



VELTEK ASSOCIATES, INC.

USP <800> Gown

Barrier Gown for USP <800> Uses

Product Description

VAI® offers sterile barrier gowns for use where handling hazardous drugs or chemicals*, where exposure to bloodborne pathogens, or where liquid splashes are a concern. **USP <800> Gowns** have been designed and tested specifically for compliance with the USP <800> recommended guidance for handling of hazardous drugs. USP <800> recommends the use of a gown during hazardous compounding that has been shown to resist hazardous drugs. These gowns are constructed of a multi-layer blend of polyethylene and propylene that has been tested and shown as resistant to hazardous drugs and chemicals per a modified test for gowns ASTM 6978 Chemotherapy Drug Permeation Testing. In addition, these gowns have low particulate shedding characteristics, therefore, are USP <797> compliant for critical environments and cleanrooms.

USP <800> Gowns come standard with liquid proof taped seams, tunnelized elastic wrists, elastic thumb loops, a Velcro neck loop closure, and extra-long coated waist ties for easy front or rear closure. All gowns have serged seams that are sealed with a proprietary co-polymer tape. This makes both the gown's fabric and seams tested and verified hazardous drug barriers. **USP <800> Gowns** are blue with blue taped seams and available in two sizes: small/medium and large/XL. Each gown is individually inspected for sizing, stitching, and workmanship. USP <800> Gowns are designed to be disposable and are not reusable after initial use.

Quality and Manufacturing

- Fully assembled in a controlled environment
- Individually inspected for sizing, stitching, and workmanship
- Individually packaged and labeled with lot number and expiration date
- Completely lot traceable
- 10 year closed bag expiration

Features and Benefits

- Designed and tested gown for compliance with USP <800> recommended procedure for the handling of hazardous drugs*
- Gown tested per modified ASTM D6978 Chemotherapy Drug Permeation Testing to demonstrate resistance to hazardous drugs as per USP <800> guidance recommendation
- Suitable for use where liquid splash is a concern and resistant to many hazardous liquids
- Resistant against bloodborne pathogens per ASTM F1671 Testing
- Suitable for critical and cleanroom environments; low particulates
- ISO Cleanroom Class 6 per Helmke Drum Testing
- Liquid proof seams
- Class 1 Flammability per CPSC 1610 Testing
- Tunnelized elastic wrists and elastic thumb loops

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15 Lee Boulevard, Malvern, PA 19355-1234

Tel: 610-644-8335 Fax: 610-644-8336 www.sterile.com www.sterile.com/patents Rev: 09Sep2021

- Velcro neck loop closure and extra long coated waist ties for easy front or rear closure
- Constructed of a blend of polyethylene and polypropylene fabrics
- Neatly folded and packaged
- Packaged in easy tear vacuum sealed bags
- 10 individual bags per sealed inner polybag, 3 inner polybags per sealed master bag

Results

Permeation Test Results on Seam Testing of USP 800 Barrier Gown per ASTM D6978-05*			
Test Chemotherapy Drugs *	Minimum Breakthrough Detection Time (Specimen 1/2/3) (Minutes)	Average Steady State Perm. Rate (Specimen 1/2/3) (µg/cm ² /minute)	Other Observations
Cisplatin, 1mg/ml (1,000 ppm)	>240 min.	0	No significant changes
Cyclophosphamide, 20 mg/ml (20,000 ppm)	>240 min.	0	No significant changes
Dacarbazine, 10 mg/ml (10,000 ppm)	>240 min.	0	No significant changes
Doxorubicin, 2 mg/ml (2,000 ppm)	>240 min.	0	No significant changes
Etoposide, 20 mg/ml (20,000 ppm)	>240 min.	0	No significant changes
Fluorouracil, 50 mg/ml (50,000 ppm)	>240 min.	0	No significant changes
Methotrexate, 25 mg/ml (25,000 ppm)	>240 min.	0	No significant changes
Mitomycin C, 0.5 mg/ml (500 ppm)	>240 min.	0	No significant changes
Paclitaxel, 6 mg/ml (6,000 ppm)	>240 min.	0	No significant changes
Vincristine, 1 mg/ml (1,000 ppm)	>240 min.	0	No significant changes
Carmustine, 3.3 mg/ml (3,300 ppm)	27.6 min.	0.01	No significant changes
Thiotepa, 10mg/ml (10,000 ppm)	>240 min.	0	No significant changes

*USP <800> recommends that while compounding hazardous drugs, the compounder don a gown that has shown resistance to hazardous drugs. Per the ASTM D6978 test method, modified to apply to gowns, the gown has shown resistance. **ASTM D6978-05** is the test standard required by USP <800> for evaluating gloves to be used for protection against hazardous drugs. This test provides information specific to the time it takes for hazardous drugs tested to permeate materials, with modification, it may also be applied to gowns. ASTM D6978-05 is a rigorous test and it is emphasized that conditions used in the assessment are intended to approximate the worst-case condition for clinical use. It is also important to note the lowest breakthrough time.

Order Number	Description	Qty/cs
1900-F -1904	USP <800> Gown, Elastic Wrists and Thumbloops, Tie Closure, Individually Packaged, Blue, Small/Medium, Non-Sterile	30
1900-F-1905	USP <800> Gown, Elastic Wrists and Thumbloops, Tie Closure, Individually Packaged, Blue, Large/XL, Non-Sterile	30

Ordering Information



1900-F-1904