

March 11, 2021

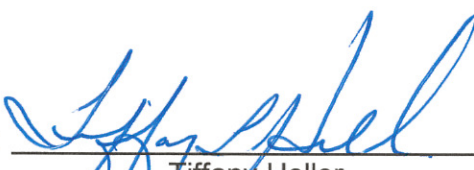
▪TEST REPORT▪

PN 158022B

PHARMACEUTICAL SERVICES

Prepared For:

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Rev 101218



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March 11, 2021

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Page 2 of 5  
PN 158022B

**SUBJECT:** Permeation testing per ASTM D6978-05(2019) on sample submitted by the above company.

**RECEIVED:** One (1) glove type identified as; Blue Nitrile Powder Free, Lot Number 011220202A01, Size Medium.

**TEST CHEMICALS:**

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	Sigma Aldrich; Batch# 0000098912; Expiration 01/2022
Carboplatin, 10 mg/ml (10,000 ppm)	Teva; Lot# 19K11KA; Expiration 11/2021
Cisplatin, 1.0 mg/ml (1,000 ppm)	Accord; Lot# P2001296; Expiration 01/2022
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	Accord; Lot# 19112225; Expiration 10/2021
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Teva; Lot# 31325414B; Expiration 09/2021
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	WestWard; Lot# BJ0051; Expiration 06/2021
Etoposide, 20.0 mg/ml (20,000 ppm)	Teva; Lot# 31325485B; Expiration 07/2021
Fluorouracil, 50.0 mg/ml (50,000 ppm)	Accord; Lot# P2001167; Expiration 01/2022
Ifosfamide, 50 mg/ml (50,000 ppm)	Baxter Healthcare; Lot# 9A018G; Expiration 01/2022
Methotrexate, 25 mg/ml (25,000 ppm)	Teva; Lot# 19F06NB; Expiration 06/2021
Mitomycin C, 0.5 mg/ml (500 ppm)	USP; Lot# R07240; Expiration 10/2021
Mitoxantrone, 2 mg/ml (2,000 ppm)	USP; Lot# J0F278; Expiration 11/2021
Paclitaxel, 6.0 mg/ml (6,000 ppm)	Teva; Lot# 19K24KA; Expiration 11/2021
ThioTepa, 10.0 mg/ml (10,000 ppm)	USP; Lot # R11380; Expiration 01/2022
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	USP; Lot# Y06331; Expiration 12/2021

**COLLECTION MEDIA:**

Table 2. Collection Media for Test Drug

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Carboplatin, 10 mg/ml (10,000 ppm)	Distilled Water
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	Distilled Water
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide, 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 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 mg/ml (2,000 ppm)	Distilled Water
Paclitaxel, 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
ThioTepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	Distilled Water

\*ARDL is ISO 17025 accredited by A2LA for the test methods listed on the certificates referenced on page one. Unless specified, the current specification version is used.

NOTE: Non-ISO 17025 accredited test methods are designated with the ^ symbol to differentiate from ISO 17025 accredited methods in the body of the test report.\*



**TESTING CONDITIONS:**

Standard Test Method Used:	ASTM D6978-05(2019)
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

**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 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 DRUG	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Carboplatin, 10 mg/ml (10,000 ppm)	192
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	200
Dacarbazine, 10.0 mg/ml (10,000 ppm)	320
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	232
Etoposide, 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Ifosfamide, 50 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 mg/ml (2,000 ppm)	242
Paclitaxel, 6.0 mg/ml (6,000 ppm)	232
ThioTepa, 10.0 mg/ml (10,000 ppm)	199
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	220

**SAMPLE CHARACTERISTICS:**

Table 4. Thickness characteristics for the tested: Blue Nitrile Powder Free, Lot Number 011220202A01, Size Medium.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Carmustine (BCNU)	0.058	0.054	0.045	0.052
Carboplatin	0.063	0.054	0.057	0.058
Cisplatin	0.060	0.053	0.055	0.056
Cyclophosphamide (Cytosan)	0.065	0.054	0.055	0.058
Dacarbazine	0.062	0.057	0.048	0.055
Doxorubicin	0.058	0.054	0.057	0.056
Etoposide	0.062	0.060	0.052	0.058
Fluorouracil	0.057	0.054	0.056	0.056
Ifosfamide	0.050	0.053	0.056	0.053
Methotrexate	0.050	0.056	0.052	0.052
Mitomycin C	0.065	0.050	0.054	0.056
Mitoxantrone	0.066	0.048	0.057	0.057
Paclitaxel	0.057	0.053	0.052	0.054
ThioTepa	0.057	0.050	0.057	0.054
Vincristine Sulfate	0.051	0.056	0.056	0.055
<b>Weight/Unit Area (g/m<sup>2</sup>)</b>	<b>55.6</b>			

**RESULTS:**

Table 5. Permeation Test Results on testing of: Blue Nitrile Powder Free, Lot Number 011220202A01, Size Medium.

TEST CHEMOTHERAPY DRUGS	AVERAGE 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)	35.0 (35.0,35.6,35.5)	0.8 (0.7,0.6,0.9)	Moderate swelling and no degradation
Carboplatin, 10 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Dacarbazine, 10.0 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Etoposide, 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Ifosfamide, 50 mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml (25,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	>240 min.	N/A	Slight swelling and no degradation
Mitoxantrone, 2 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Paclitaxel, 6.0 mg/ml (6,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
ThioTepa, 10.0 mg/ml (10,000 ppm)	64.9 (64.9,126.6,129.2)	0.4 (0.9,0.1,0.1)	Slight swelling and no degradation
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation



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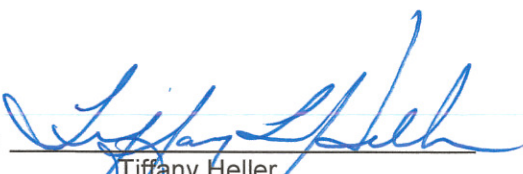
Page 5 of 5  
PN 158022B

**SAMPLES RECEIVED:**

Blue Nitrile Powder Free, Lot Number 011220202A01, Size Medium



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