

# **EVALUATION OF THE ANTI- DANDRUFF EFFICACY OF A TREATMENT**

**RUEBER S.L.**

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## EVALUATION OF THE ANTI-DANDRUFF EFFICACY OF A TREATMENT

**RUEBER S.L.**

<b>Efficacy study no.:</b>	ID108-19
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## I. EVALUATION STUDY

### 1. TITLE

Evaluation of the anti-dandruff efficacy of a treatment.

### 2. OBJECTIVES

Evaluation of the anti-dandruff efficacy (elimination) of a cosmetic treatment evaluated by instrumental techniques.

To evaluate the effect of the treatment under study at different times through the self-perception of characteristics as well as issues related to the organoleptic characteristics and tolerance of the treatment.

### 3. EXPERIMENTAL DESIGN

#### 3.1. TYPE OF STUDY

Single-center study with 20 volunteers with dandruff. The study was conducted according to the standard operating procedure of Centro de Tecnología Capilar S.L. and in compliance with the regulations established in “Guía para investigaciones con seres humanos” (Guidelines for Research on Human Beings) and the guidelines of the Scientific Committee on Consumer Safety (SCCS).

#### 3.2. STUDY DURATION

Duration: 28 days.

The tests performed at the different control points are:

- Start of the study ( $T_0$ )
  - General photograph of the scalp and hair
  - Microphotography of the scalp by microcamera
  - Survey
  
- At 28 days of the study ( $T_{28}$ ) (elimination)

- General photograph of the scalp and hair
- Microphotography of the scalp by microcamera
- Survey

#### **4. ATTRIBUTES UNDER STUDY**

In this study the following attributes are evaluated:

- ✓ Dandruff (elimination)
- ✓ General assessment of the product (consumer test)

#### **5. APARATOLOGY AND MATERIAL**

To carry out this study the following is required:

- Canon EOS 600 D photographic camera
- Microcamera I-scope

#### **6. PERSONNEL**

##### **6.1. TECHNICIANS**

A specialized technician in capillary treatments performs the experimental tests. The study director interprets the results obtained in such tests.

##### **6.2. VOLUNTEERS**

Number of volunteers:	20
Hair type:	Varied with dandruff
Sex:	12 women (60%) and 8 men (40%)
Age:	18 to 70 years (Average age $44 \pm 13$ )

Table 1. Description of the volunteers according to sex and age

Volunteer	1	2	3	4	5	6	7	8	9
Sex	M	W	M	M	M	M	W	M	W
Age	50	40	34	47	65	61	48	27	30
Volunteer	10	11	12	13	14	15	16	17	18
Sex	W	W	W	W	W	W	M	W	M
Age	56	20	47	58	49	23	43	45	59
Volunteer	19	20							
Sex	W	W							
Age	43	39							

#### 6.2.1. SELECTION CRITERIA

##### 6.2.1.1. Inclusion Criteria

- Aged 18-70
- Healthy volunteers
- No evidence of systemic diseases (e.g. heart or psychiatric disease etc.)
- Oily dandruff (middle conditions)
- Commitment not to use systemic topic or oral products with similar effect to that of the products to be tested throughout the study period
- Do not change the daily routine
- Having signed the written consent form and being informed of the study objective
- Enough motivation and availability

##### 6.2.1.2. Non-inclusion/exclusion criteria

- Clinical score of dandruff 5 because is considered a medical problem
- Not to sign the written consent
- Allergy or hypersensitivity to any of the ingredients of the products tested
- Scalp diseases: psoriasis, dermatitis, etc.
- Modification of the normal diet: hypocaloric diet, Atkins diet, etc.
- Pregnant or nursing women

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### 6.2.2. CONSENT

Each volunteer was informed orally and in writing about the characteristics and objectives of the study. Each volunteer signed a written consent form and received a copy, with another copy kept on file at C.T.C.

### 6.2.3. INCIDENTS AND WITHDRAWALS

None.

## 7. FORMULAS

### 7.1. PRODUCTS UNDER STUDY

#### **Name of the product: N5 CREMA**

INCI: Aqua; C12-20 Acid PEG-8 Ester; Glycerin; Paraffinum Liquidum; Triticum Vulgare Germ Oil; Hydrolyzed Collagen; Urea; Hydrolyzed Glycosaminoglycans; Parfum; Methylparaben; Propylparaben; Phenoxyethanol; BHT; BHA; Benzoic Acid; Sodium Benzoate; Sodium Hydroxide; Disodium EDTA; Ascorbyl Palmitate; Butylparaben; Ethylparaben; Citronellol; Benzyl Salicylate; Limonene; Hexyl Cinnamal; Linalool; Geraniol; Butylphenyl Methylpropional; Hydroxyisohexyl 3-cyclohexene Carboxaldehyde; C.I. 16035.

#### **Name of the product: N6 CHAMPU**

INCI: Aqua; Sodium Laureth Sulfate; Cocamide DEA; Cocamidopropyl Betaine; Alcohol Denat.; Climbazole; Parfum; Sodium Chloride; PEG-40 Hydrogenated Castor Oil; Lactic Acid; Sodium Benzoate; Methyl Chloro Isothiazolinone; Methyl Isothiazolinone; Magnesium Nitrate; BHT; Magnesium Chloride; C.I. 45100; Linalool; Limonene.

#### **Name of the product: N7 TONICO**

INCI: Alcohol Denat.; Aqua; Climbazole; Parfum; Lactic Acid; Limonene; Linalool; Geraniol; Citronellol; C.I. 17200.



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**Name of the product: N8 TONICO POTENCIADO**

INCI's: Aqua; Alcohol Denat.; Glycerin; Urea; Parfum<sup>1</sup>; Climbazole; Calcium Pantothenate; Niacinamide; Coumarin; Pyridoxine HCl; Cianocobalamin; Ascorbic Acid; Riboflavin; Linalool; Limonene; Geraniol; Citronellol.

Manufactured by: Rueber S.L.

## **8. PROTOCOL**

### **8.1. START OF THE STUDY (T<sub>0</sub>)**

Each volunteer goes to the C.T.C. facilities, where the following tests are carried out:

- General photograph of the scalp and hair
- Microphotography of the scalp by microcamera
- Survey

Each volunteer receives:

- Anti-dandruff treatment
- Consent and product use instructions
- Date and time for the next visit (T<sub>28</sub>)

### **8.2. AT THE VOLUNTEER'S HOME**

Volunteers apply the treatment according with the next protocol.

- **Name of the product: N5 CREMA**
  - Apply one time per week before going to sleep.
  - To do this open partings (lines on the scalp) spaced 1 cm apart.
  - Apply the cream directly along the parting and spread it out. Once you have spread it, massage the scalp for 5 minutes so that it absorbs the cream.

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<sup>1</sup> Cinnamon Oil, Clove Oil; Thyme Oil

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- Remove in the morning, washing your head with the N6 Champú without water directly on top of the cream.
- Next, wash it as indicated in the N6 Champú application method.
- Do the massaging from the neck towards the top of the head to stimulate the blood flow. Open partings in your hair, pinching the scalp with the fingers of both hands to lift it away from the skull.
- **Name of the product: N6 CHAMPU**
- Use whenever you need to wash your hair.
- Apply in dry hair, leave on for 5 minutes.
- Rinse with water several times until no shampoo is left (add a bit of water and massage, doing this 3 or 4 times until there is no shampoo left) and do the second shampooing as normal.
- **Name of the product: N7 TÓNICO**
- Apply on alternate days, alternating with the N8 Tonico Potenciado.
- Apply 3 pipet (women) and 2 pipet (men) of the product directly in the scalp, opening partings and trying to wet the hair as little as possible. Later on, massage the scalp for 5 minutes. Not rinse off.
- Do the massaging from the neck towards the top of the head to stimulate the blood flow. Open partings in your hair, pinching the scalp with the fingers of both hands to lift it away from the skull.
- **Name of the product: N8 TONICO POTENCIADO**
- Apply on alternate days, alternating with the N7 Tonico.
- Apply 10 mL (women) and 5 mL (men) of the product in the scalp, opening partings and trying to wet the hair as little as possible. Later on, massage the scalp for 5 minutes. Not rinse off.

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- Do the massaging from the neck towards the top of the head to stimulate the blood flow. Open partings in your hair, pinching the scalp with the fingers of both hands to lift it away from the skull.

### **8.3. END OF THE TREATMENT (T28)**

Each panelist goes to the C.T.C. facilities where the following tests are carried out:

- General photograph of the scalp and hair
- Microphotography of the scalp by microcamera
- Survey

## **9. TESTS PERFORMED**

### **9.1. GENERAL PHOTOGRAPH OF THE STATE OF THE SCALP**

Photographs are taken of the most dandruff affected areas of the scalp of each panelist.

### **9.2. MICROCAMERA OBSERVATION**

The microcamera is a professional diagnostic piece of equipment consisting of a probe for exploring the scalp and the software for capturing and displaying images. The microcamera's function is to allow a direct, magnified view of a scalp area to observe its state: whether flakiness, greasiness or redness are present, etc.

The attributes under study – dandruff, redness and greasiness - are evaluated on a scale of 5 values. The lowest value (0) corresponds to the level "absence" of the attribute and the highest value (5) corresponds to the level "very high". The intermediate values 1, 2, 3 and 4 correspond to the levels "low", "average", "considerable" and "high", respectively. The results of the observation of dandruff, redness and greasiness in each panelist are included in their file.

When the images obtained at the beginning and end of the trial are compared, interesting graphic evidence of the effectiveness of the products tested is obtained.

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### 9.3. VOLUNTEER ASSESSMENT

The panelists assess the initial state of their scalp at  $T_0$  and  $T_{28}$ . The assessment is collected in a survey prepared for this purpose.

## II. RESULTS

### 1. ASSESSMENT BY THE SPECIALIZED TECHNICIAN

#### 1.1. SCALP ASSESSMENT

The specialized technician, who carries out the tests, performs the clinical evaluation of the degree of dandruff on the scalp at the beginning of the study ( $T_0$ ) and at the end of the treatment ( $T_{28}$ ) following the protocol mentioned in the previous paragraphs.

The results of each of the tests for each volunteer are shown in Table 2. The overall result for each volunteer is shown in Table 3.

Table 2: Individual assessment of the level of dandruff by the specialized technician in the different tests performed.

Volunteer	General photography		Microcamera	
	$T_0$	$T_{28}$	$T_0$	$T_{28}$
1	2	1	3	1
2	3	1	3	1
3	3	2	4	2
4	2	1	3	1
5	2	2	4	3
6	2	1	2	1
7	3	3	4	3
8	3	2	3	2
9	3	1	3	3
10	3	1	3	1
11	2	1	3	1
12	3	1	3	1
13	4	3	4	3
14	2	1	3	1
15	2	1	3	2
16	4	2	4	3
17	3	1	4	1
18	2	1	3	1
19	4	2	4	3
20	2	1	4	1



Table 3: Global assessment of the level of dandruff and seborrhea by the specialized technician



Volunteer	Dandruff		Dandruff variation (%)
	T <sub>0</sub>	T <sub>28</sub>	T <sub>0</sub> vs T <sub>28</sub>
1	3	1	-60,0
2	3	1	-66,7
3	4	2	-42,9
4	3	1	-60,0
5	3	3	-16,7
6	2	1	-50,0
7	4	3	-14,3
8	3	2	-33,3
9	3	2	-33,3
10	3	1	-66,7
11	3	1	-60,0
12	3	1	-66,7
13	4	3	-25,0
14	3	1	-60,0
15	3	2	-40,0
16	4	3	-37,5
17	4	1	-71,4
18	3	1	-60,0
19	4	3	-37,5
20	3	1	-66,7
Average	3	2	-47,1

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## 1.2. GENERAL APPEARANCE OF THE SCALP

In the present report, the three most representative photographs are indexed by way of illustration.

	
<b>T<sub>0</sub></b>	<b>T<sub>28</sub></b>
Volunteer 12	

	
<b>T<sub>0</sub></b>	<b>T<sub>28</sub></b>
Volunteer 13	

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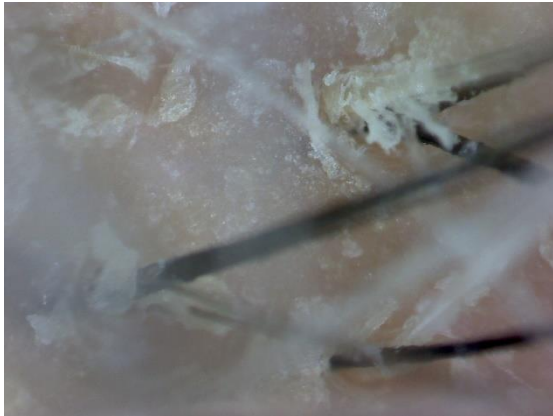

	
<b>T<sub>0</sub></b>	<b>T<sub>28</sub></b>
Volunteer 16	






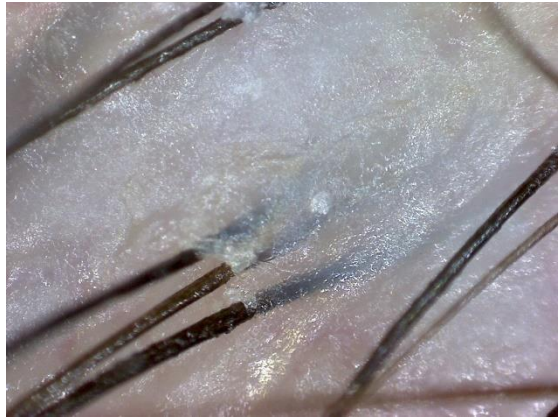
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### 1.3. MICROCAMERA OBSERVATION OF THE SCALP

In the present report, the three most representative photographs are indexed by way of illustration

	
<b>T<sub>0</sub></b>	<b>T<sub>28</sub></b>
Volunteer 1	

	
<b>T<sub>0</sub></b>	<b>T<sub>28</sub></b>
Volunteer 3	

	
<p><b>T<sub>0</sub></b></p>	<p><b>T<sub>28</sub></b></p>
<p>Volunteer 12</p>	

## 2. VOLUNTEER EVALUATION

### 2.1. T<sub>0</sub>

1. Do you have dandruff at the present time?

	Nº Answers	%
<b>Yes</b>	20	100,0
<b>No</b>	0	0,0

2. How much?

	Nº Answers	%
<b>A lot</b>	4	20,0
<b>Regular</b>	14	70,0
<b>A Little</b>	2	10,0

3. Does your scalp itch at the present time?

	Nº Answers	%
<b>Yes</b>	19	95,0
<b>No</b>	1	5,0

4. How much?

	Nº Answers	%
<b>Intense itching</b>	5	26,3
<b>Moderate itching</b>	11	57,9
<b>Mild itching</b>	3	15,8

5. Do you have tightness/discomfort on the scalp?

	Nº Answers	%
<b>Yes</b>	7	35,0
<b>No</b>	13	65,0

6. Do you have seborrhea on the scalp?

	Nº Answers	%
<b>Yes</b>	18	90,0
<b>No</b>	2	10,0

## 2.2. T<sub>28</sub>

### Organoleptic properties of different product included in the treatment.

#### 1. General Opinion

	N5 CREMA		N6 CHAMPU		N7 TONICO		N8 TONICO POTENCIADO	
	Nº Answers	%	Nº Answers	%	Nº Answers	%	Nº Answers	%
I like a lot	2	10,0	9	45,0	4	20,0	6	30,0
I like moderately	8	40,0	7	35,0	12	60,0	10	50,0
I like slightly	3	15,0	1	5,0	0	0,0	0	0,0
Neither like nor dislike	2	10,0	1	5,0	1	5,0	1	5,0
I dislike slightly	0	0,0	1	5,0	1	5,0	1	5,0
I dislike moderately	2	10,0	1	5,0	2	10,0	1	5,0
I dislike a lot	3	15,0	0	0,0	0	0,0	1	5,0

## 2. Appearance

	N5 CREMA		N6 CHAMPU		N7 TONICO		N8 TONICO POTENCIADO	
	Nº Answers	%	Nº Answers	%	Nº Answers	%	Nº Answers	%
I like a lot	5	25,0	7	35,0	4	20,0	6	30,0
I like moderately	8	40,0	8	40,0	9	45,0	9	45,0
I like slightly	1	5,0	3	15,0	3	15,0	1	5,0
Neither like nor dislike	3	15,0	1	5,0	1	5,0	1	5,0
I dislike slightly	1	5,0	0	0,0	2	10,0	1	5,0
I dislike moderately	2	10,0	0	0,0	1	5,0	2	10,0
I dislike a lot	0	0,0	1	5,0	0	0,0	0	0,0

## 3. Fragrance

	N5 CREMA		N6 CHAMPU		N7 TONICO		N8 TONICO POTENCIADO	
	Nº Answers	%	Nº Answers	%	Nº Answers	%	Nº Answers	%
I like a lot	2	10,0	6	30,0	6	30,0	5	25,0
I like moderately	6	30,0	5	25,0	4	20,0	6	30,0
I like slightly	4	20,0	5	25,0	3	15,0	3	15,0
Neither like nor dislike	4	20,0	1	5,0	3	15,0	2	10,0
I dislike slightly	0	0,0	1	5,0	0	0,0	0	0,0
I dislike moderately	3	15,0	1	5,0	2	10,0	1	5,0
I dislike a lot	1	5,0	1	5,0	2	10,0	3	15,0

## 4. Color

	N5 CREMA		N6 CHAMPU		N7 TONICO		N8 TONICO POTENCIADO	
	Nº Answers	%	Nº Answers	%	Nº Answers	%	Nº Answers	%
I like a lot	4	20,0	8	40,0	5	25,0	8	40,0
I like moderately	9	45,0	7	35,0	8	40,0	6	30,0
I like slightly	1	5,0	0	0,0	2	10,0	1	5,0
Neither like nor dislike	4	20,0	4	20,0	3	15,0	3	15,0
I dislike slightly	0	0,0	0	0,0	1	5,0	1	5,0
I dislike moderately	2	10,0	0	0,0	1	5,0	1	5,0
I dislike a lot	0	0,0	1	5,0	0	0,0	0	0,0

## 5. Texture

	N5 CREMA		N6 CHAMPU		N7 TONICO		N8 TONICO POTENCIADO	
	Nº Answers	%	Nº Answers	%	Nº Answers	%	Nº Answers	%
I like a lot	2	10,0	6	30,0	4	20,0	7	35,0
I like moderately	8	40,0	6	30,0	10	50,0	6	30,0
I like slightly	4	20,0	1	5,0	1	5,0	3	15,0
Neither like nor dislike	1	5,0	3	15,0	5	25,0	4	20,0
I dislike slightly	1	5,0	2	10,0	0	0,0	0	0,0
I dislike moderately	2	10,0	0	0,0	0	0,0	0	0,0
I dislike a lot	2	10,0	2	10,0	0	0,0	0	0,0

## 6. Hair extensibility

	N5 CREMA		N6 CHAMPU		N7 TONICO		N8 TONICO POTENCIADO	
	Nº Answers	%	Nº Answers	%	Nº Answers	%	Nº Answers	%
I like a lot	3	15,0	11	55,0	7	35,0	11	55,0
I like moderately	7	35,0	6	30,0	9	45,0	5	25,0
I like slightly	2	10,0	2	10,0	2	10,0	2	10,0
Neither like nor dislike	2	10,0	0	0,0	1	5,0	1	5,0
I dislike slightly	3	15,0	0	0,0	0	0,0	0	0,0
I dislike moderately	1	5,0	0	0,0	1	5,0	1	5,0
I dislike a lot	2	10,0	1	5,0	0	0,0	0	0,0

## 7. Packaging Comfort

	N5 CREMA		N6 CHAMPU		N7 TONICO		N8 TONICO POTENCIADO	
	Nº Answers	%	Nº Answers	%	Nº Answers	%	Nº Answers	%
I like a lot	6	30,0	11	55,0	9	45,0	8	40,0
I like moderately	6	30,0	4	20,0	3	15,0	4	20,0
I like slightly	4	20,0	1	5,0	3	15,0	3	15,0
Neither like nor dislike	1	5,0	2	10,0	0	0,0	0	0,0
I dislike slightly	0	0,0	1	5,0	2	10,0	2	10,0
I dislike moderately	1	5,0	1	5,0	3	15,0	3	15,0
I dislike a lot	2	10,0	0	0,0	0	0,0	0	0,0



## 8. Easy to use

	N5 CREMA		N6 CHAMPU		N7 TONICO		N8 TONICO POTENCIADO	
	Nº Answers	%	Nº Answers	%	Nº Answers	%	Nº Answers	%
I like a lot	5	25,0	9	45,0	9	45,0	8	40,0
I like moderately	6	30,0	4	20,0	3	15,0	4	20,0
I like slightly	6	30,0	0	0,0	4	20,0	4	20,0
Neither like nor dislike	0	0,0	4	20,0	0	0,0	0	0,0
I dislike slightly	0	0,0	2	10,0	3	15,0	3	15,0
I dislike moderately	1	5,0	1	5,0	1	5,0	1	5,0
I dislike a lot	2	10,0	0	0,0	0	0,0	0	0,0

## 9. Resistance and adaptation of the packaging

	N5 CREMA		N6 CHAMPU		N7 TONICO		N8 TONICO POTENCIADO	
	Nº Answers	%	Nº Answers	%	Nº Answers	%	Nº Answers	%
I like a lot	8	40,0	9	45,0	8	40,0	7	35,0
I like moderately	5	25,0	8	40,0	7	35,0	8	40,0
I like slightly	4	20,0	1	5,0	2	10,0	2	10,0
Neither like nor dislike	1	5,0	1	5,0	0	0,0	0	0,0
I dislike slightly	0	0,0	1	5,0	2	10,0	2	10,0
I dislike moderately	1	5,0	0	0,0	1	5,0	1	5,0
I dislike a lot	1	5,0	0	0,0	0	0,0	0	0,0

#### 10. Duration

	N5 CREMA		N6 CHAMPU		N7 TONICO		N8 TONICO POTENCIADO	
	Nº Answers	%	Nº Answers	%	Nº Answers	%	Nº Answers	%
I like a lot	7	35,0	12	60,0	9	45,0	9	45,0
I like moderately	7	35,0	4	20,0	5	25,0	6	30,0
I like slightly	3	15,0	2	10,0	4	20,0	3	15,0
Neither like nor dislike	0	0,0	0	0,0	2	10,0	2	10,0
I dislike slightly	1	5,0	1	5,0	0	0,0	0	0,0
I dislike moderately	1	5,0	1	5,0	0	0,0	0	0,0
I dislike a lot	1	5,0	0	0,0	0	0,0	0	0,0

#### 11. Oily Sensation

	N5 CREMA		N6 CHAMPU		N7 TONICO		N8 TONICO POTENCIADO	
	Nº Answers	%	Nº Answers	%	Nº Answers	%	Nº Answers	%
A lot	5	25,0	0	0,0	0	0,0	0	0,0
Quite	3	15,0	0	0,0	0	0,0	0	0,0
A little	7	35,0	10	50,0	7	35,0	7	35,0
Not at all	5	25,0	10	50,0	13	65,0	13	65,0

12. Residue after application of the product

	N5 CREMA		N6 CHAMPU		N7 TONICO		N8 TONICO POTENCIADO	
	Nº Answers	%	Nº Answers	%	Nº Answers	%	Nº Answers	%
<b>A lot</b>	4	20,0	0	0,0	0	0,0	0	0,0
<b>Quite</b>	6	30,0	0	0,0	0	0,0	1	5,0
<b>A little</b>	6	30,0	5	25,0	10	50,0	6	30,0
<b>Not at all</b>	4	20,0	15	75,0	10	50,0	13	65,0

**Efficacy of the treatment.**

13. After 28 days, The treatment reduces and/or eliminate the dandruff in the scalp

	Nº Answers	%
<b>I totally agree</b>	4	20,0
<b>I agree</b>	12	60,0
<b>Neither agree nor disagree</b>	2	10,0
<b>I disagree</b>	2	10,0
<b>I totally disagree</b>	0	0,0

14. After 28 days, The treatment reduces and/or eliminate the itch in the scalp

	Nº Answers	%
<b>I totally agree</b>	5	25,0
<b>I agree</b>	9	45,0
<b>Neither agree nor disagree</b>	3	15,0
<b>I disagree</b>	2	10,0
<b>I totally disagree</b>	1	5,0

15. After 28 days, The treatment reduces and/or eliminate the oily in the scalp

	Nº Answers	%
I totally agree	3	15,0
I agree	10	50,0
Neither agree nor disagree	2	10,0
I disagree	5	25,0
I totally disagree	0	0,0

16. The treatment reduces and/or eliminate the dandruff in the scalp from the first application

	Nº Answers	%
I totally agree	2	10,0
I agree	3	15,0
Neither agree nor disagree	7	35,0
I disagree	7	35,0
I totally disagree	1	5,0

17. The treatment provide freshness in the scalp

	Nº Answers	%
I totally agree	3	15,0
I agree	8	40,0
Neither agree nor disagree	7	35,0
I disagree	1	5,0
I totally disagree	1	5,0

18. The treatment fulfill the requirements of a antidandruff product

	Nº Answers	%
I totally agree	4	20,0
I agree	9	45,0
Neither agree nor disagree	3	15,0
I disagree	2	10,0
I totally disagree	2	10,0

19. The treatment provide a visible effect in the amount of dandruff in the scalp

	Nº Answers	%
I totally agree	6	30,0
I agree	9	45,0
Neither agree nor disagree	3	15,0
I disagree	0	0,0
I totally disagree	2	10,0

20. After 28 days, what is your assessment of the treatment tested?

	Nº Answers	%
Very satisfied	3	15,0
Satisfied	11	55,0
Neither satisfied nor dissatisfied	4	20,0
Dissatisfied	1	5,0
Very dissatisfied	1	5,0

### Future use

21. The treatment fulfill your requirements

	Nº Answers	%
<b>Yes</b>	15	75,0
<b>No</b>	5	25,0

22. Why:

Itchy decreased: Volunteers 1, 10.

Dandruff and itchy decreased: Volunteers 3, 12, 13, 15, 16, 20.

It works for my dandruff: Volunteers 2, 18.

I'm satisfied: Volunteers 4, 11.

It is the best treatment I tried: Volunteer 8.

It increases itchy and dandruff: Volunteer 6.

I still have dandruff: Volunteers 7, 19.

The shampoo is extremely liquid: Volunteer 9

23. Would you buy the treatment?

	Nº Answers	%
<b>Most probably</b>	4	20,0
<b>Probably</b>	7	35,0
<b>Probably not</b>	4	20,0
<b>Most probably not</b>	5	25,0

### **Tolerance**

24. Side effect after treatment

	Nº Answers	%
<b>Yes</b>	5	25,0
<b>No</b>	15	75,0

25. Comments:

Volunteer 2, 6, 9: Itchy in the scalp.

Volunteer 10: I wouldn't buy it because the treatment is complicate.

Volunteer 15: Oil .

Volunteer 19: It left my scalp dry.

Volunteer 20: I dislike the perfumes and the treatment causes itchy in eyes and nose.

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### III. DISCUSSION

The main objective of this experiment was to determine the efficacy of the product tested in the elimination of dandruff after 28 days of treatment application.

Dandruff can be defined as excessive removal of the stratum corneum of the scalp without signs of inflammation. It is distributed through the scalp in the form of small scales that detach easily or may be attached to it.

To carry out this evaluation, we proceeded according to what was described in the previous sections, carrying out the tests of: general photography of the scalp and microphotography of the scalp. These tests were evaluated (table 2) by a specialized technician in a scale of 5 values where the lowest value (0) corresponds to the degree “absence” of the attribute studied and the highest value (5) corresponds to the “very high” degree. The intermediate values 1, 2, 3 and 4 correspond to the degrees “little”, “regular”, “quite” and “high”. From the evaluations of the different tests, an average value was obtained (table 3) for each volunteer at each control time which allowed us to determine the level of dandruff in each case and the effectiveness of the treatment tested.

#### **SCALP DANDRUFF ASSESSMENT BY THE SPECIALIZED TECHNICIAN**

##### ***GENERAL APPEARANCE OF THE SCALP***

After the analysis of the images obtained, we can observe how after 28 days of application the amount of dandruff has decreased in most volunteers.

This decrease is evident in volunteers 12, 13 and 16. At the beginning of the experiment they present a significant level of dandruff. After 28 days of treatment the scalp involvement has importantly decreased.



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### ***MICROCAMERA OBSERVATION OF THE SCALP***

A microphotograph of the state of the scalp was used to observe in more detail the state of the scalp and the degree of dandruff. As with the general photo, in this case you can also see the improvements brought by the treatment.

So for example, in volunteers 1, 3 and 12 we can see how the desquamation of the scalp decreases greatly after the application of the treatment, arriving in some of them (voluntary 1) to almost disappear.

### ***GENERAL ASSESSMENT OF THE STATE OF THE SCALP***

As indicated in previous paragraphs, in table 3 of this report we can see the average of the individual results assigned by the specialist to each of the tests for dandruff. From these values we can conclude:

- After the treatment (28 days), 100.0% of the volunteers presented an improvement.
- These results indicate a greater capacity to eliminate dandruff for the treatment tested.
- The average improvement, taking into account the different individual values is 47.1%.
- To determine if these average results (table 3) at different time are statistically significant we apply the t-student criterion.
- According to the t-student,  $p < 0.05$  is obtained; IC: 95% indicating that the improvements observed with respect to the start of the experiment is statistically significant.

Taking into account, the differences in ratings granted by the specialized technician at the different times, in Figure 1 we can see the percent average decrease in dandruff. For greater clarity in the interpretation of the results, it has been assumed that at the beginning of the experiment the amount of dandruff could be considered as 100.0%.

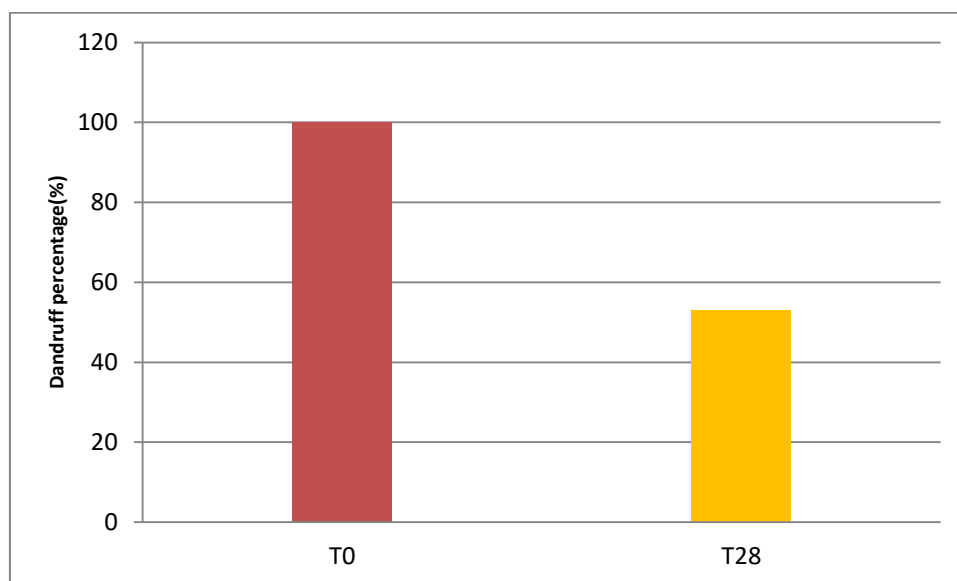


Figure 1: Overall percentage of dandruff at the different times in the study.

### **ASSESSMENT OF THE GLOBAL RESULT OF THE EXPERIMENT BY THE VOLUNTEERS**

T<sub>0</sub>:

- 100.0% of the volunteers have dandruff at the beginning of the study. 90.0% of them classify the amount of dandruff as regular or large.
- 95.0% of the volunteers presented itching on the scalp and 35.0% tension, these side effects being associated with dandruff.
- 90.0% of the volunteers say they have oily hair.

T<sub>28</sub>:

- After 28 days of application of the treatment, the general opinion of the volunteers is positive.
- The organoleptic properties, as for example appearance, fragrance, color and texture of the different component of the treatment are also positively evaluated from the volunteers.
- The extensibility in the hair and the packaging comfort for the different products are show in figure 2 and 3. In general the hair extensibility of all products is quite nice and the packaging comfort is also positively evaluated by volunteers.

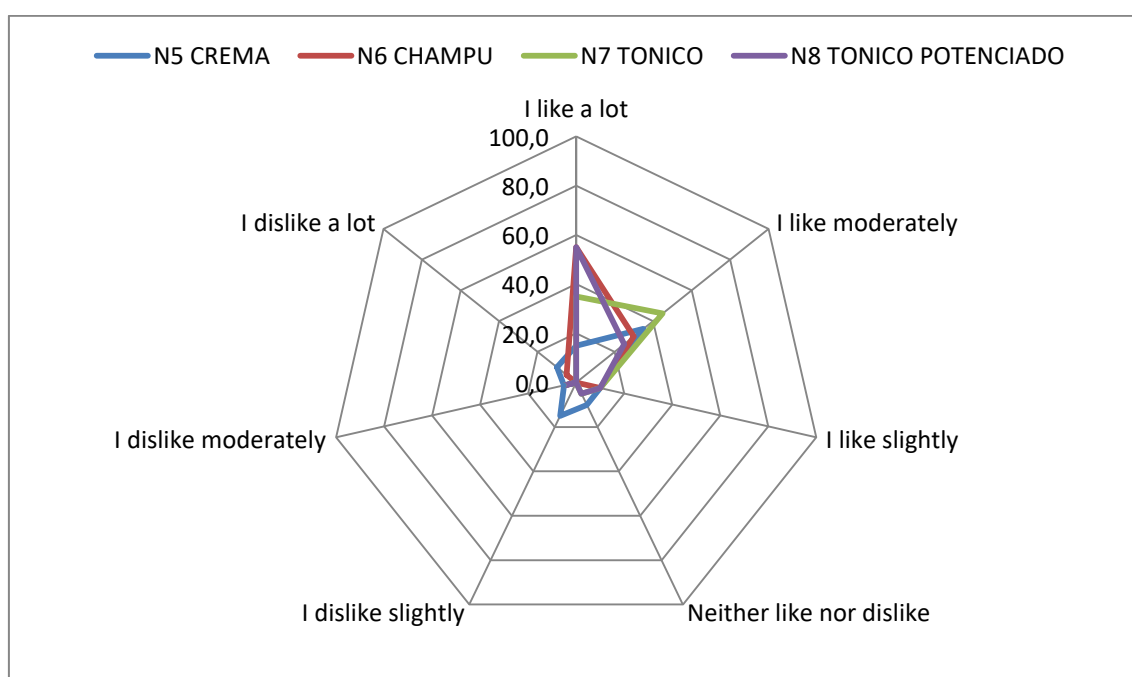


Figure 2: Evaluation of hair extensibility after 28 of treatment

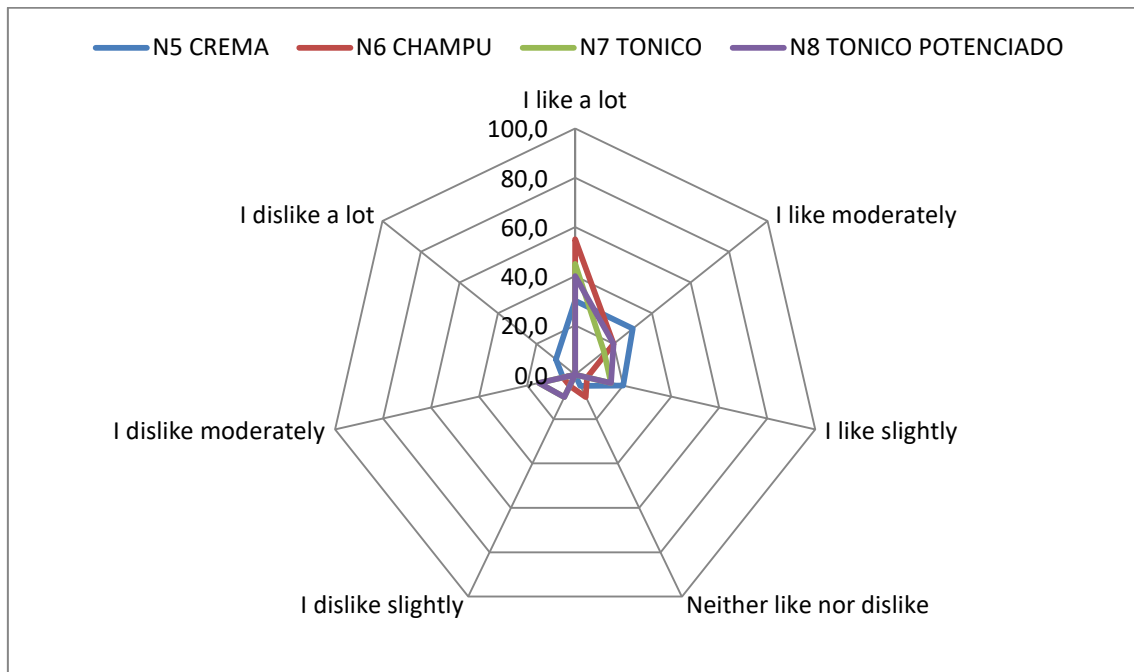


Figure 3: Evaluation of packaging comfort after 28 of treatment

- The most of the volunteers are agree with the duration of the different products contained in the treatment.
- In general, no product provides an oily sensation in the scalp. Only for cream, the 40.0% of the volunteers have this feeling, which it is normal due to the kind of formulation.

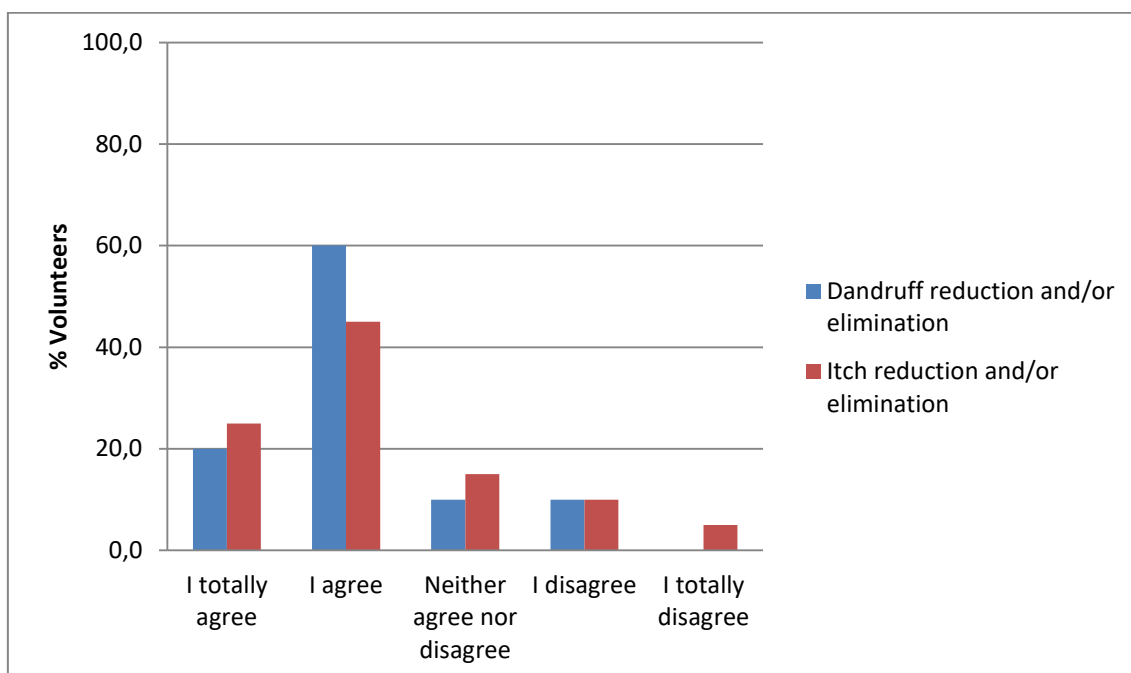


Figure 4: Dandruff and itch reduction and/or elimination after 28 of treatment

- After 28 of treatment, 80.0% of the volunteers think that the treatment eliminate or reduce the amount of dandruff and 70.0% think that the treatment eliminate or reduce the itch in the scalp.
- For 65.0% of the volunteers the treatment also reduces and/or eliminates the oily in the scalp.
- 25.0% of the volunteers think that the treatment is able to reduce the dandruff in the scalp from the first application.
- In general, the treatment fulfills the requirements of an antidandruff product for 65.0% of the volunteers after 28 days of application.
- 75.0% of the volunteers consider that the treatment provide a visible results.
- 70.0% of the volunteers are satisfied with the treatment after 28 days.
- 55.0 % of the volunteers would buy the treatment.
- 25.0% of the volunteers report any side effect. However the severity of it is very small and in our opinion could be related with other factors different to the treatment.

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#### IV. CONCLUSIONS

The main conclusions of this study are:

- ❖ In the different tests performed, improvements were observed in all cases after 28 days of treatment.
- ❖ According to the evaluations assigned by the technical specialist, after the application of the product (28 days), 100.0% of the volunteers presented an improvement.
- ❖ The average of this improvement is 47.1%.
- ❖ According to the t-student, the differences found are statistically significant ( $p < 0.05$ , CI: 95%).

#### VOLUNTEERS SUBJECTIVE EVALUATION

- ❖ After 28 days of application of the treatment, the general opinion of the volunteers is positive and the organoleptic properties, as for example appearance, fragrance, color and texture of the different component of the treatment are also positively evaluated from the volunteers.
- ❖ The hair extensibility of all products is quite nice and the packaging comfort is also positively evaluated.
- ❖ The most of the volunteers are agree with the duration of the different products contained in the treatment.
- ❖ No product provides an oily sensation in the scalp. Only for cream, the 40.0% of the volunteers have this feeling, which it is normal due to the kind of formulation.
- ❖ After 28 of treatment, 80.0% of the volunteers think that the treatment eliminate or reduce the amount of dandruff and 70.0% think that the treatment eliminate or reduce the itch in the scalp.
- ❖ For 65.0% of the volunteers the treatment also reduces and/or eliminates the oily in the scalp.
- ❖ 25.0% of the volunteers think that the treatment is able to reduce the dandruff in the scalp from the first application.

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- ❖ The treatment fulfill the requirements of a antidandruff product for 65.0% of the volunteers after 28 days of application and 75.0% of the volunteers consider that the treatment provide a visible results.
- ❖ 70.0% of the volunteers are satisfied with the treatment after 28 days and 55.0% of the volunteers would buy the treatment.

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#### **V. CERTIFICATE AND SIGNATURE**

**Efficacy study no.:** ID108-19

**Done by:** Centro de Tecnología Capilar, S.L.

**Sponsor:**

**Start date:** 01<sup>ST</sup> October 2019

**Completion date:** 04<sup>th</sup> November 2019

**Delivery date:** 07<sup>th</sup> November 2019

**This document is filed for a period of 2 years at CENTRO DE TECNOLOGÍA CAPILAR, S.L.**

**C.T.C. is not responsible for statements or conclusions that are not strictly those indicated in the present study.**

**Head of Product assessment:**



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PhD. Chemistry

**Director of the study:**



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BSc. Biology