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FORMULATION AND CHARACTERIZATION OF TABLETS FROM SIMPLICIA AND EXTRACT OF SUNGKAI'S (*Peronema canescens* Jack) LEAF

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Abstract: Tablets are solid preparations containing medicinal ingredients with or without excipients, usually consisting of one or more active substances. Preparations in tablet form have the best mechanical, chemical, and microbiological stability compared to liquid dosage forms, so they are more resistant to physical damage. This study aims to formulation and characterization of tablet from simplicia and dried extract of sungkai's (*Peronema canescens* Jack) leaf by wet granulation which consisted of three formulas, namely F1 without active substances, F2 active substances from sungkai's leaf simplicia, and F3 active ingredients from dry extracts of sungkai's leaf. The characterization of the physical properties of tablets includes size uniformity test, weight uniformity test, hardness test, friability test, and disintegration test. The results showed that F1 and F3 tablets showed a good tablet properties, but F2 tablets had 3 tablets that deviated from the tablet weight, namely 12.18%, 6.03% and 9.75%, F2 tablets had an average hardness of 3,413 kg. ie does not fullfill the requirements for tablet hardnes. The friability test for F2 tablets, which is 1.0069%, not accetable for tablet friability. The disintegration test, F2 tablets have a faster disintegration time compared to F1 and F3 tablets.
Keywords: Tablets; Wet Granulation; Sungkai's (*Peronema canescens* Jack) leaf.

INTRODUCTION

Indonesia is rich with biodiversity and is one of the main megacenters of world biodiversity, with around 40,000 plant species. Based on a search of almost 1000 types of plants or plants that have been used for traditional medicine (Parwata, 2017). Traditional medicine is currently widely used, because according to some studies it does not cause side effects and can still be digested in the body. Medicinal plants can be interpreted as plants or plants that naturally have the ability to heal which are relatively inexpensive and do not have a negative impact on their users (Prasetyo & Inoriah, 2013).

Sungkai (*Peronema canescens* Jack) belonging to the Lamiaceae family is used by the community as a medicinal plant. This plant found in West Sumatra, Jambi, Bengkulu, South Sumatra (Palembang), West Java, and throughout Kalimantan (Martawijaya *et al*., 2005). The use of sungkai leaves in Bengkulu, the Lembak Eight tribe uses boiled water of sungkai leaves as raw material for fever-reducing drugs (antipyretics), to maintain health, and to cure malaria (Yani *et al*., 2013). In addition, young sungkai leaves are also used as traditional medicine and have potential as antibacterial (Fransisca *et al*., 2020).

Several previous studies conducted by (Yani *et al*., 2014) found that sungkai leaf extract has antipyretic, antiplasmodium and teratogenic activity which was tested on Mus

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musculus mice. According to research (Latief *et al.*, 2021) Sungkai leaves also contain a lot of secondary metabolites including flavonoids, alkaloids, steroids, tannins, phenols, and saponins.

Based on research that sungkai leaf (*Peronema canecens* Jack) has the potential to have antioxidant activity which is marked by a pale yellow stain after spraying DPPH reagent, besides that sungkai leaf is used as an active ingredient in the manufacture of hand antiseptic gel preparations against several pathogenic bacteria that have been proven to be effective in inhibiting or killing *Escherichia coli*, *Salmonella typosa*, and *Staphylococcus* bacteria (Ibrahim et al., 2015).

The development of traditional medicine and traditional medicine is currently growing very rapidly, especially traditional medicine derived from plants. This can be seen by the increasing number of drug dosage forms in very attractive packaging forms (Parwata, 2017). One of the efforts to develop medicinal plants to become more modern preparations is to make them in tablet preparations. Tablet preparations compared to other oral dosage forms provide the advantage in the form of the smallest space required for storage, easy to administer and carry (Lachman et al., 1986).

The wet granulation method makes the powder flow and compressibility better and the particle size more uniform. In addition, wet granulation also reduces the mass weight lost in the tablet manufacturing process. By using wet granulation, the excipient used does not need to be an excipient with a good flow rate and usually an excipient with a good flow rate is an excipient with a more expensive price (Siregar & Wikarsa, 2010).

In connection with this, the researchers are interested in formulating sungkai leaf in tablet dosage form by comparing formulations and evaluating tablet preparations from simplicia and dried extract of sungkai leaf (*Peronema canescens* Jack). This is because the tablet dosage form is easy to pack and consistent in terms of quality and precise dosage.

MATERIAL AND METHOD

Materials

Moisture balance analyzer (Ohaus MB 45), Rotary evaporator (Heildolph), Shiever shaker (B-ONE), Oven (Yenaco), Tap volumeter (Labulk 0335), Furnace (Carbolite Gero ELF 1100), analytical balance (Biobase), tablet printing machine (Delta), Flow tester, Friabilator (Gouming), Disintegration tester (Copdex), Hardnes tester (Pharmatest PTB 111). The materials used in this study were sungkai leaf (*Peronema canescens* Jack), 96% ethanol, 70% ethanol (Novalindo), Avicel PH 101 (Brataco), aerosil (Brataco), aspartame (Planet Kimia), lactose (Dwilab Mandiri Kimia), aquadest (Novalindo).

METHOD

Preparation of Sungkai Leaf Simplicia

The preparation of sungkai leaf simplicia includes: Raw material collection, wet sorting, washing, chopping, drying, dry sorting and refining.

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Preparation of Sungkai Leaf Dry Extract

The dry extract of sungkai leaves was made by maceration method using 96% ethanol solvent (Fransisca *et al.,* 2020) with a ratio of 1:5 for 2×24 hours, the macerate was filtered and evaporated with a rotary evaporator, until a thick extract was obtained (Vitanti *et al.* ., 2016). The viscous extract obtained was weighed and calculated the percentage yield.

$$\% \text{ Rendemen} = \frac{extract\ weight}{raw\ material\ weight} \text{ x } 100\%$$

Then the thick extract is put into a mortar and lactose (1:2) is added little by little while grinding until evenly distributed and a dry mass is obtained (Zulharmita *et al*., 2017).

Characterization of Simplicia and Sungkai Leaf Extract

Examination of simplicia characteristics of Sungkai leaves includes: identity test, organoleptic examination, microscopic test, determination of water soluble extract, determination of ethanol soluble extract, determination of water content, determination of drying shrinkage, determination of total ash content and determination of acid insoluble ash content.

Phytochemical Test

Alkaloid Test

Simplicia powder as much as 0.5 grams then added 1 mL of 2 N hydrochloric acid and 9 mL of distilled water, heated over a water bath for 2 minutes, cooled and filtered. The test results were declared positive if with Mayer's reagent a yellowish white precipitate was formed, in Bouchardat's reagent a brown precipitate was formed and in Dragendorff's reagent an orange precipitate was formed.

Fenol Test

Simplicia powder as much as 10 mg was added with FeCl3 as much as 3 drops, the color change was observed. The formation of a blackish green or dark blue color in the solution indicates that the solution contains phenolics (Harbone, 2013).

Flavonoid Test

1 gram of simplicia powder was added to 10 mL of hot water and then boiled for 5 minutes, filtered while still hot. The filtrate obtained was taken as much as 5 mL, added 0.1 g of magnesium powder, 1 mL of HCl and 2 mL of amyl alcohol, shaken and allowed to separate. Positive results contain flavonoids if there is a red-yellow color change in the filtrate or orange color in the amyl alcohol layer (Depkes RI, 1995).

Saponin Test

Simplicia powder as much as 0.5 grams is put into a test tube, add 10 mL of hot water, cool then shake vigorously for 10 minutes. Positive results were indicated by the formation of a stable foam for 30 minutes and the addition of 1 drop of 2 N HCl, the foam did

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not disappear (Depkes RI, 1995).

Tanin Test

Weighed 10 mg of sungkai leaf simplicia powder dissolved in 10 mL of chloroform then 1 mL was taken and added 3 drops of FeCl3 if a blackish green is formed, it means that it is positive for tannin (Harbone, 2013).

Steroid Test

Weighed 10 mg of Sungkai leaf simplicia powder, dissolved with 2 mL of chloroform, add 10 drops of acetic anhydride and 3 drops of concentrated sulfuric acid, if a bluish green color is formed, it means that it is positive for steroids.

Wet granulation of simplisia and extract of sungkai's leaf

Manufacturing of Binders

Tablets were made by wet granulation method using Avicel PH 101 and aquadest as a binder with 1:2 treatment. Avicel PH 101 was stirred while adding distilled water little by little so that it would dissolve evenly into a binder solution. The tablet manufacturing flow includes :

Formula 1 (Without active ingredients).

Aerosil, lactose, and aspartame are mixed in a mortar while gradually adding the avicel PH 101 binder to form a dough. then sifted through mesh 12 and dried at 40-60ºC for 15 minutes, after drying do a dry sifting with a mesh sieve 12 then added lubricant.

Formula 2 and 3

Mix the active substance and additives aerosil, lactose, and aspartame into a mortar while adding a little by little the binder avicel PH 101 until it forms a dough. Then it was sifted through mesh 12 and dried at 40-60ºC for 15 minutes, after drying did a dry sifting with a mesh sieve 12 then added lubricant.

Table I. Formula Granul

Material	Formula %			Use	Concentration%
	F1	F2	F3		
Sungkai Leaf Simplicia	-	25	-	Active Substance	(Febrina, 2021)
Sungkai Leaf Dry Extract	-	-	25	Active Substance	(Febrina, 2021)
Avicel PH 101	20	20	20	Binder, Shredder and Non stick	20-90% (Rowe *et al.*, 2006), (Sa'adah *et al*., 2016)

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Aerosil	5	5	5	Stabilizers, lubricants and Glidants	1,0-5,0 % (Rowe *et al.*, 2006)
Aspartame	1.5	1.5	1.5	Sweetener	(Husni *et al*., 2020)
Laktosa	73,5	48,5	48,5	Filler	5-80% (Rowe *et al.*, 2006), (Najihudin *et al*., 2019)

Table II. Tablet Formula Each 500 mg

Material	**Formula Tablet (mg)**		
	F1	**F2**	**F3**
Sungkai Leaf Simplicia	-	125	-
Sungkai Leaf Dry Extract	-	-	125
Avicel PH 101	100	100	100
Aerosil	25	25	25
Aspartame	7.5	7.5	7.5
Laktosa	367.5	242.5	242.5

GRANUL EVALUATION

a. Test the water level

Test the water content using a Moisture balance tool, weigh 1 gram of granule, set the scale to zero, position the lamp at a height of 6 cm, turn on the lamp and set the temperature to 105ºC. Pay attention to the scale of the water content on the tool, if the granules have started to dry out, the equilibrium scale will change with the help of the indicator knob, which can be moved to achieve equilibrium again. When the equilibrium indicator has stopped, the experimental sample is completely dry and the percentage of water lost can be read immediately (Voight, 1994).

b. Flow rate test

This is done by weighing 25 grams of granules, put into a funnel with the ends of the stems closed. The funnel cover was opened and the granules were allowed to flow until they were exhausted, the granule flow time was calculated. A good granule flow time is no more than 10 seconds in 100 grams (Halim, 2012).

c. Rest angle

Weigh the granules as much as 25 grams and put into a funnel with the bottom closed with a finger, at the same time open the lid of the funnel then the finger is released from the mouth of the funnel and the material is allowed to flow freely, a cone-like pile will occur (Halim, 2012).

$$\tan \theta = \frac{h}{r}$$

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d. Bulk density

1. *Untapped density (Schudichte)*
   Of a number of materials of known weight (usually weighed 100 grams), carefully inserted into a 200 mL measuring cup so that the volume can be read immediately. From the weight and volume, the untapped bulk density can be calculated (Halim, 2012).

$$Bj_{true} = \frac{Wo}{Vo}$$

2. *Tapped density(Tap density)*
   100 grams of pulva which has been dried to constant weight, is put into a measuring cup and the top surface of the powder is leveled (Vs). The measuring cup was stomped 1250 times and the volume of powder (A) was read. Then, the stomping was carried out 1250 more times and the volume of powder (B) was read again. If the second reading (B) does not differ with (A) greater than 2 cm3 then A is the Stamp volume (tap volume). From the weight and volume can be calculated tap density (Halim, 2012).

$$Bj_{tapped} = \frac{W}{Vt1}$$

3. *Compressibility test*
   Weigh 100 grams of granules into a measuring cup and record the volume, then the granules are compressed 1250 times with a test instrument, record the test volume before it is compressed and the volume after it is compressed with 1250 taps (Halim, 2012).

4. *Factor Hausner (Halim, 2012; Voight, 1994)*
   The comparison between Stampfdichte and Schuttdichte is called the "Hausner Factor". The Hausner factor can be calculated by the equation:

$$FH = \frac{Bj\ mampat}{Bj\ nyata}$$

e. Porositas Test

Determination of porosity is carried out by determining the real density and true density. specific gravity can be calculated by the equation:

$$\rho = \frac{b-a}{V\ piknometer}$$

The true density can be calculated by the equation:

$$\text{Bj benar} = \frac{c-a}{(c-a)+(b-d)} \times \rho$$

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Porosity can be calculated by the equation:

$$\mathcal{E} = 1 - \frac{Bj\ nyata}{Bj\ benar} \times 100\%$$

f. Particle size distribution test

One hundred grams of the preparation was sieved using a Sieve Shaker graded sieve starting from 60, 100, 120, 170, 270 and 325 mesh, for 5 minutes, where the preparation was filled on the top sieve. The weight of the granules left from each sieve was then weighed (Devi et al., 2018). The total loss should not exceed 5% of the weight of the original test specimen (USP, 2015).

g. Liquid absorption test

The granules were weighed as much as 1 gram, placed on a Hirsch funnel and spread evenly. Then note the amount of water (mL) that is absorbed every certain time interval by reading the scale on the tool. Observe for 15 minutes. Then a curve of the relationship between the amount of water (mL) absorbed and the time (minutes) was made.

Tablet Formulation

Tablets are made in round shape with a weight of 500 mg per tablet. The tablet press machine is prepared and the mass of the granule that has been tested is fed into the tablet press machine.

Tablet Evaluation

a. Tablet size uniformity

The tool used in the size uniformity test is a caliper. The working procedure of uniform size is taken 20 tablets. A good tablet has a diameter of not more than 3 times and not less than 1 1/3 the thickness of the tablet (Depkes RI, 1979).

b. Weight loss

Twenty tablets taken at random were weighed on an analytical balance one by one. The average is calculated, then the percentage deviation of the weight of each tablet is calculated to be compared with the requirements of the Indonesian Pharmacopoeia (Depkes RI, 1979).

c. Tablet hardness

The test is carried out with 10 tablets, by placing a tablet between the clamping chamber and then clamping it by turning the pressure tester, so that the tablet is firmly in place and the instructions are on a scale of 0, through a turn on a screw, the tablet will break and the scale indication is read on the device. (Ansel, 1989).

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d. Tablet friability

As for it can be done by using a tool where 20 tablets are freed of dust. Weigh carefully on the analytical balance then put into the friabilator. This test is carried out for four minutes or 100 rounds. Remove the tablet from the device, free from dust again and weigh it (Lachman, 2008).

e. Tablet desintegration

The vessel is filled with distilled water at a temperature of 37.5ºC, with a volume of 900 mL, so that at the highest position the wire mesh is right above the water surface and at the lowest position the mouth of the basket is right on the water surface. Six tablets were put one by one into each basket, then the basket was moved up and down regularly until the tablets disintegrated. The tablet is declared destroyed if no part of the tablet is left on the gauze (Depkes RI, 1979).

RESULTS AND DISCUSSION

Examination of Simplicia Characteristics of Sungkai Leaves

Based on research on specific organoleptic parameters, Sungkai leaf simplicia powder is in the form of a fine powder, brownish green in color, has a slightly pungent odor and a bitter taste. For microscopic testing of Sungkai leaf simplicia powder, it was found that there were irregular epidermal cells, glandular hairs, stomata with bidiastic cell shape, and there were covering hairs and sclerenchyma fibers. Based on microscopic testing, it can be concluded that Sungkai leaf simplicia has perfect anatomy. While sungkai leaf extract is dark green, has a distinctive smell and tastes bitter.

Table III. Simplistic Characteristics

Testing	Result (%)
Water soluble essence	3,4328±0, 15
Ethanol soluble extract content	3,5958± 0,29
Drying shrink	8,9521±0, 42
Water content	5,11 ± 0,06
Total ash content	18,6463±0 ,6
Acid insoluble ash content	22,862±0, 01

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Table IV. Extract Characteristic Results

Testing	Result (%)
Randemen	11,8659
Drying shrink	3,2752±1,25
Water content	2,61± 0,05
Total ash content	5,8481±0,00

Phytochemical Test

Based on the phytochemical testing of the simplicia powder of Sungkai leaves, the chemical content of the simplicia was tested by screening secondary metabolites which included tests for flavonoids, alkaloids, saponins, tannins and steroids with all positive results presented in Table V.

Table V. Phytochemical test results

No	Testing	Test Parameters	Sungkai Leaf Simplicia Sample
1	Flavonoid	The presence of a red solution	(+)
2	Alkaloid Reagen Mayer	There is a white precipitate	(+)
	Reagen Bouchardat	There is a brown precipitate	(+)
	Reagen Dragendorff	There is an orange precipitate	(+)
3	Saponin	There is foam for 15 minutes	(+)
4	Tanin	There is a blackish green color	(+)
5	Steroid	A bluish green color is formed	(+)

Description :
(+) = Give reaction result
(-) = No reaction

Granule characteristic

Based on the granule test from simplicia and dried extract of Sungkai leaf (Peronema canescens Jack) the granule criteria include: water content of granules F2 2.61% ± 0.05 and F3 4.20% ± 0.16, granule flow rate F2 3, 37 ± 0.06 and F3 6.51 ± 0.15, angle of rest for F2 granules 38.65 ± 0.00 and F3 32 ± 0.00, compressibility of granules F2 16.12% and F3 9.52%, Hausner factor F2 1.19 and FE 1.10, porosity of granules F2 78.51% and F3 45.32%, particle size distribution of F2 244.26 m and F3 249.39 m, liquid absorption test showed that F2 granules were more likely to absorb water than F3 granules, so F3 granules have good granule criteria compared to F2 granules.

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Tablet Evaluation

Based on tablet testing, F3 tablets from dried extract of sungkai leaves met the criteria for a good tablet, including: testing for uniformity of tablet size for F2 2.47 ± 0.03 and F3 2.5 ± 0.00, testing for weight uniformity of F2 tablets 492.53 ± 20.41 and F3 500.16 ± 2.25, F2 tablet hardness test 3.413 ± 0.36 and F3 4.895 ± 0.28, F2 tablet friability test 1.0069% and F3 0.2899%, disintegration time of F2 tablet is more faster than F3 because it has a larger tablet fragility.

Picture 1. F2

Picture 2.F3

Description :
F2: Sungkai Leaf Simplicia Tablets
F3: Sungkai Leaf Dried Extract Tablets

CONCLUSION

Based on the results of the research that has been done, it can be concluded that:

1. Sungkai leaf simplicia (*Peronema canescens* Jack) cannot be formulated in tablet form.
2. The dried extract of Sungkai leaf (*Peronema canescens* Jack) can be formulated in tablet form.
3. There are many differences between tablets from simplicia and tablets from dried extract of sungkai leaf produced, including: tablet color, tablet weight, tablet hardness, tablet friability and tablet disintegration time.
4. The tablet preparation of sungkai leaf simplicia did not meet the criteria for a good tablet including: weight uniformity test, hardness test and friability test, while the dry extract tablet preparation of sungkai leaf met the criteria for a good tablet.

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