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The Utilization of Sugarcane Waste As an Alternative Material of Halal Hard Capsules Shell

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ABSTRACT

Capsules are dosage forms used to encapsulate powders, granules, pellets, liquids, and semi-solids. There are two types of capsules: soft capsules, which are usually used to encapsulate liquid and semi-solid formulas, and hard capsules, which are used to encapsulate solid formulas and non-aqueous liquids. This research aims to analyze the halal critical point of cellulose production and hard capsule shell from sugarcane waste and its handling solution, make sugarcane waste into quality halal cellulose according to pharmaceutical standards, and formulate halal cellulose into quality hard capsule shell according to pharmaceutical standards. Analyzed halal were done by material and procedure. Extraction cellulose by acetylation. Characterization of cellulose followed yield, viscosity, and swelling. Capsule shelll characterization followed size and disintegration time. This study concludes that the source of ethanol in capsule shell production is key to determining its halal status. The process must avoid using haram materials like pork, its derivatives, human body parts, khamr, blood, carrion, improperly slaughtered animals, and forbidden animals. Instead, sugarcane waste can be used to produce halal cellulose, which meets pharmaceutical standards and can be used to make hard capsule shells that are both halal and meet industry requirements.

Keywords*: Sugarcane waste, Cellulose, Capsule shell, Halal.*

INTRODUCTION

Capsules are a dosage form for encapsulating powders, granules, pellets, liquids, and semisolids. Capsules can be soft capsules, which are typically used to 'wrap' liquid formulas and semisolid formulations and hard capsules used to 'wrap' solid formulas and nonaqueous liquids (Seager, 1985; Cole, Cade, & Benameur, 2008).

Soft capsule shells are generally made from gelatin or non-gelatin polymers, water, non-volatile plasticizers, and other additives such as colorants. Hard capsule shells do not contain non-volatile plasticizers, but are harder (P.Gullapalli & L.Mazzitelli, 2017).

The quality of gelatin is highly dependent on its source, so not all of it can be used as raw material for hard capsule shells. Gelatin sourced from pigs has the best quality as a capsule shell material, but it is forbidden to use for Muslims, even though its production reaches 90% of the world's total gelatin (GMIA, 2012). The gel strength of pig gelatin (Sigma-Aldrich®) is 300 blooms. While gelatin sourced from cattle (Sigma-Aldrich®) has a gel strength of 225 blooms. However, European, Japanese and North American countries restrict the use of bovine gelatin because it is a carrier of mad cow virus (Jones & Podczeck, 2012).

Other sources of gelatin are chicken and fish, but the gel strength is not as good as bovine and porcine, less than 200 blooms (Irwandi Jaswir, 2009). Vegetarians, some of whom are Buddhists, also avoid gelatin because it comes from animals. With the exception of fish, halalness is not only determined by the type of animal, but also by the Islamic slaughter process.

Although the source of raw materials is halal, the process will use materials and processes that can contaminate the product to be non-halal (Razaly, Zakaria, Ismail, & Jusoh, 2016). Process analysis requires direct or indirect observation of the possibility of contaminants entering (Kamaruddin, Iberahim, & Shabudin, 2012; Riaz & Chaudry, 2003). Every stage from planting, manufacturing/synthesizing, and product manufacturing is scrutinized. An understanding of the fiqh postulates/texts becomes the 'key' of analysis.

This research aims to analyze the halal critical point of cellulose production and hard capsule shell from sugarcane waste and its handling solution, make sugarcane waste into quality halal cellulose according to pharmaceutical standards, and formulate halal cellulose into quality hard capsule shell according to pharmaceutical standards.

MATERIAL AND METHODS

Material

Sugarcane waste find out at PTPN XIV, Sugar Industry, Takalar, South Sulawesi.

Halal Analysis of Cellulose and Capsule Shell Manufacturing from Sugarcane Waste

This analysis aims to determine the critical points in the production of cellulose from sugarcane residue and hard capsule shell. Each phase is associated with the materials used and the ongoing process. Each material is then associated with the manufacturing process, regardless of whether they are non-halal materials. Fiqh studies were used to analyze each contaminated contact/process that was free of non-kosher materials. Each phase of the study uses only materials and procedures that guarantee a halal product.

Preparation of Sugarcane Waste

The bagasse was cut into ± 1 cm pieces, then washed with tap water until clean and rinsed with distilled water. The clean bagasse was then dried in a drying cabinet for 12 hours, followed by drying in an oven at 85°C for 16 hours. Next, the bagasse was pulverized with a blender little by little until it was completely smooth with a mesh of 18. The fine bagasse was dried again in an oven at 100°C for 6 hours (Andriyanti, Suyanti, Ngasifudin, 2012).

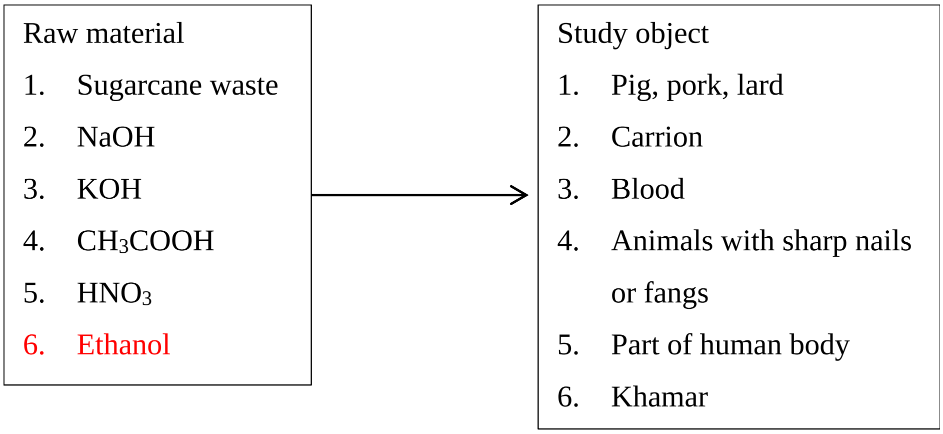


Figure 1. Critical point of halal analysis

Cellulosa Production

Cellulose production was carried out by the methods of Ferrer et al. (2017), where the resulting liquid has a nano size. Clean and dry sugarcane is dissolved in water ethanol (1:1), filtered. The residue is then dissolved with NaOH and washed. The residue was hydrolyzed again with H_2SO_4, the resulting mixture was then centrifuged to withdraw the nano-cellulose.

The nano-cellulose obtained was enhanced by acetylation through reaction with glacial acetic acid under acidic conditions (Shaikh, Pandare, Nair & Varma, 2009).

Cellulose Characterization

Cellulose characterization includes yields, viscosity, swelling, and FTIR. In this case, milkfish gelatin is used as the standard halal raw material for capsule shell.

Hard Capsule Shell Preparation

This stage only used samples with a viscosity of 35 cp and a gel strength of 200 blooms as raw materials. The hard capsule shell was prepared using the following formula at Table 1.

The ingredients in the formula were prepared in paste form, heated to 70°C until completely dissolved. The capsule size to be made is No. 2 to accommodate powder weighing about 250 mg. The paste was then made into capsule shells using a capsule molding machine.

Capsule Shell Characterization

Capsule shells were tested according to the standards of the Indonesian Pharmacopoeia

Table 1. Formulation of capsule shell

Material	F1 (%)	F2 (%)	F3 (%)
Modified Cellulose	30	-	-
HPMC	-	30	-
Fish Gelatin	-	-	30
Polyethilenglycol/ glycerol	10	10	10
Nipagin	0.12	0.12	0.12
Nipasol	0.03	0.03	0.03
Aquadest	ad 100	ad 100	ad 100

(1994). The parameters tested were size (including diameter, length and thickness) and disintegration time.

RESULTS AND DISCUSSION

This paper discusses the halalness of gelatin in medicine and food products, considering whether gelatin contains haram or unclean ingredients through its production process (Figure 1). A fiqh analysis is used to assess the halalness of gelatin based on the inputs and production process, and offers halal alternatives for the industry so as not to harm Muslim consumers.

Istiḥālah approach to argue that gelatin containing pork can be considered halal if the process changes it. The other hand between istiḥālah ṣaḥīḥah and istiḥālah fāsidah, concluding istiḥālah is relevant for food products, though not for gelatin (Jamaludin and Radzi, 2009).

Sayyid Muhammad Ridwan bin Sayyid Yusuf, et.al. (2018) analyzed gelatin and alcohol using the istiḥālah and istihlāk approaches, referring to the views of classical and contemporary scholars, but did not discuss in detail the production process of gelatin containing pork or unclean (Yūsuf, Ārif, and Zakariyya, 2018).

The prohibition of khamr is agreed upon by scholars based on the Qur'an and the Prophet's hadith, but further study is needed to analogize alcohol with khamr. Based on MUI's definition, alcohol is different from khamr. Alcohol is an organic compound that has a hydroxyl group (-OH) on the carbon atom, while khamr is an intoxicating drink made from wine or other ingredients, whether cooked or not, which is then termed as alcoholic beverages. Alcoholic beverages contain ethanol, an alcoholic compound with two carbon atoms, which is intoxicating, although alcohol can be present in various foods and beverages without being intoxicating if it is not ethanol. The intoxicating level of ethanol in a drink or food is the main cause of khamr, which is haram even if it does not cause intoxication, because the 'illat of intoxication is already present. Alcohol, unlike khamr, is not automatically haram and is lawful if it is not mixed with other intoxicating substances. However, if alcohol is mixed into an alcoholic drink, the ruling applies to the drink, not the alcohol. Alcohol used for other purposes, such as antiseptic (e.g. 70% alcohol), is permissible.

The basic principle of halal analysis for modern medicine and food industry products is based on the ushul rule which states that the original law of all things is halal, unless there is evidence that forbids it. This rule refers to the Prophet's hadith which states that Allah has justified and forbidden some things, while what is not mentioned is part of His mercy, not negligence. In the context of new products for which there is no shar'i guidance regarding their prohibition or harmful content, the basic law remains halal, as long as they do not contain or are contaminated with haram ingredients.

Table 2. Cellulose production

Sugarcane waste (g)	Cellulose (g)	Yield (%)
5	4.750	95 %

Table 3. Cellulose acetylation

Cellulose (g)	Cellulose acetat (g)	Yield (%)
2	0.901	45.075

After the halal analysis was carried out and all the materials used in this study were declared halal and had passed the halal critical point examination, the next process will be to make capsule shells from bagasse. During the process of workmanship still pay attention to the elements of halalness.

Cellulose obtained from 5 grams of bagasse was 4.750 g with a yield of 95% (Table 1). This is different from that reported by Mochtar and Tedjowahyono (1985) which was 40.3%. The difference in results is due to differences in extraction methods. In this study, the extraction results were hydrolyzed with acid while the method used by Muchtar and Tedjowahyono was fermentation.

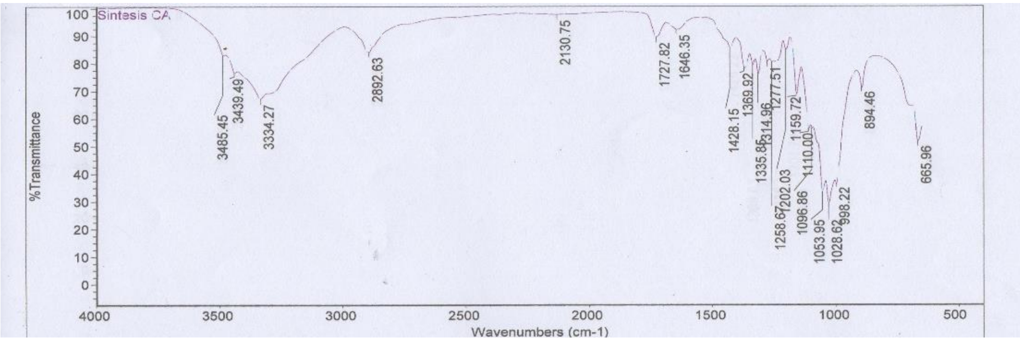
The cellulose obtained was then acetylated with glacial acetic acid under acidic conditions. The cellulose obtained was 0.901 g with a yield of 45.507% (Table 2). After the cellulose acetylation process decreased, it is suspected that the hemicellulose and lignin components in bagasse hydrolyzed into glucose which dissolved in the washing process. The breakdown of hemicellulose and lignin components into simpler compounds such as glucose can affect the production of cellulose produced.

Table 4. Characterization of cellulose

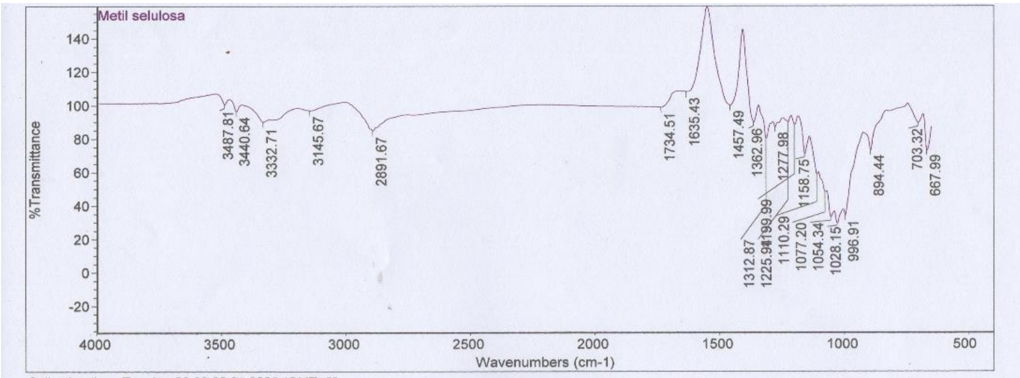
Characteristic	Result
Yield	73.7 %
Viscosity	7.8 cP
Swelling	120 g/g

Cellulose characterization includes yield value, viscosity, and development ratio were showed in Table 4. The values were 73.7%, 7.8 cP, 120 g/g, respectively. The high yield is indicated by the use of acid, where the acid penetrates quickly into the inner layers of the cellulose network and hydrolyzes the amorphous region of the cellulose chain. The viscosity of cellulose solution is related to the ability of cellulose to bind water, viscosity is also influenced by the chain length or degree of polymerization (DP) of cellulose. The higher the DP value of cellulose, the higher the viscosity of cellulose. Swelling occurs when crosslinked cellulose is placed in a liquid that is a solvent of non-crosslinked cellulose until it reaches equilibrium between the solvent and cellulose. The swelling ratio is one of the parameters of the physical properties of a sample. The tighter the structure of the film, the more difficult the diffusion of water into the film. The smaller the development ratio, the more prominent the hydrophobicity.

The infrared spectrum characterization process can be seen in Figures 2. The spectrum of acetylated cellulose was compared with the spectra of HPMC and milkfish gelatin. In Figures 2, specific cellulose groups appear in standard cellulose, namely -OH, -CH2, -O- groups that appear repeatedly. The -OH group appears at a wave number of 3348.42 cm^{-1},



a



b

Figure 2. FTIR profile of cellulose acetate (a) and HPMC (b).

while the wave number 2900.94 cm^{-1} shows the CH2 stretching vibration which is the main framework for building cellulose compounds reinforced by vibrations at wave number 2366.59 cm^{-1}. The -O- group that assembles cellulose appears at wave numbers 1319.31 and 1373.32 cm^{-1}.

Figures 2 show the similarity of FT-IR spectra of acetylated cellulose with milkfish gelatin. While the FT-IR spectra profile of acetylated cellulose is slightly different from the spectra profile of HPMC. In the FT-IR spectra profile of sugarcane bagasse, vibrations appear at a wave number of 1512.19 cm^{-1} which is a C=C stretching vibration that indicates the presence of lignin compounds. The presence of hemicellulose compounds is also indicated by the appearance of vibrations at a wave number of 1720.50 cm^{-1} which is a stretching vibration of acetyl or ester groups in hemicellulose compounds. The absence of vibrations at wave numbers 1509-1609 cm^{-1} and 1700-1740 cm^{-1} in the FT-IR spectra profile of HPMC indicates the absence of lignin and hemicellulose compounds in the extraction results.

The capsule shell was formulated using 3 different types of materials, namely acetylated cellulose from bagasse (F1), HPMC (F2), and milkfish gelatin (F3). The additional ingredients of the capsule shell include polyethilenglicol / glycerol as a plasticizer that makes the capsule shell elastic and not easily torn, nipagin and nipasol as preservatives and distilled water as a solvent.

The results of measuring the specifications of each capsule shell formula can be seen in Table 12. The results of measuring the length of capsule shells F1, F2, and F3 were 28.68, 27.95, and 28.88 mm, respectively. For the diameter of the capsule shell F1, F2, and F3 were 7.25, 7.21, and 7.28 mm, respectively. The measurement results of capsule shell length and diameter in this study were almost all close to the length and diameter of commercial capsules.

Thickness measurement was carried out on the capsule as a whole. Capsule shell thickness was measured using a micrometer. The results of capsule shell thickness measurement for F1, F2, and F3 were 0.105, 0.108, and 0.107 mm, respectively. The factor that affects the thickness of the capsule shell is the uneven dipping process of the mold, but in this study, the results of measuring the thickness of the capsule shell in this study are almost all close to the thickness of the commercial capsule shell.

CONCLUSION

The conclusion of this study shows that the source of ethanol in the production of capsule shells is a critical factor related to the halalness of the product. The capsule shell manufacturing process must avoid the use of haram materials such as pork, its derivatives, human body parts, khamr, blood, carrion, animals that are not slaughtered according to Sharia, as well as forbidden animals such as carnivores, disgusting animals, and amphibians. Alternatively, sugarcane waste can be processed into halal cellulose that meets the standards of pharmaceutical requirements, and the cellulose can be used to produce hard capsule shells that also meet halal standards and pharmaceutical requirements.

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