

Contec® CritiGear™ HD Chemo Gown Hazardous Drugs Test Report

Summary

Contec's CritiGear™ HD Chemo Gown has been tested per ASTM F3267-22 to demonstrate broad protection against common hazardous drugs and to establish acceptable criteria for adherence to USP <800> guidelines.

ASTM F3267-22¹ outlines the test method for evaluating medical gowns, with a focus on their performance against Hazardous Drugs (HDs). The standard includes procedures to assess gowns for broad or selective protection and liquid penetration resistance when exposed to hazardous substances. Broad protection indicates the material and seams demonstrated breakthrough detection at 30 minutes or greater for the seven specified HDs, with selective coverage meeting the same criteria for only five of the seven specified HDs¹. The standard is crucial for ensuring that medical gowns not only meet general protective criteria but also offer reliable safety against specific risks associated with hazardous drug exposure, thereby supporting safe and effective medical practices.

Results

Table 5. Permeation Test Results on: HCGA0800-L/XL, CritiGear Chemo Gown, Lot# V9C0270.

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Specified Chemotherapy/Hazardous Drug	Breakthrough Detection Time (minutes) ^A	Cumulative Permeation (µg/cm ²) ^B				Pass/Fail
		30 min.	60 min.	120 min.	240 min.	
Carmustine, 3.3 mg/ml (3,300 ppm)	>240	<0.1	<0.1	<0.1	<0.1	Pass
Cyclophosphamide, 20 mg/ml (20,000 ppm)	>240	<0.1	<0.1	<0.1	<0.1	Pass
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	>240	<0.1	<0.1	<0.1	<0.1	Pass
Etoposide, 20.0 mg/ml (20,000 ppm)	>240	<0.1	<0.1	<0.1	<0.1	Pass
Fluorouracil, 50.0 mg/ml (50,000 ppm)	>240	<0.1	<0.1	<0.1	<0.1	Pass
Paclitaxel, 6.0 mg/ml (6,000 ppm)	>240	<0.1	<0.1	<0.1	<0.1	Pass
Thiotepa, 10.0 mg/ml (10,000 ppm)	>240	<0.1	<0.1	<0.1	<0.1	Pass

^A Lowest breakthrough detection time for all protective clothing barrier materials and seam types tested.

^B Highest cumulative permeation for all protective clothing barrier materials and seam types tested.

Conclusions

Contec's CritiGear HD Chemo Gown had no breakthrough below the required 30 minutes; therefore, it meets the Part A requirements of ASTM F3267: Standard Specification for Protective Clothing for Use Against Liquid Chemotherapy and Other Liquid Hazardous Drugs.

¹ F3267-22: Standard Specification for Protective Clothing for Use Against Liquid Chemotherapy and Other Liquid Hazardous Drugs. American Society for Testing and Materials (ASTM). (2022). ASTM International. <https://doi.org/10.1520/F3267-22>