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Preformulation Analysis of Millet-Derived Starches: A Comparative Study

Eswara Gopala Krishna Murthy Talasila*, Sukanya Manam, and Mounika Budati

Bapatla College of Pharmacy, Bapatla – 522 101, Andhra Pradesh, India

*Corresponding author: bcp.principal@gmail.com

Abstract

Starch is a widely utilized excipient in the pharmaceutical industry, playing essential role as a multi functional adjuvant. While starches from rice, wheat, maize, corn and potato have traditionally been used, there is growing interest in alternative raw materials driven by sustainability and the demand for nutrient-rich options. Millets, small-seeded grains known for their high nutritional value and wide cultivation, present a promising alternative to conventional starch sources. This study aimed to isolate and evaluate starches from barnyard millet, finger millet, foxtail millet, kodo millet and little millet. The isolated starches were characterized for different parameters. The results revealed that the starch isolated from barnyard millet exhibited favorable rheological properties, indicating its suitability as an effective excipient. Granules were prepared using starch paste from the different millet species, and their micrometric properties were evaluated. Tablets were then formulated with these granules and subjected to various quality control tests. The results confirmed that barnyard millet starch demonstrated favorable rheological properties and served as an excellent binder, making it a promising alternative for pharmaceutical applications.

Keywords: Barnyard Millet, Finger Millet, Foxtail Millet, Kodo Millet, Little Millet, Starch.

Introduction

Millets, also known as nutria-cereals, and are valued for their high energy content. These grains are typically cultivated in degraded or marginal lands with minimal rainfall and low soil nutrients (1). Millets are small, round grains packed with essential nutrients, including crude fiber (2-7%), protein (7-11%) and fat (1.5-5%) (2). Often known as the “poor man’s crop,” these nutrient-rich foods are widely consumed for their abundance of micronutrients, dietary fiber, that promote overall health. They are recognized for their low glycemic index, which may help in reducing post-meal blood glucose levels and glycosylated hemoglobin (3). Grown in adverse conditions, millets are cost-effective yet underutilized. More research is needed to explore their potential as alternatives to traditional starch sources like corn, rice and potatoes (4).

Millet consists mainly of starch, including amylose and amylopectin, which account for approximately 70% of the grain. Due to its functional properties, this starch is widely utilized in commercial applications as an ingredient (5). Rheology, the study of the flow and deformation of substances, plays a key role in pharmaceutical formulation processing. Traditional starches from corn, rice and potatoes are commonly used in food and pharmaceuticals, but their availability is decreasing, driving the need for alternative, cost-effective substitutes (6). Millet starch has recently gained attention, though limited research exists on its rheological characteristics.

Barnyard millet (*Echinochloa frumentacea*) is a nutritional grain, rich in protein, fiber, iron, and calcium. It is useful for diabetic patients as it is having low glycemic index (7). It aids digestion, supports gut health, and has antioxidant and anti-inflammatory properties. Its starch, which has high water absorption and swelling powder, is used as a thickener, stabilizer and binder in food and

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pharmaceuticals (8). Finger millet is a high in protein, antioxidant, fiber, and essential amino acids. It promotes digestive health; regulate blood sugar levels and support heart health. Its starch, with high amylose content, is ideal for porridge, bread and gluten-free products (9). Foxtail millet (*Setaria italica*) is a nutritious, adaptable crop that supports digestion, blood sugar regulation and weight management, with starch that has excellent gelatinization properties, used in gluten-free products and medicinal formulations (10). Kodo millet (*Paspalum scrobiculatum*), a drought-resistant grain, offers high nutrition and promotes satiety, with starch useful in porridges, snacks and pharmaceutical applications (11). Little millet (*Panicum sumatrense*), known for its climate resilience, aids blood sugar control and supports weight management, with starch serving as an excipient, binder and film-forming agent in pharmaceuticals (12). These millets are valuable for both the food and pharmaceutical industries.

This study aims to assess millet starch as a viable pharmaceutical excipient, highlighting its potential as a cost-effective and sustainable alternative in pharmaceutical industry. With its unique functional properties, millet starch presents a promising substitute for traditional excipients (13). Its versatility in tablet formulations-as a binder, disintegrant and stabilizer - enhances its applicability across various pharmaceutical products. This research aims to assess and highlight the advantages of millet starch in meeting the evolving needs of the pharmaceutical sector.

Materials and Methods

Materials

Barnyard millet, Finger millet, Foxtail millet, Kodo millet, and Little millet were obtained from the local market, while all chemicals used were of standard pharmaceutical grade with minimal impurities.

Methods

Preparation of millet flour

The millets were cleaned by manually picking out stones and stubbles. Foreign matter was sieved, thoroughly washed with water and dried. These millets were then subjected to milling using a disintegrator to obtain millet flour (14).

Isolation of starch

Starch was extracted from kodo, little, barnyard, foxtail and finger millets using the alkaline extraction method. A 50 g portion of millet flour was dispersed in 300 mL of a 0.5% w/v NaOH solution, stirred continuously for 30 minutes, and then stored at 4°C for 24 hours. The upper yellowish layer was removed and fresh NaOH solution was added to the slurry, followed by centrifugation (5000 RPM, 10 Min, 20 ^{O}C). The sediment was repeatedly washed with NaOH solution until the yellowish layer was completely removed. The starch slurry was neutralized to pH 7 with 0.1M HCl, centrifuged, and dried at 40-50 ^{O}C (15). The dried starch was finely powdered, sieved (#100) and stored in an airtight container. This process was consistently applied to all millet samples, and the percentage yield of starch was determined (16).

Preparation of starch paste

A 5% w/v starch paste was prepared by dispersing starch in distilled water and heated it in a water bath for 15 minutes with continuous stirring to achieve uniform gelatinization (17). This process was repeated for all millet starches.

Identification test for starch

One gram of starch was boiled in 50 ml of distilled water and allowed to cool. From the cooled solution, 1 ml of starch mucilage was taken, and 0.1N iodine solution was added to it. The observed colour change, resulting in a blue-black hue, indicated the presence of alpha-amylase (18).

FTIR spectral studies

Barnyard millet starch was subjected to analysis by using FTIR spectrometer. It was scanned with resolution range from 600-4000 cm^{-1} region. The sample was analyzed at the rate of 16 scans (19).

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Rheological study

The viscosities of 5 % w/v starch pastes, previously subjected to different temperatures (65 - 80^{O}C) and durations (5 - 20 minutes), were measured using a Brookfield DV2T viscometer with spindle SC4-18 at a shear rate of 0.13 - 0.66 sec^{-1} and a torque range of 10 - 100%. A small sample adapter (8 ml) was utilized and shear stress was recorded. Viscosity values were analyzed using Rheocalc software. The rheological properties of all starch pastes were evaluated at a shear rate of 0.13 - 0.66 sec^{-1} at room temperature (20).

Preparation of lactose granules

For granulation, 10 g of lactose was used as an excipient, and starch paste was gradually added to form a damp mass. The amount of starch required to form damp mass was recorded. The cohesive mass was sieved through #16 mesh, subjected to drying, and then screened through sieve no #40 (21).

Micromeritic properties of granules

Bulk density (D_b)

The preweighed granules were carefully poured into a measuring cylinder, and the corresponding bulk volume was then noted (22). Bulk density was then calculated using the following formula.

$$\text{Bulk Density} = \frac{\text{Mass of granules}}{\text{Bulk volume}}$$

Tapped density (D_t)

The granules were placed in a measuring cylinder, tapped 100 times, and the resulting tapped volume was recorded (23). The tapped density was then computed using the following formula.

$$\text{Tapped Density} = \frac{\text{Mass of granules}}{\text{Tapped volume}}$$

Carr's index (or) Compressibility

It represents the flow properties of the powder and is expressed as a percentage, calculated using the following formula.

$$\text{Carr's Index} = \frac{\text{Tapped Density} - \text{Bulk Density}}{\text{Tapped Density}} \text{x}100$$

Hausner's ratio

The Hausner's ratio is an indirect measure of powder flowability and is determined using the following formula.

$$\text{Hausner's Ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

Angle of repose (θ)

The angle of repose (θ), which indicates powder flow properties, was measured by allowing granules to flow through a funnel from a fixed height (h). The base diameter of the granules heap was measured, and the average radius was used to calculate (θ) using the standard formula (24).

$$\theta = \tan^{-1}\left(\frac{h}{r}\right)$$

Compression of tablets

200 mg of lactose granules were weighed using a digital balance and compressed into tablets with 9 mm flat punches using a Cadmac 16-station rotary tablet compression machine. The granules were manually filled into the die cavity, and the compression pressure was manually adjusted (25).

Post compression parameters of tablets

Weight variation

For each formulation, twenty tablets were individually weighed using an electronic balance. The average weight was determined, and each tablet's weight was compared with the mean value. The deviation of each tablet from the average weight was then recorded (26). The percent weight variation was calculated using the following formula.

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$$\% \text{ Weight Variation} = \frac{\text{Individual weight} - \text{Average Weight}}{\text{Average weight}} x100$$

Hardness

Tablet hardness was measured using a Monsanto hardness tester. Each tablet was placed between the 2 plungers and pressure was gradually applied until fracture occurred. Hardness (kg/cm^2) was recorded from the side scale. Only tablets that fractured cleanly without lamination were analyzed (27).

Friability

Friability was determined using the Roche friability test apparatus. Ten tablets were weighed, placed in the friabilator, and rotated for 4 minutes at 25 RPM. After de dusting, the tablets were reweighted, and the percentage friability was calculated (28).

$$\text{Friability } (\%) = \frac{\text{Individual weight} - \text{Final Weight}}{\text{Initial weight}} x100$$

Disintegration time

Six tablets were individually placed in tubes equipped with a #10 mesh screen at the base and submerged in water maintained at a temperature of 37°C ± 2°C. The basket assembly was moved 5 - 6 cm at 28 - 32 cycles per minute (29). Disintegration time was recorded when all particles passed through the mesh.

Results and Discussion

Figure 1 presents the practical yield results. Starch yield varied among the different millets. The ranking is as follows: Kodo millet (60%) > little millet (24%) > barnyard millet (22%) > foxtail millet (20%) > finger millet (17.5%).

Comparison of viscosity of starches from different millets

Figures 2 and 3, present the rheological profiles of millet starches. The viscosities of 5 % w/v millet starch pastes were determined using a Brookfiled viscometer (DV2T). The viscosity values were analyzed using Rheocalc software, and the data were fitted to a Bingham plot (30). To compare the viscosities, starch pastes were analyzed at the same shear rate and at room temperature (25 ^{O}C). The viscosity of millet starches followed this order: Barnyard millet (2094 cP) > finger millet (1972 cP) > little millet (1863 cP) > Kodo millet (1851 cP) > foxtail millet (1448 cP). Barnyard millet starch had the highest viscosity (2094 cP) relative to the other millet starches, while foxtail millet had the lowest viscosity (1448 cP), may be due to the difference in amylose-amylopectin ratio.

Viscosity measurements revealed that barnyard millet starch had the highest viscosity (2094 cP), while foxtail millet had the lowest viscosity (1448 cP). The influence of temperature and extraction time on the

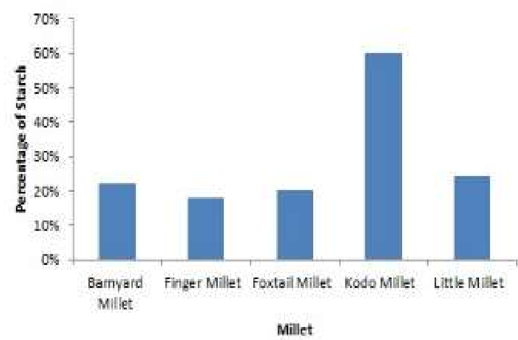

Figure 1: Percentage yield of starch isolated from different millets

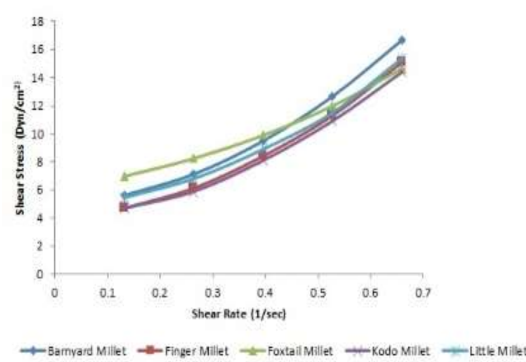

Figure 2: Rheological plot of 5 % w/v starch mucilage prepared with different millets

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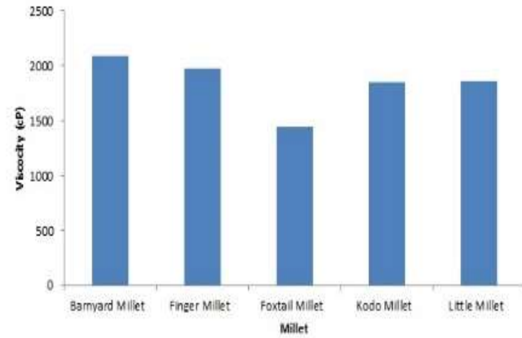

Figure 3: Viscosity plot of 5 % w/v starch mucilage prepared with different millets

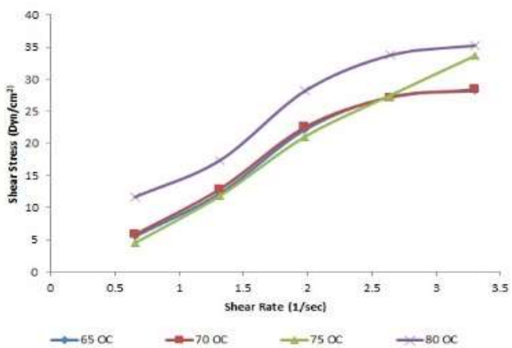

Figure 4: Rheological plot of 5 % w/v starch mucilage prepared with barnyard millet observed at different temperature

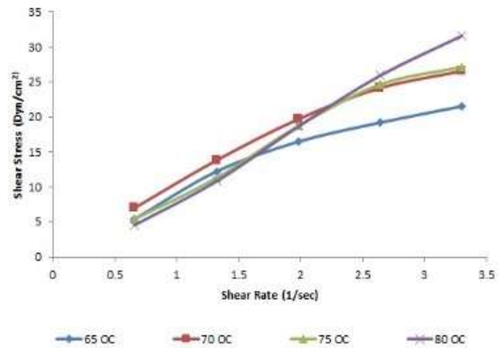

Figure 5: Rheological plot of 5 % w/v starch mucilage prepared with rice starch observed at different temperature

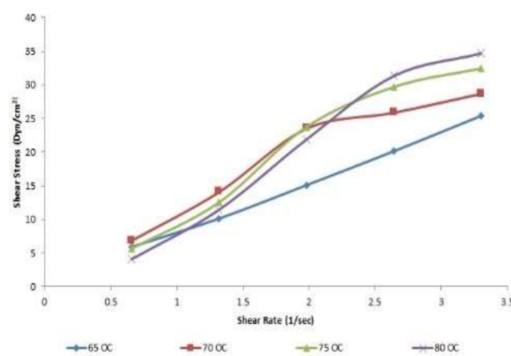

Figure 6: Rheological plot of 5 % w/v starch mucilage prepared corn starch observed at different temperatures

rheological properties was significant, with variations observed among the different millet starches.

Studies on influence of extraction temperature on rheological characteristics of starch

Figures 4 to 6 present the rheological studies of starch pastes and the observed data. To investigate this parameter on the rheological characteristics of starch, millet dispersions were heated to different temperatures (65°C, 70°C, 75°C and 80°C). The processed starch was then used to prepare 5 % w/v dispersions (31). The rheological data were analyzed using Newtonian, Bingham and Power Law models. The starch extracted from barnyard millet at 80°C demonstrated the highest viscosity. These studies clearly indicate that the viscosity of the starch paste depends on the temperature used during the extraction, as illustrated in Figure 7.

Rheological studies conducted at varying temperatures (65°C to 80°C) indicated that the plastic viscosity of the starches increased with temperature. The starch isolated from barnyard millet at 80°C exhibited the highest plastic viscosity.

Studies on influence of extraction time on rheological characteristics of starch

To investigate the influence of extraction time on the rheological characteristics

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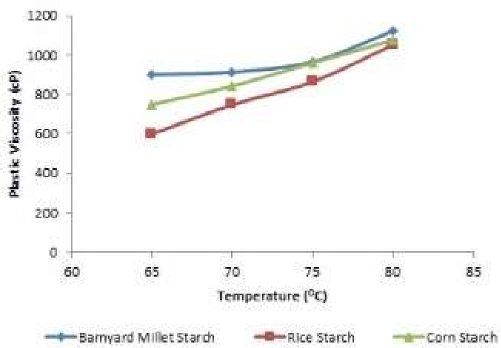

Figure 7: Influence of temperature on the plastic viscosity of 5 % w/v barnyard millet, rice and corn starch mucilage's

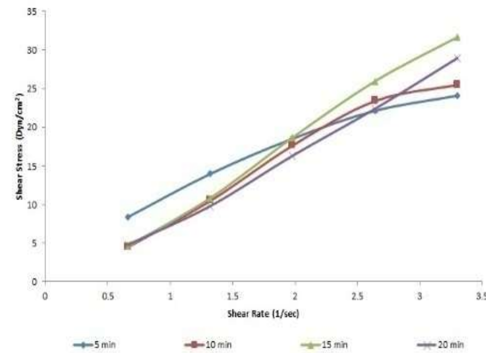

Figure 9: Rheological plot of 5 % w/v starch mucilage prepared with rice starch observed at different time

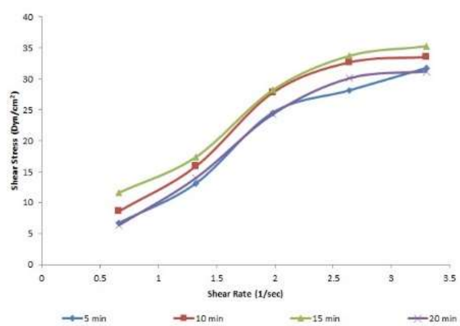

Figure 8: Rheological plot of 5 % w/v starch mucilage prepared with barnyard millet starch observed at different times and kept at 80°C

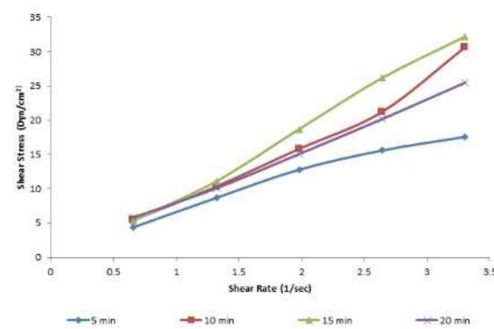

Figure 10: Rheological plot of 5 % w/v starch mucilage prepared with corn starch observed at different time

of starch, millet dispersions were exposed to 80°C for different durations (5, 10, 15 and 20 minutes) and the processed starches were used to prepare 5 % w/v dispersions (32). Figures 8 to 10 present the rheological studies and observed data of starch pastes. The rheological data were analyzed using Newtonian, Bingham and Power law models. These dispersions exhibited plastic flow, and the observed viscosities shown Figure 11. Starch isolated from barnyard millet at 80°C for 15 minutes exhibited the highest viscosity. These findings clearly indicate that the viscosity of the starch paste depends on the exposure time during starch extraction. Viscosity measurements revealed that barnyard millet starch had the highest viscosity (2094 cP), while foxtail millet had the lowest (1448 cP). The influence of both temperature and extraction time on the rheological properties was significant, with notable variations observed across different millet starches.

The rheological properties of the starches were also time-dependent; with viscosity increasing over time (5 to 15 minutes) at 80°C. Barnyard millet exhibited the highest viscosity at 15 minutes compared to the other starches.

IR spectral studies

Figure 12 confirmation of starch was conducted FTIR spectral analysis. The FTIR analysis of starch extracted from barnyard millet

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(Figure 12) displayed distinct peaks, with a prominent band at 3397 cm⁻¹ corresponding to O-H stretching, indicative of hydrogen-bonded hydroxyl groups. Another peak observed at 2922 cm⁻¹ was associated with C-H deformation in the glucose unit. Furthermore, the absorption at 1009 cm⁻¹ was linked to C-O-H stretching.

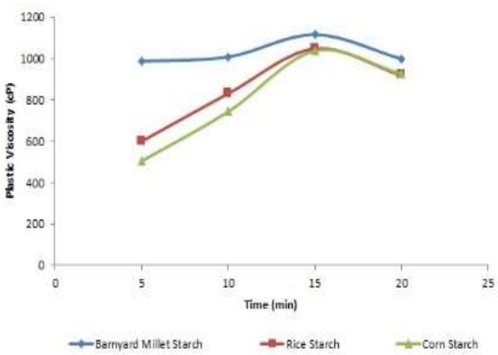

Figure 11: Influence of time on the plastic viscosity of 5 % w/v starch mucilage prepared with barnyard millet, Rice and corn starch

These spectral characteristics confirm the presence of starch in the isolated sample.

Studies on consumption of millet starch to prepare lactose granules

To study the binding potential of the millet starches, lactose granules were formulated by employing different millet starch paste (5 % w/v) with wet granulation technique. The binder solution required to form a damp mass was noted. The amount of binder required to form damp mass was found to be dependent on the type of millet starch employed to formulate granules. Table 1 presented the amount of starch consumed for the preparation of granules. The binding ability was found to be more for the starch isolated from barnyard millet as it required low quantity of starch (150 mg) to prepare lactose granules. Good correlation was observed between the viscosity and binder amount required to formulate tablets. The binder requirement was found to be decreased with the viscosity of the binder employed to prepare granules.

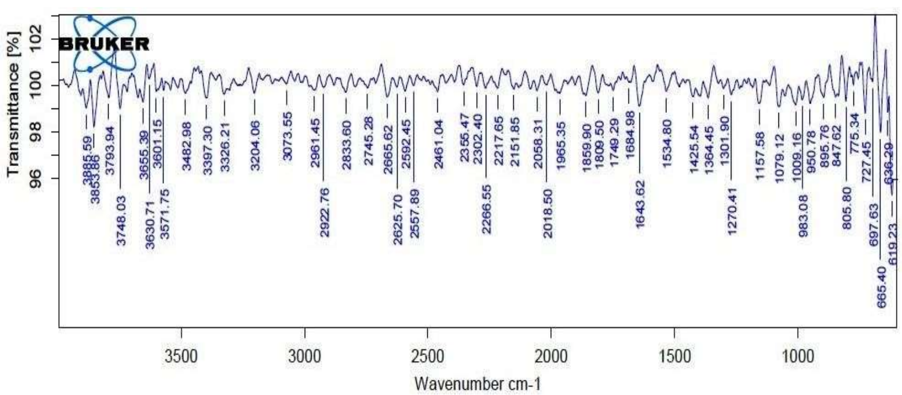

Figure 12: FTIR Spectrum of barnyard millet starch

Table 1: Studies on consumption of millet starch to prepare lactose granules		
Formulation	Lactose (g)	Starch (mg)
F1	10	150
F2	10	200
F3	10	300
F4	10	265
F5	10	235

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Table 2: Micromeritic properties of lactose granules formulated by 5 % w/v starch mucilage prepared with millet starches

Formulation	Evaluation Parameters				
	Bulk density (g/ml)	Tapped density (g/ml)	Compressibility index (%)	Hausner's Ratio	Angle of Repose (θ)
F1	0.36 ± 0.01	0.42 ± 0.02	14 ± 0.05	1.16 ± 0.14	32.61
F2	0.39 ± 0.02	0.45 ± 0.05	13.33 ± 0.02	1.15 ± 0.12	31.47
F3	0.45 ± 0.05	0.53 ± 0.07	15.09 ± 0.01	1.17 ± 0.25	33.42
F4	0.41 ± 0.01	0.49 ± 0.02	16.32 ± 0.05	1.19 ± 0.14	32.94
F5	0.37 ± 0.06	0.44 ± 0.01	15.9 ± 0.02	1.19 ± 0.21	34.21

All values (n=3) mean ± standard deviation (sd)

Table 3: Physical properties of lactose granules formulated by 5 % w/v millet starches

Formulation	Parameters			
	Average weight (mg)	Hardness (kg/cm^2)	Friability (%)	Disintegration Time (min)
F1	198 ± 0.1	4.5 ± 0.05	0.72 ± 0.08	8.32
F2	196 ± 0.2	4.2 ± 0.04	0.69 ± 0.04	10.54
F3	204 ± 0.4	4.0 ± 0.01	0.84 ± 0.02	12.56
F4	205 ± 0.2	3.4 ± 0.06	0.76 ± 0.02	9.27
F5	202 ± 0.1	3.9 ± 0.02	0.92 ± 0.05	8.45

All values (n=3) mean ± standard deviation (sd)

Micromeritic properties of lactose granules formulated with starches isolated from different millets

Table 2 presents the micromeritic properties of lactose granules formulated with starches isolated from different millets. The obtained results assessed the flow properties of lactose granules formulated with millet starch mucilage's. The granules exhibited acceptable micrometric properties indicating good flow properties.

Physical characteristics of tablets formulated with different starches

Table 3 presents the results of tablets formulated with binders, which were subjected to various quality control parameters. Tablets formulated with barnyard millet binder exhibited good mechanical strength based on hardness and friability, and they were found to disintegrate within 15 minutes. Tablets formulated with millet starches as binders showed adequate hardness, friability and disintegration times making them suitable for pharmaceutical applications.

Conclusion

This study successfully isolated starches from various millets and demonstrated their potential as pharmaceutical excipients. The findings revealed that millet starches, particularly from barnyard millet, exhibit desirable rheological properties, including high viscosity and shear stress, making them suitable for use as binders in tablet formulations. The study emphasized the considerable impact of extraction temperature and duration on the rheological properties of millet starches, indicating the necessity of optimizing these parameters for pharmaceutical applications. These results emphasize the versatility of millet starches as a promising alternative to

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traditional starch sources, offering potential benefits in the pharmaceutical industry. Future studies should focus on comprehensive stability assessments of millet starch and its suitability for formulating tablets incorporating Active Pharmaceutical Ingredients (APIs).

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Conflicts of Interest

No conflicts of interest.

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