BIO_06 - Evaluation of sporicidal activity of 2%peracetic acid against filamentous fungus strains for contamination control strategy in a pharmaceutical industry

Amanda Silva Costa[1]; Rebeca Vitória da Silva Lage de Miranda[1]; Luciana Veloso da Costa[1]; Talita Bernardo Valadão[1]; Jean Costa de Lima[1]; Milena Cristina Silva dos Santos[1]; Letícia de Sousa Albuquerque[1]; Cristhiane Moura Falavina dos Reis[1]; Lygia Maria Paulo da Silva Braga[1]; Marcelo Luiz Lima Brandão[1].
[1]Fiocruz/Bio-Manguinhos

Introduction: Pharmaceutical products must be produced according to Good Manufacturing Practices and requires appropriate quality control. The manufacture of sterile products requires a high level of sanitation and hygiene, which must be observed at all production area equipment and utensils, production materials and containers. Areas must be monitored regularly for the detection of the emergence of resistant microorganisms, and sanitizers must have proven efficacy.

Objectives: This study aimed to evaluate the sporicidal activity of 2% peracetic acid against filamentous fungus strains isolated in a pharmaceutical facility.

Methodology: Two strains identified by Matrix-Assisted Laser Desorption Ionization-Time of Flight Mass Spectrometry as Aspergillus spp. and Penicillium spp. were used for experimental assays. Three surfaces were tested using peracetic acid disinfectant: stainless steel (SS), low-density polystyrene (LDP) and vinyl (VS) surfaces; with and without friction. A fungal conidia suspension was prepared and used for surfaces spiking. A commercial disinfectant based on 15% peracetic acid was diluted in sterile water to a final concentration of 2% and evaluated. A previously assay was conducted to demonstrate absence of product residual effect.

Results: No product residual effect was identified for both strains and the concentration of peracetic acid was in accordance with specification. Aspergillus spp. exhibited initial inoculum of 4.02, 3.97 and 3.24 log and reduction with or without friction of ≥3.02, ≥2.97 and ≥2.24 log on SS, LPD and VS surfaces, respectively. Penicillium spp. exhibited initial inoculum of 5.57, 5.97 and 5.75 log and reduction with or without friction of ≥4.39, ≥4.97 and ≥4.75 log reduction on SS, LPD and VS surfaces, respectively.

Conclusion: According to Parenteral Drug Association Technical Report N.70, a reduction of >1 log is recommended for surfaces in aseptic production areas. So, peracetic acid 2% can be applied as part of the contamination control strategy of the pharmaceutical facility as corrective action in cases of microbial environmental monitoring counting above the specification limits.

Keywords: Sporicidal activity; Filamentous fungus; Contamination control strategy