

April 11, 2017

TEST REPORT

PN 133360

CHEMICAL ANALYTICAL SERVICES

Prepared For:
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Suresh Kumar
ECO Medi Sdn. Bhd.

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

RECEIVED: Glove sample identified as Blue Nitrile Medical Examination Glove (Powder Free); 2.0 mil; Mediums; Lot# TTYNM EEB1 300028.

TESTING CHEMOTHERAPY DRUGS:

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

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carboplatin, 10 mg/ml (10,000 ppm)	Teva; Lot# 16H18KA; Expiration 08/2018
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	USP; Lot# R071D0; Expiration 03/2018
Cisplatin, 1.0 mg/ml (1,000 ppm)	Fresenius Kabi; Lot# 6114286; 01/2018
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	Sigma Aldrich; Lot# BCBM8984V; Expiration 04/2017
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Teva; Lot# 31318323B; Expiration 10/8/2017
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Sigma Aldrich; Lot# SLBM7382V; Expiration 08/2017
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Teva; Lot# 31321666B; Expiration 09/2019
Fluorouracil, 50.0 mg/ml (50,000 ppm)	Accord; Lot# PT04300; Expiration 10/2018
Ifosfamide, 50.0 mg/ml (50,000 ppm)	Sigma Aldrich; Lot# 106K1063V; Expiration 12/2017
Methotrexate, 25 mg/ml, (25,000 ppm)	Teva; Lot# 16A28MA, Expiration 01/2018
Mitomycin C, 0.5 mg/ml (500 ppm)	Sigma Aldrich; Lot# SLBH6728V; Expiration 05/2018
Mitoxantrone, 2.0mg/ml (2,000ppm)	Sigma Aldrich; Lot# MKBR2210V; Expiration 11/2017
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	Hospira; Lot# C126865AA; Expiration 12/2017
Thiotepa, 10.0 mg/ml (10,000 ppm)	USP; Lot# R046R0; Expiration 1/2018
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# SLBQ9329V; Expiration 01/2018

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 ²
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area

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
Carboplatin, 10 mg/ml (10,000 ppm)	Distilled Water
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytosan), 20 mg/ml (20,000 ppm)	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
Ifosfamide, 50.0 mg/ml (50,000 ppm)	Distilled Water
Methotrexate, 25 mg/ml (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Mitoxantrone, 2.0mg/ml (2,000ppm)	Distilled Water
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	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)
Carboplatin, 10 mg/ml (10,000 ppm)	192
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytosan), 20 mg/ml (20,000 ppm)	200
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

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested specimens: Blue Nitrile Medical Examination Glove (Powder Free); 2.0 mil; Mediums; Lot# TTYNM EEB1 300028.

Testing Chemotherapy Drugs	Thickness (mm)				Weight/Unit Area (g/m ²)
	Sample 1	Sample 2	Sample 3	Average (mm)	
Carmustine (BCNU)	0.043	0.043	0.044	0.043	50.8
Cisplatin	0.042	0.042	0.043	0.042	
Cyclophosphamide (Cytoxan)	0.043	0.042	0.043	0.043	
Carboplatin	0.043	0.041	0.044	0.043	
Dacarbazine (DTIC)	0.044	0.043	0.043	0.043	
Doxorubicin Hydrochloride	0.041	0.044	0.041	0.042	
Etoposide (Toposar)	0.044	0.045	0.044	0.045	
Fluorouracil	0.043	0.043	0.042	0.043	
Ifosfamide	0.043	0.044	0.043	0.043	
Methotrexate	0.043	0.042	0.043	0.043	
Mitomycin C	0.044	0.042	0.044	0.043	
Mitoxantrone	0.043	0.041	0.043	0.042	
Paclitaxel (Taxol)	0.042	0.044	0.042	0.043	
Thiotepa	0.043	0.043	0.043	0.043	
Vincristine Sulfate	0.043	0.043	0.043	0.043	

RESULTS:

Table 5. Permeation Test Results on: Blue Nitrile Medical Examination Glove (Powder Free); 2.0 mil; Mediums; Lot# TTYNM EEB1 300028

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
Carboplatin, 10 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	24.0 (24.3,24.0,24.3)	0.4 (0.4,0.4,0.5)	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
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)	56.9 (56.9,67.7,69.3)	0.2 (0.3,0.2,0.2)	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



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