

March 14, 2019

TEST REPORT

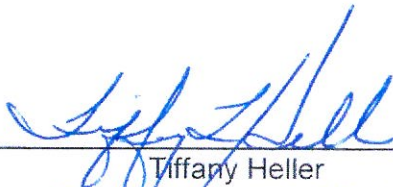
PN 146033A

Pharmaceutical Services

Prepared For:

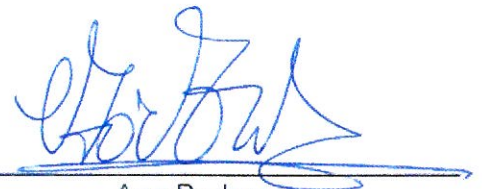
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SUBJECT: Permeation testing per ASTM D 6978 on samples submitted by the above company.

RECEIVED: One (1) glove type identified as; Nitrile Powder Free Examination Gloves, Product Type: OCF48NBBL, Lot Number 81109F10206, Size Medium.

TEST DRUG:

Table 1. List of the Testing Drugs, Sources, and Expiration Dates

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

COLLECTION MEDIA:

The collection media, which were selected, are listed in Table 2.

Table 2. Collection Media for Testing Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Fentanyl Citrate Injection, 100mcg/2mL	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978
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 area
Deviation from Standard Test Method:	Used 1" Permeation Cell

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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.*

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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 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

TEST DRUG	WAVELENGTH (nm)
Fentanyl Citrate Injection, 100mcg/2mL	199

SAMPLE CHARACTERISTICS:

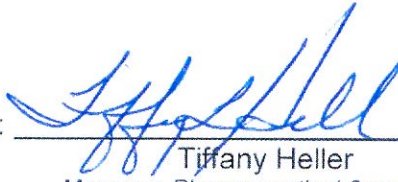
Table 4. Cuff Thickness characteristics for the tested specimens: Nitrile Powder Free Examination Gloves. Product Type: OCF48NBBL, Lot Number 81109F10206, Size Medium.

Testing Chemical	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m ²)
	Sample 1	Sample 2	Sample 3		
Fentanyl Citrate Injection	0.071	0.073	0.073	0.072	71.6

RESULTS:

Table 5. Permeation Test Results on: Nitrile Powder Free Examination Gloves. Product Type: OCF48NBBL, Lot Number 81109F10206, Size Medium.

TEST DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm ² /minute)	OTHER OBSERVATIONS
Fentanyl Citrate Injection, 100mcg/2mL	No Breakthrough up to 240 minutes	N/A	Slight swelling; no degradation

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