

December 12, 2022

## ▪TEST REPORT▪


PN 166627

### PHARMACEUTICAL SERVICES

Prepared For:

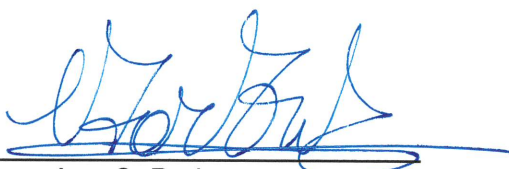
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Cert 225-01, 255-02, 255-03, 255-04

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

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

**RECEIVED:** One (1) glove type identified by customer as; Blue Nitrile Examination Gloves, Powder-Free, Textured, Single Use Only, Non-Sterile, Ambidextrous, Lot Number 01S081322.

**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 12/2022
Cytarabine HCl (Cytosine), 100 mg/ml (100,000 ppm)	Sigma Aldrich; Lot# MKCJ9806; Expiration 02/2023
Daunorubicin HCl, 5 mg/ml (5,000 ppm)	USP; Lot# M1M099; Expiration 08/2023
Docetaxel (Taxotere), 10 mg/ml (10,000 ppm)	Mylan; Lot# 7802162; Expiration 02/2025
Epirubicin HCl (Ellence), 2 mg/ml (2,000 ppm)	USP; Lot# R06270; Expiration 08/2023
Fludarabine, 25 mg/ml (25,000 ppm)	USP; Lot# H1K220; Expiration 12/2022
Gemcitabine, 38 mg/ml (38,000 ppm)	LC Labs; Lot# GMC-105; Expiration 1/6/2025
Idarubicin HCl, 1 mg/ml (1,000 ppm)	USP; Lot# R080E0; Expiration 03/2023
Irinotecan, 20 mg/ml (20,000 ppm)	Apotex Corp.; Lot# EB4E1018; Expiration 11/01/2023
Mechlorethamine HCl, 1 mg/ml (1,000 ppm)	USP; Lot# G0E271; Expiration 04/2023
Melphalan, 5 mg/ml (5,000 ppm)	USP; Lot# R086P0; Expiration 03/2023
Rituximab, 10 mg/ml (10,000 ppm)	Hetero Healthcare; Batch# RB2013A; Expiration 10/2022*

\*Tested prior to expiration

**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

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**COLLECTION MEDIA:**Table 2. Collection Media for Test Drug

TESTING CHEMOTHERAPY DRUGS	COLLECTION MEDIA
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	Distilled Water
Cytarabine HCl (Cytosine), 100 mg/ml (100,000 ppm)	Distilled Water
Daunorubicin HCl, 5 mg/ml (5,000 ppm)	Distilled Water
Docetaxel (Taxotere), 10 mg/ml (10,000 ppm)	Distilled Water
Epirubicin HCl (Ellence), 2 mg/ml (2,000 ppm)	Distilled Water
Fludarabine, 25 mg/ml (25,000 ppm)	Distilled Water
Gemcitabine, 38 mg/ml (38,000 ppm)	Distilled Water
Idarubicin HCl, 1 mg/ml (1,000 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
Rituximab, 10 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 CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	290
Cytarabine HCl (Cytosine), 100 mg/ml (100,000 ppm)	272
Daunorubicin HCl, 5 mg/ml (5,000 ppm)	269
Docetaxel (Taxotere), 10 mg/ml (10,000 ppm)	231
Epirubicin HCl (Ellence), 2 mg/ml (2,000 ppm)	233 & 253
Fludarabine, 25 mg/ml (25,000 ppm)	261
Gemcitabine, 38 mg/ml (38,000 ppm)	202
Idarubicin HCl, 1 mg/ml (1,000 ppm)	257
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
Rituximab, 10 mg/ml (10,000 ppm)	192

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**SAMPLE CHARACTERISTICS:**

Table 4. Thickness characteristics for the tested: Blue Nitrile Examination Gloves, Powder-Free, Textured, Single Use Only, Non-Sterile, Ambidextrous, Lot Number 01S081322.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Bleomycin Sulfate	0.062	0.066	0.063	0.064
Cytarabine HCl (Cytosine)	0.069	0.068	0.066	0.068
Daunorubicin HCl	0.064	0.062	0.059	0.062
Docetaxel (Taxotere)	0.064	0.073	0.063	0.067
Epirubicin HCl (Ellence)	0.066	0.065	0.067	0.066
Fludarabine	0.062	0.067	0.062	0.064
Gemcitabine	0.066	0.065	0.064	0.065
Idarubicin HCl	0.066	0.070	0.061	0.065
Irinotecan	0.063	0.066	0.068	0.066
Mechlorethamine HCl	0.063	0.062	0.066	0.064
Melphalan	0.059	0.065	0.058	0.060
Rituximab	0.068	0.065	0.069	0.067
Weight/Unit Area (g/m2)	59.9			

**RESULTS:**

Table 5. Permeation Test Results on testing of: Blue Nitrile Examination Gloves, Powder-Free, Textured, Single Use Only, Non-Sterile, Ambidextrous, Lot Number 01S081322.

TEST CHEMOTHERAPY DRUGS	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (µg/cm <sup>2</sup> /minute)	OTHER OBSERVATIONS
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Cytarabine HCl (Cytosine), 100 mg/ml (100,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Daunorubicin HCl, 5 mg/ml (5,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Docetaxel (Taxotere), 10 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Epirubicin HCl (Ellence), 2 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Fludarabine, 25 mg/ml (25,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Gemcitabine, 38 mg/ml (38,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Idarubicin HCl, 1 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Irinotecan, 20 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Mechlorethamine HCl, 1 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Melphalan, 5 mg/ml (5,000 ppm)	>240 min.	N/A	Slight swelling and degradation
Rituximab, 10 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and degradation

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**SAMPLES RECEIVED:**

Blue Nitrile Examination Gloves, Powder-Free, Textured, Single Use Only,  
Non-Sterile, Ambidextrous, Lot Number 01S081322



## **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.

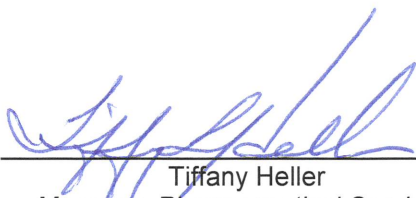
Rule 2. This rule takes into account the calculated measurement uncertainty of test results generated. Every test and piece of test equipment has an inherent amount of measurement uncertainty associated with it. Rule 2 establishes "Guard Bands", where the measurement uncertainty value is added to the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

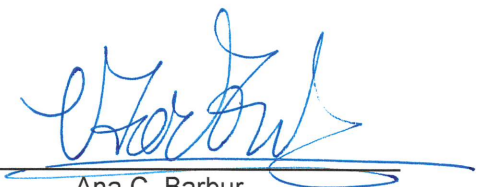
### **REPORT REVISIONS:**

<b><u>DATE</u></b>	<b><u>REVISION #</u></b>	<b><u>DETAILS</u></b>
12/12/2022	N/A	Original Final Report

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Approved By: \_\_\_\_\_

  
Ana C. Barbur  
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