Effect of Added Pectin and Microcrystalline Cellulose (MCC) on Capsule Shell Quality

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Abstract

The objective of this study was analyzing the effect of the added pectin and microcrystalline cellulose (mcc) on the capsule shell quality. The method used in this study was by combining the pectin and microcrystalline cellulose composition on capsule shell manufacture. The formulation used to test the capsule shells was through 1 gram,2-gram, 3 grams of pectin; 0 gram and 1.5 gram of microcrystalline cellulose; 1 gram of glycerol; and, 1 gram of carrageenan. The experiment tests used in this study were through the organoleptic test, the capsule weight test, the moisture test, the pH test, the dissolution time test, and the capsule-length test. The result of this study showed that the recommended formulation used to manufacture the hard capsule shells was through 3-gram pectin and 1.5-gram microcrystalline cellulose. The required temperature to heat the pectin and microcrystalline cellulose was at 90ºC with 2.5-hour heating time. The characteristics of the manufactured capsule shells were that it had a turbid colour and irregular shape, the surface was not smooth and the disintegration time was 9 minutes and 21 seconds.

Keywords: ***c****apsule shell, microcrystalline cellulose, pectin, variation, testing.*

I. INTRODUCTION

CAPSULES were the small tubes made of the water-soluble substances containing the medicinal powders. [1] According to the Ministry of Health of the Republic of Indonesia 1995, capsules were the solid preparations consisting of drugs contained in the hard or soft shells that were able to be dissolved. Capsules were generally not only made of gelatin but also of starch or suitable ingredients. The main ingredient to make gelatin came from the skin and bones of animals i.e., cows and pigs.

One of the natural ingredients that were able to be used as a basis for manufacturing capsule shells was pectin. Pectin had many benefits and was considered as an adhesive or thickener on jams and jellies. Pectin was the ingredient classified into the carbohydrate group, aside from starch, alginate, arabic gum, and other carbohydrate modifications, so that pectin was used as an alternative ingredient for making hard gelatin capsules. Another ingredient for making capsules was microcrystalline cellulose (MCC). Microcrystalline cellulose (MCC) was the result of hydrolysis of the a-cellulose process using aqueous acid solution so that it was able to reduce fragility and to increase the flexibility and resistance of the fillers [2]. Therefore, the experiment was conducted in this study to manufacture capsule shells using plant-based ingredients by combining the composition of MCC and Pectin.

The research sed the oil palm empty fruit bunch as microcrystalline cellulose and the sodium alginate for manufacturing the capsule shells with 5:5 concentrations. It showed that the tensile strength was 6,713 MPa, the extension percentage was 16.135%; and, the elasticity modulus was 44,165 MPa. The result of SEM showed that MCC was evenly distributed in sodium alginate. The result of a stability test in a room temperature was that the capsule shell colour did not change and fragile, the moisture content was 23.83%, the disintegration time with the discs was 11.33 minutes and without discs was 12.55 minutes with which the acid test was pH 6.8 at 40ºC. Therefore, it was concluded that the oil palm empty fruit bunch was considered as the microcrystalline cellulose that was not only able to be used as a blurring ingredient for manufacturing capsule shells but it also had a stability being put in the room temperature of 25ºC and 40ºC [3].

The explained that the pectin flour made of Theobroma cacao l with which the best formulation of pectin was 0.78%, carrageenan was 5%, aquades was 94.22% was able to manufacture capsule shell with 15 minutes disintegration time, 96.30 mg of capsule weight, 22.05 mm of capsule length, 7.24 mm of body diameter, and 7.65 mm of cap diameter. The characteristics of the capsule shells were brown and murky, odorless, and had a hard texture [4].

In this study, pectin and microcrystalline cellulose were used to manufacture the capsule shells as an alternative to gelatin capsules. Microcrystalline cellulose was an additive or excipient commonly used in pharmaceuticals, mainly used as fillers, binders, lubricants, and disintegrants on the tablet and capsule formulas. Microcrystalline cellulose (MCC) was the result of hydrolysis of a-cellulose process using aqueous acid solution and glycerol as plasticizer so that it was able to reduce fragility and to increase the flexibility and resistance of the fillers by adding the carrageenan as stabilizers, thickening agents, gel forming, emulsifier, and the others [2].

II. Materials and Methods

The materials used in this study were pectin, avicel® PH 101, carrageenan, glycerol, aquades, 200 ml and 100 ml measuring cups, digital balance, petri dish, zip bag lock, molds, 1ml dropper pipette, stopwatch, and water bath.

The methods were preparing (1 gram, 2 gram, 3 gram) pectin; (0 gram and 1.5 gram) microcrystalline; 1 gram glycerol; 1 gram carrageenan; and, 200 gram aquades. All of these ingredients, afterwards, were stirred well until it turned to be a thick solution. Then, they were put in a water batch and heated at 90°C in 2.5 hours. Subsequently, the solution was molded into a form of capsule shell and dried at room temperature. Accordingly, the testings were conducted i.e., the organoleptic capsule shell test, the disintegration time test, the capsule shell specification test, the water content test, and the acidic (pH) test.

III. Results and Discussions

A. Organoleptic Test

The characteristics of commercial capsule shells were odorless, had smooth surface and regular shape, and had plastic properties. However, the results of this organoleptic test showed that the capsule shells were turbid, odorless, irregular, hard, and not smooth. The capsule shells were turbid and not smooth because MCC was hygrocopically insoluble but burgeoning while they were contacted with water. The recommended formulation used in this study was 3gram pectin and 1.5gram MCC.

B. Acid (pH) Test

The level of acidity of capsule shells was in the range of 5 to 7 [5]. The result of this pH test in this study was shown in table 1 below.

Table 1. pH Test

MCC (gram)	Pectin (gram)	pH
0	1	6
	2	6
	3	6
1.5	1	6
	2	6
	3	6

The result of this experiment showed that there were 6 similar pH because the ingredients used in this study were relatively neutral.

C. Disintegration Time Test

According to the Indonesian Pharmacopoeia 5th Edition, a good disintegration time was no more than 15 minutes. This test was carried out using the disintegrated device. The result of this disintegration time test was shown in table 2 below.

Table 2. Disintegration Time Test

MCC (gram)	Pectin (gram)	Disintegration Time
0	1	14 minutes 15 seconds
	2	14 minutes 43 seconds
	3	15 minutes 10 seconds
1.5	1	9 minutes 58 seconds
	2	9 minutes 45 seconds
	3	9 minutes 21 seconds

According to the table above, the 1.5 gram-added MCC made the disintegration time lesser than 10 minutes. This was because MCC was disintegrant or dissolver. In other words, the disintegrant worked by pulling water into the capsule so that the capsule expanded and caused the capsule to burst. Moreover, pectin was able to be dissolved in water so that disintegration process was successfully.

D. Capsule Shell Specification Test

The specifications of observed capsule shells were seen on their length and weight. The type of the capsule used in this study was capsule with 0 size which ranged from 21 mm to 22 mm. The result of this length test was shown in table 3 below.

Table 3. Length of Capsule After Locking

MCC (gram)	Pektin (gram)	Length of Capsule after Locking (mm)
0	1	21.2
	2	21.7
	3	21.9
1.5	1	19.1
	2	23.5
	3	21.1

The result of this analysis on the length specification manually showed the different result.

The weight of the 0-sized capsule shells was in the range of 87 mg - 105 mg. The following result was based on their respective composition as it was shown in table 4.

Table 4. Weight of Capsule Shells

MCC (gram)	Pectin (gram)	Capsule Weight (mg)
0	1	79
	2	95
	3	96
1.5	1	90
	2	98
	3	102

According to Table 4, the 1.5 gram-added MCC was heavier than 0 gram MCC. This was because the MCC was regarded as the filler so that its weight and volume had to be added into the mixture. The added pectin also affected the weight of the capsule shells because the pectin was used as the gelling agent that was able to increase viscosity so that it slowed the flow of the liquid. Moreover, the thickness of the capsule was also affected by the dyeing and rotating mold process after dyeing. The irregular-rotating mold produced uneven capsule shell thicknesses. Besides, the manual manufacturing process of capsule shell produced different thicknesses [6].

E. Moisture Test

Commercial capsule shells had a moisture content ranging from 12.5% - 15% (PT. Kapsulindo Nusantara, 2019). The result of this experiment using 0 gram and 1.5 gram-added MCC did not show the differences from each other. This is due to the moisture content modification in the capsule shells during the keeping process.

The capsule shells would be softer and easily overgrown by microbes on condition that they were kept in humid conditions shells would be more fragile on condition that they were kept in a very dry condition. The result of this moisture test was shown in table 5 below.

Table 5. Moisture Test results

MCC (gr)	Pectin (gr)	Moister Test (%)
0	1	14.77
	2	13.82
	3	14.18
1.5	1	13.58
	2	14.23
	3	13.69

IV. CONCLUSIONS

The formulation recommended for manufacturing the hard capsule shells was through 3-gram pectin and 1.5 gram added microcrystalline cellulose heated at 90oC with a 2.5-hour heating time. The characteristics of the manufactured capsule shells were that it had a turbid color and irregular shape, the surface was not smooth and the disintegration time was 9 minutes and 21 seconds. The further study is necessarily considered to be carried out by paying attention to the varied ingredients with low-freezing characteristics of hydroxypropyl methylcellulose (HPMC).

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