

Antimicrobial Efficacy of Selected Disinfectants in the Pharmaceutical Manufacturing Environments

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Abstract:

Pharmaceutical manufacturing takes place within a series of specially controlled environments– cleanrooms. On one level, a cleanroom or clean zone is simply an area that is clean in terms of both particle counts (as defined in the international cleanroom standard ISO14644) and microbial counts (as defined in a second cleanroom standard for biocontamination control, ISO14698.1. In addition, regulatory requirements for cleanrooms are detailed by EU GMP or the FDA guidelines.

One important step towards achieving microbial control within a cleanroom is the use of defined cleaning techniques, together with the application of detergents and disinfectants. The detergents and disinfectants used in pharmaceutical grade cleanrooms need to be of a high quality and effective at killing micro-organisms. Both correct product selection and cleaning techniques are important, particularly in relation to some of the newer cleanroom technologies.

A sound cleaning and sanitization program is needed for controlled environments used in the manufacture of Pharmaceutical articles to prevent the microbial contamination of these articles. Sterile drug products may be contaminated via their pharmaceutical ingredients, process water, packaging components, manufacturing environment, processing equipment, and manufacturing operators. Dettol_ is widely used in homes and health-



care settings for various purposes including disinfection of skin, objects and equipment, as well as environmental surfaces. With prior cleaning before application, the number of microorganisms colonizing the skin and surfaces are greatly reduced (Rutala, 1996). The antimicrobial properties of chloroxylonol, the main chemical constituent of Dettol and other chlorinated phenols have been extensively studied (Hugo and Bloomfield, 1971a). The antimicrobial properties of the disinfectant against some pathogenic bacteria have earlier been reported (Mellefont et al., 2003).

Biography:

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