eurofins | BioPharma Product Testing



Fungicidal activity
Phase2 / Step 1 QST test according to EN1650:1997

Application field

This European normative is applicable to products for which disinfectant activity against fungi 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 indicated.
EN1650 (quantitative suspension test – 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 fungi.

Principle of the test

The standard fungicidal activity is verified as follows:

Two different fungi strains, Candida albicans ATCC 10231 (yeast) and Aspergillus niger ATCC 16404 (mould), are exposed to the test substance in the following conditions:

- Concentrations: three different dilutions of the test substance are tested
- Contact time: 15 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).

1:10 dilutions of the test mixture are then pour plated on Petri plates in order to evaluate the viability reduction of the fungi 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 = fungal counting for the initial test suspension (cfu/ml)
Na = fungal 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

EN1650:1997 - Chemical Disinfectants and Antiseptics Fungicidal Quantitative Suspension Test.

Restrictions

Not applicable to formulations not soluble in water.



Interpretation of the results

The fungicidal activity of the product test solution is evaluated for each exposure conditions applicable. The test substance is considered fungicidal when it causes for each fungi strain a reduction of vitality of at least 104 at 20°C after 15 minutes contact. Other test conditions (contact time, temperature, fungi) may be considered upon Sponsor's request.

Amount of samples necessary to the analysis/ TAT from sample arrival

2x100 ml per test.
TAT: 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 composition (at least % of active ingredient).
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