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DEFENDER SAFETY INC

TEST REPORT

SCOPE OF WORK
Performance Testing of Chemo Rated Examination Gloves (Non-Sterile), Lot Number 2021-03-26 to ASTM D6978 - 05(2019): *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs*

REPORT NUMBER
104746399CRT-001

ISSUE DATE
August 30, 2021

PAGES
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DOCUMENT CONTROL NUMBER
RT-L-US-Test-3470 (9/1/2017)

3933 US Route 11
Cortland, New York 13045

Telephone: 1-607-753-6711
Facsimile: 1-607-756-9891
www.intertek.com

TEST REPORT FOR DEFENDER SAFETY INC
Report No.: 104746399CRT-001
Date Issued: August 30, 2021

MANUFACTURER

Defender Safety Inc
30 Skyline Drive
Plainview, NY 11803
USA

TEST STANDARD

ASTM D6978 - 05(2019): *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs*

AUTHORIZATION

Quote Number: Qu-01187114-0

Purchase Order No: PP7257

PRODUCT DESCRIPTION

Product Description: Chemo Rated Examination Gloves (Non-Sterile), Lot Number 2021-03-26

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Cortland, New York 13045

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www.intertek.com

SAMPLE INFORMATION

Dates Samples Received:	July 8, 2021
Condition of Samples	Production Run
Dates of Testing:	July 9, 2021 – August 24, 2021

DECISION RULE

"Simple Acceptance" rule, also called "Shared Risk approach" of ILAC-G8:09/2019 guide.

The statements of conformity are reported as:

- Passed – When the measured values are within the specified limits
- Failed – When one or more measured values are outside the specified limits"

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SECTION 1
CONCLUSION

This test report completes the testing covered by Proposal No.: Qu-01187114-0

If there are any questions regarding the results contained in this report, or any of the other services offered by Intertek, please do not hesitate to contact the undersigned.

Please note: this Test Report does not represent authorization for the use of any Intertek certification marks.

Report Prepared By:	Colin P. King	**Project Reviewer:**	Kristine Perrotti
Title:	Technical Writer	**Title:**	Engineer, Team Lead
Signature:	Colin P. King	**Signature**	Kristine L. Perrotti
Date	30-Aug-21	**Date:**	30-Aug-2021

REPORT REVISIONS:

Date / Proj #	Project Handler/ Reviewer	Description of Change

SECTION 2

ASTM D6978 - 05(2019) TEST REPORT

AKRON RUBBER DEVELOPMENT LABORATORY, INC.

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August 24, 2021

▪TEST REPORT▪

PN 160591

PHARMACEUTICAL SERVICES

Prepared For:

Jeffrey Streifert
Intertek Testing Services
4700 Broadmoor SE, Suite 200
Kentwood, MI 49512

Prepared By: _____ Approved By: _____

Tiffany Heller
Manager, Pharmaceutical Services

Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

Rev 101218

www.ardl.com | 2887 Gilchrist Rd. | Akron, Ohio 44305 | answers@ardl.com | Toll Free (800) 830-ARDL
Fax (330) 794-6610 | Worldwide (330) 794-6600

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August 24, 2021

Jeffrey Streifert
Intertek Testing Services

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

RECEIVED: One (1) glove type identified by customer as; Chemo Rated Examination Gloves (Non-Sterile), Lot Number 2021-03-26.

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 07/2022
Cisplatin, 1 mg/ml (1,000 ppm)	Accord; Lot# P2001296; Expiration 01/2022
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	Accord; Lot# 19112225; Expiration 10/2021
Dacarbazine, 10 mg/ml (10,000 ppm)	Teva; Lot# 31325414B; Expiration 09/2021
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)	Teva; Lot# 19K24KA; Expiration 11/2021
ThioTepa, 10.0 mg/ml (10,000 ppm)	USP; Lot# R11380; Expiration 03/2022

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

August 24, 2021

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Intertek Testing Services

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^2
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 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: Chemo Rated Examination Gloves (Non-Sterile), Lot Number 2021-03-26.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Carmustine	0.071	0.080	0.073	0.074
Cisplatin	0.080	0.071	0.086	0.079
Cyclophosphamide	0.077	0.075	0.072	0.075
Dacarbazine	0.078	0.074	0.067	0.073
Doxorubicin HCl	0.075	0.071	0.078	0.075
Etoposide	0.085	0.074	0.080	0.080
Fluorouracil	0.070	0.074	0.069	0.071
Paclitaxel	0.082	0.076	0.081	0.080
ThioTepa	0.076	0.065	0.079	0.073
Weight/Unit Area (g/m2)		**64.8**		

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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.*

August 24, 2021

Jeffrey Streifert
Intertek Testing Services

RESULTS:

Table 5. Permeation Test Results on testing of: Chemo Rated Examination Gloves (Non-Sterile), Lot Number 2021-03-26.

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)	21.5 (21.5,21.9,22.4)	0.7 (0.7,0.8,0.7)	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)	57.7 (65.9,57.7,65.7)	1.2 (1.2,1.3,1.0)	Slight swelling and no degradation

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SAMPLES RECEIVED:

Chemo Rated Examination Gloves (Non-Sterile), Lot Number 2021-03-26

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August 24, 2021

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Intertek Testing Services

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
08/24/2021	N/A	Original Final Report

Prepared By: _____
Tiffany Heller
Manager, Pharmaceutical Services

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

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