International Journal of Pharmacy Teaching & Practices 2012, Vol.3, Issue 1, 201-206.

Evaluation of Millet (*Pennisetum Glaucum And Pennisetum Americanum)* Starches as Tablet Binders

***H. Musa,Y. Amodu,R.Oyi**

Department of Pharmaceutics and Pharmaceutical Microbiology, Faculty of Pharmaceutical Sciences, Ahmadu Bello University, Zaria-Nigeria,

Research Article

Please cite this paper as: H. Musa,Y.Amodu,R.Oyi. Evaluation of Millet (*Pennisetum Glaucum And Pennisetum Americanum)* Starches as Tablet Binders. IJPTP, 2012,3(1),201-206.

Corresponding Author:

H. Musa,
Department of Pharmaceutics and Pharmaceutical Microbiology, Faculty Of Pharmaceutical Sciences, Ahmadu Bello University, Zaria-Nigeria,

E-mail: hassanmusaf@yahoo.com

Abstract

Starch was extracted from the two varieties of millets (*pennisetum glaucum and Pennisetum americanum*) by the wet extraction methods Granules were prepared by the wet granulation method of massing screening using the two varieties of millet starches as disintegrants . The suitability of millet starches as binders at various concentrations were investigated in tablet formulations using paracetamol as the medicinal substances. The millet starches *(Pennisetum glaucum* and *Pennisetum americanum*) formulations were compared for crushing strength, weight variation, friability, disintegration time against maize starch formulations. Using the same concentrations of binders.The results indicated that millet starches were suitable binders.

Keywords: *binders,* Pennisetum glaucum, Pennisetum americanum *Starch,Paracetamol, Tablets.*

Introduction

Binders are agents used to impart cohesive qualities to the powdered materials. They impart cohesiveness to the tablet formulation which ensures that the tablet remains intact after compression as well as improving the free flowing qualities by the formulation of granules of desired hardness and size. The quantity of binder used has considerable influence on the characteristics of the compressed tablets. The use of too much binder or too strong a binder will make a hard tablet which will not disintegrate easily and which will cause excessive wear of punches and dies.(Musa, etal,2011).and (Gambo,2009).

This study was carried out to investigate The suitability of millet starches as binders at various concentrations were investigated in tablet formulations using paracetamol as the medicinal substances. The millet starches *(Pennisetum glaucum* and *Pennisetum americanum*) formulations were compared for hardness, friability, disintegration time against maize starch formulations. Using the same concentrations of binders *Peniseteum glaucum* and *Penisetum americanum* were obtained from Samaru and Funtua market in Kaduna and Katsina states Nigeria. . Paracetamol powder and Maize starch from may and Baker Nigeria. Talc, Magnesium stearate from BDH.chem. Ltd Poole England

Methodology

Extraction of millet starches.

The grains of millet were inspected and 2kg of each variety of the cereal were thoroughly washed and all extraneous materials removed. The washed cereals were soaked in water for 24hrs. The steeped grains were then taken to the mill and blended. The blended mass was mixed with enough water, this was then passed through a filter cloth to remove the chaff and 100ml of 0.1N NaoH added to separate the starch and proteineous materials and to neutralize the prevailing slight acidity. Excess sodium hydroxide was removed by washing several times with distilled water. The clear supernatant fluid was then poured away while the sedimented starches were collected and a suspension of the starch in distilled water was then centrifuged for 15 minutes at 2800 revolutions per minute to separate the non-starch components from the starch. The starch retrieved was then collected and spread to dry in an oven at 40^{o}C. The dried starch lumps were size reduced to a fine powder using a blender1

Preparation of Paracetamol granules

Using the techniques of wet granulation method of massing and screening paracetamol granules were produced based on table 1 Several batches of paracetamol granules with varying concentrations of the *Penisetum glaucum* and *Penisetum americanum* and

maize starch (MS) were produced to determine the binding properties of the millet starches compared with maize starch.

The procedures used in the granule formulation include:

Weighing: Appropriate amounts of all the ingredients as shown in the formula above with the exception of extra granular excipients/lubricants/glidants were weighed for different batches of the formula.

i. Mixing: The ingredients weighed were then mixed in a pestle and mortar using doubling up technique.

ii. Wet mixing: AS shown in table 1, varying concentrations of binder solutions were prepared. This is by dissolving the appropriate weights of binder in small quantities of water in a beaker then making up to 100ml mark with hot boiling water with proper stirring to ensure proper mixing.

Table 1:Working formular for studying the binding properties of millet starches

Materials	percentage of each excipient	percentage of excipient per tablet	Actual content of excipient per 100 tablets
Paracetamol	77%w/w	500mg	50g
Disintegrnts	9.20%w/w	60.00mg	6.00g
Binder:	0.00%w/v		
P.glaucum	2.50%w/w		
P.americanum/	5.00%w/w	QS	QS
Maize starch	7.50%w/w		
(BP)	10.00%w/w		
	12.50%w/w		
Extragranular excipient:			
Maize starch	7.80%w/w	50.70mg	5.070g
Glidant/lubricant			
Magnesium state	0.2%	1.30mg	0.130g
Talc	2%w/w	13.00mg	1.300g
TOTAL WEIGHT	650mg		65g

Small volumes of the binder solution were added to the dry powder mix gradually until a moist mass was formed. The wet mass was then screened through a 1.7mm mesh using a spatula. The resulting granules were dried in a hot air oven at 40°C for 30mins after which they were re-screened. Through a 1.6mm mesh size and further dried for another 30mm.

They were allowed to cool and over sized granules were size reduced[2]

Determination of moisture content

Samples were weighed into evaporating dishes and placed in an oven set at 105°C. The starches were weighed periodically (1hr) until constant weight was attained. The difference in weight was calculated and the moisture content determined.

Physicochemical analysis of granules

Bulk Density A sample of 50g of each of individual millet starch and granules were poured through a short stemmed glass funnel into a 200ml graduated glass cylinder and the volume occupied by the granules was read and the bulk density calculated

Tapped density

A graduated cylinder containing 50g of the millet starch granules was dropped on a bench 100 times from a height of about 20mm and the respective volumes recorded. The tapped density was the calculated in g/ml

Carr's index

The difference between the tapped and bulk density divided by the tapped density was calculated and the ratio expressed as a percentage. This is obtained using the formula below:

$$CI = \frac{\rho t - \rho b}{\rho b} \times 100$$

CI = Carr's index

ρt = Tapped density

ρb = Bulk density

Hausner ratio

This also predicts the flow characteristics of materials and is the ratio of the tapped density (ρt) to bulk density (ρb) of the starches.

Hausner Ratio = $\rho t/\rho b$

Flow rate Determination

A sample of 50g of each of the individual starches was poured into the funnel of Erweka flowability tester (type GDT) and the time taken to pass through the Orifice by individual powder was recorded. The same procedure was done for the granules also[4]

Determination of particle Density

The particlcle density was determined with a pycnometer bottle using xylene as the displacement fluid. An empty 50ml pycnometer bottle was weighed(W),filled with xylene and the excess wiped off. The filled bottle was weighed a second time(W_1) and the difference between W_1 and W obtained as W_2. A 2g quantity of the granule was weighed(W_3) and transferred into the pycnometer bottle. The excess solvent was wipped off and the bottle weighed again(W_4).The particle density,ρ_t(g/cm^3),was then calculated from the equation given below:

$$\rho_t = W_2 \times W_3 / 50(W_3 \quad W_4 + W_2 + W)$$

Where ρ_t particle density

W weight of empty bottle

W_2 is weight of xylene

W_3 is weight of granule

W_4 is weight of bottle plus sample plus xylene

Size Analysis of granules

The sieves were arranged vertically in order of decreasing mesh size(500µm-75µm). 30g of dried granules was weighed and placed on the top nest of sieve (i.e. 500µm). The lid was replaced and the sieve nest clamped on the sieve shaker which was switched on for 10minutes, to ensure adequate separations.

The sieves were than loosened from the shaker and the weight of particles retained on each nest was determined and recorded as shown below:

This procedure was repeated for the various concentrations of binder and disintegrants of starch samples and maize starch (MS).

Compression of granules

The batches were compressed into tablets after incorporation of the stated weights of extragranular excipients as shown in table 1 using a single punch tablet press (Erweka A & 400 Germany). The punch diameter used was 12mm while the compression pressure was 7.5MT.

Quality control tests on the tablets

Weight uniformity test:

Ten tablets from each batch of formulation were weighed individually. On a metler balance (Type 163, metler instruments A.G Switzerland). From the mean tablet weight, the deviation of each tablet from the mean weight was calculated, the standard deviation was then found[7]

Crushing strength test: - The hardness of the tablet given as the crushing strength was determined using Monsanto hardness tester(Manesty machines Ltd, Spoke Liverpool, England). A tablet was held between a fixed anvil and a moving jaw and the load gradually increased until the tablet just fractured. The value of the load at this point gives a measure of the tablet hardness in kg force. For each batch, the hardness of five (5) tablets was determined from which the average was obtained.

Friability test: Ten tablets were randomly picked from each batch, brushed carefully and lightly until all surface powder was removed. The tablets were weighed (w1) accurately with the mettler balance. They were placed inside the Erewka (TA 3R Germany) friabilator and operated or rotated 100 times in 4mins i.e. 25rpm removed dusted and reweighed (W2). From the two weight values friability (f) for each batch of tablets was determined. disintegration time.

Dissolution rate determination:- A dissolution test apparatus DGNA multipurpose drug test device was used, it was set at a rotation speed of 100 r.p.m while the temperature was thermostatically maintained at 37°C± 0.5°C, the medium was 1000ml of 0.1NHcl for paracetamol tablets, The revolution of the basket containing

Disintegration time test:- The time required for six tablets per batch of 100 tablets to disintegrate was determined using a device in united states pharmacepoeia (USP) adopted in British pharmacopoeia (B.P) (1993) Erweka disintegration tester (type ZTS Germany) distilled water thermostatically maintained at 37°C was used as the disintegration medium. The disintegration apparatus was calibrated to operate at thirty cycles per minute. The time taken for the last tablet or its fragment to pass through the mesh into the disintegration medium was recorded. The mean of five determinations was calculated to be the the test tablet 100 rpm.10 ml of the sample was

withdrawn at 5 minutes interval .Each volume of sample withdrawn was replaced with an equivalent volume of dissolution medium maintained at the same temperature. A tenfold dilution with the dissolution medium was done for each sample withdrawn before spectrophotometric determination of drug content at an absorbance of 257.00nm. The percentage drug released was plotted against time to generate a dissolution curve.[1b]

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Granule properties	Penisetum americanum						Maize starch BP					
Binder conc.(%w/w)	0.00	2.50	5.00	7.50	10.00	12.50	0.00	2.50	5.00	7.50	10.00	12.50
Flow rate(g/secs)	10.53	9.49	8.34	9.11	9.15	9.11	11.33	9.31	9.41	10.13	10.22	9.60
Moisture content(%)	27.00	26.00	24.50	25.50	27.00	26.50	27.25	26.50	26.50	25.00	24.00	26.00
Angle of repose(o)	33.70	31.59	33.70	31.98	31.88	32.29	31.05	25.68	39.99	32.00	32.28	31.41
Bulk densities(g/ml)	0.385	0.405	0.435	0.405	0.385	0.4000	0.420	0.380	0.375	0.380	0.380	0.395
Tapped densities(g/ml)	0.462	0.484	0.500	0.476	0.462	0.469	0.588	0.492	0.441	0.448	0.462	0.479
Carr's index(g/ml)	16.67	16.32	13.00	14.92	16.67	14.71	28.57	22.78	14.97	15.18	17.72	17.20

Table 2; Granule properties for *Penisetum americnum* starch and maize starch BP used at different binder concentrations in paracetamol tablets

Table 3: Granule properties for *Penisetum glaucum* starch and maize starch BP used at different binder concentrations in paracetamol tablets.

Tablet property	Penisetum glaucum						Maize starch BP					
Binder conc.(%w/v)	0.00	2.50	5.00	7.50	10.00	12.50	0.00	2.50	5.00	7.50	10.00	12.50
Crushing strength(Kgf)		4.16	4.98	5.99	4.10	4.00	5.30	6.10	6.88	7.90	8.01	8.52
Friability		0.80	0.69	0.48	0.21	0.15	0.98	0.88	0.72	0.58	0.46	0.32
Tablet thickness(mm)		5.536	5.267	5.180	5.418	5.393	5.162	5.404	5.352	6.186	5.782	6.068
Disintegratation time(min)		0.41	0.47	0.52	0.60	0.65	0.43	0.48	0.53	0.53	0.54	0.65
Mean weight(mg)		616	626	619	615	623	585.5	612.5	584	647	653	674
		±5.16	±5.16	±5.68	±7.07	±6.75	±6.90	±7.00	±6.90	±6.80	±6.70	±6.90

Table 4.: Properties of paracetamol tablets formulated using *Penistum americanum* starch and Maize starch BP as Binders

Tablet properties	Penisetum americanum						Maize starch BP					
Binder conc.(%w/v)	0.00	2.50	5.00	7.50	10.00	12.50	0.00	2.50	5.00	7.50	10.00	12.50
Crushing strength(Kgf)		4.6	5.10	6.10	7.04	8.88	5.30	6.10	6.88	7.90	8.01	8.52
Friability		0.40	0.60	0.81	0.96	1.09	0.98	0.88	0.72	0.58	0.46	0.32
Tablet thickness(mm)		5.624	5.638	5.630	5.514	5.74	5.162	5.404	5.352	6.186	5.782	6.068
Disintegratation time(min)		0.45	0.49	0.52	0.54	0.62	0.43	0.48	0.53	0.53	0.54	0.65
Mean weight(mg)		612	603	623	614	6.46	585.5	612.5	584	647	653	674

Table 5: Properties of paracetamol tablets formulated using *Penistum americanum* starch and *Penisetum glaucum* starch as Binders

Granule properties	*Penisetum glaucum* starch						Maize starch starch					
Binder conc.(%w/w)	0.00	2.50	5.00	7.50	10.00	12.50	0.00	2.50	5.00	7.50	10.00	12.50
Flow rate(g/secs)	11.54	8.53	8.47	8.76	8.83	8.84	11.33	9.31	9.41	10.13	10.22	9.60
Moisture content(%)	33.00	23.50	25.00	25.50	27.50	25.00	27.25	26.50	26.50	25.00	24.00	26.00
Angle of repose(o)	33.13	33.11	31.95	33.40	33.70	32.80	31.05	25.68	39.99	32.00	32.28	31.41
Bulk densities(g/ml)	0.423	0.423	0.435	0.435	0.435	0.406	0.420	0.380	0.375	0.380	0.380	0.395
Tapped densities(g/ml)	0.588	0.526	0.536	0.536	0.536	0.509	0.420	0.380	0.375	0.380	0.380	0.395
Carr's index(g/ml)	28.06	19..56	18.84	18.84	18.84	20.24	28.57	22.78	14.97	15.18	17.72	17.20
Hausner ratio	1.39	1.22	1.23	1.33	1.23	1.25	1.40	1.30	1.18	1.18	1.22	1.21

Discussion

Figures 1 and 2 shows that at lower binder concentrations the curves were almost superimposed on each other, indicating that the binders exhibited similar mean particle sizes and size distribution patern(Figures 1 and 2) this shows that they have almost the same particle sizes.

Hausner ratio and Carr's index are used to predict the flow of granules and powders predicted that values of Hausners quotient and Carr's compressibility above 1.2 or 23% respectively do not indicate good flow behavior.Neumann,(1976) reported that angle of repose values above 50º is an indication of a poor flow characteristics of a powder, whereas low angle of repose of 25^{o} is an indication of of very good flow properties The flow of a powder during manufacturing dictates the quality of the product in terms of weight and content uniformity . Weight variation in tablets can be minimised if the formulation exhibit good flow characteristics . .Apeji,.(2010).

Both granules show that there was decrease in granule bulk and tapped densities with increase in concentration of binder (Tables 2 and 3). Flow properties increase from low to higher concentration of binder. This might be due to decrease in densities with increase in binder concentration the lower the density of a material the poorer the flow properties. The flow properties of the granules also indicate that flow ability decreases with increase in size of the angle of repose of granules .(Nasipuri, (1979a) Both granules exhibited similar characteristics.

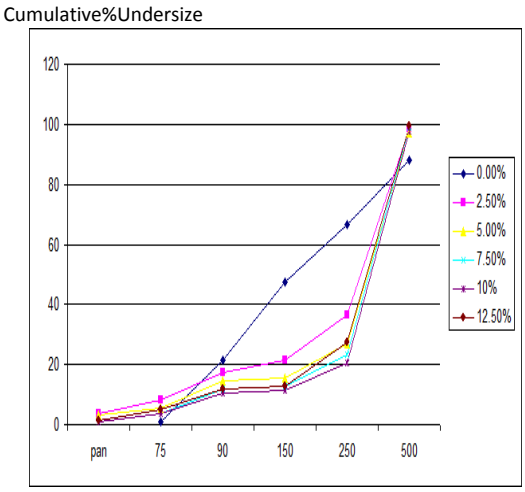

Fig 1 Size distribution of granules of *pennisetum glaucum* starch used as binder in paracetamol tablet formulations.

There was also a decrease in the friability of the tablets as binder concentration increased this was in the order *Pennisetum americanum* greater than Maize starch BP greater than *Pennisetum glaucum*. Statistically there was no significant difference between the disintegration time of maize starch BP and *Pennisetum glaucum* and *Pennisetum americanum*.($p<0.05$)

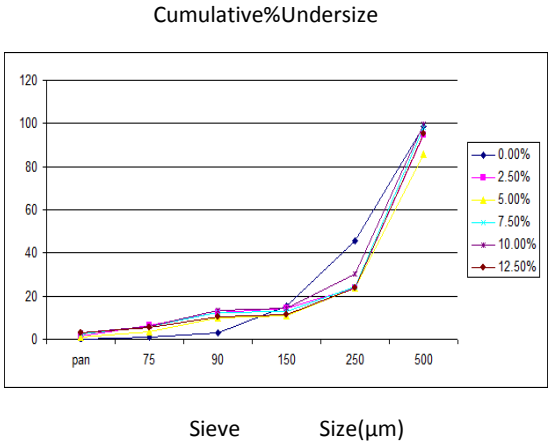

Fig 2 Size distribution of granules of *pennisetum americanum* starch used as binder in paracetamol tablet formulation.

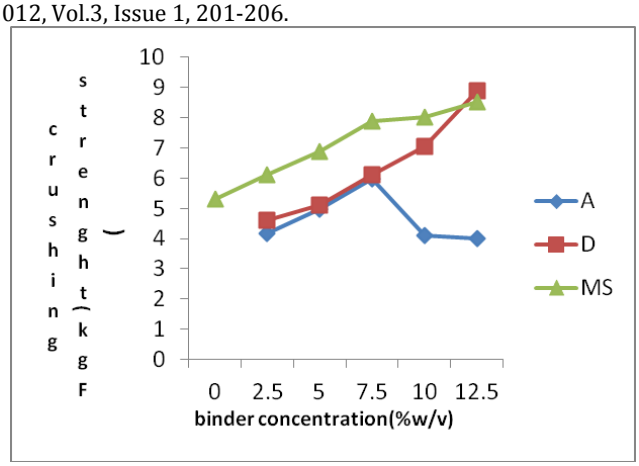

Fig 3: mean crushing strength(kgf) against binder concentration(%w/v) in paracetamol tablets using *pennisetum glaucum(A)* and *pennisetum americanum(D)* starch and maize starch BP (MS) as binder.

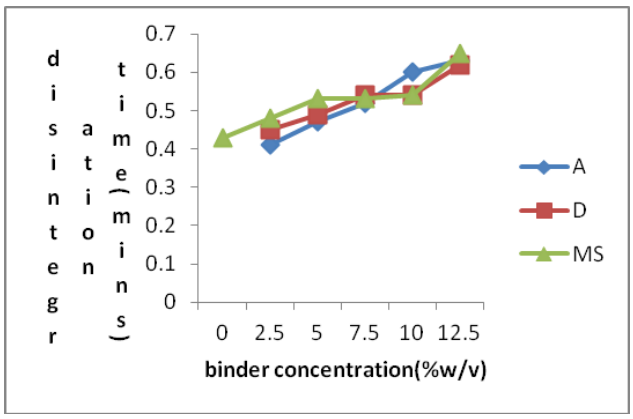

Fig 4: plots of disintegration time(min) against binder concentration(%w/v) using *pennisetum glaucum(A)*, *pennisetum americanum(D)* starch and maize starch BP (MS)

When used as binders tablets whose crushing strength increased with increase in binder concentration were produced (Fig 3) in the order *Pennisetum americanum* greater than Maize starch BP greater than *Pennisetum glaucum.* Statistically there was significant difference between the maize starch BP and Pennisetum glaucum and Penisetum americanum ($P^{<}$ 0.05).in crushing strength and disintegration time.

The increase in tablet crushing strength with increase in binder concentration implies an increase in crushing strenght(Musa.etal,2011) this might be due to the fact that the more the concentration of the binder the more the viscosity and stronger the bridges and tablet binding mechanism such binding forces includes mechanical interlocking, plastic deformation, molecular forces, van der waal forces, electrostatic forces, solid and liquid bridges. Jacob, and Plein, (1968). Similarly friability of the tablets was found to decrease with increase in binder concentration due to increase in tablet hardness. Disintegration time was found to increase with increase in

binder concentration for both binders (Fig 4). The interacting forces and bonds between the particles and the binder present are responsible for the strength of the tablets; those forces were also responsible for the increase in disintegration time of the tablets.(Nasipuri, (1975). . The hardness of tablets, depend on the compression force and the amount of binding agent present. The compression force used was same for all the batches therefore the increase in tablet hardness observed can be attributed to the amount and type of binding agents.(Ochu, 2009).

Conclusion

The results of this study conducted to evaluate the tableting properties of two varieties of millet starches*(Pennisetum glaucum* and *Pennisetum americanum*) as binders show that the type of starch used as binder in tablet formulations affects the properties of granules and tablets.

Generally, increasing the concentration of the binder produced an increase in tablet crushing strength, disintegration times and a decrease in in friability. These effects were observed with all the starches.

In general, increasing the concentrations of the millet starches as binder gave paracetamol tablets of good friability, crushing strength and disintegration time and 2.5% to 5.00%w/w binder is concentration are recommended in the formulation of 500mg Paracetamol tablet.

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AUTHORS' CONTRIBUTIONS

Authors contributed equally to all aspects of the study.

PEER REVIEW

Not commissioned; externally peer reviewed

CONFLICTS OF INTEREST

The authors declare that they have no competing interests