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Research Article

A Dermatological Safety Test of a Face Serum Formulation Derived from Honey and Propolis of Stingless Bee from East Kalimantan

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ABSTRACT

Skincare, which is a type of cosmetics, is an essential component in the process of maintaining and caring for the skin. It is known that the skin quickly absorbs the tiny molecular structure of serum. Stingless bees, widespread in East Kalimantan and Indonesia, benefit the skin's health by producing honey and propolis. This research aims to demonstrate that a face serum derived from honey and propolis of stingless bees from East Kalimantan is safe for use on the skin using dermatological standards. Here we will see whether there are allergic reactions and irritation from using facial serum. Using the Repeated Open Application Test (ROPT) technique, 20 volunteers were subjected to applying a face serum containing honey and stingless bee propolis. The serum was given to the upper arm twice daily for seven days. As part of the test, allergic reactions were evaluated using the system developed by the International Contact Dermatitis Research Group (ICDRG), and irritating reactions were evaluated using the Primary Irritation Index (PII). The results showed that on the first day, four of the volunteers reported moderate irritation reactions. Consequently, they scored 0.7, indicating they suffered minor irritation. On the other hand, the reactions of the remaining 16 volunteers were typical. Twenty participants had normal skin from the second treatment until the seventh day. The overall findings show that the facial serum based on honey and kelulut propolis from stingless bees from East Kalimantan showed a mild irritation reaction at the beginning of use and was safe to use in subsequent uses.

Keywords: Face serum, Honey, PII, Propolis, ROPT, Stingless bee

Introduction

Serum is a cosmetic product with a high concentration that has low viscosity properties (Priani et al., 2019). The choice of serum is

better than using other dosage forms such as creams, ointments, and gels. Serum is considered a tiny molecule, so it is easily absorbed by the skin (Cahya & Fitri, 2020).

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Many stingless bees from East Kalimantan are now kept by beekeepers in Samarinda, Kutai Kartanegara, Balikpapan, North Penajam Paser, Paser, Bontang, Sangatta, West Kutai and Berau (Saputra et al., 2021). One example of a stingless bee is the *Heterotrigona itama* species. Stingless bees are different from regular bees because they are smaller and do not have stingers (Afrilia et al., 2022). Stingless bee honey is the most popular honey at the moment, and almost everyone knows its properties of honey, which are very beneficial for health, for example, for strengthening the body's immunity, healing wounds, preventing cancer, and antiviral (Askary et al., 2022).

Besides honey, stingless bees also produce propolis obtained from beehives. Its use as an innovative preparation or product still needs to be developed (Kustiawan et al., 2023). Propolis from the *Tetrigona apicalis* species comes from stingless bees (Awang et al., 2018). Propolis extract has been widely used to treat skin wounds and as a cosmetic ingredient (Askary et al., 2022).

An allergy or hypersensitivity reaction is a condition with increased reactivity or sensitivity to antigens that have been previously exposed or known (Baratawidjaja & Rengganis, 2012). If someone is repeatedly exposed to an allergen, an immune reaction will appear, ranging from mild to severe, which can have harmful consequences for the body (Sherwood, 2014). Irritation is a reaction on the skin to exposure to chemicals such as strong alkalis, strong acids, solvents, and detergents. Irritation can cause various kinds of reactions on the skin, including erythema and edema (Untari & Robiyanto, 2018). Topical applications encounter challenges, including skin irritation and difficulties in achieving optimal skin permeation (Aydin et al., 2024).

This research was conducted to test the dermatological safety of using facial serum bio-cosmetic products containing honey and propolis from stingless bees from East Kalimantan by conducting dermatological safety tests using the Repeated Open Patch Test (ROPT). This test was conducted to determine allergic reactions and irritation on the skin of the upper arms of volunteers who were given this facial serum.

The treatment was given only to male volunteers and not women because men tend not to use other skin care products, which can affect the test results. Also, for women, the test results can be affected by hormonal factors during menstruation (Gianfaldoni et al., 2021).

Methods

Time and Place

The research briefing was carried out at the Mulawarman University Clinic. The serum was used by volunteers in their respective homes, and monitoring and assessment of skin reactions were seen through photo documentation sent by each volunteer, starting from 5-11 December 2023.

Population and Sample

The research subjects used in this test were male volunteers who were students at Mulawarman University without any inclusion and exclusion criteria. The sample size for allergic and irritation reactions used in this study was twenty (20) male volunteers who were students at Mulawarman University. The sample size was adjusted to the number of serum preparations available.

Measuring Instruments

The instrument used in this research was the ICDRG (International Contact Dermatitis Research Group) scoring system to assess allergic reactions and skin irritation using the PII (Primary Irritation Index). The assessment system is based on scientific journal references and has been validated by validators from the faculty.

Data Analysis

This research is experimental research. The research design used Post-Test Only Control Group Design, where this study only assessed the test results at the end after the research subjects were given treatment.

Result and Discussion

After observing for seven days, the results showed that 4 (20%) volunteers experienced complaints of redness, itching, and a burning

sensation on their skin on the first use of the serum on the first day after 2 minutes to 1 hour of use. However, these complaints were felt briefly and disappeared within a few minutes. Moreover, they did not complain of reactions on the second to seventh day of use. Meanwhile, 16 (80%) other volunteers from the first day of

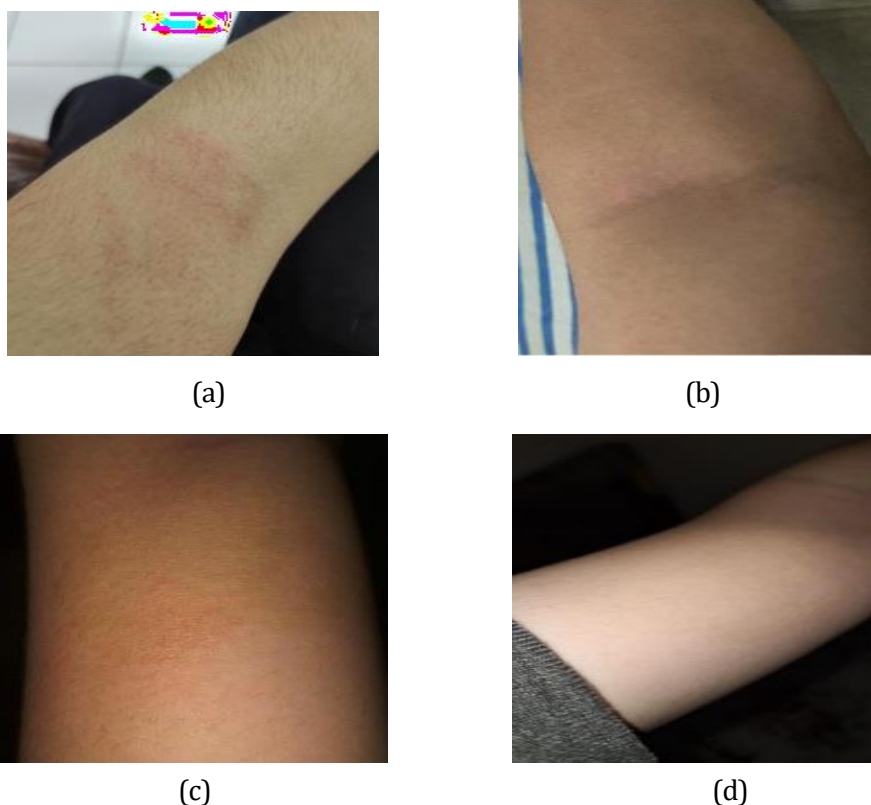
use until the seventh day did not complain of any reactions. The 20 volunteers routinely sent documentation of their skin for seven days immediately after using the serum and 1 hour after using it. The following is documentation of one volunteer who shows expected results and has no complaints.



(a) (b)
Figure 1. (a) shows immediately after application, (b) shows 1 hour after application

The skin looks normal immediately after applying the serum. No erythema, papules, edema, or ulcers were seen. The following is an example of documentation of 4 volunteers who

experienced mild irritation reactions on the first day of use, which can be seen in the image below.



(a) (b) (c) (d)
Figure 2. Photos a, b, c, and d show the reaction on the skin after 1 hour of using the serum

In photo (a), the volunteer's skin looks well-defined red, and there are complaints of itching after using the serum for 1 hour. (b), The volunteer's skin looked well-defined red after using the serum for 5 minutes. (c), the volunteer's skin looks well-defined red, and there are complaints of itching after using the serum for 2 minutes. Moreover, in photo (d), the

volunteer's skin looks reddish and complained of itching and burning after using the serum for 1 hour.

The results of dermatological safety reaction testing after seven days using the ROPT method with an assessment based on the ICDRG score on 20 volunteers can be seen in the table below.

Table 1. Table of dermatological safety test results based on the ICDRG scoring system

Skin Reactions	Day						
	1	2	3	4	5	6	7
No reaction	16	20	20	20	20	20	20
Erythema	4	(-)	(-)	(-)	(-)	(-)	(-)
Infiltration	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Papules	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Edema/vesicles	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Ulcers/bullae	(-)	(-)	(-)	(-)	(-)	(-)	(-)

From observations for seven days, the results showed that 16 volunteers did not experience reactions on their skin, and four volunteers experienced erythema reactions on the first day of use. However, on the second to seventh days, they were expected. After using the ROPT method and an assessment based on the ICDRG score above, the results of observations

can be interpreted as doubtful reactions, where there is only macular erythema.

The results of dermatological safety reaction testing after seven days using the ROPT method with an assessment of the PII based on the presence or absence of erythema and edema can be seen in Table 2 and Table 3 below.

Table 2. Table of dermatological test results for erythema assessment

Skin reactions	Scale	Day						
		1	2	3	4	5	6	7
There is no erythema	0	16	20	20	20	20	20	20
Very mild erythema (barely visible)	1	0	0	0	0	0	0	0
Erythema is well defined	2	4	0	0	0	0	0	0
Moderate to severe erythema	3	0	0	0	0	0	0	0
Severe erythema (beef redness)	4	0	0	0	0	0	0	0

On the first day of observation, the results showed that 16 volunteers did not experience erythema (scale = 0), and four volunteers experienced well-defined erythema (scale = 2).

Moreover, the results showed that 20 volunteers did not experience erythema on days two to seven.

Table 3. Table of dermatological test results for edema assessment

Skin reactions	Scale	Day						
		1	2	3	4	5	6	7
No edema	0	20	20	20	20	20	20	20
Very mild edema (barely visible)	1	0	0	0	0	0	0	0

Skin reactions	Scale	Day						
		1	2	3	4	5	6	7
Mild edema (edge of a well- defined area with definite increase)	2	0	0	0	0	0	0	0
Moderate edema (raised about 1 mm)	3	0	0	0	0	0	0	0
Severe edema (raises > 1 mm and extends beyond the exposed area)	4	0	0	0	0	0	0	0

From observations for seven days, it was found that 20 volunteers did not experience edema. From the results obtained, it can be concluded that four volunteers experienced irritation reactions in the form of erythema on the first day of using the serum and were not accompanied by edema. To conclude the irritation category, the results of the erythema scale obtained during observation will be included in the PII formula. From calculating the irritation scale for the four volunteers above, a score of 0.7 was obtained, which means the volunteer experienced a mild irritation reaction (slight irritation) with a score range for mild irritation, namely 0.5-1.9. Sixteen volunteers did not experience reactions such as erythema, infiltration, papules, edema/vesicles, or ulcers/bullae. Meanwhile, four volunteers experienced erythema reactions on the first day of serum use. During seven days of observation, 16 volunteers did not experience erythema or edema, while four volunteers experienced erythema on day 1 of observation.

In this study, four volunteers who experienced erythema reactions in the first 24 hours of using the serum received an irritation rating scale of 2, defined as well-defined erythema without edema. This scale was included in the PII calculation formula to obtain a score of 0.7, indicating that the four volunteers experienced a slight irritation reaction.

From the second serum application until the seventh day, all volunteers experienced no reaction and obtained the expected skin results. From the data obtained, it can be concluded that the four volunteers who experienced redness, itching, and a burning sensation on their skin experienced mild irritation reactions. This is supported by the explanation of the irritation theory in Untari's research (2018), which explains that irritation will cause reactions on the skin after a few minutes to an

hour after a preparation is applied to the skin (Untari & Robiyanto, 2018). The reactions found in the four volunteers cannot be considered allergic because they usually occur in the first day to three days after contact with the allergen. Allergic reactions caused by cosmetics include delayed-type allergic reactions (Sherwood, 2014). This is also supported by the results of the ICDRG scoring system, which shows that the reaction results in 4 volunteers included doubtful reactions.

In this study, the cause of mild irritation reactions in the form of erythema in 4 volunteers was unknown when using the serum. In research, Khaira (2022) explained that the suitability of the skin's pH to the pH of the topical preparation influences the skin's acceptance of the preparation. If the pH of a preparation is too acidic compared to the skin's pH, it is feared that it will irritate the skin, and if it is too alkaline, it is feared that the skin will become dry or scaly. The requirements for the pH of cosmetic preparations for good skin follow the natural pH of the skin, namely in the range of 4.5-6.5 (Khaira et al., 2022). In honey and propolis serum, the pH was within normal limits. Other factors, such as using cosmetics incorrectly or excessively and poor processing, can also cause skin irritation.

Apart from the pH factor, chemical-based cosmetics are considered unsafe for use on the skin. Based on the regulations of the Food and Drug Supervisory Agency (BPOM) of the Republic of Indonesia in 2006 and 2007, cosmetic ingredients such as Mercury (Hg), hydroquinone > 2%, and the dye Rhodamine B are ingredients that are prohibited for use in cosmetics (Astuti et al., 2016). It should also be noted that these ingredients can only be given with a doctor's prescription (Suhartini et al., 2013). Stingless bee honey and propolis serum contain several additional chemicals, such as tea

tree oil, salmon DNA, niacinamide, and hyaluronic acid. These ingredients have been widely used in skincare products, proven safe to use, and adjusted to specific indications and dosages required by the skin. Other factors, such as using cosmetics incorrectly or excessively and poor processing, can also cause skin irritation. In research, Hairiyah and Nuryati (2020) explain that Triethanolamine (TEA) can cause a burning sensation on the skin and can cause allergic reactions. TEA is an emulsifier and surfactant as a pH stabilizer in cosmetic products (Hairiyah & Nuryati, 2020).

So, in research on the dermatological safety test of facial serum containing honey and propolis of stingless bees, it was proven that it could cause a mild irritation reaction in 4 out of 20 volunteers at the start of using the serum, where this reaction could be caused by several factors such as using the serum incorrectly or excessively, poor serum processing, and the presence of additional ingredients used as product pH stabilizers.

Conclusion

Dermatological safety tests of honey and propolis-based face serum from stingless bees from East Kalimantan showed mild irritation reactions in 4 out of 20 volunteers at the start of use. They were safe to use in subsequent uses.

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