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FILM COATING FORMULATION FROM AMYLOPECTIN PLAINTAIN PEEL STARCH (Musa paradisiaca L.) AS A COATING FOR MEFENAMIC ACID DRUG

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ABSTRACT

Mefenamic acid is an anthranilic acid derivative drug that is widely used by the public as one of the drugs of choice for analgesic, anti-inflammatory, and antipyretic treatment. Mefenamic acid has side effects on the gastrointestinal tract, including dyspepsia, irritation of the gastric mucosa, and diarrhea. In this research, the method used was caplet coating, followed by evaluation tests for core caplets and coated caplets which included organoleptic tests, hardness tests, firmness tests, size uniformity tests, weight uniformity tests, disintegration time tests, coated caplet weight increase tests, dissolution tests, test the water content of coated caplets. The results of this research show that plantain peel starch amylopectin can be used as a thin coating and enteric coating or coating film, namely with the characteristic organoleptic test results, namely the form of a fine powder-like flour, odorless, white, and without foreign objects, an ash content of 1.3%, water content of 4.6%. Amylopectin plantain peel starch, caplet hardness obtained in formula 1 was 7,927 kg, formula 2 was 8,705 kg, formula 3 was 8,1668 kg, formula 1 caplet hardness test was 0.47%, formula 2 was 0.1%, formula 3 was 0.6%, size uniformity test meets the requirements, average weight uniformity test also meets the requirements, disintegration time test for formula 1 gastric medium 3 minutes, formula 2 gastric medium 5 minutes, formula 3 intestinal medium 1.20 minutes, dissolution test for F1 within 120 minutes it reached 60.75%, F2 was 52.35%, F3 was 7.9% and in the medium intestine within 210 minutes F1 was 57.95%, F2 was 101.63% and F3 was 76.62%.

Keywords: *Plantain peel starch, amylopectin, coated caplet*

ABSTRAK

Asam mefenamat adalah obat yang banyak digunakan oleh masyarakat sebagai salah satu obat pilihan untuk pengobatan analgesik, antiinflamasi dan antipiretik. Asam mefenamat mempunyai efek samping terhadap saluran cerna seperti dispepsia, iritasi mukosa lambung dan diare. Pada penelitian ini metode yang digunakan adalah penyalutan kaplet serta uji evaluasi kaplet inti dan kaplet salut. Hasil penelitian ini menunjukkan bahwa amilopektin pati kulit pisang raja dapat dijadikan sebagai salut lapis tipis serta enterik atau film coating yaitu dengan hasil karakteristik uji organoleptik serbuk halus seperti tepung, tidak berbau, berwarna putih dan tidak ada benda asing, kadar abu sebesar 1.3% dan kadar air 4,6%. Amilopektin pati kulit pisang raja kekerasan kaplet yang diperoleh pada F1,F2 dan F3 masing-masing yaitu sebesar 7.927 kg, 8.705 kg dan 8.1668 kg, uji keregasan kaplet F1, F2 dan F3 masing-masing sebesar 0,47%, 0,1%, dan

0,6%, uji keseragaman ukuran dan uji keseragaman bobot rata-rata memenuhi syarat, uji waktu hancur masing-masing di medium lambung F1 dan F2 yaitu 3 menit dan 5 menit, F3 dimedium usus 1.20 menit, uji disolusi untuk F1,F2 dan F3 masing-masing dalam waktu 120 menit mencapai 60.75%, 52.35%, 7.9% dan dimedium usus dalam waktu 210 menit untuk F1,F2 dan F3 masing-masing yaitu 57.95%, 101.63% dan 76.62%.

Kata kunci: Pati kulit pisang raja, amilopektin, kaplet salut

INTRODUCTION

Banana peels also have many benefits but are not widely used by the public. Banana peel can relieve pain in burns, overcome itching in the skin, treat warts, speed up the healing of wounds that have begun to dry, and fertilize the soil (as fertilizer). Banana peels are even used to purify water and filter heavy metals, especially lead (Pb) and copper (Cu) (Adhayanti et al., 2018). In general, banana peels are often used as waste by the community. To reduce this waste, it turns out that banana peels can be used as a base material for coated films (Alzate Acevedo et al., 2021).

One of the basic ingredients for making coated films is starch, especially amylopectin. The composition of amylose and amylopectin varies from plant to plant. The starch content of plantain peel is higher than other banana peels (Marta et al., 2022). The composition of starch in banana peel waste is estimated at 59% and can be obtained optimally by forming banana peel flour. Starch is a carbohydrate that is distributed in plants, especially plants that contain chlorophyll (Alzate Acevedo et al., 2021). Naturally, starch is a mixture of amylose and amylopectin. The composition of amylose and amylopectin varies with each plant (Melani et al., 2019). Amylopectin is a branched chain polymer with α-(1,4)-glucosidic bonds and α-(1,6)-glycosidic bonds at the branching sites. Each branch consists of 25-30 units of D-glucose (Amaraweera et al., 2021). Apart from differences in structure, polymer chain length, and type of bond, amylose and amylopectin have differences in terms of their acceptance of iodine. Amylopectin and amylose have different physical properties. Amylose is more soluble in water than amylopectin (Vamadevan & Bertoft, 2020). Amylopectin is a giant molecule and easy to find because it is one of the two compounds that make up starch, together with amylose (Vamadevan & Bertoft, 2020). Even though it is composed of the same monomer, amylopectin is different from amylose, which can be seen in its physical characteristics. Structurally, amylopectin is formed from glucose chains linked with 1,4-glycosidic bonds, the same as amylose (Reddy et al., 2015). In this study, the drug that will be coated is mefenamic acid.

Mefenamic acid is a weak acid with a pKa of 4.2 and is practically insoluble in water, but has good permeability to the intestinal membrane (Li et al., 2022). It is included in the Biopharmaceutical Classification System (BCS) class II drug class, namely low solubility and high permeability, so it has a high absorption capacity but a low dissolution rate (Lubach et al., 2013). Caplet coating is a technology that has developed in the pharmaceutical field (Kapoor et al., 2020). The purpose of caplet coating is to cover the unpleasant taste, smell, and color of the drug and make it easier for the patient to swallow the caplet. Apart from that, coated caplets can also maintain drug stability such as protecting the drug from moisture, oxygen, and light (Felton & Porter, 2013).

One of the basic ingredients for making coating films is starch, especially amylopectin, and plantain peel is one source of starch that can be obtained. The resistant starch content of plantain is 30.66%. The composition of amylose and amylopectin varies from plant to plant. The starch content is higher than other banana peels. The starch composition of banana peel waste is estimated to reach 59% and can be obtained optimally by forming banana peel flour (Melani et al., 2019). Based on the above background, a coating film formulation will be carried out using plantain peel starch amylopectin to coat the drug mefenamic acid.

METHOD

The method used in this research is an experimental method. This research design includes sampling, peeling, washing, grinding plantain skin, soaking, drying plantain peel starch and grinding it to

powder, starch characteristics test, amylopectin isolation with iodine and functional group analysis using FTIR, making coating films from amylopectin plantain peel starch (Musa paradisiaca L.) and evaluation test of mefenamic acid core caplets before being coated with coating film and after being coated.

Sample Collection
Sampling was carried out purposively, that is, without comparing samples taken from different places with the same sample. The sample used in this research was plantain peel.

Extraction of Starch from Plantain Skin
Extracting the starch content from banana peels is done by peeling the bananas and separating them from the skin, then 1 kg of banana peel is cut into small pieces. Then add water in the ratio of 1 kg banana peel: 2 liters of water then blend. Filtering is carried out using a filter cloth until dregs and liquid (starch suspension) are obtained. The dregs obtained from the filtering process are added to water (1 kg of dregs: 1 liter of water) then blended again, then filtered to obtain starch. Mix the liquid starch obtained from the first and second filtration and then settle for 1 hour, then the water resulting from the settling is discarded to obtain wet starch. The starch obtained is then dried in the sun and then dried in an oven at a temperature of 60ºC for 13 hours. After drying, the starch is ground with a blender and sieved, so that fine granulated plantain peel starch is obtained (Melani et al., 2019).

Isolation of Amylose and Amylopectin from Plantain Peel Starch with Modification
Amylopectin isolation was carried out by mixing carapati with distilled water, stirring, and then heating at 50°C for 120 minutes. The resulting precipitate is amylopectin and amylose which dissolve with water in the form of a solution above the precipitate is discarded and the precipitate is allowed to stand and then dried in an oven at 50º C for 24 hours to produce amylopectin powder (Hidayat et al., 2022).

Characteristics of amylopectin powder
The characteristics of amylopectin powder include organoleptic tests, water content tests, ash content tests, solubility tests, and functional group analysis of amylopectin powder using FTIR and iodine tests (Depkes, 1979; Pulungan et al., 2022).

Making the Salute Caplet
The process of preparing plantain peel starch coating medium
A certain amount of amylopectin was added little by little into a beaker containing some water while stirring using a homogenizer at low speed for 15 minutes. In a separate place, a suspension was made from other additional substances, namely talc, titanium dioxide, polyethylene glycol 6000, dye, and water using a homogenizer for 20 minutes. The suspension (2) was added to the mixture (1) and stirred again for 5 minutes at low speed (Santoso, 2019).

The process of preparing the comparison coating medium
A certain amount of PVA was added little by little into a beaker containing some water while stirring using a homogenizer at low speed for 15 minutes. In a separate place, a suspension was made from other additional substances, namely talc, titanium dioxide, polyethylene glycol 6000, dye, and water using a homogenizer for 20 minutes. Add suspension (2) to the mixture (1) and stir again for 5 minutes at low speed (Santoso, 2019).

Caplet coating process
The caplet coating method is the Santoso method (2019) with modifications due to inadequate equipment, namely 30 core caplets are put into a coating pan, and a plantain peel amylopectin coating solution with each concentration is sprayed. The coated pan is supplied with hot air with a temperature

of 50ºC – 70ºC. After the spraying process is complete, the caplets are left in the rotating coating pan until they cool while the drying process continues using a dryer

Evaluation of Mefenamic Acid Core Caplets
Evaluation of Mefenamic Acid Core Caplets includes caplet hardness, caplet friability, size uniformity, weight uniformity, disintegration time test, and dissolution test (Depkes, 1995).

Evaluation of Mefenamic Acid Thin-Coated Caplets
Evaluation of Mefenamic Acid Thin Coated Caplets includes weight gain test, disintegration time test, caplet hardness, caplet firmness, size uniformity, weight uniformity, dissolution test, and water content test of coated caplets.

Data analysis
Data on the percent release of mefenamic acid were analyzed using the SPSS program.

RESULTS AND DISCUSSION

The research results showed that the weight of fresh plantain peel was 3500 grams. After soaking and draining twice and drying the starch, the weight of the starch was 116.55 grams. The yield result obtained from calculating the ratio between the weight of starch and the weight of fresh banana peel was 3.33%. Meanwhile, for the isolation of amylose and amylopectin from plantain peel starch, the percent yield was obtained from the comparison between the weight of the amylopectin flour that had been isolated and the weight of the starch, namely 72.67%.

Evaluation of Amylopectin

Amylopectin evaluation carried out in this study included organoleptic tests, water content, and ash content. Tests carried out on amylopectin flour from plantain peel starch included examining the shape, smell, and taste (Hidayat et al., 2022). Amylopectin evaluation can be seen in Table 1.

Table 1.
Organoleptic test results, water content and ash content

Component	Results
Organoleptic	
Form	Fine powder
Smell	No smell
Color	White
Flavor	Tasteless
Water content (%)	2 %
Ash Content (%)	1,3 %

Based on the table above, it shows that the organoleptic test of amylopectin powder meets the SNI requirements and the ash content of amylopectin powder meets the requirements according to MMI edition VI. The amylopectin ash content test meets the requirements of 1.3%, where the ash content requirement is 3%. The lower the ash content presentation, the better the quality of the material, and vice versa, the higher the ash content, the worse the quality of the material. This is because the higher the ash content, the higher the mineral content in the material. Meanwhile, in the solubility test, the results showed that amylose was soluble in water and also soluble in methanol. Meanwhile, amylopectin dissolves in water when heated at 60ºC and cannot dissolve in methanol. Amylopectin dissolves in water when heated to 100ºC, insoluble in methanol and alcohol (Nguyen et al., 2021).

Functional Group Analysis of Amylopectin Powder by FTIR

Identification using FTIR (Fourier Transform Infra Red) can prove the existence of a functional group form of amylopectin which has been carried out in previous research by making amylopectin powder into pellets with KBr and then observing the IR spectrum with FT-IR. Measurements of the amylopectin group can be seen in Figure 1.

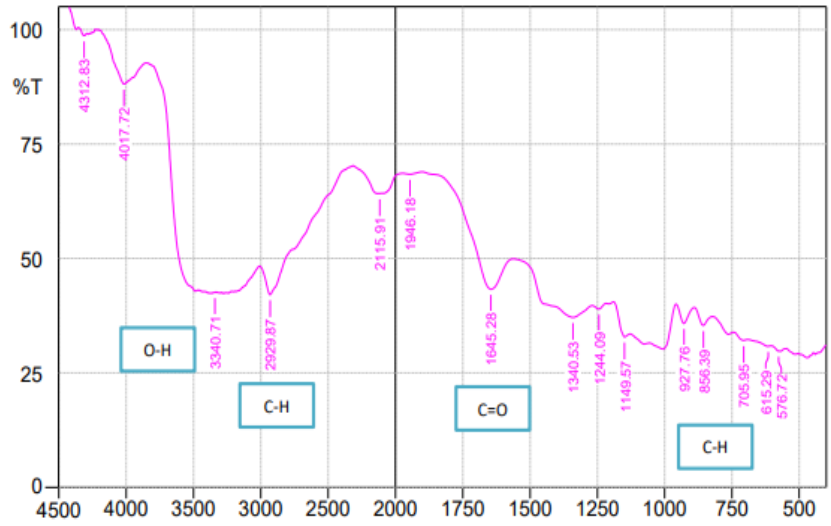

Figure 1.FT IR spectrum of amylopectin clusters

Based on the spectrum above, it shows that plantain peel contains amylopectin because spectrum data from amylopectin from plantain peel starch shows that there are main functional groups, namely hydroxyl groups (-OH), aliphatic groups (CH), and carbonyl groups (C=O) ((Dwiyani et al., 2023).

Iodine Test

The iodine test was carried out to prove that the powder was actually amylopectin and not a mixture with amylose. Where's the powder? Amylopectin is added with 2-3 drops of iodine and will form a violet-red color, while amylose with iodine will form a blue color (Mustakin and Mulyati, 2019). From the research, it was found that the amylopectin starch of plantain peel, when dripped with iodine, produces a violet-red color. Meanwhile, when amylose is added to iodine, it produces a purplish-blue color.

Caplet Evaluation

Caplet Hardness

Caplet hardness is the average of 10 caplets, where the standard value for caplet hardness of 400-700 mg is 7-12 kg/cm2 (Firmansyah, 2020). From the research results that meet the requirements for caplet hardness, the graph of caplet weight can be seen in Figure 2.

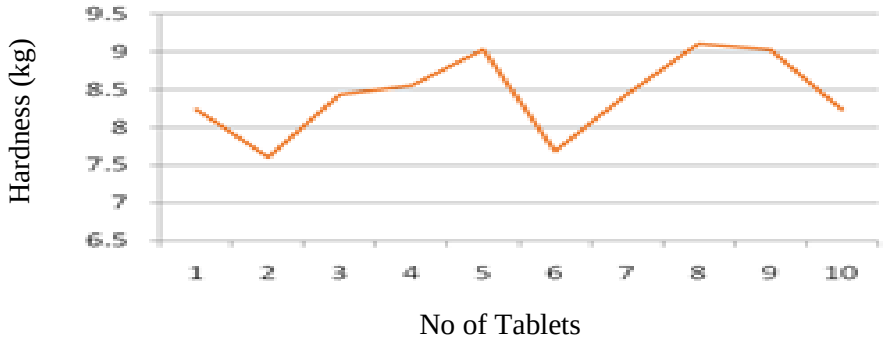

Figure 2. Hardness weight per caplet

Based on the image above, it shows that the average calculation result is 8,436 kg, this indicates that the resulting weight meets the requirements, namely 7-12 kg/cm^2.

Caplet Firmness

Caplet firmness meets the requirements, namely 0.5%, with value a, namely the weight before treatment, 11.96 grams, and value b, namely the weight after treatment, 11.90 grams. Requirements: Caplet friability is considered good enough if the results are less than 0.8% (Firmansyah, 2020).

Size Diversity

Variation in caplet size was carried out by measuring the diameter of each caplet using a caliper. Caplet size uniformity is influenced by flow properties, density uniformity, and punch stability on the caplet molding tool. According to the Indonesian Pharmacopoeia III, unless otherwise stated the diameter of the caplet is not more than 3 times and not less than 1 1/3 times the thickness of the caplet. The results of measuring the size diversity of mefenamic acid capsules met the requirements with the average diameter being 6.5 mm and the average caplet thickness being 4.9 mm.

Caplet weight uniformity was obtained by weight measurements that met the requirements. For caplets weighing > 310 mg, the deviation in weight A was 5% and the deviation in weight B was 10%. So it was found that the smallest weight limit was 568.1 mg and the largest weight limit was 657.8%. The weight uniformity test can be seen in Figure 3.

Figure 3. Weight diversity diagram

Time Crush Test

The disintegration time test can be seen in Figure 4.

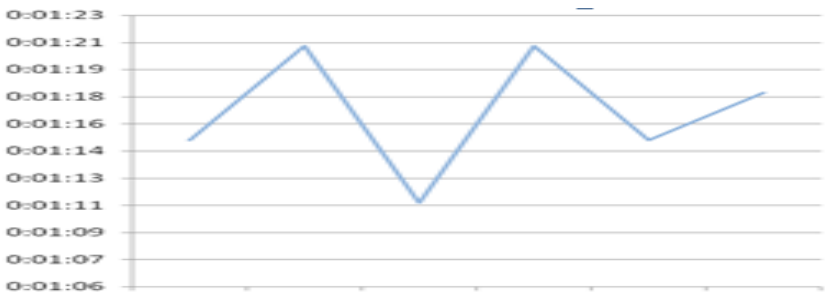

Figure 4. Diagram of the hull medium disintegration time test

Based on the picture above, shows that the results of the disintegration time test meet the requirements where after the tool is run the caplet starts to disintegrate at the lowest level at 1 minute 11 seconds where the disintegration time requirement for crushing the six caplets is no more than 15 minutes for uncoated caplets and no more than 60 minutes for caplets membrane coated.

Dissolution Test

The dissolution test for uncoated core caplets is only carried out using an artificial stomach medium pH 1.2 because it is intended to disintegrate and dissolve in the stomach. The results of mefenamic acid caplet dissolution measurements can be seen in Figure 5..

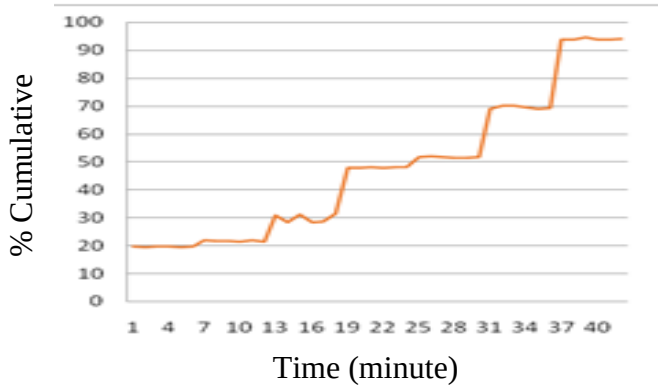

Figure 5. Mefenamic acid dissolution test curve in artificial stomach medium pH 1.2

Based on the picture above, shows that the results of the dissolution test of mefenamic acid caplets where by calculation using Y = 0.03830X + 0.0046 at 120 minutes the mefenamic acid caplets reached 93% solubility. The requirement according to FI IV is not less than 80%.

Evaluation of Mefenamic Acid Thin Coated Caplets

Weight Gain Test

The weight increase test for mefenamic acid thin-coated caplets can be seen in Figure 6.

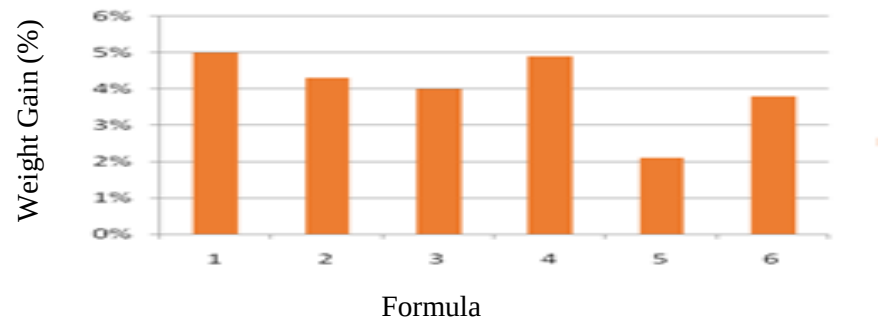

Figure 6. Weight increase test diagram for mefenamic acid coated caplets

Based on the picture above, shows that the weight increase presentation for mefenamic acid caplets meets the requirements. It can be seen that formulas 1 to formula 6 meet the requirements of the weight increase test requirements, namely 2-5%.

Desintegration Tester

Caplets are declared destroyed if no part of the caplet remains on the gauze, except for fragments originating from the coating substance. The time required to destroy the six caplets is no more than 15 minutes for uncoated caplets and no more than 60 minutes for film-coated caplets. Disintegration time plays an important role for caplets as a measure of absorption in the gastrointestinal tract. Based on the test results it can be concluded that formulas 1,2 and 4 do not meet the requirements due to the thin coating so they cannot pass through the disintegration time in the stomach medium which causes the coated caplets to dissolve in the medium. artificial stomach with an average time of 3 minutes, 5 minutes, and 3 minutes respectively.

Meanwhile, formulas 3, 5, and 6 meet the disintegration time requirements because they have passed the disintegration time requirement in the stomach medium, namely >1 hour. After carrying out further testing in the intestinal medium, the results were obtained consecutively, namely 1 minute, 1 minute, and 40 seconds.

Caplet Hardness

Caplet hardness is the average of 10 caplets. Requirements: The standard hardness value for 400-700 mg caplets is 7-12 kg/cm2 (Firmansyah, 2020). The hardness curve of mefenamic acid-coated caplets can be seen in Figure 7.

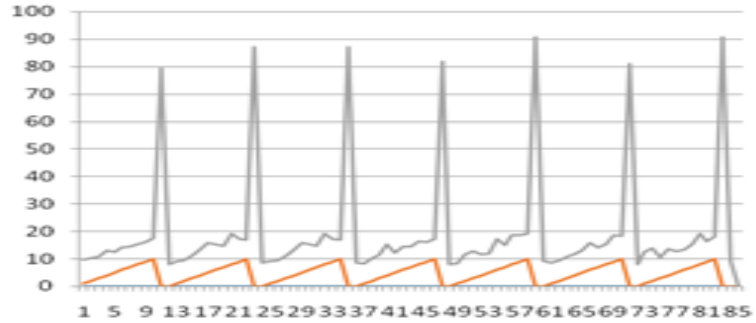

Figure 7. Hardness test curve for mefenamic acid coated caplets

Based on the image above, shows that the calculation results of formulas 1, 2, 3, 4, 5, and 6 meet the requirements with the average weights obtained respectively, namely 7,927 kg, 8,705 kg, 8,168 kg, 9,064 kg, 8,078 kg, and 9,056 kg This states that the resulting weight meets the requirements, namely 7-12 kg/cm^2.

Caplet Firmness (Friability)

Caplet friability requirements are considered good enough if the results are less than 0.8% (Henry et al., 2021). The results of caplet firmness can be seen in Figure 8.

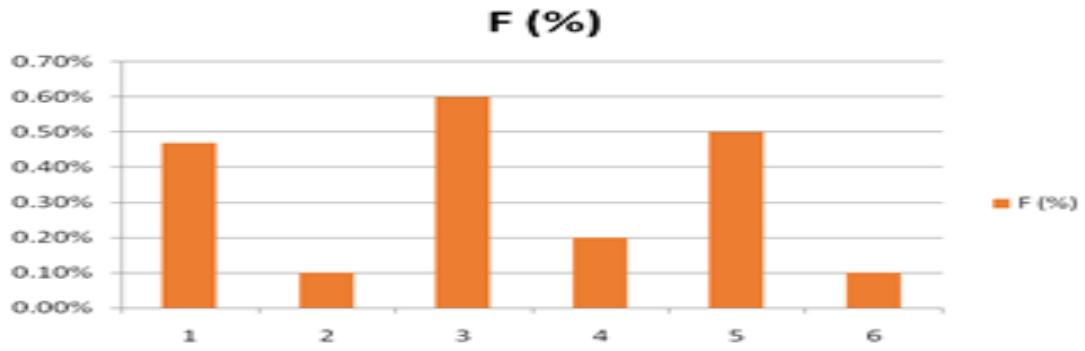

Figure 8. Percentage diagram for firmness test of Mefenamic acid coated caplets

Based on the picture above, shows that the firmness of formulas 1, 2, 3, 4, 5, and 6 meets the requirements with the following percentages respectively 0.4%, 0.1%, 0.6%, 0.2%, 0.5%, and 0.1% where caplets are considered sufficient good if the result is less than 0.8%.

Size Uniformity

The uniformity of the size of the thinly coated caplets of mefenamic acid indicates that formulas 1, 2, 3, 4, 5, and 6 meet the requirements according to the Indonesian Pharmacopoeia III, unless stated otherwise the caplet diameter is not more than 3 times and not less than 1 1/3 times caplet thickness.

Dissolution Test

The dissolution test for coated caplets, namely enteric coating, in addition to the artificial stomach medium of pH 1.2, the artificial intestine of pH 7.4 was also carried out in an alternating pH medium, namely from the artificial stomach medium of pH 1.2, then continued with the artificial intestine medium of pH 7.4. The results of the mefenamic acid dissolution test curve in artificial stomach medium pH 1.2 can be seen in Figure 9.

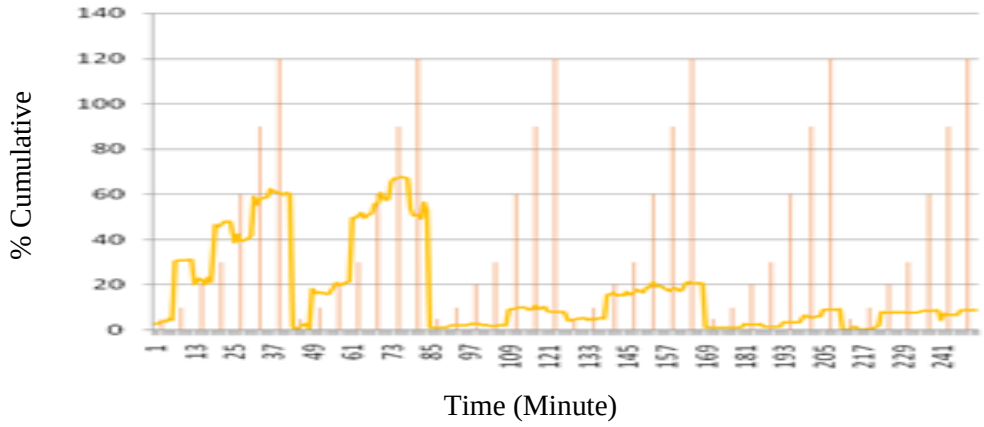

Figure 9. Mefenamic acid dissolution test curve in artificial stomach medium pH 1.2

Based on the picture above, shows that the dissolution test results of mefenamic acid thin-coated caplets are calculated using Y = 0.03830 coating for these three formulas so that the caplets can easily decompose in the artificial intestinal medium. Meanwhile, formulas 3, 5, and 6 meet the requirements, namely a cumulative solute presentation of <10%.

Dissolution Test in Changing pH Medium

Dissolution testing with medium-changing artificial stomach pH 1.2 and artificial intestine pH 7.4 was carried out for mefenamic acid caplets coated for delayed release because uncoated caplets were intended to break and dissolve completely in the stomach medium. The results of dissolution test measurements in changing pH medium can be seen in Figure 10.

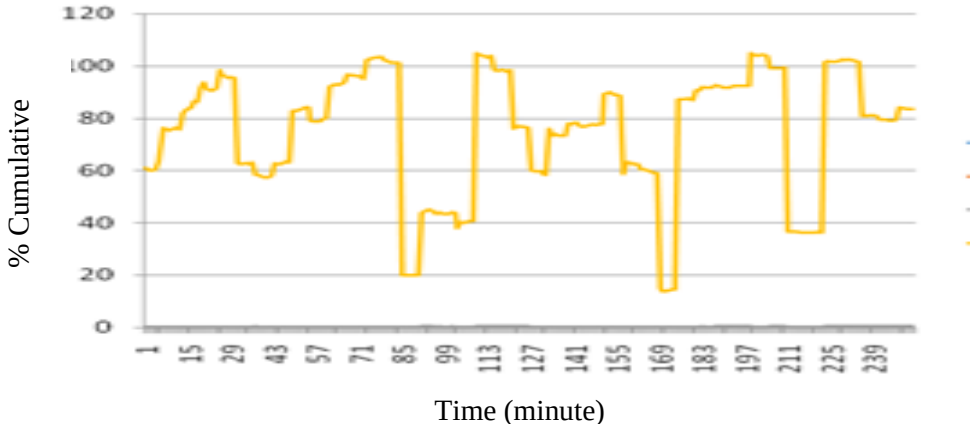

Figure 10. Mefenamic acid dissolution test curve in artificial intestinal medium pH 7.4

Based on the picture above, shows that the dissolution test results of mefenamic acid thin-coated caplets, which are calculated using Y = 0.0403 The coating is too thin for these three formulas so that the caplets can easily decompose in the artificial stomach medium so that the cumulative presentation level in the intestinal medium also does not meet the requirements. Meanwhile, formulas 3, 5, and 6 meet the requirements, namely the cumulative presentation of solutes, namely 90-105%.

Coated Caplet Water Content Test (Stability)

The results of the coated caplet water content test can be seen in Figure 11.

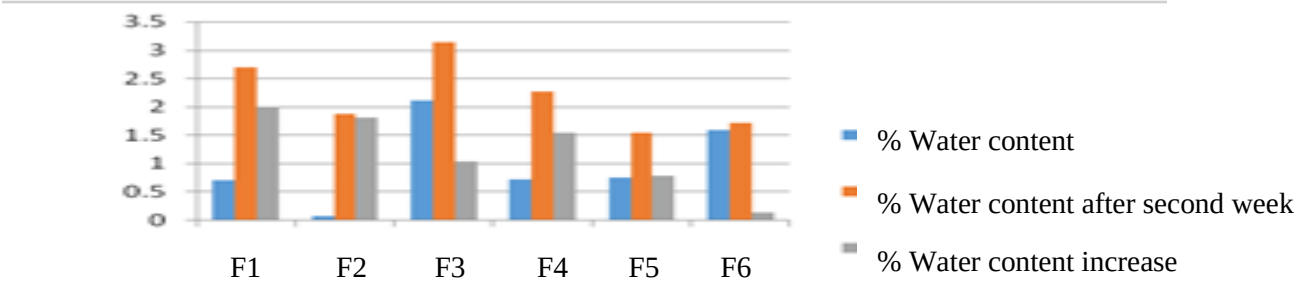

Figure 11. Percentage diagram of the water content test results for coated caplets

Based on the picture above, it shows that the stability test was carried out by measuring the water content after storage in a closed bottle at room temperature and humidity is closely related to the water content in the caplet. So the higher the concentration, the lower the difference in water content increase.

CONCLUSIONS AND SUGGESTIONS

Plantain peel starch amylopectin can be formulated as a coating film, namely as a thin coating of mefenamic acid caplets, with the addition of other ingredients, such as talc, titanium dioxide, PEG 6000, dye, and water, so that it becomes a coating medium for the amylopectin coating film. The coating film from the amylopectin starch of plantain peel can be used as a thin layer coating or coating film to protect the active substance of mefenamic acid caplets because the higher the amylopectin content, the thicker and stronger the potential to protect the active substance of mefenamic acid caplets, as seen from the water content test used as replacement stability test to see the moisture of the three coated caplet formulas. We hoped that future researchers will modify the starch from plantain peels to become digestible starch. Digestible starch has functional value for fiber

fortification, reducing calories, and oxidizing fat. Digestible starch has quite large potential to be developed as a functional food for health.

ETHICAL CONSIDERATIONS

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Conflict of Interest Statement
With regard to this article, we certify that there are no actual or possible conflicts of interest

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