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Research Article

The Effect of Combination of Porang Tuber Starch (*Amorphophallus muelleri* Blume) with Lactose on the Physical Properties of Bajakah Root (*Spatholobus littoralis* Hassk) Water Extract's Tablet

Dian Eka Ermawati*, **Ridho R. Tambunan, Ulfa Afrinurfadhilah Darojati**

Department of Pharmacy, Vocational School, Universitas Sebelas Maret, Jalan Ir. Sutami 36 A, Kentingan, Jebres, Surakarta, Indonesia

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***Corresponding author:**
Dian Eka Ermawati
email:mbaday87@gmail.com

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ABSTRACT

Kalimantan's people drink bajakah roots as a traditional medicine to restore stamina and treat various diseases. The infusion is less practical and unstable, so it was developed into a tablet. Porang is a local tuber that contains amylum and amylopectin. The combination of starch-lactose has been widely used as a tablet filler and produces tablets with good physical properties. This study aimed to determine the effect of the combination of porang starch-lactose on the granules and tablets' physical properties. Bajakah roots were infused and dried using a freeze-dryer. The antioxidant activity was measured using the DPPH method. Tablets of bajakah root water extract were made with a 1:1 porang tuber starch-lactose ratio using the dry granulation. Physical evaluations of granules and tablets were conducted, including flow rate, angle of repose of granules, and weight uniformity, hardness, friability, and disintegration time of tablets. Porang tubers-lactose with a ratio of 1:1 produced tablets with good evaluation results with a granule flow rate of 9.70±0.92 g/s and an angle of repose of 26.15±1.79°. Uniformity of tablet weight met acceptance value, with hardness of 5.38±0.90 Kg, friability of 0.26±0.05%, and disintegration of 10.60±1.33 min. Porang tuber fulfills the requirements of a good tablet filler and can be developed as a tablet filler.

INTRODUCTION

Bajakah root (*Spatholobus littoralis* Hassk) is one of the plants used by generations of Kalimantan people as traditional medicine. Bajakah roots contain alkaloids, flavonoids, triterpenes, and phenolics (Maulina *et al*., 2019). The antioxidant activity (IC_{50}) of the red bajakah root is 26.29 ppm, which is a very high category in scavenging free radicals compared to vitamin C, which has an IC_{50} value of 30.74 ppm (Fitriani *et al*., 2020). Based on the content of secondary metabolites and antioxidant activity, the bajakah root can potentially be used as an active ingredient in a pharmaceutical dosage form. However, the current processing is still very simple, namely, the preparation involving only boiled public drinking water for treatment. This is considered less practical in its use, so it was developed in a tablet delivery system.

People commonly use tablets as medicinal preparations because of their efficiency, practicality, and stability during storage compared to liquid dosage forms. Additional materials used in the formulation of tablet preparations, one of which is a filler, increase the volume of mass for easy printing. Starch and lactose are excipients commonly used as fillers in tablets (Ermawati *et al*., 2017). Starch is a natural polymer that can be produced from plant tubers. Indonesia is rich in tubers that have the potential to be developed as a filler in tablet preparations, one of which is porang tubers (*Amorphophallus muelleri* Blume). Porang is one type of plant with technological and commercial potential in the medical, industrial, and food sectors (Affandi *et al*., 2019). Amylum, or starch, is a complex carbohydrate consisting of amylose and amylopectin. Amylose has hard properties, while amylopectin causes stickiness. Porang tuber starch in tablet preparation can be used as fillers and binders because they have high amylopectin content. High amylopectin levels tend to be easy to digest due to its branched structure and larger molecular size large so that it is easy to gelatinize (Ricana & Sunarti, 2004).

Porang tuber starch is a natural starch with poor flow properties and compressibility due to the high grain of starch that has small and elastic deformation (Ricana & Sunarti, 2004). Accordingly, the use of porang starch as a filler in this study was combined with lactose that has plastic deformation properties so that when compressed, it will form a hard and not brittle tablet. In addition, other advantages of lactose are its compatibility if mixed with other ingredients (Sa'adah & Fudholi., 2011), it has a flow rate of good quality, is easy to dry, and is relatively economical. The choice of the combination of porang tuber starch and lactose is expected to be a mutually beneficial complement or cover the weakness of the porang tuber starch material to produce granules with good physical properties. The ratio of the combination of fillers used is 1:1 because the comparison results in tablet preparations meet the requirements of a good tablet physique. The combination of starch-lactose at a ratio of 1:1 resulted in the evaluation of tablets that also meets the requirements with a hardness of 2.24±0.11 kg and 0.805% friability (Ermawati *et al*., 2019). This study aimed to determine and evaluate the effect of the combination of porang starch-lactose on the granules and tablets' physical properties.

METHODS

Material: Bajakah root from Palangkaraya, Kalimantan, Indonesia; Porang tuber from Karanganyar, Central Java, Indonesia; 2,2-diphenyl-1-picryl-hydrazl-hydrate (DPPH) (Merck, German); ethanol 96% pro analysis (p.a) (Merck, German); quercetin standard (Sigma); Mannitol (repacking by Planet Kimia, Indonesia); and phosphate buffer saline (PBS) solution (repacking by Maxlab, Indonesia). Instruments: oven (Memmert, Germany); freeze dryer (Telstar, made in United Kingdom); digital analytic (bel engineering M124Ai, Germany); Spectrophotometer Ultraviolet-Visible (Uv-Vis Genesys 150 Thermo-Scientific, USA); single punch tablet machine (Korsch type Eko, German); friabillator (CS-II, China); disintegration tester (BJ-II Laobao, China); hardness tester (YD-I, China); and apparatus dissolution type 2 (RC-6 dissolution tester, China).

Sample Preparation

Plant determination was conducted in the Biology Laboratorium of Mathematics and Natural Science Faculty, UNS, Surakarta, Indonesia, with document No. 014/UN27.9.6.4/Lab/2022. Preparation steps were as follows: porang tubers were washed, then peeled and grated. Grated porang was extracted using distilled water two times with ratios of 1:3 and 5:3. Thick starch liquid was precipitated for 24 hours until a separation was seen, and the part that settles is starch from porang tubers. After the second extraction, the starch was dried at 60 °C using an oven for approximately 6 hours. Dry starch was crushed and tested for moisture content. Bajakah roots then were boiled in two stages using the method of inundation using distilled water at a ratio of 1:20 and 1:10 at a temperature of 90 °C until thick. After that, the solution was filtered and allowed to cool. The aqueous extract solution was dried using a freeze-dryer.

Antioxidant Activity of Bajakah Root Water Extract

A stock solution of DPPH 0.4 mM was taken of 1.0 mL and diluted with ethanol 96% p.a in a 5.0 mL volumetric flask. The diluted solution was scanned at a maximum wavelength of 200-700 nm using a UV-Vis spectrophotometer, where ethanol was 96% p.a as blank. Bajakah root water extract was weighed thoroughly at 500 mg and then dissolved with ethanol 96% p.a in a 50 mL volumetric flask. The stock solution I was taken was 0.5; 1.0; 2.0; 3.0; 4.0; and 5.0 mL into a 5 mL volumetric flask, then added ethanol 96% p.a. The stock solution 1 took as much as 2.0 mL, was added with 1.0 mL of 0.4 mM DPPH solution into a 5.0 mL volumetric flask and added ethanol 96% p.a solution to the mark of the volumetric flask. A series of solutions were added with 0.4 mM DPPH solution and then read for absorbance at the maximum wavelength of DPPH using a UV-Vis spectrophotometer. The standard curve is obtained by making a relationship between the concentration and the absorbance value. The curve linearity calculation standard is done by calculating the value of the relation coefficient (r) with a range of concentration series. The standard curve chosen gives the best linearity (r> 0.99) then the IC50 value can be calculated.

Tablet Formulation

The formula of bajakah root water extract tablet in this study was developed from optimum formula research by Ermawati *et al.* (2019) with modifications to the material components. Formulas were made with a comparison of porang-lactose starch as filler at a ratio of 1:1 with 500 mg tablet weight. The potential active ingredient of bajakah root water extract is 25 mg for antioxidant supplements, so there is no dose limit. All ingredients are weighed according to the weight in the formula (Table 1). Binder - polyvinylpyrrolidone (PVP), fillers (porang tuber starch and lactose), disintegrant (amprotab), and active ingredients (bajakah root water extract) were mixed until homogeneous. The mixture of materials was compacted and broken into smaller granules using the dry granulation method. In the next step, lubricants (Mg stearate and talcum) were added and stirred again until homogeneous.

Granule and Tablet Physical Evaluation

Granule preparation and evaluation steps were as follows: Granules are weighed 100 grams and put into the funnel with the bottom closed. After all the granules are in the funnel, the bottom cover is opened, and the granules let flow until it runs out. The height of the cone is formed to measure and calculate the angle of repose in degrees. The granules of 100 grams were weighed and then poured into the funnel with the bottom opened, and the flow time was recorded using a stopwatch with three replications and calculate the speed of granules flow was in g/second.

Tablet printing uses a single-punch tablet printing machine. The desired tablet weight is 500 mg; the punch on the printer is set with the upper punch being rotated to the left to increase the hardness; on the contrary, if the lower punch is rotated to the right, the hardness. While the lower punch is related to the resulting weight, if the tool has been set, the granules are put into a funnel of the machine and printing can proceed to tablet evaluation tests. Tablet properties tests were conducted including weight uniformity, hardness, friability, and disintegration time.

Table 1. Bajakah root water extract tablet formula (developed formula based on (Ermawati *et al.*, 2019)

Ingredients	Weight (mg)	Function of ingredients
Bajakah root water extract	25.00	Active substances, antioxidant
Porang tuber starch	216.25	Filler
Mannitol	216.25	Filler
PVP K-30 0.5%	2.50	Binder
Amprotab 5%	25.00	Disintegration agent
Mg Stearate 1%	5.00	Antiadherent
Talcum 2%	10.00	Lubricant, glidant
Total	500.00	

Figure 1. The result of isolation porang tuber starch and bajakah root water extract tablets.

Weight uniformity was tested by carefully weighing ten tablets one by one with a scale analysis, then the average weight is calculated. The amount of active substance is calculated in each tablet and expressed as a percent on the label of the assay results of each tablet. Hardness test of tablets is done through one tablet placed on the tip of the tablet hardness tester tool. After that, the tool is rotated fully until it beeps and shows the scale when the tablet breaks in the Kg scale. The disintegration tester is filled with water, and the chamber is filled to 900 mL. The tool is turned on and waited until the water temperature reaches 37 °C. A total of six tablets are placed into the basket, and the machine runs for 15 minutes. Each crushed tablet's duration is recorded in minutes until the tablet dissolves without residue. Friability test is done by selecting the tablet that is dust free first, then 20 tablets are weighed several times for an average weight. Afterward, the tablet is inserted into the friability tester cylinder, and the instrument was run at 100 rpm. After the process, the tablet is taken, freed, dusted, and weighed again. The lost weight is calculated from the difference between the weights before and after being rotated.

Data Analysis

The antioxidant content of the bajakah root was calculated using the linear equation regression of the results of making the standard curve of the bajakah extract concentration series with the equation of y=bx+a, where the value of y is the absorbance of the bajakah root. Physical properties of granules and tablets of bajakah root (*Spatholobus littoralis* Hassk) water extract with a combination of porang starch (*Amorphophallus muelleri* Blume) and lactose as fillers were analyzed theoretically according to the standard requirements of the Indonesian Pharmacopoeia and United States Pharmacopoeia (USP).

RESULTS AND DISCUSSION

The plants used in this study were porang tubers from *Amorphophallus muelleri* Blume species. Amylum porang tuber's product is cream in color with a porang odor (Figure 1). The average water content in porang tuber starch is 9.33%, so it can be concluded that porang tuber starch has met the moisture content standard of no more than 10% (Depkes RI, 2015). Bajakah root water extract was dried using a freeze dryer. Freeze drying is a method in which a solution is frozen to reduce the moisture content of an unprocessed sample heating so that it is suitable for drying thermolabile compounds. The freeze-drying method was chosen because it can maintain the properties of antioxidants and phenolics. This is because no thermal degradation occurs (Yulvianti *et al.*, 2015). Freeze-drying is a method with high drying efficiency because the ice crystals formed in the plant can break down the cell structure, causing cell components to exit and facilitate the solvent to enter.

DPPH radical attenuation method solution is based on the reduction of the methanol solution of DPPH, which is colored by free radical inhibition. When the DPPH solution's purple color meets the electron donor material, the DPPH will be reduced, causing the purple color to fade, and be replaced by yellow derived from the picryl group of antioxidant compounds. The result of the maximum wavelength of DPPH is 518 nm. The linear equality regression obtained is y = 356.48x – 4.66. The standard curve shows the relationship between the concentration of the extract solution of bajakah root water extract (mg/mL) with antioxidant activity. If the concentration of the extract is greater, the antioxidant activity will also increase. After that, the IC50 value of the bajakah root is calculated. The IC50 value obtained is 0.155 mg/mL, which means it is classified as very strong because it has an IC50 value of <50 mg/mL (Maulina *et al.*, 2019). Compared to research by Prayoga (2013), the IC50 value obtained is included in the same category, which is very strong at 8.25 mg/mL. Therefore, it can be concluded that bajakah root water extract in this study has relatively strong antioxidant activity (Musa *et al.*, 2013). Antioxidant activity in bajakah root is influenced by the total flavonoid compound that can stabilize free radicals.

Granule and Tablet Physical Evaluations

The flow properties are important for good tablet manufacturing because it relates to the uniformity of powder filling into the die. Die on a tablet printing machine can affect the uniformity of weight and the content of the active substance. Aspects that can affect the flow properties of the powder include the shape and size of the granule particles, particle size distribution, surface roughness or texture, energy loss surface area, and surface area (USP, 2008; USP, 2017). The good granule flow time for a 100-gram granule is less than 10 seconds. Based on the evaluation results, the granule flow rate of Bajakah root water extract averages 9.70±0.92 grams/second. This flow speed meets the requirements of a good flow rate of >10 g/second (USP, 2008; USP, 2017). The results of the evaluation indicate the angle of repose of the granules of the bajakah root water extract has an average angle of repose of 26.15±1.79°. This result shows the angle of repose of the granules according to the requirements so that the granule flow properties of the pirated root water extract tablet with a combination of porang tuber starch fillers and lactose are included in the angle of repose category with special or very good flow properties, which is between 25-30° (USP, 2008; USP, 2017). The smaller the angle of repose obtained, the more the flow properties granules can better facilitate the tableting process, and the expected uniformity of tablet weight can be achieved. The flow properties of the powder influence weight uniformity during filling from the hopper into the die with a constant volume so that a uniform tablet weight is obtained. Weight uniformity is also related to the uniformity of drug levels in tablets.

According to the requirements of Pharmacopoeia VI (Depkes RI, 2015), the maximum acceptable value allowed is 15 in the first stage (L1 = 15). The results show that the bajakah root water extract tablet has met the requirements for weight uniformity with the average acceptance value (AV) of the three replications of 3.87, which is less than 15. Hence, the tablet weight meets acceptance values. Based on the evaluation results, the hardness of the bajakah root water extract tablets has an average of 5.38±0.90 Kg. This result shows that the bajakah root water extract tablet has a good hardness according to the requirements of 4-8 Kg (USP, 2008; USP, 2017). The tablet's fragility can affect disintegration time and tablet dissolution. The more brittle the tablet, the disintegration time faster, so the release of the active substance from the tablet will also take a short time. The fragility of tablets can be overcome by increasing the concentration of the binder so that the bonding of the particles on the tablet can be increased and the level of brittleness can be reduced. The evaluation results of tablet friability showed that the percent of fragility in all three replications meets the requirements for good brittleness, which is less than 1% (USP, 2008; USP, 2017), with an average of 0.26 ± 0.05%.

Time disintegration greatly affects tablet dissolution because the tablet disintegrates into small particles of its constituents. The active substance in the preparation will be released so that the active substance can be dissolved in a suitable medium and is ready for use and absorbed by the body. Disintegration time is affected by the hardness and brittleness tablet (Zaman & Sopyan, 2020). Results show that the average disintegration time of the six bajakah root water extract tablets is 10.60±1.33 minutes, which met the time requirements. Good disintegration for uncoated tablets is <15 minutes (USP, 2008; USP, 2017). Data on the results of physical properties of granules and tablets of pirated root water extract with a combination of porang tuber starch filler and lactose at a ratio of 1: 1 showed that all meet the specified requirements, namely granule flow rate 9.70±0.92 gram/second, granule angle of repose 26.15±1.79°, uniformity of tablet weight meets the acceptance value, tablet hardness 5.38±0.90 kg, tablet friability 0.26±0.05%, and tablet disintegration time 10.60±1.33 minutes. Tablets need to be tested for dissolution to find out how long it takes for tablets to release the active substance (Figure 1).

CONCLUSIONS

Porang tuber starch (*Amorphophallus muelleri* Blume) in combination with lactose at a ratio of 1:1 affect the results of the physical properties of granules and tablets of bajakah root water extract (*Spatholobus littoralis* Hassk). The combination produces granule flow velocity of 9.70±0.92 gram/second and angle of repose of granule 26.15±1.79°. Tablet weight uniformity met the acceptance value, tablet hardness 5.38±0.90 Kg, tablet friability 0.26±0.05%, and tablet disintegration time of 10.60±1.33 minutes. Bajakah root water extract tablets meet the requirements for the physical evaluation of a good tablet preparation according to the requirements of the Indonesian Pharmacopoeia and USP.

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CONFLICT OF INTEREST

The authors stated that there was no conflict of interest.

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