

Protect800™ Sterile Chemo Gown

General Information:

ISO -Class	ISO -Class 5 Compatible
Product Features	Sealed Seams Thumb Loops Taped Impervious Seams Elastic Cuffs Latex-Free
Sterility	Sterile
Testing Methods	ASTM D6978 ASTM F739
Storage	3 Years from date of manufacture
Sizes	S-4XL

For testing data, please see following page



The **Protect 800™ Chemo Gown** is a sterile, low linting, and impervious gown for compounding chemotherapy & HDs in the cleanroom. The gown is made from a breathable polyethylene coated polypropylene material. This gown is ISO class 5 compatible with elastic wrists, mandarin collar, orange impervious taped seams, front closure, ties in the back, and thumb loops attached.

Protect800™

Sterile Chemo Gown

Performance Drug Test Results

PERMEATION TESTING PER ASTM D6978 ON FABRIC SAMPLE

Sample: Protect800 Sterile Chemo Gown. USP 800 Compliant, Lot # 20191008. Level 3 impervious. Size: Large.

TEST CHEMICALS

The list of tested drugs and their sources are shown below

TESTED DRUGS	DRUG SOURCE
Carmustine 3.3 mg/ml (3,300 ppm)	Sigma-Aldrich; Lot# 059M4075V; Expiration 11/2020
Cyclophosphamide 20 mg/ml (20,000 ppm)	Sandoz; Lot# 18050125; Expiration 04/2020
Dacarbazine 10 mg/ml (10,000 ppm)	Teva; Lot# 31326183B; Expiration 12/2021
Doxorubicin HCl 2 mg/ml (2,000 ppm)	WestWard; Lot# BJ004; Expiration 10/2020
Etoposide 20 mg/ml (20,000 ppm)	Teva; Lot# 31326913B; Expiration 04/2022
Fluorouracil 50 mg/ml (50,000 ppm)	Accord; Lot# PY02153; Expiration 03/2021
Paclitaxel 6 mg/ml (6,000 ppm)	Actavis; Lot# 8AZ5292; Expiration 05/2021

COLLECTION MEDIA FOR TESTED DRUGS

TESTED DRUG AND CONCENTRATION	
Carmustine 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cyclophosphamide 20 mg/ml (20,000 ppm)	Distilled Water
Dacarbazine 10 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin HCl 2 mg/ml (2,000 ppm)	Distilled Water
Etoposide 20 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil 50 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Paclitaxel 6 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution

TESTING CONDITIONS

Standard Test Method Used:	ASTM D 6978
Deviation from Standard Test Method:	Used 1" Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0 C +/-2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm ²
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	At random from fabric

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Sterile Chemo Gown

Performance Drug Test Results

DETECTION METHOD OF CHEMICAL PERMEATION

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The medium was circulated in a closed loop through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25. The list of the characteristic wavelengths used in the UV/VIS Absorption Spectrometry is shown below.

TESTED DRUGS	WAVELENGTH (nm)
Carmustine 3.3 mg/ml (3,300 ppm)	229
Cyclophosphamide 20 mg/ml (20,000 ppm)	200
Dacarbazine 10 mg/ml (10,000 ppm)	320
Doxorubicin HCl 2 mg/ml (2,000 ppm)	232
Etoposide 20 mg/ml (20,000 ppm)	205
Fluorouracil 50 mg/ml (50,000 ppm)	269
Paclitaxel 6 mg/ml (6,000 ppm)	231

SAMPLE CHARACTERISTICS

Characteristics of the fabric thickness for the tested sample are shown below.

TESTED DRUG	Fabric Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Carmustine	0.203	0.203	0.204	0.204
Cyclophosphamide	0.205	0.198	0.217	0.207
Dacarbazine	0.213	0.209	0.225	0.215
Doxorubicin HCl	0.222	0.209	0.216	0.216
Etoposide	0.190	0.200	0.203	0.198
Fluorouracil	0.202	0.209	0.199	0.203
Paclitaxel	0.206	0.209	0.201	0.205
Weight/Unit Area (g/m²)	51.1			

Results

Protect800 Sterile Chemo Gown USP 800 Compliant, Lot # 20191008. The permeation test results are shown below.

TESTED CHEMOTHERAPY DRUGS	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen 1/2/3) (ug/cm ² /minute)	OTHER] OBSERVATIONS
Carmustine 3.3 mg/ml (3,300 ppm)	38.3 (59.4, 49.2, 38.3)	0.01 (0.01, 0.01, 0.02)	Minimal swelling and no degradation
Cyclophosphamide 20 mg/ml (20,000 ppm)	>240 min.	0	Minimal swelling and no degradation
Dacarbazine 10 mg/ml (10,000 ppm)	>240 min.	0	Minimal swelling and no degradation
Doxorubicin HCl 2 mg/ml (2,000 ppm)	>240 min.	0	Minimal swelling and no degradation
Etoposide 20 mg/ml (20,000 ppm)	>240 min.	0	Minimal swelling and no degradation
Fluorouracil 50 mg/ml (50,000 ppm)	>240 min.	0	Minimal swelling and no degradation
Paclitaxel 6 mg/ml (6,000 ppm)	>240 min.	0	Minimal swelling and no degradation

Protect800™

Sterile Chemo Gown Performance Drug Test Results

PERMEATION TESTING PER ASTM F739 ON FABRIC SAMPLE

Sample: One (1) yellow fabric identified as: Yellow PE Coated Gown Material

TEST CHEMICALS

The list of tested drugs and their sources are shown below

TESTED DRUGS	DRUG SOURCE
Cisplatin, 1.0 mg/ml (1,000 ppm)	WG Critical Care; Lot #8D05666; Expiration 09/2019
Thiotepa, 1.0 mg/ml (1,000 ppm)	USP; Lot #R046R0; Expiration 03/2020

COLLECTION MEDIA FOR TESTED DRUGS

TESTED DRUG AND CONCENTRATION	COLLECTION MEDIUM
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Thiotepa, 1.0 mg/ml (1,000 ppm)	Distilled Water

TESTING CONDITIONS

Standard Test Method Used:	ASTM F 739-12
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	23.0° C ± 1.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm ²
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	At random from fabric

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Sterile Chemo Gown Performance Drug Test Results

PERMEATION TESTING PER ASTM F739 ON FABRIC SAMPLE

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The medium was circulated in a closed loop at 11 minutes of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25. The list of the characteristic wavelengths used in the UV/VIS Absorption Spectrometry is shown below.

TESTED DRUG	WAVELENGTH (nm)
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Thiotepa, 10 mg/ml (10,000 ppm)	199

SAMPLE CHARACTERISTICS

Characteristics of the fabric thickness for the tested sample are shown below.

TESTING DRUG	Fabric Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Cisplatin	0.229	0.238	0.239	0.235
Thiotepa	0.234	0.240	0.236	0.237
Weight/Unit Area (g/m ²)	66.2			

RESULTS

Yellow PE Coated Gown Material. The permeation test results are shown below.

CHEMICAL TESTED	AVERAGE BREAKTHROUGH DETECTION TIME (Sample 1,2,3) (Minutes)	AVERAGE STANDARDIZED BREAKTHROUGH TIME (Sample 1,2,3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Sample 1,2,3) (ug/cm ² /minute)	OTHER OBSERVATIONS
Cisplatin 1.0 mg/ml (1,000 ppm)	>480 min.	>480 min.	0	Slight swelling and degradation
Thiotepa 10 mg/ml (10,000 ppm)	>480 min.	>480 min.	0	Slight swelling and degradation

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