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RESEARCH ARTICLE

The potential of banana fruit *Ranggap* (*Musa paradisiaca var. Troglodytarum*) as an excipient alternative to oral tablet dosage form

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Abstract

Introduction: Starch is one of the ingredients that has many benefits, including in the pharmaceutical field, especially as a pharmaceutical excipient in pharmaceutical formulations. **Aim:** This study aims to isolate, characterise, and formulate the starch of banana fruit (Musa paradisiaca var. Troglodytarum) into tablet dosage forms. **Methods:** The characteristics of the perceived banana starch can be said to be comparable to that of corn starch so that it is expected to be used as a source of starch which can be used as a pharmaceutical excipient. The starch of isolated banana fruit was used as a filler, binder, and crusher in the wet granulation method tablet formulations with concentrations of 2%, 3%, and 5%. **Results:** The physicochemical characteristics of starch isolated from banana fruit are considered to meet the requirements of pharmaceutical excipients required in the Handbook of Pharmaceutical Excipients 6th edition and the United States Pharmacopeia 32nd edition. **Conclusion:** Of the total formulas tested, tablets with binder content of banana starch 3%, 5% and 10% corn starch meet the tablet evaluation requirements.

Introduction

Most of the pharmaceutical companies in Indonesia have only carried out the stage of formulating the final product into pharmaceutical preparations, while 96% of the raw materials used are still imported from abroad. Formulated pharmaceutical preparations are a complex system, which consists of several components, including active pharmaceutical ingredients (API) and excipients. Some of the objectives of adding excipient include protecting the active substance, increasing the stability of the API, and increasing the safety and effectiveness of the preparation itself (Pawar, P.D., 2015).

According to the International Pharmaceutical Excipient Council, the excipient is a substance other than a drug that is included in the manufacturing process. In tablet dosage form, the US Pharmacopeia-National Formulary (USPNF) classifies excipients based on their function at the time of formulation, such as binders, disintegrants, and others (Chaudari, 2012). One of the excipients that are often used in formulations with function as a binder or disintegrants in tablet preparations is starch. Starch is one of the carbohydrates stored in plants and is found in many plant organs such as seeds, roots, fruits and tubers. It is widely used because it is easy to obtain, has inert properties, is cheap, and can be used as a filler, binder, crusher, and lubricant (Hu A. *et al*., 2015).

Starch is a compound that has a high molecular weight consisting of glucose polymers which are branched together with glycosidic bonds. Starch is one type of

important polysaccharide that is found in several plants that are spread in nature and can be extracted from its sources, such as cereals (rice, wheat, corn), tubers (cassava, sweet potato, potato), and palm stem pith. (sago, palm, new sago). Starch is composed of two different glucan chains, namely amylose (a linear polymer of D-glucose in a 1,4 glycosidic bond) and amylopectin (a branched polymer of d-glucose in 1,4 and 1,6 glycosidic bonds) (Hartesi, 2016).

Amylose is a straight-chain consisting of glucose molecules that bind to α-1,4-D-glycosidic. The number of glucose molecules on the amylose chain ranges from 250-350 units. The length of the polymer chain will affect the molecular weight of amylose, and the length of the polymer chain is strongly influenced by the starch source. The degree of amylose polymerisation ranges from 500-6000 glucose units depending on the starch source; the amylose structure can be seen in Figure 1.

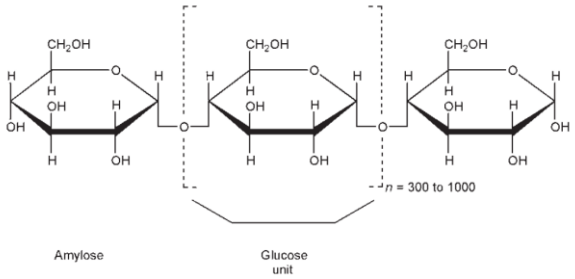


Figure 1: Amylose structure

The chemical structure of amylopectin is basically the same as amylose consisting of a short-chain α- (1,4) -D-glycosidic. The difference is that amylopectin has a high degree of branching and has a greater molecular weight in the presence of α-1,6-D-glycosidic bonds, where each branch contains 20-25 glucose units. The degree of polymerisation of amylopectin is also higher than amylose, which is between 105 to 3x106 glucose units (Hustiany, 2006). The structure of amylopectin can be seen in Figure 2.

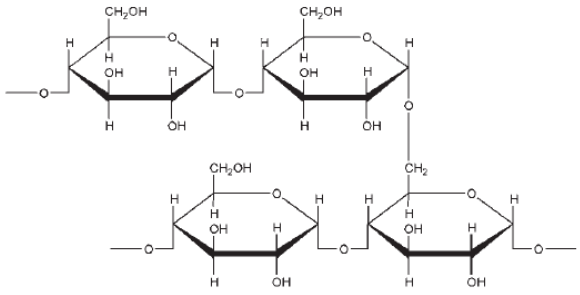


Figure 2: Amylopectin structure

Various attempts have been made to develop starch as an additional ingredient in tablet dosage formulations, for example, a starch made from cassava and durian seeds (Sapri, 2012), which function as binders and disintegrators.

Bananas are picked when the fruit is old but still green, with a total sugar content of 0.1% and starch up to 35%. In the fruit ripening process, there is an increase in total sugar because most of the starch is converted into sugar. The high starch content in bananas is expected to be used as a source of starch, which can then be used as a pharmaceutical excipient (Jime´nez-Herna´ndez, 2007).

Ranggap bananas (*Musa paradisiaca* var. Troglodytarum) is unique because it has a large fruit size and an upward bunches. Ranggap bananas are found in the foothills of Mount Galunggung, Tasikmalaya and other places, namely Lumajang, East Java. So far, it is known that the area of distribution is from Maluku to Papua, which is widely known by the surrounding community as Pisang Tongka Langit (E. Samson *et al.*, 2013).

The people around Mount Galunggung, ranggap bananas are considered commonly consumed not as bananas that are commonly eaten, but as a diabetes medicine and increase male vitality because they are not sweet.

In this research, the processing of the considered banana fruit into starch is carried out to increase the economic value for the community. Ranggap Bananas start producing at the age of 1–1.5 years. The flowering time happens throughout the season. Seven months after flowering can be harvested, the number of fruits is 5-8 per comb. The colour of the ripe fruit is brownish yellow; some are red according to the type. Fruit length reaches 17-23 cm, fruit weight 250-300 grams, and a diameter of 5-6.3 cm (Satuhu and Supriyadi, 2005). It can be an alternative for raw material needs, especially additives in the field of pharmaceuticals. The processing was also conducted to evaluate whether the starch from the banana fruit meets the Pharmaceutical Grade standards required by the USP and Handbook of Pharmaceutical Excipients. In this study, the starch from the isolated banana fruit was used as a binder in tablet preparation with metamizole as the drug model.

Methods

Plant determination

Ranggap Bananas (*Musa paradisiaca* var. Troglodytarum) were obtained from farmers in the foothills of Mount Galunggung, Tasikmalaya, with a fruiting age of seven months and estimated 10-15 days

before normal harvest. The banana was determined in Jatinangor Herbarium, Plant Taxonomy Laboratory, Department of Biology, Faculty of Mathematics and Natural Sciences, Universitas Padjadjaran.

Isolation procedure of banana starch

Isolation of the wild banana starch begins with peeling and soaking in water (1: 1) for an hour. Subsequently, chopping and soaking again with sodium metabisulfite solution with a concentration of 0.1 N for 16 hours were carried out by stirring several times.

After soaking, the ingredients were rinsed with distilled water and filtered using a filter cloth (Flannelette) to separate the starch and dregs. Then water was added to the dregs with a ratio of 1: 1 (w/v) to remove the remaining starch to be refiltered afterwards. The filtering process was repeated depending on the amount of starch until the filtrate was clear. The filtrate was allowed to stand for 12-16 hours so that it settles. After settling, the clear part was discarded. The precipitate was dried in an oven at 50^{o}C for 12 hours or until dry with a moisture content of less than 5%.

Characteristics of starch from banana fruit

Organoleptic test

The starch of isolated banana fruit was tested organoleptically, including smell, taste, colour, and visual shape with corn starch as a comparison.

Qualitative identification

An amount of 100 mg of starch from isolated banana fruit was analysed using several specific reagents to test for the presence of starch, including iodine to prove that the isolated sample was starch, and Fehling A and Fehling B reagents to prove that sugar has not been formed from the isolated starch (Prajapati *et al.*, 2013).

Fourier Transform Infrared (FTIR)

The starch of isolated banana fruit is pelleted by grinding with potassium bromide. Then, the Infrared spectrum of the sample was read with FTIR with corn starch used as a comparison. The measurements were made at a wavelength of 4000-400 cm^{-1}.

Scanning Electron Microscopy-Energy Dispersive X-Ray Spectroscopy (SEM-EDX)

The starch of isolated banana fruit was tested using Electron Microscopy-Energy Dispersive X-Ray Spectroscopy (SEM-EDX) to determine the surface morphology of the particles. The sample was placed on an aluminium stub with an adhesive conductive double-sided carbon pad and was then pressed so that the sample was evenly distributed and no air was trapped. The picture was taken with a voltage of 20.00 kV with various magnifications.

Particle Size Analyser (PSA)

The technique of measuring particle size and particle size distribution was by dispersing 10 mg of starch particles from isolated banana fruit each into 10 mL of distilled water and was then characterised using a PSA at a temperature of 25^{o}C.

Microscopic testing

The sample was prepared using liquid paraffin on a slide; then, the shape was seen using a light microscope.

pH testing

A banana starch sample of five grams was mixed with 40 mL of distilled water, shaken for 20 minutes, and centrifuged. The pH of the supernatant fluid was between 4.0 and 7.5 as measured by a pH meter (United States Pharmacopeia 32, 2009).

Test for heavy metal contamination and mineral content

Testing of the limits of heavy metal and mineral content was carried out using Atomic Absorption Spectrophotometer Spectroscopy (AAS). The heavy metals tested were Lead (Pb), Mercury (Hg), Arsenic (As), Tin (Sn), and Cadmium (Cd). Minerals that will be tested include potassium (K), calcium (Ca), magnesium (Mg), iron (Fe), and sodium (Na).

Microbial limit testing

A sample of one gram was dispersed in ten parts of a phosphate buffer solution pH 7.2 and was then homogenised using a vortex. Dilutions of 10^{-1} and 10^{-2} were made. The test for aerobic bacterial contamination was carried out using the Total Plate Number method. A total of 15-20 mL of Tryptone Soya Agar was poured into a petri dish, then 1 mL of the 10^{-1} and 10^{-2} dilution of the sample dispersion was added to the solid media. Petri dishes were incubated at 37^{o}C for 48 hours, counting the amount of aerobic bacterial contamination. The mould and yeast contamination test was carried out by using the Yeast Mould method using Sabouraud Dextrose Agar as much as 15-20 mL, which was poured into a petri dish. After solidifying, 1 mL of the 10^{-1} and 10^{-2} was a dilution of the sample dispersion added. Petri dishes were incubated at 20^{o}-25^{o}C for 72 hours. The amount of mould and yeast bacterial contamination was calculated (United States Pharmacopeia 32, 2009).

Physical properties of starch from Ranggap banana fruit

Bulk density determination

A sample of 10 g (W) was put into a measuring cup, the top surface of the powder was flattened and read the bulk volume (Vo) was read.

Determination of compressive density

A sample of 10 g (W) was put into a measuring cup, and the top surface of the powder was levelled. The tool was turned on and stomped 500 times, and the volume of the powder was read, then stamping a second time 750 times and reading the compressed volume (V_1). After knowing the bulk volume and compressed volume, the compressibility index was evaluated with the formula (Ohwoavworhua *et al.*, 2009). Compressibility(%)=(Bulk Volume-Compressed Volume) / (Compressed Volume) x 100%.

Determination of density

A dry, clean, and calibrated pycnometer was used by setting the pycnometer weight and paraffin weight. The test substance was entered into the pycnometer, and paraffin was added to the pycnometer to the maximum volume. The density was obtained by dividing the weight of the substance by the volume occupied by the substance in the pycnometer (Farmakope Indonesia V, 2014).

Moisture determination

Placed in an aluminium plate, the sample was weighed as much as 1 g. Samples were dried at 105^{o} C using a moisture balance (United States Pharmacopeia 32nd, 2009).

Determination of flow rate and angle of repose

The starch powder was put into a flow time test funnel. The flow time, height, and diameter of the powder coming out of the funnel were recorded to determine its angle of rest using millimetre graph paper. An angle of repose between 20°-40° and a flow time of more than 10 g/s indicates a good flow.

Tablet formulations

One application of the starch from the isolation of banana fruit can be used as additional material for tablet preparations. The tablet formula with the API of metamizole with the formula design is presented as in Table I.

Table I. Formulation of tablets

Ingredients	F1	F2	F3	F4
Metamizole	500 mg	500 mg	500 mg	500 mg
Banana starch	2%	3%	5%	---
Corn starch	---	---	---	5%
Amylum	5%	4%	3%	3%
Mg-stearate	2%	2%	2%	2%
Talc	1%	1%	1%	1%

Evaluation of tablets

The compressed mass that had been evaluated was compressed using a tablet machine with a tablet weight of 600 mg with a diameter of 12 mm and a hardness of 7-12 kg/cm^2. The resulting tablets were evaluated, repeated 20 times and tested statistically based on ANOVA, including uniformity of size, uniformity of weight, tablet hardness, disintegration time test, friability, friction, and dissolution. The results of the dissolution test were comparable with the PhEq-bootstrap software.

Results and discussion

Material collection and plant determination

The results of the determination showed that the plants examined were banana species (*Musa paradisiaca* var. Troglodytarum).

Isolation of banana starch

The starch obtained from the isolated banana fruit was 21.5%. This is consistent with the literature where bananas contain up to 35% starch (Jime´nez-Herna´ndez, 2007).

Characteristics of banana starch

Organoleptic examination

Organoleptic examination of the starch isolated from banana fruit was evaluated in terms of shape, taste, colour, and smell. The USP Standard and Handbook of Pharmaceutical Excipients for starch have characteristics such as odourless, white or pale white powder, consisting of very small round or ovoid granules, and tasteless. It shows the criteria that do not meet the standards organoleptically according to the sixth edition of the Handbook of Pharmaceutical Excipients, where the required colour is white, while the colour produced by

banana starch shows ivory white colour (See Figure 3a and 3b).

(a) (b)

Figure 3a: Corn starch; 3b: Banana starch

Qualitative identification

In simple identification using iodine solution, the sample of starch from isolated banana fruit gives a blue colour and the formation of a purple ring. This shows a positive result where the tested sample contains starch. In the swelling test, namely, by adding hot water to the starch sample, a thick starch solution was formed. Meanwhile, the addition of Fehling A and B solutions did not change colour. From these data, it can be concluded that the starch samples showed positive results according to the characteristics of starch, and no starch was formed into sugar.

Fourier Transform Infrared (FTIR)

In the infrared spectrum test, the starch samples from the isolation of banana fruit were tested with sodium metabisulfite and corn starch as a comparison for starch. Figure 4 shows almost the same spectrum. The results of observations using Fourier Transform Infrared (FT-IR) conclude that the infrared spectrum of the starch samples from isolated banana fruit compared to corn starch gives a spectrum with a similar pattern. This shows the similarity of the functional groups even though there are differences in wavenumber areas. (2600-2000 cm^{-1}). The infrared absorption spectrum shows the main absorption at wavenumbers 3363 cm^{-1}, 2931cm^{-1} and 1656cm^{-1}. The peak at a wavelength of 3363 cm^{-1} indicates an OH group, at a wavelength of 2931cm^{-1} indicates a C – H group, while at a wavelength of 1641.88 cm^{-1} indicates an OH bending, and at a wavelength of 1356.46 cm^{-1} indicates a C – H group bending. The test results shown in Figure 4, using Fourier Transform Infrared (FT-IR), shows that the starch samples are similar, but there are still differences in the fingerprint area. This difference may occur due to differences in starch raw materials.

Scanning Electron Microscopy-Energy Dispersive X-Ray Spectroscopy (SEM-EDX)

SEM-EDX test was carried out to see the morphology of the starch from the banana fruit. Imaging results with magnifications of 500 and 1000times show that starch has an oval shape with relatively uniform size and shape. The imaging results with a magnification of 1000 and 5000 times, on the other hand, shows the surface shape of the starch that looks smooth and regular, as shown in Figure 5.

Particle Size Analyser (PSA)

Testing using the PSA aims to analyse the size distribution of the banana starch. From the analysis, it was found that the particle size was at 2-60µm. The starch sample from which the fruit of banana fruit was tested produced a normal distribution curve where the 28.70 µm starch particles dominated the sample; this result shows that the starch sample tested had a relatively uniform size and of a good particle size characteristic as shown in Figure 6.

pH testing

The results of pH testing using a pH meter against the 1% (w / v) dispersion in distilled water showed that the isolated banana starch had a pH of 6.82. The same result was also shown by corn starch, which had a pH value of 6.98. The 1% dispersion of the two samples shows a neutral pH value and meets the pH standards required by the Handbook of Pharmaceutical Excipients 6th edition, where the standard pH of starch is 4-7.

Test for heavy metal contamination and mineral content

The result shows that starch samples isolated from the banana fruit and the place where the banana plants grew were not contaminated by the presence of heavy metal waste. Metal contamination in a material isolated from plants depends on the environment in which it is grown, which can cause organ damage if consumed for a long time (Jaishankar e*t al.*, 2014).

Microbial limits

The test results of the Total Plate Number (ALT) for 24 hours and the Khamir Yeast Rate (AKK) for 27 hours showed that the microbial limit test of the starch samples from isolated banana fruit showed the total plate number (ALT) of 0.7 x 102 CFU g and Yeast Mould Rate (AKK) of 0.67 x 102 cfu/g. These results meet the requirements criteria according to the sixth edition of the Handbook of Pharmaceutic Excipients for ALT<103 cfu/g and AKK<102 cfu/g. The microbial contamination produced by starch products is influenced by several factors, including the storage process of the resulting product.

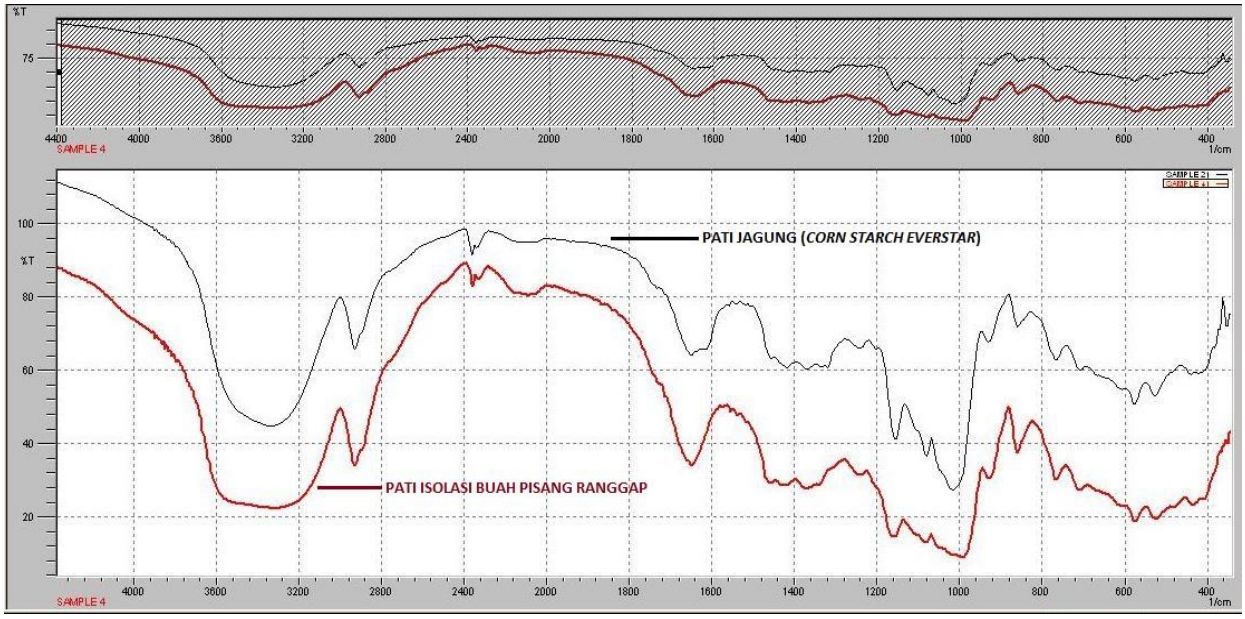
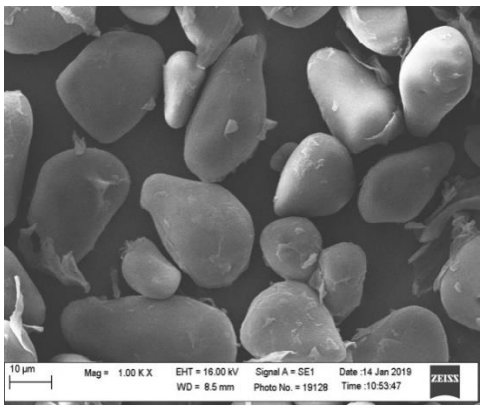
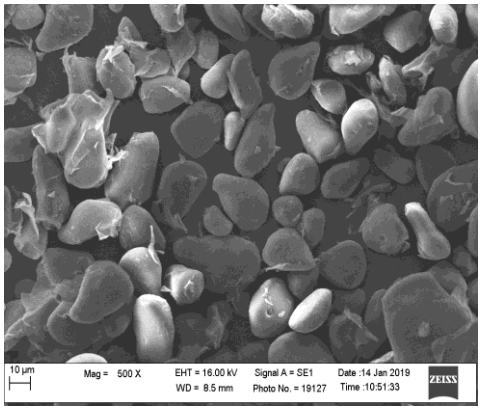


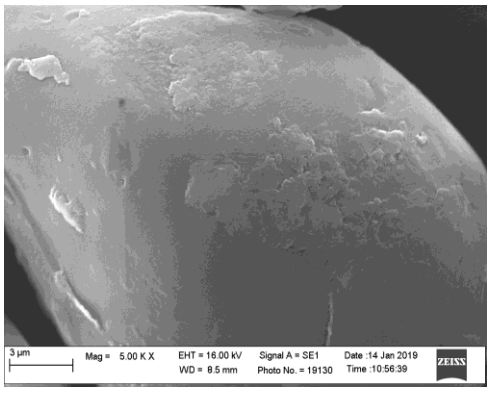
Figure 4: Results of Fourier Transform Infrared (FT-IR) Corn Starch (comparison) and Starch Banana Fruit



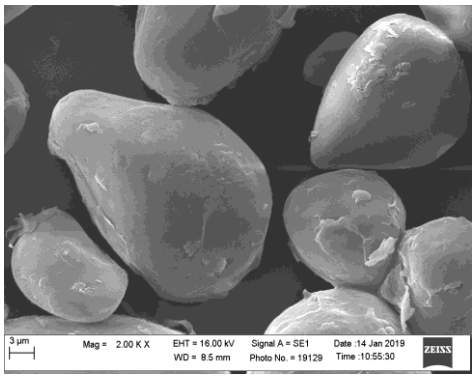
(a) 500x magnification



(b) 1000x magnification



(c) 2000x magnification



(d) Magnification of 5000x

Figure 5: Results of Scanning Electron Microscopy

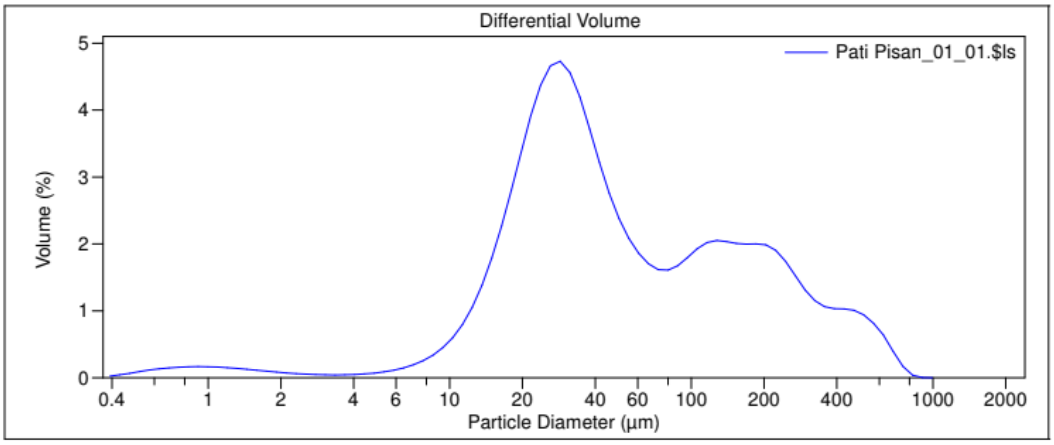


Figure 6: Results of the size distribution of banana starch

Sulfite residue testing

Sulfite residue testing was carried out to see the possibility of sulfite content remaining in the sample. This possibility can be caused by the use of sodium metabisulfite in the starch isolation process. The qualitative test was carried out by dissolving the sample with distilled water and adding barium chloride to the filtrate. The white liquid colour of the mist will be seen if the sample is positive for sulfite. The test results on the banana starch were considered to produce negative results.

Physical properties of granules

Testing of perceived banana starch includes examining according to the sixth edition of the Handbook of Pharmaceutical Excipients. In this test, the perceived banana starch was compared with corn starch. From the physical test data, it can be seen that the banana starch and corn starch tested showed quite good results when compared with the requirements, where banana starch and corn starch had a fairly good flow rate and angle of repose. This data supports the use of starch as an excipient for tablets by the direct pressing method. If it is necessary to increase the flow rate and the angle of repose that does not affect the physical properties of the active substance at the time of tablet making, it is better to use the wet granulation method (See Table II).

Tablet Formulations

The tablet formulation was carried out using starch from the isolated banana fruit as a binding agent in the form of starch paste. The process of making the mass ready for printing was done using the wet granulation method. Preparation of tablets with wet granulation has the advantage of increasing the particle size of the powder and the uniformity of the particle size so that it can improve the flow time of medicinal substances, especially those with poor flow times such as metamizole.

Table II: Physical properties of granules

Parameter	Banana starch	Corn starch	Standards of USP 32
Bulk density (g/cm^3)	0.56 ±0.0577	0.67±0.00223	0.45–0.58
Tapped density (g/cm^3)	0.70±0.1000	0.78±0.0215	0.69–0.77
True density (g/cm^3)	1.336±0.1155	1.447±0.0210	1.478
Compressibility (%)	16.26±1.4563	15.18±1.241	< 30
Haussner ratio	1.24±0.02165	1.18±0.0114	--
Flow rate (g/s)	4.59±0.04123	4.62±0.0123	--
Angle of repose	23.4^0 ±0.2130	28^0±0.0021	--
Humidity (%)	4.06±0.032	4.12±0.0210	< 12
pH	6.82±0.0012	6.98±0.0150	4.0–7.0

The binder made from starch from the isolation of banana fruit was made with a concentration of 2%, 3%, and 5%, while corn starch was used as a comparison binder with a commonly used concentration of 5%. Tablets were made using metamizole as the active ingredient, and starch in paste form was used as the inner phase binder. The active substance was added to the binder with each formula to obtain a mass that is easily clenched. The wet mass, which is easily clenched, was put into the granulator to granulate with 16 mesh. The granules were then dried at 40^0 C for 16 hours. The dried granules were then granulated again using 24 mesh. The results of granulation were tested for moisture content with a moisture content requirement of not more than 5%, and external phase substances such as starch, talc, and Mg Stearate were added.

All tablets in this test met the requirements for tablet evaluation, namely <0.8%. The results of statistical tests using SPSS 18 with the Anova method showed no significant difference, p=0.413 (p>0.05)

Granule flow properties

In testing the granule flow time, it gives good results, which is less than 10 seconds/100 grams. The test results obtained from the whole formula have a flow time of fewer than 10 seconds/100 grams. A good powder flow is needed for a uniform filling process into the hole of the tablet or dies so that it produces tablets with a uniform volume (Siregar, 2010). In testing the angle of rest, the whole formula has a value of angle of rest of <250, meaning that the flow is good. The angle of repose ranges from 25^0-$45^{0,}$ and the lower angle of rest indicates a better characteristic.

T*he Compressibility Index and the Haussner Ratio*

A good granule has a compressibility index of <21%. All the formulas were tested to produce a compressibility index of <21% so that it can be said to meet the requirements. The Haussner ratio was calculated by dividing the tapped density by the bulk density. The Haussner ratio value is said to be very good if the value is close to 1 and categorised as good if the value is <1.25. The higher the Haussner ratio value, the worse the flow of the powder/granule will be. From the test results, all formulas have a Haussner ratio of <1.25. This indicates that the Haussner ratio of the entire formula can be categorized as good. The results of the physical evaluation of the ready-to-compress mass (Table III).

Table III: Mass evaluation of the granule

Parameter	F1 (2%)	F2 (3%)	F3 (5%)	F4 (comparison)
Bulk Density	0.61±0.001	0.67±0,002	0.53±0,002	0.57±0,001
Tapped Density	0.71±0.002	0.80±0,001	0.65±0,002	0.69±0,001
Haussner Ratio	1.18±0,012	1.20±0,011	1.23±0,012	1.21±0,011
Compessibility	15.15±0,121	16.67±0,213	18.42±0,211	17.14±0,213
Angle of repose	34.61±1,230	30.06±1,211	32.08±1,113	29.47±1,212
Flowability (g/s)	13.66±1,111	15.54±1,211	15.07±1,112	14.50±1.211

The results of the evaluation of the friability of tablets F3 (banana starch 5%) and F4 (corn starch 5%) show that the required value is less than 1%, while the friability of F1 tablets (respondent banana starch 2%) and F2 tablets (banana starch 3%) shows friability results of more than 1%. Per cent friability is influenced by the amount of fine powder (fine powder) so that the compressed mass is not tightly bound at the time of pressing and will be released when there is friction between the tablet and the tablet or the tablet with the packaging.

Table IV. Evaluation of Metamizole tablet

Parameter	F1	F2	F3	F4
Weight (mg)	598.76 ± 5.42	603.11 ± 7.34	610.07 ± 4.98	597.91 ± 9.44
Hardness (kg/cm^2)	5 ± 1.20	8 ± 1.20	9 ± 1.20	8 ± 1.20
Thickness (mm)	0.58 ± 0.06	0.61 ± 0.08	0.63 ± 0.10	0.61 ± 0.08
Diameter (mm)	1.20 ± 0.01	1.20 ± 0.01	1.20 ± 0.01	1.20 ± 0.01
Disintegration time (minutes)	3.50 ± 0.012	9.15 ± 0.012	10.09 ± 0.012	5.44 ± 0.012
Friability (%)	1.18 ±0,011	1.74±0,012	0.22±0,021	0.60±0,0120

Dissolution

The tablet dissolution test was carried out on Formula 2, Formula 3 and Formula 4 tablets on the grounds that the tablets with these formulations had tablet characteristics that met the requirements for the dissolution testing process. The dissolution was carried out by method II; namely, a paddle using distilled water as much as 900 meters in a dissolution vessel and a rotation speed of 50 rpm with a temperature set at 37^0 C. Measurement of the metamizole wavelength absorption was based on literature at a wavelength of 260 nm (Table V and Figure 6).

Table V: Dissolution percentage of three Metamizole tablets with Banana starch and corn starch

Metamizole tablet with	Time (Minute)	1	5	10	15	20	30	40	50	60
3 % banana starch	% Dissolution	13.17± 0.0570	45.0 ± 0.100	69.11± 0.1155	83.40 ± 1.1234	88.84 ± 1.1134	96.73 ±1.1125	102.45± 1.1126	102.45± 1.1161	101.09± 1.1123
5 % banana starch	% Dissolution	14.53± 0.0653	37.53± 1.1116	73.73± 1.1115	80.67± 1.1123	86.80± 1.1132	96.73± 1.1114	97.01± 1.1132	98.50± 1.1121	99.59± 1.1116
5 % corn starch	% Dissolution	17.6± 0.0567	49.10± 0.1005	73.73± 1.1115	84.89± 1.1231	92.79± 1.1123	101.09± 1.1121	97.01± 1.1132	100.27± 1.1104	99.86± 1.1132

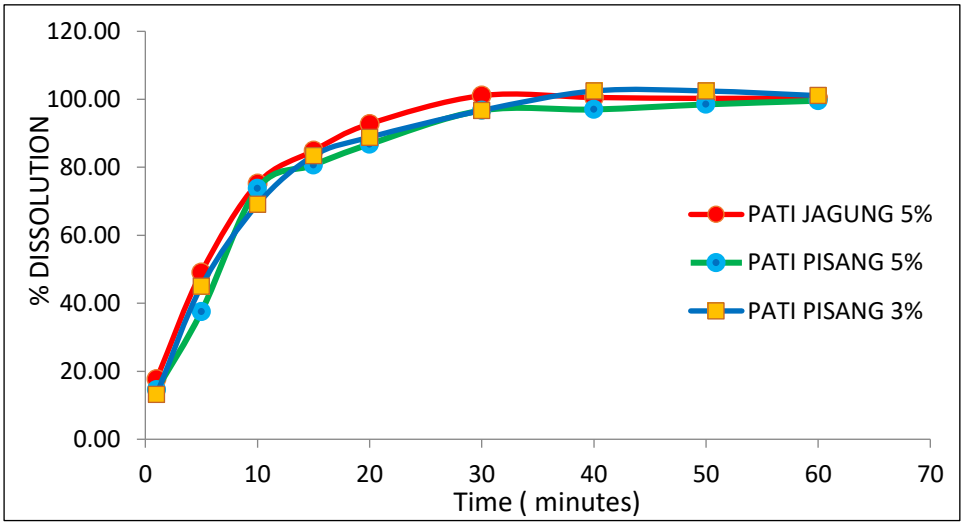


Figure 6: Dissolution profile of Metamizole tablets with 3%, 5% of banana starch binders and 5% corn starch

Indonesian Pharmacopoeia requires the release of metamizole tablets of more than 80% at 15 minutes. Based on the results of the dissolution test, the three sample formulas show a fairly good dissolution profile and meet dissolution requirements, but tablets formulated with banana starch are thought to show a slower dissolution process than corn starch. These results can be influenced by the disintegration power, causing the cohesiveness of the bonds between particles in the granules that are stronger than the formulation of corn starch tablets. The speed of disintegration affects the effectiveness of drug release for systemic absorption, but what is more influential is the speed of dissolution (J. Sinko, 2011). In this case, the binder concentration, viscosity, and swelling power of the binder affect the dissolution profile of the tablet preparation.

The similarity between tablet formulas can be seen from the calculation of the similarity value of the comparable dissolution test.

Conclusion

The starch of isolated banana fruit can be isolated by immersion technique with 0.1 N sodium metabisulfite solution for 16 hours and resulted in a yield of 21.5%. Starch isolated from banana fruit has functional characteristics that can be used as a pharmaceutical excipient especially in oral tablet formulation.

The results of the insulated banana fruit meet the additive standards Pharmaceutical Grade required by the USP and Handbook of Pharmaceutical Excipient.

Banana starch as a binder for metamizole tablets fulfills the requirements for a tablet dissolution test of more than 80% at 15 minutes. Based on the dissolution test results of the three sample formulas, the dissolution profile is quite good and meets dissolution requirements.

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