Reduction of Microbes and Hazardous Drug Residues on IV Bags with a Sporicidal Disinfectant

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BACKGROUND

• Packaging such as corrugated cardboard and reusable plastic totes for compounding supplies can harbor bacterial and fungal spores.1
• To reduce the risk of microbial contamination in cleanrooms, the current version of USP <797> states: “Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent.”2 prior to entry into ISO-classified areas.
• During compounding of hazardous drugs (HDs), the outside surfaces of containers (e.g., IV bags, syringes, portable pumps) can become contaminated with drug residues, increasing the risk of occupational exposure during administration and disposal.

KEY QUESTIONS

• Is it appropriate to use an Environmental Protection Agency (EPA)-registered, one-step, sporicidal disinfectant composed of peracetic acid, hydrogen peroxide and surfactants (PAA/HP)3 to disinfect supplies such as IV bags as they are transported into cleanrooms?
• Can this same oxidizing disinfectant be used to decontaminate HD residues on IV bags containing compounded sterile preparations?
• What is the risk of the disinfecting/decontaminating agent permeating into IV bags?

EPA DISINFECTION CLAIMS

• The PAA/HP formulation has been tested extensively for surface disinfection of bacteria, fungi, viruses, mycobacteria and bacterial spores as part of the EPA-registration process.
• The required wet contact time for most bacteria, fungi and viruses is 2 minutes; 3 minutes for bacterial spores (C. difficile).
• The formulation includes surfactants to both clean and disinfect in the presence of moderate soiling (“one-step”).

RESULTS

RESISTANCE OF IV BAGS TO PERMEATION BY DISINFECTION/DECONTAMINATING AGENT

• The standard test method ASTM F-7394 is used to measure resistance of gowns and gloves to permeation by drugs and chemicals.
• This method was utilized to measure permeation resistance of four common types of IV bags (incl. seams) to the PAA/HP sporicidal disinfectant (PeridoxRTU® Sporicidal Disinfectant and Cleaner).

Results: No migration (<5 ppm) of the PAA/HP sporicidal disinfectant was detected through 8 hrs. of continuous exposure.

DECONTAMINATION OF HAZARDOUS DRUG RESIDUES FROM THE SURFACE OF IV BAGS

• A 3”x4” area on the surface of triplicate ViaFlex® IV bags was spiked with solutions of cyclophosphamide (50,000 ng), methotrexate (62,500 ng) and 5-fluorouracil (125,000 ng).
• After drying, each bag was wiped with a low-lint wiper wetted with the PAA/HP sporicidal agent.
• After 3 minutes, the bags were wiped again with a sterile 70% isopropyl alcohol pre-saturated wiper.
• The surface of the bags were sampled for residual HD contamination using a swabbing technique, extraction and analysis with chromatography.

Results: The EPA-registered one-step disinfectant effectively decontaminated multiple HDs from the IV bags.

REFERENCES

3. EPA Master Label 8383-13 for PAA/HP Sporicidal Disinfectant