Formulation and quality validation of an antiseptic ointment from Jacaranda Flower [Jacaranda mimosifolia]: A biochemical and microbiological approach

Formulación y validación de calidad de una pomada antiséptica a base de flor de Jacaranda [Jacaranda mimosifolia]: Un enfoque bioquímico y microbiológico

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Abstract

This study evaluated the implementation of quality parameters for the development of an antiseptic ointment made with Jacaranda flower [J. mimosifolia] extract. Mexican Official Standards [NOM-248-SSA1-2011, NOM-259-SSA1-2022, and NOM-073-SSA1-2015] were applied to ensure good manufacturing practices, microbiological control, and stability. The optimal formulation included petroleum jelly, coconut oil, and menthol, resulting in a stable and safe composition with proven antimicrobial effectiveness. Organoleptic, pH, and microbiological viability studies were conducted for 21 days under three different environmental conditions. Results showed absence of pathogens such as Staphylococcus aureus, E. coli, and fungi, while maintaining physicochemical properties. It is concluded that the developed formulation is safe, effective, and suitable for topical application, with potential use in minor injuries and dermatological diseases.

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microbiological approach.					
Objetives		Methodology	Contribution		
Evaluate quality paramters in the development of an antiseptic cintement from Jacaranda flower extract.	•	Aplication of Mexican oficial Standars [NOMs] Evaluation of organolepec, Ph, Microbiological viability and stabaty And optimal and effective formulation.	An effective and sale formulation for topical use in minor injuries and dermatological diseases.		

Jacaranda, Antiseptic Ointment, Healing

Resumen

El presente estudio evaluó la implementación de parámetros de calidad para el desarrollo de una pomada antiséptica elaborada con extracto de flor de Jacaranda [J. mimosifolia]. Se aplicaron diversas normas oficiales mexicanas [NOM-248-SSA1-2011, NOM-259-SSA1-2022 y NOM-073-SSA1-2015] con el propósito de establecer criterios de buenas prácticas de manufactura, control microbiológico y estabilidad. La formulación óptima incluyó jalea de petrolato, aceite de coco y mentol, obteniendo una composición estable, segura para uso tópico y con efectividad antimicrobiana comprobada. Se realizaron diversos estudios como son; organolépticos, de pH y de viabilidad microbiológica en un periodo de 21 días en tres distintas condiciones ambientales. Los resultados mostraron ausencia de patógenos como Staphylococcus aureus, E. coli y hongos, además de mantener sus propiedades fisicoquímicas. Por lo cual se concluye que la formulación desarrollada es segura, eficaz y adecuada para aplicación tópica, proponiendo su potencial uso en lesiones leves y enfermedades dermatológicas.

	Formulación y validación de calidad de una pomada antiséptica a base de la flor de Jacaranda [Jacaranda mimosifolia]: Un enfoque bioquímico y microbiológico				
Objetivos	Metodología	Contribución			
Evaluar parámetros de calidad en el desarrollo de una pomada antiséptica con extracto de flor de jacaranda	Aplicación de Normas Oficiales Mexicanas. Evaluación de organolépticos, pH viabilidad microbiológica y estabilidad. Formulación óptima y efectiva.	Una formulación eficaz y segura de uso tópico en lesiones menores y enfermedades dermatológicas.			

Jacaranda, Pomada Antiséptica, Cicatrización

Area: Dissemination and universal access to science

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Peer review under the responsibility of the Scientific Committee MARVID[®]- in the contribution to the scientific, technological and innovation Peer Review Process through the training of Human Resources for continuity in the Critical Analysis of International Research.



Introduction

Nowadays, the development of therapeutic products from natural resources has gained special relevance in the last decades, due to the growing need of having accessible, safe and sustainable alternatives for something as valuable as health care. In this context, medicinal plants have established themselves as promising sources of bioactive compounds with antimicrobial, anti-inflammatory, healing and antioxidant properties. Among them, Jacaranda mimosifolia, commonly known as jacaranda, has been traditionally used in Mexican folk medicine for the treatment of dermal diseases, fever, diarrhea, among other ailments [Martínez, 2021; Rodríguez et al., 2020].

Several phytochemical studies show and confirm the presence of phenolic compounds, flavonoids, terpenes and tannins in the flowers of this species, which supports its potential as a material for the development pharmaceutical and dermocosmetic products. In particular, Jacaranda flower extracts have been reported to possess antibacterial activity against strains such as Staphylococcus aureus, Escherichia coli and Pseudomonas aeruginosa, microorganisms frequently implicated in skin infections [García-Luna et al., 2019].

Given the challenge posed antimicrobial resistance and the need to improve wound management practices in communities with limited access to conventional drugs, it is pertinent to explore topical formulations based on natural ingredients. This research is framed within this need, proposing the design and evaluation of an antiseptic ointment that incorporates Jacaranda flower extract as active agent, combined with excipients such as petrolatum jelly, coconut oil and menthol, which contribute to the stability of the product, skin moisturization and improvement of organoleptic properties.

The developed formulation was evaluated under the guidelines established by various Mexican Official Standards [NOM], such as NOM-248-SSA1-2011 [Secretaría de Salud, 2011], related to good manufacturing practices, NOM-259-SSA1-2022 [Secretaría de Salud, 2022], focused on microbiological control, and NOM-073-SSA1-2015 [Secretaría de Salud, 2015], related to the stability of topical medicines.

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Likewise, organoleptic tests, pH analysis, and microbiological viability studies were applied under different environmental conditions for a period of 21 days, in order to ensure the quality, efficacy and safety of the product. In a complementary manner, several application tests were carried out on real wounds and skin with lesions, documenting the healing effects, symptomatic relief and the absence of adverse reactions. The use of standardized plant extracts, in combination with traditional vehicles, represents a viable strategy for the development of accessible therapeutic products that address real needs in the field of public health, particularly in regions with limited medical infrastructure [Cristell, 2021].

This research not only seeks to provide scientific evidence on the pharmacological properties of the Jacaranda flower, but also to strengthen the link between traditional medicine and technological innovation in the development of dermotherapeutic solutions based on quality parameters and current sanitary regulations. The integrated approach adopted contributes to the validation of national phytotherapeutic resources, promotes the sustainable use of biodiversity and opens the way to new lines of research and technology transfer in the field of health.

Methodology

The present study was developed in the facilities of the Instituto Tecnológico de Tehuacán, combining qualitative and quantitative methods to ensure the reliability of the proposed product. The experimental design focused on establishing a topical formulation based on Jacaranda flower [Jacaranda mimosifolia] with antiseptic properties, evaluating physicochemical, microbiological and organoleptic parameters under controlled conditions, in compliance with current Mexican sanitary regulations.

The raw material was collected during the flowering period [March-April], selecting mature, healthy flowers free of contamination. Disinfection was carried out by three different methods: immersion in 0.5% chlorine for 3 minutes, treatment with water at 60 °C for 5 minutes and application of acetic acid [white vinegar] for 10 minutes. Subsequently, the acetic acid method was selected as the most effective for reducing the microbiological load without affecting the sensory properties of the plant material.

The flowers were dried in the sun for three consecutive days, on a metal mesh elevated 1.20 m above the ground, following the guidelines of NOM-007-RECNAT-1997 [SEMARNAT, 1997]. They were stored in amber glass jars, hermetically sealed, to avoid exposure to humidity and direct sunlight.

The formulation of the ointment was carried out by the indirect infusion method in a water bath, using a controlled proportion of petrolatum jelly, coconut oil and menthol, in addition to the dried flower extract. Mixing was carried out at 80 °C for 25 minutes to allow adequate incorporation of the active ingredient. Six different formulations [F.1 to F.6], varying the proportion of the components, were evaluated and subjected to sensory analysis [appearance, odor, texture, spreadability and coloration] to select the optimum formulation, see Table 1.

Box 1

Table 1

Parameters established for the selection of the ideal ointment

Parameter	F1	F2	F3	F4	F5	F6
Aspect	Α	Α	A	Α	A	Α
Color	Α	Α	Α	Α	A	Α
Odor	R	R	Α	Α	A	Α
Consistency	Α	Α	R	Α	R	Α
Unctuousness	Α	Α	Α	R	A	Α
Lumps	NP	Y	NP	Y	NP	NP
Impurities	Y	NP	NP	NP	Y	NP

Note: Accepted [A], Rejected [R], No submitted [NP], If submitte [Y]

Source: Own elaboration

The selected formulation [F.6] was chosen because it presented better results in terms of homogeneous appearance, pleasant odor, smooth consistency and good dermal adhesion. Subsequently, the stability of the product was evaluated for a period of 21 days in three different environmental conditions: room temperature [25 °C], medium temperature [30 °C] and high temperature [37 °C], simulating real storage scenarios in different regions of the country. Physicochemical tests were carried out, such as pH determination by means of a calibrated potentiometer, observing values between 5.6 and 6.2, suitable for dermal applications. Microbiological analyses were also performed, see Figure 1, under the parameters established in NOM-259-SSA1-2022 and NOM-073-SSA1-2015, determining the absence of pathogenic microorganisms such as aerobic mesophiles, Staphylococcus aureus, Escherichia coli and filamentous fungi.

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Box 2

Disinfection method	Disinfection with dilute acetic acid solution	Disinfection with diluted chlorine solution	Disinfection with hot water
Results	\bigcirc		

Figure 1

Microbiological stability

Source: Own elaboration

Samples were seeded in selective culture media and incubated at 37 °C for 48 hours for bacteria, and at 25 °C for 5 days for fungi. The tests were replicated in triplicate to ensure reproducibility of the results. The plate count technique was used for the determination of colony forming units [CFU], concluding that the ointment is safe for topical use in humans.

In addition, the shelf life of the product was evaluated by means of accelerated tests, subjecting it to sudden changes in temperature and humidity, documenting the persistence of its organoleptic properties and structural stability. At the same time, a pilot test was carried out on volunteer patients with minor skin lesions [scratches, slight burns, bites], with the informed consent of each participant. A favorable evolution was observed in the healing, reduction of pain and redness, with no adverse reactions.

Likewise, to guarantee the quality of the product, Good Manufacturing Practices [GMP] criteria were applied in accordance with NOM-248-SSA1-2011, maintaining controls in the cleaning of utensils, sterilization of containers, adequate labeling and use of personal protective equipment during handling. The entire process was supervised by an academic committee of the institute.

Finally, all the results obtained were systematized in laboratory records, using control sheets and comparative photographs that document the behavior of the product throughout the study.

This integral methodology made it possible to ensure that the ointment made with Jacaranda flower extract complies with the quality criteria required for topical use for therapeutic purposes.

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Results

The development of the antiseptic ointment based on Jacaranda flower [J. mimosifolia] involved a rigorous process of formulation, physicochemical analysis, microbiological evaluation and therapeutic validation. The results obtained during the different stages of the study are presented below, organized by type of analysis and tests.

1. Formulation selection

Six formulations [F.1 to F.6] were prepared, varying the proportions of petrolatum jelly, coconut oil, Jacaranda dried flower extract and menthol. An initial organoleptic evaluation was carried out, considering the following criteria: color, odor, consistency, smoothness and homogeneity. Formulation F.6 stood out for having:

- Uniform texture and pleasant to the touch.
- Characteristic, non-irritating odor.
- Good greasiness without leaving excessive greasy residues.
- Homogeneous appearance without the presence of visible impurities.

These results led to its selection as the optimum formulation to continue with the following phases of the study.

2. Final composition of formulation F.6, see Table 2

Box 3

Table 2

Final compositión F.6

Component	Quantity [g]	Percentage [%]	Functión
Petrolatum jelly	45	45%	Base vehicle
Coconut oil	35	35%	Moisturizer and emollient
Jacaranda flower	19	19%	Healing Agent
Menthol	1	1%	Organoleptic corrector

3. Stability evaluation

It is worth mentioning that, during 21 days, the F.6 ointment was stored at controlled temperatures of 25 °C, 30 °C and 37 °C. Organoleptic characteristics [color, odor, texture], pH and phase separation were monitored. The results indicated that:

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- There were no significant changes in color or odor.
- Texture remained stable under all three conditions.
- There was no evidence of phase separation, indicating good emulsification.
- The pH remained between 5.6 and 6.2, which corresponds to the tolerable range for human dermal use.

4. Microbiological analysis

Tests were performed to detect the presence of pathogenic microorganisms. The analyses included counts of:

- Colony forming units [CFU] of aerobic mesophilic bacteria.
- Staphylococcus aureus.
- Escherichia coli.
- Molds and yeasts.

The crops were incubated in specific media and optimal conditions according to the type of microorganism. In all cases, the results showed a **total absence of microbial growth**, which indicates that the formulation is **microbiologically safe and safe** for application.

5. Application on real lesions

F.6 ointment was applied on **volunteer patients** with different skin lesions: mild burns, see Figure 2, scrapes, see Figure 3, third-degree wounds, see Figure 4, and initial cases of psoriasis, see Figure 5.



Figure 2
Mild burns

Source: Own elaboration

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Figure 3

Scratches

Source: Own elaboration

Box 6 Before After 6 Days Cuts

Figure 4
Third degree wounds

Source: Own elaboration

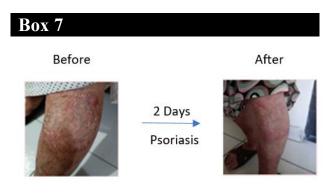


Figure 5
Initial cases of psoriasis

Source: Own elaboration

Follow-up was performed for 7 to 14 days, documenting the following effects:

- Accelerated healing: Reepithelialization was visible from day 3 in most cases.
- **Reduction of inflammation:** Reduction of erythema and edema was evidenced.
- Relief of pain and itching: Patients reported a sensation of freshness due to menthol and relief from the first application.
- **Absence of adverse reactions:** No allergies or secondary irritation were reported.

Daily photographic records, clinical records and user satisfaction surveys were included. The qualitative results were consistent with the expected effects of the active principles of Jacaranda flower and coconut oil.

6. Sensory evaluation by user panel

A panel of 10 evaluators rated the ointment on a scale of 1 to 5 considering:

- Ease of application
- Residual odor
- Texture and absorption
- Sensation on the skin

The average scores ranged from 4.2 to 4.8, highlighting the favorable sensory acceptance of the product [Castillo & Paredes, 2022]. The comments collected highlighted its ease of use, natural odor, and smooth, non-greasy texture.

7. Comparison with commercial products

A comparative table was made between formulation F.6 and two commercial antiseptic ointments, considering parameters such as active ingredients, origin, pH, microbiological tests, results on wounds and user acceptance. The developed ointment showed advantages in terms of:

- Lower number of synthetic chemical compounds.
- Proven antimicrobial activity.
- Lower production costs.
- Better dermal tolerance.

Conclusions

The development of an antiseptic ointment based on Jacaranda flower extract [Jacaranda mimosifolia] represented an effective, natural and accessible alternative for the treatment of mild skin conditions, such as wounds, burns, bites and incipient cases of psoriasis.

The results obtained in the different phases of the research led to the conclusion that the F.6 formulation, composed of 45% petrolatum jelly, 35% coconut oil, 19% Jacaranda flower and 1% menthol, met the necessary requirements to guarantee its physicochemical stability, microbiological safety and therapeutic efficacy.

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From the organoleptic point of view, the ointment presented optimal characteristics in terms of texture, odor, color and smoothness, achieving favorable acceptance both by the technical evaluation panel and by users in the actual application test. The stability of the product was maintained for 21 days under different environmental conditions, without phase separation or sensory alterations, suggesting good durability in storage and future commercialization.

It is important to highlight that the microbiological analysis confirmed the total absence of pathogenic agents such as *Staphylococcus aureus*, *E. coli* and filamentous fungi, evidencing that the formulation process and the manufacturing practices applied were adequate for the production of a safe product for topical use in humans. These results were reinforced by shelf-life tests and simulated storage conditions.

The therapeutic effects observed during application in volunteer patients show that the ointment not only accelerates the healing process but also provides immediate relief from pain, inflammation, and itching. These benefits, attributed to the bioactive compounds in the Jacaranda flower and the synergistic effect with coconut oil and menthol, consolidate its value as a complementary treatment in public health, especially in communities with limited access to conventional medicines [Rodríguez et al., 2020]. In addition to the experimental findings, this research contributes to the rescue of traditional knowledge on the use of Mexican medicinal plants, offering a solid scientific basis for the validation of their therapeutic potential. The study also establishes a methodological precedent for future research focused on phytopharmaceuticals, by applying official Mexican standards in each of the quality evaluation stages.

In conclusion, it is established that the antiseptic ointment based on Jacaranda flower:

- Is microbiologically safe.
- Meets organoleptic and physicochemical quality standards.
- It presents effective therapeutic properties in mild dermal lesions.
- It has the potential to be produced at low cost with accessible raw materials.
- It represents a viable natural alternative with a positive impact on community health.

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This evidence opens the possibility of advancing towards new lines of research, such as the expansion of clinical studies, evaluation in populations with specific pathologies and the development of derivative products [gel, cream, topical solution]. Likewise, it is recommended to establish inter-institutional alliances for its productive scaling and itary registration, promoting biotechnological development with a focus on sustainability and social innovation.

Declarations

Conflict of interest

The authors declare that they have no conflicts of interest. They have no known competing financial interests or personal relationships that might have appeared to influence the article reported in this paper.

Authors' Contribution

Gómez-Flores, Nidia Esther: Contributed to experimental development, analysis of results, and technical review.

Hernández-Cortés, Elsa: Contributed to the writing of the manuscript and academic supervision.

Ramírez-Vaquero, Eduardo Osbaldo: Contributed to the conception of the project idea and methodological guidance.

Vásquez-Jiménez, Juan Carlos: Final revision of the article.

Availability of data and materials

Data obtained during this research are available upon request to the corresponding author.

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Abbreviations

GMP Good Manufacturing

Practices

CFU **Colony Forming Units NOM** Mexican Official

Standard

RECNAT Natural Resources

SEMARNAT Ministry of Environment

and Natural Resources

Ministry of Health SSA

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Background

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Differences

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Discussions

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