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TABLET FORMULATION OF BANANA FRUIT EXTRACT (*MUSA TROGLODYTARUM* L.) FOR ANTIDIABETIC TREATMENT

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ABSTRACT

Previous studies reported that extracts of banana fruit (*Musa troglosytarum* L.) had antidiabetic activity in vivo. In order to be more efficient and easy to use by consumers, it is necessary to do a formulation of the extract of banana fruit extract ranggap (*Musa troglodytarum* L.). In this study, banana fruit extract tablets were formulated in using wet granulation method through 2 stages, namely optimization and production. Optimization to see fillers suitable for the characteristics of banana extract and the result is avicel PH 101 is the best filler for extracting banana fruit. The next stage of production is using variations in the concentration of polyvinylpyrolidone (PVP) binder. Variations used are 1%, 3%, and 5%. From the three formulations, granules and tablets were evaluated physically to determine the best formula of the three formulas. From the evaluation results it was concluded that the best formulas were formulas 1 and 2. The results of TLC showed that making tablet formulations did not damage or eliminate the chemical content of the extract of banana fruit (*Musa troglodytarum* L.).

Keywords : Tablet, wet granulation, fruit of ranggap banana, *Musa troglodytarum* L.

INTRODUCTION

Globally, the number of people with diabetes has increased significantly from year to year. The 8th edition of the Diabetes Atlas published by the International Diabetes Federation 2017 states that 425 million of the world's total population, or around 8.8 percent of adults aged 20-79 years are diabetic.The data also reveals that it is ranked 6th as the highest number of adult diabetics in the world with a total of more than 10.3 million people. This figure is predicted to continue to increase and reach 16.7 million in 2045.In Indonesia itself, based on the latest data from the 2018 Basic Health Research, in general, the prevalence of diabetes has increased quite significantly over the last five years. In 2013, the prevalence rate of diabetes in adults reached 6.9 percent, and in 2018 the figure continues to increase to 8.5 percent. One of the plants that empirically has antidiabetic effects is the ranggap banana (*Musa Troglodytarum* L). This fruit is a fruit that has a fairly narrow spread on galunggung Mountain in Tasikmalaya West Java and the islands of Maluku and Papua (Ploetz et.al, 2007).

Bananas ranggap is one of the plants that has high potential as an alternative therapy for diabetes mellitus, this is supported by research conducted by Samson et.al (2013) which states that bananas ranggap contains β-carotene compounds. B-carotene compounds are antioxidant compounds that have the main function as precursors of provitamin A (Sharma, et.al., 2012). According to research conducted by Englberger (2003) the sky-banana banana has a very high total carotenoid content of 6360 µg / 100 gram and 4960 µg / 100 gram is β-carotene.

According to Soviana et al. (2014) antioxidant compounds have the potential as antidiabetic through the mechanism of free radical inactivation. Diabetes mellitus is a disease that is triggered through a poor lifestyle so that free radicals become activated and cause damage to pancreatic β cells. B-carotene compounds can inhibit the activation of free radicals which cause inhibition of oxidative stress causing a protective effect on pancreatic tissue. The results of the study showed a significant decrease in blood sugar levels in the treatment group by giving a multilevel dose of β-carotene.

The use of ranggap bananas in herbal development, especially pharmaceutical preparations, is still rarely done, therefore the authors develop pharmaceutical preparations in the form of tablets which tend to be easily used by the public by using variations in the concentration of binders namely PVP. This compound is an excipient of pharmaceutical preparations that have many functions, one of which is as a binder on tablets. Binding compounds have a very important function in the creation of good, solid, and strong tablet preparations. In its use, PVP is a very good binder excipient, PVP has non-toxic properties when given orally, gives excellent granule characteristics and has properties easily absorbed by the digestive tract (Rustiani et al, 2017). The use of variations in the concentration of binding

aims to see its effect in physical and chemical properties. The tablet formulation is intended to keep the compound content in the banana extract more secure and stable, so it is expected that by using the tablet formulation, the quality and efficacy of the banana extract can still be maintained.

MATERIALS AND METHODS

Materials

The plant material used was simplicia of banana tongka langit (Musa troglodytharum L.) which was obtained from the Galunggung Mountain , Tasikmalaya.Chemical materialThe extraction process used was 70% ethanol. The solvents and reagents used for phytochemical screening included reagents of FeCl3, 10% chloroform, 1% gelatin solution, 2 N hydrochloric acid, Mayer reagent, Dragendorff reagent, 1 N sodium hydroxide, magnesium powder, amyl alcohol, vanillin-sulfate reagent, ether and distilled water. In the test of extract parameters the ingredients used include saturated water chloroform, formic acid, 95% ethanol, ethylacetate, toluene. In the formulation process, the ingredients used were distilled water, aerosil, amprotab, lactose monohydrate, Mg stearate, PVP, and talk.

Methods

The method used in this study is an experimental method in the laboratory. The steps taken were collecting simplicia and plant determination, extracting simplicia, extracting phytochemical extracts, formulating tablet preparations, evaluating granules and tablets and testing the levels of β-carotene using UV-Vis spectrophotometers.

Collection of Simplicia and Plant Determination

Plant material used in the form of simplicia banana ranggap (*Musa troglodytharum* L.) was obtained from the Galunggung Mountain Tasikmalaya, West Java. Determination of banana trees in the sky is done at the Laboratory of Taxonomy, Department of Biology, Faculty of Mathematics and Natural Sciences, Universitas Padjadjaran.

Simplicia Extraction

Simplicia of banana ranggap fruit was weighed as much as 5 kg and extracted by maceration method. The solvent used for extraction was 70% ethanol as much as 50 L for 3 times 24 hours. The obtained maserate was concentrated using a rotary evaporator at a temperature of 60-70^{0}C with a rotation speed of 60-75 rpm until at least 3 of the 4 parts of the solvent were evaporated or called viscous extract. The thick extract was then evaporated at 65^{0}C. After the thick extract was obtained, weighed and calculated the extract extract. (Kasmawati et.al, 2021)

Recovery (%) = (weight of total extract) / (weight of simplicia) x 100%

Phytochemical Screening of Extracts

Phytochemical screening of banana fruit extract tongka Langit is done by the method according to Farnsworth (1966), which included:

Flavonoid Test

The extract was dissolved in hot water then

cooled, then filtered and added 2N hydrochloric acid solution and magnesium powder. The mixture was filtered and the filtrate was added with an amyl alcohol solution and shaken. The yellow to red color in the amyl alcohol layer indicates the presence of flavonoids.

Alkaloid Test

10% ammonia was used to make the extract then crushed, added chloroform and then scour again. The chloroform layer was pipetted using a cotton corked pipette. After that, the chloroform layer was added with 2N hydrochloric acid solution and then divided into three parts as follows:a. The first part was a blank. The second part was added by Mayer reagent. The presence of alkaloid compounds was indicated by the formation of white depositsc. The third part was added by Dragendorff reagent. The presence of alkaloid compounds was indicated by the formation of brown orange deposits.

Tanin and Polyphenol Test

The polyphenol testing was carried out by extracting it in hot water, cooling it and filtering it and dropping a solution of iron (III) chloride. The presence of polyphenol compounds was indicated by the formation of blue-black. Tannin testing was done by extracting a 1% gelatin solution. The formation of white deposits shows the presence of tannin compounds. Test Monoterpenoid and SesquiterpenoidA number of banana extracts from the sky were added to the ether solution and then evaporated to dryness. Dropped vanillin sulfate reagent into the residue formed. The presence of monoterpenoid and sesquiterpenoid compounds was indicated by the formation of colors.

Steroid and Triterpenoid Tests

The extract was added to the ether solution and then evaporated to dryness. Dropped Liebermann-Burchard reagent into the residue formed. The presence of steroid compounds was indicated by the formation of blue-green color, while the presence of triterpenoid compounds was indicated by the formation of purple.

Saponin Test

The extract was dissolved in hot water, cooled, filtered and then added hydrochloric acid then shaken vigorously for 30 seconds. The presence of saponin compoundswas indicated by the formation of persistent foam with a height of 1 cm and not disappear for several minutes.

Quinone Test

The extract was dissolved in hot water, cooled, then filtered. The filtrate was poured with a solution of KOH 1N. The formation of yellow to red indicated the presence of quinone compounds.Thin layer chromatographyQualitative tests were carried out using thin layer chromatography using silica gel as a stationary phase and using the mobile phase in the form of petroleum ether: benzene (9: 1). Stains were observed using ultraviolet light at 254 nm and 10% sulfuric acid (Fuller et.al, 2011).

Tablet formulationIn this study, tablet formulations were carried out with various variations on tablets. The weight of one tablet that will be made is 650 mg tablets.

The formula for banana extract tablets in the sky is presented in the following table:

Table 1. Formulation of Tablets

Ingredients	Quantity per Tablet (mg)		
	F1	F2	F3
Fruit extracts	300	300	300
Aerosil	12	12	12
Amprotab	30	30	30
Mg stearate	12	12	12
PVP	6	18	30
Talc	12	12	2
Avicel PH 101	228	216	204

The procedure for making tablets was made by wet granulation method with the following stages: the ingredients used were all sifted and then weighed and the ingredients included in the inner phase (banana fruit extract tongka sky, amprotab and fillers namely lactose monohydrate) were mixed into the container and stirred homogeneously . After stirring, a binding agent (PVP) was added until a thick mass could be formed. The mixture was then granulated using mesh No. 16, then stored in an oven tray, put into a 70° C oven for 24 hours. After the moisture content reached 2-5% the granule was passed through mesh No. 36, then the outer phase ingredients (amprotab, mg stearate and talc) were added. Then it was printed using a printing machine with a punch tablet with a diameter of 1 cm with a weight of 650mg / tablet and carried out an evaluation of the tablet.

Evaluation of Granules

Flow Measurements

Angle of Repose The angle of repose was the angle formed by the horizontal base of the bench surface and the edge of a cone-like pile of granules. Funnel used was a stainless steel funnel and the size of the orifice was 10 mm and the height from the beginning of funnel to end of orifice was 111 mm. The funnel was fixed in place, 4 cm above the bench surface. After the cone from 5 g of sample was built, height of the granules forming the cone (h) and the radius ® of the base were measured. The angle of repose (θ) was calculated as follows:

$$\theta = \tan^{-1} \frac{h}{r} \quad (1)$$

Results were only considered valid when a symmetrical cone of powder was formed.

Bulk Density and Tapped Density

Bulk and tapped densities were determined using the methods outlined in the USP (2). Samples (9–13 g) of MgSt were passed through a no. 18 sieve into a pre-weighed 25 ml graduated cylinder with 0.5 ml markings. The bulk volume was measured after manually tapping the cylinder two times on a flat table top surface.

Compressibility Index and Hausner Ratio

The bulk and tapped densities were used to calculate the Carr's compressibility index (3) (Eq. 2) and the Hausner ratio(4) (Eq. 3) to provide a measure of the flow properties and compressibility of the granules.

$$CI = \frac{\rho tap - \rho bulk}{\rho tap} \quad (2)$$

where ρtap was the tap density and ρbulk is the bulk density.

Evaluation of Tablet Preparations

Hardness Test

Testing of tablet hardness was done using Hardness tester by means of tablets tested one by one as many as 20 tablets by placing them in the Hardness tester and then seeing the hardness. The requirement for testing the violence is> 40 (Lachman et.al, 1994).

Weight Uniformity Test

Variation between tablet with respect to dose and weight must be reduced to a minimum. Uniformity of weight was an in process test parameter which ensures consistency of dosage units during compression.

Tests were carried out on 20 tablets by weighing one tablet at a time that was.

Friability Test

Testing was done using a friabilator. 20 tablets were weighed, then the dust was removed. Put the tablets into the appliance and then the device ws operated with a number of rotations of 500 times (20 minutes). Calculate the final weight of the test results. After that, calculated% Friability by using the following formula (Agoes, 2006):

Percentage of Friability = (Wo-W) / Wo x 100%

Description: Wo = Initial WeightW = Final weightThe maximum loss of mass is 0.8% (Gupta, 1994).

The maximum loss of mass is 0.8% (Gupta, 1994).

Indonesian Pharmacopoeia requirements mentioned: unless stated otherwise, all tablets must be destroyed <15 minutes (without salute) and <60 minutes (salute) (DepKes RI, 2014)

RESULTS AND DISCUSSION

Results of Material Collection and Plant DeterminationCollection of simplicia raw materials was done in the area of Gunung Galunggung, Tasikmalaya. After that the bananas were used for plant determination carried out in the Department of Biology, Faculty of MIPA UNPAD.

Simplicia Extraction Results

Simplicia	Viscous extract	Yield
2.05 kg	330.97 kg	16.14 %

The fruit that had been obtained was processed by means of peeling and thinly sliced, then dried by airing for 2 weeks. The goal was to dry the fruit to become simplicia. Direct sunlight was avoided to prevent the content in bananas from

being damaged during drying. After that extraction was done by maceration method because this method was easier to do, the equipment used was simple, and was safe to use for compounds that were not stable against heating (Gozali and Mustarichie, 2019). The solvent used was 70% ethanol with a water content of 30% because the simplicia used was dry simplicia so that the water content in the solvent can wet the simplicia and penetrated the cell wall which then ethanol could penetrate into the pores and attract secondary metabolites contained in plants. The liquid extract which had been obtained was then concentrated so that the thick extract was obtained. From 2.05 kg simplicia of tongka sky bananas, 330.97 g viscous extracts were obtained. So that the yield of banana ranggap fruit extract was equal to 16.14%.

Phytochemical Testing and TLC

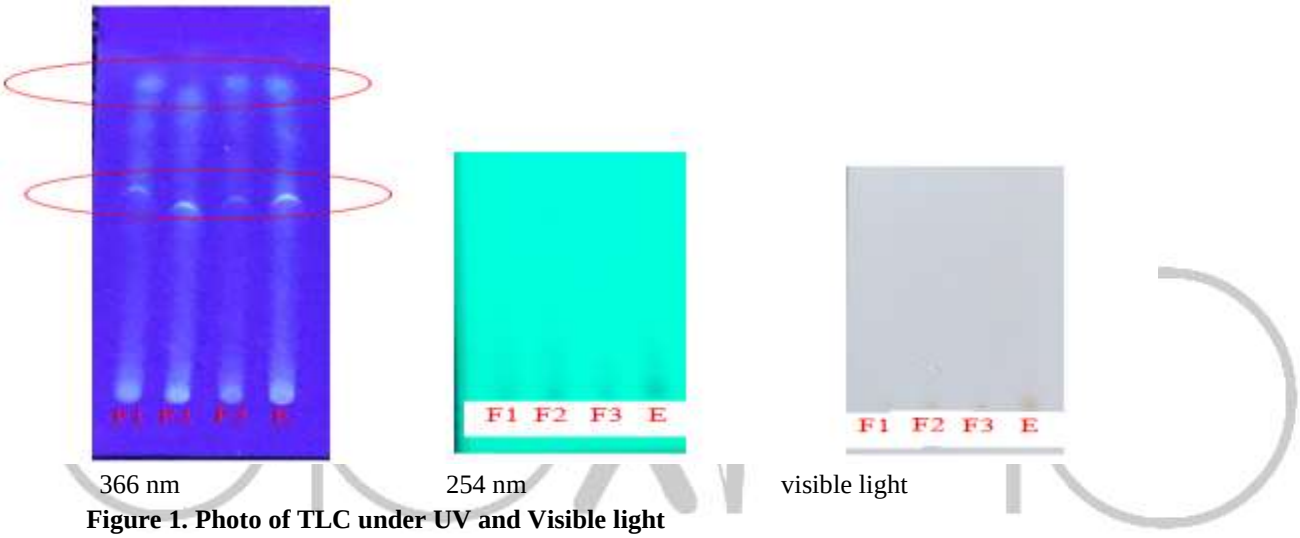

Figure 1. Photo of TLC under UV and Visible light

The next process was to perform phytochemical screening tests on extracts consisting of alkaloids, phenols, tannins, saponins, quinones, terpenoids and flavonoids tests. Furthermore, TLC testing was carried out using a mobile phase in the form of methanol 1: 1 chloroform which was then observed under UV rays of 254 nm and 366 nm.

Table 2. Phytochemical Screening of the Extracts

Name of Compounds	70 % Ethnaol
Alkaloids	+
Flavonoids	-
Tannins	-
Polyphenols	-

Saponins	-
steroids	+
Triterpenoids	+
Quinones	-

Phytochemical screening of the extract was carried out to determine the secondary metabolic content. The results of phytochemical screening of tongkalangit banana fruit extract can be seen in Table 2.

Screening Results Phytochemical ExtractPhytochemical screening of the extract was carried out to determine the secondary metabolic content

Table 3. Evaluation of Granules

Batch	Bulk density (g/mL)	Tapped density (g/mL)	Carr's Index (%)	Hausner's Ratio	Angle of Repose (°)
F1	0.46	0.50	15.60	1.13 ± 0.30	32.20
F2	0.42	0.51	25.60	1.07 ± 0.32	32.00
F3	0.44	0.53	13.70	1.046± 0.26	31.79

Optimize the formula first on the tablet to see and determine the additives suitable for the banana fruit extract tablet formula. Tablets were made with a weight of 600 mg. Based on Gozali's research (2018), the dose of banana fruit extract tongka heavens in mice that were effective as antidiabetic is 300 mg / Kg BB mice. The results of dose conversion from mice to humans (70 kg BW) gave a dose of 2,327 g. In the formulation used a dose of 50% of the content of banana extract from the weight of tablet 600 mg which was equal to 300 mg / tablet.In optimizing the formula, variations in filler types that were commonly used in tablet preparations weree made, namely lactose monohydrate, amprotab and avicel PH 101. The filler influences the physical properties of the tablet, therefore it was necessary to study what filler material could produce the physical properties of the tablet good (Hebbink et.al, 2019). Then the results showed that the best filler was Avicel pH 101 because it produced a powder mixture that was drier and could be granulated, then based on the results of the

evaluation of the granule the flow test, resting angle, and dissolution time produced the best results. The use of lactose monohydrate and amprotab cannot be granulated because the mixing of extracts which are hygroscopic is too fast to bind the water so that the mixed powder is in the form of paste and must be dried using an oven at 70°C for 2 x 24 hours. In the drying process the mixture cannot be in the form of powder but a lump that is slightly wet so that the

granulation does not run perfectly so that the conclusion of the granule with avicel filler pH 101 is the optimal filler.

After obtaining Avicel pH 101 as the best filler, the formulation was carried out with variations in the concentration of PVP binder 1%, 3%, and 5%. This use is intended to see the evaluation of tablets in the best physical terms and in accordance with the evaluation parametersof the tablet. From the results of the optimization of the formulation using variations of avicel pH101, lactose monohydrate, and amprotab, it was concluded that the best formula of the three formulas was a formula with avicel filler pH101. This is because in the formulation process, in the form of an amprotab and lactose monohydrate the granulation process cannot be carried out. This is caused by the formation of a semi-solid mass in the form of a paste, so that the mass cannot be passed to the mesh. Whereas in the formulation using avicel pH101, mixing results can form a head mass that can be passed on the mesh. Basically the compatibility of an excipient is very dependent on the characteristics of the extract to be used, while the extract of banana fruit tongka the sky has characteristics that are very thick and hygroscopic so that the right fillers and dryers are needed to make the dry preparation. And from the optimization results obtained the right filler is avicel pH101. The end result is why granules cannot be made.4.6 Results of Binder Variation Granule EvaluationAfter obtaining the optimization results with the best fillers, namely avicel PH101 because the physical properties of the tablets are drier and have good flow properties then proceed with an examination of the physical evaluation of variations in the concentration of PVP binders. Excellent granule requirements have a resting angle of 25 – 30° and are said to be good if between 31-35°. If the resting angle value is> 40°, the granule has a poor flowing power (Lachman et al, 1994). Evaluation of resting angle was related to the cohesive properties of granules. The flatter the pile of granules, the smaller the inclination so that the granule can flow at a constant speed and amount. A good resting angle would produce good flow properties and good flow properties would produce good weight uniformity. Based on the test results, all three tablet formulas had good angles of repose .

In the results of testing the flow of the three formulas, there was a slight difference. This could be caused by the higher concentration of the binder (PVP) resulting in an increase in the cohesion force so that there was a less significant decrease in flow power. The flow of granules affected the ability of the granule to pass through the hopper during the tablet printing process. Granules weree stated to have good flowability when the flow power was at 4-10 g / s (Person et.al, 2011). And it was said to be very good if it had a flow rate of> 10 g / s (Aulton, 2021) Granule flow power is influenced by the moisture of the granule. The shrinkage value of the drying of the three formulas was declared good. The more moist the granule, the lower the

velocity of the granule. However, granules that were too dry could also cause a decrease in flow power because the amount of fines produced could inhibit the flow of granules. In addition, the difference in granular flow power can also be caused by differences in particle size. From the results above, it could be concluded that the three formulas had very good flow.

From the results of the compressibility index test data obtained that the testing of formulas 1 and 3 showed good flow properties, while in formula 2 the results were not good, this was because in testing formula 2, the granules used have small or too fine particle sizes. So as to give poor results. While in formula 1 and 3 the size of the granule tends to be larger and homogeneous. Good granules had compressibility index 12-18% (Agoes, 2000). The lower the compressibility of the granule, the higher the density of the granule so that the mass of the granule would be more compact. Granule size could affect the compressibility of granules where the greater the size of the granule, the better the compressibility.

Results of Tablet Variation in Binder Variation

Appearance Test ResultsAppearance testing is performed to see the difference or influence of variations in the concentration of the binder on the appearance of the tablet. This test consists of appearance, thickness, diameter and weight. The results of this test were as follows.

From the results of the visual appearance test there were no significant differences from the three formulations. While from the weight uniformity test, it showed good results. Where the requirements for weight uniformity deviation for tablets with an average weight of> 300 mg were no more than 2 tablets with a deviating weight of 5% and no one tablet with a weight deviating from 10%. For formula 1 (1% PVP) of 20 tablets tested the average weight was 606.2, so the requirement for formula 1 (PVP 1%) was that there were no two tablets weighing 606.2 ± 5.43 and none tablet that weighs 606.2 ± 5.43. Whereas for formula 2 (PVP 3%) the conditions apply, there were no 2 tablets weighing 603.20 ± 5.08 and there was no one tablet weighing 603.2 ± 5.08. And for formula 3 (5% PVP) the condition was that there were no 2 tablets weighing 605.85 ± 5.44 and there was no single tablet weighing 605.85 ± 5.44

Table 4. Evaluation of Tablets

Batch	Hardness (kg/cm^2)	Thickness (mm^2)	% Weight Of	% Friability	Disintegration Time (minutes)

			variation		
F1	165.50 ± 16.53	5.45 ± 0.02	606.20 ± 5.43	0.69 ± 0.06	29.46
F2	148.65 ± 14.50	5.39 ± 0.02	603.20 ± 5.08	0.79 ± 0.07	29.26
F3	156.05 ± 17.43	5.57 ± 0.01	605.85 ± 5.44	0.73 ± 0.07	30.12

CONCLUSION

1. From the results of evaluation tests, it could be concluded that the best formula was formula F1
2. The effect of binder concentrations such as polyvinylpyrolidone (PVP) on the ranggap banana extract tablet formula showed no significant difference based on physical and chemical evaluation. The difference occurs in the flowability properties which were getting better with the smaller PVP concentration and the disintegration time which increases with the high PVP concentration.

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