

TESTING TO DETERMINE THE CLEANING EFFICACY OF DISINFECTANTS



Cleaning is defined as removal of contaminants. Disinfectants are a type of cleaning agents known to inactivate microorganisms.

The efficacy of a disinfectant itself can be tested using a suspension test. The disinfectant at its working strength is challenged with a suspension containing a known titer of a microorganism. For testing the disinfectant in the actual cleaning process, the efficacy of a disinfectant on a contaminated surface can be tested using the surface sampling method. Surfaces, as used by the client, are spiked with bacterial load and subsequently exposed to the disinfection process. Using both methods, the reduction of the microbial load is determined.

WHAT TYPES OF DISINFECTANT AGENTS CAN BE TESTED?

The products to be tested are the disinfectants used in the cleaning procedures of the client. For example:

- 70% Isopropanol alcohol (IPA)
- Chloride
- 3% Hydrogen peroxide (H₂O₂)
- Or other bactericidal, fungicidal, sporicidal agents

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Your partner for
critical testing in
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WHY IS TESTING REQUIRED?

In order to secure your production process from environmental cross contamination, it is critical that disinfectant agents are validated for their efficacy to inactivate a range of environmental microorganisms.

Regulatory authorities will ask you to prove the effectiveness of your cleaning agents. Our test program will help you to prove compliance of your cleaning methods.

STUDY DESIGN

Suspension test

- First, the test circumstances and dilution-neutralization procedure are validated.
- Then the actual efficacy of the disinfectant is evaluated using the experimental conditions determined in the validation.
- The titers in absence and presence of the disinfectant solution are determined and compared to each other. A reduction factor is determined.

Surface test

- First the recovery capabilities of the sampling method are determined and optimized.
- Then the actual efficacy of the disinfectant method for a specific surface is determined.
- Recovery of microorganisms with and without applying the disinfectant is compared and a reduction factor is determined.
- The surfaces to be tested should reflect the materials used in your facility on floor and work surfaces: e.g. Trespa and stainless steel.

Regulatory compliance

- The disinfectant study is performed according to EN 1275 and EN 1276
- Studies can be performed in accordance with cGMP and/or GLP guidelines
- Tests can be customized to meet local regulatory requirements

CUSTOM ASSAYS

We understand that no production plant is identical and that every process is unique. Using a combination of practical experience and a scientific approach, we will customize disinfectant testing methods to meet your specific requirements including scientifically sound data that will be accepted by regulatory authorities around the globe.

Efficacy of disinfectants can be tested using control strains as described in the applicable regulations. The tests can be completed by including your specific house flora strains.

YOUR PARTNER IN MICROBIOLOGY

Our MicroSafe Biosafety Solutions Laboratory, Europe delivers a complete range of critical testing and consultancy services for the development and production of bio- pharmaceuticals. Leaders in the field of microbiology including in vitro virology testing, our staff of accomplished scientists, engineers and microbiologists will help you meet your specific critical testing requirements throughout every phase of drug production. All testing is conducted under cGMP or GLP.

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For more information on our critical support services, please contact Millipore Tech Service.

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