Decontamination of Hazardous Drug Residues using a Sporicidal Disinfectant

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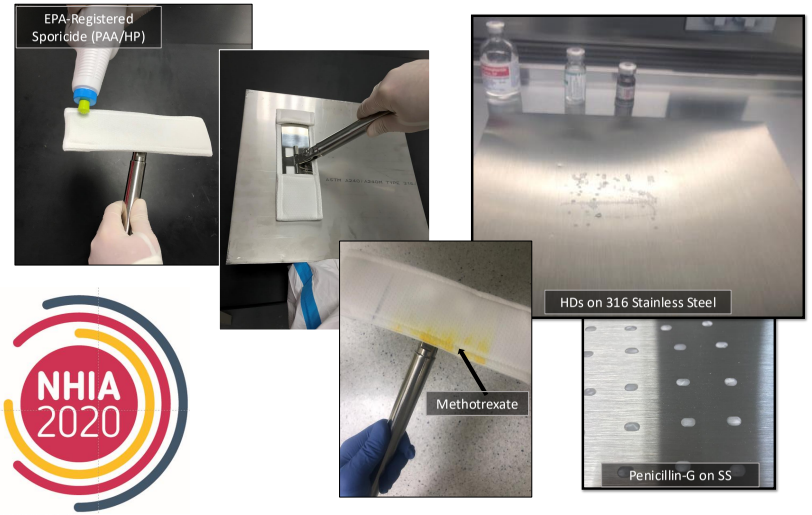
INTRODUCTION

- Decontamination of hazardous drugs (HDs) and β-lactam antibiotics from surfaces:
  - Is essential to reduce the risk of cross-contamination and occupational exposure.
  - Is required by several guidance documents[1,2,3].
- To explore alternatives, studies were conducted to:
  - Determine the feasibility of an EPA-registered sporicidal disinfectant to decontaminate HDs and β-lactams from stainless steel and plastic surfaces.
  - Understand the roles of physical removal versus degradation of the parent drugs.

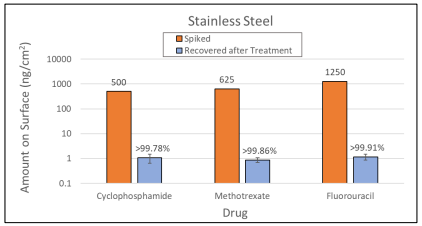
MATERIALS & METHODS

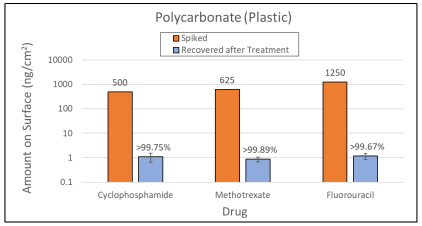
- Triplicate tiles (one square foot) of 316 stainless steel and polycarbonate (plastic) were spiked with one or more HDs as might occur during normal compounding or after a spill.
- After allowing the drugs to dry or waiting at least 30 minutes, the tiles were wiped twice with sterile wipers or mop pads saturated with an EPA-registered sporicidal disinfectant composed of peracetic acid, hydrogen peroxide and surfactants (PAA/HP)[4].
- After 3 minutes (dwell time for sporicidal efficacy)[4], the tiles were wiped with 70% sterile isopropyl alcohol (IPA).
- After drying, the tiles were sampled for residual contamination using a swabbing technique, extraction and analysis with chromatography. Mean levels of residual drugs were compared to initial levels after consideration of recovery efficiencies.
- Additional experiments examined the recovery efficiency of the sampling technique and whether degradation of the parent drugs played a role in the decontamination effect.



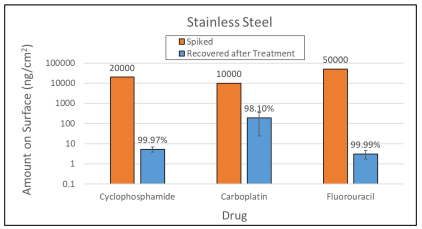
RESULTS

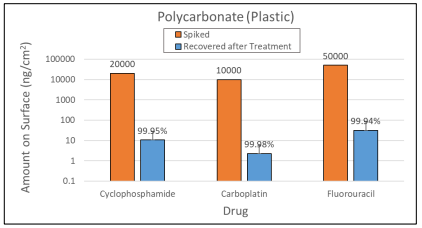
Multiple HDs (0.1 mL of each drug at ≥500 ng/cm²)





Multiple HDs (0.1 mL of each drug at ≥10,000 ng/cm²)





Individual HDs (0.1 mL at 1,000 ng/cm²)

Drug Residue (1000 ng/cm²)	Mean Level (ng/cm²) after Treatment (SD)	% Decontamination	Protocol
Antineoplastics			
Cisplatin	5.3 (2.7)	99.47	2x PAA/HP + 2x IPA (wipers)
Cyclophosphamide	0.8 (0.6)	99.92	2x PAA/HP + 2x IPA (wipers)
Fluorouracil	0.9 (0.8)	99.91	2x PAA/HP + 2x IPA (wipers)
Fluorouracil	1.1 (0.7)	99.89	2x PAA/HP + 1x IPA (mop pads)
Ifosfamide	0.6 (0.8)	99.91	2x PAA/HP + 2x IPA (wipers)
Methotrexate	0.6 (0.5)	99.94	2x PAA/HP + 2x IPA (wipers)
Paclitaxel	0.1 (0.1)	99.99	2x PAA/HP + 2x IPA (wipers)
Hormones			
Estradiol	<1.3 (0.0)	>99.9	2x PAA/HP + 1x IPA (mop pads)
Progesterone	<1.3 (0.0)	>99.9	2x PAA/HP + 1x IPA (mop pads)

Decontamination and Deactivation of Penicillin

Mean Level before Treatment	Mean Level after Treatment	% Reduction	Protocol
β-lactam Antibiotic (Penicillin-G)			
Removal + Degradation			
500 mcg/cm²	<0.01 mcg	>99.98%	1x Dry Wiper + 2x PAA/HP + 1x IPA (mop pads)
Degradation (Deactivation)			
20 mcg	<0.01 mcg	>95%	PCN-G mixed with 0.2 mL PAA/HP
200 mcg	<0.01 mcg	>99.5%	PCN-G mixed with 0.2 mL PAA/HP
2000 mcg	<0.01 mcg	>99.95%	PCN-G mixed with 0.2 mL PAA/HP
200 mcg	193 mcg	3.5%	PCN-G mixed with 0.2 mL water

CONCLUSIONS

- A cleaning protocol utilizing a non-bleach sporicidal disinfectant can effectively decontaminate antineoplastics, hormones and β-lactam antibiotics from common cleanroom surfaces.
- Similar results (% decontamination) were observed whether drugs were tested individually or in combination with initial residue levels ranging from 500-50,000 ng/cm².
- Recovery efficiency can vary substantially across drugs, surfaces and sampling protocols and should be considered when assessing results of environmental wipe sampling.
- Initial results suggest the PAA/HP formulation can degrade/deactivate Penicillin-G, but more studies are needed with other β-lactams and HDs.

REFERENCES

1. USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings (2019). USP 42—NF 37.
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4. EPA Master Label 8383-13 for PeridoxRTU® Disinfectant and Cleaner

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Disclosure of Financial Relationships: M. Bedenbaugh (Consultant - Contec, Inc.); M. Wiencek (Contec, Inc.)