Development and physicochemical and microbiological characterization of a lip balm containing *Pentaclethra macroloba* (Willd.) Kuntze oil

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***Abstract* — A vegan lip balm was developed, formulated with Pentaclethra macroloba oil and other components from Brazilian biodiversity, with the purpose of promoting lip hydration. The lip balm underwent characterization, organoleptic assessment, as well as physicochemical and microbiological quality control analyses to evaluate its safety, quality, and stability. Across all analyses performed, the lip balm met the required technical parameters, being considered safe and suitable for use.**

Keywords* — *Pentaclethra macroloba; Lip balm, Dermocosmetic; Bioactive.

I. INTRODUCTION

The Amazon Rainforest represents a unique ecological system, composed of a complex network of interactions among plant formations, water bodies, and microclimates, resulting in an environmental mosaic with broad structural and functional diversity. It spans approximately 8 million square kilometers and extends across eight South American countries (Bolivia, Brazil, Colombia, Ecuador, Guyana, Peru, Suriname, and Venezuela) as well as French Guiana [1]. It is the largest continuous tropical rainforest on the planet, whose relevance transcends biogeographical boundaries due to its contribution to global climate regulation and the provision of ecosystem services of planetary significance [1].

Nevertheless, a significant portion of these resources is still commercialized as raw materials with low added value, perpetuating external dependence on technologies and industrial processes. A notable example is the pracaxi oil [*Pentaclethra macroloba* (Willd.) Kuntze], widely used in the international cosmetic and pharmaceutical industries. Despite its abundant occurrence in regions such as the Lower Rio Branco–Jauaperi, between Novo Airão (Amazonas, Brazil) and Rorainópolis (Roraima, Brazil), which represents an underexplored opportunity [2], the economic benefits related to its application as a bioactive are often appropriated outside the region, as observed in the United States market [3].

Traditionally recognized for its medicinal properties, pracaxi oil has attracted increasing interest in the cosmetic industry, being incorporated into formulations for skin and hair care. Its lipid profile provides unique emollient and film-forming characteristics, being considered a viable plant-based alternative to synthetic silicones [4,5].

The current cosmetic market values ingredients that combine efficacy, innovation, and sensory appeal, as highlighted by recent analyses of consumer behavior [6]. There is a growing demand for natural, sustainable products with reduced environmental impact [7,8]. Within this context, hydration is considered essential for maintaining physiological processes and healthy skin appearance [9]. In the case of lips, the lower concentration of ceramides compromises barrier function, which justifies the use of lip moisturizers. These products form an occlusive film that reduces transepidermal water loss [10]. Commonly used ingredients in the development of lip balms include waxes, butters, and oils, which may also contain flavoring agents and colorants [11].

Therefore, this study aimed to develop and evaluate the physicochemical properties of a lip moisturizer, formulated according to market trends favoring natural ingredients, with the goal of enhancing the value of Amazonian biodiversity by incorporating pracaxi oil into the formulation.

II. Results and Discussion

A. Organoleptic characteristics

The lip balm exhibited a homogeneous whitish-yellow coloration and a characteristic odor derived from its raw materials. No visual deviations in quality, such as clumps, bubbles, or cracks, were identified.

B. Water activity (Aw)

The lip balm showed a water activity (Aw) at 25°C ± 0.5 °C equivalent to 0.584 ± 0.051. The higher the Aw, the greater the availability of free water for chemical and biological interactions, which may negatively influence processes such as microbial growth and the stability of cosmetic products [12,13]. The Aw value obtained for the lip balm (0.584) is below the minimum values required for microbial growth (Table I).

TABLE I. Minimum water activity required for microbial growth [12]

Microorganism	Water activity (Aw)
Escherichia coli	0.95
Pseudomonas aeruginosa	0.97
Staphylococcus aureus	0.86
Salmonella spp.	0.95
Clostridium botulinum	0.95

C. Microbiológico Microbiological quality control

No pathogenic microorganisms were detected in the pracaxi lip balm, and the count of mesophilic microorganisms remained within acceptable limits (Table II).

TABLE II.

TABLE II. Results obtained from microbiological analyses of the developed pracaxi lip balm.

Product	Pathogen detection (per gram of lip balm)	Total mesophilic microorganism count (CFU/g)
Pracaxi lip balm	absent	< 1.0×10^2

CFU = colony-forming unit

D. pH

The pH analysis of the lip balm aimed to verify its compatibility with the physiological pH of the lip mucosa, an essential parameter to ensure safety, sensory comfort, and the integrity of the skin in the application area. Lip products should have a pH between 4.0 and 6.5 to be compatible with the physiological pH of the lips [14,15]. The value found was 5.0, demonstrating compliance with the range considered ideal for topical products intended for sensitive areas.

E. Spreadability

The developed lip balm exhibited satisfactory performance in forming an occlusive film, with an opaque appearance and uniform texture, without signs of visible fragmentation. The product showed homogeneous application, with no perceptible resistance to spreading, indicating good plasticity and flow under light friction—desirable characteristics for lip products, as they enhance user comfort during daily use. The opacity and spreading force are directly related to the formulation's composition. The presence of waxes in such formulations is important for ensuring consistency, while the presence of pasty and fluid fatty compounds facilitates application and provides shine and smoothness [16]. The pracaxi lip balm is composed of waxes (mixed carnauba and synthetic beeswax), butters (cupuaçu and murumuru), and oils (pracaxi and licuri), in addition to phytosqualane and vitamin E. No silicones were included in the formulation.

F. Heat stability

After 24 hours of exposure in an oven at 55 °C, the lip balm demonstrated satisfactory thermal resistance, with no evidence of dripping or leakage of the lipid matrix. This result indicates physicochemical stability under high-temperature conditions, simulating tropical environments or inadequate transportation situations.

G. Occlusivity test

This analysis measures the product's ability to form a physical barrier on the lip surface, thereby reducing transepidermal water loss and promoting moisture retention over time. This parameter is crucial for products intended for lip hydration, as the skin of the lips is thin, sensitive, and exposed to harsh environmental conditions. The performance was considered satisfactory for the lip balm under experimental conditions simulating high temperatures, which accelerate the evaporation process. The results are shown in Table III. This behavior indicates that the lip balm contains a lipid composition capable of forming a protective film, useful in preventing dryness of the lip mucosa.

TABLE III. Results of the occlusivity test

Product	Occlusivity over time (%)		
	6 hours	***24 hours***	***48 hours***
Pracaxi lip balm	98.73	96.90	94.67

H. Drop point

The mean drop point value obtained for the lip balm was 72.7 ± 2.1 °C (n=3), indicating a suitable thermal profile for transportation, storage, and use under warm environmental conditions.

I. Colorimetry

The coordinate system selected for the readings was L*C*h*, where each letter represents a specific axis in the color space. The values obtained are presented in Table IV. The use of this system allows for objective color standardization, verification of color uniformity between production batches, reproduction of shades, and monitoring of potential changes throughout the product's shelf life, thereby ensuring quality.

TABLE IV. MEAN COLORIMETRIC COORDINATES FOR THE PRACAXI LIP BALM

Product	Coordinates		
	L*	***C****	***h****
Pracaxi lip balm	72.48	20.29	98.91

L* = lightness; C* = chroma; h = hue

III. EXPERIMENTAL

A. Plant material

The taxonomic identification of the species as *Pentaclethra macroloba* (Willd.) Kuntze was performed by a specialist in the field (Dr. Marta Regina Silva Pereira), followed by the deposition of the specimen in the herbarium of the National Institute of Amazonian Research (voucher specimen no. MRP866). This procedure provides scientific and documentary validity to the collection, as well as ensuring the availability of a botanical voucher, in accordance with the guidelines of the Brazilian Botanical Society [17]. The project was also registered in the National System for the Management of Genetic Heritage and Associated Traditional Knowledge (registration no. A783517), reinforcing the commitment to legality and ethical use of genetic resources. The vegetable oil was obtained from mature pracaxi seeds collected manually in the Baixo Rio Branco–Jauaperi Extractive Reserve (Brazil). Seeds were oven-dried with forced air circulation at 40 °C for 48–72 hours, then shelled and ground. Oil extraction was performed by cold pressing to preserve the bioactive compounds. The yield obtained was 21.5%.

B. Development of the lip balm

For the preparation of the lip moisturizer, the waxes, butters, and pracaxi oil were weighed individually. Using a ceramic heating plate, the fusion of components was initiated in descending order of melting point. Once all formulation components were melted and properly homogenized, the filling process was carried out by manually pouring the mixture into stick containers, which were then stored at room temperature for 24 hours to allow complete solidification. The lip balm formulation consisted of a mixture of carnauba wax (Fênix Ceras e Produtos Derivados LTDA), synthetic beeswax (Sarfam Indústria Comércio e Importação), cupuaçu and tucumã butters (Bielus Distribuidora LTDA), in addition to phytosqualane (Atina Ativos Naturais) and vitamin E (Fênix Ceras e Produtos Derivados LTDA).

C. Organoleptic characteristics

The color, odor, and appearance of the formulation were analyzed after 24 hours of crystallization of the ingredient mixture. Initially, color and appearance were examined, while odor was defined through the researcher's perception.

D. Water activity

Water activity was digitally estimated by the dew point method, under controlled temperature (25 ± 0.5 °C), according to [13]. The test was performed in triplicate.

E. Microbiological quality control

The detection and identification of pathogenic microorganisms were performed in accordance with the Brazilian national regulatory agency (Resolution No. 752/2022, National Health Surveillance Agency – ANVISA [18]), which establishes microbiological parameters for this type of product. Tests included screening for total and fecal coliforms (*Escherichia coli*), *Staphylococcus aureus*, and *Pseudomonas aeruginosa*, with the acceptance criterion being the absence of these pathogens per gram of product. Additionally, the total aerobic mesophilic microorganism count was performed, with the acceptance limit defined as ≤ 5.0 × 10^3 colony-forming units (CFU)/g of product [18].

F. pH

While the formulation was in a molten state, the pH of the lip balm was evaluated using Macherey-Nagel test strips. This procedure was performed in triplicate.

G. Spreadability

This test was conducted according to the method proposed by [19], with adaptations. An aliquot of the formulation (0.036 g) was applied at room temperature onto a glass plate and repeatedly spread. The characteristics of the film formed (uniformity, presence of fragments, opacity, and spreading force) were then evaluated. This procedure was performed in triplicate.

H. Heat stability

Three samples of the filled lip balm were placed horizontally on a test tube rack, fully exposing the product, with paper positioned underneath each sample to facilitate visualization of possible dripping. The rack with the products was then placed in an oven at 55 ± 1 °C for 24 hours. After this period, the samples were evaluated for the occurrence or absence of dripping or product deformation [20].

I. Occlusivity test

The occlusivity test was performed using an adaptation of the method described by [21]. The determination of the occlusive effect of the lip balm formulation was conducted as follows: plastic cups of 180 mL, with a diameter of 7.2 cm and filled with 135 mL of distilled water, were covered with filter paper. The formulation (13.3 mg/cm²) was evenly spread over the filter paper. This system was assembled four times: three replicates for the lip balm and one blank (no product applied). These cups with water and filter paper were initially weighed and then placed in an oven at 40 °C. After 6, 24, and 48 hours, their masses were recorded again. The occlusion factor (F) for each replicate was calculated according to the following equation:

$$F = \frac{\mathrm{A-B}}{\mathrm{A}}\ x\ 100 \quad (1)$$

Where “A” represents the water loss of the blank (without product), and “B” is the water loss from the cup with the pracaxi lip balm.

J. Drop point

The formulation was heated until complete melting. Then, the bulb of a thermometer was dipped into the mixture and quickly removed, forming a thin solid film around it. The thermometer, with the solidified sample film, was then placed inside a test tube, which was immersed in a water bath system. The water bath was heated on a ceramic hot plate, under controlled conditions and magnetic stirring, until the first drop of the formulation detached from the thermometer bulb. The temperature recorded at that moment was considered the drop point [20].

K. Colorimetry

The lip balm color was evaluated using a spectrocolorimeter. The content of each lip balm container was heated until complete melting and then transferred to a Petri dish, where it was allowed to solidify for 24 hours. The equipment was calibrated with light and dark standards, and three readings were taken at different points of the plate for each triplicate. The analysis system employed for coordinate measurement was the three-dimensional L*C*h*. system. The perceived color is widely accepted as a three-dimensional space, in which the three dimensions are lightness (L), chroma (C), and hue (h).

CONCLUSION

The integrated analysis of the data allows us to conclude that it was possible to develop a vegan lip balm containing *Pentaclethra macroloba* (Willd.) Kuntze (pracaxi) oil and other ingredients derived from Brazilian biodiversity. The organoleptic evaluation, along with physicochemical and microbiological quality control tests, demonstrated conformity of the developed product with national regulatory standards, reinforcing its potential application in the health, wellness, and cosmetic sectors.

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