Short Communication | Food & Industrial Microbiology | 2020
Vol.6 No.2

Microbiology 2020: Antimicrobial Efficacy of Selected Disinfectants in the Pharmaceutical Manufacturing Environments- Hamza A Aboelenin- Alexandria University

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In pharmaceutical manufacturing, it is a serious matter to work in controlled environments, cleanrooms and some cases in completely sterile zones. At one point, a cleanroom or clean zone is simply an area that is free of particles counts and microbial counts. However, EU GMP or the FDA guidelines outline other regulatory criteria for cleanrooms which depend on the use of defined cleaning techniques along with the application of detergents and disinfectants as an important step towards achieving microbial control within a cleanroom. To destroy microorganisms, the detergents and disinfectants used in cleanrooms of pharmaceutical grade need to be of high quality and efficiency. Good product selection and cleaning techniques are important, particularly with regard to some of the latest cleanroom technologies.

In pharmaceutical industries, Pharmacopeia is the reference that offers guidelines for cleaning and sanitization systems required for regulated environments to prevent microbial contamination. It also discusses everything included in sterile drug products: pharmaceutical ingredients, process water, packaging components, manufacturing environment, processing equipment, and manufacturing operators. Current Good Manufacturing Practices (cGMPs) emphasize on the scale, design, and location of buildings and building materials, and the correct material flow to promote the cleaning, repair, and proper drug product manufacturing operations. Where disinfectants are used in manufacturing environments, where care should be taken to prevent contamination of the drug product with chemical disinfectants that may result inherent toxicity of the disinfectants. The types of detergents and disinfectants used are of significant decision for the pharmaceutical manufacturer as there are multiple types with specific activity spectrums and mode of action. There have been a number of advances in clean room technologies over the past few years which have helped in reducing the risk of contamination and streamline process operations. The final assessment of cleaning products and techniques is revealed in terms of the number and types of microorganisms recovered through environmental monitoring programs.

Dettol is commonly used in homes and healthcare facilities for a range of purposes, including disinfection of bodies, artifacts and appliances, as well as environmental surfaces. The number of microorganisms colonizing the skin and surfaces is significantly reduced with prior cleaning prior to application. Antimicrobial properties of chloroxylenol, the main chemical constituent of Dettol and other chlorinated phenols have been extensively examined. Antimicrobial properties of the disinfectant to some pathogenic bacteria have been recorded earlier.

The aim of this study is to determine the efficacy of Dettol in comparison to alcohol if used on Epoxy surfaces in the production environment. The experiment was designed to compare the efficacy of 4 Dettol concentrations (5, 2.5, 1.25 and 0.625%) versus alcohol 70% in time intervals 5, 10, 15 and 30 minutes. Log reduction in bacterial or fungal count was chosen as a parameter of disinfectant effect. *Bacillus subtilis* ATCC 6633, *Escherichia coli* ATCC 8739, *Staphylococcus aureus* ATCC 6538, *Pseudomonas aeruginosa* ATCC 9027, *Aspergillus niger* ATCC 16404 and *Candida albicans* ATCC 10231 were chosen as test microbes. The concentration of Dettol that resulted in the highest log reduction in microbial count in the shortest contact time compared to alcohol 70% on epoxy surfaces would be considered a potential alternative in the production environment. The efficacy represented in log reduction is calculated according to the following equation:

Log10 reduction (R)= log10 pre-value cfu/ plate – log10 post value cfu/ plate

Data represent the mean of 4 replicates with estimated standard deviation (SD) equals to 0.5 for each sub-group using α error equal 0.05 will provide a power of 20%.

The results showed that the most significant concentration of Dettol was 2.5% if used for 5 minutes on epoxy surfaces this concentration reduced the count for *Escherichia coli*. *Staphylococcus aureus*, *Pseudomonas aeruginosa Aspergillus niger*, and *Candida albicans* by 100, 100, 98, 100 and 100%, respectively, compared with alcohol 70%. *Bacillus subtilis* maximum log reduction by Dettol was 82.5% in 15 min. This could be attributed to its ability to form spores.

In conclusion, Dettol (2.5% for 15min) can be considered a good alternative as disinfectant in controlled ad clean areas in pharmaceutical industry.

This work is partly presented at 49th World Congress on Microbiology, June 15-16, 2020, Webinar