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Research Article

EVALUATION OF FINGER MILLET (ELEUSINE CORACANA) STARCH AS A BINDER IN HIGH DOSE TABLETS

SHIIHII SU[1]*, MUSA H.[2], BHATIA PG[2]

1Pharmacists Council of Nigeria, Lagos 2Department of Pharmaceutics and Pharmaceutical Microbiology, Ahmadu Bello University, Zaria, Nigeria. Email: soloshi_uk@yahoo.com

ABSTRACT

Starch remains the most commonly used excipient in the Pharmaceutical Industries. Starch has been extracted from grains of Finger millet (*Eleusine corocana*), by steeping in water for 24 hours. The extracted starch was used to compressed paracetamol tablet in comparism with maize starch BP. On average the hardness of tablets formulated with *Eleusine corocana* starch was found to be slightly lower than those of maize starch however the friability value of tablets from *Eleusine coracana* starch were higher. Generally speaking the native *Eleusine corocana* starch when used as a binder for compression of paracetamol tablets competes favourably with Maize starch. *Eleusine corocana* starch could match the requirement for Pharmaceutical use especially when treated or modified.

Keywords: Starch, Compression, Binder, *Eleusine corocana.*

INTRODUCTION

Starch is a widely used material with various applications in the Pharmaceutical, food and textile industries. Its uses are based mainly on its adhesive`, thickening, gelling, swelling and film forming properties (Kunle et al, 2003). Freshly prepared starch paste has been widely used as binder for the preparation of granules for tablets and capsule dosage forms. The high demand for starch places a tremendous pressure on the few known official sources and propel efforts for continuous exploitation of local plants in search for a viable newer source of starch.

There are many botanical species in Nigeria that can serve as sources of starch for use in Pharmaceutical industry. Some of this species have already been investigated(Mital and Ocran (1968), Khan and Rhodes (1972), Nasipuri (1979))The grain *Eleusine corocana*, that bears a Hausa name Tamba, is expected to contain starch.Starch is obtained from the grains of *Eleusine corocana*, family *poaceae* (www.wikipedia.org.).

MATERIALS AND METHOD

Materials

Eleusine corocana starch was isolated from the grain of *Eleusine corocana* which was bought at Sabon Gari makert, Zaria, Kaduna State, Nigeria. The Starch was extracted using the method described below.

Method

The grain was thoroughly washed to remove all foreign particles. Washed grain were steeped in water for 24hrs at room temperature and the steeped grains was crushed using blender (Magic blender,SG300D, Japan).The resulting pulp was added with enough quantity of water and was passed through a calico sieve. The slurry was allowed to settle and 0.1N Sodium Hydroxide was added to it to separate starch and protein materials as well as neutralized the slight acidity. Excess Sodium Hydroxide was removed by washing several times with water. The clean supernatant was decanted while the sediment was collected on a tray and air dried. Using pestle and mortar, the dried starch lumps were grounded and the powder was passed through 250 micro meters (Muazu 2007)

Preparation Of Paracetamol Granules

Using the wet granulation method of massing and screening and the formula shown in table 1 & 2 with varying binder concentration the granules were prepared as follows.

Weighing

Appropriate amount of paracetamol powder and starches were weighed for different batches of the formulation.

Mixing

The batches were small (100 tablets per batch), mixing was done in a mortar, paracetamol powder and other exipients were mixed thoroughly using doubling up technique.

Preparation of binder solution

For binder determination, 2.5% w/w of starch paste was prepared by weighing 2.5g of *Eleusine corocana* powder and dispersing it into 30 g of water. It was then put on a hot plate with continuous stirring until translucent paste was formed. Different weights of the materials were weighed in accordance to different binder concentrations.

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 (Termaks Oven) at 60°C

Table 1: Showing the working formula for studying the binding properties of Eleusine corocana starch compared with Maize starch (MS) BP in Paracetamol tablets.

Materials	% Of each excipient	Actual content of each excipient per tablet (mg)	Actual content of excipient per 100 tablets (g)
Paracetamol	77%w/w	500	50
Binder	2.5%w/w	16.25	1.625
Eleusine corocana			
	5%w/w	32.50	3.25
	7.5%w/w	48.75	4.875
	10%w/w	65	6.5
	12.5%w/w	81.25	8.125
Disintegrant(MS)	9.2%w/w	60	6
Extragranular excipient (MS)	7.8%w/w	50.70	5.07
Glidant/Lubricant Mg stearate	0.2%w/w	1.3	0.13
Talc	2%w/w	13	1.3

Table 2: Showing the working formula for studying the binding properties of standard maize starch (MS) BP in Paracetamol tablets.

Materials	% of each excipient	Actual content of each excipient per tablet (mg)	Actual content of excipient per 100 tablets (g)
Paracetamol	77%w/w	500	50
Binder Maize starch	2.5%w/w	16.25	1.625
	5%w/w	32.50	3.25
	7.5%w/w	48.75	4.875
	10%w/w	65	6.5
	12.5%w/w	81.25	8.125
Disintegrant(MS)	9.2%w/w	60	6
Extragranular excipient (MS)	7.8%w/w	50.70	5.07
Glidant/Lubricant Mg stearate	0.2%w/w	1.3	0.13
Talc	2%w/w	13	1.3

Analysis of granules

Sieve Analysis

Different weights as per batches of the granules were dropped into an already arranged set of sieve (from top to bottom of sizes 500 µm, 250 µm, 150 µm, 90 µm,75 µm and the pan). The sieve set was then put on a mechanical shaker (Endecott Test Sieve Shaker Made in England) for shaking, for 10mins; the weight retained by individual sieve was then recorded.

Flow rate of granules

The time required for 16g of granules to pass through an orifice of Erweka flowability tester was measured as the flow rate of the granules.

Bulk density

Different weights of granules in grams were poured through a short-stemmed glass funnel into a 20ml graduated glass cylinder and the volume occupied by the granules was read and the bulk density calculated.

Tapped density

Graduated cylinder containing the granules was dropped on a bench fifty (50) times each until a constant volume was attained from a height of about 20mm and the volume recorded. Tapped density was then calculated in g/ml

Carr's Index

The difference between the tapped and bulk density divided by the tapped density was calculated and ratio expressed as a percentage.

Compression of Granules

Appropriate amount of external disintegrant and lubricant/glidant were added (as shown in tables 1&2).Using sixteen (16) stations rotatory punch tablet press, the granule mixture was compressed with die and punch of diameter 12.5mm at a hardness of 5.8kp to produce paracetamol tablet.

Quality Control Tests

a) Weight uniformity test

Ten tablets from each batch of formulation were weighed individually, and the mean variation calculated as percentage.

b) Tablet thickness

Using micrometer screw gauge, the thickness of 10 tablets was measured and the variation recorded.

c) Crushing strength test

The force required to crush paracetamol tablet was measured using electric tester (Kraemer GmbH, HC 97, India). Three tablets were used and the average hardness was recorded automatically by the machine.

d) Friability test

Using tablet friability test apparatus (VEEGO VFHDv), 10 tablets were weighed and put inside the friabilator chamber and set at 25 revolutions per minute for 4 minutes.

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

e) Disintegration time

Using disintegration test apparatus(Tab – CT – 04), six tablets were placed in the basket individually. The water bath was thermostatically set at 37ºC±1ºC. The time that took the tablet to disintegrate was recorded using a stop clock attached to the apparatus.

f) Dissolution rate

Using a dissolution rate apparatus (DA = 6D USP Standard) and dissolution medium of 900ml of thermostatically maintain at 37ºC± 0.5ºC, six tablets were placed each in the vessel containing the medium. The machine was set at 100 revolutions per minute. 5ml samples of the dissolution medium were withdrawn at every 15 minutes and replaced with 5ml buffer solution. The withdrawn samples were diluted for spectrophotometric determinations using a spectrophotometer (CECIL, CE 7200). The spectrophotometric assay was carried out at wavelength 243nm; readings were used for the drug estimation.

RESULTS AND DISCUSSION

Evaluation of Tablets

Hardness and Friability tests

It has been reported that increase in binder concentration decreases slightly the bulk and tapped densities (table 5), increases granule size, this may be due to increase in bond formation. There is also an increase in wetting and covering of the drug as well as penetration as a result of increase in binder concentration. (Odutose and Nasipuri 1987)

Table 5 shows the effect of concentration of *Eleusine corocana* and Maize starches used as binder on the physical properties of tablet.

Increasing the concentration of binder was found to increase the hardness of tablets and decrease its friability (Table 5). This observation was also reported by Esezebo (1986), Odusote and Nasipuri (1987), Panya, Kunle (1988), Garr (1988) and Akande (1988). The strength of the interparticulate bond depends on the concentration of binder used while the number of bonds depends on nature of the starch itself.

The hardness of tablet formulated with *Eleusine corocana* starch as a binder was found to be slightly lower than those of Maize starch except for binder concentrations 2.5%w/w and 7.5%w/w that the hardness of tablets produced with *Eleusine corocana* was higher than those of maize starch BP; however the friability value of tablets from *Eleusine corocana* starch were higher (Tables 5).

Tablets from *Eleusine corocan* starch at binder concentration of 2.5% and above passed the required friability test with deviation being less than 1% except at the binder concentration 7.5%w/w. This shows that *Eleusine corocana* starch is as suitable as Maize starch in binding properties.

Disintegration and Dissolution tests

For both starches, an increase in binder concentration resulted in increased disintegration time . As explained earlier, since more bonds are formed, the bonds take longer time to break and the resulting harder tablets are difficult for the disintegration medium to penetrate.

Table 5 summarizes the disintegration and dissolution time of *Eleusine corocana* and Maize starches as binder.

The disintegration time of *Eleusine corocana* starch formulation was observed to be longer than that of Maize starch.

For dissolution, table 5 shows the results of the dissolution rate of Paracetamol tablet formulated from different binder concentration of *Eleusine corocana* and Maize starch . The details of time taken for 50% of the drug to dissolve for the different batches are shown in table 5.

The results show that an increase in binder concentration increases dissolution time. At all concentrations investigated, the tablet from *Eleusine corocana* starch has shorter dissolution time than that of Maize starch.

Weight uniformity and Tablet thickness

The results obtained from Weight Variation Test for *Eleusine corocana* and Maize starches were shown in tables 5 for. Maximum standard deviation was found to be 1.99% which is within the USP acceptable limit of not more than 5% for uncoated tablet weighing more than 324mg active ingredient. It indicates good flow property that resulted in uniform filling of the die during compression.

The thicknesses of the tablets produced with varying concentration of binder also shown in tables 5 was within ±5%. The uniformity in tablet thickness indicates that, there was uniform die fill during the tableting process for both *Eleusine coracana* and Maize starches.

Table 3: Granule Properties of *Eleusine corocana* starch compared to Maize starch BP as a binder

Binder	Granules	*Eleusine corocana* Starch	Maize Starch BP	7.5	10	12.5	2.5	5	7.5	10	12.5
Flow	rate (g/sec)	5.43	5.49	5.73	5.41	5.81	5.34	5.61	5.20	5.54	5.39
Bulk	Density (g/cm3)	0.4966	0.4904	0.4803	0.4816	0.4600	0.5151	0.5093	0.5055	0.4981	0.4841
Tapped	Density (g/cm3)	0.6208	0.5543	0.5661	0.5927	0.5558	0.6225	0.6151	0.6145	0.6131	0.5867
Carrs	Index (%)	20	11.52	15.16	18.71	17.24	17.25	17.20	17.74	18.76	17.49

Table 4: Particle size distribution of granules (Cumulative % oversize) *Eleusine corocana* and maize starch

Sieve Size	Binder Concentration									
	Eleusine corocana Starch					Maize Starch BP				
	2.5	5	7.5	10	12.5	2.5	5	7.5	10	12.5
500	71.28	63.74	64.81	67.88	70.91	64.21	66.82	74.33	70.81	71.35
250	6.87	12.95	12.84	14.17	12.82	13.81	12.06	11.62	13.27	12.99
150	4.85	3.81	1.64	3.16	7.47	2.21	2.14	2.31	1.04	1.63
90	13.70	14.60	13.35	10.05	1.98	6.03	7.43	6.99	7.77	5.27
75	5.52	4.09	5.89	4.11	4.10	8.78	3.29	3.49	4.08	5.42
Pan	0.78	0.77	1.46	0.63	2.71	4.96	8.27	1.25	3.04	3.34

Table 5: Effect of Binder on Paracetamol tablet

Tablet Properties	Binder Concentration									
	Eleusine corocana Starch					Maize Starch BP				
Binder Conc. (%w/w)	2.5	5	7.5	10	12.5	2.5	5	7.5	10	12.5
Crushing Strength (Kp)	3.5	3.6	5.0	3.9	4.1	2.8	3.7	3.8	7.2	6.3
Friability (%w/w)	0.93	0.93	1.28	0.93	0.88	0.63	0.32	0.32	0.31	0.31
Disintegration time (Sec.)	38	40	40	61	72	39	39	60	63	64
Disolution time T_{15} (Min)	0.084	0.152	0.181	0.183	0.180	0.163	0.192	0.197	0.179	0.171
Disolution time T_{30} (Min)	0.135	0.222	0.189	0.373	0200	0.215	0.198	0.214	0.191	0.194
Disolution time T_{45} (Min)	0.173	0.234	0.224	0.249	0.269	0.267	0.204	0.221	0.215	0196
Disolution time T_{60} (Min)	0.181	0.238	0.227	0.223	0.210	0.244	0.204	0.233	0.217	0.188
Mean wight (mg)	650	648	664	661	655	663	655	658	670	657
Standard deviation	0.00	0.00	9.33	7.33	3.33	8.66	3.33	5.33	13.33	4.66
% standard deviation	0	0	1.41	1.11	0.50	1.31	0.51	0.81	1.99	0.71
Tablet mean thickness (mm)	5.389	5.417	5.388	5.442	5.390	5.474	5.458	5.348	5.371	5.389

CONCLUSION

The grains of *Eleusine corocana* or finger millet contain starch with distinct properties. The differences observed compared to maize starch BP reflects the fundamental differences of starches from different botanical sources. The native *Eleusine corocana* starch when used as a binder in comparism with maize starch BP, competes favourably with maize starch BP.

These reveals that native starch can be improved to meet Pharmaceutical grade when an improved technique of extraction is used and or it is subjected to purification techniques considering its relative abundance.

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