eurofins | BioPharma Product Testing



Bactericidal efficacy for hygienic handwash

Phase2 / Step 2 test according to EN1499:1997

Application field

This European normative is applicable to products for which skin disinfectant efficacy against bacteria is claimed.

It is applicable to products to be used in the area of human medicine. In this area it is applicable to chemical disinfectants and antiseptics to be used in areas and situations where disinfection or antisepsis are medically indicated.

Such indications occur in patient care:

- in hospitals, in community medical facilities and in dental institutions,
- in clinics of schools, in clinics of kindergartens and nursing facilities

and may also occur in the workplace and at home.

It may also include services such as in laundries and kitchens supplying products directly for the patient.

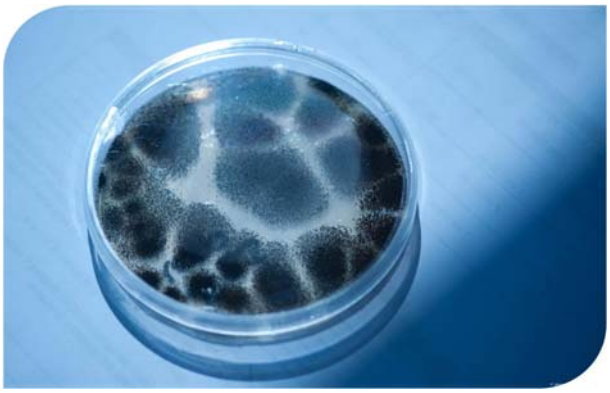
Interests

The aim of the tests schematically reported below is to evaluate the capability of a skin disinfectant product to produce a reduction in the number of viable bacterial cells of the test organism simulating practical conditions.

Principle of the test

The bactericidal effectiveness is verified as follows:

15 volunteers rub their hands for 1 minute with a linseed oil-based soap to remove normal bacterial flora present on the hands.



After, volunteers dip their fingertips in a E. coli K12 suspension for 5 seconds and then let them dry in the air for 3 minutes.

After drying, volunteers dip the same area of the fingers in Petri plates, containing TSB, for 1 minute (initial values).

Immediately after the detection of initial values, each member of the first group composed by 8 volunteers rub the hands for 60 seconds with an amount of soft soap corresponding to about 5 ml per person.

After that, they rinse their hands for 15 seconds under tap water

At the end of hand-rubbing volunteers dip their fingertips in Petri plates containing TSB with neutraliser (final values).

Then the test is repeated exchanging the two groups of volunteers.

Bacterial count is performed on sampling liquids.

Normative references

EN1499:1997 - Chemical Disinfectants and Antiseptics – Hygienic Handwash – Test Method and Requirements.

Restrictions

Alcohol-based lotions or gels must be tested according a different CEN standard (EN1500:1997)



Interpretation of the results

The number of colonies for each Petri plate and the number of ufc/ml of sampling liquid is determined. The calculated ufc/ml value is transformed into common logarithm.

The test is considered valid if the results of 15 subjects are available and if the mean value of initial logarithmic values for the test and reference procedures are 5.00 or more.

The test results have been evaluated in compliance with the following acceptance criteria:

- The average factor of logarithmic reduction that has been obtained must be significantly greater, from a statistical point of view, than the one obtained for reference standard;
- If the average factor of logarithmic reduction of a test product is greater than the one obtained with reference standard, the statistical meaningfulness of differences must be evaluated;
- If the average factor of logarithmic reduction is not significantly greater than the one obtained with reference standard, the product is not compliant with the regulation.

The test of statistical meaningfulness was performed via Wilcoxon test, setting a meaningfulness level p = 0.01.

Amount of samples necessary to the analysis

2x100 ml per test.

TAT from sample arrival

28 days.

Information to be provided with the sample

- name of product or formula code (compulsory)
- batch number (compulsory for studies to be performed under GLP accreditation)
- manufacture date
- expiry date
- storage and stability conditions (compulsory for studies to be performed under GLP accreditation)
- qualitative composition (at least % of active ingredient)
- quantitative composition (at least % of active ingredient)
- dosage (volume and frequency of application)