

disinfectant efficacy

WuXi AppTec provides a fully integrated approach to help manufacturers of highly regulated products bring their product to market and keep them there. This includes offering a comprehensive menu of sterility assurance services, including sterility, microbial, and endotoxin testing; process and container closure/packaging validations; cleaning and disinfectant studies; and environmental monitoring.

... for the life of your product

WuXi AppTec's Disinfectant Efficacy Program determines the effectiveness of a current or proposed cleaning process by evaluating the ability of the selected disinfectants/sanitizers to reduce microorganisms in their critical environments. Disinfectant efficacy testing and validations are required for your facility as well as your reusable product.

Our experts will work with you to design customized testing strategies that meet regulatory requirements – for devices, biologics, and combination products.

Driving Regulatory Guidance

United States Pharmacopeia, current edition, Chapter <1072>, "Disinfectants and Antiseptics."

ASTM E-2614, "Standard Guide for Evaluation of Cleanroom Disinfectants."

ASTM E-1153, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces."

United States Pharmacopeia, current edition, Chapter <1227>, "Validation of Microbial Recovery."



Study Parameter Considerations

Neutralization Validation

The neutralization method should be validated to ensure sufficient neutralization of the sanitizer has occurred and there are no residual inhibitory properties that may result in an over-estimation of antimicrobial efficacy.

Materials

The test materials should be representative of the product or critical surfaces within the facility or equipment, as well as the conditions for use.

Disinfectant / Sanitizer

The antimicrobial/cleaning agents and processes should be representative of those detailed in the cleaning procedures of the product, facility or equipment.

Organisms

These studies are typically conducted with variety of microorganisms, from different organism groups, and should be most often those that are of concern in the environment of the product use or facility manufacturing areas. Not all disinfectants/sanitizers claim efficacy against all organism groups; therefore, special consideration should be given when selecting organisms to be tested with each agent.

Talk to us and find out how our disinfectant efficacy testing services can work for you.

Contact a WuXi AppTec Account Manager at 888-794-0077 or email: info@wuxiapptec.com