

FORMULATION OF KATUK (*Sauropus androgynus* L. Merr) LEAVEN EXTRACT EFFERVESCENT AID WITH VARIATIONS OF PEG 6000 LUBRICANT CONCENTRATION

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ABSTRACT

Katuk leaves are one type of herbal galactagogue that can increase prolactin and oxytocin levels, and contain nutrients that can be used to facilitate breast milk. This study aims to determine the optimal PEG 6000 Lubricant concentration variation that produces effervescent tablet physical properties that meet the physical properties test requirements. This research is a preexperimental laboratories research. The concentration variation of PEG 6000 lubricant used was 1%, 2% and 3%. Tablets were evaluated for their physical properties including organoleptics, weight uniformity, dissolving time, hardness, pH and fragility. The results of this study indicate that the physical properties of effervescent tablets from katuk leaf extract (*S. androgynus*) with varying concentrations of PEG 6000 Lubricant meet the requirements of physical properties of Organoleptics, Weight Uniformity, Dissolving Time and Fragility. However, the physical properties of hardness and pH value have not met the requirements of the physical properties test set, the effect of variations in the concentration of PEG 6000 Lubricant on the physical properties of effervescent tablets, namely on Weight Uniformity, Dissolving Time, Hardness test, pH test and Friability test. But in the Organoleptical test, Weight Uniformity, Dissolving Time does not give the effect of differences in lubricant concentration variations.

Key words: Effervescent, Katuk Leaf (*S. androgynus* (L) Merr), Lubricant PEG 6000, Physical Property Test.

INTRODUCTION

Katuk (*S. androgynus* L. Merr) is a vegetable commodity that is also an important medicinal plant. Katuk is known as a vegetable and medicinal plant, especially for increasing breast milk (ASI). The classification of katuk plants is Kingdom Plantae, Division Magnoliophyta, Class Magnoliopsida, Order Malpighiales, Family Phyllanthaceae, Genus *Sauropus*, and Species *S. androgynus* L. Merr (Pujiastuti et al., 2023). A very famous property of katuk leaves is that it can launch breast milk (ASI) (Handayani et al., 2021).

Based on research conducted by Handayani, the results of giving katuk leaf extract to breastfeeding mothers at a dose of 900 mg / day can increase prolactin and oxytocin gene expression. breast milk volume by 66.7 ml or 50.7% and reduce the number of subjects lacking breast milk by 12.5%. The increase in breast milk volume is caused by katuk leaves containing phytochemical compounds, namely alkaloids (papaverine), and sterols (phytosterols) which can increase prolactin and oxytocin levels, and contain nutrients that can be used as raw materials for breast milk synthesis (Handayani et al., 2021). Katuk leaves contain phytochemical compounds, namely



steroids and polyphenols, which can increase levels of prolactin, the hormone that facilitates breast milk production. These high prolactin levels will increase, speed up, and facilitate breast milk production (A. Syahadat & N. Siregar, 2020). In addition to facilitating breast milk, katuk leaves also have antioxidant properties (Arista, 2013). Katuk leaf extract (*S. androgynus*) has been shown to have a wide range of pharmacological functions (Salsabila, 2018). In addition, katuk leaves also contain important nutrients such as protein, vitamin C, vitamin D, calcium and folic acid. (Handayani et al., 2021).

Effervescent tablets are an option for the development of pharmaceutical preparations from katuk leaf extract because effervescent tablet type pharmaceutical preparations will be dissolved in water and taken orally in the form of a solution. (Greene et al., 2016; Yulianti & Sutoyo, 2021). This preparation is expected to accelerate drug initiation so that it does not require disintegration time. (Greene et al., 2016). Effervescent tablets dissolve easily in water and can provide a fresh taste sensation like a soft drink, making it easier for consumers who cannot take medicine by swallowing capsules or pills directly. Effervescent tablets create a different sensation of taking medicine because of the carbon dioxide (CO₂) gas produced so that it can cover the bitter taste. Effervescent tablet preparation of katuk leaf extract is one of the alternative preparations intended to provide a solution in water so that people who have difficulty swallowing drugs can easily use Effervescent tablet preparations. (Anonim, 1995). The components in tablet formulation consist of active substances, fillers, binders, disintegrants, acid bases and lubricants can also contain coloring agents, flavoring agents and sweetening agents. (Puspadina et al., 2021).

The components that play a role in the success of an effervescent tablet are the use of citric acid and tartaric acid variations (Anova dkk., 2016). According to Anwar, (2016) the variation in the amount between citric acid and tartaric acid has a significant effect on the physical properties of effervescent tablets. In addition to the acid component, additional ingredients are needed in the form of lubricants or lubricants to improve the physical properties of the granules and effervescent tablets produced. Choosing appropriate additives to obtain specific functions in effervescent tablet formulations such as PEG 6000 lubricants can be a critical parameter to obtain physical properties that meet the requirements. Different variations of PEG 6000 affect the physical properties of effervescent tablets. The addition of PEG 6000 as a lubricant at a concentration can affect the physical properties of effervescent tablets (Apsari et al., 2018). Lubricant serves to reduce friction during the tablet forging process and also to prevent the tablet mass from adhering to the felt machine used so that it will affect the test results of the physical properties of tablets (Puspadina et al., 2021). In this study, researchers used PEG 6000 lubricant, because of its water-soluble nature (Deshmukh & Kapadia, 2017).

MATERIAL AND METHODS

Material

The tools used in the study were single punch tablet forging machine (TDP-6T Single Punch), oven (Memmert), furnace/muffle/furnace (SAFETHERM), desiccator, viscometer (ROTAVISC IKA lo-vi), maceration apparatus, soaking vessel, stirrer, and filter, blender (Miyako), analytical balance (KERN), color reader Cr-10



(KONICAMINOLTA), beaker glass (Pirex), stopwatch, 60 mesh sifter, hardness tester (ERWEKA GmbH), tablet friability tester (Labindia), weighing bottle (Pirex), crucible tongs, pH meter (Phs-3CB). The materials used in this study include katuk leaf extract (*Sauropus androgynus*, L. Merr) obtained from UPT Laboratorium Herbal Medika Batu, citric acid (pt), tartaric acid (mg), sodium bicarbonate (mg), PVP (mg), sodium benzoate (mg), aspartame (mg), PEG 6000 (mg) and lactose (mg) obtained from chemical manufacturer PT. Bintang Gemilang Indonesia.

Method

1. Design of effervescent tablet formula of katuk leaf extract.

Effervescent Tablet Formulation of katuk leaf extract (*Sauropus androgynus*, L. Merr) which has been determined by UPT. Laboratorium Herbal Medika Batu was made with a design of 3 formulations with reference to research that has been done by Yulianti. (Yulianti & Sutoyo, 2021).

2. Research Procedure

Preparation of katuk leaf extract

The active ingredient of katuk leaves was obtained from Jatisari Village, Cerme Kulon Hamlet, Tempeh District, Lumajang Regency and has been determined by UPT. Laboratorium Herbal Medika Batu, based on the results of the determination of katuk leaves used in this study is the species *Sauropus androgynus* (L) Merr. Samples were cleaned of impurities, pulverized using a blender until katuk leaf powder was obtained and then dried in the open air. The sample was then weighed. A total of 1000 g of dried katuk leaf powder was extracted with 3000 mL of 96% ethanol by maceration method for 5 days. The purpose of maceration for 5 days is because in general the time used for maceration is 5 days, after that time the balance between the extracted material on the inside of the cell and outside the cell has been achieved (Voigt, 1994). The residue obtained was then remacerated twice using 2000 mL of 90% ethanol each. The filtrate obtained was combined, the solvent was evaporated using a vacuum rotary evaporator at 50°C until a thick extract was formed. The characteristics of the extract obtained after being evaporated using a vacuum rotary evaporator were obtained in the form of a thick extract.

Procedure for making effervescent tablets

In this study, effervescent tablets were made using the wet granulation method. The materials for making tablets are divided into two, namely material-1 and material-2 which are processed by wet granulation. Material-1 consisted of sodium bicarbonate, lactose, polyvinyl pyrrolidone, and PEG 6000. Each ingredient was weighed according to formulations I, II and III. After the ingredients were weighed according to the formulation, the ingredients were mixed and sieved using a 16 mesh sieve. Material-1 was then dried in an oven for 15 minutes at 60°C. Then material-2 consists of a granule mixture of katuk leaf extract, aspartame, tartaric acid, and citric acid that has been weighed according to formula 1, formula 2 and formula 3. The mixture was stirred homogeneously and then sieved with a 16 mesh sieve. Ingredient-1 and ingredient-2 were mixed and stirred until homogeneous then sodium benzoate was added. Next, the mixture was stirred again and sieved using a 16 mesh sieve. Enrichment is done so that the mixture has a uniform size and is mixed homogeneously. The homogeneous mixture was then molded into effervescent tablets with a tablet press (Anwar Syahadat & Nurelilasari Siregar, 2020).



Physical properties test of effervescent tablets of katuk leaf extract *Uji Organoleptic*

Organoleptic test of effervecent tablets was carried out on the parameters of shape, taste, aroma and color. The measurement results were written on the data collection sheet and then described and discussed based on the literature obtained.

Weight Uniformity Test

A total of 20 tablets are weighed carefully one by one, then the average weight and coefficient of variation are calculated. The requirements are no more than 2 tablets whose weight deviates more than the average weight set in column A and no tablet whose weight deviates more than the price set in column B (Anonim, 1995).

Dissolving Time Test

Dissolution time was conducted by placing an effervescent tablet into distilled water with a volume of 200 ml. The disintegration time was calculated with a stopwatch from the time the effervescent tablet was submerged until all the tablets disintegrated and dissolved. (Siregar, 2010). The dissolution time of effervescent tablets is less than 5 minutes (Frisca Vidya Ningrum et al., 2022). Solubility was measured by calculating the dissolution time required by the tablet for one serving size using a 500ml measuring cup. Tablets to be measured solution time, put into 200ml of water in a measuring cup simultaneously with the start of time counting using a stopwatch (Yulianti & Sutoyo, 2021).

Tablet Hardness Test

The tablet is inserted into the Hardnerss tester, then the device is rotated until the number or hardness value is obtained. The minimum hardness suitable for tablets is 4 kg (Syahrina & Noval, 2021). One tablet is placed in the center or perpendicular to the hardness tester, at first the scale position is zero, then the tool presses until the tablet breaks. Read the scale reached when the tablet is broken or destroyed. The working principle of the hardness test is the ability of the tablet to withstand the load or pressure on the diameter of the tablet (Yulianti & Sutoyo, 2021).

Degree of Acidity (pH)

An effervescent tablet was dissolved in distilled water. Then the solution is measured for pH using a pH meter. Effervescent tablets are said to be good if they have a pH value close to neutral, namely 6-7 (Ansel, 1989). The method for the pH test is carried out by dissolving effervescent into 200ml of distilled water then the pH is measured with a pH meter, the measurement results are said to be good if the pH of the effervescent solution is close to neutral (Yulianti & Sutoyo, 2021).

Tablet Friability Test

Tablet friability was performed by freeing 20 tablets and then weighing them and putting them into the friabilator tester. The tool was run for 4 minutes at a speed of 25 revolutions per minute. After that, the tablets were freed again and weighed. Acceptable tablet fragility is less than 1%. Friability is expressed as % (Siregar, 2010).

Data Analysis

Analysis in this study used 2 analysis methods, namely:

1. Organoleptic data was analyzed descriptively arranged in tables and loaded in graphical form.
2. Data on weight uniformity, tablet hardness, tablet friability and dissolution time were analyzed using the one way anova method..



RESULT AND DISCUSSION

This effervescent preparation uses the active ingredient of katuk leaf extract. Extraction was carried out using the maceration method which obtained a yield of 9%. The purpose of doing it for 5 days is because in general the time used for maceration is 5 days, after that time the balance between the extracted material on the inside of the cell and outside the cell has been achieved (Voigt, 1994). After obtaining the thick extract, the formulation process continued. Effervescent tablet formulations were made from katuk leaf extract with variations of PEG 6000 Lubricant with a total tablet weight of 2000mg. Tablets were molded with formulas (Formula 1 to Formula 4) using variations in the concentration of PEG 6000 Lubricant with concentrations of 1%, 2% and 3% of the 2000mg tablet weight, respectively. The results of the formulation table were tested for the physical quality of the tablets including:

Organoleptic Test

Organoleptical test is a prelude to all tablet tests that will be carried out. This test is carried out using the five senses method carried out by 3 respondents with the aim of knowing the shape, color, smell and taste of effervescent tablets that have been formulated.

The results of the organoleptic test shown in table 2 can be seen that the tablets that have been made have the same characteristics ranging from shape, taste, aroma and color. This round tablet shape is obtained from the use of tablet molds using a single punch tablet felting machine so that the same characteristics are obtained in all three formulas, both formula 1, formula 2 and formula 3. From the results obtained, there is no influence from all formulas based on shape, color, aroma and taste. Where the resulting shape is flat round, has a distinctive aroma of katuk leaves, yellowish green in color and has a fresh, not sweet taste. These results are in line with research conducted (Yulianti & Sutoyo, 2021) that the results of organoleptical evaluation most likely have no influence on the difference in formula.

1. Weight uniformity test

Weight uniformity is a parameter to determine the weight variation obtained from the tablet forging process that has been made. The weight uniformity test aims to determine the weight of the tablets produced and become a reference to the active substances contained in the tablet preparation (Yulianti & Sutoyo, 2021).

Based on tables 3-5, the uniformity of weight in formula 1, formula 2 and formula 3 does not deviate from column A (5%) and column B (10%). So it can be concluded that the effervescent tablet formulation of katuk leaf extract with variations in PEG 6000 concentration in formula 1, formula 2 and formula 3 has met the requirements of the weight uniformity test where the Pharmacopoeia Edition IV requirements are no more than 2 tablets whose weights deviate more than the average weight set by column A (5%) and not a single tablet whose weight deviates more than the price set by column B (10%). The uniformity of weight did not deviate because the tablet manufacturing process used the same dieyang tool (Frisca Vidya Ningrum et al., 2022).

2. Dissolution time test

The tablet dissolution time test is an indicator that shows the time required for the tablet to dissolve completely in water with a certain volume. The dissolution time of



effervescent tablets is less than 5 minutes. (Syahrina & Noval, 2021).

From table 6, the average value of the effervescent tablet dissolving time test in formula 1 was obtained for 134 seconds, formula 2 for 126 seconds and formula 3 for 130 seconds. These results show that the three formulas have met the requirements of the effervescent tablet dissolving time test. Formula 2 gives the fastest dissolving time results, this means that with a lubricant concentration of 2%, it gives the best effect on the dissolving time of effervescent tablets, because the faster the tablet dissolves, the faster the effervescent reaction occurs, and the faster the effervescent tablets are drunk. This can be caused by the overlubricity factor of PEG 6000 which is used as a lubricant in this study so that it will prolong the solubility of the tablet (Banne et al., 2012).

However, if it is related to the hardness of the tablet, namely the harder the tablet produced, the longer the tablet will dissolve, while the results are that the tablet formula 2 has the greatest hardness of 2.25 kgf dissolving in a faster time of 126 seconds and on tablets with a hardness value (1.25 kgf) dissolving longer (130 seconds) Another factor affecting solubility is that the process of forging effervescent tablets only uses manual techniques so that uniform hardness is not produced on all tablets made, and what happens is that the tablets tested for hardness are not the same as the tablets tested for dissolving time so that the results obtained are not in accordance with the theory. The weakness in this study is that the dissolving time test uses tablets that have been tested for fragility so that this will affect the results of the dissolving time test itself due to the limited tablet samples used.

3. Hardness test of tablets

Tablet hardness test is a parameter that describes the resistance of tablets to mechanical stress, shock and the occurrence of tablet cracks during packaging, transportation and distribution to consumers.

Tablet hardness test is conducted to determine the strength and resistance of tablets to impact or mechanical stress during the production process to drug distribution (Syahrina & Noval, 2021). Table 7 shows that the average hardness of effervescent tablets in formula 1 is 1.24 kgf, in formula 2 the average hardness of effervescent tablets is 2.25 kgf. While in formula 3 the average hardness of effervescent tablets is 1.25 kgf. These results show that of the three formulas, formula 2 has the highest value of hardness but is still below the specified requirements, so it can be concluded that all three formulas do not meet the tablet hardness test requirements. Where the minimum hardness that is suitable for tablets is 4 kgf (Ansel, 1989). Sufficient hardness of a tablet is one of the important requirements of a tablet.

The value is related to the theory that high concentrations of PEG 6000 can increase the hardness value of tablets and accelerate the time of solubility (Apsari et al., 2018). When connected with the theory, it is different from the results obtained from the test of physical properties of hardness considering that this study uses a single punch tablet felting tool that uses manual techniques so that compression can not be maximized between tablets. Another factor affecting hardness is used as a measure of forging pressure, the greater the pressure exerted when pentabletan will increase the hardness of the tablet (Banne et al., 2012). Other factors that can affect tablet hardness are the effect of storage temperature and the hygroscopicity of the material on the physical properties of the tablet (Utami et al., 2018). Tablet hardness of less than 4kgf is



acceptable as long as the friability does not exceed the set limit. However, tablets with low hardness values will experience fragility during packaging and transportation. Tablet hardness of more than 10kgf is still acceptable, as long as it still meets the required disintegration and dissolution time requirements ⁽²³⁾.

4. Acidity pH test

The pH acidity test is carried out to determine the acidity of effervescent tablets that have been dissolved in water.

The effervescent tablets were dissolved into 200 ml of distilled water and then the acidity was measured using a pH meter (Yulianti & Sutoyo, 2021). A good effervescent tablet has a pH value close to neutral (RI, 2014). Based on the results of the pH test in table 8 effervescent tablets of katuk leaf extract, formula 1 has an average pH value of 4.78 with an SD value of 0.077, while formula 2 has an average pH value higher than formula 1 of 5.11 with an SD value of 0.015 and formula 3 has the smallest average pH value of the three formulas of 4.71 with an SD value of 0.06. The results of the three formulas show that formula 2 with a pH value of 5.11 which is close to neutral pH 6-7 (RI, 2014). The higher the concentration of PEG in the formula, the pH of the preparation decreases (Rismarika et al., 2020).

5. Brittleness test

The tablet friability test aims to describe the strength of the tablet associated with particle bonding at the edges or surface of the tablet. The greater the tablet friability value, the greater the loss of tablet mass.

Friability value A good tablet friability value is less than 1%. High tablet fragility will affect the active substance content of the tablet ⁽²⁵⁾. From table 9, the average value of the effervescent tablet friability test in formula 1 has an average friability value of 0.56%, formula 2 has an average of 0.55%, while formula 3 has the largest average value of 0.66%. From the results obtained, it can be concluded that the three formulas have met the requirements of the tablet friability test. Acceptable tablet fragility is less than 1%. Fragility is expressed in percent (%) (Siregar, 2010). The high fragility of effervescent tablets of katuk leaf extract in formula 3 can be caused by the addition of PEG 6000 as a lubricant which has the ability to reduce internal bonds between particles of tablet material, so that the resulting tablets are easily eroded (Deshmukh dan Kapadia, 2017). The addition of PEG 6000 as a lubricant at large concentrations can produce quite high brittleness values (Apsari et al., 2018).



CONCLUSION

Differences in PEG 6000 lubricant variations affect the physical properties of effervescent tablets of katuk leaf extract. The physical properties of Effervescent Tablets from katuk leaf extract (*Sauropus androgynus* (L.) Merr) with varying concentrations of PEG 6000 Lubricant meet the requirements of organoleptical physical properties, weight uniformity, dissolving time and friability. However, the physical properties of hardness and pH value have not met the requirements of the physical properties test. There is an effect of variation in the concentration of PEG 6000 Lubricant on the physical properties of effervescent tablets, namely on Weight Uniformity, Dissolving Time, Hardness test, pH test and Friability test. In the Organoleptical physical properties test, Weight Uniformity, Dissolving Time PEG 6000 does not affect the physical properties of effervescent tablets on variations in lubricant concentration of each formula. The test results showed that formula 2 containing 2% PEG 6000 lubricant produced the most acceptable physical properties of effervescent tablets of the entire formula.

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TABLE

Table 1. Formula of effervescent tablet of katuk leaf extract

Bahan	Formula			Fungsi
	F-1	F-2	F-3	
Katuk leaf extract	30%	30%	30%	Active ingredients
Citric acid	60%	60%	60%	Acidic component
Tartric acid				
Sodium bicarbonate				Base component
Polyvinylpyrrolidone	2,5%	2,5%	2,5%	Binder
Sodium benzoate	0,16%	0,16%	0,16%	Base component
Aspartame	2%	2%	2%	Sweetener
PEG 6000	1%	2%	3%	Lubricant
Lactose (up to 100%)	4,3%	3,3%	2,3%	Fillers
Total bobot	2000 mg	2000 mg	2000 mg	

Table 2. Organoleptic test results of effervescent tablets of katuk leaf extract

Formula	Shape	Taste	Aroma	Color
F1	Round	Fresh with no sweetness	Typical katuk leaf	Yellowish green
F2	Round	Fresh with no sweetness	Typical katuk leaf	Yellowish green
F3	Round	Fresh with no sweetness	Typical katuk leaf	Yellowish green

Table 3 Weight Uniformity Test Results of F1 Tablets

Tablet Weight (gram)			
Replication	Weight	Replication	Weight
Tablet 1	2,03	Tablet 11	1,98
Tablet 2	2,05	Tablet 12	1,91
Tablet 3	1,97	Tablet 13	1,92
Tablet 4	1,93	Tablet 14	1,93
Tablet 5	1,97	Tablet 15	1,97
Tablet 6	1,94	Tablet 16	1,91
Tablet 7	1,98	Tablet 17	1,93
Tablet 8	1,97	Tablet 18	1,93
Tablet 9	1,93	Tablet 19	1,96
Tablet 10	1,95	Tablet 20	1,93
Average weight \pm SD : 1,96 \pm 35,584			



Table 4 Weight Uniformity Test Results of F2 Tablets

Tablet Weight (gram)			
Replication	Weight	Replication	Weight
Tablet 1	1,97	Tablet 11	1,92
Tablet 2	1,96	Tablet 12	1,93
Tablet 3	1,92	Tablet 13	1,91
Tablet 4	1,97	Tablet 14	1,93
Tablet 5	1,96	Tablet 15	1,93
Tablet 6	1,91	Tablet 16	1,91
Tablet 7	1,93	Tablet 17	1,92
Tablet 8	1,95	Tablet 18	1,91
Tablet 9	1,96	Tablet 19	1,97
Tablet 10	2,04	Tablet 20	1,96
Average weight \pm SD : 1,95 \pm 33,290			

Table 5 Weight Uniformity Test Results of F3 Tablets

Tablet Weight (gram)			
Replication	Weight	Replication	Weight
Tablet 1	1,91	Tablet 11	1,92
Tablet 2	1,94	Tablet 12	1,91
Tablet 3	1,97	Tablet 13	1,97
Tablet 4	1,93	Tablet 14	1,92
Tablet 5	1,98	Tablet 15	2,02
Tablet 6	1,97	Tablet 16	1,98
Tablet 7	1,89	Tablet 17	1,93
Tablet 8	1,98	Tablet 18	1,94
Tablet 9	2,01	Tablet 19	1,92
Tablet 10	1,98	Tablet 20	1,91
Average weight \pm SD: 1,95 \pm 36,704			

Table 6. Dissolution time test results of effervescent tablets of katuk leaf extract

Formulation	Dissolution time (seconds)
F 1	134
F 2	126
F 3	130



Table 7. Hardness test results of cotton leaf extract effervescent tablets

Formulation	Hardness value (kgf)
F 1	1,24
F 2	2,25
F 3	1,25

Table 8. Results of pH test of effervescent tablets of katuk leaf extract

Formulation	pH Values
F 1	4,78
F 2	5,11
F 3	4,71

Table 9. Friability test results of effervescent tablets of katuk leaf extract

Formulation	Brittleness values (%)
F 1	0,56%
F 2	0,55%
F 3	0,66%

