

The test consists in the inoculation, at known titration, of micro-organisms into the product and, through their survival time analysis, in the determination of the preservative system efficacy. Usually pure micro-organisms cultures are used to determine the rates of die-off of each test organism. The inoculated product is preserved at ambient temperature for the whole test duration.

The test method and the acceptance criteria used to determine whether a formula is adequately preserved, are mainly those recommended by the European and Italian Pharmacopoeias (as in the table below). Nevertheless, Chelab carry out test also according to USP method, CTFA method, Japanese Pharmacopoeia or British Pharmacopoeia methods.

Ph. Eur. Acceptance Criteria for topical preparation:

- *Bacteria* :

### Time Criteria

- |            |                 |
|------------|-----------------|
| • 48 hours | no variation    |
| • 7 days   | 3-log reduction |
| • 14 days  | no variation    |
| • 28 days  | no variation    |

- *Mycetes*:

### TimeCriteria

- |           |                 |
|-----------|-----------------|
| • 14 days | 2-log reduction |
| • 28 days | no variation    |