SHORT TERM EVALUATION OF THE SOOTHING AND RE-EPITHELIZING ACTIVITY OF IDRO/LIPO-GEL FORMULATIONS VS REFERENCE PRODUCTS

PROTOCOLS N°: 2647, 2648, 2649, 2650

TEST CODE: E0715

SUBMITTED TO: Fondazione Samiarc
Via Lanzone, 7
20123 MILANO (MI)
ITALY

Adele Sparavigna

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DN: cn=Adele Sparavigna gn=Adele Sparavigna c=Italy l=IT o=DermIng ou=DermIng e=adele.sparavigna@derming.com
Reason: I am the author of this document
Location:
Date: 09/22/15 13:31:02

PRODUCTS: **LIPOGEL SOLUZIONE P 1%**
IDROGEL SOLUZIONE B
LIPOGEL SOLUZIONE CONTROLLO 1%
IDROGEL SOLUZIONE CONTROLLO

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FINAL REPORT

PROCEDURE

FINAL REPORT

DermIng S.r.l., Clinical Research and Bioengineering Institute
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E0715

FINAL REPORT

SHORT TERM EVALUATION OF THE SOOTHING AND RE-EPITHELIZING ACTIVITY OF IDRO/LIPO-GEL FORMULATIONS VS REFERENCE PRODUCTS

TEST CODE: E0715 **DATE: May 29th 2015**

SUBMITTED TO: **FONDAZIONE SAMIARC**
Via Lanzone, 7
20123 MILANO (MI)
ITALY

STUDY PRODUCT: LIPOGEL SOLUZIONE P 1%

PROTOCOL N°: 2647

CONTAINER TYPE:	-MATERIAL: plastic
	-FORM: dispenser
	-COLOUR: transparent white
PRODUCT:	-QUANTITY: 30 ml
	-PHYSICAL FORM: gel
	-COLOUR: transparent

STUDY PRODUCT: LIPOGEL SOLUZIONE CONTROLLO 1%

PROTOCOL N°: 2648

CONTAINER TYPE:	-MATERIAL: plastic
	-FORM: dispenser
	-COLOUR: transparent white
PRODUCT:	-QUANTITY: 30 ml
	-PHYSICAL FORM: gel
	-COLOUR: transparent

STUDY PRODUCT: IDROGEL SOLUZIONE CONTROLLO

PROTOCOL N°: 2649

CONTAINER TYPE:	-MATERIAL: plastic
	-FORM: dispenser
	-COLOUR: transparent white
PRODUCT:	-QUANTITY: 30 ml
	-PHYSICAL FORM: gel
	-COLOUR: transparent

STUDY PRODUCT: IDROGEL SOLUZIONE B

PROTOCOL N°: 2650

CONTAINER TYPE:	-MATERIAL: plastic
	-FORM: dispenser
	-COLOUR: transparent white
PRODUCT:	-QUANTITY: 30 ml
	-PHYSICAL FORM: gel
	-COLOUR: transparent

PRODUCTS ARRIVAL DATE: April 07th 2015

STUDY START DATE: April 27th 2015

RESPONSIBLES OF THE STUDY:

Dermatologist, Research Director: Dr. Adele Sparavigna

Signature:

Project manager: Dr. Beatrice Tenconi

Signature:

Quality assurance: Dr. Ileana De Ponti

Signature:

STUDY CONDUCTED BY: DermIng S.r.l., Clinical Research and Bioengineering Institute, Viale Cesare Battisti, 38 – 20900 Monza (MB) - Italy

1. SUMMARY OF THE PROTOCOL

1.1. STUDY OBJECTIVE AND DEFINITIONS

Open clinical study to evaluate the soothing and re-epithelizing activity of a single application of two gel formulations ("Lipogel soluzione P1%" and "Idrogel soluzione B") on experimentally induced erythema by repeated tape stripping on the forearm (volar surface) of 20 healthy volunteers.

Products study activity was assessed in comparison to two reference products ("Lipogel soluzione controllo 1%" and "Idrogel soluzione controllo").

1.2. CHARACTERISTICS OF THE POPULATION AT INCLUSION

The study was conducted on 21 healthy volunteers (18 females and 3 males), aged between 20 and 68 years (mean= 51), whose informed consent had been obtained.

1.3. SUMMARY OF THE STUDY METHODOLOGY

To investigate the activity of the study products, a visible skin erythema was induced, for each volunteer, on 4 different adjacent skin areas of the forearms (volar surface - 2 areas on each side) by "repeated tape stripping" technique (see procedure par. 7.2), as follows:

- area treated with "Lipogel soluzione P1% (named during the test "P1")
- area treated with "Idrogel soluzione B" (named during the test "P2")
- area treated with "Lipogel soluzione controllo 1%" (named during the test "Ref1")
- area treated with Idrogel soluzione controllo" (named during the test "Ref2").

These areas were turned in accordance with a previously defined randomisation list (see "Subjects' randomisation list" table).

A fixed quantity of 1 ml (see procedure par. 6.4 and 6.5) of each product was prepared immediately before application, applied on the assigned skin area of 14 cm^2 (by a trained technician, by gloved fingers and light massage) and left absorbing on the skin for at least 15 minutes.

Soothing efficacy of the tested products was determined by clinical (visual score) and instrumental (optical densitometry and colorimetry) evaluations of skin erythema (see procedure par. 7.3), while ***re-epythelizing activity*** was defined by the measurement of:

- transepidermal water loss (TEWL – see procedure par. 7.4.1)
- skin electrical capacitance (hydration – see procedure par.7.4.2)
- tissue dielectric constant of deep skin layers (deep hydration – see procedure par. 7.4.3)
- epicutaneous pH (see procedure par. 7.4.4)
- surface microrelief profilometry (see procedure par 7.4.5).

All evaluations were carried out at baseline (T0 - immediately after stripping execution) and 1 (T1h), 6 (T6h), 24 (T24h) and 48 (T48h) hours after study products application, except for the surface microrelief profilometry performed at T0 and T48h by image analysis (Primos compact portable device - GFMesstechnik).

2. RESULTS

Obtained results are summarised below and detailed in the annexed graphs and tables.

Volunteer N. 17 was excluded from the study because the TEWL values measured at T0 were lower than the threshold values ($\geq$15g/m^2-h) required by the study procedure as index of a skin barrier damage induced by repeated tape stripping (see procedure par. 4.4.1).

The statistical analysis was performed on the data of 20 subjects who meet the inclusion criteria, in accordance to our internal procedures (descriptive and inferential analysis) as follows:

- ***Evaluation vs basal conditions (T0)***

  For each study area, comparison of the different study times (T1h, T6h, T24h and T48h) versus T0 using :

  - *for the clinical evaluations*

    Friedman test followed, in case of statistically significant result by Dunnett test.

  - *for the instrumental evaluations (excluding profilometric parameters)*

    non-parametric test (Friedman test) when the normality hypothesis was rejected by the Shapiro-Wilk normality test (threshold at 5%) or parametric test (ANOVA for repeated-measures), when the normality hypothesis was confirmed and followed in case of statistically significant result by Dunnett/Tukey test.

  - *for the profilometric parameters*

    non-parametric test (Wilcoxon test) when the normality hypothesis was rejected by the Shapiro-Wilk normality test (threshold at 5%) or parametric test (Student t test) when the normality hypothesis was confirmed.

- ***Comparison among the 4 skin tested areas time by time***

  - *for the clinical evaluations*

  Kruskal Wallis test followed, in case of statistically significant result by Tukey test.

  - *for the instrumental evaluations*

  non-parametric test (Kruskal Wallis test) when the normality hypothesis was rejected by the Shapiro-Wilk normality test (threshold at 5%) or parametric test (one way ANOVA

test), when the normality hypothesis was confirmed and followed in case of statistically significant results by Tukey test.

2.1. SOOTHING EFFICACY

2.1.1. Erythema index (E.I. – Optical densitometry)

Stripping corneum determined on all areas a significant increase of skin erythema index measured by optical densitometry; this alteration resulted similar for all tested areas (see raw data tables); in fact no clinical or statistical difference was found at T0 among the 4 compared areas.

The following table summarizes the obtained variation percentages vs T0:

OPTICAL DENSITOMETRY	*Variation (%) vs T0*			
	T1h	*T6h*	*T24h*	*T48h*
LIPOGEL SOLUZIONE P 1%	-26.1% (*)	-16.1% (*)	-27.8% (*)	-28.9% (*)
IDROGEL SOLUZIONE B	-21.7% (*)	**-21.5% (*)**	**-28.3% (*)**	**-30% (*)**
LIPOGEL SOLUZIONE CONTROLLO 1%	-22.5% (*)	-13.9% (*)	-27.8% (*)	-26% (*)
IDROGEL SOLUZIONE CONTROLLO	-25.9% (*)	-11.5% (*)	-25.3% (*)	-24.7% (*)

(*) Dunnett test $p<0.05$ vs T0

Starting from T1h, a clinically or statistically (Dunnettt test $p<0.05$ vs T0) significant reduction of erythema index (E.I.) versus baseline (T0) was obtained on each treated area.

Although, at any study time, no statistically difference was highlighted between the 4 tested areas, the most clinically significant E.I. reduction was found starting from T6h for the skin area treated with *IDROGEL SOLUZIONE B*, and at T1h and T48h also for the skin area treated with *LIPOGEL SOLUZIONE P 1%.*

2.1.2. Skin erythema (Optical colorimetry)

Skin colour is a mixture of the L* (white-black), a* (red-green) and b* (blu-yellow) values. The statistical analysis performed on a* parameter data (a* positive values indicate skin redness) showed, already at T1h, a significant reduction of this parameter, index of a lowering of skin erythema achieved for all the skin areas under study (Dunnett test $p<0.05$ T1h, T6h, T24h and T48h vs T0).

The following table summarized the percentages of reduction vs T0:

OPTICAL COLORIMETRY **a* parameter**	*Variation (%) vs T0*			
	T1h	*T6h*	*T24h*	*T48h*
LIPOGEL SOLUZIONE P 1%	**-27.9% (*)**	**-16.7% (*)**	**-25.8% (*)**	**-28.6% (*)**
IDROGEL SOLUZIONE B	*-22.7% (*)*	**-14.2% (*)**	**-24.8% (*)**	**-25.8% (*)**
LIPOGEL SOLUZIONE CONTROLLO 1%	-23% (*)	-11.4% (*)	-21.5% (*)	-23.2% (*)
IDROGEL SOLUZIONE CONTROLLO	-24.1% (*)	-11.7% (*)	-23.6% (*)	-23.8% (*)

(*) Dunnett test $p<0.05$ vs T0

No statistically differences was highlighted among the 4 tested areas, but the obtained results confirm a more marked anti-redness activity of *LIPOGEL SOLUZIONE P 1%* and of *IDROGEL SOLUZIONE B,* starting respectively from T1h and T6h .

No statistically or clinically significant variation of L* (skin brightness) and b* (skin pigmentation) parameters was detectable at any study time.

2.1.3. Clinical evaluation of skin erythema

Skin stripping determined on all skin study areas a visible skin redness; already 1 hour after products application skin redness visual score was statistically reduced (Dunnett test $p<0.05$ T1h, T6h, T24h, T48h vs T0) on each tested area (see table below). No significant difference among the 4 tested products was showed at any study time, but on the skin areas treated with the IDROGEL SOLUZIONE B it is possible to note a more marked and clinically relevant decrease of skin basal erythema starting from T6h.

ERYTHEMA VISUAL SCORE		*Variation (%) vs T0*		
	T1h	*T6h*	*T24h*	*T48h*
LIPOGEL SOLUZIONE P 1%	-35.8% (*)	-20.9%	-56.4% (*)	-77.7% (*)
IDROGEL SOLUZIONE B	-27.6% (*)	**-41.4% (*)**	**-67.5% (*)**	**-82.2% (*)**
LIPOGEL SOLUZIONE CONTROLLO 1%	-39.9% (*)	-29.4%	-61.4% (*)	-75.2% (*)
IDROGEL SOLUZIONE CONTROLLO	-41.8% (*)	-35.8%	-54.5% (*)	-74% (*)

(*) Dunnett test $p<0.05$ vs T0

2.2. RE-EPITHELIZING EFFICACY

2.2.1. Skin hydration

Measurements of skin hydration were performed:

- on skin surface by Corneometer CM825 (see procedure par. 7.4.2)
- on deep skin layers (see procedure par. 7.4.3) by MoistureMeterD.

IDROGEL SOLUZIONE CONTROLLO and IDROGEL SOLUZIONE B determined at T1h a statistically significant increase (Tukey test $p<0.05$ T24h vs T0) of skin hydration mean value vs T0 respectively of 19% and 14.2%, index of an immediate moisturizing activity that gradually decreases within 48 hours .

Regarding LIPOGEL SOLUZIONE P 1% a statistically significant increase of skin hydration was detectable at T6h (+14.9%, Dunnett test $p<0.05$ T6h vs T0), while for LIPOGEL SOLUZIONE CONTROLLO 1% no statistically significant improvement of the considered parameter was found.

Moreover a single application of IDROGEL SOLUZIONE B determined already at T1h an important reduction of deep hydration (1.5 mm), index of an activity control of skin irritation/damage induced by tape stripping on the deep skin layers. A T48h the reduction percentage resulted statistically significant vs T0 (Dunnett test $p<0.05$ T48h vs T0).

On the contrary at T24h for IDROGEL SOLUZIONE CONTROLLO, a statistically significant increase of deep hydration was showed (Dunnett test $p<0.05$ T24h vs T0).

This trend is clinically comparable to the one obtained for the lipogel reference formulation (LIPOGEL SOLUZIONE CONTROLLO 1%).

2.2.2. Epicutaneous pH

The application of IDROGEL SOLUZIONE B and IDROGEL SOLUZIONE CONTROLLO determined at T1h a statistically significant decrease of pH mean values, probably imputable to the presence of alcohol in both formulations. In fact already at T6h this effect tends to reduce and at T24h the variation percentages vs T0 are similar to the ones obtained for the 2 lipogel formulations.

2.2.3. Transepidermal water loss (TEWL)

Stripping corneum determined on all skin study areas an increase of TEWL mean value; this alteration resulted similar for all tested areas (see raw data tables); in fact no clinical or statistical difference was found at T0 among the 4 compared formulations.

A single study products application determined, already at T1h, a clinically/statistically significant reduction of TEWL (Dunnett test $p<0.05$ T1h vs T0), index of an important "re-epithelizing" activity, in percentage more marked at T24h and at T48h for IDROGEL SOLUZIONE B.

2.2.4. Microrelief surface evaluation (Profilometry)

A picture of each skin area was taken at T0 and T48h thanks to Primos compact portable device (GFMesstechnik); the image analysis of surface roughness was performed using the "surface roughness evaluation" function. In particular, the profilometric parameter analyzed in this study was Sa (average roughness of the analyzed profile), that represents an overall measure of the surface texture.

The following table summarized the percentages of variation vs T0:

SKIN SURFACE PROFILOMETRY	*Variation (%) T48h vs T0*
	Sa
LIPOGEL SOLUZIONE P 1%	+5%
IDROGEL SOLUZIONE B	***+7% (**)***
LIPOGEL SOLUZIONE CONTROLLO 1%	+5.2%
IDROGEL SOLUZIONE CONTROLLO	+0.5%

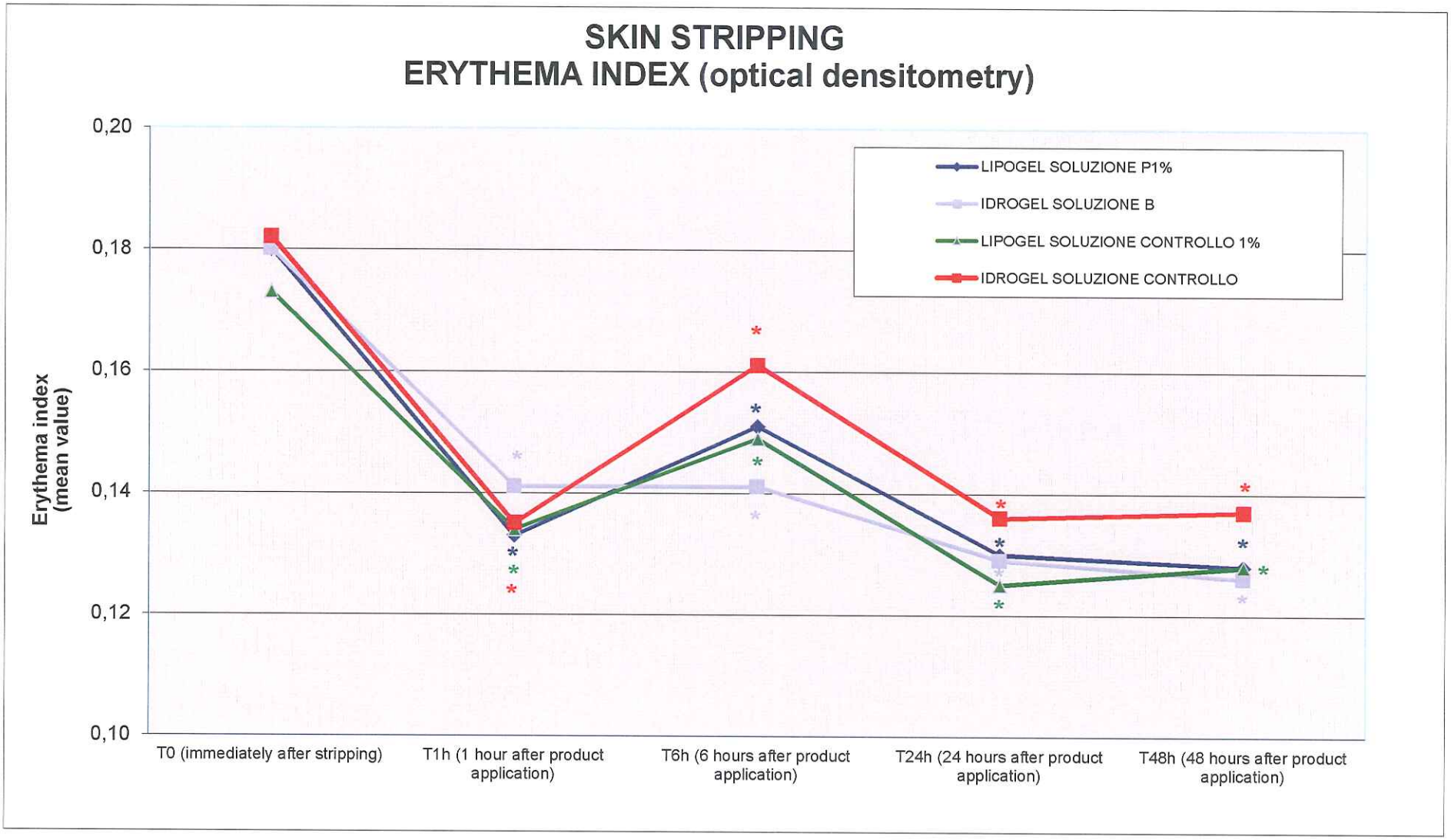
Student t test (**) $p<0.01$ vs T0

Although no statistically significant difference among the 4 tested area was showed at any study time, obtained results highlighted for the product IDROGEL SOLUZIONE B a clinically and statistically significant increase of Sa profilometric parameter, index of an important re-epithelizing activity of the tested formulation, more marked than the one showed for the reference product (IDROGEL SOLUZIONE CONTROLLO) and for the two lipogels.

3. CONCLUSIONS

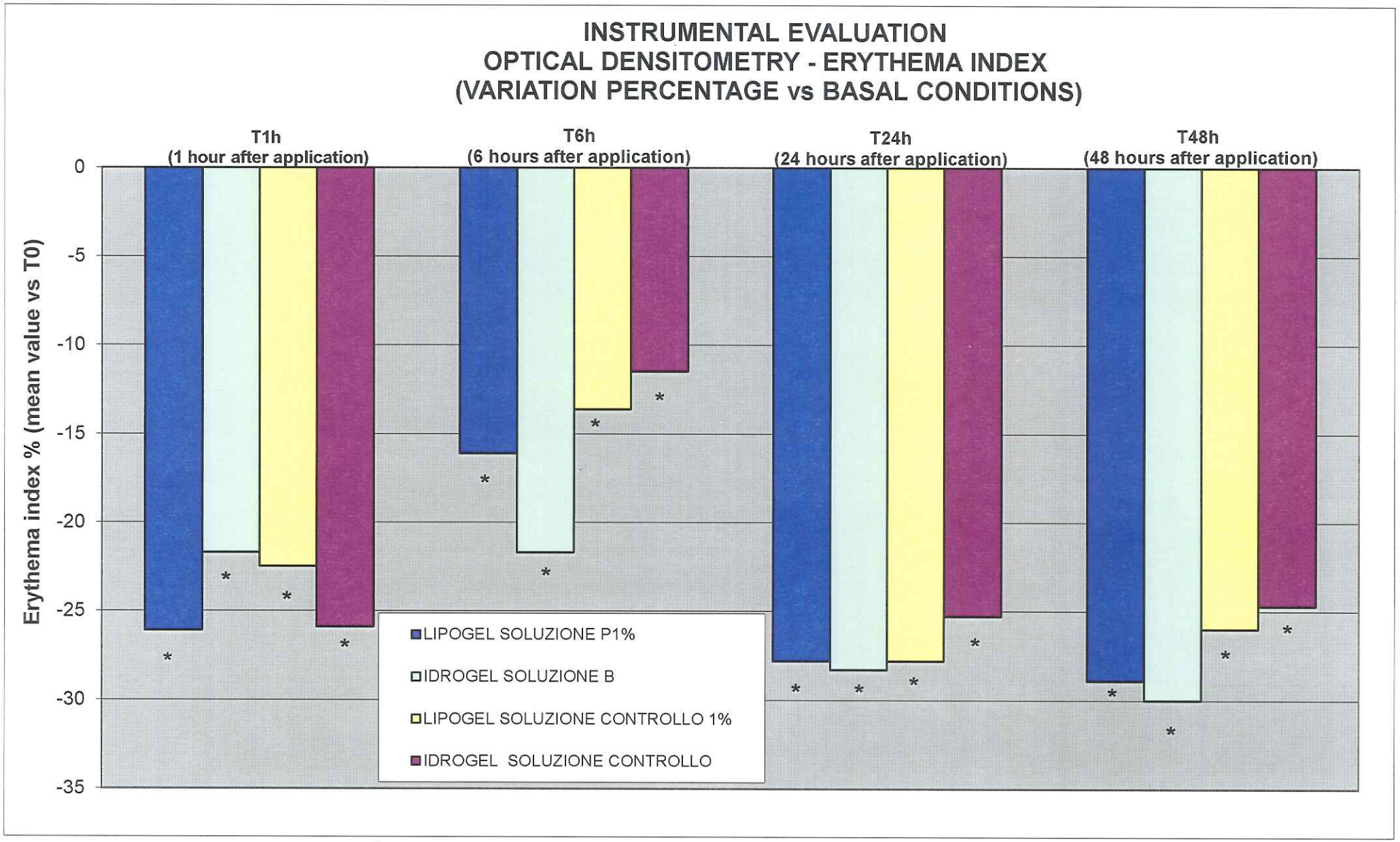
Considering the soothing and re-epithelizing efficacy of the tested products, the best results were obtained for the formulation "IDROGEL SOLUZIONE B"; in fact a single application of this gel determined the most important efficacy on skin erythema and skin microrelief restoring, caused by stripping procedure.

GRAPHS



Statistical analysis : Dunnett test *p<0.05 vs T0

Test code
E0715



Statistical analysis : Dunnett test * p<0,05 vs T0

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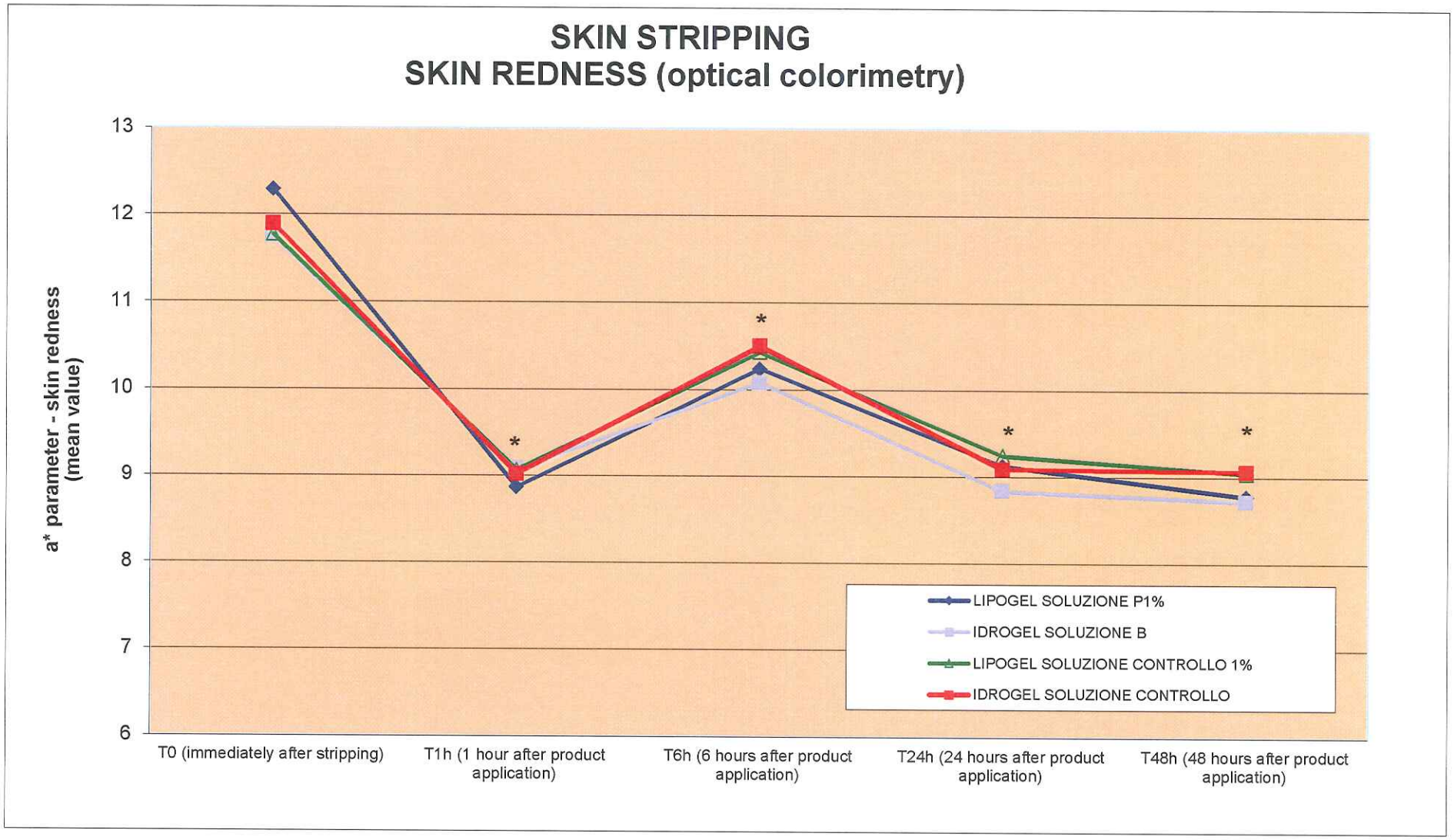

Statistical analysis : Dunnett test *p<0.05 vs T0

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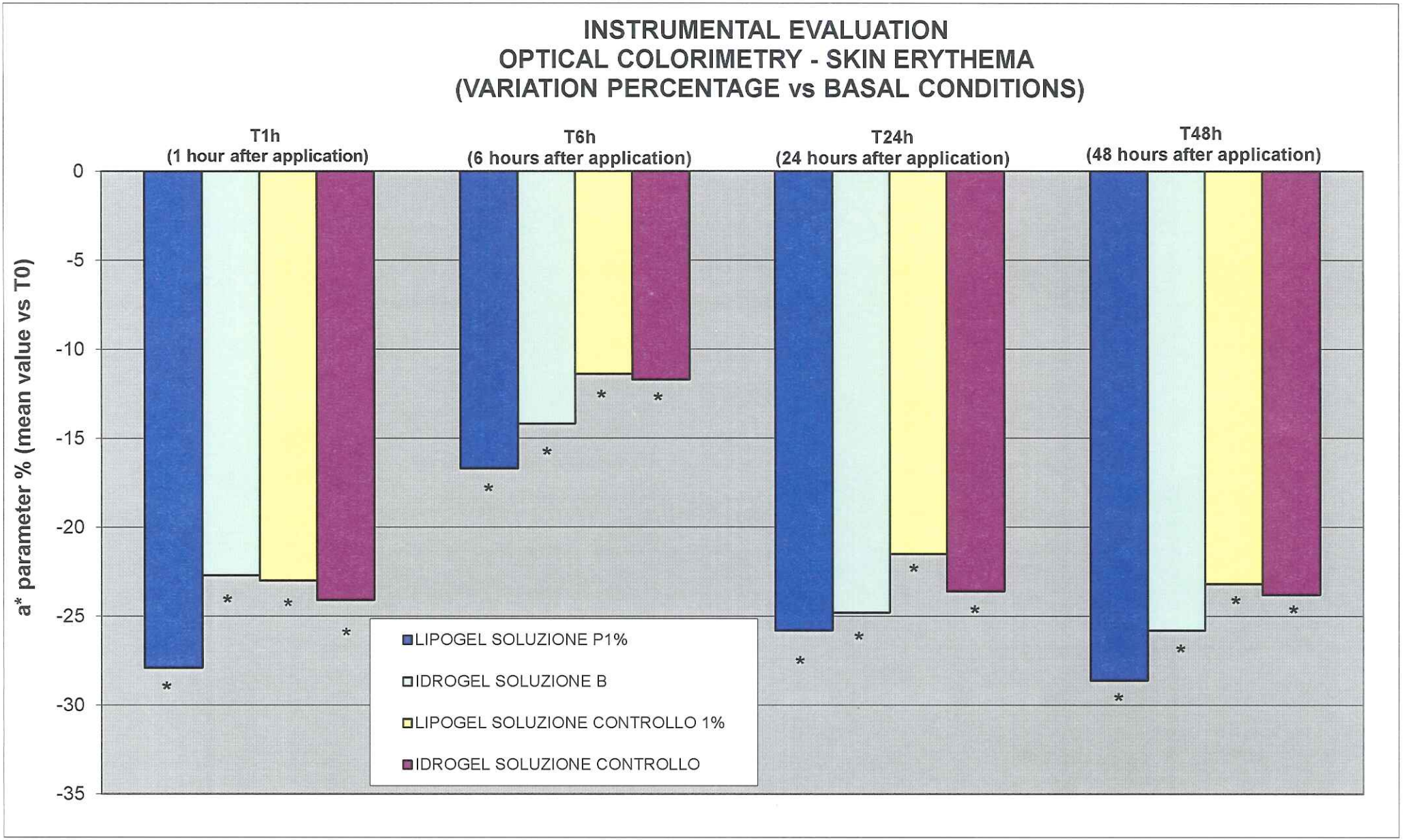

Statistical analysis : Dunnett test * p<0,05 vs T0

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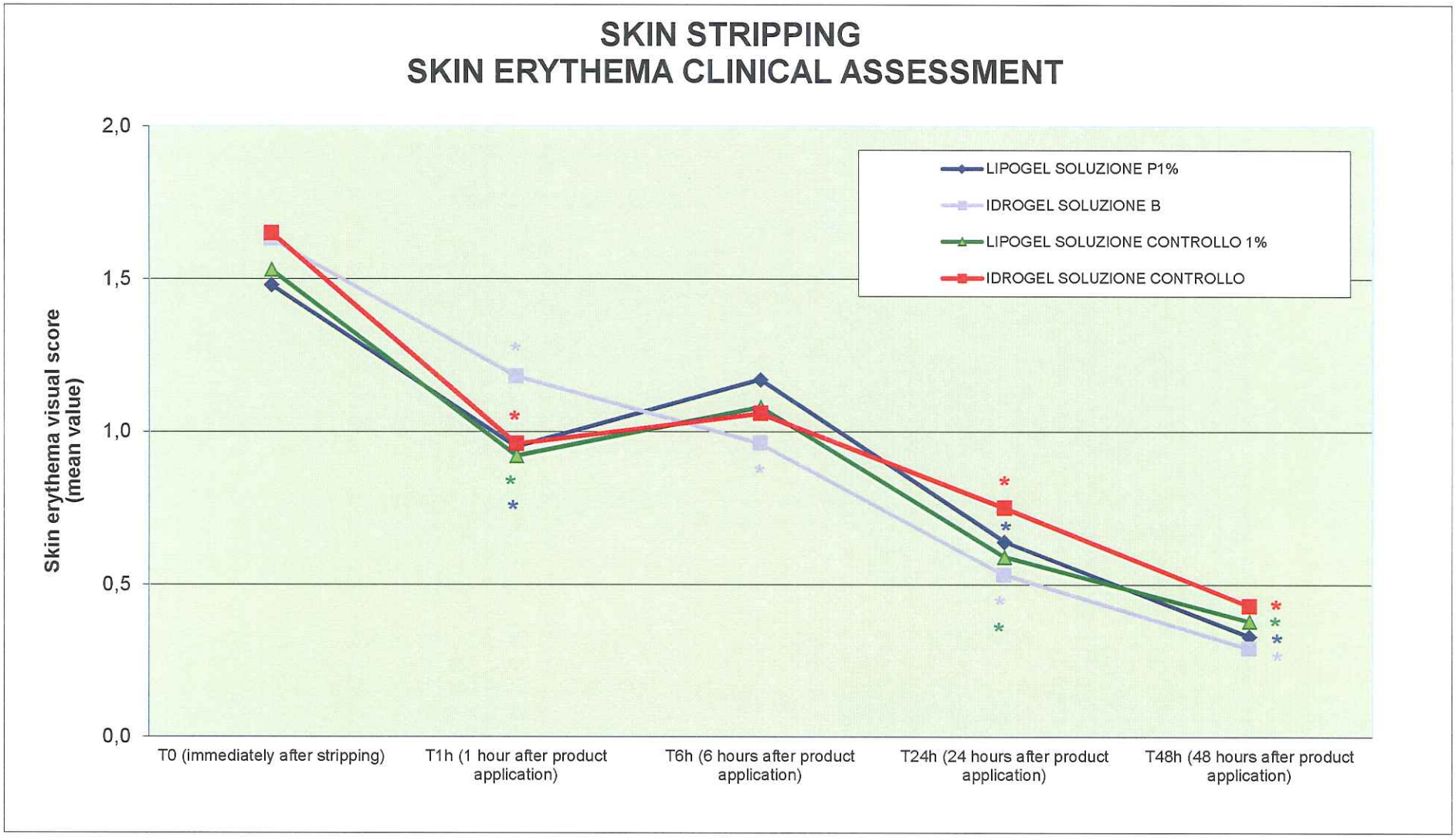

Statistical analysis : Dunnett test *p<0.05 vs T0

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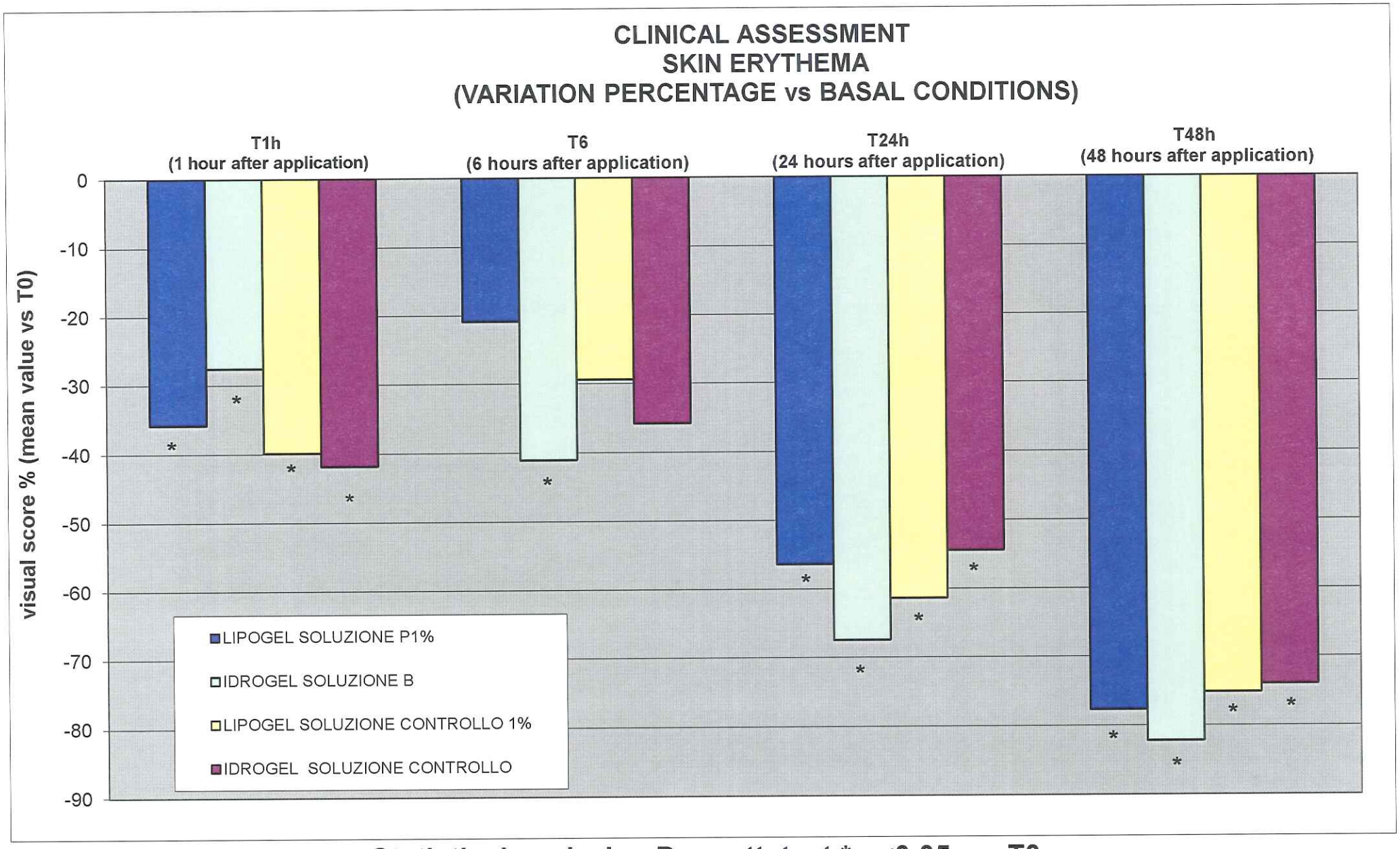

Statistical analysis : Dunnett test * p<0,05 vs T0

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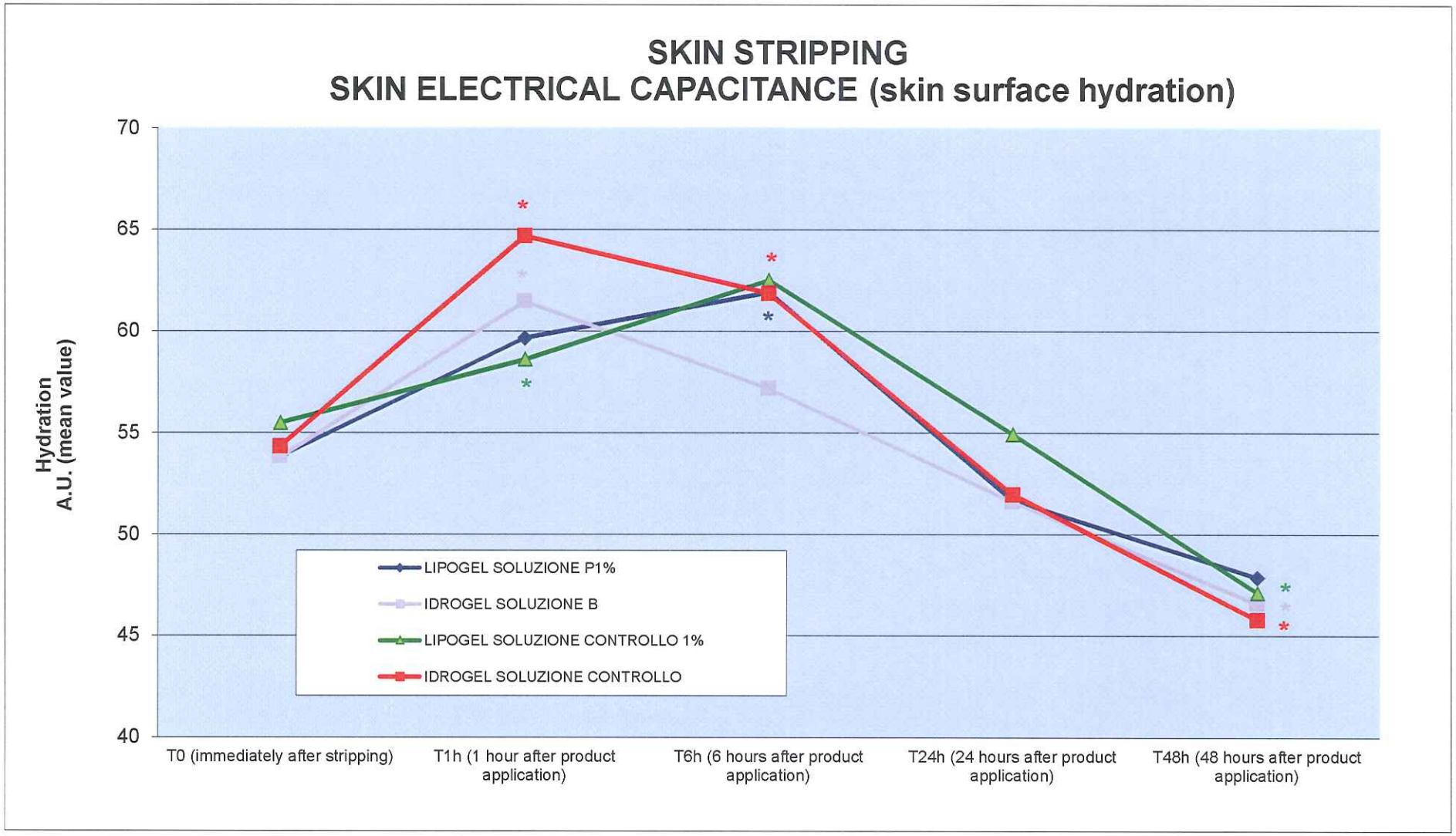

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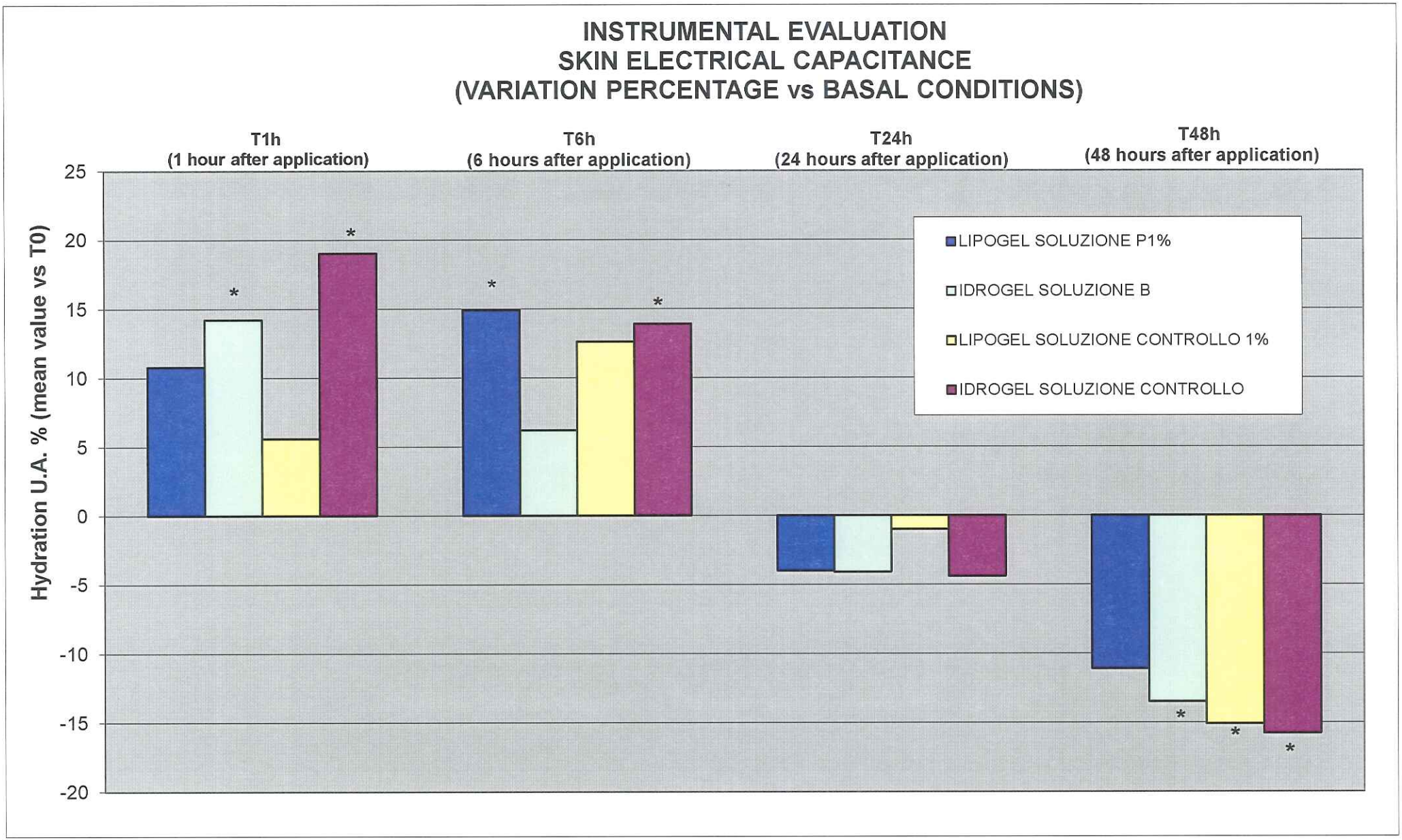
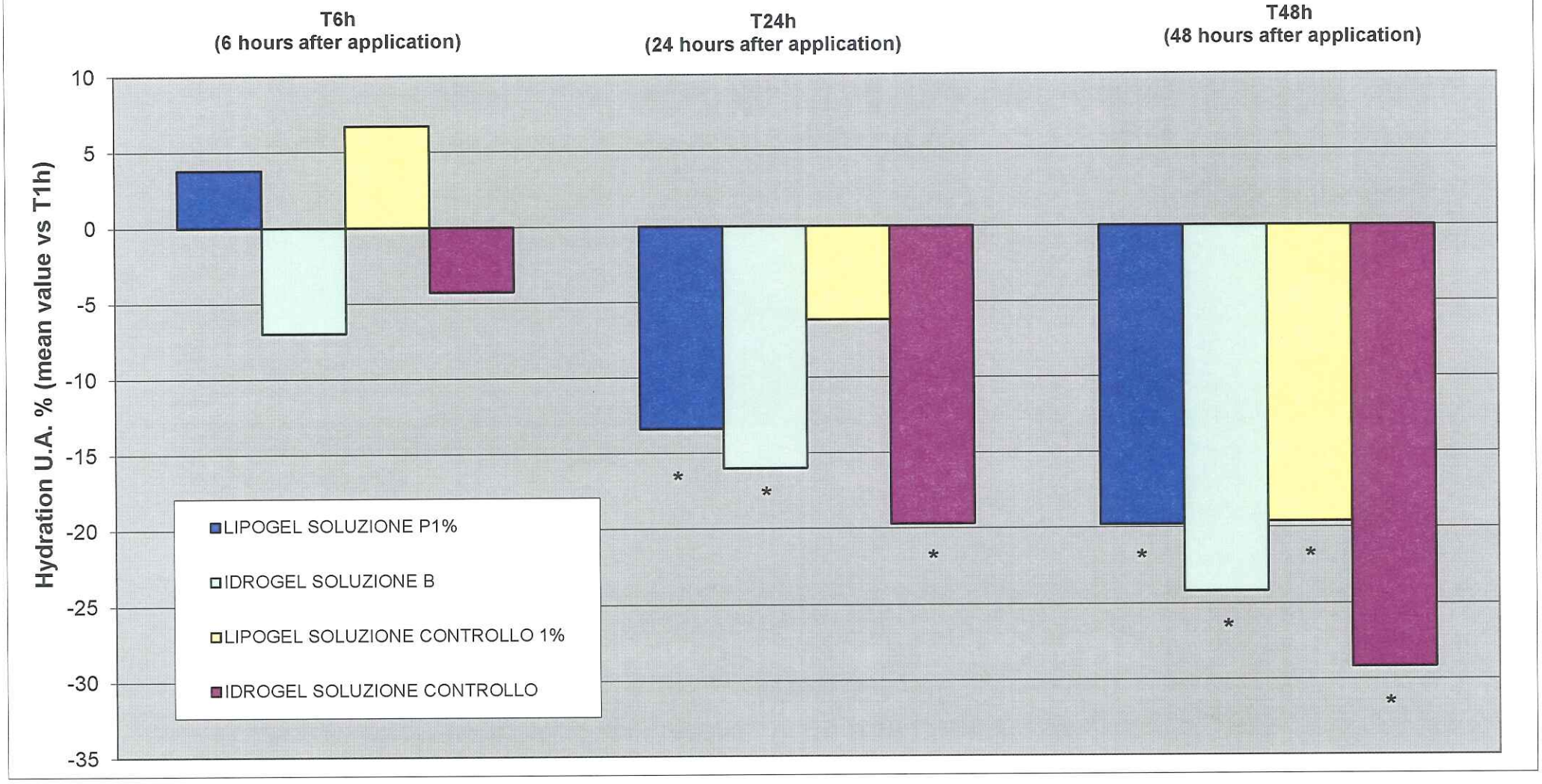


Statistical analysis : Tukey test * p<0,05 vs T0

Test code
E0715

INSTRUMENTAL EVALUATION
SKIN ELECTRICAL CAPACITANCE
(VARIATION PERCENTAGE vs T1h)



Statistical analysis : Tukey test * p<0,05 vs T1h

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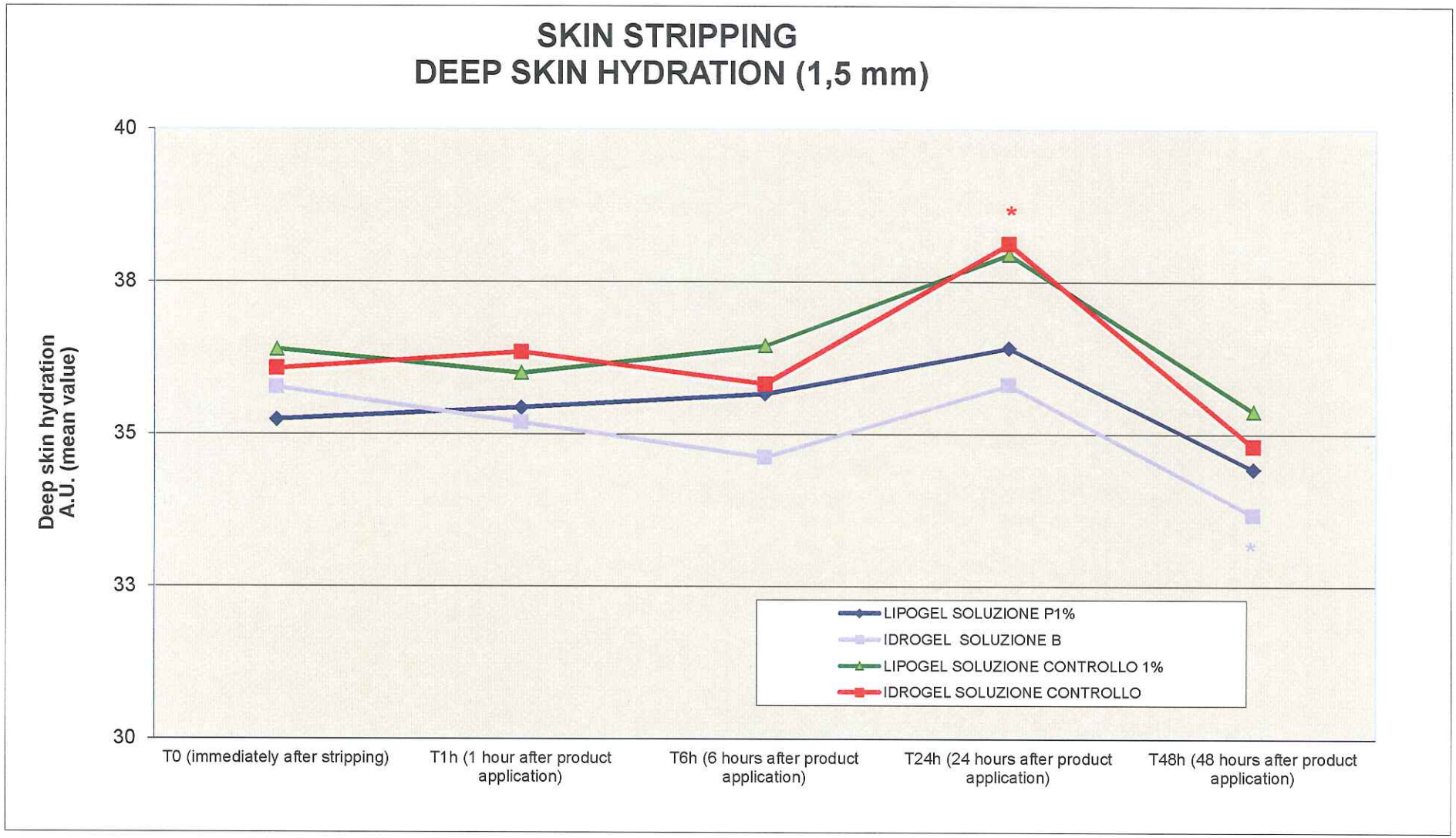
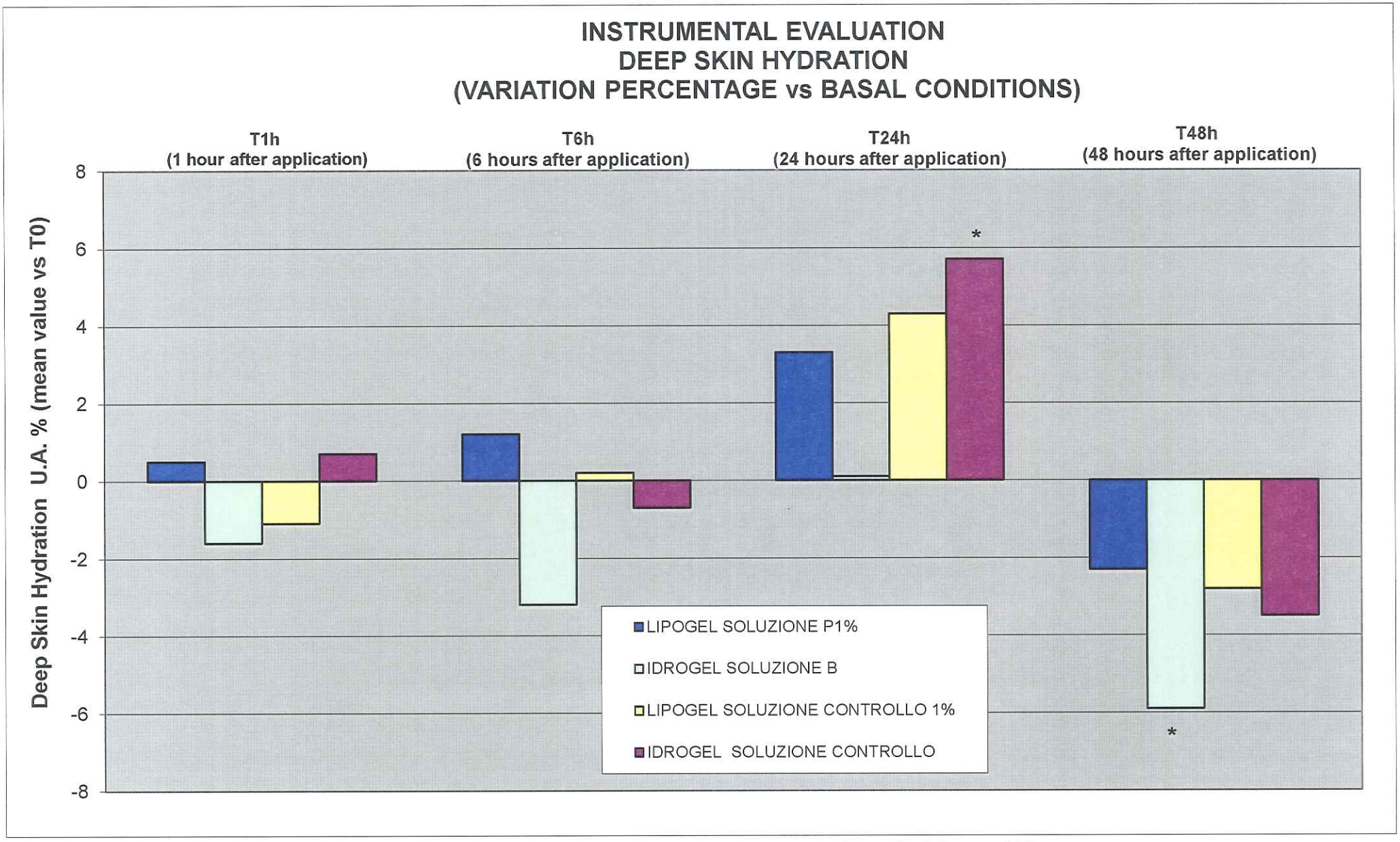


Statistical analysis : Dunnett test *p<0.05 vs T0



Statistical analysis : Dunnett test * p<0,05 vs T0

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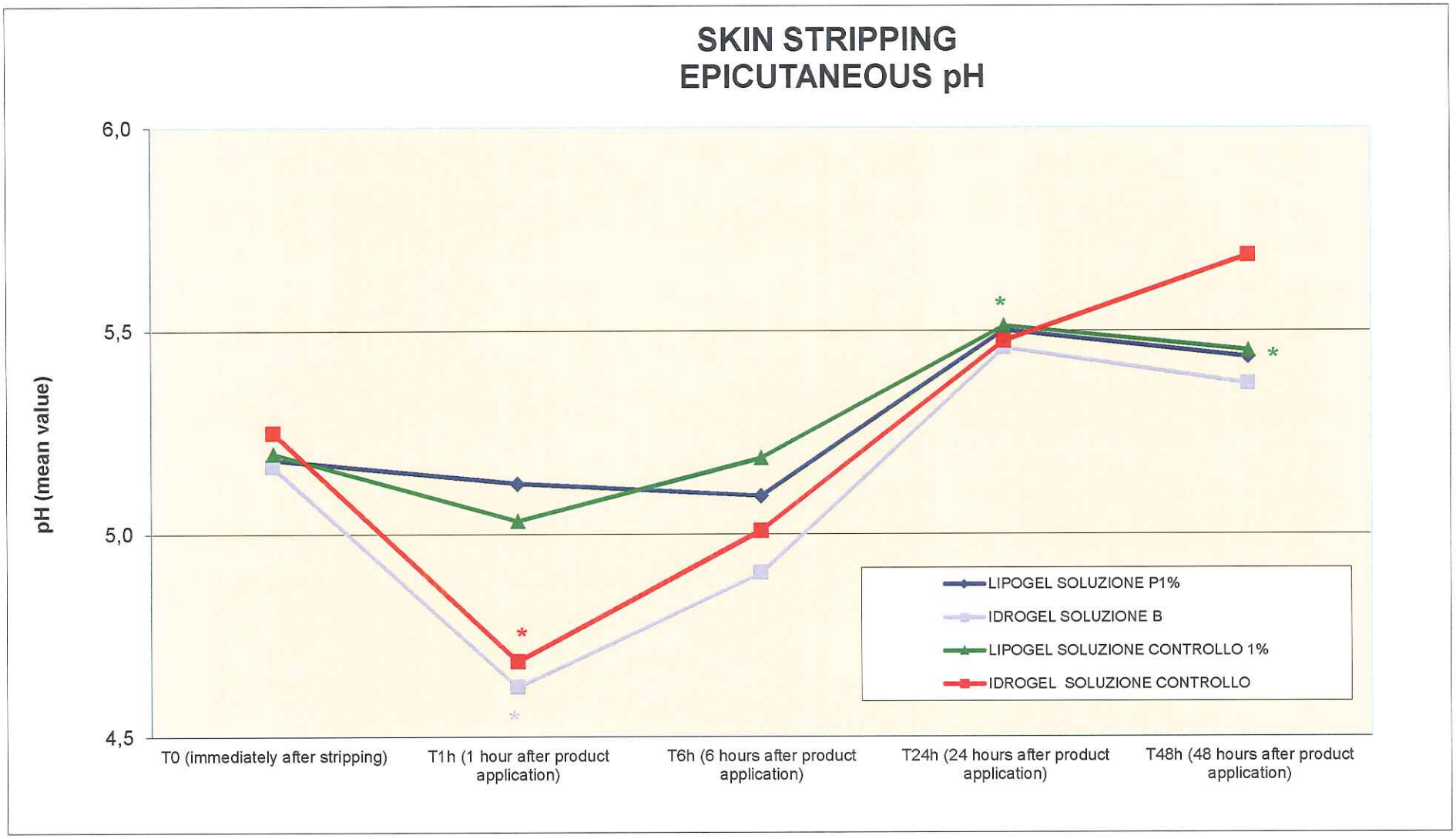

Statistical analysis : Dunnett test *p<0.05 vs T0

Test code
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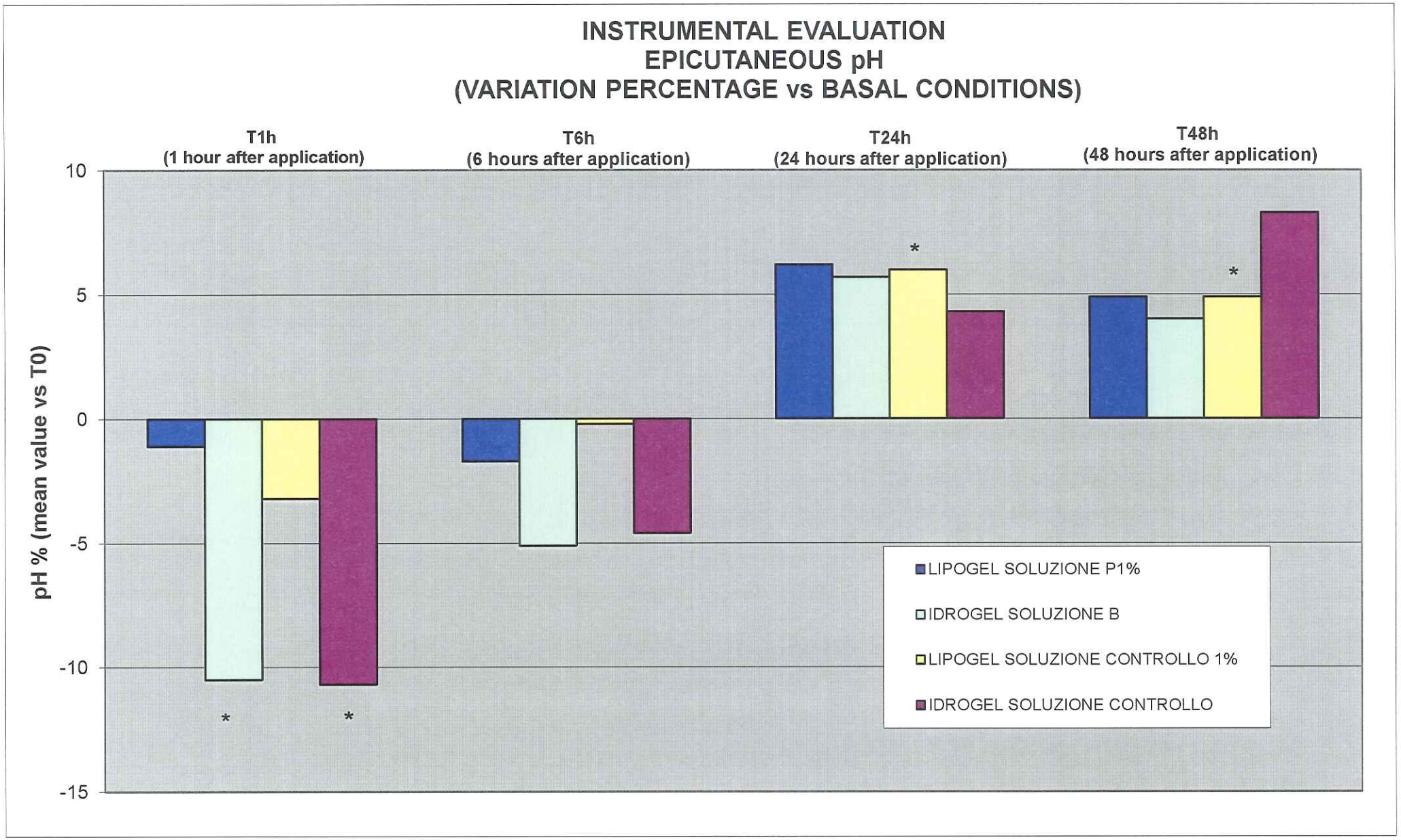

Statistical analysis : Dunnett test * p<0,05 vs T0

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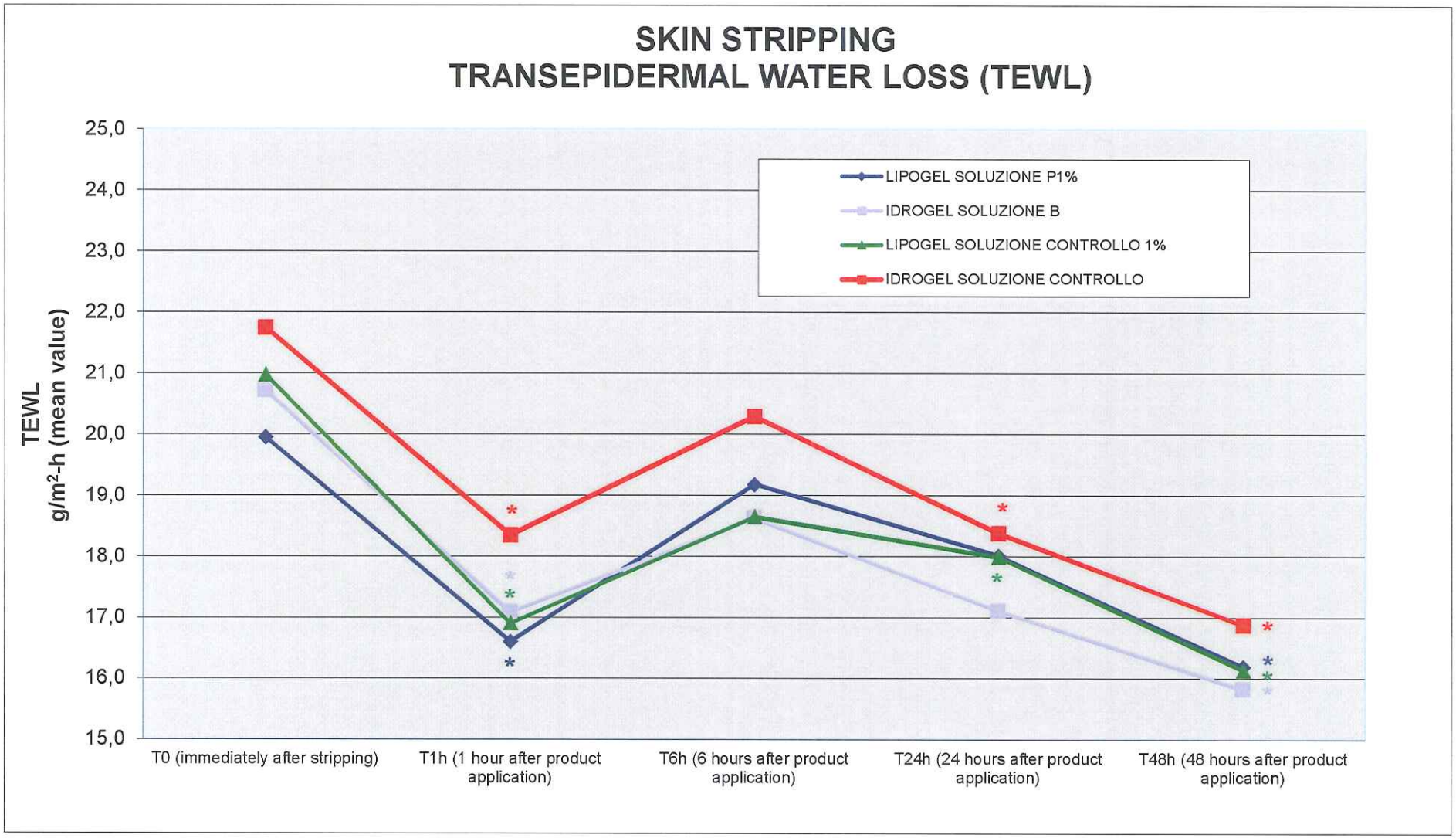

Statistical analysis : Dunnett test *p<0.05 vs T0

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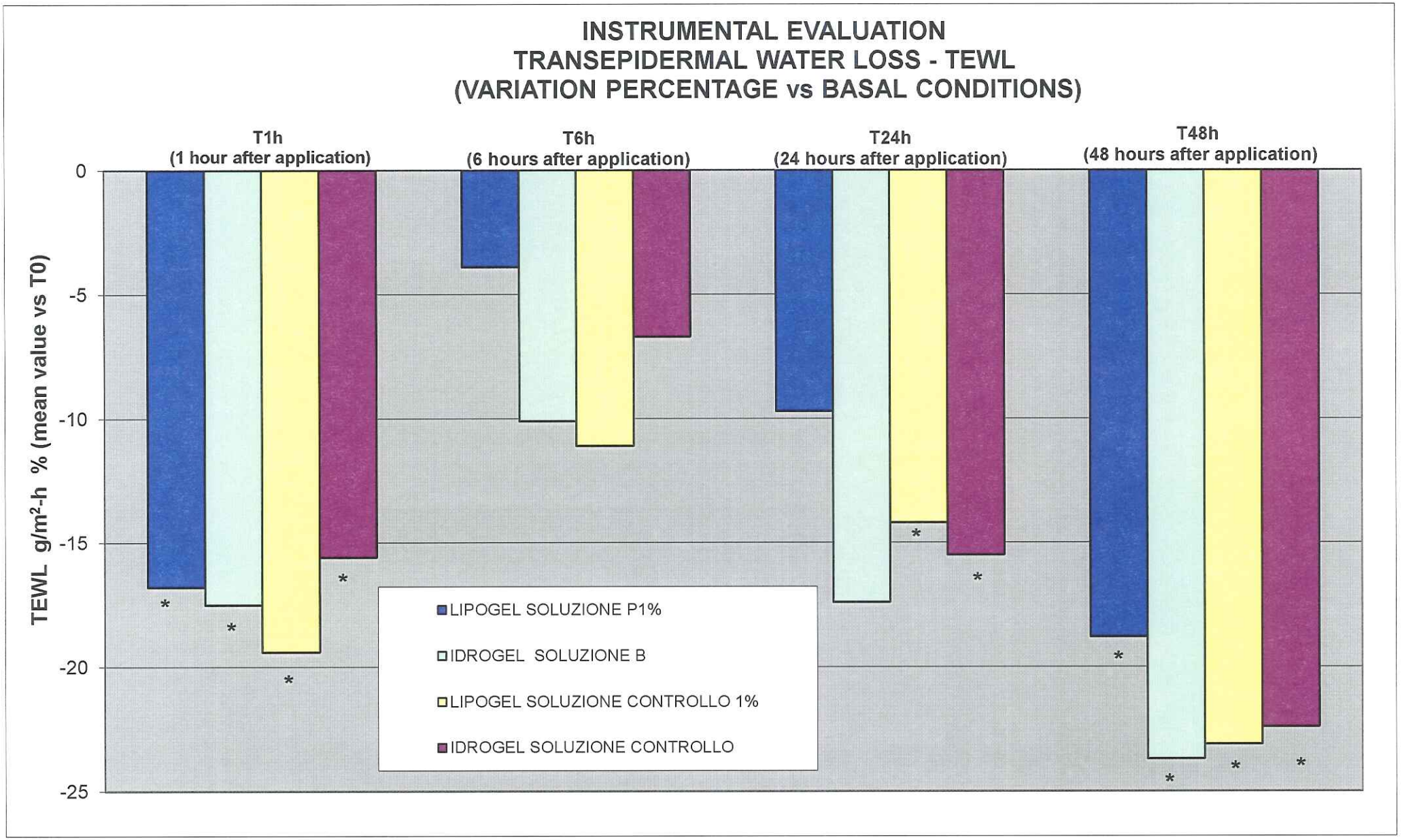

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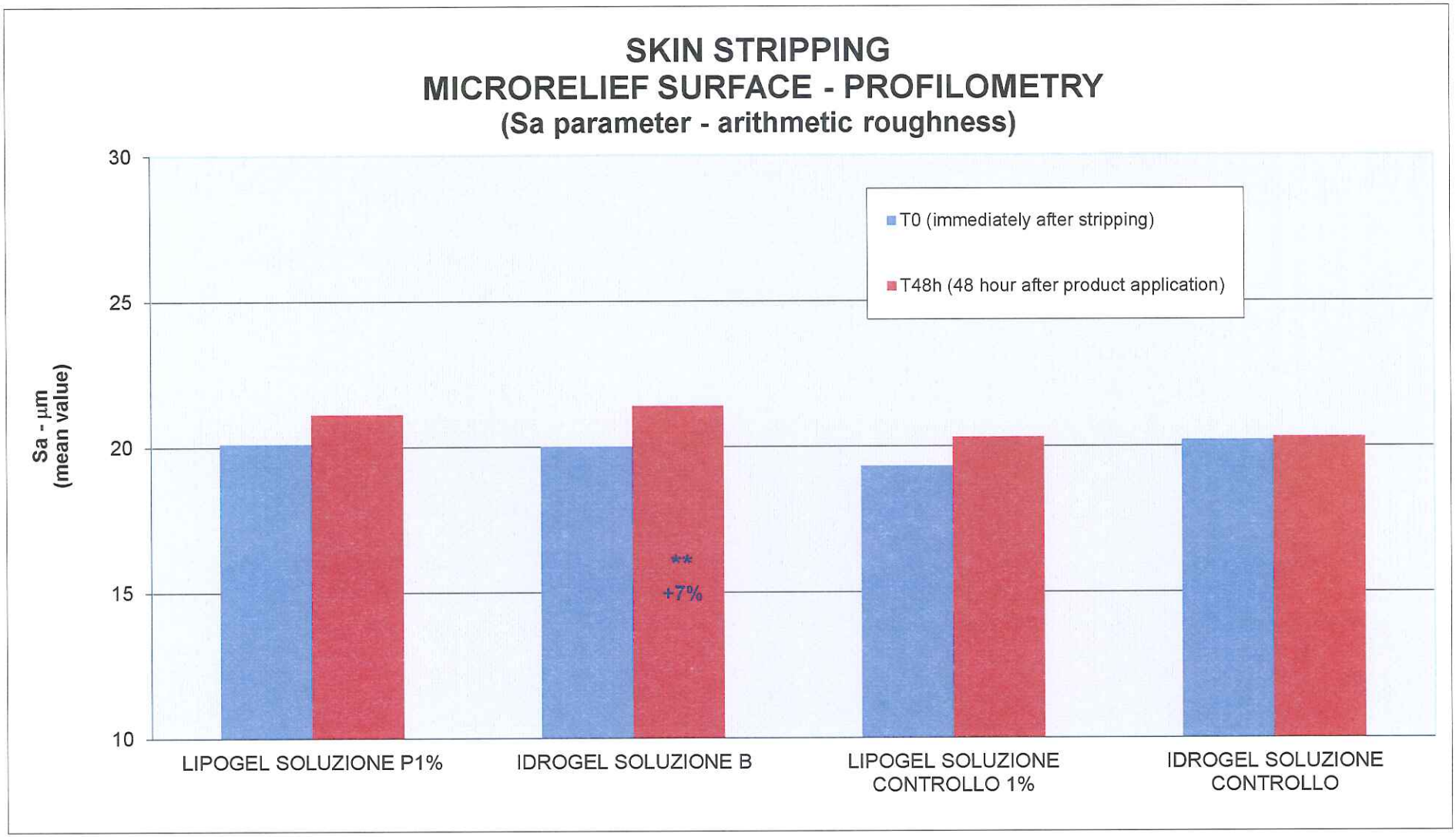

Statistical analysis : Student t test **p<0.01 vs T0

RAW DATA TABLES

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Test code
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VOLUNTEERS' GENERAL TABLE

VOL. N	INITIALS	SEX	AGE
1	EMN	F	53
2	CL	F	48
3	LA	F	64
4	FC	F	51
5	PL	F	29
6	DMR	F	66
7	LFC	M	45
8	SAM	F	53
9	BS	F	60
10	PP	F	55
11	VM	F	56
12	SE	F	62
13	PM	M	42
14	DM	F	46
15	TM	F	20
16	FB	F	52
17	DN	M	68
18	OF	F	52
19	DPI	F	31
20	MP	F	58
21	CD	F	58
MEAN			51
MIN			20
MAX			68

SUBJECTS' RANDOMISATION LIST

VOL. N.	RIGHT FOREARM ELBOW	RIGHT FOREARM WRIST	LEFT FOREARM ELBOW	LEFT FOREARM WRIST
1	P2	P1	REF2	REF1
2	P1	REF1	P2	REF2
3	P1	P1	P2	REF2
4	REF2	P2	REF1	P1
5	P2	P1	REF2	REF1
6	P2	P1	REF2	REF1
7	P1	REF1	P2	REF2
8	REF1	REF2	P1	P2
9	REF2	P2	REF1	P1
10	P2	P1	REF1	REF2
11	P2	P1	REF2	REF1
12	P1	REF1	P2	REF2
13	REF1	REF2	P1	P2
14	REF2	P2	REF1	P1
15	P2	P1	REF2	REF1
16	P2	P1	REF2	REF1
17	P1	REF1	P2	REF2
18	P1	P2	REF2	REF1
19	REF2	P2	REF1	P1
20	P2	P1	REF2	REF1
21	P2	P1	REF2	REF1

LEGEND:

P1 = Lipogel soluzione P 1%

P2 = Idrogel soluzione B

REF1 = Lipogel soluzione controllo 1%

REF2 = Idrogel soluzione controllo

Test code
E0715

INSTRUMENTAL EVALUATION

OPTICAL DENSITOMETRY

ERYTHEMA INDEX

LIPOGEL SOLUZIONE P 1% (prot. 2647)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)
1	0,17	0,15	0,16	0,14	0,12
2	0,17	0,09	0,08	0,09	0,08
3	0,18	0,11	0,11	0,09	0,11
4	0,17	0,11	0,13	0,12	0,14
5	0,16	0,09	0,11	0,13	0,13
6	0,24	0,20	0,24	0,21	0,19
7	0,18	0,18	0,23	0,18	0,17
8	0,23	0,14	0,23	0,19	0,17
9	0,22	0,15	0,14	0,13	0,11
10	0,16	0,13	0,17	0,09	0,14
11	0,17	0,11	0,13	0,11	0,10
12	0,14	0,10	0,12	0,08	0,09
13	0,22	0,20	0,19	0,18	0,18
14	0,17	0,15	0,13	0,11	0,12
15	0,13	0,07	0,15	0,12	0,10
16	0,16	0,12	0,13	0,13	0,13
17	[0,11]	NE	NE	NE	NE
18	0,21	0,17	0,21	0,19	0,17
19	0,12	0,09	0,09	0,06	0,07
20	0,18	0,13	0,15	0,13	0,11
21	0,22	0,16	0,12	0,12	0,13
MEAN	0,180	0,133	0,151	0,130	0,128
ST. DEV.	0,033	0,037	0,047	0,041	0,034
MIN	0,12	0,07	0,08	0,06	0,07
MAX	0,24	0,20	0,24	0,21	0,19
MSE	0,007	0,008	0,010	0,009	0,008

Legend: NE = not evaluated

VARIATION (%) vs T0			
T1h	**T6h**	**T24h**	**T48h**
-26,1%	-16,1%	-27,8%	-28,9%

Statistical analysis: Dunnett test p<0,05 T1h, T6h, T24h and T48h vs T0

INSTRUMENTAL EVALUATION

OPTICAL DENSITOMETRY

ERYTHEMA INDEX

IDROGEL SOLUZIONE B (prot. 2650)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)
1	0,21	0,15	0,14	0,16	0,14
2	0,16	0,15	0,08	0,13	0,11
3	0,15	0,12	0,11	0,10	0,12
4	0,10	0,07	0,10	0,10	0,12
5	0,18	0,09	0,09	0,09	0,12
6	0,28	0,19	0,22	0,19	0,20
7	0,24	0,21	0,21	0,18	0,18
8	0,18	0,20	0,21	0,16	0,16
9	0,20	0,16	0,15	0,11	0,08
10	0,16	0,14	0,12	0,11	0,11
11	0,19	0,13	0,13	0,11	0,10
12	0,11	0,10	0,13	0,08	0,09
13	0,21	0,21	0,20	0,17	0,19
14	0,17	0,16	0,14	0,14	0,12
15	0,14	0,14	0,16	0,14	0,12
16	0,20	0,12	0,12	0,14	0,12
17	[0,1]	NE	NE	NE	NE
18	0,19	0,16	0,19	0,21	0,17
19	0,13	0,07	0,08	0,06	0,07
20	0,18	0,09	0,09	0,08	0,08
21	0,22	0,15	0,16	0,12	0,12
MEAN	0,180	0,141	0,141	0,129	0,126
ST. DEV.	0,043	0,043	0,045	0,040	0,037
MIN	0,10	0,07	0,08	0,06	0,07
MAX	0,28	0,21	0,22	0,21	0,20
MSE	0,010	0,010	0,010	0,009	0,008

Legend: NE = not evaluated

VARIATION (%) vs T0			
T1h	**T6h**	**T24h**	**T48h**
-21,7%	-21,5%	-28,3%	-30,0%

Statistical analysis: Dunnett test p<0,05 T1h, T6h, T24h and T48h vs T0

INSTRUMENTAL EVALUATION

OPTICAL DENSITOMETRY

ERYTHEMA INDEX

LIPOGEL SOLUZIONE CONTROLLO 1% (prot. 2648)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)
1	0,17	0,16	0,19	0,16	0,18
2	0,12	0,10	0,08	0,07	0,07
3	0,15	0,10	0,11	0,09	0,11
4	0,17	0,11	0,15	0,13	0,15
5	0,15	0,09	0,12	0,15	0,15
6	0,23	0,19	0,21	0,16	0,19
7	0,19	0,18	0,23	0,19	0,18
8	0,22	0,16	0,18	0,16	0,10
9	0,20	0,17	0,14	0,13	0,10
10	0,18	0,16	0,17	0,15	0,17
11	0,18	0,13	0,17	0,14	0,10
12	0,12	0,10	0,07	0,07	0,10
13	0,19	0,14	0,14	0,14	0,12
14	0,16	0,16	0,11	0,10	0,14
15	0,13	0,08	0,15	0,10	0,09
16	0,17	0,14	0,14	0,13	0,14
17	[0,1]	NE	NE	NE	NE
18	0,21	0,16	0,22	0,10	0,17
19	0,15	0,10	0,12	0,07	0,07
20	0,15	0,07	0,11	0,12	0,11
21	0,21	0,17	0,17	0,13	0,12
MEAN	0,173	0,134	0,149	0,125	0,128
ST. DEV.	0,032	0,037	0,044	0,034	0,037
MIN	0,12	0,07	0,07	0,07	0,07
MAX	0,23	0,19	0,23	0,19	0,19
MSE	0,007	0,008	0,010	0,008	0,008

Legend: NE = not evaluated

VARIATION (%) vs T0			
T1h	**T6h**	**T24h**	**T48h**
-22,5%	-13,9%	-27,8%	-26,0%

Statistical analysis: Dunnett test p<0,05 T1h, T6h, T24h and T48h vs T0

INSTRUMENTAL EVALUATION

OPTICAL DENSITOMETRY

ERYTHEMA INDEX

IDROGEL SOLUZIONE CONTROLLO (prot. 2649)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)
1	0,17	0,14	0,16	0,16	0,17
2	0,16	0,15	0,13	0,12	0,11
3	0,17	0,11	0,12	0,11	0,12
4	0,14	0,09	0,10	0,08	0,08
5	0,22	0,14	0,18	0,16	0,17
6	0,28	0,18	0,22	0,17	0,20
7	0,18	0,19	0,20	0,19	0,19
8	0,21	0,15	0,23	0,20	0,16
9	0,20	0,15	0,15	0,11	0,10
10	0,18	0,14	0,19	0,15	0,18
11	0,20	0,13	0,22	0,14	0,10
12	0,11	0,11	0,14	0,10	0,14
13	0,20	0,15	0,14	0,14	0,14
14	0,18	0,16	0,12	0,09	0,13
15	0,15	0,08	0,16	0,09	0,09
16	0,19	0,13	0,13	0,14	0,13
17	[0,11]	NE	NE	NE	NE
18	0,19	0,16	0,19	0,19	0,16
19	0,11	0,09	0,09	0,07	0,07
20	0,16	0,08	0,11	0,11	0,11
21	0,24	0,17	0,24	0,19	0,18
MEAN	0,182	0,135	0,161	0,136	0,137
ST. DEV.	0,040	0,032	0,045	0,040	0,039
MIN	0,11	0,08	0,09	0,07	0,07
MAX	0,28	0,19	0,24	0,20	0,20
MSE	0,009	0,007	0,010	0,009	0,009

Legend: NE = not evaluated

VARIATION (%) vs T0			
T1h	**T6h**	**T24h**	**T48h**
-25,9%	-11,5%	-25,3%	-24,7%

Statistical analysis: Dunnett test p<0,05 T1h, T6h, T24h and T48h vs T0

INSTRUMENTAL EVALUATION

OPTICAL COLORIMETRY - SKIN ERYTHEMA

LIPOGEL SOLUZIONE P 1% (prot. 2647)

VOL N.	T0 - BASELINE (immediately after stripping)			T1h (1 hour after product application)			T6h (6 hours after product application)			T24h (24 hours after product application)			T48h (48 hours after product application)		
	L*	a*	b*	L*	a*	b*	L*	a*	b*	L*	a*	b*	L*	a*	b*
1	67,11	9,14	12,64	66,85	7,43	13,48	65,00	10,34	13,88	65,35	11,11	14,17	66,68	8,54	14,36
2	66,06	11,51	11,11	67,65	5,97	11,51	69,46	5,65	12,16	68,13	5,27	12,59	68,77	5,83	12,64
3	64,41	13,97	12,09	67,29	8,78	12,21	66,40	9,18	12,36	67,89	7,66	13,02	67,38	7,64	12,92
4	65,73	10,44	11,36	67,05	6,62	12,24	65,16	9,70	12,21	67,89	7,05	12,27	65,65	8,88	11,98
5	65,77	13,86	10,46	68,62	7,98	11,00	67,48	9,03	11,25	68,68	8,59	11,70	67,52	8,29	10,88
6	61,24	13,97	16,04	60,07	13,77	13,67	60,80	13,95	15,25	60,19	13,41	14,95	61,06	13,35	15,48
7	63,84	12,08	14,43	64,89	8,97	13,96	60,44	15,51	15,19	61,97	11,97	14,34	62,19	11,38	15,03
8	65,96	13,75	10,79	66,92	8,64	11,35	64,51	11,01	11,71	61,83	15,40	12,83	64,45	11,50	12,92
9	61,63	17,35	13,06	63,42	10,92	11,60	64,04	11,29	12,01	66,70	8,84	13,42	65,57	9,06	12,45
10	65,67	9,72	13,31	65,68	8,02	13,90	64,88	9,83	14,25	68,48	6,82	14,13	67,89	7,27	14,17
11	61,96	11,67	15,18	62,51	7,29	14,72	62,79	8,25	15,16	63,27	8,46	14,71	63,80	7,81	14,58
12	68,53	10,00	10,47	69,63	7,32	11,11	68,79	7,67	10,99	70,80	6,24	11,50	70,41	5,74	10,90
13	60,18	14,66	11,94	61,64	12,00	12,69	59,48	14,61	12,59	61,75	11,08	13,79	62,88	10,44	13,73
14	66,67	12,43	11,28	66,35	10,44	10,43	66,26	9,23	10,44	67,71	8,50	9,38	68,48	7,37	11,14
15	68,57	6,90	11,51	68,72	5,95	11,53	65,28	9,79	12,04	67,81	6,27	12,39	66,87	6,70	14,21
16	64,31	10,94	14,91	63,15	8,98	14,56	65,17	8,96	14,50	63,37	9,44	15,55	63,11	9,96	14,60
17	[65,98]	[9,19]	[11,29]	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
18	59,52	16,54	15,29	62,03	9,92	15,79	59,37	13,64	15,86	62,21	12,92	16,61	60,01	12,09	16,18
19	66,14	9,50	8,30	69,98	6,52	8,56	69,36	6,39	8,44	70,28	5,38	8,28	69,82	5,96	8,54
20	64,31	14,62	12,18	64,51	10,68	11,25	65,46	10,73	11,75	65,58	9,93	13,11	66,68	8,06	13,70
21	62,86	12,81	14,81	61,95	11,07	14,52	63,00	9,99	14,85	61,66	8,16	14,94	63,14	9,60	14,76
MEAN	64,524	12,293	12,558	65,446	8,864	12,504	64,657	10,238	12,845	65,578	9,125	13,184	65,618	8,774	13,259
ST.DEV	2,596	2,617	2,032	2,912	2,125	1,781	3,005	2,581	1,943	3,270	2,791	1,987	2,929	2,158	1,873
MIN	59,52	6,90	8,30	60,07	5,95	8,56	59,37	5,65	8,44	60,19	5,27	8,28	60,01	5,74	8,54
MAX	68,57	17,35	16,04	69,98	13,77	15,79	69,46	15,51	15,86	70,80	15,40	16,61	70,41	13,35	16,18
MSE	0,580	0,585	0,454	0,651	0,475	0,398	0,672	0,577	0,434	0,731	0,624	0,444	0,655	0,482	0,419

Legend: NE = not evaluated

Test code
E0715

INSTRUMENTAL EVALUATION

OPTICAL COLORIMETRY - SKIN ERYTHEMA

LIPOGEL SOLUZIONE P 1% (prot. 2647)

% VARIATION vs BASELINE											
L*				a*				b*			
T1h	T6h	T24h	T48h	T1h	T6h	T24h	T48h	T1h	T6h	T24h	T48h
1,4%	0,2%	1,6%	1,7%	-27,9%	-16,7%	-25,8%	-28,6%	-0,4%	2,3%	5,0%	5,6%

Statistical analysis: Dunnett test p<0,05 T1h, T6h, T24h and T48h vs T0

INSTRUMENTAL EVALUATION

OPTICAL COLORIMETRY - SKIN ERYTHEMA

IDROGEL SOLUZIONE B (prot. 2650)

VOL N.	T0 - BASELINE (immediately after stripping)			T1h (1 hour after product application)			T6h (6 hours after product application)			T24h (24 hours after product application)			T48h (48 hours after product application)		
	L*	a*	b*	L*	a*	b*	L*	a*	b*	L*	a*	b*	L*	a*	b*
1	66,33	11,49	13,67	66,84	7,86	13,34	63,59	11,28	13,05	65,47	10,37	13,91	66,01	9,05	14,00
2	65,43	10,40	10,66	67,19	8,41	11,60	68,58	6,43	12,92	68,32	6,25	13,00	67,70	6,29	12,70
3	64,51	12,98	13,20	66,35	10,52	13,13	66,23	9,57	13,17	65,93	9,11	12,68	66,72	9,10	12,47
4	66,59	8,55	10,75	67,44	6,48	11,45	66,64	7,92	11,85	67,51	6,45	11,38	66,89	7,05	11,88
5	64,87	13,45	10,74	67,95	8,30	11,30	67,97	7,54	11,33	67,37	8,14	11,61	67,51	7,77	11,19
6	58,68	17,82	16,06	59,02	13,10	13,70	60,48	13,34	15,06	61,58	10,96	16,86	59,63	13,09	16,13
7	62,57	12,69	13,78	63,07	9,35	13,30	59,55	15,32	13,86	63,01	12,01	14,22	61,18	11,87	14,88
8	66,68	9,48	10,57	65,65	9,52	12,56	63,46	11,71	11,65	64,19	11,92	12,51	63,82	11,20	13,76
9	64,68	13,41	12,95	63,67	11,38	10,71	65,36	10,46	11,55	64,75	8,62	11,56	67,38	7,41	12,71
10	66,73	8,19	13,68	65,75	7,56	14,60	66,80	7,53	12,88	68,18	6,99	12,64	67,26	7,02	12,48
11	60,83	12,89	14,65	62,86	7,97	15,13	63,21	7,71	15,23	62,51	8,15	14,31	62,78	7,72	14,54
12	68,36	10,51	10,18	70,17	6,65	10,94	67,71	7,89	9,50	69,48	6,30	10,48	68,23	6,62	9,42
13	62,10	13,39	10,61	62,88	11,15	12,84	60,17	15,21	12,48	61,75	11,36	12,21	62,73	10,60	13,78
14	63,99	15,14	10,88	64,20	12,00	9,73	66,50	9,60	10,46	68,05	7,71	11,27	67,15	8,87	10,48
15	69,00	6,65	10,94	68,58	6,26	11,18	64,10	11,87	11,25	68,11	8,06	12,59	66,48	8,13	13,07
16	63,32	12,80	14,39	63,48	9,36	15,12	63,84	9,58	15,15	64,20	9,13	15,13	64,85	9,32	14,05
17	[66,44]	[7,43]	[10,83]	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
18	61,42	11,82	15,12	61,55	10,08	15,56	59,72	12,47	15,47	60,76	12,79	16,10	60,66	12,21	14,37
19	68,90	8,02	8,14	69,26	7,12	8,64	69,23	6,45	8,32	70,99	4,85	8,55	69,69	5,94	8,11
20	65,23	13,25	12,55	68,16	7,61	13,20	67,70	8,46	13,06	67,71	8,47	13,60	69,38	6,07	13,61
21	61,12	11,96	15,08	61,68	10,81	14,88	61,49	11,14	14,87	62,44	8,99	14,78	63,14	9,01	14,50
MEAN	64,567	11,745	12,430	65,288	9,075	12,646	64,617	10,074	12,656	65,616	8,832	12,970	65,460	8,717	12,907
ST.DEV	2,836	2,667	2,124	2,972	1,965	1,918	3,116	2,681	1,971	2,966	2,173	1,969	2,932	2,131	1,942
MIN	58,68	6,65	8,14	59,02	6,26	8,64	59,55	6,43	8,32	60,76	4,85	8,55	59,63	5,94	8,11
MAX	69,00	17,82	16,06	70,17	13,10	15,56	69,23	15,32	15,47	70,99	12,79	16,86	69,69	13,09	16,13
MSE	0,634	0,596	0,475	0,665	0,439	0,429	0,697	0,600	0,441	0,663	0,486	0,440	0,656	0,477	0,434

Legend: NE = not evaluated

Test code
E0715

INSTRUMENTAL EVALUATION

OPTICAL COLORIMETRY - SKIN ERYTHEMA

IDROGEL SOLUZIONE B (prot. 2650)

% VARIATION vs BASELINE											
L*				a*				b*			
T1h	T6h	T24h	T48h	T1h	T6h	T24h	T48h	T1h	T6h	T24h	T48h
1,1%	0,1%	1,6%	1,4%	-22,7%	-14,2%	-24,8%	-25,8%	1,7%	1,8%	4,3%	3,8%

Statistical analysis: Dunnett test p<0,05 T1h, T6h, T24h and T48h vs T0

INSTRUMENTAL EVALUATION

OPTICAL COLORIMETRY - SKIN ERYTHEMA

LIPOGEL SOLUZIONE CONTROLLO 1% (prot. 2648)

VOL N.	T0 - BASELINE (immediately after stripping)			T1h (1 hour after product application)			T6h (6 hours after product application)			T24h (24 hours after product application)			T48h (48 hours after product application)		
	L*	a*	b*	L*	a*	b*	L*	a*	b*	L*	a*	b*	L*	a*	b*
1	66,54	10,91	13,37	65,19	11,19	14,03	64,50	12,81	13,33	65,59	11,53	13,51	65,63	10,20	14,26
2	68,08	8,99	10,97	66,90	7,62	12,14	69,31	5,97	11,56	67,92	6,49	11,47	66,96	6,14	11,10
3	66,97	10,36	12,44	67,17	8,21	11,68	67,49	8,20	12,47	67,75	6,72	12,85	67,45	8,40	13,85
4	63,89	12,43	11,46	65,98	7,74	11,60	64,34	11,12	12,23	65,28	9,63	12,37	64,95	9,90	12,32
5	65,74	12,12	11,71	67,07	8,44	11,04	64,88	9,45	10,87	66,17	9,08	12,20	65,08	9,64	11,80
6	61,07	15,05	15,81	60,25	12,91	14,25	59,20	14,99	14,74	62,42	11,39	16,02	62,60	11,21	15,43
7	63,89	11,49	14,10	63,85	10,82	13,73	58,82	15,46	14,39	61,36	11,11	13,76	60,58	10,58	14,17
8	64,79	12,98	12,30	68,59	6,88	11,86	64,62	10,37	11,99	65,89	11,90	12,73	67,62	7,78	12,82
9	61,39	16,12	12,57	63,72	10,77	11,81	63,28	10,99	12,11	65,71	9,58	13,58	65,36	10,61	13,24
10	64,32	12,53	12,66	65,82	9,33	12,10	63,51	12,34	13,40	66,00	10,41	14,12	64,35	10,89	13,84
11	60,04	13,04	14,22	61,71	9,79	14,37	60,41	10,97	14,29	62,14	9,43	14,29	62,19	8,56	14,82
12	69,61	9,87	9,79	70,10	7,38	9,82	69,18	7,28	10,70	71,34	5,96	11,23	70,22	6,60	10,67
13	60,40	13,09	11,21	62,12	10,88	12,45	59,93	12,76	11,67	63,17	11,56	12,30	61,76	9,86	12,78
14	65,56	10,81	11,56	66,31	9,50	11,16	66,01	8,99	11,49	67,36	6,53	10,96	67,32	8,20	11,61
15	69,92	7,31	11,25	69,40	6,10	11,53	66,10	10,46	11,90	69,09	6,57	12,59	69,03	5,96	13,09
16	64,69	10,13	14,12	64,77	8,39	14,50	64,68	9,35	13,61	62,23	8,54	14,04	62,95	9,40	13,35
17	[67,20]	[7,65]	[10,85]	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
18	61,58	15,02	14,62	63,06	10,10	15,00	64,01	9,63	15,86	61,72	14,70	15,75	62,20	12,41	16,24
19	67,00	11,35	9,09	68,49	7,89	8,28	68,31	8,05	8,78	68,83	5,65	7,58	69,48	6,98	8,60
20	65,81	10,82	13,22	67,34	7,24	13,02	66,63	8,60	13,37	66,59	8,65	13,91	67,12	8,42	13,74
21	62,25	11,05	13,98	63,77	10,12	14,29	61,36	10,75	13,54	61,65	9,42	13,93	62,89	9,12	14,46
MEAN	64,677	11,774	12,523	65,581	9,065	12,433	64,329	10,427	12,615	65,411	9,243	12,960	65,287	9,043	13,109
ST.DEV	2,913	2,121	1,690	2,667	1,748	1,725	3,146	2,413	1,631	2,880	2,409	1,840	2,806	1,762	1,763
MIN	60,04	7,31	9,09	60,25	6,10	8,28	58,82	5,97	8,78	61,36	5,65	7,58	60,58	5,96	8,60
MAX	69,92	16,12	15,81	70,10	12,91	15,00	69,31	15,46	15,86	71,34	14,70	16,02	70,22	12,41	16,24
MSE	0,651	0,474	0,378	0,596	0,391	0,386	0,703	0,540	0,365	0,644	0,539	0,411	0,628	0,394	0,394

Legend: NE = not evaluated

Test code
E0715

INSTRUMENTAL EVALUATION

OPTICAL COLORIMETRY - SKIN ERYTHEMA

LIPOGEL SOLUZIONE CONTROLLO 1% (prot. 2648)

% VARIATION vs BASELINE											
L*				a*				b*			
T1h	T6h	T24h	T48h	T1h	T6h	T24h	T48h	T1h	T6h	T24h	T48h
1,4%	-0,5%	1,1%	0,9%	-23,0%	-11,4%	-21,5%	-23,2%	-0,7%	0,7%	3,5%	4,7%

Statistical analysis: Dunnett test p<0,05 T1h, T6h, T24h and T48h vs T0

INSTRUMENTAL EVALUATION

OPTICAL COLORIMETRY - SKIN ERYTHEMA

IDROGEL SOLUZIONE CONTROLLO (prot. 2649)

VOL N.	T0 - BASELINE (immediately after stripping)			T1h (1 hour after product application)			T6h (6 hours after product application)			T24h (24 hours after product application)			T48h (48 hours after product application)		
	L*	a*	b*	L*	a*	b*	L*	a*	b*	L*	a*	b*	L*	a*	b*
1	65,89	11,75	13,24	67,59	7,71	13,04	65,07	11,33	13,66	66,02	10,75	14,44	64,40	10,05	14,62
2	65,68	11,38	11,06	65,51	9,02	11,13	66,87	7,25	11,61	67,12	6,66	10,81	66,80	6,73	10,72
3	64,81	13,14	13,20	64,93	10,68	13,09	67,23	8,16	13,97	66,09	8,53	14,13	66,13	9,04	13,72
4	65,59	9,18	10,62	67,32	5,29	11,57	66,68	5,74	11,40	68,85	4,97	12,73	67,57	5,56	11,92
5	63,90	15,52	12,56	66,45	9,49	11,93	63,42	13,28	12,29	6,27	10,40	13,20	64,45	11,89	13,16
6	59,58	17,42	15,44	58,71	13,99	14,21	60,48	13,48	14,01	61,37	12,16	15,49	62,51	10,90	14,87
7	63,24	11,95	13,56	61,69	11,67	13,24	59,31	14,45	13,07	62,58	11,98	13,91	60,24	12,24	13,71
8	68,12	8,80	12,13	67,96	7,56	10,95	62,22	14,28	10,60	64,12	13,22	11,79	66,65	10,80	13,15
9	62,17	15,42	12,50	62,46	10,46	11,48	64,61	11,06	12,04	66,53	8,09	13,30	66,64	8,94	12,84
10	66,29	10,13	11,56	65,63	8,38	13,36	63,99	11,74	14,43	64,95	10,12	14,35	64,49	9,27	13,89
11	59,17	14,31	14,17	59,87	11,08	15,08	59,03	12,41	14,75	62,37	8,75	17,10	62,88	7,87	15,35
12	68,36	11,30	10,64	69,73	6,39	10,48	66,85	9,10	10,31	69,27	7,47	11,31	69,12	7,82	12,03
13	61,55	12,29	11,80	61,92	9,08	10,97	61,44	12,69	12,64	63,32	8,59	12,31	63,69	7,44	12,26
14	65,47	13,30	10,94	65,34	10,60	9,71	67,40	8,27	10,41	68,66	5,33	11,80	66,97	8,22	10,51
15	69,33	7,03	10,95	69,39	5,68	11,45	66,39	9,14	11,28	69,42	6,35	12,16	68,34	5,99	12,14
16	64,25	11,36	15,25	65,18	8,84	14,87	63,86	9,00	13,79	63,23	8,34	14,03	64,06	9,91	14,95
17	[65,39]	[7,06]	[11,45]	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
18	62,85	11,82	14,20	63,46	9,68	14,91	63,08	9,53	15,26	61,71	12,80	15,65	61,59	11,96	15,09
19	68,80	8,26	7,87	68,90	6,85	8,94	68,72	7,36	8,89	70,42	4,53	8,65	69,31	6,64	7,89
20	66,84	11,38	13,95	68,50	6,97	14,05	67,60	8,02	14,24	65,43	10,15	14,51	65,99	9,41	14,25
21	62,67	12,05	13,64	62,45	10,99	14,07	60,09	13,75	13,35	61,80	12,58	14,63	63,62	10,62	15,44
MEAN	64,728	11,890	12,464	65,150	9,021	12,427	64,217	10,502	12,600	62,477	9,089	13,315	65,273	9,065	13,126
ST.DEV	2,882	2,552	1,839	3,196	2,213	1,809	3,012	2,663	1,737	13,534	2,691	1,932	2,482	2,007	1,917
MIN	59,17	7,03	7,87	58,71	5,29	8,94	59,03	5,74	8,89	6,27	4,53	8,65	60,24	5,56	7,89
MAX	69,33	17,42	15,44	69,73	13,99	15,08	68,72	14,45	15,26	70,42	13,22	17,10	69,31	12,24	15,44
MSE	0,644	0,571	0,411	0,715	0,495	0,405	0,673	0,595	0,388	3,026	0,602	0,432	0,555	0,449	0,429

Legend: NE = not evaluated

Test code
E0715

INSTRUMENTAL EVALUATION

OPTICAL COLORIMETRY - SKIN ERYTHEMA

IDROGEL SOLUZIONE CONTROLLO (prot. 2649)

% VARIATION vs BASELINE											
L*				a*				b*			
T1h	T6h	T24h	T48h	T1h	T6h	T24h	T48h	T1h	T6h	T24h	T48h
0,7%	-0,8%	-3,5%	0,8%	-24,1%	-11,7%	-23,6%	-23,8%	-0,3%	1,1%	6,8%	5,3%

Statistical analysis: Dunnett test p<0,05 T1h, T6h, T24h and T48h vs T0

CLINICAL EVALUATION

SKIN ERYTHEMA
LIPOGEL SOLUZIONE P 1% (prot. 2647)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)
1	1,0	1,0	1,5	1,0	1,0
2	1,5	0.5	0,0	0,0	0,0
3	1,5	0.5	0.5	0,0	0,0
4	2,0	0.5	1,5	1,0	1,0
5	1,5	0,0	0.5	0.5	0.5
6	1,5	0.5	0.5	0.5	0,0
7	1,5	1,5	2,0	1,5	1,0
8	2,0	0.5	1,5	1,5	1,0
9	2,0	1,0	1,0	0,0	0,0
10	1,0	0.5	1,0	0.5	0.5
11	1,0	0,0	0,0	0,0	0,0
12	1,5	0.5	0.5	0,0	0,0
13	1,5	2,0	2,0	1,5	1,0
14	1,5	1,0	0.5	0.5	0,0
15	1,0	0.5	1,5	1,0	0.5
16	1,0	0.5	0.5	0,0	0,0
17	[1,0]	NE	NE	NE	NE
18	1,5	1,0	1,0	1,5	0.5
19	1,5	0.5	0.5	0,0	0,0
20	2,0	1,0	1,0	0.5	0.5
21	1,5	1,0	0.5	0.5	0,0
MEAN	1,48	0,95	1,17	0,64	0,33
ST. DEV.	0,343	0,599	0,651	0,691	0,488
MIN	1,00	0,00	0,00	0,00	0,00
MAX	2,00	2,00	2,00	1,50	1,00
MSE	0,077	0,189	0,188	0,185	0,126

LEGEND:

0= no erythema
0,5= very slight erythema
1= well defined erythema
1,5= moderate erythema
2= severe erythema
NE = not evaluated

VARIATION (%) vs T0			
T1h	T6h	T24h	T48h
-35,8%	-20,9%	-56,4%	-77,7%

		SUBJECTS %			
		T1h	T6h	T24h	T48h
Improved	0,5 grades	15%	20%	5%	10%
	1 grade	30%	20%	20%	30%
	1,5 grades	30%	40%	40%	45%
	2 grades	10%	0%	0%	10%
	Not changed	10%	5%	25%	5%
	Worsened	5%	15%	10%	0%

Statistical analysis: Dunnett test p<0,05 T1h, T24h and T48h vs T0

Test code
E0715

CLINICAL EVALUATION

SKIN ERYTHEMA
IDROGEL SOLUZIONE B (prot. 2650)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)
1	1,5	0.5	1,5	1,0	1,0
2	1,5	1,5	0.5	0,5	0.5
3	1,5	0.5	0.5	0,0	0,0
4	1,5	0.5	1,0	0.5	0.5
5	2,0	0,0	0,0	0,0	0,0
6	2,0	0.5	0,0	0,0	0,0
7	2,0	2,0	1,5	1,5	1,0
8	1,5	1,0	1,5	1,0	1,0
9	1,5	1,0	1,0	0,0	0,0
10	1,0	0.5	0.5	0.5	0,0
11	1,5	0.5	0,0	0,0	0,0
12	1,5	0.5	0.5	0,0	0,0
13	1,5	2,0	2,0	1,5	1,0
14	2,0	1,5	1,0	0.5	0,0
15	2,0	2,0	2,0	1,5	1,0
16	1,5	0.5	0.5	0,0	0,0
17	[0.5]	NE	NE	NE	NE
18	1,5	1,0	1,0	1,5	0.5
19	1,5	0.5	0,0	0,0	0,0
20	2,0	0,0	0.5	0,0	0,0
21	1,5	1,0	0.5	0.5	0,0
MEAN	1,63	1,18	0,96	0,53	0,29
ST. DEV.	0,275	0,717	0,749	0,670	0,470
MIN	1,00	0,00	0,00	0,00	0,00
MAX	2,00	2,00	2,00	1,50	1,00
MSE	0,062	0,216	0,208	0,168	0,114

LEGEND:
0= no erythema
0,5= very slight erythema
1= well defined erythema
1,5= moderate erythema
2= severe erythema
NE = not evaluated

VARIATION (%) vs T0			
T1h	T6h	T24h	T48h
-27,6%	-41,1%	-67,5%	-82,2%

		SUBJECTS %			
		T1h	T6h	T24h	T48h
Improved	0,5 grades	25%	20%	20%	15%
	1 grade	5%	10%	10%	15%
	1,5 grades	35%	35%	40%	50%
	2 grades	15%	15%	20%	20%
	Not changed	15%	15%	10%	0%
	Worsened	5%	5%	0%	0%

Statistical analysis: Dunnett test p<0,05 T1h, T6h, T24h and T48h vs T0

Test code
E0715

CLINICAL EVALUATION

SKIN ERYTHEMA
LIPOGEL SOLUZIONE CONTROLLO 1% (prot. 2648)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)
1	1,5	1,5	2,0	1,5	1,5
2	1,0	1,0	0,0	0,0	0,0
3	1,0	0.5	0.5	0,0	0,0
4	2,0	1,0	1,5	1,5	1,5
5	1,5	0,0	1,0	1,0	1,0
6	1,5	0.5	0,0	0,0	0,0
7	1,5	1,5	2,0	1,5	1,0
8	2,0	0.5	1,0	1,0	0.5
9	2,0	1,0	1,0	0,0	0,0
10	1,0	1,0	1,5	1,0	1,0
11	1,5	0.5	0.5	0.5	0,0
12	1,5	0.5	0,0	0,0	0,0
13	1,5	1,0	1,0	1,0	0.5
14	2,0	1,0	0.5	0,0	0,0
15	1,5	0.5	1,5	0.5	0,0
16	1,0	0.5	0.5	0,0	0,0
17	[0.5]	NE	NE	NE	NE
18	1,5	1,0	1,5	1,0	0.5
19	1,5	0.5	0.5	0,0	0,0
20	2,0	0,0	0.5	0.5	0.5
21	1,5	1,0	0.5	0.5	0,0
MEAN	1,53	0,92	1,08	0,59	0,38
ST. DEV.	0,343	0,469	0,703	0,638	0,592
MIN	1,00	0,00	0,00	0,00	0,00
MAX	2,00	1,50	2,00	1,50	1,50
MSE	0,077	0,135	0,195	0,160	0,148

LEGEND:

0= no erythema
0,5= very slight erythema
1= well defined erythema
1,5= moderate erythema
2= severe erythema
NE = not evaluated

VARIATION (%) vs T0			
T1h	T6h	T24h	T48h
-39,9%	-29,4%	-61,4%	-75,2%

		SUBJECTS %			
		T1h	T6h	T24h	T48h
Improved	0,5 grades	15%	15%	20%	15%
	1 grade	25%	25%	20%	15%
	1,5 grades	30%	25%	30%	40%
	2 grades	10%	10%	15%	20%
	Not changed	20%	10%	15%	10%
	Worsened	0%	15%	0%	0%

Statistical analysis: Dunnett test p<0,05 T1h, T24h and T48h vs T0

Test code
E0715

CLINICAL EVALUATION

SKIN ERYTHEMA
IDROGEL SOLUZIONE CONTROLLO (prot. 2649)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)
1	1,5	0.5	1,5	1,5	1,5
2	1,5	2,0	1,0	0,5	0.5
3	1,5	0.5	0.5	0.5	0,0
4	2,0	0.5	0.5	0.5	0,0
5	2,0	1,0	1,5	1,0	1,5
6	2,0	0,0	0,0	0,0	0,0
7	1,5	1,5	1,5	1,5	1,0
8	2,0	1,0	1,5	1,5	1,0
9	1,5	1,0	1,0	0,0	0.5
10	1,0	0.5	1,5	1,0	1,0
11	2,0	0.5	1,0	0.5	0,0
12	1,0	1,0	1,0	0,0	0.5
13	1,5	1,0	1,0	0.5	0,0
14	2,0	1,0	0,0	0,0	0,0
15	1,5	0.5	1,5	0.5	0,0
16	1,5	0.5	0.5	0,0	0,0
17	[0.5]	NE	NE	NE	NE
18	1,5	1,0	1,5	1,5	0.5
19	2,0	0.5	0,0	0,0	0,0
20	2,0	0,0	0.5	0.5	0.5
21	1,5	1,0	1,5	2,0	0.5
MEAN	1,65	0,96	1,06	0,75	0,43
ST. DEV.	0,328	0,542	0,574	0,753	0,616
MIN	1,00	0,00	0,00	0,00	0,00
MAX	2,00	2,00	1,50	2,00	1,50
MSE	0,073	0,156	0,143	0,201	0,165

LEGEND:

0= no erythema
0,5= very slight erythema
1= well defined erythema
1,5= moderate erythema
2= severe erythema
NE = not evaluated

VARIATION (%) vs T0			
T1h	T6h	T24h	T48h
-41,8%	-35,8%	-54,5%	-74,0%

	SUBJECTS %			
	T1h	T6h	T24h	T48h
Improved 0,5 grades	20%	25%	5%	10%
1 grade	20%	5%	15%	10%
1,5 grades	20%	10%	25%	40%
2 grades	25%	25%	30%	30%
Not changed	10%	30%	20%	10%
Worsened	5%	5%	5%	0%

Statistical analysis: Dunnett test p<0,05 T1h, T24h and T48h vs T0

Test code
E0715

INSTRUMENTAL EVALUATION

SKIN ELECTRICAL CAPACITANCE (SKIN SURFACE HYDRATION)
LIPOGEL SOLUZIONE P 1% (prot. 2647)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)	Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
1	58,5	68,0	75,8	56,5	37,9	9,5	17,3	-2,0	-20,6
2	44,1	57,0	57,2	39,0	40,0	12,9	13,1	-5,1	-4,1
3	54,1	47,3	56,9	50,8	43,8	-6,8	2,8	-3,3	-10,3
4	43,4	67,8	74,0	60,2	48,1	24,4	30,6	16,8	4,7
5	60,3	47,2	60,9	53,3	48,9	-13,1	0,6	-7,0	-11,4
6	62,9	60,4	52,2	59,1	46,5	-2,5	-10,7	-3,8	-16,4
7	76,9	69,4	72,3	44,7	30,3	-7,5	-4,6	-32,2	-46,6
8	47,6	51,5	72,5	54,2	57,9	3,9	24,9	6,6	10,3
9	69,7	53,9	69,0	68,2	66,9	-15,8	-0,7	-1,5	-2,8
10	61,6	59,3	67,1	56,7	47,4	-2,3	5,5	-4,9	-14,2
11	42,1	69,1	49,0	53,3	50,0	27,0	6,9	11,2	7,9
12	44,1	57,2	52,1	37,8	45,1	13,1	8,0	-6,3	1,0
13	57,6	62,9	55,5	46,8	43,5	5,3	-2,1	-10,8	-14,1
14	45,2	51,4	56,8	48,7	40,9	6,2	11,6	3,5	-4,3
15	44,9	57,5	51,3	43,9	49,5	12,6	6,4	-1,0	4,6
16	48,9	61,7	52,1	52,4	51,5	12,8	3,2	3,5	2,6
17	[52,1]	NE	NE	NE	NE	-	-	-	-
18	57,9	74,2	77,9	59,6	64,0	16,3	20,0	1,7	6,1
19	44,7	55,6	57,1	39,2	41,7	10,9	12,4	-5,5	-3,0
20	48,6	50,7	59,4	56,2	50,5	2,1	10,8	7,6	1,9
21	63,9	70,9	68,8	52,8	52,8	7,0	4,9	-11,1	-11,1
MEAN	53,85	59,65	61,90	51,67	47,86				
ST. DEV.	9,964	8,154	9,320	7,939	8,515				
MIN	42,10	47,20	49,00	37,80	30,30				
MAX	76,90	74,20	77,90	68,20	66,90				
MSE	2,228	1,823	2,084	1,775	1,904				

VARIATION (%) vs T0			
T1h	T6h	T24h	T48h
10,8%	14,9%	-4,0%	-11,1%
	VARIATION (%) vs T1h		
	T6h	T24h	T48h
	3,8%	-13,4%	-19,8%

Legend: NE = not evaluated

Statistical analysis: Tukey test p<0,05 T6h vs T0
p<0,05 T24h and T48h vs T1h and T6h

Test code
E0715

INSTRUMENTAL EVALUATION

SKIN ELECTRICAL CAPACITANCE (SKIN SURFACE HYDRATION)

IDROGEL SOLUZIONE B (prot. 2650)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)	Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
1	61,0	69,0	66,6	50,6	35,7	8,0	5,6	-10,4	-25,3
2	44,0	57,3	49,8	32,2	34,4	13,3	5,8	-11,8	-9,6
3	49,1	49,0	39,3	38,5	32,0	-0,1	-9,8	-10,6	-17,1
4	52,1	57,4	69,4	51,7	53,9	5,3	17,3	-0,4	1,8
5	58,2	54,6	48,9	43,7	44,2	-3,6	-9,3	-14,5	-14,0
6	59,5	52,9	56,4	54,9	42,7	-6,6	-3,1	-4,6	-16,8
7	54,8	73,1	59,3	50,4	31,9	18,3	4,5	-4,4	-22,9
8	47,9	71,6	66,0	64,7	41,4	23,7	18,1	16,8	-6,5
9	65,9	70,4	57,1	69,1	61,5	4,5	-8,8	3,2	-4,4
10	53,6	61,8	48,5	58,6	49,7	8,2	-5,1	5,0	-3,9
11	46,2	59,2	43,1	46,4	44,8	13,0	-3,1	0,2	-1,4
12	47,4	48,1	49,6	38,9	42,6	0,7	2,2	-8,5	-4,8
13	60,4	67,2	62,3	55,0	54,5	6,8	1,9	-5,4	-5,9
14	47,8	54,2	64,7	49,5	43,9	6,4	16,9	1,7	-3,9
15	56,0	67,1	59,0	60,4	51,3	11,1	3,0	4,4	-4,7
16	52,2	64,1	54,5	44,5	55,1	11,9	2,3	-7,7	2,9
17	[47,4]	NE	NE	NE	NE	-	-	-	-
18	56,4	74,7	71,8	62,8	62,3	18,3	15,4	6,4	5,9
19	49,8	51,2	51,2	48,1	46,7	1,4	1,4	-1,7	-3,1
20	47,9	66,1	66,8	54,4	56,3	18,2	18,9	6,5	8,4
21	65,8	59,6	58,6	57,4	46,2	-6,2	-7,2	-8,4	-19,6
MEAN	53,80	61,43	57,15	51,59	46,56				
ST. DEV.	6,465	8,266	8,981	9,352	9,043				
MIN	44,00	48,10	39,30	32,20	31,90				
MAX	65,90	74,70	71,82	69,10	62,30				
MSE	1,446	1,848	2,008	2,091	2,022				

VARIATION (%) vs T0			
T1h	**T6h**	**T24h**	**T48h**
14,2%	6,2%	-4,1%	-13,5%

VARIATION (%) vs T1h		
T6h	**T24h**	**T48h**
-7,0%	-16,0%	-24,2%

Legend: NE = not evaluated

Statistical analysis: Tukey test p<0,05 T1h and T48h vs T0
p<0,05 T24h and T48h vs T1h and T6h

Test code
E0715

INSTRUMENTAL EVALUATION

SKIN ELECTRICAL CAPACITANCE (SKIN SURFACE HYDRATION)
LIPOGEL SOLUZIONE CONTROLLO 1% (prot. 2648)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)	Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
1	81,3	69,7	85,8	74,4	34,6	-11,6	4,5	-6,9	-46,7
2	41,5	41,6	54,2	42,3	39,3	0,1	12,7	0,8	-2,2
3	47,5	52,8	46,9	41,7	35,3	5,3	-0,6	-5,8	-12,2
4	62,7	70,2	72,9	59,7	42,8	7,5	10,2	-3,0	-19,9
5	59,0	47,9	69,4	50,9	47,6	-11,1	10,4	-8,1	-11,4
6	60,0	68,0	57,6	48,3	45,6	8,0	-2,4	-11,7	-14,4
7	65,7	56,6	80,8	65,0	30,8	-9,1	15,1	-0,7	-34,9
8	50,7	53,0	65,1	59,7	54,1	2,3	14,4	9,0	3,4
9	66,3	42,4	62,6	62,7	59,9	-23,9	-3,7	-3,6	-6,4
10	63,5	59,1	68,2	61,4	38,4	-4,4	4,7	-2,1	-25,1
11	51,6	72,2	61,8	60,5	50,9	20,6	10,2	8,9	-0,7
12	49,5	58,2	55,1	40,3	44,8	8,7	5,6	-9,2	-4,7
13	46,9	54,7	45,3	45,0	41,8	7,8	-1,6	-1,9	-5,1
14	43,3	51,5	56,6	50,4	39,7	8,2	13,3	7,1	-3,6
15	42,0	58,3	54,4	52,4	53,3	16,3	12,4	10,4	11,3
16	50,5	56,3	58,6	54,6	62,9	5,8	8,1	4,1	12,4
17	[54,3]	NE	NE	NE	NE	-	-	-	-
18	73,3	81,7	61,8	80,7	63,0	8,4	-11,5	7,4	-10,3
19	38,4	53,0	49,1	47,6	46,1	14,6	10,7	9,2	7,7
20	53,4	48,7	67,6	56,2	57,2	-4,7	14,2	2,8	3,8
21	62,6	75,8	76,1	44,8	54,3	13,2	13,5	-17,8	-8,3
MEAN	55,49	58,59	62,50	54,93	47,12				
ST. DEV.	11,386	10,993	10,923	10,799	9,542				
MIN	38,40	41,60	45,30	40,30	30,80				
MAX	81,30	81,70	85,80	80,70	63,00				
MSE	2,546	2,458	2,442	2,415	2,134				

VARIATION (%) vs T0			
T1h	T6h	T24h	T48h
5,6%	12,6%	-1,0%	-15,1%

VARIATION (%) vs T1h		
T6h	T24h	T48h
6,7%	-6,2%	-19,6%

Legend: NE = not evaluated

Statistical analysis: Tukey test p<0,05 T48h vs T0
p<0,05 T24h vs T6h and T48h **p<0,05 T48h vs T1h and T6h**

Test code
E0715

INSTRUMENTAL EVALUATION

SKIN ELECTRICAL CAPACITANCE (SKIN SURFACE HYDRATION)
IDROGEL SOLUZIONE CONTROLLO (prot. 2649)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)	Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
1	74,5	78,1	78,2	60,7	32,4	3,6	3,7	-13,8	-42,1
2	42,8	68,8	73,0	31,7	32,5	26,0	30,2	-11,1	-10,3
3	42,2	53,9	47,1	44,8	33,5	11,7	4,9	2,6	-8,7
4	50,4	54,7	55,9	45,3	44,7	4,3	5,5	-5,1	-5,7
5	67,9	70,3	67,5	49,0	35,3	2,4	-0,4	-18,9	-32,6
6	55,9	64,2	52,0	41,7	42,4	8,3	-3,9	-14,2	-13,5
7	64,1	64,4	71,8	60,6	42,0	0,3	7,7	-3,5	-22,1
8	67,7	68,7	71,7	70,1	57,4	1,0	4,0	2,4	-10,3
9	71,7	60,8	62,2	66,5	57,9	-10,9	-9,5	-5,2	-13,8
10	53,8	60,1	55,7	44,6	44,0	6,3	1,9	-9,2	-9,8
11	53,2	68,6	51,5	40,3	40,8	15,4	-1,7	-12,9	-12,4
12	49,0	64,2	59,5	43,0	41,8	15,2	10,5	-6,0	-7,2
13	48,3	67,8	64,8	51,4	44,6	19,5	16,5	3,1	-3,7
14	46,7	42,9	56,9	53,1	49,6	-3,8	10,2	6,4	2,9
15	38,3	70,0	53,1	52,2	58,4	31,7	14,8	13,9	20,1
16	51,1	66,6	65,0	54,6	58,8	15,5	13,9	3,5	7,7
17	[47,2]	NE	NE	NE	NE	-	-	-	-
18	60,7	76,7	67,3	72,3	62,1	16,0	6,6	11,6	1,4
19	34,3	46,0	43,2	44,0	44,6	11,7	8,9	9,7	10,3
20	45,9	68,3	62,4	55,2	44,5	22,4	16,5	9,3	-1,4
21	67,8	78,1	78,2	57,9	47,9	10,3	10,4	-9,9	-19,9
MEAN	54,32	64,66	61,85	51,95	45,76				
ST. DEV.	11,587	9,501	9,961	10,547	9,140				
MIN	34,30	42,90	43,20	31,70	32,40				
MAX	74,50	78,10	78,20	72,30	62,10				
MSE	2,591	2,125	2,227	2,358	2,044				

VARIATION (%) vs T0			
T1h	T6h	T24h	T48h
19,0%	13,9%	-4,4%	-15,8%

VARIATION (%) vs T1h		
T6h	T24h	T48h
-4,3%	-19,7%	-29,2%

Legend: NE = not evaluated

Statistical analysis: Tukey test p<0,05 T1h, T6h and T48h vs T0
p<0,05 T24h and T48h vs T1h and T6h

Test code
E0715

INSTRUMENTAL EVALUATION

DEEP SKIN HYDRATION (1,5 mm)
LIPOGEL SOLUZIONE P 1% (prot. 2647)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)	Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
1	44,0	44,5	44,0	46,6	39,8	0,5	0,0	2,6	-4,2
2	30,7	32,5	35,0	35,0	29,1	1,8	4,3	4,3	-1,6
3	35,5	35,4	35,6	36,5	33,5	-0,1	0,1	1,0	-2,0
4	32,0	32,5	31,7	39,1	34,2	0,5	-0,3	7,1	2,2
5	30,7	32,5	30,4	31,6	32,5	1,8	-0,3	0,9	1,8
6	36,7	36,7	33,5	33,3	32,5	0,0	-3,2	-3,4	-4,2
7	37,2	36,7	46,1	46,4	33,6	-0,5	8,9	9,2	-3,6
8	36,7	36,4	36,4	42,2	36,9	-0,3	-0,3	5,5	0,2
9	39,9	36,7	39,5	39,5	38,0	-3,2	-0,4	-0,4	-1,9
10	36,7	36,9	39,2	39,4	34,5	0,2	2,5	2,7	-2,2
11	30,9	29,6	28,3	29,8	31,1	-1,3	-2,6	-1,1	0,2
12	35,4	33,7	33,4	31,7	29,9	-1,7	-2,0	-3,7	-5,5
13	35,8	35,8	37,1	37,4	36,2	0,0	1,3	1,6	0,4
14	37,0	36,7	36,7	36,5	35,0	-0,3	-0,3	-0,5	-2,0
15	35,1	36,1	37,1	33,5	36,9	1,0	2,0	-1,6	1,8
16	37,0	43,2	39,2	35,2	40,0	6,2	2,2	-1,8	3,0
17	[36,7]	NE	NE	NE	NE	-	-	-	-
18	34,4	32,5	36,1	40,0	35,8	-1,9	1,7	5,6	1,4
19	28,7	31,4	30,5	30,0	31,6	2,7	1,8	1,3	2,9
20	37,1	37,1	34,8	34,7	34,8	0,0	-2,3	-2,4	-2,3
21	33,2	31,6	28,5	29,8	32,5	-1,6	-4,7	-3,4	-0,7
MEAN	35,24	35,43	35,66	36,41	34,42				
ST. DEV.	3,532	3,684	4,649	5,000	3,003				
MIN	28,70	29,60	28,30	29,80	29,10				
MAX	44,00	44,50	46,10	46,60	40,00				
MSE	0,790	0,824	1,040	1,118	0,672				

VARIATION (%) vs T0			
T1h	T6h	T24h	T48h
0,5%	1,2%	3,3%	-2,3%

Legend: NE = not evaluated

Test code
E0715

INSTRUMENTAL EVALUATION

DEEP SKIN HYDRATION (1,5 mm)
IDROGEL SOLUZIONE B (prot. 2650)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)	Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
1	42,3	41,2	39,8	41,6	36,1	-1,1	-2,5	-0,7	-6,2
2	33,8	32,5	35,8	35,8	30,3	-1,3	2,0	2,0	-3,5
3	36,3	35,0	32,5	33,5	33,5	-1,3	-3,8	-2,8	-2,8
4	31,1	31,7	29,6	35,3	31,7	0,6	-1,5	4,2	0,6
5	28,7	29,6	27,4	27,5	28,6	0,9	-1,3	-1,2	-0,1
6	36,7	36,7	33,5	33,5	32,5	0,0	-3,2	-3,2	-4,2
7	43,0	41,7	44,5	45,9	32,7	-1,3	1,5	2,9	-10,3
8	36,9	37,9	37,9	41,5	37,4	1,0	1,0	4,6	0,5
9	37,9	39,9	39,5	37,9	36,9	2,0	1,6	0,0	-1,0
10	35,7	35,7	34,1	36,6	35,2	0,0	-1,6	0,9	-0,5
11	29,7	29,6	27,8	29,8	28,6	-0,1	-1,9	0,1	-1,1
12	35,7	32,0	34,2	33,9	31,6	-3,7	-1,5	-1,8	-4,1
13	44,7	40,7	40,8	38,2	39,1	-4,0	-3,9	-6,5	-5,6
14	36,3	36,7	33,6	34,6	34,2	0,4	-2,7	-1,7	-2,1
15	39,7	39,1	39,1	36,7	36,1	-0,6	-0,6	-3,0	-3,6
16	36,5	36,7	37,1	36,1	36,7	0,2	0,6	-0,4	0,2
17	[36,8]	NE	NE	NE	NE	-	-	-	-
18	32,5	32,5	33,7	45,4	36,7	0,0	1,2	12,9	4,2
19	29,4	28,7	27,8	28,8	30,9	-0,7	-1,6	-0,6	1,5
20	36,7	35,0	35,0	36,3	35,8	-1,7	-1,7	-0,4	-0,9
21	31,5	30,7	28,5	27,0	28,6	-0,8	-3,0	-4,5	-2,9
MEAN	35,76	35,18	34,61	35,80	33,66				
ST. DEV.	4,477	4,120	4,817	5,229	3,227				
MIN	28,70	28,70	27,40	27,00	28,60				
MAX	44,70	41,70	44,50	45,90	39,10				
MSE	1,001	0,921	1,077	1,169	0,721				

VARIATION (%) vs T0			
T1h	**T6h**	**T24h**	**T48h**
-1,6%	-3,2%	0,1%	-5,9%

Legend: NE = not evaluated

Statistical analysis: Dunnett test p<0,05 T48h vs T0

Test code
E0715

INSTRUMENTAL EVALUATION

DEEP SKIN HYDRATION (1,5 mm)
LIPOGEL SOLUZIONE CONTROLLO 1% (prot. 2648)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)	Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
1	46,4	48,1	48,1	50,9	44,0	1,7	1,7	4,5	-2,4
2	38,2	35,8	37,9	37,9	33,2	-2,4	-0,3	-0,3	-5,0
3	36,4	31,7	35,9	36,7	35,3	-4,7	-0,5	0,3	-1,1
4	32,1	34,6	34,8	37,0	35,0	2,5	2,7	4,9	2,9
5	35,3	33,3	32,5	33,5	32,5	-2,0	-2,8	-1,8	-2,8
6	33,0	33,5	33,5	32,1	33,5	0,5	0,5	-0,9	0,5
7	39,9	36,7	46,7	48,1	37,2	-3,2	6,8	8,2	-2,7
8	35,3	36,4	35,7	41,4	36,8	1,1	0,4	6,1	1,5
9	36,7	36,7	37,4	38,2	35,8	0,0	0,7	1,5	-0,9
10	37,2	37,3	35,6	43,0	33,5	0,1	-1,6	5,8	-3,7
11	34,6	33,0	30,5	31,8	31,7	-1,6	-4,1	-2,8	-2,9
12	36,7	37,2	37,1	37,2	36,3	0,5	0,4	0,5	-0,4
13	35,0	38,1	40,1	39,1	34,5	3,1	5,1	4,1	-0,5
14	36,3	36,6	37,2	33,3	34,0	0,3	0,9	-3,0	-2,3
15	37,0	36,1	37,1	35,8	35,0	-0,9	0,1	-1,2	-2,0
16	40,8	40,8	37,4	40,7	44,7	0,0	-3,4	-0,1	3,9
17	[35,9]	NE	NE	NE	NE	-	-	-	-
18	36,0	32,5	32,5	38,9	35,8	-3,5	-3,5	2,9	-0,2
19	29,8	31,8	30,5	28,6	29,1	2,0	0,7	-1,2	-0,7
20	38,8	35,8	35,8	42,0	37,9	-3,0	-3,0	3,2	-0,9
21	32,3	34,0	32,6	32,7	31,6	1,7	0,3	0,4	-0,7
MEAN	36,39	36,00	36,45	37,95	35,37				
ST. DEV.	3,554	3,667	4,529	5,480	3,730				
MIN	29,80	31,70	30,50	28,60	29,10				
MAX	46,40	48,10	48,10	50,90	44,70				
MSE	0,795	0,820	1,013	1,225	0,834				

VARIATION (%) vs T0			
T1h	T6h	T24h	T48h
-1,1%	0,2%	4,3%	-2,8%

Legend: NE = not evaluated

Test code
E0715

INSTRUMENTAL EVALUATION

DEEP SKIN HYDRATION (1,5 mm)
IDROGEL SOLUZIONE CONTROLLO (prot. 2649)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)	Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
1	42,3	44,5	44,0	46,5	42,3	2,2	1,7	4,2	0,0
2	37,8	40,7	43,0	43,0	33,5	2,9	5,2	5,2	-4,3
3	36,3	36,5	35,8	36,8	37,4	0,2	-0,5	0,5	1,1
4	29,9	31,6	30,5	27,6	30,1	1,7	0,6	-2,3	0,2
5	34,0	34,8	32,5	33,5	30,6	0,8	-1,5	-0,5	-3,4
6	35,4	35,6	33,1	32,4	32,5	0,2	-2,3	-3,0	-2,9
7	39,9	37,9	40,9	47,4	38,0	-2,0	1,0	7,5	-1,9
8	37,9	36,3	36,9	42,5	37,2	-1,6	-1,0	4,6	-0,7
9	36,3	39,9	39,5	36,7	34,5	3,6	3,2	0,4	-1,8
10	37,4	37,4	32,3	41,3	33,5	0,0	-5,1	3,9	-3,9
11	34,8	33,4	30,5	34,8	31,7	-1,4	-4,3	0,0	-3,1
12	36,7	37,2	37,1	39,8	35,0	0,5	0,4	3,1	-1,7
13	38,5	39,9	37,1	36,1	36,7	1,4	-1,4	-2,4	-1,8
14	35,8	36,4	36,7	36,7	34,9	0,6	0,9	0,9	-0,9
15	40,6	36,1	37,1	38,4	36,4	-4,5	-3,5	-2,2	-4,2
16	36,7	39,2	39,2	36,1	36,5	2,5	2,5	-0,6	-0,2
17	[39,6]	NE	NE	NE	NE	-	-	-	-
18	32,3	32,3	32,3	45,2	36,2	0,0	0,0	12,9	3,9
19	29,4	28,7	30,5	29,2	29,3	-0,7	1,1	-0,2	-0,1
20	36,2	34,8	34,8	42,6	36,9	-1,4	-1,4	6,4	0,7
21	33,1	33,5	32,6	35,8	32,5	0,4	-0,5	2,7	-0,6
MEAN	36,07	36,34	35,82	38,12	34,79				
ST. DEV.	3,252	3,574	4,076	5,415	3,147				
MIN	29,40	28,70	30,50	27,60	29,30				
MAX	42,30	44,50	44,00	47,40	42,30				
MSE	0,727	0,799	0,911	1,211	0,704				

VARIATION (%) vs T0			
T1h	**T6h**	**T24h**	**T48h**
0,7%	-0,7%	5,7%	-3,5%

Legend: NE = not evaluated

Statistical analysis: Dunnett test p<0,05 T24h vs T0

Test code
E0715

INSTRUMENTAL EVALUATION

EPICUTANEOUS pH
LIPOGEL SOLUZIONE P 1% (prot. 2647)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)	Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
1	5,94	5,54	5,59	7,06	6,04	-0,4	-0,4	1,1	0,1
2	5,40	5,20	5,38	5,01	5,77	-0,2	0,0	-0,4	0,4
3	5,20	5,00	5,20	5,49	5,71	-0,2	0,0	0,3	0,5
4	5,24	5,27	5,36	5,31	5,38	0,0	0,1	0,1	0,1
5	5,16	5,11	4,60	5,30	5,17	0,0	-0,6	0,1	0,0
6	5,04	4,53	5,01	6,01	6,05	-0,5	0,0	1,0	1,0
7	5,50	5,29	5,65	5,49	5,41	-0,2	0,2	0,0	-0,1
8	5,55	5,28	5,58	5,42	5,80	-0,3	0,0	-0,1	0,3
9	5,14	5,14	4,84	4,96	5,08	0,0	-0,3	-0,2	-0,1
10	5,29	5,22	4,95	5,45	5,61	-0,1	-0,3	0,2	0,3
11	5,04	5,00	4,93	5,40	6,40	0,0	-0,1	0,4	1,4
12	5,11	5,32	5,31	6,42	5,65	0,2	0,2	1,3	0,5
13	5,10	5,10	5,19	5,10	5,10	0,0	0,1	0,0	0,0
14	4,65	4,54	4,58	4,30	4,36	-0,1	-0,1	-0,4	-0,3
15	5,00	5,17	4,59	4,61	5,04	0,2	-0,4	-0,4	0,0
16	5,02	5,14	5,10	5,16	4,87	0,1	0,1	0,1	-0,1
17	[4,58]	NE	NE	NE	NE	-	-	-	-
18	5,16	5,12	4,82	5,31	5,08	0,0	-0,3	0,1	-0,1
19	5,04	4,95	5,07	5,43	5,56	-0,1	0,0	0,4	0,5
20	5,12	5,21	5,29	5,70	5,40	0,1	0,2	0,6	0,3
21	4,93	5,34	4,82	7,08	5,21	0,4	-0,1	2,2	0,3
MEAN	5,182	5,124	5,093	5,501	5,435				
ST. DEV.	0,267	0,242	0,331	0,698	0,471				
MIN	4,65	4,53	4,58	4,30	4,36				
MAX	5,94	5,54	5,65	7,08	6,40				
MSE	0,060	0,054	0,074	0,156	0,105				

Legend: NE = not evaluated

Statistical analysis: Tukey test p<0,05 at T1h vs prot. 2649

VARIATION (%) vs T0			
T1h	T6h	T24h	T48h
-1,1%	-1,7%	6,2%	4,9%

Test code
E0715

INSTRUMENTAL EVALUATION

EPICUTANEOUS pH
IDROGEL SOLUZIONE B (prot. 2650)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)	Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
1	5,82	4,83	5,28	6,96	5,97	-1,0	-0,5	1,1	0,1
2	5,40	4,50	5,20	6,12	5,86	-0,9	-0,2	0,7	0,5
3	5,10	4,80	4,72	4,89	5,04	-0,3	-0,4	-0,2	-0,1
4	5,04	4,48	5,09	5,00	5,32	-0,6	0,0	0,0	0,3
5	5,11	4,48	4,23	4,91	5,00	-0,6	-0,9	-0,2	-0,1
6	5,20	4,02	5,51	5,85	6,15	-1,2	0,3	0,6	1,0
7	5,39	4,95	5,48	5,47	5,31	-0,4	0,1	0,1	-0,1
8	5,62	4,69	5,36	5,68	5,91	-0,9	-0,3	0,1	0,3
9	4,87	4,66	4,61	4,85	5,07	-0,2	-0,3	0,0	0,2
10	5,29	4,76	4,89	5,16	5,29	-0,5	-0,4	-0,1	0,0
11	4,94	4,27	4,43	5,02	6,10	-0,7	-0,5	0,1	1,2
12	5,00	4,65	4,62	6,23	5,70	-0,4	-0,4	1,2	0,7
13	5,10	4,71	5,02	5,10	5,03	-0,4	-0,1	0,0	-0,1
14	4,71	4,78	4,72	4,61	4,40	0,1	0,0	-0,1	-0,3
15	5,20	4,87	4,76	4,77	5,08	-0,3	-0,4	-0,4	-0,1
16	4,94	4,57	4,75	5,13	4,86	-0,4	-0,2	0,2	-0,1
17	[4,58]	NE	NE	NE	NE	-	-	-	-
18	5,11	4,50	4,68	5,32	5,33	-0,6	-0,4	0,2	0,2
19	5,18	4,36	4,67	5,72	5,52	-0,8	-0,5	0,5	0,3
20	5,31	4,75	4,94	5,37	5,37	-0,6	-0,4	0,1	0,1
21	4,94	4,80	5,10	6,97	5,05	-0,1	0,2	2,0	0,1
MEAN	5,164	4,622	4,903	5,457	5,368				
ST. DEV.	0,260	0,227	0,347	0,680	0,460				
MIN	4,71	4,02	4,23	4,61	4,40				
MAX	5,82	4,95	5,51	6,97	6,15				
MSE	0,058	0,051	0,078	0,152	0,103				

Legend: NE = not evaluated

VARIATION (%) vs T0			
T1h	T6h	T24h	T48h
-10,5%	-5,1%	5,7%	4,0%

Statistical analysis: Dunnett test p<0,05 T1h vs T0 ; Tukey test p<0,05 at T1h vs prot. 2647 and 2648

Test code
E0715

INSTRUMENTAL EVALUATION

EPICUTANEOUS pH
LIPOGEL SOLUZIONE CONTROLLO 1% (prot. 2648)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)	Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
1	6,01	6,12	6,17	6,61	5,90	0,1	0,2	0,6	-0,1
2	5,30	5,10	5,44	5,24	5,83	-0,2	0,1	-0,1	0,5
3	5,00	4,90	4,90	6,40	5,34	-0,1	-0,1	1,4	0,3
4	5,40	5,26	5,80	5,53	5,38	-0,1	0,4	0,1	0,0
5	5,29	4,80	4,77	5,03	5,19	-0,5	-0,5	-0,3	-0,1
6	5,03	4,10	4,81	5,70	5,75	-0,9	-0,2	0,7	0,7
7	5,52	5,50	5,74	5,61	5,35	0,0	0,2	0,1	-0,2
8	5,54	5,32	5,68	5,84	5,65	-0,2	0,1	0,3	0,1
9	5,14	4,79	4,88	5,25	5,20	-0,4	-0,3	0,1	0,1
10	5,56	4,96	5,12	5,65	5,59	-0,6	-0,4	0,1	0,0
11	5,00	4,83	4,91	5,16	6,25	-0,2	-0,1	0,2	1,3
12	4,97	5,13	5,24	5,69	5,59	0,2	0,3	0,7	0,6
13	4,95	4,98	5,10	5,30	5,23	0,0	0,1	0,4	0,3
14	4,61	4,50	4,50	4,33	4,67	-0,1	-0,1	-0,3	0,1
15	5,30	5,09	4,70	4,68	5,13	-0,2	-0,6	-0,6	-0,2
16	4,96	4,93	5,29	5,76	5,51	0,0	0,3	0,8	0,6
17	[4,63]	NE	NE	NE	NE	-	-	-	-
18	5,12	5,20	4,96	5,28	5,16	0,1	-0,2	0,2	0,0
19	5,01	4,91	5,01	5,33	5,49	-0,1	0,0	0,3	0,5
20	5,27	5,12	5,92	5,61	5,41	-0,1	0,7	0,3	0,1
21	4,96	5,10	4,78	6,21	5,40	0,1	-0,2	1,3	0,4
MEAN	5,197	5,032	5,186	5,511	5,451				
ST. DEV.	0,309	0,394	0,461	0,537	0,338				
MIN	4,61	4,10	4,50	4,33	4,67				
MAX	6,01	6,12	6,17	6,61	6,25				
MSE	0,069	0,088	0,103	0,120	0,075				

Legend: NE = not evaluated

Statistical analysis: Dunnett test p<0,05 T24h and T48h vs T0

VARIATION (%) vs T0			
T1h	T6h	T24h	T48h
-3,2%	-0,2%	6,0%	4,9%

Test code
E0715

INSTRUMENTAL EVALUATION

EPICUTANEOUS pH
IDROGEL SOLUZIONE CONTROLLO (prot. 2649)

VOL N.	T0 - BASELINE (immediately after stripping)	T1h (1 hour after product application)	T6h (6 hours after product application)	T24h (24 hours after product application)	T48h (48 hours after product application)	Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
1	6,03	5,05	5,35	7,03	6,08	-1,0	-0,7	1,0	0,0
2	5,40	4,50	5,33	5,23	5,86	-0,9	-0,1	-0,2	0,5
3	5,00	4,50	4,61	5,06	5,40	-0,5	-0,4	0,1	0,4
4	5,02	4,56	5,36	4,85	4,96	-0,5	0,3	-0,2	-0,1
5	5,41	4,51	4,96	5,15	5,44	-0,9	-0,5	-0,3	0,0
6	5,25	4,25	4,68	5,65	6,06	-1,0	-0,6	0,4	0,8
7	5,53	4,95	5,38	5,63	5,41	-0,6	-0,2	0,1	-0,1
8	5,65	4,51	5,43	5,92	5,70	-1,1	-0,2	0,3	0,0
9	5,19	4,65	4,58	5,36	5,16	-0,5	-0,6	0,2	0,0
10	5,57	4,98	5,97	5,60	5,35	-0,6	0,4	0,0	-0,2
11	5,22	4,47	4,58	4,64	6,12	-0,8	-0,6	-0,6	0,9
12	5,06	4,94	5,21	6,28	5,76	-0,1	0,2	1,2	0,7
13	4,75	4,61	4,93	5,49	5,43	-0,1	0,2	0,7	0,7
14	4,50	4,70	4,79	4,72	7,98	0,2	0,3	0,2	3,5
15	4,95	4,87	4,71	4,67	5,30	-0,1	-0,2	-0,3	0,4
16	5,15	4,65	5,21	5,86	5,74	-0,5	0,1	0,7	0,6
17	[5,11]	NE	NE	NE	NE	-	-	-	-
18	5,20	4,82	4,71	5,67	5,61	-0,4	-0,5	0,5	0,4
19	5,31	4,51	4,64	5,31	5,43	-0,8	-0,7	0,0	0,1
20	5,32	4,66	4,94	5,53	5,33	-0,7	-0,4	0,2	0,0
21	5,44	5,02	4,79	5,82	5,58	-0,4	-0,7	0,4	0,1
MEAN	5,248	4,686	5,008	5,474	5,685				
ST. DEV.	0,333	0,222	0,378	0,577	0,622				
MIN	4,50	4,25	4,58	4,64	4,96				
MAX	6,03	5,05	5,97	7,03	7,98				
MSE	0,075	0,050	0,085	0,129	0,139				

Legend: NE = not evaluated

VARIATION (%) vs T0			
T1h	T6h	T24h	T48h
-10,7%	-4,6%	4,3%	8,3%

Statistical analysis: Dunnett test p<0,05 T1h vs T0 ; Tukey test p<0,05 at T1h vs prot. 2648

Test code
E0715

INSTRUMENTAL EVALUATION

TEWL (Transepidermal Water Loss)

LIPOGEL SOLUZIONE P 1% (prot. 2647)

VOL N.	T0 - BASELINE (immediately after stripping)		T1h (1 hour after product application)		T6h (6 hours after product application)		T24h (24 hours after product application)		T48h (48 hours after product application)		Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
	mean value	st.dev	mean value	st.dev	mean value	st.dev	mean value	st.dev	mean value	st.dev	mean value	mean value	mean value	mean value
1	25,0	0,17	19,0	0,11	26,2	0,39	28,6	0,07	19,9	0,41	-6,0	1,2	3,6	-5,1
2	20,3	0,16	15,9	0,41	15,9	0,19	17,8	0,33	15,6	0,29	-4,4	-4,4	-2,5	-4,7
3	17,7	0,30	16,4	0,19	17,0	0,32	17,5	0,26	17,2	0,37	-1,3	-0,7	-0,2	-0,5
4	15,0	0,17	13,1	0,26	15,6	0,34	13,9	0,08	8,8	0,17	-2,0	0,6	-1,1	-6,2
5	20,2	0,19	17,8	0,28	23,3	0,15	21,8	0,16	18,4	0,21	-2,4	3,1	1,6	-1,8
6	17,1	0,10	15,6	0,25	18,1	0,17	16,1	0,19	15,8	0,05	-1,5	1,0	-1,0	-1,3
7	42,8	0,25	27,5	0,35	32,0	0,30	22,4	0,33	12,7	0,37	-15,3	-10,8	-20,4	-30,1
8	23,3	0,25	18,0	0,50	23,2	0,24	19,2	0,90	16,1	0,34	-5,3	-0,1	-4,1	-7,2
9	18,5	0,22	15,9	0,68	18,1	0,14	18,7	0,10	17,5	0,19	-2,6	-0,4	0,2	-1,0
10	15,1	0,54	10,9	0,47	12,9	0,17	12,9	0,40	12,9	0,26	-4,2	-2,2	-2,2	-2,2
11	16,5	0,12	15,8	0,28	17,1	0,08	18,8	0,13	14,9	0,12	-0,7	0,6	2,3	-1,6
12	17,3	0,16	16,6	0,55	17,4	0,23	17,2	0,51	18,2	0,07	-0,7	0,1	-0,1	0,9
13	19,2	0,34	10,6	0,11	16,5	0,35	10,3	0,48	10,9	0,31	-8,6	-2,7	-8,9	-8,3
14	17,3	0,48	19,0	0,33	21,9	0,34	18,4	0,26	21,5	0,19	1,7	4,6	1,1	4,2
15	19,2	0,43	11,1	0,59	14,4	0,23	15,0	0,14	10,9	0,36	-8,1	-4,8	-4,2	-8,3
16	20,8	0,41	18,1	0,11	26,2	0,18	17,4	0,26	19,4	0,06	-2,7	5,4	-3,4	-1,4
17	[4,8]	[0,54]	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-
18	15,1	0,26	15,3	0,13	15,7	0,20	16,1	0,25	13,2	0,17	0,2	0,6	1,0	-1,9
19	19,9	0,13	19,1	0,28	18,0	0,42	23,3	0,20	19,6	0,43	-0,8	-1,9	3,4	-0,3
20	18,6	0,35	16,4	0,24	16,4	0,69	15,3	0,15	15,9	0,29	-2,2	-2,2	-3,3	-2,7
21	20,1	0,28	19,9	0,13	17,6	0,13	19,5	0,43	24,4	0,63	-0,2	-2,5	-0,6	4,3
MEAN	19,95	0,266	16,60	0,313	19,18	0,263	18,01	0,282	16,19	0,265				
ST.DEV.	5,961	0,125	3,761	0,172	4,784	0,138	4,014	0,195	3,892	0,145				
MSE	1,333	0,028	0,841	0,038	1,070	0,031	0,898	0,044	0,870	0,032				
MIN	15,0	0,10	10,6	0,11	12,9	0,08	10,3	0,07	8,8	0,05				
MAX	42,8	0,54	27,5	0,68	32,0	0,69	28,6	0,90	24,4	0,63				

% VARIATION vs BASELINE			
T1h	T6h	T24h	T48h
-16,8%	-3,9%	-9,7%	-18,8%

Legend: NE = not evaluated

Statistical analysis: Dunnett test p<0,05 T1h and T48h vs T0

Test code
E0715

INSTRUMENTAL EVALUATION

TEWL (Transepidermal Water Loss)

IDROGEL SOLUZIONE B (prot. 2650)

VOL N.	T0 - BASELINE (immediately after stripping)		T1h (1 hour after product application)		T6h (6 hours after product application)		T24h (24 hours after product application)		T48h (48 hours after product application)		Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
	mean value	st.dev	mean value	st.dev	mean value	st.dev	mean value	st.dev	mean value	st.dev	mean value	mean value	mean value	mean value
1	33,9	0,40	19,5	0,21	27,3	0,38	24,5	0,35	17,4	0,89	-14,4	-6,6	-9,4	-16,5
2	19,6	0,15	13,2	0,21	14,3	0,41	15,0	0,21	13,0	0,65	-6,4	-5,3	-4,6	-6,6
3	17,5	0,18	16,9	0,17	16,1	0,24	18,1	0,21	19,8	0,04	-0,6	-1,4	0,6	2,3
4	16,4	0,16	7,7	0,15	11,6	0,05	8,6	0,42	4,7	0,23	-8,7	-4,8	-7,8	-11,7
5	16,6	0,07	15,5	0,14	15,0	0,29	16,4	0,05	14,6	0,09	-1,1	-1,6	-0,2	-2,0
6	17,8	0,25	16,2	0,12	18,1	0,14	17,8	0,10	16,9	0,19	-1,6	0,3	0,0	-0,9
7	30,8	0,25	35,9	0,32	28,5	0,27	24,4	0,69	15,9	0,15	5,1	-2,3	-6,4	-14,9
8	21,5	0,19	19,2	0,20	28,4	0,45	20,0	0,25	17,5	0,38	-2,3	6,9	-1,5	-4,0
9	16,7	0,14	16,8	0,13	22,0	0,34	14,2	0,44	14,3	0,28	0,1	5,3	-2,5	-2,4
10	21,5	0,69	18,6	0,23	20,2	0,25	21,5	0,16	21,1	0,16	-2,9	-1,3	0,0	-0,4
11	15,7	0,25	13,8	0,39	16,2	0,16	15,6	0,10	13,2	0,68	-1,9	0,5	-0,1	-2,5
12	17,6	0,19	19,4	0,41	17,6	0,69	19,2	0,14	18,4	0,26	1,8	0,0	1,6	0,8
13	29,5	0,48	12,4	0,30	16,4	0,74	9,6	0,30	15,8	0,15	-17,1	-13,1	-19,9	-13,7
14	17,3	0,88	18,6	0,37	19,5	0,37	17,1	0,43	17,4	0,16	1,3	2,2	-0,2	0,1
15	32,9	0,28	20,6	0,14	15,7	0,12	14,8	0,65	14,5	0,50	-12,3	-17,2	-18,1	-18,4
16	17,0	0,29	16,4	0,62	17,8	0,30	17,5	0,22	18,7	0,10	-0,6	0,8	0,5	1,7
17	[3,2]	[0,19]	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-
18	15,8	0,38	8,7	0,34	14,7	0,22	14,8	0,18	12,0	0,13	-7,1	-1,1	-1,0	-3,8
19	18,0	0,22	15,9	0,31	17,2	0,22	18,1	0,19	17,1	0,08	-2,1	-0,8	0,1	-0,9
20	18,2	0,17	16,2	0,20	16,2	0,15	15,5	1,03	14,4	0,16	-2,0	-2,0	-2,7	-3,8
21	19,8	0,22	20,0	0,30	19,5	0,19	19,3	0,26	19,4	0,33	0,2	-0,3	-0,5	-0,4
MEAN	20,71	0,292	17,08	0,263	18,62	0,299	17,10	0,319	15,81	0,281				
ST.DEV.	5,952	0,196	5,654	0,125	4,679	0,176	4,006	0,240	3,574	0,230				
MSE	1,331	0,044	1,264	0,028	1,046	0,039	0,896	0,054	0,799	0,051				
MIN	15,7	0,07	7,7	0,12	11,6	0,05	8,6	0,05	4,7	0,04				
MAX	33,9	0,88	35,9	0,62	28,5	0,74	24,5	1,03	21,1	0,89				

% VARIATION vs BASELINE			
T1h	T6h	T24h	T48h
-17,5%	-10,1%	-17,4%	-23,7%

Legend: NE = not evaluated

Statistical analysis: Dunnett test p<0,05 T1h and T48h vs T0

Test code
E0715

INSTRUMENTAL EVALUATION

TEWL (Transepidermal Water Loss)

LIPOGEL SOLUZIONE CONTROLLO 1% (prot. 2648)

VOL N.	T0 - BASELINE (immediately after stripping)		T1h (1 hour after product application)		T6h (6 hours after product application)		T24h (24 hours after product application)		T48h (48 hours after product application)		Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
	mean value	st.dev	mean value	st.dev	mean value	st.dev	mean value	st.dev	mean value	st.dev	mean value	mean value	mean value	mean value
1	32,2	0,33	23,0	0,40	21,5	0,33	22,8	0,20	18,1	1,92	-9,2	-10,7	-9,4	-14,1
2	19,0	0,27	7,9	0,24	7,6	0,14	13,0	0,18	9,2	0,11	-11,1	-11,4	-6,0	-9,8
3	16,2	0,19	14,5	0,38	15,0	0,10	15,6	0,23	16,8	0,08	-1,7	-1,2	-0,6	0,6
4	21,1	0,90	19,6	0,23	23,0	0,21	19,7	0,10	11,0	0,14	-1,5	1,9	-1,4	-10,1
5	18,1	0,07	19,6	0,14	21,6	0,43	26,4	0,44	18,2	0,10	1,5	3,5	8,3	0,1
6	19,5	0,12	16,5	0,20	18,3	0,16	17,0	0,19	16,3	0,22	-3,0	-1,2	-2,5	-3,2
7	37,9	0,39	23,4	0,19	27,9	0,21	24,7	0,27	16,0	0,23	-14,5	-10,0	-13,2	-21,9
8	18,9	0,33	13,7	0,21	15,3	0,37	13,5	0,25	11,9	0,15	-5,2	-3,6	-5,4	-7,0
9	17,6	0,21	17,0	0,12	21,5	0,34	16,7	0,37	17,6	0,63	-0,6	3,9	-0,9	0,0
10	25,9	0,45	18,7	0,21	21,5	0,49	18,4	0,50	15,8	0,22	-7,2	-4,4	-7,5	-10,1
11	17,5	0,07	18,3	0,17	17,8	0,17	16,1	0,26	14,7	0,12	0,8	0,3	-1,4	-2,8
12	17,6	0,15	15,7	0,52	17,3	0,45	17,2	0,75	17,8	0,29	-1,9	-0,3	-0,4	0,2
13	21,4	0,21	13,0	1,31	20,0	0,39	18,2	0,36	17,6	0,43	-8,4	-1,4	-3,2	-3,8
14	17,6	0,12	15,5	0,30	17,9	0,12	16,8	0,33	18,8	0,30	-2,1	0,3	-0,8	1,2
15	16,6	0,20	12,2	0,10	13,8	0,23	13,2	0,45	12,8	0,21	-4,4	-2,8	-3,4	-3,8
16	20,4	0,42	19,7	0,13	19,2	0,26	16,4	0,30	20,1	0,49	-0,7	-1,2	-4,0	-0,3
17	[5,5]	[0,26]	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-
18	18,4	0,19	15,5	0,58	15,9	0,10	15,8	0,24	13,6	0,68	-2,9	-2,5	-2,6	-4,8
19	18,2	0,13	17,5	0,04	15,8	0,48	18,1	0,68	16,6	0,55	-0,7	-2,4	-0,1	-1,6
20	22,0	0,35	17,7	0,73	20,9	0,49	20,1	0,21	19,1	0,43	-4,3	-1,1	-1,9	-2,9
21	23,3	1,22	18,9	0,79	21,1	0,39	20,1	0,37	20,6	0,55	-4,4	-2,2	-3,2	-2,7
MEAN	20,97	0,316	16,90	0,350	18,65	0,293	17,99	0,334	16,13	0,393				
ST.DEV.	5,452	0,283	3,641	0,308	4,229	0,138	3,556	0,165	3,074	0,406				
MSE	1,219	0,063	0,814	0,069	0,946	0,031	0,795	0,037	0,687	0,091				
MIN	16,2	0,07	7,9	0,04	7,6	0,10	13,0	0,10	9,2	0,08				
MAX	37,9	1,22	23,4	1,31	27,9	0,49	26,4	0,75	20,6	1,92				

% VARIATION vs BASELINE			
T1h	T6h	T24h	T48h
-19,4%	-11,1%	-14,2%	-23,1%

Legend: NE = not evaluated

Statistical analysis: Dunnett test p<0,05 T1h, T24h and T48h vs T0

Test code
E0715

INSTRUMENTAL EVALUATION

TEWL (Transepidermal Water Loss)

IDROGEL SOLUZIONE CONTROLLO (prot. 2649)

VOL N.	T0 - BASELINE (immediately after stripping)		T1h (1 hour after product application)		T6h (6 hours after product application)		T24h (24 hours after product application)		T48h (48 hours after product application)		Δ (T1h-T0)	Δ (T6h-T0)	Δ (T24h-T0)	Δ (T48h-T0)
	mean value	st.dev	mean value	st.dev	mean value	st.dev	mean value	st.dev	mean value	st.dev	mean value	mean value	mean value	mean value
1	31,7	0,27	25,3	0,40	27,1	0,31	27,5	0,39	19,9	0,37	-6,4	-4,6	-4,2	-11,8
2	19,7	0,17	15,6	0,30	16,3	0,19	11,8	0,49	13,3	0,27	-4,1	-3,4	-7,9	-6,4
3	19,3	0,60	17,3	0,10	19,1	0,14	19,3	0,20	19,2	0,28	-2,0	-0,2	0,0	-0,1
4	15,7	0,18	14,9	0,19	16,7	0,10	14,0	0,17	12,3	0,08	-0,8	1,0	-1,7	-3,4
5	30,5	0,19	27,2	0,20	27,7	0,14	20,3	0,16	15,7	0,56	-3,3	-2,8	-10,2	-14,8
6	19,2	0,22	17,7	0,10	20,2	0,10	19,2	0,58	17,2	0,25	-1,5	1,0	0,0	-2,0
7	34,6	0,32	25,7	0,19	24,2	0,43	19,5	0,94	15,9	0,10	-8,9	-10,4	-15,1	-18,7
8	32,1	0,12	23,9	0,22	26,2	0,26	23,1	0,30	17,0	0,10	-8,2	-5,9	-9,0	-15,1
9	15,9	0,10	14,8	0,05	19,7	0,24	13,9	0,24	14,7	0,82	-1,1	3,8	-2,0	-1,2
10	21,7	0,39	15,3	0,19	10,5	0,39	19,2	0,26	14,2	0,26	-6,4	-11,2	-2,5	-7,5
11	20,8	0,18	18,5	0,17	21,0	0,17	16,2	0,43	16,3	0,33	-2,3	0,2	-4,6	-4,5
12	15,5	0,22	16,5	0,19	21,1	0,28	13,4	0,38	14,3	0,69	1,0	5,6	-2,1	-1,2
13	21,4	0,32	15,4	0,20	21,2	0,31	17,9	0,45	15,9	0,42	-6,0	-0,2	-3,5	-5,5
14	17,4	0,11	16,4	0,39	16,1	0,90	16,1	1,71	18,0	0,13	-1,0	-1,3	-1,3	0,6
15	20,8	0,10	20,3	0,37	22,3	0,19	23,5	0,10	21,9	0,04	-0,5	1,5	2,7	1,1
16	17,0	0,67	20,3	0,15	20,2	0,20	18,3	0,08	20,9	0,31	3,3	3,2	1,3	3,9
17	[6,4]	[0,25]	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-
18	17,7	0,13	10,7	0,15	13,1	0,22	15,2	0,36	14,4	0,15	-7,0	-4,6	-2,5	-3,3
19	16,9	0,94	15,6	0,90	18,5	0,18	16,7	0,23	15,6	0,94	-1,3	1,6	-0,2	-1,3
20	22,3	0,11	19,0	1,71	21,9	0,52	20,3	0,35	19,3	0,85	-3,3	-0,4	-2,0	-3,0
21	24,6	0,17	16,6	0,52	22,7	0,12	22,2	0,24	21,3	0,27	-8,0	-1,9	-2,4	-3,3
MEAN	21,74	0,276	18,35	0,335	20,29	0,270	18,38	0,403	16,87	0,361				
ST.DEV.	5,921	0,222	4,276	0,375	4,382	0,186	3,889	0,363	2,776	0,272				
MSE	1,324	0,050	0,956	0,084	0,980	0,042	0,870	0,081	0,621	0,061				
MIN	15,5	0,10	10,7	0,05	10,5	0,10	11,8	0,08	12,3	0,04				
MAX	34,6	0,94	27,2	1,71	27,7	0,90	27,5	1,71	21,9	0,94				

% VARIATION vs BASELINE			
T1h	T6h	T24h	T48h
-15,6%	-6,7%	-15,5%	-22,4%

Legend: NE = not evaluated

Statistical analysis: Dunnett test p<0,05 T1h, T24h and T48h vs T0

Test code
E0715

INSTRUMENTAL EVALUATION

PROFILOMETRY (Surface microrelief)
Sa (arithmetic roughness)

LIPOGEL SOLUZIONE P 1% (prot. 2647)

VOL N.	T0 - BASELINE (immediately after stripping)	T48h (48 hours after product application)	Δ (T48h-T0)
1	26	30	4
2	17	17	0
3	25	24	-1
4	21	26	5
5	16	19	3
6	21	21	0
7	18	22	4
8	21	24	3
9	31	34	3
10	15	18	3
11	23	24	1
12	15	15	0
13	19	18	-1
14	17	15	-2
15	15	12	-3
16	19	23	4
17	[27]	NE	-
18	24	21	-3
19	17	15	-2
20	25	23	-2
21	17	20	3
MEAN	20,1	21,1	
ST.DEV	4,400	5,326	
MIN	15	12	
MAX	31	34	
MSE	0,984	1,191	

LEGEND: NE= not evaluated

% VARIATION vs BASELINE
5,0%

INSTRUMENTAL EVALUATION

PROFILOMETRY (Surface microrelief)
Sa (arithmetic roughness)

IDROGEL SOLUZIONE B (prot. 2650)

VOL N.	T0 - BASELINE (immediately after stripping)	T48h (48 hours after product application)	Δ (T48h-T0)
1	24	27	3
2	15	19	4
3	31	31	0
4	20	20	0
5	15	18	3
6	22	22	0
7	20	20	0
8	18	20	2
9	35	34	-1
10	14	18	4
11	20	22	2
12	15	17	2
13	18	17	-1
14	17	15	-2
15	11	11	0
16	22	28	6
17	[26]	NE	-
18	26	29	3
19	15	16	1
20	24	24	0
21	17	20	3
MEAN	20,0	21,4	
ST.DEV	5,916	5,826	
MIN	11	11	
MAX	35	34	
MSE	1,323	1,303	

LEGEND: NE= not evaluated

% VARIATION vs BASELINE
7,0%

Statistical analysis: Student t test p<0,01 vs T0

INSTRUMENTAL EVALUATION

PROFILOMETRY (Surface microrelief)
Sa (arithmetic roughness)

LIPOGEL SOLUZIONE CONTROLLO 1% (prot. 2648)

VOL N.	T0 - BASELINE (immediately after stripping)	T48h (48 hours after product application)	Δ (T48h-T0)
1	22	23	1
2	16	19	3
3	20	24	4
4	26	22	-4
5	17	16	-1
6	20	21	1
7	17	20	3
8	21	20	-1
9	31	34	3
10	16	20	4
11	19	20	1
12	14	16	2
13	16	14	-2
14	17	14	-3
15	14	15	1
16	22	25	3
17	[22]	NE	-
18	22	22	0
19	19	16	-3
20	21	22	1
21	16	23	7
MEAN	19,3	20,3	
ST.DEV	4,143	4,658	
MIN	14	14	
MAX	31	34	
MSE	0,927	1,042	

LEGEND: NE= not evaluated

% VARIATION vs BASELINE
5,2%

INSTRUMENTAL EVALUATION

PROFILOMETRY (Surface microrelief)
Sa (arithmetic roughness)

IDROGEL SOLUZIONE CONTROLLO (prot. 2649)

VOL N.	T0 - BASELINE (immediately after stripping)	T48h (48 hours after product application)	Δ (T48h-T0)
1	24	25	1
2	14	20	6
3	30	35	5
4	22	20	-2
5	16	15	-1
6	23	24	1
7	16	18	2
8	18	16	-2
9	34	30	-4
10	18	21	3
11	17	22	5
12	15	15	0
13	16	15	-1
14	16	15	-1
15	20	12	-8
16	32	25	-7
17	[28]	NE	-
18	21	24	3
19	14	14	0
20	21	18	-3
21	16	22	6
MEAN	20,2	20,3	
ST.DEV	5,914	5,796	
MIN	14	12	
MAX	34	35	
MSE	1,322	1,296	

LEGEND: NE= not evaluated

% VARIATION vs BASELINE
0,5%

STATISTICAL ANALYSIS

SUMMARY TABLES

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Test code
E0715

STATISTICAL ANALYSIS - SUMMARY TABLE

CLINICAL ASSESSMENT

ERYTHEMA VISUAL SCORE comparison vs T0	Friedman test	Dunnett test	
	p-value	Times	Significance
Lipogel soluzione P 1%	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	NS
		T0-T24h	*p<0,05
		T0-T48h	*p<0,05
Idrogel soluzione B	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	*p<0,05
		T0-T24h	*p<0,05
		T0-T48h	*p<0,05
Lipogel soluzione controllo 1%	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	NS
		T0-T24h	*p<0,05
		T0-T48h	*p<0,05
Idrogel soluzione controllo	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	NS
		T0-T24h	*p<0,05
		T0-T48h	*p<0,05

	Kruskal Wallis test		
	p-value	Times	Significance
ERYTHEMA VISUAL SCORE products comparison time by time	0,492	**T0**	NS
	1,000	**T1h**	NS
	1,000	**T6h**	NS
	1,000	**T24h**	NS
	1,000	**T48h**	NS

Legend: S = statistically significative NS = statistically not significative

STATISTICAL ANALYSIS - SUMMARY TABLE

INSTRUMENTAL EVALUATION (1)

OPTICAL DENSITOMETRY comparison vs T0	ANOVA test	Dunnett test	
	p-value	Times	Significance
Lipogel soluzione P 1%	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	*p<0,05
		T0-T24h	*p<0,05
		T0-T48h	*p<0,05
Idrogel soluzione B	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	*p<0,05
		T0-T24h	*p<0,05
		T0-T48h	*p<0,05
Lipogel soluzione controllo 1%	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	*p<0,05
		T0-T24h	*p<0,05
		T0-T48h	*p<0,05
Idrogel soluzione controllo	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	*p<0,05
		T0-T24h	*p<0,05
		T0-T48h	*p<0,05

	ANOVA test		
	p-value	Times	Significance
OPTICAL DENSITOMETRY products comparison time by time	0,861	**T0**	NS
	0,909	**T1h**	NS
	0,600	**T6h**	NS
	0,848	**T24h**	NS
	0,807	**T48h**	NS

Legend: S = statistically significative NS = statistically not significative

STATISTICAL ANALYSIS - SUMMARY TABLE

INSTRUMENTAL EVALUATION (2)

OPTICAL COLORIMETRY a* parameter comparison vs T0	ANOVA test	Dunnett test	
	p-value	Times	Significance
Lipogel soluzione P 1%	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	*p<0,05
		T0-T24h	*p<0,05
		T0-T48h	*p<0,05
Idrogel soluzione B	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	*p<0,05
		T0-T24h	*p<0,05
		T0-T48h	*p<0,05
Lipogel soluzione controllo 1%	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	*p<0,05
		T0-T24h	*p<0,05
		T0-T48h	*p<0,05
Idrogel soluzione controllo	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	*p<0,05
		T0-T24h	*p<0,05
		T0-T48h	*p<0,05

	ANOVA test		
	p-value	Times	Significance
OPTICAL COLORIMETRY a* parameter products comparison time by time	0,892	**T0**	NS
	0,986	**T1h**	NS
	0,953	**T6h**	NS
	0,963	**T24h**	NS
	0,924	**T48h**	NS

Legend: S = statistically significative NS = statistically not significative

STATISTICAL ANALYSIS - SUMMARY TABLE

INSTRUMENTAL EVALUATION (3)

SKIN ELECTRICAL CAPACITANCE comparison vs T0	ANOVA test	Dunnett test	
	p-value	Times	Significance
Lipogel soluzione P 1%	0.000 S	T0-T1h	NS
		T0-T6h	*p<0,05
		T0-T24h	NS
		T0-T48h	NS
		T1h-T6h	NS
		T1h-T24h	*p<0,05
		T1h-T48h	*p<0,05
		T6h-T24h	*p<0,05
		T6h-T48h	*p<0,05
		T24h-T48h	NS
Idrogel soluzione B	0.000 S	T0-T1h	*p<0,05
		T0-T6h	NS
		T0-T24h	NS
		T0-T48h	*p<0,05
		T1h-T6h	NS
		T1h-T24h	*p<0,05
		T1h-T48h	*p<0,05
		T6h-T24h	*p<0,05
		T6h-T48h	*p<0,05
		T24h-T48h	NS
Lipogel soluzione controllo 1%	0.000 S	T0-T1h	NS
		T0-T6h	NS
		T0-T24h	NS
		T0-T48h	*p<0,05
		T1h-T6h	NS
		T1h-T24h	NS
		T1h-T48h	*p<0,05
		T6h-T24h	*p<0,05
		T6h-T48h	*p<0,05
		T24h-T48h	*p<0,05
Idrogel soluzione controllo	0.000 S	T0-T1h	*p<0,05
		T0-T6h	*p<0,05
		T0-T24h	NS
		T0-T48h	*p<0,05
		T1h-T6h	NS
		T1h-T24h	*p<0,05
		T1h-T48h	*p<0,05
		T6h-T24h	*p<0,05
		T6h-T48h	*p<0,05
		T24h-T48h	NS

	Anova test		
	p-value	Times	Significance
SKIN ELECTRICAL CAPACITANCE products comparison time by time	0,947	T0	NS
	0,188	T1h	NS
	0,287	T6h	NS
	0,654	T24h	NS
	0,902	T48h	NS

Legend: S = statistically significative NS = statistically not significative

Test code
E0715

STATISTICAL ANALYSIS - SUMMARY TABLE
INSTRUMENTAL EVALUATION (4)

DEEP SKIN HYDRATION comparison vs T0	Friedman/Anova test	Dunnett test	
	p-value	Times	Significance
Lipogel soluzione P 1%	0.736 NS	**T0-T1h**	na
		T0-T6h	na
		T0-T24h	na
		T0-T48h	na
Idrogel soluzione B	0.013 S	**T0-T1h**	NS
		T0-T6h	NS
		T0-T24h	NS
		T0-T48h	*p<0,05
Lipogel soluzione controllo 1%	0.031 S	**T0-T1h**	NS
		T0-T6h	NS
		T0-T24h	NS
		T0-T48h	NS
Idrogel soluzione controllo	0.000 S	**T0-T1h**	NS
		T0-T6h	NS
		T0-T24h	*p<0,05
		T0-T48h	NS

	Kruskal Wallis/Anova test		
	p-value	Times	Significance
DEEP SKIN HYDRATION products comparison time by time	0,792	**T0**	NS
	1,000	**T1h**	NS
	1,000	**T6h**	NS
	0,427	**T24h**	NS
	0,896	**T48h**	NS

Legend: S = statistically significative NS = statistically not significative

na = not applicable (Friedman/Anova test not significant)

STATISTICAL ANALYSIS - SUMMARY TABLE
INSTRUMENTAL EVALUATION (5)

EPICUTANEOUS pH comparison vs T0	Friedman/Anova test	Dunnett test	
	p-value	Times	Significance
Lipogel soluzione P 1%	0.0100 S	**T0-T1h**	NS
		T0-T6h	NS
		T0-T24h	NS
		T0-T48h	NS
Idrogel soluzione B	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	NS
		T0-T24h	NS
		T0-T48h	NS
Lipogel soluzione controllo 1%	0.000 S	**T0-T1h**	NS
		T0-T6h	NS
		T0-T24h	*p<0,05
		T0-T48h	*p<0,05
Idrogel soluzione controllo	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	NS
		T0-T24h	NS
		T0-T48h	NS

	Kruskal Wallis/Anova test		Tukey test	
	p-value	Times	Products comparison	Significance
EPICUTANEOUS pH products comparison time by time	0,824 NS	**T0**	-	na
	0,000 S	**T1h**	Lipogel soluzione P 1% vs Idrogel soluzione controllo	S
			Idrogel soluzione B vs Lipogel soluzione P 1%	S
			Idrogel soluzione B vs Lipogel soluzione controllo 1%	S
			Lipogel soluzione controllo 1% vs Idrogel soluzione controllo	S
	0,263 NS	**T6h**	-	na
	1,000 NS	**T24h**	-	na
	0,305 NS	**T48h**	-	na

Legend: S = statistically significative NS = statistically not significative

na = not applicable (Kruskal Wallis/Anova test not significant)

STATISTICAL ANALYSIS - SUMMARY TABLE
INSTRUMENTAL EVALUATION (6)

TEWL comparison vs T0	Friedman test	Dunnett test	
	p-value	Times	Significance
Lipogel soluzione P 1%	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	NS
		T0-T24h	NS
		T0-T48h	*p<0,05
Idrogel soluzione B	0.001 S	**T0-T1h**	*p<0,05
		T0-T6h	NS
		T0-T24h	NS
		T0-T48h	*p<0,05
Lipogel soluzione controllo 1%	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	NS
		T0-T24h	*p<0,05
		T0-T48h	*p<0,05
Idrogel soluzione controllo	0.000 S	**T0-T1h**	*p<0,05
		T0-T6h	NS
		T0-T24h	*p<0,05
		T0-T48h	*p<0,05

	Kruskal Wallis/Anova test		
	p-value	Times	Significance
TEWL products comparison time by time	0,808	**T0**	NS
	1,000	**T1h**	NS
	0,465	**T6h**	NS
	0,757	**T24h**	NS
	1,000	**T48h**	NS

Legend: S = statistically significative NS = statistically not significative

STATISTICAL ANALYSIS - SUMMARY TABLE

INSTRUMENTAL EVALUATION (7)

	SURFACE MICRORELIEF (PROFILOMETRY) comparison vs T0	Wilcoxon/Student t test		
		p-value	Times	Significance
Sa parameter	Lipogel soluzione P 1%	0,1247	**T0-T48h**	NS
	Idrogel soluzione B	0,0054	**T0-T48h**	**p<0,01
	Lipogel soluzione controllo 1%	0,1369	**T0-T48h**	NS
	Idrogel soluzione controllo	0,8514	**T0-T48h**	NS

	Kruskal Wallis/Anova test			
	p-value		Times	Significance
SURFACE MICRORELIEF (PROFILOMETRY) products comparison time by time	Sa	1,000	**T0**	NS
		1,000	**T48h**	NS

Legend: S = statistically significative NS = statistically not significative

PROCEDURE

DermIng S.r.l., Clinical Research and Bioengineering Institute
Viale Cesare Battisti, 38 - 20900 Monza (MB) - ITALY
Tel.: 039/329666 - www.derming.com

Test code
E0715

STUDY PROCEDURE

SHORT TERM EVALUATION OF THE SOOTHING AND RE-EPITHELIZING ACTIVITY OF IDRO/LIPO-GEL FORMULATIONS VS REFERENCE PRODUCTS

Test code: E0715

Sponsor:
Fondazione Samiarc
Via Lanzone, 7
20123 Milano (MI)
Italy

Study conducted by :
DermIng S.r.l. Single Member Company
Clinical Research and Bioengineering Institute
Viale Cesare Battisti, 38
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Italy

Investigators :
Responsible of the Study: Dr. Andrea Pensotti
Fondazione Samiarc

Main Investigator: Dr. Adele Sparavigna
Clinical Research Director DermIng S.r.l.

1. AIM OF THE STUDY

Aim of the study is to evaluate the soothing and re-epithelizing activity of a single application of two idro/lipo-gel formulations on experimentally induced erythema by repeated tape stripping on the skin forearm (volar surface) of 20 healthy volunteers.

2. MATERIALS

- Densitometer X-RITE 404 (U.S.A)
- Chroma meter CR – 200 Minolta (Japan)
- Tewameter® TM300 (MPA 5 Courage-Khazaka, Germany).
- Corneometer CM825 (Courage – Khazaka, Köln, Germany)
- MoistureMeterD (Delfin Technologies, Kuopio - Finland)
- pH meter HI5221 and electrode with flat tip HI11413B (Hanna® Instruments – USA)
- Primos compact portable (GFMesstechnik)
- Clear tape 15.mm (Scotch® 3M – Italy).

3. STUDY DESIGN

Double blind trial conducted by one centre, under the supervision of a dermatologist.
Study products activity will be evaluated versus the reference products.
Five visits will be performed during the study: a basal visit after erythema induction (T0), three intermediate visits 1, 6 and 24 hours after products application (T1h, T6h and T24h) and a final visit after 48 hours (T48h).

4. RECRUITMENT OF THE VOLUNTEERS

4.1. Recruitment, selection and admission

The recruitment, selection and admission procedure of volunteers who accepted, on the basis of free, clear and expressed consent to take part in this study, has been elaborated in order to guarantee clear and precise information about the purposes and the consequences of the research.
This procedure involves a meeting with the investigator who will explain to each volunteer the purposes of the research, the expected duration of the test, the frequency of the examinations, the description of the procedures to be followed, any foreseeable risks to the subject, expected benefits of the test. The volunteer will be able to ask questions and to receive clear and exhaustive answers.
Afterwards, each volunteer must sign a standard consent form that includes the following elements:

I) an explanation of the purposes of the research, the expected duration of the test and frequency of the examinations, a brief description of the procedures to be followed;
II) information about any foreseeable risks to the subject;
III) a description of the expected benefits of the test;
IV) a statement describing the confidentiality of records;
V) name and telephone number of the dermatologist to be contacted for additional information about the research and in case of a research-related injury to the subject;
VI) a statement that the participation in the study is completely voluntary and free of charge;
VII) a statement that the treatment of obtained data is made according to Italian Law n°196 of 30.07.2003;
VIII) a statement that participation in the study can be interrupted by the volunteers without any consequence to them.

The definitive admission of the volunteers is determined by the investigator on the basis of their correspondence to inclusion and exclusion criteria, fixed by protocol, as well as to the interdiction and restriction criteria cited in the protocol.

4.2. Characteristics of the population to be included

The study will be conducted on 20 healthy volunteers of both genders, aged more than 18 years old. The subjects will be precisely informed about the study and will sign a consent form. Any cosmetic treatment and/or exposure to the sun or to UV light, on the test area, will not be permitted during the previous 2 weeks and during all the study period.

4.3. Source

Volunteers are selected from the general volunteer panel belonging to the centre.

4.4. Recruitment of the volunteers

4.4.1. Inclusion criteria

- Adult volunteers of both sexes, aged more than 18 years old
- TEWL value on tested skin areas immedialely after tape stripping $\geq 15 g/m^2$-h
- Volunteers in a good general state of health in the Investigator opinion
- Volunteers not taking drugs or undergoing surgical procedure
- Volunteers who are giving a written informed consent.

4.4.2. Exclusion criteria

4.4.2.1 Dependent on the volunteers' characteristics

- Pregnancy *(only for female subjects)*
- lactation *(only for female subjects)*
- TEWL value on tested skin areas immedialely after tape stripping $<15 g/m^2$-h
- change in the normal habits in the last month
- participation in a similar study during the previous month
- known allergy to one or several ingredients of the products on trial
- insufficient adhesion to the study protocol.

4.4.2.2. Dependent on a clinical condition

- Dermatological disease
- clinical and significant skin condition on the test area (e.g. lesions, scars, malformations)
- diabetes
- endocrine disease
- hepatic, renal or cardiac disorder
- cancer.

4.4.2.3. Dependent on a pharmacological treatment

- Topical drugs or surgical procedure on the test areas during the previous 3 months
- systemic corticosteroids
- aspirin or non-steroid anti-inflammatory drugs (FANS)
- diuretic drugs
- antibiotics and chemotherapics
- pshycotropic drugs
- retinoids
- psoralens
- cardiologic and vascular drugs.

The use of other drugs, not mentioned above, can be authorised by the Investigator. The trade name, the dosage, the start and stop date of the therapy will be reported on the Case Record Form (CRF).

4.5. Restrictions

During the period of treatment normal cleansing habits have to be maintained, sun and UV light exposure, other cosmetic and aesthetic treatments have to be avoided on the tested area.

5. CASE RECORD FORM

The investigator will use an electronic CRF (eCRF) specially engineered "ad hoc" for the study by a trained and specialized DermIng technician. In the eCRF all information about subjects (personal data, subject's history, inclusion/exclusion criteria, clinical evaluations, instrumental data etc.) will be recorded directly on a tablet (interactive form).

The tabulation of the collected data is direct and totally automatic (not manual), assuring an higher level of quality and security.

Every step of the eCRF creation and filling processes are performed in accordance to DermIng internal quality procedure assuring the validation of data and the prevention of data loss.

6. SAMPLE ACCEPTANCE, IDENTIFICATION AND APPLICATION

6.1. Samples record

The products to be tested are recorded, with a reference number, in the Human Studies Record Book together with additional information such as the arrival date, the test requested, Sponsor's name, the product code, the order number and any other information reported on the container.

6.2. Samples storage

Samples to be tested are supplied by the customer and are kept in a dark site at room temperature. During the twelve months following the issue date of the report, a counter-sample will be kept in the same conditions as those described above.

Samples management will be conducted by DermIng according to modalities reported on company operating procedures (SOPs).

6.3. Site of application

Site of application are the forearms (volar surface).

6.4. Quantity of products applied

Test products are applied at the rate of $2mg/cm^2$ for each study area ($14\ cm^2$).

6.5. Application and absorption of the study products

Test products will be applied by the investigator with gloved fingers and light massage, on adjacent cutaneous areas, turning in accordance with a randomization list and left absorbing on the skin.

7. TREATMENT EVALUATION

7.1. Preliminary examination

Volunteers are examined by the Dermatologist who ensures that the skin areas to treat are free from dermatitis and that each volunteer has understood the test, the consent form being completed and signed.

Clinical and instrumental measurements will be performed on each skin tested areas (study and reference products treated areas), in basal conditions (T0 - immediately after stripping execution) and 1 (T1h), 6 (T6h), 24 (T24h) and 48 (T48h) hours from products application.

7.2. Skin erythema induction

Skin erythema will be induced on the subjects' forearms by repeated tape stripping. Tape stripping is a technique used in dermatological research to selectively and exhaustively remove the skin's stratum corneum. In particular the skin of the forearms will be stripped with repeated applications of clear tape 15.mm (Scotch® 3M – Italy); for each skin tested area 40 tape stripping performed by the same specialised technician are required to achieve the barrier disruption.

7.3. Soothing efficacy evaluation

7.3.1. Clinical evaluation of skin erythema

Skin erythema is scored and recorded according to the grades reported in the following table:

0	no erythema
0.5	very slight erythema (barely perceptible)
1	well-defined erythema
1.5	moderate to severe erythema
2	severe erythema (beet redness) to slight eschar formation (injuries in depth).

7.3.2. Instrumental evaluation of skin erythema

7.3.2.1. Optical densitometry

An optical densitometer (X-RITE 404) allows to quantify, on a logarithmic scale, the total reflected optical density (visual=V) and the values of primary subtractive colours of reflected light: cyan(=C), magenta(=M) and yellow(=Y). The erythema index is calculated as follows:

E.I.=logRmagenta-logRcyan

7.3.2.2. Optical colorimetry

Chroma Meter CR-200® is a tri-stimulus colorimeter equipped with three special filters which allows to obtain R,G,B values in accordance with CIE (Commission Internationale de l'Eclarage), the main international organisation concerned with colour and colour measurement.

CIE *L*a*b* system* (CIELAB) is the most complete colour-space specified by the CIE (1976). It describes all the colours visible to the human eye; the three coordinates of ***L*a*b**** represent the lightness of the colour (***L**** = 0 yields black and ***L**** = 100 indicates diffuse white; specular white may be higher), its position between red/magenta and green (***a****, negative values indicate green while positive values indicate magenta) and its position between yellow and blue (***b****, negative values indicate blue and positive values indicate yellow).

7.4. Re-epithelizing efficacy evaluation

7.4.1. Transepidermal water loss (TEWL)

In normal intact skin, the stratum corneum is a very effective barrier so the water loss rate, which is expressed in terms of the amount of water evaporated per unit area of skin (TEWL) in absence of sweating, is low. The measurement of TEWL allows to objectively monitor skin responses to cosmetic treatments. Decreased water loss rates accompany treatments which occlude skin surface (e.g. lipid coating). Occlusion of the skin is not cosmetically accepted. A shift from high water loss rates in subjects with altered skin barrier function to normal rates could mean skin lipids replacement and restored barrier function. On the contrary a shift from low-normal rates of TEWL

to high levels is due to barrier disruption. In case of moisturising products, humectant ingredients may act by encouraging the normal circulation of water from low layers of the epidermis and allow this water to evaporate from the surface.

7.4.2. Electrical capacitance of skin (superficial hydration)
Superficial hydration is measured by the instrument Corneometer CM825 (Courage – Khazaka, Köln, Germany): a square sensor (49mm^2) frontally covered by a special glass, mounted on a spring cursor able to measure electrical capacity. Leaning the sensor on the skin surface, with a constant pressure thanks to the spring cursor it is possible to perform measures. The sensor acts as a capacitor. When a voltage is applied to this capacitor, the quantity of electric charge stored will be dependent on the dielectric properties of the material in contact with the probe. Water has an unusually high dielectric constant and so its presence in the skin is readily detectable by this method. So the measure of the skin capacitance properties is an indirect expression of its hydration level.
To reduce the variability of measurement methods, for each volunteer, three measures on the same skin area will be executed: the adjusted mean will be considered as the real measure value.

7.4.3. Tissue dielectric constant of deep skin layers (deep hydration)
The MoistureMeterD measures non-invasively the dielectric constant of the skin and subcutaneous fat. The dielectric constant is a dimensionless physical quantity and it is directly proportional to the water content in the measured tissue. The MoistureMeterD generates a high frequency, low power electromagnetic (EM) wave which the tissue is exposed to. The reflected EM wave is registered and the obtained value is a dielectric constant, which is proportional to the water content of the measured tissue; the measured value increases when water content increases.
The dielectric constant of water molecules depends on the used radiofrequency. Free and bound water behave electrically differently with different frequencies. At around 300 MHz, the electrical properties of free and bound water are quite identical, thus the MoistureMeterD measures changes in the total water content of the tissue.
The measurement depth can be determined by using differently sized probes (the deeper the measurement need the larger the probe); for this study a 1.5 mm depth probe was used.

7.4.4. Epicutaneous pH
Surface cutaneous pH represents a useful signal of epidermis state health.
The hydrogenionic concentration on cutaneous surface is measured by an instrument composed by a flat combined bottom cylindrical sensor. Measurements are performed by leaning the electrode flat tip on skin surface; after few seconds on the display appears the pH value.

7.4.5. Microrelief surface evaluation (profilometry)
The microrelief surface evaluation is determined with the "surface roughness evaluation" function in the Primos 3d portable software. Through the use of this function, the software evaluates the whole area of the acquired image. Once evaluation is complete, all the surface parameters are saved in an external file, which will then be imported into an excel table.
The primary profilometric parameter analyzed in this study will be Sa (average roughness), that represents an overall measure of the surface texture.

7.5. Standard conditions for the treatment evaluations
Before the clinical and instrumental measurements the volunteer will be acclimatised under relax conditions for at least 15 min. During the 3 hours before the test, the volunteer must not smoke,

drink coffee or alcohol and must not use on the skin test area any product. The instrumental measurements are performed under standard environmental conditions (Temperature=22+\-2°C; Relative Humidity<60%).

8. SCHEDULE OF STUDY PROCEDURE

8.1. Baseline visit (T0)

The visit includes:

- filling the CRF (personal data)
- visual examination of the tested side
- identification and assignment of 4 skin areas under test on the forearms (according to a randomisation list)
- skin erythema induction (repeated tape stripping)
- clinical and instrumental evaluation (clinical and instrumental assessment of skin erythema and pH, TEWL, superficial and deep hydration measurement).
- profilometry skin image acquisition
- study products application.

8.2. Intermediate visits (1, 6 and 24 hours after products application)

These visits includes:

- clinical and instrumental evaluation (clinical and instrumental assessment of skin erythema and pH, TEWL, superficial and deep hydration measurement).

8.3. Final visit (48 hours after products application)

These visit includes:

- clinical and instrumental evaluation (clinical and instrumental assessment of skin erythema and pH, TEWL, superficial and deep hydration measurement)
- profilometry skin image acquisition.

9. PREMATURE END OF THE STUDY/ END OF THE STUDY

9.1. Withdrawal criteria

Any person who in the course of the trial:

- decides to withdraw the consent for any reason
- does not present to the study visits
- does not comply with the treatment
- develops any of the conditions specified in the original exclusion criteria
- contracts a serious illness that does not allow the study continuation.

9.2. Procedure

All breaks in a volunteer's participation in the trial have to be recorded in the study termination form the reasons for discontinuation being mentioned. In case of volunteers did not perform the expected visit, the Investigator has to try to understand the reason of the absence.

9.3. Restrictions

The volunteers who stop the trial, cannot be enrolled again or be replaced by other volunteers with the same randomization number.

10. STATISTICAL ANALYSIS PLAN

10.1. Main criteria

The statistical evaluations of clinical and instrumental data (adjusted means and standard deviation) and relative graphs will be performed at the times required by the protocol. The values will be rounded off to the decimal in accordance to our internal procedures.

10.2. Population description

This sample includes all subjects that completed the study according to the protocol.

10.3. Clinical data

The statistical analysis of clinical data is carried out with not parametric test.

10.4. Instrumental data

The analysis of all numeric parameters (arithmetic mean, standard deviation) are carried out by non-parametric test (Friedman/Kruskal Wallis test) when the normality hypothesis is rejected by the Shapiro-Wilk normality test (threshold at 5%) and by parametric test (one way ANOVA/ANOVA for repeated measures), when the normality hypothesis is confirmed.

10.5. Statistical plan

The activity of the tested products at T1h, T6h, T24h and T48h will be expressed in absolute values versus baseline (T0) and in comparison to each other.

11. QUALITY CONTROL AND ASSURANCE

This trial is carried out by DermIng in accordance with the methods described in the company standard operating procedures (SOP). The information and data on the trial are generated, recorded, documented and processed in accordance with the methods described in the following procedure, based on ICH GCP 1996.

12. ETHIC

12.1. Commitment attestation of insurance

The test starts only after the evaluation of the documentation provided by the Sponsor (with products identification, date and Sponsor signature).

This documentation contains: the declaration that the products are submitted to the E.C.C. legislation, the qualitative composition of the products with the declaration that any component presents a serious toxicological effects at the established concentration, all available data about toxicological and tolerability pre-clinical prove, the normal conditions products use, an attestation of insurance that ensures the risks for volunteers using the articles.

12.2. Consent form for the volunteer

Each volunteer is precisely informed about the study, a consent form being completed and signed (Appendix 1). At the end of the study the investigator will declare to have informed all the volunteers participating it, signing and dating the relative form (Appendix 2).

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14. APPENDICES

1) Information for the volunteers and informed consent form
2) Certificate of subjects information

APPENDICES

DERMING
WHERE DERMATOLOGICAL EXPERIENCE BECOMES RESEARCH

MODULO DI CONSENSO LIBERO E CONSAPEVOLE

INFORMAZIONI

Sono stato invitato/a a partecipare ad uno studio clinico che valuti l'attività lenitiva e ristrutturante di 2 prodotti cosmetici ad uso topico, formulati e prodotti in conformità alla normativa vigente, verso 2 prodotti di riferimento.
In particolare su 4 piccole aree cutanee, 2 per ogni avambraccio (superficie volare), verrà determinato un leggero arrossamento mediante "stripping corneo ripetuto"; si tratta di un semplice strappo di cellule morte di superficie mediante l'utilizzo di scotch, che verrà ripetuto più volte a livello della stessa sede cutanea. Quindi lo sperimentatore applicherà sulle 4 aree una piccola quantità dei prodotti in studio.
Le valutazioni cliniche (valutazione visiva del grado di arrossamento) e le misurazioni sperimentali (indice di eritema, idratazione superficiale e profonda, pH, perdita d'acqua transepidermica, ripresa del microrilievo di superficie), del tutto innocue ed indolori, verranno eseguite dopo 1 ora, 6, 24 e 48 ore dall'applicazione dei prodotti. Nelle 3 ore precedenti le suddette valutazioni no dovrò fumare, bere caffè o alcolici, sottoporre le sedi cutanee oggetto del test ad alcun trattamento.
Per poter partecipare allo studio non devo presentare alterazioni cutanee nell'area destinata al saggio quali ferite, cicatrici, malformazioni ecc. Per questo motivo il dermatologo valuterà lo stato di salute della mia pelle prima di decidere la mia inclusione nella sperimentazione.

CONSENSO

Accetto di partecipare alla prova sopraindicata, ossia:
"Valutazione dell'efficacia lenitiva e ristrutturante di due prodotti cosmetici destinati ad uso topico vs prodotti di riferimento".
Dichiaro di essere stato/a informato/a degli obiettivi, delle condizioni, della durata dello studio, della possibile comparsa di fenomeni di intolleranza al trattamento (ad es. irritazione, allergia ecc.) / art. 13 D.LGS 30 GIUGNO 2003 N°196).
Nulla mi sarà addebitato per la partecipazione al test (la prova è interamente a carico di DermIng) e non riceverò alcun compenso. Anche in caso di accettazione rimango libero/a di interrompere la prova in qualsiasi momento, senza fornire spiegazioni: mi impegno unicamente a comunicare la mia decisione al medico. Dichiaro di aver ricevuto risposte esaurienti relative alle mie domande sullo studio in oggetto. Autorizzo espressamente DermIng ad elaborare sul computer le informazioni che mi riguardano. Avrò la possibilità di avere accesso a queste informazioni, di correggerle o di annullarle (se lo ritengo necessario) presso il Centro DermIng, Viale Cesare Battisti, 38 a Monza (MB) (art. 7 D.LGS 30 GIUGNO 2003 N°196). Accetto inoltre che i risultati di queste ricerche siano comunicati (rispettando l'anonimato) da DermIng alla Società Committente. I dati ottenuti saranno resi anonimi ed utilizzati esclusivamente per scopi scientifici e statistici.
(2 copie di cui una in mio possesso)

Cognome: _____ Nome: _____

Luogo e data di nascita: _____

Indirizzo: _____ Città: _____

Tel.: _____

Firma del volontario: _____ Monza, lì _____

Firma del Responsabile della Prova: _____

Dott.ssa Adele Sparavigna

DermIng S.r.l., Clinical Research and Bioengineering Institute
Viale Cesare Battisti, 38 - 20900 Monza (MB) - Italy
Tel.: 039/329666 - www.derming.com

Test code
E0715

DERMING
WHERE DERMATOLOGICAL EXPERIENCE BECOMES RESEARCH

MODULO DI ARRUOLAMENTO
DermIng, Istituto di Ricerche Cliniche e Bioingegneria

Per poter essere ammessi allo studio in corso il soggetto non deve presentare nessuna delle seguenti condizioni:

- Dermatiti;
- Psoriasi;
- Eczemi;
- Dermatite seborroica;
- Dermatite atopica;
- Orticaria;
- Vitiligine;
- Allergie a prodotti cosmetici;
- Presenza di alterazioni cutanee nell'area destinata all'esecuzione del saggio;
- Diabete;
- Disendocrinie;
- Malattie autoimmunitarie;
- Alterazioni ormonali;
- Malattia epatica evolutiva;
- Insufficienza renale;
- Insufficienza cardiaca;
- Malattie neoplastiche evolutive;
- Tumori della pelle;
- Gravidanza;
- Allattamento.

Per poter essere ammesso allo studio in corso il soggetto non deve essersi sottoposto, nel mese precedente allo studio, a nessuno dei trattamenti sotto elencati:

- Terapia con farmaci topici;
- Terapia sistemica con corticosteroidi, aspirina, antinfiammatori non steroidei;
- Trattamenti farmacologici topici ed interventi di tipo medico e/o chirurgico a livello delle sedi di applicazione eseguite da meno di tre mesi antecedenti lo studio;
- Diuretici;
- Cicli di chemioterapia.

NOME: _____

COGNOME: _____

LUOGO DI NASCITA: _____ DATA DI NASCITA: _____

FIRMA: _____ DATA: _____

DermIng S.r.l., Clinical Research and Bioengineering Institute
Viale Cesare Battisti, 38 - 20900 Monza (MB) - Italy
Tel.: 039/329666 - www.derming.com

Test code
E0715

APPENDIX 2

CERTIFICATE OF SUBJECTS INFORMATION

Regarding the study:

SHORT TERM EVALUATION OF THE SOOTHING AND RE-EPITHELIZING ACTIVITY OF IDRO/LIPO-GEL FORMULATIONS VS REFERENCE PRODUCTS

Test code: E0715

Prot: 2647, 2648, 2649, 2650

I, Dott. Adele Sparavigna,
certify that all subjects were informed about the study protocol modalities and their relatives rights, and that I have obtained their informed consent form.

Date: 05/29/2015

Signature _____

DermIng S.r.l., Clinical Research and Bioengineering Institute Viale Cesare Battisti, 38 - 20900 Monza (MB) - ITALY Tel.: 039/329666 - www.derming.com
Test code E0715