

December 12, 2022

▪TEST REPORT▪

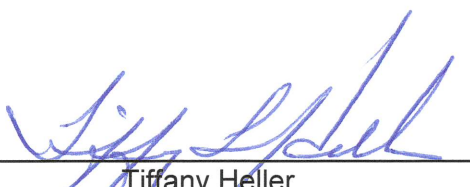
PN 165757A

PHARMACEUTICAL SERVICES


Prepared For:

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Rev 101218



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Page 2 of 7
PN 165757A

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

RECEIVED: One (1) glove type identified by customer as; Blue Nitrile Exam Powder Free Textured Single Use Non-Sterile, Ambidextrous Gloves, Lot Number 01S081322.

TESTED CHEMOTHERAPY DRUGS:

Table 1. List of the Testing Drugs and their Sources, Lot Numbers and Expiration Dates

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Busulfan, 6 mg/ml (6,000 ppm)	Sigma Aldrich; Lot# MKBW4481V; Expiration 11/2022
Carboplatin, 10 mg/ml (10,000 ppm)	Teva; Lot# 21I23KA; Expiration 09/01/2023
Carmustine, 3.3 mg/ml (3,300 ppm)	USP; Lot# R116Y0; Expiration 02/2023
Cisplatin, 1 mg/ml (1,000 ppm)	Accord; Lot# P2102309; Expiration 03/2023
Cyclophosphamide, 20 mg/ml (20,000 ppm)	Sandoz; Lot# 21062925; Expiration 05/2023
Dacarbazine, 10 mg/ml (10,000 ppm)	Hikma; Lot# BS0005; Expiration 02/2023
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	Accord; Lot# BJ0110; Expiration 08/01/2023
Etoposide, 20 mg/ml (20,000 ppm)	Teva; Lot# 31328501B; Expiration 03/2023
Fluorouracil, 50 mg/ml (50,000 ppm)	Accord; Lot# P2100647; Expiration 01/2023
Ifosfamide, 50 mg/ml (50,000 ppm)	Hikma; Lot# BH0039; Expiration 03/01/2024
Methotrexate, 25 mg/ml (25,000 ppm)	Accord; Lot# P2107432; Expiration 07/01/2023
Mitomycin, 0.5 mg/ml (500 ppm)	USP; Lot# R07240; Expiration 11/2022
Mitoxantrone HCl, 2 mg/ml (2,000 ppm)	USP; Lot# J0F278; Expiration 06/2023
Oxaliplatin, 5 mg/ml (5,000 ppm)	Accord; Lot# P2108105; Expiration 11/01/2024
Paclitaxel, 6 mg/ml (6,000 ppm)	Alvogen; Lot# F0560001; Expiration 12/2023
Thiotepa, 10 mg/ml (10,000 ppm)	USP; Lot# R154V0; Expiration 08/2023
Trisenox, 1 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# BCCB5045; Expiration 11/2022
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	USP; Lot# Y15370; Expiration 08/2023

TESTING CONDITIONS:

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

*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.*

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Fax (330) 794-6610 | Worldwide (330) 794-6600

COLLECTION MEDIA:

Table 2. Collection Media for Test Drug

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Busulfan, 6 mg/ml (6,000 ppm)	Distilled Water
Carboplatin, 10 mg/ml (10,000 ppm)	Distilled Water
Carmustine, 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide, 20 mg/ml (20,000 ppm)	Distilled Water
Dacarbazine, 10 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	Distilled Water
Etoposide, 20 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50 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, 0.5 mg/ml (500 ppm)	Distilled Water
Mitoxantrone HCl, 2 mg/ml (2,000 ppm)	Distilled Water
Oxaliplatin, 5 mg/ml (5,000 ppm)	Distilled Water
Paclitaxel, 6 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa, 10 mg/ml (10,000 ppm)	Distilled Water
Trisenox, 1 mg/ml (1,000 ppm)	Distilled Water
Vincristine Sulfate, 1 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 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)
Busulfan, 6 mg/ml (6,000 ppm)	197
Carboplatin, 10 mg/ml (10,000 ppm)	192
Carmustine, 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1 mg/ml (1,000 ppm)	199
Cyclophosphamide, 20 mg/ml (20,000 ppm)	200
Dacarbazine, 10 mg/ml (10,000 ppm)	320
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	232
Etoposide, 20 mg/ml (20,000 ppm)	205
Fluorouracil, 50 mg/ml (50,000 ppm)	269
Ifosfamide, 50 mg/ml (50,000 ppm)	200
Methotrexate, 25 mg/ml (25,000 ppm)	303
Mitomycin, 0.5 mg/ml (500 ppm)	217
Mitoxantrone HCl, 2 mg/ml (2,000 ppm)	242
Oxaliplatin, 5 mg/ml (5,000 ppm)	199
Paclitaxel, 6 mg/ml (6,000 ppm)	231
Thiotepa, 10 mg/ml (10,000 ppm)	199
Trisenox, 1 mg/ml (1,000 ppm)	197
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	220

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested: Blue Nitrile Exam Powder Free Textured Single Use Non-Sterile, Ambidextrous Gloves, Lot Number 01S081322.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Busulfan	0.067	0.066	0.067	0.067
Carboplatin	0.067	0.060	0.050	0.059
Carmustine	0.069	0.061	0.063	0.064
Cisplatin	0.068	0.063	0.054	0.062
Cyclophosphamide	0.061	0.063	0.052	0.059
Dacarbazine	0.056	0.062	0.062	0.060
Doxorubicin HCl	0.053	0.053	0.072	0.059
Etoposide	0.059	0.061	0.052	0.057
Fluorouracil	0.060	0.062	0.066	0.063
Ifosfamide	0.061	0.060	0.054	0.058
Methotrexate	0.063	0.065	0.057	0.062
Mitomycin	0.053	0.067	0.061	0.060
Mitoxantrone HCl	0.063	0.054	0.055	0.057
Oxaliplatin	0.069	0.061	0.054	0.061
Paclitaxel	0.071	0.065	0.058	0.065
Thiotepa	0.064	0.062	0.049	0.058
Trisenox	0.053	0.062	0.054	0.056
Vincristine Sulfate	0.055	0.061	0.059	0.058
Weight/Unit Area (g/m²)	53.4			

RESULTS:

Table 5. Permeation Test Results on testing of: Blue Nitrile Exam Powder Free Textured Single Use Non-Sterile, Ambidextrous Gloves, Lot Number 01S081322.

TEST CHEMOTHERAPY DRUGS	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (µg/cm ² /minute)	OTHER OBSERVATIONS
Carboplatin, 10 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Carmustine, 3.3 mg/ml (3,300 ppm)	18.0 (19.5,18.0,18.9)	0.4 (0.4,0.4,0.3)	Moderate swelling and degradation
Cisplatin, 1 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Cyclophosphamide, 20 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Dacarbazine, 10 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Etoposide, 20 mg/ml (20,000 ppm)	>240 min.	N/A	Moderate swelling and degradation
Fluorouracil, 50 mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Ifosfamide, 50 mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Methotrexate, 25 mg/ml (25,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Mitomycin, 0.5 mg/ml (500 ppm)	>240 min.	N/A	Slight swelling and degradation
Mitoxantrone HCl, 2 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Oxaliplatin, 5 mg/ml (5,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Paclitaxel, 6 mg/ml (6,000 ppm)	>240 min.	N/A	Moderate swelling and degradation
Thiotepa, 10 mg/ml (10,000 ppm)	56.8 (66.7,56.8,57.1)	0.3 (0.3,0.4,0.3)	Slight swelling and degradation
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and degradation

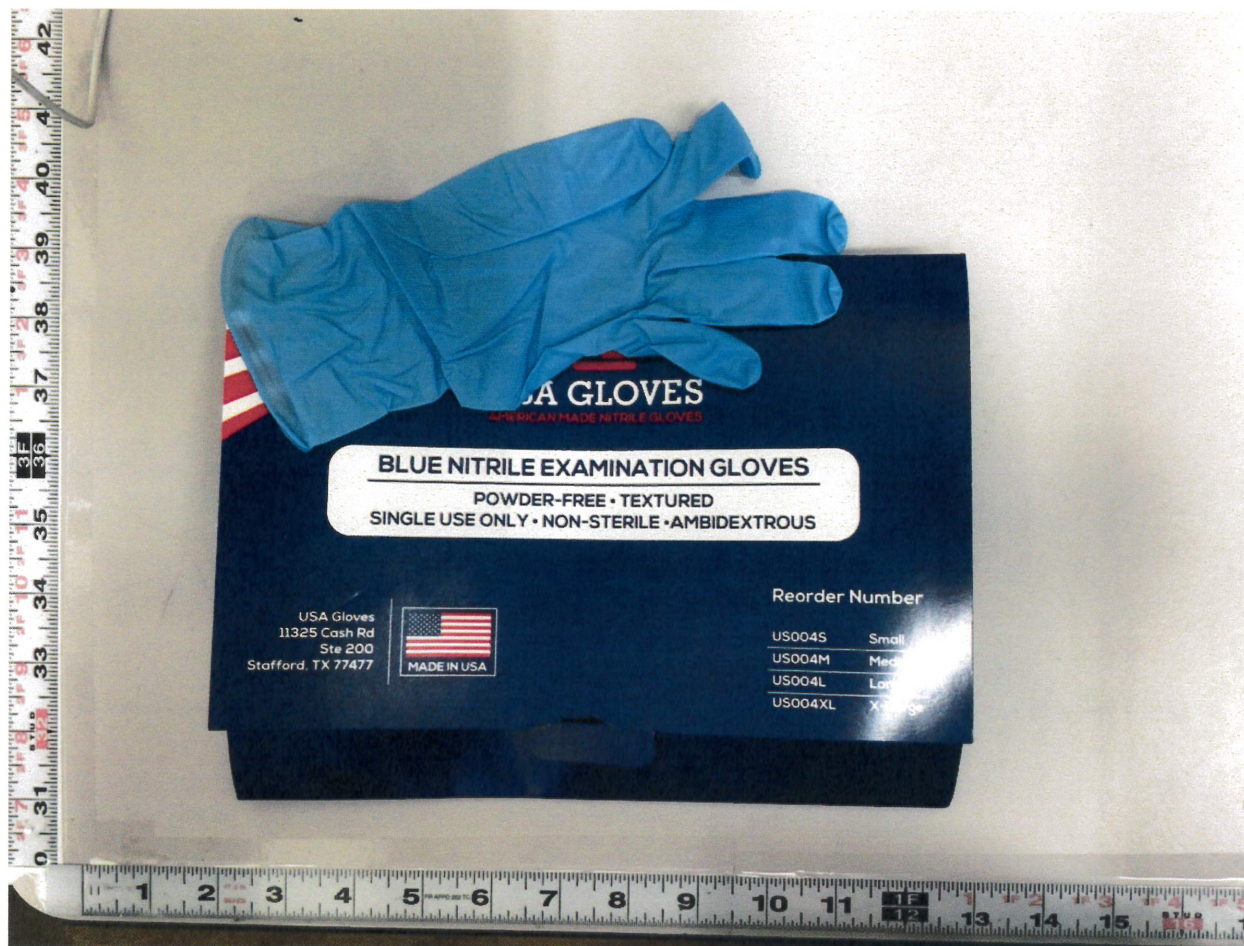
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Page 6 of 7
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SAMPLES RECEIVED:

Blue Nitrile Exam Powder Free Textured
Single Use Non-Sterile, Ambidextrous Gloves, Lot Number 01S081322



APPENDIX

Testing Location: 2887 Gilchrist Road, Akron Ohio 44305

Decision Rules

Customer Selected Decision Rule: Decision Rule 1

Rule 1. This is the way test results have traditionally been reported by ARDL. If ARDL runs a test for you that has pass/fail requirements, ARDL will report the values observed and then state "Pass" or "Fail", based on those values only. By default, ARDL will apply this rule to all Category I tests and those tests which are not on ARDL's Scope of Accreditation.

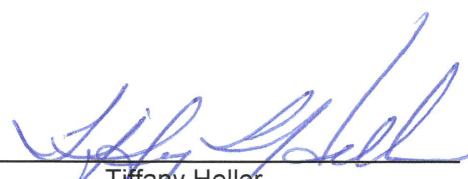
Rule 2. This rule takes into account the calculated measurement uncertainty of test results generated. Every test and piece of test equipment has an inherent amount of measurement uncertainty associated with it. Rule 2 establishes "Guard Bands", where the measurement uncertainty value is added to the Minimum Passing requirement and is subtracted from the Maximum Passing requirement. The Pass/Fail requirements thus become tighter and customers may be more "Certain" of their Pass/Fail result.

Rule 3. This rule also takes into account measurement uncertainty but does not set up guard bands. Rule 3 may be used when values are reported, but there is no Pass/Fail requirement called out in the test specification. Rule 3 simply states that the measurement uncertainty is reported to the customer, along with the testing result generated, and the customer decides if the results are suitable for their purposes.


REPORT REVISIONS:

<u>DATE</u>	<u>REVISION #</u>	<u>DETAILS</u>
12/12/2022	N/A	Final Report

Prepared By: _____


Tiffany Heller
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