TECHNOTES
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The Effectiveness of the **TexQ® Decontamination Protocol** in Cleaning Surfaces Soiled with **Hazardous Drugs**

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Summary

The Texwipe-developed decontamination protocol that includes TexQ® cleaner and disinfectant and 70% USP-grade Isopropyl Alcohol (IPA) pre-wetted wipers was shown to remove at least 99.99% of several hazardous drugs commonly processed in compounding pharmacies. The testing was performed by *Bureau Veritas North America (BVNA).*

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. The upcoming USP <800> includes other personnel who may potentially be exposed to HDs (Hazardous Drugs): pharmacists, pharmacy technicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians. These health risks may range from a skin rash to reproductive issues (infertility, birth defects), organ damage and possible cancerous outcomes. Because of the severe impact to a wide range of personnel, the ASHP Guidelines, OSHA's Technical Manual, and current USP chapter <797> prescribe safe handling practices for these drugs. At the time of this writing, USP has a pending chapter, USP <800>, titled, "Hazardous Drugs—Handling in Healthcare Settings," which will apply to the above healthcare workers, who receive, store, compound, dispense, administer, and dispose the hazardous drugs.

According to that chapter, handling hazardous drugs safely using proper engineering controls and correct handling practices including good decontamination protocols plays a crucial role in maintaining a controlled environment and ensuring personnel protection in the workplace. An effective process of hazardous drugs decontamination requires their safe removal from fixed work and adjacent surfaces to the appropriate disposal outside the compounding area.

Texwipe developed a protocol which includes TexQ®, a disinfectant and cleaner, and wipers pre-wetted with a 70% USP-grade IPA solution for the decontamination of surfaces exposed to hazardous drugs. The efficacy of that protocol was assessed at **Bureau Veritas North America (BVNA)**, an independent testing organization internationally recognized as a leader in testing, inspection, and certification.

What is a hazardous drug?

Drugs considered hazardous include those that exhibit one or more of the following six characteristics in humans or animals:

- Carcinogenicity
- Teratogenicity or other developmental toxicity†
- Reproductive toxicity†
- Organ toxicity at low doses†
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

†*All drugs have toxic side effects, but some exhibit toxicity at low doses. The level of toxicity reflects a continuum from relatively nontoxic to production of toxic effects in patients at low doses (for example, a few milligrams or less).*

Source:
NIOSH [2014]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2014. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2014-138 (Supersedes 2012-150).

Purpose

BVNA proposed activities to assess the efficacy of the Texwipe decontamination protocol that uses sterile TexQ® cleaner and disinfectant and sterile 70% IPA pre-wetted wipers for the removal of hazardous drug residues from a standard test surface. All tests were performed using 316-grade stainless steel as the substrate test surface. Spiking of substrate surfaces was performed in a consistent manner throughout the study using hazardous drug solutions in solvent, according to the relevant BVNA Standard Operating Procedures (SOPs). Texwipe's protocol was adapted by BVNA to be performed in a standardized and consistent manner. The post cleaning sample collection, extraction and analysis are as defined and validated in the relevant BVNA testing methods. The protocol efficacy was evaluated in two phases to ensure its proper validation.

Phase I was limited to evaluation of the protocol's decontamination efficacy for 5-fluorouracil (5-FU). A successful result of 99.99-100.00% efficacy (mean effectiveness) was obtained in Phase I. With these results, the study was broadened to include other hazardous drugs, and the study was moved into Phase II.

Phase II, testing with multiple drug products, was implemented to show that the decontamination protocol was effective for multiple hazardous drug products. The test results for this phase showed an efficacy of 99.99-100.00% for all tested compounds.

Experimental

A 316-grade stainless steel coupon was spiked with one hundred micrograms of a specific hazardous drug in solution. This process was performed according to relevant BVNA Standard Operating Procedures (SOPs). The dried, spiked coupons were decontaminated according to Texwipe's protocol. The cleaned surfaces were sampled by swabbing the coupon surface. The swabs were extracted, and the extract was analyzed using a LC/MS/MS separation, detection, quantification technique for the level of the remaining spiked hazardous drug on the coupon as defined and validated in the relevant BVNA testing method SOPs.

The decontamination protocol consisted of wetting a dry wiper with TexQ® TX650 cleaner and disinfectant, wiping the contaminated surface using parallel, overlapping strokes, wiping again with a 70% IPA pre-wetted wiper using parallel, overlapping strokes, and repeating these steps again at ninety degrees to the first steps. These steps are better described in **Appendix 1**. The results of the protocol efficacy testing are shown below.

Results

The decontamination protocol efficacy was first evaluated using one hazardous drug, 5-fluorouracil. The results of this evaluation were compiled in **Table 1**. The results for 5-fluorouracil indicated that the protocol was **99.99% effective** for decontaminating surfaces soiled with the hazardous drug, 5-fluorouracil. The test was repeated for a total of three samples.

Table 1. *Phase I results using 5-fluorouracil as the test substance*

Drug	Sample #	Dosed, mcg	Recovered*, mcg	Cleaned, %	Mean Effectiveness
5-fluorouracil	1	100	0.006	99.994	**99.990%**
	2	100	0.010	99.990	
	3	100	0.013	99.987	

mcg - micrograms
**The limit of quantitation (LOQ) is 0.001 mcg per sample for 5-fluorouracil.*

With the protocol shown to be effective for 5-fluorouracil, Phase I was completed. The protocol was next validated against other hazardous drugs for the Phase II evaluation. These results are compiled in **Table 2**.

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Table 2. *Phase II results using five hazardous drug substances*

Drug	Sample #	Dosed, mcg	Recovered*, mcg	Cleaned, %	Mean Effectiveness
5-fluorouracil	1	100	0.001	99.999	**99.994%**
	2	100	0.007	99.993	
	3	100	0.009	99.991	
Cyclophosphamide	1	100	0.001	99.999	**99.999%**
	2	100	0.001	99.999	
	3	100	0.002	99.998	
Ifosfamide	1	100	0.001	99.999	**99.998%**
	2	100	0.001	99.999	
	3	100	0.002	99.998	
Paclitaxel	1	100	0.002	99.998	**99.996%**
	2	100	0.009	99.991	
	3	100	0.002	99.998	
Methotrexate	1	100	0.002	99.998	**99.997%**
	2	100	0.003	99.997	
	3	100	0.005	99.995	

mcg - micrograms
**The limit of quantitation (LOQ) is 0.001 mcg per sample for 5-fluorouracil, Cyclophosphamide, Ifosfamide, and Methotrexate. The LOQ is 0.002 mcg per sample for Paclitaxel.*

These results complete Phase II, showing **at least 99.99% effectiveness** for decontaminating surfaces soiled with several hazardous drugs: 5-fluorouracil, Cyclophosphamide, Ifosfamide, Paclitaxel and Methotrexate.

Conclusion

The decontamination protocol containing TexQ® cleaner and disinfectant and 70% IPA (Isopropyl Alcohol) pre-wetted wipers was shown to remove **at least 99.99%** of numerous hazardous drugs compounds commonly used in sterile compounding pharmacies: 5-fluorouracil, Cyclophosphamide, Ifosfamide, Paclitaxel and Methotrexate.

The proper combination of products, wiping technique and the protocol steps proposed by Texwipe are important to obtain effective surface cleaning results in the decontamination process. The protocol is described in **Appendix 1**.

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

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Visit us at www.texwipe.com

Reference

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 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.

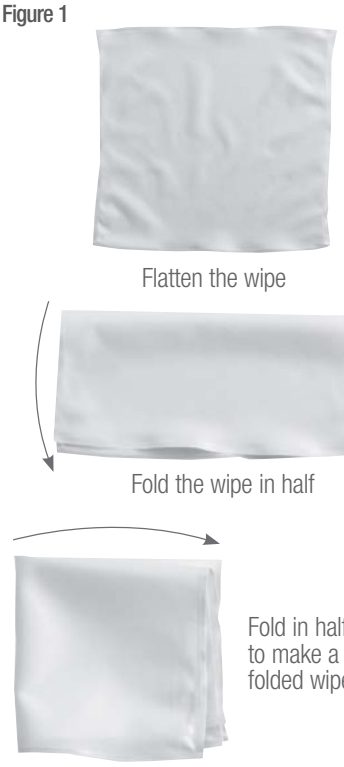
Centers for Disease Control and Prevention, NIOSH (The National Institute for Occupational Safety and Health), Workplace Safety and Health Topics, Hazards and Exposures: Hazardous Drug Exposures in Health Care, www.cdc.gov/niosh/topics/hazdrug. May 4, 2015.

Appendix 1.

The TexQ® Decontamination Protocol for Hazardous Drugs Removal

1. Remove any excess liquid from the surface to be decontaminated using **any sterile Texwipe dry wiper*** listed in **Appendix 2**. Discard the contaminated wiper in a manner consistent with the facility SOP.
2. Spray the TexQ® solution on a sterile dry wiper. Use a **TexQ-compatible wiper*** from the chart in **Appendix 2**.
   a. Quarter fold a wiper. See **Figure 1**.
   b. With the nozzle on stream, not spray, pump the TexQ® TX650 trigger four or five times, until the wiper is well dampened, but not wet and certainly not dripping.
3. Wipe the surface with the TexQ-wetted wiper, using parallel, unidirectional overlapping strokes. **Use one wiper for each stroke** (up to 40 inches in length). See **Figure 2**.
4. Discard the contaminated wiper in a manner consistent with the facility's SOP.
5. Wipe the surface with a sterile 70% isopropyl alcohol (IPA) pre-wetted wiper using the same wiping technique described in Step 3. Discard the wiper. (See Texwipe's pre-wetted wipers offering in **Appendix 3**).
6. Repeat Steps 1-4 using the same wiping technique at ninety degrees (90˚) to the previous wiping direction.

Figure 1



Appendix 2.

Texwipe Wipers/TexQ® Disinfectant Compatibility Chart

Wiper Material/Fabric	Wiper Product Part Numbers	TexQ® TX650, TX651
Polyester/Cellulose	TX622, TX624, TX629, TX604, TX606, TX609, TX612,TX1109, TX1112, TX1118, **TX3210**	✗
Microdenier (100% polyester)	TX59, **TX3059**	✓
Polyester	TX1010, TX1012, TX1029, TX1050, TX1052, TX1060, TX1069, TX1070, TX1080, TX8659, TX1003, TX1004, TX1009, TX1009B, TX1013, TX1008, TX1008B, TX2064, TX2069, TX2424, TX2452, TX2409, TX2412, TX2418, TX49, TX42, TX29, TX22, **TX3042, TX3049, TX3215, TX3225, TX3220, TX3211, TX3212, TX3221, TX3224**	✓
Nylon	TX4004, TX4009, TX4012	✗
Cotton	TX309, TX306, TX304, TX318, TX312, TX329	✗
Foam	TX704	✓
Polypropylene/ Cellulose	TX699	✗

✓ Compatible
✗ Not compatible

Texwipe Sterile Product Part Numbers are **highlighted in bold text**.

*Recommended dry wipers: TX3059, TX3221

Figure 2

Wipe from a clean area to the dirtiest, usually back to front on horizontal surfaces and from top to bottom on vertical surfaces. Consistently move left-to-right or right-to-left. Do not mix. **Use one wiper for each stroke.**

Appendix 3.

Texwipe's Pre-wetted Wipers Product Offering

Solution	Material	Name	Size	TX#	Bag Qty	Case Qty	ISO Class	EU Grade
Non-Sterile								
IPA 70%	Polyester	Vertex® HS	12" x 12" (30 cm x 30 cm)	TX42P	50	4	3-7	A-D
			9" x 9" (23 cm x 23 cm)	TX49P	75	4	3-7	A-D
		AlphaSat®	4" x 4" (10 cm x 10 cm)	TX1034	200	4	4-8	A-D
			6" x 6" (15 cm x 15 cm)	TX1036	75	12	4-8	A-D
			9" x 9" (23 cm x 23 cm)	TX1039	50	4	4-8	A-D
		QuanSat™	9" x 9" (23 cm x 23 cm)	TX1084	50	12	3-7	A-D
	Polyester/ Cellulose	TechniCloth®	6" x 8" (15 cm x 20 cm)	TX1045	100	12	5-8	B-D
			9" x 11" (23 cm x 28 cm)	TX1041	70	12	5-8	B-D
			9" x 11" (23 cm x 28 cm)	TX1065	50	24	5-8	B-D
			7" x 11" (18 cm x 28 cm)	TX1067	200	4	5-8	B-D
	Polypropylene	PolySat®	7" x 11" (18 cm x 28 cm)	TX1040	200	4	5-8	B-D
			9" x 11" (23 cm x 28 cm)	TX1051	50	24	5-8	B-D
			6" x 11" (15 cm x 28 cm)	TX8723	75	24	5-8	B-D
			6" x 11" (15 cm x 28 cm)	TX8727	75	20 & 1 case container	5-8	B-D
Ethanol 70%	Polyester/ Cellulose	TechniCloth®	7" x 11" (18 cm x 28 cm)	TX1068	25	20	5-8	A-D
Sterile								
IPA 70%	Polyester	Vertex® HS	12" x 12" (30 cm x 30 cm)	TX3042P	25	5	3-7	A-D
			9" x 9" (23 cm x 23 cm)	TX3049P	25	5	3-7	A-D
		AlphaSat®	12" x 12" (30 cm x 30 cm)	TX3252	25	5	4-8	A-D
		AlphaSat® 10	12" x 12" (30 cm x 30 cm)	TX3280	50	5	2-7	A-D
			9" x 9" (23 cm x 23 cm)	TX3285	20	20	2-7	A-D
	Polyester/ Cellulose	TechniCloth®	9" x 11" (23 cm x 28 cm)	TX3214	50	24	5-8	B-D
			9" x 11" (23 cm x 28 cm)	TX3217	20	24	5-8	B-D
	Polypropylene	PolySat®	9" x 11" (23 cm x 28 cm)	TX3213	50	24	5-8	B-D
			9" x 11" (23 cm x 28 cm)	TX3216	20	24	5-8	B-D
Ethanol 70%	Polyester/ Cellulose	TechniCloth®	7" x 11" (18 cm x 28 cm)	STX1068	50	20	5-8	B-D
	Polyester	Vertex® HS	12" x 12" (30 cm x 30 cm)	TX3044P	25	5	3-7	A-D

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