

Potassium-Azeloyl-Diglycinate BB-Cream formulation with Triethanolamine variation, and its effects on In-Vitro SPF stability and values

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ABSTRACT

Many cosmetic innovations can be used as sunscreens, one of which is Potassium Azeloyl Diglycinate which is a new generation ingredient of an innovative water-soluble molecule that normalizes sebum activity and brightens the skin. One of the cosmetic products favored by women is the beauty balm cream (BB cream) is a multifunctional cosmetic product such as foundation, moisturizer, and sunscreen in a lighter and more practical shape. To obtain a good cream base, the use and selection of the emulgator is crucial. One type of emulgator that is often used, is Triethanolamine. This research was conducted to compare the variation in the amount of Triethanolamine as the emulgator in the manufacture of Potassium Azeloyl Diglycinate BB Cream, which would be compared to the stability of its physical and chemical properties during the storage period, using the cycling test method, hydration power test, and in-vitro SPF test. The difference in the concentration of the triethanolamine in each formula affects the adhesion, the viscosity, and pH increase, yet the spreadability decreases. The storage at a temperature of $4\pm 2^{\circ}\text{C}$ and $40\pm 2^{\circ}\text{C}$ affects the results of the chemical properties test on the BB Cream. The Potassium-Azeloyl-Diglycinate BB Cream is known to have the SPF value and there is a decrease in the value after cycling test. The Formula 2 with 4% TEA concentration has the best stability of physical and chemical properties. The Potassium-Azeloyl-Diglycinate BB Cream Formula 2 is known to affect humidity.

Keywords: Potassium-Azeloyl-Diglycinate, Beauty-Balm Cream, Triethanolamine, Sun-Protecting-Factor

Introduction

Sunlight is needed by all living things for their survival. However, sometimes the sunlight reaching the surface has negative effects on the skin. This light is in the form of UV A and UV B rays which can adversely affect various skin types, including erythema such

as sunburn, photosensitivity, and phototoxicity. Long-term issues include photoaging and carcinogenesis [1]. These two ultraviolet rays work synergistically, therefore prevention or protection is needed to reduce bad effects on the skin due to UV A and UV B radiation [2]. Developments in cosmetics include a product known as sunscreen which is used to prevent harmful effects of UV exposure. Sunscreen is a cosmetic product containing substances that absorb and/or reflect UV radiation, reducing radiation energy that penetrates the skin. Sunscreen should have a high Sun Protecting Factor (SPF) value as it is important to measure its effectiveness based on the Minimum Erythematous Dose (MED) ratio of skin that is protected and unprotected by sunscreen. The mechanism of sunscreen is to absorb UV rays, scatter UV rays, and reflect UV rays, therefore it can reduce redness on the skin [3].

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One of the cosmetic products favored by women is the Beauty Balm cream (BB cream) or foundation that is used to coat redness on the face, acnes, acne scars, and different colors of facial skin. It also contains SPF and can protect the skin from sun exposure when used, especially in the morning. BB cream is a multifunctional cosmetic product such as foundation, moisturizer, and sunscreen in a lighter and more practical shape [4].

Many cosmetic innovations exist that can be used as sunscreens, such as Potassium Azeloyl Diglycinate which is a new generation ingredient of an innovative water-soluble molecule that normalizes sebum activity and can also brighten the skin which is obtained by reacting azelaic acid chloride with two molecules of glycine and KOH. It can also treat hyperpigmentation in uneven and dark skin tones, as well as the presence of freckles, and also improve skin quality with its ability to moisturize for brighter skin and a more radiant appearance [5].

To obtain a good cream base, the use and selection of the emulgator is crucial [6]. One type of emulgator that is often used is Triethanolamine that is an anionic emulgator. Anionic emulgator has the advantage of being able to penetrate and interact well with skin fat and protein. It is also neutral, non-toxic, and produces a stable emulsion.

This research was conducted to compare the variation in the amount of Triethanolamine as the emulgator in the manufacture of Potassium Azeloyl Diglycinate BB Cream, which would be compared to the stability of its physical and chemical properties during the storage period, using the cycling test method, hydration power test, and in-vitro SPF test, against the BB Cream product formulation with Potassium Azeloyl Diglycinate as the active ingredient.

Materials and Methods

Instruments

The instruments used are analytical scales (OHAUS), UV-Vis spectrophotometer (GENESYS 10S), water bath (MASPION S-302), refrigerator (SHARP), oven (Mettler), viscotester (RION VT-04E), pH meter (LUTRON pH-208), adhesion test equipment, microscope (Nikon E100), and other supporting tools.

Materials

Potassium Azeloyl Diglycinate (Nardev Chemie), Stearic Acid (Oleochemical), Nipasol, ZnO (Oleochemical), TiO₂ (Oleochemical), Triethanolamine (Technical), Mineral Oil (Technical), Olive Oil, Propylene glycol (Oleochemical), Glycerin (Technical), Methyl Paraben, Iron Oxide, Vanilla, Mica Silver Powder, and Aquadestilata (water for injection)

Design formula

The design of the BB cream formulation is shown in **Table 1**.

Table 1. Potassium-Azeloyl-Diglycinate BB Cream Formulation

Material	Function	BB Cream Formula (b/b)		
		F1	F2	F3
Potassium Azeloyl Diglycinate	Active Substance	5%	5%	5%
TEA	Emulsifier	2%	4%	6%
Asam Stearat	Thickening agent	6%	6%	6%
Nipasol	Preservative	0.1%	0.1%	0.1%
ZnO	UV Protector	3 %	3 %	3 %
TiO ₂	UV Protector	4 %	4 %	4 %
Olive oil	Antioxidant	2%	2%	2%
Mineral Oil	Emollient	4%	4%	4%
Glycerin	Humectant	5%	5%	5%
Propylene glycol	Humectant	4%	4%	4%
Nipagin	Preservative	0.2%	0.2%	0.2%
Mika powder (Silver)	Corrigen Coloris	q.s.	q.s.	q.s.
Iron Oxide	Corrigen Coloris	0.4 %	0.4%	0.4%
Vanilla	Corrigen Odoris	q.s.	q.s.	q.s.
Aquadestilata	Solvent	Ad 100 g	Ad 100 g	Ad 100 g

Making Potassium-Azeloyl-Diglycinate BB Cream product

The cream consisted of an active substance (Potassium Azeloyl Diglycinate), two cream phases, namely the oil phase (stearic acid, Nipasol (propylparaben), ZnO, TiO₂, TEA, mineral oil, and olive oil) and the water phase (glycerin, propylene glycol, Aquadestilata, and Nipagin), as well as other additives (iron oxide, vanilla, and mica powder). Both the water and oil phases were heated to 70°C each in the water bath or until being dissolved. The water phase was transferred to the hot mortar and added to the oil phase, homogenized it quickly and regularly until it was cool and a creamy mass was formed. The next step was to add Potassium Azeloyl Diglycinate, then add mica, vanilla, and iron oxide powder, and finally homogenization.

Potassium-Azeloyl-Diglycinate BB cream product evaluation

Organoleptic test

Organoleptic examination was carried out by checking the color, consistency, and odor of the product, before and after the test conditions [7].

Homogeneity test

1g of cream on the top, middle, and bottom were taken and then smeared on the slide. Then it was observed for phase separation. The requirement for cream products is that there is no separation between the components that make up the emulsion if they are applied to a piece of glass [8].

Adhesion test

Totally 0.5g of cream was smeared on a glass object whose area was known. Then another glass object was put on the cream and pressed with a weight of 1 kg for 5 minutes. Then, the object-glass was installed on the test equipment and given a load of 80g and recorded the time until the two object glasses were separated [8].

Spreadability test

Totally 0.5g of cream was placed on a glass coated with graph paper, then glass was placed on it and left for 1 minute, and the area was calculated by the product. Then a load of 50, 100, and 250g was given on each product, respectively, and left for 60 seconds, then the area of the produced product was calculated [9].

Viscosity test

The viscosity of the cream was determined with a viscotester. Measurements were made by placing the product in a container, then mounted on a portable viscotester. The viscosity value is known by observing the movement of the pointer until it is stable and shows a certain number.

Stability test

The stability test was carried out using the Cycling Test method. The test was carried out in 6 cycles. Product conditions were compared during the experiment with the initial product, whether there was separation or not [10].

pH Test

Totally 1g of cream was diluted with 10mL of aquadestilata. The pH measurements were carried out using a pH meter. A good and non-irritating product will have a pH based on the skin's normal pH range, namely 4.5 - 6.5 [8].

SPF test

The cream solution was made by weighing 0.1g of each formula. Then it was put in a beaker, and dissolved with aquadestilata. Next, each solution was put into a 10 mL volumetric flask, and the volume was sufficient with aquadestilata up to 10 mL, homogenized and then filtered using filter paper [11]. The absorbance measurement of each of these solutions was measured at a wavelength of 290-320 nm using a UV-Vis spectrophotometer. In the measurements, the aquadestilata was used as a blank. The SPF value was calculated using the Mansur equation [12]:

$$SPF = CF \times \sum_{290}^{320} EE(\lambda) \times I(\lambda) \times abs(\lambda) \quad (1)$$

Information:

CF: Correlation Factor

EE: Erythema Efficiency

I: Solar Light Simulation Spectrum

Abs: Readable Absorption Value

Hydration test

The humidity test lasted for 7 consecutive days. The test was carried out on the skin of the panelist's arm [13]. Panelists were asked not to apply for one week before and during the study. The application of the test cream was carried out at night before going to bed by making a box pattern on the arm with a modification of the size of 2x2 cm, as much as 1 box for the best formula [14]. The measurements were carried out at the time before the test started, and on the 7th day, the panelists stayed in the testing room for at least 30 minutes to allow temperature and humidity adaptation [15].

Emulsion type test

The dilution method was used to observe the type of emulsion. If the cream is soluble in water, it is an o/w cream. Conversely, if it dissolves in oil, it is a w/o cream.

Results and Discussion

Organoleptic test

Organoleptic examination checks the color, consistency, and odor of the product, before and after the test conditions [16]. Stimulation can be mechanical pressure, puncture, physical, and chemical properties [17].

Based on the carried out tests, all the formulas tested had a distinctive smell of vanilla. Formula 2 and Formula 3 had a slightly thick consistency which was stable during the testing process, and it was different with Formula 1 which had a slightly liquid consistency, thus this was influenced by Triethanolamine with the smallest level of 2%; because in addition to being an emulgator, Triethanolamine functions as a thickening agent [18]. This showed that the higher the TEA concentration, the thicker the resulting consistency. The product color for all formulas was light cream and changed to cream after a cycling test was done. The cream was examined for organoleptic change parameters for ± 14 days of storage at room temperature, and 6 cycles. The results showed that all dominant creams did not change in terms of consistency, color, and smell.

Homogeneity test

A good cream product must be homogeneous and free from clotted particles [19]. Homogeneity test is carried out to find out whether the ingredients of the cream product have been mixed perfectly, which is marked by the absence of material lumps [20]. If the product has been declared homogeneous, it can be assumed that each product application will contain the same levels of

active substances so that product homogeneity affects product effectiveness [21]. The results showed that the cream products in all formulas were homogeneous, and neither the cycling test nor the storage time affected the homogenization level. This can be caused by the correct homogenization rate during the emulsion formulation to prevent lumps or materials that are not evenly distributed [22].

Adhesion test

The good adhesion allows the drug not to come off easily and the longer it sticks to the skin, so it can produce the desired effect. The thicker the cream, the longer it will take to separate the two slide glasses and vice versa. The results are shown in **Table 2**.

Table 2. The Adhesion Test Results for Pottasium Azeloil Diglycinate BB Cream

Formula	Adhesion test (seconds)		
	Day-0 (25±5°C)	Day-14 (25±5°C)	Cycling (4±2°C and 40±2°C)
F1	2.9 ± 0.2	2.7 ± 0.5	2.3 ± 0.4
F2	6.1 ± 0.3	6.0 ± 0.7	5.5 ± 1.1
F3	6.8 ± 0.3	8.1 ± 1.0	6.1 ± 1.8

After going through a cycling test, the adhesion obtained changed, and this was related to the other physical changes of BB Cream, namely viscosity.

The difference in emulgator concentration (triethanolamine) in each formula and differences in storage temperature affected the adhesion of the product. The requirement for adhesion to topical products was not less than 4 seconds [8].

Spreadability test

The spreadability test of the cream aimed to determine the product's ability to spread when applied to the skin. Good spreadability causes extensive contact between the drug and the skin, so that drug absorption to the skin takes place quickly [23]. The speed of dispersion depends on the viscosity of the formulation, the rate of solvent evaporation, the rate at which viscosity increases as a result of evaporation, and the shearing stress that is applied [24]. The results are shown in **Table 3**.

Table 3. Spreadability Test Results of the Potassium-Azeloil-Diglycinate BB Cream

Formula	Spreadability test (cm)		
	Day-0 (25±5°C)	Day-14 (25±5°C)	Cycling Test (4±2°C and 40±2°C)
F1	4.5 ± 0.3	5.4 ± 1.4	6.4 ± 0.6
F2	3.7 ± 0.4	4.3 ± 0.9	5.3 ± 0.4
F3	3.3 ± 0.1	3.2 ± 0.7	3.1 ± 0.5

After going through the cycling test, the spreadability obtained had changed, and this was related to the other physical changes of BB Cream, namely viscosity. The dispersion power test results showed that the higher the TEA concentration, the smaller the

dispersion power. There were differences in the concentration of emulgator (triethanolamine) in each formula, as well as the storage conditions affected the product dispersibility.

Viscosity test

The product viscosity examination aimed to see the thickness of the resulting cream product. The desired specification for the viscosity of semi-solid products is between 30,000 - 700,000 cps [25].

Table 4. Viscosity Test Results for Potassium-Azeloil-Diglycinate BB Cream

Formula	Viscosity Test (cps)		
	Day-0 (25±5°C)	Day-14 (25±5°C)	Cycling Test (4±2°C and 40±2°C)
F1	47250 ± 6128	39187 ± 3662.4	42493 ± 3100.8
F2	58263 ± 6071.3	56920 ± 8639.8	53226 ± 3005
F3	80673 ± 543.07	82034 ± 8602	83040 ± 6497

The results showed in **Table 4** that the more the amount of TEA was added to the cream, the more the viscosity value of the cream. One of the factors for the decrease in viscosity was temperature. High temperatures will increase the distance between particles so that the force between the particles will decrease. The greater the distance, the lower the viscosity [26]. Conversely, there was an increase in viscosity in Formula 3 after the conditions were imposed, and this could be because the viscosity value was influenced by the thickening agent (in this formula, was influenced by TEA), the surfactant selected, the proportion of the dispersed phase, and the particle size. When the proportion of the dispersed phase increases, the emulgator concentration increases, and the particle size gets smaller, the viscosity of the emulsion will increase [26].

The difference in the concentration of the emulgator (triethanolamine) in each formula affected the viscosity of the product. This is because the function of triethanolamine in the formulation is not only as an alkaline emulgator, but also as a thickening agent [18]. The viscosity of the TEA is due to the repulsion between the negatively charged sulfate groups, which are along the polymer chain, causing the polymer chain to be stiff and tightened [27].

Emulsion type test

A stable cream emulsion must be able to maintain its emulsion type during storage [28]. Inversion is the time the emulsion of M/A type changes to A/M, or vice versa.

The emulsion type test within ± 2 weeks of storage showed that the optimum formula did not change the emulsion type. The optimum formula after storage remained diluted when dissolved in aqueous medium. This can be caused by the proper homogenization speed during the emulsion formulation to prevent damage to the formulation during the test [22].

In addition, this is based on the fact that anionic type emulgators (TEAs) are often used in dermatology for topical applications.

Anionic emulgators can ionize, thus the presence of droplets with a strong charge and repulsion will increase the stability of the emulsion [7].

pH test

The pH test aimed to see the degree of acidity of the product. If the cream product has a pH that is too alkaline, it can cause the skin to become scaly, and vice versa, if the cream product has a pH of the product that is too acidic, it can cause skin irritation [29]. The normal pH range for the skin is 4.5 - 6.5 [8].

TEA is an alkalizing agent, and the presence of a high concentration of TEA can cause the neutralization process to accelerate so that the pH is getting closer to alkaline [22]. An increase in pH in the product can be caused by enzymatic reactions that occur in the product during the storage process. The results showed in **Table 5**.

Table 5. The pH Test Results of Potassium-Azeloyl-Diglycinate BB Cream

Formula	pH Test		
	Day-0 (25±5°C)	Day-14 (25±5°C)	Cycling Test (4±2°C and 40±2°C)
F1	6.0 ± 0.2	6.8 ± 0.3	6.9 ± 0.2
F2	6.6 ± 0.2	6.8 ± 0.4	7.0 ± 0.3
F3	7.4 ± 0.3	7.3 ± 0.6	7.6 ± 0.2

Changes in pH that occur in products are due to environmental factors such as light, temperature, and air humidity which can change the condition of the product to be slightly acidic, yet still in the skin pH range category [30]. In the research by Sehro and Desnita (2015), the greater the concentration of TEA added, the greater the pH of the base produced [27].

It can be said that the TEA concentration affected the pH value of the Potassium-Azeloyl-Diglycinate BB Cream product, and the storage carried out on the product affected the changes in the pH value.

Potassium-Azeloyl-Diglycinate BB cream stability evaluation

Stability test carried out by the Cycling Test method, namely the storage of cream at two extreme temperatures, is to see the effect of temperature on the separation of the cream phase. The results showed that all creams were stable and there was no phase separation before and after the cycling test.

The freeze thaw process might or might not result in phase separation depending on the cream's ability to recover immediately from the crystalline water pressure. During the freeze process, water crystals were formed which had a more regular and tighter structure, so that the cream could not flow [31, 32]. In the thaw process, the crystals would melt and return to spread in the system. If the speed of recovery from cream is slow, instability can occur [33]. The higher the product viscosity,

the smaller the dispersed and dispersing phase separation rate, so that the product is more stable [34].

In-vitro evaluation for Potassium-Azeloyl-Diglycinate BB cream with SPF

The SPF mechanism can counteract free radicals by absorbing and inhibiting the melanin pigment that can accumulate, so that it can inhibit the appearance of black spots caused by excessive UV exposure. UV protection can absorb at least 85% of sunlight at a wavelength of 290 - 320 nm for UV B, however, it can transmit light at a wavelength of more than 320nm for UV A [35]. Sunscreen is said to provide protection if it has an SPF value of at least 2 and a good category if the test sample has an SPF value >15, which is included in the ultra-protection category sunscreen. This is because an SPF value above 15 will be able to provide better protection from the risk of long-term skin damage, such as skin cancer. In addition, SPF >15 can protect the skin longer than sun exposure [36]. The results showed in **Table 6**.

Table 6. In-vitro SPF Test Results for Potassium-Azeloyl-Diglycinate BB Cream

Formula	SPF Test (2000 ppm)		
	Before Cycling	After Cycling	SPF Value Category (before to after cycling test)
F1	5.35 ± 2.39	3.08 ± 1.17	Medium to Minimal
F2	9.86 ± 0.41	7.22 ± 2.78	Maximum to Extras
F3	11.11 ± 4.22	7.73 ± 2.00	Maximum to Extras

The SPF test results showed that the Potassium-Azeloyl-Diglycinate BB cream, which was Formula 3 (F3), had the highest SPF value, namely 11.11; while the lowest result was obtained in the Formula 1 (F1), namely 5.35. Several factors can influence the determination of the SPF value, among others, the absence of the application of a proper method for evaluating sunscreen products, the combination, and concentration of ingredients, the use of inappropriate solvents, the type of emulsion, the effects and interactions of other additional components such as esters, emollients, and emulsifiers used in formulations, the addition of other active ingredients, system pH, viscosity and rheological properties of emulsions, among other factors, that can increase or decrease the UV absorption of any sunscreen [37]. Therefore, the formulator must understand the principles of physics, not only the UV absorbance of the active substance but also other additional components such as esters, emollients, and emulsifiers used in the formulations. Whereas, sunscreen can interact with other additional components, and this interaction can affect the effectiveness of sunscreen. The application of sunscreen must be done properly and in the correct amount, about 2g/cm² [37].

Concentration is one of the factors that can influence the determination of the SPF value. This factor can increase or decrease the UV absorption of sunscreen products. Based on the data above, it can be concluded that the sunscreen ability of the Potassium-Azeloyl-Diglycinate BB Cream product is influenced

by differences in TEA concentrations. This can be due to TEA functions as an emulgator or emulsifying agent that can package the active substance molecules on the surface to make them stronger so that they can increase the strength of the interface layer as well as increase the stability and effectiveness of the product.

Potassium-Azeloyl-Diglycinate BB cream hydration ability evaluation

Research has been conducted on women aged between 20 - 35 years, and this is because, in addition to being more cooperative, the process of skin thinning and drying occurs faster in women than men [38]. The balance of the testosterone, estrogen, and progesterone hormones in women and men is also different. Testosterone and estrogen affect sebum production [39]. Thus, women are more suitable as research subjects to use the best formula BB Cream (Formula 2) which will be tested for its moisturizing effectiveness.

Skin moisture is a condition that is influenced by the moisture content in the skin. If the skin's moisture level is low or the water content is inadequate, it can cause xerosis cutis or dry skin. Dehydration of the skin is a condition when the water content in the outer layer of the skin is less than 10% while under normal conditions, the water content in the outer layer of the skin reaches 30%. A decrease in water content in the stratum corneum to less than 10% will cause the skin to look scaly, rough, and dry [40]. The reference value of water content in the skin measured by the Skin Analyzer on the arm 30%-50%, wrist 35%-45%, face 30%-50%, and forehead 30%-50% [38].

The skin naturally has a mechanism to prevent a lack of water content in the stratum corneum in the presence of an intracellular compound, Natural Moisturizing Factor (NMF) produced by the lamella body is very hygroscopic so that it attracts water to maintain corneocyte turgidity. The skin also loses water every day, or commonly known as Trans-Epidermal Water Loss (TEWL), which is the amount of water that evaporates into the external environment due to a water vapor pressure gradient. The measurement results were calculated for the average value in each group. The average value was then compared, before and after the use of the product. If the decrease in the average TEWL value between before and after treatment is $\geq 8\%$, then there is a difference in the value of skin moisturizer due to product treatment, which means that the product can increase skin moisture. The result of the percentage of moisture obtained is then processed based on the following scale [40]: Dry skin moisture level category: 0-45%, normal or humid: 46%-55%, and very humid: 56%-100%.

Humectants are materials that absorb water. The water that is taken to keep the skin moist comes from the deeper layers of the epidermis, less often from the environment. Thus, the presence of humectants in the product, both glycerin and propylene glycol, keeps the skin surface moist, however, can also dry out the deeper layers of the body [38]. Another ingredient that can prevent the skin from becoming dry due to exposure to UV rays,

experienced by the panelists, during outdoor activities in the product is derived from the active ingredient, namely Potassium Azeloyl Diglycinate, which also functions as an antioxidant. Antioxidants are substances that give electrons to free radicals and help stabilize free radicals so that they protect cells from damage [5]. The results showed in **Table 7**.

Table 7. Pretest and Posttest Data Results of Formula 2 Moisture Value

Description	Water Content		Oil Content	
	Pre (Day-0)	Post (Day-7)	Pre (Day-0)	Post (Day-7)
Mean	37.58	42.4	16.12	20.28
SD	6.74	9.16	3.31	5.83

The factors causing the difference in the percentage of panelists' skin moisture were due to the influence of hormones, and different natural skin moisture (NMF) of the panelists, as well as external influences such as sunlight and panelists' activities that were not the same [38]. The results of the pre-test and post-test analysis of Formula 2 obtained sig. > 0.05 , so, it can be concluded that the average skin moisture, before and after using Potassium-Azeloyl-Diglycinate BB Cream Formula 2, was the same. In addition, the difference in water content between pre and posttest was not $\geq 8\%$, which means that, according to research by Patzelt *et al.*, (2011) it could not be stated that the product was not able to increase skin moisture [39].

Conclusion

1. The difference in the concentration of the emulgator (triethanolamine) in each formula affects the adhesion, the viscosity, and pH increase, yet the spreadability decreases. The storage conditions at a temperature of $4 \pm 2^\circ\text{C}$ and $40 \pm 2^\circ\text{C}$ affect the results of the chemical properties test on the Potassium-Azeloyl-Diglycinate BB Cream.
2. The Potassium-Azeloyl-Diglycinate BB Cream is known to have the SPF value with *moderate* category, namely in the Formula 1, and Formula 2 and 3 with *maximum* category; and there is a decrease in the value after cycling test, in which the SPF value in the Formula 1 with *minimal* category, and the Formula 2 and 3 with *extra* category.
3. Formula 2 with 4% TEA concentration has the best stability of physical and chemical properties during the test time of \pm two weeks using the cycling test method.
4. The Potassium-Azeloyl-Diglycinate BB Cream Formula 2 is known to affect the humidity, it is just that the results given are less than optimal since they do not provide a significant change between the results of the pre and posttests.

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