July 12, 2021

▪TEST REPORT▪

PN 160012

PHARMACEUTICAL SERVICES

Prepared For:

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Rev 101218

July 12, 2021

Yang Jiatian
Fujian Jixiang Medical Technology Co., Ltd.

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

RECEIVED: One (1) glove type identified by customer as; Disposable Medical Nitrile Examination Gloves, Lot # JX210315.

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# 0000117593; Expiration 05/2022
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	Accord; Lot# 19112225; Expiration 10/2021
Dacarbazine, 10 mg/ml (10,000 ppm)	Teva; Lot# 31328143B; Expiration 10/2022
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# 31325485B; Expiration 07/2021
Fluorouracil, 50.0 mg/ml (50,000 ppm)	Accord; Lot# P2001167; Expiration 01/2022
Methotrexate, 25 mg/ml (25,000 ppm)	Teva; Lot# 20A06KB; 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
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
Methotrexate, 25 mg/ml (25,000 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

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
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
Methotrexate, 25 mg/ml (25,000 ppm)	303
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: Disposable Medical Nitrile Examination Gloves, Lot # JX210315.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Carmustine	0.065	0.064	0.065	0.065
Cyclophosphamide	0.064	0.060	0.062	0.062
Dacarbazine	0.063	0.060	0.063	0.062
Doxorubicin HCl	0.056	0.063	0.063	0.061
Etoposide	0.059	0.058	0.062	0.060
Fluorouracil	0.061	0.062	0.062	0.062
Methotrexate	0.062	0.061	0.061	0.061
Paclitaxel	0.056	0.058	0.064	0.059
ThioTepa	0.056	0.059	0.064	0.060
Weight/Unit Area (g/m2)	**64.9**			

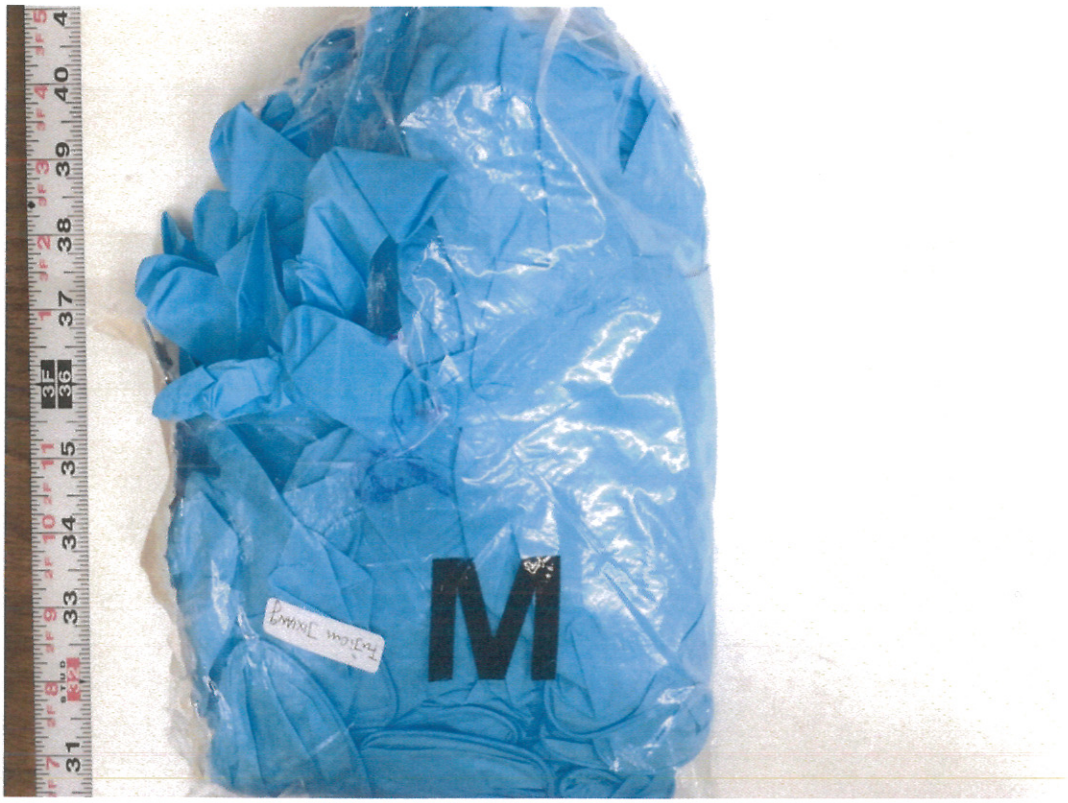
RESULTS:

Table 5. Permeation Test Results on testing of: Disposable Medical Nitrile Examination Gloves, Lot # JX210315.

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)	23.1 (24.6,23.3,23.1)	0.5 (0.5,0.5,0.4)	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
Methotrexate, 25 mg/ml (25,000 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)	47.0 (47.3,47.6,47.0)	0.3 (0.3,0.3,0.3)	Slight swelling and no degradation

SAMPLES RECEIVED:

Disposable Medical Nitrile Examination Gloves, Lot # JX210315



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
07/12/2021	N/A	Original Final Report

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