



Laboratoire d'Expertise Clinique Espagne S.A.U.

## Study report

for : **INDUSTEX, S.L.**



Eficacy

Date : 27/04/2022

N° : E220113

[www.lab-ex.org](http://www.lab-ex.org)

CONFIDENTIAL

## REPORT : OBJECTIVATION STUDY

### REDUCING, TONING AND ANTI-CELLULITE EFFICACY

CLINICAL STUDY FOR THE EVALUATION OF THE REDUCING, TONING AND CELLULITE-IMPROVING EFFECT OF AN INVESTIGATIONAL PRODUCT, AFTER REPEATED APPLICATIONS UNDER NORMAL CONDITIONS OF USE, FOR 4 WEEKS, IN ADULT SUBJECTS OF BOTH SEXES

INVESTIGATIONAL PRODUCT : **GF ELECTRO FAT REDUCER+GF ELECTRO FAT REDUCER CONDUCTIVE GEL**  
(ref.: VDPGYCIND0144+VDPGYFBOT0006)

LABEX PRODUCT CODE : E220113 062001

EXPERIMENTAL PROTOCOL N° : E220113PE version 1, of 09 March 2022

REPORT N° : E220113RD version 2, of 27 April 2022

START OF OBSERVATIONS : 10 March 2022

INTERMEDIATE DATE : 24 March 2022

END OF OBSERVATIONS : 07 April 2022

STUDY MONITOR	RESPONSIBLE FOR THE STUDY
E. SOUTO <b>INDUSTEX, S.L.</b> Av. Països Catalans, 34 – 8ª Planta 08950 ESPLUGUES DE LLOBREGAT	M. JIMÉNEZ Degree in Biotechnology Master in Biomedical Research <b>LABEX.</b> Passeig Sant Joan, 76 08009 BARCELONA

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. Quality system management certified by AENOR, register nº ER-0352/2006.

**A U T H E N T I C A T I O N**

The study purpose of this present report was conducted under my responsibility, in compliance with the experimental protocol and in accordance with Labex Standard Operating Procedures, and according to the spirit of the general principles of the Good Clinical Practices.

All observations and numerical data obtained during this study are reported in the present document.



**M. JIMÉNEZ**  
Responsible for the study

**Q U A L I T Y   C O N T R O L**

This study was performed in conformity with the Standard Operating Procedures of the Laboratoire d'Expertise Clinique Espagne, the protocol signed with the sponsor and "in the spirit" of the general principles of the Good Clinical Practices published by I.C.H. (Topic E6: CPMP/ICH/135/95).

Audits of clinical studies are conducted every 6 months for each type of study. They are intended to check the correct application of the procedures during the study. The results of these audits are subject to reporting to the Investigator, the Technical Responsible and the Responsible for the Study.

Labex. Quality Unit confirms the compliance of this report with the data generated during the study.

Barcelona, 27 April 2022



**Amina RADI**  
Auditor Quality

P R O T O C O L									
<b><u>STUDY OBJECTIVE</u></b>	<p>To assess the reducing, toning and cellulite improvement efficacy of an investigational product, by means of centimetric measurements of the abdomen, thighs and arm circumference, and clinical assessment by the Investigator of the degree of cellulite, after repeated applications under normal conditions of use, for 4 weeks, in adult subjects of both sexes with a BMI between 24 and 32 and the presence of cellulite on thighs.</p> <p>Claim to justify: "Reducing efficacy", "Toning efficacy" and "Cellulite improvement".</p>								
<b><u>TYPE OF STUDY</u></b>	Objectivation study: Reducing, toning and cellulite-improving efficacy.								
<b><u>STUDY RELEVANCE</u></b>	<p>Centimetric measurements (waist, thigh and arm) in an upright and weight-bearing position, taken before and after repeated applications of a cosmetic investigational product, make it possible to objectively evaluate the reducing properties of this product, compared to the initial values.</p> <p>Measurements with the Cutometer™ before and after repeated applications of the cosmetic investigational product make it possible to objectively evaluate the effect of this product on the biomechanical properties of the skin. The device measures the deformation of a skin area under mechanical suction and its resilience (Wilhelm &amp; al., 1993). The viscoelastic properties of the skin are directly correlated with the flexibility, elasticity, tonicity and firmness of the skin.</p> <p>Taken together, the clinical evaluation carried out by the Investigator and the assessment made by the subjects, on the basis of a specific, targeted and adapted questionnaire, makes it possible to assess the efficacy of the investigational product and its acceptability.</p>								
<b><u>INCLUSION CRITERIA</u></b> <i>(in addition to the standard criteria of Labex.)</i>	<ul style="list-style-type: none"> <li>. Number of subjects : 20</li> <li>. Sex : both</li> <li>. Age : 35 to 65 years old</li> <li>. Body skin type : indifferent</li> <li>. Other : subject with BMI 24 to 32</li> <li>. Other : subject with cellulite on thighs</li> <li>. Sensitivity of skin : maximum of 60% of the panel, being considered sensitive the subjects that have a recent history and repeated functional symptomatology of skin discomfort (ex. tingling, stiffness, warmth, stinging, burning, redness ...)</li> <li>. Healthy subjects with atopy background: 25% maximum, currently admitted proportion for the Spanish population</li> </ul>								
<b><u>METHODOLOGY</u></b>	<p><b>Modalities application of the investigational product</b></p> <table border="1"> <tr> <td>Area</td><td>Thighs, abdomen and arms</td></tr> <tr> <td>Frequency and duration</td><td> <p>Once a day, during 4 weeks, with the following duration times for each zone:</p> <ul style="list-style-type: none"> <li>▪ Arms: 3 - 5 minutes</li> <li>▪ Thighs: 5 - 10 minutes</li> <li>▪ Abdomen: 10 - 20 minutes</li> </ul> </td></tr> <tr> <td>Application conditions</td><td>By the subjects themselves, at home (starting on D1 and ending on D28), under the normal conditions of use, following the Sponsor's instructions (see Appendix 3) and maintaining a healthy diet (see Appendix 4):</td></tr> <tr> <td>Concomitant application of other products</td><td>Usual cleansing and moisturizing products</td></tr> </table>	Area	Thighs, abdomen and arms	Frequency and duration	<p>Once a day, during 4 weeks, with the following duration times for each zone:</p> <ul style="list-style-type: none"> <li>▪ Arms: 3 - 5 minutes</li> <li>▪ Thighs: 5 - 10 minutes</li> <li>▪ Abdomen: 10 - 20 minutes</li> </ul>	Application conditions	By the subjects themselves, at home (starting on D1 and ending on D28), under the normal conditions of use, following the Sponsor's instructions (see Appendix 3) and maintaining a healthy diet (see Appendix 4):	Concomitant application of other products	Usual cleansing and moisturizing products
Area	Thighs, abdomen and arms								
Frequency and duration	<p>Once a day, during 4 weeks, with the following duration times for each zone:</p> <ul style="list-style-type: none"> <li>▪ Arms: 3 - 5 minutes</li> <li>▪ Thighs: 5 - 10 minutes</li> <li>▪ Abdomen: 10 - 20 minutes</li> </ul>								
Application conditions	By the subjects themselves, at home (starting on D1 and ending on D28), under the normal conditions of use, following the Sponsor's instructions (see Appendix 3) and maintaining a healthy diet (see Appendix 4):								
Concomitant application of other products	Usual cleansing and moisturizing products								



<b>METHODOLOGY</b>	<p><b>Modalities of evaluations</b></p> <p>. <i>Centimetric measurements and weight measurements:</i></p> <ul style="list-style-type: none"> <li>→ Area of measurement: abdomen, thigh and arm</li> <li>→ Principle of analysis: circumference measurements made with a tape measure and pre-established anatomical markers, with the help of a system that allows the measurement areas to be defined accurately and reproducibly throughout the study.</li> <li>→ Studied parameter: waist, thigh and arm circumference (cm)</li> <li>→ Kinetics: D1 (baseline), D15 and D29.</li> </ul> <p>. <i>Status of cellulite:</i> Visual scoring by the investigator at D1, D15 and D29 at the level of thighs using the Nürnberger-Müller 4-point visual scale:</p> <ul style="list-style-type: none"> <li>- Type I: No skin surface alterations;</li> <li>- Type II: The skin of the affected area is smooth while the subject is standing or lying down, but the alterations in the surface of the skin can be seen when the skin is pinched or there is a muscle contraction;</li> <li>- Type III: There is an orange skin appearance when standing, without the use of any device to observe it;</li> <li>- Type IV: There is an orange skin appearance when standing, without the use of any device to observe it, in addition to the presence of raised areas and nodules.</li> </ul> <p>. <i>Measurement of the biomechanical properties of the skin (Cutometer™):</i></p> <ul style="list-style-type: none"> <li>→ Area of measurements: in the centre of an area of 35 cm<sup>2</sup> (7 x 5 cm), located in a hairless area of the abdomen</li> <li>→ Principle: the viscoelastic properties of the skin are evaluated, in vivo, using a Cutometer™ MPA 580 (Courage + Khazaka electronic). This device measures the deformation of a cutaneous area submitted to a mechanical suction and its recovering power.</li> <li>→ Analysed parameters: <b>Uf</b>: final distension (maximal amplitude)  <b>Minimal amplitude</b>: residual deformation after strain (Uf - Ua)  <b>Ua/Uf</b>: recover rate after strain  <b>Ur/Ue</b>: elastic deformations rate  <b>Uv/Ue</b>: visco-elasticity rate  <b>Ur/Uf</b>: elastic recover rate  <b>Ua</b>: recovered distensions after strain</li> <li>→ Kinetics: D1 (baseline), D15 and D29</li> </ul> <p><i>Measurements shall be made in an air-conditioned room at a constant temperature of 21°C (+/- 2°C) and controlled relative humidity, after a rest of 30 minutes.</i></p> <p>. <i>Qualities and efficacy:</i> by means of an acceptability questionnaire drawn up in collaboration with the Study Monitor, to be filled in by the subject, at home, before his/her last visit to Labex, and completed with an overall assessment written in the presence of the Investigator on D29.</p>
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<b><u>DATA ANALYSIS</u></b>	<p><u>Clinical scoring and centimetre measurements:</u></p> <ul style="list-style-type: none"> <li>. Determination of the mean values of the criteria assessed at each time point of the study, by calculating the means and standard errors of the mean (SEM) of the individual data.</li> <li>. Comparison of the values obtained at the time points considered with the initial values using the Wilcoxon test ("two-tail", significance: <math>p &lt; 0,05</math>).</li> </ul> <p><u>Instrumental measures:</u></p> <ul style="list-style-type: none"> <li>. Determination of the mean values and standard errors of the mean (S.E.M.) of the individual data, at each time point of the study.</li> <li>. Test for normality of distributions using the Shapiro Wilk test (significance: <math>p &lt; 0.05</math>).</li> <li>. Analysis by: <ul style="list-style-type: none"> <li>⇒ Paired Student's t-test ("two-tail", significance: <math>p &lt; 0.05</math>) in case of normality of distributions;</li> <li>⇒ or the Wilcoxon test ("two-tail", significance: <math>p &lt; 0.05</math>) in the opposite case;</li> </ul> </li> <li>. In case of statistically significant evolution, calculation of the corresponding percentage of variation, from the mean values.</li> </ul> <p><u>Interpretation of the results obtained under the adopted experimental conditions of use, based on:</u></p> <ul style="list-style-type: none"> <li>. the expected effects, according to the Study Monitor,</li> <li>. the type of investigational product,</li> <li>. analysis of the nature, location, intensity, frequency, duration and appearance period of the reactions.</li> </ul>
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## R E S U L T S   A N D   C O N C L U S I O N

### STUDIED POPULATION

Number of subjects recruited	26
Number of subjects who came to Labex.	21
Number of subjects included by the Investigator	21
Number of subjects discontinued from the study	0
- Non-related undesirable effect	0
- Non-related serious undesirable effect	0
- Related undesirable effect	0
- Related serious undesirable effect	0
- Concomitant treatment incompatible with the study	0
- Consent withdrawal by the subject	0
- Lost to follow up	1 (n° 14)
- Emergence of a non-inclusion criterion	0
- Decision of the Investigator	0
- Violation of the protocol	0
Number of subjects for the analysis of the results	20

The characteristics of the subjects included into the study are summarized in the following table:

Subjects	Body skin nature	Body skin sensitivity	Subjects with cellulite on thighs
Number : 20 Women : 17 (85%) Men : 3 (15%) Mean age : 49.4 y.o. Age minimum : 40 y.o. Age maximum : 63 y.o. BMI : 24 to 32	Normal : 15 (75%) Dry : 5 (25%)	2 (10%)	20 (100%)

Subjects with atopy background	With antecedents of reactions to cosmetics	With antecedents of reactions to this type of products
1 (5%)	0 (0%)	0 (0%)

## RESULTS AND DISCUSSION

### 1/ ACCEPTABILITY AND EFFICACY

**As regards its acceptability and efficacy**, a positive judgment and a favourable appraisal of these subjects for, in particular, the following criteria (in % of the subjects questioned):

The device is easy to use	90%
The fastening belt is comfortable to wear	85%
When using the device, the sensations it gives you are pleasant	30%
With continued use of the product, your skin feels smoother	70%
With continued use of the product, your skin feels firmer	70%
With continued use of the product, your muscles feel more toned	60%
With continued use of the product, your muscles feel stronger	55%
With continued use of the product, you feel your muscles firmer	50%
Continued use of the product reduces cellulite on your thighs	45%
Continued use of the product reduces cellulite on the abdomen	65%
Continued use of the product reduces cellulite on the arms	40%
Continued use of the device improves the elasticity of your skin	65%
The device stimulates all abdominal muscles, even the deepest ones	60%
After continued use of the product, you have observed a reduction in localised fat accumulation on the thighs	45%
After continued use of the product, you have observed a reduction of localised fat accumulation in the abdomen	60%
After continued use of the product, you have observed a reduction in the accumulation of localised fat on the arms	35%
After continued use of the product, you have noticed a redefinition of your silhouette	50%
The intensity of the electrostimulation is easy to regulate	90%
The conductive gel allows for an even distribution of the electrostimulation	90%
Globally, I like the product	50%
Would recommend this product	45%



By comparing with the product generally used, the subject found their body skin “just as good” to “better”	33%	(1/3●)
Preferred product:		
. investigational product	0%	(0/3●)
. no preference	33%	(1/3●)
. usual product	67%	(2/3●)
By comparing the efficiency of the investigational product with the one normally used:		
. the investigational product was more efficient	0%	(0/3●)
. no difference	33%	(1/3●)
. the usual product was more efficient	67%	(2/3●)
Purchase intention	40%	

● regular users of this kind of product

**2/ REDUCING EFFECT**

The analysis of the results obtained after the measures of the “abdominal perimeter”, “thigh perimeter” and “arm perimeter” by the technician is detailed below.

After 14 days of use of the investigational product (n=20):

**ABDOMINAL**

	Mean and standard error of the mean – S.E.M (n = 20)			
	D1	D15	$\Delta$ (D15 - D1)	Probability p: Wilcoxon Test
<b>Abdominal perimeter (cm)</b>	90.80 $\pm$ 2.41	88.85 $\pm$ 2.27	-1.95 $\pm$ 0.56	<b>0.0022</b>

**bold:** Statistically significant probability (significance:  $p < 0.05$ )

**A statistically significant reduction has been observed for the parameter “abdominal diameter”,** after 14 days of use of the investigational product, compared to the initial values. This means that the abdominal perimeter has been significantly reduced after 14 days of use.

**THIGH**

	Mean and standard error of the mean – S.E.M (n = 20)			
	D1	D15	$\Delta$ (D15 - D1)	Probability p: Wilcoxon Test
<b>Thigh perimeter (cm)</b>	60.00 $\pm$ 1.32	59.30 $\pm$ 1.21	-0.70 $\pm$ 0.38	0.6875

*italic:* statistically non-significant probability ( $p > 0.05$ )

**It has not been found differences statistically significant for the “thigh perimeter” parameter,** after 14 days of use of the investigational product, in comparison with the initial values.

After 28 days of use of the investigational product (n=20):

#### ABDOMINAL

	Mean and standard error of the mean – S.E.M (n = 20)			
	D1	D15	Δ (D29 - D1)	Probability p: Wilcoxon Test
<b>Abdominal perimeter (cm)</b>	90.80 ± 2.41	87.90 ± 2.31	-2.90 ± 0.46	<b>&lt;0.0001</b>

**bold:** Statistically significant probability (significance:  $p < 0.05$ )

**A statistically significant reduction has been observed for the parameter “abdominal diameter”,** after 28 days of use of the investigational product, compared to the initial values. This means that the abdominal perimeter has been significantly reduced after 28 days of use.

#### THIGH

	Mean and standard error of the mean – S.E.M (n = 20)			
	D1	D29	Δ (D29 - D1)	Probability p: Wilcoxon Test
<b>Thigh perimeter (cm)</b>	60.00 ± 1.32	58.60 ± 1.19	-1.40 ± 0.41	<b>&lt;0.0001</b>

**bold:** Statistically significant probability (significance:  $p < 0.05$ )

**A statistically significant reduction has been observed for the parameter “thigh diameter”,** after 28 days of use of the investigational product, compared to the initial values. This means that the thigh perimeter has been significantly reduced after 28 days of use.

ARM

	Mean and standard error of the mean – S.E.M (n = 20)			
	D1	D29	$\Delta$ (D29 - D1)	Probability p: Wilcoxon Test
<b>Arm perimeter (cm)</b>	31.05 $\pm$ 0.88	30.50 $\pm$ 0.77	-0.55 $\pm$ 0.29	<u>0.0625</u>

underline: Statistically close to significant probability (significance:  $0.1 > p > 0.05$ )

**A statistically close to significance reduction has been observed for the parameter “arm diameter”, after 28 days of use of the investigational product, compared to the initial values.**

**3/ WEIGHT LOSS**

The analysis of the results after weighing the subjects before and after use of the product, is detailed below.

Weight loss at D15

	Mean and standard error of the mean – S.E.M (n = 20)			
	D1	D15	$\Delta$ (D15 - D1)	Probability p: Wilcoxon Test
<b>Weight (kg)</b>	75.48 $\pm$ 3.24	75.20 $\pm$ 3.23	-0.28 $\pm$ 0.11	<b>0.0192</b>

**bold**: Statistically significant probability (significance:  $p < 0.05$ )

**A statistically significant reduction has been observed for the parameter “weight”, after 14 days of product use and a healthy diet, compared to the initial values. This means that the weight has been significantly reduced after 14 days of use.**

Weight loss at D29

	Mean and standard error of the mean – S.E.M (n = 20)			
	D1	D29	$\Delta$ (D29 - D1)	Probability p: Wilcoxon Test
<b>Weight (kg)</b>	75.48 $\pm$ 3.24	74.35 $\pm$ 3.23	-1.13 $\pm$ 0.46	<b>0.0020</b>

**bold**: Statistically significant probability (significance:  $p < 0.05$ )

**A statistically significant reduction has been observed for the parameter “weight”, after 28 days of product use and a healthy diet, compared to the initial values. This means that the weight has been significantly reduced after 28 days of use.**

**4/ CELLULITE IMPROVEMENT**

- In reference to the scoring of the “cellulite improvement” parameter: visual scale of 4 points (from 0 to 3) Nürnberger-Müller.

After 14 days of use of the investigational product:

**EVALUATION BY THE INVESTIGATOR (n=20)**

	n	Mean and standard error of the mean (S.E.M.)		Variation percentage #	Probability p: Wilcoxon Test
		D1 Initial value	D15		
Degree of cellulite	20	2.35 ± 0.17	2.20 ± 0.16	-5%	0.2500

*italics: probability not statistically significant:  $p > 0.10$*

*# Variation compared to the initial values*

It has been not found differences statistically significant in the “degree of cellulite” parameter, after 14 days of use of the investigational product, in comparison with the initial values. This means that the application of the cosmetic investigational product not provides a cellulite improvement after 14 days of application.

After 28 days of use of the investigational product:

**EVALUATION BY THE INVESTIGATOR (n=20)**

	n	Mean and standard error of the mean (S.E.M.)		Variation percentage #	Probability p: Wilcoxon Test
		D1 Initial value	D29		
Degree of cellulite	20	2.35 ± 0.17	1.65 ± 0.11	-5%	<b>0.0002</b>

**bold: Statistically significant probability (significance:  $p < 0.05$ )**

*# Variation compared to the initial values*

It has been found differences statistically significant in the “degree of cellulite” parameter, after 28 days of use of the investigational product, in comparison with the initial values. This means that the application of the cosmetic investigational product provides a cellulite improvement after 28 days of application.

## **5/ MEASUREMENT OF THE BIOMECHANICAL PROPERTIES OF THE SKIN (Cutometer™)**

The analysis of the results obtained after 14 days of use of the investigational product is presented below:

In terms of efficacy, the following claims can be supported if the sets of variations cited are statistically justified:

**- “improves skin tone”:**

- . stabilisation or decrease of  $U_f$
- . increase of  $U_r/U_f$  or of  $U_a/U_f$  or decrease of  $U_v/U_e$

The parameters measured by the Cutometer™ are as follows:

- .  $U_f$ : final distension (maximal amplitude)
- . Minimal amplitude: residual deformation after strain ( $U_f - U_a$ )
- .  $U_a/U_f$ : recover rate after strain
- .  $U_r/U_e$ : elastic deformations rate
- .  $U_v/U_e$ : visco-elasticity rate
- .  $U_r/U_f$ : elastic recover rate
- .  $U_a$ : recovered distensions after strain

The results obtained by the instrument are as follows:

$R0 = U_f$  (maximum amplitude)

$R2 = U_a/U_f$  (rate of recovery after contraction)

$R6 = U_v/U_e$  (visco-elasticity ratio determining the importance of the viscous response with respect to the elastic response)

$R7 = U_r/U_f$  (biological elasticity or elastic recovery rate: capacity to return to the initial position after deformation).



The normality of the distributions has been verified in all cases, except for the parameters “Ua/Uf (rate of recovery after contraction)” and “Ur/Uf (elastic recover rate)”. The values obtained are detailed below:

At D15:

MEAN AND STANDARD ERROR OF MEAN (S.E.M.), n = 20		
PARAMETERS	Uf (maximum amplitude)	Ua/Uf [%] (rate of recovery after contraction)
D1	1.431 ± 0.064	93.4 ± 0.6
D15	1.331 ± 0.049	93.5 ± 1.0
Δ (D15-D1)	- 0.099 ± 0.039	+ 0.1 ± 0.4
Probability p: Student “t” Test or Wilcoxon Test	<u>0.0726</u>	0.4250

*italics: statistically non-significant probability ( $p > 0.10$ )*

*underlined: probability close to significance ( $0.05 \leq p \leq 0.10$ )*

MEAN AND STANDARD ERROR OF MEAN (S.E.M.), n = 20		
PARAMETERS	Uv/Ue [%] (visco-elasticity rate)	Ur/Uf [%] (elastic recover rate)
D1	24.2 ± 1.3	82.8 ± 1.5
D15	27.5 ± 1.3	81.0 ± 1.8
Δ (D15-D1)	+ 3.3 ± 1.3	- 1.8 ± 1.4
Probability p: Student “t” Test or Wilcoxon Test	<b>0.0137</b>	0.1862

**bold: statistically significant probability ( $p < 0.05$ )**

*italics: statistically non-significant probability ( $p > 0.10$ )*

Statistically significant differences were found for the “Uv/Ue [%] (visco-elasticity rate)” parameter and stability was observed for the other parameters analysed after 2 weeks of use of the investigational product.

However, these results do not indicate a significant and favourable change in the biomechanical properties of the skin.

At D29:

MEAN AND STANDARD ERROR OF MEAN (S.E.M.), n = 20		
PARAMETERS	Uf (maximum amplitude)	Ua/Uf [%] (rate of recovery after contraction)
D1	1.431 ± 0.064	93.4 ± 0.6
D29	1.383 ± 0.050	93.8 ± 0.8
Δ (D29-D1)	- 0.048 ± 0.037	+ 0.4 ± 0.8
Probability p: Student "t" Test or Wilcoxon Test	<i>0.4099</i>	<i>0.6807</i>

*italics: statistically non-significant probability (p > 0.10)*

MEAN AND STANDARD ERROR OF MEAN (S.E.M.), n = 20		
PARAMETERS	Uv/Ue [%] (visco-elasticity rate)	Ur/Uf [%] (elastic recover rate)
D1	24.2 ± 1.3	82.8 ± 1.5
D29	31.0 ± 1.7	81.5 ± 1.7
Δ (D29-D1)	+ 6.7 ± 1.6	- 1.3 ± 1.8
Probability p: Student "t" Test or Wilcoxon Test	<b>0.0004</b>	<i>0.5038</i>

**bold: statistically significant probability (p < 0.05)**

*italics: statistically non-significant probability (p > 0.10)*

Statistically significant differences were found for the "Uv/Ue [%] (visco-elasticity rate)" parameter and stability was observed for the other parameters analysed after 4 weeks of use of the investigational product.

However, these results do not indicate a significant and favourable change in the biomechanical properties of the skin.

## CONCLUSION

The repeated use of the investigational product designated as:

**“GF ELECTRO FAT REDUCER+GF ELECTRO FAT REDUCER CONDUCTIVE GEL  
(ref.: VDPGYCIND0144+VDPGYFBOT0006)”**

once a day, for 15 minutes in each area (abdomen, thighs and arms), during 4 consecutive weeks, by 20 adult subjects of both sexes, with a BMI between 24 and 32 and with cellulite in thighs, led to a statically decrease of abdominal, thigh and arm perimeter, weight and cellulite in thighs.

The claims such as "REDUCING EFFICACY" and "CELLULITE IMPROVEMENT" can thus be justified.

Barcelona, 27 April 2022



**M. JIMÉNEZ**  
**Responsible for the study**

This study was conducted by LABORATOIRE D'EXPERTISE CLINIQUE ESPAGNE, managed by Mr. B. RAÏS, PhD Biological and Medical Sciences, European Registered Toxicologist - EUROTOX.

**P R O T O C O L   C O M P L I A N C E**

No deviation has significantly affected the quality or the interpretation of the obtained results.

**S T O R A G E   O F   T H E   I N V E S T I G A T I O N A L  
P R O D U C T**

The investigational product was kept under lock and key, from heat (between + 5°C and + 25°C) and from light.

A sample of the investigational product will be kept in our facilities for 4 months as of the date of dispatch of the final report. From this date on, and without contrary advice of the Sponsor, the investigational product will be destroyed.

**D A T A   R E C O R D I N G   A N D   A R C H I V I N G**

Raw data are defined as all the hand-written information input in the case report form elaborated before the start of the study. Raw data are then synthesized in compilation document, which are mainly electronic Excel files (Microsoft Corp.) and allow either direct analysis of the data, or transfer to a more specific software for statistical analysis (SPSS...).

All raw data (case report forms, questionnaires if any), as well as the original documents of the compilation, of the final protocol (amendments if any), of the final report (all different versions and/or amendments if any) and of the statistical analysis if any, are scanned and kept in the LABEX servers for 15 years from the date of sending the final report.

All documentation, communication and data, on paper support, will be kept in our facilities centre for 4 months from the sending the final report date. From this date and unless otherwise requested by the Study Monitor, this documentation will be destroyed.

**APPENDIX 1: SUBJECT'S CHARACTERISTICS**

<i>Subject</i>	<i>Sex</i>	<i>Age</i>	<i>Body skin nature</i>	<i>Sensitive body skin</i>	<i>Healthy subject with history of atopy</i>	<i>Subject with cellulite on thighs</i>	<i>BMI 24 to 32</i>
01	F	52	Dry	-	-	yes	yes
02	F	46	Normal	-	-	yes	yes
03	F	50	Dry	yes	-	yes	yes
04	F	60	Normal	-	-	yes	yes
05	F	49	Normal	-	-	yes	yes
06	F	58	Dry	-	-	yes	yes
07	F	47	Normal	-	-	yes	yes
08	F	47	Normal	-	-	yes	yes
09	F	45	Normal	-	-	yes	yes
10	F	55	Normal	-	-	yes	yes
11	M	47	Normal	-	-	yes	yes
12	M	63	Normal	-	-	yes	yes
13	F	51	Dry	-	-	yes	yes
15	F	40	Normal	-	-	yes	yes
16	F	40	Normal	-	-	yes	yes
17	F	44	Normal	-	-	yes	yes
18	M	48	Normal	-	-	yes	yes
19	F	51	Dry	yes	yes	yes	yes
20	F	46	Normal	-	-	yes	yes
21	F	49	Normal	-	-	yes	yes

**APPENDIX 2: SUBJECT'S DISCONTINUATIONS**

<i><b>Subject</b></i>	<i><b>Sex</b></i>	<i><b>Age</b></i>	<i><b>Body skin nature</b></i>	<i><b>Sensitive body skin</b></i>	<i><b>Healthy subject with history of atopy</b></i>	<i><b>Past history of reactions to cosmetics</b></i>	<i><b>Past history of reactions to this kind of product</b></i>	<i><b>Clinical examination (D0)</b></i>	<i><b>Date of the discontinuation</b></i>	<i><b>Reason of discontinuation</b></i>
14	F	64	Normal	yes	yes	-	-	10/03/2022	24/03/2022	Lost to follow up



**APPENDIX 3: REDUCING EFFECT**

Abdominal perimeter (cm):

SUBJECT	D1	D15	D29
1	83.0	84.0	83.0
2	93.0	85.0	85.0
3	86.0	83.0	82.0
4	83.0	80.0	79.0
5	95.0	93.0	91.0
6	81.0	77.0	76.0
7	77.0	76.0	77.0
8	95.0	93.0	92.0
9	87.0	87.0	85.0
10	95.0	96.0	95.0
11	120.0	116.0	116.0
12	98.0	96.0	95.0
13	90.0	85.0	85.0
15	112.0	107.0	107.0
16	81.0	84.0	80.0
17	80.0	78.0	77.0
18	93.0	92.0	91.0
19	97.0	97.0	96.0
20	88.0	86.0	86.0
21	82.0	82.0	80.0

Thigh perimeter (cm):

SUBJECT	D1	D15	D29
1	59.0	60.0	56.0
2	62.0	62.0	60.0
3	58.0	56.0	56.0
4	51.0	51.0	51.0
5	64.0	64.0	64.0
6	70.0	68.0	65.0
7	62.0	62.0	62.0
8	53.0	54.0	53.0
9	68.0	67.0	67.0
10	60.0	56.0	55.0
11	64.0	64.0	64.0
12	55.0	55.0	55.0
13	56.0	58.0	56.0
15	69.0	64.0	64.0
16	56.0	56.0	55.0
17	61.0	61.0	61.0
18	53.0	54.0	54.0
19	69.0	68.0	68.0
20	55.0	53.0	53.0
21	55.0	53.0	53.0

Arm perimeter (cm):

SUBJECT	D1	D15	D29
1	27.0	27.0	27.0
2	35.0	37.0	34.0
3	29.0	29.0	29.0
4	28.0	28.0	28.0
5	35.0	35.0	35.0
6	33.0	32.0	32.0
7	30.0	30.0	30.0
8	25.0	25.0	25.0
9	33.0	33.0	33.0
10	28.0	28.0	28.0
11	41.0	37.0	36.0
12	29.0	29.0	29.0
13	27.0	27.0	26.0
15	33.0	34.0	33.0
16	28.0	28.0	28.0
17	31.0	31.0	28.0
18	33.0	31.0	33.0
19	37.0	37.0	37.0
20	28.0	28.0	28.0
21	31.0	31.0	31.0

Weight (kg):

SUBJECT	D1	D15	D29
1	68.8	68.3	69.2
2	80.6	80.0	78.9
3	71.6	71.1	71.2
4	60.8	60.8	60.7
5	90.5	90.5	89.6
6	76.9	75.5	73.8
7	62.0	60.8	60.0
8	71.3	71.0	71.0
9	75.2	75.0	74.4
10	73.9	73.1	73.1
11	119.5	119.1	119.7
12	85.2	85.0	84.1
13	66.9	66.8	65.2
15	93.0	92.8	91.5
16	61.2	61.5	60.4
17	65.7	65.8	65.5
18	79.8	79.3	78.3
19	85.4	85.4	85.4
20	60.7	61.1	60.9
21	60.6	61.1	61.4

**APPENDIX 4: DEGREE OF CELLULITE**

SUBJECT	D1	D15	D29
1	2.0	2.0	1.0
2	2.0	2.0	1.0
3	3.0	2.0	2.0
4	2.0	2.0	2.0
5	3.0	3.0	2.0
6	3.0	3.0	2.0
7	3.0	3.0	2.0
8	3.0	3.0	2.0
9	2.0	2.0	2.0
10	3.0	3.0	2.0
11	2.0	2.0	2.0
12	1.0	1.0	1.0
13	2.0	2.0	2.0
15	3.0	3.0	2.0
16	3.0	3.0	2.0
17	2.0	2.0	1.0
18	1.0	1.0	1.0
19	3.0	2.0	2.0
20	3.0	2.0	1.0
21	1.0	1.0	1.0

## APPENDIX 5: MEASUREMENT OF THE BIOMECHANICAL PROPERTIES OF THE SKIN (Cutometer™)

R0 parameter:

SUBJECT	D1	D15	D29
1	1.362	1.349	1.365
2	1.548	1.528	1.590
3	1.320	1.186	0.935
4	1.240	1.572	1.782
5	1.917	1.635	1.759
6	1.735	1.198	1.410
7	1.393	1.257	1.157
8	2.047	1.478	1.432
9	1.551	1.578	1.505
10	1.182	1.220	1.205
11	1.371	0.987	1.196
12	1.361	1.031	1.464
13	1.589	1.374	1.382
15	0.918	0.943	1.017
16	1.512	1.369	1.647
17	1.213	1.207	1.447
18	1.311	1.351	1.302
19	0.923	1.184	1.169
20	1.448	1.447	1.391
21	1.671	1.729	1.500



R2 parameter:

SUBJECT	D1	D15	D29
1	85.0	92.4	89.4
2	93.0	95.3	94.7
3	89.7	88.1	89.0
4	92.8	89.7	98.5
5	92.0	79.3	92.1
6	93.2	95.6	96.0
7	95.1	96.9	97.9
8	95.8	97.0	93.8
9	95.5	97.0	92.3
10	94.5	96.4	96.2
11	94.7	91.3	91.8
12	94.6	94.1	89.3
13	95.7	94.0	96.0
15	89.9	92.6	85.2
16	92.6	96.5	97.3
17	96.1	95.9	95.5
18	92.3	90.6	94.9
19	95.3	96.5	96.7
20	95.5	94.7	92.7
21	94.4	96.5	96.3

R6 parameter:

SUBJECT	D1	D15	D29
1	25.9	24.2	31.4
2	17.6	23.9	25.8
3	27.2	35.4	44.7
4	26.5	25.1	41.0
5	20.9	26.0	22.3
6	29.7	32.8	41.6
7	36.6	33.3	39.1
8	20.4	25.5	25.7
9	16.3	16.4	25.0
10	31.8	28.1	21.8
11	25.7	22.6	32.3
12	21.0	38.8	24.4
13	17.2	25.0	29.0
15	27.5	35.3	43.9
16	19.7	25.4	22.5
17	31.4	32.5	26.8
18	18.5	23.3	33.8
19	30.7	27.7	30.5
20	21.4	27.7	28.8
21	18.7	20.7	29.0

R7 parameter:

SUBJECT	D1	D15	D29
1	69.5	68.1	69.8
2	81.9	81.2	76.7
3	71.5	72.8	72.9
4	79.4	77.0	86.1
5	82.7	69.0	80.6
6	72.4	88.5	82.6
7	83.8	85.1	88.8
8	88.0	90.8	84.0
9	90.0	86.1	76.5
10	85.3	93.0	92.8
11	89.3	83.8	86.8
12	82.4	65.0	71.3
13	86.9	86.8	87.2
15	74.3	72.0	68.5
16	79.7	79.9	90.8
17	90.6	85.9	86.8
18	89.3	81.9	74.9
19	88.6	91.8	92.0
20	86.7	77.7	76.1
21	83.4	82.9	84.6