WipeDown 1-2-1 Sterile

3 Step Applicator

WIPEDOWN™ 1-2-3
3 Step Applicator Kit

Wipe Kit

For addressing <USP 800> Hazardous Drugs - Handling in Healthcare Settings

Product Overview

VAI's **WipeDown 1-2-3** was designed to address the risk of occupational exposure to most hazardous drugs during compounding sterile preparations, and administering, as outlined in USP <800>. **WipeDown 1-2-3** is a sterile 3 step application kit including individually packaged saturated wipes with 5.25% Sodium Hypochlorite, 2 % Sodium Thiosulfate, and 70% Isopropyl Alcohol. When used in sequence the 3 sterile saturated wipers provide deactivation, decontamination, and disinfection/cleaning of sterile compounding surfaces from most hazardous drugs.

Each WipeDown 1-2-3 *Sterile* Kit Contains:

- Packet #1 – HYPO-CHLOR®, 5.25% Sodium Hypochlorite for deactivation
- Packet #2 – THIO-WIPE, 2% USP Thiosulfate for decontamination
- Packet #3 – ALCOH-WIPE®, 70% USP Isopropyl Alcohol for disinfecting/cleaning

WipeDown 1-2-3 wipes consist of, non-woven, non-shedding 9"x12" premium wiper materials that are designed to be exceptionally clean, have excellent absorption capabilities, and provide substantial surface coverage. WipeDown #1 is made of 100% polypropylene while WipeDown #2 and WipeDown #3 are made of 100% polyester. Both fabrics are soft, strong, and have outstanding non-shedding particulate performance. Each material was chosen for its specific compatibility with each chemical.

All three chemical components used in **WipeDown 1-2-3** are formulated with Water for Injection (WFI) and filtered at 0.2 microns. Each wiper is individual packaged with sterility assured through gamma irradiation and/or aseptic filtration into sterile components. Each lot of **WipeDown 1-2-3** comes with lot specific documentation including, three certificates of analysis for each of the chemicals, a certificate of irradiation, and a certificate of sterility. Each kit containing three individually packaged wipers is bagged and packaged into a liner bag for easy transport into the sterile area. Each kit is labeled with lot number and expiration date.

Product Use

USP<797> Compounding sterile preparations, in an ISO 5 (Grade A/B, Former Class 100) operation require materials that are entering into the classified area to be sterile. Whereas, USP <800> requires hazardous drug deactivation in compounding sterile preparations for patient and handler protection. **WipeDown 1-2-3** assures the highest quality compounding sterile preparations program possible by developing a *sterile* three step kit to deactivate most hazardous drugs.

Ordering Information

Product Numbers

VEL13-9X12-S-3123	WipeDown 1-2-3, 3 Step Applicator Kit, Sterile	3 wipes/kit, 15 kits/box

Step #1: HYPO-CHLOR® 5.25% Wipe

Wiper #1 of **WipeDown 1-2-3** is saturated with a sterile 5.25% sodium hypochlorite solution with Water for Injection (WFI) for deactivation of most hazardous drugs. This HYPO-CHLOR 5.25% wipe protects the compounding preparers by deactivating the potentially active drugs present on the compounding surface. After use of the HYPO-CHLOR 5.25% wipe and subsequent wipes in the kit, the surface is rendered safe and decontaminated for future handlers. Therefore, it ensures that these compounding preparations are following USP <797> compounding sterile preparations for patient protection protocol along with USP <800> compliance for hazardous drugs - handling in healthcare settings.

Wiper #1, HYPO-CHLOR 5.25% wipe is a 9”x12” premium, non-woven, 100% polypropylene wipe that has low shedding characteristics. Each wipe covers approximately a 6 square foot area for optimal surface deactivation of most hazardous drugs present within the compounding operation. Each HYPO-CHLOR 5.25% wipe comes individually packaged. Sterility of the HYPO-CHLOR wipe is assured though aseptic filtration into sterile components via gamma irradiation. Lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation are issued and delivered with each shipment.

Quality and Manufacturing

- Lot sterility test according to current USP compendium
- Assayed according to current USP compendium
- Sodium Hypochlorite is filtered at 0.2 microns
- Each kit is labeled with lot number and expiration date
- Packaged neatly folded for easy removal
- Completely lot traceable
- Easy tear perforations on each wiper packet for easy open
- Double bagged sterile
- Aseptically filled into sterile components via gamma irradiation

Features and Benefits

- Delivered with lot specific documentation
- 9” x 12” in size
- Low in particulate shedding and soluble extractable
- Designed to comply with USP <797>
- Deactivates most hazardous drugs present on compounding surface
- Delivered with lot specific certificates
- Formulated with WFI
- Ready-to-use

Chemical Specifications

Chemical Specifications	HYPO-CHLOR, Sodium Hypochlorite 5.25% Wipe
Assay Test	4.0-6.0% w/w
Litmus paper turns blue	Pass
Addition of HCL gives off CL2 gas	Pass
Yellow Flame Test	Pass
Sterility	Aseptic Fill
Shelf Life	1 year

Material Specifications

WipeDown Wipe #1 – HYPO-CHLOR 5.25%		
Material Specification	**Value**	**Test Method**
Material	100% Polypropylene	N/A
Color	White	N/A
Composition	Melt/Spun/Melt with hydrophilic additive, non-woven	N/A
Basis Weight	34g/m^2 +/- 10%	ASTM D3776M-09A
Thickness	0.34 mm	WSP 120.6.R4(12)

*Treats approximately 6 square feet

Step #2: THIO-WIPE 2%

Wiper #2 of **WipeDown 1-2-3** is saturated with 2% USP grade sodium thiosulfate solution formulated with Water for Injection (WFI). The sodium thiosulfate solution is developed especially for cleaning, decontaminating, and neutralizing of the sodium hypochlorite solution and previously deactivated hazardous drugs. Sodium Thiosulfate protects the stainless steel, compounding surface from corrosion and pitting due to the presence of harsh sodium hypochlorite and potent, hazardous drugs. Cleaning the surface from these residues improves the overall longevity of the sterile compounding equipment while staying USP<797> and USP<800> compliant.

Wiper #2, THIO-WIPE 2% wipe is a 9”x12” premium, non-woven, 100% polyester wipe that has low shedding characteristics. Each wipe covers approximately a 6 square foot area for optimal surface decontamination present within the compounding operation. Each THIO-WIPE 2% wipe comes individually packaged. Sterility of the THIO-WIPE 2% is assured through gamma irradiation of the entire packet contents. Lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation are issued and delivered with each shipment.

Quality and Manufacturing

- Gamma irradiated for sterility assurance
- Lot sterility test according to current USP compendium
- Assayed according to current USP compendium
- USP Sodium Thiosulfate is filtered at 0.2 microns
- Each kit is labeled with lot number and expiration date
- Packaged neatly folded for easy removal
- Completely lot traceable
- Easy tear perforations on each wiper packet for easy open
- Double bagged sterile

Features and Benefits

- Delivered with lot specific documentation
- 9” x 12” in size
- Low in particulate shedding and soluble extractables
- Designed to comply with USP <797>
- Decontaminates post deactivation of hazardous drug
- Delivered with lot specific certificates
- Formulated with WFI
- Ready-to-use

Chemical Specifications

Chemical Specifications	THIO-WIPE, Sodium Thiosulfate 2% Wipe
Appearance	Clear, free of suspended matter
Solubility in Water	Completely
pH	6.0-9.5
Assay	1.8%-2.2%
Sterility	Gamma irradiation
Shelf Life	1 year

Material Specifications

WipeDown Wipe #2 – THIO-WIPE 2%		
Material Specification	**Value**	**Test Method**
Material	100 % Polyester	N/A
Composition	Non-woven	N/A
Color	White	N/A
Basis Weight	2.0 oz/yd^2	ASTM D3776
Thickness	0.51 mm	ASTM D5034

*Treats approximately 6 square feet

Step #3: ALCOH-WIPE 70% IPA

Wiper #3 of **WipeDown 1-2-3** is 70% USP isopropyl alcohol formulated with 30% Water for Injection (WFI). The USP IPA provides an additional measure against contaminates present on the compounding surfaces for added patient and preparer's protection. After deactivation of the work surface, additional disinfection is needed in order to maintain a critical, controlled, work environment for compounding sterile products. Once the surface has been fully treated by all three wipes in the **WipeDown 1-2-3** kit, the surface will be able to return to its natural composition.

Wiper #3, ALCOH-WIPE 70% IPA wipe is a 9"x12" premium, non-woven, 100% polyester wipe that has low shedding characteristics. Each wipe covers approximately a 6 square foot area for optimal isopropyl alcohol wipe down on surfaces present within the compounding operation. Each ALCOH-WIPE 70% IPA wipe comes individually packaged. Sterility of the ALCOH-WIPE 70% IPA is assured through gamma irradiation of the entire packet contents. Lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation are issued and delivered with each shipment.

Quality and Manufacturing

- Gamma irradiated for sterility assurance
- Lot sterility test according to current USP compendium
- Assayed according to current USP compendium
- USP Isopropyl Alcohol is filtered at 0.2 microns
- Each kit is labeled with lot number and expiration date
- Packaged neatly folded for easy removal
- Completely lot traceable
- Easy tear perforations on each wiper packet for easy open
- Double bagged sterile

Features and Benefits

- Delivered with lot specific documentation
- 9" x 12" in size
- Low in particulate shedding and soluble extractables
- Designed to comply with USP <797>
- Provides added protection from contaminates on the work surface
- Delivered with lot specific certificates
- Formulated with WFI
- Ready-to-use

Chemical Specifications

Chemical Specifications	ALCOH-WIPE 70% Isopropyl Alcohol
Appearance	Clear Colorless
Assay Test	68.0-72.0%
Acidity Test	≤ 1.0 ml
Nonvolatile Residue Test	< 5.0 mg
Specific gravity @ 20 degrees C	0.872-0.883
Expiration Dating	1 year
Sterility	Gamma irradiation

Material Specifications

WipeDown Wipe #3 – ALCOH-WIPE 70% IPA		
Material Specification	**Value**	**Test Method**
Material	100 % Polyester	N/A
Composition	Non-woven	N/A
Color	White	N/A
Basis Weight	2.0 oz/yd^2	ASTM D3776
Thickness	0.51 mm	ASTM D5034

*Treats approximately 6 square feet

Other Documentation

The following documentation is available upon request.

- Product Validation Reports
- MSDS
- Specific Testing Report

Veltek Associates, Inc. covers every aspect of cleaning and decontaminating necessary for full compliance to USP including consultation from industry experts on setting up and maintaining aseptic processes during the compounding of sterile products. VAI has a complete line of sterile cleaning agents and disinfectants with easy to use sterilizable cleaning systems. The Core2Clean® Plus System addresses the cleaning and disinfection of environmental surface areas. The SimpleMix® System provides easy-to-use disinfectants in a pre-measured container system. In addition, VAI offers complete line of sterile, individually packaged, saturated wipes.

To further address the requirements, VAI provides a unique innovative gowning system to address aseptic gowning requirements. Furthermore, the easy to use SMA air samplers are an accepted industry standard that simplifies microbial air testing in aseptic compounding areas. As the compounding pharmacy industry moves forward to require greater control of environmental production areas, be assured VAI is one step ahead with innovation and support.

Please visit our website www.sterile.com or call 1-888-4-STERILE for more information regarding our products and services for USP <797> compliance.