

Products for \_\_\_\_\_  
**USP <797>**  
Compliance

*From the leader in contamination control  
in critical environments*

# USP <797>

## About

# USP <797>

### *Pharmaceutical Compounding—Sterile Preparations*

The objective of USP <797> is to describe conditions and practices to prevent harm, including death, to patients that could result from:

- Microbial contamination
- Excessive bacterial endotoxins
- Variability in the intended strength of ingredients
- Chemical and physical contaminants
- Incorrect type or quality of ingredients in Compounded Sterile Preparations (CSPs)

USP <797> provides practice and quality standards for all persons who prepare CSP drugs and nutrients and all places they are prepared.

USP <797> requires that the preparation of CSPs occur in ISO Class 5 (Class 100) environments, buffer areas of ISO Class 7 (Class 10,000), and ante-areas of ISO Class 8 (Class 100,000). Achieving and maintaining cleanroom environments requires new procedures and protocols.

ITW Texwipe® has been the cleaning technology leader in controlled environments for more than four decades. We have the advice, tools and products for such USP <797> requirements as:

- Cleaning ISO Class 5 surfaces every shift
- Cleaning counters, work surfaces and floors daily
- Cleaning walls, ceilings and shelves monthly
- Cleaning supplies while transferring them to clean areas
- Cleaning spills
- Spraying and wiping gloves throughout the shift
- Cleaning supplies in the controlled environment
- Cleaning validation

This brochure includes the key products compounding pharmacies need to meet these requirements. These products are available through a network of specialty distributors and supported by the ITW Texwipe technical support.



# Product Selection Guide

## USP <797> MANDATE

## RECOMMENDED TEXWIPE PRODUCTS

	Sterile Environment	Non-sterile Environment
Clean bottles, syringes, vials and other supplies transferred into the clean area	<p><b>Pre-wetted Wipers</b> Sterile AlphaSat® 10 Sterile TechniSat® Sterile PolySat®</p> <p><b>Dry Wipers and Sterile Alcohol</b> SterileWipe™ HS II SterileWipe™ LP Sterile 70% Isopropanol</p>	<p><b>Pre-wetted Wipers</b> TechniSat® PolySat®</p> <p><b>Dry Wipers and Sterile Alcohol</b> QuanTex™ AlphaWipe® Technicloth® VersaWipe® Sterile 70% Isopropanol</p>
<p>Clean equipment:</p> <ul style="list-style-type: none"> <li>- Buffer room and anteroom carts</li> <li>- Walls and ceilings</li> <li>- Surfaces</li> <li>- Floors</li> <li>- Shelving</li> </ul>	<p><b>Pre-wetted Wipers</b> Sterile AlphaSat® 10 Sterile TechniSat®</p> <p><b>Dry Wipers and Sterile Alcohol</b> SterileWipe™ HS II SterileWipe™ LP Sterile 70% Isopropanol</p> <p><b>Mops and Sterile Alcohol</b> AlphaMop™ AlphaMop™ Covers Mini AlphaMop™ ICT Sterile 70% Isopropanol</p>	<p><b>Pre-wetted Non-sterile Wipers</b> TechniSat® PolySat®</p> <p><b>Dry Wipers and Sterile Alcohol</b> QuanTex™ AlphaWipe® Technicloth® VersaWipe® Sterile 70% Isopropanol</p> <p><b>Mops and Sterile Alcohol</b> AlphaMop™ AlphaMop™ Covers Mini AlphaMop™ ICT Sterile 70% Isopropanol</p>
Documents in controlled environment	<p><b>Cleanroom Notebooks</b> TexWrite® Spirals TexWrite® Bound</p>	<p><b>Cleanroom Notebooks</b> TexWrite® Spirals TexWrite® Bound</p>
Sanitize gloves	<p><b>Pre-wetted Wipers</b> Sterile AlphaSat® 10 Sterile TechniSat®</p> <p><b>Dry Wipers and Sterile Alcohol</b> SterileWipe™ HS II SterileWipe™ LP Sterile 70% Isopropanol</p>	<p><b>Pre-wetted Wipers</b> TechniSat®</p> <p><b>Dry Wipers</b> Technicloth® VersaWipe®</p>
<p>Clean floors, walls and ceilings Apply and remove disinfectants</p> <p>Clean and disinfect:</p> <ul style="list-style-type: none"> <li>- Laminar flow hoods</li> <li>- Compounding Aseptic Isolators (CALs)</li> <li>- Biological Safety Cabinets (BSCs)</li> </ul>	<p><b>Mops and Sterile Alcohol</b> AlphaMop™ Sterile 70% Isopropanol</p> <p>Mini AlphaMop™ ICT CleanTips® Swabs Alpha® Belt Mopping System</p>	<p><b>Mops</b> AlphaMop™ AlphaMop™ Covers AlphaMop™ Pre-wetted Mop Covers</p> <p>Mini AlphaMop™ ICT CleanTips® Swabs Alpha® Belt Mopping System</p>
Contamination control in buffer areas	<p><b>Cleanroom Adhesive Mats</b> FirstStep® Mat CleanStep™ Mat CleanStep™ Refills</p>	<p><b>Cleanroom Adhesive Mats</b> FirstStep® Mat CleanStep™ Mat CleanStep™ Refills</p>
<p>Environmental surface monitoring Cleaning validation Disinfection of ampoules and stoppers when wetted with IPA</p>	<p><b>CleanTips® Swabs</b></p>	<p><b>CleanTips® Swabs</b></p>



## Sterile Pre-Wetted Wipers with 70% IPA

### Sterile TechniSat®

Hydroentangled cellulose/polyester wiper, pre-wetted with 70% IPA. ISO Class 6-7.

<b>TX3214</b>	9" x 11" wiper	50/flexpack
<b>TX3217</b>	9" x 11" wiper	20/flexpack

### Sterile PolySat®

Polypropylene wipers pre-wetted with 70% IPA. ISO Class 6-7.

<b>TX3213</b>	9" x 11" wiper	50/flexpack
<b>TX3216</b>	9" x 11" wiper	20/flexpack

### Sterile AlphaSat® 10

Polyester wiper with thermally sealed-borders, folded for small footprint, pre-wetted with 70% IPA. ISO Class 4-5.

<b>TX3285</b>	9" x 9" wiper	20/flexpack
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### Sterile AlphaSat® 10 with WFI

Polyester wiper with thermally sealed-borders pre-wetted with 70% IPA/30% WFI. ISO Class 4-5.

<b>TX3280</b>	12" x 12" wiper	50/flatpack
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## Pre-Wetted Wipers with 70% IPA

### PolySat®

Polypropylene wiper pre-wetted with 70% IPA, economical. ISO Class 6-7.

<b>TX1051</b>	9" x 11" wiper	50/flexpack
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### TechniSat®

Hydroentangled cellulose/polyester wiper, pre-wetted with 70% IPA. ISO Class 6-7.

<b>TX1041</b>	9" x 11" wiper	70/flip-top tub
<b>TX1045</b>	6" x 8" wiper on roll	100/canister
<b>TX1065</b>	9" x 11" wiper	50/flexpack





## Sterile Dry Wipers

### SterileWipe™ HS II

Absorbent, hydroentangled cellulose/polyester wiper. ISO Class 6-7.

<b>TX3210</b>	12" x 12" wiper	100/bag 20/pack 5 packs/bag
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### SterileWipe™ LP

Knitted polyester wiper for use in critical sterile environments. ISO Class 3-5.

<b>TX3211</b>	9" x 9" wiper	100/bag 10/pack 10 packs/bag
<b>TX3212</b>	12" x 12" wiper	100/bag 20/pack 5 packs/bag



## Dry Wipers

### TechniCloth®

Hydroentangled cellulose/polyester wiper, good strength and durability. ISO Class 6-7.

<b>TX609</b>	9" x 9" wiper	300/bag
<b>TX612</b>	12" x 12" wiper	150/bag

### VersaWipe®

Hydroentangled cellulose/polyester wiper, high absorbency, best value. ISO Class 6-7.

<b>TX622</b>	12" x 12" wiper	150/bag
<b>TX624</b>	4" x 4" wiper	1,200/bag
<b>TX629</b>	9" x 9" wiper	300/bag

### AlphaWipe®

Absorbent polyester wiper, low particles and fibers. ISO Class 5-6.

<b>TX1004</b>	4" x 4" wiper	300/bag
<b>TX1009</b>	9" x 9" wiper	150/bag
<b>TX1013</b>	12" x 12" wiper	75/bag

### Vectra® QuanTex™ Wipers

State of the art wiper provides maximum performance in critical environments. ISO Class 3-6.

<b>TX1080</b>	9" x 9" wiper	150/bag
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Additional wiper products are available. Visit [www.texwipe.com](http://www.texwipe.com) for more information.



## Sterile Alcohol

### Sterile 70% Isopropanol

Filtered to 0.2 microns and gamma irradiated.

<b>TX3270</b>	16 oz trigger-spray bottle	12/case
<b>TX8270</b>	8 oz. trigger-spray bottle	12/case
<b>TX3290</b>	1 gallon polybottle	4/case

## Cleanroom Notebooks

### TexWrite® 30 Spiral Notebooks

Economical choice for note taking and data recording. College-ruled pages.

<b>TX5840</b>	100 pages, 8.5" x 11"	10/box
<b>TX5841</b>	100 pages, 5.5" x 8.5"	10/box

### TexWrite® 30 Bound Notebooks

Sewn binding prevents removal of pages without damage. Provides security of permanent, legally binding data records. College-ruled pages.

<b>TX5807</b>	Blue, 100 pages, 5.5" x 8.5"	10/box
<b>TX5808</b>	Blue, 100 pages, 8.5" x 11"	10/box



## Contamination Control Mats

### FirstStep® Mat

Removes foot-borne particulates prior to entering the clean work area. An antimicrobial additive protects against microorganism growth. Adheres directly to floor.

<b>AMA183613BB01</b>	Blue	18" x 36" mat 60-layer	4 mats/box
<b>AMA254513BB01</b>	Blue	25" x 45" mat 60-layer	4 mats/box
<b>AMA254513WW01</b>	White	25" x 45" mat 60-layer	4 mats/box

### CleanStep™ Mat

Provides the same protection properties as FirstStep against particulates and microorganisms with the ability and convenience to relocate the mat when necessary. Non-skid reusable frame.

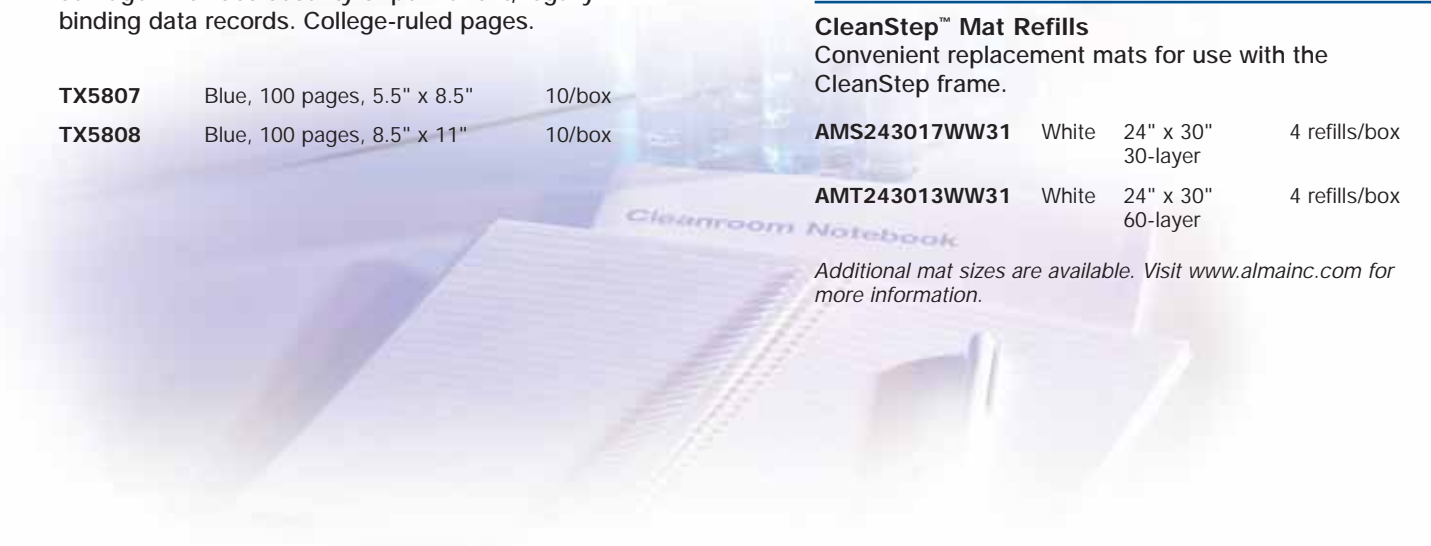
<b>AMQ263215WW31</b>	White	25.5" x 31.5" frame 24" x 30" white refill mat 30-layer	One frame and mat/box
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### CleanStep™ Mat Refills

Convenient replacement mats for use with the CleanStep frame.

<b>AMS243017WW31</b>	White	24" x 30" 30-layer	4 refills/box
<b>AMT243013WW31</b>	White	24" x 30" 60-layer	4 refills/box

Additional mat sizes are available. Visit [www.almainc.com](http://www.almainc.com) for more information.





## Cleanroom Mops

### AlphaMop™

Large polyester flat mop for wiping ceilings, walls and floors. ISO Class 4-8.

<b>TX7108</b>	Cleanroom mop with fiberglass handle and 15" x 7" single head assembly	1 mop/case
<b>TX7118</b>	Polyester replacement covers and foam pads for TX7108	150 covers/case 6 foam pads/case
<b>TX718H</b>	Honeycomb® 10 textured polyester covers for scrubbing	150/case

### Mini AlphaMop™ Isolator Cleaning Tool

Cleaning system for isolators, laminar flow hoods and biological safety cabinets.

<b>TX7101</b>	Isolator cleaning mop with two handles (18" and 24") (ISO Class 4-8)	1 mop/case
<b>TX7111</b>	TechniCloth® replacement covers (ISO Class 6-8)	150 covers/case 6 foam pads/case
<b>TX7114</b>	Polyester replacement covers (ISO Class 4-8)	150 covers/case 6 foam pads/case

### Alpha® Belt Mopping System

Save time and money while eliminating buckets and carts in the controlled environment. ISO Class 4-8.

<b>TX7211</b>	Cleanroom belt, 16-oz. empty squirt bottle, two plastic rings, 20 disposable cleanroom bags	10/case
<b>TX7250</b>	Alpha® Belt Mopping System Refill Bags	100/case

## CleanTips® Swabs

### Large Alpha® Swab

Knitted polyester head with polypropylene handle. Recommended for environmental surface monitoring and cleaning validation. Autoclavable. ISO Class 4-8.

**TX714A** 100/bag  
10 bags/case



### Small Alpha® Swab

Knitted polyester head with polypropylene handle. Wet with IPA for disinfecting stoppers on bags and vials before piercing with sterile needles and for necks of ampoules before they are broken. Autoclavable. ISO Class 4-8.

**TX743B** 500/bag  
5 bags/case



### Absorbond® Swab with Long Handle

Nonwoven polyester head with polypropylene handle. Recommended for surface sampling and cleaning hard-to-reach areas. May be wetted with IPA. Autoclavable. ISO Class 4-8.

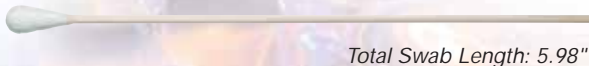
**TX762** 100/bag  
10 bags/case



### Wrapped Cotton Swab

High sorption, 100% cotton fiber swab for routine cleaning and for spill clean-up. Autoclavable. ISO Class 6-8.

**TX705** 1,000/bag  
5 bags/case



Additional swabs are available. Visit [www.texwipe.com](http://www.texwipe.com) for more information.

## About ITW Texwipe®

For over 40 years, ITW Texwipe has provided innovative materials for cleaning critical environments. Cleanrooms are widely used in a multitude of industries, including pharmaceutical, medical device, semiconductor, data storage, optics and aerospace.

ITW Texwipe has corporate headquarters in North America, offices in Europe and Asia and manufacturing facilities in the United States and the Philippines.

Our worldwide network of distributors serves over 20,000 customers and is backed by our specialized technical support.

ITW Texwipe's cleaning and contamination control products include a complete line of sterile wipers, sterile alcohols, sealed-border wipers, sealed-edge wipers, pre-wetted wipers, swabs, TOC validation kits, cleanroom mopping systems, and documentation systems.

*More detailed information about these or any other Texwipe products can be obtained by contacting your ITW Texwipe representative or by visiting us online at [www.texwipe.com](http://www.texwipe.com)*



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**ITW Texwipe®**

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