Sterile Chemo Gowns for Hazardous Drug Compounding

Our ISO-MED Sterile Chemo Gown is disposable and composed of anti-static material that is designed to meet USP 8ØØ proof requirements. Weighing 52gsm+/-3gsm, this ISO-MED gown is breathable with PE/PP and offers Level 3 protection as well as protection against impervious and chemo-tested materials. Each gown is individually packaged 1 pc/sterile bag and there are 5Ø ISO-MED gowns to a case.

Quality Standards

- Polypropylene Spun-bound Fabric with a Polyethylene Exterior Coating
- ISO-certified breathable fabric
- Low linting
- Thumb loops
- Seam seals
- Elastic cuffs
- Latex-free

Shelf Life & Storage

Three (3) years from date of manufacture.
Store in a dry, cool place

Sizes:

Small, Regular, Medium, XL, XXXL,

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Sterile Chemo Gowns for Hazardous Drug Compounding

Performance Drug Test Results

PERMEATION TESTING PER ASTM D6978 ON FABRIC SAMPLE
Sample: ISO 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	COLLECTION MEDIUM
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 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	At random from fabric

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Performance Drug Test Results

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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 DRUG	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	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

ISO 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/cm2/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

• ARDL is ISO 17025 accredited by A2LA for the test methods listed on the certificates referenced on the first section of this document. Unless specified, the current specification version is used. NOTE: Non-ISO 17015 accredited test methods are designated with the" symbol to differentiate from ISO 17015 accredited methods in the body of the test report.•

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Sterile Chemo Gowns for Hazardous Drug Compounding

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, 10 mg/ml (10,000 ppm)	USP; Lot #R046RO; 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, 10 mg/ml (10,000 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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Performance Drug Test Results

ISO-MED

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 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/m2)	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