determined using established method (Solsulski, 1962). To 2.5 g of each starch sample in a weighed 50 mL centrifuge tube, 15 mL of distilled water was added and agitated on a vortex mixer for two minutes after which it was centrifuged at 400 rpm for 20 minutes and the supernatant decanted.

The residue was weighed (w_1) and the absorbed drops of water were removed by drying the residue at 60 ^{o}C to constant weight (w_2) in an oven. WAC was then expressed as the weight of water bound by 100 g of each starch sample.

$$WAC = [(w_1 - w_2)/2.5] \times 10 \quad \text{…Eq. 3}$$

Solubility

Percentage solubility was determined for the starch samples by established method (Leach *et al*., 1959). One gramme of dried and finely powdered starch sample (w) was weighed into a conical flask; 15 mL of distilled water was then added and shaken slowly for 5 minutes. This was then transferred into a pre-weighed centrifuge tube (w_1), 7.5 mL of distilled water was added and centrifuged at 2200 rpm for 20 minutes. The supernatant was carefully decanted into a pre-weighed dish (w_2), dried at 100 ^{o}C to constant weight (w_3) and cooled for 30 minutes. From the weights taken, the following formula was used for the calculation.

$$\text{Solubility (\%)} = [(w_2 - w_3)/w] \times 100 \quad \text{…Eq. 4}$$

Swelling index

The swelling index of the starch sample was determined using an established procedure (Adebowale *et al*., 2002). A quantity 2.5 g of powdered and dried sample was poured into a 100 mL measuring cylinder (v_1). 40 mL of distilled water was added and the dispersion was well shaken for 5 minutes. The dispersion was then made up to 50 mL with distilled water and allowed to stand for 24 hours before sedimentation volume was obtained (v_2). The swelling power was then calculated as follows:

$$\text{Swelling Index} = V_2/V_{1...} \quad \text{Eq. 5}$$

Rheological characteristics

A heating and cooling viscometer (Rapid Visco Analyser) coupled with Thermocline Windows software (Newport Scientific Pty. Ltd, Warriewood, Australia) was used to obtain the viscosity profiles of the starch (Sirivongpaisal, 2008). The starch slurry was heated at a constant rate of shear using a time-temperature regime covering 12 min as follows: Idle temperature 50 °C for 1min, heated from 50 ^{o}C to 95 ^{o}C in 3 min 45 secs, then held at 95 ^{o}C for 2 min 30secs, the sample was subsequently

cooled to 50 ^{o}C over 3 min 45 secs period followed by a period of 2 min where the temperature was controlled at 50 ^{o}C. The viscosity increase was measured as torque on the spindle.

Tableting

The powder formulations with drug-excipient ratios (DER) of 1:2, 1: 4 and 1: 9 for different batches (100g) containing NMS, PFDMS, PODMS and Avicel® were prepared by mixing in a tumbling mixer for 10 min. Chloroquine phosphate tablets (500 mg) were compressed for 30 seconds using a Carver Hydraulic Hand Press (Model C, Carver Inc, Menomonee Falls, Wisconsin, USA). The punches were lubricated with 1 % Magnesium stearate in acetone and the tablets were stored over silica for 24 hours to allow for hardening and elastic recovery of tablets before analysis.

Compressional characteristics of starch in formulations

The Heckel equation below was used to analyze the compressional properties of the starch samples in the chloroquine formulations (Heckel, 1961).

$$\ln (1/1\text{-}D) = KP + A \quad \ldots Eq.6$$

In the equation;

D is the relative density of the tablet at pressure P.

Slope K is a measure of the plasticity of the tablet.

Constant A is related to the die filling and particle rearrangement before deformation and bonding of the individual particles.

Plots of In (1/1-D) against applied pressure (P) were obtained and values of K and A were found from the slope and intercepts while the mean yield pressure (P_y) was obtained from the reciprocal of K. In addition, the total pre-compression pressure density (D_a) and the values of relative density at zero pressures (D_o) were obtained from the equations:

$$D_a = 1\text{-}e^{-A} \quad \ldots\ldots Eq.\ 7$$

$$D_b = D_a - D_o \quad \ldots\ldots Eq.\ 8$$

Mechanical properties of tablets

The crushing strength (CS) was determined using a PTB 301 crushing strength tester (Pharmatest, Switzerland) at room temperature to obtain the load which diametrically breaks the tablet into two equal halves (Adebowale *et al*., 2002). Likewise, the friability (FR) of ten randomly selected tablets was obtained using a friabilator (Model TF 2D, Scientific Equipment Ltd., Bombay, India) operated at 25 revolutions per minute for 4 minutes. CSFR was also determined from the values of crushing strength and friability.

Disintegration time for tablets

The disintegration time (DT) of the tablets was determined in distilled water at 37±0.5 °C in an Erweka disintegration testing apparatus (Model: Copley ZT2, Erweka Apparatebau GMBH, Heusenstamm, Germany). The CSFR/DT was calculated from the values of CSFR and DT (Alebiowu and Itiola, 2003).

RESULTS AND DISCUSSION

Material properties of the starch

The photomicrographs of the natural and pregelatinized starches are shown in Fig. 1. The results revealed that the natural starch granules were spherical in shape while PFDMS were angular and PODMS cuboid. This suggests that the pregelatinisation caused changes in the morphology of the starch granules. The material properties of the starches are shown in Table 1.

The PFDMS and PODMS both have higher values of water absorption capacity, solubility and swelling index with a ranking of PFDMS > PODMS > NMS. The differences thus observed in these properties may be attributed to divergent intensities of molecular association forces inside the particles. Higher water absorption capacity of the modified starch has been ascribed to loose structure of the starch polymer while low values for the natural implies firmness of the natural granules (Akin-Ajani *et al*., 2014). Past researchers had reported that pregelatinization increases cold water swellability of starches (Alebiowu and Itiola, 2002). The swelling index is crucial in tablet formulation as it affects the usefulness of starch in tablet disintegration.

The results of bulk and tapped densities showed that PFDMS and PODMS exhibited the largest maximum volume reduction due to packing while NMS showed the lowest. The ranking is in the increasing order NMS< PFDMS< PODMS. The bulk and tapped densities of a powder describes its packing behavior during the various unit operations of tableting such as die filling, mixing, granulation and compression. Higher values are beneficial in tableting because of reduction in the fill volume of the die. Pregelatinisation of the starch has produced higher bulk and tapped densities compared to the natural form. This improves the packing properties of the modified starch in the die.

The particle density for the modified starch was also lower than the natural in the order of PFDMS < PODMS < NMS. Particle density has been reported to affect the compaction behavior of powders since dense and stiff powders require higher compression pressure to produce tablets with improved mechanical strength (Okunlola and Odeku, 2009). This implies that the modified starch samples in this study will be expected to produce tablets with higher bond strength than the natural form. The values for the angle of repose showed that the PFDMS was freer flowing than PODMS with NMS having the highest value and thus have a poor flow. The ranking is in the decreasing order NMS >PODMS >PFDMS. The Hausner's ratio (HR) and Carr's index has been reported to show the degree of densification that would occur during vibration from the feed hopper when tablet compression is ongoing and as the values of these indices increase, the flow of the powder decreases. A higher HR predicts significant densification while lower values equal or less than 1.25 indicating low interparticulate friction and good flowability (Staniforth and Aulton, 2007). Furthermore, the Carr's index or Carr's Compressibility Index (CI) is an indication of the compressibility

of a powder and when greater than 25% is considered to reflect poor flowability (Odeku and Picker-Freyer, 2009). The modified starch samples had HR and CI lower than that of the natural starch in the reducing order of NMS > PFDMS > PODMS showing improved flow properties. The changes observed in the viscosity profiles of the starch samples are also presented in Table 1.The ranking for pasting temperature, peak viscosity, trough viscosity and final viscosity was PFDMS < PODMS < NMS. In all cases, modification reduced these parameters in the starch showing that the natural starch is more susceptible to heat changes during the heating and cooling process. Final viscosity is the viscosity at the end of the test and it serves as a measure of the effectiveness of starch pastes when used as binders in tablet formulation and it was higher for NMS than for PODMS and PFDMS. The low values of the peak and final viscosity for the pregelatinized starch samples is a reflection of strong resistance to heat changes which usually prevents pasting.

Compressional properties

The compressional characteristics of the staches in chloroquine tablet formulations evaluated using the Heckel plots (Figures 2, 3 and 4) showed some linearity at both low and high pressures. The Heckel analysis is a popular method of describing the mode of deformation under applied compression force and is based on the assumption that powder compression follows first order kinetics with the inter-particulate pores as the reactants and the densification of the powder as the product (Heckel, 1961). Normally, it would be expected that the starches would consolidate by fragmentation first at low pressures but the apparent linearity at low pressures suggests that some degree of plastic deformation was also taking place. This is probably due to the fact that the system would start deforming plastically from the moment the yield value for one particle is exceeded during compression. Thus, it should be expected that the process of fragmentation of the formulations would occur to some extent simultaneously with plastic and elastic deformation of the constituent particle. The parameters derived from density measurements and the Heckel plots are shown in Table 2. The ranking of mean yield pressure (P_y) is in the decreasing order of AVICEL®>NMS> PODMS> PFDMS. This means that chloroquine tablets containing PFDMS exhibited the fastest onset of plastic deformation during compression implying faster tablet formation while those containing AVICEL® had the slowest onset of plasticity. The density of the formulations at zero pressure (D_0) had no particular order of increase with increase in the concentration of excipients added. However, the ranking is in the order of PFDMS >PODMS >NMS >AVICEL® indicating that formulations containing PFDMS exhibited the highest degree of packing at zero pressure. The D_a values which represent the total degree of packing at low pressures is in the ranking of PFDMS > AVICEL® > PODMS > NMS meaning that the formulations containing PFDMS also showed the highest degree of packing at low pressures. The ranking of values of D_b is in the order of AVICEL® > PFDMS >NMS >PODMS, which indicates that formulations containing AVICEL® have the highest degree of fragmentation of particles at low pressures. The Heckel plots of the formulations shows linearity at low pressures and this indicates that the materials used as excipients are soft materials and exhibit plastic deformation at low pressures.

Mechanical and disintegration properties of formulated tablets

The tablet properties are presented in Table 3; the result of the crushing strength (CS) showed that the values for tablets containing Avicel®, PFDMS and PODMS increased with an increase in applied pressure and concentration of the excipients. The tablets also possess adequate CS while those containing NMS as excipient had crushing strength of less than 40 N which was inadequate and much smaller than for the pregelatinised starches. Crushing strength shows the ability of tablets to withstand pressure or stress during handling, packaging and transportation. It is the property of a tablet that reveals its resistance to permanent deformation (Celik, 1992). Generally a crushing strength of 40 N is normally considered to be the minimum for a satisfactory tablet (King and Schwartz, 1985). Tablets formulated with NMS had significantly higher ($p< 0.05$) friability and lower ($p< 0.05$) crushing strength-friability ratio (CSFR). Generally the trend of friability was NMS > PODMS > PFDMS > Avicel® and the ranking for CSFR was NMS< PODMS < PFDMS < Avicel®. Friability test is designed to evaluate the ability of the tablet to withstand abrasion during packaging, handling and shipping. For compressed tablets, the percentage loss in weight of less than or equal to 1% is usually considered acceptable (BP, 1998). The CSFR is also a measure of the mechanical strength of tablets and it portrays the balance between tablet strength and weakness. Generally the higher the CSFR, the stronger the tablet (Itiola and Pilpel, 1986; Ajala *et al*., 2011). All the tablets disintegrated within 2.83 ± 0.25-10.03 ± 0.68 minutes and it increases with increase in compressional pressure with a trend of AVICEL®< PODMS< PFDMS< NMS. Disintegration time (DT) measures the time required for the tablet to crumble into particles and it is a necessary condition for dissolution and could be the rate determining step in the process of drug absorption. The BP stipulated a disintegration time of not more than 15 minutes for uncoated tablets (BP, 1998). A change from natural to pregelatinized starch led to a decrease in DT, which could be due to the increased swelling index and water absorption capacity of the modified starch. This higher swelling ability could lead to the absorption of large quantities of water into the tablet mass and the subsequent initiation of the active mechanism of disintegration at a faster rate than for natural starch disintegrants (odeku and Alabi, 2007). The starch samples after gelatinization showed higher water absorption capacity and swelling index. The CSFR/DT values for the Chloroquine tablets were in the increasing order: NMS<PODMS<PFDMS<AVICEL®. The CSFR/DT ratio is considered as a better index of measuring tablet quality than CSFR because apart from evaluating mechanical strength (crushing) and weakness (friability), it also evaluates the effects of these parameters on disintegration time (Upadrashta *et al*., 1992).

Table 1: The material properties of starch samples (mean ± SD, n=3).

Material property	NMS	PFDMS	PODMS
Water absorption capacity (%)	50.64 ± 0.27	179.84 ± 1.02	161.76 ± 0.89
Solubility (%)	12.5 ± 0.33	94.80 ± 0.54	81.30 ± 0.67
Swelling index	2.2 ± 0.03	3.50 ± 0.02	2.70 ± 0.29
Bulk Density	0.47 ± 0.01	0.67 ± 0.04	0.71± 0.05
Tapped Density	0.71 ± 0.02	0.77 ± 0.07	0.79 ± 0.03
Particle density	1.97 ± 0.04	1.68 ± 0.05	1.75 ± 0.06
Hausner's ratio	1.52 ± 0.05	1.15 ± 0.01	1.11± 0.03
Carr's index	34.31 ± 1.01	13.26 ± 0.98	9.51±1.02
Angle of Repose (^{o})	64.60 ± 1.02	27.50 ± 0.78	32.50 ± 0.95
Pasting temperature (^{o}C)	388.45 ± 1.82	82.23 ± 0.99	87.88 ± 1.91
Peak viscosity (RVU)	163.17 ± 1.23	109.24 ± 1.19	108.58 ± 1.25
Trough viscosity (RVU)	135.01 ± 1.21	66.57 ± 0.11	67.67 ± 0.34
Final viscosity (RVU)	243.58 ± 2.07	167.54 ± 1.19	170.08 ± 1.23

Table 2: Parameters derived from density measurements and Heckel plots.

Excipient	Drug-Excipient Ratio	D_o	P_y (MNm^{-2})	D_a	D_b
AVICEL	1:2	0.14	41.67	0.68	0.54
	1:4	0.11	47.62	0.66	0.55
	1:9	0.13	142.86	0.66	0.54
NMS	1:2	0.21	71.43	0.56	0.35
	1:4	0.20	90.91	0.58	0.38
	1:9	0.19	55.56	0.55	0.36
PFDMS	1:2	0.32	71.43	0.65	0.33
	1:4	0.33	52.63	0.66	0.33
	1:9	0.40	12.82	0.84	0.44
PODMS	1:2	0.26	76.92	0.58	0.32
	1:4	0.31	55.56	0.61	0.29
	1:9	0.30	76.92	0.54	0.25

Table 3: The mechanical and disintegration properties of the tablets (Mean ± SD).

EXCIPIENT	DRUG-EXCIPIENT RATIO	APPLIED PRESSURE (MNm-2)	CRUSHING STRENGTH (N)	FRIABILITY (%)	CSFR	DISINTEGRATION TIME (Mins)	CSFR/DT
AVICEL	1:2	56.57	179.83±5.16	0.29	620.10	3.22±0.25	192.58
		113.13	224.27±3.03	1.15	195.02	5.67±0.63	34.39
	1:4	56.57	284.03±7.65	0.23	1234.91	2.83±0.25	436.37
		113.13	288.60±8.22	0.28	1030.7	4.30±0.54	239.70
	1:9	56.57	314.37±25.16	0.61	515.36	2.39±0.46	215.63
		113.13	323.80±35.44	0.24	1349.1	3.22±0.39	418.99
NMS	1:2	56.57	36.0±0.40	4.86	7.41	7.53±0.24	0.98
		113.13	30.7±0.46	5.74	5.35	10.03±0.68	0.53
	1:4	56.57	36.0±1.20	5.06	7.12	5.63±0.57	1.26
		113.13	29.3±1.22	5.65	5.19	6.75±0.37	0.77
	1:9	56.57	30.7±0.83	4.97	6.18	4.52±0.38	1.37
		113.13	45.3±1.29	3.87	11.71	5.17±0.48	2.27
PFDMS	1:2	56.57	146.40±3.50	1.32	110.91	5.88±0.05	18.86
		113.13	145.83±8.47	1.41	103.43	6.33±0.14	16.34
	1:4	56.57	145.43±10.81	1.40	103.88	5.52±0.36	18.82
		113.13	124.43±3.52	1.65	75.41	5.87±0.12	12.85
	1:9	56.57	177.53±7.90	1.66	106.95	3.74±0.09	28.59
		113.13	164.97±9.35	1.94	85.04	5.88±0.05	14.46
PODMS	1:2	56.57	48.13±1.65	4.86	9.9	4.7±0.28	2.11
		113.13	52.07±1.56	2.26	23.04	5.9±0.16	3.91
	1:4	56.57	56.23±1.01	5.50	10.22	6.2±0.07	1.65
		113.13	64.33±1.82	1.90	33.86	3.5±0.08	9.67
	1:9	56.57	69.33±1.84	3.59	19.31	7.1±0.25	2.72
		113.13	74.03±4.16	2.29	32.33	4.2±0.17	7.69

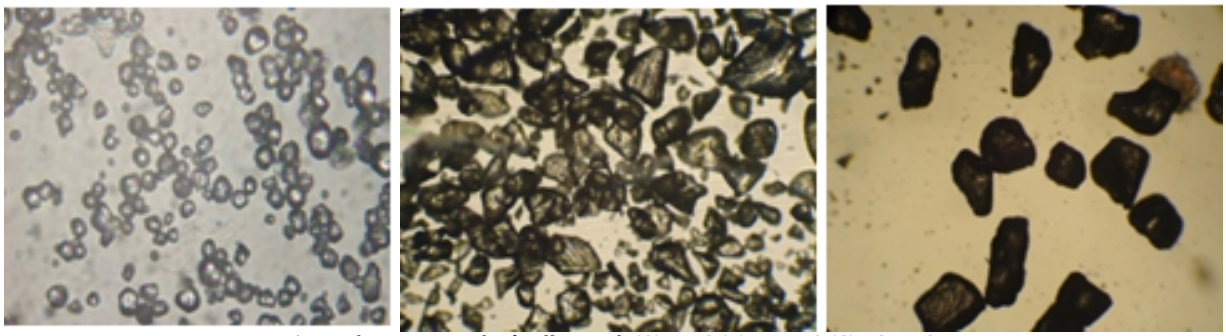

Fig. 1: Photomicrograph of millet starch (A) NMS (B) PFDMS (C) PODMS.

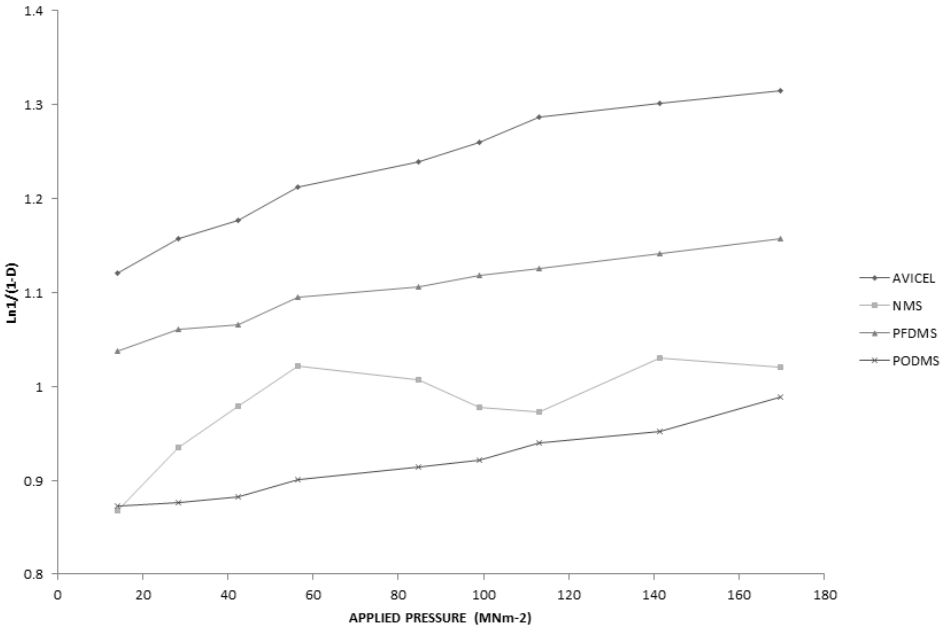

Fig. 2: Heckel plots for chloroquine tablet formulations containing 1:2 drug–excipient ratio of the starch samples.

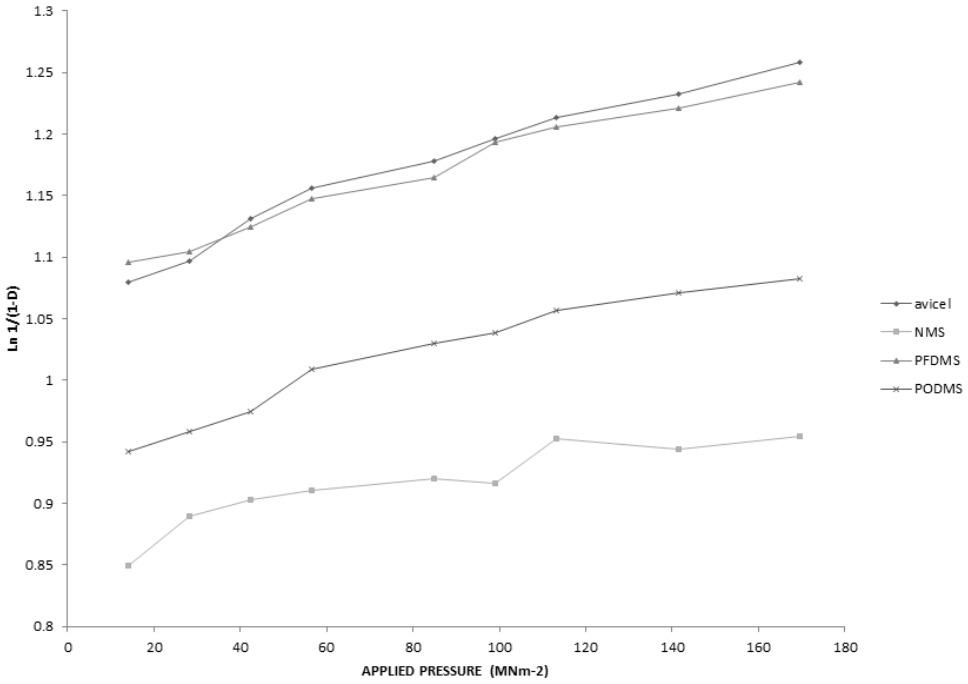

Fig. 3: Heckel plots for chloroquine tablet formulations containing 1:4 drug–excipient ratio of the starch samples.

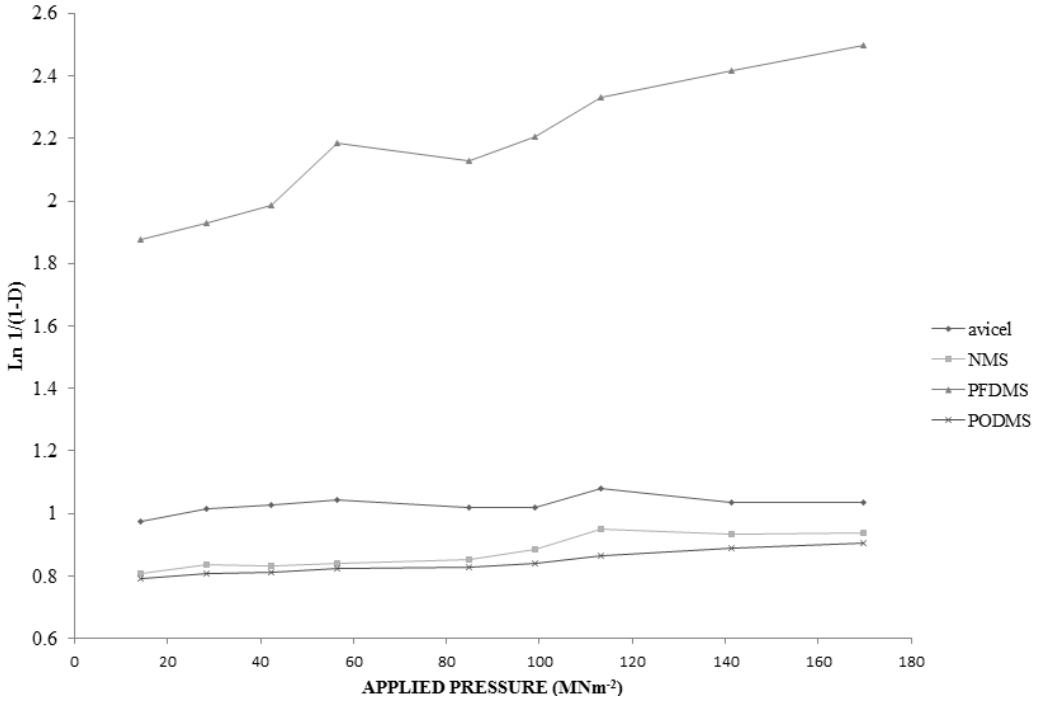

Fig. 4: Heckel plots for chloroquine tablet formulations containing 1:9 drug–excipient ratio of the starch samples.

CONCLUSION

A change from natural to pregelatinisation improved the flow properties of *Pennisetum glaucum* starch. The increased flowability improved the compressibility of the starches and tablets obtained using PFDMS and PODMS as direct compression excipients showed acceptable mechanical and disintegration properties comparable with those containing Avicel®. Generally, pregelatinised freeze-dried and oven-dried millet starches can be considered for use in place of Avicel ® as directly compressible excipients.

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