

December 19, 2022

**TEST REPORT**

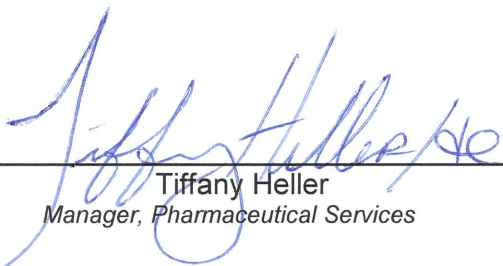
**PN 148381A – Rev 1**

**PHARMACEUTICAL SERVICES**


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Rev 101218



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Page 2 of 4  
PN 148381A – Rev 1

**SUBJECT:** Permeation testing per ASTM D6978 on samples submitted by the above company.

**RECEIVED:** One (1) glove type identified as; Fishscale Powder Free (PU) Size L; 8mil 300mm Blue, Product Code 67-308.

**TEST CHEMOTHERAPY DRUGS:**

Table 1. List of the Testing Drugs and their Sources

TESTING DRUGS	DRUG SOURCE
Fentanyl Citrate Injection, 100mcg/2mL	Hospira; Lot# 95214-DK; Expiration 11/01/2020

**COLLECTION MEDIA:**

Table 2. Collection Media for Test Drugs

TESTING DRUGS AND CONCENTRATION	COLLECTION MEDIA
Fentanyl Citrate Injection, 100mcg/2mL	Distilled Water

**TESTING CONDITIONS:**

Standard Test Method Used:	ASTM D6978
Analytical Method:	UV/Vis Spectrometer
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm <sup>2</sup>
Selected Data Points:	25
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff

\*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.\*

**DETECTION METHOD OF CHEMOTHERAPY DRUG 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 at 11 ml/minute of flow rate 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)
Fentanyl Citrate Injection, 100mcg/2mL	199

**SAMPLE CHARACTERISTICS:**

Table 4. Cuff thickness for glove identified as; Fishscale Powder Free (PU) Size L; 8mil 300mm Blue, Product Code 67-308.

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Fentanyl Citrate Injection	0.165	0.150	0.163	0.159
<b>Weight/Unit Area (g/m<sup>2</sup>)</b>	<b>157.5</b>			

**RESULTS:**

Table 5. Permeation Test Results on testing of: Fishscale Powder Free (PU) Size L; 8mil 300mm Blue, Product Code 67-308.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Sample 1,2,3) (Minutes)	STEADY STATE PERM. RATE (Sample 1,2,3) ( $\mu\text{g}/\text{cm}^2/\text{minute}$ )	OTHER OBSERVATIONS
Fentanyl Citrate Injection, 100mcg/2mL	>240 minutes	0	Slight swelling and degradation

## 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.

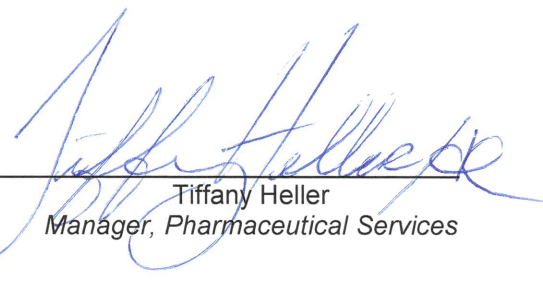
#### RULE 3.

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.

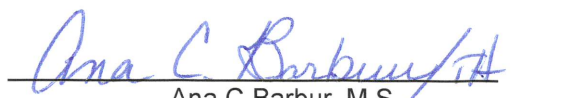
### **REPORT REVISIONS:**

<u>DATE</u>	<u>REVISION #</u>	<u>DETAILS</u>
06/25/2019	N/A	Original Final Report
12/19/2022	Rev 1	Added Glove Product Code

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