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DISINTEGRANT EFFECT OF FINGER MILLET (*ELEUSINE COROCANA*) STARCH ON DISSOLUTION PROFILE AND DISINTEGRATION TIME IN HIGH DOSE TABLETS

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ABSTRACT

Starch was extracted from the grains of finger millet (*Eleusine corocana*), by steeping in water for 24 hours. The extracted starch was used as a disintegrant, at the concentrations of 2.5-12.5%w/w to compressed paracetamol tablet in comparism with maize starch BP. Results show that, there is no significant difference in the disintegration time or dissolution rate of tablets containing the two starches. Tablets containing *Eleusine corocana* met compendia requirements for disintegration time and dissolution rate. The starch is recommended as a disintegrant in tablet formulation.

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 [1]. The high demand for starch places a tremendous pressure on the few known official sources and propels 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 [2, 3, 4].

The grain *Eleusine corocana*, that bears a Hausa name Tamba, is expected to contain starch. Starch is obtained from the grains of *Eleusine coracana*, family *poaceae* [5].

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 grains were steeped in water for 24hrs at room temperature and the steeped grains were 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 ground and the powder was passed through 250 micro meter (Muazu 2007)

Preparation of Paracetamol Granules: Using the wet granulation method of massing and screening and the formula shown in **tables 1** with different disintegrant concentrations, the granules were prepared as follows.

1. Weighing: appropriate amount of paracetamol powder and starches were weighed for different batches of the formulation.

2. Mixing: the batches were small (100 tablets per batch), mixing were done in a mortar, paracetamol powder and other excipients were mixed thoroughly using doubling up technique.

3. Preparation of binder solution: for disintegrant determination, 2.5% w/w of starch was incorporated as 2.5g in 30 ml of paste.

4. 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.

5. Drying: the wet granules were dried in a hot air oven (Termaks Oven) at 60°C for 1 hour.

TABLE 1: FORMULA FOR THE DISINTEGRATION PROPERTIES OF *ELEUSINE COROCANA* AND MAIZE STARCHES 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
Disintegrant: *Eleusine corocana*	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
Binder (MS)	5%w/w	25	2.5g
Extra granular 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:

1. **Sieve Analysis**: Different weights as per batches of the granules were poured 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.

2. **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.

3. **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.

4. **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.

5. **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 the above table).

Using sixteen (16) stations rotatory punch tablet press, the granule mixture was compressed with die and punch of diameter 12.5mm at hardness of 5.8kp to produce paracetamol tablet.

Quality Control Tests:

1. **Disintegration time:** Using disintegration test apparatus (Tab – CT – 04), six tablets were placed in the basket individually. The water bath was thermostatically set at $37^{o}C \pm 1^{o}C$. The time that took the tablet to disintegrate was

recorded using a stop clock attached to the apparatus.

2. **Dissolution rate:** Using a dissolution rate apparatus (DA = 6D USP Standard) and dissolution medium of 900ml of thermostatically maintain at 37°C± 0.5°C, 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 with the help of Bear Lamberts plot**.**

Evaluation of Tablets:

Disintegration and Dissolution tests: The disintegration time of *Eleusine corocana* starch formulation was observed to be longer than that of Maize starch (**Fig. 1**).

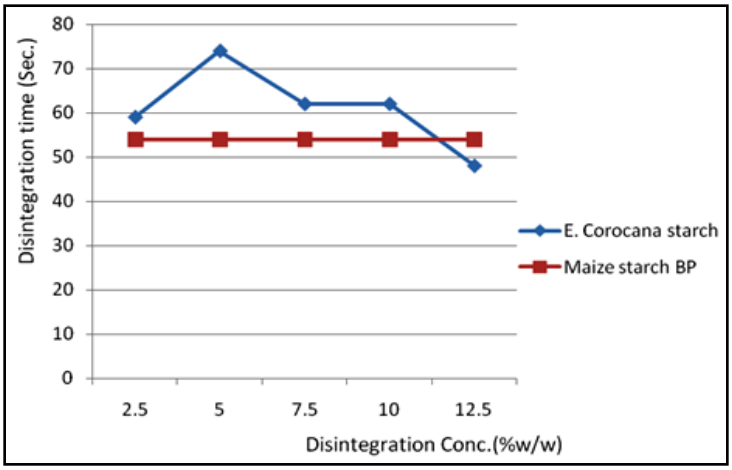

FIG. 1: EFFECT OF DISINTEGRANT CONCENTRATION ON THE DISINTEGRATION TIME OF PARACETAMOL TABLETS CONTAINING THE STARCHES

For a drug to be absorbed from a solid dosage form after oral administration it must first be in solution and the first important step towards this condition is usually the breakup of the tablet, a process known as disintegration [6, 7].

It has been reported that penetration of water into a tablet is proportional to its mean pore diameter or porosity [8, 9]. Generally, short disintegration times are associated with rapid fluid penetration [10, 11].

The higher the tabletting pressure, the lower the porosity and permeability [12], subsequently the lower the porosity, the higher the disintegration time [13, 14].

For dissolution, **Fig. 2 & 3** shows the results of the dissolution rate of Paracetamol tablet formulated from different concentration of *Eleusine corocana* and Maize starch disintegrant.

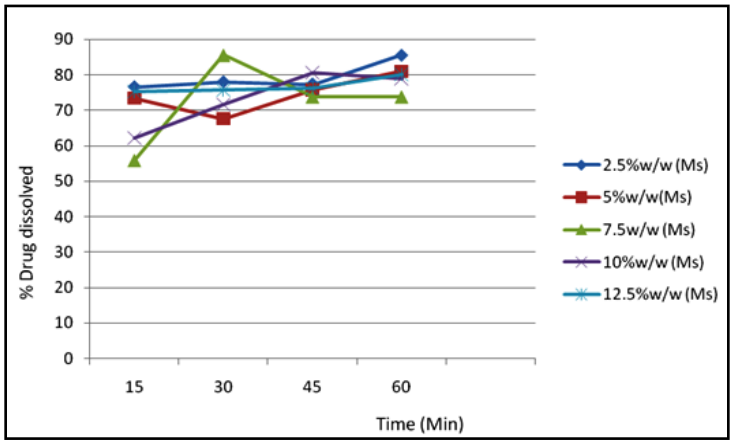

FIG. 2: DISOLUTION PROFILE OF PARACETAMOL TABLETS CONTAINING VARYING CONCENTRATIONS OF MAIZE STARCH AS DISINTEGRANT

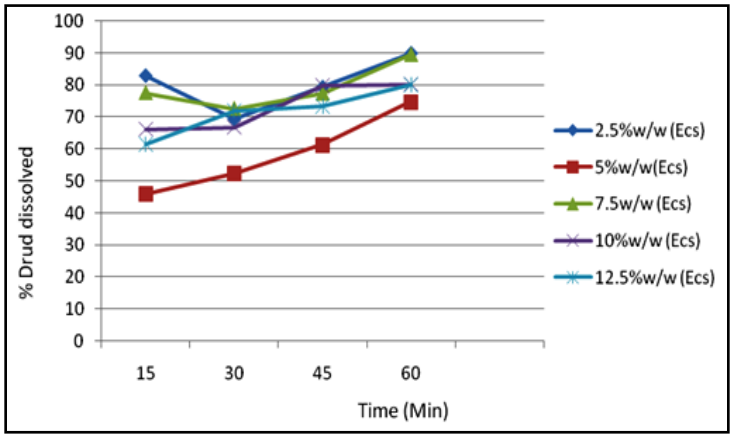

FIG. 3: DISOLUTION PROFILE OF PARACETAMOL TABLETS CONTAINING VARYING CONCENTRATIONS OF *ELEUSINE COROCANA* STARCH AS DISINTEGRANT

The details of the percentage of drug dissolved at various disintegrant concentrations for the different batches are shown in **table 3**. The results show that at all the concentrations, more than 75% of the drug was dissolved except at concentration 5 & 7.5%w/w for *Eleusine corocana* and maize starch respectively.

The Carr's index of both *Eleusine corocana* and Maize starches are below 25 which is considered to be an indication of good flowability, hence good compressibility (**table 4**).

TABLE 3: EFFECT OF DISINTEGRANT CONCENTRATION ON SOME PHYSICAL PROPERTIES OF PARACETAMOL TABLETS

Property	*Eleusine corocana* starch					Maize starch				
Disintegrant conc. (%w/w)	2.5	5	7.5	10	12.5	2.5	5	7.5	10	12.5
Disintegration time (Sec)	59	74	62	62	48	54	54	54	54	54
Dissolution T_{50} (Min)	84	66	82	80	76	82	78	72	80	78

TABLE 4: THE PHYSICAL PROPERTIES OF PARACETAMOL GRANULES CONTAINING *ELEUSINE CORACANA* OR MAIZE STARCH AS DISINTEGRANT

Granules	*Eleusine coracana* Starch					Maize Starch BP				
Disintegrant (%w/w)	2.5	5	7.5	10	12.5	2.5	5	7.5	10	12.5
Flow rate (g/sec)	5.2	5.67	5.72	5.37	5.87	5.49	5.33	5.25	5.60	5.30
Bulk density (g/cm^3)	0.4924	0.5063	0.4741	0.4838	0.4916	0.4714	0.5083	0.4770	0.5084	0.4689
Tapped density (g/cm^3)	0.6209	0.6231	0.6068	0.5954	0.5936	0.5696	0.6142	0.5855	0.5947	0.5667
Cars index (%)	20.69	18.74	21.87	18.74	17.18	17.24	17.24	18.53	14.51	17.26

CONCLUSION: The native *Eleusine corocana* starch when used in comparison with maize starch BP as a disintegrant does very well. The starch may be use in place of maize starch as a disintegrant if modified.

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