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Synthesis of Gelatin-Free Halal Capsule Shells Based on Microcrystalline Cellulose from Solid Sugar Palm (Aren) Waste

Erika Putri Pradaniz*, Widya Ayu Prawesti, Intan Iwahyuningtyas, Nasywa Alya Naufiannida, Anggistia Maharani, Fadilah*

Chemical Engineering Department, Engineering Faculty, Universitas Sebelas Maret, Surakarta, Indonesia 57126

*Corresponding author: erikaputripradaniz@student.uns.ac.id, fadilah@staff.uns.ac.id

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ABSTRACT. Capsules are one of the most used drug delivery media. Capsule shells are made from gelatin, a protein derived from hydrolyzed collagen, which is extracted from animal skin, tissue, and bones. Gelatin from animals is susceptible to contamination with pathogens. Alternative ingredients that are safe to use include those derived from vegetables, such as palm starch dregs. The cellulose content in solid sugar palm waste is quite high, so it has potential for use in making capsule shells. However, cellulose does not dissolve easily in water. Improving this property can be done by changing the size. Microcrystalline Cellulose (MCC) is obtained by acid hydrolysis of cellulose, resulting in the loss of the amorphous portion, leaving the crystalline portion. Its good dispersion in water makes MCC a matrix-forming agent when mixed with HPMC, a gelatin substitute. This research intends to examine the impact of involving MCC derived from solid sugar palm waste on the characteristics of the capsule shell. The properties include uniformity of weight, water content, ash content, pH, and solubility. The acid hydrolysis method is used in the synthesis of MCC. FTIR results show that MCC has the same functional groups as α-cellulose. SEM results show that although some parts are nano-sized, there are still other parts that are micron-sized. Capsule shells were made with varying concentrations of MCC 1%, 4%, 7%, and 10% with the addition of HPMC 2%, PEG-400 2%, and water. The results show that the best variation is at 4% MCC, which meets the standards of Farmakope Indonesia VI edition. On average, the capsule's weight is 0.0938 grams, water content is 13.73%, ash content is 1.35%, pH 6, solubility in water is 19 minutes 49 seconds, and solubility in acid is 2 minutes 40 seconds.

1. INTRODUCTION

Capsules are a popular pharmaceutical dosage form due to their ability to mask the unpleasant taste of medications [1]. The demand for capsules in Indonesia reaches 6 billion units per year, yet the majority still rely on imported gelatin-based materials [2]. Generally, capsule shells are made of gelatin. Gelatin, derived from the hydrolysis of animal collagen, poses risks of pathogen contamination and raises religious concerns [3]. Therefore, a halal and plant-based capsule shell alternative provides a safer solution for the community.

A plant-derived cellulose-based polymer called hypromellose or hydroxypropyl methylcellulose (HPMC) has become popular as a replacement for gelatin. HPMC successfully overcomes many of gelatin's restrictions since it is utilized widely as an excipient in pharmaceutical items for a variety of coating and formulation applications. Meanwhile, microcrystalline cellulose (MCC) is a material that can function as a matrix-forming agent if mixed with HPMC [4]. Lignocellulose, which is plant dry matter, contains at least 30–60% cellulose, 14–40% hemicellulose, and 7–25% lignin. Holocellulose, a mixture of cellulose and hemicellulose, accounts for 40–70% of the total dry matter. The presence of hydrogen bonds in cellulose results in its crystalline structure. Natural cellulose consists of 500–15,000 glucose units, and when the amorphous regions within its microfibrils are broken down through acid or enzymatic treatment, microcrystalline cellulose (MCC) is produced. [5]. MCC is composed of linear chains of β-D-glucose units linked by β-1,4-glycosidic bonds. Upon hydrolysis, crystalline domains form, contributing to the stiffness and mechanical strength of MCC [4].

A typical alternative method for making MCC is the hydrolysis of strong acids that serve as catalysts to speed up reactions. Haliman obtained MCC from Corn Waste and reported that the MCC obtained had a crystallinity of 99.4%, supported by a yield percentage of 77.09%, a pH of 5.84, a moisture content of 5.81%, and a particle size of 210.82 μm [6]. Using nata de soya as raw material, Yugatama [7] reported that the MCC obtained had particle

sizes ranging from 26.67 to 253.33 μm, with irregular shapes and uneven surface textures that formed sharp and blunt corners. Meanwhile, MCC from pineapple produced a yield of 10.68%, with a particle size of isolated microcrystalline cellulose of 141.3 μm [8]. MCC derived from roselle fiber has an average diameter of 44.28 μm, indicating a degree of crystallization that increases from 63% in roselle fiber to 78% in MCC [Kian, 2017] [9].

In the production of starch from sugar palm (aren) trees in Klaten Regency, the largest solid waste contains quite high cellulose, around 48.9% [10]. Cellulose in this material can be processed into microcrystalline cellulose (MCC). MCC has better mechanical properties than cellulose and is a commonly used material in the pharmaceutical industry [11] No research has yet explored MCC derived from sugar palm waste, even though its cellulose content is high (48.9%)[10]. This study utilizes sugar palm waste to develop gelatin-free capsule shells based on mixture of HPMC and MCC. The effect of MCC concentration on the physical properties of the capsules was studied. This innovation not only repurposes local waste but also aligns with SDG 12 policies on waste management and sustainability.

2. MATERIALS AND METHODS

2.1 Materials and Equipment

The materials used in this research are solid sugar palm waste from Klaten, aquadest, HNO_3, $NaNO_2$, NaOH, Na_2SO_3, NaOCl, H_2O_2, H_2SO_4, HPMC, PEG-400, and HCl. Meanwhile, the equipments used in this research are blender, sieve 80 mesh, beaker glass, measuring cup, erlenmeyer, volume pipette, three-necked flask, filter paper, glass stirrer, magnetic stirrer, glass funnel, porcelain cup, stand, clamp, digital scale, hot plate, oven, furnace, digester, desiccator, centrifugator, ultrasonicator, thermometer, and pH meter.

2.2 Methods

2.2.1 Isolation of α-Cellulose

Dried solid sugar palm waste was ground and sifted using an 80-mesh sieve. Then, 75 grams of sugar palm waste was added to 1 L of a mixture of 3.5% HNO_3 and 10 mg $NaNO_2$, and the mixture was heated at 90°C for 2 hours. The heated mixture is filtered, and the solids are washed until neutral. The sugar palm waste was digested with a 750 mL solution of 2% NaOH and 2% Na_2SO_3 at 50°C for 1 hour, then filtered and washed until the solution was neutral. The solids were bleached with 250 mL of 1.75% NaOCl solution at 70°C for 30 minutes, then filtered and washed until neutral. Purification of α-cellulose was carried out using 500 mL of a 17.5% NaOH solution at 80°C for 30 minutes. The solution was then filtered, and the solids were washed until the filtrate was neutral. The solids were bleached with 10% H_2O_2 at 60°C for 1 hour, filtered, and washed until neutral, then dried at 60°C for 3 hours [12]. The solids are α-cellulose.

2.2.2 Isolation of Microcrystalline Cellulose (MCC)

One gram of α-cellulose was dissolved in 25 mL of 45% H_2SO_4 at a temperature of 45°C for 25 minutes. The homogenized solution was cooled, and 25 mL of water was added, then left for 24 hours. The suspension formed was centrifuged at a speed of 10.000 rpm for 20 minutes. The white suspension formed was ultrasonicated for 15 minutes at 60% power, then the water was evaporated at 60°C to obtain MCC [12]. MCC was then analyzed using Fourier Transform Infrared Spectroscopy (FTIR) to determine the functional groups of cellulose and analyzed using Scanning Electron Microscopy (SEM) to determine the surface morphology.

2.2.3 Making Capsule Shells

Gels were made by dissolving MCC with varying concentrations of 1%, 4%, 7% and 10%. The solution was added to 2% HPMC and 2% PEG-400 in distilled water solution at a temperature of 30°C for 30 minutes at a speed of 500 rpm. The resulting gel is printed using a dipping pen, and then dried for three hours at 60°C in an oven [13].

2.2.4 Characterization of Capsule Shells

2.2.4.1 Weight Uniformity Test

Three capsule shells were weighed with an analytical balance, and the average weight and standard deviation were computed.

2.2.4.2 Water Content Test

One gram of capsule shell was placed in a dish, then dried in an oven at 105°C for 12 hours. The sample was

cooled in a desiccator and then weighed.

$$\text{Water content (\%)} = \left(\frac{(\text{dish} + \text{initial sample weight}) - (\text{dish} + \text{final sample weight})}{(\text{dish} + \text{initial sample weight}) - \text{dish weight}}\right) \text{x } 100\% \quad (1)$$

2.2.4.3 Ash Content Test

One gram of capsule shell was placed into the porcelain crucible, then heated in a furnace at 600°C for 3 hours. The sample was cooled in a desiccator and then weighed.

$$\text{Ash content (\%)} = \left(\frac{\text{ash weight}}{\text{sample weight}}\right) x\ 100\% \quad (2)$$

2.2.4.4 pH Test

One gram of capsule shell was dissolved in 50 mL of water, and then the pH was measured using a pH meter.

2.2.4.5 Solubility Test

A total of 10 capsule shells were placed into a container containing 75 mL of water at 37°C for the water solubility test, and 10 capsule shells were placed into 100 mL of 0.35% HCl solution for the acid solubility test. Each was stirred, and the time was recorded from the moment the capsule was inserted until the capsule shell broke or dissolved [14].

3. RESULTS AND DISCUSSION

3.1 Isolation of α-cellulose

Isolation of α-cellulose was carried out by delignification, swelling, bleaching of cellulose, purification of α-cellulose, and bleaching of α-cellulose. Delignification removed lignin from sugar palm waste. Swelling aimed to develop the fiber structure so that hemicellulose, mineral salts, and ash are lost [12]. These processes produce brownish-yellow pulp. The pulp is then bleached to degrade the remaining lignin and increase the purity of cellulose, and the white cellulose is obtained. To separate the α-cellulose, a 17.5% NaOH solution was used, which causes β and γ cellulose to dissolve, while α-cellulose precipitates [12]. This process produces brownish-yellow α cellulose, which is then bleached and produces 16.41 grams of white α cellulose with a yield of 21.88%.

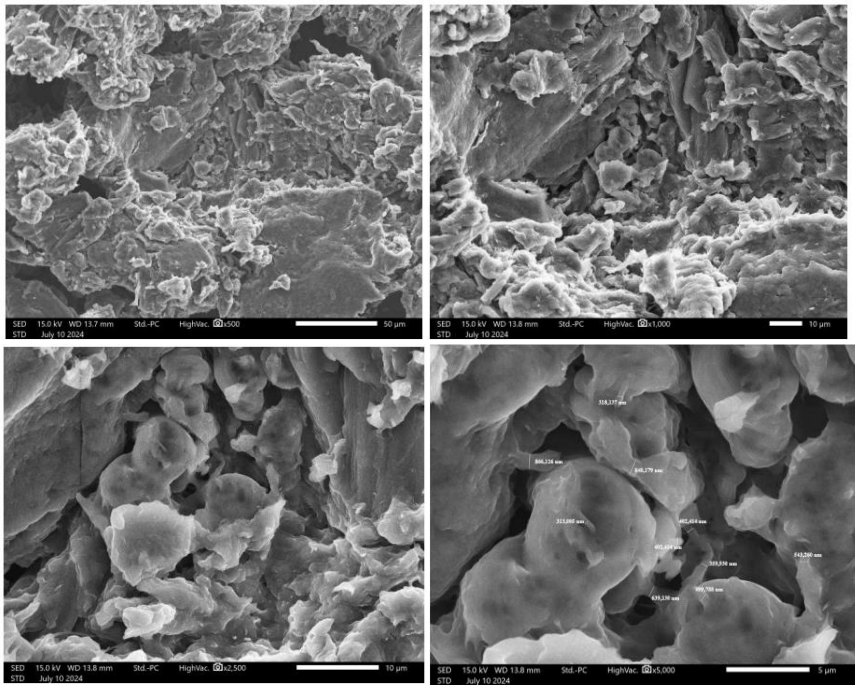

Figure 1. SEM characterization results on microcrystalline celluloses.

3.2 Isolation of microcrystalline cellulose (MCC)

Isolation of microcrystalline cellulose was carried out by acid hydrolysis, centrifugation, and ultrasonication. Hydrolysis of α-cellulose using 45% H_2SO_4 causes the breakdown of the amorphous part of cellulose crystals. The reduced amorphous region increases the crystallinity of cellulose, which will produce microcrystalline cellulose.

The hydrolysis results were then centrifuged to separate the solids and solutions. The suspension formed was then ultrasonicated to break down the aggregates of nanoparticles formed so that the size would be smaller [12]. This process produced microcrystalline cellulose as much as 0.73 grams with a yield of 73%.

3.3 Characterization of microcrystalline celluloses (MCC)

At first, it was planned to synthesize cellulose nanocrystals, but the cellulose crystals obtained were still micron-sized and only very few had nano-sized ones. These results are not much different from Hendrawati's research [15]. In another study conducted by Putri and Gea [12], the synthesis of nanocrystals using dialysis membranes successfully formed nanoparticle sizes. In our study, we did not use this method because the necessary equipment is not available.

Microcrystalline celluloses were characterized using SEM and FTIR. SEM testing was carried out to determine the surface structure of the resulting microcrystalline celluloses. Scanning electron micrographs of microcrystalline cellulose is presented in Figure 1. At low magnification, the fibrous morphology of cellulose disappears and is replaced by a fragmented, plate-like structure, indicating effective acid-induced depolymerization. The particles exhibit an irregular morphology with micrometer-scale dimensions, characteristic of microcrystalline cellulose. The rough and eroded surface observed at higher magnification reflects the selective removal of amorphous regions during acid hydrolysis. A clear agglomeration is observed, caused by strong intermolecular hydrogen bonding between the microcrystalline cellulose particles.

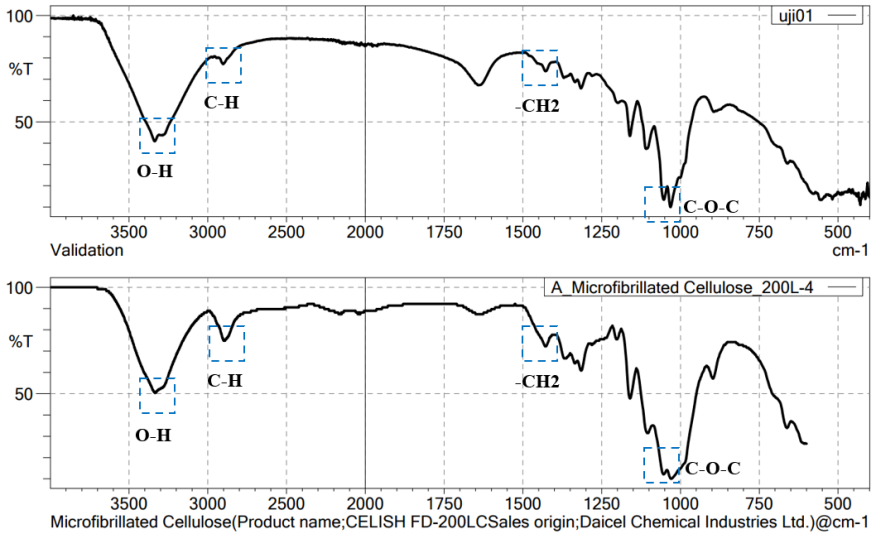

Figure 2. FTIR characterization results on microcrystalline celluloses and α-cellulose.

FTIR testing was carried out to determine the functional groups. Figure 2 shows that both samples, microcrystalline celluloses (upper image) and α-cellulose (lower image), exhibit similar spectra, indicating that the extraction process did not alter the chemical composition of the material. Therefore, both samples share similar functional groups. The absorption peaks of 3350 and 3335 cm^{-1} indicate the presence of -OH stretching groups from cellulose. The absorption bands of 2910 and 2900 cm^{-1} indicate the presence of C-H groups which are associated with the organized structure of cellulose crystals [9]. The wave numbers of 1430 and 1425 cm^{-1} indicate the presence of symmetric $-CH_2$ groups, and the wave numbers of 1030 and 1028 cm^{-1} indicate the presence of C-O-C groups. In addition, there is absorption at 850-950 $cm^{-1,}$ which indicates β-glycosidic bonds between glucose units of cellulose [12]. Therefore, it can be seen that microcrystalline cellulose has been successfully synthesized from α-cellulose.

Table 1. Capsule shell formulation

	Variation 1	Variation 2	Variation 3	Variation 4
Microcrystalline celluloses	1%	4%	7%	10%
HPMC	2%	2%	2%	2%
PEG-400	2%	2%	2%	2%
Aquadest	95%	92%	89%	86%

3.4 Capsule Shells

The formulation for making capsule shell gel is carried out with variations of microcrystalline cellulose as tabulated in Table 1. HPMC was used as the base formula for the mixture, while PEG-400 acts as a plasticizer to reduce polymer stiffness and increase the flexibility of the resulting capsule shell. The capsule shell molding process was carried out manually using a glass stirrer as a modified capsule shell molding tool. The results of the capsule shells obtained are shown in Table 2.

Table 2. Result of capsule shells

Variation of MCC	Properties of Capsule Shells	
1%	Soft, brittle texture and clear color	
4%	The texture is not too hard, stronger, and white in color	
7%	Stiff, strong, white texture	
10%	Stiff, strong, white texture	

The structure of MCC is a linear chain of β-D-glucose units linked by β-1,4-glycosidic bonds. This structure gives MCC its characteristic property of being insoluble in water but dispersible [4]. Table 2 shows capsules obtained at various MCC concentrations. It can be seen that increasing the MCC concentration results in stiffer capsules. This increase in stiffness with increasing MCC concentration is due to the rigid nature of MCC crystals, which leads to increased hydrogen bonding between MCC and HPMC. In SPI-gelatin composite films, the addition of MCC increases the Young's Modulus of the film, indicating that the film becomes stiffer with increasing MCC content [16]. Due to its limited solubility, the MCC tends to disperse in water rather than dissolve, which is why the hard capsule's surface is uneven. This was also reported by Hamdan [17].

Qualitative visual observation shows that increasing MCC concentration results in increased capsule opacity. This is likely due to a higher insoluble crystalline fraction. An increase in opacity in the presence of MCC was reported by Di Liberto for chitosan-MCC composite films [18].

3.5 Characterization of Capsule Shells

3.5.1 Weight Uniformity Test

The capsule shell weight test is to determine the thickness of the capsule shell. The standard weight of the

capsule shell is set by Farmakope Indonesia edition VI [14], which ranges from 87-107 mg. The test results show that only the capsule shell with a variation of MCC 4% complies with the standards.

Table 3. Result of the weight uniformity test

	Weight (gram)			
Testing	MCC 1%	MCC 4%	MCC 7%	MCC 10%
Average	0.0748	0.0938	0.1347	0.1877
Standard Deviation	0.0006	0.0016	0.0018	0.0018
Relative Standard Deviation (%)	0.8055	1.7240	1.3033	0.9323

Based on these results, it can be seen that the higher the concentration of MCC, the thicker and heavier the capsule shells. The higher concentration of MCC would increase the total solids in the solution. This makes the film thicker. Al-Tabakha reported that capsules made from a mixture of HPMC with carrageenan weighed 0.05735 g and 0.09392 g [19]. In addition, the thickness of the capsule shell is also affected by the dipping process. Manually making capsule shells causes irregular dipping and mold rotation, so that the thickness of the capsule shell obtained is uneven.

3.5.2 Water Content Test

Water content testing is needed to determine the resistance of the capsule shell to antimicrobial activity, especially bacteria. The higher the water content, the softer the capsule will be, causes bacteria to grow easily [3]. Water content decreased from 13.94% at 1% MCC to 13.11% at 10% MCC. Based on these results, it can be seen that the formulation of capsule shells affects the water content. The decrease in capsule water content as the MCC content increases is understandable because HPMC has higher hydrophilicity compared to MCC. In microcrystalline cellulose (MCC)/hydroxypropyl starch (HPS) composite films, the water content decreased 11.87±0.74% to 8.74±0.11% as the MCC content increased from 3% MCC/HPS to 9% MCC/HPS [20].

The water content of the capsule shell that meet the standard of the Farmakope Indonesia edition VI [14], is between 13-16%. The results show that all variations of the capsule shell have a water content that meet the standard.

Table 4. Result of water content test

Variation	MCC 1%	MCC 4%	MCC 7%	MCC 10%
Water content (%)	13.94	13.73	13.44	13.11

3.5.3 Ash Content Test

Ash content testing aims to show the amount of minerals contained and the purity of the capsule shell [3]. The presence of minerals in the capsule shell should be kept to a minimum. Ash content that is too high causes contamination that affects the mechanical properties and performance of the capsule. Based on the results, it can be seen that all variations of capsule shells have an ash content according to the standard of Farmakope Indonesia edition VI [14], which is not more than 5%.

Table 5. Result of the ash content test

Variation	MCC 1%	MCC 4%	MCC 7%	MCC 10%
Ash content (%)	3.13	1.35	1.66	1.36

3.5.4 pH Test

The pH value test was conducted to determine the acidity level of the capsule shell. The test results showed that all variations of the capsule shell had a pH of 6. This value meets the standard pH range of the Farmakope Indonesia edition VI [14], which is a pH value between 5-7.

3.5.5 Solubility Test

Water solubility testing is used to measure how quickly the capsule disintegrates into finer aggregates or particles. The capsule shell that is easily penetrated by water can cause the drug preparation inside to dissolve so that the bitter taste of the drug will be felt. According to the standard of Farmakope Indonesia edition VI [14], the solubility time of the capsule shell in water must be in the range of 15-30 minutes. This test was carried out at a

temperature of 37°C because it is considered the temperature of the human body [3]. The results showed that the capsule shell with a concentration variation of 4% and 7% followed the standard, with solubility of 19 minutes 49 seconds and 21 minutes 21 seconds, respectively. Capsules produced from 1% HPMC with the addition of NCC varying at 1%, 2%, 4%, and 7% required 30 minutes to disintegrate [13].

Meanwhile, acid solubility testing is carried out to determine the length of time the capsule shell can dissolve in human gastric fluid [3]. Testing was conducted on HCl solution at 37°C, which is considered as gastric fluid in the human body. The solubility time of the capsule shell in acid, according to the standard of Farmakope Indonesia edition VI [9], is not more than 5 minutes. The results show that the capsule shells with concentration variations of 1%, 4%, and 7% meet the standard, with solubility of 1 minute 44 seconds, 2 minutes 40 seconds, and 3 minutes 15 seconds, respectively.

Table 6. Result of solubility test

	Solubility Time	
Variation	In Water	In Acid Solution
MCC 1%	12 min 29 s	1 min 44 s
MCC 4%	19 min 49 s	2 min 40 s
MCC 7%	21 min 21 s	3 min 15 s
MCC 10%	31 min 58 s	5 min 47 s

Based on these results, it can be seen that the higher the concentration of MCC, the longer the solubility time in water or acid. This is because the higher concentration of MCC, the thickness of the capsule shell increases, so it takes longer to disintegrate. The MCC-HPMC capsules show promising potential as non-gelatin hard capsules. However, there are still shortcomings, for example the opacity of the capsules, which will limit the use of the capsules.

4. CONCLUSION

In this research, microcrystalline cellulose (MCC) has been synthesized from α-cellulose from solid sugar palm waste with the acid hydrolysis method. SEM results show that the formed crystalline celluloses are micron-scale. The FTIR spectrum shows the presence of functional groups -OH stretching, C-H, -CH2 symmetric, and C-O-C in the microcrystalline celluloses. The microcrystalline celluloses (MCC) can be formulated as a raw material in the production of gelatin-free halal capsule shells. The best results in this research were shown in the capsule shells, with the addition of HPMC 2% and PEG-400 2%, at 4% MCC concentration. All test results met the standards of Farmakope Indonesia edition VI [14]. The MCC 4% capsule shell weighs 0.0938 grams (93.8 mg), water content of 13.73%, ash content of 1.35%, pH of 6, water solubility time of 19 minutes and 49 seconds, and acid solubility time of 2 minutes and 40 seconds.

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