

March 22, 2021

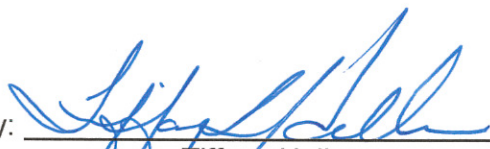
**TEST REPORT**

**PN 157848 – Rev 1**

**PHARMACEUTICAL SERVICES**

Prepared For:

Renmin  
Shanxi Hongjin Plastic Technology Co., LTD  
Coal Bed Gas Industrial Zone Qu'e Town,  
Daning County  
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Rev 101218



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

**RECEIVED:** One (1) glove type identified as; Disposable Nitrile Examination Glove (Blue), Tested for use with Chemotherapy Drugs, Lot Number 2101C4A3-PF.

**TEST CHEMICALS:**

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	USP; Lot# R118Q0; Expiration 06/2021
Bortezomib (Velcade), 1 mg/ml (1,000 ppm)	LC Labs; Lot# BBZ-116; Expiration 4/2025
Busulfan, 6 mg/ml (6,000 ppm)	Sigma Aldrich; Lot# BCBZ9160; Expiration 01/2022
Carboplatin, 10 mg/ml (10,000 ppm)	USP; Lot# R064P0; Expiration 11/2021
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	USP; Lot# R116Y0; Expiration 07/2021
Chloroquine, 50 mg/ml (50,000 ppm)	Rising; Lot# 409517; Expiration 02/2021 (Tested prior to expiration)
Cisplatin, 1.0 mg/ml (1,000 ppm)	Accord; Lot# P2001296; Expiration 01/2022
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	Accord; Lot# 19112225; Expiration 10/2021
Cyclosporin A, 100 mg/ml (100,000 ppm)	Sigma Aldrich; Lot# 098M4002V; Expiration 02/2021 (Tested prior to expiration)
Cytarabine, 100 mg/ml (100,000 ppm)	Sigma Aldrich; Lot# MKCJ9806; Expiration 01/2022
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Teva; Lot# 31325414B; Expiration 09/2021
Daunorubicin HCl, 5 mg/ml (5,000 ppm)	USP; Lot# M1M099; Expiration 01/2022
Docetaxel, 10 mg/ml (10,000 ppm)	LC Labs; Lot# BDC-117; Expiration 01/2025
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	WestWard; Lot# BJ0051; Expiration 06/2021
Epirubicin HCl (Ellence), 2 mg/ml (2,000 ppm)	USP; Lot# R06270; Expiration 10/2021
Etoposide, 20.0 mg/ml (20,000 ppm)	Teva; Lot# 31325485B; Expiration 07/2021
Fludarabine, 25 mg/ml (25,000 ppm)	USP; Lot# H1K220; Expiration 08/2021
Fluorouracil, 50.0 mg/ml (50,000 ppm)	Accord; Lot# P2001167; Expiration 01/2022
Gemcitabine, 38 mg/ml (38,000 ppm)	LC Labs; Lot# GMC-105; Expiration 1/6/2025
Idarubicin HCl, 1 mg/ml (1,000 ppm)	Teva; Lot# 31325163B; Expiration 05/2021
Ifosfamide, 50 mg/ml (50,000 ppm)	Baxter Healthcare; Lot# 9A018G; Expiration 01/2022
Irinotecan, 20 mg/ml (20,000 ppm)	USP; Lot# R10230; Expiration 12/2020
Mechlorethamine HCl, 1 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# MKBW4481V; Expiration 02/2022
Melphalan, 5 mg/ml (5,000 ppm)	USP; Lot# R086P0; Expiration 02/2021
Methotrexate, 25 mg/ml (25,000 ppm)	Teva; Lot# 19F06NB; Expiration 06/2021
Mitomycin C, 0.5 mg/ml (500 ppm)	USP; Lot# R07240; Expiration 07/2021
Mitoxantrone, 2 mg/ml (2,000 ppm)	USP; Lot# J0F278; Expiration 11/2021
Oxaliplatin, 5 mg/ml (5,000 ppm)	Accord; Lot# PY05035; Expiration 08/2021
Paclitaxel, 6.0 mg/ml (6,000 ppm)	Teva; Lot# 19K24KA; Expiration 11/2021
Paraplatin, 10 mg/ml (10,000 ppm)	Teva; Lot# 19K11KA; Expiration 11/2021
Retrovir, 10 mg/ml (10,000 ppm)	GlaxoSmithKline; Lot# 3D8X; Expiration 06/2022
Rituximab, 10 mg/ml (10,000 ppm)	Hetero Healthcare; Batch# RB1921B; Expiration 08/2021
ThioTepa, 10.0 mg/ml (10,000 ppm)	USP; Lot # R11380; Expiration 04/2021
Topotecan HCl, 1 mg/ml (1,000 ppm)	USP; Lot# R093L0; Expiration 12/2021
Trisenox, 1 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# BCCB5045; Expiration 10/2021
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Hospira; Lot# G057139AA; Expiration 03/31/2021

\*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.\*

**COLLECTION MEDIA:**

Table 2. Collection Media for Test Drug

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	Distilled Water
Bortezomib (Velcade), 1 mg/ml (1,000 ppm)	Distilled Water
Busulfan, 6 mg/ml (6,000 ppm)	Distilled Water
Carboplatin, 10 mg/ml (10,000 ppm)	Distilled Water
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Chloroquine, 50 mg/ml (50,000 ppm)	Distilled Water
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	Distilled Water
Cyclosporin A, 100 mg/ml (100,000 ppm)	Distilled Water
Cytarabine, 100 mg/ml (100,000 ppm)	Distilled Water
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Distilled Water
Daunorubicin HCl, 5 mg/ml (5,000 ppm)	Distilled Water
Docetaxel, 10 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	Distilled Water
Epirubicin HCl (Ellence), 2 mg/ml (2,000 ppm)	Distilled Water
Etoposide, 20.0 mg/ml (20,000 ppm)	Distilled Water
Fludarabine, 25 mg/ml (25,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Gemcitabine, 38 mg/ml (38,000 ppm)	Distilled Water
Idarubicin HCl, 1 mg/ml (1,000 ppm)	Distilled Water
Ifosfamide, 50 mg/ml (50,000 ppm)	Distilled Water
Irinotecan, 20 mg/ml (20,000 ppm)	Distilled Water
Mechlorethamine HCl, 1 mg/ml (1,000 ppm)	Distilled Water
Melphalan, 5 mg/ml (5,000 ppm)	Distilled Water
Methotrexate, 25 mg/ml (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Mitoxantrone, 2 mg/ml (2,000 ppm)	Distilled Water
Oxaliplatin, 5 mg/ml (5,000 ppm)	Distilled Water
Paclitaxel, 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Paraplatin, 10 mg/ml (10,000 ppm)	Distilled Water
Retrovir, 10 mg/ml (10,000 ppm)	Distilled Water
Rituximab, 10 mg/ml (10,000 ppm)	Distilled Water
ThioTepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Topotecan HCl, 1 mg/ml (1,000 ppm)	Distilled Water
Trisenox, 1 mg/ml (1,000 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 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 <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 DRUG	WAVELENGTH (nm)
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	290
Bortezomib (Velcade), 1 mg/ml (1,000 ppm)	206
Busulfan, 6 mg/ml (6,000 ppm)	197
Carboplatin, 10 mg/ml (10,000 ppm)	192
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Chloroquine, 50 mg/ml (50,000 ppm)	220
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	200
Cyclosporin A, 100 mg/ml (100,000 ppm)	199
Cytarabine, 100 mg/ml (100,000 ppm)	272
Dacarbazine, 10.0 mg/ml (10,000 ppm)	320
Daunorubicin HCl, 5 mg/ml (5,000 ppm)	269
Docetaxel, 10 mg/ml (10,000 ppm)	231
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	232
Epirubicin HCl (Ellence), 2 mg/ml (2,000 ppm)	233 & 253
Etoposide, 20.0 mg/ml (20,000 ppm)	205
Fludarabine, 25 mg/ml (25,000 ppm)	261
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Gemcitabine, 38 mg/ml (38,000 ppm)	202
Idarubicin HCl, 1 mg/ml (1,000 ppm)	257
Ifosfamide, 50 mg/ml (50,000 ppm)	200
Irinotecan, 20 mg/ml (20,000 ppm)	200
Mechlorethamine HCl, 1 mg/ml (1,000 ppm)	194
Melphalan, 5 mg/ml (5,000 ppm)	260
Methotrexate, 25 mg/ml (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Mitoxantrone, 2 mg/ml (2,000 ppm)	242
Oxaliplatin, 5 mg/ml (5,000 ppm)	199
Paclitaxel, 6.0 mg/ml (6,000 ppm)	231
Paraplatin, 10 mg/ml (10,000 ppm)	192
Retrovir, 10 mg/ml (10,000 ppm)	266
Rituximab, 10 mg/ml (10,000 ppm)	192
ThioTepa, 10.0 mg/ml (10,000 ppm)	199
Topotecan HCl, 1 mg/ml (1,000 ppm)	254
Trisenox, 1 mg/ml (1,000 ppm)	197
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	220

**SAMPLE CHARACTERISTICS:**

Table 4. Thickness characteristics for the tested: Disposable Nitrile Examination Glove (Blue), Tested for use with Chemotherapy Drugs, Lot Number 2101C4A3-PF.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Bleomycin Sulfate	0.064	0.063	0.063	0.063
Bortezomib (Velcade)	0.064	0.068	0.067	0.066
Busulfan	0.063	0.066	0.059	0.063
Carboplatin	0.065	0.067	0.065	0.066
Carmustine (BCNU)	0.064	0.066	0.060	0.063
Chloroquine	0.065	0.066	0.067	0.066
Cisplatin	0.063	0.064	0.066	0.064
Cyclophosphamide (Cytosan)	0.065	0.061	0.062	0.063
Cyclosporin A	0.065	0.063	0.064	0.064
Cytarabine	0.062	0.064	0.066	0.064
Dacarbazine	0.065	0.064	0.063	0.064
Daunorubicin HCl	0.064	0.066	0.067	0.066
Docetaxel	0.062	0.067	0.063	0.064
Doxorubicin HCl	0.065	0.066	0.060	0.064
Epirubicin HCl (Ellence)	0.064	0.059	0.064	0.062
Etoposide	0.066	0.060	0.062	0.063
Fludarabine	0.064	0.068	0.061	0.065
Fluorouracil	0.060	0.064	0.064	0.063
Gemcitabine	0.062	0.063	0.065	0.064
Idarubicin HCl	0.063	0.067	0.065	0.065
Ifosfamide	0.064	0.063	0.064	0.064
Irinotecan	0.069	0.064	0.064	0.066
Mechlorethamine HCl	0.064	0.064	0.061	0.063
Melphalan	0.065	0.063	0.064	0.064
Methotrexate	0.066	0.063	0.067	0.065
Mitomycin C	0.065	0.066	0.063	0.065
Mitoxantrone	0.064	0.068	0.065	0.065
Oxaliplatin	0.063	0.065	0.065	0.064
Paclitaxel	0.062	0.065	0.062	0.063
Paraplatin	0.067	0.064	0.063	0.065
Retrovir	0.063	0.066	0.063	0.064
Rituximab	0.065	0.066	0.066	0.065
ThioTepa	0.063	0.065	0.063	0.064
Topotecan HCl	0.066	0.066	0.065	0.066
Trisenox	0.068	0.069	0.065	0.067
Vincristine Sulfate	0.060	0.069	0.064	0.064
<b>Weight/Unit Area (g/m<sup>2</sup>)</b>	<b>56.3</b>			

**RESULTS:**

Table 5.1 Permeation Test Results on testing of: Disposable Nitrile Examination Glove (Blue), Tested for use with Chemotherapy Drugs, Lot Number 2101C4A3-PF.

TEST CHEMOTHERAPY DRUGS	AVERAGE 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
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Bortezomib (Velcade), 1 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Busulfan, 6 mg/ml (6,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Carboplatin, 10 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	7.0 (7.0,7.9,7.4)	0.4 (0.4,0.4,0.5)	Moderate swelling and no degradation
Chloroquine, 50 mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Cyclosporin A, 100 mg/ml (100,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Cytarabine, 100 mg/ml (100,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Dacarbazine, 10.0 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Daunorubicin HCl, 5 mg/ml (5,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Docetaxel, 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
Epirubicin HCl (Ellence), 2 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	Moderate swelling and no degradation
Fludarabine, 25 mg/ml (25,000 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
Gemcitabine, 38 mg/ml (38,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Idarubicin HCl, 1 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Ifosfamide, 50 mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Irinotecan, 20 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation

**RESULTS cont.:**

Table 5.2 Permeation Test Results on testing of: Disposable Nitrile Examination Glove (Blue), Tested for use with Chemotherapy Drugs, Lot Number 2101C4A3-PF.

TEST CHEMOTHERAPY DRUGS	AVERAGE 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
Mechlorethamine HCl, 1 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Melphalan, 5 mg/ml (5,000 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
Mitomycin C, 0.5 mg/ml (500 ppm)	>240 min.	N/A	Slight swelling and no degradation
Mitoxantrone, 2 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Oxaliplatin, 5 mg/ml (5,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Paclitaxel, 6.0 mg/ml (6,000 ppm)	>240 min.	N/A	Moderate swelling and no degradation
Paraplatin, 10 mg/ml (10,000 ppm)	>240 min.	N/A	Moderate swelling and no degradation
Retrovir, 10 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Rituximab, 10 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
ThioTepa, 10.0 mg/ml (10,000 ppm)	23.0 (37.1,25.0,23.0)	0.9 (0.9,0.9,0.9)	Slight swelling and no degradation
Topotecan HCl, 1 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Trisenox, 1 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation

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**SAMPLES RECEIVED:**

Disposable Nitrile Examination Glove (Blue), Tested for use with Chemotherapy Drugs,  
Lot Number 2101C4A3-PF





## 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.

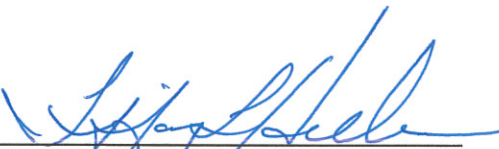
Rule 2. This rule takes into account the calculated measurement uncertainty of test results generated. Every test and piece of test equipment has an inherent amount of measurement uncertainty associated with it. Rule 2 establishes "Guard Bands", where the measurement uncertainty value is added to the 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:

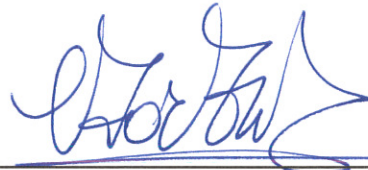
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03/11/2021	N/A	Original Final Report
03/22/2021	Rev – 1	Typist Error; Incorrect Lot Number Reported

Prepared By:



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