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Antimicrobial Activity and Controlled Environment in Pharmaceutical Microbiology

Emmett Walters*

Department of Microbiology, Islamic Azad University, Hamedan, Iran

Commentary

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***For Correspondence:**
Emmett Walters, Department of Microbiology, Islamic Azad University, Hamedan, Iran
E-mail: walters.emmett@gmail.com

DESCRIPTION

Pharmaceutical microbiology is a subfield of microbiology that is used in pharmaceutical industries. It entails the study of microorganisms associated with pharmaceutical manufacturing, such as reducing the number of microorganisms in a process environment, excluding microorganisms and microbial by products such as exotoxin and endotoxin from water and other starting materials, and ensuring sterility of the finished pharmaceutical products. Other aspects of pharmaceutical microbiology include anti-infective agent research and development, the use of microorganisms to detect mutagenic and carcinogenic activity in prospective drugs, and the use of microorganisms in the manufacture of pharmaceutical products such as insulin and human growth hormone. Pharmaceutical microbiology is heavily focused on drug safety. Pathogenic bacteria, fungus (yeasts and moulds), and microorganism-produced toxins are all potential pollutants of medicines, while strong, regulated systems are in place to guarantee the danger is limited. Another important aspect of pharmaceutical microbiology is determining how a product will react during contamination. As an example, assume individuals having as flask of prescription medicine. Assume that taking off of the cover, sprinkle oneself a daily intake, and afterwards ignore to put it through.

When an individual begin taking someone succeeding medicine, users recognise individuals left the cap exposed for several minutes. How this actually occurs when a micro-organisms "declines throughout" whereas the cap is accessible? There seem to be assessments that glance into all of this. The product is "challenged" with a known amount of certain microbes such as *E. coli* and *Candida albicans*, and its antimicrobial activity is measured. Pharmaceutical microbiology is also involved in disinfectant validation, either according to AOAC or CEN standards, to examine the efficacy of disinfectants in suspension, on surfaces, and in field trials. Field trials aid in determining

the frequency with which detergents and disinfectants should be used. Pharmaceutical microbiologists must inspect cleanrooms and controlled environments for contamination (both viable and particle) and implement contamination control techniques. This includes knowledge of risk assessment. Risk management has been successfully implemented in a variety of industrial sectors, including the US space industry (NASA), nuclear power industry, and automobile industry, benefiting these businesses in a variety of ways. However, the pharmaceutical business is still in its infancy, and the application of risk assessment techniques to pharmaceutical production is just getting started, with potential benefits yet to be realized. Cleanrooms and zones are often classified according to their use (the primary activity within each room or zone) and confirmed by particle monitoring. Environmental monitoring methods are used to analyze the microbiology of cleanrooms. Viable monitoring is intended to detect amounts of bacteria and fungus present in certain locations/areas during a specific stage of the processing activity and slipping a good or service. The purpose of viable monitoring is to detect mesophilic microorganisms in an aerobic state. Some manufacturers, however, may have needs to test for different types of bacteria (such as anaerobes if nitrogen lines are used as part of the manufacturing process).

Surface procedures include testing for microorganisms on a variety of surfaces, including:

- Product Contact Surfaces
- Floors
- Walls
- Ceilings

Using approaches such as:

- Surface Rinse Method
- Contact Plates
- Touch Plates

For air monitoring, agar settle plates (positioned in areas of highest risk) or active (volumetric) air-samplers are used (to provide a quantitative assessment of the number of microorganisms in the air per volume of air sampled). Active air-samplers are classified into the following models:

- Slit to Agar
- Membrane Filtration
- Centrifugal Samplers

All monitoring methods will employ either a general purpose culture medium such as Tryptone Soya Agar (TSA) at a dual incubation regime of 30°C-35°C and 20°C-25°C, or two separate culture media at two different temperatures, one of which is selective for fungi (e.g. Sabouraud Dextrose Agar, SDA). Validation is required for the selection of culture media, incubation times, and temperatures.