December 21, 2021

# ▪TEST REPORT▪

## PN 162378A

## PHARMACEUTICAL SERVICES

Prepared For:

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Rev 101218

December 21, 2021

Chuck Holcomb
Clean Space Project



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

**RECEIVED:** One (1) glove type identified by customer as; Nitrile Exam Gloves, Lot Number 202107, Size Medium, Color Black.

**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) | USP; Lot# R116Y0; Expiration 11/2022 |
| Cisplatin, 1 mg/ml (1,000 ppm) | Accord; Lot# P2001296; Expiration 01/2022 |
| Cyclophosphamide, 20 mg/ml (20,000 ppm) | North Star; Lot# 20061925; Expiration 06/2022 |
| Dacarbazine, 10 mg/ml (10,000 ppm) | Hikma; Lot# BS0005; Expiration 02/2023 |
| Doxorubicin HCl, 2.0 mg/ml (2,000 ppm) | USP; Lot# R11760; Expiration 07/2022 |
| Etoposide, 20.0 mg/ml (20,000 ppm) | Teva; Lot# 31328501B; Expiration 03/2023 |
| Fluorouracil, 50.0 mg/ml (50,000 ppm) | Accord; Lot# P2001167; Expiration 01/2022 |
| Paclitaxel, 6.0 mg/ml (6,000 ppm) | USP; Lot# R04650; Expiration 12/2023 |
| ThioTepa, 10.0 mg/ml (10,000 ppm) | USP; Lot# R11380; Expiration 10/2022 |

**TESTING CONDITIONS:**

| | |
|---|---|
| Standard Test Method Used: | ASTM D6978-05(2019) |
| Permeation Cell Size: | Used 1" Permeation Test 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 |

**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 |
| Cisplatin, 1 mg/ml (1,000 ppm) | Distilled Water |
| Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm) | Distilled Water |
| Dacarbazine, 10 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 |
| Paclitaxel, 6.0 mg/ml (6,000 ppm) | 30% Methanol Aqueous Solution |
| ThioTepa, 10.0 mg/ml (10,000 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) |
|---|---|
| Carmustine (BCNU), 3.3 mg/ml (3,300 ppm) | 229 |
| Cisplatin, 1 mg/ml (1,000 ppm) | 199 |
| Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm) | 200 |
| Dacarbazine, 10 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 |
| Paclitaxel, 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: Nitrile Exam Gloves, Lot Number 202107, Size Medium, Color Black.

| Testing Drug | Thickness (mm) | | | Average (mm) |
|---|---|---|---|---|
| | Sample 1 | Sample 2 | Sample 3 | |
| Carmustine | 0.092 | 0.087 | 0.088 | 0.089 |
| Cisplatin | 0.087 | 0.084 | 0.091 | 0.087 |
| Cyclophosphamide | 0.091 | 0.090 | 0.088 | 0.090 |
| Dacarbazine | 0.093 | 0.090 | 0.088 | 0.090 |
| Doxorubicin HCl | 0.090 | 0.093 | 0.088 | 0.090 |
| Etoposide | 0.090 | 0.087 | 0.086 | 0.088 |
| Fluorouracil | 0.087 | 0.089 | 0.088 | 0.088 |
| Paclitaxel | 0.091 | 0.088 | 0.087 | 0.088 |
| ThioTepa | 0.090 | 0.087 | 0.088 | 0.088 |
| **Weight/Unit Area (g/m2)** | **88.7** | | | |

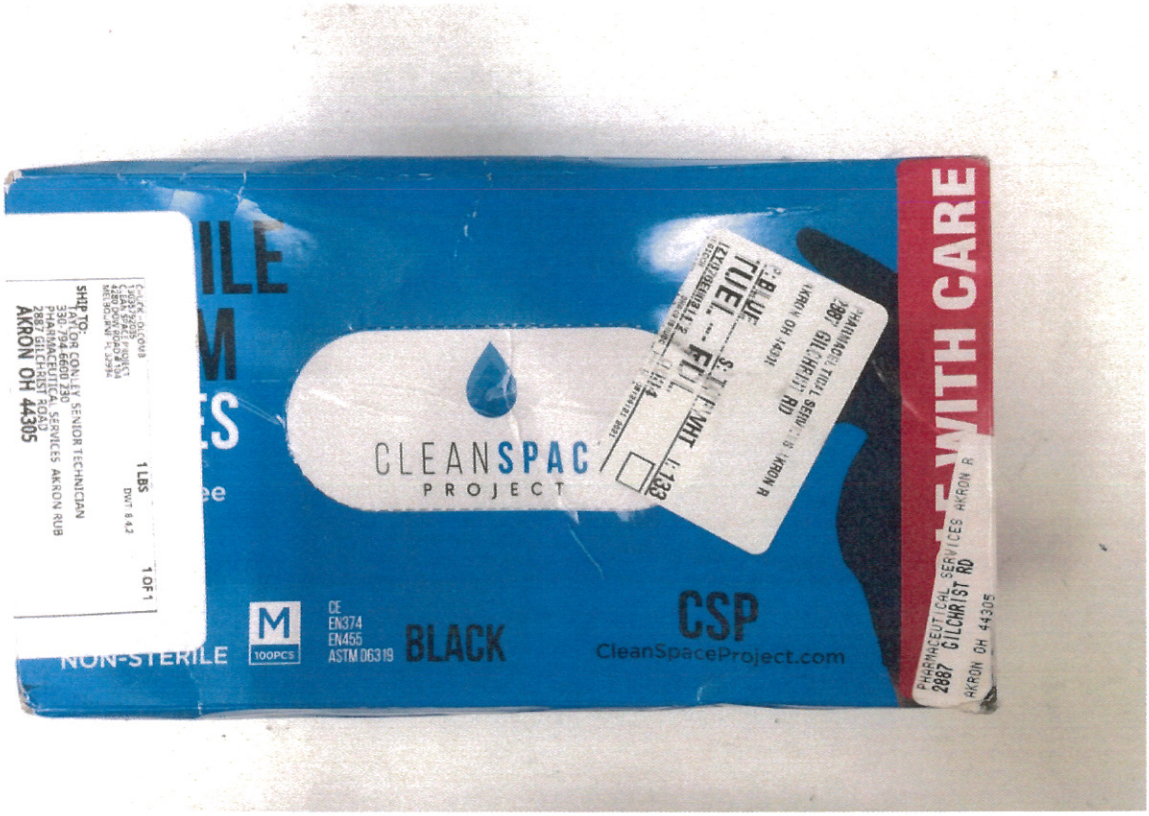
**RESULTS:**

Table 5. Permeation Test Results on testing of: Nitrile Exam Gloves, Lot Number 202107, Size Medium, Color Black.

| TEST CHEMOTHERAPY DRUGS | MINIMUM BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes) | AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (µg/cm²/minute) | OTHER OBSERVATIONS |
|---|---|---|---|
| Carmustine (BCNU), 3.3 mg/ml (3,300 ppm) | 23.6 (29.2,23.6,28.1) | 0.5 (0.7,0.4,0.5) | Slight swelling and no degradation |
| Cisplatin, 1 mg/ml (1,000 ppm) | >240 min. | N/A | Slight swelling and no degradation |
| Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm) | >240 min. | N/A | Slight swelling and no degradation |
| Dacarbazine, 10 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 |
| 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) | 56.7 (67.0,58.9,56.7) | 1.0 (1.1,1.0,1.0) | Slight swelling and no degradation |

## SAMPLES RECEIVED:

Nitrile Exam Gloves, Lot Number 202107, Size Medium, Color Black



# Appendix

**Decision Rules**

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:**

| DATE | REVISION # | DETAILS |
|---|---|---|
| 12/21/2021 | N/A | Original Final Report |

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