

Contec® CritiGear™ Chemo Gown with BloxTech™ Fabric Hazardous Drugs Test Report

Summary: Contec's CritiGear Chemo Gown with BloxTech Fabric has been tested per ASTM D6978-05 to demonstrate protection against common hazardous drugs and to establish acceptable criteria for adherence to USP <800> guidelines.

ASTM D6978-05 is the test standard required by USP <800> for evaluating gloves to be used for protection against hazardous drugs. Because this test provides information specific to the time it takes for hazardous drugs tested to permeate materials, it is also applicable to gowns. The information derived from the testing can also be used as a guide to determine frequency of gown changing. ASTM D6978-05 is a rigorous test and *"it is emphasized that the conditions used in this assessment are intended to approximate the worst-case condition for clinical uses."* It is also important to note that the lowest breakthrough time is reported.

Results: Table 5. Permeation Test Results on: One white gown identified as Contec Coverall (HCGA0800 Series); Quality Sample Garment Style No. CTL417-3X.

Minimum Breakthrough Detection Time: The time in minutes measured from the start of the test to the sampling time that immediately precedes the sampling time at which the permeation rate reaches 0.01 µg/cm²/min.¹

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Lot A/B/C) (Minutes)	STEADY STATE PERM. RATE (Lot A/B/C) (0.01 µg/cm ² /minute)	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,000 ppm)	16.8 (19.0, 18.2, 16.8)	0.05 (0.05,0.05,0.06)	Slight swelling and degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and degradation
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and degradation
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and degradation
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and degradation
Methotrexate, 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and degradation
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and degradation
Thiotepa, 10.0 mg/ml (10,000 ppm)	16.6 (19.5, 16.6, 17.3)	0.4 (0.3,0.3,0.7)	Slight swelling and degradation

Summary: Contec's CritiGear Chemo Gown with BloxTech fabric, when used responsibly, is an acceptable choice for promoting worker safety as prescribed by USP <800>. This is demonstrated by the results of above independent laboratory testing and the design of the gown. Contec's gown meets all design criteria specified in section 7.2 of USP <800> (including sealed/taped seams) with consideration for USP <797> requirements for use of low linting materials compatible with ISO Class 7 environments.

¹ ASTM International Designation: D6978-05 (Reapproved 2013)