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Comparative Tableting Properties of Three Local Potato StarchesI:The Glidant and Binding Properties

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ABSTRACT

The glidant and binding properties of starches extracted from three local potato tubers have been evaluated and compared with corn starch BP. The glidant properties studied include angle of repose, flow rate and flow factor while the binding properties were assessed by crushing strength and friability. The result indicated that potato starches employed as glidant were not as efficient as talc or corn starch but produced tablets with higher crushing strength and lower friability values. The results indicate that potato starches can be employed as an alternative binder to corn starch BP in the formulation of paracetamol tablets.

Keywords: comparative, glidant, binder, potato starches,

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INTRODUCTION

Kaffir potato (*Plectranthusesculentus* N.E Br) is African specie belonging to the family Lamiaceae to which many aromatic plants such as mints and sages belong[1]. These are erect perennial, herbaceous plant up to 60cm tall with yellow flowers and lumpy edible tubers at base of the stem that are used as potato substitute[2]. Kaffir potato is an indigenous African plant that is widespread throughout the continent; this widespread distribution suggests that they were domesticated early by Niger-Congo speakers and were carried from West African North of the rain forest and spread down through the Bantu speaking areas of Eastern and Southern Africa. The rapid spread of cassava in the 20th century has confined these tubers to residual cultivation and they are now little known[3]. It is economically more important than solenostemon, its cultivation is more demanding than solenostemon but yields are correspondingly larger[3].

The plant is widely cultivated as a minor root in Nigeria especially Kaduna and Plateau states[4], it is either eaten raw as snack after peeling and washing or boiled and eaten alone or with rice, while the leaves are also consumed as vegetable[5].Chemical analysis of the raw tubers of kaffir potato have shown crude protein, crude lipid and crude carbohydrate values of 13.5, 0.6 and 81.4 g per 100 g, respectively[1], indicating that the tubers can be a potential source starch.

Sweet potato (*Ipomeabatatas* Lam.) is Perennial root crop, belonging to the family *Convolvulaceae* believed to be improved from *Ipomea trifida* complex in Central America and Northern S. America. Used for food, animal feed and industrial materials. Sweet potato is usually propagated from vine cuttings or sprouts from tubers, very rarely from seed.

Favourable growth temperature for potato is 20-30°C and it requires 4-6 months to produce economic yield. Growth period comprises two stages: the first, a period of extensive growth of fibrous roots, vines and leaves, and initiation of tuberous roots; the second, swelling of the tubers. In the former, a higher temperature favours vine and leaf growth; in the latter, a lower temperature favours swelling of the tubers. The crop can be grown throughout the year in the tropics and sub-tropics but in warmer temperate regions it is grown as an annual tuber. Planting time in temperate regions is usually May/June for September/October harvest.

The plant is relatively tolerant to drought but cannot withstand water logging, with preferred soil moisture content 60-75 % of maximum water-holding capacity and soil pH of 5.5-6.5.

Sweet potato is grown in more than 100 countries worldwide but China accounts for 80 % of production, grows well in Nigeria and employed as food item[6].

Irish potato

According to FAO statistics Irish potato (*Solanumtuberosum*) is the world's fourth most important food crop after wheat, maize and rice with 314 million tonnes fresh-weight produced in 2006. Over half of this production (159 million tonnes) was in Asia, Africa and Latin America where the potato is a major source of carbohydrate[7]. It also provides significant amounts of protein, with a good amino acid balance, vitamins C, B6 and B1, folate, the minerals potassium, phosphorus, calcium, and magnesium and the micronutrients iron and zinc in addition to the source of carbohydrate. The potato is high in dietary fiber, especially when eaten unpeeled with its skin, and is rich in antioxidants comprising polyphenols, vitamin C, carotenoids and tocopherols[8]. Fresh potatoes are virtually free of fat and cholesterol.

Chemically, Irish fresh potato composed of Starch 19, Fiber 1.6,Protein (including amino acids) 2, Sugars 1.1, Salts (including sand and dirt) 1.2, Lipid 0.15 and Water 75 (Storey, 2007)

A binders or adhesives are substances used in the granulation to hold the powder particles (API and other excipients) together and hold granules together during compression. It imparts cohesive qualities and gives strength to the tablet. The incorporation of binder depends on the method of granulation, it may be added as a powder (dry granulation) e.g. microcrystalline cellulose, amylose and polyethylene glycol or as a solution (wet granulation) e.g. starch, gelatin, natural and synthetic gum etc. However, binders added as solution are more effective[9]. The use of binders improves the free flowing properties of granules and ensures that tablet remains intact after compression and can withstand rigours of handling, packaging and transportation.

The concentration of binder to be used depends on nature of the binder as well as the powdered material to be granulated. Generally, too much binder in a formulation will result in bigger and harder granules, while too little will produce smaller and softer granules and tablets[10].

Glidants are inert excipients that are added to tablet formulations to reduce interparticulate friction and to improve the flow properties of granules from the hopper into the feed mechanism and ultimately into the tablet die. Tablet presses have been so much automated that they undertake batch size that run into millions within few hours and hence the need for higher flow rate of granules[9]. Glidants are classified into hydrophobic glidants which include talc, silicon dioxide, calcium phosphate and metallic stearate[11]; and hydrophilic glidants example corn starch BP. Other starches have been studied as a hydrophilic glidants e.g. pregelatinised starch[9], cassava starch[11], yam starch[12] and fonio starch[13].

The aim of the study is to compare the binding and glidant properties of local potato starches in paracetamol tablets.

MATERIALS AND METHODS

Paracetamol powder: May and Baker LTD Dagenham England, Maize starch: May and Baker LTD Dagenham England, Talc: BDH Chem. LTD Poole England, Magnesium stearate: BDH Chem. LTD Poole England, Lactose (East Anglia Chemicals), Sulphoric acid (Merck, Germany), Sodium nitrite (Merck, Germany), Hydrochloric acid (Merck, Germany), , Kaffir potato: BarikinLadi, market, Plateau, Nigeria, Sweet potato: Gamboru Market, Maiduguri, Nigeria, Irish potato: Gamboru Market, Maiduguri, Nigeria

The three potatoes were identified by Prof. S. Sanusi, a taxonomist of Department of Biological Sciences, University of Maiduguri, Nigeria.

Extraction

Kaffir potatoes were thoroughly washed and all foreign materials were removed. The potato was peeled allowed to steep in water for about 24 hours; the steeped potato was pulverised using Philips blender (cucina HR1757, Japan). Enough quantity of water was added to the pulp which was then passed through an 180µm sieve. The filtrate was allowed to settle and 0.1N sodium hydroxide was added to separate the starch and proteinous materials as well as to neutralize the prevailing slight acidity. Excess sodium hydroxide was removed by washing several times with distilled water.

The clear supernatant fluid was poured away while sedimented starch was collected on a tray and air-dried on a table at room temperature. Using pestle and mortar the dried starch lumps were ground and fine powder passed through 180µm sieve.

Same was done for sweet and Irish potato, but the potatoes here were sliced with knife before they were pulverised.

Preparation of Paracetamol Granules

Using the wet granulation method of massing and screening, granules were prepared as follows.

Weighing: 250g of Paracetamol powder, 30g of starch were weighed.

Mixing: the batches were small (500 tablets per batch), mixing were done for 10 minutes, Paracetamol powder and other exipients were mixed thoroughly.

Preparation of binder solution: various concentrations (2.5 – 10%w/w) of starch paste was prepared by weighing appropriatequantities of corn starch powder or potato starches and dispersed into 100 ml of distilled water. It was then placed on a hot plate with continuous stirring until translucent paste was formed. Addition of binder**:** small quantity of the paste was added gradually to the powder mixture until moistened mass was formed. The quantity of paste used was determined.

Wet screening: the moistened mass was passed through a 1.7mm sieve.

Drying: the wet granules were dried in a hot air oven (Venticell, Germany) at 40°C

Dry screening: the granules were then passed through 1.4mm sieve and oversize granules were size reduced.

Lubrication of granules

Magnesium stearate and talc were respectively weighed and added to the dried granule depending on the batch. A 1, 2 and 3 % w/w of the potato starches or 2 % w/w talc or corn starch were added as glidants.

Analysis of granules

Angle of Repose and flow rate of the granules were determined using standard methods[13].

Determination of flow factor: the flow factor of thegranules was calculated as

$$\text{Flow factor} = \frac{\text{Flow rate of granules containing a glidant}}{\text{Flow rate of granules containing no glidant}}$$

COMPRESSION OF TABLETS

Using single punch tablet press (Manesty, England), the granule mixture was compressed with die and punch set of diameter 12.5mm to produce Paracetamol tablets. The tablets were kept in a desiccator for twenty four hours before the quality control tests to allow hardening and elastic recovery[14].

QUALITY CONTROL TESTS

The following quality control tests were carried out to study the properties of the tablets produced

Weight uniformity test

Twenty tablets from each batch of formulation were weighed individually and as a whole, and the mean variation calculated as percentage[18].

Tablet thickness

Using micrometer screw gauge, the thicknessof 3 tablets picked at random from each batch was individually measured and the standard deviation was also recorded.

Tablet diameter

The diameter of 3 tablets picked at random from each batch was measured using Vernier caliper. Each tablet was placed in between the teeth of the caliper and the diameter measured. The mean of 3 and standard deviation calculated[18].

Crushing strength test

The force required to crush Paracetamol tablet was measured using Erweka hardness tester (Erweka TBH 100, Germany). The test was repeated five times and the mean and standard deviation taken.

Friability test

Using Erweka friabilator, 20 tablets were picked at random from each batch weighed and put inside the friabilator chamber set at 25 resolutions per minute for 4 minutes[16].

The tablets were dusted and weighed again and the difference in weight was calculated as the percentage friability.

Disintegration time

Using BP[15] disintegration test apparatus (Erweka, Germany), six tablets were picked at random from each batch placed in the basket individually. The water bath was thermostatically set at 37±1ºC. The time that took the tablet to disintegrate was recorded using a stop clock. The mean of five determinations was taken as the disintegration time.

Dissolution time

The USP[16] apparatus 2 method was used throughout the study and buffered solution was used as dissolution medium. Using a dissolution time apparatus (Ewerka DT700 HH, Germany) and dissolution medium of 900ml of buffered phosphate solution thermostatically maintain at 37± 0.5ºC, a tablet picked at random from each batch was placed in a basket and then immersed in the medium. The apparatus was set to rotate at 100 rpm. A 5ml sample of dissolution medium was removed at designated time internal and replaced with an equal volume of fresh sample of dissolution medium.

The withdrawn sample were filtered and appropriately diluted for spectrophotometric determinations using Beckmann Coulter spectrophotometer. The spectrophotometric assay was carried out at wavelength 243nm, and a mean value of three individual spectrophotometric readings was used for the drug estimation. All withdrawn samples were replaced with fresh dissolution medium.

Statistical analysis

SPSS a statistical software program version 16 was used to compare means and the analysis of variance. $P<0.05$ was considered significant.

RESULTS AND DISCUSSION

The flow properties of granules have a significant effect on the physical properties and ultimately on the quality of tablets formulated such as tablet weight, hardness and content uniformity[17].

Various methods of measurements are available for the study of flow characteristics of powder and granules. Some of these methods, however, suffer from lack of producibility and predictability, as a result no single test is considered as standard for the measurement of power flow[18]. Table 1 shows the comparison among Talc, Corn Starch, kaffir potato starch, sweet potato starch and Irish potato starch in their respective effect on the angle of Repose of paracetamol granulations. Corn Starch produced effects similar to those of talc. Increase in concentration of potato starches was observed to decrease the angle of Repose, however, concentration above 2% w/w showed an increase in angle of Repose.

The acceptability of angle of Repose parameter as a measure of granule flowability remains a matter of individual conviction, and poor correlation with other flow parameters[19], it is necessary to ascertain with other flow parameters. The flow rate, which measures the time granules pass through the orifice of a flow meter is a quick method for determining glidant property of substances the result show the comparison of flow rate of various glidants, kaffir potato starch compares well with both sweet potato and Irish potato starches. Flow factor, which is the ratio of the flow rate of granules containing a glidant and that with no glidant was also used to compare the glidants (starch) with talc. The flow factor of glidants is also shown in Table 1. The higher the flow factor the better the flow of granules, a flow factor greater than 1.0 indicates good flow.

Table 1: Comparison of glidant properties of starches and talc

Glidant	Conc. (%w/w)	Angle of Repose(°)	Flow Rate(g/sec)	Flow Factor
	0.0	36.50±0.54	29.93±0.67	
Kaffir	1.0	32.417±0.34	29.967±0.02	1.001±0.0005
	2.0	31.473±0.20	30.580±0.01	1.022±0.0000
	3.0	33.017±0.08	30.953±0.02	1.034±0.0001
Sweet	1.0	32.120±0.01	30.820±0.03	1.030±0.0010
	2.0	32.387±0.02	31.060±0.04	1.038±0.0012
	3.0	33.157±0.12	31.017±0.01	1.036±0.0000
Irish	1.0	32.740±0.28	30.843±0.07	1.031±0.0025
	2.0	32.117±0.06	31.257±0.02	1.044±0.0026
	3.0	33.123±0.45	31.347±0.01	1.047±0.0006
Talc	2.0	31.893±0.04	33.027±0.06	1.104±0.0021
Corn	2.0	30.423±0.19	32.860±0.05	1.098±0.0346

The result showed that increase in concentration of starches increases flow factor i.e. better flow. This also shows poor correlation at concentration 3% w/w with angle of Repose as describe earlier[13]. The ranking of the flow factor at 2%w/w is talc > corn starch > Irish potato > sweet potato > kaffir potato starch. This could be as a result of larger particle sizes of the potato starches.

Table 2: The results of varying binder concentration on Paracetamol tablet properties

Binder	Conc. (%w/v)	Weight (mg)	Diameter (mm)	Thickness (mm)	Crushing Strength (KgF)	Friability (%)	DT (min)	Dissolution T50 (min)	Dissolution T80 (min)	CSFR
	0.0	621.00±0.45	12.81±0.01	5.09±0.02	1.04±0.24	100±0.00	0.41±0.61	4.11±0.34	10.49±0.12	0.01
Kaffir	2.5	624.33±2.08	12.72±0.01	5.11±0.02	3.48±0.02	1.84±0.07	4.32±1.14	6.5±0.25	18.53±0.11	1.89
	5.0	631.33±1.53	12.71±0.02	5.11±0.01	3.99±0.02	0.91±0.03	5.49±0.01	9.66±0.19	22.34±0.63	4.37
	7.5	628.33±0.58	12.64±0.02	5.12±0.01	5.85±0.11	0.90±0.03	6.79±0.11	13.21±0.83	25.45±0.17	6.52
	10.0	641.67±1.53	12.61±0.02	5.14±0.01	7.26±0.32	0.51±0.03	8.71±0.23	15.41±0.14	27.91±0.50	14.34
Sweet	2.5	629.00±1.00	12.73±0.05	5.13±0.01	3.91±0.05	1.12±0.08	3.92±0.06	7.06±0.10	18.17±0.23	3.50
	5.0	631.33±0.58	12.61±0.02	5.11±0.01	4.27±0.06	0.66±0.05	6.35±0.04	11.44±0.39	23.88±0.19	6.47
	7.5	648.00±3.00	12.52±0.02	5.13±0.01	6.71±0.16	0.52±0.01	8.91±0.11	13.31±0.73	26.38±0.27	12.90
	10.0	654.00±3.61	12.52±0.01	5.12±0.01	8.25±0.12	0.37±0.07	9.98±0.12	17.17±0.10	28.99±0.21	22.11
Irish	2.5	630.33±1.15	12.72±0.02	5.12±0.01	3.16±0.05	1.53±0.10	2.99±0.02	5.00±1.64	13.08±0.04	2.07
	5.0	629.00±1.00	12.70±0.02	5.11±0.01	3.80±0.06	0.99±0.02	5.46±0.14	8.64±0.06	18.47±0.47	3.83
	7.5	649.67±1.53	12.64±0.02	5.10±0.02	5.14±0.24	0.84±0.06	6.74±0.12	11.53±0.36	23.76±0.15	6.12
	10.0	642.33±0.58	12.54±0.04	5.13±0.01	6.19±0.06	0.56±0.06	7.25±0.13	13.36±0.44	29.54±0.49	11.13
Corn	2.5	632.67±1.53	12.64±0.03	5.11±0.01	3.09±0.07	2.29±0.19	2.80±0.02	5.21±0.05	11.6±0.44	1.35
	5.0	643.33±3.21	12.59±0.02	5.13±0.02	3.70±0.05	1.08±0.07	3.14±0.07	7.84±0.08	14.71±0.07	3.41
	7.5	640.67±1.15	12.52±0.01	5.12±0.01	4.81±0.04	0.55±0.02	3.68±0.11	10.07±0.16	24.16±0.56	8.70
	10.0	658.00±2.00	12.53±0.01	5.12±0.01	6.12±0.04	0.46±0.04	4.98±0.18	14.11±0.10	27.77±1.31	13.41

Table 2 showed tablet properties of Paracetamol tablets produced from different binder types and concentrations. Increase in binder concentration was found to increase the weight of Paracetamol tablet for all the starches, this might be due to an increase in forces that binds the particles together, such as binding forces which included solids and liquids bridges, Vander Waal forces[10] as well as mechanical interlocking[20]. It is believed that Vander Waal forces are the most important bonding mechanism for pharmaceutical materials[21], at concentrations 2.5 and 5.0%w/v, there was no significant difference ($p>0.05$) between the potato starches but there was significant difference ($p<0.05$) between corn starch and potato starches. The tablet thickness also slightly decreases with increase in concentration of binder.

The crushing strength provides a measure of tablet strength. The compendial requirement[15], for the crushing strength is largely dependent on the intended use of the tablet. The result of effect of binder concentration on crushing strength was illustrated in figure 1. For all starches, increase in binder concentration have been found to increase hardness (crushing strength) of the tablet, this observation was also supported by several authors[6,7]. This might be as a result of increase in bonds formed within the tablets because of increase in binder concentration. The strength of the interparticulate bond and the number of bonds depends on the concentration of binder used. This occurs up to an optimum concentration above which the crushing strength decreases[9].

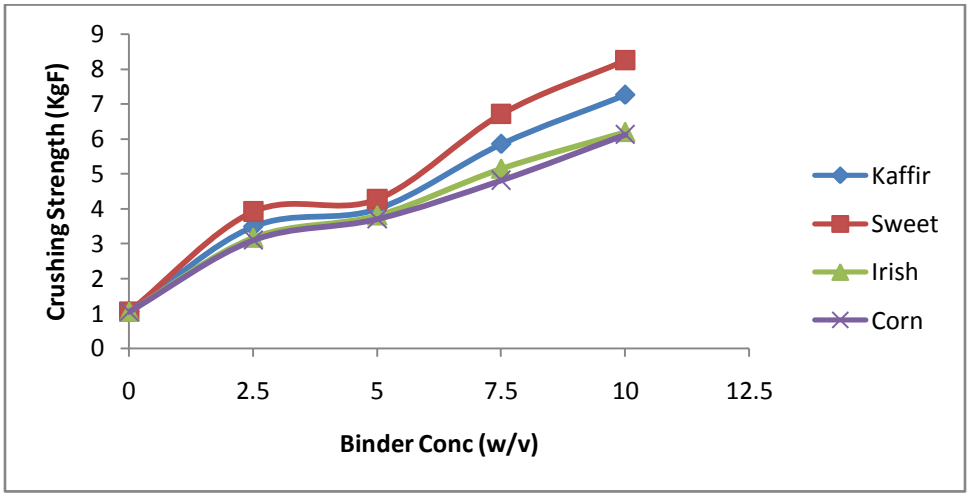

Figure 1: Plots of Mean Crushing Strength (KgF) against Binder Concentration (%w/w) in Paracetamol tablets produced from Kaffir, Sweet, Irish and Corn starches as binder

Formulation with corn starch as binder was found to have lower crushing strength than those of the potato starches,this might be as a result of low level of amylose in corn starch compared to the potato starches. Among the potato starches, sweet potato starch showed superiority in binding characteristics. The ranking was sweet>Kaffir>Irish>corn. Statistically, there was

significant difference between all the starches ($p<0.05$) at all concentrations studied except Irish and corn at higher concentrations ($p>0.05$).

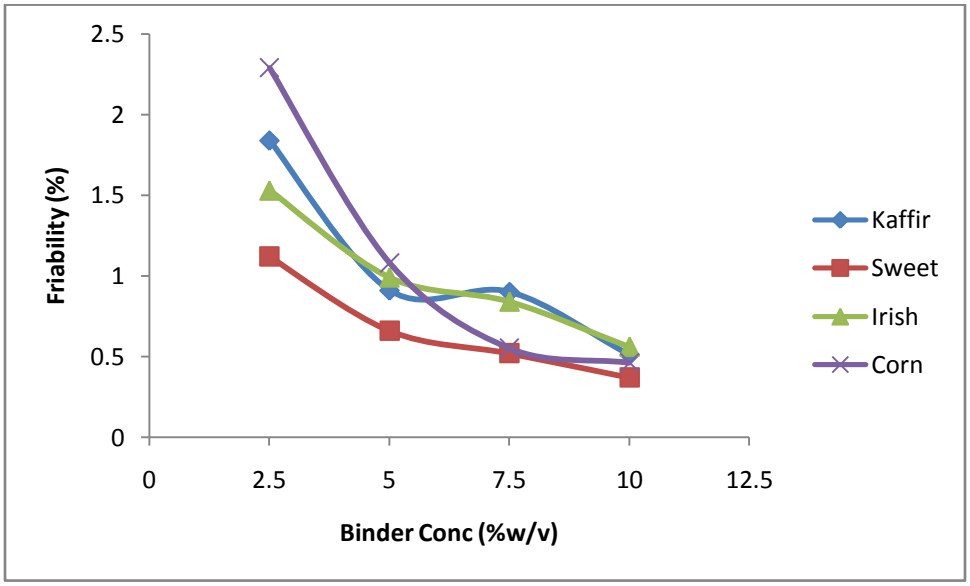

Figure 2: Plots of Friability (%w/w) against Binder Concentration (%w/w) in Paracetamol tablets produced from Kaffir, Sweet, Irish and Corn starches as binder

The friability is a measure of tablet weakness[14]. Result of friability of tablet produced with different starch is illustrated in Figure 2, it showed that friability decrease with increased binder concentration with the highest friability observed when binder was not applied, as explained above for crushing strength, and this was also supported[10,21] in separate reports. This relationship has been previously noted and can be attributed to the increase in the potential of the powder particles to bond together as the binder concentration is increase thus producing stronger tablets with decrease friability.

Tablets from all the starches at binder concentration of 2.5 % w/v failed the friability test while concentrations above 2.5% w/v passed the compendial[15] friability test of not more than 1%w/w. However, there was significant difference between the starches ($p<0.05$). This suggests that at certain concentrations, potato starches should be able to provide adequate protection for tablets against abrasive motions during production and handling.

Both crushing strength and friability indicate the ability of tablet to withstand fracture and abrasion during production and subsequent use[22] but the friability is especially important because the tablet is likely to the subjected to various abrasive motions during production and even subsequent use.

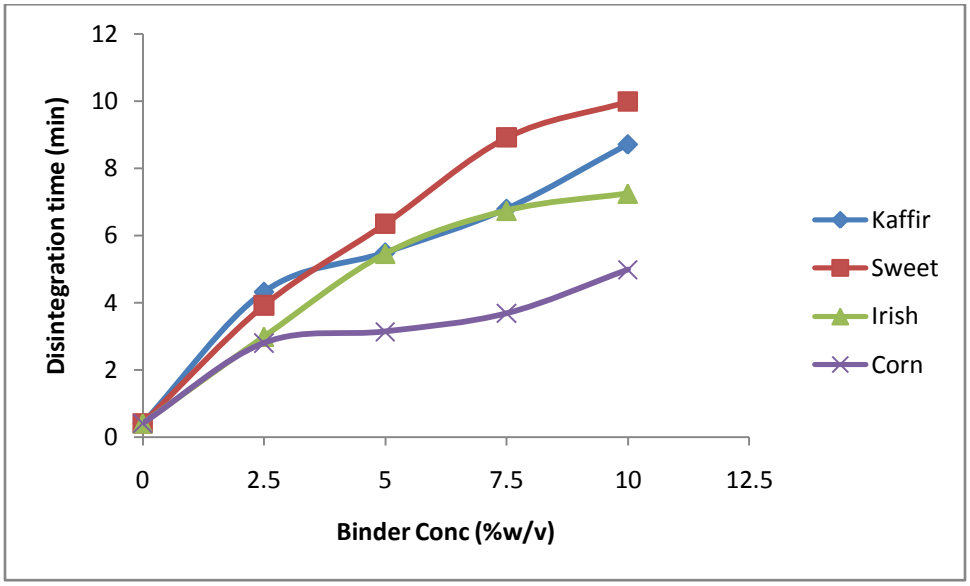

Figure 3 Plots of Disintegration Time (min) against Binder Concentration (%w/w) in Paracetamol tablet formulated fromKaffir, Sweet, Irish and Corn starches as binder

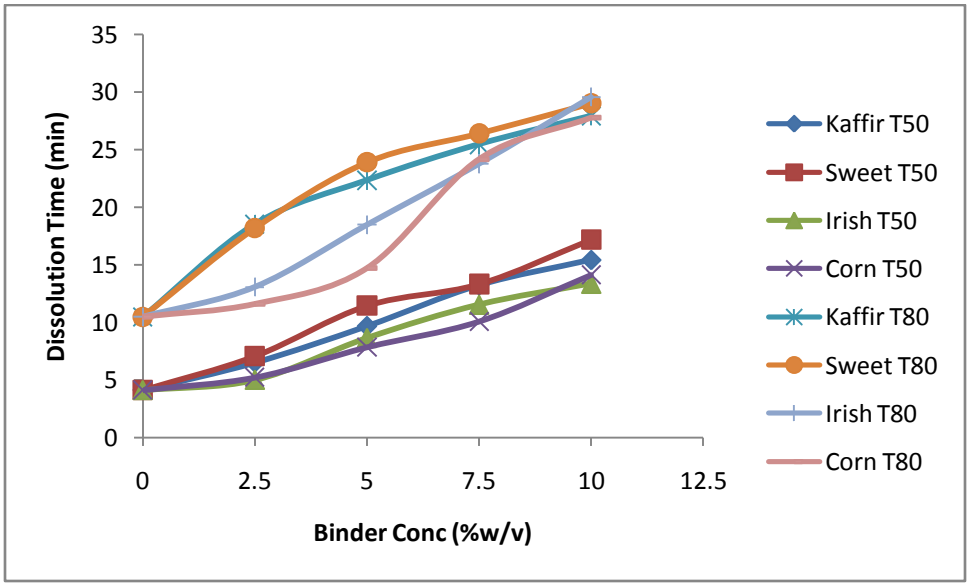

Figure 4: Plots of Dissolution Time (min) against Binder Concentration (%w/v) in Paracetamol tablet formulated from Kaffir, Sweet, Irish and Corn starches as binder

Crushing Strength-Friability Ratio (CSFR)

As earlier stated, the values of crushing strength and friability provide measures of tablet strength and weakness, respectively. Thus, the CSFR can he used as a measure of the mechanical strength of the Paracetamol tablets, the higher the CSFR, the stronger the tablets. Theresult of CSFR is shown on table 1. The CSFR value increases with increase in binder concentration. Potato starch powders generally formed stronger tablets, the ranking of the CSFR values did not

follow that of crushing strength, the ranking was sweet>kaffir>corn>Irish. This is as a result of higher friability value observed in Irish potato starch formulation at 10%w/w concentration.

The plots of disintegration time against varying binder concentration were illustrated in Figure 3. Disintegration time was found to be significantly increased ($p<0.05$) with increase in binder concentration. As explained earlier, more bonds are formed with increasing binder concentration; the bonds take longer time to break and the resulting harder tablets were difficult for the disintegration medium to penetrate.

At binder concentration 2.5 to 7.5%w/v, there was no significant difference between kaffir and Irish potato starches, ($p>0.05$) but there was significant difference ($p<0.05$) between either of the starches and sweet or corn starches.

Disintegration exposes a greater surface area of the tablets to the dissolution medium, thus, it plays an important role in tablets dissolution before the API is release from the tablet matrix. The dissolution time - binder concentration relationship of Paracetamol tablets was illustrated in Figure 4. Disintegration plays an important role in tablets dissolution before the active drug substance is finally released[23]. The time taken for 50% and 80% (T50 and T80) of the drug to dissolve showed that an increase in binder concentration increase dissolution time at both T50 and T80 for kaffir potato, sweet potato, Irish potato and corn starches. The order of disintegration time was followed. It is pertinent to note that, it is not only disintegration time that predicts dissolution.

CONCLUSION

The results from various tests conducted showed that local starches could be useful to produce tablets with desired mechanical properties for specific purposes depending on whether stronger or softer tablets are required.All the tablets formulated passed the official and unofficial requirements for tablets.

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