

August 16, 2017

▪ **TEST REPORT** ▪

PN 135713

CHEMICAL ANALYTICAL SERVICES

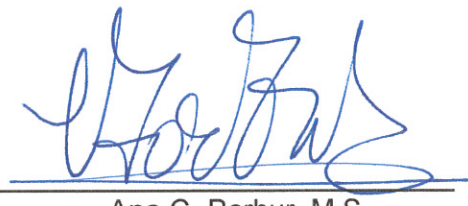
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SUBJECT: Permeation testing per ASTM D 6978-05 on sample submitted by the above company.

RECEIVED: One glove type identified as Nitrile Examination Powder Free Glove, Blue; Ref# RA/046/006/2017/C.

TESTING CHEMOTHERAPY DRUGS:

Table 1. List of the Testing Chemotherapy Drugs, Sources, and Expiration Dates

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU)	Sigma Aldrich; Lot# 016M4028V; Expires 09/2017
Cisplatin	Sigma Aldrich; Lot# LRAA8721; Expiration 08/2018
Cyclophosphamide (Cytoxan)	Sigma Aldrich; Lot# SLBG4216V; Expiration 02/2018
Dacarbazine (DTIC)	Teva; Lot# 31318323B; Expiration 10/8/2017
Doxorubicin Hydrochloride	Sigma Aldrich; Lot# SLBM7382V; Expiration 08/2017
Etoposide (Toposar)	Teva; Lot# 31321666B; Expiration 09/2019
Fluorouracil	Sigma Aldrich; Lot# BCBR1712V; Expiration 08/2017
Paclitaxel (Taxol)	Hospira; Lot# C126865AA; Expiration 12/2017
Thiotepa	USP; Lot# R046R0; Expiration 04/2018

COLLECTION MEDIA:

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

Table 2. Collection Media for Testing Chemotherapy Drugs

TEST CHEMICAL AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	Distilled Water
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978-05
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm ²
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

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)	229
Cisplatin	199
Cyclophosphamide (Cytoxan)	200
Dacarbazine (DTIC)	320
Doxorubicin Hydrochloride	232
Etoposide (Toposar)	205
Fluorouracil	269
Paclitaxel (Taxol)	231
Thiotepa	199

SAMPLE CHARACTERISTICS:

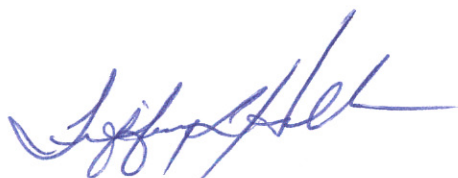
Table 4. Thickness characteristics for the tested specimens on: Nitrile Examination Powder Free Glove, Blue; Ref# RA/046/006/2017/C.

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m ²)
	#1	#2	#3		
Carmustine (BCNU)	0.056	0.055	0.064	0.058	54.0
Cisplatin	0.055	0.060	0.059	0.058	
Cyclophosphamide (Cytoxan)	0.056	0.058	0.060	0.058	
Dacarbazine (DTIC)	0.056	0.056	0.060	0.057	
Doxorubicin Hydrochloride	0.056	0.052	0.061	0.056	
Etoposide (Toposar)	0.055	0.054	0.055	0.054	
Fluorouracil	0.054	0.056	0.054	0.055	
Paclitaxel (Taxol)	0.055	0.058	0.057	0.057	
Thiotepa	0.057	0.065	0.059	0.060	

RESULTS:

Table 5. Permeation Test Results on: Nitrile Examination Powder Free Glove, Blue; Ref# RA/046/006/2017/C.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	15.9 (22.5,15.9,16.9)	0.6 (0.5,0.5,0.7)	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), 20.0 mg/ml (20,000ppm)	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	Moderate 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
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)	47.3 (58.7,59.3,47.3)	0.6 (0.5,0.6,0.6)	Slight swelling and no degradation



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