

TECHNOTES

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An Observational Study of Using the
TexQ® Disinfectant Cleaning
Protocol in Removing
**Hazardous Drug Contamination
During Sterile Compounding** ►

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Introduction

The American Society of Health-System Pharmacists (ASHP), National Institute for Occupational Safety and Health (NIOSH), part of Centers for Disease Control and Prevention (CDC), Occupational Safety & Health Administration (OSHA), and The United States Pharmacopeial Convention (USP) have documented the health risks associated with handling hazardous drugs for workers associated with the healthcare industry, including compounding pharmacists, nurses and doctors, and others such as janitorial personnel, researchers, even shipping and receiving personnel. These health risks may range from a skin rash to reproductive issues (infertility, birth defects) and possible cancerous outcomes. Because of the severe impact to a wide range of personnel, the ASHP Guidelines, OSHA's Technical Manual, current USP chapter 797 prescribe safe handling practices for these drugs. USP has a pending chapter 800 titled, "Hazardous Drugs – Handling in Healthcare Settings," which will apply to healthcare workers, who receive, store, compound, dispense, administer, and dispose of hazardous drugs.

The sterile compounding of hazardous drugs is in a sense the intersection of chemical hygiene and contamination control – handle hazardous drugs safely using engineering controls and safe handling practices while maintaining a controlled environment to ensure continued product sterility. An effective process of hazardous drugs decontamination requires their effective and safe removal from fixed work and adjacent surfaces to a disposable place to protect personnel and the working environment. The uncontrolled contaminants are safely controlled and removed for disposal.

A compounding pharmacy inquired of Texwipe to assist with their chemo-drug removal cleaning protocol for the compounding hood. Their previous test results indicated a continued level of hazardous drug contamination remaining on work and environmental surfaces after using their cleaning protocol. The concentration of 5-fluorouracil (5-FU) left on the hood work surface after cleaning was in the range of 35.62 to 76.39 ng/ft². The ChemoGLO™ test kit was used for the determining the contamination level.

Texwipe provided a cleaning protocol which included TexQ®, a disinfectant and cleaner, and wipers pre-wetted with a 70% USP-grade isopropyl alcohol (IPA) solution, and instructions for proper wiping technique, and proposed to determine the protocol's effectiveness for decontaminating the same hood surface exposed to hazardous drugs.

Purpose

The observational study includes the evaluation of the drug removal efficiency of Texwipe's cleaning protocol, i.e., how much of the hazardous drug is removed after all the cleaning steps outlined below are followed. This involves measuring the amount of 5-FU remaining on the surface after using the prescribed cleaning protocol.

Products used in the cleaning protocol

- **TexQ® disinfectant (TX650)**, gamma-irradiated, is a one-step cleaning and disinfecting agent for hard, non-porous surfaces such as glass, laminated surfaces, metals such as stainless steel, and plastics such as polycarbonate, polyvinylchloride, polypropylene, vinyl, and Plexiglas®. TexQ® cleans and disinfects in one step, removing soils and decontaminating the surface. The product is an EPA registered disinfectant and has kill claims for 61 germs (32 bacteria, 25 viruses and 4 fungi).

TexQ® is able to remove both inorganic-, such as metal ions, and organic-based surface contaminants. The product formulation ensures uniform wetting of the surface and penetration into surface imperfections which results in uniform cleaning and disinfection.

- **SterileWipe™ HS II 12" x 12" dry wipers (TX3210)**, sterile, are cellulose/polyester-blend wipers which are cleanroom processed having high absorbency, excellent chemical compatibility with a variety of solutions, and relatively low levels of particles and extractables. These wipers are suitable for general cleaning and wiping in clean and controlled environments. SterileWipe™ HS II allows for a quick and efficient removal of liquid from the surface.
- **Sterile 9" x 11" TechniSat® pre-wetted wipers (TX3214)**, sterile, cellulose/polyester-blend wipers which are cleanroom processed and pre-wetted with 70% USP-grade



isopropyl alcohol to provide a consistent, repeatable wetness level for optimized cleaning efficiency and a predictable VOC level. They are ideal for residue removal purposes.

- **ChemoGLO™** (ChemoGLO™, LLC, North Carolina) is a kit used to evaluate the contamination level of the work environment after compounding of chemotherapy agents. Each kit allows testing of six surfaces for common chemotherapy active ingredients.

Experimental

The study consisted of testing the hood compounding work area for the 5-FU contamination level after six compounding activities of 5-fluorouracil (total of six tests) in a laminar airflow stainless steel hood at a compounding pharmacy. Before compounding, the hood surfaces were cleaned and disinfected according to the facility's approved SOP cleaning protocol. The proposed cleaning protocol was performed after each compounding (with the initial drug quantities ranging from 4500 to 6000 mg, or 3.33×10^8 to 5.00×10^8 ng/ft²) using the products listed above.

The cleaning steps were the following:

1. A dry wipe (TX3210) was saturated with TexQ® solution (TX650) by spraying the wiper. (The surface should not be sprayed directly to prevent the possibility of spreading any contaminants.)
2. The surface was cleaned with the TexQ-saturated wipe using overlapping strokes. The wiping technique is described in Appendix 1.
3. This contaminated wiper was discarded in a manner consistent with the facility guidelines and local regulations.
4. The surface was cleaned with a sterile 70% IPA saturated wipe (TX3214) using the same wiping technique. This wipe was also discarded.
5. Steps 1-4 were repeated using the same wiping technique but at ninety degrees to the previous wiping direction. The repeat process helps ensure all surface areas are wiped to minimize the possibility of any contaminated areas being left behind.

After the cleaning procedure, the work surface was sampled using the ChemoGLO™ test kit instructions to determine the 5-FU level left on the surface. After that the surface was re-cleaned and disinfected using the facility's SOP protocol to maintain the current validation.

Results

The previous 5-FU contamination level results after using the compounding pharmacy's current cleaning protocol ranged from 35.62 to 76.39 ng/ft².

The 5-FU contamination level results after Texwipe's cleaning protocol were less than 10 ng/ft², which is below the Lower Limit of Quantitation (LLQ). The results that are lower than the LLQ are considered as Not Detectable.

Conclusion

Texwipe performed an observational study under real working conditions of an active compounding pharmacy where the amount of 5-FU was followed through a decontamination process that encompasses chemical contamination control through the use of a sterile one-step cleaner/disinfectant, a residue remover and wipers. When finished, the surface was left 5-FU free.

The cleaning protocol, which consisted of using a TexQ solution, other Texwipe cleaning products and the proper wiping technique, was shown to be effective in cleaning and removing chemotherapy drugs from the tested surfaces. The quantity of hazardous drugs left on the surface was below the Lower Limit of Quantitation (LLQ) (less than 10 ng/ft²) which is considered Not Detectable.

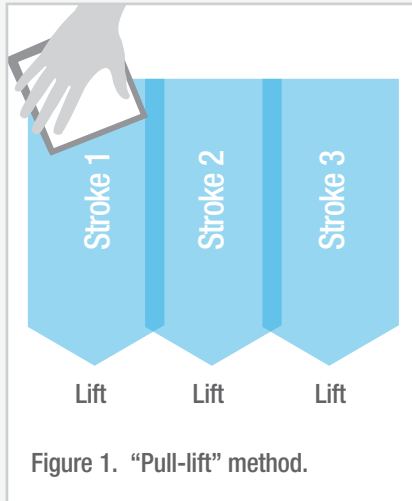
The proper combination of products, cleaning technique and the protocol steps proposed by Texwipe are important to achieve effective results in a hazardous drug decontamination process.

Note: The rule of aseptic compounding is that cleaning (or decontamination) must be performed before disinfection. In this study, TexQ Disinfectant was used as a part of the cleaning protocol for chemo drug removal purposes. TexQ Disinfectant may be also used for surface disinfection, after the chemo drug cleaning process/removal is completed. **For the best disinfection results, the following Texwipe wipers may be used with TexQ Disinfectant: Sterile: TX3211, TX3220, TX3042, TX3049; Non-sterile: TX409.**



References

- ASHP Guidelines for Handling Hazardous Drugs, Developed by the ASHP Council On Professional Affairs And Approved By The ASHP Board Of Directors On January 12, 2006, Am J Health-Syst Pharm. 2006; 63:1172-93. This document can be found at <http://www.ashp.org/menu/PracticePolicy/PolicyPositionsGuidelinesBestPractices/BrowsebyDocumentType/GuidelinesMain.aspx>, Handling Hazardous Drugs. May 4, 2015.
- OSHA Technical Manual (OTM) Table of contents, https://www.osha.gov/dts/osta/otm/otm_toc.html, found on May 4, 2015; Section VI: Health-Care Facilities Chapter 2. Controlling Occupational Exposure to Hazardous Drugs, https://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html. May 4, 2015.
- Centers for Disease Control and Prevention, NIOSH (The National Institute for Occupational Safety and Health), Workplace Safety and Health Topics, Hazards and Exposures: Hazardous Drug Exposures in Health Care, <http://www.cdc.gov/niosh/topics/hazdrug>. May 4, 2015.



Appendix 1.

Wiping technique

- Wipe from the cleanest area to the dirtiest.
- The **"pull-lift" method**: The wipe is placed onto the surface, for example, pulled toward the person for 2 feet (could also be from the left to the right), lifted off the surface and relocated for a second stroke as shown in Figure 1 for Strokes 1 and 2. Use another wipe for Strokes 3 and 4.
- Each stroke should overlap the previous stroke by **20%** for even coverage.
- Note: Traditional cleanroom wiping guides suggest quarter folding the wipe to maximize the useable surface area of the wipe and unfolding the wiper to reveal new surfaces for cleaning. When cleaning hazardous drugs, do not follow this technique as precautions should be taken to minimize the potential contact of a contaminated wiper surface with the operator's hand conducting the cleaning. The wiping technique should be done to ensure even contact with the surface being wiped, similar to a squeegee when cleaning a window.

Texwipe recommends to use the CleanStep™ adhesive mat (18" x 36", part number AMA183681W), a 30-layer adhesive mat to be used for reducing the spread of the chemotherapy drugs throughout the compounding facility that may fall to the floor in front of the hood as well as for helping minimize the tracking of chemo drug by walking to other areas of the facility.

For additional information, please contact Texwipe Customer Service at the number listed below.

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