

## *Assessment of sebum-normalising action – short term test*

**Test aim:** the test allows the assessment of sebum-normalising action of a cosmetic product, through the quantification of sebaceous secretion before and after treatment. Sebum sampling technique consists of an opaque polymeric belt placed on a rotating support and moved manually after every measurement. The transparency degree of the plastic film is measured by a photocell after the double passage of light through the film. The result is estimated by a microprocessor using an internal standard and it is expressed as  $\mu\text{g}/\text{cm}^2$  of skin lipids.

### **Subjects undergoing the trial:**

- ❑ n 20 - 60 subjects, age: 18 – 60, sex: M/F with greasy skin
- ❑ Criteria of volunteers selection:
  - Good health condition
  - Greasy or unctuous skin
  - 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 subdivision of treatments on controlateral areas
- ❑ As the test is based on instrumental detection of results, it is not necessary to perform it with blind or double-blind technique

### **Scheme of test performance:**

- ❑ Sebaceous secretion is normally measured on the volunteers forehead and temples.
- ❑ Measurements are carried out before treatment and at the following intervals of time from application: 30 - 120 - 360 minutes and 24 hours
- ❑ The sample is applied on precise areas ( $16 \text{ cm}^2/\text{area}$ ) and the operator will favour absorption by employing a finger cot for manipulation, thus granting an average application equal to  $2 \text{ mg product}/\text{cm}^2$ .
- ❑ Before every measurement, volunteers should be relaxed and acclimatized to the measuring environment for at least 20 minutes ( $23^\circ\text{C} \pm 2^\circ\text{C}$ ;  $50\% \pm 5\% \text{ RH}$ ).

**Instrumentation:** The measurement is carried out by SEBUMETER SM810.

**Guidelines:** "EEMCO guidance for the in vivo assessment of Skin Greasiness" Skin Pharmacol Appl Skin Physiol 2000; 13: 372-389

### **Analysis and assessment of results:**

- ❑ Assessment of criticality
- ❑ Statistic treatment of data: Wilcoxon test (significance level  $\alpha$ : 5%)

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