

Surface challenge testing to qualify disinfectants including sporicides for control of bioburden on production facility surfaces

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Procedures for managing control of bioburden levels in cleanrooms used for pharmaceutical manufacturing include cleaning, disinfection, and environmental monitoring. Often several different types of disinfectants are used in a company's facilities cleaning program, and at least one agent should have sporicidal activity against bacterial endospores. Regulatory agencies such as the US Food and Drug Administration (FDA) may encourage the qualification of disinfectants for their intended use by testing their efficacy on surfaces similar to those present in a manufacturer's cleanrooms. In such surface challenge testing, it is desirable to include in-house environmental isolates and demonstrate that cleanroom disinfectants have key performance characteristics such as a suitable level of efficacy with a short contact time. It is advantageous to include in the overall design of a surface challenge study a description of the combinations of surfaces, disinfectants, and microbes that will be included in the testing (guided by risk analysis or other factors), contact time(s), acceptance criteria, and documentation. Development work may be needed to establish procedures for the preparation (and storage) of cell suspensions that will be used to inoculate carriers, dilution and plating methods for determining viable counts, preparation of disinfectant solutions, preparation and sterilization of carrier surfaces prior to and after testing, inoculating and recovering microbes, and quenching disinfectant activity to assure that contact times are accurately determined. Specific examples of results from such development work will be discussed for several types of disinfectants, including the use of pH-adjusted bleach as a highly effective sporicide. Bleach solutions of 0.12 to 0.50% sodium hypochlorite with pH ranging from 5.5 to 8.2 have been shown to be active on hard surfaces resulting in greater than a 5 log₁₀ reduction in viable spores after 0.5 minutes of contact.

Biography

Anne Cornish Frazer received her Ph.D. from Tulane University, did postdoctoral research at the Oak Ridge National Laboratory, USA, held research and teaching appointments at the University of Alabama in Birmingham, New York University, Rutgers University, and the University of California, Berkeley. She is conducting research in microbial physiology and environmental microbiology. She focused on pharmaceutical microbiology for over nine years at several pharmaceutical companies in the San Francisco Bay Area where she designed and oversaw QC projects to qualify disinfectants for use in controlling bioburden on manufacturing facilities surfaces, and has presented the results of these studies at meetings and in the scientific literature.

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