

Advantages of Pre-Wetted Wipers in Sterile Environments

Introduction

If you had to describe the overriding characteristic of sterile environments in one word, that word might be “uncompromising”. This word conveys the sense that sterility requirements in these environments are indeed inflexible.

It follows then that items introduced into a sterile environment must not “compromise” or pollute the area. Such items must themselves be sterile and must not introduce unacceptable levels of contaminants – e.g. particles, residues, etc. Such requirements apply equally (and ironically) to contamination control products such as wipers and cleaning solutions that are used within the sterile areas. These products are not excused from the inflexible requirements for sterility and purity. Some pharmaceutical and biotechnology manufacturing plants have adopted sterile pre-wetted wipers as the best way to address critical cleaning issues in sterile environments. They have found that these cleaning products allow them to achieve the best results in a cost-effective manner.

What Are Sterile Pre-Wetted Wipers?

As the name suggests, these are cleanroom wipers that have been pre-wetted with the optimum amount of 0.2 um filtered solvent (typically 70% IPA solutions) to accomplish the cleaning task at hand. Further, these pre-wetted wipers are sterilized by gamma irradiation to a probability of non-sterility (Sterility Assurance Level) of 10^{-6} . This insures that only one wiper out of a million would not be sterile.

Generally, sterile pre-wetted wipers are packaged in sufficient quantities to last just one shift, on the premise that any consumable opened during the shift will not be used in a subsequent shift. Enough wipers are packaged to fulfil the wiping or cleaning requirements of that shift, with few, if any, left over. This generally translates into 20-50 pre-wetted wipers per package. The package is made from materials that will withstand gamma irradiation at the necessary dosage levels, and that can be opened conveniently to withdraw the pre-wetted wipers and closed (or resealed) to prevent evaporation of the wetting solution (Figure 1).

Advantages of Sterile Pre-Wetted Wipers

a) Contamination Control

These wipers, as delivered, are ready for immediate use to wipe down critical surfaces before, during, and after production shifts, inside and outside the sterile suite. Sterile pre-wetted wipers provide a means of sanitizing key surfaces and simultaneously removing particulate matter that can act as transport vehicles for bacteria. They are particularly useful for wiping down any articles brought into the sterile suite, to sanitize those articles and to physically remove endotoxins from surfaces.

Sterile pre-wetted wipers have been used for wiping down gloves to maintain glove sterility during sterile suite activity. This has the advantage of simultaneously sanitizing the glove and as well, physically removing dead bacteria from the glove surface, thereby reducing or eliminating a potential source of endotoxins. Spraying gloves with 70% IPA solution will sanitize the glove, but will not remove the dead bacteria. Sterile pre-wetted wipers have been found to reduce the incidence of false particle alarms caused by IPA spraying.

These wipers are also used to wipe down surfaces that have been contacted with environmental sampling devices such as Rodac plates, to remove residual agar. If this is not done, the agar on the sampled surface acts as a culturing medium for opportunistic bacteria.

b) Elimination of squirt bottles

When alcohol is dispensed onto a dry wiper from a squirt bottle, often excessive amounts of alcohol are used, since the operator's gloves prevent tactile feedback to indicate the optimum amount of dampness.

Since sterile pre-wetted wipers incorporate the optimum amount of 70% IPA for contamination control activities, there is less alcohol used in the facility and there may be an opportunity to eliminate squirt bottles and the transfer of bulk solvent. This can represent cost savings in solvent expenses and in charges for volatile organic compound (VOC) emissions. Also, sterile pre-wetted wipers eliminate fugitive emissions from squirt bottle dispense nozzles and from alcohol transfer operations.

c) Convenience

It would be difficult, but not impossible, to prepare sterile pre-wetted wipers within the sterile suite. Users could follow these steps:

1. Bring sterile dry wipers, packaging materials, graduated cylinders and sterile-filtered 70% IPA into the sterile environment,
2. Transfer the required number of wipers into the solvent-resistant packaging,
3. Transfer the required volume of sterile-filtered 70% IPA from the delivery container onto the wipers,

4. Then close the packaging to allow the IPA to thoroughly dampen the wipers and prevent the IPA from evaporating.

Of course, all of the process steps would need to be documented and validated to satisfy regulatory audits. Also, this seems like a lot of manual effort, if only 20 to 50 sterile pre-wetted wipers are needed for the shift. Likewise, it would be difficult, but not impossible, to prepare sterile pre-wetted wipers outside of the sterile suite. One could follow the steps outlined above except that non-sterile wipers would be used. Once the package of pre-wetted wipers had been formed, the product would then be gamma irradiated¹ and transferred into the sterile suite. Now bioburden measurements, sterility validation and package integrity testing would also be needed in addition to the usual documentation requirements.

It would appear that if one is going to employ sterile pre-wetted wipers, they are best purchased rather than made in-house. The vendor of these products takes full responsibility for the necessary bioburden measurements, sterility validation program, package integrity testing, certificates of compliance and sterility and the process audit trail. Also, the vendor enjoys the economies of scale to provide a lower-cost product than could be made by the customer.

Summary

Sterile pre-wetted wipers are useful for the cleaning and maintenance of critical surfaces inside and outside sterile suites and for wiping gloves during sterile manufacturing processes.

References

1. "Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing", FDA, September, 2004; <http://www.fda.gov/cder/guidance/index.htm>
2. "EC Guide to Good Manufacturing Practice, Revision to Annex 1"; http://pharmacos.eudra.org/F2/eudralex/vol-4/pdfs-en/revan1vol4_3.pdf

THE AUTHOR

Howard Siegeman Ph.D.

Director Technology

ITW Contamination Control
partner of basan

Skejby Nordlandsvej 307

Dk - 8200 Aarhus N

Denmark

Tel: +45 87 400 220

Fax: +45 87 400 222

¹ Obviously, one would not autoclave pre-wetted wipers to try to render them sterile. The high temperatures within the autoclave would volatilize the 70% IPA solution through the packaging material and would create internal pressures within the package that could likely burst the package.