eurofins | BioPharma Product Testing



Bactericidal activity
Phase2 / Step 1 QST test according to EN1276:1997

Application field

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

It is applicable to chemical disinfectants and antiseptics to be used in food, industrial, domestic and institutional areas where disinfection or antisepsis are medically indicated.

EN1276 (quantitative suspension tests – phase 2 step1) norm is applicable as a stand alone test to products to be used in the manufacture of cosmetics, in breweries, in the beverage and soft drinks industry and in dairies.

Interests

The aim of the test schematically reported below is to evaluate the capability of a chemical disinfectant formulation, to produce in vitro a reduction in the number of viable vegetative bacteria.

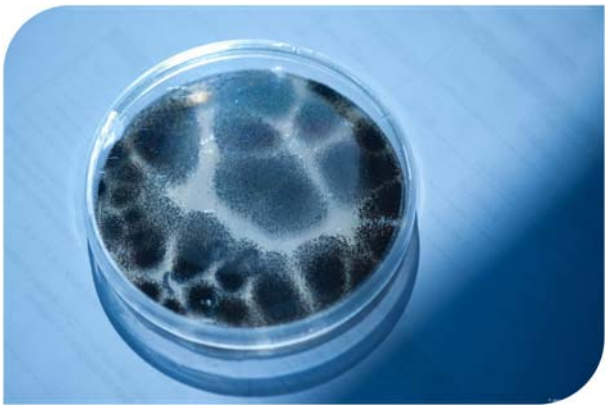
Principle of the test

The standard bactericidal activity is verified as follows:

Four different bacterial strains, Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541, Escherichia coli ATCC 10536 and Pseudomonas aeruginosa ATCC15442, are exposed to the test substance in the following conditions:

- Concentrations: three different dilutions of the test substance are tested
- contact time: 5 minutes
- temperature test 20°C ±1°C

The test may be performed by using as interfering substance either a solution of bovine albumin with a final concentration of 0.3% (simulating dirty conditions) or a solution of bovine albumin with a final concentration of 0.03% (simulating clean conditions).



The test suspensions containing the different bacterial suspensions of known viability are mixed with the test substance and the chosen interfering substance.

After the prescribed contact time, the test mixture is immediately neutralised in order to inactivate the killing activity.

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1:10 dilutions of the test mixture are then pour plated on Petri plates in order to evaluate the viability reduction of the bacteria after exposure to the test substance.

Viability reduction is calculated for each microorganism and test concentration using the following formula:

$$R = \frac{N \times 10^{-1}}{Na}$$

R = Reduction of viability
N = bacterial counting for the initial test suspension (cfu/ml)
Na = bacterial counting for the test mixture at the end of the contact time (cfu/ml)

Validation of the neutralising procedure is always performed. If neutralisation of the test substance can't be achieved the membrane filtration procedure is validated and applied as prescribed by the norm.



Normative references

EN1276:1997 - Chemical Disinfectants and Antiseptics Bactericidal Quantitative Suspension Test.

Restrictions

Not applicable to formulations not soluble in water.

Interpretation of the results

The bactericidal activity of the product test solution is evaluated for each exposure condition applicable. The test substance is considered bactericidal when it causes for each bacterial strain a reduction of vitality of at least 105 at 20°C after 5 minutes contact.

Other test conditions (contact time, temperature, non sporulating bacteria) may be considered upon Sponsor's request.

Amount of samples necessary to the analysis

2x100 ml per test.

TAT from sample arrival

14 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/quantitative composition (at least % of active ingredient).