

November 16, 2016

• **TEST REPORT** •

PN 131645

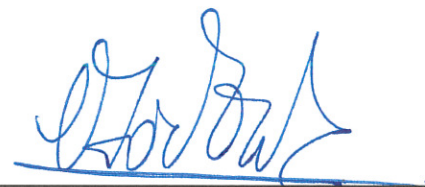
CHEMICAL ANALYTICAL SERVICES

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November 16, 2016

Yap Peak Geeh
Maxter Glove Manufacturing 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 Powder Free Nitrile Examination Gloves, Mediums, Lot# 86382 25689.

TESTING CHEMOTHERAPY DRUGS:

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

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU)	USP; Lot# F01274; Expiration 04/2017
Cisplatin	Sigma Aldrich; Lot# LRAA8721; Expiration 08/2018
Cyclophosphamide (Cytoxan)	USP; Lot# R01530; Expiration 02/2017
Cytarabine	USP; Lot# H1M420; expiration 02/2017
Dacarbazine (DTIC)	Teva; Lot# 31317605B; Expiration 11/2016
Doxorubicin Hydrochloride	Sigma Aldrich; Lot# SLBM7382V; Expiration 08/2017
Etoposide (Toposar)	Teva; Lot# 31317608B; Expiration 02/2017
Fluorouracil	Sigma Aldrich; Lot# BCBR1712V; Expiration 08/2017
Ifosfamide	Sigma Aldrich; Lot# 106K1063V; Expiration 01/2017
Methotrexate	USP; Lot# R020L0, Expiration 03/2017
Mitomycin C	Sigma; Lot# MKBR2210V; Expiration 03/2017
Mitoxantrone	Sigma Aldrich; Lot# MKBR2210V; Expiration 11/2016
Paclitaxel (Taxol)	USP; Lot# I1I393; Expiration 04/2017
Thiotepa	Sigma Aldrich; Lot# SLBM7142V; Expiration 12/2016
Vincristine Sulfate	USP; Lot# R0K248; Expiration 02/2017

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
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 mg/ml (20,000 ppm)	Distilled Water
Cytarabine, 100 mg/ml (100,000 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)
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

SAMPLE CHARACTERISTICS:

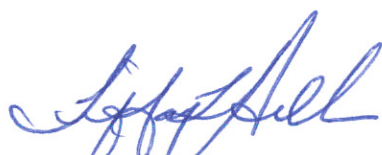
Table 4. Thickness characteristics for the tested specimens: Glove sample identified as Powder Free Nitrile Examination Gloves, Mediums, Lot# 86382 25689

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m ²)
	Sample 1	Sample 2	Sample 3		
Carmustine (BCNU)	0.049	0.053	0.052	0.051	46.2
Cisplatin	0.050	0.049	0.054	0.051	
Cyclophosphamide (Cytoxan)	0.049	0.043	0.050	0.047	
Cytarabine	0.049	0.046	0.051	0.049	
Dacarbazine (DTIC)	0.047	0.048	0.048	0.047	
Doxorubicin Hydrochloride	0.049	0.048	0.050	0.049	
Etoposide (Toposar)	0.051	0.048	0.047	0.049	
Fluorouracil	0.049	0.049	0.051	0.049	
Ifosfamide	0.051	0.052	0.047	0.050	
Methotrexate	0.048	0.046	0.047	0.047	
Mitomycin C	0.048	0.051	0.048	0.049	
Mitoxantrone	0.046	0.046	0.054	0.048	
Paclitaxel (Taxol)	0.048	0.050	0.047	0.049	
Thiotepa	0.056	0.053	0.052	0.054	
Vincristine Sulfate	0.055	0.052	0.044	0.050	

RESULTS:

Table 5. Permeation Test Results on: Glove sample identified as Powder Free Nitrile Examination Gloves, Mediums.
Lot# 86382 25689

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)	8.3 (21.0,13.1,8.3)	0.5 (0.4,0.5,0.7)	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 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)	38.0 (39.0,38.5,38.0)	1.0 (1.0,1.0,1.0)	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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