



Advantages of Presaturated Low-Lint Wipes vs. Spraying Sterile Alcohol on Dry Low-Lint Wipes

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Summary

In 1988, Contec was the first to introduce presaturated wipes, which were used in semiconductor cleanrooms to increase convenience and reduce solvent utilization and volatile organic compounds (VOCs) emissions. Sterile presaturated alcohol wipes were introduced to the pharmaceutical industry in 1990, where users reported a reduction in the amount of alcohol use by 15 to 50%.¹ Since that time, pharmacy sterile compounding standards have evolved. Primary Engineering Controls (PECs) are now cleaned and disinfected with an EPA-registered one-step disinfectant cleaner after which interior surfaces of these units are wiped with sterile IPA (sIPA) to remove any cleaning agent residues from the ISO Class 5 space before compounding.

Although the purchase price of presaturated wipes may be slightly higher than that of bottled sIPA and dry wipes, their use has advantages over the use of dry wipes sprayed with sIPA at the point of use. Though neither version of USP <797> (2008) or (2019) draft standards require the use of sterile presaturated wipes, they have come to be viewed as best practice in ISO 5 spaces.² In ISO 5 spaces where hazardous drug (HD) sterile compounding occurs, sterile presaturated alcohol wipes are the obvious choice since spraying sIPA in ISO 5 spaces is not permitted due to the potential of spreading HD residue within the direct compounding area and inside the Containment Primary Engineering Control (C-PEC).

Other benefits related to the use of sterile presaturated alcohol wipes may include, but are not limited to, a reduction of risk of environmental sampling excursions (microbial growth beyond a predefined limit) in ISO 5 spaces. Though a direct relationship has not been established, several studies have verified that dry wipes and sprayed sIPA do not remove bioburden sufficiently and are responsible for microbial transfer to other surfaces.^{1,3,4,5} Certainly, regulators would look favorably on repeatable practices using sIPA presaturated wipes. Should an excursion occur in ISO 5 spaces, the cost of investigation and remediation can be significant depending on the recurrence and severity of the excursions.

Advantage	Explanation
Enhanced cleaning and disinfection outcomes	<p>"Alcohol impregnated wipes performed better at reducing microbial bioburden than the alcohol spray/dry wipe applications."³ In the 2009 Panousi <i>et al.</i> study, presaturated wipes reduced greater amounts of bioburden (methicillin-resistant <i>Staphylococcus aureus</i> and spores of <i>Bacillus subtilis</i>) than dry wipes sprayed with alcohol. Use of dry wipes sprayed with alcohol also readily transferred viable organisms between surfaces.</p> <p>"The removal of microorganisms depends in part on the inherent properties of the wipe itself and its ability to retain particles."⁶ Contec products are low-lint, and can be constructed of polyester, polyester/cellulose, or polypropylene, which has "very good particle removal due to tiny fiber diameter and melt-blown manufacturing process."⁶</p> <p>Increased compliance and ability to focus on practices may lead to a lower environmental bioburden, and reduced risk to patients.⁷</p>
Decreases potential for process failure	Each lot is traced and sterilized by gamma irradiation to a sterility assurance level (SAL) of 10 ⁻⁶ .



Ensures consistent saturation of wipe	<p>"When dry wipes are wetted with disinfectant or used to wipe a surface which has been sprayed with disinfectant, the ratio of disinfectant to wipe cannot be standardized."⁸</p> <p>Presaturated wipes can reduce human error such as selection of the incorrect wipe and/or cleaning agent, rewetting wipes, and failure to moisten wipe with adequate solution.⁷</p>
Ensures compatibility with alcohol	Verified compatibility between alcohol and the wipe eliminates interactions which can affect wipe fibers, how the disinfectant binds to the wipe as well as the amount of disinfectant released onto the target surface. ⁶
Saves time and simplifies process	Decreasing the time for cleaning and disinfection and simplifying the process may enhance employee focus on actual cleaning and disinfection practices. ⁷
Prevents undersaturation associated with spray method	If a wipe is undersaturated (<i>e.g.</i> , wetting the wipe with a volume of liquid that is below its capacity), fewer particles (including microbes) are picked up when wiping the target surface. ⁴
Reduces potential for cross-contamination	Use of presaturated wipes eliminates the need for workers to make decisions about how often to rewet and/or change the wipe. ⁵
Simplifies staff training and ensures consistency	Though detailed worker training on how to use wipes is still required, ready-to-use presaturated wipes enhance consistency and repeatability between operators during the chemical application process.

No product can eliminate risk of contamination, so it falls to the sterile compounding operation to ensure effective, efficient and consistent practices. Regardless of the type of fiber in the wipe, the fibers themselves do not have any antimicrobial activity. Aside from the facility’s chosen disinfectant, reduction of bioburden is “in part due to physical removal using pressure and wiping action.”⁶

A (Right Product) + B (Right Practice) = C (BEST Repeatable Outcome)

USP Chapters <797> only establishes cleaning and disinfecting frequencies. The chapters do not get into detail about the process of cleaning and disinfecting surfaces. That’s why it is critical to establish Standard Operating Procedures (SOPs). Standard operating procedures, training, and worker competencies must be detailed and specific, explicitly defining desired behaviors. Human factors are always a major variable in the implementation of any process. Human factors that can negatively impact outcomes when using wipes inside ISO 5 spaces include:

- Skipping surfaces
- Wiping surfaces incorrectly or out of sequence
- Improper dilution (for cleaning and disinfection agents not Ready-to-use (RTU))
- Undersaturation of wipe/ Using wipe not sufficiently wetted
- Use of single wipe over too large a surface
- Rewetting wipes
- RTU container used improperly (not expressing air before closing peel and reseal packs, not closing seal completely, removing from ISO 5 space)

Another interesting observation from the Panousi *et al.*, study is that even the presaturated wipes did not remove low amounts of *Staphylococcus epidermidis* which is a bacterium associated with human skin.³ The takeaway from this finding is that strict garbing practices matter and are an equal part of this equation! Never forget, humans are the potential biggest contributor to contamination in critical environments. To keep microbial bioburden at a minimum, many products and practices must work together to achieve and maintain acceptable spaces for sterile compounding. Given this information, sterile, presaturated, low-lint, alcohol wipes are the best choice for use inside ISO 5 spaces.

References

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About Contec, Inc.

For more than 33 years, Contec has been developing innovative products to meet the demanding standards of cleanroom environments in the pharmaceutical, biotech, medical device, and microelectronics industries. With the healthcare market developing increasingly sensitive processes which demand effective cleaning, Contec has designed a truly unique line of products rooted in best practices to provide solutions for Pharmacy, Operating Room Turnover and Terminal Cleaning, Ambulatory Surgery Centers, Procedure Rooms, Isolation Rooms, Central Sterile and other critical patient areas.



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