

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



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November 12, 2019

John Zhao
Intco Medical Industries Inc.

Page 2 of 5
PN 149986A

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:	ASTM D 6978
Deviation from Standard Test Method:	Used 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 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. *

COLLECTION MEDIA:Table 2. Collection Media for Test Chemicals

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

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.

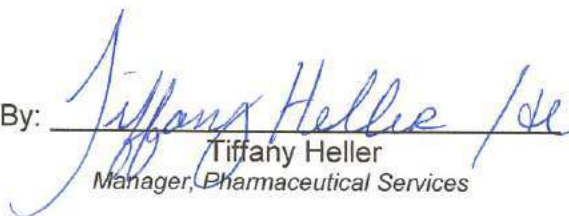
Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Bortezomib (Velcade)	0.059	0.062	0.060	0.060
Carboplatin	0.058	0.057	0.061	0.059
Cyclophosphamide	0.070	0.073	0.060	0.068
Etoposide (Toposar)	0.058	0.067	0.057	0.061
Fluorouracil (5 Flu)	0.059	0.062	0.057	0.060
Gemcitabine	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			

RESULTS:

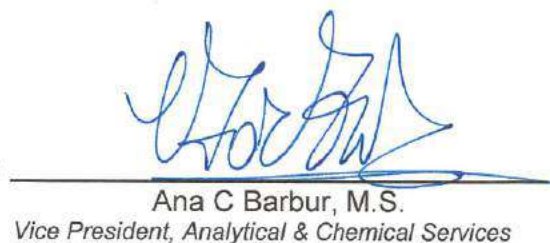
Table 5. Permeation Test Results on: Light blue glove identified as: Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Sample 1,2,3) (Minutes)	STEADY STATE PERM. RATE (Sample 1,2,3) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	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

October 30, 2019

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PN 149986B

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805 Barrington Avenue
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Tiffany Heller
Manager, Pharmaceutical Services

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October 30, 2019

John Zhao
Intco Medical Industries Inc.

Page 2 of 5
PN 149986B

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 HCl (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

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978
Deviation from Standard Test Method:	Used 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 Area

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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.*

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 HCl (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:**

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)
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 HCl (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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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. *

SAMPLE CHARACTERISTICS:

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

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
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 HCl	0.061	0.066	0.070	0.066
Epirubicin HCl (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			

RESULTS:

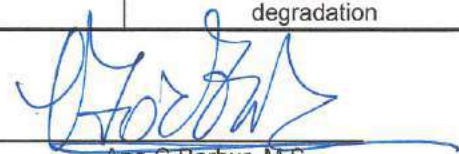
Table 5 Permeation Test Results on Testing of: Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	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 HCl, 2 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Epirubicin HCl (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

October 30, 2019

▪TEST REPORT▪

PN 149986C

PHARMACEUTICAL SERVICES


Prepared For:

John Zhao
Intco Medical Industries Inc.
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October 30, 2019

John Zhao
Intco Medical Industries Inc.

Page 2 of 5
PN 149986C

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

RECEIVED: One (1) Periwinkle colored 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
Arsenic Trioxide, 1 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# BCCB5045; Expiration 10/2021
Azacitidine (Vidaza), 25 mg/ml (25,000 ppm)	LC Labs; Lot# AZC-101; Expiration 12/2019
Bendamustine, 5 mg/ml (5,000 ppm)	USP; Lot# F070G0; Expiration 07/2020
Carfilzomib, 2 mg/ml (2,000 ppm)	LC Labs; Lot# CFZ-103; Expiration 1/21/2025
Cladribine, 1 mg/ml (1,000 ppm)	EDQM; Lot# 00716; Expiration 10/2020
Cytovene, 10 mg/ml (10,000 ppm)	Sigma Aldrich; Lot# 097M4004V; Expiration 07/2020
Decitabine, 5 mg/ml (5,000 ppm)	LC Labs; Lot# DCT-103; Expiration 08/2024
Fentanyl Citrate Injection, 100mcg/2mL	WestWard; Lot# 059334; Expiration 06/2022
Fulvestrant, 50 mg/ml (50,000 ppm)	USP; Lot# R062G0; Expiration 10/2019
Mesna, 50 mg/ml (50,000 ppm)	Sigma Aldrich; Lot# LRAB9114; Expiration 12/2022
Temsirolimus, 25 mg/ml (25,000 ppm)	LC Labs; Lot# BTM-109; Expiration 1/6/2025
Triclosan, 2 mg/ml (2,000 ppm)	Sigma Aldrich; Lot# LRAA9132; Expiration 12/2020
Vinblastine, 1 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# 039M4086V; Expiration 09/2020
Vinorelbine, 10 mg/ml (10,000 ppm)	Sigma Aldrich; Batch# 0000071266; Expiration 10/2020
Zoledronic Acid, 0.8 mg/ml (800 ppm)	USP; Lot# R05910; Expiration 12/2019

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978
Deviation from Standard Test Method:	Used 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 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.*

COLLECTION MEDIA:

Table 2. Collection Media for Test Chemicals

TESTING CHEMOTHERAPY DRUGS	COLLECTION MEDIUM
Arsenic Trioxide, 1 mg/ml (1,000 ppm)	Distilled Water
Azacitidine (Vidaza), 25 mg/ml (25,000 ppm)	Distilled Water
Bendamustine, 5 mg/ml (5,000 ppm)	Distilled Water
Carfilzomib, 2 mg/ml (2,000 ppm)	Distilled Water
Cladribine, 1 mg/ml (1,000 ppm)	Distilled Water
Cytovene, 10 mg/ml (10,000 ppm)	Distilled Water
Decitabine, 5 mg/ml (5,000 ppm)	Distilled Water
Fentanyl Citrate Injection, 100mcg/2mL	Distilled Water
Fulvestrant, 50 mg/ml (50,000 ppm)	Distilled Water
Mesna, 50 mg/ml (50,000 ppm)	Distilled Water
Temsirolimus, 25 mg/ml (25,000 ppm)	Distilled Water
Triclosan, 2 mg/ml (2,000 ppm)	Distilled Water
Vinblastine, 1 mg/ml (1,000 ppm)	Distilled Water
Vinorelbine, 10 mg/ml (10,000 ppm)	Distilled Water
Zoledronic Acid, 0.8 mg/ml (800 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)
Arsenic Trioxide, 1 mg/ml (1,000 ppm)	197
Azacitidine (Vidaza), 25 mg/ml (25,000 ppm)	201
Bendamustine, 5 mg/ml (5,000 ppm)	232 & 329
Carfilzomib, 2 mg/ml (2,000 ppm)	254
Cladribine, 1 mg/ml (1,000 ppm)	199
Cytovene, 10 mg/ml (10,000 ppm)	251
Decitabine, 5 mg/ml (5,000 ppm)	210
Fentanyl Citrate Injection, 100mcg/2mL	199
Fulvestrant, 50 mg/ml (50,000 ppm)	196
Mesna, 50 mg/ml (50,000 ppm)	202
Temsirolimus, 25 mg/ml (25,000 ppm)	276
Triclosan, 2 mg/ml (2,000 ppm)	197
Vinblastine, 1 mg/ml (1,000 ppm)	214
Vinorelbine, 10 mg/ml (10,000 ppm)	212
Zoledronic Acid, 0.8 mg/ml (800 ppm)	215

SAMPLE CHARACTERISTICS:

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

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Arsenic Trioxide	0.062	0.070	0.057	0.063
Azacitidine (Vidaza)	0.062	0.068	0.060	0.063
Bendamustine	0.062	0.060	0.057	0.059
Carfilzomib	0.066	0.061	0.060	0.062
Cladribine	0.062	0.061	0.060	0.061
Cytovene	0.069	0.061	0.067	0.065
Decitabine	0.059	0.056	0.069	0.061
Fentanyl Citrate Injection	0.059	0.057	0.062	0.059
Fulvestrant	0.060	0.055	0.066	0.061
Mesna	0.060	0.054	0.063	0.059
Temsirolimus	0.065	0.070	0.068	0.068
Triclosan	0.061	0.058	0.068	0.063
Vinblastine	0.062	0.064	0.068	0.065
Vinorelbine	0.058	0.065	0.070	0.064
Zoledronic Acid	0.060	0.057	0.075	0.064
Weight/Unit Area (g/m²)	64.0			

RESULTS:


Table 5. Permeation Test Results on: Periwinkle colored glove type 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) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	OTHER OBSERVATIONS
Arsenic Trioxide, 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Azacitidine (Vidaza), 25 mg/ml (25,000 ppm)	>240	N/A	Slight swelling and no degradation
Bendamustine, 5 mg/ml (5,000 ppm)	>240	N/A	Slight swelling and no degradation
Carfilzomib, 2 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Cladribine, 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Cytovene, 10 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Decitabine, 5 mg/ml (5,000 ppm)	>240	N/A	Slight swelling and no degradation
Fentanyl Citrate Injection, 100mcg/2mL	>240	N/A	Slight swelling and no degradation
Fulvestrant, 50 mg/ml (50,000 ppm)	>240	N/A	Slight swelling and no degradation
Mesna, 50 mg/ml (50,000 ppm)	>240	N/A	Slight swelling and no degradation
Temsirolimus, 25 mg/ml (25,000 ppm)	>240	N/A	Slight swelling and no degradation
Triclosan, 2 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Vinblastine, 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Vinorelbine, 10 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Zoledronic Acid, 0.8 mg/ml (800 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

October 30, 2019

▪TEST REPORT▪

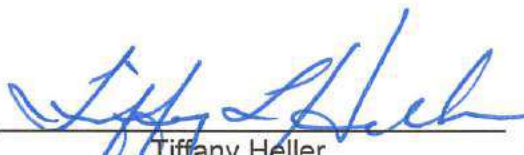
PN 149986D

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:


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Vice President, Analytical & Chemical Services

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October 30, 2019

John Zhao
Intco Medical Industries Inc.

Page 2 of 3
PN 149986D

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

RECEIVED: One (1) Light Blue colored 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
Chloroquine, 50 mg/ml (50,000 ppm)	Rising; Lot# 409517; Expiration 02/2021

COLLECTION MEDIA:

Table 2. Collection Media for Test Chemicals

TESTING CHEMOTHERAPY DRUGS	COLLECTION MEDIUM
Chloroquine, 50 mg/ml (50,000 ppm)	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978
Deviation from Standard Test Method:	Used 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 area

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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

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Chloroquine, 50 mg/ml (50,000 ppm)	220

SAMPLE CHARACTERISTICS:

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


Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Chloroquine	0.072	0.070	0.071	0.071
Weight/Unit Area (g/m ²)	64.0			

RESULTS:


Table 5. Permeation Test Results on: Light Blue colored glove type 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/cm ² /minute)	OTHER OBSERVATIONS
Chloroquine, 50 mg/ml (50,000 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

October 30, 2019

■TEST REPORT■

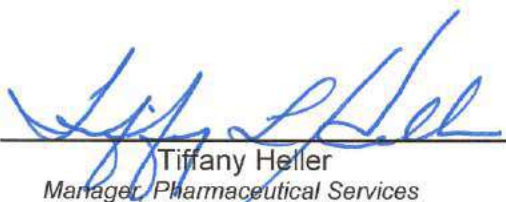
PN 149986E

PHARMACEUTICAL SERVICES


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Prepared By:


Tiffany Heller
Manager, Pharmaceutical Services

Approved By:


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Rev 101218



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October 30, 2019

John Zhao
Intco Medical Industries Inc.

Page 2 of 3
PN 149986E

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

RECEIVED: One (1) Light Blue colored 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
Mechlorethamine HCl, 1 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# 07118JJV; Expiration 04/2021
Raltitrexed, 0.5 mg/ml (500 ppm)	Sigma Aldrich; Lot# R9156; Expiration 11/2019

COLLECTION MEDIA:

Table 2. Collection Media for Test Chemicals

TESTING CHEMOTHERAPY DRUGS	COLLECTION MEDIUM
Mechlorethamine HCl, 1 mg/ml (1,000 ppm)	Distilled Water
Raltitrexed, 0.5 mg/ml (500 ppm)	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978
Deviation from Standard Test Method:	Used 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 area

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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

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Mechlorethamine HCl, 1 mg/ml (1,000 ppm)	194
Raltitrexed, 0.5 mg/ml (500 ppm)	226

SAMPLE CHARACTERISTICS:

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


Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Mechlorethamine HCl	0.064	0.066	0.066	0.065
Raltitrexed	0.063	0.068	0.069	0.067
Weight/Unit Area (g/m ²)	64.0			

RESULTS:


Table 5. Permeation Test Results on: Light Blue colored glove type 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/cm ² /minute)	OTHER OBSERVATIONS
Mechlorethamine HCl, 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Raltitrexed, 0.5 mg/ml (500 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

October 30, 2019

▪TEST REPORT▪


PN 149986F

PHARMACEUTICAL SERVICES


Prepared For:

John Zhao
Intco Medical Industries Inc..
805 Barrington Avenue
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Prepared By:


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Manager, Pharmaceutical Services

Approved By:


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October 30, 2019

John Zhao
Intco Medical Industries Inc.

Page 2 of 3
PN 149986F

SUBJECT: Permeation testing per ASTM F739 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 CHEMICAL	CHEMICAL SOURCE
Silver Nitrate, 0.5%	Sigma Aldrich; Lot# MKBS1748V; CAS# 7761-88-8

COLLECTION MEDIA:

Table 2. Collection Media for Test Chemicals

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Silver Nitrate, 0.5%	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM F739
Analytical Method:	UV/Vis Spectrometer
Testing Temperature:	23.0°C ± 1.0
Collection System:	Closed Loop
Specimen Area Exposed:	18.726 cm ²
Selected Data Points:	25/Test
Number of Specimens Tested:	3/test
Location Sampled From:	Palm area

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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 CHEMICALS	WAVELENGTH (nm)
Silver Nitrate, 0.5%	205

SAMPLE CHARACTERISTICS:

Table 4. Palm thickness characteristics for the tested: light blue glove type identified as; Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Silver Nitrate, 0.5%	0.073	0.073	0.074	0.073
Weight/Unit Area (g/m2)	73.4			

RESULTS:


Table 5. Breakthrough Time and Steady State Permeation Results on: light blue glove type identified as; Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.

TEST CHEMICAL	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STANDARDIZED BREAKTHROUGH TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	OTHER OBSERVATIONS
Silver Nitrate, 0.5%	>480 min.	>480 min.	0	Minimal swelling and no degradation

Prepared By:


 Tiffany Heller
 Manager, Pharmaceutical Services

Approved By:


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

November 12, 2019

▪TEST REPORT▪

PN 149986G

PHARMACEUTICAL SERVICES

Prepared For:

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Prepared By:

Tiffany Heller
Tiffany Heller
Manager, Pharmaceutical Services

Approved By:

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November 12, 2019

John Zhao
Intco Medical Industries Inc.

Page 2 of 3
PN 149986G

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
Carmustine, 3.3 mg/ml (3,300 ppm)	USP; Lot# R071D0; Expiration 09/2020

COLLECTION MEDIA:

Table 2. Collection Media for Test Chemicals

TESTING CHEMOTHERAPY DRUGS	COLLECTION MEDIUM
Carmustine, 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978
Deviation from Standard Test Method:	Used 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 area

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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.*

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)
Carmustine, 3.3 mg/ml (3,300 ppm)	229

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)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Carmustine	0.068	0.058	0.061	0.062
Weight/Unit Area (g/m2)	64.0			

RESULTS:

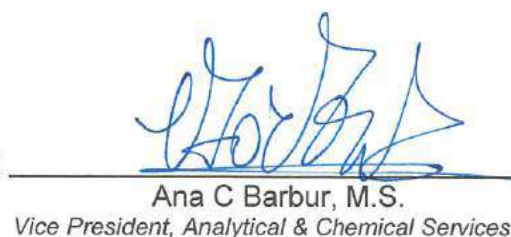
Table 5. Permeation Test Results on: Light blue glove identified as: Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Sample 1,2,3) (Minutes)	STEADY STATE PERM. RATE (Sample 1,2,3) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	OTHER OBSERVATIONS
Carmustine, 3.3 mg/ml (3,300 ppm)	13.0 (17.8,13.0,23.4)	0.3 (0.3,0.3,0.2)	Moderate swelling and no degradation

Prepared By:


Tiffany Heller
Manager, Pharmaceutical Services

Approved By:


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

November 13, 2019

▪TEST REPORT▪


PN 149986H

PHARMACEUTICAL SERVICES

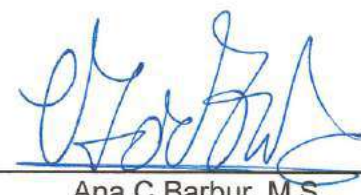
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Prepared By:


Tiffany Heller
Manager, Pharmaceutical Services

Approved By:


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November 13, 2019

John Zhao
Intco Medical Industries Inc.

Page 2 of 4
PN 149986H

SUBJECT: Permeation testing per ASTM F739 on one glove type 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

TEST CHEMICAL	CHEMICAL SOURCE
Chlorhexidine Gluconate, 4%	Sigma; Lot# BCBH4944V; CAS# 18472-51-0
Cidex OPA	ASP; Lot # 731800118; Exp. 11/10/2019
Hydrogen Peroxide, 30%	Sigma Aldrich; Lot# MKBX1362V; CAS# 7722-84-1
Isopropyl Alcohol, 99%	Pharmco-Aaper; Lot# C1712007; CAS# 67-63-0

COLLECTION MEDIA:

Table 2. Collection Media for Test Chemicals

TEST CHEMICAL AND CONCENTRATION	COLLECTION MEDIUM
Chlorhexidine Gluconate, 4%	Distilled Water
Cidex OPA	Distilled Water
Hydrogen Peroxide, 30%	Distilled Water
Isopropyl Alcohol, 99%	Helium

TESTING CONDITIONS:

Standard Test Method Used:	ASTM F 739
Deviation from Standard Test Method:	Used 2" ASTM Standard Permeation Cell
Analytical Method:	UV/VIS Spectrometry /GC Chromatography
Testing Temperature:	23.0°C ± 1.0
Collection System:	Closed Loop (UV/VIS)/ Open Loop (Arnel GC)
Specimen Area Exposed:	18.726 cm ²
Selected Data Points:	10 -25/test depending on the sample and/or technique
Number of Specimens Tested:	3/test
Location Sampled From:	Palm 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.*

DETECTION METHOD OF CHEMICAL PERMEATION:**A) 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 in Table 3.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TEST CHEMICAL	WAVELENGTH (nm)
Chlorhexidine Gluconate, 4%	192
Cidex OPA	206
Hydrogen Peroxide, 30%	191

B) GAS CHROMATOGRAPHY (GC):

Instrument: Perkin Elmer Clarus 500 Gas Chromatograph with Autosampler*

Column: Zebron ZB-5 7HM-G002-11 (30m x 0.32mm I.D. x 0.25mm)

Detector: FID

GC was run at specific conditions to separate and measure the amount of permeated test chemical throughout the testing period.

* For gas sampling, an ARNEL multi-permeation chamber analyzer was used.

SAMPLE CHARACTERISTICS:

Table 4. Palm thickness characteristics for the tested: One (1) light blue glove type identified as: Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.


Testing Chemicals	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Chlorhexidine Gluconate, 4%	0.080	0.065	0.068	0.071
Cidex OPA	0.067	0.065	0.070	0.067
Hydrogen Peroxide, 30%	0.069	0.077	0.067	0.071
Isopropyl Alcohol, 99%	0.065	0.075	0.075	0.072
Weight/Unit Area (g/m²)	73.4			

RESULTS:


Table 5. Permeation Test Results on: One (1) light blue glove type identified as: Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.

CHEMICAL TESTED	AVERAGE BREAKTHROUGH DETECTION TIME (Sample 1,2,3) (Minutes)	AVERAGE STANDARDIZED BREAKTHROUGH TIME (Sample 1,2,3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Sample 1,2,3) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	OTHER OBSERVATIONS
Chlorhexidine Gluconate, 4%	>480 min.	>480	0	Slight swelling and no degradation
Cidex OPA	66.7 (80,60,60)	68.8 (82.1,62.2,62.2)	2.8 (2.6,2.8,2.9)	Slight swelling and no degradation
Hydrogen Peroxide, 30%	0 (0,0,0)	29.1 (27.5,22.6,37.3)	4.8 (5.3,4.7,4.4)	Slight swelling and no degradation
Isopropyl Alcohol, 99%	27.0 (33,24,24)	37.3 (44.0,28.8,39.0)	4.8 (3.5,5.7,5.2)	Moderate swelling and slight degradation

Prepared By:


Tiffany Heller
Manager, Pharmaceutical Services

Approved By:


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

November 13, 2019

▪TEST REPORT▪

PN 149986I

PHARMACEUTICAL SERVICES

Prepared For:

John Zhao
Intco Medical Industries
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Rev 101218



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November 13, 2019

John Zhao
Intco Medical Industries Inc.

Page 2 of 4
PN 1499861

SUBJECT: Permeation testing per ASTM F739 on one glove type 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

TEST CHEMICAL	CHEMICAL SOURCE
Acrylamide, 40%	Sigma Aldrich; Lot# SLBC1495V; CAS# 79-06-1
Benzalkonium Chloride, 50%	Spectrum; Lot# YP0272; CAS# 8001-54-5
Hydrochloric Acid, 37%	JT Baker; Lot# 119228; CAS# 7722-84-1
Methanol, 99%	Sigma Aldrich; Lot# SHBK0449; CAS# 67-56-1
Sodium Hydroxide, 40%	EMD; Lot# B0484969 016; CAS# 1310-73-2
Sodium Hypochlorite, 13%	VWR; Lot# 192229; CAS# 7681-52-9

COLLECTION MEDIA:

Table 2. Collection Media for Test Chemicals

TEST CHEMICAL AND CONCENTRATION	COLLECTION MEDIUM
Acrylamide, 40%	Distilled Water
Benzalkonium Chloride, 50%	Distilled Water
Hydrochloric Acid, 37%	Distilled Water
Methanol, 99%	Helium
Sodium Hydroxide, 40%	Distilled Water
Sodium Hypochlorite, 13%	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM F 739
Deviation from Standard Test Method:	Used 2" ASTM Standard Permeation Cell
Analytical Method:	UV/VIS Spectrometry/pH Measurement/GC Chromatography
Testing Temperature:	23.0°C ± 1.0
Collection System:	Closed Loop (UV/VIS & pH Measurement)/ Open Loop (Arnel GC)
Specimen Area Exposed:	18.726 cm ²
Selected Data Points:	10 -25/test depending on the sample and/or technique
Number of Specimens Tested:	3/test
Location Sampled From:	Palm area

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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.*

DETECTION METHOD OF CHEMICAL PERMEATION:**A) 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 in Table 3.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TEST CHEMICAL	WAVELENGTH (nm)
Acrylamide, 40%	197
Benzalkonium Chloride, 50%	192
Sodium Hypochlorite, 10-13%	292

B) GAS CHROMATOGRAPHY (GC):

Instrument: Perkin Elmer Clarus 500 Gas Chromatograph with Autosampler*

Column: Zebron ZB-5 7HM-G002-11 (30m x 0.32mm I.D. x 0.25mm)

Detector: FID

GC was run at specific conditions to separate and measure the amount of permeated test chemical throughout the testing period.

* For gas sampling, an ARNEL multi-permeation chamber analyzer was used.

C) POTENTIOMETRY (pH MEASUREMENT):

Instruments: Oakton pH/mV/°C Meter; Cole-Parmer pH/mV/°C Meter

Electrodes: Oakton "2 in 1" pH Glass Electrode

The pH of the collection medium was measured for the acidic and basic test chemicals. Dual point standardization was performed for pH 7 and pH 4 or pH 10. Automatic Temperature Compensator (ATC) automatically compensated temperature change of the system during the test.

SAMPLE CHARACTERISTICS:

Table 4. Palm thickness characteristics for the tested: One (1) light blue glove type identified as: Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.

Testing Chemicals	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Acrylamide, 40%	0.068	0.061	0.069	0.066
Benzalkonium Chloride, 50%	0.070	0.066	0.071	0.069
Hydrochloric Acid, 37%	0.067	0.062	0.077	0.069
Methanol, 99%	0.075	0.071	0.073	0.073
Sodium Hydroxide, 40%	0.070	0.074	0.074	0.073
Sodium Hypochlorite, 13%	0.062	0.071	0.070	0.067
Weight/Unit Area (g/m2)	73.4			

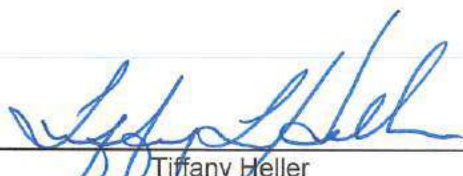
RESULTS:

Table 5. Permeation Test Results on: One (1) light blue glove type identified as: Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.

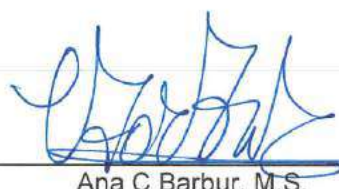
CHEMICAL TESTED	AVERAGE BREAKTHROUGH DETECTION TIME (Sample 1,2,3) (Minutes)	AVERAGE STANDARDIZED BREAKTHROUGH TIME (Sample 1,2,3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Sample 1,2,3) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	OTHER OBSERVATIONS
Acrylamide, 40%	133.3 (120,140,140)	220.9 (235.4,228.2,199.2)	0.2 (0.1,0.2,0.2)	Slight swelling and no degradation
Benzalkonium Chloride, 50%	>480 min.	>480 min.	0	Slight swelling and no degradation
Hydrochloric Acid, 37%	71.0 (71,71,71)	90.6 (85.0,100.1,86.7)	224.7 (260.0,189.0,222.0)	Severe swelling, degradation and discoloration
Methanol, 99%	0 (0,0,0)	0.6 (0.6,0.6,0.7)	N/A*	Moderate swelling and slight degradation
Sodium Hydroxide, 40%	>480 min.	>480 min.	0	Slight swelling and no degradation
Sodium Hypochlorite, 13%	>480 min.	>480 min.	0	Slight swelling and no degradation

*Due to strong permeation, steady state is unavailable; permeation outside of instruments reading range.

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