

**CLINICAL RESEARCH STUDY REPORT**  
**SUBJECTIVE CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 – 13410**

**ABIONÁ HAIR PRODUCTS**  
**Subjective clinical efficacy study for hair loss, internally validated.**

**Sponsored By: ABIONÁ COSMÉTICOS LTDA**  
RUA JOÃO DE SOUSA DIAS, 292 - CAMPO BELO – SP – ZIP CODE:04618-001

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**PREPARED FOR:**  
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**CLINICAL STUDIES REPORT**  
**SUBJECTIVE CLINICAL EFFICACY FOR**  
**HAIR LOSS**  
**6003-1-2018.0 - 13410**

**TABLE OF CONTENTS**

<b>1. INTRODUCTION.....</b>	<b>3</b>
<b>2. PURPOSE.....</b>	<b>4</b>
<b>3. STUDY METHODOLOGY .....</b>	<b>4</b>
<b>4. RESULTS .....</b>	<b>7</b>
<b>5. CONCLUSION .....</b>	<b>21</b>
<b>7. APPROVALS.....</b>	<b>24</b>
<b>ANNEX 1 – PRODUCT INFORMATION .....</b>	<b>25</b>
<b>ANNEX 2 – RESULTS.....</b>	<b>26</b>
<b>ANNEX 3 – STUDY GROUP .....</b>	<b>28</b>

**CLINICAL STUDIES REPORT**  
**SUBJECTIVE CLINICAL EFFICACY FOR**  
**HAIR LOSS**  
**6003-1-2018.0 - 13410**

## **1. INTRODUCTION**

Hair loss is as old as time. According to Desmond Morris (1996), a phenomenon called neoteny has been responsible for man's hair loss. Nowadays, hair has an extremely important role in social integration, as it is directly related to self-image and self-confidence. As a result of this, products which minimize hair loss are more and more requested and wanted by consumers. In order to understand the excessive/abnormal hair loss process better, it is essential to know the hair's biological cycle. Hair has a biological cycle of growth and loss. A hair strand grows continuously for an average period from two to six years. This is the period in which the matrix stops proliferating and the lower part of the follicle – below the insertion of the piloerector muscle – becomes atrophied and hair stops being produced. This is known as the catagen phase, which only lasts a few weeks. After the complete disappearance of the matrix and the maximum involution of the follicle, the hair remains in a resting phase: the telogen phase. After some time in the telogen phase, which lasts three months, a new matrix is organized and new hair is created in the anagen phase and, in this way, the cycle continues, successively, for life (ABRAHAM et al., 2009). There are some factors that affect said increase of hair strand loss, such as stress, excessive pulling of the strands, an inadequate diet (iron and vitamin deficiency), hormonal disturbances, exposure to toxic substances and to drugs (such as antivirals and antineoplastic drugs), among others (ADDOR et al., 2014). To diagnose hair loss, two unknown factors must be clarified: defining what the amount normal amount of hair lost it; and secondly, specifying what the capacity for hair restoration is, both under normal conditions and before pathology.

### **Scientific knowledge regarding trichology and the different procedures carried out.**

Tests performed with human beings are regulated according to quite strict laws, in order to protect and safeguard individuals. These laws vary depending on the country. In Brazil, this research is allowed provided that protocols are approved by a Medical Ethics Committee and that provisions appearing in the Declaration of Helsinki and Resolution 466/12 are complied with (NATIONAL HEALTH COUNCIL, 2012).

**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

## **2. PURPOSE**

To clinically and subjectively verify the efficacy of the product under investigation in the reduction of hair loss.

## **3. STUDY METHODOLOGY**

### **3.1. SCREENING OF PARTICIPANTS**

For the subjective clinical efficacy research, participants aged between 35 and 65 years old of phototypes II to IV (FITZPATRICK), both female and male, were selected.

The total sample of the studies was composed of 20 (twenty) participants. The distribution of participants in the investigations was according to the table below:

NUMBER OF PARTICIPANTS	SEX		AGE	
	Female	Male	Minimum	Maximum
20	17	03	35	65

### **Inclusion and exclusion criteria**

The exclusion criteria for this research were:

- ✓ Pregnancy or risk of pregnancy;
- ✓ Lactation;
- ✓ One of the following topical use or systemic use drugs: immunosuppressants, antihistamines, non-hormonal anti-inflammatory drugs, and corticoids up to 30 days before the screening or, in case of immunosuppressants, the interval will be of 3 months before the screening;
- ✓ Adrenogenital syndrome or ovarian, adrenal or pituitary gland cancer;
- ✓ Presence of polycystic ovary;
- ✓ Pathologies and/or active skin lesions (local and/or disseminated) in the assessment area;
- ✓ Relevant clinical record or current evidence of abuse of alcohol or other drugs;
- ✓ Record known or suspicion of intolerance to products of the same category;
- ✓ Intense sun exposure up to 15 days before the assessment;
- ✓ Beauty or dermatological treatment in the assessment area up to 04 weeks before the screening;
- ✓ Localized or generalized dermatological diseases;

**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

- ✓ Participant included in another survey during the period of this study;
- ✓ Professionals directly involved in the carrying out of this study;
- ✓ Other conditions considered by the examining physician as reasonable for disqualification to participate in the study.

The inclusion criteria for this research were:

- ✓ Female and male sex;
- ✓ Age between 50 to 65 years for females and 35 to 40 for males;
- ✓ Loss present in the initial exam;
- ✓ Intact skin in the test region (scalp);
- ✓ Absence of hormonal problems;
- ✓ Healthy participants.
- ✓ To understand, agree on and sign the Free and Informed Consent Form.

Any beauty, cosmetic or dermatological treatment in the body was still prohibited during the study. If therapeutic use of any of the aforementioned drugs were necessary, the participant would be withdrawn from the study.

The participants underwent a dermatological exam.

### **3.2. PRODUCT ASSESSED**

Product information, declared by the industry, is described in Annex 2. A sample of the product was stored and kept in Ecolyzer® for a period of 5 months after the issuance of the Test Report.

### **3.3. MATERIAL**

The materials used for carrying out the tests were:

- ✓ Research notebook;
- ✓ Product samples (provided by the contracting company);
- ✓ Usage journal;

**CLINICAL STUDIES REPORT SUBJECTIVE  
CLINICAL EFFICACY FOR HAIR LOSS  
6003-1-2018.0 - 13410**

**3.4. APPLICATION OF THE PRODUCT**

The purpose and the methodology of the research was explained to participants and they signed a Free and Informed Consent Form (Annex 1).

The sample was delivered to participants and they were instructed to use it according to the usage directions determined by the Sponsor. Therefore, normal conditions of use were characterized (Annex 2).

**3.5. SCALES USED IN CLINICAL ASSESSMENTS**

**3.5.1. Clinical efficacy assessment - Hair Loss (D0 – D60)**

For the clinical efficacy assessment of this product, the dermatologist assessed the following parameters in relation to hair loss at the beginning (D0) and after 60 +/- 2 days of using the product at home (D60):

<b>Capillary caliber*</b>	<b>*Classification:</b> 1 = Mild; 2 = Moderate; 3 = Severe
<b>Strands density*</b>	
<b>Strands volume*</b>	

**3.6. SCALES USED WHEN ASSESSING PARTICIPANT OPINION**

**3.6.1. Cosmetic appreciability questionnaire – Participant Opinion (D60)**

For the subjective efficacy assessment of this product, the following parameters were assessed after 60 +/- 2 days (D60) of using the product at the home:

<b>In relation to thicker strands*</b>	<p><b>*Classification:</b> 1 = I totally agree; 2 = I agree; 3 = I do not agree nor disagree; 4 = I totally disagree; 5 = I disagree</p> <p><b>**Classification:</b> 1= 7 days; 2= 15 days; 3= 20 days; 4= 60 days;</p> <p><b>***Classification:</b> 1 = Loss increase; 2 = Loss Reduction; 3 = There were changes; 4 = No problem with hair loss.</p>
<b>Did my hair grow faster?*</b>	
<b>With the continuous use of the product, after how many days did you start noticing strands were growing?*</b>	
<b>With the continuous use of the product, in relation to loss, did you***</b>	
<b>In relation to the general appearance of the hair, is it stronger and more resistant?*</b>	
<b>Did you notice more volume in your hair?*</b>	
<b>The areas with flaws were visibly reduced*</b>	
<b>Hair oiliness was reduced*</b>	
<b>With the continuous use of the product, after how many days did you start noticing strands were stronger?*</b>	

**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

**4. RESULTS**

20 participants returned after 60 +/- 2 days of study. None of the participants stated having a feeling of discomfort attributable to the product being tested.

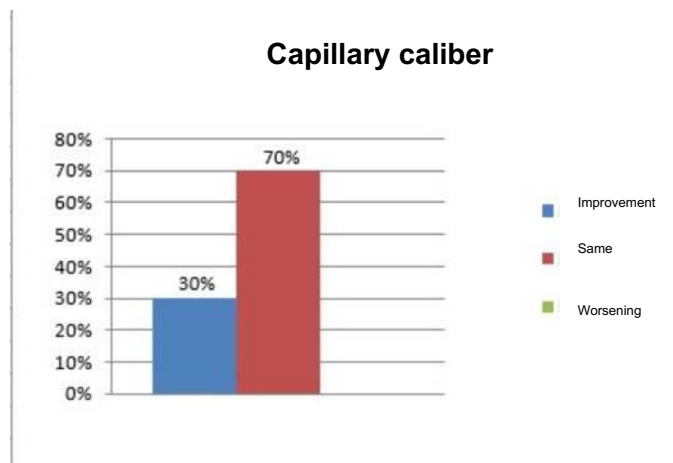
**4.1. Clinical efficacy assessment - Hair Loss (D0 – D60)**

The product efficacy was discovered by means of the clinical assessment according to predefined scales.

The results obtained are described in ANNEX 3.

a) Capillary caliber:

- After 60 +/- 2 days of using the product, 06 participants (30%) showed an improvement in the capillary caliber, 14 participants (70%) showed the same caliber and no participant (0%) showed a worsening, according to the graphic below:

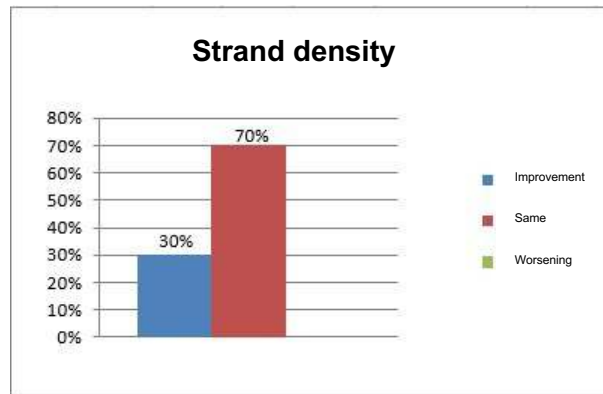


*Graphic 1: Clinical assessment of the capillary caliber change (thickness).*

**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

b) Strands density:

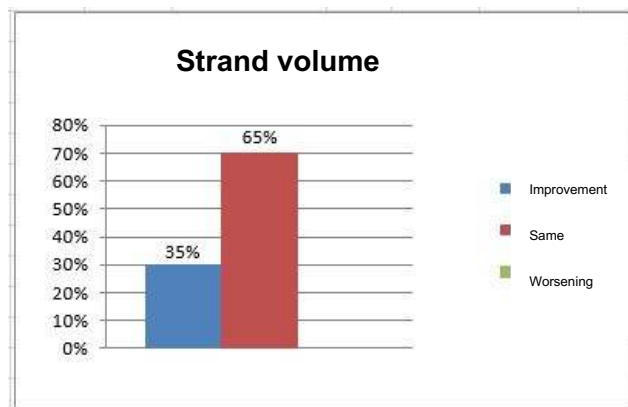
- After 60 +/- 2 days of using the product, 06 participants (30%) showed an improvement in strand density, 14 participants (70%) showed the same density and no participant (0%) showed a worsening, according to the graphic below:



Graphic 2: Clinical assessment of the change in strand density.

c) Strand volume:

- After 60 +/- 2 days of using the product, 07 participants (35%) showed an improvement in the strand volume, 13 participants (65%) showed the same volume and no participant (0%) showed a worsening, according to the graphic below:



Graphic 3: Clinical assessment of the change in strand volume.



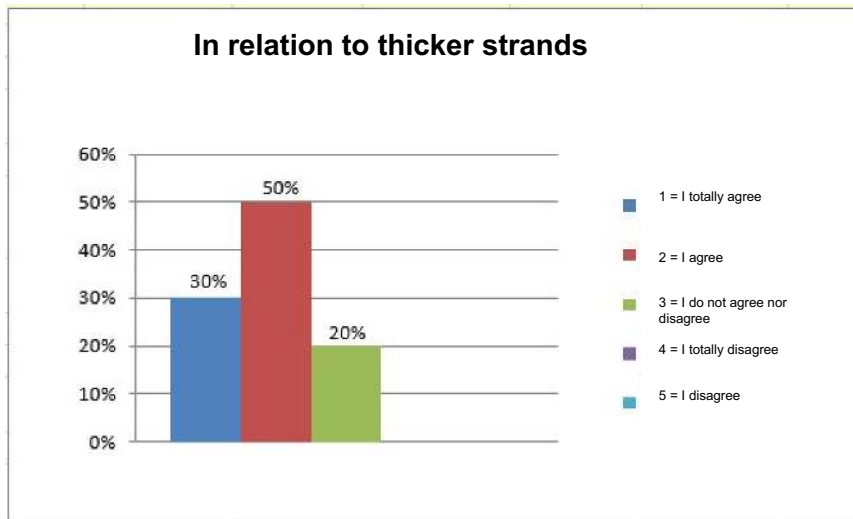
**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

**4.2. Cosmetic appreciability questionnaire – Participant Opinion (D60)**

The product efficacy was discovered by means of the questionnaire with participant opinion according to predefined scales. The results obtained are described in ANNEX 3.

d) In relation to thicker strands?

- After 60 +/- 2 days of using the product, 06 participants (30%) totally agreed that their strands were thicker, 10 participants (50%) agreed, 04 participants (20%) did not agree nor disagree and no participants (0%) totally disagreed or disagreed, according to the graphic below:

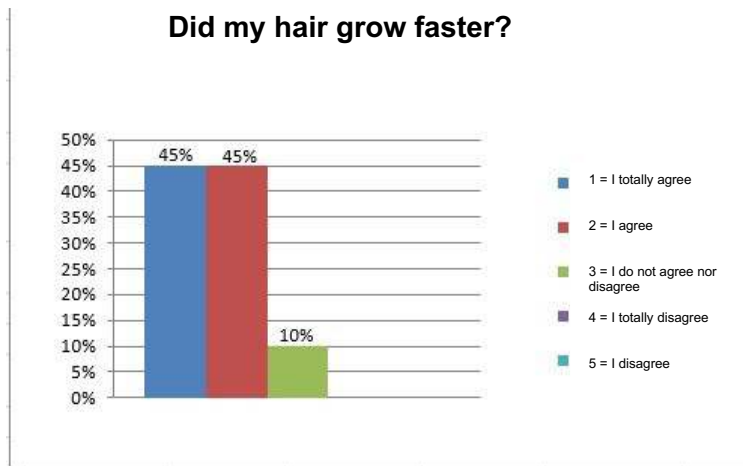


*Graphic 04: Assessment in relation to strand thickness.*

**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

e) Did my hair grow faster?:

- After 60 +/- 2 days of using the product, 09 participants (45%) totally agreed that their hair had grown faster, 09 participants (45%) agreed, 02 participants (10%) did not agree nor disagree and no participants (0%) totally disagreed or disagreed, according to the graphic below:

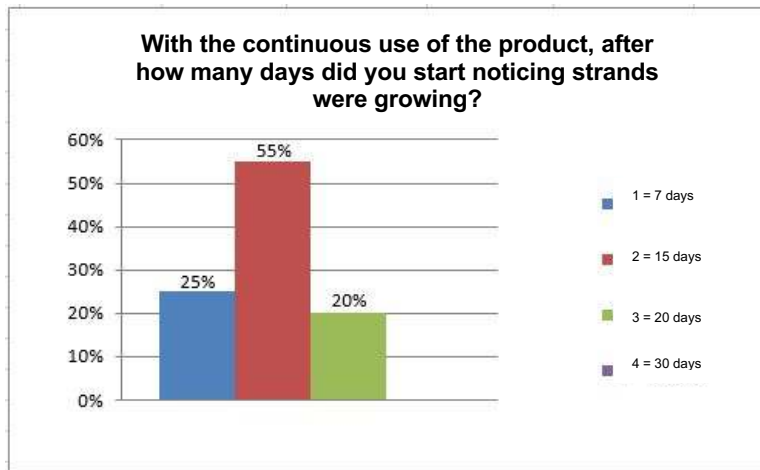


*Graphic 05: Assessment in relation to faster hair growth.*

**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

f) With the continuous use of the product, after how many days did you start noticing strands were growing?:

- After 60 +/- 2 days of using the product, 05 participants (25%) noticed that their strands were growing in 7 days, 11 participants (55%) noticed it in 15 days, 04 participants (20%) noticed it in 20 days and no participants (0%) noticed it in 30 days, according to the graphic below:

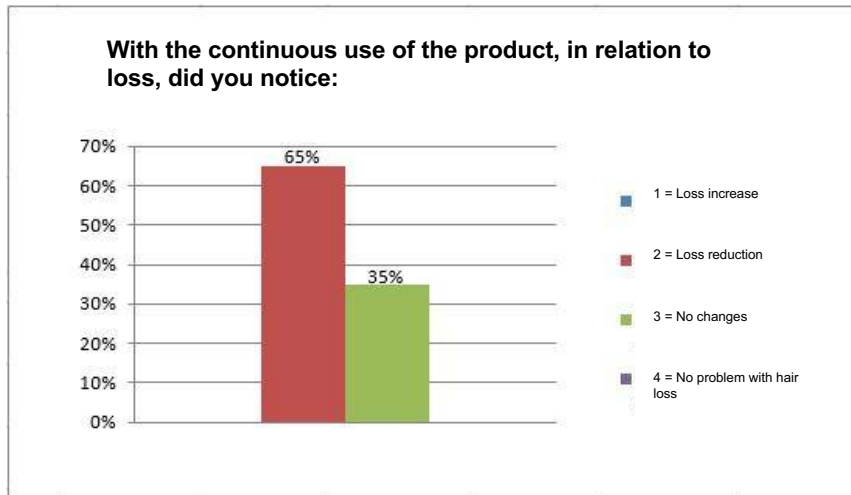


Graphic 06: Assessment in relation to the time in which strands grew.

**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

g) With the continuous use of the product, in relation to loss, did you notice:

- After 60 +/- 2 days of using the product, 13 participants (65%) reported that there was a reduction of hair loss, 07 participants (35%) reported that there were no changes and no participants (0%) reported an increase or did not have any problem with hair loss, according to the graphic below:

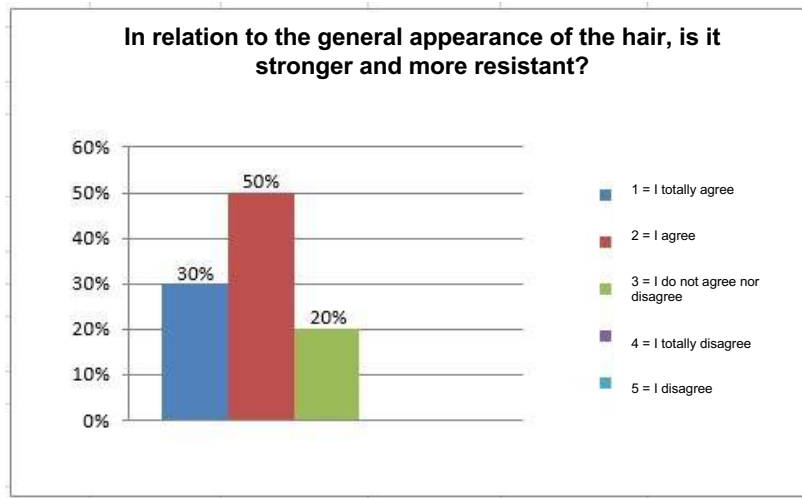


*Graphic 07: Assessment in relation to hair loss.*

**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

h) In relation to the general appearance of the hair, is it stronger and more resistant?:

- After 60 +/- 2 days of using the product, 06 participants (30%) totally agreed that their hair was stronger and more resistant, 10 participants (50%) agreed, 04 participants (20%) did not agree nor disagree and no participants (0%) totally disagreed or disagreed, according to the graphic below:

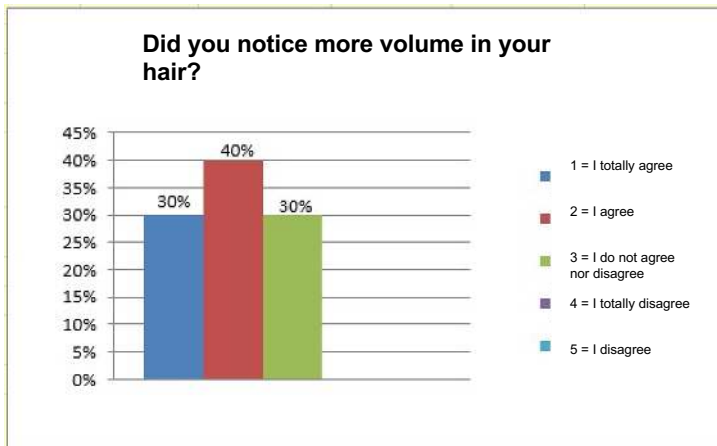


*Graphic 08: Assessment in relation to stronger and more resistant hair after using the product.*

**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

i) Did you notice more volume in your hair?:

- After 60 +/- 2 days of using the product, 06 participants (30%) totally agreed that their hair had more volume, 08 participants (40%) agreed, 06 participants (30%) did not agree nor disagree and no participants (0%) totally disagreed or disagreed, according to the graphic below:

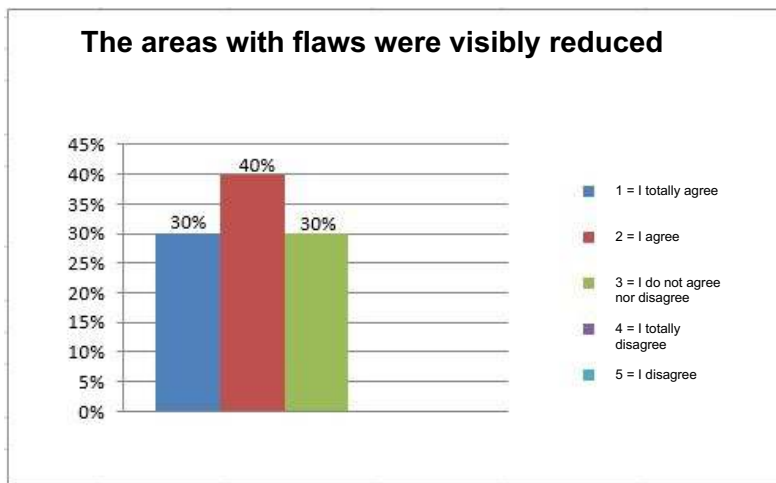


*Graphic 09: Assessment in relation to the increase of hair volume.*

**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

j) The areas with flaws were visibly reduced:

- After 60 +/- 2 days of using the product, 06 participants (30%) totally agreed that the flaws had visibly reduced, 08 participants (40%) agreed, 06 participants (30%) did not agree nor disagree and no participants (0%) totally disagreed or disagreed, according to the graphic below:

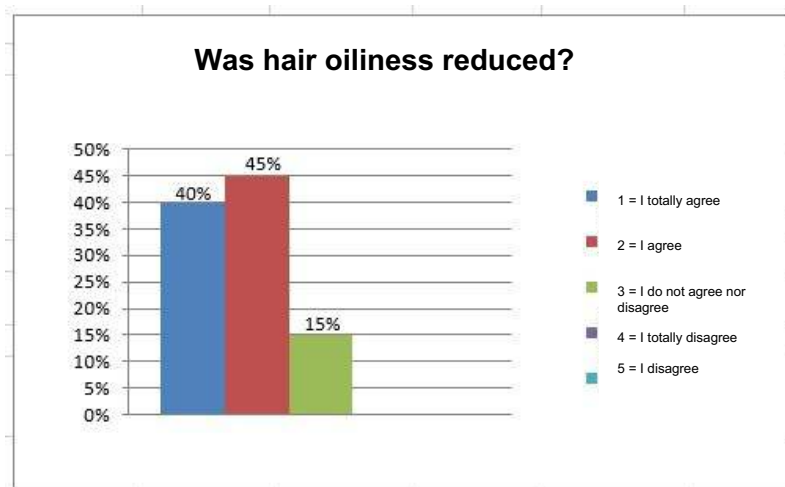


*Graphic 10: Assessment in relation to flaws visibly reduced.*

**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

k) Was hair oiliness reduced?:

- After 60 +/- 2 days of using the product, 08 participants (40%) totally agreed that hair oiliness had reduced, 09 participants (45%) agreed, 03 participants (15%) did not agree nor disagree and no participants (0%) totally disagreed or disagreed, according to the graphic below:



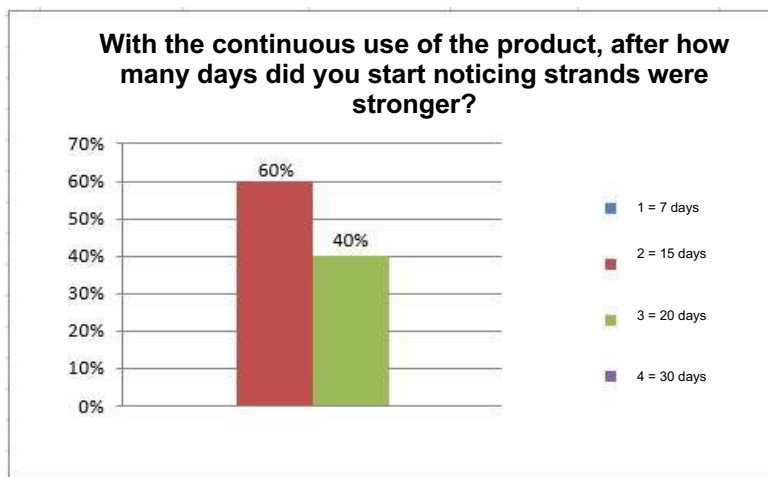
*Graphic 11: Assessment in relation to the reduction of hair oiliness.*



**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

I) With the continuous use of the product, after how many days did you start noticing strands were stronger?:

- After 60 +/- 2 days of using the product, participants (60%) noticed it in 15 days, 08 participants (40%) noticed it in 20 days and no participants (0%) noticed it in 7 or 30 days, according to the graphic below:



Graphic 12: Assessment in relation to the time in which strands became stronger.

**CLINICAL STUDIES REPORT SUBJECTIVE  
CLINICAL EFFICACY FOR HAIR LOSS  
6003-1-2018.0 - 13410**

**4.3. PHOTOGRAPHIC RECORD**

Records of the images were created at the beginning (D0) and at the end of the treatment (D60) to make a comparison (the photos were selected per sampling).

**PARTICIPANT 02**



BEFORE (D0)



AFTER (D60)

**CLINICAL STUDIES REPORT SUBJECTIVE  
CLINICAL EFFICACY FOR HAIR LOSS  
6003-1-2018.0 - 13410**

**PARTICIPANT 07**



BEFORE (D0)



AFTER (D60)

**PARTICIPANT 08**



BEFORE (D0)



AFTER (D60)

**CLINICAL STUDIES REPORT SUBJECTIVE  
CLINICAL EFFICACY FOR HAIR LOSS  
6003-1-2018.0 - 13410**

**PARTICIPANT 09**



BEFORE (D0)



AFTER (D60)

**PARTICIPANT 17**



BEFORE (D0)



AFTER (D60)



**CLINICAL STUDIES REPORT SUBJECTIVE  
CLINICAL EFFICACY FOR HAIR LOSS  
6003-1-2018.0 - 13410**

**5. CONCLUSION**

In the Clinical Research of subjective clinical efficacy for hair loss of the product HAIR LOTION, CODE 6003-1-2018.0 – 13410, sent by the company ABIONÁ COSMÉTICOS LTDA., it was possible to conclude that:

**5.1. Clinical efficacy assessment monitored by dermatologist – Hair Loss (D0/D60)**

<b>Capillary caliber</b>	<i>After 60 +/- 2 days of using the product, 30% of the participants showed an improvement in the capillary caliber;</i>
<b>Strands density</b>	<i>After 60 +/- 2 days of using the product, 30% of the participants showed an improvement in strand density;</i>
<b>Strands volume</b>	<i>After 60 +/- 2 days of using the product, 35% of the participants showed an improvement in strand volume.</i>

**5.2. Cosmetic appreciability questionnaire – Participant Opinion (D60)**

<b>In relation to thicker strands</b>	<i>After 60 +/- 2 days of using the product, 80% of the participants noticed that strands were thicker.</i>
<b>Did my hair grow faster?</b>	<i>After 60 +/- 2 days of using the product, 90% of the participants noticed that their hair had grown faster.</i>
<b>With the continuous use of the product, after how many days did you start noticing strands were growing?</b>	<i>After 60 +/- 2 days of using the product, 25% of the participants noticed that their strands were growing in 7 days, 55% noticed it in 15 days and 20% noticed it in 20 days.</i>
<b>With the continuous use of the product, in relation to loss, did you notice</b>	<i>After 60 +/- 2 days of using the product, 65% of the participants reported that there was a reduction of hair loss.</i>
<b>In relation to the general appearance of the hair, is it stronger and more resistant?</b>	<i>After 60 +/- 2 days of using the product, 80% of the participants reported that their hair was stronger and more resistant.</i>
<b>Did you notice more volume in your hair?</b>	<i>After 60 +/- 2 days of using the product, 80% of the participants reported that their hair had more volume.</i>

**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

<b>The areas with flaws were visibly reduced</b>	<i>After 60 +/- 2 days of using the product, 70% of the participants reported that flaws had been visibly reduced.</i>
<b>Hair oiliness was reduced</b>	<i>After 60 +/- 2 days of using the product, 85% of the participants reported that their hair was less oily</i>
<b>With the continuous use of the product, after how many days did you start noticing strands were stronger?</b>	<i>After 60 +/- 2 days of using the product, 60% of the participants noticed that their strands were stronger in 15 days and 40% in 20 days.</i>

This report is exclusively for the purposes of the **National Sanitary Surveillance Agency** of the **Ministry of Health** and for the internal use by the company **ABIONÁ COSMÉTICOS LTDA**. No information in this report may be disclosed by any means of communication without the written authorization of the author.

**NOTE 1:** The result refers to the sample received.

**NOTE 2:** The sampling was taken by the study Sponsor.

**NOTE 3:** The condition for carrying out the test ensures the traceability of the data generated.

**NOTE 4:** Partial reproduction of this Test Report is forbidden.

**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

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<[HTTP://BVSMS.SAUDE.GOV.BR/BVS/SAUDELEGIS/CNS/2013/RES0466\\_12\\_12\\_2012.HTML](http://BVSMS.SAUDE.GOV.BR/BVS/SAUDELEGIS/CNS/2013/RES0466_12_12_2012.HTML)>.

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**CLINICAL STUDIES REPORT SUBJECTIVE  
CLINICAL EFFICACY FOR HAIR LOSS  
6003-1-2018.0 - 13410**


**7. APPROVALS**

<b>Approved by:</b>

-
_____ Andrea Trugilo Jurado Cosmetics Technologist (CRQ: 04267041 IV – Region) Date: 01/09/2019

<b>Approved by:</b>

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_____ Roberta Pontes Farath, MD Dermatologist CRM: 112.458 Date: 01/09/2019

<b>Approved by:</b>

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_____ Claudia C. Ramos Quality Assurance (CRQ: 04161558 – IV Region) Date: 01/09/2019



**CLINICAL STUDIES REPORT SUBJECTIVE  
CLINICAL EFFICACY FOR HAIR LOSS  
6003-1-2018.0 - 13410**

**ANNEX 1 – PRODUCT INFORMATION**

Formula not declared.

**CLINICAL STUDIES REPORT SUBJECTIVE  
CLINICAL EFFICACY FOR HAIR LOSS  
6003-1-2018.0 - 13410**

**ANNEX 2 – RESULTS**

**Clinical efficacy assessment - Hair Loss (D0 – D60)**

CAPILLARY CALIBER*					STRANDS DENSITY*					STRANDS VOLUME*				
Vol. Ref.	D0	D60	Δ	improvement/ worsening	Vol. Ref.	D0	D60	Δ	improvement/ worsening	Vol. Ref.	D0	D60	Δ	improvement/ worsening
1	2	2	0	same	1	2	2	0	same	1	3	3	0	same
2	2	2	0	same	2	2	3	1	improvement	2	3	3	0	same
3	3	3	0	same	3	3	3	0	same	3	2	3	1	improvement
4	3	3	0	same	4	3	3	0	same	4	3	3	0	same
5	2	3	1	improvement	5	2	2	0	same	5	2	3	1	improvement
6	1	2	1	improvement	6	1	2	1	improvement	6	2	2	0	same
7	3	3	0	same	7	3	3	0	same	7	3	3	0	same
8	1	2	1	improvement	8	1	2	1	improvement	8	2	3	1	improvement
9	3	3	0	same	9	3	3	0	same	9	3	3	0	same
10	2	3	1	improvement	10	2	2	0	same	10	2	3	1	improvement
11	3	3	0	same	11	3	3	0	same	11	3	3	0	same
12	3	3	0	same	12	2	3	1	improvement	12	3	3	0	same
13	3	3	0	same	13	3	3	0	same	13	2	3	1	improvement
14	1	1	0	same	14	1	1	0	same	14	2	2	0	same
15	2	3	1	improvement	15	1	2	1	improvement	15	2	3	1	improvement
16	1	2	1	improvement	16	1	2	1	improvement	16	2	2	0	same
17	2	2	0	same	17	2	2	0	same	17	2	3	1	improvement
18	3	3	0	same	18	3	3	0	same	18	3	3	0	same
19	3	3	0	same	19	3	3	0	same	19	2	2	0	same
20	2	2	0	same	20	2	2	0	same	20	2	2	0	same

*Classification D0 - D60	
0	Absent
1	Mild
2	Moderate
3	Severe
	Participant Withdrew

**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

**Cosmetic appreciability questionnaire – Participant Opinion (D60)**

Cosmetic appreciability questionnaire D60									
Participant No.	In relation to thicker strands*	Did my hair grow faster?*	With the continuous use of the product, after how many days did you start noticing strands were growing?*	With the continuous use of the product, in relation to loss, did you notice?*	In relation to the general appearance of the hair, is it stronger and more resistant?*	Did you notice more volume in your hair?*	The areas with flaws were visibly reduced*	Hair oiliness was reduced*	With the continuous use of the product, after how many days did you start noticing strands were stronger?*
1	1	2	2	2	1	1	1	1	2
2	2	1	1	2	2	2	2	2	3
3	2	2	2	2	2	3	3	1	2
4	3	3	3	3	3	3	3	2	3
5	2	1	2	2	2	3	3	2	2
6	2	2	3	3	2	1	1	1	3
7	1	1	2	3	1	2	2	2	2
8	2	2	2	2	2	2	2	2	3
9	3	3	2	2	3	3	3	3	2
10	1	1	3	2	1	1	1	1	3
11	2	1	1	3	2	3	3	2	2
12	2	2	2	3	2	2	2	2	2
13	2	1	1	2	2	2	2	3	3
14	1	2	2	3	1	1	1	1	2
15	3	2	2	2	3	1	1	1	2
16	2	1	1	2	2	2	2	2	2
17	1	1	2	2	1	1	1	1	2
18	3	2	3	3	3	3	3	3	3
19	1	1	1	2	1	2	2	2	3
20	2	2	2	2	2	2	2	1	2

\*Classification: 1 = I totally agree; 2 = I agree; 3 = I do not agree nor disagree; 4 = I totally disagree; 5 = I disagree.

\*\*Classification: 1= 7 days; 2= 15 days; 3= 20 days; 4= 60 days;

\*\*\*Classification: 1 = Loss increase; 2 = Loss reduction; 3 = No changes; 4 = No problem with hair loss.

**CLINICAL STUDIES REPORT SUBJECTIVE**  
**CLINICAL EFFICACY FOR HAIR LOSS**  
**6003-1-2018.0 - 13410**

**ANNEX 3 – STUDY GROUP**

<b>Participant Ref.</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>
<b>Initials (Name)</b>	PPJS	SSD	ACRS	LACS	NMS	RLC	MCS	VBC	RSD	TSO
<b>Sex</b>	F	F	F	M	F	F	F	F	F	F
<b>Age (years)</b>	50	60	53	39	65	50	58	60	61	50
<b>Phototype</b>	IV	II	IV	IV	IV	III	III	III	III	III
<b>Participant Ref.</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>	<b>17</b>	<b>18</b>	<b>19</b>	<b>20</b>
<b>Initials (Name)</b>	PO	VS	AO	HMC	MJSC	MCT	RSAF	FOB	CSP	DRO
<b>Sex</b>	F	F	F	F	M	F	M	F	F	F
<b>Age (years)</b>	50	52	56	62	48	62	65	61	52	57
<b>Phototype</b>	III	IV	IV	II	III	IV	IV	IV	III	III

<b>Key:</b>	
	Participant withdrew
F	Female
M	Male