

March 13, 2023

▪TEST REPORT▪

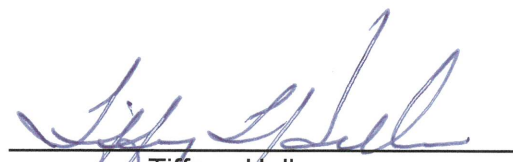
PN 168504
Wire Transfer

PHARMACEUTICAL SERVICES


Prepared For:

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DCN 1176



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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; Product Code: 67-246, Fishscale Powder Free Nitrile, Size XL, 6 mil, 240 mm, Black, Lot Number 23112022.

TEST CHEMICALS:

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Fentanyl Citrate Injection, 100mcg/2mL	USP; Lot# R128C0; Expiration 05/2023

COLLECTION MEDIA:

Table 2. Collection Media for Test Drug

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

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 ²
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff

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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)
Fentanyl Citrate Injection, 100mcg/2mL	199

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested: Product Code: 67-246, Fishscale Powder Free Nitrile, Size XL, 6 mil, 240 mm, Black, Lot Number 23112022.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Fentanyl Citrate Injection, 100mcg/2mL	0.115	0.114	0.115	0.115
Weight/Unit Area (g/m²)	110.2			

RESULTS:

Table 5. Permeation Test Results on testing of: Product Code: 67-246, Fishscale Powder Free Nitrile, Size XL, 6 mil, 240 mm, Black, Lot Number 23112022.

TEST CHEMOTHERAPY DRUGS	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (µg/cm ² /minute)	OTHER OBSERVATIONS
Fentanyl Citrate Injection, 100mcg/2mL	>240 min.	N/A	Slight swelling and degradation

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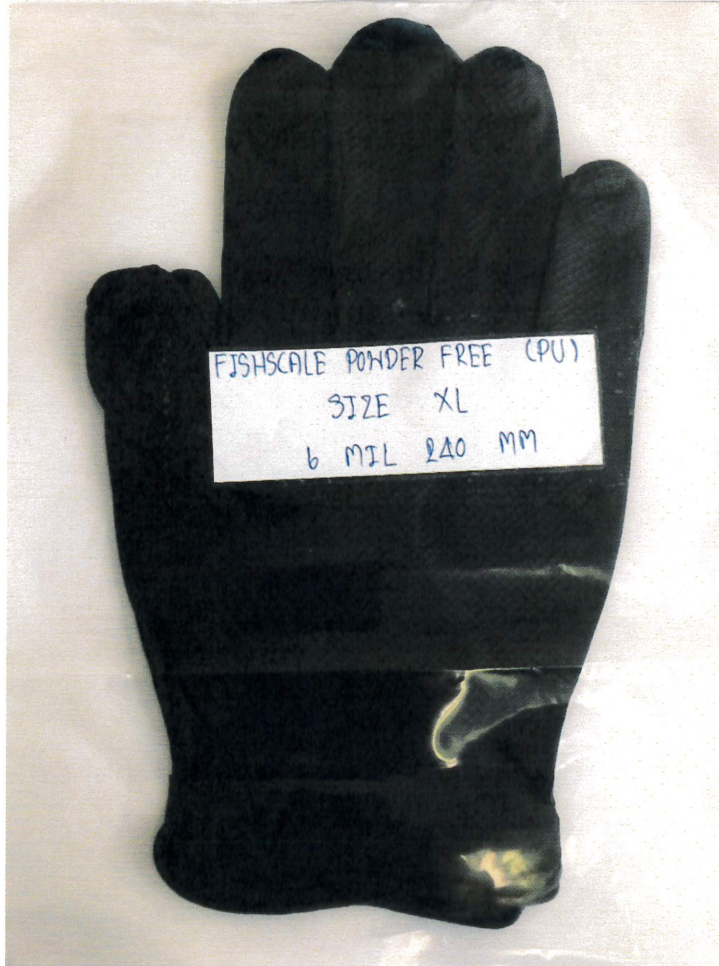
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SAMPLES RECEIVED:

Product Code: 67-246, Fishscale Powder Free Nitrile,
Size XL, 6 mil, 240 mm, Black, Lot Number 23112022



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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:

DATE

03/13/2023


REVISION #

N/A


DETAILS

Original Final Report

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Approved By:


Ana C. Barbur
Vice President, Analytical & Chemical Services

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