

GN92 Chemotherapy Statement

Product Brand:	Nitrex Ultra Sensitive
Product Description:	Powder free nitrile examination glove - blue
Product Code:	GN92

The Nitrex Ultra Sensitive nitrile examination grade gloves were submitted by the OEM factory, to Akron Rubber Development Laboratory Inc, for testing in accordance with ASTM D 6978-05: Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs (test report reference: PN 122150B).

ASTM D 6978-05 was the preferred standard against which the gloves were tested; as opposed to EN 374-1 owing to:

- EN 374-1 does not take into account chemotherapy drugs.
- Testing is conducted at a temperature similar to that of the hand ($35 \pm 2^{\circ}\text{C}$) as opposed to the EN 374-1 test temperature of $23 \pm 1^{\circ}\text{C}$.
- The ASTM breakthrough occurs at one hundredth less concentration than that of EN 374-1. The ASTM breakthrough occurs when the permeation rate reaches $0.01 \mu\text{g}/\text{cm}^2/\text{min}$ against that of EN 374-1 which occurs at $1 \mu\text{g}/\text{cm}^2/\text{min}$.

Minimum breakthrough time:

Test Chemotherapy Drug & Concentration	Minimum measured breakthrough detection time (Specimen 1,2,3) (minutes)	Steady state permeation rate (Specimen 1,2,3) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	Other Observations
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	10.1 (10.2,10.1,10.2)	N/A*	Moderate swelling and no degradation
Cisplatin 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytosan) 20 mg/ml (20,000 ppm)	No breakthrough up to 240	N/A	Slight swelling and no degradation
Cytarabine 100 mg/ml (100,000 ppm)	No breakthrough up to 240	N/A	Slight swelling and no degradation
Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240	N/A	Slight swelling and no degradation
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240	N/A	Slight swelling and no degradation
Fluorouracil 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240	N/A	Slight swelling and no degradation
Ifosfamide 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240	N/A	Slight swelling and no degradation
Methotrexate 25 mg/ml (25,000 ppm)	No breakthrough up to 240	N/A	Slight swelling and no degradation
Mitomycin C 0.5 mg/ml (500 ppm)	No breakthrough up to 240	N/A	Slight swelling and no degradation

Mitoxantrone, 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240	N/A	Slight swelling and no degradation
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240	N/A	Moderate swelling and no degradation
Thiotepa 10.0 mg/ml (10,000 ppm)	30.2 (40.4,40.4,30.2)	1.5 (1.4,1.6,1.6)	Slight swelling and no degradation
Vincristine Sulfate 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240	N/A	Slight swelling and no degradation

Note: *The steady state was not available at the end of the testing period due to the strong permeation process (absorbance values out of linear range).