



Physical Properties and Compactability of Various Blends of Fully Gelatinised and Pregelatinised Maize Starch

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Abstract

The use of pregelatinised maize starch in direct compression as a sole binder produces tablets with relatively low tensile strength. Fully gelatinised maize starch possesses better binding properties but its use is limited in immediate release tablets. The aim of this work was to prepare a blend of fully gelatinised and pregelatinised maize starch possessing optimum tableting properties. The pregelatinised starch was prepared by heating a 15 % slurry at 65 °C for 15 min followed by filtration and drying. The fully gelatinised starch was prepared by heating a 10 % slurry at 80 °C for 5min followed by precipitation with acetone, filtration and drying. The two samples were blended in 100:0, 25:75, 50:50, 75:25 and 0:100 proportions. Both local and BP starch samples were used and their blends compared for flow, packing characteristics and compactability. The disintegration time of the compacts was also determined. The results indicated that the BP starch blends exhibited better tableting properties compared to the local starch. The proportion with 100 % fully gelatinised starch showed the best flow and compactability. Compacts containing 50:50 modified starch blends and those containing higher pregelatinised starch content disintegrated within 15 min. The fully gelatinised starch had better tableting characteristics though physical mixing of the powder sample with pregelatinised starch may not improve the binding properties of the latter, and it could be used for immediate release tablets in such blends at a concentration of <50%.

1 Introduction

Starch is a polysaccharide that has been used as a pharmaceutical excipient in tableting for many years. This is due to its cheapness and abundancy in cereal grains (such as corn, wheat, and sorghum), roots or tubers (yams, sweet potatoes, cassava, coco yams, yam bean etc.) and even fruits¹⁻³. There are two main building blocks of this polymer i.e. amylose which has a linear structure with d- (1-4) linkage and constitutes 15-20% of starch, and amylopectin which is highly branched with both d-(1-4) and d-(1-6) linkages⁴.

The latter unit is the major component of starch and is responsible for crystalline region (30%) in starch granules while

70% is regarded as amorphous and contains both the amylose (main unit) and a considerable amount of amylopectin⁵.

The polymer has been extensively studied and is used as a binder in form of a paste (5 – 10%) and a disintegrant (3 – 25%) in wet granulation^{6,7}. However, the use of the native starch polymer in direct compression is limited by poor flow, compactability, compressibility and packing^{8,9}.

Direct compression (DC) is the simplest and cheapest technology of tableting because of the few processing steps involved. The manufacturing method is also preferred for drugs such as ascorbic acid that are sensitive to moisture. The success of DC depends to a great extent on the choice of excipients which impart flow and compression characteristics to the powder

blend⁹. Some of the few materials that are presently used in direct compression other than starch include microcrystalline cellulose, lactose, dibasic calcium phosphate but the use of each is limited by one or more factor(s) such as cost, unsatisfactory tableting properties and etc. Therefore, there is a need to search for cheaper excipients with nearly ideal properties for direct compression to minimize the cost of tablet production.

Corn starch is the most widely used and cost-effective excipient in tableting¹⁰, and its use in direct compression has been extended by physical modifications to improve the flow and compactability (also known as tableability). The most common modification method, thermal gelatinisation, has already yielded products such as pregelatinized starch (starch 1500) which possesses improved flowability, compressibility and disintegration. But still it produces tablets with low tensile strength when used as a sole binder in the formulation^{11,12}. Hence, the starch 1500 is always used in combination with other directly compressible binders to obtain a tablet with sufficient and acceptable strength.

Fully gelatinized starch (starch dispersion heated to a temperature above its gelatinisation temperature, 64.3–77.2 °C for corn starch¹³) is known to possess better binding properties than pregelatinised starch (starch dispersion heated below the gelatinisation temperature). The fully gelatinised starch has longer disintegration time in aqueous media due to its tendency to form a gel which has been exploited as a matrix for slow release dosage forms. Thus, the completely gelatinised starch has limited application in immediate release tablet dosage forms.

Our work reports on the possibility of improving the binding properties of pregelatinised maize starch by physically mixing it with the fully gelatinised maize starch in a suitable proportion. The compaction, physical and disintegration properties of the different blends of fully gelatinised and pregelatinised locally extracted maize starch samples were compared with those from maize starch BP (standard starch) and Microcrystalline Cellulose (Avicel 102).

2 Material and Methods

2.1 Materials

The following materials were used for the study: Distilled water; Magnesium stearate B.P (Amed Drug and Chemical Co., U.S.A); Xylene (BDH Chemicals Ltd Poole, England); Acetone (Guandang Guanghua Chemical Factory Co Ltd, JHD, China); Microcrystalline cellulose pH 101 (ATOZ Pharmaceuticals Ltd, Ambaltur, India); Standard starch (De Tulpen, Amsterdam, Holland). Local maize starch was extracted in the Pharmaceutics Laboratory of department of Pharmaceutics and Pharmaceutical Technology, Faculty of Pharmaceutical Sciences, University of Jos, Jos, Nigeria.

2.2 Extraction of Local Native Starch

The maize grains were collected from Faringata Market, Jos City, Plateau State, Nigeria and taken for authentication to a botanist (Mr. J.J Azila) at Federal College of Forestry Jos as *Zea mays L. var. Cuscoensis*. A method previously used was adapted¹⁴, with modifications as follows. The starch slurry was spread on a tray and air-dried at room temperature for 24 h, and later transferred to an oven set at 60 °C for 2 h. The dry starch powder was ground and stored in clean glass bottles at room temperature for subsequent use.

2.3 Preparation of Pregelatinized Maize Starch

The method reported earlier was used⁷, with the following modifications. Aqueous starch slurry (15% w/w) was prepared in a Pyrex (G-17) beaker (1000 ml). The beaker containing the slurry was heated directly on a hot plate (Stuart, UC 152, UK) with constant stirring (using a rod) while monitoring the increase in temperature with a thermometer. The heating continued up to 65°C and the temperature was maintained for 15 min, the beaker was removed and cooled. The slurry was later filtered using a Whatman's filter paper and spread on a tray. It was dried in an oven at 60°C for 2h and drying completed under fan. The dry flakes were then weighed, milled, sieved (# 355 µm) and stored in clean glass bottles at room temperature. The same method was used for preparation of pregelatinised maize starch from maize starch BP.

2.4 Preparation of Fully Gelatinised Maize Starch

A slurry (10%) was prepared and heated up to 80 °C after a gel was formed (complete gelatinization). The temperature was maintained for 5 min and the beaker removed from the plate and cooled. The gel was then precipitated with acetone by adding an equal amount of the solvent and blending the mixture using a blender (Mascot Turbo, Turkey).

The resulting fine product was then filtered using a Whatman's filter paper. The precipitation procedure was repeated three (3) times until a powdery mass was formed. The mass was spread on a fresh filter paper and air-dried under fan. The dry material was milled, sieved (# 355 µm) and stored at room temperature in a glass bottle for later use. The same method was also adopted for preparation of fully gelatinised maize starch from BP maize starch.

2.5 Preparation of the various modified Starch Blends

The pregelatinised sample (A) and fully gelatinised sample (B) were blended in percent ratios of A: B as shown in Table 1. The mixing was done by trituration using a mortar and a pestle to obtain a homogenous mixture. The blends (as designated in the table) were then used for the following evaluations.

2.6 Physical Properties of the Blends

Moisture Content

The sample (1g) was placed in a crucible with a known weight and dried in an oven at 105°C until a constant weight obtained. The following formula was then used to calculate the percentage moisture content (MC),

$$MC = \frac{\text{Initial weight} - \text{final weight}}{\text{Initial weight}} * 100 \dots\dots\dots \text{Eq. 1}$$

Microscopy

Powder sample (0.2g) was mounted in glycerol on a slide and stained within lugols iodine solution. The slide was observed under a light microscope (Nikon Eclipse TE300, USA) connected to a digital camera (1.4MP, Sony ICX205AK) and computer which automatically captured the photomicrographs at a total resolution of 1360 x 1024.

Swelling Index (SI)

Sample (4g) introduced in to a measuring cylinder (50ml) and the tapped volume (V_1) noted. Distilled water was added on to the powder up to the 50ml mark, and the final volume, V_2 of the powder dispersed in the solvent after 24h of standing was noted. The Index was then calculated as,

$$SI = \frac{V_2}{V_1} \dots\dots\dots \text{Eq. 2}$$

Determination of Flow Properties

The different blends were evaluated for Angle of repose, Bulk and Tapped densities, Hausner's Ratio, Carr's index using the standard procedures^{15,16}, as follows. Angle of Repose, α . The powder sample (20g) was passed through a funnel (stem diameter 10mm) clumped 10cm above the bench covered with a clean paper. The height (h) and the radius (r) of heap of cone formed was measured (in cm). The angle was calculated as,

$$\alpha = \tan^{-1}(h/r) \dots\dots\dots \text{Eq. 2}$$

Bulk density (ρ_b) and Tapped Density (ρ_t)

The powder sample (20g) was carefully poured in to a measuring cylinder tilted at angle of 45° to minimize tapping. The volume

occupied by the powder was then noted, V_b . The cylinder was tapped until a constant volume was obtained and the final volume, V_t noted. The densities were calculated as,

$$\rho_b = \frac{\text{Weight}}{V_b} \dots\dots\dots \text{Eq. 2}$$

$$\rho_t = \frac{\text{Weight}}{V_t} \dots\dots\dots \text{Eq. 3}$$

Carr's Index (CI)

This was calculated according to the equation,

$$CI = \frac{\rho_t - \rho_b}{\rho_t} * 100\% \dots\dots\dots \text{Eq. 4}$$

Hausner's ratio (HR)

This was calculated from tapped and bulk density according to the following relationship,

$$HR = \rho_t / \rho_b. \dots\dots\dots \text{Eq. 5.}$$

True density (ρ_{true})

It was determined using the pycnometer bottle method as described¹⁷.

Porosity (ϵ)

This was calculated from the equation,

$$\epsilon = [1 - (\rho_b / \rho_{true})] * 100\% \dots\dots\dots \text{Eq. 6}$$

2.7 Formulation of Powder Compacts and Compactability Analysis

Compacts (500mg) were directly compressed at a range of pressures (4.905 – 24.525 kN) from the different blends of pregelatinised and fully gelatinised samples illustrated in Table 1. Three compacts were made at each pressure level except for 14.715 kN (6 compacts formed). A dwell time of 30s was maintained for each compression. Before compaction, the die (12.0 mm diameter) and the flat – faced punch were lubricated with 0.2% dispersion of magnesium stearate in acetone. The compacts were kept in a room temperature for 24 h (to allow for elastic recovery and hardening).

Table 1: Formula for Blends of Pregelatinised (A) and fully gelatinised (B) maize starch samples

Blends	L1	L2	L3	L4	L5	S1	S2	S3	S4	S5
Pregelatinised maize starch (A) (%)	100	75	50	25	0	100	75	50	25	0
Fully gelatinised maize starch (B) (%)	0	25	50	75	100	0	25	50	75	100
Total (%)	100	100	100	100	100	100	100	100	100	100

L- Local maize starch, S – Standard BP maize starch, 1, 2, 3, 4 and 5- the different blends in various percentages of A and B

The crushing strength (CS) of the compacts were determined manually using a Monsanto hardness tester and their corresponding tensile strength (TS) calculated as,

$$TS = \frac{2CS}{\pi dh} \quad \dots\dots\dots\text{Eq. 9.}$$

Where;

d is the diameter and h, the thickness of the compacts. A graph of tensile strength (TS) against compression pressure (P) was plotted for evaluating the compactability property of the powder materials¹⁸.

2.8 Disintegration test for Compacts

The disintegration time for three (3) compacts directly compressed at 14.715 kN were individually determined in distilled water at 37±0.5°C using disintegration test apparatus (Type ZT3, Erweka, Germany). The mean disintegration time was then calculated.

3 Results and Discussion

3.1 The Percentage Yield for Native and Modified Starch Samples

The percentage yield of the local starch extracted and for the ones modified are presented in Table 2. The native starch extracted has the lowest percentage yield compared to the one for modified starch samples. The yield for local native starch is lower, compared to the expected >66% for maize starch on dry basis¹⁹. The lower percentage yield could be attributed to the quality of the maize grains and the source. This is because previous studies³, reported that the tropical cereals generally have a starch content in the range of 40 – 80 % which covers our yield (46.46%).

The yield for modified starch samples increased in the order LA>SA>SB>LB. The pregelatinised starch which was dried without acetone precipitation had higher yield compared to the fully gelatinised acetone precipitated one in both the local and BP starch samples. This could be explained by the processes of gelatinisation especially the full gelatinisation at 80°C which destroyed all the granules and their arrangement leading to lower amounts of powder material measured compared to the pregelatinised. Increased solubilisation of starch granules after complete gelatinisation may have also contributed to the lower yield values observed in fully gelatinised samples²⁰.

Table 2: Percentage yield of native maize starch, pregelatinised maize starch (A) and fully gelatinised maize starch, Mean ± SD, N=3

Starch Sample	L-N	L-A	L-B	S-A	S-B
Percentage yield (%)	46.46 ± 1.00	81.78 ± 1.68	68.33 ± 1.91	81.11 ± 2.03	77.92 ± 3.15

Key: L-N= Local Native; L-A= Local pregelatinised; L-B= Local fully gelatinised, S-A= Standard pregelatinised; S-B= Standard fully gelatinised

3.2 Physical Properties of the blends

3.2.1 Moisture Content

The moisture content of the different blends for both standard and local starch samples range from 15.33 ± 1.53 to 10.7 ± 0.3 % as summarized in Table 3. The values for the starch samples were significantly higher than the one for Avicel 101 (P<0.05) with a very low moisture content of 2.73 ± 1.01 %. The standard modified starch samples had generally lower values compared to the local starch samples. The BP recommends that the moisture content for pregelatinised starch should be ≤ 15 %⁷. This was not different from the values we reported. Moisture increases cohesiveness between the particles of a powder hence affecting the ability of the powder to flow freely. The consolidation and compressibility characteristics of a pharmaceutical powder can also be affected by its level of moisture¹⁷. Below the critical moisture content, the flowability increases as water content increases because of its lubrication property, but above this point the flowability decreases due to increased cohesion²¹. According to previous reports²², tensile strength of tablets compressed from MCC is reduced if the moisture content is outside the range of 3.5 and 5 % (the critical moisture content for MCC). Our reported

value for MCC (the standard excipient) is outside the range but other researchers²³ had earlier found that, the tensile strength is only reduced if the moisture is above 3 % as the moisture disrupts the particle bonds, indicating that our MCC was not affected by moisture content level. For the starch samples, the moisture content levels were all below the BP permissible higher limits and above 10% (the acceptable limit for lubrication and compressibility).

3.2.2 Microscopy

The photomicrographs in figure 1, show that some of the granules were destroyed or ruptured while others remained intact in the partially pregelatinised starch samples. Meanwhile all the granules were ruptured in the fully pregelatinised starch sample. This means that the method employed for gelatinising the starch granules were robust and achieved their intended purposes. Our observations were in agreement with the previous findings highlighted by Wajira and David²⁰, where 10 % corn starch slurry was used and granule destruction started at 60 °C and almost all the granules were irreversibly disrupted at or before 80 °C. The modified starch samples possessed a mixture of spherical and irregular shaped granules. There was no clear difference observed in the shapes of the ruptured granules in the different

samples. The starch granule shape affects the flow behavior in such a way that dominance of sphericity is associated with better flow while irregularity leads to poor flow. Particle shape also affects the compaction characteristics just as it influences the

packing behavior of starches²⁴. So any differences that were not captured in the microscopy would be reflected in the above properties exhibited by each sample.

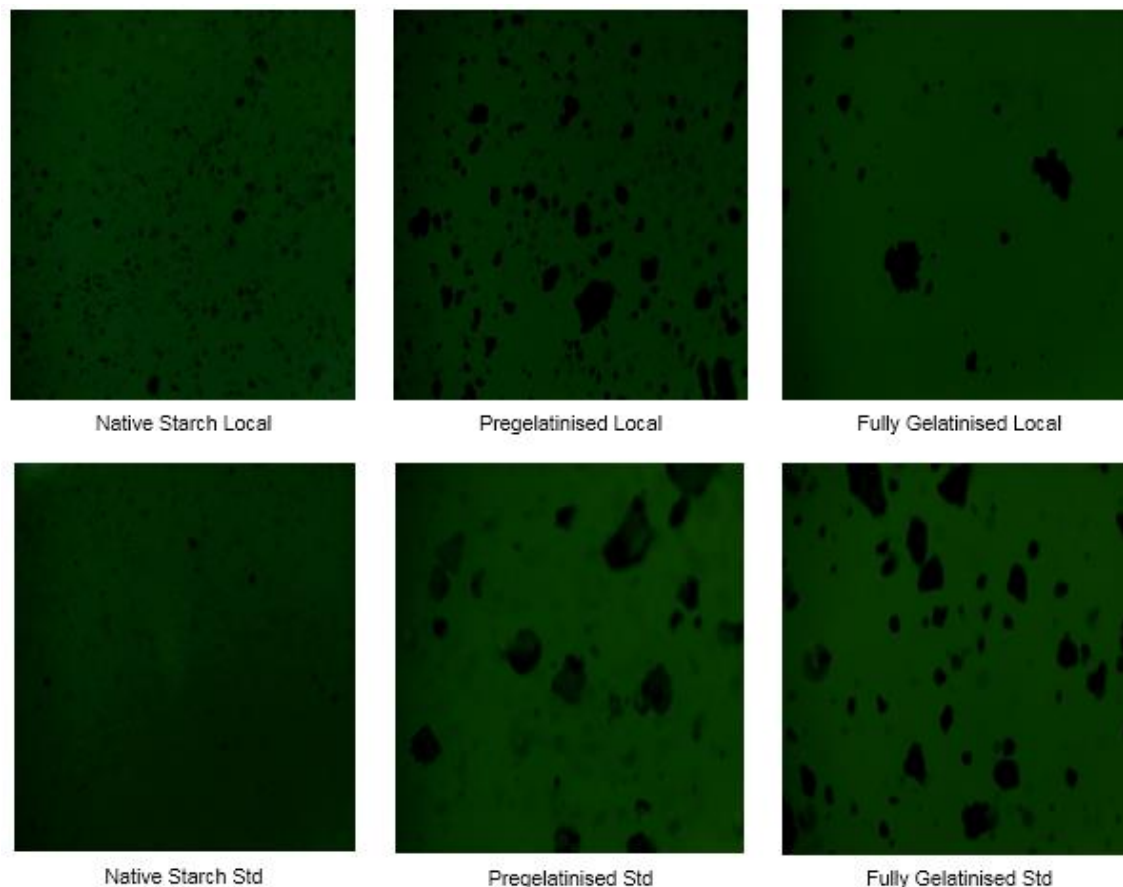


Fig 1: Photomicrographs of Native, Pregelatinised and Fully gelatinised maize starch samples from Local Source and BP standard starch, Resolution: 1360 x 1024; Std – Standard

3.2.3 Swelling Index

Swelling is a measure of the ability of a starch material to release an active component by influencing the time taken for a tablet to disintegrate or a matrix to release a drug in a controlled release formulations^{25,26}. The swelling index of SIV was the highest and MCC, the lowest with ranking of S4 > S3 > S5 > S2 > S1 for the standard modified starch samples and L5 > L2 > L1 > L3 > L4 for the local counterparts (Table 3). Starch gelatinisation is known to increase the extend of swelling and water absorption²⁷, meaning fully gelatinised starch samples are expected to exhibit higher swelling index compared to pregelatinised one. This also means that the index would increase as the amount of fully gelatinised starch increases in the blends. However, this trend was not very clear in our findings, though the fully gelatinised samples (L5 and S5) had relatively higher values compared to the pregelatinised samples (L1 and S1) and the blends with lower levels of fully gelatinised samples. Previous reports²⁸ show that starch granular swelling is primarily a property of amylopectin. However, the differences observed within the same source could not be

explained by possible variations in amylopectin contents. It is likely that the different blends exhibited unique swelling capacities irrespective of the level of fully gelatinised starch.

3.2.4 Flow and Packing Characteristics

The local starch blends demonstrated a higher angle of repose ranging from 38.40 ± 3.01 to 43.27 ± 1.73 (L2 < L5 < L1 < L4 < L3) when compared with the blends of standard starch which had lower values in a range of 13.04 ± 0.90 – 14.10 ± 0.89 (S5 < S3 < S1 < S4 < S2), as presented in Table 3. Aulton¹⁶, classified the flow of powders based on their angle of repose as excellent (< 30°), good (31 – 35 °), fair (36 - 40°) and passable which needs a flow aid (41 – 45°). Based on this, the blends of BP starch have excellent flow while the local starch blends ranges from good to passable flow. According to BP⁷, the angle of repose for a pregelatinised maize starch should be 40.7°. This means that the modification method used was able to produce a starch with flow properties superior to the BP specifications especially for the BP starch blends. The local starch blends had their values were

distributed around the BP specification. The higher angle of repose values of local starch blends compared to the ones of the BP starch could be attributed to its substandard purity. The angle of repose obtained in our findings for blends of BP starch were in the same classification with the previous reports²⁵, for gelatinised acetone precipitated BP starch. However, our values were lower than theirs (26.7 – 30°). The differences could be attributed to variations in the methods of drying used and gelatinisation temperatures, as they used fluidized bed dryer and a temperature of 90 °C compared to our fan drying, full gelatinisation at 80 °C and pregelatinisation at 60 °C. There was also no trend along the levels of fully gelatinised or pregelatinised samples in the blends. Thus, each blend exhibited unique flow behavior.

In Table 3, the bulk density for standard starch blends are significantly higher than for local blends ($P < 0.05$). Also the values for all the starch blends are higher than MCC with statistically significance at $P < 0.05$. The same trend with bulk density was also followed by tapped density. The densities (bulk and tapped) both give information on a powder's packing behavior during various unit operations such as die filling, mixing and compression²⁹. Higher values are desirable because of reduction in fill volume of the die during tableting. This indicates that the BP blends have better die filling and compression properties compared to the local blends and MCC in the order of BP blends > Local starch blends > MCC. Different proportions of pregelatinised and fully gelatinised starch had no significant effect on packing properties of the powders based on bulk and tapped densities.

The Carr's Index (CI) and Hausner's Ratio (HR) have been developed as indirect methods to predict the degree of flow of a powder material during vibration from the feed hopper when tablet compression is ongoing. As the values of these indices increase, the flow of the powder decreases. CI values (Table 3) for standard starch ranged from 19.27 ± 6.33 to 24.72 ± 1.27 ($S5 < S3 < S1 < S4 < S2$) and for local starch blends varied from 30.50 ± 0.46 to 37.10 ± 1.69 ($L3 < L2 < L4 < L5 < L1$). According to the index classifications¹⁶, the blends of BP starch have fair (16 – 20) to passable flow (21 – 25) while the blends of local starch have poor (26 – 31) to very poor flow (32 – 37). All the values showed no particular trend with an increasing or decreasing levels of either pregelatinised or fully gelatinized starch in the blends as summarized in Table 3. The HR values (Table 3) range from 1.24 ± 0.09 to 1.33 ± 0.02 for standard starch blends in the same order as for CI and 1.48 ± 0.02 to 1.59 ± 0.04 for local starch blends also in the same order as for CI. The HR classification also followed the same descriptions as CI for BP starch (fair to passable) while for local starch blends, the HR indicated that they all had very poor flow (1.46 – 1.59). Therefore, the standard starch blends possessed better flow compared to the local starch blends, and blend SV had the best flow. This could be attributed to the acetone precipitation which

might have yielded more spherical particles though this was not observed with the local starch which was treated in the same way. The purity concerns with the locally prepared starch may have distorted the trend observed in the BP starch blends. And generally lower moisture contents reported in BP starch blends may explain the better flow compared to the local starch blends which had higher moisture since it increases the interparticulate friction through cohesion.

There was no any significant difference observed in the true density of both the standard starch blends and the local starch blends except for L1 vs S5 as shown in Table 3. The values for all the blends were not any different from MCC. Even within the same sources of starches (BP and Local blends) there was no significant difference at $P < 0.05$. Okunlola and Odeku³⁰, reported that particle density affects the compaction behavior of powders in a way that denser powders require higher compression pressure to produce tablets with improved mechanical strength. Based on this influence of true density on compaction, the blends would be expected to easily form strong tablets at the same pressure as MCC. The significant difference between L1 (pregelatinised local starch) and S5 (fully gelatinised BP starch) could not be explained succinctly with the data gathered in our study ($P = 0.0358$).

Porosity (Table 3) was higher in the local starch blends (62.52 – 70.02 %, in order $L1 < L4 < L3 < L2 < L5$) than in the BP pregelatinised starch blends (51.34 – 61.85 %), in order $S3 < S1 < S2 < S4 < S5$). Porosity is related to the packing fraction of the powder i.e. higher the porosity is associated with poor packing. The BP starch blends therefore have better and closer packing of the particles compared to the local starch blends. Though no particular trend was observed with increasing or decreasing levels of either pregelatinised or fully gelatinised levels, the pregelatinised samples (L1 and S1) generally demonstrated better packing characteristics compared to the fully gelatinised. This could be attributed to differences in particle shapes.

3.3 Compactability of the blends

Compactability is the capacity of a material to form compact tablets with sufficient tensile strength under the impact of densification^{18,21}. It is based on the principle that the tensile strength of a compact will increase as porosity of the compact reduces. The relationship between tensile strength and increase in compression pressure (Fig 2 and 3) clearly shows higher area under curves for BP modified starch blends compared to the ones of local modified starch. There was a general increase in tensile strength for standard starch blends at lower pressures (4.905 – 9.81 kN) except for S1 which exhibited increase in tensile strength throughout the pressure range used. This could be attributed to plastic deformation that might have dominated in this pressure range since it is the desired inter-particle bonding mechanism during compression to obtain tablets with adequate strength. Non-linearity of the plot at higher compression pressures could

be due to breakage of bonds (fragmentation) resulting in to weak compacts, capping and lamination³¹. The same trend of S1 was observed with L1, meaning the pregelatinised starch samples are resistant to fragmentation at these pressure ranges. The AUC (Area under Curve) calculated from the compactability plot (Table 4) was in the ranking of L1 > L2 > L4 > L5 > L3 and S5 > S1 > S4 > S3 > S2 for local and BP starch blends respectively. The AUC is used to quantify the tableability of a powder material i.e. the higher the AUC, the higher the compactability^{18,25}. Based on this, SV and L1 are the best two materials from BP starch blends while L1 and L2 from the local starch. But S5 is superior to all. The coefficient of tableability, k which is the slope of the linear portion of the tensile strength vs compression pressure plot is also used to quantify tableability or compactability¹⁸. As shown in table 4, the trend for 'k' is different from the one of AUC i.e. L3 > L4 > L1 > L2 > L5 and S4 > S5 > S1 > S2 > S3. From this, we think that

the 'k' model could be suitable for data that shows linear relationship between tensile strength and compression pressure because using the linear portion only of the curve leaves out other relevant values, making it less quantitative. The compactability of the test samples (blends) could not be compared with MCC in our study because the crushing strength could not be measured using the available equipment (the compacts did not break at the maximum limit of the hardness tester, 15kgf), thus no compactability plot was made for MCC, though their mechanical strength can be reported as >15kgf. This indicates that the Avicel 101 exhibited superior tableability since it formed excessively stronger tablets throughout the pressure ranges used, which is contrary to the above predictions based on the true density. This means that particle density is not a reliable measure of the ability of a powder to form strong tablets at lower pressure as suggested earlier³⁰.

Table 2: Percentage yield of native maize starch, pregelatinised maize starch (A) and fully gelatinised maize starch

Samples	S1	S2	S3	S4	S5	L1	L2	L3	L4	L5	MCC
MC (%)	13.90	15.33	11.03	10.7	11.17	13.47	13.03	14.60	15	14.2	2.73
	±	±	±	±	±	±	±	±	±	±	±
	3.80	1.53	0.84	0.3	0.91	0.45	0.25	0.4	0.1	0.26	1.01
SI	3.38	3.68	3.92	4.11	3.80	3.21	3.24	3.09	2.81	3.52	1.42
	±	±	±	±	±	±	±	±	±	±	±
	0.22	0.20	0.13	0.10	0.11	0.29	0.21	0.00	0.17	0.20	0.04
α (°)	13.98	14.10	13.47	14.07	13.04	42.50	38.40	43.27	42.94	40.74	35.81
	±	±	±	±	±	±	±	±	±	±	±
	0.85	0.89	0.10	0.77	0.90	0.48	3.00	1.73	1.07	2.19	1.85
ρ _b (g/ml)	0.68	0.65	0.71	0.62	0.65	0.48	0.50	0.51	0.51	0.50	0.33
	±	±	±	±	±	±	±	±	±	±	±
	0.02	0.02	0.02	0.01	0.05	0.01	0.01	0.01	0.01	0.01	0.002
ρ _t (g/ml)	0.89	0.86	0.91	0.81	0.81	0.77	0.74	0.73	0.75	0.74	0.44
	±	±	±	±	±	±	±	±	±	±	±
	0.02	0.02	0.02	0.02	0.00	0.03	0.03	0.02	0.02	0.02	0.00
CI (%)	23.39	24.72	21.84	24.13	19.27	37.10	31.88	30.5	32.17	32.49	23.63
	±	±	±	±	±	±	±	±	±	±	±
	2.94	1.27	0.34	0.94	6.33	1.69	3.46	0.46	2.43	0.82	0.50
HR	1.31	1.33	1.30	1.32	1.24	1.60	1.47	1.44	1.48	1.48	1.31
	±	±	±	±	±	±	±	±	±	±	±
	0.05	0.02	0.04	0.02	0.10	0.04	0.07	0.01	0.05	0.02	0.01
D _i (g/cm ³)	1.41	1.40	1.47	1.54	1.72	1.29	1.52	1.48	1.43	1.67	1.38
	±	±	±	±	±	±	±	±	±	±	±
	0.10	0.07	0.05	0.10	0.36	0.13	0.05	0.12	0.08	0.15	0.01
Porosity (%)	51.45	54.03	51.34	60	61.85	62.41	66.71	65.60	64.39	70.02	75.99

Mean ± SD, N=3

3.4 Compact Disintegration

The compacts for SI and SII disintegrated in less than 15 min while the other blends for standard starch exceeded 15 min with the last one disintegrating in 30min in the order of S1 < S2 < S3

< S4 < S5 as shown in figure 4. The disintegration time increased with increase in the level of fully gelatinised starch. The same trend was followed by blends of local starch except that the first three blends disintegrated in less than 15 min (L1, L2 and L3). MCC compacts failed to break even after 60 min. This agrees Pharm & Biosci J. 2020: 8(1); 41

with the previous reports that fully gelatinised starch is not suitable for immediate release since it gels in the presence of water to form a matrix that controls the release of an active ingredient^{25,32}. But according to our findings, lower levels of the fully gelatinised starch in the blends (25 and 50%) ameliorated this controlled release effect.

Table 4: Constants for Compactability Plots

Excipient	k'	AUC
L1	0.3626	5.3291
L2	0.3344	4.5565
L3	0.615	3.3464
L4	0.4543	3.9685
L5	0.2528	3.5169
S1	1.6564	9.3288
S2	1.349	4.4828
S3	0.5885	7.9651
S4	3.395	9.3700
S5	3.144	9.7225

Key: k' – coefficient of compactability, AUC – Area under curve

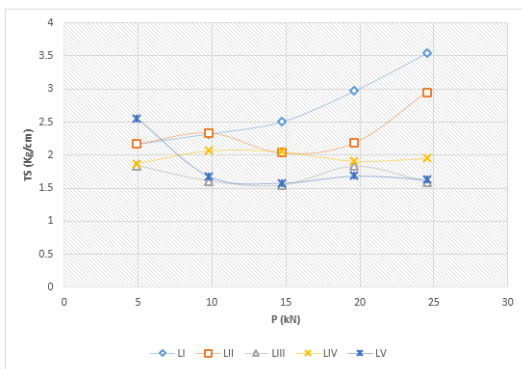


Fig 2: Compactability Plots for Blends of Local Starch

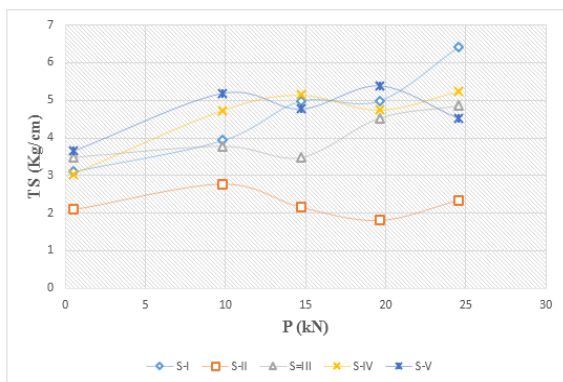


Fig 3: Compactability Plots for Blends of BP Starch

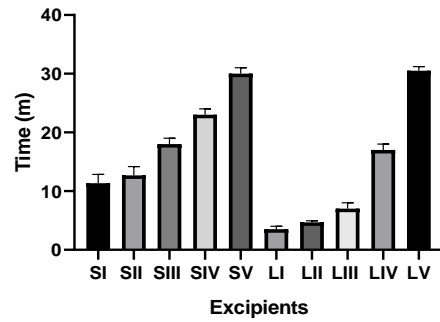


Fig 4: Disintegration time of compacts compressed at 14.715 kN

4 Conclusion

The different blends of locally extracted starch proved be inferior to those of BP starch in terms of physical properties and compactability. The fully gelatinised acetone precipitated maize starch had improved physical and compaction characteristics but physical mixing of the powder with pregelatinised maize starch may not improve the binding properties of the latter. However, the rate of disintegration of fully gelatinised maize starch could be reduced by mixing it with pregelatinised maize starch and the later could therefore be used at a concentration of <50% in such a blend as a binder for immediate release directly compressed tablets.

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6 Conflict of Interest

The authors declare no conflict of interest.

7 Author's Contributions

AJR birthed the research idea, designed and conducted the experiments, reviewed the literature and drafted the manuscript. OPE reviewed first draft of the manuscript and OSI provided guidance during the idea development, design and conduct of the study. All the authors read and approved the final copy of the manuscript.

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