**EVALUATION OF THE ANTI-AGING EFFICACY
OF A COSMETIC PRODUCT**

**CHECKING ITS ACCEPTABILITY AFTER APPLICATION
UNDER NORMAL CONDITIONS OF USE**

OBJECTIVE ASSESSMENT OF ITS QUALITIES AND EFFICACY

*In use test with clinical control by a dermatologist
and with instrumental evaluation*

Short Report

*This report is a summary of the report 790613.A, and reflects all data concerning
the study developed with the product.*

I . OBJECTIVE

Skin aging is a combination of multiple aspects that consistently modify the appearance of skin. The most characteristic signs are the stratum corneum dryness, the loss of skin elasticity and firmness, due to a decrease in the fibroblast number and a decrease in the levels of collagen and elastin, the loss of architectural regularity, with the consequent appearance of wrinkles and fine lines, a change in the integrity of the skin barrier function, the appearance of hyperpigmented spots and a yellow type aspect.

The aim of the present study is to assess the **anti-wrinkle efficacy** and **cutaneous recovery of elasticity,** as well as to check the **acceptability** and assess the **qualities and efficacy** of the cosmetic product **CREME FACIAL LEITE DE BURRA, BATCH 330127/A 655** after application under the normal conditions of use planned by the Sponsor.

The **anti-aging efficacy** and **cutaneous recovery of elasticity** of the product was assessed:
- objectively and quantitatively**,** by instrumental measurements of the wrinkles with a VISIA-CA system, before and after treatment,
- objectively and quantitatively**,** by instrumental measurements of the wrinkle, skin roughness and topography with a Fringe projection system (Primos 3D®), before and after treatment,
- objectively and quantitatively**,** by instrumental measurements of the skin firmness and elasticity with a Cutometer® (Dual-Cutometer MPA 580®), before and after treatment.

The **acceptability** was:
- controlled after visual examination of the experimental area, by the dermatologist or the technician, under his authority, and after questioning of the subjects.
- checked every day, by the subjects themselves at home,

The subjective **qualities and efficacy** of the products are assessed, at the end of the study, using a target questionnaire.

This study allows to justify the claim "anti-aging".

II . DATES OF STUDY

Beginning: June 26th, 2013
End: July 24th, 2013

The protocol and test conditions were reviewed by the Internal Review Board (**opinion nº 467/13 from June 21st, 2013**) and the standard protocol was submitted to the Ethical Commission of PhD Trials (**opinion nº 04/2012 from May 4th, 2012**).

III . SUBJECTS

Fifteen (15) subjects were included in the study. There were neither withdrawals nor exclusions. The efficacy and compatibility of the test product was, therefore, assessed in fifteen (15) subjects, corresponding to these specific inclusion criteria:

a) Age: 35 to 65 years,

b) Gender: female,

c) Phototype (Fitzpatrick) : I to V,

d) with visible signs of ageing (expression wrinkles in ocular area),

e) Type of skin: all types of skin.

IV. METHODOLOGY

IV.1. Frequency of measurements

The measurements were performed on **D0 and D28.**

IV.2. Checking of the acceptability

The results were mainly expressed as descriptive data and do not require a statistical treatment. The test products been well accepted by the subjects, under these experimental conditions, by extrapolation it should be safe for human health when applied by a great panel of consumers.

IV.3. Experimental conditions of use of the test product

The experimental conditions, defined by protocol, were the following ones:

Experimental area(s)	Product directions of use	Application(s) at the Institute	Application(s) at home Frequency/duration
Face	Application of CREME FACIAL LEITE DE BURRA, on clean skin by gentle digital massage until complete absorption, twice a day.	-	From D0 to D28 Application, twice a day (morning -after bath, evening – at bedtime) for 28 +/- 2 consecutive days

V . RESULTS

V.1. Results from the dermatological evaluation

There is no skin reaction in any volunteer.

V.2. Results from the questionnaire asked to the volunteers and observation of the individual observation sheet

There is no sensations of discomfort noted by the volunteers at home.

Therefore both products presented **very good** skin compatibility during the study.

V.3. Assessment of qualities and efficacy (self-assessment) of the products

Q1. The product has a pleasant fragrance? **86,7% satisfied volunteers**
Q2. The product is easy to spread? **93,3% satisfied volunteers**
Q3. The product has a nice texture? **86,7% satisfied volunteers**
Q4. The product is easily absorbed by the skin? **80% satisfied volunteers**
Q5. The product has a nice colour? **73,3% satisfied volunteers**
Q6. The product des not leave the skin greasy? **86,7% satisfied volunteers**
Q7. The product is pleasant to touch? **86,7% satisfied volunteers**
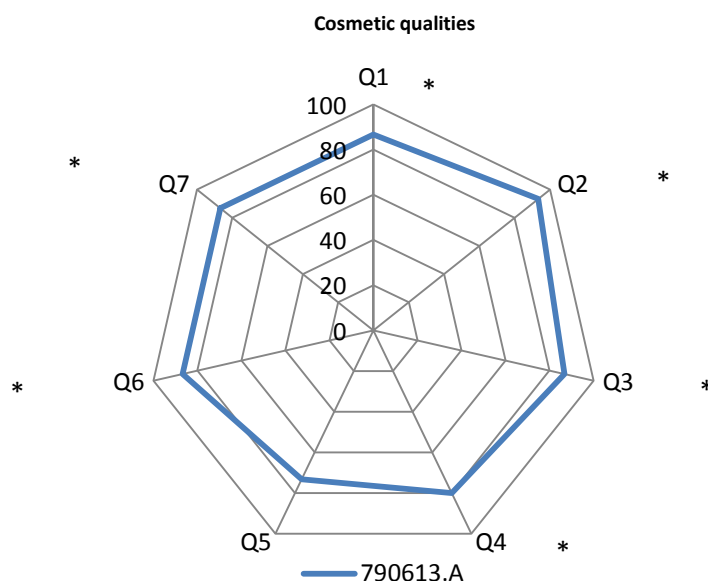
Cosmetic qualities

Figure 1: Self-assessment of qualities. % of total number of volunteers (n = 15), the favorable responses to the questionnaire cosmetic quality. It is also indicated that the responses were statistically significant (* p <0.05)

The product evaluation showed that, for a significant percentage of volunteers, the product:

- Has a pleasant fragrance,
- It is easy to spread,
- Has a nice texture,
- Is easily absorbed by the skin,
- Leaves no greasy skin,
- Is pleasant to touch.

The following summary show the results for each item, the number of volunteers, and % of satisfied volunteers:

Q1. After using the product, I feel the skin more moisturized. **73,3% satisfied volunteers**
Q2. After using the product, I feel the skin softer and smoother. **80% satisfied volunteers**
Q3. After using the product, I notice an improvement in the overall appearance of my skin. **60% satisfied volunteers**
Q4. The skin looks smoother, with a more uniform appearance. **66,7% satisfied volunteers**
Q5. After using the product, I noticed reduced wrinkles. **53,3% satisfied volunteers**
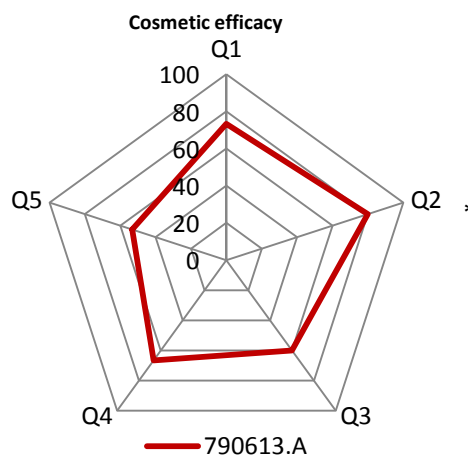
Figure 2: % of total number of volunteers (n = 15), the favorable responses to the cosmetic efficacy questionnaire. It is also indicated that the responses were statistically significant (* $p < 0.05$).

The product evaluation showed that for a significant percentage of volunteers, the product:
- Leaves skin softer and smoother.

V.4. Assessment of the firming effect and skin elasticity recovery

The results of skin elasticity and firmness before and after use of the product expressed in % change relative to D0 and are summarized in the following charts:
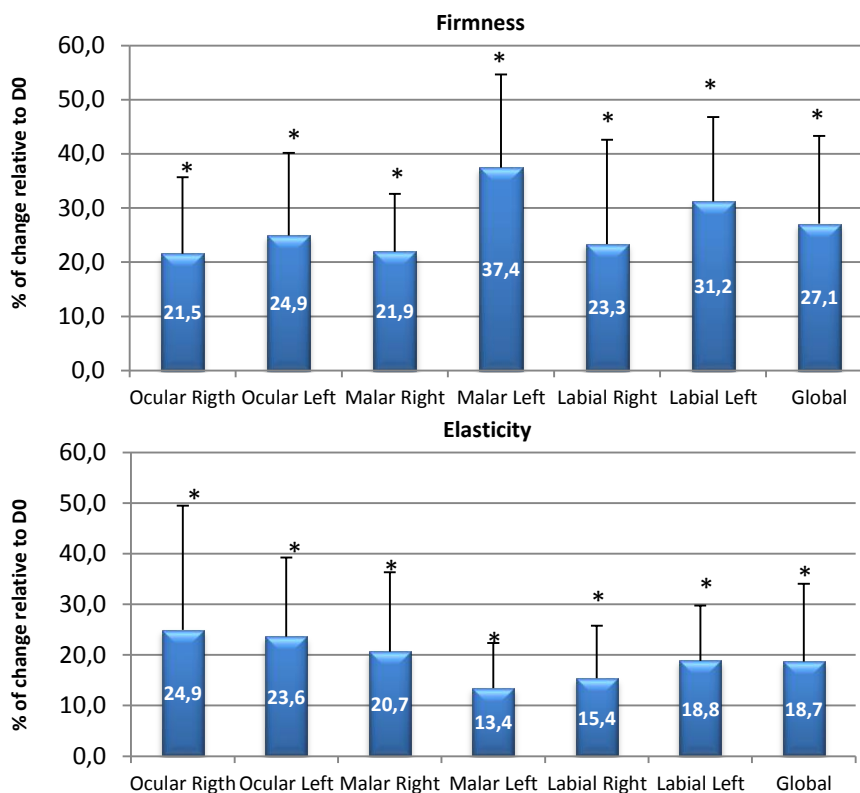

Figure 3 and 4: (Mean + std. Standard) graphic showing the variation of firmness parameter (R0) and of elasticity parameter (Rz) relative to D0. It is also indicated statistically significant (* $p < 0.05$).

V.4.1 Evaluation of skin relief - Eye Zone

The results of the skin relief, before and after using the product, expressed as the number of wrinkles and volume µm are summarized in the chart below :
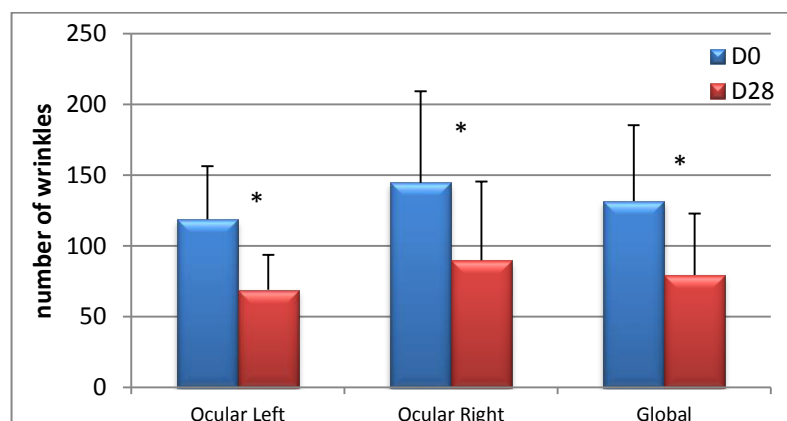

Figure 5: (Mean + std. Standard) graphic showing the evolution of wrinkles in the ocular area during the study. It is also indicated statistically significant (* $p < 0.05$).
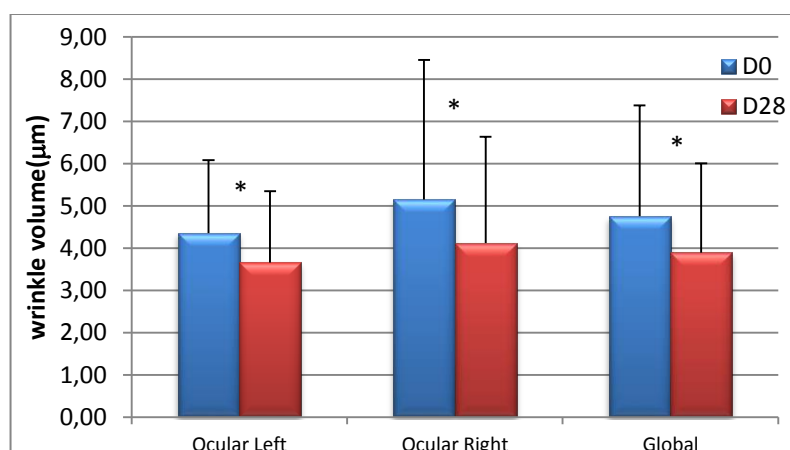

Figure 6: (Mean + std. Standard) graphic showing the evolution of wrinkles volume (ocular) during the study. It is also indicated statistically significant (* $p < 0.05$).

ocular	Left side	Right side	Global
% Change in the number of wrinkles after 28 days	-42.3	-39.6	-41.0
% Change in the wrinkles volume after 28 days	-18.3	-20.6	-19.5

Vol # 1 – D0 (left ocular)	Vol #1 – D28 (left ocular)

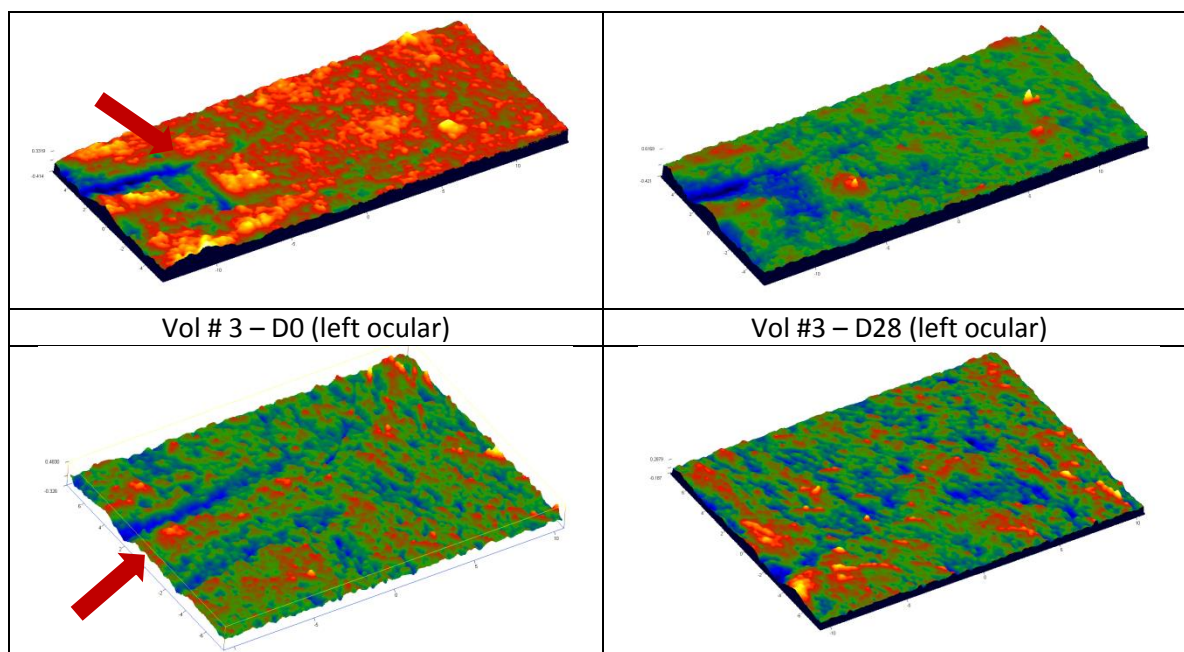| Vol # 3 – D0 (left ocular) | Vol #3 – D28 (left ocular) |

Figure 7: Representative graphic of wrinkle reduction (Vols 1 and # 3) before and after applying the product.
Figure obtained after detection of the common area and standard automatic alignment.

V.4.2 Evaluation of skin relief – Labial area

The results of the skin relief, before and after using the product, expressed as the number of wrinkles and volume μm are summarized in the chart below:
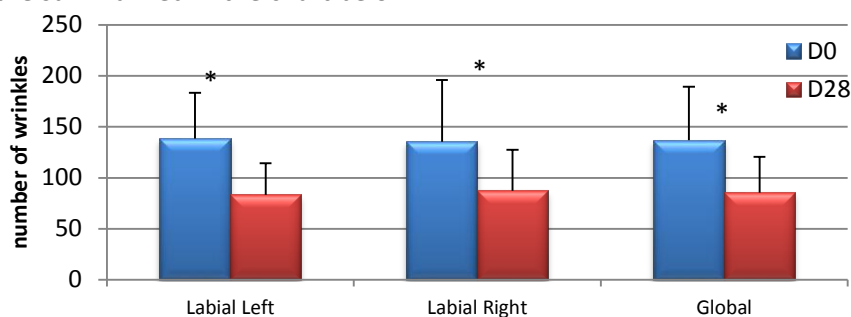

Figure 8: (Mean + std. Standard) graphic showing the evolution of wrinkles in the labial area during the study.
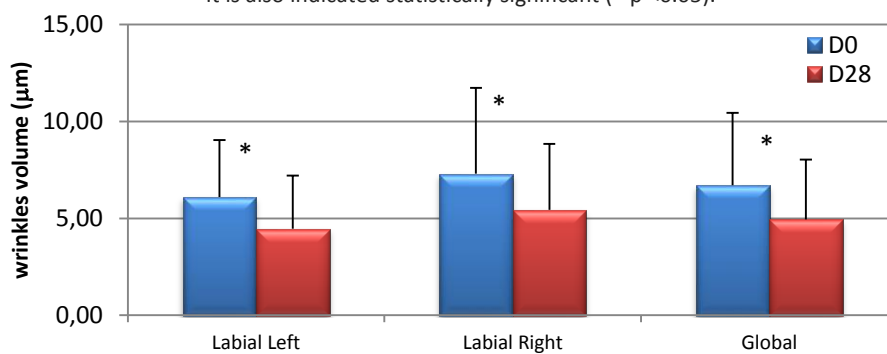It is also indicated statistically significant (* $p < 0.05$).

Figure 9: (Mean + std. Standard) graphic showing the evolution of wrinkles volume (labial area) during the study.
It is also indicated statistically significant (* $p < 0.05$).

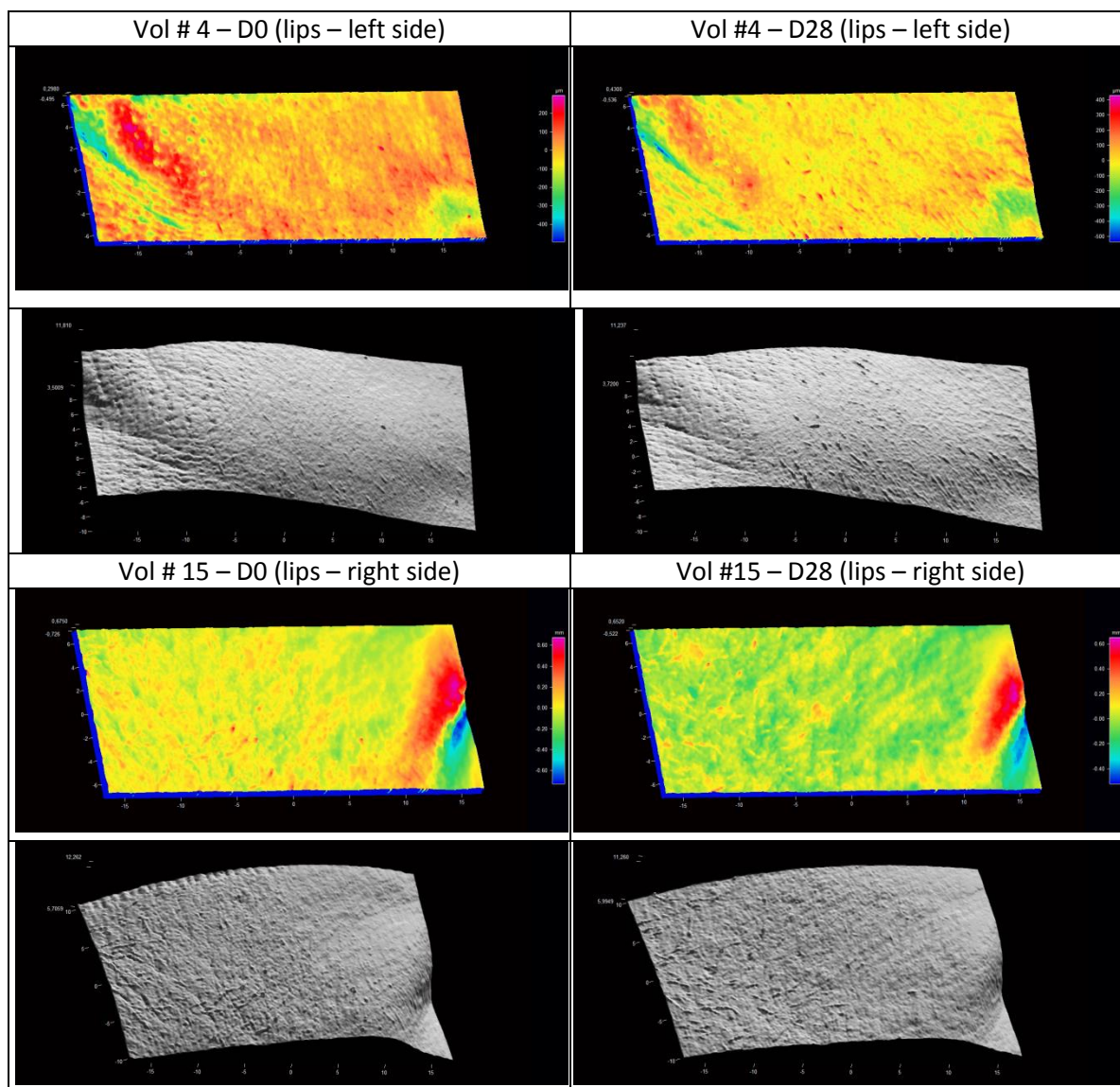| lips	Left side	Right side	Global
% Change in the number of wrinkles after 28 days	-40.0%	-34.4%	-37.2%
% Change in the wrinkles volume after 28 days	-28.9%	-25.8%	-27.3%

Figure 10: Representative graphic of wrinkle reduction (Vols #4 and 15) before and after applying the product. Figure obtained after detection of the common area and standard automatic alignment.

V.4.2 Evaluation of photoaging – standard image

The evaluation results of photoaging, expressed as UV spots, brown spots and pores before and after the use of the product, expressed in number of spots / pores, are summarized in the chart below:
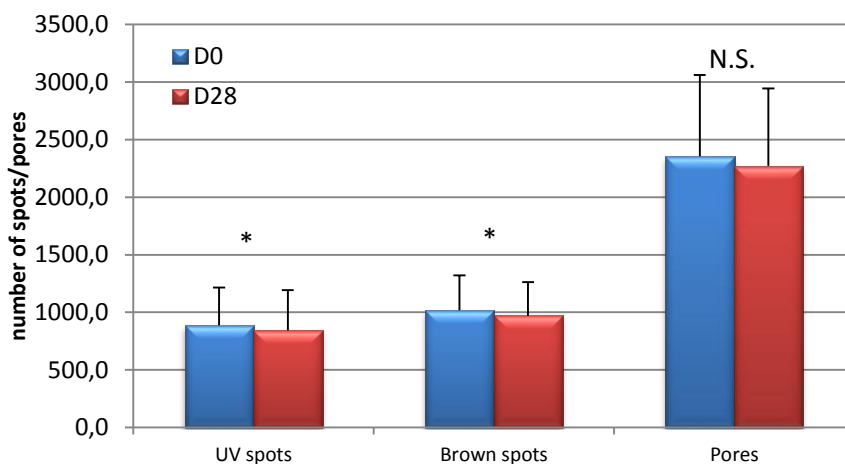

Figure 11: (Mean + std. Standard) graphic showing the evolution of spots and pores during the study. It is also indicated statistically significant (* p <0.05).
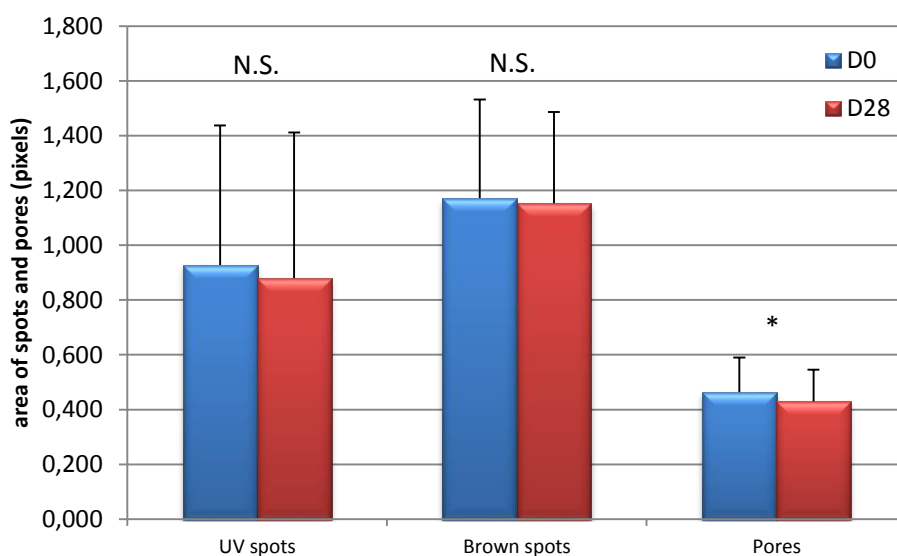

Figure 12: (Mean + std. Standard) graphic showing the area occupied by spots and pores during the study. It is also indicated statistically significant (* p <0.05).

	UV spots	Brown spots	Pores
% Change in the number of spots and pores after 28 days	-10,57%	-4,61%	-2,65%
% Change in the area of spots and pores after 28 days	-8,15%	1,54%	-6,24%

Vol # 7 – D0 (left)	Vol #7– D28 (left)

Vol # 15 – D0 (right)	Vol #15 – D28 (right)

Vol # 15 – D0 (left)	Vol #15 – D28 (left)

Figure 13: Representative pictures of Wrinkle Reduction (Vols # 7 and 15), before and after applying the product. Pictures obtained by the VISIA system.

VI . CONCLUSION

Under the experimental conditions and taking into account the grading scale established by the researcher center, the product **CREME FACIAL LEITE DE BURRA, batch 330127/A 655** has a very good acceptability. A very good skin tolerance was thus confirmed.

Regarding other features, the product was well assessed for its cosmetic qualities, notably its:
- Pleasant fragrance,
- Ease of spreading,
- Nice texture,
- Easier to be absorbed by the skin,
- Does not leave the skin greasy,
- Pleasantness to the touch.

Likewise, the product was much appreciated for its cosmetic efficacy, including:
- Capability to leave the skin softer and smoother.

In quantitative terms:

The application of the product significantly increased the skin firmness by 27.1%.

The application of the product significantly increased the skin elasticity by 18.7%.

The application of the product significantly reduced the number of wrinkles in the ocular area by 41.0%.

The application of the product significantly reduced the volume of skin wrinkles in the ocular area by 19.5%.

The application of the product significantly reduced the number of wrinkles in the nasolabial area by 37.2%.

The application of the product significantly reduced the volume of skin wrinkles in the ocular area by 27.3%.

The application of the product significantly reduced the number of brown and UV spots in the skin by 4.6% and 10.6%, respectively.

The application of the product maintained the number of pores, but significantly reduced its area by 6.2%.

The results suggest that the product **CREME FACIAL LEITE DE BURRA, batch 330127/A 655** - after application for 28 days on 15 volunteers under the conditions described - **improved skin elasticity** and **has the capability of reducing the wrinkles' appearance**. Moreover, the product **CREME FACIAL LEITE DE BURRA, batch 330127/A 655** significantly reduces some of the parameters of skin aging.

Scientific Manager : Pedro CONTREIRAS PINTO

I the undersigned, Pedro CONTREIRAS PINTO, declare that:
- the final report was examined on August 2nd, 2013,
- the results reported accurately and completely reflect the raw data of the study.