

EVALUATION OF PHYSICAL STABILITY OF GEL WITH CAPA LEAF EXTRACT (*Blumea Bassamifera* L.) AS ACTIVE INGREDIENT: TRADITIONAL MEDICINES PLANT FROM ACEH-INDONESIA

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ABSTRACT

Capa leaves (*Blumea Balsamifera* L.) have long been traditionally used by the Acehnese-Indonesian people as a wound medicine. The results of the capa leaf extract test proved to contain active ingredients as anti-bacterial and anti-inflammatory. This study aims to test the formulation of gel with active ingredients of capa leaves by examining the stability of the resulting gel. The gel base was made with the main ingredients carbopol 940, TEA, Methyl Paraben, and Propylenglicol, and then combined with the active ingredient capa leaf extract with varying concentrations of extract, carbopol, and TEA. Gel stability was tested for 4 weeks by looking at the pH, spreadability, and viscosity of the gel. The results showed that, physically, the homogeneity of the gel in all variations was homogeneous. Organoleptically, the resulting capa leaf gel is dark green and has a distinctive aroma of capa leaf extract. The pH stability, viscosity, and spreadability for 4 weeks in all variations are still within the limits of pharmaceutical recommendations for gel preparations as wound medicines. The average pH value of the gel was 6.4, the average viscosity value was 4323 cP, and the average spreadability value was 5.8 cm. The capa leaf extract gel is still stable in 1-month storage at room temperature, so this formulation meets the gel standards as a topical medicine.

Keywords: *Blumea Bassamifera* L, Tradicional Medicinal Plant, Gel, Stability.

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INTRODUCTION

The community of Aceh has long used the Capa plant (*Blumea balsamifera* L.) as a plant with medicinal properties.^{1,2} GC-MS results of capa leaf extracts contain Borneol, Jasmolin, Dimethoxyphenyl, Camphor, and other compounds known to function as anti-bacterial.³ The results of the phytochemical test of capa leaves are known to contain flavonoids, saponins, phenolics, tannins, and steroids.^{4,5} Capa leaves can also reduce PEG-2 and protein transudation. This capa leaf extract is also able to reduce inflammatory cytokines such as IL-1, IL-6, and TNF- α . Capa plant extract also functions as an anti-inflammatory. Capa extract using water as a solvent at a dose of 92 mg/kg body weight can reduce edema by 6.4%.⁶ Topical gel formulations can increase the effectiveness and comfort of their users, including being able to deliver medicinal ingredients well, easily spread when applied to the skin, provide a cold sensation, and not cause marks on the skin. Gels can retain skin moisture, supporting the principles of wound care. Gel or jelly is a system with a semisolid form made of inorganic or organic suspensions penetrated by liquid. Gels have many advantages over other semi-solid preparations because they are easy to use, practical, and durable.^{7,8} For the medicinal benefits of capa leaves to be better, they need to be formulated into a topical drug form that is easy to use and practical.^{9,10} In this study, capa leaf extract was obtained by the maceration method. Formulation variations in gel bases affect the characteristics and stability of the gel. In this study, variations

were made to capa leaf extract, carbopol, and TEA; the composition variations were arranged using *Box-Behnken* design from *Response Surface Methodology*. The resulting capa leaf gel must meet pharmacological standards so as to increase the ability of active ingredients as medicinal ingredients. Gel stability was observed for 1 month of storage at room temperature.

EXPERIMENTAL

Materials and Methods

Study Location

Leaves of the *B. balsamifera* plant were collected from the Gunongpulo village in the Kluet Utara subdistrict of the South Aceh-Indonesia Regency (Fig.-1, coordinates 03°07'13.7"N and 97°20'28.2" E). The location of the sampling was the same as it was in our earlier paper regarding the bioactive chemicals found in *B. balsamifera* leaf extracts from South Aceh, Indonesia.

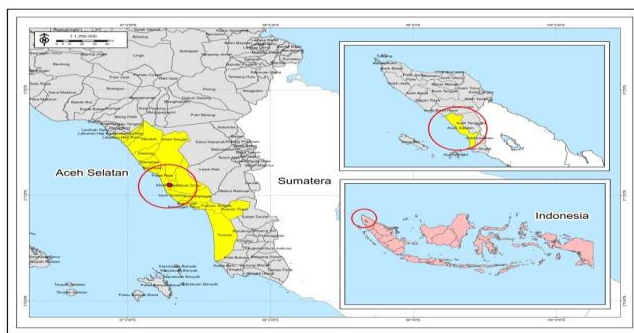


Fig.-1: Location Sampling

Material and Tools

While the materials used are capa leaf extract (*Blumea Balsamifera* L.), gel base consisting of carbopol 940, TEA, Propylenglicol, Methyl Paraben, and Aquadest. *B. balsamifera* leaves extracted with ethyl acetate solvent and gel base with formula Carbopol 940, TEA, propylenglycol, methylparaben, and aquadest. The tools used are Brookfield viscometer type LVDV-E, flannel cloth, vessel, rotary evaporator, vacuum, balance (Ohaus Balance), glass jar (Poyrex), micropette, dropper pipette, blue tips, yellow tips, incubator, autoclave, test tube (pyrex), petri dish, porcelain cup, volume pipette, pH stick, blender, object glass, spiderglass, glass cylinder. *B. balsamifera* plant can be seen in Fig.-2 below:



Fig.-2: Capa Plants (*Blumea balsamifera* L.)

Plant Identification

The plants were determined to be members of the genus *Blumea* and the species *Blumea balsamifera* L, as stated in the letter of determination result no. B/647/UN11.18.1/TA/00.01.2020, which was written at the Biology Laboratory of the Faculty of Mathematics and Natural Sciences at Syiah Kuala University in Banda Aceh. This decision was necessary to verify that the plants utilized as research samples were accurate representations of their species.

Preparation of Capa Leaf Extract

Capa leaf extract was obtained from the maceration process using ethyl acetate solvent. The results of previous research on the anti-bacterial activity of capa leaf extract, with a comparison of 3 types of solvents,

namely ethanol, ethyl acetate, and n-hexane, showed that capa leaf extract using ethyl acetate solvent was the strongest. So, this extract is continued to the gel formulation to be used as a topical wound care medicine. The process of making extracts was carried out in previous research by the author.

Preparation Gel with Extract of the Capa Leaf

The process of formulating the capa leaf gel begins with making the gel base. Carbopol 940 was weighed according to the treatment and put into a beaker. Then 70 mL of distilled water was added and the solution was stirred using a magnetic stirrer at 80 °C for 30 minutes. The carbopol base was then crushed in a mortar, TEA was added according to the treatment, and propylenglycol 15 g, then the mixture was stirred evenly. 0.2 g of methylparaben was added and homogenized.¹¹ After the gel base was formed, the capa leaf extract was added according to the treatment variations as in Table-2, and distilled water was added up to 100 mL and stirred until humogen. After that, the gel was stored in a closed container and allowed to stand for 24 hours to see the stability of the gel, and the stability of the gel was evaluated 1 x a week for 4 weeks.^{12,13} The design of variations in the composition of the capa leaf extract gel can be seen in Table-1 and 2.

Table-1. Design Varian Composes Gel Extract Capa Leaves with 3 Factors and 3 Levels

Factor	Parameters	Levels		
		Low (-)	Medium (0)	High (+)
x1	Extract capa Leaves (%)	0.25	0.5	0.75
x2	Carbopol (%)	0.75	1	1.25
x3	TEA (%)	5	10	15

Table-2: Design Variants Compose Gel Extract Capa Leaves 17 Run Box Bankhen

Run	Factor 1 A: Capa leave extract (%)	Factor 2 B: Carbopol (%)	Factor 3 C: TEA (%)
1	5	0,25	1
2	10	0,5	1
3	5	0,5	0,75
4	10	0,5	1
5	10	0,75	0,75
6	15	0,5	0,75
7	10	0,25	1,25
8	10	0,75	1,25
9	15	0,75	1
10	5	0,5	1,25
11	10	0,5	1
12	10	0,25	0,75
13	10	0,5	1
14	10	0,5	1
15	5	0,75	1
16	15	0,25	1
17	15	0,5	1,25

Detection Method

Characterization and Evaluation

The homogeneity test is carried out by applying 0.1 gram of the preparation on a transparent glass plate and then observing its homogeneity. The preparation must show a homogeneous composition, indicated by the absence of coarse grains on the glass object. Testing was done once a week for 4 weeks. While the organoleptic test was carried out, the shape, color, and odor were observed at room temperature. The shape is seen from the preparation that is able to flow in the container, the color is seen from a white paper background accompanied by lamp lighting, while the smell is smelled by waving it over the preparation.^{14,15} The pH measurement was carried out using a digital pH meter (Hanna) at room temperature. Before use, the pH meter electrode was washed and rinsed with running water and then dried. The pH meter was dipped in 1 g of gel that had been diluted with 10 mL of distilled water. After it was completely dipped, the pH meter was turned on and then waited until the number on the pH meter screen showed a stable value. The

gel preparation spreadability test was carried out by weighing 0.5 g of gel preparation and then placing it on a glass plate on graph paper, covering the glass plate with another glass plate and applying a load of 500 g to it, and then looking at the diameter of the gel spread.¹² The viscosity test was conducted using a Brookfield Cone and Plate Viscometer (Engineering Laboratories, Inc., Stoughton, MA, USA) with the appropriate spindle and speed. The gel was put into a glass beaker until it reached a volume of 200 mL, then the spindle was attached to the specified limit. Measurements were taken 3 times to obtain stable values. The process of formulating capa leaf gel begins with making the gel base can be seen in Fig.-3.

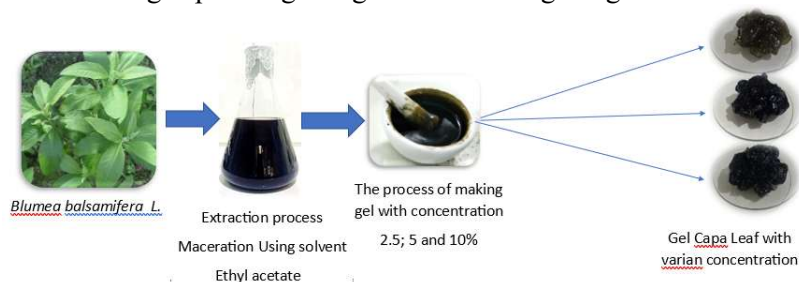


Fig.-3: Preparation of Gel *B. balsamifera* Leaf Extract

RESULTS AND DISCUSSION

The resulting gel with capa extract has a dark green color with a distinctive aroma of capa leaf extract; capa leaf extract gel has good homogeneity. The pH of the resulting capa leaf gel is 6.2-6.6; this value is still included in the range of skin pH values. As for the average viscosity value of 4351 cP and the average spreadability value of 5.7 cm, both values are still included in the standard value of gel preparations, so this formulation meets the gel standards as a topical medicine.¹⁶ The resulting extract is then formulated into a gel preparation so that it is more practical to use as a wound medicine candidate. Gels are known to have advantages such as being cool on the skin, non-sticky, and able to deliver drugs better, so they are considered capable of collaborating with active substances from capa leaves for wound healing. In gel formulation, each extract is varied in concentration; the amount of extract in the gel base will also affect the shape and stability of the gel. The best concentration of active ingredient extracts in the gel increases the ability of the preparation to treat wounds better. The physical characteristics of the capa leaf extract gel, which include pH, viscosity, and spreadability, produced in this study, can be seen in Table-3.

Table-3: Physical Response of Capa Leaf Extract Gel Formulation with 3 Factors and 3 Levels

Run	Factor 1 A: Capa leaf extract (%)	Factor 2 B: Carbopol (%)	Factor 3 C: TEA (%)	Response 1 pH	Response 2 Viscosity (cP)	Response 3 Spreadability (cm)
1	5	0,25	1	6,2	3215	6
2	10	0,5	1	6,5	5623	5,5
3	5	0,5	0,75	6,4	4852	5,5
4	10	0,5	1	6,5	5234	5,6
5	10	0,75	0,75	6,4	4253	5,8
6	15	0,5	0,75	6,6	3211	6,2
7	10	0,25	1,25	6,5	3625	6,1
8	10	0,75	1,25	6,5	4758	5,7
9	15	0,75	1	6,4	3056	6
10	5	0,5	1,25	6,3	4105	5,5
11	10	0,5	1	6,5	5465	5,5
12	10	0,25	0,75	6,4	3278	6,1
13	10	0,5	1	6,5	4235	5,9
14	10	0,5	1	6,4	4628	5,6
15	5	0,75	1	6,3	6452	5,2
16	15	0,25	1	6,5	3102	6,1
17	15	0,5	1,25	6,6	4875	5,6

Table-4: ANOVA Analysis for Quadratic Model of Response pH

Source	Sum of Squares	df	Mean Square	F Value	p-Value Prob > F	Characterization
Model	0.161	9	0.018	6.096	0.0132	significant
A-Extract	0.101	1	0.101	34.573	0.0006	
B-Cabopol	0.000	1	0.000	0.000	1.0000	
C-TEA	1.25×10^{-3}	1	1.25×10^{-3}	0.427	0.5344	
AB	0.010	1	0.010	3.415	0.1071	
AC	2.5×10^{-3}	1	2.5×10^{-3}	0.854	0.3862	
BC	0.000	1	0.000	0.000	1.0000	
A ²	0.012	1	0.012	3.963	0.0868	
B ²	0.025	1	0.025	8.635	0.0217	
C ²	9.5×10^{-3}	1	9.5×10^{-3}	3.244	0.1147	
Residual	0.020	7	2.9×10^{-3}			
Lack of Fit	0.012	3	4.1×10^{-3}	2.083	0.2451	not significant
Pure Error	8.0×10^{-3}	4	2.0×10^{-3}			
Cor Total	0.181	16				

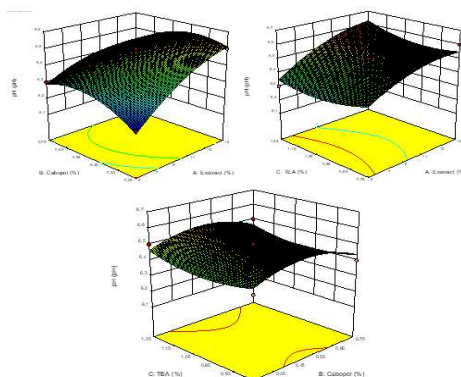


Fig.-4: Relationship between Capa Extract, Carbopol, and TEA with pH Gel

Table 4- shows that the Model F value of 6.10 implies the model is significant. There is only a 1.32% chance that an F value of this magnitude could occur due to interference. “A “” Prob > F“” value of less than 0.0500 indicates the model term is significant.” In this case A, B2 is a significant model. A value greater than 0.1000 indicates the model term is not significant. The Lack of Fit F-value of 2.08 implies the Lack of Fit is not significant relative to the pure error. There is a 24.51% chance that a Lack of Fit F-value of this magnitude could occur due to interference. An insignificant lack of fit is a good value, so this model can be used to run the design space. The 3D relationship between extract, carbopol, TEA, and pH of the capa leaf extract gel as seen in Fig.-4. It can be seen that the capa leaf extract greatly affects the pH value of the resulting gel; the higher the extract used, the higher the pH value will be.

Table-5: ANOVA Analysis for Quadratic Model of Response Viscosity

Source	Sum of Squares	df	Mean Square	F Value	p-Value Prob > F	Characterization
Model	1.4×10^7	9	1.6×10^6	4.56	0.0291	significant
A-Extract	2.4×10^6	1	2.4×10^6	7.02	0.0330	
B-Cabopol	3.5×10^6	1	3.5×10^6	10.27	0.0150	
C-TEA	3.9×10^5	1	3.9×10^5	1.14	0.3202	
AB	2.7×10^6	1	2.7×10^6	7.88	0.0262	
AC	1.5×10^6	1	1.5×10^5	4.25	0.0782	
BC	6.2×10^3	1	6.2×10^3	0.02	0.8963	
A ²	6.7×10^5	1	6.7×10^5	1.96	0.2039	
B ²	2.0×10^6	1	1.5×10^6	5.73	0.0480	
C ²	6.0×10^6	1	6.0×10^5	1.75	0.2274	

Residual	2.4×10^6	7	3.4×10^5			
Lack of Fit	1.0×10^6	3	3.4×10^5	0.99	0.4839	not significant
Pure Error	1.4×10^6	4	3.4×10^5			
Cor Total	1.6×10^7	16				

Table-5 shows the ANOVA analysis results for the quadratic model of the viscosity response. The model's F value of 4.56 implies that the model is significant. There is only a 2.91% chance that an F value of this magnitude could occur due to noise. A Prob > F value of less than 0.0500 indicates that the model term is significant. In this case, A, B, AB, and B2 are significant model terms. A value greater than 0.1000 indicates that the model terms are not significant. The Lack of Fit F value of 0.99 implies that Lack of Fit is insignificant relative to the pure error. There is a 48.39% chance that a Lack of Fit F value of this magnitude could occur due to noise. An insignificant Lack of fit is a good value, so this model can be used to navigate the design space. The 3D relationship between extract, carbopol, TEA, and the viscosity of capa leaf extract gel is shown in Fig.-5. It can be seen that capa leaf extract and carbopol 940 greatly affect the viscosity value of the resulting gel.

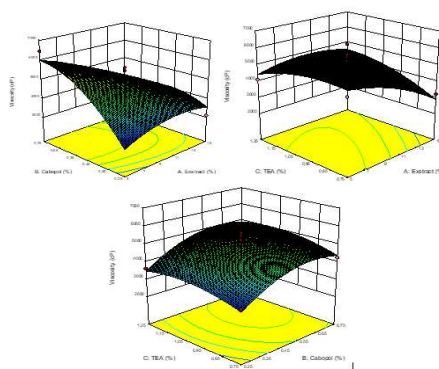


Fig.-5: 3D Relationship Between Extract, Carbopol, and TEA with Viscosity Gel

The Model F value of 6.39 implies the model is significant for the scatter response as seen in Table-6. There is only a 1.15% chance that an F value of this magnitude could occur due to noise. A Prob > F value of less than 0.0500 indicates the model term is significant. In this case, A, B, AB, and B2 are significant model terms. A value greater than 0.1000 indicates the model term is not significant. The Lack of Fit F value of 0.46 implies Lack of Fit is not significant relative to the pure error. There is a 72.35% chance that an F Lack of Fit value of this magnitude could occur due to noise. An insignificant Lack of fit is a good value, so this model can be used to navigate the design space of capa leaf gel spreadability. The 3D relationship between extract, carbopol, TEA, and the spreadability of capa leaf extract gel is shown in Fig.-3. It can be seen that capa leaf extract and carbopol 940 greatly affect the spreadability value of the resulting gel. In addition, the viscosity value also greatly affects the spreadability value. The higher the viscosity value, the lower the spreadability value.

Table-6: ANOVA Analysis for Quadratic Model of Response Spreadability

Source	Sum of Squares	df	Mean Square	F Value	p-Value Prob > F	Characterization
Model	1.20	9	0.13	6.39	0.0115	significant
A-Extract	0.36	1	0.36	17.38	0.0042	
B-Cabopol	0.32	1	0.32	15.40	0.0057	
C-TEA	0.061	1	0.061	2.95	0.1298	
AB	0.12	1	0.12	5.89	0.0456	
AC	0.090	1	0.090	4.33	0.0760	
BC	2.5×10^{-3}	1	2.5×10^{-3}	0.12	0.7389	
A ²	4.2×10^{-4}	1	4.2×10^{-4}	0.020	0.8908	
B ²	0.19	1	0.19	9.36	0.0183	
C ²	0.034	1	0.034	1.64	0.2410	
Residual	0.15	7	0.021			

Lack of Fit	0.038	3	0.013	0.46	0.7235	not significant
Pure Error	0.11	4	0.027			
Cor Total	1.34	16				

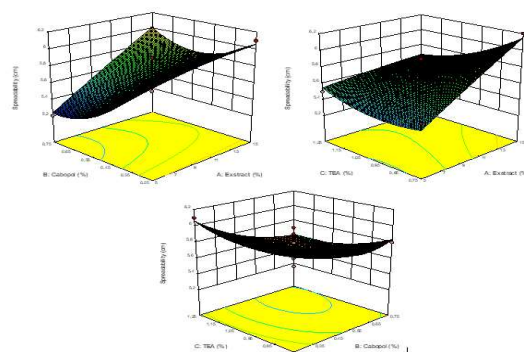


Fig.-6: 3D Relationship between Extract, Carbopol, TEA, and Spreadability of Capa Leaf Extract Gel

Physical Stability of Capa Leaf Extract Gel

The pH test results of the capa leaf extract gel (*Blumea Balsamifera* L.) in weeks 1-4 were in the range of 6.2 - 6.6, which means that all preparations have the same pH as the pH of human skin, as shown in Table-7 and Fig.-7. The characterization of a good gel is that it has the same pH as the pH of the skin, which is in the range of 4.5-6.5. If the gel has an acidic pH, it will irritate the skin, but if the gel has an alkaline pH, it will cause dry skin.⁸ The viscosity of the gel was measured using a Brookfield Cone and Plate Viscometer (Engineering Laboratories INC, Stoughton MA, USA), the results of the viscosity test of the capa leaf extract gel after 4 weeks in an average of 4323 cP Table-7 and Fig.-8 and an average spreadability value of 5.8 cm cP Table-7 and Fig.-9, meaning that it is still by the standard. The gel formulation of capa leaf extract shows that the gel has met the standards of topical medicinal gels.

pH Stability of Capa Leaf Extract Gel

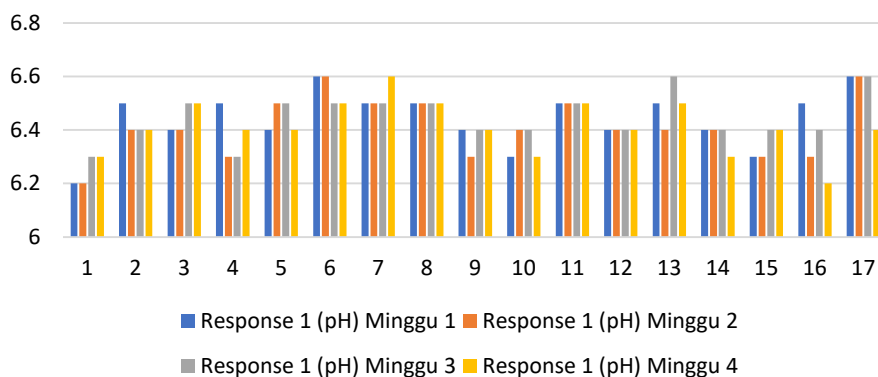


Fig.-7: pH Stability Graph of Capa Leaf Extract Gel Storage for 4 Weeks

This is known from the results of the organoleptic test, homogeneity test, viscosity test, pH test, and spreadability test of capa leaf extract gel, which showed values within the limits of good standards.¹⁷ In making this gel, carbopol formulated together with humectants such as propylene glycol and glycerin can produce good stability with the right ratio. Propylenglycol humectants can relate to water to form hydrogen bonds, so that they can absorb water; therefore, the use of these two humectants should not be too large so that carbopol can still relate to water and can maintain gel consistency.¹⁸ Propylenglycol is recommended not to exceed 30% of the total ingredients formulated into the gel.^{19,20} The use of humectants that are too high will cause the water in the preparation to interact completely with propylenglycol and form hydrogen bonds, even the skin moisture when applied can lose its moisture and can be dehydrated. However, if the concentration of propylene glycol is too small, there is a concern that the water content in the preparation

cannot be maintained.^{13,21} Other ingredients used include methyl paraben as a preservative, TEA as a flavoring agent that helps form gel properties, and distilled water.⁸ Based on the results of the research formulation that the researchers conducted and the three previous research results above, the optimum area of use of propylenglycol is in the range of 5 to 30%. In this study, researchers used 15% propylenglycol with other ingredients as a base, including Carbopol 940, TEA, methyl paraben, distilled water, and capa leaf extract (*Blumea Balsamifera* L). Homogeneity testing shows that the gel preparation is homogeneous, and there are bubbles. In this study, the carbopol used was 2%. This research is in line with Amoo's research (2022) that a 2% carbopol concentration has bubbles.²² Researchers assume these bubbles are also influenced by the saponin content contained in the active ingredients of capa leaves (*Blumea Balsamifera* L).

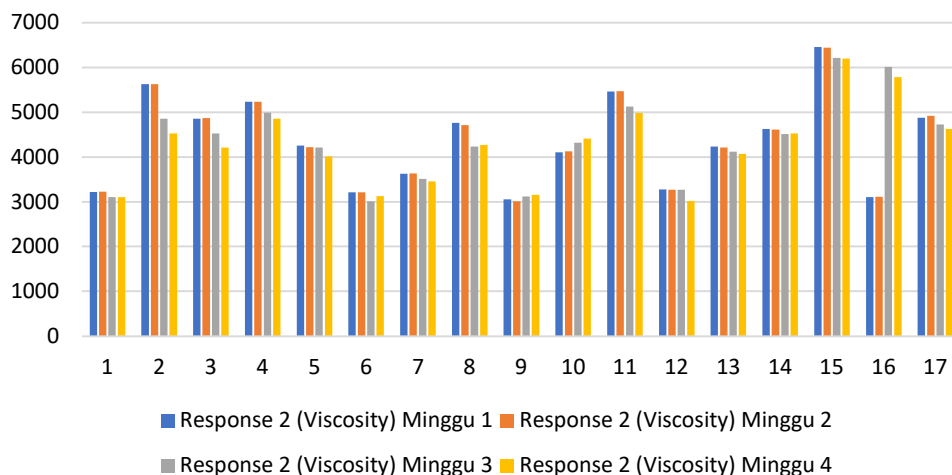


Fig.-8: Viscosity Stability Graph of Capa Leaf Extract Gel Storage for 4 Weeks

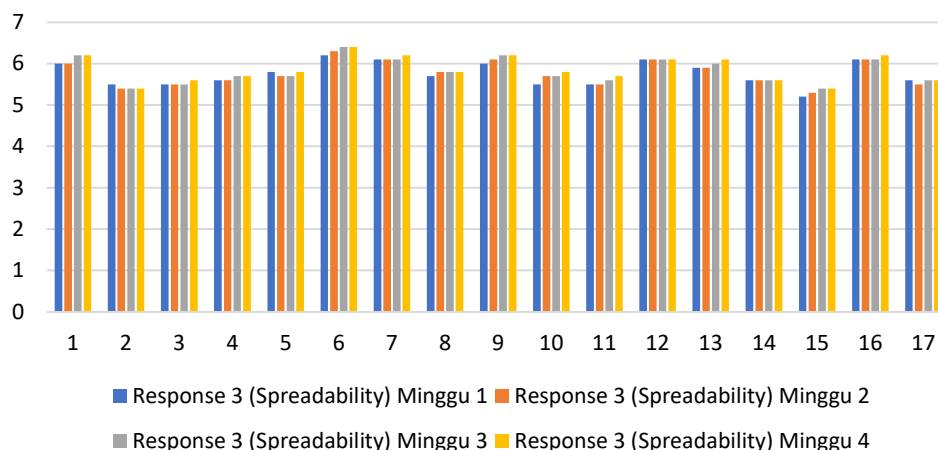


Fig.-9: Graph of Dispersibility Stability of Capa Leaf Extract Gel Storage for 4 Weeks

CONCLUSION

Based on the results of the study, it can be concluded that the results of the test conducted for 4 weeks on the stability of pH, spreadability and viscosity of capa leaf extract gel (*Blumea Balsamifera* L) with the formula in this study meet the standards of typical medicinal gels and have the potential to be used as wound medicine.

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CONFLICT OF INTERESTS

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTIONS

The present work is related to *SDG-3: Good Health and Well-being*. All the authors contributed significantly to this manuscript, participated in reviewing/editing and approved the final draft for publication. The research profile of the authors can be verified from their ORCID ids, given below:

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