Journal of Science and Practice of Pharmacy
December 2018; 5 (2): 231-239 Available at http://www.jsppharm.org
ISSN: 2449-0458 (print); 2449-0466 (electronic)

Original Research Article

Evaluation of millet (*Pennisetum glaucum* and *Pennisetum americanum*) starches as tablet disintegrants

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Abstract

Purpose: This study is aimed at evaluating the disintegrant property of locally sourced millet (*Pennisetum glaucum* (PG) and *Pennisetum americanum* (PA)) starches in comparison with maize starch BP (MS).
Methods: The millet starches were extracted by the wet extraction method and compared with MS as disintegrants at various concentrations (0-12.5%w/w) in the preparation of paracetamol granules and tablets. The granules were analyzed for their physicochemical properties such as; flow rate, moisture content, angle of repose, Carr's index (CI), Hausner ratio (HR) and sieve analysis while the tablets were subjected to weight uniformity test, tablet thickness, crushing strength (CS) test, friability (FR) test and disintegration time (DT) test evaluations.
Results: The percentage yield of PA and PG starches were 56.2 and 50.0 % w/w respectively. PA and PG granules' flow rate increased as the disintegrant concentration increased (8.06 to 13.17 g/sec) but MS had a better flow rate (<9.28 g/sec). The angle of repose for PA and PG ranges from 30.52 to 33.98o compared with MS of 23.11 to 33.11o. Moisture content of PA, PG and MS granules exceeded 20 %. The CI values for PA was <25 % PG increased from 18.40 to 28.06 % while MS was <25 %. HR values were all >1.2.The weight of the tablets produced ranges from 602±5.6 to 656±4.6 mg. Their thickness was in the range of 5.35 to 6.09 mm. The tablets were relatively hard (CS >5.0 kgf). Tablets with disintegrant concentration of 12.5 % w/w had values of FR >1.0 %. The DT for PA and PG decreased as disintegrant concentration increases but all the tablets DT was <1.0 min. The (CS/FR)/DT values for PA and PG (18.62 to 29.41) were greater than MS (7.41 to 23.97).
Conclusion: The study revealed that the locally sourced PA and PG starches can be used as disintegrants. The starches compared well with MS and could serve as an alternative to MS as a disintegrant in the manufacture of solid dosage forms.

Keywords: Disintegrant, tablets, *Pennisetum glaucum*, *Pennisetum americanum*, starch

Indexing: Index Copernicus, African Index Medicus

Introduction

A disintegrant is a substance, or a mixture of substances, added to a tablet to facilitate break up after administration. Disintegrants are employed in tablet formulations to enhance the breakdown of tablet into granules upon entry into the stomach thereby promoting rapid drug dissolution. Starches are commonly used in an amount of 3 to 15 percent when it functions as a disintegrant [1]. Disintegrants are an essential tableting excipient, enabling tablet disintegration to occur within the specifications defined by various pharmacopoeias. Several mechanisms by which disintegrants elicit their effects include; increase in the porosity and wettability of compressed tablet e.g. starch; microcrystalline cellulose (MCC) and sodium starch glycolate; swelling in the presence of aqueous fluids, thus increasing the internal pressure of the tablet e.g. sodium starch glycolate, croscarmellose sodium,

crospovidone and pre-gelatinized starch; production of gas within the tablet when in contact with fluid, a mechanism of disintegration by effervescent tablets and the destruction of binders by enzymatic action [2,3].

Starch is a carbohydrate consisting of a large number of glucose units joined by glycosidic bonds. Pure starch is a white, tasteless and odorless powder that is insoluble in cold water or alcohol. It consists of two types of molecules: the linear and helical amylose and the branched amylopectin. Depending on the plant, starch generally contains 20 to 25 % amylose and 75 to 80 % amylopectin [4].In normal starch, the amylose: amylopectin (Am:AP) ratio is approximately 1:4.Amylose is a hydrocolloid which extended conformation causes the high viscosity of water soluble starch which varies relatively little with temperature. Amylopectin interferes with the interaction between amylose chains and its solution can lead to an initial loss in viscosity and followed by a slimy consistency. Amylose in starch gives stronger film whereas amylopectin generally leads to lower mechanical properties [5,6].

Millets belongs to the grass family Poacea formally Gramineae [7]. They are a group of highly variable small-seeded grasses, widely grown around the world as cereals or grains for fodder and human food. Millets are important crops cultivated in the semi-arid climate tropics of Asia and Africa with up to 97 percent of the world's millet production in developing countries especially in China, India, Mali, Nigeria and Niger [8].The crop is favored because it thrives under dry, high-temperature conditions. The most widely grown millet is pearl millet, which is an important crop in India and parts of Africa. Finger millet, proso millet, and foxtail millet are also important crop species. Millets have been important food staples in human history, particularly in Asia and Africa. They have been in cultivation in East Africa for the last 10,000 years [9]. The top five millet producers in the world include: India Nigeria-Niger-China- and Mali [10].

Several research works have been carried out on the use of millet starches as tablet excipient. Some of them include: investigation of functional and tableting properties of acetylated and oxidized finger millet (*Eleusine corocana*) starch [11], disintegrant effect of finger millet (*Eleusine corocana*) starch on dissolution profile and disintegration time in high dose tablet [12], evaluation of pearl millet starch as tablet disintegrant [13] and super-disintegrant activity of acid-modified millet starch in diclofenac tablet formulations [14].

The research work is aimed at investigating the disintegrant property of PA and PG starches in the formulation of paracetamol tablet in comparison with MS as a standard disintegrant

Materials and Methods

Materials

Pennisetum glaucum and *Pennisetum americanum* were purchased from local markets in Samaru, Kaduna State and Funtua, Katsina State, Nigeria respectively. The grains were taken to the Herbarium of Department of Biological Sciences, Ahmadu Bello University Zaria for authentication and certification. Paracetamol powder and Maize Starch BP were obtained from May and Baker Nigeria Plc, talc and magnesium stearate from BDH Chem. Ltd, Poole, England.

Methods

Extraction of millet starches

The grains of millet were inspected and 2 kg of each variety of the cereal were thoroughly washed to remove all extraneous materials. The washed cereals were soaked in water for 24 h. The steeped grains were then blended and mixed with sufficient quantity of water before passing it through a filter cloth to remove the chaff. One hundred milliliters of 0.1 N NaOH was added to the filtered mass 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 until the filtrate tested neutral to litmus. The starch was re-suspended in excess water and allowed to settle for about 1 h. The clear supernatant fluid above the starch sediment was decanted and the wet mass of starch collected. A suspension of the starch in

distilled water was then centrifuged (Laboratory Centrifuge - 2, Japan) for 15 min at 2800 rpm to separate the non-starch components from the starch. The starch retrieved was then collected and spread to dry in an oven at 40oC on a tray. The dried starch lumps were size reduced to a fine powder using a blender [15]. The powder was then stored in a clean dried container until required for use.

Preparation of paracetamol granules

Using the wet granulation method of massing and screening, six batches of paracetamol granules with varying concentrations of the *Pennisetum glaucum* and *Pennisetum americanum* and maize starch (MS) were produced with maize starch BP as standard, using the formula in Table 1.

Table 1: Formula used in the preparation of the paracetamol granules and tablets

Ingredients	Quantity /tablet (mg)	Quantity /100 tablets (g)
Paracetamol	500.00	50.0
Disintegrant*		
Binder mucilage (7.5 %w/v maize starch)	q.s	q.s
Magnesium stearate (0.2 % w/w)	1.30	0.13
Talc (2.0 % w/w)	13.00	1.30

*The disintegrant, *P.glaucum* starch or *P.americanum* starch or maize starch BP (0, 2.5, 5.0, 7.5 10.0and 12.5 %w/w)

The paracetamol powder and PG, PA and MS starches (intra disintegrant) were weighed appropriately and dry mixed for 5 min in a mortar with pestle until fine powder was obtained. An appropriate quantity of freshly prepared binder of concentration of 7.5 % w/v was added depending on the batch to produce a moist and cohesive mass. The wet mass was then passed through a 1.7 mm sieve mesh screen and then oven dried at 40 oC for 30 min after which they were re- screened through a 1.6 mm mesh size and further dried for another 30 min. The granules were allowed to cool and stored in an air tight container.

Granule analysis

Bulk density: Granules weighing 50 g were 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 bulk density calculated.

Tapped density: A graduated cylinder containing 50 g of the 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:

$$Carr's\ Index = Tapped\ density - Bulk\ density / Tapped\ density\ x\ 100\ \%$$

Hausner ratio: The ratio of the tapped density to bulk density was calculated as the Hausner's ratio.

$$Hausner\ ratio = Tapped\ density / Bulk\ density$$

Flow rate: Granules of 50 g of PG, PA and MS were poured into the funnel of Erweka flowability tester (GDT, Germany)and the time taken to pass through the orifice by individual powder was recorded [16].

Moisture content: The granules were weighed (5 g) into evaporating dishes and placed in an oven set at 105°C. The sample was weighed on an hourly basis until a constant weight was attained. The difference in weight was calculated and the moisture content determined.

Size analysis of granules: The sieves were arranged vertically in order of decreasing mesh size (500-75 µm). Thirty grams of the 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 10 min, 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 disintegrants of starch samples and maize starch (MS).

Compression of granules

The granules were mixed in a Tumble mixer for 5 min with extra-granular excipients namely; 2.0 % w/w dried talc and 0.2 % w/w magnesium stearate. Quantities of the granules (650 mg) from each batch were compressed at 7.0 metric tonnes using 12.0 mm normal concave-faced punches on a single punch tablet machine (Type

Eko Erweka Apparatebau. G.M.B.H Heusentamm, Germany).

Quality control test on the tablets

Weight uniformity test

Ten tablets from each batch of formulation were weighed individually on a Mettler balance (Type 163, Mettler 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.

Thickness measurement

The thickness of five tablets from each batch was measured using a digital caliper. A mean of five determinations was obtained and recorded.

Hardness 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 Erweka (TA 3R Germany) friabilator and operated or rotated 100 times in 4 min i.e. 25revolution per minute removed dusted and reweighed (W2). The percentage weight loss was calculated as the friability (FR) of the tablets.

Disintegration time test

The time required for six tablets per batch to disintegrate was determined using Erweka disintegration tester (Type ZTS Germany) containing distilled water thermostatically maintained at 37± 2°Cas the disintegration medium. The disintegration apparatus was calibrated to operate at thirty cycles per minute. The time taken for the 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 disintegration time.

Results and Discussion

Physical properties of paracetamol granules

The effects of disintegrant concentrations on the physicochemical properties of paracetamol granules are presented in Table 2. Alteration of particle size by the process of granulation produced relatively large sized granules with improved flowability [17]. The flow properties were assessed using the parameters of angle of repose and flow rate while Carr's index and Hausner ratio were used to evaluate compressibility. The result revealed that the value of angle of repose at all disintegrant concentrations was between 30.52 to 33.98° for PA and PG granules while the MS granules had values between 23.11 to 33.11°. The angle of repose of the granules was less than 50° thus granules have satisfactory flow properties [17].

The Carr's index and Hausner ratio values were computed from bulk density and tapped density values. Carr's index and Hausner ratio previews the degree of densification which would occur during tableting. As the values of these parameters increase, the flow of the powder decreases and gives more likelihood of producing tablets with more weight variation [18].The Carr's index values for PA and PG granules at all concentrations were ≤ 29.50 % and the Hausner ratio values were ≤ 1.40 compared to ≤ 20.46 % and ≤ 1.26 respectively for MS. The Carr's index and the Hausner ratio values of PA and PG reflect satisfactory free flowing powdered granules [17,19].

These values give a measure of the ability of a material to be reduced in volume under pressure and the indication of the likely flow behavior of granules when subjected to compression forces to form compact mass. It has been reported that the flow of the granules is better when Carr's index is lower [20]. These parameters indicate that the granules have a satisfactory compressibility profile. Moisture content for the material as shown in Table 2, exceeded the official limit of 15 % specified for starches [21]. Moisture content affects flow property and stability of a product. This could affect tablet parameters such as weight and content uniformity [16]. Moisture is known to modify

the flow and mechanical properties of many powders including starches [22]. The size distribution of the granules prepared with *Pennisetum glaucum* and *Pennisetum americanum* starches as disintegrant are presented in Fig. 1 and 2 respectively. The sieve sizes indicated that the granules exhibited similar size distribution pattern. It also revealed that 60 to 100 % of the granules lie between 250 to 500 µm size ranges.

Table 2: Physicochemical properties of granules prepared with PA and PG starches with Maize starch BP as disintegrants

Starch	Disintegrant concentration (% w/w)	Flow rate (g/sec)	Moisture content (%)	Angle of repose (º)	Bulk density (g/mL)	Tapped density (g/mL)	Carr's index (%)	Hausner ratio
Pennisetum americanum	0.00	9.30	21.70	32.90	0.381	0.463	17.70	1.22
	2.50	8.87	24.50	32.78	0.435	0.509	14.54	1.17
	5.00	8.06	24.00	32.82	0.432	0.526	17.30	1.21
	7.50	9.40	28.50	32.29	0.429	0.546	21.43	1.27
	10.00	13.75	24.50	33.98	0.417	0.456	23.63	1.31
	12.50	13.17	27.50	33.39	0.417	0.546	23.63	1.31
Pennisetum glaucum	2.50	8.63	23.50	30.52	0.423	0.509	16.90	1.20
	5.00	9.63	26.00	30.62	0.429	0.577	26.69	1.37
	7.50	10.56	26.50	33.48	0.423	0.577	26.69	1.37
	10.00	12.52	24.00	32.28	0.429	0.600	29.50	1.40
	12.50	12.42	20.50	31.74	0.423	0.588	28.06	1.39
Maize starch BP	2.50	9.28	21.00	28.53	0.405	0.492	17.68	1.22
	5.00	8.72	24.50	33.11	0.405	0.484	16.32	1.20
	7.50	9.07	25.00	28.53	0.405	0.484	16.32	1.20
	10.00	8.80	25.50	26.07	0.405	0.500	19.00	1.24
	12.50	8.64	25.50	23.11	0.385	0.484	20.46	1.26

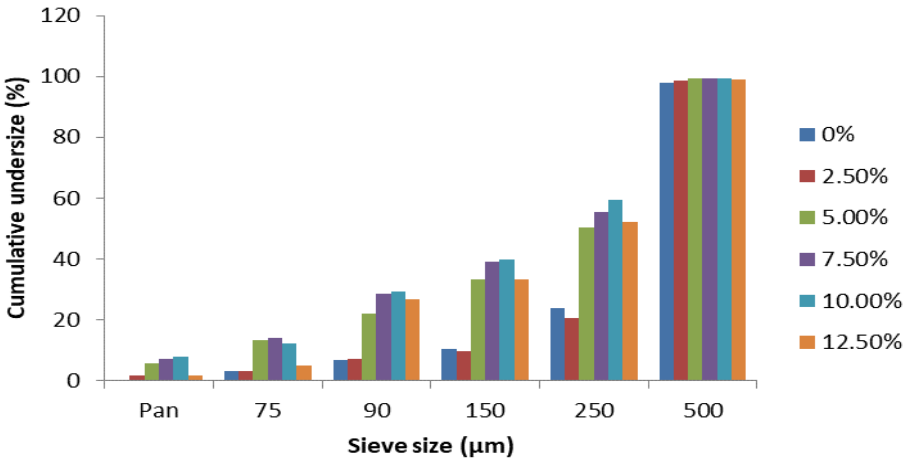

Figure 1: Size distribution of granules prepared with *Pennisetum glaucum* starch

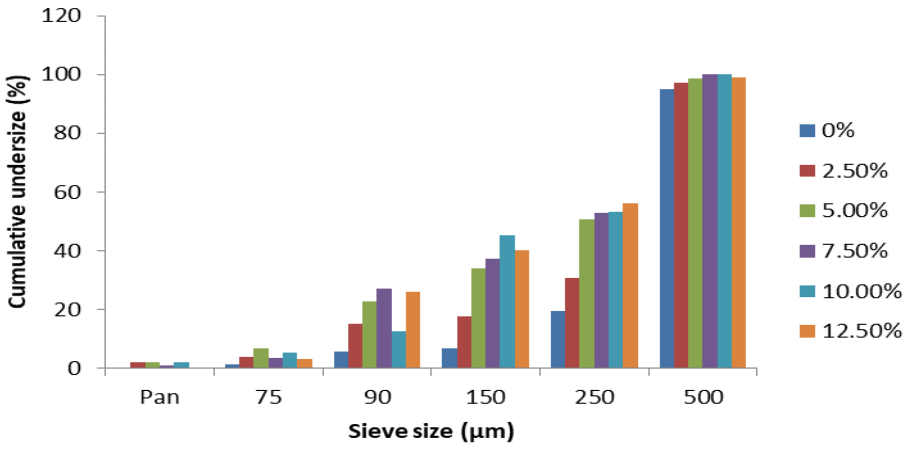

Figure 2: Size distribution of granules prepared with *Pennisetum americanum* starch

Properties of tablets

The results of the tablet parameters are presented in Tables 3. The values of the uniformity of weight for the tablets ranged from 602±5.6 to 656±4.6 mg. The values are within the acceptable official limits for the respective weights of the tablets (BP, 2002). The uniform filling of the die cavity was as a result of the good flow properties of the granules and was also enhanced by the addition of glidant. It was stated that any variation in the weight of individual tablets is a valid indication of the corresponding variation in the drug content [23].

The crushing strength (CS) is a measure of tablet strength [24]. The CS was in the range of 5.0 to 8.28. The friability (FR) is a measure of tablet weakness [24]. The FR values increased with increase in disintegrant concentration. All the tablets disintegrated in <1.0 min. The CS/FR index for disintegrant concentration decreased with increase in concentration. (CS/FR)/DT is a better index of measuring the quality of tablets. It measures tablet strength and weakness and evaluates all negative effects of these parameters on the disintegration time [25].

The (CS/FR)/DT values revealed that MS<PG<PA.The time taken for a tablet to disintegrate when immersed in some test fluid should not exceed 15 min for uncoated tablets [21]. It has been suggested that the starches disintegrant action in tablets is due to capillary action in tablets rather than swelling. It was also stated that the intrusion of fluid by capillary forces enlarges the particles. The spherical shape of the starch grains increases the pore size of pores in the tablet. It was also shown that narrower pore sizes of capillaries produced higher capillary forces of sucking in more fluids. Also the decreased disintegration time increased with increased disintegrant concentration can be as a result of enhanced water penetration by capillary forces into the tablets to cause the swelling of some components in the tablet to break apart [26-29].

Tablets produced with PA as disintegrant had the highest disintegration time this might be due to formation of stronger interparticulate bonds between particles and/or between the excipients. This revealed that the more compact a tablet is, the less the porosity or the voids between the particles. Therefore less penetration of water into the tablet would tend to cause a longer disintegration time [30-32]. There was an increase in tablet crushing strength as the disintegrant concentration increased (Fig. 3) this effect varied with disintegrant type. The effect was in the order PA>MS>PG. The increase in tablet crushing strength with increase in disintegrant concentration implies an increase in tablet hardness and increase in friability (Fig. 3 and 4).

Table 3: Physical properties of the formulated paracetamol tablets

Starch	Disintegrant conc. (% w/w)	Weight (mg)	Thickness (mm)	Crushing strength CS (kg/f)	Friability FR (%)	Disintegration time DT (min)	CS/FR	(CS/FR) /DT
Pennisetum americanum	0.00	602±5.6	5.35	5.00	0.43	0.45	11.04	24.53
	2.50	625±5.3	5.81	5.08	0.60	0.44	8.47	19.25
	5.00	626±5.2	5.53	6.10	0.78	0.42	7.82	18.62
	7.50	635±5.3	5.60	6.94	0.89	0.36	7.80	21.66
	10.00	644±5.2	5.73	7.40	0.96	0.34	7.71	22.67
	12.50	655±5.3	6.09	8.28	1.33	0.32	6.23	19.45
Pennisetum glaucum	2.50	618±6.3	5.50	6.61	0.48	0.44	12.71	28.88
	5.00	618±6.3	5.61	5.15	0.59	0.43	8.73	20.30
	7.50	613±6.9	5.55	4.98	0.64	0.40	7.78	19.45
	10.00	620±4.1	5.50	5.47	0.79	0.29	6.92	23.88
	12.50	644±6.9	5.58	6.47	1.10	0.20	5.88	29.41
Maize starch BP	2.50	615±4.7	5.66	5.10	0.81	0.33	6.30	19.08
	5.00	626±4.6	5.80	6.40	0.89	0.30	7.19	23.97
	7.50	636±4.6	5.67	6.90	0.98	0.41	7.04	17.17
	10.00	647±4.2	5.76	7.30	1.18	0.60	6.19	10.31
	12.50	656±4.6	5.94	8.10	1.54	0.71	5.26	7.41

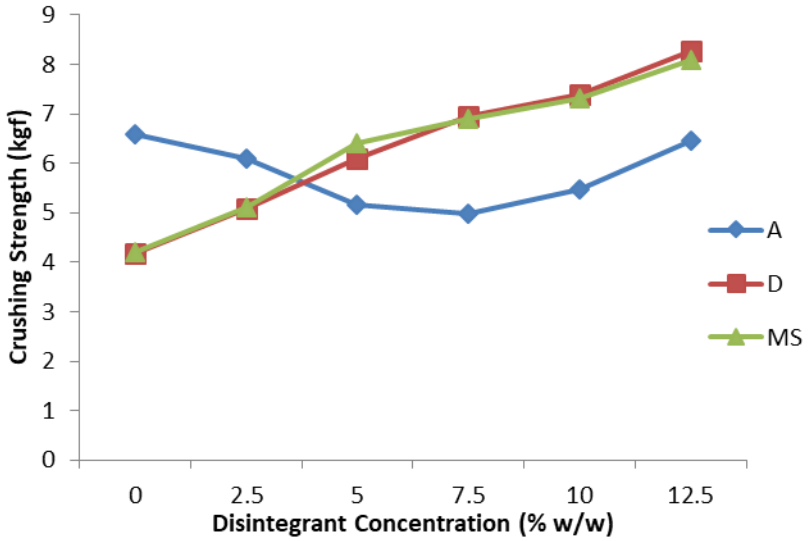

Figure 3: Mean crushing strength (kgf) against disintegrant concentration (%w/w) in paracetamol tablet using *Pennisetum glaucum* (A) and *Pennisetum americanum* (D) starch and maize starch BP (MS) as disintegrant

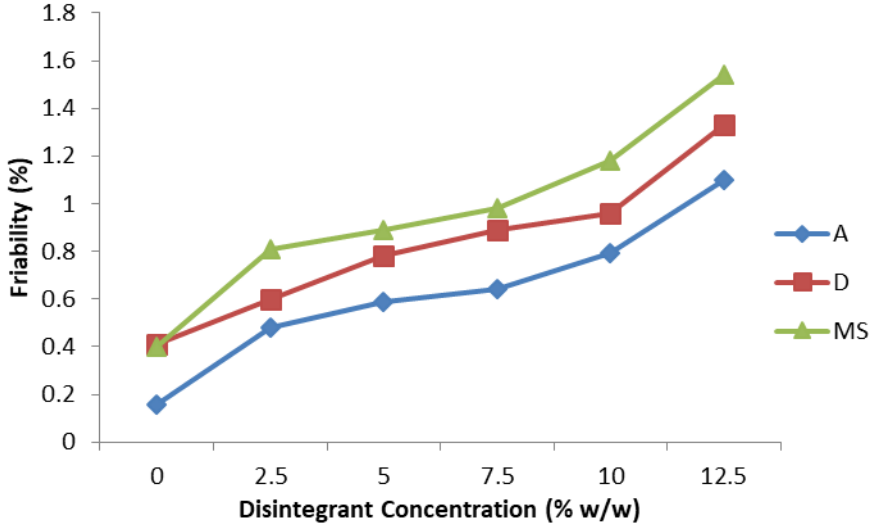

Figure 4: Friability against disintegrant concentration (%w/w) in paracetamol tablet using *Pennisetum glaucum* (A) and *Pennisetum americanum* (D) starch and maize starch BP (MS) as disintegrant

Conclusion

The results of this study conducted to evaluate the tableting properties of two varieties of millet starches(*Pennisetum glaucum* and *Pennisetum americanum*) as disintegrants show that the type of starch used as disintegrant in tablet formulations affects the properties of granules and tablets. The physicochemical properties of the starches ranked as follows; PG <PA<MS. The flow properties ranked in the order: PG<PA<MS. Increase in the disintegrant concentration of PG and PA caused a decrease in the disintegration time of the tablets. The (CS/FR)/DT results showed that tablets produced were generally weak. The PG and PA starches compared well with Maize starch BP in physicochemical properties and could serve as an alternative to maize starch BP as a disintegrant in the manufacture of solid dosage forms. In general, increasing the concentrations of the millet starches as disintegrant gave paracetamol tablets of good friability, crushing strength and disintegration time. The 5.00%w/w to 7.50%w/w disintegrant concentrations is recommended in the formulation of 500 mg paracetamol tablet.

Conflict of Interest

No conflict of interest is associated with this work.

Contribution of Authors

We declare that this work was done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by the authors. GOO (writing of the article, data analysis and interpretation, critical review of the article), AY (research concept and design, collection and assembly of data), HM (research concept and design, final approval of article) and ARO (data interpretation).

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