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Formulation of Acetaminophen Granules with Porang Tuber Amylum (Amorphophallusoncophyllus) that Meets the Parameters of Particle Size Distribution and Destruction Time

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ABSTRACT

Many farmers are interested in planting porang tubers, with many farmers planting porang tubers, the price of porang tubers will decrease during harvest . Porang tubers have several contents, namely starch, glucomannan, fiber, fat, protein, minerals and vitamins. Glucomannan content can be used as a tablet binder, thickener, gilling agent, film former, coating material emulsifier, and stabilizer. The purpose of this study was to determine the concentration of porang tuber flour as a binder in Acetaminophenum granules using the wet granulation method. Granules were made into three formulations with variations in the concentration of porang tuber flour, namely FI 5%, FII 7.5% and FIII 10%. GRANULES were tested for tablet uniformity, tablet hardness, tablet fragility , disintegration time, and granule size distribution. The data obtained were analyzed using Kruskal Wallis. The results of the analysis showed that variations in the concentration of porang tuber flour had different effects, based on the Kruskal Wallis analysis which showed a significant value of 0.10 (p> 0.05). The formulation that has a good physical quality test is formulation III, with a tablet hardness value of 6.84 kg and a disintegration time of 5.74 minutes which is almost close to the control (+) 14.27 kg and 6.38 minutes. The higher the concentration of porang tuber flour , the higher, the longer the disintegration time.

Keywords: Acetaminophenum, Porang Tuber Flour, Wet Granulation

INTRODUCTION

Porang tubers (Amorphophallus oncophyllus) are a type of taro plant that grows wild almost throughout Indonesia (Sugiyono et al., 2016). Recently, many farmers have been interested in planting porang tubers, with many farmers planting porang tubers, the price of porang tubers will decrease at harvest time (Idris, 2021). According to (Rachmawati, 2021) porang tubers are usually processed into rice, shirataki, mixed ingredients in cakes, bread, ice cream, and syrup. In fact, porang tubers have several contents of starch , glucomannan, fiber, fat, protein, minerals, and vitamins (Saleh et al., 2015). According to (Wardani et al., 2021) Glucomannan has the ability to thicken and form gels, so glucomannan can be used as a tablet binder, thickener, gilling agent, film former, coating materials, emulsifier, and stabilizer. Porang tubers have a glucomannan content of around 55% (Saleh et al., 2015). Tablet preparations are solid preparations that are very often used. Tablets are compact solid preparations, made by molding, in the form of flat or circular tubes, both surfaces are flat or convex, contain one or more types of drugs, use or do not use additional materials. Additional materials or excipients can act as fillers, developers, binders, wetting agents or other appropriate materials (Ministry of Health of the Republic of Indonesia, 1979). In making tablets there are several additional materials, namely fillers, binders, lubricants and disintegrants. 2 Binders are divided into natural binders, synthetic polymers and sugars (Murtini et al., 2018). The binders commonly used are CMC Na, HPC, PVP, and gelatin (Murtini et al., 2018). One of the binders used is porang tubers (Amorphophallus

oncophyllus). Porang tubers (Amorphophallus oncophyllus) are one type of taro plant that grows wild in Indonesia (Sugiyono et al., 2016). Porang tubers have a fairly high glucomannan content (Saleh et al., 2015). Glucomannan has physical properties that can expand in water up to 139-200% (Widjanarko et al., 2015). Glucomannan, in addition to being used as a binder, can also be used as a filler and tablet disintegrant (Sugiyono et al., 2016). In making tablets, the addition of disintegrants is also required. Disintegrants are added to the manufacture of tablets to facilitate the process of drug absorption. Disintegrants help to destroyrelease of active ingredients in tablets into granules that can increase the speed of drug dissolution (Murtini et al., 2018). In this study, the disintegrant used was sodium starch glycolate. Sodium starch glycolate is effective as a disintegrant and is not affected by the presence of hydrophobic excipients (Rowe et al., 2009). The use of the concentration of the binder starts from the smallest, then the physical and chemical properties of the tablets produced from the results of the study of porang tuber flour can be used as a variation of the binder in making tablets.

METHODS

Tools

The tools used in this study were knives, baking paper, blenders, sieves, mortars, stampers, spatulas, single punches, funnels, stopwatches, rulers, analytical scales, hardness testers, friabilator testers.

Materials

The materials used in this study were HCl, NaHCO3, metamizole Na, porang tuber flour, sodium starch glycolate, mg stearate, talc, lactose, and distilled water. F.

Sample Preparation

1. Sample Collection The collection was carried out with the aim of collecting porang tubers before being made into flour. The porang tubers used in the study were obtained from Sumberdadi hamlet, Kandangan village, Pesanggaran sub-district, Banyuwangi regency, East Java. 2. Making Porang Tuber Flour (Amorphophallus oncophyllus) Porang tubers were washed and sliced with a thickness of ±0.2 cm. The tuber slices are soaked in water at 40°C for 3 hours, then drained and soaked in 15% HCl solution for 60 minutes. The tuber slices are then washed with running water until clean. Next, the slices are dried. Dried by drying in the sun until the chips (porang chips) are easy to break. The porang chips are then ground into flour using a grinding machine and sieved with a 35 mesh sieve to obtain porang tuber flour (Wardani et al., 2021).

Bahan	Formulasi Tablet				
	Kontrol (+)	Kontrol (-)	FI	FII	FIII
Metamizole Na	Produk jadi	500 mg	500 mg	500 mg	500 mg
Tepung Umbi Porang	Granul Paracetamol	-	5%	7,5%	10%
Sodium starch glycolate	500 mg	4%	4%	4%	4%
Mg Stearat		5%	5%	5%	5%
Talk		5%	5%	5%	5%

Granule Making a. Control (–) Weigh 50 g of Acetaminophen, 2.6 g of sodium starch glycolate, 0.65 g of Mg stearate, 0.65 g of talc and 11.1 g of lactose. Put Acetaminophen, sodium starch glycolate, Mg. stearate and Talc into a mortar and stir until homogeneous. Then, add 6 ml of water to the mixture and stir until homogeneous. Then, bake the powder at a temperature of 50°C for 60 minutes. Then, mold the granules using a single punch machine

with a weight of 650 mg. b. Formulation I Weigh 50 grams of Acetaminophen, 3.25 grams of porang tuber flour, 2.6 grams of sodium starch glycolate, 0.65 grams of Mg stearate , 0.65 grams of talc. Put Acetaminophen, 19 sodium starch glycolate, Mg. stearate and talc into a mortar, stir until homogeneous. Then the mixture is added with 6 ml of water, stir until homogeneous. Next, the powder is ovened at a temperature of 50°C for 60 minutes. Next, the granules are molded using a single punch machine with a weight of 650 mg. c. Formulation II Weigh 50 grams of Acetaminophenum, 4.875 grams of porang tuber flour, 2.6 grams of sodium starch glycolate, 0.65 grams of Mg. stearate, and talc. Put Acetaminophenum, sodium starch glycolate, Mg. stearate and talc into a mortar, stir until homogeneous. Then, the mixture is added with 6 ml of water, stir until homogeneous. Next, the powder is ovened at a temperature of 50°C for 60 minutes. Next, the granules are molded using a single punch machine with a weight of 650 mg. d. Formulation III Weigh 50 grams of Acetaminophen, 6.5 grams of porang tuber flour, 2.6 grams of sodium starch glycolate, 0.65 grams of Mg stearate, 0.65 grams of talc. Put Acetaminophen, sodium starch glycolate, Mg. stearate and talc into a mortar, stir until homogeneous. Then, the mixture is added with 6 ml of water, stir until homogeneous. Next, the powder is oven at a temperature of 50°C for 60 minutes. Then print the granules using a single punch machine with a weight of 650 mg.

RESULTS

This study aims to determine the Acetaminophenum granule test using a binder of porang tuber flour (Amorphophallus oncophyllus) which meets the parameters of disintegration time and granule size distribution, in addition to that, compressibility tests, water content tests, angle of repose tests and flow time tests were also carried out. Before conducting the study, porang tubers (Amorphophallus oncophyllus) were first determined at the UPT Materia Medika Batu Malang City to determine the correct identity of the porang tubers to be studied. This was done to ensure that the plants used had the correct identity (Sawiji et al., 2020). In granulation, flow time and angle of repose tests were carried out. Flow time testing was carried out by weighing 25 mg of granules then inserting them into a funnel then turning on the stopwatch while opening the funnel lid, making sure all granules were not left in the funnel and recording the time needed until the granules in the funnel ran out. The average flow time results for formulation I, formulation II, formulation III and control (-) were 2.74 seconds, 2.84 seconds, 2.83 seconds and 2.11 seconds. From table 6. it can be seen that the flow time for all formulations from formulation I, formulation II, formulation III and Control (-) had a flow time of less than 10 seconds. Therefore, all formulations meet the flow time requirements, which are less than 10 seconds (NF et al., 2020). The angle of repose test on granules was tested by calculating the height and radius of the granules, which was carried out by the angle of repose with the following formula Tan $\alpha = h$. The angle of repose is the maximum angle of 25 formed by the powder surface with the horizontal surface at the time of testing (Rijal et al., 2022). Granules are said to be good when the angle of repose obtained is not less than 280 -420 (Fadlil et al., 2017). The results of the angle of repose of formulation I, formulation II, formulation III and control (–) are 32.63°; 33.40°; 34, 40° and 31.71°. It is known that formulation I, formulation II, formulation III and control (–) meet the requirements of the angle of repose test of granules.

DISCUSSION

The disintegration time test is carried out by preparing distilled water and putting it into a 1 liter beaker glass, attaching the beaker glass to the disintegrator tester. Set the tool at a temperature of 37°C, after the temperature of the distilled water reaches 37°C, put 6 tablets in each tube, then hook the tube to the disintegrator tester, run the tool and set the time for 15 minutes (Ministry ofHealth of the Republic of Indonesia, 2020). The results of the

disintegration time test on formulation I, formulation II, Formulation III, Control (-) and control (+) were 3.28 minutes; 4.51 minutes; 5.74 minutes; 0.31 minutes and 6.38 minutes. All formulations met the requirements for the disintegration time test, which was <15 minutes. The results were tested statistically on the normality test, the significant value was 0.018 and on the homogeneity test, the significant value was 0.004. The results of the homogeneity test and normality test were less than 0.05, so the Kruskal Wallis test was carried out. The results of the Kruskal Wallis test obtained a significant value of less than 0.05, which can be said that there is a significant difference, so the post hoc test was continued. The results of the post hoc test were that the control (-) had differences with all formulations and control (+), in formulation I it had differences with all formulations, control (-) and control (+), in formulation II it had differences with all formulations, control (-) and control (+), in formulation III it had a difference of 26 with the differences in all formulations and control (-), in control (+) it had differences with formulation I, formulation II and control (-). It can be concluded that differences in binder concentration affect the disintegration time (Fadhilah et al., 2019). The higher the binder concentration, the longer the tablet disintegrates.

CONCLUSION

Porang tuber flour as a binder with a concentration of 5%, 7.5%, and 10% in the formulation of granule preparations using the wet granulation method can have different effects on the evaluation of the resulting tablets. Where at a concentration of 10% it has the best binding power compared to Acetaminophenum®. 2. The Acetaminophenum granule formulation with porang tuber flour as a 10% binder has the best physical quality test of the tablet, namely with a hardness test value of 6.84 kg and has a disintegration time of 5.74 minutes and the slowest dissolution. This is because the binder used is greater than formulation I and formulation II.

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