

October 11, 2022

**▪TEST REPORT▪**

**PN 166490A**

**PHARMACEUTICAL SERVICES**

Prepared For:

John Zhao  
**Intco Medical Industries Inc.**  
805 Barrington Avenue  
Ontario, CA 91764

Prepared By:

  
Tiffany Heller  
Manager, Pharmaceutical Services

Approved By:

  
Ana C. Barbur  
Vice President, Chemical & Analytical Services

DCN 1176



An A2LA ISO 17025 Accredited Testing Laboratory-Certificate Numbers 255-01, 255-02, 255-03 and 255-04  
ISO 9001-2015 Registered

ISO 9001:2015  
Registered

This report is for the exclusive use of the client(s) to which it is addressed and shall not be reproduced, except in full, without written permission of Akron Rubber Development Laboratory, Inc. (ARDL). The information provided herein applies to the specific material, products, or processes tested or evaluated. Statements of Conformity included herein are based on the option as agreed in the client testing contract. No warranty of any kind is herein construed or implied. The liability of ARDL, Inc. shall be limited to the amount of consideration paid for services rendered. ARDL Inc. is ISO 17025 accredited by A2LA (American Association for Laboratory Accreditation) for the test methods listed on the referenced certifications.

October 11, 2022

John Zhao  
Intco Medical Industries Inc.

Page 2 of 6  
PN 166490A

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

**RECEIVED:** One (1) glove type identified by customer as; Disposable Nitrile Gloves Black Color, Lot Number 207451, Size Large.

**TEST CHEMICALS:**

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine, 3.3 mg/ml (3,300 ppm)	USP; Lot# R116Y0; Expiration 05/2023
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)	Hikma; Lot# BJ0110; Expiration 08/2023
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
Paclitaxel, 6 mg/ml (6,000 ppm)	Alvogen; Lot# F0560001; Expiration 12/2023
Thiotepa, 10 mg/ml (10,000 ppm)	USP; Lot# R154V0; Expiration 09/2023

**COLLECTION MEDIA:**

Table 2. Collection Media for Test Drug

TESTING CHEMOTHERAPY DRUGS	COLLECTION MEDIA
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
Paclitaxel, 6 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa, 10 mg/ml (10,000 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: The mark ^ is used to designate non-accredited test methods in the body of the report and that any opinions or interpretations for of results for these non-accredited tests are outside the scope of this organization's accreditation

**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 <sup>2</sup>
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff

**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 CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
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
Paclitaxel, 6 mg/ml (6,000 ppm)	231
Thiotepa, 10 mg/ml (10,000 ppm)	199

**SAMPLE CHARACTERISTICS:**

Table 4. Thickness characteristics for the tested: Disposable Nitrile Gloves Black Color, Lot Number 207451, Size Large.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Carmustine	0.057	0.053	0.058	0.056
Cisplatin	0.057	0.057	0.055	0.056
Cyclophosphamide	0.054	0.058	0.056	0.056
Dacarbazine	0.055	0.056	0.057	0.056
Doxorubicin HCl	0.055	0.055	0.057	0.056
Etoposide	0.055	0.056	0.058	0.056
Fluorouracil	0.057	0.058	0.055	0.057
Paclitaxel	0.057	0.054	0.056	0.055
Thiotepa	0.054	0.055	0.056	0.055
<b>Weight/Unit Area (g/m<sup>2</sup>)</b>	<b>54.4</b>			

\*ARL 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: The Mark ^ is used to designate non-accredited test methods in the body of the report and that any opinions or interpretations of results for these non-accredited tests are outside the scope of this organization's accreditation

**RESULTS:**

Table 5. Permeation Test Results on testing of: Disposable Nitrile Gloves Black Color, Lot Number 207451, Size Large.

TEST CHEMOTHERAPY DRUGS	MINIMUM 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, 3.3 mg/ml (3,300 ppm)	21.2 (21.2,21.8,21.7)	0.9 (0.7,0.9,1.0)	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
Paclitaxel, 6 mg/ml (6,000 ppm)	>240 min.	N/A	Moderate swelling and degradation
Thiotepa, 10 mg/ml (10,000 ppm)	25.5 (27.0,25.5,25.5)	2.3 (2.2,2.4,2.2)	Slight swelling and degradation

\*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: The Mark ^ is used to designate non-accredited test methods in the body of the report and that any opinions or interpretations of results for these non-accredited tests are outside the scope of this organization's accreditation

October 11, 2022

John Zhao  
Intco Medical Industries Inc.

Page 5 of 6  
PN 166490A

**SAMPLES RECEIVED:**  
Disposable Nitrile Gloves Black Color,  
Lot Number 207451, Size Large



**APPENDIX**

**Testing Location:** 2887 Gilchrist Road, Akron Ohio 44305

**Decision Rules**

**Customer Selected Decision Rule:** Decision Rule 1

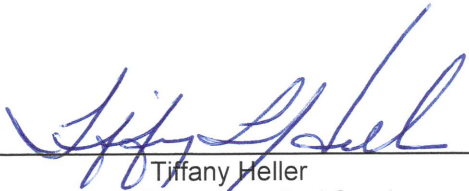
Rule 1. This is the way test results have traditionally been reported by ARDL. If ARDL runs a test for you that has pass/fail requirements, ARDL will report the values observed and then state "Pass" or "Fail", based on those values only. By default, ARDL will apply this rule to all Category I tests and 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>
10/11/2022	N/A	Original Final Report

Prepared By:   
Tiffany Heller  
Manager, Pharmaceutical Services

Approved By:   
Ana C. Barbur  
Vice President, Chemical & Analytical Services

\*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: The Mark ^ Is used to designate non-accredited test methods in the body of the report and that any opinions or interpretations of results for these non-accredited tests are outside the scope of this organization's accreditation