

CHAPTER 1

INTRODUCTION

1.1 Research Background

Capsules are medicinal preparations consisting of active compounds in hard or soft shells that can dissolve in water. one of the ingredients that serves as a gelling agent to make capsules is gelatin. Gelatin is obtained from the denaturation and hydrolysis of animal bones, muscles or muscle membranes which include a type of macromolecular protein that can dissolve in water¹. In Indonesia, gelatin needs still depend on the import sector from other countries. Based on BPS data (2023) the amount of gelatin imports until November reached 2.45 million kg with a value of 20.77 million USD².

Gelatin Manufactures of Europe (GME) states that almost 80% of gelatin produced comes from pigskin, 15% from cattle skin, and 5% from cattle and fish bones³. Gelatin from pigs is a polemic on the aspect of halalness, because for Muslims it is forbidden to consume pigs or parts of their bodies including gelatin. Based on this in accordance with the word of Allah, namely:

إِنَّمَا حَرَّمَ عَلَيْكُمُ الْمَيْتَةَ وَالدَّمَ وَلَحْمَ الْخِنْزِيرِ وَمَا أُهْلِيَ بِهِ لِغَيْرِ اللَّهِ ۖ فَمَنْ اضْطُرَّ غَيْرَ بَاغٍ وَلَا عَادٍ فَلَا إِثْمَ عَلَيْهِ ۗ إِنَّ اللَّهَ غَفُورٌ رَحِيمٌ

“*Verily, Allah has only forbidden to you carrion, blood, pork, and animals which (when slaughtered) are called by names other than Allah. But whoever is compelled to eat them and does not desire to do so, nor does he transgress the limits, there is no sin on him. Indeed, Allah is Forgiving and Merciful.*”⁴

¹ Xin Feng et al., 2022, A Green Extraction Method for Gelatin and Its Molecular Mechanism, Food Hydrocolloids 124 (March 1, 107344, <https://doi.org/10.1016/J.FOODHYD.2021.107344>).

² Erin Apriliani Wulandari Putri et al., “The Effect of NaOH Concentration and Soaking Time on The Characteristics of Striped Catfish (*Pangasianodon Hypophthalmus*) Skin Gelatin,” *Jurnal Pengolahan Hasil Perikanan Indonesia* 26, no. 1 (2023): 117–26, <https://doi.org/10.17844/jphpi.v26i1.45489>.

³ Fauzan Amin and Desi Nur Alam, “Karakterisasi Dan Pembuatan Cangkang Kapsul Keras Dari Ekstrak Daun Cincau Hijau (*Premna Oblongifolia* Merr),” *Jurnal ITEKIMA* 8, no. 2 (2020): 2548–2947.

⁴ Quran, “Surah Al-Baqarah Ayat 173,” Quran.com, 2024, <https://quran.com/id>.

The need for halal capsule shells with vegetable-derived raw materials is an alternative to gelatin. One of the requirements that must be met is biodegradable and biocompatibility. Natural polymers that have the potential to make capsule shells are starch (amylum), which has glucose homopolymers and a-glycosidic bonds consisting of two fractions, namely amylopectin and amylose⁵. Amylopectin has poor flow properties and compressibility, because it has granular properties that expand, but has good binding properties.⁶

One of the materials that contain starch (amylum) and can be utilized to make halal capsule shells is durian skin. Durian skin is waste and can cause unpleasant odors and become a source of disease if not processed properly. Its utilization into materials to make halal capsule shells is one alternative to processing the waste. This is because durian skin contains 15.45% lignin fiber, 13.09% hemicellulose, 60.45% cellulose⁷ and pectin which is quite high at 2.56%⁸. However, the amylopectin content of durian peel is still not strong enough to form a gel, so a combination polymer is needed. *Eucheumma cottonii* (*E. cottonii*) carrageenan is one of the alternatives chosen to be combined with durian peel amylopectin because it has a high polysaccharide content, sturdy gel content, and high gel strength⁹, and yield of 43.42% so that carrageenan can be used as edible film while starch serves as an emulgator to stabilize carrageenan which forms gelation¹⁰.

The manufacture of capsule shells from cassava starch and *E cottonii* carrageenan has been carried out previously by Christi (2016) which resulted in capsule shells that did

⁵ G Jeni Christi A, Laksmi Ambarsari, and Heri Purwoto, "Optimasi Formula Film Berbasis Amilopektin Pati Singkong Dan Karagenan Sebagai Bahan Baku Cangkang Kapsul," *Current Biochemistry* 3, no. 1 (2016): 20–32, <http://biokimia.ipb.ac.id>.

⁶ Sansan Kadarusman, "Pembuatan Dan Karakteristik Komposit Polimer Dengan Bahan Pati Garut-Karagenan Sebagai Cangkang Kapsul Halal" (Universitas Islam Negeri Sunan Gunung Djati, 2022).

⁷ S Rahmawati et al., "The Utilization of Durian Peels (*Durio zibethinus*) for the Manufacturing of Charcoal Briquettes as Alternative Fuel," *JPSL (Journal of Natural Resources and Environmental Management)* 13, no. 1 (2023): 76–87, <https://doi.org/10.29244/jpsl.13.1.76-87>.

⁸ Dewi Susanti et al., "Pelarut Terbaik Dalam Pembuatan Pektin Dari Limbah Albedo Durian (*Durio Zibethinus Murray*) Dengan Menggunakan Metode MAE (*Microwave Assisted Extraction*)," in *Prosiding SNST Ke-6* (publikasiilmiah.unwahas.ac.id, 2015), 23–, https://publikasiilmiah.unwahas.ac.id/index.php/PROSIDING_SNST_FT/article/view/1090.

⁹ Emi Erawati et al., "Drug Release Kinetics of Capsule Shells from Seaweed Carrageenan Extract (*Eucheuma Cottonii*) and Potato Starch as a Gelling Agent," *Bulletin of the National Research Center*, 2023, <https://doi.org/10.1186/s42269-023-01045-6>.

¹⁰ Muhammad Ryan Nurshodiq, yuli Darni, and Edwin Azwar, "Application of Chitosan as an Antimicrobial In Carrageenan-Based Capsule Shell from Seaweed," *Jurnal Baliambangan* 10, no. 1 (April 2022).

not meet commercial standards so that it was necessary to add other excipients such as glycerin and sucrose¹¹. Based on this research, this study utilizes amylopectin from starch from durian skin combined with E. cottoni carrageenan with the addition of glycerin and sucrose to obtain a halal capsule shell that is in accordance with PT Kapsulindo Nusantara and Pharmacopeia Edition V in 2014.

1.2 Research Problems

The problem formulations in this study are:

1. What are the results of the evaluation of halal capsule shell preparation from the combination of durian skin amylopectin and E. cottoni carrageenan?
2. Which capsule shell formulation best meets the standards of PT Kapsulindo Nusantara and Pharmacopoeia V Edition 2014?

1.3 Research objectives

The objectives of this study are:

1. Knowing the results of the evaluation of halal capsule shell preparations from a combination of durian skin amylopectin and E. cottoni carrageenan and the results of the evaluation of preparations.
2. Knowing the results of capsule shell formulation from a combination of durian skin amylopectin and E. cottoni carrageenan that meets the standards of PT Kapsulindo Nusantara and Pharmacopoeia Edition V in 2014

1.4 Reseach benefits

1. Theoretical benefits

The results of this study can be used as reference material for research, add to the repertoire of science and add insight to readers, especially in the manufacture of halal capsule shells from durian skin amylopectin formulations and E. cottoni carrageenan.

2. Practical benefits

The results of this research are expected to reduce durian peel waste and accumulate in the community, as well as help the industry.

¹¹ G Jeni Christi A, Laksmi Ambarsari, and Heri Purwoto, "Optimasi Formula Film Berbasis Amilopektin Pati Singkong Dan Karagenan Sebagai Bahan Baku Cangkang Kapsul," *Current Biochemistry* 3, no. 1 (2016): 20–32, <https://repository.ipb.ac.id/handle/123456789/78955>.

1.5 Authenticity Research

Research on the utilization of natural materials for capsule shells has been researched in the table below as shown in the table below 1:

Tabel 1. Originality of research

| Research Title | Research Methods | Variable | Result | Research Differences |
|--|-------------------------|--|--|---|
| Characterization and manufacture of hard capsule shells from green grasshopper leaf extract (<i>Premna oblongifolia</i>) ¹² | Ekperimental Laboratory | Dependen: Characteristic s of capsule shells. Independen: Pectin concentrator of green grasshopper leaves | The characteristics of the green grasshopper leaf pectin capsule shell were produced with varying weights: capsule shell A (500 mg), and crush time 19 minutes 55 seconds, capsule shell B (400 mg) and crush time 18 minutes 50 seconds, and capsule C shell (300 mg) and crush time 17 minutes 01 seconds. The results of the study also showed that capsule shells A, B, C had material properties that were not similar and different from gelatin capsule shells. | Dependen: Characteristics of capsule shells Independen: Durian peel starch and carrageenan concentrators |
| Formulation of capsule shells from a combination of carrageenan and pectin of apples using the <i>Design of Experiment approach</i> | Ekperimental Laboratory | Dependen: Characteristic s of capsule shells Independen: Percentage of apple pectin, carrageenan, and glycerin levels | The results of Optimization for capsule weight of 0.47 grams, durability of 1148.4 seconds, acid solubility of 308.4, and viscosity eleven of 1135.7 so that the recommended solution is quite good. | Dependen: Characteristics of capsule shells Independen: Durian peel starch and carrageenan concentrators |
| Optimization of Film Formulation Based on Amylopectin, Cassava Starch and Carrageenan as Raw Materials for Capsule Shells ¹³ | Ekperimental Laboratory | Dependen: Characteristic s of capsule shells Independen: Percentage of cassava starch and carrageenan | The optimization results of amylopectin and carrageenan cocentrased formation in formula 6 was 1.01%. at fomulas 28, which is 3% and 2%. Thus, causing the capsules formed in formula 28 to be sturdier and harder. With an aiq content of 17.67%, an ab content of 7.78%, it | Dependen: Characteristics of capsule shells Independen: Durian peel starch and carrageenan concentrators |

¹² Amin and Alam, "Karakterisasi Dan Pembuatan Cangkang Kapsul Keras Dari Ekstrak Daun Cincau Hijau (*Premna Oblongifolia Merr*)."

¹³ A, Ambarsari, and Purwoto, "Optimasi Formula Film Berbasis Amilopektin Pati Singkong Dan Karagenan Sebagai Bahan Baku Cangkang Kapsul," 2016. A, Ambarsari, and Purwoto, "Optimasi Formula Film Berbasis Amilopektin Pati Singkong Dan Karagenan Sebagai Bahan Baku Cangkang

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|--|-------------------------|--|---|--|
| Synthesis and Characteristics of non-gelatin capsule shells from aloe vera (<i>Aloe vera</i>) and carrageenan ¹⁴ | Ekperimental Laboratory | <p>Dependent: Characteristics of capsule shells</p> <p>Independent: Percentage of aloe vera and carrageenan</p> | <p>does not meet the standards of commercial capsule shells</p> <p>F1 capsule shell test results 15 minutes 54 seconds, 22 minutes 08 seconds, 23 minutes 42 seconds.</p> <p>Average capsule shell weight F1 300.2, F2 299.7, F3 300.2 mg,</p> | <p>Dependent: Characteristics of capsule shells</p> <p>Independent: Durian peel starch and carrageenan concentrators</p> |
| Formulation and characteristics of banana bongol (<i>Musa paradisiaca L</i>) as raw material for making capsule shells combined with carrageenan ¹⁵ | Laboratory Experiments | <p>Dependent: Characteristics of capsule shells</p> <p>Independent: Durian peel starch and carrageenan concentrators</p> | <p>The results of the capsule shell test characteristics the capsule shell obtained had a capsule length specification of 18.21–18.95 mm and cap 11.25–11.83 mm, body diameter 7.21–7.28 mm and cap 7.23–7.63 mm, volume 0.60-0.66 mL, thickness 0.123-0.206 mm, capsule weight 0.1227-0.1545 g. capsule shell crushing time 13–21 minutes.</p> | <p>Dependent: Characteristics of capsule shells</p> <p>Independent: Durian peel starch and carrageenan concentrators</p> |

Kapsul,” 2016.A, Ambarsari, and Purwoto, “Optimasi Formula Film Berbasis Amilopektin Pati Singkong Dan Karagenan Sebagai Bahan Baku Cangkang Kapsul,” 2016.

¹⁴ Micha Mahardika et al., “Synthesis and Characterization of Capsule Shells Non Gelatin Grass Jelly Leaves-Seaweed as Drug Delivery System Material Article History,” *Jurnal Pendidikan Kimia* 13, no. 1 (2021): 1–9, <https://doi.org/10.24114/jpkim.v13i1.24138>.

¹⁵ Nurminah, "Formulation and Characterization of Starch of Banana Kepok (*Musa paradisiaca L*) as a Raw Material for Making Capsule Shells Combined with Carrageenan," *Repositoty* 1965 6, no. 1 (2019): 5–10.