eurofins | BioPharma Product Testing



Bactericidal efficacy for surgical handrub Phase2 / Step 2 test according to EN12791:2005

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 pre-surgical situations.

Interests

The aim of the test 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

20 subjects are divided into 2 groups of 10 volunteers each.

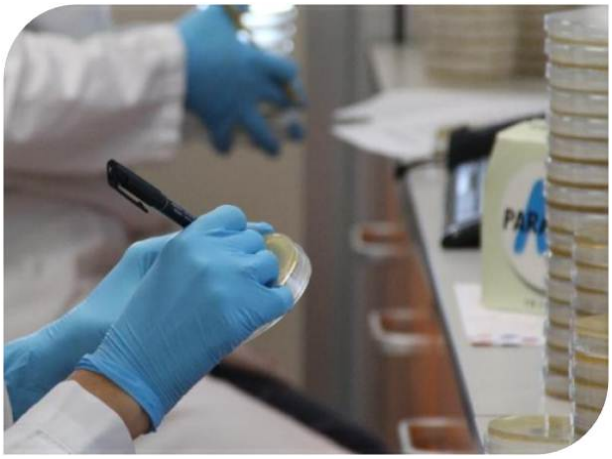
In the first phase of the experiment group 1 is first treated with positive control (1-propanol) whereas group 2 is treated with the test substance; in the following phase group 1 is treated with the test substance and group 2 with positive control (1-propanol).

The bactericidal effectiveness is verified as follows:

Volunteers wash their hands for 1 minute with soft soap, rinse with tap water and then dry them with a disposable paper towel.

Immediately after drying, volunteers dip the fingertips of both hands into two different Petri plates containing 10 ml of TSB, in order to detect the number of microorganisms present on the hands before treatment.

Starting from this suspensions decimal dilutions in TSB are prepared. For each dilution 1 ml is placed into Petri plates containing TSA.
Plates are incubated for 48 hours at 37°C ±1°C.



Treatment with positive control:

3 ml of 1-propanol 60% (v/v) are poured on volunteers' hands, arranged as a cup, previously moistened.

3 ml of 1-propanol are added each time the hands are about to get dry. Volunteers rub their hands for 5 minutes and then rinse them under tap water for 15 seconds.

Total volume of 1-propanol added is recorded.

Treatment with test substance:

Test substance has been used as such, by pouring 3 ml of it directly on the hands of the volunteers. 3 ml of the test substance were added each time the hands were abput to get dry.

Volunteers rub their hands for 5 minutes and then rinse them under tap water.
Total volume of test substance added is recorded.

Immediately after treatment, volunteers dip for 1 minute fingertips of left hand into a Petri plate containing 10 ml of TSB containing neutralizing agent.

Starting from this suspension decimal dilutions are prepared. For the obtained suspension and for its decimal dilutions, 1 ml is placed into Petri plates containing TSA.

Plates are incubated for 48 hours at 37°C ±1°C (immediate post-values).

After drying with a sterile towel, to the right hand is applied a sterile surgical glove for 3 hours; then, the same procedure for the determination of the immediate post-values is applied (3 hours post-values).



Interpretation of the results

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

The test is considered valid if the results of at least 18 subjects is available and if the average of initial logarithmic values for the test and reference procedures is at least 3.50.

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

- The average factor of logarithmic reduction that is obtained with the test substance (both immediate and 3-hours post-values) must not be significantly smaller than the one obtained with 1-propanol 60% v/v, from a statistical point of view;
- If the average factor of logarithmic reduction of the test substance is smaller than the one obtained with positive control, the statistical meaningfulness of differences must be evaluated;
- If the average factor of logarithmic reduction is significantly smaller than the one obtained with positive control, the product is not compliant with the regulation.

If the explicit claim for a sustained effect exists, the mean reduction factor for the 3-hour effect shall, additionally, be significantly larger than that obtained with propan-1-ol 60 % (volume concentration).

Normative references

EN12791:2005 - Chemical Disinfectants and Antiseptics – Surgical Handrub – Test Method and Requirements.

Restrictions

Pre-surgical alcohol-based lotions or gels must be tested according handrub procedure.

Amount of samples necessary to the analysis

3x100 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).