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Production of Pharmaceutical Microcrystalline Cellulose (MCC) as Tablet Excipient from Sugarcane Bagasse

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Abstract. Waste from sugarcane milling in Langsa is abundant but remains unprocessed, so it is necessary to explore more useful ways of utilizing it without causing environmental pollution. Sugarcane bagasse, which is rich in cellulose, has the potential to be developed into microcrystalline cellulose (MCC), which can be used as a filling material in tablet production. The preparation of bagasse MCC was carried out in two stages: the first stage involved α-cellulose isolation, which included delignification, swelling, and bleaching processes, while the second stage was the hydrolysis of α-cellulose using 2.5 N HCl to obtain bagasse MCC. The results of this study show that the sugarcane bagasse MCC produced has the following physical characteristics: it is crystalline, white in color, odorless, and tasteless, with a moisture content of 3.78%, a pH of 7, a permanganate content of 2.54%, and a particle size of 33.843 µm. In conclusion, the sugarcane bagasse MCC produced meets the tablet excipient requirements as outlined in the *Handbook of Pharmaceutical Excipients*.

Introduction

Sugarcane waste, known as bagasse, is rich in lignocellulose, a biomass composed of lignin, cellulose, and hemicellulose, which can be processed into cellulose microcrystals for use as tablet excipients. For some, bagasse may seem worthless, often being burned and turned into ash. However, in the field of pharmaceutics, cellulose microcrystals are valuable excipients in tablet formulations, acting as a filling material and considered a dry binder due to their ability to enhance the cohesiveness of tablets during compression. The utilization of bagasse as a raw material for cellulose microcrystals also holds the potential to reduce the importation of pharmaceutical raw materials, which is a pressing issue for Indonesia. Currently, approximately 90% of the raw materials used in pharmaceutical formulations are imported.

Bagasse comprises approximately 35.01% cellulose, 25.24% hemicellulose, 6.4% lignin, 9.35% silicates, along with various minerals, waxes, and other minor compounds (Hidayati et al., 2016). In pharmaceutical applications, microcrystalline cellulose (MCC) serves as a commonly used excipient in tablet formulations. It functions primarily as a filler and is classified as a dry binder due to its ability to enhance the cohesiveness of powders during the compression process(Widia & Wathoni, 2015). Moreover, MCC contributes to improved flow properties during tablet manufacturing.

Microcrystalline cellulose (MCC) is widely utilized as an additive in the pharmaceutical industry, primarily serving as a binder in tablet formulations produced via the direct compression method. It is also commonly employed in vitamin supplements. Beyond pharmaceuticals, MCC is used in the food industry as an anti-caking agent, thickener, texturizer, emulsifier, bulking agent, and fat substitute. In cosmetics, it functions as a filler (Hindi, 2017). Furthermore, MCC plays a critical role in pharmaceutical formulations as a binder, lubricant, and diluent (Lestari et al., 2022).

MCC is a partially purified form of cellulose obtained from α-cellulose through controlled hydrolysis of plant-based fibrous pulp using mineral acids. It is characterized by a degree of polymerization typically less than 400. The particle size distribution indicates that no more than 10%

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of the material has a diameter smaller than 5 μm^2. In general, MCC particles range from 1 to 100 μm in length and exhibit a crystallinity index between 55% and 85%.

The physicochemical properties of MCC significantly contribute to the tablet manufacturing process, particularly through the direct compression method. This approach requires high-quality and consistent excipients to ensure successful tablet formation. Although direct compression is considered the preferred method in tablet production due to its simplicity and cost-effectiveness, it is highly dependent on the flowability and compressibility of the powder blend. It is estimated that less than 20% of active pharmaceutical ingredients are suitable for direct compression without the use of specialized excipients (Rojas et al., 2012). Furthermore, MCC has been reported to enhance drug delivery systems (Bala et al., 2013) and acts as a water-insoluble solid carrier (Widia & Wathoni, 2015).

This study introduces a novel approach to the utilization of biomass waste, specifically sugarcane bagasse, as an alternative raw material for the production of microcrystalline cellulose (MCC). In contrast to previous studies, which typically utilize wood or cotton as cellulose sources, this research employs an abundant yet underutilized agricultural residue, thereby aligning with the principles of the circular economy and promoting waste reduction.

Moreover, the α-cellulose isolation method in this study has been optimized through a combination of efficient delignification, swelling, and bleaching processes, followed by a hydrolysis step using 2.5 N HCl. Characterization results demonstrate that the resulting MCC meets the standards outlined in the Handbook of Pharmaceutical Excipients, thus highlighting its potential as a pharmaceutical tablet excipient comparable to commercial MCC products.

This research further contributes to the advancement of cost-effective and sustainable local MCC production and may serve as a viable alternative to imported pharmaceutical raw materials in Indonesia.

Experimental

Material and Methods

The equipment used in this study includes a digital balance, standard laboratory glassware, hot plate, spatula, thermometer, mortar and pestle, filter paper, oven, universal indicator, pH meter, desiccator, sieves, pycnometer, and particle size analyzer.

The materials utilized comprise bagasse, distilled water, 3.5% nitric acid (HNO_3), sodium nitrite ($NaNO_2$), 2% sodium hydroxide (NaOH), 2% sodium thiosulfate ($Na_2S_2O_3$), 1.75% sodium hypochlorite (NaOCl), 10% hydrogen peroxide (H_2O_2), 2.5 N hydrochloric acid (HCl), ethanol, diethyl ether, potassium permanganate ($KMnO_4$), potassium iodide (KI), and sulfuric acid (H_2SO_4).

Procedures

Preparation of bagasse raw materials

The bagasse was first cleaned and thoroughly washed with clean water to remove adhering impurities. It was then sun-dried until completely free of moisture. Once dried, the bagasse was cut into smaller pieces and mechanically blended to obtain fine fibrous material.

Isolation process of α-cellulose from bagasse

A total of 75 grams of bagasse powder was mixed with 1 L of a solution containing 3.5% nitric acid (HNO_3) and 10 mg sodium nitrite ($NaNO_2$), then heated at 90°C for 2 hours. The mixture was subsequently filtered, and the residue was washed repeatedly until the filtrate reached neutral pH. The residue was then digested with 750 mL of a solution containing 2% sodium hydroxide (NaOH) and 2% sodium thiosulfate ($Na_2S_2O_3$) at 50°C for 1 hour. After digestion, the mixture was filtered and the residue washed until the filtrate was neutral. Next, bleaching was performed using 250 mL of 1.75% sodium hypochlorite (NaOCl) solution at 70°C for 30 minutes, followed by filtration and washing until neutral pH was achieved. The α-cellulose was then purified by treatment with 500 mL of 17.5% NaOH at 80°C for 30 minutes, followed by filtration and washing to neutrality. A final bleaching step was conducted using 10% hydrogen peroxide (H_2O_2) at 60°C, followed by filtration and washing. The resulting α-cellulose was dried in an oven at 60°C. The dried product obtained is referred to as α-cellulose (Putri & Gea, 2018).

Determination of α-cellulose content

The α-cellulose content of bagasse-derived microcrystalline cellulose (MCC) was determined following the Alpha, Beta, and Gamma Cellulose Content Test method as outlined in the Indonesian National Standard (Adel et al., 2011). The α-cellulose content was calculated according to Equation 1.

$$X = \frac{6.25\ (V1 - V2)\ x\ N\ x\ 20}{A\ x\ W} \times 100\% \qquad (1)$$

Description:
X : α-cellulose content (%)
V1 : Titration volume of blank (mL)
V2 : Titration volume of pulp filtrate (mL)
N : Normality of ferrous ammonium sulfate solution

A : Volume of pulp filtrate analyzed (mL)
W : Dry weight of pulp (g)

Preparation of bagasse MCC

A total of 5 g of α-cellulose was hydrolyzed with 100 mL of 2.5 N hydrochloric acid (HCl) and refluxed at 105°C for 15 minutes. The hydrolyzed material was then washed repeatedly with distilled water until the washings reached a neutral pH, followed by drying in an oven. The dried product was subsequently ground into a fine powder (Ohwoavworhua & Adelakun, 2010; Siagian et al., 2016)

Characteristic test of bagasse MCC

The bagasse-derived MCC was characterized using several parameters including organoleptic properties, moisture content, pH, permanganate number, functional group analysis, and particle size distribution.

Organoleptic test

The organoleptic evaluation of MCC was conducted visually, assessing its shape, color, aroma, and taste.

Moisture content test

Moisture content was determined by placing 5 grams of the MCC sample into a pre-weighed porcelain crucible. The crucible and sample were weighed (initial weight), then placed in an oven at 105°C and heated for 2 hours. After heating, the crucible was cooled in a desiccator and reweighed. The drying process was repeated until a constant weight was obtained. Moisture content was calculated using the following equation (Edison et al., 2019):

$$\text{Moisture Content} = \frac{B - C}{B - A} \times 100\% \qquad (2)$$

Description:
A : Weight of empty crucible (g)
B : Weight of crucible + sample before drying (g)
C : Weight of crucible + sample after drying (g)

pH determination

The pH of the MCC was measured using a pH meter. A 15% (w/v) dispersion of MCC was prepared in distilled water, and the pH electrode was immersed in the solution. The pH value was recorded once stabilized (Thoorens et al., 2014).

Permanganate number test

The permanganate number was determined according to the Indonesian National Standard (SNI 0494:2008). A total of 0.1 g of MCC was dissolved in 70 mL of distilled water in a beaker, followed by the addition of 2.5 mL of 4 N sulfuric acid (H_2SO_4) and 2.5 mL of 0.1 N potassium permanganate ($KMnO_4$). After 5 minutes, 1 mL of 10% potassium iodide (KI) was added, and the solution was titrated with 0.1 N sodium thiosulfate ($Na_2S_2O_3$), using 0.2% starch solution as an indicator.

Functional group analysis (FTIR test)

Functional group identification of the MCC was carried out using Fourier Transform Infrared Spectroscopy (FTIR). The sample film was clamped onto the sample holder and exposed to infrared radiation. The absorbance spectrum was recorded as a plot of wave number versus intensity to identify characteristic functional groups.

Particle size analysis

The particle size distribution of MCC derived from bagasse was analyzed using a Laser Scattering Particle Size Distribution Analyzer (HORIBA LA-951). This method allows determination of the size and distribution range of the MCC particles in micrometers.

Result and Discussion

Results of MCC isolation from bagasse

The production of microcrystalline cellulose (MCC) from bagasse was carried out in two main stages.

Stage I: Isolation of α-cellulose

In this initial phase, α-cellulose was isolated from bagasse through a multi-step chemical treatment. The delignification process was conducted using 3.5% nitric acid (HNO_3) in combination with sodium nitrite ($NaNO_2$) to remove lignin content. This was followed by an alkaline swelling treatment using 2% sodium hydroxide (NaOH) and 2% sodium thiosulfate ($Na_2S_2O_3$) to eliminate hemicellulose. The resulting material was then bleached using 1.75% sodium hypochlorite (NaOCl) to yield white cellulose fibers. Further purification of α-cellulose was carried out using 17.5% NaOH to remove β-cellulose and γ-cellulose fractions. A final bleaching step with 10% hydrogen peroxide (H_2O_2) ensured the production of purified α-cellulose, which was subsequently oven-dried at 60°C.

Stage II: Isolation of Microcrystalline Cellulose (MCC)

The second stage involved the conversion of purified α-cellulose into MCC through acid hydrolysis. This process

was performed using 2.5 N hydrochloric acid (HCl) under reflux at 105°C for 15 minutes. The hydrolyzed product was then washed to neutral pH, dried, and ground into a fine powder. The process yielded MCC from an initial 75 grams of bagasse raw material.

Table 1. Percentage of MCC produced.

Weight α-Cellulose.	Weight MCC	MCC Percentage
15,0 g	7,80 g	52%

From the initial isolation process, 15.0 grams of α-cellulose were obtained. This α-cellulose was then subjected to acid hydrolysis to produce microcrystalline cellulose (MCC). The resulting MCC weighed 7.80 grams, corresponding to a yield of 52% relative to the α-cellulose input.

Characterization and functional group analysis of sugarcane bagasse-derived MCC

The physical and chemical characteristics of both α-cellulose and microcrystalline cellulose (MCC) derived from bagasse were evaluated through a series of standard tests. These included organoleptic observations, moisture content determination, pH measurement, permanganate number test, Fourier Transform Infrared Spectroscopy (FTIR) for functional group analysis, and Particle Size Analysis (PSA) to determine particle distribution.

Table 2. Physical parameter characteristics of bagasse MCC.

Physical Parameters	Sugarcane Bagasse MCC	Pharmaceutical Standard (Handbook of Pharmaceutical Excipients)
Organoleptical Test		
Shape	Crystalline	Crystalline
Color	White	White
Odor	Bo odor	No odor
Teste	Tasteless	Tasteless
Moisture Content	3.78%	<5%
pH	7	5-7
Permanganate content	2.54%	<6%

The microcrystalline cellulose (MCC) derived from sugarcane bagasse exhibited a crystalline shape, white color, was odorless, and tasteless. The moisture content was measured at 3.78%, the pH was found to be 7, and the permanganate number was 2.54%, indicating the presence of approximately 6% residual lignin. The permanganate index was determined in accordance with SNI 0494: 2008. These physical characteristics align with the standards outlined in the Handbook of Pharmaceutical Excipients, indicating that the bagasse-derived MCC meets the criteria to be used as a pharmaceutical excipient, particularly as a tablet filler.

The moisture content value (3.78%) is within acceptable limits (<5%). Excessive moisture in MCC can promote enzymatic activity or microbial contamination, leading to degradation and reduced shelf life. Therefore, maintaining moisture content below the threshold is essential for stability and safety during storage.

The permanganate number (2.54%) reflects the presence of organic impurities, including residual lignin. While most lignin is removed during the delignification process using NaOH and $NaNO_2$, traces may remain, potentially influencing the rigidity and color of the final product (Sunardi, 2021). A low permanganate number, however, confirms satisfactory purity. The pH value of 7 confirms the neutrality of the MCC, which is desirable for pharmaceutical applications, as stability is typically enhanced in neutral pH environments.

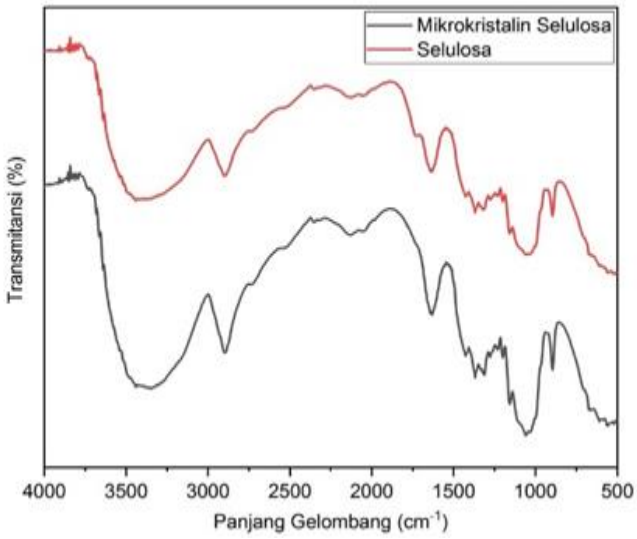

Figure 1. FT-IR Spectra of MCC and Sugarcane Bagasse α-Cellulose.

The Fourier Transform Infrared (FT-IR) spectroscopy was used to identify the functional groups present in sugarcane bagasse MCC and α-cellulose. The FT-IR spectra revealed distinct absorption bands corresponding to the molecular vibrations of characteristic functional groups.

Table 3. FT-IR analysis of MCC and bagasse α-Cellulose.

Sample	Wavenumbers (cm^{-1})	Function Group	Interpretation
Sugarcane Bagasse MCC	3344,57	–OH stretching	Presence of hydroxyl groups (cellulose backbone)
	2897,08	C–H stretching	Aliphatic –CH bonds
	1053,13	C–O stretching	Polysaccharide fingerprint region
	1430	CH_2 scissoring	Cellulose structure indicator
	948	β-glycosidic linkage	Typical of cellulose structure
α- Cellulose	3437,15	–OH stretching	Presence of hydroxyl groups (cellulose backbone)
	2897,08	C–H stretching	Aliphatic –CH bonds
	1049,28	C–O stretching	Polysaccharide fingerprint region
	1421	CH_2 scissoring	Cellulose structure indicator
	900	β-glycosidic linkage	Typical of cellulose structure

The functional group analysis of sugarcane bagasse-derived microcrystalline cellulose (MCC) and α-cellulose was carried out using Fourier Transform Infrared (FT-IR) spectroscopy. The FT-IR spectrum of MCC revealed the presence of –OH functional groups indicated by a broad absorption band at 3344.57 cm^{-1}, and a C–H stretching vibration at 2897.08 cm^{-1}. A distinct absorption peak at 1053.13 cm^{-1} corresponded to the stretching vibration of C–O–C linkages, indicative of the ether groups presented in the cellulose backbone.

Similarly, the α-cellulose spectrum exhibited an –OH stretching band at 3437.15 cm^{-1}, and a C–H stretching peak at 2897.08 cm^{-1}. The presence of a C–O–C stretching band at 1049.28 cm^{-1} was also noted. These findings are consistent with those reported by Huang, (2012) and Azubuike & Okhamafe, (2012), who indicated that cellulose exhibits O–H stretching vibrations within the range of 3300–3500 cm^{-1}, C–H stretching between 2800–2900 cm^{-1}, and C–O stretching within 1050–1300 cm^{-1}.

Particle Size Distribution of Sugarcane Bagasse MCC

The particle size distribution of the MCC obtained from sugarcane bagasse was analyzed using a Laser Scattering Particle Size Distribution Analyzer (HORIBA LA-951). The instrument, capable of measuring particle diameters ranging from 11 nm to 3000 μm, was used to evaluate MCC powder that had been pre-treated by grinding and sieving through a 100 mesh sieve.

The analysis revealed that the average particle diameter of sugarcane bagasse MCC was 33.843 μm, which falls within the micro-size range of 0.5–3360 μm as defined for pharmaceutical dispersions (Sinko & Singh, 2011). This result is also in accordance with the commercial MCC particle size range reported by Nazzal et al., (2002), which is 20–180 μm.

Table 4. Particle size analysis of sugarcane bagasse MCC.

Parameter	Result
Average Particle Size (μm)	33.843
Acceptable MCC Particle Range	20 – 180 μm

Conclusion

The production of bagasse MCC was conducted in two distinct stages: the α-cellulose isolation stage, which encompassed delignification, swelling, and bleaching processes, followed by the hydrolysis of α-cellulose using a 2.5 N hydrochloric acid (HCl) solution to obtain bagasse MCC. The findings of this study indicate that the resultant sugarcane bagasse MCC exhibited physical characteristics including crystallinity, whiteness, absence of odor, and tastelessness. The MCC demonstrated a moisture content of 3.78%, a pH value of 7.0, a permanganate index of 2.54%, and an average particle size of 33.843 μm. Consequently, it can be concluded that the produced bagasse MCC satisfies the criteria required for tablet excipients, as outlined in the Handbook of Pharmaceutical Excipients.

Conflict of Interest

The authors declare that there is no conflict of interest.

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