



(USP 797) Pharmaceutical Compounding-Sterile Preparations

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 standards-setting authority for all prescriptions and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United 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.

CLEANING AND DISINFECTING THE COMPOUND AREA

“Environmental contact is a major source of microbial contamination of CSPs.” Therefore, thorough attention to cleaning and disinfection 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 properties¹

Chemical Category of Disinfectant	Concentration Used	Microbial Inactivation ²							Important Chemical & Physical Properties						
		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 ³	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)	30-60 ppm	+	+	±	±	±	-	+	±	+	±	±	+	-	+

CONCLUSION

The USP's 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.

IMPLICATIONS FOR AHP®

AHP® has mass potential in compound pharmacy as it gains stronger recognition and credibility. What has gained AHP® its reputation are its 5 pillars of strength.

AHP® Disinfectants are One-Step Disinfectant Cleaners

- AHP® has proven cleaning efficiency resulting in added confidence that disinfection can occur which results in lower costs and faster results

AHP® Disinfectants have realistic contact times

- Short contact times ensure surfaces remain wet for the required contact time, providing comfort and confidence that disinfection has occurred

AHP® Disinfectants provide the perfect balance between safety and efficacy

- AHP® is designed to be easier on employees and occupants resulting in protocol compliance

Technical Bulletin



- AHP® provides a HMIS rating of "0", meaning that handling the product does not require the use of personal protective equipment meaning less cost and downtime

AHP® Disinfectants are compatible

- AHP® formulations are tested to ensure compatibility that preserve your investments in equipment, furniture and building surfaces by reducing corrosion and wear

AHP® Disinfectants are environmentally sustainable

- AHP®'s active ingredient, hydrogen peroxide, breaks down into water and oxygen leaving no active residues
- AHP® is formulated to ensure that it will not negatively impact indoor air quality