

Nitrile Chemo Exam Gloves





Specifications

NITRILE CHEMO EXAM GLOVES

Material 100% Butyronitrile

Brand V12

Name Forza

Use Medical, Chemo rated

USA ASTM D6978-5

EU EN 374-5

Sizes S, M, L, XL

SKU S-12214201 / M-12214202 / L-12214203 / XL-12214204

Sterility Non-sterile

Color Violet

Thickness Avg Finger 3.9mil, Avg Palm 3.1mil

Description

Our Violet color, V12 Forza Nitrile Chemo Exam Gloves conforms with ASTM D6978-5 and EN 374.



Product Packaging

NITRILE CHEMO EXAM GLOVES



CASE:

10 boxes/case

Case size: 35.3x24x26cm

Weight: **S** 4.8kg / **M** 5.3Kg / **L** 5.6Kg / **XL** 5.8Kg

PALLET:

84 Cases/pallet

NW: **S** 403Kg / **M** 445Kg / **L** 470Kg / **XL** 487Kg





November 12, 2019

-TEST REPORT-

PN 149986A

PHARMACEUTICAL SERVICES

Prepared For:

John Zhao Intco Medical Industries Inc. 805 Barrington Avenue Ontario, CA 91764

Prepared By:

Tiffany Heller Manager, Pharmaceutical Services

Approved By:

Ana C Barbur, M.S.

Vice President, Analytical & Chemical Services

Rev 101218

ACCREDITED

ISO 9001:2015





November 12, 2019

John Zhao Intco Medical Industries Inc.

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

RECEIVED: One (1) light blue glove type identified as; Disposable Exam Nitrile Gloves, Blue Color, Powder-Free,

Non-sterile, Lot# ISCT201907.

TEST CHEMICALS:

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Bortezomib (Velcade), 1 mg/ml (1,000 ppm)	LC Labs; Lot# BBZ-116; Expiration 4/2025
Carboplatin, 10 mg/ml (10,000 ppm)	TEVA; Lot# 18F06MA; Expiration 06/2020
Cyclophosphamide, 20 mg/ml (20,000 ppm)	Sandoz; Lot# 18050125; Expiration 04/2020
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	Teva; Lot# 31325485B; Expiration 07/2021
Fluorouracil (5 Flu), 50 mg/ml (50,000 ppm)	MedChem; Lot# 22009; Expiration 12/2019
Gemcitabine, 38 mg/ml (38,000 ppm)	LC Labs; Lot# GMC-105; Expiration 1/6/2025
Ifosfamide, 50 mg/ml (50,000 ppm)	Baxter Healthcare; Lot# 8C015G; Expiration 03/2021
Irinotecan, 20 mg/ml (20,000 ppm)	LC Labs; Lot# RCN-105; Expiration 03/2024
Mitoxantrone, 2 mg/ml (2,000 ppm)	Sigma Aldrich; Lot# MKBR2210V; Expiration 04/2021
Oxaliplatin, 2 mg/ml (2,000 ppm)	LC Labs; Lot# XAP-111; 12/2019
Paclitaxel, 6 mg/ml (6,000 ppm)	Actavis; Lot# 8AZ5292, Expiration 05/2021
Pemetrexed, 25 mg/ml (25,000 ppm)	LC Labs; Lot# PEM-106; Expiration 04/2024
Thiotepa, 10 mg/ml (10,000 ppm)	USP; Lot# R11380; Expiration 10/2020
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	USP; Lot # R046R0; Expiration 10/2019

TESTING CONDITIONS:

Standard Test Method Used: Deviation from Standard Test Method:

Analytical Method: Testing Temperature: Collection System: Specimen Area Exposed:

Selected Data Points: Number of Specimens Tested: Location Sampled From:

ASTM D 6978 Used 1" Permeation Cell **UV/VIS Spectrometry**

35.0°C ± 2.0 Closed Loop 5.067 cm2 25/test 3/test Cuff area

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.



November 12, 2019

John Zhao Intco Medical Industries Inc.

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<u>COLLECTION MEDIA:</u>
<u>Table 2. Collection Media for Test Chemicals</u>

TESTING CHEMOTHERAPY DRUGS	COLLECTION MEDIUM	
Bortezomib (Velcade), 1 mg/ml (1,000 ppm)	Distilled Water	
Carboplatin, 10 mg/ml (10,000 ppm)	Distilled Water	
Cyclophosphamide, 20 mg/ml (20,000 ppm)	Distilled Water	
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	Distilled Water	
Fluorouracil (5 Flu), 50 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution	
Gemcitabine, 38 mg/ml (38,000 ppm)	Distilled Water	
Ifosfamide, 50 mg/ml (50,000 ppm)	Distilled Water	
Irinotecan, 20 mg/ml (20,000 ppm)	Distilled Water	
Mitoxantrone, 2 mg/ml (2,000 ppm)	Distilled Water	
Oxaliplatin, 2 mg/ml (2,000 ppm)	Distilled Water	
Paclitaxel, 6 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution	
Pemetrexed, 25 mg/ml (25,000 ppm)	Distilled Water	
Thiotepa, 10 mg/ml (10,000 ppm)	Distilled Water	
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	Distilled Water	

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

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Bortezomib (Velcade), 1 mg/ml (1,000 ppm)	206
Carboplatin, 10 mg/ml (10,000 ppm)	192
Cyclophosphamide, 20 mg/ml (20,000 ppm)	200
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	205
Fluorouracil (5 Flu), 50 mg/ml (50,000 ppm)	269
Gemcitabine, 38 mg/ml (38,000 ppm)	202
Ifosfamide, 50 mg/ml (50,000 ppm)	200
Irinotecan, 20 mg/ml (20,000 ppm)	200
Mitoxantrone, 2 mg/ml (2,000 ppm)	242
Oxaliplatin, 2 mg/ml (2,000 ppm)	199
Paclitaxel, 6 mg/ml (6,000 ppm)	231
Pemetrexed, 25 mg/ml (25,000 ppm)	196
Thiotepa, 10 mg/ml (10,000 ppm)	199
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	220

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November 12, 2019

John Zhao Intco Medical Industries Inc.

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SAMPLE CHARACTERISTICS:
Table 4. Cuff Thickness characteristics for the tested specimens: Light blue glove identified as; Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.

Testing Chemotherapy Drugs	Thickness (mm)			
resting Chemotherapy Drugs	Sample 1	Sample 2	Sample 3	Average (mm)
Bortezomib (Velcade)	0.059	0.062	0.060	0.060
Carboplatin	0.058	0.057	0.061	0.059
Cyclophosphamide	0.070	0.073	0.060	0.068
Etoposide (Toposar)	0.058	0.067	0.057	0.061
Fluorouracil (5 Flu)	0.059	0.062	0.057	0.060
Gemcitabine	0.068	0.060	0.059	0.063
Ifosfamide	0.070	0.061	0.059	0.064
Irinotecan	0.054	0.060	0.056	0.057
Mitoxantrone	0.055	0.060	0.056	0.057
Oxaliplatin	0.056	0.069	0.060	0.062
Paclitaxel	0.056	0.059	0.062	0.059
Pemetrexed	0.069	0.056	0.059	0.061
Thiotepa	0.063	0.063	0.060	0.062
Vincristine Sulfate	0.066	0.060	0.057	0.061
Weight/Unit Area (g/m2)	64.0			

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November 12, 2019

John Zhao
Intco Medical Industries Inc.

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RESULTS:

Table 5. Permeation Test Results on: Light blue glove identified as; Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Sample 1,2,3) (Minutes)	STEADY STATE PERM. RATE (Sample 1,2,3) (µg/cm²/minute)	OTHER OBSERVATIONS
Bortezomib (Velcade), 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Carboplatin, 10 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Cyclophosphamide, 20 mg/ml (20,000 ppm)	>240	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	>240	N/A	Slight swelling and no degradation
Fluorouracil (5 Flu), 50 mg/ml (50,000 ppm)	>240	N/A	Slight swelling and no degradation
Gemcitabine, 38 mg/ml (38,000 ppm)	>240	N/A	Slight swelling and no degradation
Ifosfamide, 50 mg/ml (50,000 ppm)	>240	N/A	Slight swelling and no degradation
Irinotecan, 20 mg/ml (20,000 ppm)	>240	N/A	Slight swelling and no degradation
Mitoxantrone, 2 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Oxaliplatin, 2 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Paclitaxel, 6 mg/ml (6,000 ppm)	>240	N/A	Slight swelling and no degradation
Pemetrexed, 25 mg/ml (25,000 ppm)	>240	N/A	Slight swelling and no degradation
Thiotepa, 10 mg/ml (10,000 ppm)	125.8 (128.0,134.6,125.8)	0.6 (0.6,0.5,0.6)	Slight swelling and no degradation
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation

Prepared By:

Tiffany Heller Manager, Pharmaceutical Services Approved By:

Ana C Barbur, M.S.

Vice President, Analytical & Chemical Services

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October 30, 2019

TEST REPORT

PN 149986B

PHARMACEUTICAL SERVICES

Prepared By: Tiffany Heller Manager, Pharmaceutical Services

Approved By:

Ana C Barbur, M.S.

Vice President, Analytical & Chemical Services

Rev 101218



An A2LA ISO 17025 Accredited Testing Laboratory — Certificate Numbers 255.01 & 255.02 ISO 9001:2015 Registered

ISO 9001:2015





October 30, 2019

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SUBJECT:

Permeation testing per ASTM D 6978 on gloves submitted by the above company.

RECEIVED:

One (1) glove type identified as; Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile,

Lot# ISCT201907.

TEST CHEMICALS:

Table 1.1 List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	TEVA; Lot# 31321906B; Expiration 09/2019 (Tested prior to exp.)
Busulfan, 6 mg/ml (6,000 ppm)	Sigma; Lot# BCBS8240V; Expiration 12/2021
Cetuximab, 2 mg/ml (2,000 ppm)	Lilly; Lot# C1700079; Expiration 04/2020
Cisplatin, 1 mg/ml (1,000 ppm)	Accord; Lot# PY02454; Expiration 04/2021
Cyclosporin A, 100 mg/ml (100,000 ppm)	USP; Lot# J0M382; Expiration 11/2019
Cytarabine, 100 mg/ml (100,000 ppm)	Sigma Aldrich; Lot# LRAB3688; Expiration 12/2021
Dacarbazine, 10 mg/ml (10,000 ppm)	Teva; Lot# 31325414B; Expiration 09/2021
Daunorubicin, 5 mg/ml (5,000 ppm)	Sigma Aldrich; Lot# 125M4750V; Expiration 03/2020
Docetaxel, 10 mg/ml (10,000 ppm)	Sigma Aldrich; Lot# LRAB0750; Expiration 12/2021
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	WestWard; Lot# BJ0044; Expiration 10/2020
Epirubicin HCI (Ellence), 2 mg/ml (2,000 ppm)	Actavis; Lot 7U15152; Expiration 10/2020
Fludarabine, 25 mg/ml (25,000 ppm)	USP; Lot# H1K220; Expiration 12/2019
Idarubicin, 1 mg/ml (1,000 ppm)	Sigma Aldrich, Lot# R080E0; Expiration 12/2019
Melphalan, 5 mg/ml (5,000 ppm)	USP; Lot# R086P0; Expiration 04/2021
Methotrexate, 25 mg/ml (25,000 ppm)	Mylan; Lot# 7801774; Expiration 04/2020
Mitomycin C, 0.5 mg/ml (500 ppm)	Sigma Aldrich; Lot# MKCD6056; Expiration 03/2020
Paraplatin (Carboplatin), 10 mg/ml (10,000 ppm)	TEVA; Lot# 18F06MA; Expiration 06/2020
Retrovir, 10 mg/ml (10,000 ppm)	GlaxoSmithKline; Lot# C819185; Expiration 04/2020
Rituximab, 10 mg/ml (10,000 ppm)	Hetero Healthcare; Batch# RB1921B; Expiration 08/2021
Topotecan, 1 mg/ml (1,000 ppm)	USP; Lot# R093L0; Expiration 11/2020
Trisenox, 1 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# 129K0039V; Expiration 12/2020

Location Sampled From:

TESTING CONDITIONS:
Standard Test Method Used: Deviation from Standard Test Method: Analytical Method: Testing Temperature: Collection System: Specimen Area Exposed: Selected Data Points: Number of Specimens Tested:

ASTM D 6978 Used 1" Permeation Cell **UV/VIS Spectrometry** 35.0°C ± 2.0 Closed Loop 5.067 cm2 25/test 3/test Cuff Area

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COLLECTION MEDIA:
Table 2 Collection Media for Test Chemotherapy Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM		
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	Distilled Water		
Busulfan, 6 mg/ml (6,000 ppm)	Distilled Water		
Cetuximab, 2 mg/ml (2,000 ppm)	Distilled Water		
Cisplatin, 1 mg/ml (1,000 ppm)	Distilled Water		
Cyclosporin A, 100 mg/ml (100,000 ppm)	Distilled Water		
Cytarabine, 100 mg/ml (100,000 ppm)	Distilled Water		
Dacarbazine, 10 mg/ml (10,000 ppm)	Distilled Water		
Daunorubicin, 5 mg/ml (5,000 ppm)	Distilled Water		
Docetaxel, 10 mg/ml (10,000 ppm)	Distilled Water		
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	Distilled Water		
Epirubicin HCI (Ellence), 2 mg/ml (2,000 ppm)	Distilled Water		
Fludarabine, 25 mg/ml (25,000 ppm)	Distilled Water		
Idarubicin, 1 mg/ml (1,000 ppm)	Distilled Water		
Melphalan, 5 mg/ml (5,000 ppm)	Distilled Water		
Methotrexate, 25 mg/ml (25,000 ppm)	Distilled Water		
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water		
Paraplatin (Carboplatin), 10 mg/ml (10,000 ppm)	Distilled Water		
Retrovir, 10 mg/ml (10,000 ppm)	Distilled Water		
Rituximab, 10 mg/ml (10,000 ppm)	Distilled Water		
Topotecan, 1 mg/ml (1,000 ppm)	Distilled Water		
Trisenox, 1 mg/ml (1,000 ppm)	Distilled Water		

DETECTION METHOD OF CHEMICAL PERMEATION:

UV/VIS ABSORPTION SPECTROMETRY:

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 Emer 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)
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	290
Busulfan, 6 mg/ml (6,000 ppm)	197
Cetuximab, 2 mg/ml (2,000 ppm)	199
Cisplatin, 1 mg/ml (1,000 ppm)	199
Cyclosporin A, 100 mg/ml (100,000 ppm)	199
Cytarabine, 100 mg/ml (100,000 ppm)	272
Dacarbazine, 10 mg/ml (10,000 ppm)	320
Daunorubicin, 5 mg/ml (5,000 ppm)	269
Docetaxel, 10 mg/ml (10,000 ppm)	231
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	232
Epirubicin HCI (Ellence), 2 mg/ml (2,000 ppm)	233 & 253
Fludarabine, 25 mg/ml (25,000 ppm)	261
Idarubicin, 1 mg/ml (1,000 ppm)	257
Melphalan, 5 mg/ml (5,000 ppm)	260
Methotrexate, 25 mg/ml (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Paraplatin, 10 mg/ml (10,000 ppm)	192
Retrovir, 10 mg/ml (10,000 ppm)	266
Rituximab, 10 mg/ml (10,000 ppm)	192
Topotecan, 1 mg/ml (1,000 ppm)	254
Trisenox, 1 mg/ml (1,000 ppm)	197

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SAMPLE CHARACTERISTICS:
Table 4. Cuff thickness for glove identified as: Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.

Teeting Chamathanan D	Thickness (mm)				
Testing Chemotherapy Drugs	Sample 1	Sample 2	Sample 3	Average (mm)	
Bleomycin Sulfate	0.068	0.062	0.066	0.065	
Busulfan	0.066	0.058	0.069	0.064	
Cetuximab	0.060	0.069	0.065	0.065	
Cisplatin	0.063	0.073	0.062	0.066	
Cyclosporin A	0.065	0.064	0.066	0.065	
Cytarabine	0.065	0.065	0.063	0.064	
Dacarbazine	0.067	0.064	0.068	0.066	
Daunorubicin	0.067	0.061	0.068	0.065	
Docetaxel	0.065	0.063	0.068	0.065	
Doxorubicin HCI	0.061	0.066	0.070	0.066	
Epirubicin HCI (Ellence)	0.068	0.065	0.075	0.069	
Fludarabine	0.072	0.074	0.063	0.070	
Idarubicin	0.068	0.065	0.073	0.068	
Melphalan	0.056	0.061	0.065	0.060	
Methotrexate	0.064	0.062	0.081	0.069	
Mitomycin C	0.060	0.071	0.068	0.066	
Paraplatin	0.056	0.068	0.064	0.063	
Retrovir	0.060	0.064	0.064	0.063	
Rituximab	0.073	0.063	0.075	0.070	
Topotecan	0.073	0.066	0.063	0.067	
Trisenox	0.074	0.068	0.063	0.069	
Weight/Unit Area (g/m²)	64.4				

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RESULTS:
Table 5 Permeation Test Results on Testing of: Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Busulfan, 6 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cetuximab, 2 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cisplatin, 1 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclosporin A, 100 mg/ml (100,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cytarabine, 100 mg/ml (100,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine, 10 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Daunorubicin, 5 mg/ml (5,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Docetaxel, 10 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin HCI, 2 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Epirubicin HCI (Ellence), 2 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Fludarabine, 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Idarubicin, 1 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Melphalan, 5 mg/ml (5,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Paraplatin, 10 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Retrovir, 10 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Rituximab, 10 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Topotecan, 1 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Trisenox, 1 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation

Prepared By:

Tiffany Heller Manager, Pharmaceutical Services Approved By: _

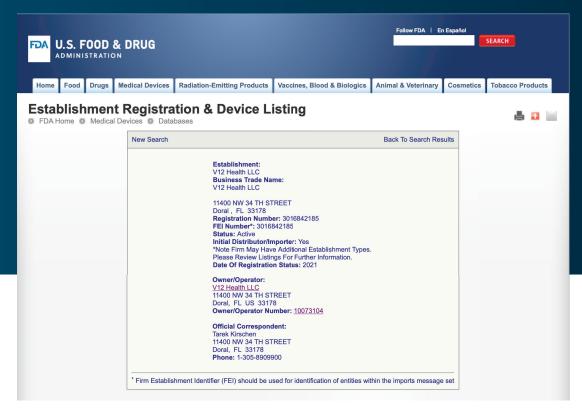
Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

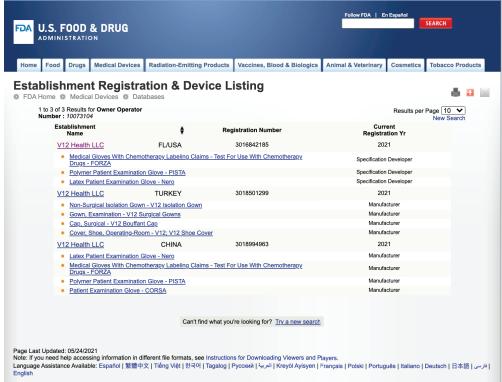
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Certifications









WE MAKE GL VES

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"Everyone Is Essential" is a trademark of V12 Health, LLC

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