

Potential of Native and Pregelatinized Yellow Sweet Potato Starch as Binders in Fenofibric Acid Tablets via Wet Granulation

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ABSTRACT

Introduction: Sweet potato starch has potential as a pharmaceutical excipient. **Aims:** This study aimed to evaluate the potential of native and pregelatinized yellow sweet potato starch as binders in tablet formulations prepared by the wet granulation method. **Method:** The starch was extracted and pregelatinized, then incorporated at concentrations of 10%, 12.5%, and 15%. Granules and tablets were evaluated for particle size, flow rate, angle of repose, compressibility index, Hausner ratio, porosity, moisture content, weight and size uniformity, hardness, friability, abrasion, and disintegration time. **Result:** The results show that both native and pregelatinized starch produce tablets of comparable quality, with no significant differences between them. However, the 10% concentration does not perform optimally as a binder in either type of starch. The best tablet characteristics are observed at the 15% concentration, meeting pharmacopoeial standards in terms of hardness, friability, and disintegration. **Conclusion:** It is concluded that yellow sweet potato starch, in both native and pregelatinized forms, serves as a promising natural binder for wet granulation tablets, with 15% being the optimal concentration.

KEYWORDS: Binder, native, pregelatinized, starch, yellow sweet potato, wet granulation.

INTRODUCTION

The development of pharmaceutical dosage forms requires the use of excipients that can influence the quality, stability, and overall performance of the final product (Ozkan et al., 2021). One of the most essential excipients in tablet formulation is the binder, which provides mechanical strength and ensures the structural integrity of tablets. With increasing emphasis on sustainability, natural binders

derived from locally available materials have gained attention due to their biocompatibility, cost-effectiveness, and environmental friendliness (Amponsah et al., 2025).

Among natural materials, starch is one of the most widely investigated candidates for use as a tablet binder. The functional properties of starch are primarily determined by the proportions of its two major polysaccharides: amylose and

amylopectin. Amylose, with its linear structure, can form strong intermolecular hydrogen bonds, thereby improving tablet hardness and binding capacity. In contrast, the highly branched structure of amylopectin enhances granule cohesiveness and elasticity, influencing flow properties and tablet disintegration. The ratio between these components determines the overall effectiveness of starch as a binder during granulation and compaction (Labelle et al, 2023).

Indonesia possesses rich biodiversity, including numerous starch-producing plants with potential pharmaceutical applications. One such plant is the yellow sweet potato (*Ipomoea batatas* (L.) Lam), which is widely cultivated and contains high levels of starch (Kunle, 2019). Yellow sweet potato starch can be further modified through pregelatinization to enhance its flowability, binding capacity, and compressibility in tablet formulations (Hong & Liu, 2023). A study by Ardiyani et al. (2022) reported that yellow sweet potato starch contains 23.42% amylose and 35.68% amylopectin, a composition suggesting promising binding characteristics for use in wet granulation.

Previous studies have also explored the use of cassava starch (*Manihot esculenta*) as a binder in tablet formulations. Both native and modified cassava starch have been shown to improve granule flow, enhance

compressibility, and produce tablets with acceptable hardness and friability. Cassava starch has demonstrated performance comparable to certain synthetic binders, particularly when modified through pregelatinization or cross-linking. These findings further support the potential of tuber-derived starches as effective and sustainable alternatives to conventional binders.

Despite these advancements, no studies have investigated the use of yellow sweet potato starch, either in its native or pregelatinized form, as a binder in fenofibric acid tablet formulations. Fenofibric acid is a lipid-lowering agent typically formulated as a tablet and requires an effective binder to ensure consistent performance, especially when manufactured using the wet granulation method (Al-Maqtari et al., 2024). Moreover, a copy (generic) of fenofibric acid is not yet available in the Indonesian market. This is because the compound remains under patent protection, highlighting the relevance of research aimed at developing alternative formulation strategies that utilize locally sourced excipients. This absence of prior work represents a notable scientific gap that warrants investigation.

Therefore, this study aims to evaluate the binding potential of native and pregelatinized yellow sweet potato starch in fenofibric acid tablet formulations

prepared using the wet granulation method. The performance of both starch types was assessed through various physicochemical tests on granules and tablets to determine their suitability as alternative pharmaceutical binders.

METHODS

Materials

Yellow sweet potato (Pekanbaru, Riau), fenofibric acid (BOC Sciences, USA), amylum pro tablet (Shadong Bio-tecnology, China), lactose monohydrate and talcum (J.T Baker®, USA), magnesium stearate (Faci Asia PasiFlc Pte Ltd, Italy), KH_2PO_4 and NaOH (Merck, Germany), distilled water.

Preparation of Native Yellow Sweet Potato Starch

Eight kilograms of yellow sweet potatoes were peeled, weighed, washed, and grated. Distilled water was then added at a ratio of 2:1 (w/v; sweet potato: water). The resulting slurry was manually squeezed and filtered through flannel cloth, after which it was allowed to settle for 6 hours to facilitate starch sedimentation. The supernatant was decanted, and the remaining sediment was washed repeatedly with distilled water until a clear starch sediment was obtained. The starch was then dried in a drying cabinet at 50°C for 12 hours, ground, and sieved using an 80-mesh sieve. The final dried starch was weighed (Li et al, 2022).

Preparation of Pregelatinized Yellow Sweet Potato Starch

Native yellow sweet potato starch was dispersed in distilled water at a ratio of 1:2 (w/v). The suspension was then heated to 69°C, which is 2°C below its gelatinization temperature (71°C), and maintained at this temperature for 5 minutes. Following thermal treatment, the starch was dried in a hot air oven at 50°C for 12 hours. The dried starch was then ground and sieved through an 80-mesh sieve to obtain a uniform particle size (Hong & Liu, 2023).

Moisture Content Determination of Native and Pregelatinized Starch

One gram of each starch sample (native and pregelatinized) was weighed and evenly distributed on the plate of a moisture analyzer. The temperature was set to 105°C, and the moisture content was determined directly from the instrument's display. Each measurement was performed in triplicate.

Formulation Fenofibric Acid Tablet by Wet Granulation

All ingredients were accurately weighed (Table 1). Mucilage was prepared from both native and pregelatinized yellow sweet potato starch at concentrations of 10%, 12.5%, and 15% by dissolving the starch in distilled water and heating the mixture on a hotplate at 50–70°C until mucilage formed. The mucilage was then allowed to cool. Fenofibric acid (active pharmaceutical

Table 1. Fenofibric acid tablet formula

Materials % b/b	Native starch			Pregelatinized starch		
	FI	FII	FIII	Fi	Fii	Fiii
Fenofibric acid	21	21	21	21	21	21
Amylum pro tablet	10	10	10	10	10	10
Native starch (mucilage)	10	12.5	15	-	-	-
Pregelatinized starch (mucilage)	-	-	-	10	12.5	15
Lactose monohidrate	ad 92	ad 92	ad 92	ad 92	ad 92	ad 92
Amylum pro tablet	5	5	5	5	5	5
Magnesium stearate	1	1	1	1	1	1
Talcum	2	2	2	2	2	2

ingredient), Amprotab® (disintegrant), and lactose monohydrate (Filler) were mixed and triturated until homogeneous. The prepared mucilage was gradually added to each formulation to form a damp mass suitable for granulation. The mass was passed through a 14-mesh sieve, collected, and dried in a drying cabinet at 50–60°C for 12 hours. The dried granules were then sieved through a 16-mesh sieve and weighed before evaluation.

Evaluation of Granule Properties

Granules were evaluated for the following pre-compression parameters: particle size distribution (using a vibratory sieve), true density, bulk density, tapped density, Hausner ratio, compressibility index, porosity, flow rate, angle of repose, and moisture content (Siregar& Wikarsa, 2010).

Tablet Compression

Tablet compression was performed using a single-punch Delta FSP-30 (China) tablet press, producing round tablets with a diameter of 10 mm.”

Tablet Evaluation

Tablets were evaluated for physical evaluations, including appearance (shape and size), weight uniformity, uniformity of size, hardness tester, friability and abrasion tester, and disintegration time (Kementrian Kesehatan RI, 2020).

Data Analysis

All data were statistically analyzed using one-way analysis of variance (ANOVA). If a statistically significant difference was observed ($p < 0.05$), post-hoc comparisons were performed using the Tukey test.

RESULTS AND DISCUSSION

A total of 378.241 grams of native yellow sweet potato starch was obtained after six successive washings, resulting in a clean and white starch sediment. The extraction yield was calculated at 5.11%, based on the ratio of dry starch weight to the initial weight of yellow sweet potatoes used. This yield is considered relatively low compared to the Findings of Irhami et al, 2019, who reported a yield of 11.53% in their study on the physicochemical characterization of yellow sweet potato starch.

The low yield observed in this study may be attributed to several factors. First, the incomplete breakdown of the starch matrix during the grating process likely resulted in residual starch being retained in the Fibrous material. Second, starch loss during the washing steps may have further reduced the Final yield (Sriroth et al, 2000). In contrast, the production of 50 grams of pregelatinized yellow sweet potato starch resulted in a yield of 91.8%, indicating a relatively efficient modification process.

Moisture content, defined as the percentage of water present in a material, is an important parameter as high moisture levels can promote microbial growth (bacteria, molds, and yeasts), which may lead to degradation and undesirable changes in the material. In this study, the moisture content of native yellow sweet potato starch was found to be 9.44%, which

meets the general standard for natural starch, with a maximum limit of 14%. Meanwhile, the moisture content of pregelatinized starch was 9.02%, also within the acceptable range for modified starches, which should be below 11.73% (BSN, 2011).

The particle size distribution analysis showed that granules prepared with native starch had average sizes of 327.69 μm (FI), 336.03 μm (FII), and 364.06 μm (FIII), while those with pregelatinized starch were 307.89 μm (Fi), 307.91 μm (Fii), and 310.95 μm (Fiii). These results indicate that as the concentration of starch used as a binder increases, the granule size also increases. This is because the higher viscosity of the mucilage promotes the formation of larger particle agglomerates. All formulations produced relatively large particles, which may result in inter-particle voids, reduced tablet hardness, and increased friability (Siregar&Wikarsa, 2010).

Flow rate analysis showed values above 10 g/s for all formulations, indicating good flowability. Native starch granules had flow rates of 11.16 g/s (FI), 15.33 g/s (FII), and 16.02 g/s (FIII), while pregelatinized starch granules had rates of 13.46 g/s (Fi), 13.44 g/s (Fii), and 16.86 g/s (Fiii). The angle of repose, another flow indicator, was lowest in FIII (23.89°) and Fiii (29.31°), suggesting better flow due to larger particle sizes (Aulton & Taylor, 2018).

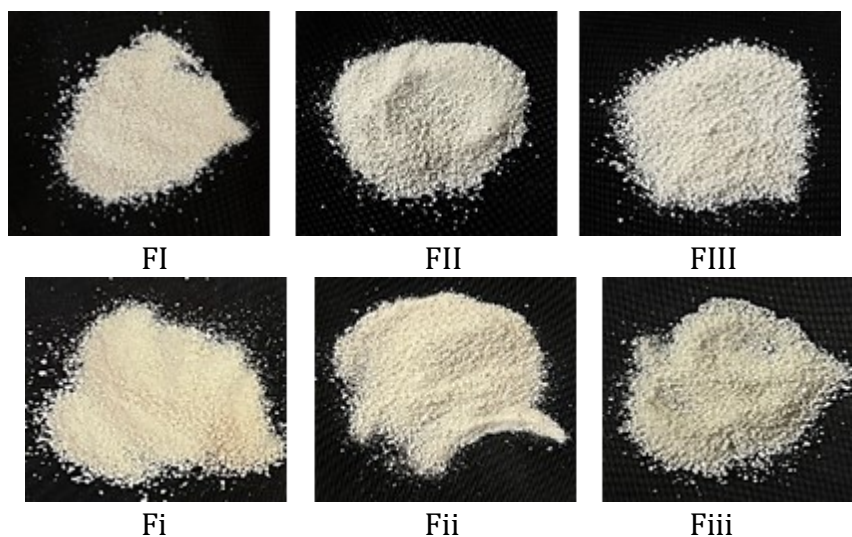


Figure 1. Granule of fenofiric acid tablets

Table 2. Evaluation of fenofibric acid granule

Evaluation	Native starch			Pregelatinized starch		
	FI	FII	FIII	Fi	Fii	Fiii
Moisture content (%)	1.93	2.32	2.13	2.01	2.29	2.32
True density (g/ml)	1.43	1.23	1.27	1.36	1.29	1.39
Bulk density (g/ml)	0.49	0.52	0.54	0.52	0.49	0.54
Tapped density (g/ml)	0.64	0.65	0.61	0.63	0.62	0.65
Compressibility index (%)	22.22	19.51	12.27	17.68	20.82	16.64
Hausner factor	1.28	1.24	1.14	1.21	1.26	1.20
Porosity (%)	65.11	57.11	57.51	61.51	61.60	60.72
Angle of repose (°)	31.25	28.54	23.89	29.41	32.37	29.31
Flow rate (g/sec)	11.16	15.33	16.02	13.46	13.44	16.86
Average granule diameter (µm)	327.69	336.03	364.06	307.89	307.91	310.95

Tapped density and true density values (Table 2) varied slightly across formulations, likely due to inter-particle voids (Aulton & Taylor, 2018). Compressibility Index values were lowest in FIII (12.24%) and Fiii (16.66%), indicating good flow (acceptable range: ≤ 18 –23%). Similarly, Hausner ratios for FIII (1.13) and Fiii (1.20) were below the 1.25 threshold, confirming superior flowability (Martin et al., 2011).

Porosity ranged from 57.11–65.11% (native) and 60.72–61.60%

(pregelatinized), influenced by binder concentration and affecting tablet properties. Moisture content was within the ideal 1–5% range, ranging from 1.93–2.32% (native) and 2.01–2.32% (pregelatinized). These levels support stability and compressibility without risk of microbial growth (Martin et al., 2011). The results of all granule evaluations are presented in Table 2 and Fig. 1.

Tablet size uniformity was assessed by measuring both diameter and thickness. According to the Indonesian Pharmacopoeia, The diameter of a tablet

Table 3. Physical evaluation of fenofibric acid tablet

Evaluation	Native starch			Pregelatinized starch		
	FI	FII	FIII	Fi	Fii	Fiii
Uniform weight (NP)	13.39	12.24	11.80	10.44	11.59	12.74
Uniform size (cm):						
Diameter	1.01±0.00	1.01±0.00	1.01±0.00	1.01±0.00	1.01±0.00	1.01±0.00
Thickness	0.57±0.00	0.57±0.01	0.55±0.00	0.57±0.00	0.57±0.00	0.57±0.00
Hardness (kg/cm ²)	3.73±0.79	4.09±0.71	4.04±0.68	3.03±0.91	3.46±0.84	3.87±0.85
Friability (%)	1.45	0.75	0.57	0.86	0.90	0.77
Abrasion (%)	0.66	0.69	0.35	0.61	0.62	0.50
Desintegration time (minutes)	2.43±0.04	2.46±0.03	2.50±0.03	2.20±0.04	2.23±0.03	2.26±0.03

should not exceed three times nor be less than $1\frac{1}{3}$ times its thickness (Kementrian Kesehatan RI, 2020). All formulations exhibited a uniform tablet diameter of 1.015 cm (Table 3). Thickness values ranged from 0.553 cm to 0.579 cm for FI–FIII and from 0.572 cm to 0.578 cm for Fi–Fiii. Minor variations in thickness may result from differences in granule flowability and porosity; however, these variations were not significant, and all formulations complied with the pharmacopoeial size uniformity criteria.

Tablet weight variation for all formulations met the Indonesian Pharmacopoeia requirements, with acceptance values below 15.0. Weight uniformity is primarily influenced by the flow properties of the powder blend—better flow ensures more consistent die filling and uniform tablet weights. The weight variation (NP) for the first 10 tablets of each formula also complied with the requirement, with NP values not

exceeding the L1 limit of 15.0% (Kementrian Kesehatan RI, 2020).

Tablet hardness, which reflects the internal bonding strength, varied across formulations. The hardness values were 3.73 kg/cm² (FI), 4.09 kg/cm² (FII), and 4.04 kg/cm² (FIII), while Fi–Fiii showed values of 3.03 kg/cm², 3.46 kg/cm², and 3.87 kg/cm², respectively. Formulations FII and FIII met the acceptable range of 4–8 kg/cm², whereas FI and Fi–Fiii displayed values slightly below this range, potentially due to lower binder concentrations or insufficient compression force during tablet manufacturing (Aulton & Taylor, 2018).

Friability, indicating the mechanical resistance of tablets to surface abrasion, must not exceed 1.0% (USP, 2024). The friability values were 1.45% (FI), 0.75% (FII), and 0.57% (FIII), and 0.86% (Fi), 0.90% (Fii), and 0.77% (Fiii). All formulations except FI complied with the pharmacopoeial friability limit. Abrasion resistance results were also within acceptable limits, with values of 0.66% (FI),

0.69% (FII), 0.35% (FIII), and 0.61% (Fi), 0.62% (Fii), and 0.50% (Fiii).

Disintegration time, which assesses how quickly a tablet breaks apart, should be under 15 minutes for uncoated tablets (Kementrian Kesehatan RI, 2020). All formulations met this requirement, with disintegration times of 2 minutes 26 seconds (FI), 2 minutes 28 seconds (FII), 2 minutes 30 seconds (FIII), and 2 minutes 12 seconds (Fi), 2 minutes 14 seconds (Fii), and 2 minutes 16 seconds (Fiii).

Statistical analysis using One-Way ANOVA revealed no significant differences in tablet hardness or disintegration time between the formulas ($p > 0.05$).

CONCLUSION

Based on the results of all tablet evaluations, both formulations using native yellow sweet potato starch (FI–FIII) and those using pregelatinized yellow sweet potato starch as a binder (FI–FIII) showed no significant differences in the quality of the resulting tablets. This indicates that both native and modified starches are comparable in their functionality as binders. However, when considering the different binder concentrations used, the 12.5% concentration (FI and Fi) was found to be suboptimal for use in wet granulation tablet formulations. The most favorable results were observed at a starch concentration of 15% (FIII and FIII),

indicating that this concentration provides better binding performance

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