ReadySAT™ with PeridoxRTU® Sporicidal Wipes Efficacy Test Study and Results

ReadySAT™ with PeridoxRTU® Sporicidal Wipes is a ready-to-use (RTU) cleaner and disinfectant consisting of hydrogen peroxide (H_2O_2) and peroxyacetic acid. ReadySAT with PeridoxRTU Sporicidal Wipes are dry wipes packaged in a tray with PeridoxRTU chemistry to be saturated at the point of use.

ReadySAT with PeridoxRTU Sporicidal Wipes are effective against a broad spectrum of bacteria, fungi and viruses and bacterial spores and are registered with the Environmental Protection Agency (EPA). Details of efficacy testing for EPA are available upon request under an NDA.

However, efficacy testing for EPA does not address how disinfectants are used in cGMP manufacturing operations. Also, the US Pharmacopeia (USP) indicates that even EPA-registered disinfectants and sanitizers must be validated for use in aseptic processing areas operating under a cGMP framework.

The US Pharmacopeia (USP) indicates that EPA-registered disinfectants and sanitizers must be validated for use in aseptic processing areas operating under a cGMP framework. Under <USP> 1072 Disinfectants and Antiseptics, it is necessary to demonstrate the efficacy of a disinfectant within the manufacturing environment and comply with USP regulations when choosing and implementing a disinfectant:

> *"The selection of suitable disinfectants and the verification of their effectiveness in surface challenge testing is critical in the development of a cleaning and sanitization program."*

While the responsibility for disinfectant validations resides primarily with the end-user, leveraging and adopting the results obtained from 3rd-party efficacy studies sponsored by the manufacturer of the disinfectant can save valuable time for end-users. Additionally, results of these studies provide confidence that the disinfectant will pass subsequent efficacy tests against facility-specific isolates and surfaces.

Contec-Sponsored Disinfectant Efficacy Study: To further substantiate the efficacy of ReadySAT with PeridoxRTU Sporicidal Wipes for use in controlled environments such as pharmaceutical and medical device cleanrooms, the product has been tested for efficacy against bacteria, fungi and bacterial endospores based on the guidelines in USP <1072> and <1227>. The common critical aspects included validation of the disinfectant neutralization process and the evaluation of disinfectant efficacy on typical cleanroom surfaces. These surfaces were inoculated with microorganisms and then disinfected with a defined disinfectant concentration at a defined disinfection contact time.

In the pharmaceutical industry, efficacy data generated from Disinfectant Efficacy Studies (DE Study) are routinely leveraged as part of wipe validation and cleaning/disinfection qualification programs, because they provide foundational evidence of what the biocide is capable of under controlled conditions and serve as a benchmark for expected performance. Manufacturers then assess wipes not only for the inherent microbicidal activity of the impregnated solution but also for the added benefit of mechanical removal of contaminants, recognizing that wiping physically dislodges contamination from surfaces in addition to any kill the biocide provides. This combined evaluation, applying by a presaturated wipe helps demonstrate that a wipe can achieve acceptable microbial reduction and effective surface decontamination in the specific manner in which it will be used, which is a regulatory expectation in cleanroom and GMP environments. Such approaches are reflected in test standards that include mechanical action (e.g., EN 16615) that incorporate wipe performance into cleanroom disinfectant validation strategies.

Successful Neutralization: To provide an accurate result during the disinfectant efficacy study, the disinfectant must be neutralized after the target contact time. Effective neutralization of the disinfectant was demonstrated according to USP <1227> (Validation of Microbial Recovery from Pharmacopeial Articles). After the neutralization process, the microorganisms were recovered in the neutralized disinfectant solution.

Proper neutralization studies require two aspects – that the neutralization solution can effectively quench the disinfectant activity and that the neutralization solution itself is not toxic to the microbes. Both these aspects were demonstrated successfully using criteria from

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the current version of USP <1227>. These two (2) aspects are critical to avoid negative interference during the next stage of the study. Upon the completion of this stage, the next stage of the study: Disinfectant Efficacy Testing, was ready to be executed.

Disinfectant Efficacy Testing Design: Testing was conducted against standard American Type Culture Collection (ATCC) strains of bacteria and fungi on a variety of materials commonly found in cleanrooms. Challenges were executed using a gamma-sterilized lot of the disinfectant after 7 daily simulated uses of the product. The lot had expired several months prior to testing but the active ingredient was still within specification.

- The efficacy testing was conducted in triplicate using 2" x 2" coupons of each test material by direct addition (pipetting) of the disinfectant onto a film of microbes dried onto the material surface and allowing the disinfectant to contact the microbes for the times shown in the table below.
- All test results exceeded the minimum requirements for efficacy (≥ 3 log reduction for bacteria and fungi and ≥2 log reduction for bacterial spores) as indicated in USP <1072>.
- It is expected that application of PeridoxRTU with wipes/mops or presaturated wipes will result in equivalent or even higher efficacy due the mechanical action of wiping.

Disinfectant Efficacy Study Summary

Challenge Organisms	Typical Cleanroom Surfaces	Disinfection Contact Time
Bacteria *Pseudomonas aeruginosa* (ATCC 9027) *Staphylococcus aureus* (ATCC 6538)	• Glass • Stainless Steel (304) • Plastic (Polycarbonate) • PVC-coated Wall Panels • Epoxy Flooring • Vinyl Flooring	1 minute for bacteria and fungi 3 minutes for bacterial spores
Fungi *Aspergillus brasiliensis* (ATCC 16404) *Candida albicans* (ATCC 10231)		
Bacterial Spores *Bacillus cereus* (spores) (ATCC 11778)		

As indicated above, PeridoxRTU is an effective disinfectant against Gram-negative and Gram-positive bacteria and fungi (mold and yeast) at a 1-minute contact time and a 3-minute contact time for bacterial spores on surfaces typical to cGMP environments.

This is a small example of information that can be found in the ReadySAT with PeridoxRTU Sporicidal Wipes Product Information Files (PIFs), including the protocols used for neutralization and efficacy and the test results. A PIF encompasses all information available for ReadySAT with PeridoxRTU Sporicidal Wipes contained in one master document. The information in the PIF is provided to end users to supplement and support validation and implementation of ReadySAT with PeridoxRTU Sporicidal Wipes. The ReadySAT with PeridoxRTU Sporicidal Wipes PIF contains the following information as shown below:

- Company Overview
- Regulatory Certificates
- Product Overview
- Product Specification
- Product Certificates
- Product Labels
- Production Process
- Safety Data Sheet (SDS) and Instructions for Use
- Efficacy
- Residues
- Material Compatibility
- Chemical Shelf Life
- Sterility Validation

This information is provided only after execution of a Non-Disclosure Agreement (NDA).

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