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Evaluation of *Setaria Italica* Starch as Pharmaceutical Excipient

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ABSTRACT

A study has been carried out to investigate the physicochemical, binding and disintegrating properties of millet starch obtained from *Setaria italica* (Family Gramineae). The isolated starch has been evaluated and characterized for various parameters like ash values, loss on drying, viscosity, amylose content and preformulation studies like sieve analysis, micrometry, flow properties, moisture content, compatability studies and compared with that of commercial available maize starch. The tablets were prepared by wet and dry granulation methods using drugs paracetamol and aspirin respectively with *Setaria italica* starch and maize starch as binder, disintegrant, binder and disintegrant and were evaluated. The results showed that *Setaria italica* starch employed in paracetamol tablets as binder(15%) and disintegrant(10%) and in aspirin tablets as binder(5%) and disintegrant(15%) concentrations produced hard and good quality tablets, comparable in friability, weight variation, disintegration and dissolution time to tablets produced with maize starch. The results indicate that *Setaria italica* starch can be employed as an alternative binder to maize starch in the formulation of paracetamol and aspirin tablets.

Keywords: *Setaria italica* starch, maize starch, binder, disintegrant and excipient.

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INTRODUCTION

A pharmaceutical excipient is an inactive substance formulated along with the active ingredient ("API") of a medication, for the purpose of bulking-up formulations that contain potent active ingredients (thus often referred to as "bulking agents," "fillers," or "diluents")which allows convenient and accurate dispensation of a drug substance when producing a dosage form[1.] Excipient facilitates drug absorption, solubility, and aids in the handling of the active substance such as by facilitating powder flowability or non-stick properties, and prevention of denaturation over the expected shelf life[2]. The selection of appropriate excipients depends upon the route of administration, dosageform, active ingredient. Starch is widely used as thickening, stabilizing, gelling and filling agent in many food applications and is considered as the most used excipient in pharmaceutical formulations in tablets as a filler, binder or disintegrant[3]. Starch is the major carbohydrate reserve in plant tubers and seed endosperm in the form of granules. It contains mainly two types of polymer molecule consists of highly branched amylopectin molecules (normally 70-80%) accompanied by a higher number of largely linear amylose molecules (normally 20-30%)[1-7, 4]. Examples of starch sources are maize, rice, potato and wheat. Starches with different physicochemical properties were proved to act differently in preparation of tablet dosage forms. Hence, the search for new starches is a continuous ongoing process worldwide. In this we report the isolation of starch from a new source (*Setaria italica*) and formulated in paracetamol and aspirin tablets and used as an alternative binder and disintegrant to maize starch following an evaluation in preformulation and formulation studies. ***Setaria italica*** (Poaceae) is the second-most widely planted species of millet, commonly known as Foxtail millet is distributed extensively in central Asia, northern east India, china, north and South America. Seeds are used in the treatment of dyspepsia, food stagnancy in the abdomen, cholera, fever (refrigerant) and specially used in snake poisoning. Seeds are diuretic, strengthening to virility, emollient and astringent for diarrhoea. Millet grain possess good amount of starch. The main compositions of foxtail millet grains are carbohydrates, proteins, lipids, with a small amount of free sugar and non-starch [5, 6].

MATERIALS AND METHOD

Materials

The grains of *Setaria italica*(1 kg) were collected in the month of January 2014, in Hyderabad, Andhra Pradesh. Paracetamol was purchased from Pradeep organic fine chemicals, Hyderabad, India. Maize starch was purchased from S.D. fine chemicals, Mumbai, India. Magnesium

stearate was purchased from Ottokemi, Mumbai. Aspirin was purchased from Oxford laboratory, Mumbai.

Method

Extraction of starch from *Setaria italica* grains

Setaria italica grains were thoroughly washed with water to remove foreign material. The washed grains were allowed to steep in water for about 24 hours and crushed using a blender. Enough quantity of water was added to the pulp and then passed through a twofold muslin cloth. The starch was allowed to settle and 0.1N sodium hydroxide was added to separate the starch and protein materials as well as to neutralize the slight acidity and washed several times with distilled water. The clear supernatant fluid was poured away while sedimented starch was collected on a tray and air-dried on a table. Using pestle and mortar the dried starch lumps were grounded and utilized as obtained. The yield was found to be 11.085% (w/w). The electron photograph of purified *Setaria italica* starch is illustrated in Figure 1.

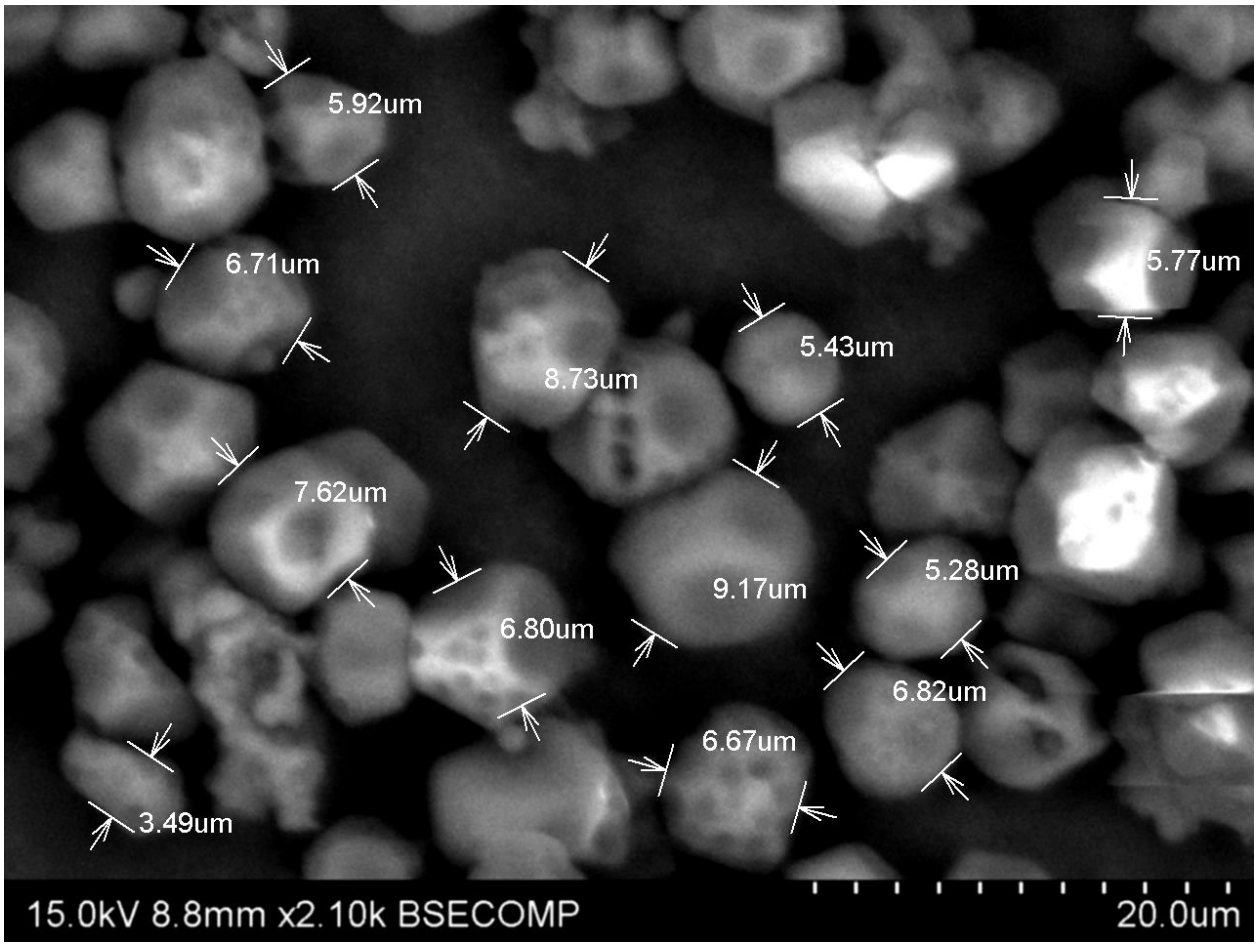

Figure 1: Electron microscopic photograph of *Setaria italica* starch.

Evaluation and Characterisation of *Setaria Italica* Starch [7-9]

The *Setaria italica* starch was evaluated for various parameters viz., description, solubility, identification, ash values (total ash, acid insoluble, water soluble and sulphated ash), test for fluorescence, test for oxidizing substances, test for acidity, test for iron and loss on drying as described in Indian Pharmacopoeia for starch[8, 9] and amylose content was determined as described by Martinez and Prodolliet[9].

Preformulation Studies

Preformulation studies like micrometry, sieve analysis, flow properties, moisture content and compatibility with drug were done. To carry out the preformulation studies, the *Setaria italica* starch should meet the uniformity of particle size to the commercial size. Thus *Setaria italica* starch is subjected for size reduction by using ball mill containing 10 balls with 100 rpm for 1h.

Micrometry

The diameter of the *Setaria italica* and maize starch grains is determined by using stage and eyepiece micrometers. The frequency distribution curve was plotted based on the number of particles lying within the range[10].

Sieve analysis

Sieve analysis is used for knowing particle size distribution. 5 g of *Setaria italica* starch was placed in a sieve shaker (Jayanth industries, Hyderabad) which has sieves of different sizes from sieve no: 4 -170 having size range 80 µm - 1785 µm and shaken for 10 min in definite manner. The amount of the starch retained on the each sieve was weighed separately. Finally the size distribution of *Setaria italica* starch was plotted and compared with maize starch[11].

Flow properties[10, 12]

The flow properties of *Setaria italica* and maize starches were characterized in terms of angle of repose, Carr's index and Hausner's ratio.

Angle of repose

The dried glass funnels of 3 different sizes (small, medium, large) were taken and fixed firmly to the stand at a height of 2 cm from the orifice to the surface. After adjusting the height, graph sheet was placed on the surface and starch was transferred slowly with the help of spatula till the heap of starch touches to the orifice of funnel. The surface covered by the heap is marked. Same procedure was repeated by using 3 funnels. The angle of repose was calculated and determined according to the relationship.

$\tan \theta = 2h/d$

Where, h = height of the cone.

d = diameter of the cone.

Carr's Index(CI)

10 g of starch powder is filled in a measuring cylinder (250 ml) and initial volume occupied by the powder (v_o) is noted. After 100 tappings the volume was noted (v_r).

Bulk density = Mass/ volume (v_o)

Tapped density = Mass/Tapped volume (v_r)

Carr's index (CI) = (Tapped density – Bulk density) / Tapped density x 100.

Hausner's ratio (HR) = Tapped density / Bulk density

Moisture content

An empty dried glass stopper shallow weighing bottle was weighed accurately (w_1). 3 g of starch *Setaria italica* was transferred into the bottle and considered it as w_2 (weight of empty bottle + starch). Transfer 2 g of water to moisten the starch and noted it as w_3. The bottle was kept in hot air oven at 100^0C for 15 min. Then the weight of the resultant was noted as w_4. Repeat the same till a constant weight is occurred[11]. Moisture content in wet solid is calculated on dry weight basis.

% Moisture content = Weight of water in sample / Weight of dry weight x 100.

Compatibility study

The compatibility of paracetamol, aspirin with *Setaria italica* starch was studied by IR spectra (Shimadzu, FTIR – 8400 s). The FTIR spectra of the paracetamol are compared with IR spectrum of paracetamol with excipient (*Setaria italica*) by the KBr pellet method using IR spectrophotometer in the range of 400 – 4000 cm-1. Similarly, the IR spectrum of aspirin is also compared with IR spectrum of aspirin with excipients (*Setaria* starch).

Formulation Studies [8,10,13,14]

Preparation of paracetamol tablets by wet granulation

The composition of different formulations of paracetamol tablets is shown in table 1.Weighed amount of paracetamol powder and microcrystalline cellulose were mixed in geometrical progression with half the amount of disintegrant. The slurry of binder was prepared, added to paracetamol mixture and mixed to obtain dough mass. This was subjected to wet screening through sieve #16. The granules obtained by sieving were dried at 60^0C for 1 h. The dried granules were passed through sieve #18 for dry screening to obtain uniform granules. Lubricant (magnesium stearate) and the remaining disintegrant were added to the granules. Finally granules were subjected to compression by using rimek minipress punching machine with punch size 11.9mm. Each batch consists of 30 tablets and weight of each tablet was 675mg.

Table 1: Composition of Paracetamol tablets

Ingredients	Ingredients quantity in grams								
	PSB1	PSB2	PSB3	PSB4	PSD1	PSD2	PSD3	PSBD	PMBD
Paracetamol	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
S.italica starch (binder)	0.033	0.067	0.101	0.135	-	-	-	0.101	-
S.italica starch (disintegrant)	-	-	-	-	0.033	0.067	0.101	0.067	-
Maize starch (binder)	-	-	-	-	0.067	0.067	0.067	-	0.337
Maize starch (disintegrant)	0.067	0.067	0.067	0.067				-	0.337
Magnesium stearate	0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.006
Microcrystalline cellulose	0.067	0.033	0.016	0.008	0.067	0.033	0.016	0.016	0.104

PSB1-PSB4 contains *Setaria italica* starch as binder in concentrations 5%, 10%, 15%, 20% respectively and maize starch as disintegrant (10%), PSD1-PSD3 contains *Setaria italica* starch as disintegrant in concentrations 5%, 10%, 15% respectively and maize starch as binder (10%) and PSBD contains *Setaria italica* starch as binder (15%) and as disintegrant (10%). PMBD contains maize starch as binder (5%) and as disintegrant (5%).

Preparation of aspirin tablets by dry granulation:

The composition of different formulations of aspirin tablets is shown in Table 2. The aspirin, binder, diluent and half the amount of disintegrant were accurately weighed and thoroughly mixed .The material was then compacted into slugs using compression machine and the slugs were screened through sieve # 16. The remaining amount of disintegrant and lubricant was added to the screened material and mixed. The lubricated blend was then finally compressed into tablets weighing 600 mg by using rimek minipress using die of 11.1 mm size. Each batch of formulation consists of 30 tablets.

Table 2: Composition of Aspirin tablets

Ingredients	Ingredients quantity in grams								
	ASB1	ASB2	ASB3	ASB4	ASD1	ASD2	ASD3	ASBD	AMBD
Aspirin	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35
S.italica starch (binder)	0.03	0.06	0.09	0.12	-	-	-	0.03	-
S.italica starch (disintegrant)	-	-	-	-	0.03	0.06	0.09	0.09	-
Maize starch (binder)	-	-	-	-	0.06	0.06	0.06	-	0.06
Maize starch (disintegrant)(10%)	0.06	0.06	0.06	0.06	-	-	-	-	0.06
Magnesium stearate	0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.006
Microcrystalline cellulose	0.154	0.124	0.094	0.064	0.154	0.124	0.094	0.124	0.124

ASB1-ASB4 contains *Setaria italica* starch as binder in concentrations 5%, 10% 15%, 20% respectively and maize starch as disintegrant (10%), ASD1-ASD3 contains *Setaria italica* starch as disintegrant in concentrations 5%, 10%, 15% respectively and maize starch as binder (10%) and ASBD contains *Setaria italica* starch as binder (5%) and *Setaria italica* starch as disintegrant (15%). AMBD contains maize starch as binder (10%) and as disintegrant (10%)

PROCEDURE OF EVALUATION

Weight Variation:

10 tablets were taken and weighed. Their average weight and standard deviation were noted down. Then each tablet was weight and their % difference from the average weight was determined [8, 10].

Hardness Test:

A tablet was placed vertically on the Monsanto hardness tester. The load was then applied along the radial axis of the tablet. The weight or load required for breaking the tablet was noted down. Similarly it was done for 5 tablets [8, 10].

Friability:

It was performed using Roche Friabilator. 3 tablets were weighed and placed in apparatus. The apparatus was rotated at a speed of 25 rpm for 4 min. The tablets were then weighed and the weights were compared with the initial weights. The % age friability was calculated using the formula [8, 10].

$\% F = [1 - (W/Wo)] \times 100$ Where,

% F = Percentage friability, Wo = Initial weight of tablets, W = Weight of the tablets after revolution.

Tablet Disintegration:

It was performed using Tablet disintegration test machine four – stage IP / BP/ USP standard. 6 tablets were placed in disintegration test apparatus. It was maintained at $37 \pm 2^{o}C$ containing 1 L beaker of water. Noted down the time taken for tablets to disintegrates [8, 10].

Tablet Dissolution:

For this test Dissolution Tester (USP) Electrolab TDL-08L 6 Paddle Apparatus was used. Gastric Fluid as dissolution medium, the tablets formed were immersed into 900 ml of dissolution medium, simulated gastric fluid (0.1N HCl). The temperature of the dissolution medium was maintained at $37 \pm 0.5^{o}C$. The paddle was rotated at a speed of 50 rpm. After an interval of every 5 minutes, 5 ml. of the medium was pipette out and replaced with fresh medium (0.1N HCl). This was continued all along for 1 hour. The pipetted out samples were then diluted to 50 ml

with fresh dissolution medium and were then filtered. The drug paracetamol content was determined at 245 nm and aspirin content is determined at 228 nm using an UV Spectrophotometer (ELICO double beam spectrophotometer SL 164) [8, 10].

RESULTS AND DISCUSSION

Evaluation and Characterisation of *Setaria Italica* Starch as Per Monograph

Setaria italica starch is a colourless powder with no taste and odour. The granules are polygonal and spherical shaped and 13.4µm- 24.50µm-41µm in size. The amylose content was 16.12%, which was less than amylose content of maize starch and in other analyzed parameters the results were comparable to maize starch (Table 3).

Table 3: Evaluation of *Setaria italica* and maize starch

Parameters	*Setaria italica* starch	Maize starch
Source	*Setaria italica*	*Zea mays*
Description	Coarse, fine colourless powder	Very fine, colourless powder
Odour	Odourless	Odourless
Taste	Tasteless	Tasteless
Solubility	Insoluble in water and 95% ethanol	Insoluble in water and 95% ethanol
Size	13.4µm- 24.50µm-41µm	14.7µm- 19.50µm-29.4µm
Shape	polygonal and spherical shaped	Polyhedral or sub spherical
Test for iron	Passes the limit	Passes the limit
Loss on drying	15%	11.4%
Total ash	0.33%	0.3%
Acid insoluble ash	0.033%	0.05%
Water soluble ash	0.66%	0.04%
Sulphated ash	0.66%	0.8%
Test for fluorescence	- ve	- ve
Test for oxidizing substances	+ ve	+ ve
Amylose content	16.12%	19.83 %
Swelling index	0.55ml	0.6 ml
P^H	6.48	6.02
Density	1.1 g/ml	1.3g/ml
Viscosity	13.06 m Pa	14.5m Pa

Values are mean of triplicates

Evaluation of *Setaria Italica* Starch by Preformulation Studies

Sieve analysis: The size of particle was expressed by the sieve number, which describes diameter of spheres that passes through the sieve aperture as asymmetric particle. The percent distribution of particles was tabulated in Table 4.

Table 4: particle size distribution of *Setaria italica* starch by sieve analysis

Sieve no.	Particle size range(µm)	Amount of spheres retained	Percentage of weight retained	Cumulative percentage retained
8/16	4000-2057 µm	0.187 g	3.74%	3.74%
16/30	2057-1003 µm	1.13 g	22.6%	26.3%
30/60	1003-500 µm	1.30 g	26%	52.34%
60/100	500-250 µm	0.62g	12.4%	64.7%
100/150	250-150µm	0.44 g	8.8%	73.5%
150/170	150-105µm	0.91 g	18.2%	91.74%
Left on 170	105-90µm	3.09 g	61.8%	91.74%

Values are mean of triplicate, 8.26% loss of material during sieving.

Micrometry:

The comparative results showed that 90% Setaria italica starch cumulative size distribution is ranging from 10-40 µm, which was similar to maize starch.

Flow properties:

The Angle of repose (37.13), CI (25%) and HR (1.33) was resulted for *Setaria italica* starch, whereas 37.3, 30.92, 1.453 were observed with maize starch.

Compatibility of paracetamol and aspirin with *Setaria italica* starch was evaluated by IR spectra and found that both paracetamol and aspirin are compatible with *Setaria italica* starch.

Formulation studies

Setaria italica starch possesses suitable rheological properties and compressibility, permitting its use in compression technology. There by, the design of paracetamol and aspirin tablets using *Setaria italica* and maize starch in varying compositions as a binder, disintegrant, binder and disintegrant was performed. Both paracetamol and aspirin tablets were evaluated for weight variation, friability, hardness and disintegration test as per the Indian Pharmacopoeia. Paracetamol and aspirin tablets weight variation content compiles the weight variation tolerance for uncoated tablets which was within the limits of less than 5% which was illustrated in table 5 and 6. The effect of *Setaria italica* starch concentrations on the paracetamol and aspirin tablets hardness/crushing strength and friability. The percentage friability of all the formulations was within the limits of 0.5% and the hardness was within the scope of 4-6 kg/cm^2 limits which was illustrated in table 5 and 6. Increasing the concentration of binder was found to increase the hardness of tablets and decrease its friability. Increasing the concentration of disintegrant no change in hardness of tablets as binder concentration was constant and increase in friability was observed. Paracetamol tablets possess disintegration time in the range of 30-90 sec and were comparable with disintegration time of paracetamol tablets prepared from maize starch. On the

other hand the aspirin tablets disintegration time in the range of 20-35 sec and compiles with the results of aspirin tablets prepared from maize starch which was illustrated in table 5 and 6. For both tablets, an increase in binder concentration resulted in increased disintegration time. An increase in disintegrant concentration resulted in decreased disintegration time. The dissolution time was also found to increase with increased concentration of binder and disintegrant. The results of dissolution studies indicate that 90% of paracetamol and aspirin were released from tablets within 60 min which was illustrated in Figure 2 and 3. The overall dissolution time indicated that the tablets prepared from *Setaria italica* starch as binder, disintegrant, binder & disintegrant was significantly comparable with drug releasing time of paracetamol and aspirin tablets prepared from maize starch.

Table 5: Evaluation of paracetamol tablets

Formulation	Hardness (kg/cm^2) n=5	Friability (%) n=3	Weight variation (mg) n=10	Disintegration time(sec) n=6
PSB1	4.0±0.61	0.45±0.34	660±4.2	32.33±3.05
PSB2	5.0±0.44	0.39±0.21	670±3.5	47.33±6.02
PSB3	5.5±0.36	0.31±0.29	667±4.6	50.66±4.16
PSB4	6±0.72	0.25±0.12	665±3.9	58.66±4.5
PSD1	4.5±0.25	0.20±0.42	670±4.5	88±2.64
PSD2	4.5±0.53	0.35±0.28	665±3.6	57.33±3.21
PSD3	4.5±0.32	0.45±0.35	660±2.9	49.66±2.5
PSBD	5.5±0.47	0.3±0.24	665±4.1	41±1.15
PMBD	4.5±0.30	0.22±0.41	670±4.7	45±4.0

Values are expressed as mean ± SD

PSB1-PSB4 contains *Setaria italica* starch as binder in concentrations 5%, 10%, 15%, 20% respectively and maize starch as disintegrant (10%), PSD1-PSD3 contains *Setaria italica* starch as disintegrant in concentrations 5%, 10%, 15% respectively and maize starch as binder (10%) and PSBD contains *Setaria italica* starch as binder (15%) and as disintegrant (10%). PMBD contains maize starch as binder (5%) and as disintegrant (5%).

Table 6: Evaluation for aspirin tablets

Formulation	Hardness (kg/cm^2) n=5	Friability (%) n=3	Weight variation (mg) n=10	Disintegration time(sec) n=6
ASB1	4±0.63	0.70±0.22	580±3.9	20.33±1.52
ASB2	4.5±0.46	0.63±0.56	585±4.5	22±2.64
ASB3	4.5±0.82	0.45±0.41	588±2.8	27±4.58
ASB4	5±0.57	0.23±0.37	595±3.1	29.67±3.78
ASD1	4.5±0.7	0.25±0.63	591±4.4	34.33±4.16
ASD2	4.5±0.56	0.28±0.32	580±3.6	26±2.0
ASD3	4.5±0.34	0.37±0.4	585±4.9	20±2.5
ASBD	4±0.61	0.35±0.24	590±3.8	21.6±1.52

AMBD	4.5±0.35	0.28±0.52	585±4.2	30.33±4.72

Values are expressed as mean ± SD

ASB1-ASB4 contains *Setaria italica* starch as binder in concentrations 5%, 10% 15%, 20% respectively and maize starch as disintegrant (10%), ASD1-ASD3 contains *Setaria italica* starch as disintegrant in concentrations 5%, 10%, 15% respectively and maize starch as binder (10%) and ASBD contains *Setaria italica* starch as binder (5%) and *Setaria italica* starch as disintegrant (15%). AMBD contains maize starch as binder (10%) and as disintegrant (10%).

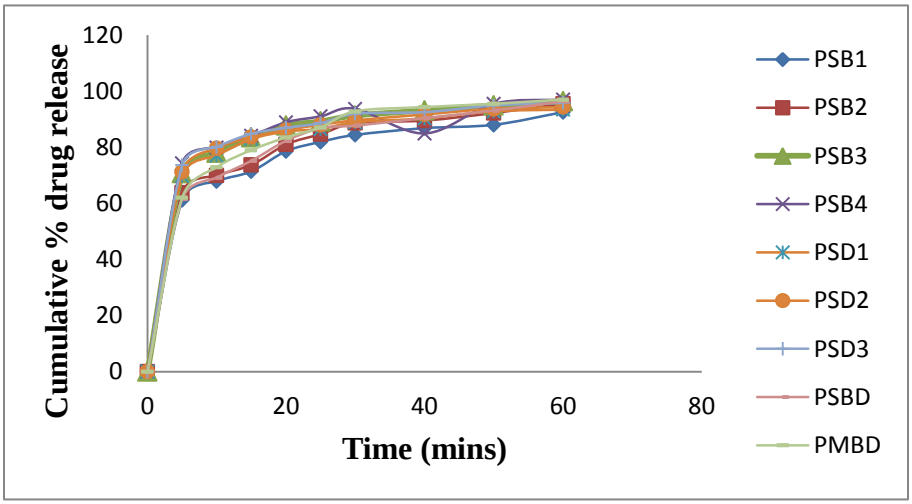

Figure 2: Comparative invitro release of Paracetamol from different formulations

PSB1-PSB4 contains *Setaria italica* starch as binder in concentrations 5%, 10%, 15%, 20% respectively and maize starch as disintegrant (10%), PSD1-PSD3 contains *Setaria italica* starch as disintegrant in concentrations 5%, 10%, 15% respectively and maize starch as binder (10%) and PSBD contains *Setaria italica* starch as binder (15%) and as disintegrant (10%). PMBD contains maize starch as binder (5%) and as disintegrant (5%).

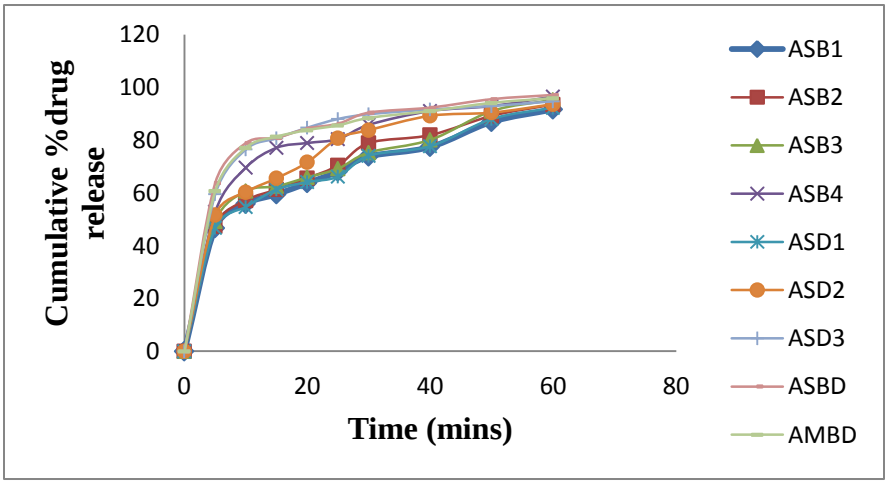

Figure 3: Comparative *in-vitro* release of Aspirin from different formulations.

ASB1-ASB4 contains *Setaria italica* starch as binder in concentrations 5%, 10% 15%, 20% respectively and maize starch as disintegrant (10%), ASD1-ASD3 contains *Setaria italica* starch as disintegrant in concentrations 5%, 10%, 15% respectively and maize starch as binder (10%) and ASBD contains *Setaria italica* starch as binder (5%) and *Setaria italica* starch as disintegrant (15%). AMBD contains maize starch as binder (10%) and as disintegrant (10%).

CONCLUSION

Setaria italica starch was isolated from grains and the percentage yield was 11.08%. The isolated starch was used as binder and disintegrant in formulations of both paracetamol and aspirin tablets and compared with tablets prepared from maize starch. The results of disintegration and dissolution suggests that, *Setaria italica* starch can be used in paracetamol tablets as binder(15%) and disintegrant(10%) compared to maize starch as binder(5%) and disintegrant(5%) and in aspirin tablets as binder(5%) and disintegrant(15%) compared to maize starch as binder(10%) and disintegrant(10%). In conclusion *Setaria italica* starch appears to be a promising excipient in preparation of tablets as the yield of starch is more, cost is less, availability of raw material is abundant, and compatible with drugs. This suggests that *Setaria italica* starch can be explored commercially.

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