

DEVELOPMENT OF AN EXFOLIATING DERMOCOSMETIC FORMULATION WITH BABASSU FIBERS TO HELP ON THE TREATMENT OF ANDROGENETIC ALOPECIA



Anna Vitória Bastos Gonçalves¹, Amouni Mohmoud Mourad2, Solange A. P. C. Brícola², Marcelo Guimarães^{2,A}

¹Mackenzie Presbyterian University, Pharmacy Graduate, São Paulo - Brazil ²Mackenzie Presbyterian University, Pharmacy Course Professor, São Paulo - Brazil

ABSTRACT

Androgenetic alopecia is a condition characterized by hair loss associated with exposure to androgens, occurring in genetically predisposed individuals. It causes terminal hair to be replaced by vellus hair, miniaturizing the hair shaft and decreasing hair density. The removal of the stratum corneum of skin due to mechanical exfoliation facilitates the penetration of active ingredients into the scalp by stimulating blood circulation, which can help hair growth. Society's consumption patterns are constantly changing, being the search for sustainability and ESG (*Environment, Social and Governance*) trends a very popular topic. The aim of this study was to develop an exfoliating dermocosmetic formulation with babassu fibers to help on the treatment of androgenetic alopecia, using the part of the babassu coconut that was originally discarded by the industry. An oil-in-water emulsion was developed with the surfactant's lauryl glucoside and cocoamidopropyl betaine, and the emulsifiers cetostearyl alcohol and glyceryl monostearate. The formulation showed instability in the presence of direct sunlight and heat, indicating possible impasses for its commercialization, since storage in the bathroom may trigger instability. In this way, it can be assumed that storing the product in a refrigerator or even at room temperature (<25°C) will maintain its stability. Based on the results, future studies are needed to assess the stability of the scrub, and the optimization of the formulation will make it possible to obtain an innovative product.

Keywords: Exfoliant, Androgenetic Alopecia, Dermocosmetic.

RESUMO

A alopecia androgenética é uma condição caracterizada pela perda de cabelos associada à exposição a andrógenos, ocorrendo em indivíduos geneticamente predispostos. Ela causa substituição dos pelos terminais por pelos velus, miniaturizando a haste capilar, diminuindo a densidade capilar. A remoção da camada córnea da pele devido a esfoliação mecânica facilita a penetração de princípios ativos no couro cabeludo ao estimular a circulação sanguínea, podendo auxiliar no crescimento dos fios. O padrão

^ACorresponding author:: Marcelo Guimarães- E-mail: marcelo.guimaraes@mackenzie.br - ORCID: https://orcid.org/0000-0002-9480-2957

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de consumo da sociedade tem se alterado a cada dia, sendo a busca por sustentabilidade e tendências em ESG (*Environment, Social and Governance*) pautas cada vez mais buscadas. Devido a isso, o objetivo desse trabalho foi desenvolver uma formulação dermocosmética esfoliante com fibras de babaçu para auxiliar no tratamento da alopecia androgenética, utilizando a parte do babaçu que originalmente seria descartada pela indústria. Foi desenvolvida uma emulsão óleo em água com os tensoativos lauril glicosídeo e cocoamidopropil betaina, e emulsionantes álcool cetoestearílico e monoestearato de glicerila. Em seguida, a formulação foi analisada quanto aos parâmetros organolépticos (cor, odor e aspecto), densidade, pH e centrifugação. A formulação apresentou instabilidade na presença de luz solar direta e calor, indicando possíveis impasses para sua comercialização, já que o provável armazenamento no banheiro pode desencadear a instabilidade. Dessa forma, pode-se inferir que o armazenamento em geladeira ou até mesmo à temperatura ambiente (<25°C) manterá a estabilidade do produto. Com base nos resultados, são necessários futuros estudos para avaliar a estabilidade do esfoliante, e a otimização da formulação possibilitará a obtenção de um produto inovador.

Palavras-chave: Esfoliante, Alopecia Androgenética, Dermocosmético.

INTRODUCTION

Alopecia is a condition in which there is an absence of hair, mainly on the scalp, either totally or partially¹. It is caused by an interruption in the hair growth cycle and can be classified into nonscarring and scarring. Non-scarring alopecia involves hair loss with preservation of the hair follicle, which can grow again. In scarring alopecia, the hair follicle is irreversibly destroyed and replaced by fibrous scar tissue, resulting in permanent hair loss².

Among the classifications, alopecia has different types, the most common being areata, androgenetic and fibrosing. Alopecia areata is an autoimmune condition that affects the hair follicle in the anagen phase³, while androgenetic alopecia is an autosomal dominant condition characterized by a reduction in the anagen phase and an increase in the telogen phase⁴. Fibrosing alopecia, on the other hand, occurs in the frontotemporal line, due to a perifollicular lichenoid infiltrate⁵.

Androgenetic alopecia is characterized as patterned hair loss, occurring in genetically predisposed individuals who are exposed to androgens, and can affect both men and women. It triggers miniaturization of the hair shaft, which is characterized by a coordinated and progressive decrease in color and thickness⁶, and occurs due to the return of the production of vellus hair, which are thin and short, replacing the terminal hair in the hair follicle⁷.

The pattern of androgenetic alopecia varies between women and men⁸, and in men it usually starts on the vertex of the head, top, frontoparietal and bitemporal regions⁶. Female pattern androgenetic alopecia is characterized by progressive thinning of the hair in the centroparietal region⁶, and there is no recession of the frontal line of the scalp, as occurs in other alopecias⁹. Due to the influence of androgens on alopecia, the situation is accentuated after the menopause, because of hyperandrogenism, which can also include signs such as seborrhea, acne and hirsutism. The main classifications for female pattern alopecia are the Ludwig (Figure 1) and Sinclair¹⁰ (Figure 2) scales, and for male pattern alopecia, Norwood-Hamilton (Figure 3)⁸.

Figure 1: Ludwig classification for female alopecia



Source: Ribeiro et al. 2021

Figure 2: Sinclair classification for female alopecia

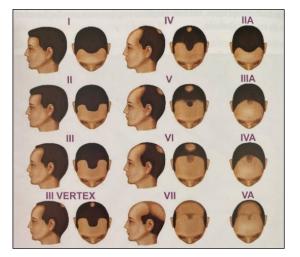


Source: Sinclair et al. 2015

Although frequent, hair loss is also responsible for psychological disorders and suffering, especially in children, men and people undergoing cancer treatment. The impacts affect identity and routine, leading to low self-esteem, a feeling of being less attractive, difficulty socializing, rejection, and even anxiety, depression and suicide¹¹.

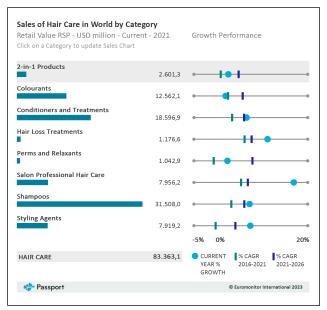
According to the Euromonitor International¹² database, in 2021 the global market for hair loss treatment products had sales of just over 1 million dollars and, furthermore, the growth forecast between 2021 and 2026 is just over 5% (Figure 4), which reinforces the need to invest in new products.

Figure 3: Norwood-Hamilton classification for male alopecia



Source: Ribeiro et al. 2021

Figure 4: Sales and growth projections for the hair loss treatment market



Source: Euromonitor Internacional 2023

Mechanical exfoliation consists of removing dead cells from the stratum corneum of the skin using physical ingredients such as granules, favoring the penetration of the active ingredient into the scalp^{13,14}. Babassu exfoliating granules come from the part of the coconut's mesocarp that would otherwise be discarded as it couldn't be used to produce babassu flour¹⁵, being a substitute for other exfoliating products found on the market and encouraging the practice of ESG¹⁶.

Considering the growing market for hair loss products and ESG trends, it is necessary to invest in products that meet these demands and can, in fact, help treat androgenetic alopecia with less environmental impact.

METHODOLOGICAL PROCEDURE

Materials

The babassu fiber scrub and alpha-bisabolol were donated by Atina Ativos Naturais. Cocoamidopropyl betaine, cetostearyl alcohol, glyceryl monostearate and biotin were provided by Aqia Química Inovativa. D-panthenol, niacinamide, lauryl glucoside and propanediol were provided by Focus Química. EDTA, sodium chloride, phenoxyethanol and citric acid were obtained from the Semi Industrial Laboratory at Mackenzie Presbyterian University.

The following equipment were also used: pycnometer, analytical balance, digital pH meter (Digimed DM-22, Brazil), centrifuge (Quimis Q222TM216, Brazil), refrigerator (Electrolux, Duplex DC49A - 462 L, Brazil) and oven (Q317M42, Brazil).

Method of preparation

Two formulations were developed, a liquid one and a semi-solid one. The liquid formulation was developed using the babassu fiber scrub, D-panthenol, niacinamide, biotin and rosemary essential oil, alpha-bisabolol, lauryl glycoside and cocoamidopropyl betaine, propanediol, sodium chloride, EDTA, phenoxyethanol and water.

For the semi-solid formulation, an oil-in-water emulsion was developed, using the same components as the liquid formulation, except for sodium chloride. The emulsifiers cetostearyl alcohol and glyceryl monostearate were added for the emulsion. The emulsion was prepared as follows: at 60°C, the aqueous phase was poured into the oily phase, also at 60°C, and manual stirring was carried out until the emulsion cooled. In a grater, the powders (babassu fiber scrub and niacinamide) were homogenized by geometric dilution and incorporated into the emulsion using the same technique. The other components of the formulation were added at the end, followed by pH correction with the addition of citric acid.

Stability analysis

Accelerated stability analyses were carried out from November 2023 to March 2024 at the Mackenzie Presbyterian University's Semi-Industrial Laboratory.

For the study, organoleptic characteristics (color, odor, appearance), pH, density and centrifugation were analyzed for the following periods: 0, 7th, 14th, 21th, 28th, 60th, 90th (Brasil 2004)¹⁷ and 120th days. According to Brasil (2004)¹⁷, the samples were stored in a refrigerator (5±2 °C), an oven (40±2 °C), at room temperature and under light exposure (sunlight).

The pH was determined by preparing a 10% aqueous dispersion and introducing the electrode directly, in triplicate. Density was determined in duplicate using a metal pycnometer, based on the ratio between the masses of the emulsion and water¹⁸.

To carry out the centrifugation test, initially 10g of the samples were centrifuged at 3000 rpm for 30 minutes¹⁷. After this, for the other analyses, 1g of the samples in each of the conditions was centrifuged at 3000 rpm for 15 minutes for process control¹⁹ to check stability over the 120-day period.

RESULTS AND DISCUSSION

Development of the formulations

Initially, two formulations (liquid and semi-solid) were prepared on different days, and their viability and need for correction was assessed. After manipulation, it was observed that they were unstable, and corrections were made according to the type of formulation. For the liquid one, the pH was adjusted with citric acid and more sodium chloride was added in order to obtain the right consistency for a shampoo, but there was separation, and the expected result was not obtained. As a result, it was decided to discontinue investing in this formulation.

For the semi-solid formulation, the amount of the emulsifiers cetostearyl alcohol and glyceryl monostearate (F2) was increased to obtain the firm appearance of a cream, since it had previously had the appearance of a lotion. This formulation proved to be stable, with no phase separation and the desired consistency. However, after a few days, it was observed that the formulation (F2) was a little more viscous than expected and had lumps, so it was corrected by reducing the emulsifiers glyceryl monostearate and cetostearyl alcohol (F3), in order to obtain greater fluidity (Figure 5). Table 1 shows the percentages of emulsifiers used in each test of the formulation described.

Figure 5: Semi-solid formulation adjusted with reduction of emulsionants (F3)



Source: The Authors

Table 1 - Percentage composition of emulsifiers during tests

INCI name	% of components		
	F1	F2	F3
Cetostearyl alcohol	4	9	8
Glyceryl monostearate	2	6	5

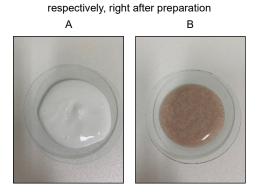
Formulation 1 (F1), Formulation 2 (F2) e Formulation 3 (F3) -Source: The Authors Once the formulation (F3) had been obtained, a 600g batch was produced for stability analysis, with half (300g) containing the active ingredients and the other half being the "blank", to assess the performance of the active ingredients in the base and possible instabilities. The samples (blank and with active ingredient) were divided into specific containers for stability analysis in four different conditions: exposure to light (sunlight), protected from light (room temperature), oven and refrigerator, and the first analysis was carried out immediately after preparation.

Accelerated stability study

After separating the samples and exposing them to stress conditions, the organoleptic characteristics, pH, density and centrifugation were analyzed.

After developing the formulation (Figure 6), the final product (formulation with active ingredient) had a characteristic smell of rosemary essential oil, a slightly brownish color with brownish dots (typical of the scrub), shiny and had low viscosity, due to the recent manipulation. The blank one had no smell, was white and shiny, and had little viscosity.

Figure 6: Samples of the blank (A) and final product (B),



Source: The Authors

On the 7th day, the final product sample in contact with light (Figure 7) showed separation and was not eligible for stability analysis. This shows that the product needs to be stored in opaque, dark packaging that does not allow light in.

Figure 7: Final product sample under light exposure after 7 days



Source: The Authors

The sample of the final product stored in the oven on the 7th day was only slightly darker than the samples in the other conditions, and had a higher viscosity, while the corresponding blank had a higher viscosity (Figure 8). The other formulations in all conditions showed the same characteristics (color and odor) compared to the day of preparation, and there was an increase in viscosity, as expected.

Figure 8: Samples of the final product (A) and the blank (B) after 7 days in the oven



Source: The Authors

On the 14th day, the samples maintained the same organoleptic characteristics as on the 7th day, except for the samples stored in the oven, which showed greater viscosity, as shown in Figure 9.

Figure 9: Samples of the final product (A) and the blank (B) after 14 days in the oven



Source: The Authors

On the 28th day, the sample of the final product that was in the oven lost its viscosity. The other samples maintained the organoleptic characteristics reported in the last analysis.

On the 60th and 90th days, the samples maintained the organoleptic characteristics reported in the 28th day analysis.

In order to find out the reason for the instability under light exposure, a base was manipulated and divided into two portions, adding rosemary essential oil to one, and babassu scrub to the other. Since the day of the manipulation for stability, it was suspected that the essential oil was involved in instability, as it was observed that the addition of the substance made the formulation less viscous. After 7 days under exposure to light and heat, phase separation occurred in the sample containing the scrub, and the sample with the essential oil showed an almost imperceptible change in the base, as if there were small "lumps". On the 120th day, instability was noticed in the final product sample stored in the oven, with phase separation, making it impossible to analyze it, as shown in Figure 10.

Figure 10: Sample of the final product after 120 days in the oven



Source: The Authors

The blank sample in the oven also showed a change in its color, being slightly yellow when compared to the blank from the 7th day (Figure 11), and a rancid smell, due to the oxidation of the components. In addition, when the waxy layer that had formed on the surface was cut, liquid leaked out of it, as shown in Figure 12.

Figure 11: Comparison of blank samples from the 7th and 120th days in the oven, respectively



Source: The Authors

Figure 12: Blank sample after 120 days in the oven

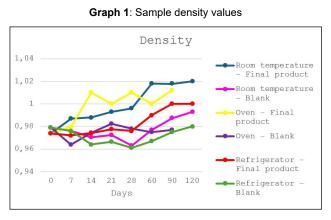


Source: The Authors

The density values of the blank and final product samples remained within the established range, from 0.950 to 1.05. Graph 1 shows that there were no significant changes in the density values. On the 120th day, it was not possible to analyze the density of the

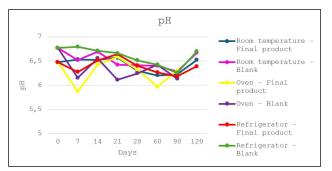
samples stored in the oven due to phase separation.

Regarding pH, after diluting 1/10 of the samples in distilled water, the analysis showed that they were within the established range (5.5 to 7.0), as shown in Graph 2. However, it was not possible to analyze the samples stored in the oven on the 120th day due to emulsion breakage.



Source: The Authors

Graph 2: pH values of the samples



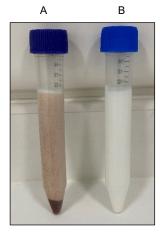
Source: The Authors

From the detailed analysis of the pH values, the final product stored in the oven appeared to have the most noticeable variation, although all the conditions showed a pattern of changes in the value each day. All the blanks on the 60th, 90th and 120th days have very similar values, while the final products vary with each stability condition; however, on the 120th day, all the pH values increased. These variations could perhaps be explained by the calibration of the pH meter.

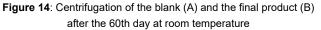
The centrifugation test was carried out for 15 minutes at 1500 rpm, except for the first test, that lasted 30 minutes. All the samples eligible for the stability study were stable after the stress conditions, remaining the same as at the time of preparation, with no sign of emulsion separation. However, sedimentation of the babassu granules was expected, as they are insoluble and suspended in the emulsion (Figure 13). From the analysis on the 60th day, there was a difference in the centrifugation pattern of the final product at room temperature, with the appearance of a dark region (concentration of the exfoliant) in the top portion, shown in

Figure 14. Despite this variation, there was no phase separation.

Figure 13: Centrifugation of the final product (A) and the blank (B) immediately after preparation



Source: The Authors





Source: The Authors

FINAL CONSIDERATIONS

Androgenetic alopecia is constantly appearing in our daily lives, and it is essential to find products that can help its treatment and that are aligned with ESG and sustainability trends.

The developed formulation, in principle, proved to be unstable under light exposure, and long-term, under storage at a high and controlled temperature. The instability may have originated from the incompatibility of the exfoliant or the bases when exposed to light and heat (mainly), and, after 120 days in the oven, due to oxidation of the components as a result of the long period stored in this condition.

Despite the instability under conditions of exposure to heat and light, the formulation was stable when stored at room temperature and in the refrigerator. It is therefore possible to estimate that storage in these conditions does not pose any problems for its commercialization, as long as the packaging is opaque and dark, in order to avoid contact with light, and it remains out of places with high temperatures for a long time.

In order to assess incompatibility between the base and the active ingredients, it is considered necessary in the future to optimize the product by changing the base and exposing it to light and heat. That is also necessary to carry out further research into the scrub, given the limited data available about it.

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