

Assessment in human of the moisturizing effect of Hyal Ceutic after single application to the skin

Instrumental assessment

B. Hannand., A. Ryan., Paul Scannell., Clotilde Quelen.
1. Study Director 2. Quality Assurance Unit 3. Head Manager 4. Scientific Department

Aim and principle of the study

This study intended:

A- To assess the efficacy of **HYAL CEUTIC** on the hydration level of the upper layers of the epidermis after single application to the skin, on the forearm, under strictly controlled conditions.

B- To meet the requirements of the Directive 93/35/EEC of 14/6/93 -Art 7 bis - concerning the justification of the effect claimed in the advertising media.

The hydration level of the upper layers of the skin was quantitatively assessed by capacitance measurements at different experimental times.

The moisturizing effect of the product was assessed by comparing the measurements taken on 2 experimental treated and control areas.

Type of the study

This monocentric study was performed in open. The subject was used as own control. 10 volunteers were included in the study. No volunteer discontinued and no exclusion was decided by the investigator.

Specific inclusion criteria

The specific inclusion criteria, defined in the protocol, were the following ones:

- 1- Age: 18-70 years old.
- 2- Sex: male and female
- 3- Phototype (Fitzpatrick): I to V, dry and hairless skin on the anterior side of the forearms (corneometric index at inclusion < 55).

Methodology

Experimental areas

The experimental areas were the anterior sides of the forearms : one of the forearms, chosen at

random, received the test product, the other one served as untreated control area.

Conditions of product application

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

- 1- Treated area: Application of the product, with a fingerstall by gentle digital massage until penetration, to a delimited skin surface of approximately **25 cm²**, at the rate of 2 mg/cm², once by the responsible technician at the Institute.
- 2- Control area: An area of approximately **25 cm²** was delimited in the same way than for the treated area but received no product.

Instrumental assessment of the moisturizing effect

- 1- Principle: The hydration level of the upper layers of the skin was quantitatively assessed by capacitance measurements at different experimental times. The moisturizing effect of the product was assessed by comparing the measurements taken on the 2 experimental areas.
- 2- Equipment: The measurements were performed with the Corneometer CM 825 PC (Courage & Khazaka) which works at a mean frequency of 1MHz and is equipped with a 0.64 cm' probe made up of 75 μ m electrodes. The capacitance of the system, represented by the electrodes and the upper layers of the skin, being influenced by the changes of the dielectric constant of the skin surface, when the hydration level of the stratum corneum varies, the dielectric properties of this medium are modified and consequently the capacitance of the system is modified.
- 3- Measurement sites: The instrumental measurements were performed on a perfectly defined and documented site, in the centre of the control and treated areas.
- 4- Rate of the measurements: The measurements had to be performed before then 2 and 4 hours (i.e. T0, T2 and T4) after application to the treated area.

5- Assessment criteria: The capacitance values of the system were expressed in arbitrary units ranging from approximately 0 to 120 (corneometric indexes).

6- Expression and interpretation of the results: The interpretation of the results was absolute, referring to :

A- The percentage of "reactive" volunteers at each experimental time: volunteers for whom the difference between the percentage of variation in comparison with TO / treated area and the percentage of variation in comparison with TO / control area is superior or equal to 10%.

B- The mean percentage of skin hydration level improvement due to the product, at each experimental time (difference between the percentage of variation in comparison with TO / treated area and the percentage of variation in comparison with TO / control area).

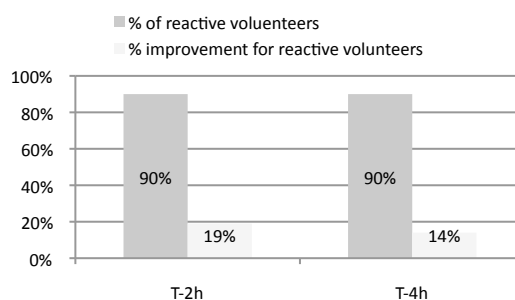
C- The results of the statistical analysis of data (comparison of the values obtained on the control area with those obtained on the treated area using the Anova test for repeated measurements).

Results – Discussion

In brief

Variation of the corneometric indexes in comparison with TO	Experimental times	
	T2h	T4h
Treated area	16,6%	12,0%
Control area	-1,7%	-0,9%
Difference between treated area and control area	18,3%	12,9%
% of "reactive" volunteers	90%	90%
% improvement for "reactive" volunteers	19,3%	13,9%

Maximal moisturizing effect 2 hours after application
% of increase in the corneometric index = 19%



Volunteers for whom the difference between the percentage of variation in comparison with TO / treated area and the percentage of variation in comparison with TO / control area was superior or equal to 10%.

Statistical analysis of the results

The analysis of the results, using the statistical Anova test, shows a statistically significant increase in the corneometric indexes on the treated area, at all the experimental times and therefore a statistically significant moisturizing effect.

Conclusion

Under the experimental conditions adopted and taking into account the evolution of the instrumental parameter considered, the product HYAL CEUTIC has a good moisturizing effect on the upper layers of the epidermis in about 90 % of the volunteers which lasts after 4 hours of application.

Bibliography

Berardesca E , EEMCO guidance for the assessment of stratum comeum hydration: electrical methods, Skin Research and Technology, 1997,3, pp. 126-132

Clarys P , Barel A.O , In vitro calibration of the capacitance method (Corneometer CM 825 ®) and conductance method (Skicon 200 ®) for the evaluation of the hydration state of the skin, Skin Research and Technology, 1997, 3, pp. 107-113

Clarys P , Barel A.O , Gabard B , Noninvasive electrical measurements for the evaluation of the hydration state of the skin : comparison between three conventional instruments - the Comeometer, the Skicon, and the ova DPM, Skin Research and Technology. 1999,5, pp. 14-20

Fluhr J,W , and col. , Comparative study of five instruments measuring stratum comeum hydration (Comeometer CM 820 and CM 825 ®, Skicon 200 ®, Nova DPM 9003 ®, Del111alab ®) Part II In vivo , Skin Research and Technology, 1999,5, pp. 171-178