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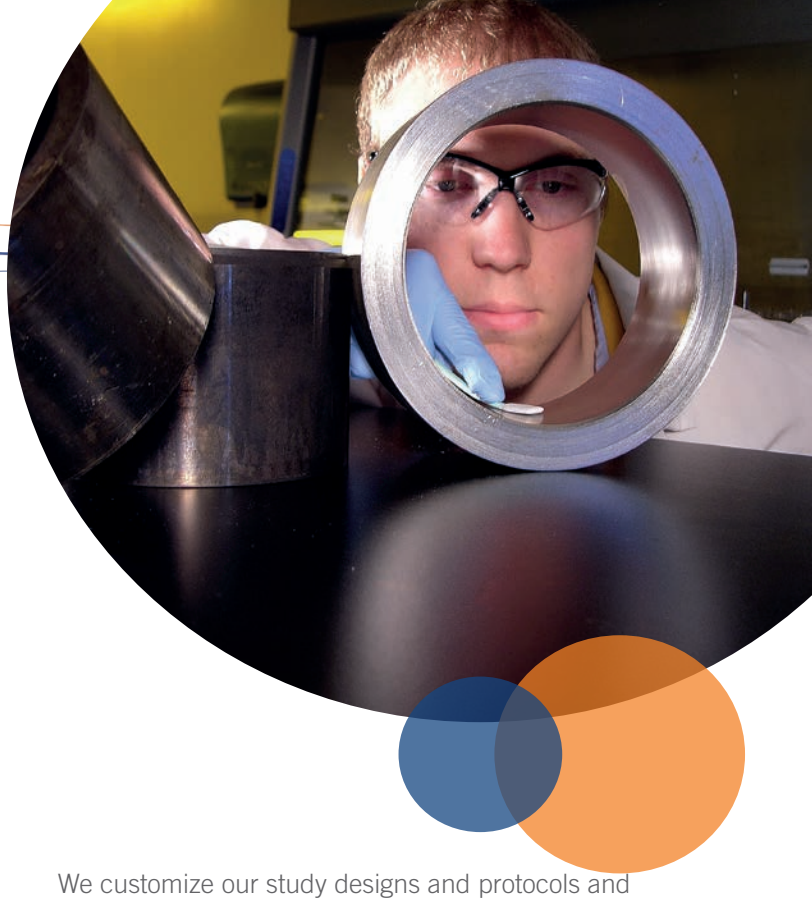

Cleaning Validation and Disinfectant Efficacy Studies

According to Good Manufacturing Practice (GMP) regulations, FDA guidance and USP <1072> manufacturers of finished bio/pharmaceutical products must demonstrate that harmful residues or organisms are properly removed during cleaning to predetermined safety levels, thus eliminating contamination of manufacturing equipment.

Cleaning validations are conducted to show that the cleaning process and frequency, including any mechanical cleaning actions, are sufficient to maintain surfaces in a defined state that is free of product, cleaning chemical residues and objectionable organisms. These studies demonstrate that materials can be cleaned to the desired chemical and microbiological levels.

Disinfectant efficacy studies are performed to demonstrate that the disinfectants used on surfaces in manufacturing areas, laboratories and other facility areas are effective in inactivation or removal of microorganisms, such as bacteria, fungi (yeast and molds), bacterial spores, viruses and mycoplasma. Disinfectant studies can support cleaning studies by showing that application of the disinfectant reduces or eliminates microorganisms, but they should not be considered a substitute for establishing that the cleaning agents and physical cleaning actions are acceptable.

Eurofins BioPharma Product Testing is experienced in effective cleaning, disinfection and monitoring programs to eliminate chemical cleaning agent residues and microorganism levels on laboratory surfaces and equipment. We perform monitoring of these areas to confirm that chemical residues and bioburden are within acceptable limits for the area.

Why Choose Eurofins BioPharma Product Testing?

We have more than 20 years of experience developing and validating detection methods, as well as designing and performing disinfectant studies with a variety of organisms, surfaces and disinfectants. Our established protocols were developed to evaluate efficacy of disinfectants on your representative facility surfaces under laboratory test conditions.

We customize our study designs and protocols and develop specific and/or non-specific methods based on client's individual project needs.

We have experience using a variety of methodologies for chemical cleaning validations, including LC with various detectors and other methods, such as a validated TOC swab and rinse methods that can be extended to a wide variety of surfaces and compounds specialized for the client.

Disinfectant efficacy studies typically are not routinely performed by an in-house pharmaceutical quality control laboratory. We have staff who are specialized and qualified operators that utilize well-controlled test systems. These aspects are critical for assuring reproducibility of results. As we routinely perform these tests, we can guarantee our technical competence and quality of results.

We streamline and prioritize test combinations to meet client budgets, timelines and regulatory expectations.

Cleaning Validations

Eurofins BioPharma Product Testing works with drug manufacturers to develop and validate methods capable of detecting low level residuals to verify the cleaning processes. We have performed cleaning validations on virtually every type of product and surface, allowing us to streamline the study in order to save time and money.

Phases for Chemistry Cleaning Validation

- Method Establishment and Sampling Plan Generation – Define analyte(s) of interest, applicable surfaces and finishes, appropriate maximum contamination limit (MCL), sampling technique (swab vs. rinse) and method of detection (specific vs. non-specific).

- Method Development – Develop a cleaning detection method that addresses all specific client needs.
- Method Feasibility – Method is evaluated to establish performance criteria and ensure that the method will be suitable for its intended purpose (typically would evaluate both swab and surface recovery, linearity, sensitivity and accuracy).
- Protocol Writing and Method Validation – Create a validation protocol and execute the method validation in a controlled GMP environment.
- Routine Analysis – Method is used to analyze samples as part of a routine monitoring program.

Phases for Microbiology Cleaning Validation

- Protocol and Sampling Plan Generation – Establish the sites to be sampled for microorganism contamination (bioburden), the collection method to be used and how data will be handled.
- Risk Identification – Define the health based exposure limits as suggested by the relevant agency guidelines for shared facilities.
- Method Qualification/Neutralization/Recovery Execution – Establish that microorganisms can be recovered in an acceptable range from the surface using the proposed collection method. Neutralization studies of cleaning agent or disinfectant residues are incorporated into this phase of the study if needed.
- Sampling Plan Execution and Analysis – Collection of samples is performed using the determined method, and samples are evaluated for microorganisms prior to and/or after the cleaning procedure is performed to show cleaning is effective. Where available, corresponding chemical analysis from adjacent areas ensures chemical residuals are not at an inhibitory range for the microorganism recovery.
- Routine Monitoring – Periodically analyze collected samples after cleaning to ensure process remains in control over time.

Disinfectant Efficacy Studies

A disinfectant study confirms that disinfectant agents used are active against organisms isolated during the environmental monitoring program and/or against other relevant organisms, under experimental conditions that simulate their practical use.

These studies, which are especially critical for sterile manufacturing facilities, have been performed for bacteria and fungi for many years. In the past decade, as more biopharmaceutical products enter the market, disinfectant efficacy studies are being routinely performed for products using mycoplasma and viruses.

Phases for Disinfectant Studies

- Study Design and Protocol Generation – Determine microorganisms, surfaces, disinfectants and treatment conditions to be tested.
- Surface Efficacy Studies – Determine the effectiveness of inactivation of the desiccated microorganism by disinfectants on appropriate surfaces.
- Suspension-Efficacy Studies – Evaluate the effectiveness of the disinfectant in suspension (optional). This test provides relevant information about the activity of the product against non-dried microorganisms. Desiccated microorganisms may be stressed and may offer different challenges.
- Use-Dilution Expiration Studies – Verify the effectiveness of the disinfectant up to and beyond the pre-determined expiration date.

These studies include the following controls:

- Recovery Controls – Evaluate the ability to recover the organisms applied to the surfaces (conducted prior to or simultaneously with efficacy studies).
- Disinfectant Neutralization/Toxicity/Interference Controls – Establish that disinfectants and sample matrix do not impact the assay for the organisms being tested.

Routine Chemical & Microbial Monitoring

Ongoing environmental monitoring and chemical monitoring (e.g., TOC swabs) confirm that the surfaces and equipment are free of microorganisms and inhibitory residues that might interfere with the microorganism recovery and establish that the cleaning frequency maintains the desired condition of the equipment between cleanings.