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Evaluation of the Glidant Property of Fonio Starch

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Abstract: Fonio starch was evaluated as a glidant in comparison with corn starch and talc in Folic acid tablet formulation. The glidant property was analysed using the Flow rate, flow factor and angle of Repose of the granules while the quality of the tablet was assessed by crushing strength, Friability, disintegration and dissolution times of the tablet. The result of angle of repose, flow rate and flow factor indicated that Fonio starch compares well with both corn starch and talc at concentration of 2%w/w and at that concentration the tablet properties (crushing strength, friability, disintegration and dissolution times) were similar, it may therefore serve as an alternative glidant for pharmaceutical granulations.

Key words: Angle of repose, flow factor, fonio starch, glidant

INTRODUCTION

The plant Fonio (*Digitaria exilis* Family *Poaceae*) originated from West Africa. It is called *findi* by fulanis, *acha* in Hausa and Fonio or Hungry rice in English. People across fifteen countries in the Northwest of Africa have enjoyed its grains for centuries (Jideani, 1999); it is probably the oldest plant in Africa, which survived for several centuries mostly as weed (Harlan, 1993). Fonio thrives in the sandy, rocky soils of the Sahel both in drought and flood, and grows so fast that its crops can be harvested two or three times each year. The seeds are small, each kilogram of the plant contains about two million seeds and each seed weighs about 0.0005 g (Karen, 1997). It is used as a source of food, malting and brewing.

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 call for higher flow rate of granules (Musa *et al.*, 2003). Glidants are classified into hydrophobic glidants which include talc, silicon dioxide, calcium phosphate and metallic stearates (Okore, 1998); and hydrophilic glidants example corn starch BP (Gold *et al.*, 1968; Chowhan, 1983). Other starches have been studied as a hydrophilic glidants e.g. pregelatinised starch (Musa *et al.*, 2003), cassava starch (Okore, 1998) and yam starch (Jaiyeoba and Opakunle, 1978).

However, the use of Fonio starch as a possible glidant for granules in pharmaceutical formulations does not seem to have been documented. Therefore this study aims at evaluation of Fonio starch as an alternative glidant in Folic acid tablet formulations. The glidant action of Fonio starch would be compared with that of corn starch and talc at similar concentrations. Angle of Repose, flow rate and flow factor were used to assess the glidant property while crushing strength, friability, disintegration time and dissolution time tests were used to assess the tablet properties thereof.

MATERIALS AND METHODS

Folic acid powder (Roche ltd), talc (BDH chemicals ltd Poole, England), corn starch (Eagle Scientific ltd, Nottingham England), lactose (East Anglia Chemical) were purchased from commercial sources. The Fonio starch was processed following the standard procedures (Musa *et al.*, 2008). The study was conducted in 2008 at the department of pharmaceutics and pharmaceutical Microbiology, Ahmadu Bello University Zaria, Nigeria

Preparation of granules: Wet granulation method of massing and screening was used in the study. Corn starch mucilage (5%w/v) was used as the granulating medium. 7.6% w/w of Folic acid was thoroughly mixed with 52.4% w/w lactose and 10% w/w corn starch disintegrant using Z-blade mixer (Erweka type LH 5, Germany). The mixture was moistened with corn starch mucilage, and the moistened mass was forced through a 1.6 mm sieve. The resulting granules were dried in an oven (Gallenkamp, England) at 40ºC for 3 h and the dried granules were allowed to pass through 1.4 mm sieve and the granules were kept in airtight container.

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Physicochemical properties of granules:
Determination of granules Density:

Initial Bulk density: 50 g each of granules was poured through a short-stemmed glass funnel into a 200 ml graduated glass cylinder and the volume occupied by the granules was read and the initial bulk density (ρ_{Bmin}) calculated.

$$\text{Bulk density} = \frac{\text{Mass of granule}}{\text{Volume of granule}} \quad (1)$$

Final bulk density: Graduated cylinder containing the granules was tapped on a bench from a height of about 20 mm until it has attained its most stable i.e. unchanging arrangement and the volumes recorded. The final bulk density (ρ_{Bmax}) also called tapped density was then calculated in g/ml.

Carr's Index: the Carr's index was calculated as

$$\text{Carr's index} = \frac{\rho Bmax - \rho Bmin}{\rho Bmax} \times 100 \quad (2)$$

Estimation of true density: The specific gravity bottled method was adopted, and xylene was used as displacement fluid.

Determination of flow properties of granules:
Angle of Repose: A glass funnel was mounted on a laboratory stand at a height of 10 cm from the bench. 50 g of the granules were poured into the funnel (0.8 cm diameter of orifice and 10 cm diameter of the base) with the tip closed. The tip-plug was removed and the granules were allowed to fall, the height and diameter of the starch heap were measured. The angle of Repose, θ, was calculated by the equation:

$$\theta = \tan^{-1}(h/r) \quad (3)$$

Where h is height of conical powder heap and r is the radius of the circular base

Flow rate: using Erweka Flow tester with a stainless steel funnel (0.8 cm diameter of orifice and 8 cm diameter of the base), 50 g of the granules were allowed to pass through its orifice and the time taken was recorded. Mean of three readings was taken as the flow rate of the granule.

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

$$\text{Flow factor} = \frac{\text{Flow rate of granules containing a galidant}}{\text{Flow rate of granules containing no galidant}} \quad (4)$$

The angle of Repose and flow rate tests were repeated with addition of 0.5, 1, 2 and 3% w/w of Fonio starch or 2% of talc or corn starch.

Compression of granules: Using single punch tablet press (Erweka, AR 400 Germany) the granules were compression with die and punch set of diameter 5mm and Compression force of 6.5 metric tonnes was applied to produce Folic acid tablet. The die was previously immersed in dispersion of 1%w/v of Magnesium Stearate in chloroform. The tablet were kept in a desicator for 24 h before analysis to allow for elastic recovery and hardening (Akin-Ajani *et al.*, 2005; Emeje *et al.*, 2008; Majekodunmi *et al.*, 2008).

Quality control test:
Crushing strength test:
The force required to crush folic acid tablet was measured using Mosanto hardness tester. The test was repeated ten times and the mean taken.

Friability test: Using Erweka friabilator, 20 tablet were picked at random from each batch weighed and put inside the friabilator chamber and set at 25 resolutions per minute for 4 min.

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

Disintegration test: The disintegration times of the tablet were determined in distilled water thermostatically set at 37º±1ºC using pharmacopoeia (BP, 2002) method and disintegration testing apparatus (Erweka ZT 100, Germany). The time that took the tablet to disintegrate was recorded using a stop clock.

Dissolution test: Using a dissolution rate apparatus (Ewerka DT700 HH Germany) and dissolution medium of 900 ml of 0.1N HCl 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 machine was set at 100 revolutions per minute. 5ml samples of the dissolution medium were withdrawn at an appropriate time interval and replaced with 5 ml of 0.1N HCl. The withdrawn sample were filtered and appropriately diluted for spectrophotometric determinations at wavelength of maximum absorbance (446 nm) using Beckmann Coulter spectrophotometer (DU 500 series).

RESULTS AND DISCUSSION

The densities of Folic acid granules are shown in Table 1; the Carr's Index is a direct measure of the potential powder bridge strength and stability and

Table 1: Densities of Folic acid granules

Properties	Granules
Bulk density	0.69
Tapped density	0.86
True density	1.68
Carr's index	19.77

Table 2: The result of comparison of angle of Repose, flow rate and flow factor of various glidants.

Glidant	(%w/w)	Angle of repose	Flow rate	Flow factor
	0	36.48	29.92	
Fonio starch	0.5	32.98	30.8	1.03
	1.0	32.74	31.19	1.04
	2.0	31.06	32.06	1.07
	3.0	33.41	32.61	1.09
Talc	2.0	31.92	33.01	1.1
Corn starch	2.0	30.41	32.87	1.1

Table 3: The tableting properties of various glidants in Folic acid tablet formulations

Glidant	(%w/w)	Crushing Strength(KgF)	Friabilty (%)	Disintegration time (min)	Dissolution time (min)
	0.0	4.12±0.67	0.8±0.09	7.61±1.48	13.48±2.81
Fonio starch	0.5	3.80±0.33	0.4±0.07	8.25±1.96	14.38±1.74
	1.0	4.21±0.74	0.7±0.13	8.42±2.14	14.31±2.49
	2.0	4.92±0.32	0.6±0.09	8.13±1.34	13.60±1.63
	3.0	5.16±0.71	0.9±0.03	6.36±2.09	13.20±3.41
Talc	2.0	4.84±0.64	0.8±0.11	8.79±1.37	15.40±1.08
Corn starch	2.0	5.29±0.41	0.3±0.21	9.41±0.74	14.81±2.92

described powder having fair flow if it has Carr's Index of 18-22 (Staniforth and Aulton, 2007). Therefore, Fonio granules with Carr's Index of 19.77 have a fair flow property.

Table 2 shows the comparison between Talc, Corn Starch and Fonio Starch in their respective effect on the angle of Repose of Folic acid granulations. Fonio Starch produced effects similar to those of talc and corn starch. Increase in concentration of Fonio starch 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 (Carstensen and Chan, 1977), 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 Table 2 show the comparison of flow rate of various glidants, Fonio starch compares well with both talc and corn starch at the same concentration of 2 %$^{w}/_{w}$.

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 with Fonio starch. The flow factor of glidants is shown on Table 2. The higher the flow factor the better the flow of granules, a flow factor greater than 1.0 indicates good flow. The result shows that increase in concentration of Fonio starch increases flow factor i.e. better flow. This also shows poor correlation at concentration 3% $^{w}/_{w}$ with angle of Repose as describe earlier (Carstensen and Chan, 1977).

The tablet properties of glidants are shown on Table 3, the result indicates that concentration of glidant tends to have effect on the tablet properties. However at glidant concentration of 2%$^{w}/_{w}$, all the glidants exhibited similar tablet characteristics.

CONCLUSION

At concentration 2% $^{w}/_{w}$ Fonio starch compares well with corn starch and talc as glidant in Folic acid tablet formulation and does not affect the tablet properties. Fonio starch can therefore be used as an alternative glidant in tablet formulations.

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