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· TEST REPORT ·

PN 128129A

CHEMICAL ANALYTICAL SERVICES

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May 18, 2016

Sumathi Saravana Sami
MTR LLC

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

RECEIVED: One blue glove sample identified as Powder Free Nitrile Examination Gloves – Blue; Product Type: OCF35BL; Lot# 60221M05-02.

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	USP; Lot# J0L420; Expiration 08/2016
Cyclophosphamide (Cytoxan)	USP; Lot# R01530; Expiration 02/2017
Dacarbazine (DTIC)	Teva; Lot# 31317605B; Expiration 11/2016
Doxorubicin Hydrochloride	USP; Lot# L0K258; Expiration 06/2016
Etoposide (Toposar)	Teva; Lot# 31317608B; Expiration 02/2017
Fluorouracil	USP; Lot# I0G371; Expiration 09/2016
Paclitaxel (Taxol)	Hospira; Lot# B036865AA; Expiration 05/2016
Thiotepa	Sigma Aldrich; Lot# SLBM7142V; Expiration 12/2016

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
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
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 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area

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
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
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	231
Thiotepa, 10.0 mg/ml (10,000 ppm)	199

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested specimens: Powder Free Nitrile Examination Gloves – Blue; Product Type: OCF35BL; Lot# 60221M05-02

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m^2)
	Sample 1	Sample 2	Sample 3		
Carmustine (BCNU)	0.052	0.054	0.054	0.053	55.3
Cisplatin	0.051	0.057	0.054	0.054	
Cyclophosphamide (Cytoxan)	0.053	0.054	0.054	0.054	
Dacarbazine (DTIC)	0.047	0.052	0.055	0.051	
Doxorubicin Hydrochloride	0.048	0.051	0.051	0.050	
Etoposide (Toposar)	0.051	0.055	0.055	0.054	
Fluorouracil	0.045	0.053	0.052	0.050	
Paclitaxel (Taxol)	0.049	0.051	0.053	0.051	
Thiotepa	0.052	0.055	0.053	0.053	

RESULTS:

Table 5. Permeation Test Results on: Powder Free Nitrile Examination Gloves – Blue; Product Type: OCF35BL; Lot# 60221M05-02

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) ($\mu g/cm^2$/minute)	OTHER OBSERVATIONS
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	18.2 (18.2,24.6,18.6)	0.3 (0.3,0.3,0.4)	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 (Cytoxan) 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
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)	57.3 (80.7,57.3,69.4)	0.5 (0.4,0.5,0.5)	Slight swelling and no degradation

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