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The Use of Ambon Banana Starch (*Musa paradisiaca* var. *sapientum* L.) as a New Binder in Tablet Formulation

Penggunaan Pati Pisang Ambon (Musa paradisiaca var. *sapientum* L.*) sebagai Bahan Pengikat Baru dalam Formulasi Tablet*

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ABSTRACT

Background: Synthetic materials are commonly used as binders in tablet formulations that causes the price of tablets being more expensive. For this reason, new materials discoveries are sought to replace synthetic materials by utilizing materials from nature. One of the binders from natural ingredients that easily obtained is the Ambon banana starch (*Musa paradisiaca* var. *sapientum* (L.)). **Objectives:** This study was conducted to determine the physical characteristics of paracetamol tablets from Ambon banana starch as a binder. **Materials and Methods:** Paracetamol tablets were compressed using wet granulation method by adding a binder in the form of Ambon banana starch mucilago. The concentration of Ambon banana starch used was 15% (Formula I), 17,5% (Formula II) and 20% (Formula III). Evaluation of the physical characteristics of the tablets were determined through the parameters of granule testing and tablet testing. **Results:** Formula I, II, and III have met the requirements for the granule test. Meanwhile, in tablet testing, the results of size uniformity test, weight uniformity test, hardness test, and disintegration time test met the requirements for all formulations. However, in the friability test, Formula I (15%) did not meet the requirements with a value of 2.07% (requirement <1%), while formulas II and III had met the requirements. **Conclusions:** This study showed that Ambon banana starch can be used as a binder in tablet formulation.

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ABSTRAK

Latar Belakang: Bahan sintetik menjadi bahan yang umum digunakan sebagai pengikat dalam formulasi sediaan tablet. Untuk itu dibutuhkan penemuan baru yang dapat menggantikan bahan sintetik dengan memanfaatkan bahan dari alam. Tujuan: Penelitian ini dilakukan untuk mengetahui sifat fisik tablet parasetamol dari pati pisang ambon (*Musa paradisiaca* var. *sapientum* L.) sebagai bahan pengikat secara granulasi basah. Bahan dan Metode: Tablet parasetamol dicetak menggunakan metode granulasi basah dengan menambahkan bahan pengikat berupa mucilago pati pisang ambon. Konsentrasi pati pisang ambon yang digunakan yaitu 15% (Formula I), 17.5% (Formula II), dan 20% (Formula III). Evaluasi karakteristik fisik sediaan ditentukan melalui parameter pengujian granul dan pengujian tablet. Hasil: Formula I, II, dan III telah memenuhi persyaratan pada pengujian granul, sedangkan pada pengujian tablet diperoleh hasil uji keseragaman ukuran, uji keseragaman bobot, uji kekerasan, dan uji waktu hancur yang memenuhi persyaratan untuk semua formula. Namun pada uji kerapuhan Formula I (15%) tidak memenuhi syarat dengan nilai 2,07% (Syarat <1%), sementara formula II dan III telah memenuhi persyaratan. Kesimpulan: Penelitian ini menunjukkan bahwa pati pisang ambon dapat digunakan sebagai bahan pengikat dalam formulasi tablet.

Kata kunci: *Musa paradisiaca* var. *sapientum* L., Tablet, Bahan Pengikat, Parasetamol.

INTRODUCTION

In the manufacture of tablets, it is necessary to pay attention to the physical quality of the tablet itself. Tablets are only able to give the desired effect if they are of good quality. Many problems arise during tablet formulation such as the characteristics of the active substance which has poor flow properties and poor compactibility, for example paracetamol. As for the common defects found in tablet formulations such as capping and lamination. Capping is the removal or separation of the compressed top or bottom of the tablet from the main body of the tablet whereas lamination is when the tablet separates into single or multiple layers. One of the factors is due to the selection of an inappropriate binder to produce a formulation that meets the requirements of good tablet quality (Dewi & Karim, 2019).

The binder functions in increasing the durability and compactness of the tablet in the manufacturing process, so that it will play a role in the unification of several powder particles into granules so that they are easy to print (Manik, 2020). Binders are also used in tablet formulations to provide cohesion to the granule mixture. This cohesion ensures that the tablet remains intact after the compression process. The characteristics of the printed tablet are closely related to the amount of binder. The concentration of the binder certainly can affect the disintegration time of the tablet (Hartesi *et al.*, 2016). As for an example of a binder that is commonly used, namely Polyvinyl Pyrolidone (PVP), which is a synthetic binder.

The binders used in the formulation of tablet preparations are generally derived from synthetic materials. This causes the average tablet price to be expensive. For this reason, a breakthrough is sought by utilizing materials from nature as a substitute for these synthetic materials so that they can reduce tablet production costs which in turn produce tablets that have relatively cheap selling prices (Galeri, 2014). One of the binders that comes from natural ingredients and is easily obtained is the Ambon Banana Starch (*Musa paradisiaca* var. *sapientum* (L.)).

These bananas are easy to find, even in mini markets there are already packages for one meal (Khusuma *et al.*, 2019). According to Patil (2010), the binder used in the wet granulation process should be water soluble and hydrophilic. This is in accordance with the water-soluble nature of starch, making it an appropriate binder in the wet granulation process of tableting. Green and unripe fruits such as bananas, breadfruit, and mangoes contain quite a lot of starch, which can reach 70% of their dry weight (Ifmaily, 2018). Ambon banana starch itself contains amylopectin of 15.90% and amylose of 11.39%. Amylose is easy to absorb water and its swelling power is very good as a tablet crusher. While amylopectin has properties that are more sticky and tends to form a gel when suspended in water. Therefore, it is good to be used as a binder in tablets. The use of Ambon banana starch as a binder is relatively good because the amylopectin content is greater than the amylose content (Nugraha, 2012). Based on the description above, we are interested in conducting research on the use of Ambon banana starch (*Musa paradisiaca* var. way (L.)) as a binder to the physical properties of paracetamol tablets.

MATERIAL AND METHODS

Materials

Ambon Bananas were obtained from a local market at Makassar City (South Sulawesi), lactose, magnesium stearate, paracetamol, purified water, and talc.

Methods

Preparation of Ambon Banana Starch

The ambon banana is separated between the flesh and the skin. The pulp is taken and then mashed by means of a blender with additional purified water. The mixture is kneaded so that more starch is released from the flesh cells. Then filtered using a cloth so that the starch escapes from the sieve as a starch suspension, and the fiber remains on the sieve. The starch suspension obtained was then accommodated in a sedimentation container and allowed to stand for ± 24 hours or until there was starch deposition. The liquid above was drained while the resulting starch precipitate was dried at 50°c for 2 x 24 hours. After drying, the starch was sieved using an 80 mesh sieve (Mustafa, 2015).

Preparation of Binder Solution

The binder solution is prepared by dissolving starch powder in water. The binder was prepared by dispersing the starch powder sample according to the w/v percentage in 100 ml of water. Mucilago of Ambon banana starch 15% w/v was prepared by mixing 15 g of Ambon banana starch with 100 ml of pure water. Added 2 times the weight of starch, which is 30 ml for 15 g. The remaining 70 ml of pure water is heated on a hot plate, then poured into the starch solution. The same thing was done to make a binder solution at a concentration of 17.5% w/v and a concentration of 20% w/v (Elisabeth et al, 2018).

Formulation of Paracetamol Tablet

Table 1. Formulation of paracetamol tablets using Ambon Banana Starch.

Ingredients	Functions	Formulation		
		I	II	III
Paracetamol	Active Subtance	500 mg	500 mg	500 mg
Ambon Banana Starch	Binding	2,31 mg	2,70 mg	3,08 mg
Magnesium Stearate	Lubricant	0,15 mg	0,15 mg	0,15 mg
Talc	Glidant	0,15 mg	0,15 mg	0,15 mg
Lactosum	Filling	Ad 650 mg	Ad 650 mg	Ad 650 mg

The ingredients needed (paracetamol, lactosum, magnesium stearate and talcum) were weighed (Table 1). Paracetamol and Lactosum were ground until homogeneous. The binder solution is added gradually while stirring until a good granule mass is obtained. After that, it was sifted using Mesh 20. Then it was dried in a drying cabinet at a temperature of about 45°C for ±18 hours. After drying, the granules were weighed again, sieved using a Mesh 24 sieve. After that, magnesium stearate and talc were added and mixed until homogeneous, then the granules were tested. The granules that have met the requirements were then compressed using an appropriate tablet press machine so that the desired weight is obtained.

Tablet Physical Characteristics Test

Weight Uniformity Test

Weighed 10 tablets one by one carefully. The uniformity of the preparations meets the requirements if the acceptability value of the first 10 dosage units is not more or equal to L1%. If the acceptability value is greater than L1%, perform the test on an additional 20 units of preparation, and calculate the acceptability value (DepKes, 2020).

Size Uniformity Test

This test used 20 tablets which were measured with a caliper. Tablets are said to meet the requirements if the diameter is not more than 3 times the thickness of the tablet and not less than 1 1/3 the thickness of the tablet (DepKes, 1979).

Hardness Test

The tablet hardness test uses 6 tablets with a tool called a *Hardness tester.* The principle of measurement in this test is to apply pressure until the tablet breaks, the minimum strength of the tablet is 4-8 kg/cm^3(Ansel, 2008).

Friability Test

Tablets with a weight equivalent to or less than 650 mg the number of tablets tested refers to the total weight which is about 6.5 g. Meanwhile, for tablets weighing more than 650 mg, the number of tablets tested is only 10 tablets. The tablets were weighed before and after the test. The two weights are then

compared. The tablet to be tested first is cleaned of dust (Niazi, 2004). The fragility of tablets above 1% means that the tablet is considered brittle and not good (Ulfa et al, 2018).

Disintegration Time Test

This test uses a tool called a *disintegration tester*. Put 1 tablet in each of the 6 tubes from the basket, if otherwise put 1 disc in each tube. Run the tool, using water at 37 ± 2° as the medium unless otherwise stated in the respective monograph. At the end of the 15 minute time limit, lift the basket and observe all the tablets: all the tablets must be completely crushed. If 1 or 2 tablets are not completely disintegrated, repeat the test with another 12 tablets. Not less than 16 of the 18 tablets tested must be completely disintegrated (DepKes, 2020).

RESULTS AND DISCUSSION

Figure 1. Dried ambon banana starch.

This study used Ambon banana starch (*Musa paradisiaca* var. *sapientum* L.) (Fig 1) as a binder in the manufacture of paracetamol tablets by wet granulation (Fig 2). Wet granulation is a method of making tablets which is carried out on materials that are resistant to heat and moisture. The characteristic of paracetamol is that it has poor flow characteristic (Kurniati et al, 2017). To improve the flow characteristic, the wet granulation method is used. This method uses a binder in the form of a solution in order to increase the cohesiveness so that the tablet hardness also increases.

Figure 2. Paracetamol tablets from Ambon banana starch.

Weight Uniformity Test

The tablet weight uniformity test is intended to ensure uniformity of the active substance content. The uniformity of weight is influenced by the flow characteristic of the granules where good granule flow characteristic will affect the filling in the compression chamber with a constant volume so that tablets with uniform weight are obtained. The easier the flow of a material, the better the uniformity of its weight. The test results showed that all formulas had met the requirements of the weight uniformity test. The results of the weight uniformity test of each formula can be seen in table 2.

Table 2. The results of the uniformity test of the weight of paracetamol tablets using Ambon Banana Starch as a binder.

Weight Uniformity Test	Formulation			Requirements
	I	II	III	
Average weight (g)	0,458	0,473	0,485	The acceptability value of the first 10 units of dose is not more or equal to L1% (DepKes, 2020).
Standard Deviation	0,0075	0,0067	0,0086	

Size Uniformity Test

The tablet size uniformity test is intended to test the uniformity of tablet size from each formula made, then compare it with the tablet size uniformity requirements listed in the monograph. The test results showed that all formulas I, II and III had met the requirements, namely the diameter of the tablet was not less than 1 1/3 and not more than 3 times the thickness of the tablet (DepKes, 1979). The results of the size uniformity test of each formula can be seen in table 3.

Table 3. The results of the uniformity test of paracetamol tablet size using Ambon Banana Starch as a binder.

Size Uniformity Test	Formulation			Requirements
	I	II	III	
Diameter (cm)	1,089	1,091	1,097	The diameter of the tablet is not more than 3 times the thickness of the tablet and not less than 1 1/3 times the thickness of the tablet (DepKes, 1979).
Thickness (cm)	0,494	0,503	0,506	
Standar Deviation				
Diameter (cm)	0,0002	0,00	0,00	
Thickness (cm)	0,0002	0,00	0,0002	

Hardness Test

The tablet hardness test is intended to describe the tablet's resistance to mechanical stresses such as shock. Factors that affect tablet hardness include the granulation method, compression pressure, and the type and amount of binder used. The results obtained indicate that Formula I, II and III meet the requirements of an ideal tablet hardness of 4-8 kg/cm^3 (Ansel, 2008). The results of the tablet hardness test for each formula can be seen in table 4.

Table 4. The results of the paracetamol tablet hardness test using Ambon Banana Starch as a binder.

Test	Formulation			Requirements
	I	II	III	
Tablet hardness (kg/cm^2)	4,67	5,33	5,67	4-8 kg/cm^2 (Ansel, 2008)
Standard Deviation	0,1650	0,0981	0,1650	

Friability Test

The tablet's brittleness or friability test is intended to see the tablet's resistance to shock and abrasion during the production process, packaging, shipping and when it is in the hands of consumers. The results obtained indicate that Formula II and III have met the requirements of the tablet stiffness test where the good friability value is not more than 1% (Ulfa et al, 2018). However, in Formulation I the results obtained did not meet the requirements due to the brittleness of more than 1%. One of the factors that affect tablet brittleness is tablet hardness, where the lower the tablet hardness, the greater the brittleness (Kusmawati, 2012). This is directly proportional to the hardness results obtained, where Formula I has a hardness of 4.67 which shows the smallest value compared to the hardness in Formula II and Formula III. Another factor that affects tablet stiffness is the concentration of the binder. According to Kusmawati (2012), the higher the concentration of the binder, the harder the tablets produced because the resulting powder particles stick together strongly so that the tablets are not easily brittle. In Formula I, the binder used was 15% which is the lowest concentration of the other formulas. Another factor causing brittleness according to Anwar (2012), is that the starch used is unmodified starch so that it has poor compressibility and high friability. This is also in line with research conducted by (Fortuna et al, 2001) which states that natural starch (native) causes several problems related to retrogradation, low stability, and low pasta resistance. The results of the tensile test of each formula can be seen in table 5.

Table 5. The results of the tensile test of paracetamol tablets using Ambon Banana Starch as a binder.

Test	Formulation			Requirements
	I	II	III	
Friability of tablets (%)	2,07	0,96	0,89	No more than 1% (Ulfa dkk, 2018)
Standard Deviation	0,0576	0,0173	0,1401	

Disintegration Time Test

Tablet disintegration time test is intended to determine the time required for tablets to disintegrate in a suitable medium. Factors that affect tablet disintegration time include the physical characteristics of the granules, porosity and tablet hardness. The greater the hardness of the tablet, the longer the disintegration time. The results of the weight uniformity test of each formula can be seen in table 6.

Table 6. The results of the disintegration time of paracetamol tablets using Ambon Banana Starch as a binder.

Test	Formulation			Requirements
	I	II	III	
Disintegration Time (minutes)	3,61	5,28	6,14	Not more than 15 minutes for uncoated tablets (DepKes, 2020).
Standard Deviation	0,0600	0,1815	0,1700	

CONCLUSION

This study showed that Ambon banana starch (*Musa paradisiaca* var. *sapientum* L.) can be used as a binder in tablet formulations by using an appropriate starch concentration and has met the requirements for testing the physical properties of tablets. Suggestions for the next formula, there should be a comparison for starch samples. Positive control can be formulated using commercial starch. The author hopes that the use of natural materials can be maximized, one of which is as a binder.

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CONFLICT OF INTEREST

The author declared no conflict of interest.

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