

**▪ TEST REPORT ▪**

**PN 110652**

**CHEMICAL ANALYTICAL SERVICES**

**(DYNAMIC)**

**SUBJECT:** Permeation testing per ASTM D 6978-05 on sample submitted by the above company.

**RECEIVED:** Glove sample identified as Powder Free Nitrile Examination Glove, White Colored, Non-Sterile; Lot# 030713-12-1-03.

**TESTING CHEMOTHERAPY DRUGS:**

Table 1. List of the Testing Chemotherapy Drugs, Sources

<b>TESTING CHEMOTHERAPY DRUGS</b>	<b>DRUG SOURCE</b>
Carmustine (BCNU)	Bristol-Myers; Lot# 1C7008A
Cisplatin	Pfizer; Lot# 7800808
Cyclophosphamide (Cytoxan)	Sigma, Lot# 120M1253V
Cytarabine	Sigma Aldrich; Lot# 060M5051V
Dacarbazine (DTIC)	APP; Lot# 6103390
Doxorubicin Hydrochloride	USP; Lot# L0K258
Etoposide (Toposar)	Teva; Lot# 31314884B
Fluorouracil	APP; Lot# 6104355
Ifosfamide	Baxter; Lot# 1B304B
Methotrexate	USP; Lot# J0D109
Mitomycin C	USP; Lot# L0L428
Mitoxantrone	Sigma, Lot# 011M1240V
Paclitaxel (Taxol)	Hospira; Lot# Z086865AA
Thiotepa	Sigma Aldrich; Lot# SLBD4239V
Vincristine Sulfate	USP; Lot# R0K248

**COLLECTION MEDIA:**

The collection media, which were selected, are listed in Table 2.

Table 2. Collection Media for Testing Chemotherapy Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU)	10% Ethanol Aqueous Solution
Cisplatin	Distilled Water
Cyclophosphamide (Cytoxan)	Distilled Water
Cytarabine	Distilled Water
Dacarbazine (DTIC)	Distilled Water
Doxorubicin Hydrochloride	Distilled Water
Etoposide (Toposar)	Distilled Water
Fluorouracil	9.20 pH Sodium Hydroxide Solution
Ifosfamide	Distilled Water
Methotrexate	Distilled Water
Mitomycin C	Distilled Water
Mitoxantrone	Distilled Water
Paclitaxel (Taxol)	30% Methanol Aqueous Solution
Thiotepa	Distilled Water
Vincristine Sulfate	Distilled Water

**DETECTION METHOD OF CHEMICAL PERMEATION; UV/VIS ABSORPTION SPECTROMETRY:**

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute 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. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	200
Cytarabine, 100 mg/ml (100,000 ppm)	272
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	320
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	232
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Ifosfamide, 50.0 mg/ml (50,000 ppm)	200
Methotrexate, 25 mg/ml (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Mitoxantrone, 2.0mg/ml (2,000ppm)	242
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	231
Thiotepa, 10.0 mg/ml (10,000 ppm)	199
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	220

**TESTING CONDITIONS:**

Standard Test Method Used:	ASTM D 6978-05
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 cm <sup>2</sup>
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area
Comments/Other Conditions:	Magnetic stir bar was used in the sampling chamber

**SAMPLE CHARACTERISTICS:**

Table 4. Thickness characteristics for the tested specimens: Powder Free Nitrile Examination Glove, White Colored, Non-Sterile; Lot# 030713-12-1-03.

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m <sup>2</sup> )
	Sample 1	Sample 2	Sample 3		
Carmustine (BCNU)	0.057	0.051	0.057	0.055	45.7
Cisplatin	0.048	0.050	0.057	0.052	
Cyclophosphamide (Cytoxan)	0.050	0.053	0.049	0.050	
Cytarabine	0.047	0.046	0.049	0.048	
Dacarbazine (DTIC)	0.048	0.048	0.052	0.049	
Doxorubicin Hydrochloride	0.057	0.052	0.052	0.054	
Etoposide (Toposar)	0.055	0.054	0.050	0.053	
Fluorouracil	0.053	0.052	0.052	0.052	
Ifosfamide	0.053	0.054	0.051	0.053	
Methotrexate	0.051	0.054	0.052	0.053	
Mitomycin C	0.053	0.055	0.055	0.054	
Mitoxantrone	0.053	0.058	0.055	0.055	
Paclitaxel (Taxol)	0.051	0.048	0.053	0.050	
Thiotepa	0.055	0.047	0.055	0.052	
Vincristine Sulfate	0.051	0.055	0.050	0.052	

**RESULTS:**

Table 5. Permeation Test Results on: Powder Free Nitrile Examination Glove, White Colored, Non-Sterile; Lot# 030713-12-1-03.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) ( $\mu\text{g}/\text{cm}^2/\text{minute}$ )	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	15.2 (15.2,15.2,15.3)	1.1 (1.1,1.1,1.0)	Moderate swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytosan), 20 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cytarabine, 100 mg/ml (100,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Ifosfamide, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitoxantrone, 2.0mg/ml (2,000ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Thiotepa, 10.0 mg/ml (10,000 ppm)	45.7 (46.0,45.8,45.7)	0.7 (0.6,0.7,0.8)	Slight swelling and no degradation
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation