

Assessment of skin hydration – short term test

Test aim: the test allows the assessment of the possible improvement in skin hydration after a cosmetic treatment.

Subjects undergoing the treatment:

- ❑ n 20 - 60 subjects, age: 18 – 60, sex: M/F
- ❑ Criteria of volunteers selection:
 - Good health condition
 - Absence of skin pathologies
 - Absence of topic pharmacological treatment in progress
 - Negative anamnesis for atopy
 - Obligation not to use any other topic product in treatment area during the 24 hours before measurement
 - Exclusions: women during pregnancy or lactation, minors
- ❑ Every volunteer is given a form to fill in and subscribe in order to express free consent to the test and to the above mentioned conditions.

Experimental procedures: one of the following experimental procedures can be employed

- Active vs placebo
- Positive control or market benchmark of proven efficacy
- Comparison among differently formulated products

Test performance:

- ❑ Random distribution of treatments on controlateral areas
- ❑ Being a short term test based on instrumental detection of results, it is not necessary to perform it with blind or double-blind technique.

Scheme of test performance:

- ❑ Skin hydration is normally measured on the volar surface of the volunteers forearm.
- ❑ Volunteers should be relaxed and acclimatized to the measuring environment for at least 20 minutes (23°C ± 2°C; 50% ± 5% RH). The measurements are carried out by the same operator before treatment and at the following intervals of time from application: 30 - 60 - 90 – 120 - 360 minutes and 24 hours.
- ❑ The sample is applied on precise areas (16cm²/area) and the operator will favour absorption by employing a finger cot for manipulation, thus granting an average application equal to 2 mg product/cm².

Instrumentation: All measurements are carried out by Cornemeter CM 825, a low-frequency instrument to measure "capacitance", sensitive to relative dielectric constant of the material in contact with electrode surface. Skin horny layer is a dielectric medium whose properties vary according to water content. The measurement is based on the great difference between water dielectric constant (81) and the one of the other substances (< 7) and it supplies an estimate of skin water content at a relative depth of 60 - 100µm.

Guidelines: "Assessment of stratum corneum hydration according to EEMCO guidance for the assessment of stratum corneum hydration: electrical methods." Skin Research and Technology 1997; 3: 126-132

Analysis and assessment of results:

- ❑ Criticality assessment
- ❑ Statistic treatment of data: Wilcoxon test (significance level α : 5).

Documentation: a report is compiled with the following structure: identification — objective — significance — work plan — protocol — results — statistics — discussion of results — signature.