Hazardous Drugs in Healthcare Settings

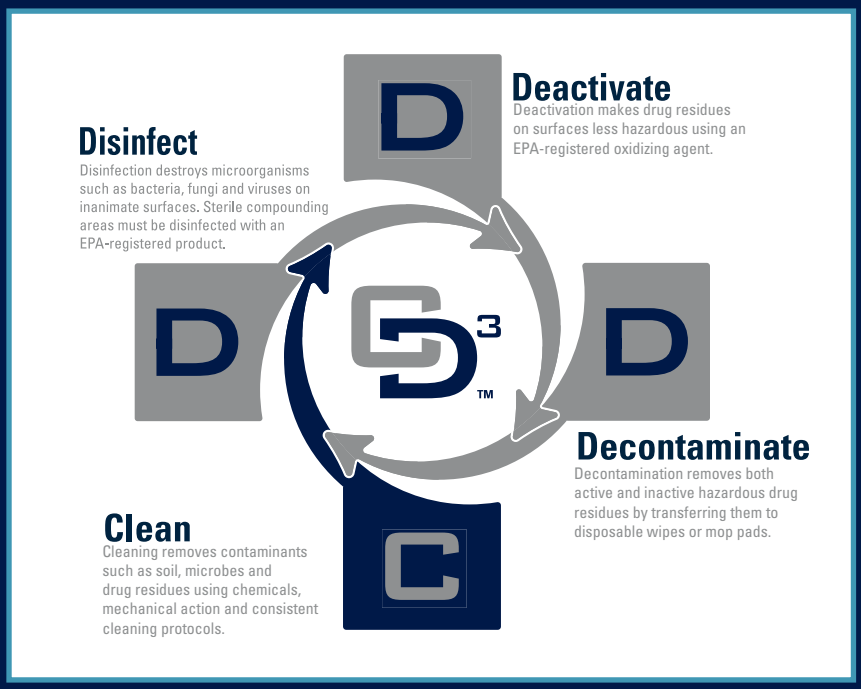
Decontamination in Compounding Environments

Unintended exposure to hazardous drugs (HDs) can pose serious health risks to personnel involved with compounding, administration, and disposal of these preparations. These potential risks, as well as recommended mitigation strategies, have been well documented by numerous organizations and peer-reviewed publications. For example, USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings contains details, requirements, ("shalls") and recommendations ("shoulds") to help address this issue. USP Chapter <800> is intended "to protect personnel and the environment when handling HDs. This includes but is not limited to receipt, storage, mixing, preparing, compounding, dispensing, administering, disposing, and otherwise altering, counting, crushing, or pouring HDs, and includes both sterile and nonsterile products and preparations." A key strategy in USP <800> to mitigate HD residues is introduced in Section 15: "All areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned. Additionally, sterile compounding areas and devices must be subsequently disinfected." (USP Compounding Compendium 2017. Rockville, Maryland: United States Pharmacopeial Convention; 2017. USP <800> Hazardous Drugs - Handling in Healthcare Settings; pp. 83-101).

Contec® Healthcare is committed to providing quality products and education to reduce bioburden in the compounding areas, but also to protect employees and patients from unintended exposure to hazardous drugs. This technical bulletin introduces the C-D^{3}™ Protocol and describes the use of an EPA-registered, sporicidal disinfectant to accomplish the four steps described in USP <800> for reducing hazardous drug residues in sterile compounding.

C-D^{3}™ Protocol

Contec Healthcare has introduced the C-D^{3}™ Protocol to demonstrate that all four aspects discussed in Section 15 of USP <800> – deactivation, decontamination, cleaning, and disinfection – can be accomplished with a single chemical formulation if applied with an appropriate wiping protocol. Currently, when used with appropriate textiles, PeridoxRTU® qualifies as a C-D^{3} Protocol.



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As shown below, the C-D³ Protocol with PeridoxRTU® addresses all the steps indicated in Table 5 of the current revision of USP <800> (2016).

Table 5. Cleaning Steps

Cleaning step	Purpose	Example agents	C-D³™ Protocol with PeridoxRTU®
Deactivation	Render compound inert or inactive	As listed in the HD labeling or other agents which may incorporate Environmental Protection Agency (EPA) registered oxidizers (*e.g.*, peroxide formulations, sodium hypochlorite etc.)	PeridoxRTU contains two EPA-registered oxidizers: hydrogen peroxide and peracetic acid
Decontamination	Remove HD residue	Materials that have been validated to be effective for HD decontamination, or through the use of other materials proven to be effective through testing, which may include alcohol, water, peroxide, or sodium hypochlorite	The C-D³ Protocol has been proven >99.9% effective by independent lab tests and field trials*
Cleaning	Remove organic and inorganic materials	Germicidal detergent	PeridoxRTU meets the definition of a germicidal detergent
Disinfection (for compounding sterile preparations)	Destroy microorganisms	EPA-registered disinfectant and/or sterile alcohol as appropriate for use	PeridoxRTU is an EPA-registered disinfectant

*Please visit www.contechealthcare.com or contact your local Contec Technical Sales Representative for updated testing results.

The cleaning steps described in Table 5 of USP <800> are targeted to the Containment Primary Engineering Control (C-PEC). However, an effective strategy for reducing occupational exposure to HDs should include all areas where contamination and exposures can occur – from receipt, through administration, and even including disposal. Although most of the historical studies conducted and sponsored by Contec also have focused on using the C-D³ protocol to reduce HD residues in the C-PEC, more recent efforts have expanded and modified the core protocol to address decontamination in between Compounded Sterile Preparations (CSPs) for different patients and in other areas where HDs are handled.

Recommended Best Practice C-D³ Protocol for C-PECs during the Daily Cleaning Operation

1. Using a wipe saturated with PeridoxRTU, wipe all irregular surfaces in the C-PEC. Allow the liquid to dwell for 3 minutes to ensure cleaning and sporicidal disinfection* occurs simultaneous to deactivation/decontamination.
2. Using a wipe or a mop pad with the EasyReach™ Cleaning Tool (preferred) wetted with PeridoxRTU, wipe all flat surfaces using unidirectional, overlapping strokes. Allow the liquid to dwell for 3 minutes* to ensure cleaning and sporicidal disinfection occurs simultaneous to deactivation/decontamination.
3. Rewet the wipe or mop pad as necessary. The same wipe/mop head can be used for the entire first pass of all flat surfaces provided it is not visibly soiled. The wipe or mop pad must be rewetted with PeridoxRTU as necessary to ensure dwell time is achieved.
4. Based upon the HD Residue Risk Assessment (see FAQ section below), repeat Steps 1-3, preferably with a new wipe/mop pad. It is only necessary to keep the surfaces wet for 3 minutes for one of the two passes to achieve sporicidal disinfection.
5. Wipe all irregular surfaces with sIPA.
6. Wipe all flat surfaces with sIPA.
7. Discard used wipes/mopheads according to facility SOPs.
8. Ensure all surfaces inside the C-PEC are completely dry before resuming compounding.

*Disinfection of *C. difficile* spores requires 3 minutes dwell time per the EPA-registered product label.

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Summary of C-D³ Protocols to Reduce HD Residues Based on Requirements in USP <800>, <797> and Recommended Best Practices				
What Surface?	**How Often?**	**Is it Required?**	**Why?**	**What is process and why?**
All surfaces inside C-PEC	Daily	Yes (<800>) Yes (<797>)	Deactivate/decontaminate Reduce microbial bioburden, including bacterial spores (3-minute dwell) per USP <797> Removes residues Clean and disinfect Remove residues	The interior of the C-PEC is likely to be more contaminated with HD residues than other work surfaces. Two passes of PeridoxRTU are recommended but may be reduced to one pass based on the outcome of the facility evaluation of risk for HD residue. 1. Wipe irregular surfaces, then flat surfaces with PeridoxRTU (3-minute dwell) 2. Wipe irregular surfaces, then flat surfaces with PeridoxRTU (no dwell required) 3. Wipe irregular then flat surfaces with sIPA to remove residues and allow to dry
Work surface (deck) inside Direct Compounding Area (DCA)	Between different HDs *(for different patients – See FAQ below)* Apply sIPA every 30 minutes or between CSPs	Yes (<800>) Yes (<797>)	Deactivate/decontaminate HDs so patients are not exposed to drugs they are not prescribed Reduce microbial bioburden and remove residues	1. Wipe entire deck or the work surface inside the DCA (depending on HD residue risk assessment) with PeridoxRTU (no dwell). 2. Facility decides if 1 or 2 passes with PeridoxRTU based on HD residue risk assessment. 3. Wipe entire deck or work surface area inside the DCA (depending on HD residue risk assessment) with sIPA and allow to dry
All surfaces in C-SEC/C-SCA* Work surfaces and floor in C-SEC/C-SCA	Weekly if desired	No, best practice recommendation No, best practice recommendation	Reduce microbial bioburden including bacterial spores (3-minute dwell) Reduce potential HD residue	1. Wipe irregular surfaces then flat surfaces with PeridoxRTU (3-minute dwell) 2. Wipe flat work surfaces and floor with PeridoxRTU (no dwell) if indicated by HD residue risk assessment. 3. Consider application of sIPA to work surfaces such as staging tables if desired to minimize residues from PeridoxRTU (not required).
All surfaces in C-SEC/C-SCA Work surfaces and floor in C-SEC/C-SCA	Monthly	Yes (<797>) No, best practice only	Reduce microbial bioburden including bacterial spores (3-min dwell) Reduce potential HD residue	1. Wipe irregular surfaces then flat surfaces with PeridoxRTU (3-minute dwell) 2. Wipe flat work surfaces and floor (including refrigerators and other at-risk surfaces) with PeridoxRTU (no dwell) if indicated by HD residue risk assessment and outcome of wipe sampling. 3. Consider application of sIPA to work surfaces such as staging table if desired to minimize residues from PeridoxRTU (not required).

* Containment Secondary Engineering Control/Containment Secondary Compounding Area
Requirements based on the 2016 version of USP <800> (not yet compendially-applicable) and the 2019 draft version of <797>

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Frequently Asked Questions

Do I have to wipe each surface twice with PeridoxRTU®?

- Though most recommended versions of the C-D^3 protocol involve wiping contaminated surfaces twice with PeridoxRTU, followed by wiping with 70% IPA, effective decontamination of areas with lower relative HD contamination may be achieved with one wipe of Peridox without rinsing with IPA. If there is less drug residue on surfaces, then less wiping is needed to reduce the contamination to non-detectable levels.
- As described above, the number of passes with PeridoxRTU should be justified based on a risk assessment (see below) of the likelihood that hazardous drug residues will be present and potentially at a high enough level to require two passes.
- Examples of surfaces with where HD contamination levels are expected to be lower include staging tables outside of the C-PEC, the DCA of the C-PEC between different types of HDs (especially where Closed System Transfer Devices (CSTDs) are used for compounding), and the floor of the C-SEC or C-SCA.
- Excessive contamination, like as might occur after a spill, requires immediate attention to remove any excess liquid as described in the protocol above. Additional treatments using the C-D^3 protocol may be required to reduce the contamination to non-detectable levels.

If I am only decontaminating HD residues, but not disinfecting, do surfaces have to stay wet for 3 minutes?

- When the C-D^3 protocol includes sporicidal disinfection, surfaces must remain wet with PeridoxRTU for 3 minutes as described on the product label.
- If PeridoxRTU is being applied twice, it does not matter whether the 3-minute dwell-time occurs with the first or second pass.
- For decontamination of HD residues, the longer PeridoxRTU remains in contact with the drug, the more degradation of the residues is likely to occur. This dwell time also could help solubilize dried residues of drugs, making them easier to remove with subsequent wiping steps.
- In many cases, users start in one area of a C-PEC or other space using a single pass with PeridoxRTU. By the time the entire area has been wiped with one pass of PeridoxRTU, at least 3 minutes have passed. Another pass with PeridoxRTU using the same process followed by IPA ensures maximum effectiveness of the C-D^3 protocol in C-PECs which may be appropriate based on the outcome of the HD risk assessment.

Do I have to decontaminate the work surface (deck) inside the direct compounding area (DCA) between different HDs?

- Section 15.2 of USP <800> states: "The work surface of the C-PEC must be decontaminated between compounding of different HDs."
- While USP <800> does not provide further explanation of this requirement, it is logical to assume that instruction pertains to different HDs prepared for different patients. A single patient often receives multiple HDs compounded and administered at the same time so that individual will be exposed to all those drugs and there is no risk of unintentional exposure from HD residues on the work surface. Therefore, it is not necessary to decontaminate the work surface (deck) inside the direct compounding area (DCA) between different HDs for the same patient.
- It is necessary to decontaminate between HDs for different patients.
- What are the factors to consider in a Hazardous Drug Residue Risk Assessment?
- Based on material handling and compounding processes, the consistency with which processes are followed, and feedback about relative HD contamination, a facility may quantify the relative risk to surfaces and decide on a 1- or 2-pass C-D^3 protocol.

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Examples of Work Practices that May Reduce HD Residues or Provide Feedback on the Effectiveness of Current Work Practices		
Before Compounding	**During Compounding**	**After Compounding**
HD inventory "received" inside C-SEC	CSTDs used for compounding and administration (for applicable preparations)	Final HD CSP is decontaminated according to SOPs
HDs stored in secondary packaging (boxes) inside C-SEC refrigerator or shelving	HD compounding in C-PEC staged in areas of "less" vs. "more" contamination	Final HD CSP placed into outer packaging for delivery using techniques that prevent contamination of the container
Dose removed from secondary packaging and decontaminated before placement into C-PEC	Decontamination of gloved hands and/or glove changes	Staging tables decontaminated and then wiped with sIPA between patients
Secondary packaging properly disposed of in trace chemo waste	Gloved hands not removed from C-PEC unless decontaminated	Periodic wipe sampling for HD residues for feedback on contamination levels

What data support the effectiveness of C-D^3 protocols?

- The effectiveness of C-D^3 protocols has been verified through several studies conducted at independent labs and from wipe sampling results in pharmacies that compound hazardous drugs. Generally, the lab studies involve spiking known amounts of HDs onto surfaces and then measuring for HD residues after contacting the C-D^3 protocol. Results of these studies indicate the C-D^3 protocol with PeridoxRTU is >99.9% effective at reducing HD residues.
- Tests to measure the contamination of HDs using the C-D^3 protocol include many of the marker drugs described in USP <800> and many surfaces found in cleanrooms. With over 200 drugs on the NIOSH list, it is not practical to test all drugs. However, the protocol is likely to produce similar results on other nonporous surfaces as well as other HDs.
- Contec Healthcare continues to perform testing on different surfaces and other HDs. Please visit www.contechealthcare.com or contact your local Contec Technical Sales Representative for updated testing results.

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