

November 30, 2020

▪TEST REPORT▪

PN 156279B

PHARMACEUTICAL SERVICES

Prepared For:

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Brightway Holdings Sdn. Bhd.

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

RECEIVED: One (1) glove type identified as; Brightway Brand Nitrile Examination Gloves Powder Free 3.5mil Cobalt Blue Color.

TEST CHEMICALS:

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Fentanyl Citrate Injection, 100mcg/2mL	WestWard; Lot# 059420; Expiration 06/2022

COLLECTION MEDIA:

Table 2. Collection Media for Test Chemicals

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

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D6978
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 DRUG	WAVELENGTH (nm)
Fentanyl Citrate Injection, 100mcg/2mL	199

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested: Brightway Brand Nitrile Examination Gloves Powder Free 3.5mil Cobalt Blue Color.

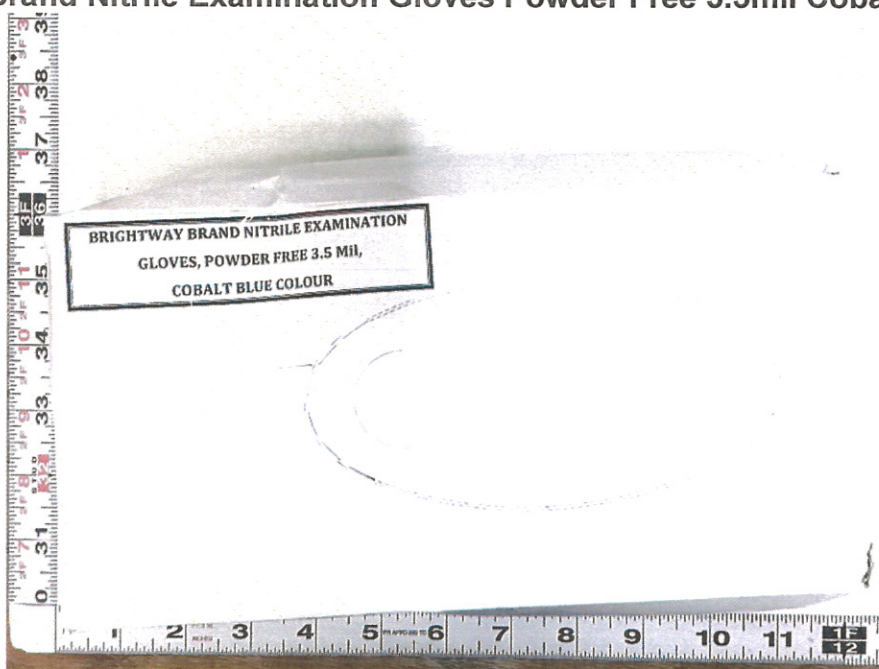
Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Fentanyl Citrate	0.057	0.049	0.056	0.054
Weight/Unit Area (g/m²)	57.9			

RESULTS:

Table 5. Permeation Test Results on testing of: Brightway Brand Nitrile Examination Gloves Powder Free 3.5mil Cobalt Blue Color.

TEST CHEMOTHERAPY DRUGS	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm ² /minute)	OTHER OBSERVATIONS
Fentanyl Citrate Injection, 100mcg/2mL	>240 min.	N/A	Slight swelling and no degradation

SAMPLES RECEIVED:
Brightway Brand Nitrile Examination Gloves Powder Free 3.5mil Cobalt Blue Color



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