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

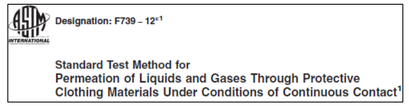
- Is it appropriate to use an Environmental Protection Agency (EPA)-registered, one-step, sporicidal disinfectant composed of peracetic acid, hydrogen peroxide and surfactants (PAA/HP)[3] to disinfect supplies such as IV bags as they are transported into cleanrooms?
- Can this same oxidizing disinfectant 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").

RESISTANCE OF IV BAGS TO PERMEATION BY DISINFECTION/DECONTAMINATING AGENT

- The standard test method ASTM F-739[4] is used to measure resistance of gowns and gloves to permeation by drugs and chemicals.


Designation: F739 – 12[ε1]

Standard Test Method for
Permeation of Liquids and Gases Through Protective
Clothing Materials Under Conditions of Continuous Contact[1]

Sample of IV bag with seam

- 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).

Source, Brand	REF	Material
Baxter, Viaflex®	2B1324X	Poly-vinyl chloride
B. Braun, Excel™	L8000	Rubberized blend of propylene and ethylene
B. Braun, E[3]™	E8000	Homogenous blend of polypropylene
B. Braun, CP0500 (For use with Pinnacle™ TPN System)	2112347	Ethylene vinyl acetate

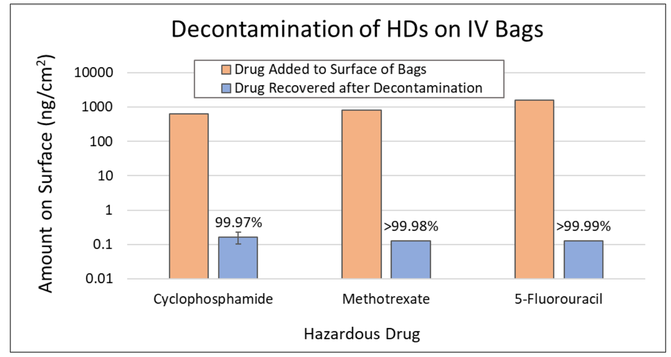
Results: No migration (<5 ppm) of the PAA/HP sporicidal disinfectant was detected through 8 hrs. of continuous exposure.

- Previous studies have used a sensitive assay for peroxides to understand permeation of IV bags with vapor-phase disinfectants.[5]
- This assay (PeroxiDetect™ Kit, Sigma-Aldrich) was utilized to measure potential permeation of the primary ingredient (hydrogen peroxide) in PAA/HP into the IV bags.

Results: No migration (<9 nanomoles/mL) of hydrogen peroxide was detected after 1 hr. of immersion in the sporicidal disinfectant.

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

1. Sandle, T. (2006). Clean Air and Containment Review, 28:4-6.
2. USP Compounding Compendium. (2017). USP <797> Pharmaceutical Compounding—Sterile Preparations.
3. EPA Master Label 8383-13 for PAA/HP Sporicidal Disinfectant
4. ASTM Standard F739-20. (2020). American Society for Testing and Materials.
5. Gérard, C., et. al. (2017). Pharmaceutical Technology in Hospital Pharmacy, 2:17-21.

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