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P88: EFFICIENCY DETERMINATION TESTS FOR THE BIOCIDAL PRODUCTS FOR QUALITY CONTROL

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Objective: Biocidal (bactericidal and fungicidal) products produced in the pharmaceutical industry should be tested according to EN 1276 (Evaluation of chemical disinfectants and antiseptics/bactericidal activities), TS EN 1275 (Chemical disinfectants and antiseptics/Basic Fungicidal Activity), TS EN 1040 (Chemical disinfectants and antiseptics/Basic bactericidal activity) standards. Efficiency determination tests are required to determine the quality control of the biocidal products microbiologically. Besides, for quantification, proof of the efficiency of the biocidals and the evaluation of the results according to the established standards by bactericidal and fungicidal efficiency determination methods are required.

Method: Dilution-neutralization method is used for the determination of the bactericidal and fungicidal efficiency. The basic principle of the efficiency determination tests of biocidal products is based on the determination of the reduction in the number of microorganisms at the end of a certain time and the temperature by the contact of the certain concentrated biocidal product with the certain concentrated standard microorganisms (McFarland standards, BioMerieux, France). *Enterococcus hirae* (ATCC#10541), *Staphylococcus aureus* (ATCC#6538), *Pseudomonas aeruginosa* (ATCC#15442), *Escherichia coli* (ATCC#10536), *Aspergillus niger* (ATCC#16404) and *Candida albicans* (ATCC#10231) strains are used as standard test microorganisms.

Results: According to the known concentrations of standard microorganisms used in biocidal efficiency tests after a specific incubation period, the reduction is evaluated. Under the conditions determined by dilution-neutralization test method, for fungicidal products, 4 log or more reduction in the the number and viability of microorganisms at 20±1°C temperature and 5min±10sec time (EN-1275), for bactericidal products, 5 log or more reduction in the viability of microorganisms at 20±1°C temperature and 5min±10sec time (EN-1276, EN-1040) is considered to pass the tests.

Conclusion: Efficiency tests of the biocidal products are an important issue not only for the quality of the company but also the public health as well.

Keywords: Biocidal product, quality control, microbiological efficiency tests