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**Research Article** 

### Formulation and Clinical Evaluation of Anti-Aging Activity of Blemish Balm Cream Vitamin E and Determination of SPF Value with Spectrophotometry

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#### ABSTRACT

Objective: to formulate face powder and foundation cream preparations into Blemish Balm Cream preparations with the addition of vitamin E, avobenzone and octyl methoxoxycinamic acid and to determine the effect of vitamin E on anti-aging activity and SPF values.

Design: Blemish Balm Cream formulated from face powder and foundation cream in a ratio of 1: 2 and the addition of vitamin E in various concentrations, F0 (blank), F1 (1%); F2 (3%), and F3 (5%) and Avobenzone 3% sunscreen and 7.5% Octvlmethoxycinamic.

Interventions: the intervened variable was the concentration of vitamin E used.

Main outcome measures: the main measurement in this study were organoleptic test (shape, color and odor), homogeneity, pH, type of emulsion, viscosity, cycling test, spreadability, storage stability at room temperature, low temperature and high temperature for 12 weeks, irritation test, anti-activity aging with skin analysis and determination of SPF values by UV-Vis spectrophotometry.

Results: The Formulated Blemish Balm Cream was homogeneous, yellowish brown, has an emulsion type m / a, stable in room temperature storage (20-25 ° C), unstable in low temperature (4 ± 2 ° C), and high temperature (40 ± 2 ° C), had a pH of 6.0-7.9, produces a viscosity value that meets the requirements, was stable in the cycling test and did not irritate the skin. The results of anti-aging activity on F3 (5%) had a better effect than F0 (blank), F1 (1%) and F2 (3%) which characterized by increased skin moisture, pore reduction, reduction in the number of blemishes and reduction in wrinkles and produced higher SPF value.

Conclusion: Vitamin E (5%) and avobenzone 3% sunscreen and 7.5% octylmethoxycinamic could formulated into Blemish Balm Cream preparations used face powder and foundation formulas (1: 2) and provided good anti-aging activity effects, did not irritate the skin and could increased the value of the Sun Protecting Factor to 22.21

Keywords: Formulation, Vitamin E, Blemish Balm Cream, Anti-aging, Sun Protecting Factor, Clinical test

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#### **INTRODUCTION**

ndonesia is a tropical country with sun exposure throughout the season. Exposure to UV light can accelerate the process of photoaging that causes changes in the skin such as skin redness, formation of wrinkles on the skin, premature aging, increased inflammatory mediators, decreased skin elasticity and decreased collagen synthesis<sup>1</sup>.

One of the cosmetic facial preparations that can be used as an alternative to avoid skin from sun exposure is Blemish Balm Cream. Blemish Balm Cream is a mild form of facial

cosmetics consisting of the formula Face Powder and Foundation Cream in the form of a cream that has the advantage of being able to protect facial skin from the sun, slowing the aging process, moisturizing facial skin and blemishes<sup>2</sup>.

Blemish Balm Cream (BB Cream) includes multifunctional facial cosmetics that can be used as decorative cosmetics and cosmetic treatments that are lighter and more practical, so they will not feel heavy on the face when worn. In addition, Blemish Balm Cream is suitable for all skin types, both oily and dry skin, can be

used according to the needs of facial skin, and can be used in adolescents, adults and the elderly, so Blemish Balm Cream is considered a complete and efficient facial cosmetic product<sup>2</sup>.

Sunscreen products generally contain many vitamins and antioxidants that are beneficial to the skin because it is safer applied to the skin. One of them is Vitamin E, Vitamin E is an antioxidant that can fight free radicals so that it can slow the aging process, nourish the skin, smooth the skin, brighten hyperpigmentation, stimulate collagen synthesis, anti-inflammatory, as a photoprotective agent and reduce the condition of dry skin so that it can help increase activity cosmetic preparations. The concentration of vitamin E that is commonly used in topical preparations is  $1-5\%^{-3}$ .

The ability of sunscreen to protect the skin and prevent sun exposure is seen from the value of the SPF (Sun Protection Factor). The higher the SPF value of a sunscreen cosmetics, the faster the protection of the skin. This SPF value ranges from 0 to 100 and the ability of sunscreens that are considered good with SPF values above 15<sup>4</sup>. To optimize exposure to sunscreen the addition of a combination of chemical sunscreen and physical sunscreen is added so as to increase the protective activity against UV radiation <sup>5</sup>.

Avobenzone is a UVA antidote and Octyl Methoxycinnamate is a UVB antidote, so in this study the selected sunscreen ingredients are Avobenzone 3% and Octyl Methoxycinnamate 7.5%. Common Avobenzone concentration is 3% and Octyl Methoxycinnamate concentration is 7.5% <sup>6</sup>. The combination of these two ingredients can increase the stability of the preparation and can increase the SPF value in sunscreen preparations <sup>7</sup>.

Zinc Oxide is a physical inhibitor that is added to the Blemish Balm Cream preparation which serves to reflect UV radiation by preventing or minimizing the sunburn and skin tanning effect so that it can provide better skin protection and increase the SPF value  $^{8}$ .

Based on the description above, the researcher aims to make Blemish Balm Cream Anti-aging face cosmetics containing vitamin E with variations in concentrations of 1%, 3% and 5% and using a combination of chemical sunscreen Avobenzone 3% and Octyl Methoxycinnamate 7.5 and Zinc Oxide 5% as a physical sunscreen. Formed preparations were carried out physical evaluation test preparations, clinical trials on volunteers and pre-clinical trials on rabbits, anti-aging activity using a skin analyzer, measuring the effectiveness of sunscreen by determining the SPF value using a spectrophotometer and comparing the SPF value of Blemish Balm Cream with variations concentration of Vitamin E with Blemish Balm Cream preparations without the addition of Vitamin E.

#### MATERIALS AND METHODS

The method used in this research is an experimental method, including the manufacture of Blemish Balm Cream formulation Anti-aging with Vitamin E content and a combination of sunscreen ingredients Avobenzone 3% and Octyl methoxycinamic 7.5%, physical evaluation of the preparation formulations, pre-clinical trials (irritation of test animals), clinical trials (irritation test for volunteers), determination of Anti-aging activity.

#### **Research sites**

The study was conducted from February 2019 to June 2019 in the Cosmetology Laboratory of the Faculty of Pharmacy, the Physical Pharmacy Laboratory of the Faculty of Pharmacy, and the Research Laboratory of the Faculty of Pharmacy, University of North Sumatra, Medan.

#### Material, chemical reagents and tools

The tools used in this study are analytical balance (Ohrus), magnetic stirrer (BOECO Germany), sonicator (Branson), Brookfield DV-E viscometer, pH meter (Hanna Instrument), centrifugation device (Hitachi CF 16 RX II), Skin analyzer (Aramo), UV Vis spectrophotometer (Shimadzu), Centrifuge (Hitachi CF 16 RX II), water bath, oven (Memmert), spatula and spatula, plastic pots, Petri dishes, glass objects, glass objects and stamper, and tools laboratory glassware.

The ingredients used in this study are Avobenzone (Vivimed), Octylmethoxycinnamate (BTC), Vitamin E (Zhejuang), Talcum (Galenova), Kaolin (Takehara Kagaku Kogyo), Calcium Carbonate (CSPC), Zinc Oxide (Phar Grade), Zinc Stearate (CSPC), Magnesium Carbonate, Yellow Iron Oxide (BTC) ), Parfume, Cetil Alcohol, Stearic Acid (Petronas), Aquades, Glyserin, Nipagin

#### **Blemish Balm Cream Formula**

In this study, variations in the concentration of Vitamin E and Avobenzone sunscreen and Octyl Methoxycinnamat used in Blemish Balm Cream preparations were seen according to the Standard Formula according to Kumar <sup>9</sup> and previous studies using vitamin E concentrations of 1-5% <sup>3</sup>. Based on FDA Monograph (1999) the maximum concentration of Avobenzone used is 3% and the commonly used Octyl Methoxycinnamat concentration is 2-7.5% <sup>10</sup>. Then the modified formula can be seen in table 1.

Ingredients	F0 (% w/w)	F1(% w/w)	F2(% w/w)	F3(%w/w)
Vitamin E	0	1	3	5
Avobenzone	3	3	3	3
Octylmethoxycinamic	7,5	7,5	7,5	7,5
Face powder	29,8	29,5	28,8	28,2
Foundation cream 59,7		59	57,7	56,3
Blemish Balm Cream ad 100		100	100	100

Tabel 1. Percentage of Blemish Balm Cream Vitamin E, Avobenzone and Octylmethoxycinamic formulas

\*Note:

F0: Blemish Balm Cream without vitamin E (blank),F1:Blemish Balm Cream vitamin E concentration: 1%,F2:Blemish Balm Cream concentration of vitamin E 3%,F3: Blemish Balm Cream 5% vitamin E concentration

#### Physical Evaluation of Blemish Balm Cream

Physical evaluation of the preparation includes organoleptic, homogeneity, pН measurement, determination of the type of emulsion, viscosity of the preparation, centrifugation test, Cycling Test, Scattering Test, stability test conducted for 12 weeks at low temperature storage, room temperature, and high temperature, determination of the Sun value Protecting Cream using Factor Blemish Balm UV Vis spectrophotometer, Pre-clinical trials, Clinical Tests of irritation to volunteers, and Anti-aging activities which include water content, smoothness, pores, blemishes, and wrinkles.

#### **Clinical Trial for Blemish Balm Cream**

The irritation test was carried out randomly (randomized controlled trial) of 24 volunteers with a preventive method by applying formula in the area behind the ear or behind the lower arm and then left in the open state and observed what happened. Performed two to three times a day in the test area for two consecutive days, a positive irritation reaction is characterized by itching, redness, and skin tearing in the test area <sup>4</sup>.

# Anti-aging Activity Test for Blemish Balm Cream with Skin Analyzer

Anti-aging Blemish Balm Cream activity testing was conducted on female volunteers aged 20-35 years as many as 24 people. The grouping is divided into 4 groups:

Group I: 6 volunteers for the BB cream formula without Vitamin E

Group II: 6 volunteers for 1% BB cream formula Group III: 6 volunteers for BB cream 3% formula

Group IV: 6 volunteers for the 5% BB cream formula

All volunteers measured facial skin conditions from initial conditions including moisture, pore, spots (melanin) and wrinkles using a skin analyzer. Treatment is done by applying the Blemish Balm Cream preparation on the face twice a day morning and afternoon. Skin condition was measured before and after using Blemish Balm Cream preparations every week for 4 weeks using a Skin Analyzer.

#### Data analysis

Data from measurements of anti-aging activities with a skin analyzer were analyzed using the SPSS (Statistical Product and Service Solution) program. The data obtained were analyzed using the Kolmogorov-Smirnov Test. Furthermore the data were analyzed using Two Way Anova to analyze the effect of the formula on the condition of the skin during the use of the preparation within four weeks of treatment.

#### Determination of the Value of Sun Protecting Factor Blemish Balm Cream

Determination of the Sun Protecting Factor (SPF) value is done by dissolving the sample in ethanol, then testing the value using a UV-Vis spectrophotometer. in the wavelength range of 290nm to 400nm wavelength. Do the same treatment 3 times for each formula.

SPF values are calculated using the Mansur equation <sup>11</sup>.

SPF<sub>spectrophotometric</sub> = CF x  $\sum_{320}^{290}$  EE ( $\lambda$ ) x Abs ( $\lambda$ )

Note:

- CF = Correction Factor (10)
- EE = Spectrum of Erythemal Effects
- I = Spectrum of Intensity of the Sun.

Abs = Absorbance of a Sample

To find out the differences in the SPF values that differed between formulas a statistical test was performed using the ANOVA (Analysis of Variance) method with the SPSS (Statistical Package for the Social Sciences) program with a 95% confidence level.

#### **RESULT AND DISCUSSION**

#### **Formulation Results**

In this study Blemish Balm Cream preparations were made using a modified formula from face powder and foundation cream formulas as seen from Kumar's formula (2018). Blemish Balm Cream preparations that are made contain vitamin E and sunscreen ingredients. Vitamin E is a vitamin used in the manufacture of dermatological preparations, especially facial and skin cosmetic products. The addition of Vitamin E to Blemish Balm Cream serves as an emolient in preparations so that it is beneficial for skin anti-aging and antioxidants which can neutralize free radicals and avoid skin dryness. For each formula, the concentration of Vitamin E used is 0%, 1%, 3%, and 5%, while the concentration of sunscreen ingredients in each formula is Avobenzone 3% and Octyl Methoxycinnamate 7.5%.

The results of Blemish Balm Cream Vitamin E preparations with variations in the concentration of 0%, 1%, 3% and 5% produce preparations that are brownish yellow and odorless.

#### **Results of Physical Evaluation of Blemish Balm Cream**

The results of organoleptic evaluation of Blemish Balm Cream preparations can be seen in Table 2.

 Table 2 Physical Evaluation Results of Blemish Balm Cream preparations

Evaluations	Result	
Organoleptic:		
Color	Brownish yellow	
Smell	Odorless	
Form	Cream	
Homogenity	No coarse grains were found in each formula	
рН	6-7,8	
Emulsion type	Oil in water (m / a)	

Viscosity	At room temperature: 2100-3650cp; low temperature: 2600-3895cp; high temperature: 1950-3450cp	
Cycling test	Stable	
Scattering:		
F0	5,54 cm	
F1	5,92 cm	
F2	6,25 cm	
F3	6,77 cm	
Stability		
Room temperature (22-25°C)	Stable, no changes in color, odor and shape	
Low temperature( $4 \pm 2^{\circ}$ C)	A change in the color of light brown to light brown in the 4th week	
High temperature $(40 \pm 2^{\circ}C)$	A color change from weak brown to light brown and softer in the 6th week	

\*Note: F 0: Blemish Balm Cream without vitamin E (Blank), F 1: Blemish Balm Cream concentration of vitamin E 1%, F 2: Blemish Balm Cream Concentration of Vitamin E 3%, F 3: Blemish Balm Cream Concentration of Vitamin E 5%

Based on the results of pH measurements it can be seen from each table and graph that the pH of Blemish Balm Cream during storage at room temperature, low temperature and storage at high temperature of each preparation of Blemish Balm Cream with varying concentrations of vitamin E experienced a slight decrease in pH after storage for 12 week, the pH of the preparations at F0, F1, F2 and F3 still meets the skin pH range in accordance with the normal skin pH requirements, which is between 4.5-7.0. Skin pH value based on SNI 16-4399-1996 pH quality requirements for sunscreen preparations are 4.5-8 so that preparations made are still safe to use and do not cause skin irritation <sup>4</sup>.

Decrease in the degree of acidity or pH of the preparations that occur after 12 weeks of storage at different temperatures in each of the Blemish Balm Cream preparations is caused by the interaction of Vitamin E with sunscreen avobenzone 3% and 7.5% octyl methoxycinamic. Vitamin E is an antioxidant the alpha tocopherol group which is easily oxidized and unstable to air and light during storage where oxygen can affect the stability of easily oxidized substances, especially substances that contain antioxidants but can increase the effectiveness of sunscreens <sup>12</sup>.

Emulsion type test results show that the addition of methylene blue to the preparation can be evenly dispersed. So it can be concluded that the type of Blemish Balm Cream preparations with varying concentrations of vitamin E has the type of oil in water (m / a). This is because most of the ingredients used in the formula are hydrophilic or polar so Blemish Balm Cream is oil in water (m / a). Types of preparations that are O / W one type of cosmetic preparations that are often used because it has the advantage of more easily spreading on the surface of the skin when applied topically, easily removed when washed with water, more acceptable because it is easily applied to the skin and is more comfortable to use compared to preparations of the type W / O emulsion <sup>13</sup>.

Based on the viscosity test results obtained that the viscosity of Blemish Balm Cream preparations stored at room temperature and low temperature for 12 weeks an increase in viscosity, while the viscosity at high temperatures decreased, this is due to the influence of temperature changes and the ratio of vitamin E concentrations in each formula, the physical and chemical

properties of each material differ, emulsifiers are not mixed evenly with excipients, and oxidation reactions occur. In preparations stored at room temperature produces a significant increase in Blemish Balm Cream and still meets the specified viscosity value requirements<sup>14</sup>.

The results of the Cycling Test of Blemish Balm Cream showed that the preparation was stable during the storage period of 6 cycles. From the results that have been tested can be seen that there is no change in color, odor, or phase separation in the preparation, so it can be concluded that the preparation of Blemish Balm Cream was stable. The Cycling Test is carried out at different temperatures with varying time intervals. This test is carried out by storing each Blemish Balm Cream formula at 4 °C for 24 hours and then transferred at 40 °C for 24 hours. The treatment is 1 cycle and to clarify the changes that occur there are 6 cycles for 12 days in each formula <sup>4</sup>.

From the results of the Power Test it was found that the average yield of the power obtained in each formula is F0 (Blank) is 5.54cm, F1 5.92cm, F2; 6.52cm and F3 6.77cm. The highest dispersion is found in F3, this is due to the influence of the concentration of vitamin E which is used the most so that the ability of drug absorption to the skin is faster. Low scatter power is found in the formula F0 (blank), so the ability of the skin absorbed preparation is getting longer. From the explanation above, the three formulas still meet the spreadability requirements so the preparations made still have optimal effects. The results of the effect of storage time on the spread of Blemish Balm Cream.

#### **Clinical Test Results**

# Test Results for Blemish Balm Cream Irritation against Volunteers

The primary irritation index results are calculated based on the Federal Hazardouz Substance Act. Based on observations of Blemish Balm Cream irritation test on volunteers who have met the inclusion criteria that indicate that the preparation of Blemish Balm Cream in each formula F0, F1, F2, and F3 obtained a primary irritation index score of 0 with no visible irritation reaction categories such as erythema and edema on voluntary skin. This shows that the addition of Vitamin E with concentrations of 0%, 1%, 3% and 5% and the additives used in the formula do not have an effect or effect that causes irritation to the skin so that the Blemish Balm Cream preparation made is safe to use.

Components in cosmetics that have great potential that can irritate the skin include preservatives (antimicrobial substances), antioxidants, fragrances, dyes and UV protectors. However, these components are often present in

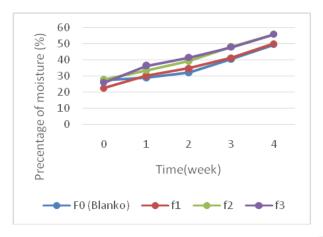


Figure 1: Graph of the results of measurements of water content (moisture) for 4 weeks

\*Note: Normal: 30-44; Dehydration: 0-29; Hydration: 45-100, F0: Blemish Balm Cream without vitamin E (Blank), F1: Blemish Balm Cream concentration of vitamin E 1%, F2: Blemish Balm Cream Concentration of Vitamin E3%, F3: Blemish Balm Cream Concentration of Vitamin E 5%

Based on the measurement of water content obtained, it can be seen that before the use of Blemish Balm Cream the face of volunteers experiencing dry skin (dehydration), after the use of Blemish Balm Cream Anti-aging there is a gradual increase in skin moisture percentage which makes the skin of volunteers normal. This is supported by the results of statistical analysis calculated by the Two Way Anova and Kolmogorov-Smirnov Test methods. The statistical analysis results of the Kolmogorov-Smirnov Test from the measurement of water content show a significant difference ( $p \le 0.05$ ) in F0, F1, F2 and F3 after using Blemish Balm Cream for 4 weeks which shows that there is a significant difference in the increase in water content and the influence of skin conditions between Blemish Balm Cream without vitamin E (blank) with Formula containing vitamin E (F1, F2 and F3) Vitamin E activity easily penetrates through the skin layers and increases the water content in the skin to be more effective. Blemish Balm Cream preparations without containing Vitamin E (blank) has a percentage increase in water content that is longer than F1, F2 and F3, where the average percentage of water content obtained before use until after 4 weeks of use is F0: 27.3- 49.6%., F1: 22.6-50.16%., F2: 28-56.1% and F3: 26-56.1%. The percentage limit of normal water levels on facial skin is 30-44% and the percentage of moisture> 45% can prolong the process of skin aging <sup>16</sup>.

According to Loden and Maibach, that an increase in skin water content is influenced by the ability of vitamin E to protect oxidative degradation of the skin because vitamin E functions as a substance that maintains skin's moisture <sup>17</sup>. Meanwhile, according to Tranggono, Iswari and

cosmetic formulas in small amounts and so do not affect the overall irritation potential of the product made <sup>15</sup>.

## Anti-aging activity results Blemish Balm Cream preparation with Skin Analyzer

#### Moisture measurement results with the Skin Analyzer

Data from the measurement of water content (moisture) can be seen in Figure 1.

Latifah, Vitamin E as a moisturizer that can maintain the bond of water in the skin  $^{18}$ .

#### Pore measurements with a Skin Analyzer

Data from pore measurements on volunteer facial skin can be seen in Figure 2.

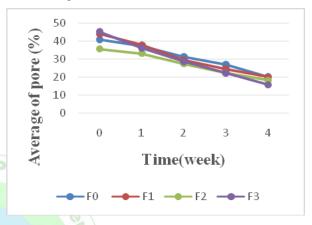


Figure 2. Graph of the results of pore measurements for 4 weeks

\*Note: Normal: 30-44; Dehydration: 0-29; Hydration: 45-100, F0: Blemish Balm Cream without vitamin E (Blank), F 1: Blemish Balm Cream concentration of vitamin E 1%, F 2: Blemish Balm Cream Concentration of Vitamin E 3%, F 3: Blemish Balm Cream Concentration of Vitamin E 5%

Pore measurement results show that the Blemish Balm Cream Anti-aging formula changes the skin pore condition from a large pore condition to a little smaller after 4 weeks of using Blemish Balm Cream preparations. Statistical analysis results obtained showed a significant difference (p  $\leq 0.05$ ) between the formula after the use of Blemish Balm Cream without vitamin E (blank) and Formula containing vitamin E (F1, F2 and F3) during 4 weeks of use in the presence of reduction in pore size on the volunteer's face.

According to Dreyfuss, one of the factors affecting enlarged pores is skin that is often exposed to sunlight, temperature changes, genetic factors, collagen damage, acne and water content, decreased skin elasticity, accumulation of dead skin cells (dirt)<sup>19</sup>.

The percentage of pore measurements obtained that volunteers who use Blemish Balm Cream preparations without containing Vitamin E (blank) have a percentage of pore changes that are longer than F1, F2 and F3, where the average percentage of pore obtained before use until after use 4 weeks are F0: 41-20.3%., F1: 44.1-20.16%., F2: 35.8-18.5% and F3: 45.3-16%. The percentage limit of the number of small pores on facial skin is 0-19 and the pore is 20-39<sup>3</sup>. Pore measurement results show that the Blemish Balm Cream Anti-aging formula changes the skin pore condition from a large pore condition to a little smaller after 4 weeks of using Blemish Balm Cream preparations. Statistical analysis results obtained showed a significant difference ( $p \le 0.05$ ) between formulas after the use of

Blemish Balm Cream preparations without vitamin E (blank).

# Spots measurement results (melanin) with a Skin Analyzer

Measurement of the number of blemishes or melanin on facial skin is measured using the same skin analyzer with a 60x lens magnification<sup>16</sup>, starting from the initial conditions and after the use of Blemish Balm Cream preparations.

Data on the measurement of blemishes or melanin on the skin of volunteers can be seen in Figure 3.

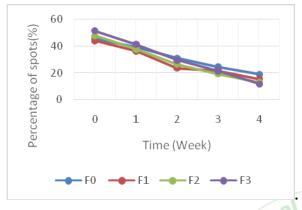


Figure 3. Graph of the results of spots measurements for 4 weeks

\*Note: Normal: 30-44; Dehydration: 0-29; Hydration: 45-100, F 0: Blemish Balm Cream without vitamin E (Blank),F 1: Blemish Balm Cream concentration of vitamin E 1%,F 2: Blemish Balm Cream Concentration of Vitamin E 3%, F 3: Blemish Balm Cream Concentration of Vitamin E 5%

Based on the results of spots or melanin measurements, the percentage of spots or melanin measurements obtained showed that volunteers who used Blemish Balm Cream preparations without containing Vitamin E (blank) had a longer spots change percentage and had more spotss than F1, F2 and F3, where results the average percentage of spotss obtained before use until after 4 weeks of use is F0: 39.83-27.3%, F1: 39.33-22.1%, F2: 49-19.5% and F3: 51.5-18.1%. The percentage limit on the number of blemishes on facial skin is 0-19 and medium spotss 20-39<sup>3</sup>. Statistical analysis results obtained showed a significant difference ( $p \le 0.05$ ) between the formula after the use of Blemish Balm Cream without vitamin E (blank) and Formula containing vitamin E (F1, F2 and F3) during 4 weeks of use in the presence of reduction of blemishes on the faces of volunteers. Limit percentage of blemishes on normal facial skin is 0-39<sup>16</sup>. The results of data obtained from the measurement of blemishes that the percentage of blemishes on the facial skin of volunteers is still within normal limits.

The formation of excess melanin can cause hyperpigmentation which is characterized by the appearance of black patches on the face, melanin is formed with the help of the enzyme tyrosinase, Vitamin E and sunscreen ingredients have a very important function in preventing spotss or melanin because both ingredients has a very important function in cosmetic products Blemish Balm Cream so that it can treat or eliminate the symptoms of aging on the skin caused by UV rays and is able to slow the emergence of symptoms of photo-aging  $1^5$ .

#### Wrinkle measurement results with a Skin Analyzer

Measurement of the amount of wrinkles on the volunteer's facial skin begins with measurement from the initial condition and after the use of Blemish Balm Cream preparations. Data on wrinkle measurements on volunteer facial skin can be seen in Figure 4.

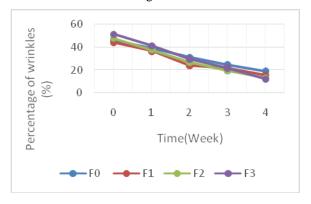


Figure 4: Graph of the results of Wrinkles measurements for 4 weeks

Note: Normal: 30-44; Dehydration: 0-29; Hydration: 45-100, F0: Blemish Balm Cream without vitamin E (Blank), F1: Blemish Balm Cream concentration of vitamin E 1%, F2: Blemish Balm Cream Concentration of Vitamin E 3%, F3: Blemish Balm Cream Concentration of Vitamin E 5%

Based on the results of measurements of wrinkles the percentage of measurements of wrinkles obtained showed that volunteers who used Blemish Balm Cream preparations without containing Vitamin E (blank) had a longer percentage of wrinkles changes and had more wrinkles than F1, F2 and F3, where the average percentage of wrinkles obtained before use until after use 4 weeks is F0: 45.8-19%., F1: 44-15.5%., F2: 47.8-13.1% and F3: 51.3-12%. The results of the analysis obtained showed a significant difference ( $p \le 0.05$ ) between the formula after the use of Blemish Balm Cream without vitamin E (blank) and Formula containing vitamin E (F0, F1, F2 and F3) during 4 weeks of use with a reduction in wrinkles on the faces of volunteers.

The percentage limit for normal facial skin wrinkles is 0-19 <sup>16</sup>. The results of the data obtained from the measurement of wrinkles (wrinkle) that Blemish Balm Cream F0, F1, F2 and F3 obtain a percentage of wrinkle reduction within normal limits. the results of the static analysis obtained showed a significant difference ( $p \le$ 0.05) between the formula after the use of Blemish Balm Cream without vitamin E (blank) and Formula containing vitamin E (F1, F2 and F3) during 4 weeks of use in the presence of reduction of wrinkles on volunteers' faces.

## Blemish Balm Cream Sun Protecting Factor Determination Test Results

Determination of the SPF value was carried out in vitro using a UV-Vis spectrophotometer by means of blemish Balm Cream preparation on the solvent used, then measured and obtained absorbance. The absorbance of each preparation is calculated by the Mansur equation. Sunscreen ingredients used are 3% Avobenzone and 7.5% Octylmethoxycinamate. Avobenzone 3% is an anti-UV chemical and Octyl Methoxycinnamate 7.5% as a UV-B antidote. SPF results can be seen in Figure 5 below.

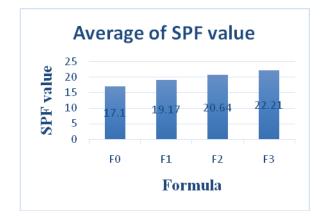


Figure 5: Graph of Average Values of SPF for Blemish Balm Cream

Note: Normal: 30-44; Dehydration: 0-29; Hydration: 45-100,F 0: Blemish Balm Cream without vitamin E (Blank),F 1: Blemish Balm Cream concentration of vitamin E 1%,F 2: Blemish Balm Cream Concentration of Vitamin E 3%,F 3: Blemish Balm Cream Concentration of Vitamin E 5%

From the results of determining the effectiveness of the SPF (Sun protecting Factor) value from Blemish Balm Cream preparations obtained in table 4.20 and figure 4.21 the average SPF value of each formula are: F0 obtains an average value of SPF 17.10; F1 obtained an average SPF of 19.17; F2 obtained an average SPF of 20.64; and F3

obtained an average SPF of 22.21. The concentration of Vitamin E added to the formula influences the SPF value, the higher the concentration of vitamin E added to the Blemish Balm Cream preparation, the higher the SPF value, the increase in the SPF value is because vitamin E can provide absorbance in the range of UV light wavelengths so that it can increase longer protection from sun exposure <sup>12</sup>.

Vitamin E is a reduced form photoprotective agent, so that when UV light interacts with sunscreen it will be blocked by vitamin E. Vitamin E does not only play a role in increasing SPF values in vitro, but also prevents photodegradation in UV light.

According to Wasitaatmadja, the categories for each sunscreen preparation based on SPF indigo given as a protection factor against sunlight are as follows:

1. At a minimum, if the SPF is between 2-4.

- 2. Medium, if the SPF is between 4-6
- 3. Extra, if the SPF is between 6-8
- 4. The maximum, if the SPF is between 8-15
- 5. Ultra, if the SPF is more than  $15^{4}$ .

verage value of SPF 17.10; F1 obtained an average SPF f 19.17; F2 obtained an average SPF of 20.64; and F3 Table 4: Effectiveness categories of SPF values in Blemish Balm Cream Vitamin E preparations containing Avobenzone 3% and Octyl methosinamic

No	Formula	2	Formula Average	Effectiveness category
1.	F0 (blank)	a	17,10	Ultra
2.	F1	5	19,17	Ultra
3.	F2		20,64	Ultra
4.	F3		22,21	Ultra

7.5%

Note: Normal: 30-44; Dehydration: 0-29; Hydration: 45-100,F 0: Blemish Balm Cream without vitamin E (Blank),F 1: Blemish Balm Cream concentration of vitamin E 1%,F 2: Blemish Balm Cream Concentration of Vitamin E 3%,F 3: Blemish Balm Cream Concentration of Vitamin E 5%

From the results of table 4.20 the effectiveness category of SPF values on Blemish Balm Cream Vitamin E preparations containing Avobenzone 3% and 7.5% methyl octamylate have Ultra effectiveness categories contained in the Blanko, F1, F2 and F3 formulas. From the results of the measurement of the effectiveness of the SPF value of all formulas obtained meet FDA requirements, according to FDA requirements that cosmetics sunscreen preparations that can provide a better protective effect against UV rays have an SPF value of at least 15 or more so that they can provide longer protective effect against UV rays <sup>10</sup>.

After testing the normality of the data using the Kolmogorov-Smirnov method, it was found that the data were normally distributed with the decision rule if significant more than 0.05. The results of the average SPF after being calculated using a statistical test showed that there was no significant effect between the average value of the SPF in each treatment with a significant value  $\geq$  0.05 (P = 0.196) with the conclusion that the hypothesis H0 was accepted.

#### CONCLUSION

Based on the results of the research that has been done, it can be concluded that the Blemish Balm Cream preparations produced are stable and homogeneous preparations using an appropriate ratio of face powder formula and foundation cream formula. Blemish Balm Cream with the addition of vitamin E, avobenzone and octylmethoxycinamic at low temperature, room temperature and high temperature for 12 weeks affects the stability of the preparation. Storage at low temperature and high temperature produces unstable preparations due to changes in color and shape of the preparations, but preparations at room temperature storage produce stable preparations for 12 weeks storage.

Vitamin E in Blemish Balm Cream preparations can provide good anti-aging activity which is characterized by increased skin moisture, pore reduction, reduction of blemishes and reduction of wrinkles on volunteer skin during the use of Blemish Balm Cream preparations.

Blemish Balm Cream preparation with the addition of vitamin E (1%, 3% 5%), avobenzone 3% and octyl methoxoxycinamate 7,5% can increase the SPF value higher than the Blemish Balm Cream preparation without vitamin E (blank). The SPF value obtained in the formula is F0 (blank): 17.10; F1 (vit E 1%): 19.17; F2 (vit E 3%): 20, .64; F3 (vit E 5%): 22.21

#### **CONFLICT OF INTERESTS**

All author have no to declare

#### REFERENCES

- Arakane, K. and Naru, E. Cosmeceuticals and Active Cosmetics, 3rd Ed., 281, CRC Press, New York. 2016. p. 75-78.
- Baldecchi T., Lage Zur J., Bai R., Wu S, Zhuang J., and Witte G, Pflueker F. From BB to CC Cream Innovative Formulation of Multitasking Care. International Journal for Applied Science. 2012; 138:1-7.
- 3. Mukul, S., Surabhi K., and Atul N. Cosmetical For Skin: An Overview. Asian Journal of Pharmaceutical and Clinical Research. 2011; 4:974-2441.
- 4. Wasitaatmadja, S.M. *Penuntun Ilmu Kosmetik Medik*. Jakarta: Penerbit UI- Press. 1997; 75:111-120.
- Afonso. S., Horita. K., Silva. J.P.S., Almeida. I.F., Amaral. M.H., Lobao, P.A., *et al.* Photodegradation of avobenzone Stabilization effect of antioxidants. *Journal of Photochemistry and Photobiology B: Biology.* 2014; 140:36–40.
- 6. Baki, G., and Alexander, K.S. Introduction to Cosmetic Formulation and Technology. New Jersey. 2015. p. 283, 292.
- Rege, S., Momin, S., *and* Bhowmick, D. Effect of Ascorbic Acid on the Oxidative Stability of Water-In-Oil Emulsion in the Presence of Lipophilic Antioxidants. *Int. J. Food Prop.* 2014; 18:259-265.
- Rosita, N., Purwanti, P., and Agustin. Stabilitas Fisik dan Efektivitas Sediaan Tabir Surya Kombinasi Oksibenson dan Oktil Metoksisinamat dengan Penambahan Asam Glikolat. Majalah Ilmu Kefarmasian. 2010; 7(2):16-26.
- Kumar, B.K., Kotnala, A., Verma, K., Sharma, A., Parashar, S., Rathi, B., & Singh, J. Indian Medicinal Plants For Skin Care and Cosmeceuticals: A review. *Journal of Biomedical and Therapeutic Sciences*, 2018; 6(2), 24-60.
- FDA Monograph. FDA Sunscreen Monograph. Federal Register 1999; 64:2766-2769.

- Mansur, M.C.P.P.R., Suzana, G.L., Cristal, C.C., Alane, B.V., Ronald, S.S., Octavio, A.F.P., *et al.* In Vitro and In Vivo Evaluation of Efficacy and Safety of Photoprotective Formulations Containing Antioxidant Extracts. *Revista Brasileira de Farmacognosia*. 2016; 26(1):251-258.
- Ditjen POM. Farmakope Indonesia. Edisi kelima. Jakarta. Departemen Kesehatan Republik Indonesia. 2014;77-882.
- Bernatoniene, J., Masteikova, R., Davalgiene, J., Peciura, R., Gauryliene, R., Bernatoniene, R., & Muselik, J. Topical Application of *Calendula officinalis* (L.): Formulation and Evaluation of Hydrophilic Cream with Antioxidant Activity. *Journal of Medicinal Plants Research*, 2011; 5(6):868-877.
- Lachman, L., Lieberman, H.A., and Kanig, J.L. The Theory and Practise of Industrial Pharmacy. Philadelphia: Varghese Publishing House. 1994; 1081-1083.
- Barel, A.O., Paye M., and Maibach H.I. Handbook of Cosmetic Science and Technology Third Edition. New York: Taylor and Francis Group. 2009; 137-141.
- Aramo. Skin and Hair Diagnosis System. Sungnam Aram Huvis Korea Ltd. 2012; 1-10.
- Loden, M., Maibach, H. I., Appelbe, G. E., Wingfield, J., Smith, E. W., Enhancers, P. P., & Smith, I. ISBN 853696012. Steven B. Kayne Sport and Exercise Medicine for Pharmaceists Pharmaceutical Press; 2006; 376. American Journal of Pharmaceutical Education, 2006; 70(2):47.
- 18. Tranggono, R.I., and Latifah, F. Buku Pegangan Ilmu Pengetahuan Kosmetik. Jakarta: PT. Gramedia Pustaka Utama. 2007; 3(47):58-59, 79, 81-83.
- Dreyfuss, S., Alépée, N., Piroird, C., Aujoulat, M., Hoffmann, S., Hohenstein, A., & Cotovio, J. Prospective multicentre study of the U-SENS test method for skin sensitization testing. *Toxicology in Vitro*, 2015; 30(1):373-382.

