

## USP <797> Compliant Cleaning Procedures for Sterile Compounding Pharmacies and Contec® Product Solutions

### DAILY & MONTHLY CLEANING REQUIREMENTS

#### Daily: Disinfecting Supplies Prior to Use

##### What does USP <797><sup>1</sup> say?

###### Page 15 Additional Personnel Requirements

Packaged compounding supplies and components, such as needles, syringes, tubing sets, and small and large-volume parenterals, should be uncartoned and wiped down with a disinfectant that does not leave a residue (e.g., Sterile 70% IPA), when possible in an ante-area of ISO Class 8 (see Table 1) air quality, before being passed into the buffer areas. *Note: This is also mentioned in Appendix 1, page 31.*

###### Page 16 Cleaning and Disinfecting the Compounding Area

Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent (e.g., Sterile 70% IPA) delivered from a spray bottle or other suitable delivery method. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes.

###### Page 19 Suggested Standard Operating Procedures (SOPs)

#17: Supplies used in the DCA for the planned procedures are accumulated and then decontaminated by wiping or spraying the outer surface with Sterile 70% IPA or removing the outer wrap at the edge of the DCA as the item is introduced into the aseptic work area.

#### Contec® Healthcare Product Solutions:

- **Contec® Sterile 70% IPA** Available in 16 oz. and 32 oz. bottles. It is important to note that Sterile IPA is not a regulated product and that not all sterile IPA products are the same. Contec is an ISO 9001-registered manufacturer and our quality systems ensure that our products are of the highest quality. Our Sterile 70% IPA is made in the USA.
- **Amplitude™ EcoCloth™ Wipes** Cleanroom compatible dry wipes, perfect for general cleaning in pharmacy cleanrooms (ISO 8 and 7 anterooms, and buffer zones).
- **Sanotex® Environmental Surface Wipes** These wipes provide an easy to use alternative to spray bottles and wipes. Sanotex Wipes are low-linting and work effectively with various disinfectants. The spring-loaded canister lid keeps wipes wet, minimizes waste, and prevents chemical vapors and splashes. (Sanotex Wipes should only be used in ISO Class 8 or other less critical areas).
- **PeridoxRTU®** Industry experts have recommended the use of a sporicide to wipe supplies when removing them from shipping cartons. This is considered best practice due to the risk of spore contamination associated with cardboard and other environmental sources. Use appropriate Personal Protective Equipment (PPE), and as always, consult product label for proper use.

#### Daily: Floors

##### What does USP <797> say?

Table [3] on page 15 of the USP <797> chapter requires that floors be cleaned daily. The chapter states that, "Floor in the buffer or clean area, ante area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent once daily at a time when no aseptic operations are in progress."

USP <797> (page 16) also recommends that, "All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic micro fibers" and "Ideally, all cleaning tools are discarded after one use by collection in suitable plastic bags and removed with minimal agitation."

In selecting a disinfectant to use for floor cleaning, page 15 of USP <797> states, "When the surface to be disinfected has heavy soiling, a cleaning step is recommended prior to the application of the disinfectant." And... "Many disinfectants registered by the EPA are one-step disinfectants. This means that the disinfectant has been formulated to be effective in the presence of light to moderate soiling."

USP <797> (page 16) states that all "...wipers, sponges and mops...should be dedicated to use only in the buffer or clean area, ante area and segregated compounding areas and shall not be removed from these areas except for disposal." In other words, your mops and cleaning supplies must be stored and remain in the clean area.

#### **Contec® Healthcare Product Solutions:**

- **MicroCinch™ Mop & Klean Max™ Mopping System** Contec offers two mopping systems designed specifically for the compounding environment. The MicroCinch Mop and Klean Max Mopping System meet all USP <797> requirements through incorporating microfiber for excellent cleaning efficiency, simple to use hardware, have disposable mop pads that are available sterile if needed. They can be used separately or in conjunction with each other, offering pharmacies a tailored solution to meet each facility's unique mopping needs.
- **PeridoxRTU®** See details on last page.
- **PREempt® RTU (Accelerated Hydrogen Peroxide)** See detail on last page.
- **Available Now! Contec® Healthcare TB1-3300™ Disinfectant** See detail on last page.

### **Daily: Counters and Easily Cleanable Work Surfaces**

#### **What does USP <797> say?**

Table [3] on page 15 of the USP <797> chapter recommends that work surfaces be cleaned daily. The chapter states, "Work surfaces in ISO Class 7 (see Table 1) buffer areas and ISO Class 8 (see Table 1) ante-areas as well as segregated compounding areas shall be cleaned and disinfected at least daily." And..."All cleaning materials such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer or clean area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal."

#### **Contec® Healthcare Product Solutions:**

- **Amplitude™ EcoCloth™ Wipe** Cleanroom compatible dry wipes that are perfect for general cleaning on counters and all vertical surfaces in anterooms, buffer zones, and cleanrooms.
- **Contec® Sterile 70% IPA** Available in 16 oz. and 32 oz. bottles. It is important to note that Sterile IPA is not a regulated product and that not all sterile IPA products are the same. Contec is an ISO 9001 registered manufacturer and our quality systems ensure that our products are of the highest quality. Our Sterile 70% IPA is made in the USA.
- **PeridoxRTU®** See details on last page.
- **PREempt® RTU (Accelerated Hydrogen Peroxide)** See detail on last page.
- **Contec® Healthcare TB1-3300™ Disinfectant** See detail on last page.

### **Daily: Cleaning of ISO-5 Laminar Flow Hoods, Biological Safety Cabinets and other PEC (Primary Engineering Controls)**

#### **What does USP <797> say?**

From page 15 of this chapter, "Cleaning and disinfecting surfaces in the LAFWs, BSCs, CAIs, and CACIs are the most critical practices before the preparation of CSPs. Consequently, such surfaces shall be cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches."

The chapter also requires that this be done with "residue free disinfecting agent such as Sterile 70% IPA which is allowed to dry before compounding begins." And..."When sterile supplies are received in sealed pouches designed to keep them sterile until opening, the sterile supplies may be removed from the covering pouches as the supplies are introduced into the ISO Class 5 (see Table 1) PEC (LAFW, BSC, CAI, CACI) without the need to disinfect the individual sterile supply items." Page 15 of the USP <797> Chapter states that the disinfecting step, "shall be followed by wiping with a residue-free disinfecting agent such as Sterile 70% IPA, which is allowed to dry before compounding begins."

**Contec® Healthcare Product Solutions:**

- **Contec® Sterile 70% IPA** Available in 16 oz. and 32 oz. bottles makes cleaning all Primary Engineering Controls easy and convenient. Each bottle is in sterile double bag packaging so it can be easily placed into ISO-5 areas without the additional step of disinfecting each bottle. Available in spray trigger or flip top configurations. Contec's Sterile 70% IPA meets the USP required post-disinfecting step necessary to ensure that disinfectant residue or potential residue has been removed.
- **SterileSorb™ Wipes** Our SterileSorb Wipes meet all USP requirements for both non-shedding particle generation and sterility. SterileSorb is extremely absorbent, excellent for wiping spills, and general purpose cleaning in ISO Class 5 filling zones.
- **PROSAT® Sterile™ IPA presaturated wipes (PS-911EB)** Presaturated wipes can be used in place of Sterile IPA and a dry wipe. The use of presaturated wipes makes the cleaning task easier and more repeatable. When using a spray with a dry wipe, the results vary greatly as different personnel will spray different amounts of Sterile IPA onto the surface. The use of presaturated wipes ensures that a consistent amount of Sterile IPA is applied by all personnel. Also, the use of Contec's Sterile 70% IPA presaturated wipes meet the USP requirement that after the use of disinfectants such as PeridoxRTU® or PREempt™ RTU "shall be followed by wiping with a residue-free disinfecting agent such as Sterile 70% IPA."
- **PeridoxRTU®** See details on last page.
- **PREempt® RTU (Accelerated Hydrogen Peroxide)** See detail on last page.
- **Contec® Healthcare TB1-3300™ Disinfectant** See detail on last page.

All of Contec's sterile products are validated sterile at 10<sup>-6</sup> Sterility Assurance Level (SAL), one of the strictest guidelines put forth by the Association for the Advancement of Medical Instrumentation (AAMI). Note: USP only requires the use of Sterile IPA. The delivery method—presaturated IPA wipe or spray—is dictated by facility protocol.

## Monthly: Walls, Ceilings, and Storage Shelving

**What does USP <797> say?**

Table [3] on page 15 of the USP <797> chapter requires that walls, ceilings, and storage shelving be cleaned monthly. The text on page 16 of the chapter states, "In the buffer or clean area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly."

**Contec® Healthcare Product Solutions:**

- **Amplitude™ EcoCloth™ Wipes** Cleanroom compatible dry wipes are ideal for general cleaning on counters and all vertical surfaces in your cleanroom (ISO 8 and 7, anteroom, and buffer zones).
- **MicroCinch™ Mop & Klean Max™ Mopping System** Used at the beginning or end of each shift to clean horizontal and vertical surfaces in your cleanroom area. The MicroCinch Mop and Klean Max Mopping System meet all USP <797> requirements through incorporating microfiber for excellent cleaning efficiency, simple to use hardware, have disposable mop pads that are available sterile if needed.
- **PeridoxRTU®** See details on last page.
- **PREempt® RTU (Accelerated Hydrogen Peroxide)** See detail on last page.
- **Contec® Healthcare TB1-3300™ Disinfectant** See detail on last page.

## DETAILED INFORMATION FOR DISINFECTANTS

### Benefits of Ready-To-Use Disinfectants

- Convenience
- Easy to implement as there are no mixing procedures to document and validate in Pharmacy SOPs and record logs.
- No storage space demands as required by concentrate's mixing stations and related supplies.
- Reliability – use of RTU eliminates potential mixing errors resulting in efficacy issues.
- Longer shelf life than diluted concentrated solutions

### Contec® Healthcare's RTU Cleaners and Disinfectants:

- **PeridoxRTU®** A fast-acting, RTU surface sporicide and disinfectant, killing *Clostridium difficile* in only 3 minutes. Its excellent wetting agents eliminate the need to reapply solution to achieve proper dwell times. The active ingredients in PeridoxRTU break down into water, vinegar, and oxygen during use, leaving no persistent, harmful, or corrosive residues behind. Therefore, the additional step of rinsing with sterile alcohol or sterile water is not needed when cleaning or disinfecting the ceilings, walls, and floors. However, Contec suggests following Peridox and all disinfectants in ISO 5 PECs with sterile IPA to remove potential trace elements left behind. Available in sterile and nonsterile configurations, in 32 oz. and 1 gallon packaging.
- **PREempt® RTU (Accelerated Hydrogen Peroxide)** A desirable disinfectant for use on surfaces in compounding pharmacies requiring short dwell times. No active residues are left behind since the product breaks down into water and oxygen. PREempt is a one-step disinfectant that can clean and disinfect in the presence of light to moderate soiling. The USP chapter does require that heavily soiled areas must be pre-cleaned before disinfecting. Available in 32 oz. spray bottles or gallons. PREempt does leave slight surfactant residue that requires it to be followed with sterile IPA (especially when used on floors). PREempt can be used daily and augmented with Peridox Sporicidal Disinfectant and Cleaner products.
- **Contec® Healthcare TB1-3300™ Disinfectant** A fast-acting, low-residue disinfectant available in both sterile and nonsterile configurations. TB1-3300 is a unique blend of ethyl alcohol, quaternary ammonium compound, and wetting agents to ensure contact dwell times are met when used as directed. The one-step disinfectant cleans and disinfects in the presence of moderate to light soiling and can be used daily or augmented with PeridoxRTU® Sporicidal Disinfectant and Cleaner products as needed. Sterile TB1-3300 has sterility assurance levels (SAL) of  $10^{-6}$ , and both configurations are available in 32 oz. bottle with push-pull cap or 1 gallon.

**Available  
Now!**