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Formulation and Determination of Sun Protection Factor (SPF) of Sunscreen Gel Preparations Containing Epigallocatechin Gallate (EGCG) Using the Spectrophotometric Method

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ABSTRACT

Long-term exposure to the sun causes various kinds of abnormalities in human skin so it requires skin protection from the outside. Sunscreen is a cosmetic therapy that can shield the skin and face against UV radiation, including the potential to induce accelerated ageing, sunburn, and skin cancer. Tea leaf-derived polyphenol compounds, particularly EGCG, have the most potent and plentiful antioxidant action. The objective of this work is to investigate the impact of variations in epigallocatechin gallate (EGCG) levels on the physical properties and effectiveness of sunscreen gel. This study used an experimental design with four EGCG gel formulas (negative control (0%), F1 (0.1%), F2 (0.2%), F3 (0.4%)) and tested with a UV-Vis spectrophotometer with the resulting absorbance calculated using the Mansur formula.The results showed that the SPF value increased with increasing EGCG concentrations (negative control, F1, F2, F3, positive control: 18.94 (moderate), 22.55 (moderate), 29.10 (moderate), 41.58 (high), 48.11 (high)). The highest SPF value on Formulation 3 indicates a high level of sunscreen capability. EGCG gel with a concentration of 0.4% has good physical characteristics (slightly thick texture, odorless, transparent white color, homogeneous, pH 6.57, adhesion 3.30, diffusion 6.36) and the highest SPF value (41.58). The statistical test using Kruskall-Wallis followed by the Man-Whitney test showed a significant difference in a p-value of 0.05.

Keywords : EGCG, Sunscreen Gel, SPF

INTRODUCTION

Prolonged exposure to sunlight can cause various skin diseases in humans, such as skin cancer, reduced elasticity, and premature aging, which are common health problems in individual life (Istighfarini, Elma Tri et al., 2021). Public health disorders caused by the penetration of UV radiation from the sun to the earth's surface. The wavelength range of ultraviolet light is 200 to 400 nanometers. There are basically three wavelength groups in the ultraviolet (UV) spectrum. Three bands of ultraviolet light: band C (200-290 nm), band B (290-320 nm), and band A (320-400 nm). There are two parts of the ultraviolet (UV) A spectrum: UV A1 (340–400 nm) and UV A2 (320–340 nm). Windows and clouds are not shields from ultraviolet A radiation. UVB rays can reach the dermal layer and cause damage there. Prolonged exposure to sunlight can cause sunburn and, in extreme cases, blistering. (Shoviantari, et al. 2020).

Various techniques can be used to reduce the adverse effects of UV radiation. Dermatological protection against UV radiation is achieved through physical and chemical means. Effective physical protection can be achieved by using an umbrella, hat, or jacket. Chemical protection can be achieved by using sunscreen skin care products (Sari, et al. 2020). Sunscreen is a cosmetic component that can block the entry of UV radiation into the skin either physically or chemically. An indicator of sunscreen effectiveness is the Sun Protection Factor (SPF) rating. The formula is as follows: divide the amount of UV energy needed to obtain a minimum erythema dose on skin protected by sunscreen by the amount of UV energy needed to obtain a MED on unprotected skin. The lowest exposure time or the amount of ultraviolet light needed to cause skin redness is called the erythema trigger dose (MED). (Pratama et al., 2015).

vegetables, epigallocatechin gallate is only found in tea. Furthermore, epigallocatechin gallate is a very powerful and very common antioxidant molecule. Based on the description given, EGCG was formulated in gel form with different concentrations. The purpose of this formula was to determine the concentration of EGCG that produces good physical properties observed in organoleptic testing, namely homogeneity, pH, spreadability, adhesion, and high potential for sun protection.

METHODS

Laboratory experiments are the method of choice for this research.

TOOLS

Analytical scales, measuring cups, measuring cups, horn spoons, porcelain cups, stirring rods, droppers, filter paper, mortars, stampers, and UV-Vis spectrophotometry are some of the tools used in this work.

MATERIALS

The materials used in this study include distilled water, glycerin, methyl paraben, carbopol 940, HPMC, triethanolamine, and tea media.

1. Formulation

No	Nama Bahan	Kontrol Negatif (%)	Formulasi I (%)	Formulasi II (%)	Formulasi III (%)
1	EGCG (M******)	0	0.1	0.2	0.4
2	Karbopol 940	0.5	0.5	0.5	0.5
3	HPMC	0.5	0.5	0.5	0.5
4	Propilenglikol	10	10	10	10
5	Metil paraben	0.18	0.18	0.18	0.18
6	Propil paraben	0.02	0.02	0.02	0.02
7	Trietanolamin	3 tetes	3 tetes	3 tetes	3 tetes
8	Asam askorbat	1	1	1	1
9	Aquadest ad	100	100	100	100

. Physical Quality Test of Preparations

a. Organoleptic test

Organoleptic testing is carried out to assess the visual characteristics of a preparation by systematically examining its color, aroma, and texture. (Akbar et al., 2020).

b. Homogeneity test

Homogeneity checks are carried out visually by installing another glass preparation and then conducting an examination. Observations are made by ensuring that there are particles that have not been mixed evenly. (Akbar et al., 2020).

c. pH test

To measure pH, a regular pH meter is used. To start the pH test, a buffer solution with a pH of 4.01 is used to calibrate the pH meter. A solution of 0.1 grams in 100 milliliters of distilled water used to make gel. After immersing the electrode in the solution, the pH is determined. The pH of the skin determines the pH range that all formulations must adhere to, which is 4.5-8.0. (Akbar et al., 2020).

d. Adhesion Test

To conduct the adhesion test, one piece of glass is coated with a gel mixture weighing 0.25 grams and then covered with another piece of glass. A pressure of 1 kilogram is applied to the glass object for 5 minutes. After that, the glass object is placed on the adhesion tester and the load is increased. We measure the time it takes for the gel to detach between the two glass objects after applying a load of 80 grams to the tester. (Emelda, 2020). There are no specific criteria for the adhesion of semisolid preparations, although the resulting coefficient must exceed 1 second. (Kurniasari, F. 2020).

e. Spreadability test

The spreadability test is carried out to evaluate the capacity of the gel preparation to spread evenly on the skin surface, as this can affect the rate of absorption and release of active ingredients. A 0.5 gram gel preparation was positioned on a glass surface and supported by another glass surface positioned above the sample. The gel diameter was determined by measuring the diameter length from various angles. Next, loads of 50 g, 100 g, 150 g, 200 g, and 300 g were applied to the gel and allowed to dry for 1 minute. Each additional load was measured for the gel diameter in the same manner as before. The optimal gel spread ranges from 5-7 cm. (Nurlely, 2021).

RESULTS

The purpose of this work is to assess the physical parameters and calculate the SPF value of a sunscreen gel formulation containing Epigallocatechin gallate (EGCG), where the sample used is a product circulating in the community, namely EGCG branded M******. This sample was chosen because it has been clinically tested and is made from original green tea leaves without a mixture of other active compounds and is extracted so that it has a high Epigallocatechin gallate content. The dosage form chosen in this formulation is a gel form. This topical gel formulation is preferred because of its ability to produce a protective film layer when applied, its elasticity and effective drug release, as well as the attractive appearance of the preparation. The preparation of the gel preparation is made with the active substance The preparation of the gel preparation is made with the active substance Epigallocatechin gallate 0% as a negative control, Epigallocatechin gallate 0.1% as formulation one, Epigallocatechin gallate 0.2% as formulation two, Epigallocatechin gallate 0.4% as formulation three and sunscreen branded A******** as a positive control. For gel preparation, a combination of carbopol 940 and HMPC is needed as a gelling agent, TEA acts as an alkalizing agent to keep the pH stable in the solution formed. Distilled water as a solvent, propylene glycol as a humectant, and methyl paraben and propyl paraben as preservatives. The low stability of epigallocatechin gallate is due to its susceptibility to oxidation and its capacity to penetrate the epidermis, which is the lowest layer. (Sugihartini, 2016). To avoid low stability, this study was added with 1% ascorbic acid. Research conducted by suguhatini 2016, The expiration date of green tea extract cream containing 1% ascorbic acid is longer than vitamin E. The reason is because ascorbic acid and EGCG are polar so they dissolve in water. Vitamin C acts as an antioxidant that is balanced with EGCG in the water phase, thus protecting EGCG from oxidative damage. Before being developed into a good dosage form, it will go through several tests to see the physical quality produced from the formulation being designed.

The purpose of the physical quality investigation is to produce an Epigallocatechin gallate gel formulation and assess its physical quality according to the Standards used. The physical quality analysis carried out in this work includes organoleptic tests, homogeneity, pH, adhesion, and spreadability.

A. ORGANOLEPTIC TEST

Organoleptic testing aims to provide a gel formulation with a visually attractive color, an aroma that is considered acceptable to consumers, and a form that is easy to use. It is important to consider the aesthetic value of the gel formulation, because it is a cosmetic preparation. Organoleptic evaluation of the sunscreen gel formulation containing epigallocatechin gallate (EGCG) was carried out by evaluating the texture, shape, odor, and color produced. The findings of the organoleptic investigation are shown in Table 1. Optimal requirements for organoleptic testing include a gel preparation that is transparent or clear and free from turbidity. (Kresnawati, Y. et al. 2022).

B. HOMOGENITY TEST

The results of the homogeneity test carried out on the sunscreen gel formulation containing epigallocatechin gallate (EGCG) are presented in table 2. The purpose of the homogeneity test is to assess the level of mixing between the components used in the gel preparation. This is necessary because the gel preparation should not have visible particle grains or hard lumps when touched. (Kresnawati, Y. et al. 2022). Homogeneous gel preparations have several positive effects on the skin, such as even distribution of active ingredients, a smoother and easier application sensation, a more aesthetic appearance, and better stability, thereby increasing the effectiveness of the gel and patient compliance with treatment, as well as increasing the attractiveness of the product to consumers. If the resulting formulation is not homogeneous, it will cause negative effects on the skin, such as uneven distribution of active ingredients, a rough and uncomfortable application sensation, an unaesthetic appearance, and lower stability. These effects can reduce the effectiveness of the gel and patient compliance with treatment, as well as reduce the attractiveness of the product to consumers.

C. pH TEST

A pH analysis is performed to ensure that the pH level of a formulation is suitable for skin application. The optimal pH range for topical formulations is set at 4.5-8.0 (Akbar et al., 2020). Excessive acidity in the preparation can cause irritation, while alkaline conditions in the preparation can cause scaly skin, dry quickly, and potentially have an impact on elasticity. From the results obtained, the epigallocathecin gallate gel preparation has met the standard requirements, namely in the range of 4.5 - 8.

Based on the results of the pH test, further data analysis was carried out using SPSS. The difference in EGCG concentration between the negative controls, F1, F2, and F3, as well as the positive control, significantly affected the pH of the preparation. Statistical analysis was carried out using the Kruskall Wallis test, with a significance level of 0.009 <0.05, indicating that there was a significant variation in each formula. Gel preparations with a pH that meets standards have several positive effects on the skin, such as maintaining the skin's pH balance, increasing the absorption of active ingredients, reducing the risk of skin irritation, and increasing comfort of use.

From the results obtained, the epigallocathecin gallate gel preparation has met the standard requirements, which is more than one second. The adhesive power of a preparation is closely related to the viscosity of the preparation, where high viscosity produces high adhesive power. A higher gel adhesive value corresponds to a stronger bond between the gel and the skin, which facilitates increased drug absorption through the skin. Based on the results of the adhesive test, further data analysis was carried out using SPSS. The adhesive power of the preparation was significantly influenced by variations in EGCG concentration between negative controls, F1, F2, and F3, and positive controls. Statistical analysis was carried out using the Kruskall Wallis test, with a significance level of 0.014 <0.05, indicating that there was a significant variation in each formula.

D. ADHESIVE POWER TEST

The purpose of the adhesion test on the sunscreen gel formulation containing epigallocatechin gallate (EGCG) is to assess the gel's ability to adhere to the skin for a certain duration, maintain optimal drug delivery and achieve a value exceeding one second. (Kurniasari, 2020).

From the results obtained, the epigallocatechin gallate gel preparation has met the standard requirements, which is more than one second. The adhesive power of a preparation is closely related to the viscosity of the preparation, where high viscosity produces high adhesive power. A higher gel adhesive value corresponds to a stronger bond between the gel and the skin, which facilitates increased drug absorption through the skin.

Based on the results of the adhesive power test, further data analysis was carried out using SPSS. The adhesive power of the preparation was significantly influenced by variations in EGCG concentration between negative controls, F1, F2, and F3, and positive controls. Statistical analysis was performed using the Kruskall Wallis test, with a significance level of 0.014 < 0.05, indicating that there was significant variation in each formula.

E. SPREADING POWER TEST

The spreading power test on sunscreen gel preparations containing epigallocatechin gallate (EGCG) was carried out to assess the extent to which the gel preparation can be evenly distributed on the skin surface. The spreading power of a drug can affect its absorption and the rate of release of active compounds at the application site. The optimal and desired formulation should be easy to stick to the skin and comfortable enough to apply. The specifications for conducting a comfortable spreading power test in practical applications range from 5 to 7 cm (Kurniasari, 2020). Effective spreading power is an important factor in the development of gel preparations. Spreading power that is less than that recommended in the literature can cause several negative effects on the skin, such as uneven distribution of active ingredients, difficulty in application, undesirable cosmetic effects, and potential skin irritation. In addition, spreading power that exceeds the range recommended in the literature can cause several negative effects on the skin, such as a sticky and uncomfortable sensation, potential skin irritation, excessive absorption of active ingredients, and difficulty in cleaning.

CONCLUSION

Physical quality tests of the sunscreen gel formulation with Epigallocatechin gallate (EGCG) showed good physical quality, as indicated by findings that were within the range reported in the literature.

1. There is a significant influence from providing counseling by pharmacists on compliance with taking medication for hypertension patients at the Ngletih Community Health Center as proven by the Wilcoxon test results which obtained a p-value of 0.000, which is ≤ 0.05.

2. Of the 130 patients who were respondents in this study, before and after being given counseling, their compliance increased by 1.4. There was 1 respondent (0.8%) with a low level of compliance, 50 respondents (38.5%) with a medium level of compliance, and as many as 79 respondents (60.8%) with a high level of compliance.There is a significant relationship between gender and medication adherence with a p-value of 0.007 ($p<0.05$). There is also a significant relationship between age and medication adherence with a p-value of 0.017 ($p<0.05$). There is no significant relationship between education level and medication adherence with a p-value of 0.829. There is no significant relationship between employment level and medication adherence with a p-value of 0.264. There was no significant relationship between the length of diagnosis and adherence to taking medication with a p-value of 0.158

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