International Clinical and Medical Case Reports Journal
Research Article (ISSN: 2832-5788)

Scalp Psoriasis Natural Treatment. Shampoo Based on Bacterial Nanocellulose. Design, Technological studies and Concept Tests

Sesto Cabral Maria Eugenia*, González Exequiel

Laboratorio de Estudios Farmacéuticos y Biotecnología Farmacéutica (LEFyBiFa)-Instituto de Biotecnología Farmacéutica y Alimentaria (INBIOFAL) - CONICET-UNT - Tucumán, Argentina

Citation: *Sesto Cabral Maria Eugenia, González Exequiel. Scalp Psoriasis Natural Treatment. Shampoo Based on Bacterial Nanocellulose. Design, Technological studies and Concept Tests. Int Clinc Med Case Rep Jour. 2024;3(6):1-15.*

Received Date: 31 May, 2024**; Accepted Date:** 03 June, 2024**; Published Date:** 05 June, 2024

***Corresponding author:** Sesto Cabral Maria Eugenia, Laboratorio de Estudios Farmacéuticos y Biotecnología Farmacéutica (LEFyBiFa)-Instituto de Biotecnología Farmacéutica y Alimentaria (INBIOFAL) - CONICET-UNT - Tucumán, Argentina

ABSTRACT

Scalp psoriasis is an inflammatory dermatosis whereit causes redness, peeling and swelling and givestheperson a sensationofitching and/or pain. It is a more common disease tan we may think. Hair makes the scalp difficult to treat and the adjacent facial skin is particularly sensitive to topical treatments. A metadata study carried out in 2016 reveals that the main treatments are those that involve the combination of vitamin D with corticosteroids for the treatmen tof the inflammatory process. The difficulty in applying creams and lotions for the treatment of scalp psoriasis led us to design a product for hair from the first instance. In this frame work we developed a vehicle treatment in the form of a shampoo. For this design we use bacterial nano cellulose as an ingredient in the formula, facilitating there placemen to firritating agents in comercial shampoo. BNC has distinctive characteristics mainly due to its size and fibrillar arrangement. BNC introduces modifications in its behavior as a biomaterial, its biological and physicochemical properties. Two plantex tracts with recognized pro-healing and anti-inflammatory activity were used as active ingredients *Matricaria chamomilla* and *Calendula officinalis*.

The objective of this work was to design a low ormedium detergent action shampoo with natural ingredients for the anti-inflammatory and pro-healing adjuvant treatment of scalp psoriasis. Using the properties of BNC were place irritating excipients such as sodium lauryl sulfate and NaCl. The designed product was tested pharmaco-technologically according to what is indicated in the Argentine Pharmacopoeia VII edition. Tests on healthy volunteers were carriedout to determine the functionality of the designed natural shampoo. The tests on volunteers with scalp psoriasis were carriedout to prove, ease of application of treatments, absence of irritation, reduction of inflammation and attenuation of symptoms.

The designed product isuse ful for the adjuvant treatment of scalp sebopsoriasis. The pharmaceutical form of choice, is a good vehicle for topical administration of the natural active ingredients. The ingredients of the formula were added in the properproportions to ensure conform it yboth therapeutically and aesthetically required by the panel so volunteers. Prototypetested by healthy volunteers achieved the máximum levels of conformity by the user. The designed natural shampoo proved its therapeutic effectiveness in a panel of 9 volunteers diagnosed with cebo psoriasis. The formula is suitable for daily use in a permanent way in patients with scalp psoriasis. None of the patients reported occurrence of local irritation, skin pain, folliculitis, typical side effects of conventional reatment. Although more studies are necessary in volunteers with psoriasis, this natural, biodegradable and effective formula would allow the dose of corticosteroids to be reduced, reducing the side effects of the conventional treatment used.

Keywords: Bacterial nano cellulose; Scalp psoriasis; Topical formulation; Nanobiotecnology; Shampoo

INTRODUCTION

Scalp psoriasis is an inflammatory dermatosis that affects this area of the body, where it causes redness, peeling and swelling and gives the person a sensation of itching and/or pain. It is a more common disease than we may think. Symptoms can affect the entire scalp or just small patches. They can also spread to the ears, hairline, and neck.[1]The National Psoriasis Foundation reports that between 2% and 3% of the United States population suffer from this condition. [2] The most common type of psoriasis causes dry red plaques or patches to form on the skin. On black skin, the spots may be purple or violet, rather than red. According to the American Academy of Dermatology (AAD), at least 50% of all people with plaque psoriasis experience at least one scalp flare-up. Psoriasis is more common in adults, but can develop in children. [3] Up to 75% of children who suffer from chronic plaque psoriasis suffer from capillary psoriasis at some point, with the scalp being considered one of the most prevalent areas, along with elbows and knees. [4] The lesions are round/oval plaques, either delimited, with adherent silvery white scales. [3] Although skin involvement is the most prominent manifestation of this disease, it is imperative to recognize psoriasis as a multisystem chronic inflammatory disorder. Hair makes the scalp difficult to treat and the adjacent facial skin is particularly sensitive to topical treatments. A metadata study carried out in 2016 reveals that the main treatments are those that involve the combination of vitamin D with corticosteroids for the treatment of the inflammatory process. [5] Their studies provided information on the importance of the combined action of both active pharmaceutical ingredients. Common adverse events with these three interventions were local irritation, skin pain and folliculitis. Systemic adverse events were rare and probably not drug-related. Topical corticosteroids may exacerbate acne, rosacea, perioral dermatitis, and tinea infections and may occasionally cause contact dermatitis. [6]

The difficulty in applying creams and lotions for the treatment of scalp psoriasis led us to design a product for hair from the first instance. In this framework we developed a vehicle treatment in the form of a shampoo. The application of commercial shampoos based on sodium lauryl sulfate and NaCL represents extra discomfort when it comes to the patient's personal hygiene, since the microdermal abrasions that occur on the scalp are irritated by the action of strong detergents. In this work we propose a natural alternative, which addresses the reduction of the inflammatory state, and cathegorize the three most

frequent forms of psoriasis in adults: plaque psoriasis (with a predominance of erythema, silvery white scales and twisted vessels of red loops and swollen red dots); thin scales (silver-white, simple red lines and seal-red annular vessels); sebopsoriasis (greasy scales, erythema with red dots, edema); psoriatic cap (with silvery-white scales, erythema and polymorphic vascular pattern). [5] The available formulas, such as creams, ointments, emulsions and lotions, are difficult to apply due to the presence of hair, they cause excessive oiling and discomfort in the patient applying the treatment. In the desire to improve pharmaceutical and cosmetic products by replacing the toxic substances conventionally requiered, we designed a shampoo free of sodium lauryl sulfate, NaCl and synthetic preservatives derived from paraben. [7] For this purpose we select natural ingredients derived from coconut as detergents categorized as having low and moderate detergent power and natural ingredients for the treatment of inflammation, potential mycoses, and bacteremia and the promotion of scalp healing. As an alternative to provide the appearance of a traditional commercial shampoo, which facilitates patient acceptance and better adaptation and maintenance of the treatment, we incorporate nanotechnology in the design process.

Nanotechnology introduction into pharmaceutical industry is a challenge to the traditional pharmacy techniques, excipients selection and production processes. A constant defiance of updating potential that offers unexplored opportunities. Subtle physicochemical interactions generate significant changes in the compatibility and interaction of a formula's ingredients. The incorporation of nanocellulose as a non-active pharmaceutical ingredient represent asophistication to processes and products, favoring innovation in the bioinspired products design. Obtaining nanocellulose from plant sources supports a harmful industrial system opposite to the paradigm for the development of a new pharmacy, safer, cleaner and more natural-oriented. The top-down approach used so far generates environmental pollution, indiscriminate logging, expansion of monocultures and other natural disasters that large-volume industrialization promotes. This approach involves a variety of negative aspects also due to the complex separation processes, the high volume of strong chemical substances, desertification among others. [8] This is an expensive process in energy terms that can be directly replaced by a bottom-up approach using the biotechnological tools at our disposal. It is possible to obtain nanocellulose from bacterial static reactors using producer microbial strains. [9] It is possible to obtain, through cleaner production methods, friendly to the environment, with low or no waste production, a pure, nano-scale product, free of intermediate chemical processes and of excellent quality and biocompatibility. Bacterial species such as *Pseudomonas fluorecens*, Gluconacetobacterxylinus and Gluconacetobacterhansenni produce celluloseas one of its metabolites. Gluconacetobacterxylinus was used to elucidate the biosynthetic mechanisms involved. [10] The producing bacteria excrete a film of cellulose nanofibrils of controllable thickness at the air-culture medium interface. [11,12]Cellulose is a primary metabolite synthesized within the bacterial cell.The chains are twisted into nanofibrils and mechanically amplified. [13,14] Chemical interactions between hydroxyl groups and oxygen from adjacent molecules promotethe parallel stacking of multiple cellulose chains that form elemental groups of fibrils to aggregate intolarger microfibrils. [15] BNC has distinctive characteristics mainly due to its size and fibrillar arrangement.BNC introduces modifications in its behavior as a biomaterial, its biological and physicochemical properties. BNC fibers are lighter, have greater optical transparency and their surface ischemically adaptable, allowing the union of multiple functional groups and improving its mechanical properties. [16,17] This biotechnological process allow us

to obtaina raw material with particular characteristics that position it as an interesting object of study due to the variability of its applications. [8]The field of designing new drug carrier systems for the pharmaceutical industry is one of the most sought after. In addition to the technological advantages, it presentsenvironmental and economic advantages compared to the traditional process. Resource economy isbased on significant energy savings, using static cultures, fewer man hours, without chemical substances such asstrong acids or bases and the waste obtained can be reinserted into the production cycle. BNC obtention it's aecological process and the raw material obtained is biodegradable. [18,19] Added to this is a possible solution to the problem mentioned in this work, the shortage of suitable products for the topical application of treatments for scalp conditions.

The objective of this work was to design a low or medium detergent action shampoo with natural ingredients for the anti-inflammatory and pro-healing adjuvant treatment of scalp psoriasis. Using the properties of BNC we replace irritating excipients such as sodium lauryl sulfate and NaCl. The designed product was tested pharmaco-technologically according to what is indicated in the Argentine Pharmacopoeia VII edition. Tests on healthy volunteers were carried out to determine the functionality of the designed natural shampoo. The tests on volunteers with scalp psoriasis were carried out to test, ease of application of treatments, absence of irritation, reduction of inflammation and attenuation of symptoms.

MATERIALS AND METHODS

Natural origin inputs

Inputs of natural origin were divided for greater understanding into products of bacterial origin and products of plant origin.

Bacterial strains and culture conditions

A *Pseudomonas fluorescens* WS strain (wrinkly spreader) (donated by PhD Andrew Spears, School of Science, Engineering and Technology, Abertay University) It was grown in King B broth (Britania-C.A.B.A-Argentina) and kept at 25ºC.

BNC production process

For BNC production, static cultivation was used. All growing test were made on petri dishes with 50 mL of fresh medium 72h at 28±1°C. All BNC obtained were washing with distillate water to remove medium. BNC was centrifuged 20 min at 8000rpm. Then 1mL of NaOH 2% v/v was added and autoclaved 15min at 121ºC, this procedurewas made for detach some bacterial cell which could by immerse on BNC. BNC were washed with distilled water until neutralization.20

BNC dry weight

Dry weight was measured in dry films. The results were reported as ‘production’ and expressed in weight of dry BNC per liter of King B medium (g/L). [21]

Natural pro-healing oily extract of *Calendula officinalis*.

The oil extract was prepared by maceration of agroecologically grown marigold petals in sweet almond oil (Eiffel cosmetica- Bs As - Argentina) for 45 days. The extract was filtered and reserved until use, protected from light and humidity.

Natural anti-inflammatory *Matricaria chamomilla* hydrolate

Chamomile hydrolate is a by-product of the soxlet distillation of chamomile essential oil. This byproduct is marketed for its anti-inflammatory properties as an active pharmaceutical ingredient (Eiffel – cosmetica -Bs As -Argentina).

Evaluation of natural shampoo.

The detergency capacity and effectiveness of the product were evaluated in healthy scalp voluntaries, including studies required for quality control: organoleptic characteristics, pH, physicochemical characterization. To ensure the nature of the pharmaceutical product, particular tests of surface tension, foam volume, foam stability and wetting time were carried out using a standard protocol.

Sensory evaluation

The following parameters were considered relevant for adequate acceptance. The color, clarity, odor and foam type of the prepared formulation were evaluated. For color, the appearance of pearly effects and opacity was used as a criterion. To determine clarity, 10mL of shampoo was placed against a 20W lamp with a white background and contrasted with a tube with the same volume of distilled water. It was classified as total clarity when the product allows light to pass through, and medium clarity when the product has moderate permeability to the passage of light, and opaque when the product did not let the light pass through the tube. The smell was tested in a survey of 30 healthy volunteers. The type of foam was tested against a commercial shampoo, the foam formed was categorized as: high formation capacity when it equals that of the commercial shampoo, capacity half the foam of the commercial shampoo and low capacity below half the foam. which makes up commercial shampoo.

Determination of pH

The pH of the natural shampoo was determined in distilled water (10% v/v) at 25°C. It was measured in a pHmeter (Broadley James Corporation, Irvine, CA). [22]

Wetting test

The wetting time was calculated as the time necessary for the total wetting of a piece of paper of two centimeter in diameter and 0.5 g in weight. The time was measured from the moment the absorbent paper was placed until it was moistened and sank, using a stopwatch, this test was carried out in quintuplicate. [23]

Foam stability test

The cylinder shaking method was used. Approximately 50 ml of formulated shampoo solution (1%) was placed in a 250 mL and shaken vigorously 10 times. Foam stability was measured by recording the foam volume of the shaking test after 5 min, respectively. [24] The test was performed in quintuplicate.

Informed consent form development[25]

Informed consent sheet was designed by the protocols approved for the World Health Organization[25] and the provisions of the national regulatory entity National Administration of Drugs, Food and Medical Technology (ANMAT) Nº6677/10. [26]

Evaluation of functionality as a shampoo tested by 30 healthy volunteers

To know the opinion regarding the main function of a shampoo, which is the ability to clean the hair and scalp. This is a fundamental factor because a pharmaceutical product that is difficult or uncomfortable to apply, which has aesthetic consequences such as over greasing of the hair, favors abandonment of the

treatment. The patient with scalp psoriasis needs to feel comfortable and satisfied with the appearance of their hair, so that they do not discontinue treatment and to improve their self-image. A positive self-image favors the patient's propensity to continue treatment. The volunteers called for this shampoo prototype study were a total of 30 adults between 30 and 45 years old with healthy scalps and no underlying predisposing diseases, with no known allergies to the ingredients in the prototype. The prototype was used in frequent washing for 30 days. The evaluated factors were divided into two, function factors (Detergency, over greasing, volume, shape and nutrition) and aesthetic factors (Shiny, docility, ease of combing). To know the behavior of the product, the following characteristics were evaluated: Detergency capacity, poor, medium, good, very good (the incidence factor was appearance of the hair after washing and rinsing), Over greasing within 24 hours of application measured as presence or absence of opacity and oiliness to the touch of the hair fibers. Volume, shape and nutrition of the hair fiber were rated as poor, medium, good and very good. Finally, hair health was evaluated considering aesthetic parameters such as shine, docility, ease of combing; these factors were evaluated as poor, medium, good and very good.

Evaluation of effectiveness due to the absence of edema, erythema and burning on the scalp in 9 volunteer patients with sebopsoriasis.

The distinctive characteristic of sebopsoriasis is the appearance of greasy scales, erythema with red dots and edema. The natural shampoo designed as an adjuvant in the treatment contains pro-healing, antibacterial, antifungal and anti-inflammatory active ingredients. The patients were interviewed, the composition of the adjuvant product and the results obtained in healthy volunteers were reported. The possibility of allergies and incompatibilities, as well as other predisposing underlying diseases, was investigated. After evaluation, 9 patients with sebopsoriasis were selected for this first prototype study. Parameters related to the effectiveness of the therapeutic action and effectiveness of the functionality of the prototype were evaluated. Patients received shampoo to use for 30 days and registration forms. The patients tested the shampoo in two instances to observe the possibility that the formula could be adapted for daily preventive use. Patients received shampoo for 30 days during an outbreak of scalp psoriasis and then again for 30 days, repeating the treatment during a latency period of the disease. The trials were carried out for 1 year to achieve iterative monitoring of the skin manifestation in the 9 volunteers.Specific characteristics of their type of psoriasis were evaluated. The decrease in edema was rated as: significant, medium and non-significant. The decrease or absence of erythema was classified as: significant, medium and non-significant decrease. Regarding the functionality of the product, over greasing, hair docility, burning during application, general appearance of the hair such as shine, docility and softness were evaluated, rated as: bad, average, good and very good.

Ethical considerations

This study meets the ethical and scientist's standards to design, conduct, recording and reporting studies that involve the participation of human beings stipulated by the Ministry of Health of Argentina, (Resolution Nº 1490/07) [27]. They are based in the International Declarations of Human Rights and Ethics Research (Nuremberg, 1948) [28], Helsinki treated (1964 and updates of the World Medical Association) [29], the Operational Guidelines for Ethics Committees (WHO 2000 - World Health Organization) [30] and

the International Ethical Guidelines for Health research Involving Human Subjects (CIOMS 2017 - Council for International Organizations of Medical Sciences). [31]

Statistics

The t-test was used for statistical analysis. $p<0.001$ was considered statistically significant.

RESULTS AND DISCUSION

BNC dry weight

The BNC dry weight per liter of King B medium (g/L) was 15.27±0.18 g/L. For quality control and studies in healthy volunteers, a total of 85.34g was prepared.

Natural pro-healing oily extract of *Calendula officinalis*.

Calendula oleate was chosen for its marked pro-healing action. [32-35]*Calendula officinalis L.* (marigold) belongs to the Asteraceae/Compositae family. Its oleate is of choice in the formulation of natural products with therapeutic and cosmetic action. Oleate contains bioactive compounds with recognized pro-healing, vascularizing and anti-inflammatory action such as: terpenoidsand terpenes, carotenoidsflavonoids (mainly quercetin, isorhamnetinand kaempferol aglycones) and polyunsaturated fatty acids (mainly calendic acid). [35]15mL/L of calendula oleate were used for the shampoo formulation.

Natural anti-inflammatory *Matricaria chamomilla* hydrolate

Matricaria chamomilla (MC) is one of the mostuseful immunomodulatory plants with anti-inflammatory effects. MC also has antioxidant,antibacterial, antispasmodic, wound healing, and antiallergyeffects. It has been used to digestive,bacterialinfections treatment and respiratory diseases. [36-39]The shampoo formula contains 25 mL/L of chamomile hydrolate in its composition.

Evaluation of natural shampoo

Our objective is to create a vehicle for natural products with known anti-inflammatory and pro-healing action, easy to apply, that provide the patient with relief from their discomfort from topical application without losing sight of the fact that it is not only about effectiveness, but also about comfort that allow the patient to continue treatment during periods of irritation psoriasis onset.Commercial shampoos based on sodium lauryl sulfate as a detergent and NaCL as a thickening agent application generates extra discomfort for the patient. Micro-dermoabrasions that occur on the scalp are irritated by the action of strong detergent and NaCl, which can reach concentrations of 35g/L. Lauryl sulfate detergent is recommended in commercial formulas at a concentration of 10%, meaning that 100 g of concentrated sodium lauryl sulfate are added per liter of commercial shampoo. There are numerous publications regarding the irritating action of this detergent, which is chosen not only for the hygiene of our hair, but also as a detergent agent for clothes, dishes and even automotive engines.[40-44]The surfactant serves as a cleaning mechanism within the shampoo, eliminating the oily envelope, the solid particles attached to the oil in the hair fiber. Technologically, it favors the union of the active ingredients and their state of suspension in the formula, moderates the viscosity and contributes to the formation of foam that facilitates the arrival of the detergent and the active ingredients to the scalp. Ideally, a shampoo should remove dirt from the hair without irritation and dryness of the skin. However it often results in the elimination of beneficial proteins and lipids affecting the health of the scalp. There are numerous possible

interactions with proteins in the hair fiber and scalp, which can generate dryness and penetration of the surfactant into the dermis, triggering biochemical responses such as inflammation and irritation. In a more advanced state and with a higher concentration of surfactants, essential proteins are denatured, accentuating irritation and adverse effects due to destabilization during interaction with the lipid bilayers of cell membranes.The viscosity is determined by the union of the surfactant sodium lauryl sulfate and the salt NaCl. [45-47]Due to their low cost, salts such as sodium chloride are the most used viscosity modifier in the personal care industry. The concentrations allow the overall viscosity of the system to be tuned to the desired function. Production of a "salt curve" is essential to determine the correct sodium chloride loading for optimal viscosity adjustment in a specific system. Adjusting the viscosity generates skin irritation and dryness of the hair fiber. [48]Viscous agents such as bacterial nanocellulose (BNC) allow the replacement of NaCl and the decrease in detergency activity by replacing the strong detergent with agents derived from coconut. NBC, which is capable of taking 200 times its weight in water, acts by hemming, giving the shampoo the appropriate density to facilitate its application and gives the formula softness and facilitates the sliding of the shampoo through the hair fiber. This behavior prevents tangling of the fibers and makes the hair easier to comb, reducing hair loss. The incorporation of NBC allows us to reduce the detergent concentration and eliminate drying agents such as NaCl. These low and medium detergency power agents that do not cause irritation, edema and erythema. Due to its gelling behavior, it favors hair styling and the arrival of active ingredients to the scalp. With the designed formula, the tests required by the Argentine Pharmacopoeia VII edition were carried out. The results are summarized in (**Table 1)**. The color is adequate, the transparency contrasted with a test tube with distilled water was of medium transparency, partially allowing the passage of light. The smell is pleasant and was tested by thirty healthy volunteers, who also tested the detergent action, the cleaning action, the effect on the hair and characterized as "very good". The pH values were recorded at 6.8 ± 0.3, these values are within acceptable parameters to avoid irritation and edema of the scalp. In the case of foam formation, it is a requirement of the consumer who prefers, for a marketing reason, that the shampoo generate a lot of foam and the false expectation that more foam cleans better. To maintain patient compliance and acceptability, the product was designed to maximize foam formation, which is logically directly proportional to the detergency power of the shampoo. All trials were contrasted with a commercial brand shampoo of recognized in our country Argentina. When wetting time was tested, the time required for a paper disc of 2 cm diameter and 0.5g weight no significant differences were found regarding the behavior of the commercial shampoo. The timed time was of 100s time estimated as normal for wet ability assay.

Table 1. Physicochemical study of the herbal shampoo.

Study Test Characteristics	Natural ShampooDesigned
Color	Mildbrown
Transparency	Medium
Odor	Verygood
pH	6,8 ± 0,3

Foam volumen (mL)	23
Foamtipe	Dense, high
Wetting time (s)	100

Evaluation of functionality as a shampoo tested by 30 healthy volunteers

Effectiveness and ease of application are advantages to the time of design of pharmaceuticals that focus the focus on the proper administration of the dose of active pharmaceutical ingredient. In a deeper analysis, capillary psoriasis disease drags in addition to a series of symptoms that appear and disappear many times a year, a self-image stigma, where the patient also faces the emotional discomfort caused by the flakes on his clothes, the greasy appearance of the hair, the lack of volume and shape, pain when combing due to scalp irritation among many more. The design of a pharmaceutical product, goes beyond effectiveness and ease of application. In these circumstances, he also attends to the emotional well-being of the patient and the attainment of his greatest state of comfort. In this framework we designed a natural product, free from irritating agents, proven active in its constituents with pharmacological action and convened a panel of 30 healthy volunteers, who accessed the use of the natural shampoo for Psoriasis for a period of 30 days. To equalize the experiences, it was also asked to preview extra products such as: conditioners and cream baths and capillary boots. Volunteers received the product and a grid of questions to answer upon completion of the experience. The parameters analyzed, have to do with the action and/or adjuvant cosmetic and therapeutic effect due to the potential improvement of capillary health by the replacement of the ingredients commonly used in commercial shampoos. A number of aspects that make hair and scalp health were evaluated from two perspectives: Functional factors of the prototype and Aesthetic parameters of capillary health. For further understanding factors related to operational functionality of the prototype were evaluated: detergency capacity, measured as the ability to drag particles adhered to scalp and capillary fiber, as well as dead cells and/or oils, compared to the commercial shampoo they use commonly. **(Table 2)** summarizes these parameters and categorizes them into poor, average, good and very good detergency ability. The volunteers rated it as "very good" in 90% of the cases and a 10% rated the detergency ability as "good". The volume that the hair acquires is another factor associated with capillary fiber health, the broken, cracked and/or dried fiber generates electrostatic interactions with the environment, increasing volume and decreasing shape. A hair without volume, adhering to the scalp is symptom of oily scalp, which peels the capillary fiber where oils and environmental particles accumulate, eventually contributing to the shedding of the capillary fibers. A normal hair volume is considered an indicator of capillary health. After 30 days of use of the natural shampoo prototype 100% of the volunteers as observed in table 2. This parameter is associated with shape, since hair shape depends on hair vitality and its ability to hold the volume that gives it shape. In this case 26 volunteers recorded that the shape of the hair during the analysis period, was categorized as "very good" and 4 volunteers rated it as "good". Nutrition is usually taken as a medicinal action but with the boom in nutraceutics, it is added to comprehensive cosmetics. When nutrition was evaluated in

function of scalp health, decrease in hair fall, observable improvement in appearance, weight and thickness of capillary fiber 100% of the volunteers rated this property as "very good."

Table 2. Healthy skin voluntaries 30 daystriaal of functionfactors.

Parameters	Poor	Medium	Good	Verygood
Detergencycapacity	-	-	3	27
Volume	-	-	-	30
Shape	-	-	4	26
Nutrition	-	-	-	30

(Figure 1) shows the results of the evaluated overgreasing parameter.In this test two variables that normally produce over greasing of capillary fiber and scalp were considered. This over greased generates scabies, pruritus, comedones formation and odor. In addition the decrease in the rate of cellular respiration decreases and the capillary fiber weakens. The first variables are the absence of strong irritating detergents and their replacement by detergents derived from plant seeds. the sebaceous glands are activated by the irritation produced by the strong detergent such as lauryl sulphate and the NaCl used as thickener which was replaced by NCB. The second variable is that of not producing the over greased by having dry scalp, the contact with the detergent on the capillary fiber affects it leaving it brittle, cindery, and of unvital appearance. When the healthy volunteers were interviewed after 30 days of use of the natural shampoo, they replied that in 100% of the cases there was an "Absence of opacity." As for the sensation of over greased reported only 7.5% identified more than once, presence of greasiness after using the prototype, 92.5% did not record sensation of greasiness. Aesthetic parameters related to capillary health, are shine, docility and ease of combing. All these are expected and desired factors. After the 30 days of use of the natural shampoo the healthy volunteers, categorized the three parameters as "very good" in 100% of the cases. The data were recorded in **(Table 3)**.

Table3. Aesthetic parameters in hair health.

Parameters	Poor	Medium	Good	Verygood
Shine	-	-	-	30
Docility	-	-	-	30
Ease of combine	-	-	-	30

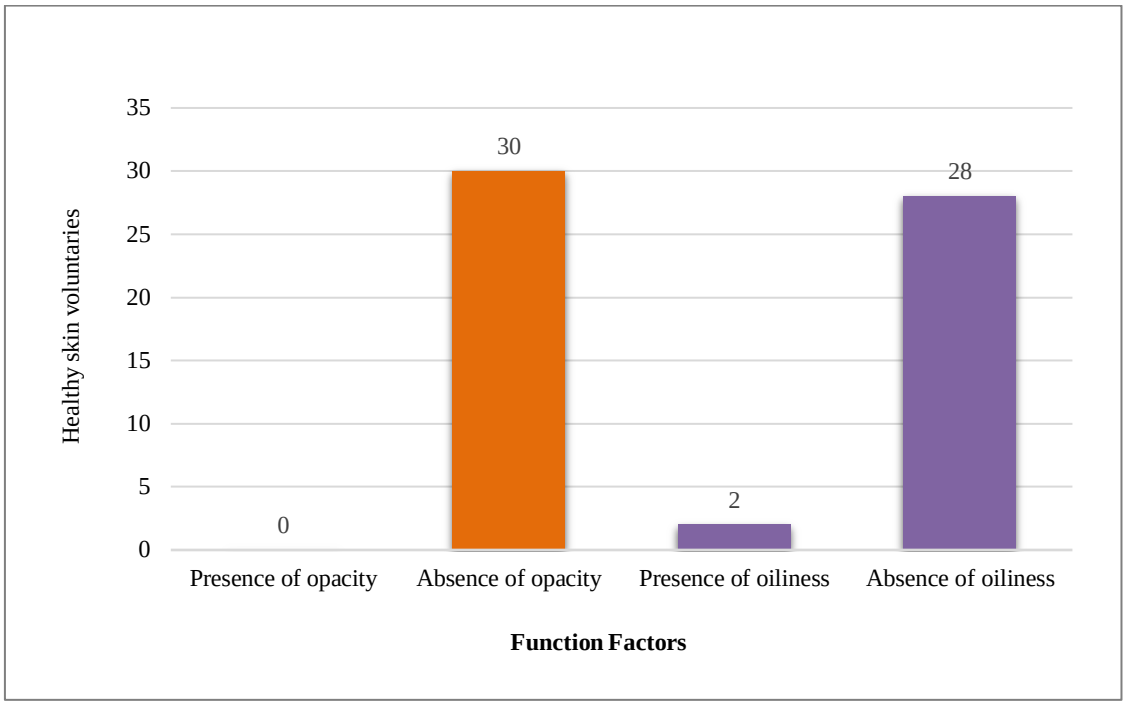

Figure 1. Overgreasingafter 24 hours of washing - Measurement of funtionfactors as opacity and oiliness. n=30.

Evaluation of effectiveness due to the absence of edema, erythema and burning on the scalp in 9 volunteer patients with sebopsoriasis.

The 9 volunteers with scalp psoriasis, were diagnosed by their dematologists as sebopsoriasis is the appearance of greasy scales, erythema with red dots and edema. In this study conducted on volunteers the effectiveness of the proof of concept of natural pro-healing and anti-inflammatory shampoo was evaluated. Volunteers used for 30 days during a scalp psoriasis outbreak and 30 days during a recessive period of cutaneous manifestation. The 9 volunteers with scalp psoriasis, were diagnosed by their dematologists as sebopsoriasis for the appearance of greasy scales, erythema with red dots and edema. In this study conducted on volunteers the effectiveness of the proof of concept of natural pro-healing and anti-inflammatory shampoo was evaluated. Volunteers used for 30 days during a scalp psoriasis outbreak and 30 days during a recessive period of cutaneous manifestation.During the 30 days involving a psoriasis outbreak, the therapeutic effectiveness parameters were evaluated considering the decrease in edema and erythema as success of the prototype. **(Table 4)** shows the results recorded by the volunteers and rated as "significant", "medium" and "non-significant". In all cases significant decrease in erythema was recorded and in about 92% of cases significant decrease in edema was recorded, only one volunteer recorded "medium" decrease in edema during the trial. As for the parameters quantified during the period in which desquamations, microulcerations, exacerbated cebaceous discharge are found in latency period. The parameters evaluated were: over greasing, hair docility, burning during application, general appearance of the hair such as were evaluated, rated as: bad, average, good and very good. All volunteers recorded as "very good" in all parameters evaluated such as: shine, docility and softness. Non report was made

aboutburning during application nor over greasing. Patient's recorded impressions about well-being and improved person hairgeneral appearance and its incidence on mood and immune system.

Table 4. Effectiveness of therapeutic action.

TherapeuticEffect	Category		
	Significative	Medium	No significative
Decreased Edema	8	1	-
DecreasedErythema	9	-	-

CONCLUSIONS

The designed product is useful for the adjuvant treatment of scalp sebopsoriasis. The pharmaceutical form of choice, is a good vehicle for topical administration of the natural active ingredients. The ingredients of the formula were added in the proper proportions to ensure conformity both therapeutically and aesthetically required by the panels of volunteers. Prototype tested by healthy volunteers achieved the maximum levels of conformity by the user. The designed natural shampoo proved its therapeutic effectiveness in a panel of 9 volunteers diagnosed with cebopsoriasis. The formula is suitable for daily use in a permanent way in patients with scalp psoriasis. None of the patients reported occurrence of local irritation, skin pain, folliculitis, typical side effects of conventional treatment.Although more studies are necessary in volunteers with psoriasis, this natural, biodegradable and effective formula would allow the doce of corticosteroids to be reduced, Reducing the side effects of the conventional treatmentused. The extracts of selected plants *matricaria chamomilla* and caléndula officinalis at the concentrations used, demonstrated very good anti-inflammatory and pro-healing activity when conveyed in the form of shampoo.

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