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OPTIMIZATION TYPE OF STIFFENING AGENT IN FORMULATION CREAM *Melastoma malabathricum* L. LEAF WATER FRACTION

Raden Hasya Nadhira[1], Desy Siska Anastasia[1*], Pratiwi Apridamayanti[1], Meri Ropiqa[1]
[1]*Faculty of Medicine, Tanjungpura University, Indonesia*
**Email Corresponding: desysiska@pharm.untan.ac.id*

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ABSTRACT

The skin is one of the visible outer parts of the body, and cosmetics are used for its care. Senggani (*Melastoma malabathricum*) leaves contain flavonoids, saponins, alkaloids, tannins, and polyphenols. The polyphenol content found in M. malabathricum leaves has high antioxidant activity and has the potential to be used as a sunscreen that can block the negative effects of UVA and UVB rays. These secondary metabolites can be obtained from the water fraction and used as antioxidants in cream preparations. Cream formulations require compounds that can maintain the consistency of the preparation to produce good physical properties and stability. This study aimed to analyze the type of stiffening agent in the formulation of cream preparation of aqueous fraction of senggani leaf (*Melastoma malabathricum* L.) using organoleptical tests, homogeneity, pH, spreadability, adhesiveness, and viscosity of cream preparation. The results showed that cetyl alcohol (FII) has different physical properties, and the evaluation and accelerated stability test (cycling test) resulted in the most physically stable preparation, as evidenced by the sig. (p value) > 0.05, indicating that storage did not affect the cream preparation.

Keywords: senggani leaf (*Melastoma malabathricum* L.), water fraction, cream, cycling test

INTRODUCTION

Antioxidants are compounds that can inhibit reactive oxygen species (ROS), reactive nitrogen species (RNS), and free radicals, thereby preventing diseases associated with free radicals, such as carcinogenesis and aging (Halliwell & Gutteridge, 2000). The skin, as one of the visible outer parts of the body, uses cosmetics in its care, so it needs the first bastion of defense from external threats, including viruses, bacteria, and exposure to other free radicals such as ultraviolet radiation (UVR) (Riandari, 2017). Senggani leaves (*Melastoma malabathricum*) can be utilized as a source of antioxidants and contain polyphenolic compounds (Laia et al., 2019). Senggani leaves also contain flavonoid compounds that function as anti-inflammatory and antioxidants with an IC50 value of 21.86 ± 0.625 µg/mL (Anggraini & Lewandowsky, 2015).

In this study, a vanishing cream base (O/W) was used, which has a non-greasy appearance, fast skin absorption, and better organoleptic properties than the W/O type (Robatjazi et al., 2022). Vanishing cream is an oil-in-water cream base, usually containing wetting agents such as triethanolamine, as well as potassium, ammonium, and sodium hydroxides mixed with free stearic acid to form an emulsion. The choice of a stiffening agent in cream is also a factor that affects the physical characteristics and stability of the preparation (Cahyati et al., 2015). Cera alba affects the consistency of the preparation. The higher the concentration of cera alba, the denser the consistency of the preparation (Ambari et al., 2020). Cetyl alcohol has the ability to increase the viscosity and stability of O/W creams. Candelilla wax has a higher melting point, making it more stable and suitable for cosmetic products (Kadu et al., 2014).

Therefore, this study aimed to formulate an antioxidant cream preparation with the active ingredient of the water fraction of senggani leaves, which is efficacious as an antioxidant. A water-soluble cream base is needed to make the cream more comfortable to apply without reducing the antioxidant content contained in the cream.

RESEARCH METHODS

Equipment and Materials

The tools used in this research are mortar, stamper, analytical balance (OHAUS), test tube (IWAKI), test tube rack, volumetric flask (IWAKI), oven, glass stirrer, spatula, measuring cup (IWAKI), beaker (PYREX), cuvette, waterbath, viscosmeter (BROOKFIELD METEK), pH meter F-71 (HORIBA), micropipette (Thermo Scientific). The materials used in the study of the water fraction of senggani leaves and stearic acid (PT. Kimia Jaya Abadi), cera alba (PT. Kimia Jaya Abadi), cetyl alcohol (PT. Kimia Jaya Abadi), candelilla wax (CV. Subur Kimia Jaya), triethanolamine (TEA) (Petronas Chemicals Group), propylenglycol (PT. Kimia Jaya Abadi), distilled water.

Research Procedure

1. Preparation of Senggani Leaf Water Fraction

   The simplicia leaves were extracted using 78% ethanol by the maceration method. The mixture was filtered and rotated to obtain the crude extract. The crude extract was separated using a separatory funnel with solvents of different polarities (Nur et al., 2017). In this study, the fractionation results were obtained using a polar solvent, namely, water. The dry fraction was then stored at room temperature (Apridamayanti et al., 2022).

2. Preparation of Cream Senggani Leaf Water Fraction

   Three formulas were prepared using stiffening agents, including cera alba, cetyl alcohol, and candelilla wax. The cream base was prepared by melting the oil phase, namely the stiffening agent, stearic acid, and vaselin album, using a water bath at 70°C. The water phase, namely TEA, propylenglycol, and aquadest, was heated using a waterbath at 70°C. The oil phase was placed in a hot mortar, and the water phase was added and crushed. The added water fraction was dissolved in distilled water after the base was formed.

3. Evaluation of Cream

   a. Organoleptical

      Organoleptic observations were made by observing the color, odor, and presence of phase separation in the cream. Organoleptic observations were performed immediately after manufacture (Dina et al., 2017).

   b. Homogenity

      Homogeneity test is carried out by applying the cream that has been made on a glass object, then clenched with another glass object and then seeing whether the base applied to the glass object is homogeneous and whether the surface is smooth and evenly distributed (Saryanti et al., 2019).

   c. pH

      The pH of the cream was measured using a pH meter. pH testing is performed on freshly made creams and creams that have been stored (Saryanti et al., 2019). A good and non-irritating preparation will have a pH in accordance with the normal skin pH range (Anggraini & Lewandowsky, 2015).

   d. Viscosity

      Viscosity testing was performed by inserting the cream preparation that has been made into the viscotester and then reading the viscosity according to the rotor used (Saryanti et al., 2019).

   e. Spreadability

      The spreadability test was carried out by placing 0.5 grams of cream on a glass that had been coated with graph paper, then placing a glass on it and leaving it for 1 minute, and calculating the area given by the preparation. Furthermore, a load was

successively applied to each preparation of 50, 100, and 250 grams for 60 seconds and the resulting preparation area was calculated (Utari et al., 2018).

f. Adhesion

A cream preparation of 0.5 g was placed on an object glass, and another object glass was placed on it and pressed with a load weighing 500 g for 5 minutes. Next, the glass slide was mounted on the test device. The 80 g load on the test device was released, and the time was recorded until the two object glasses were released (Dewantari & Sugihartini, 2016; Saryanti et al., 2019).

g. Cycling Test

The cream was weighed ± 2 grams, placed into several vials and stored at ±4°C for 24 hours and then ±40°C for 24 hours. Testing was carried out for 6 cycles, where each cycle observed physical changes in the cream including organoleptic, homogeneity, pH, spreadability, adhesiveness, and viscosity (Hamsinah et al., 2016; Suryani et al., 2017).

Data Analysis

The results of the study were processed and presented in the form of tables and analyzed using IBM SPSS Statistics 26.

RESULTS AND DISCUSSION

1. Extractions

The extracts were prepared by the maceration method using ethanol, covered, left for several days, protected from light, and repeatedly stirred. This method was chosen because the sample used was in the form of leaves. In addition, the advantage of this method is that it can use a large number of samples, the implementation is simple, does not require special treatment, and the possibility of decomposition of active substances by temperature effects can be avoided because there is no heating process (Misfadhila et al., 2020). Ethanol is a universal solvent because it is easy to dissolve active substance compounds that are polar, semi-polar, and non-polar, and it is non-toxic, so it is safe to use. The macerate was then filtered to obtain a crude extract. The thick extract was separated by liquid-liquid extraction using a separating funnel with solvents of different polarities, namely n-hexane, chloroform, ethanol, and water fractions (Nur et al., 2017). The water fraction of senggani (*Melastoma malabathricum* L.) leaves was 59.29% (w/w) (Apridamayanti et al., 2022).

2. Cream Preparation

Table I. Formulation of cream using *Melastoma malabathricum* L. leaf water fraction (Budiman et al., 2019)

Component	Concentration (%)		
	I	II	III
Senggani Leaf Water Fraction	1,2	1,2	1,2
Cera Alba	2		
Cetyl Alcohol		2	
Candelilla Wax			2
Stearic Acid	12	12	12
TEA	0,5	0,5	0,5
Vaselin Album	10	10	10
Propylenglycol	15	15	15
Aquadest	Add. 100	Add.100	Add.100

Note:
F I : Cera alba
F II : Cetyl alcohol
F III : Candelilla wax

The process of making a cream preparation of the water fraction of senggani leaves begins with weighing all the ingredients that will be used. The oil phase was prepared by

melting the stiffening agent (cera alba, cetyl alcohol, and candelilla wax), stearic acid, and vaseline album at 70°C in a water bath while stirring until homogeneous. The aqueous phase (propylene glycol, TEA, and distilled water) was prepared by melting at 70°C in a water bath while stirring until homogeneous. The mixing of the oil and aqueous phases was carried out under hot conditions at 70 °C to facilitate the formation of emulsions. Emulsions are easily formed under hot conditions because of the energy that helps disperse one phase into another (Naya & Mardiyanti, 2021). A mixing temperature of 70°C with a stirring time of 10 minutes produces a cream preparation that does not separate (Baskara et al., 2020).

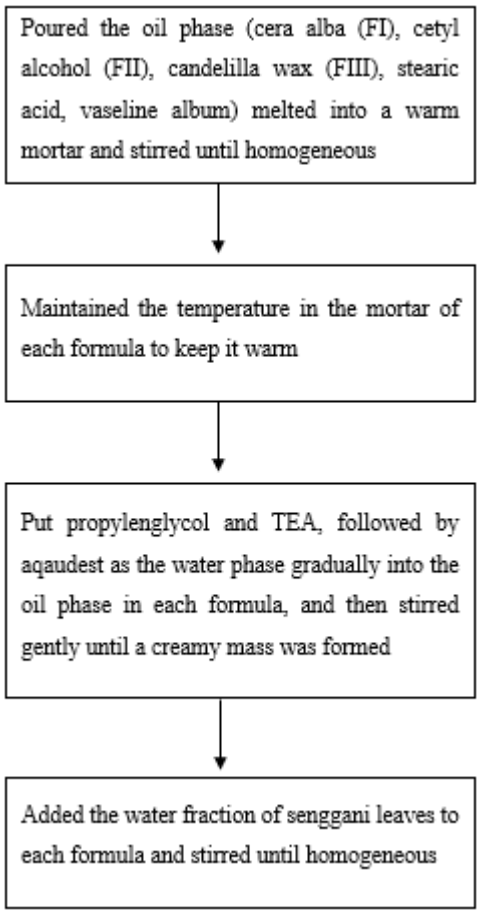

Figure 1. Procedure for Making Senggani Leaf Water Fraction Cream

The melted oil phase was poured into the warm mortar and stirred until homogeneous. During the creaming process, the mortar needs to be kept warm, and because it uses oil-soluble ingredients, it must be stirred continuously. These oil-soluble ingredients easily harden into wax (Kumalasari et al., 2020). The water phase was added gradually to the oil phase while stirring gently until a creamy mass was formed. The water fraction of the senggani leaves was then added and stirred until homogeneous. The length of stirring is also one of the important factors in the process of making cream preparations because stirring in the process of making cream preparations can affect the particles that are getting smaller so that a good cream preparation is obtained. Optimum mixing produces good physical properties and physical stability in cream preparations. Stirring for too long cannot guarantee the ideal homogeneity expected in cream preparations. The cream preparation was then placed in a container and evaluated.

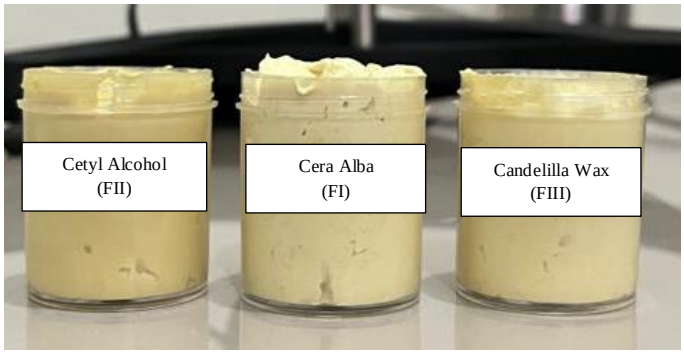

Figure 2. Cream Melastoma malabathricum L. Leaf Water Fraction

3. Evaluation of Cream

Table II. Evaluation of cream using Melastoma malabathricum L. leaf water fraction

Evaluation	Formula			Parameters
	FI (Cera Alba 2%)	FII (Setil Alkohol 2%)	FIII (Candelilla wax 2%)	
Organoleptic	Pale yellow color, typical waxy aroma, semisolid	Intense yellow color, typical waxy aroma, semisolid	Yellow color, typical waxy aroma, semisolid	Typical active substance, semisolid
Homogenity	Homogenous	Homogenous	Homogenous	Homogenous
pH	6.62 ± 0.16	5.10 ± 0.39	6.43 ± 0.04	4.5 – 6.5
Viscosity (cP)	6173.3 ± 647.9	7933.3 ± 1671.6	9013.3 ± 1220.1	2000 – 50000
Spreadibility (cm)	4.2 ± 0.21	4.7 ± 0	4.3 ± 0.1	4 – 7
Adhesion (sec)	2.95 ± 0,56	10.39 ± 0.82	12.5 ± 0.88	>1

a. Organoleptical

Organoleptical testing is a qualitative parameter that aims to observe the color, smell, and texture of the cream preparation, which affects user comfort (Purwaningsih et al., 2020). The aroma obtained from the cream preparation was the distinctive aroma of Vaseline. The shape obtained from the cream preparation was semi-solid. The resulting cream preparation was neither too liquid nor too solid. This is due to the balanced amounts of water and oil phases in each formula. The color obtained in the cream preparation of each formula produced a different preparation color. Preparations with an acidic pH affect the dominant color produced from the water fraction of senggani leaves to be less dominant (Rahayu et al., 2023). Cetyl alcohol has a pH that tends to be acidic, namely 6-6.5 so that the resulting color becomes concentrated.

b. Homogenity

Homogeneity testing is a qualitative research method used to determine the homogeneity of each formula. Homogeneous cream preparations indicate that the active ingredient content in the formula is evenly distributed in the cream base, so that each application of the cream already contains the same or evenly distributed active ingredient components (Purwaningsih et al., 2020).

c. pH

The pH test was carried out to determine the pH of the preparation and evaluate the safety of the cream preparation so that it does not irritate the skin. This test was performed because the cream preparation was applied topically, and the pH of the preparation must match that of the skin. If the pH of the preparation is too acidic, it will

cause irritation to the skin, and if the pH of the preparation is too alkaline, it can cause scaly skin (Pertiwi et al., 2020).

The results obtained show that the pH of the entire formula met the pH requirements of the skin. The average pH values of all formulations ranged from 5 to 6.6. This test was performed three times for each formula to ensure the validity of the results. The addition of stearic acid to the topical preparation formula is used as an emulgator, namely an emulsion stabilizer; however, in addition to functioning as an emulsion stabilizer, stearic acid is also used as a pH stabilizer of cream preparations (Lestari et al., 2023).The data obtained was continued with testing using the SPSS application analyzed statistically on the normality test. The results showed that the cream preparations were normally distributed because the sig value. (p value) > 0.05, namely 0.306 (FI), 0.917 (FII), and 0.881 (FIII), so it can be continued with the homogeneity test. Homogeneity test obtained sig value. (p value) Based on Mean > 0.05, namely 0.148 which concludes that the data variance is homogeneous, in other words the homogeneity test is fulfilled. This means that the cream preparation has the same pH value during the test.

d. Viscosity

Viscosity testing is one of the test requirements for cream preparations. If the preparation has a high viscosity value, the thicker the preparation. The requirements for cream viscosity values are 2,000 - 50,000 cP (Mektildis, 2018). Viscosity is a resistance of a liquid to flow, the higher the viscosity, the greater the resistance to flow. To determine the viscosity of the cream, a Brookfield viscometer was used. This test is useful, among others, to determine the flow properties of a liquid, distribution and attachment to the skin, removal from the tube, the ability of solids to mix with liquids that are mixed with each other and release from the base. The viscosity test measurement results of the three preparations entered the specified requirements. In the viscosity test, FI has the lowest test value and FII has the highest test value. The longer the storage time, the thinner the cream preparation will be because the base used cannot retain the water that penetrates into the base (Aqsyal & Mardiyanti, 2023).

This can be caused because storage time will affect the stability of the preparation. The longer the storage time will cause insoluble particles to form agglomerates and cause the particle contact area to decrease (Oktaviasari & Zulkarnain, 2017). The data obtained was continued with testing using the SPSS application analyzed statistically on the normality test. The results showed that the cream preparations were normally distributed because the sig value. (p value) > 0.05, namely 0.118 (FI), 0.775 (FII), and 0.982 (FIII), so it can be continued with the homogeneity test. Homogeneity test obtained sig value. (p value) Based on Mean > 0.05, namely 0.470 which concludes that the data variance is homogeneous, in other words the homogeneity test is fulfilled. This means that the cream preparation has the same viscosity during the test.

e. Spreadibility

Spreadability testing is carried out to determine the ability of the cream to spread inside the skin when the cream is used. The expected cream preparation is to have a large level of spreadability so that it can be used on the skin without requiring emphasis on the skin. Good cream spreadability has a diameter in the range of 4 - 7 cm (Eliska et al., 2016). Cream spreadability testing is an important requirement for cream preparations. If the spreadability of the cream is greater, the active substance spreads evenly and is more effective in producing its therapeutic effect. Good spreadability results in extensive contact between the active substance and the skin, so that absorption of the active substance into the skin takes place quickly. In the results of the spreadability test, the average cream preparation of the water fraction of senggani leaves was 4.2 to 4.7 cm.

The data obtained was continued with testing using the SPSS application analyzed statistically on the normality test. The results showed that the cream preparations were normally distributed because the sig value. (p value) > 0.05, namely 0.468 (FI), 0.593

(FII), and 0.608 (FII), so it can be continued with the homogeneity test. Homogeneity test obtained sig value. (p value) Based on Mean > 0.05, namely 0.151 which concludes that the data variance is homogeneous, in other words the homogeneity test is fulfilled. This means that the cream preparation has the same spreadability during test.

f. Adhesion

The ability of adhesion is a factor that affects the therapeutic effect. The longer the ability of the cream preparation to adhere to the skin, the longer the therapeutic effect is given. The value of the adhesion of a preparation is directly proportional to the viscosity value of a preparation. The greater the viscosity value of the preparation, the longer the ability of the preparation to adhere to the skin. The increasing level of contact time of the preparation will be beneficial when the preparation is applied to the skin. The level of contact time of the preparation is a factor that affects the absorption of drugs through the skin. The longer the contact time of the drug on the skin, the concentration of the drug absorbed by the skin will increase (Swastini et al., 2015). A good adhesion test value for creams is 2-300 seconds (Safitri et al., 2014).

The data obtained was continued with testing using the SPSS application analyzed statistically on the normality test. The results showed that the cream preparation was normally distributed because the sig. (p value) > 0.05, so it can be continued with the homogeneity test. Homogeneity test testing obtained sig value. (p value) Based on Mean <0.05, which is 0.047 which concludes that the data variance is not homogeneous, in other words the homogeneity test is not fulfilled. The test was continued with a non-parametric test using Kruskal Wallis with the results obtained <0.05 so that there was a significant difference in the adhesion test.

High molecules cause an increase in the consistency of the preparation and stick together. Cetyl alcohol has the highest molecular weight of 242.22. If the molecular weight is high, the distance between molecules is smaller, if the distance between molecules is smaller, there will be an attractive force between molecules called van der wals force. As a result of these forces, fatty acids in fat molecules will align with each other and overlap to form crystals (Winarno, 1984). The more crystals formed in the preparation cause the preparation to become harder so that the adhesion lasts longer (Amalia, 2020).

4. Cycling Test

Table III. Cycling Test Results of Cream

Evaluation	Formula					
	FI		FII		FIII	
	Before	After	Before	After	Before	After
Organoleptic	Pale yellow color, typical waxy aroma, semisolid	Changed	Intense yellow color, typical waxy aroma, semisolid	Not Changed	Yellow color, typical waxy aroma, semisolid	Not Changed
Homogenity	Homogeneous	Cracking	Homogeneous	Homogeneous	Homogeneous	Homogeneous
pH	6,62 ± 0,16	6,24 ± 0,33	5,10 ± 0,39	5,60 ± 0,47	6,43 ± 0,04	5,63 ± 0,13
Adhesion (second)	2,95 ± 0,56	1,15 ± 0,12	10,39 ± 0,82	8,42 ± 0,26	12,5 ± 0,88	3,74 ± 0,61
Spreadilibility (cm)	4,2 ± 0,21	4,5 ± 0,06	4,7 ± 0	4,5 ± 0,06	4,3 ± 0,1	4,4 ± 0,06
Viscosity Brookfield (Cps)	6173,3 ± 647,9	1946 ± 1298,8	7933,3 ± 1671,6	8760 ± 312,4	9013,3 ± 1220,1	6720 ± 341,8

Organoleptical examination of the three creams did not have significant color differences because the concentration of the water fraction of senggani leaves had the same concentration of 1.2%. The three cream preparations have the same aroma, namely the typical aroma of wax, namely from vaselin album. Creams that meet organoleptical requirements have a color like the active substance, a distinctive aroma, and an appearance like a creamy mass. The results of the dosage form test show that the formula can form a cream mass and can be applied to the skin. Visibly, the three preparations have a good cream dosage form. The observation results showed that there were no visible changes that occurred in the cream preparation from the beginning of manufacture to cycle 6 of stability testing.

The observation results showed that one of the preparations was not homogeneous, marked by the presence of clumps or large particles and cracking or phase separation between the water phase and the oil phase from cycle 2 to cycle 6, the separation was marked by the formation of white granules. This is because the level of cera alba in FI added is still small so that the cera alba in the formula is less able to reduce the surface tension between water and oil. An unstable emulsion system can result in coalescence. Unstable emulsions can also experience biological instability, such as contamination and microbial growth (Suena et al., 2022). Phase separation occurred in FI cycle 2 and III cycle 4 in the freeze thaw stability test characterized by the separation between the oil phase and the water phase which is the main basis for making cream. This can be seen by the presence of oil that appears on the surface of the top of the cream which is dark brown in color. This may be due to extreme temperature changes from hot to cold which causes cera alba and candelilla wax as an oil base to be more non-polar compared to stearic acid which is unstable so that the cream preparation becomes broken.

The pH measurement results in each preparation show differences. Variations in stiffening agents can affect the pH of the preparation, but all preparations have pH values that fall within the pH requirements of human skin. The pH value of the cream preparation can meet the requirements due to the use of stearic acid combined with triethanolamine. Triethanolamine can affect the increase in pH of the preparation because triethanolamine is alkaline, which has a pH of 10.5 (Saryanti et al., 2019). During the cycling test process (cycle 1 - cycle 6), the pH value decreased and increased due to the influence of temperature (Opod et al., 2024), but these results still meet the pH standards for topical preparations. A good topical preparation is in accordance with the natural pH of the skin, which is 4.5 to 6.5 because cosmetic preparations must be close to the physiological pH of the skin or equal to that pH. The data obtained were then analyzed using SPSS. The pH value test data were statistically analyzed in the normality test, showing that the cream preparation was normally distributed, with a significance value of 0.057 to 0.784 (>0.05). In the homogeneity test, a significance value of 0.247 (>0.05) was obtained, which means that there is an equal variance between groups (homogeneous), so it can be said that there is no difference in the pH value of the cream during the test. This means that the cream preparation has the same pH value during stability testing.

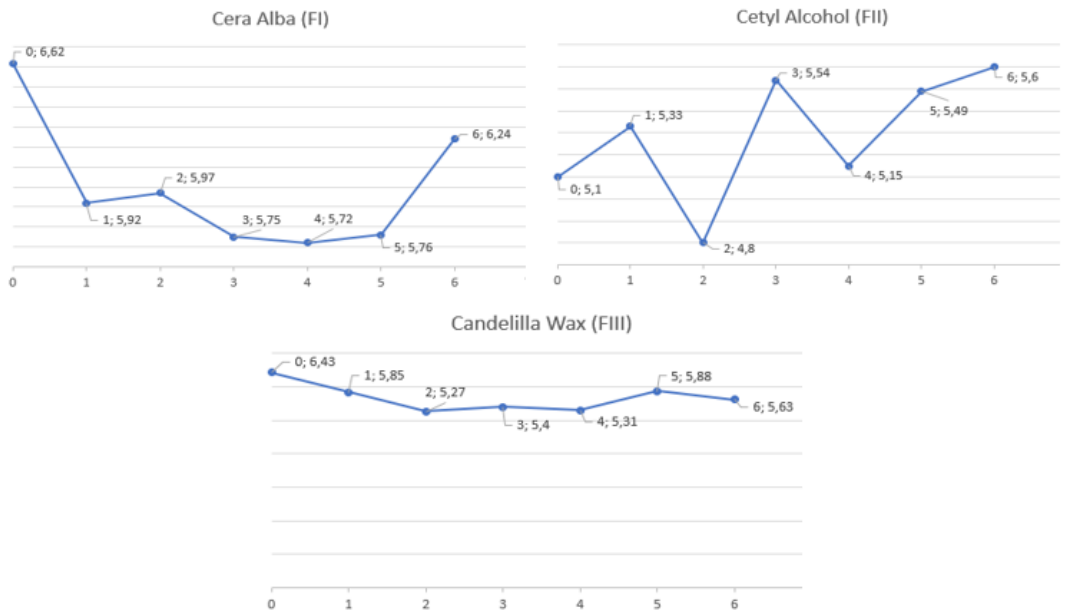

Figure 3. Graph of pH during the Cycling Test

In this study there was a decrease and increase in viscosity which could be caused by several things including emulsion mixing or stirring factors, thickening agent concentration, and extreme temperature changes during the cycling test (Erwiyani et al., 2018). These results were analyzed statistically in the normality test using SPSS, which showed that the viscosity of the cream preparation did not have a significant difference p>0.05, indicating that there was no significant difference, which means that storage time has no effect on the viscosity of the cream. Testing continued with the homogeneity test obtained a significance value of 0.277 (>0.05) which means there is an equal variance between groups (homogeneous). This means that the cream preparation has the same viscosity during stability testing. The decrease that occurs can be caused by the joining of insoluble particles to form agglomerates and cause the particle contact area to decrease (Oktaviasari & Zulkarnain, 2017).

The test results show that the spreadability of the cream after testing has increased slightly. The increase occurred due to the influence of the storage place with a high enough temperature to make the consistency of the cream remain soft and its spreading ability remains during storage, besides that it can be caused by cream formulations that contain water (Naya & Mardiyanti, 2021), the more liquid the cream preparation is, the wider the diameter of the spread of the cream preparation will be because the spreadability is inversely proportional to the viscosity of the cream so that the high spread value, the viscosity value will be low (Erwiyani et al., 2018). These results are continued with statistical analysis in the normality test using SPSS showing that the spreadability of the cream preparation has a significant difference p <0.05 indicating a significant difference which means that storage time affects the spreadability of the cream. The longer the storage time of the cream preparation, the greater the spreadability results will be due to the fact that the cream preparation will become thinner because the base used cannot retain water that penetrates into the base (Rahayu et al., 2023).

The value of the cream adhesion test has a relationship with the spreadability of the cream, where the smaller the spreadability of the cream, the longer the time for the cream to adhere and vice versa the greater the spreadability of the cream, the faster the time for the cream to adhere, due to the consistency of the concentrated cream. Adhesion test results that do not meet the specified requirements can affect the release of active substances when applied to the skin. The longer it stays on the skin, the more active substances are absorbed and the longer the therapeutic effect lasts (Somba et al., 2019). Based on the value obtained, formula I experienced a decrease so that it did not enter the adhesion range, which is 2.00 - 300.00 seconds (Roosevelt et al., 2019). These results are continued with statistical analysis in the

normality test using SPSS, which shows that the spreadability of the cream preparation has a significant difference p>0.05, indicating that there is no significant difference, which means that storage time does not affect the adhesiveness of the cream. The test continued with the homogeneity test obtained a significance value of 0.998 (>0.05) which means there is an equal variance between groups (homogeneous). This means that the cream preparation has the same adhesion during stability testing.

CONCLUSION

Different stiffening agents showed different physical properties, and evaluation and cycling test. Cetyl alcohol 2% (FII) resulted in the most physically stable preparation compared with cera alba 2% (FI) and candelilla wax 2% (FIII).

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