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FORMULATION AND EVALUATION OF SACHA INCHI OIL LIP BALM PREPARATIONS WITH CONCENTRATION VARIATIONS OF CERA ALBA AND LANOLIN AS LIP BALM

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ABSTRACT

Lip balm is used on lips that require protection, such as when humidity is low, to prevent the evaporation of water and epithelial cells on the lip mucosa. The active substance used in making this lip balm is Sancha inchi oil, which is a cold-pressed oil from the seeds of Plukenetia volubilista. This oil contains omega 3 (40–50%) and omega 6 (30–40%), as well as lower oleic acid (10%) than olive oil. Natural antioxidants, including tocopherols and polyphenols, have also been found in Sacha Inchi oil. Sacha inchi oil has a fatty acid ratio and phytochemical composition, it can be used as a cosmetic ingredient as an emollient and skin protector. An experimental laboratory method was used for this study. The research was carried out by preparing lip balm from various ingredients containing the active ingredient Sacha inchi oil (*Plukenetia volubilis L*) at a concentration of 15%, as well as varying concentrations of cera alba (range 5-25%) and lanolin (range 2-10%) as bases and additional ingredients for preparations, whose optimization had been determined using the simplex lattice design method. The aim of this study was to identify the lip balm formulation from Sacha inchi oil and identify the effect of changes in the concentration of cera alba and lanolin based on the results of the preparation evaluation. The results of this test show that sacha inchi oil can be used as an active lip-moisturizing agent in lip balm preparations. The test evaluation showed that all formulations had a range of standard values and met the requirements, while the optimum formula obtained from the Simplex Lattice Design was F3, F4, and F7 with concentrations of Cera alba 23% and Lanolin 2%.

Keywords: Cera alba; Lanolin; Lip balm.

INTRODUCTION

Indonesia is a tropical country that receives sufficient sunlight. Sunlight is a vital source of energy for sustaining human existence. The sun emits several wavelengths of light, including both the visible and invisible spectra. The apparent emission of sunlight is ultraviolet (UV) radiation with a wavelength of 400 nm. Prolonged exposure to UV rays can harm the skin, particularly the lips, leading to dryness (Hapsah Isfardiyana et al., 2014).

The skin on the lips is thin. The skin of the lips lacks a protective barrier against UV radiation, making it vulnerable to damage from UV light. Exposure of the lips to UV radiation can result in chapped lips caused by breaking of the keratin surface. Prolonged exposure to UV radiation can harm keratin-producing cells on the lip surface, leading to burning and peeling of the skin. The absence of cells leads to lip cracking and dying (Hasanah, 2020).

A lip balm was used to avoid dry lips or moisturize them. A lip balm is applied to the lips to moisturize them by creating an oil coating that prevents moisture loss. A lip balm creates a protective barrier on the lips to shield them from external factors. Lip balm is often applied to the lips to protect them, especially under low humidity conditions, to prevent evaporation of water and epithelial cells on the lip mucosa (Dominica et al., 2023).

This lip balm contains the active component of Sacha Inchi oil. Previous studies have shown that Sacha Inchi oil seeds exhibit biological activity, indicating their potential as active ingredients and cosmetic additives. This suggests that Sacha Inchi oil seeds can be used for cosmetic development and innovation. Sacha Inchi oil seeds can serve as active compounds with anti-aging and antioxidant properties, as well as emollients that soften and smooth the skin, humectants, and penetration enhancers (Maya & Sriwidodo, 2022).

Currently, there is a lack of knowledge on the chemical components, physiognomic properties, and potential of Sacha inchi oil as an active ingredient in cosmetics, particularly lip balm production. There have been no published studies on this topic. This study aimed to investigate and present findings on the effects of Sacha Inchi oil in lip balm formulations.

Sacha inchi seeds have a higher omega-3 content (40%–50%) than olive oil, which has moisturizing activity, as well as ingredients such as tocopherol (vitamin E), flavonoids, and polyphenols as antioxidants. Sacha inchi seeds produce an IC50 value that is classified as very strong because of the chemical content, such as flavonoids and tannins, which play a role in preventing the formation and elimination of free radicals by inhibition of hydrogen peroxide, reducing the activity of iron ions to iron. vitamin E also exhibits antioxidant activity in biological systems by protecting unsaturated fatty acids from oxidation (Maya & Sriwidodo, 2022). Therefore, Sacha inchi oil is able to inhibit the formation of free radicals, which can damage the structure and layers of the skin. This enables it to act as a skin protector.

RESEARCH METHODS

The study was conducted in an experimental laboratory. The study involved creating lip balm formulations using various components with active compounds from Sacha Inchi Oil (*Plukenetia volubilis L*), with modifications in the proportion of cera alba and lanolin as bases and other ingredients, which was determined using a simplex lattice design. The results of the formulation with the simplex lattice design can be shown in **Table I**.

The independent variable in this study was the use of the active ingredient, Sacha Inci Oil (*Plukenetia volubilis L*), as a lip moisturizer. Lip balm preparations are made into eight formulas with varying concentrations of cera alba and lanolin. The dependent variable in this research is the physical characteristics test of herbal lip balm preparations as lip moisturizers, which include the organoleptic test, homogeneity test, pH test, spreadability test, adhesion test, and moisture test.

Equipment and Materials

Equipment

The equipment utilized included digital scales, a 10 ml measuring cup, a drip pipette, a heated plate, a horn spoon, a 50 ml beaker glass, a watch glass, a pot lip balm, a pH metre, a stirring rod, a ruler, spreadability testing equipment, adhesion testing equipment, and a prepared glass.

Materials

Table I. Standard Grade Range of Materials Used

Standard materials used			
Material	**Benefit**	**Material Standards**	**Reference**
Sacha Inci Oil	Active substance	-	-
Cera alba	Base	5-25%	-
Lanolin	Humectant	2-10%	-
Nipagin	Preservative	0.02%-0.3%	HOPE 6th Edition
Vaseline album	Emollient	2-10%	HOPE 6th Edition
Butyl hydroxy Toluene	Antioxidant	0.05%	HOPE 6th Edition
Olive oil	Emollient	-	-
Lemon essential oil	Aroma	-	-

	Std	Run	Component 1 A:Cera alba %	Component 2 B:Lanolin %
	5	1	19	6
	2	2	15	10
	1	3	23	2
	8	4	23	2
	7	5	15	10
	4	6	17	8
	6	7	23	2
	3	8	21	4

Figure 1. Optimization of Cera alba and Lanolin Ingredients in SLD

Table II. Concentration of Ingredients Used in Each Formula

Bahan	F1	F2	F3	F4	F5	F6	F7	F8
Sacha Inchi Oil	15%	15%	15%	15%	15%	15%	15%	15%
Cera alba	19%	15%	23%	23%	15%	17%	23%	21%
Lanolin	6%	10%	2%	2%	10%	8%	2%	4%
Nipagin	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
Vaseline album	10%	10%	10%	10%	10%	10%	10%	10%
BHT	0,05%	0,05%	0,05%	0,05%	0,05%	0,05%	0,05%	0,05%
Olive oil	Ad 20	Ad 20	Ad 20	Ad 20	Ad 20	Ad 20	Ad 20	Ad 20
Lemon essensial oil	5 tetes	5 tetes	5 tetes	5 tetes	5 tetes	5 tetes	5 tetes	5 tetes

Procedure

In the first step, 1 g of cera alba was warmed in a water bath at 100°C until melting, and 0.025 gram of butyl hydroxy toluene was added. Combine 0.5 g lanolin, 0.5 g album vaseline, and 0.075 ml of sacha inchi oil in a beaker in a water bath until melting. The temperature of the water bath was then reduced to 90°C. Nipagin (0.01 grammes) was added as a preservative to the lip balm mixture, followed by the addition of 20 millilitres of olive oil. Blended lemon-flavored essential oil was added to the homogenous mixture to enhance the scent of the lip balm being prepared. Once lip balm preparation is completed, it is transferred into a tube and allowed to firm. The lip balm formulation is now available for evaluation.

Evaluation of the preparation of lip balm

1. Organoleptic Test
   Organoleptic testing evaluates the efficiency of preparations using human senses as the primary technique. The tests involved examining the colour, shape, and odour of the preparation.
2. Test Homogeneity
   The samples were placed on a glass slide and meticulously examined for the presence of large granules. The presence of coarse granules signifies a lack of homogeneity in the preparation, whereas the absence of coarse grains indicates homogeneity.
3. pH Test
   The test utilizes a pH metre calibrated with Aquadest. If a pH meter can provide a standard pH value, it is deemed suitable for use. The sample was then weighed at 1 gramme, combined with 10 ml of distilled water, and cooked on a hot plate. Once the electrode reached room temperature, it was immersed in preparation. The pH of the preparation must fall within the lip pH range of 4.5-7.0 to fulfil. criteria.

4. Spread Power Test
   The test involved placing a sample (0.5) on a watch glass with a closed scale paper base and allowing the lip balm to stand for 2 minutes. The diameter of the lip balm spread was measured using a ruler and replicated three times. The lip balm meets the Indonesian National Standard and has a spreading capability ranging from 5 to 7 cm.
5. Adhesion Test
   Lip balm samples weighing 0.25 grammes were placed on an object glass or a watch glass. The two watch glasses were permanently joined via fusion. The object was subjected to a 1 kg weight for 5 minutes before being freed. The glass items were loaded at 80 g and the time taken for their release was recorded.
6. Irritation Test
   During the irritant test, an open patch test was conducted on the forearms of 24 participants. They were required to meet the specific parameters and provide a written declaration. The open paste test involves applying the preparation to an adhesion area measuring approximately 2.5 * 2.5 cm and then evaluating the subsequent reaction without covering it. The irritation test was conducted three times daily for two consecutive days. Panelists must be women between the ages of 20 and 30, in good physical and mental health, without any history of allergic illness, and willing to participate as replies. The test revealed erythema, papules, vesicles, and oedema (Imani, 2022).

Data Analysis

The obtained data were tested using the Design Expert application with a Simple Lattice Design method.

RESULTS AND DISCUSSION

Organoleptic Test

Table III. Organoleptic Test Results Formulation of lip balm preparations

Formulas	Organoleptic Test		
	Colour	Smell	Texture
F1	Cloudy yellow	Citrus lemon essential oil	Semi-solid
F2	Cloudy yellow	Citrus lemon essential oil	Semi-solid
F3	White bone	Citrus lemon essential oil	Semi-solid
F4	White bone	Citrus lemon essential oil	Semi-solid
F5	Cloudy yellow	Citrus lemon essential oil	Semi-solid
F6	Cloudy yellow	Citrus lemon essential oil	Semi-solid
F7	White bone	Citrus lemon essential oil	Semi-solid
F8	Cloudy yellow	Citrus lemon essential oil	Semi-solid

An organoleptic test for lip balm preparation was conducted to visually assess characteristics such as colour, odour, and dose form. The findings of the study involving 8 different lip balm recipes are shown in **Table III**. The eight compositions demonstrate a resemblance in odour with citrus lemon essential oil and texture since both are semi-solid. The colour test differed in numerous aspects among the eight formulae. Formulae F3, F4, and F7 yield a white bone color, while formulae F1, F2, F5, F6, and F8 result in a murky yellow hue. This may be attributed to variations in the concentrations of cera alba and lanolin used in the preparation. Higher concentrations of cera alba resulted in lighter colour in the preparation. Formulas with lower concentrations of cera alba result in a murky yellow colour, whereas those with higher concentrations of lanolin and active ingredients generate a bone-white and turbid yellow colour.

Homogeneity Test

Table IV. Test Results of Homogeneity Test of Lip Balm Preparation Formulation

Formulas	Homogeneity
F1	Homogeneous
F2	Homogeneous
F3	Homogeneous
F4	Homogeneous
F5	Homogeneous
F6	Homogeneous
F7	Homogeneous
F8	Homogeneous

The homogeneity test aims to determine whether the lip balm formulation is uniform or well combined. The outcomes derived from the eight lip balm preparation recipes are listed in **Table IV**. All the tested recipes resulted in consistent lip balm compositions. This was due to the absence of large grains and particle segregation in the formulations.

Test pH

Table V. pH Test Results of Lip Balm Preparation Formulations

Formulas	pH	Standard	Information
F1	5.92	4.5-7.0 (Sarwanda et al., 2021)	Qualify
F2	4.9		Qualify
F3	6.93		Qualify
F4	6.93		Qualify
F5	4.90		Qualify
F6	7		Qualify
F7	6.93		Qualify
F8	6.5		Qualify

The pH test is conducted to assess the safety of lip balm formulations when used on the lips. The acidity of lip balm formulations does not cause skin irritation (Sarwanda et al., 2021). The pH test results for the 8 formulae are listed in **Table VIII**. **Table V** shows the pH test results of the eight lip balm preparation formulae, indicating that all formulations met the required pH standards, with the average pH of each composition being within the normal lip pH range. Lip balm compositions must have a pH within the range of 4.5-7.0 to fulfil the criteria (Sarwanda et al., 2021).

The pH test was performed to generate a standard pH value. If the pH falls below 4.5, the substance becomes acidic and can cause skin irritation. If the pH is elevated, the solution becomes alkaline, which may lead to dry and scaly skin (Lumentut et al., 2020).

Spreadability Test

Table VI. Dispersion Test Results of Lip Balm Preparation Formulation

Formulas	Dispersion Diameter (cm)	Standard	Information
F1	5.7	5-7 cm (Sarwanda et al., 2021)	Qualify
F2	6		Qualify
F3	5.2		Qualify
F4	5.2		Qualify
F5	6		Qualify
F6	5		Qualify
F7	5.2		Qualify
F8	5.5		Qualify

The dispersion test demonstrated the ability of lip balm formulations to be evenly distributed on the skin upon application. The dispersion test results are presented in **Table VI**. The spreadability test results of the 8 lip balm dose formulae indicated that the spreadability diameter of the product fulfilled the standards. The dispersion test was considered successful if the spreading diameter fell within the range of 5-7 cm (Sarwanda et al., 2021). The lip balm formulation includes Sacha Inchi Oil as the active ingredient, which has a semi-solid consistency that is not too firm, allowing for easy and uniform application, resulting in effective dispersion.

Adhesion Test

Table VII. Adhesion Test Results of Lip Balm Preparation Formulation

Formulas	Sticking Diameter (Seconds)	Standard	Information
F1	12.45		Qualify
F2	18.38	Good adhesion	Qualify
F3	45	if the adhesive	Qualify
F4	45	strength of the	Qualify
F5	18.38	preparation is	Qualify
F6	15.8	more than 4	Qualify
F7	45	seconds	Qualify
F8	24.88		Qualify

An adhesion test was conducted to assess the adhesive properties of lip balm upon application. Extended contact between the lip balm and lips enhances its effectiveness because of its enduring adhesive properties (Suena et al., 2022).

The adhesion test results are listed in **Table VII**. The adhesion test results for the 8 lip balm formulae indicate that the test meets the standards for more than 4 seconds. To achieve these standards, the preparation must have an adhesion time of at least 4 seconds (Ridhani & Nurul Hidayah, 2022). An increased duration of the adhesion test indicated improved adherence to lip preparation. The active component can be strongly attached to the base in the lip balm formulation, which can affect the extended adhesion test duration of the product. In previous research, strong adherence to the preparation resulted in a longer duration of contact with the skin, enhancing the effectiveness of delivering active compounds. Excessive adhesion can cause discomfort during escape (Ridhani & Nurul Hidayah, 2022).

Irritation Test

Table VIII. Irritation Test Results of Lip Balm Preparations

Formulas	Erythema	Papules	Vesicles	Edema
F1	-	-	-	-
F2	-	-	-	-
F3	-	-	-	-
F4	-	-	-	-
F5	-	-	-	-
F6	-	-	-	-
F7	-	-	-	-
F8	-	-	-	-

Information:
(-) : Showed no reaction
(+) : Showing reaction

This irritation test is utilized to assess the impact of irritation on the skin and analyze the properties of a substance while in contact with the skin (Fadila et al., 2024). **Table VIII** presents the results of irritation tests. Results from irritation testing on 8 lip balm formulae indicated that none of the participants showed signs of irritation, such as erythema, papules, vesicles, or oedema. It can be inferred that the lip balm passed the irritant test and was deemed safe for use.

CONCLUSION

Based on the results of this research, it can be concluded that sacha inchi oil can be used as a cosmetic ingredient, especially as an active ingredient in lip balm preparations. From the results of the evaluation test of lip balm preparations, the standard test values that met the requirements were obtained. The optimum formula obtained from the Simplex Lattice Design provisions for Sacha inchi oil lip balm preparation was produced in F3, F4, and F7 with the optimized ingredients of Cera alba 23% and Lanolin 2%.

Suggestions that can be made after carrying out this research are to be able to develop Sacha inchi oil as a cosmetic active ingredient, especially in making lip balm preparations that are more attractive and have more optimal test results.

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REFERENCES

Dominica, D., Sari, D. K., Handayani, D., Zulkarnain, D., Simanjuntak, A. T., Khairunisah, D., & Shufyani, F. (2023). FORMULASI PELEMBAB BIBIR ALAMI DARI SARI BUAH JERUK KALAMANSI (Citrofortunella microcarpa) DAN EKSTRAK BUNGA ROSELLA (Hibiscus sabdariffa). *Journal of Pharmaceutical and Sciences*, *6*(1), 26–36. https://doi.org/10.36490/journal-jps.com.v6i1.4

Fadila, N., Umar, A., & Syahril Samsi, A. (2024). Formulasi dan Uji Stabilitas Fisik Sediaan Lip Balm Ekstrak Etanol Buah Coppeng (Syzigium cumini) Sebagai Antioksidan. *Jurnal Mandala Pharmacon Indonesia (JMPI)*, *10*(1), 169–180.

Hapsah Isfardiyana, S., Sita, ;, & Safitri, R. (2014). Pentingnya Melindungi Kulit Dari Sinar Ultraviolet Dan Cara Melindungi Kulit Dengan Sunblock Buatan Sendiri. *Jurnal Inovasi Dan Kewirausahaan*, *3*(2), 126–133.

Hasanah, S. S. (2020). Uji Aktivitas Antioksidan serta Penentuan Nilai SPF(Sun Protection Factor) pada Formula Lip Balm Bunga Rosella (Hibiscus sabdariffa L.). In *Skripsi Digital Repository Unversitas Jaber*.

Imani, C. F. (2022). (Aloe vera L .) MOISTURE TEST OF ALOE VERA (Aloe vera L .) LEAF EXTRACT LIP BALM Cahaya Firdausi Imani , 1 Fenita Shoviantari *. *Jurnal Pharma Bhakta*, *2*(44), 44–51.

Lumentut, N., Edi, H. J., & Rumondor, E. M. (2020). Formulasi dan Uji Stabilitas Fisik Sediaan Krim Ekstrak Etanol Kulit Buah Pisang Goroho (Musa acuminafe L.) Konsentrasi 12.5% Sebagai Tabir Surya. *Jurnal MIPA*, *9*(2), 42. https://doi.org/10.35799/jmuo.9.2.2020.28248

Maya, I., & Sriwidodo. (2022). Review: Potensi Minyak Biji Sacha Inchi (Plukenetia Volubilis) Sebagai Anti-Aging Dalam Formula Kosmetik. *Majalah Farmasetika*, *7*(5), 407–423.

Ridhani, A., & Nurul Hidayah. (2022). Formulasi dan Evaluasi Stabilitas Sediaan Lip Balm Ekstrak Buah Mahkota Dewa. *Jurnal Riset Farmasi*, 145–150. https://doi.org/10.29313/jrf.v2i2.1546

Sarwanda, H., Fitriani, N., & Indriyanti, N. (2021). Formulasi Lip Balm Minyak Almond

dan Ekstrak Biji Kesumba Keling (Bixa orellana L.) Sebagai Pewarna Alami. *Proceeding of Mulawarman Pharmaceuticals Conferences, April 2021*, 80–84.

Suena, N., Intansari, N., Suradnyana, I., Mendra, N., & Antari, N. (2022). Formulasi dan Evaluasi Mutu Fisik Lip balm dari Ekstrak Kulit Buah Hylocereus lemairei dengan Variasi Konsentrasi Cera Alba Formulation and Physical Quality Evaluation of Hylocereus lemairei Rind Extract Lip Balm with Cera Alba Concentration Variations. *Jurnal Intergrasi Obat Tradisional*, *2*(1), 65–72.