PHARMASIPHA : Pharmaceutical Journal of Islamic Pharmacy
E-ISSN : 2580-9202
P-ISSN : 2581-0820
https://pharmasipha.journal.unida.gontor.ac.id/index.php/pharmasipha

Formulasi tablet ekstrak buah mangrove (*Rhizophora mucronata*): variasi konsentrasi Avicel PH 101 dan PVP K-30

Formulation of mangrove fruit (Rhizophora mucronata) extract tablets: variation in concentration of Avicel PH 101 and PVP K-30

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Article Info:
Received: 22-06-2026
Revised: 08-09-2026
Accepted: 25-09-2026

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ABSTRACT

Mangrove fruit (*Rhizophora mucronata*) contains flavonoids, tannins, and saponins. The presence of these chemical compounds indicates a hepatoprotective mechanism. To utilise this potential, we formulated mangrove fruit extract tablets using PVP K-30 as a binder and Avicel PH 101 as a disintegrant. This study aims to determine the effect of PVP K-30 and Avicel PH 101 on the physical properties of mangrove fruit extract granules and tablets. The method is the wet granulation. Granule evaluation includes organoleptics, compressibility, flow time, and angle of repose. Tablet evaluations include weight uniformity, friability, hardness, and disintegration time. This research shows that concentrations of Avicel PH 101 and PVP K-30 affect granule testing in the form of compressibility, flow time, and angle of repose. It also affects tablet evaluation in terms of weight uniformity, hardness, friability, and disintegration time. This study concludes that Formula 2 (PVP K-30 25 mg : Avicel PH 101 50 mg) is the best, considering physical and statistical analysis, Granule testing was obtained from the compaction test with a value of 76 ± 0.58%, flow time of 6.6 ± 0.14 g/second, and a static angle of 29 ± 0 degrees. In tablet testing, the weight uniformity test yielded 501 ± 1.7 mg, the hardness test 6.25 ± 0.28 kg, the friability test 0.6 ± 0.1%, and the tablet disintegration time was 10 minutes 31 seconds ± 19.82 seconds.

Keywords: *Rhizophora mucronata*; Tablets; PVP K-30; Avicel PH 101

ABSTRAK

Buah mangrove (*Rhizophora mucronata*) mengandung flavonoid, tanin, dan saponin. Keberadaan senyawa-senyawa kimia ini mengindikasikan adanya mekanisme hepatoprotektif. Untuk memanfaatkan potensi tersebut, kami memformulasikan tablet ekstrak buah mangrove menggunakan PVP K-30 sebagai bahan pengikat dan Avicel PH 101 sebagai bahan penghancur (*disintegrant*). Penelitian ini bertujuan untuk mengetahui pengaruh PVP K-30 dan Avicel PH 101 terhadap sifat fisik granul dan tablet ekstrak buah mangrove. Metode yang digunakan adalah granulasi basah. Evaluasi granul meliputi uji organoleptik, kompresibilitas, waktu alir, dan sudut diam. Evaluasi tablet meliputi keseragaman bobot, kerapuhan, kekerasan, dan waktu hancur. Penelitian ini menunjukkan bahwa konsentrasi Avicel PH 101 dan PVP K-30 memengaruhi hasil pengujian granul, yaitu kompresibilitas, waktu alir, dan sudut diam. Konsentrasi tersebut juga memengaruhi evaluasi tablet dalam hal keseragaman bobot, kekerasan, kerapuhan, dan waktu hancur. Penelitian ini menyimpulkan bahwa Formula 2 (PVP K-30 25 mg : Avicel PH 101 50 mg) merupakan formula terbaik berdasarkan analisis fisik dan statistik; hasil pengujian granul menunjukkan nilai kompresibilitas 76 ± 0,58%, waktu alir 6,6 ± 0,14 g/detik, dan sudut diam 29 ± 0 derajat. Pada pengujian tablet, diperoleh hasil keseragaman bobot 501 ± 1,7 mg, kekerasan 6,25 ± 0,28 kg, kerapuhan 0,6 ± 0,1%, serta waktu hancur tablet 10 menit 31 detik ± 19,82 detik.

Kata Kunci: *Rhizophora mucronata*; Tablet; PVP K-30; Avicel PH 101

1. INTRODUCTION

The liver is an organ that plays an important role in the function of the human body. The liver is essential for metabolism, nutrient storage, and detoxification of chemical compounds. Because of its critical role, the liver is very susceptible to various diseases and damage. One of the diseases that often affects the liver is hepatitis.(1) Hepatitis is caused by hepatitis virus infection or other factors, such as free radicals. The virus can cause inflammation and damage to liver cells.(2) In addition, the use of overdose drugs such as paracetamol can also cause hepatotoxic.(3) Drugs such as dantrolene, diclofenac, didanosine, disulfiram, efavirenz, and erythromycin have hepatotoxic potential.(4) Therefore, alternative hepatoprotectors are needed to overcome this problem, such as the use of mangrove plants.

Based on previous research has been conducted to determine the activity of mangrove fruit extract (*Rhizophora mucronata*) as a hepatoprotector. It is known that a dose of mangrove extract of 1 mg/kg BW is effective when given to Sprague Dawley strain rats with the effect being able to protect against liver cell damage with antioxidant parameters, AST enzymes, ALT enzymes, liver histopathology and MDA levels.(5) To utilize the potential of mangrove fruit extract as a hepatoprotector, it is necessary to formulate tablets.

Tablets are one of the most popular forms of pharmaceutical preparations. Tablets are solid preparations containing active substances and excipients.(6,7) Excipients have functions to improve the flow properties, stability, and bioavailability of active substances so that it can produce optimal tablets (8,9) This study aims to determine the effect of binder and disintegrant excipients. Binders and disintegrants are components that play a role in determining the physical properties of tablets (10) In this study, the binder is polyvinyl pyrrolidone (PVP K-30) and the disintegrant agent Avicel PH 101.

PVP is a tablet binder.(11) PVP is an inert, non-toxic, temperature-resistant, pH-stable, biocompatible, and biodegradable polymer that helps encapsulate and has a mechanism that can bind hydrophilic and lipophilic drugs with interactions such as hydrogen bonds, and polar or hydrophobic attractions.(12) Avicel can be used as a tablet disintegrant.(11) The mechanism of Avicel as a disintegrant is swelling.(13) The combination of PVP K-30 with Avicel PH 101 can produce tablet characteristics that meet the requirements for weight uniformity, hardness, friability, and disintegration time.(14)

Based on urgency and novelty, the objective is to obtain a Formula of mangrove fruit extract tablets (*Rhizophora mucronata*) that meets the compendial requirements for the physical properties of tablets (organoleptic, weight uniformity, hardness, friability, and disintegration time). Therefore, it is necessary to research the effect of a combination of binders and disintegrants on the physical properties of granules and tablets.

2. METHODS

Materials and Instruments

The materials are mangrove fruit (*Rhizophora mucronata*) (Mangrove Restoration and Learning Center, Pekalongan City, Central Java, Indonesia), 95% ethanol (Pharmco), PVP K-30 (MP Biomedical), Avicel PH 101 (DFE Pharma), lactose (Grande), Mg stearate (Macron), aerosil (Evonik), talc (J.T. Baker), and other materials for phytochemical tests obtained from the laboratory of Universitas Pekalongan. The instruments are analytical balance (Ohaus), rotary evaporator (Boeco), water bath (Memmert), granule flow test (PT. Bawono), tap density volumeter BKDY-100B (Biobase), oven (Memmert), single punch tablet machine (Biobase), hardness tester THT-3 (Biobase), friability tester CS-2 (Biobase), disintegration tester (Minhua pharmaceutical machinery), and glassware (Pyrex, Herma and Duran).

Sample Preparation and Extraction

Mangrove (*Rhizophora mucronata*) was determined in the Biology Laboratory, Faculty of Mathematics and Natural Sciences, Universitas Ahmad Dahlan. The mangrove fruit that had been taken was wet-sorted. It was then cleaned of dirt using water, cut into pieces, and sun-dried. The dried mangrove fruit was sorted, then ground to a fine powder and extracted. The solvent used was 95% ethanol at a 1:5 ratio for 5 days. The filtrate was evaporated using a rotary evaporator and continued with a water bath at 50 °C until a thick extract was obtained.(5)

Phytochemical test

a. Flavonoid test
   Dissolve mangrove fruit extract in sufficient 50% methanol by heating. The mixture is added with Mg powder and 5-6 drops of HCl. The red solution indicates flavonol, and the orange colour indicates flavone.(15)
b. Tannins test
   Put the mangrove fruit extract into a test tube (up to 1 mL), then add FeCl3 reagent. The presence of tannin is indicated by blue or blackish-green colour.(16)
c. Saponins test
   Add mangrove fruit extract to a test tube (up to 1 mL), then add distilled water (up to 2 mL), shake, and observe the foam formed. The presence of saponin indicates that the foam is stable and does not disappear when added with 2N HCl.(17)

Tablet Formulation

The mangrove fruit extract tablet Formula is shown in Table 1. The rat dose of 1 mg/kg BW is converted into a human dose of 11.2 mg/tablet. The daily dose of mangrove fruit ethanol extract in rats is 1 mg/kg.(5) It equal to 1 mg/1000 g; so, for a rat with an average weight of 200 g, the conversion factor from rat (200 g) to human (60 kg) = 56. Therefore, the dose of mangrove fruit ethanol extract for humans is the conversion factor multiplied by the absolute dose = 56 x 0.2 mg = 11.2 mg per day. There are 3 tablet Formulas with variations in the concentration of PVP K-30 and Avicel PH 101. Details of the ingredients for each tablet are shown in Table 1. The tablets to be made are 200 tablets with details of the ingredients listed in Table 2.

 DOI : 10.21111/pharmasipha.v10i2.264

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Table 1. Mangrove Fruit Extract Tablet Formula

Materials	Formula 1 (mg)	Formula 2 (mg)	Formula 3 (mg)	Function
Mangrove fruit extract	11.20	11.20	11.20	Active Ingredients
Aerosil	3.73	3.73	3.73	Adsorbent
PVP K-30	5	25	50	Binder
Avicel PH 101	75	50	25	Disintegrant
Lactose	400.07	405.07	405.07	Filler
Mg stearate	0.50	0.50	0.50	Lubricant
Talc	4.50	4.50	4.50	Glidant
Tablet weight	500	500	500	

Table 2. Mangrove fruit extract tablet Formula (200 tablets)

Materials	Formula 1 (g)	Formula 2 (g)	Formula 3 (g)	Function
Mangrove fruit extract	2.24	2.24	2.24	Active Ingredients
Aerosil	0.75	0.75	0.75	Adsorbent
PVP K-30	1	1	1	Binder
Avicel PH 101	15	10	5	Disintegrant
Lactose	80.01	81.01	81.01	Filler
Mg stearate	0.10	0.10	0.10	Lubricant
Talc	0.90	0.90	0.90	Glidant

The procedure in the Formulation refers to the previous research.(14) The Formulation begins by weighing the ingredients according to Table 2. Formula 1: the extract (2.24 g) was dried with Aerosil (0.746 g), then mixed until homogeneous with lactose (80 g) and Avicel PH 101 (15 g). PVP K-30 (1 g, made into mucilage 10 ml) was added to the mixture. The granules are sieved through a no.12 mesh and then dried in an oven at 40°C for 4 hours until dry granules are obtained. The dry granules are sieved again. Then, Mg stearate (0.1 g) and talc (0.9 g) were mixed until homogeneous. The granules were evaluated for flow properties. The granules were compressed to a weight of 500 mg on a machine. Tablets were evaluated for their physical properties. The steps in the other formulas are the same as in Formula 1, except for the ingredient (PVP and Avicel) weights shown in Table 2.

Granule Evaluation

a. Organoleptic
   Organoleptic testing on granules (shape, colour, taste, and odour).(18)
b. Compressibility
   Granules (50 g) were placed in a 100 mL measuring cylinder. The measuring cylinder was installed on a volumenometer and then tapped 100 times until the volume of the granules was constant. The volume changes that occurred were measured and the resulting volume changes were recorded.(19) The compressibility results were shown in equation (1).
   $$Compressibility\ (\%) = \frac{Initial\ volume - Final\ volume}{Initial\ volume} x100\% \quad (1)$$
c. Flow time

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Granules (100 g) were placed into the flow time test funnel. Then the funnel cover was opened so that the granules fell and collected. A stopwatch is used to calculate time.(19) The flow rate was calculated using equation (2).

$$Flow\ time = \frac{Granule\ weight\ (g)}{Time\ (detik)} \quad (2)$$

d. Angle of Repose

Granules (100 g) were then loaded into the funnel. The funnel cover is opened, and the angle formed is measured.(19) The angle of repose was calculated using equation (3).

$$Tg\ (\beta) = \frac{h\ (Cone\ height)}{r\ (Cone\ radius)} \quad (3)$$

Tablet Evaluation

a. Organoleptic

Organoleptic tests are carried out using human senses with general tablet parameters. It is the shape, colour, odour and taste.(18)

b. Uniformity of Weight

20 tablets were weighed, and then the weight of each tablet was calculated. Then, the deviation in the tablet weight with the compendial requirements by the weight of 500 mg tablets was seen.(18)

c. Hardness

Hardness testing with 6 tablets using a digital tablet hardness tester. The tablets are placed on the device in a horizontal position, then the device is calibrated at position 0.00. Then the tool is operated. The hardness tester scale indicates the tablet hardness.(19)

d. Friability

Cleaned 20 tablets of attached fine particles, then weighed them. The tablets were inserted into the friability tester and rotated for 100 rotations at a speed of 25 rpm, then the tablets were taken, cleaned and reweighed. The weight of the lost tablets was weighed and the percentage of the tablet friability value was determined.(19) Tablet friability was calculated using equation (4).

$$Friability = \frac{(Initial\ tablet\ weight - Final\ tablet\ weight)}{Initial\ tablet\ weight} x100\% \quad (4)$$

e. Disintegration time

6 tablets were put into the disintegration tester, each tube was filled with 1 tablet. The basket was raised and lowered into the water at 37°C ± 2 °C regularly 30 times per minute. The time required for the tablet to disintegrate was calculated. The tablet was considered disintegrated when no part of the tablet remained.(18)

Data Analysis

The data analysis conducted was descriptive and quantitative. Quantitative analysis used SPSS (Trial), starting with a normality test using the Shapiro-Wilk test; if the result is >0.05, the data are considered normal. If the data are normal, a homogeneity of variances test is performed; it is considered homogeneous if the result is >0.05, followed by One-Way ANOVA (Analysis of Variance) at the 95% confidence level to determine differences among the formula groups. If the data are not normal, the Kruskal-Wallis test is used to identify differences among the formula groups. If the p-

 DOI : 10.21111/pharmasipha.v10i2.264

value < 0.05, it indicates that there is an effect of the concentration variations of PVP K-30 and Avicel PH 101 on the physical properties of the mangrove propagule ethanol extract tablets. The best formula was selected from the ethanol extract tablets of mangrove fruit with good physical properties and statistically significant results.

3. RESULTS AND DISCUSSION

Preparation and Extraction of Mangrove Fruit

The results of determining mangrove fruit (*Rhizophora mucronata*) based on the number: 467/Lab.Bio/B/XII/2023 stated that the sample was indeed a mangrove plant (*Rhizophora mucronata*). The mangrove fruit samples obtained were dried and then made into powder. Drying the sample aims to reduce moisture content and prevent microbial growth that can damage the sample. The results of the moisture content of the mangrove fruit simplicia were 6.32%, which is below the requirement for the moisture content of the simplicia, which is <10%.(20) The simplicia is made into powder so that the particle size of the simplicia becomes smaller. Particle size is one of the factors that influence extraction. The smaller the particle size the larger and wider the contact surface between the simplicia particles and the solvent, and the shorter the diffusion distance of the solution so that the extraction is greater.(21) The results of simplicia preparation are shown in Table 3.

Table 3. Mangrove fruit simplicia results

Sample (Fruit)	Simplicia	Moisture content
3000 g	1850 g	6,32%

Extraction was carried out using the maceration method using 95% ethanol. Extraction using the maceration method ensures that the extracted active substances are not damaged. The results of the mangrove fruit extract is shown in Table 4. From 1000 g of mangrove fruit simplicia powder, 126.46 grams of thick extract were obtained. The yield value produced was 12.64%. Yield is the percentage of the amount of processed material that can be produced from the raw materials used.(22) Determination of the moisture content of the extract aims to determine the percentage of moisture content in the material after the drying or thickening process through an appropriate method, such as maceration. Moisture content quality depends on the material obtained. The moisture content quality requirements of a material in the form of a thick extract are 5-30%.(23) The moisture content obtained was 26.29%, meaning that the moisture content obtained met the moisture content quality requirements.

Table 4. Mangrove fruit extraction results

Simplicia powder	Extract	Yield	Moisture content
1000 g	126,46 g	12,64%	26,29%

Phytochemical Test

Phytochemical tests were conducted on the content of compounds in mangrove fruit (*Rhizophora mucronata*). It is flavonoids, tannins and saponins. The purpose of the phytochemical test was to ensure that the desired compounds could be extracted. The test results are shown in Table 5.

Table 5. Phytochemical test

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Phytochemical test	Reagent	Result
Flavonoid	Mg powders + HCl	Positive (orange)
Tannins	FeCl3	Positive (blackish green)
Saponins	Aquadest + HCl 2N	Positive (foam present)

a. Flavonoid test

The test results on flavonoids produced an orange colour. The same results were also obtained in the previous research.(24) The purpose of adding Mg and HCl metals is to reduce the benzopyrone core contained in the flavonoid structure so that a flavilium salt is formed with a certain colour. A red solution indicates flavonol and an orange color indicates flavone.(15)

b. Tannins test

The tannin test produced a blackish-green colour. The same result was also obtained in previous research.(24) Phytochemical tests using FeCl3 were used to determine whether the sample contained phenol groups. The presence of phenol groups is indicated by a blackish-green or dark blue color after adding FeCl3. The formation of a blackish-green or ink-blue colour in the extract after adding FeCl3 is because tannin will form a complex compound with Fe3+ ions.(16)

c. Saponins test

In the saponin test, foam was produced and did not disappear when dripped with 2N HCl with a saponin standard. The same results were also obtained in the previous research.(24) Saponin is a compound that has hydrophilic and hydrophobic groups. When shaken, the hydrophilic group binds to water, while the hydrophobic group binds to air to form foam.(25)

Granules Evaluation

Granulation prevents segregation and improves granule flow, porosity, and compressibility. The granules produced are then checked for their physical properties. The examination of these granules' physical properties aims to determine whether they meet the requirements. Furthermore, it has been determined to produce a good tablet. The granule evaluation results are listed in Table 6.

Table 6. Granule evaluation

Granules evaluation	Formula 1	Formula 2	Formula 3
Organoleptic	Shape: Granules Colour: Bone white Odour: Odourless Taste: Slightly sweet	Shape: Granules Colour: Bone white Odour: Odourless Taste: Slightly sweet	Shape: Granules Colour: Bone white Odour: Odourless Taste: Slightly sweet
Compressibility	15,6 ± 0,58%	7,6 ± 0,58%	6 ± 0%
Flow time	3,8 ± 0,15 g/s	6,6 ± 0,14 g/s	7,2 ± 0,42 g/s
Angle of repose	30,5 ± 0,17°	29 ± 0°	28,2 ± 0,17°

a. Organoleptic

An organoleptic test of granules was conducted to determine the physical appearance of the granule preparation. An organoleptic test was conducted visually to see the colour, shape, aroma and taste of the granules. The results of the organoleptic

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test are listed in Table 6. Physical observations of the granules in Formula 1 produced mostly powder granules that were bone white, odourless, and slightly sweet. In Formula 2, the granules were produced with a little powder, bone white, odourless, and slightly sweet. In Formula 3, the granule form was produced with a minority of powder, bone white in colour, odourless and slightly sweet. In Formula 1, granules were produced with a smaller size because the binder used was smaller than Formula 2 and 3 so the bound particles were lower, the bone white colour was produced because the excipient used was white, odourless because the odour of the active substance used was smaller in concentration compared to the excipient, the slightly sweet taste produced because the filler used was lactose which has a sweet taste.

b. Compressibility

A compressibility test is conducted to determine the compression of the granule preparation in order to determine the suitability of the granules to be compressed into tablet preparations. Compressibility is important because it is related to the process of filling the compression hole in the tablet press.(10) The results of the Compressibility test of the granules are listed in Table 6. The average results of the Compressibility test on Formula 1 is 15.6±0.58%, on Formula 2 is 7.6±0.58%, and on Formula 3 is 6± 0%. The requirement for a good Compressibility value for granules is <20%.(26) PVP K-30 as a binding agent can strengthen the bonds between granule particles, resulting in granules that are more compact and have good compressibility properties.(27,28) The use of Avicel PH 101 as a disintegrant is able to produce granules with good compressibility properties.(8) According to previous research, the combination of PVP K30 and Avicel PH 101 produces granules that have good compressibility.(14) From this study, it was obtained information that the higher the concentration of PVP K-30 binder and the less Avicel PH 101 disintegrant, the harder the granules formed so that the resulting Compressibility value is lower. The lower the compressibility value, the better the compression produced by the granules.

The results of the Shapiro-Wilk test yielded a significance value (P Value) of 0.001, indicating that the data do not follow a normal distribution. Therefore, the analysis was continued with the Kruskal-Wallis test. The obtained Asymp. Sig. (P-Value) was less than 0.023, leading to the conclusion that there is a significant difference. Subsequently, a pairwise comparison was conducted using the Mann-Whitney test. The results of the Mann-Whitney test showed an Asymp. Sig. (2-tailed) value less than 0.05 for differences between each formula, indicating that the differences between the formulas are statistically significant.

c. Flow time

Flow time tests relate to the uniformity of filling the mould space, which affects weight uniformity.(19) The results of the granule flow time test are listed in Table 6. The test results gave an average of 3.8 ± 0.15 g/second for Formula 1, 6.6 ± 0.14 g/second for Formula 2, and 7.2 ± 0.42 g/second for Formula 3. From these results categorized according to reference(29), Formula 2 and 3 are included in the easy flowing category (flow time 4-10 g/second) and Formula 1 is cohesive (1.6-4 g/second). The research

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results showed that using PVP K-30 with a high concentration and Avicel PH 101 low concentration can produce fewer fines, making the granules easy to flow.

The values in the Shapiro-Wilk test include two formulas, FII and FIII, which produce a significance (P Value) of 0.001, indicating that some data do not follow a normal distribution. Therefore, the test was continued with the Kruskal-Wallis test. The obtained Asymp. Sig. (P-Value) of 0.026 concludes that there is a significant difference. The results of the Mann-Whitney test show an Asymp. Sig. (2-tailed) value less than 0.05 for the differences between each formula, indicating that the flow time between formulas differs significantly.

d. Angle of Repose

The angle of repose test aims to determine the granules' ability to flow.(19) The results of the angle of repose test are shown in Table 6. The results obtained from the average angle of repose test of granules in Formula 1 are 30.5 ± 0.17º, Formula 2 it is 29 ± 0º and on Formula 3 it is 28.2 ± 0.17º. These results indicate that all Formulas are appropriate to the requirements because the granule angle value indicates that the granules can flow freely and are within the very good (25-30º) and good (31-35º) acceptance range.(29) The cohesiveness between particles is affected by the angle of repose. The smaller the particle size, the higher the cohesiveness obtained. This causes the granules to be difficult to flow and the angle of repose obtained is greater. In addition, the angle of repose relates to flow properties: the faster the flow time, the smaller the angle of repose. This occurs because using PVP K-30 at a high concentration produces fewer fines, allowing the granules to form a minimum angle of repose.(30) From this research, information was obtained that the use of a binder with a high concentration will reduce the angle of repose, and the use of a disintegrant with a high concentration will increase the resulting angle of repose.

The results obtained from the testing data involved statistical calculations. In the Normality Test using Shapiro-Wilk for the resting angle data, the data was found to be not normally distributed. The Shapiro-Wilk test yielded a significance value (P Value) > 0.05, indicating that the data is normally distributed, allowing the continuation of the tests with Homogeneity and ANOVA. Based on the homogeneity test, a significance value of 0.169 > 0.05 was obtained, which means that the variances of the three formulas being compared are equal or homogeneous. According to the ANOVA test, a significance value of 0.001 < 0.05 was obtained, indicating that the means of the three formulas differ significantly. The Post Hoc Tukey test results showed an Asymp. Sig. (2-tailed) difference for each formula < 0.05, meaning that the differences in resting angles between the formulas are statistically significant.

Tablet Evaluation

The tablets were compressed with a weight of 500 mg per tablet. Then the compressed tablets were evaluated. The purpose of the evaluation was to determine whether the finished tablets met the requirements for good physical properties. The results of the tablet evaluation are listed in Table 7.

Table 7. Tablet evaluation

Tablet evaluation	Formula 1	Formula 2	Formula 3
Organoleptic	Shape: Flat round	Shape: Flat round	Shape: Flat round

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	Colour: Bone white Odour: Odourless Taste: Slightly sweet	Colour: Bone white Odour: Odourless Taste: Slightly sweet	Colour: Bone white Odour: Odourless Taste: Slightly sweet
Weight uniformity	Appropriate	Appropriate	Appropriate
Friability	1,2 ± 0,2%	0,6 ± 0,1%	0,3 ± 0,1%
Hardness	3,68 ± 0,11 kg	6,25 ± 0,28 kg	9,69 ± 0,35 kg
Disintegration time	6,69 ± 1,44 minute	12,38 ± 0,28 minute	19 ± 0,71 minute

a. Organoleptic

Organoleptic tests were conducted using the senses to determine the shape, colour, odour, and taste of the tablets that had been made. The results of the organoleptic test are listed in Table 7. Based on the data results, it is known that the tablets have the same characteristics of colour, odour, and taste of the tablets. The flat round shape is obtained from a tablet printing machine. The bone white colour of the tablet is produced from a mixture of all ingredients because most of the colours of the ingredients used are white. The tablets are odourless because the concentration of active ingredients is smaller than the excipients. The taste tablets in all Formulas have the same taste, which is slightly sweet because it is influenced by the high concentration of lactose filler which has a sweet taste.

b. Weight uniformity

The weight uniformity test is carried out to determine weight variations. Tablet weight uniformity is appropriate. If weighed one by one, there should be no more than 2 tablets whose weights deviate from the average weight more than the price set in column A and no tablet whose weight deviates from the average weight more than only that set in column B.(31) Since the tablet weight is 500mg, the deviation in column A has a limit of 5% and column B has a limit of 10%. The results of the tablet weight uniformity test are shown in Table 7. The results obtained for all Formulas showed that no tablets deviated from the average weight greater than the weight set in column A and none of them deviated from the average weight in column B. These results are from previous studies, the use of PVP K-30 and Avicel PH 101 produced appropriate weight uniformity.(14) Uniformity of weight is related to the flow properties of the granules. That is, if the flow time, angle of repose, and compressibility are good, it facilitates powder flow in the moulding machine and fills the moulding space, so the solid preparation has a high density.

The results obtained from the testing data were analysed using statistical calculations. In the Shapiro-Wilk Normality Test for weight homogeneity, the data obtained was not normally distributed. The Shapiro-Wilk test results showed that the sig. (P Value) > 0.05, which means that the data is normally distributed, so the testing can proceed with the Homogeneity Test and ANOVA. Based on the homogeneity test results, a sig. value of 0.372 > 0.05 was obtained, indicating that the variances of the three formulas being compared are equal or homogeneous. According to the ANOVA test, a sig. value of 0.001 < 0.05 was obtained, so it can be concluded that the means of the three formulas differ significantly. The Post Hoc Tukey test results show that the Asymp. Sig. (2-tailed) value for the differences between each formula is < 0.05,

indicating that the homogeneity of weights between formulas shows a significant difference.

c. Friability

The tablet friability test aims to describe the tablet's strength in maintaining its shape under mechanical stress. The acceptable brittleness requirement is 1%. The results of the tablet friability test are shown in Table 7. The brittleness percentages of Formula 2 and 3 tablets meet the requirements. The difference in tablet brittleness values is due to the influence of the concentration of binders and disintegrants. Based on previous research, the use of binders and disintegrants that affect tablet friability.(10) With a high concentration of binding material and a low disintegrant, the bonds between the resulting particles will be strong.(30) The percentage result of Formula 1 is too high. This is because Formula 1 has a small concentration of PVP K-30 as a binder with avicel PH 101 as a disintegrant with a high concentration.

The results obtained from the testing data were subjected to statistical calculations. In the Normality Test using Shapiro-Wilk for fragility, the data obtained was not normally distributed. The Shapiro-Wilk test results showed a significance value (P Value) > 0.05, indicating that the data are normally distributed, allowing the continuation of the test with Homogeneity and ANOVA. Based on the homogeneity test, a significance value of 0.241 > 0.05 was obtained, which means that the variances of the three formulas being compared are equal or homogeneous. According to the ANOVA test, a significance value of 0.001 < 0.05 was obtained, indicating that the means of the three formulas differ significantly. The Post Hoc Tukey test results showed an Asymp. Sig. (2-tailed) difference between formula 1 and formula 2, and between formula 1 and formula 3, both < 0.05, meaning that the fragility differences between these formulas are statistically significant.

d. Hardness

The tablet hardness test is a parameter that describes the resistance of the tablet to resist mechanical stress such as shocks, pressure and the possibility of tablet cracking during packaging, transportation and storage. The tablet hardness requirement is 4-8 kg. The results of the tablet hardness test are shown in Table 7. Based on the results obtained, the average value of the tablet hardness test is only Formula 2 which is appropriate to the tablet hardness requirements. In Formula 1, the tablet hardness is too low because the binder concentration is low and the disintegrant is high. In Formula 3, the tablet hardness is too high because the binder concentration is high and the disintegrant is low. This is influenced by variations in the concentration of PVP K-30 and aviel PH 101. Based on previous research, binders can increase tablet hardness and disintegrants can decrease tablet hardness.(10)

The results obtained from the testing data were subjected to statistical calculations. In the Normality test using Shapiro-Wilk for hardness, the data obtained was normally distributed. The Shapiro-Wilk test yielded a significance value (P Value) > 0.05, indicating that the data is normally distributed, allowing the continuation of the tests with Homogeneity and ANOVA. Based on the homogeneity test, a significance value of 0.298 > 0.05 was obtained, which means that the variances of the three

 DOI : 10.21111/pharmasipha.v10i2.264

formulas being compared are equal or homogeneous. From the ANOVA test, a significance value of 0.001 < 0.05 was obtained, indicating that the means of the three formulas differ significantly. Subsequently, a Post Hoc Tukey test was conducted. Based on the Multiple Comparisons output, the significance value for the differences in means between each formula was less than 0.05, indicating that the hardness values between the formulas are significantly different.

e. Disintegration time

Disintegration time shows how long it takes for the tablet to disintegrate into free granules that are not bound by one form of particle composition when in contact with liquid media. Conventional tablets have a dissolution time of less than 15 minutes. The results of the disintegration time test are shown in Table 7. The results of the disintegration time test for Formula 1 and 2 disintegrated in less than 15 minutes so it is appropriate for the requirements. In Formula 3, the tablet dissolved beyond the tablet disintegration time requirements. Disintegration time can be influenced by the disintegrant and binder used in the tablet Formulation. The higher the PVP K-30 and the lower the Avicel PH 101, the longer the tablet disintegration time. PVP can increase the strength of the granule bond to be stronger to keep the tablet from disintegrating easily in water.(32) Meanwhile, Avicel PH 101 can act as a tablet disintegrator with a wicking and swelling agent mechanism which will help accelerate tablet disintegration.(33)

The results obtained from the testing data were subjected to statistical calculations. In the Normality test using Shapiro-Wilk for the failure time data, the data was found to be not normally distributed. The Shapiro-Wilk test results showed a significance (P Value) > 0.05, indicating that the data is normally distributed, allowing the continuation of the tests with Homogeneity and ANOVA. Based on the homogeneity test, a significance value of 0.705 > 0.05 was obtained, which means that the variances of the three compared formulas are equal or homogeneous. From the ANOVA test, a significance value of 0.001 < 0.05 was obtained, indicating that the means of the three formulas differ significantly. Subsequently, a Post Hoc Tukey test was conducted. The results of the Post Hoc Tukey test showed an Asymp. Sig. (2-tailed) difference for each formula < 0.05, or not greater than this value, meaning that the failure times between formulas are significantly different.

Determination of the Best Formula for Mangrove Fruit Extract Tablets

The best Formula for making mangrove fruit (Rhizophora mucronata) ethanol extract tablets can be determined based on the test results carried out and the statistical results. Formula 1 has poor flow properties and produces very friability tablets and low hardness. Formula 3 has good flow properties but the resulting tablets have very high hardness and long disintegration time. Formula 2 has good flow properties and has tablet characteristics that meet the requirements. Therefore, the best Formula for mangrove fruit extract tablets (500mg) is Formula 2, with a ratio of PVP-K30 binder (25mg) and Avicel PH 101 disintegrant (50mg).

4. CONCLUSION

 DOI : 10.21111/pharmasipha.v10i2.264

PVP as a binder and Avicel PH101 as a disintegrant affect the physical properties of granules (compressibility, flow time, and angle of repose) and tablets (organoleptic, weight uniformity, friability, hardness, and disintegration time). Mangrove fruit extract tablets (500mg) were obtained in Formula 2 with a ratio of PVP-K30 binder (25mg) and Avicel PH 101 disintegrant (50mg). The limitation in this research is that there has been no in vitro or in vivo testing.

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