

TEST REPORT N. 20/000012687

THIS CANCELS AND REPLACES TEST REPORT N° 19/000518861

date of issue 14/01/2020

Customer ID 0077144

Messrs
ALPS SOUTH ITALY SRL
VIALE DELLA MERCANZIA 85
40050 ARGELATO (BO)
IT

Sample information

Acceptance number 19.528524.0001
Delivered by Bartolini on 11/09/2019
Receiving Date 11/09/2019
Place of origin ALPS SOUTH ITALY SRL VIALE DELLA MERCANZIA 85 40050 ARGELATO (BO) IT
Sample Description ALPS ANTIOXIDANT CREAM

Sampling information

Sampled by Customer

ANALYTICAL RESULTS

	Value/ Uncertainty	Unit of measure	LoQ	LoD	Start/end date of analysis	Op. units w	Ro
ON SAMPLE AS IT IS							1
SIGNATURE OF DERMATOLOGIST					09/12/2019- -10/12/2019	11	2
Met.:							
EVALUATION OF SKIN TOLERABILITY	view attached				09/12/2019- -10/12/2019	11	3
Met.: MP 2321 rev 0 2019	report						
SEBUM NORMALIZING EFFICACY	view attached				09/12/2019- -10/12/2019	11	4
Met.: MP 1916 rev 1 2019	report						

Operative units

Unit 11 : Via Marradi 41 Prato PO

Amendment reasons

Sample detailed /description modified after registration error was discovered

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- If not otherwise specified, the uncertainty is extended and has been calculated with a coverage factor k=2 corresponding to a probability interval of about 95%. - LoD is the detection limit and identifies a confidence interval of zero with a probability interval of about 99%. - LoQ is the limit of quantification. "n.d" is not detected and indicates a value inferior to the LoD. "traces (X)" means a value between LoD and LoQ, this value is indicative. "<x" or ">x" indicate inferior or superior to the measurement field of the test. - If not differently specified, the sums are calculated by lower bound criteria (L.B.). - In case of alteration of the sample the laboratory declines any responsibility on the results that can be influenced by the deviation in case the customer asks for the execution of the test anyway. - If the sampling is not carried out by the laboratory staff, the results obtained are considered referring to the sample as received and the laboratory declines its responsibility for the results calculated considering the sampling data provided by the Customer. The name and contact information of the Customer are always provided by the Customer. - If there is a specification (customer specifications, law limits) which has been compared to the analytical results, the values shown in bold indicate a result which is out of the specification. - If not differently specified the judgments of compliance /non-compliance eventually reported are referred to analysed parameters and are based on the comparison of the value with the reference values without considering the confidence interval of measure.



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Efficacy evaluation of a sebum normalizing treatment: ALPS ANTIOXIDANT CREAM

Document drawn up by Mérieux NutriSciences Italia for



December 2019



Aim, Method, Target



AIM OF THE STUDY

The test's aim is the evaluation of a sebum normalizing efficacy of **ALPS ANTIOXIDANT CREAM lotto 468 794** on 20 volunteers after its continuous application for 30 days

METHOD

To meet the purpose, a long term study was developed with T0 clinical and instrumental evaluation (before using the product), T1 with only instrumental evaluation (after 10 days of daily treatment) and T2 with clinical and instrumental evaluation (after 30 days of daily treatment) . Each volunteer was asked to apply the product on the entire face, once a day for all the duration of the test, suspending the application of anyother topical product in the 7 days prior to the test.

OBJECTIVE APPROACH-Instrumental and clinical evaluation

At each time point, for all the volunteers, the cutaneous homogeneity of the face was analyzed using FrameScan (with skin homogeneity analysis), and the sebum amount of the entire face with Sebumeter®. Finally, a clinical-dermatological evaluation was performed for each volunteer before (T0) and at the end of the treatment period (T2) using the GAGS system.

The verification of statistical significance was performed with T Test.

SUBJECTIVE APPROACH: self-assessment questionnaire

Each volunteers was asked to answer a self-assessment questionnaire to obtain a judgement from potential customers about product's performances at the beginning and after 30 days of daily treatment

TIME POINT

T0 instrumental and clinical evaluation before using the product **ALPS ANTIOXIDANT CREAM lotto 468 794**

T1 instrumental evaluation after 10 days of daily use of the product **ALPS ANTIOXIDANT CREAM lotto 468 794**

T2 instrumental and clinical evaluation after 30 days of daily use of the product **ALPS ANTIOXIDANT CREAM lotto 468 794**

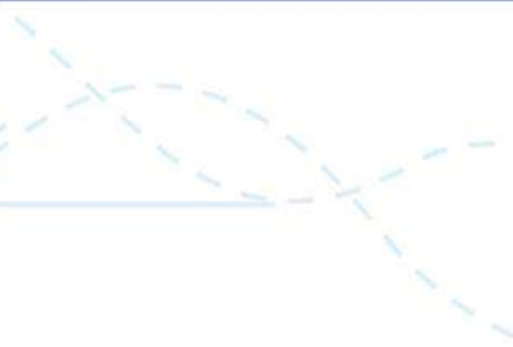
TARGET

20 volunteers with oily or acne-prone skin, 10 male and 10 female under 45 years. Average age 28 years

Exclusion volunteer criteria:

- Pregnant women and women in breast-feeding period
- Allergy and/or hypersensitivity or any other known and/or probable incompatibility towards one or more of the components of the cosmetic treatment
- Positive anamnesis for atopy.
- Minors
- Subjects who underwent cosmetic treatments on face in the month before the study

Sample



INCI

Aqua;Hydrogenated Avocado Oil;Paraffinum Liquidum;Petrolatum;Pentaerythrityl Tetra-Di-t-Butyl Hydroxyhydrocinnamate;Tocopherol;Glycerin; Stearic Acid; Steareth-2 2; Parfum; Steareth; Propylene Glycol;Diazolidinyl Urea;Methylparaben;Propylparaben.



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RESULTS

OBJECTIVE APPROACH



Equipment

At each time point images were acquired with CameraScan, subsequently processed with FrameScan for the evaluation of the Skin Homogeneity on each volunteer.

CameraScan: software that allows you to obtain good quality images ensuring the same repositioning of subjects at different times of the study. Software usable with Nikon D7000.

FrameScan: software dedicated to quantitative colorimetric and morphological analysis of calibrated digital photographic images. The measurements of this study are performed on a computerized analysis of the image of the face. The software processes the previously recorded images at preset time intervals, providing as output the homogeneity of the analyzed face region (Skin Homogeneity)

Skin Homogeneity: calculation of skin homogeneity (Haralick algorithm) in the area of interest. The values range from 0 to 1, the closer the value to 1 the more the analyzed skin is homogeneous

Sebumeter® SM810 (Courage + Khazaka, Köln - Germany): photometric device equipped with a cartridge for sebum collection and a photodiode reader. The sebum is collected on a stretch of opaque polymer tape placed on a rotating support. For this purpose the probe is pressed against the surface of the skin for 30 seconds and then reinserted into the central body of the Sebumeter®. The tape takes on a degree of transparency directly proportional to the amount of skin sebum absorbed. The photometer with photodiode reads the tape before and after contact with the skin, thus providing the quantity of sebum per cm² of skin, in reference to an internal standard. The output obtained is the amount of sebum expressed in µg of sebum per cm² of skin.

Evaluation Results **FrameScan (Skin Homogeneity)**



Base: 20 volunteers

Volunteer	Skin Homogeneity values		
	T0 – Before the treatment	T1 – After 10 days of treatment	T2 – After 30 days of treatment
1	0,0045	0,0046	0,0048
2	0,0170	0,0172	0,0170
3	0,0015	0,0016	0,0016
4	0,0156	0,0159	0,0163
5	0,0151	0,0153	0,0181
6	0,0120	0,0118	0,0117
7	0,0117	0,0149	0,0197
8	0,0155	0,0156	0,0167
9	0,0139	0,0128	0,0145
10	0,0023	0,0024	0,0029
11	0,0115	0,0115	0,0128
12	0,0101	0,0134	0,0171
13	0,0089	0,0090	0,0118
14	0,0115	0,0120	0,0121
15	0,0149	0,0154	0,0174
16	0,0118	0,0114	0,0119
17	0,0090	0,0098	0,0098
18	0,0173	0,0186	0,0191
19	0,0111	0,0115	0,0141
20	0,0122	0,0131	0,0119
AVERAGE	0,0114	0,0119	0,0131
SD	0,0044	0,0046	0,0051
Significance		*	***
% Average variation vs T0		4,5%	14,8%

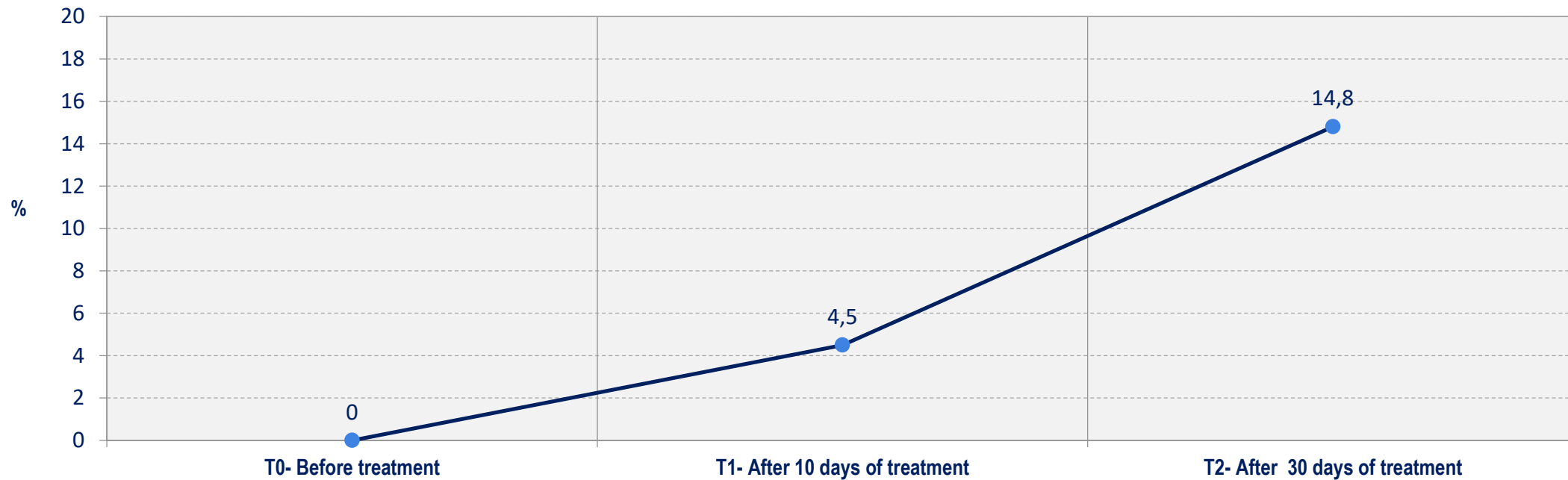
Statistical Significance Test T test: N.S. no significant differences emerged: * 95% significant difference; ** 99% significant difference; *** 99.9% significant difference

Evaluation Results **FrameScan (Skin Homogeneity)**

Base: 20 volunteers



The graph shows the average % variation of cutaneous homogeneity detected in T1 e T2 compared to T0 before treatment



Evaluation Results **Sebumeter®**



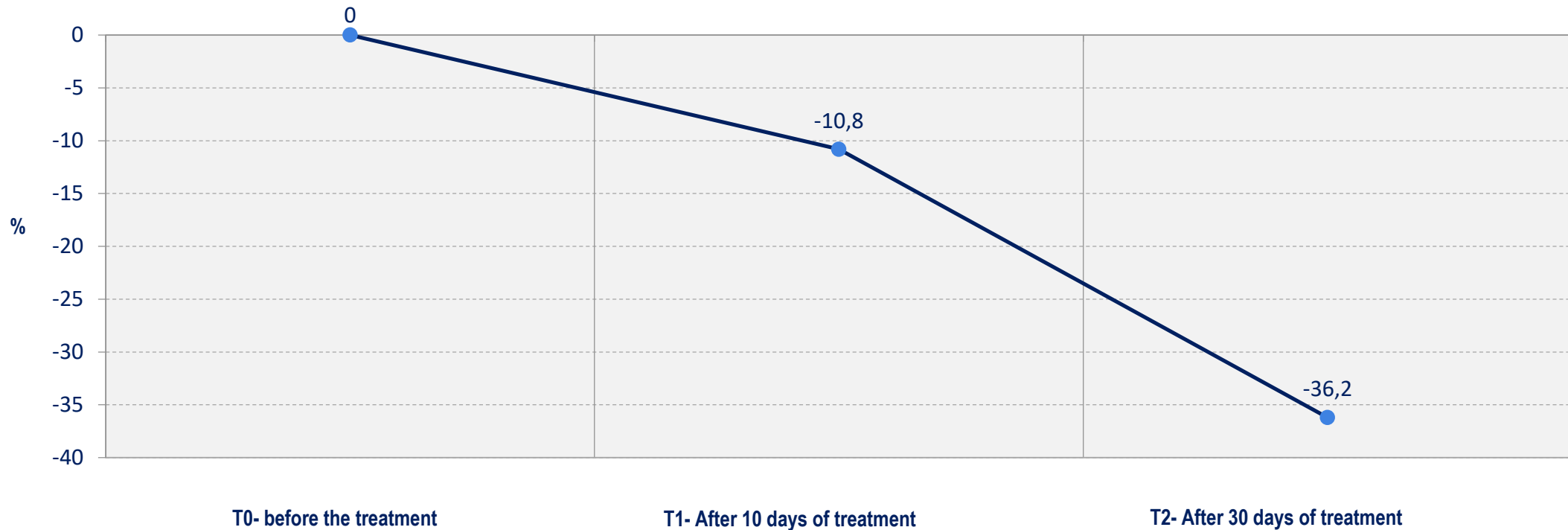
Base: 20 volunteers

<i>Volunteer</i>	T0 – Before the treatment	T1 – After 10 days of treatment	T2 – After 30 days of treatment
1	448,0	440,1	420,1
2	378,7	364,1	156,7
3	279,1	270,9	163,9
4	247,3	199,7	180,0
5	209,4	207,8	87,0
6	407,7	307,6	209,4
7	189,9	130,6	122,6
8	248,7	163,3	109,9
9	355,1	334,9	309,7
10	247,7	238,1	218,5
11	245,9	246,1	170,1
12	269,9	270,0	273,0
13	372,7	320,1	199,6
14	323,4	298,7	210,7
15	411,9	392,4	200,6
16	220,1	200,7	116,3
17	198,4	199,1	155,6
18	498,8	421,4	253,3
19	287,8	199,6	125,0
20	151,1	141,1	139,4
AVERAGE	299,6	267,3	191,1
<i>SD</i>	95,3	90,9	78,5
Significance		***	***
% Average variation vs T0		-10,8%	-36,2%

Statistical Significance Test T test: N.S. no significant differences emerged; * 95% significant difference; ** 99% significant difference; *** 99.9% significant difference



The graph shows the % variation of the quantity of cutaneous sebum detected in the different steps of the evaluation compared to T0 before the treatment.



Clinical Evaluation Results



The clinical evaluation was carried out at T0 (baseline condition) and T2 (after 30 days of daily product application)

The dermatologist examined at T0 and T2 on each volunteer both the level of **seborrhea** using a 1-4 scale (absent-mild-moderate-severe) and the **number of dilated large pore** using another 1-4 scale (absent-few-moderate-numerous).

The clinical-dermatological evaluation related to the **presence of comedones, pustules and papules** was carried out using the GAGS (Global Acne Grading System) System usually used for acne assessment (*Doshi et Al, International Journal of Dermatology, 1997*).

The GAGS system considers six assessment zones located on the face and on the neck/shoulders of a person, each zone corresponds to a specific factor (1,2,3) based approximately on the surface of the area and on the distribution and density of pilosebaceous units of the area. To each of the six zones the dermatologist assigns a score on a scale from 0 to 4. The most serious lesion determines the local score of the evaluated area.

The score of each zone must be multiplied by the specific zone factor.

The **global score** is the sum of all the local scores recorded for each zone.

GAGS SYSTEM	Location	Factor × Grade (0–4)* = Local score
	I Forehead	2
	II Right cheek	2
	III Left cheek	2
	IV Nose	1
	V Chin	1
	VI Chest and upper back	3

Global score = _____	
0	None
1–18	Mild
19–30	Moderate
31–38	Severe
>39	Very severe

*0, No lesions; 1, ≥ one comedone; 2, ≥ one papule; 3, ≥ one pustule; 4, ≥ one nodule.

Clinical Evaluation sheet



Volunteer:
Name:
Surname:
Age:

1. Seborrhea:

- 1 Absent
- 2 Mild
- 3 Moderate
- 4 Severe

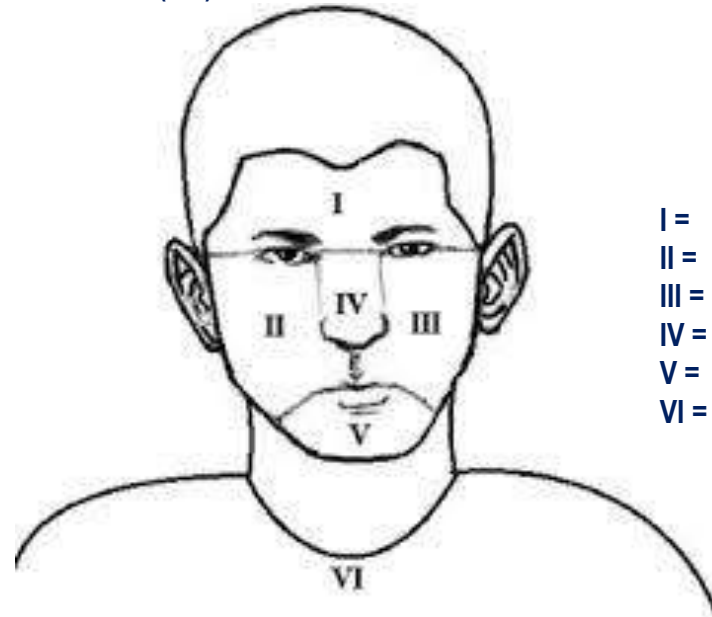
2. Number of large pores:

- 1 Absent
- 2 Few
- 3 Moderate
- 4 Large number

3. Observable injuries:

- 1 Comedones (open and/or closed)
- 2 Papules
- 3 Pustules

4. Evaluation of local scores on the GAGS scale (0-4)



I =
II =
III =
IV =
V =
VI =

Clinical Evaluation Results

Base: 20 volunteers
Min 0- Max 4

<i>Seborrhea (scala 1-4)</i>		
<i>Volunteers</i>	<i>T0 before treatment</i>	<i>T2 – After 30 days of daily treatment</i>
1	3	2
2	3	3
3	3	2
4	3	2
5	2	1
6	3	3
7	3	2
8	3	2
9	3	3
10	3	2
11	3	2
12	3	2
13	3	3
14	3	3
15	3	2
16	4	3
17	3	3
18	2	2
19	4	3
20	3	2
AVERAGE	3,0	2,4
Significance		***
% Average variation vs T0		-22%

<i>Numerousness of large pores (scala 1-4)</i>		
<i>Volunteers</i>	<i>T0 before treatment</i>	<i>T2 – After 30 days of daily treatment</i>
1	4	4
2	3	2
3	3	2
4	2	2
5	3	2
6	3	3
7	3	3
8	3	3
9	2	2
10	3	2
11	4	3
12	2	2
13	3	3
14	3	2
15	4	4
16	3	3
17	3	3
18	4	4
19	3	2
20	3	2
AVERAGE	3,0	2,6
Significance		***
% Average variation vs T0		-13%

Statistical Significance Test T test: N.S. no significant differences emerged; * 95% significant difference; ** 99% significant difference; *** 99.9% significant difference

Clinical Evaluation Results

Base: 20 volunteers
GAGS Score single volunteer

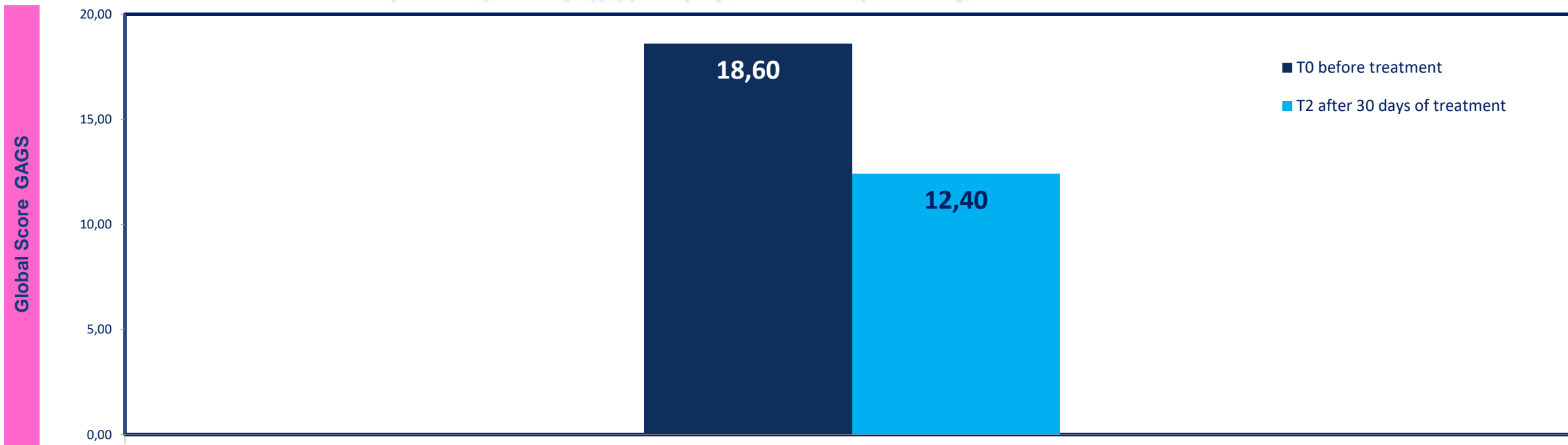
Each volunteer's evaluation on GAGS scale at two time points (T0, T2)

GAGS score (density blackheads, papules and pustules)		
Volunteer	T0 – Before the treatment	T2 – After 30 days of treatment
1	11	11
2	19	19
3	22	19
4	22	10
5	28	1
6	6	6
7	30	12
8	30	30
9	22	14
10	27	27
11	18	6
12	8	8
13	30	22
14	8	8
15	16	2
16	27	22
17	12	8
18	16	7
19	8	8
20	12	8
AVERAGE	18,60	12,40
Significance		***

Statistical Significance Test T test: N.S. no significant differences emerged; * 95% significant difference; ** 99% significant difference; *** 99.9% significant difference

Clinical Evaluation Results

Base: 20 volunteers
Score GAGS Average value



The histogram represents the GAGS scores average of the 20 volunteers attributed by the dermatologist at the two time points (T0, T2). There is an average decrease in the number of skin imperfections (comedones, papules, pustules) detectable by the dermatologist.



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OBJECTIVE EVALUATION CONCLUSION

Clinical Evaluation Conclusion



The data show that the ALPS ANTIOXIDANT CREAM lot 468 794 after 30 days of daily treatment, determined an increase in skin homogeneity of 14.8 %, besides a decrease of 36.2% in seborrhea.

The clinical evaluation confirmed the efficacy of the cream in regulating cutaneous sebum and making the skin more homogeneous.

There are no adverse reactions to treatment



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RESULTS SUBJECTIVE APPROACH SELF-ASSESSMENT EVALUATION RESULTS

Self-assessment Questionnaire



T0 – before treatment					
Name and Surname:					
1. How do you consider your face skin ?		Slightly oily(1)		Enough oily (2)	Very oily (3)
2. How do you consider your skin before the begin of treatment?	Hydrated	Not at all (1)	Little (2)	Enough (3)	A lot (4)
	Greasy	Not at all (1)	Little (2)	Enough (3)	A lot (4)
	Soft	Not at all (1)	Little (2)	Enough (3)	A lot (4)
	Elastic	Not at all (1)	Little (2)	Enough (3)	A lot (4)
	Smooth	Not at all (1)	Little (2)	Enough (3)	A lot (4)
	Compact	Not at all (1)	Little (2)	Enough (3)	A lot (4)
	Glossy	Not at all (1)	Little (2)	Enough (3)	A lot (4)

Self-assessment Questionnaire



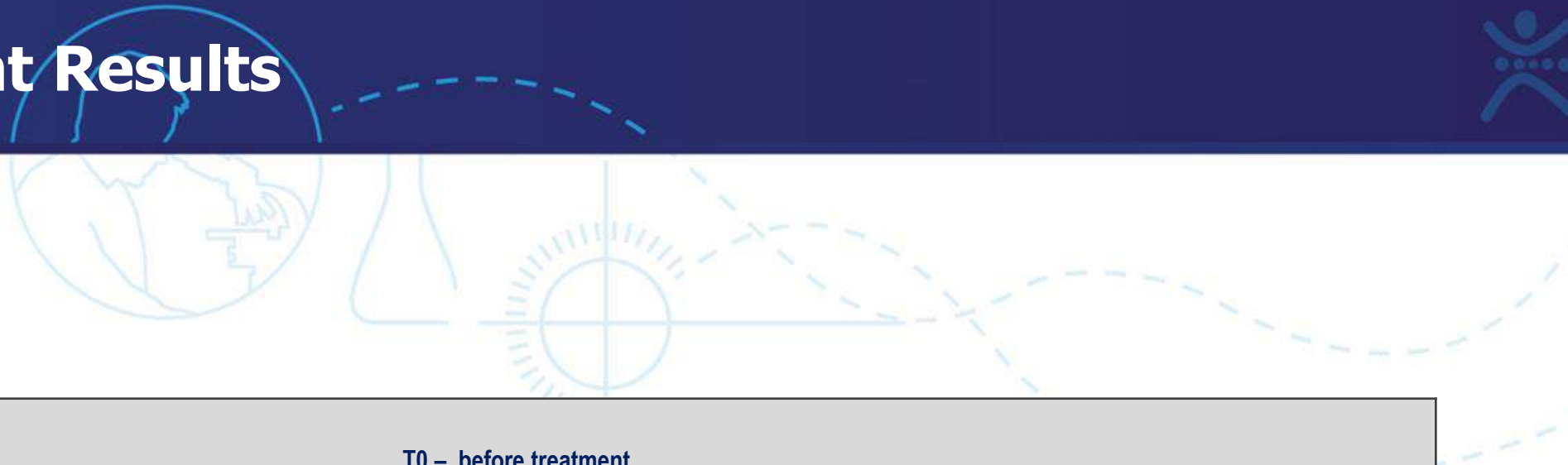
T2- after 30 days of treatment					
3. How do you consider your skin after 30 days of daily treatment?	Hydrated	Not at all (1)	Little (2)	Enough (3)	A lot (4)
	Greasy	Not at all (1)	Little (2)	Enough (3)	A lot (4)
	Soft	Not at all (1)	Little (2)	Enough (3)	A lot (4)
	Elastic	Not at all (1)	Little (2)	Enough (3)	A lot (4)
	Smooth	Not at all (1)	Little (2)	Enough (3)	A lot (4)
	Compact	Not at all (1)	Little (2)	Enough (3)	A lot (4)
	Glossy	Not at all (1)	Little (2)	Enough (3)	A lot (4)
4. After 30 days of treatment, how much better is your skin?		Not at all (1)	Little (2)	Enough (3)	A lot (4)
5. How is the oiliness rate of your skin after using the product?		Not at all oily (1)	Little oily (2)	Enough oily (3)	A lot oily (4)
6. After the cosmetic treatment, have you noticed a decrease of pimples or other inflammatory lesions?	not at all reduced (1)	Little reduced (2)	Enough reduced (3)	A lot reduced (4)	No more appearance (5)
7. After the cosmetic treatment, have you noticed a decrease of black/white heads?	not at all reduced (1)	Little reduced (2)	Enough reduced (3)	A lot reduced (4)	No more appearance (5)

Self-assessment Questionnaire



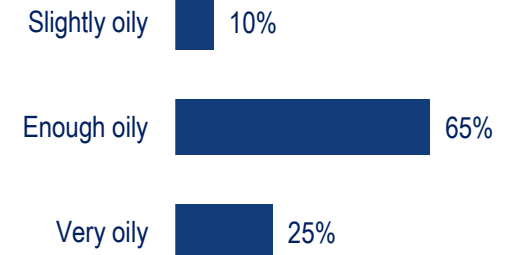
T2- after 30 days of treatment					
8. After 30 days of treatment, does your skin seem more opaque?	Not at all (1)	Little (2)	Enough (3)	A lot (4)	
9. After 30 days of treatment, is your skin smoother and free of imperfections?	Not at all (1)	Little (2)	Enough (3)	A lot (4)	
Now, focus on product					
10. How much did you like the following aspects?	Colour	Not at all (1)	Little (2)	Enough (3)	A lot (4)
	Odour	Not at all (1)	Little (2)	Enough (3)	A lot (4)
	Texture	Not at all (1)	Little (2)	Enough (3)	A lot (4)
11. How much do you agree with the following statements? This product is ...	Easily spread	Not at all (1)	Little (2)	Enough (3)	A lot (4)
	Easily absorbed	Not at all (1)	Little (2)	Enough (3)	A lot (4)
12. On the whole, how do you consider the matting effect of this cosmetic product?	Not at all effective (1)	Little effective (2)	Effective (3)	Very effective (4)	
13. On the whole, how do you consider the elasticizing effect of this cosmetic product?	Not at all effective (1)	Little effective (2)	Effective (3)	Very effective (4)	
14. On the whole, how do you consider the smoothing effectiveness of this cosmetic product?	Not at all effective (1)	Little effective (2)	Effective (3)	Very effective (4)	
15. After the cosmetic treatment, are you satisfied of this sebu-regulating product?	Unsatisfied at all (1)	A little satisfied (2)	Satisfied (3)	Very satisfied (4)	

Self-assessment Results



T0 – before treatment

1. How do you consider your face skin ?



Self-assessment Results



T0 – before treatment		
2. How do you consider your skin before the begin of treatment?	Hydrated	Not at all ■ 10% Little ■ 20% Enough ■ 15% A lot ■ 55%
	Greasy	Not at all % Little ■ 10% Enough ■ 50% A lot ■ 40%
	Soft	Not at all % Little % Enough ■ 90% A lot ■ 10%
	Elastic	Not at all % Little % Enough ■ 16% A Lot ■ 84%
	Smooth	Not at all ■ 68% Little ■ 27% Enough ■ 5% A lot %
	Compact	Not at all ■ 55% Little ■ 40% Enough ■ 5% A lot %
	Glossy	Not at all ■ 5% Little ■ 5% Enough ■ 75% A lot ■ 15%

Self-assessment Results



T2- after 30 days of treatment		
3. How do you consider your skin skin after 30 days of daily treatment?	Hydrated	Not at all % Little % Enough 35% A lot 65%
	Greasy	Not at all 10% Little 44% Enough 46% A lot %
	Soft	Not at all % Little % Enough 95% A lot 5%
	Elastic	Not at all % Little % Enough 11% A Lot 89%
	Smooth	Not at all % Little 34% Enough 56% A lot 10%
	Compact	Not at all 5% Little 35% Enough 55% A lot 5%
	Glossy	Not at all 34% Little 41% Enough 10% A lot 15%

Self-assessment Results



T2- after 30 days of treatment	
4. After 30 days of treatment, how much better is your skin?	Not at all <input type="checkbox"/> % Little <input type="checkbox"/> 5% Enough <input type="checkbox"/> 30% A lot <input type="checkbox"/> 65%
5. How is the oiliness rate of your skin after using the product?	Not at all reduced <input type="checkbox"/> 5% Little reduced <input type="checkbox"/> % Enough reduced <input type="checkbox"/> 35% A lot reduced <input type="checkbox"/> 55% No more appearance <input type="checkbox"/> 5%
6. After the cosmetic treatment, have you noticed a decrease of pimples or other inflammatory lesions?	Not at all reduced <input type="checkbox"/> % Little reduced <input type="checkbox"/> 5% Enough reduced <input type="checkbox"/> 45% A lot reduced <input type="checkbox"/> 25% No more appearance <input type="checkbox"/> 25%
7. After the cosmetic treatment, have you noticed a decrease of black/white heads?	Not at all reduced <input type="checkbox"/> % Little reduced <input type="checkbox"/> 25% Enough reduced <input type="checkbox"/> 35% A lot reduced <input type="checkbox"/> 30% No more appearance <input type="checkbox"/> 10%
8. After 30 days of treatment, does your skin seem more opaque?	Not at all <input type="checkbox"/> % Little <input type="checkbox"/> 5% Enough <input type="checkbox"/> 55% A lot <input type="checkbox"/> 40%
9. After 30 days of treatment, is your skin smoother and free of imperfections?	Not at all <input type="checkbox"/> % Little <input type="checkbox"/> 5% Enough <input type="checkbox"/> 75% A lot <input type="checkbox"/> 20%

Self-assessment Results















Now, focus on product

Now, focus on product		
10. How much did you like the following aspects?	Colour	Not at all % Little % Enough 55% A lot 45%
	Odour	Not at all 5% Little 30% Enough 65% A lot %
	Texture	Not at all % Little 15% Enough 55% A lot 30%
11. How much do you agree with the following statements? This product is ...	Easily spread	Not at all % Little 20% Enough 55% A lot 25%
	Easily absorbed	Not at all 10% Little 30% Enough 60% A lot %

Self-assessment Results



Now, focus on product	
<p>12. On the whole, how do you consider the matting effect of this cosmetic product?</p>	<p>Not at all effective %</p> <p>Little effective  10%</p> <p>Effective  44%</p> <p>Very effective  46%</p>
<p>13. On the whole, how do you consider the elasticizing effect of this cosmetic product?</p>	<p>Not at all effective %</p> <p>Little effective  10%</p> <p>Effective  55%</p> <p>Veru effective  35%</p>
<p>14. On the whole, how do you consider the smoothing effectiveness of this cosmetic product?</p>	<p>Not at all effective %</p> <p>Little effective  5%</p> <p>Effective  45%</p> <p>Very effective  50%</p>
<p>15. After the cosmetic treatment, are you satisfied of this sebu-regulating product?</p>	<p>Unsatisfied at all %</p> <p>A little satisfied  5%</p> <p>Enough satisfied  10%</p> <p>Very satisfied  85%</p>



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APPENDIX



Representative CameraScan images at the three time point

Chin and cheek sx volunteer n 3



T0- before the treatment



T1- after 10 days of treatment



T2- after 30 days of treatment



Face volunteer n 7



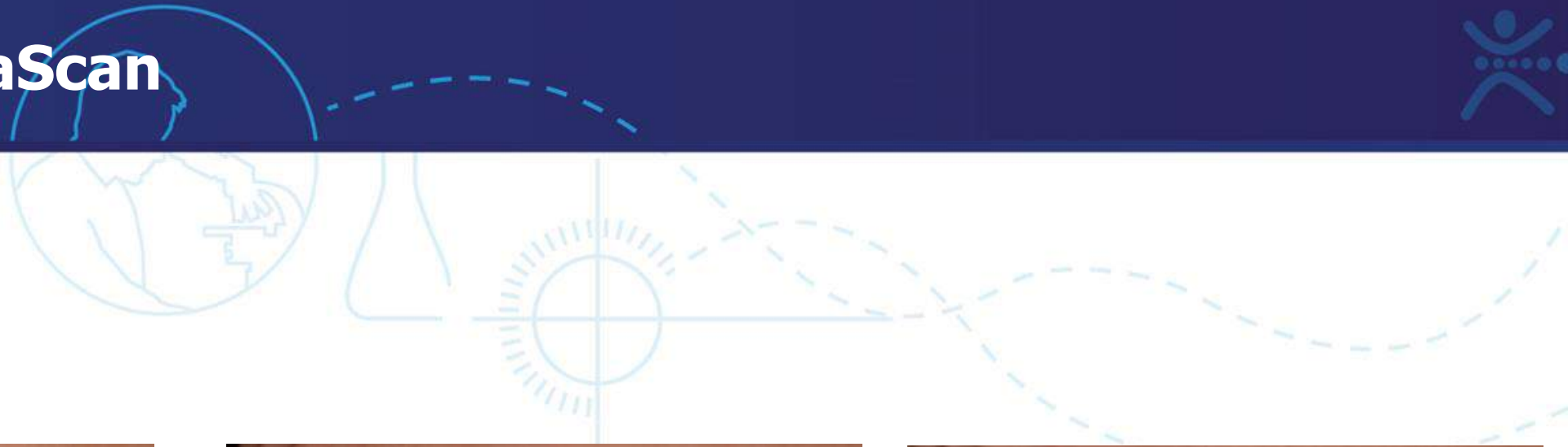
T0- before treatment



T1- after 10 days treatment



T2- after 30 days treatment



Chin and cheek dx volunteer n 10



T0- before treatment



T1- after 10 day of treatment



T2- after 30 days of treatment



Nose volunteer n 16



T0- before treatment



T1- after 10 days of treatment



T2- after 30 days of treatment



Forehead volunteer n 20



T0- before treatment



T1- after 10 days of treatment



T2- after 30 days of treatment



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