Contec® CritiGear™ Sterile Nitrile Gloves

Permeation Resistance to Drugs

Hazardous Drugs

Summary Contec® CritiGear™ Sterile Nitrile Gloves have been tested per ASTM Method D6978-05 (Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs) to demonstrate protection against common hazardous drugs and to establish acceptable criteria for adherence to USP <800> guidelines.

ASTM Method D6978-05 is the test standard required by USP <800> for evaluating gloves to be used for protection against hazardous drugs. The standard covers a protocol for assessment of resistance of glove materials to permeation by potentially hazardous drugs under conditions of continuous contact. The information derived from the testing can also be used as a guide.to determine the appropriate frequency for changing gloves. 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."[1] It is also important to note that the minimum breakthrough time from triplicate tests is reported.

Results Permeation Test Results Contec CritiGear HCGS0022 (Medium).

Minimum Breakthrough Detection Time is defined as 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/cm^2/min.[1]

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Lot A/B/C) (Minutes)	STEADY STATE PERMEATION RATE (Lot A/B/C) (0.01 µg/cm^2/minute)	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	39.0 (47.9, 65.9, 39.0)	0.3 (0.3, 0.3, 0.2)	Moderate swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml (25,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	>240 min.	N/A	Moderate swelling and no degradation
Thiotepa, 10.0 mg/ml (10,000 ppm)	97.6 (98.8, 118.5, 97.6)	0.2 (0.2, 0.1, 0.2)	Slight swelling and no degradation

Conclusion Contec's CritiGear Sterile Nitrile Gloves, when used responsibly, are an acceptable choice for promoting worker safety as prescribed by USP <800>. This is demonstrated by the results from independent laboratory testing shown above as well as the design of the gloves. Contec's gloves meet all design criteria specified in section 7.0 for administering hazardous drugs and 7.1 of USP <800> with consideration for USP <797> requirements for glove usage.

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

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