

BioPharma Product Testing







Antimicrobial activity test according to ASTM E 2180:2007

Application field

This normative is applicable to polymeric or hydrophobic materials for which antimicrobial efficacy against vegetative bacteria or fungi is claimed.

This method can confirm the presence of antimicrobial activity in plastics or hydrophobic surfaces and allows determination of quantitative differences in antimicrobial activity between untreated plastics or polymers and those with bound or incorporated low water-soluble antimicrobial agents.

Interests

The aim of the test schematically reported below is to evaluate quantitatively the antimicrobial effectiveness of agents incorporated or bound into or onto hydrophobic or polymeric surfaces, against microbial strains.

The procedure also permits determination of "shelf-life" or long term durability of an antimicrobial treatment.

Principle of the test

The standard antimicrobial activity is verified against two different bacterial strains, Staphylococcus aureus ATCC 6538 and Pseudomonas aeruginosa ATCC 15442 or Klebsiella pneumoniae ATCC 4352, according to following procedure:

For each test strain, six specimens of treated material and six specimens of the untreated material (negative control) are used.

Each test specimen are placed into a separate sterile Petri dish and the inner surface of test material is inoculated with 1 ml of the test suspensions in agar slurry.

Immediately after inoculum (T0), 3 specimens of untreated and 3 specimens of treated material are processed by adding neutralizer and, in order to remove microorganism, agitated mechanically for 2 minutes.



The viable microbial count is performed by inclusion in Agar Medium, by seeding 1 ml twice of previously prepared solution and 1 ml twice of 10-fold serial dilutions in neutralizer.

The remaining specimens are incubated at 37°±1°C for 24 h.

At the end of the contact time, the specimens are processed like T0 specimens.

The plates are incubated at 37°C±1°C for 48 hours

After incubation, the colonies in the Petri plates are counted and the final results are expressed as antimicrobial activity of the test product compared to the negative control at the contact time.

- for log expression: geometric mean = (LogR1 + LogR2 + LogR3)/3

where:

R: number of microorganisms recovered from the incubation period untreated or incubation period treated samples

- for % expression

$$R(\%) = \frac{(N_u - N_a)}{N_u} \times 100$$

Nu: the antilog of the geometric mean of organisms recovered from each contact time (untreated samples)

Na: the antilog of the geometric mean of organisms recovered from each contact time (treated samples).









Normative references

ASTM E-2180-07: Determining the activity of incorporated antimicrobial agents in polymeric or hydrophobic materials.

Interpretation of the results

Other test conditions (contact times, temperature, microorganisms) may be considered upon Sponsor's request.

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

For each test strain: 6 treated specimens; 6 untreated specimens

TAT: 14 days

Restrictions

Specimen with very high (visible) porosity may produce results with very high bias.

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).

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