CRYSTALWARE

MATERIAL SAFETY DATA SHEET
Nitrile Powderfree Examination Gloves (Finger Textured)

SECTION I : PRODUCT DESCRIPTION

1. 1	Type	Nitrile Examination Glove, **Powderfree**, Online Chlorinated, Non-sterile
1. 2	Material	100% Nitrile
1. 3	Color (Pigment)	o **Blue** o **Special Blue**
1. 4	Design and Feature	Ambidextrous, **finger textured**, beaded cuff
1. 5	Powder	No powder lubricant added
1. 6	Storage Condition	The gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight.
1. 7	Shelf-Life	The gloves shall have shelf life of 5 years from the date of manufacture with the above storage condition.
1. 8	Packing Style	100 pcs gloves x 10 dispensers x 1 carton
1. 9	Size Marking	The size of gloves shall be marked on every carton

SECTION II: PERFORMANCE REQUIREMENTS
(Sampling Plan – ISO 2859 Single Normal)

#	Characteristics	Inspection Level	Acceptable Quality Level	Reference Standard
2.1	Dimensions	S2	4.0	ASTM D6319-00a$^{\varepsilon 3}$
2.2	Physical Properties	S2	4.0	ASTM D6319-00a$^{\varepsilon 3}$
2.3	Freedom from Holes (Water Tight Test)	GI	2.5	FDA 1000MIL Test Method ASTM D6319-00a$^{\varepsilon 3}$
2.4 (i) (ii)	Visual Defects: Major Visual Minor Visual	GI	 1.5 2.5	In-house practice
2.5 (i) (ii) (iii)	Packaging Defects: Regulatory Visual Critical (incl. Gloves Counting)	 GI GI S2	 ** 4.0 4.0	In-house practice
2.6	Powderfree Residue	N=5	-	ASTM D6319-00a$^{\varepsilon 3}$ ASTM D6124-06
2.7	Mix Size / Mix Glove / Mix Hand	Not Allowed		

**Unacceptable at any level

CRYSTALWARE

SECTION III: PERFORMANCE SPECIFICATION

3.1 Dimensions

Description	Size	Standard
Length (mm)	All Sizes	Min 240
Palm Width (mm)	XS S M L XL	76 +/- 3 84 +/- 3 94 +/- 3 105 +/- 3 113 +/- 3
Thickness (mm) *single wall	All Sizes	Finger : 0.10 +/- 0.02 (Typical value: 0.09 – 0.12) Palm : 0.07 +/- 0.02 (Typical value: 0.06 – 0.08)

3.2 Physical Properties

Description	Standard	
	Before Aging	After Aging
Elongation at break (%)	min 500 (Typical value: 500 – 600)	min 400 (Typical value: 400 – 500)
Tensile Strength (MPa)	min 14 (Typical value: 14 – 23)	min 14 (Typical value: 14 – 20)

3.3 Freedom from holes

The sample size and allowable number of non-conforming gloves in the samples shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

3.4 Visual Defects

The sample size and allowable number of non-conforming gloves in the samples for both major and minor defects shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

3.5 Packaging Defects

The Sample size and allowable number of non-conforming in the samples for regulatory, visual and critical packaging defects shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements (Gloves Counting=100 pcs by weight per Dispenser).

3.6 Powderfree Residue

Maximum 2 mg per glove

CrystalWare

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 Glove.

TEST DRUG:

Table 1. List of the Testing Drugs

TESTING DRUG	DRUG SOURCE
Fentanyl Citrate Injection, 100mcg/2mL	Nitrile Powder Free Exam Gloves #NEBPFGS/M/L/XL

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 cm2
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

CrystalWare

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 Glove.

Testing Chemical	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m^2)
	Sample 1	Sample 2	Sample 3		
Fentanyl Citrate Injection	0.051	0.051	0.050	0.051	51.2

RESULTS:

Table 5. Permeation Test Results on: Nitrile Powder Free Examination Glove.

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

Prepared By: _____
Tiffany Heller
Manager, Pharmaceutical Services

Approved By: _____
Ana Barbur
Vice President, Analytical & Chemical Services