(797) Pharmaceutical Compounding-Sterile Preparations (2008)

The United States Pharmacopeial Convention

ABSTRACT

Accelerated Hydrogen Peroxide® (AHP®) is continuing to gain popularity as one of the most effective and safest disinfectant chemistries. AHP is highlighted in the United States Pharmacopeia (USP) as THE product with a perfect balance between efficacy, safety and compatibility, revealing the technologies potential within compound pharmacy. The inclusion of AHP in the most recent USP edition reinforces AHP as an accepted disinfectant in the Pharmaceutical Industry.

BACKGROUND

The United States Pharmacopeia (USP) is the official public standardssetting authority for all prescriptions and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the Unites States. However, many other countries (including Canada) require the use of high-quality standards such as USP's to assure the quality of medicines and related products. Therefore, the USP disseminates standards to pharmaceutical manufacturers, pharmacists, and other users worldwide through its various publications. This document deals with the conditions and practices required to prevent harm to patients resulting from, among other things, microbial contamination of Compounded Sterile Preparations (CSPs). The focus of this document is on the avoidance of direct or contact contamination, in particular, the cleaning and disinfecting of the compounding area.

STUDY

Cleaning and Disinfecting the Compounding Area

"Environmental contact is a major source of microbial contamination of CSPs." Therefore, thorough attention to cleaning and disinfecting is required to minimize this as a source of contamination. The cleaning and disinfection practices and frequencies are determined by each individual area's likeliness to come in contact with the CSP and cause contamination. Direct compounding areas such as laminar air flow workbenches, bio-safety cabinets etc are more intimate to the exposure of CSPs and therefore require cleaning and disinfection daily, whereas housekeeping surfaces such as walls and ceilings of buffer or ante-areas require monthly cleaning and disinfection. The products used for cleaning and disinfecting are to be chosen with careful consideration of effectiveness, safety and compatibility. Ideally, a disinfectant technology should display broad spectrum microbicidal efficacy, good cleaning efficacy, be safe to use, environmentally sustainable and have widespread material compatibility. Table 2 (taken from Appendix II of the USP 797 document) highlights the most commonly used surface disinfectant technologies and their respective attributes.

Table 2

Appendix II
Common disinfectants used in health care for inanimate surfaces and non-critical devices, and their microbicidal activity and properties[1]

		Microbial Inactivation[2]						Important Chemical & Physical Properties						
Chemical Category of Disinfectant	Concentration Used	Bacteria	Lipophilic viruses	Hydrophilic viruses	M.tuberculosis	Mycotic agents (fungi)	Bacterial spores	Shelf life >1 week	Corrosive or deleterious effects	Non-evaporable residue	Inactivated by organic matter	Skin irritant	Eye irritant	Respiratory irritant	Systemic toxicity
Isopropyl alcohol	60-95%	+	+	±	+	+	-	+	±	-	+	±	+	-	+
Accelerated Hydrogen peroxide[4]	0.5%	+	+	+	+	+	-	+	-	-	±	-	-	-	-
Quaternary Ammonium (eg, dodecyl dimethyl ammonium chloride)	0.4-1.6% aq	+	+	±	±	+	-	+	-	+	+	+	+	-	+
Phenolics	0.4-1.6% aq	+	+	±	+	+	-	+	-	+	±	+	+	-	+
Chlorine (e.g., sodium hypochlorite)	100-5000 ppm	+	+	+	+	+	+	+	±	-	+	+	+	+	+
Iodophors (e.g., povidone-iodine)	30-50 ppm	+	+	±	±	±	-	+	±	+	+	±	+	-	+

STUDY CONCLUSION

The USPs guidelines for choosing a disinfectant technology emphasizes the importance of a well rounded product. As demonstrated, AHP provides the perfect balance between microbicidal effectiveness and safety. Most disinfectant technologies are inherently toxic, however, AHP's unique synergy provides superior broad-spectrum performance, without sacrificing the user's health.