

Ophthalmologic test performed in collaboration with the oculist department of the University of Padua

Test aim: : the test allows the assessment of cosmetic formulations compatibility destined to come into contact with eyes and adjacent areas. The test is performed in order to confirm that the product is not irritating in normal or reasonable expectable usage conditions. In fact the test can be carried out only after a safety surveyor has attested that no significant risk to volunteers is expected in method conditions.

Subjects undergoing the trial:

- n 20 subjects, age: 18 – 60, sex: M/F.
- Criteria of volunteers selection:
 - Good health condition
 - No participation in analogous trials in the two previous months
 - Negative anamnesis for allergenic skin reactions
 - Absence of skin pathologies
 - Absence of topic pharmacological treatment in progress
- 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.

Every volunteer is given a form to fill in and subscribe in order to express free consent to the test and confirm that no condition of test exclusion is present.

Scheme of test performance:

After 30 minutes application of the products, the oculist performs a first assessment of the eventual irritation, scoring both erythema and edema according to a scale from 0 to 4. After 48 hours from the first application, the oculist carries out a second assessment of erythema and/or edema in the same conditions and modalities of the first lecture.

After 30 days of daily application, the oculist perform the third evaluation.

Expression of results:

The average irritation index is defined as the sum of the assessment score of both erythema and edema. The values of irritation index at 30 minutes, at 48 hours, and 30 days are indicated in the experimental report completing the form concerning the volunteers.

Analysis and assessment of results:

It is necessary to calculate - for every product - the mathematical average of all irritation indexes obtained for the 20 volunteers recruited for this test. According to the index, the product is classified as *not irritating, lightly irritating, moderately irritating or strongly irritating*

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