



## Prescription Compounding in the Office – Proper Disinfection of the Environment

An interesting article appeared in the March/April issue of the Parenteral Drug Association's (PDA) Journal of Pharmaceutical Science and Technology. We are summarizing this article for our clients who manufacture their own patient prescriptions. The article, entitled, "Evaluation of Disinfecting Procedures for Aseptic Transfer in Hospital Pharmacy Departments"<sup>1</sup> sheds some light on pharmacy operations and is valuable for anyone who wants to excel in their preparation of patient injections.

Everyone who compounds prescription medication is familiar with the risks of accidentally contaminating the product with bacteria from the environment; bacteria which may lead to skin infections or sepsis. So we all disinfect our work areas in an attempt to exclude the bacteria from getting into the vials. But what type of procedure should we follow to get the best results?

In an earlier newsletter, we outlined the requirements of USP <797> as applicable to the practice of allergy. The JCAAI developed industry guidelines based on the USP recommendations, that are important for allergists to follow. One aspect of these guidelines concerns the demonstration of disinfection of mixing surfaces. Additionally, the USP discusses the prevention of microbial contamination. Together, these recommendations demonstrate a concern for environmental control.

Allermed employs dedicated personnel to clean and disinfect the Prescription Compounding area each night prior to work. We use phenolic disinfectants, and rotate their use each week between an acidic and a caustic formulation. Every two weeks we use a sporicide to disinfect the area to ensure that no resistant organisms survive. This is a complex process, and may not be necessary for your facility. But we understand that bacteria have evolved to survive under some of the most stressed conditions on the planet, and it takes more than one disinfectant type to remove them all to ensure none end up in your prescription vial.

The PDA article we reviewed tested some of the more common disinfectants used in a pharmacy operation. These include:

Test Disinfectant
QUAT/Biguanide
QUAT /Chlorine dioxide
6% Hydrogen peroxide
Amphoteric surfactant
70% v/v denatured ethanol with deionised water
70% IPA with water for injection
Sterile distilled water (control)

<sup>1</sup>Mehmi, M., Marshall, L., Lambert, P., and Smith, J.C., *Evaluation of Disinfecting Procedures for Aseptic Transfer in Hospital Pharmacy Departments*, PDA J. Pharm. Tech., Vol. 63, No. 2, March/April 2009, pp. 123 – 138.



For test organisms, they chose some of the more difficult to kill. All were of the genus *Bacillus*, spore forming, gram positive organisms. They tested each disinfectant against each organism and as an additional attribute compared spraying alone vs. wiping alone vs. spraying and wiping.

In most of the test cases, the researchers found that spraying and wiping of surfaces was most effective at removing the organisms. The second most effective form of disinfection was wiping alone. Apparently the mechanical action of wiping removes a fair number of spores. The least effective method was spraying alone.

Sterile distilled water should be viewed as a control for this experiment although it is interesting to note that spraying and wiping with sterile distilled water consistently resulted in a 1.00 log (90%) reduction in the number of organisms on the surface. Alcohol (70%) is commonly used to disinfect the skin and is a good disinfectant for non-sporulating organisms such as Staphylococcus, but this study supported earlier research that demonstrated 70% alcohol is not a good environmental disinfectant. Upon testing alcohol laden wipes used in the study, many viable spores were recovered.

“Of the biocides tested, 6% hydrogen peroxide and a quaternary ammonium compound/chlorine dioxide combination were most effective compared to a Quat/biguanide, amphoteric surfactant, 70% v/v ethanol in deionised water and isopropyl alcohol in water for injection. Of the different application methods tested, spraying followed by wiping was the most effective, followed closely by wiping alone. Spraying alone was least effective.”

This conclusion may be used to help you decide what are the most appropriate disinfectants and methods to be used at your facility. The application of effective disinfectants in an effective manner are important considerations for you when considering the best manner of environmental control when compounding prescriptions.

If you or your staff have any questions about the facilities, techniques or supplies related to the aseptic manufacture of prescription products, please feel free to contact us by email at [info@allarmed.com](mailto:info@allarmed.com), or at (800) 221-2748. Our technical support staff will be happy to assist you.