

July 25, 2019

▪TEST REPORT▪

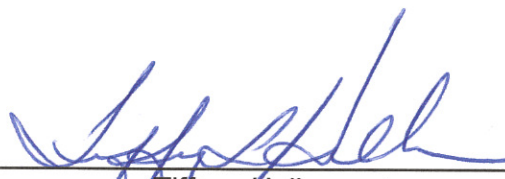
PN 146293C #5

PHARMACEUTICAL SERVICES

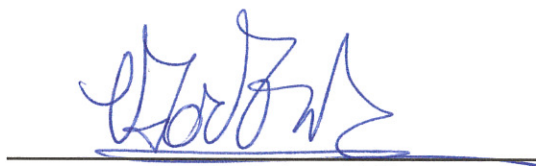
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Josh Kolof
Medline International B.V.

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PN 146136C #5

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

RECEIVED: One (1) glove type with various sizes identified as; Sensicare Neoprene.

TEST CHEMICALS:

Table 1. List of the Testing Drugs and their Sources

| TESTING CHEMOTHERAPY DRUGS | DRUG SOURCE |
|---|---|
| Bleomycin, 15 mg/ml (15,000 ppm) | Teva; Lot# 31321906B; Expiration 09/2019 |
| Busulfan, 6 mg/ml (6,000 ppm) | Sigma; Lot# BCBS8240V; Expiration 12/2021 |
| Carboplatin, 10.0 mg/ml (10,000 ppm) | Teva; Lot# 18F06MA; Expiration 06/2020 |
| Carmustine (BCNU), 3.3 mg/ml (3,300 ppm) | Sigma Aldrich; Lot # 018M4057V; Exp. 02/2020 |
| Cisplatin, 1 mg/ml (1,000 ppm) | WG Critical Care; Lot# 8D05666; Expiration 09/2019 |
| Cyclophosphamide (Cytosan), 20 mg/ml (20,000 ppm) | Sandoz Inc.; Lot# 17101325; Expiration 10/12/2019 |
| Cytarabine, 100.0 mg/ml (100,000 ppm) | Sigma Aldrich; Lot# LRAA8717; Expiration 04/2020 |
| Dacarbazine (DTIC), 10 mg/ml, (10,000 ppm) | Teva; Lot# 31325414B; Expiration 09/2021 |
| Doxorubicin Hydrochloride, 2 mg/ml (2,000 ppm) | Actavis Pharma; Lot# 7LJ5121; Expiration 07/2019 |
| Epirubicin (Ellence), 2 mg/ml (2,000 ppm) | USP; Lot# R06270; Lot# Expiration 02/2020 |
| Etoposide (Toposar), 20 mg/ml (20,000 ppm) | Teva; Lot# 31325485B; Expiration 07/2021 |
| Fludarabine, 25.0 mg/ml (25,000 ppm) | USP; Lot# H1K220; Expiration 12/2019 |
| 5-Fluorouracil, 50 mg/ml, (50,000 ppm) | Intas Pharmaceuticals; Lot# PX04154; Expiration 07/2019 |
| Idarubicin, 1.0 mg/ml (1,000 ppm) | Teva; Lot# 31322658B; Expiration 02/2020 |
| Ifosfamide, 50.0 mg/ml (50,000 ppm) | USP; Lot# H0F233; Expiration 05/2020 |
| Mechlorethamine HCl, 1 mg/ml (1,000 ppm) | Sigma Aldrich; Lot# MKBW4481V; Expiration 12/2019 |
| Melphalan, 5 mg/ml (5,000 ppm) | USP; Lot# R068T0; Expiration 09/2019 |
| Methotrexate, 25 mg/ml (25,000 ppm) | Sigma Aldrich; Lot# LRAA9182; Expiration 04/2020 |
| Mitomycin C, 0.5 mg/ml (500 ppm) | Sigma Aldrich; Lot# MKCD6056; Expiration 03/2020 |
| Mitoxantrone, 2.0 mg/ml (2,000 ppm) | Sigma Aldrich; Lot# MKBR2210V; Expiration 04/2021 |
| Paclitaxel (Taxol), 6 mg/ml (6,000 ppm) | Hospira; Lot# F066865AA; 08/31/2020 |
| Paraplatin, 10 mg/ml (10,000 ppm) | Teva; Lot# 17I110A; Expiration 09/2019 |
| Rituximab, 10 mg/ml (10,000 ppm) | Hetero; Lot# RB1725A; Expiration 05/2020 |
| Thiotepa (THT), 10 mg/ml (10,000 ppm) | USP; Lot# R11380; Expiration 06/2020 |
| Vincristine, 1.0 mg/ml (1,000 mg/ml) | Hospira; Lot# F027139AA; Expiration 09/30/2019 |

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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 Drug

| TEST DRUG AND CONCENTRATION | COLLECTION MEDIUM |
|---|-----------------------------------|
| Bleomycin, 15 mg/ml (15,000 ppm) | Distilled Water |
| Busulfan, 6 mg/ml (6,000 ppm) | Distilled Water |
| Carboplatin, 10.0 mg/ml (10,000 ppm) | Distilled Water |
| Carmustine (BCNU), 3.3 mg/ml (3,300 ppm) | 10% Ethanol Aqueous Solution |
| Cisplatin, 1.0 mg/ml (1,000 ppm) | Distilled Water |
| Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm) | Distilled Water |
| Cytarabine, 100 mg/ml (100,000 ppm) | Distilled Water |
| Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm) | Distilled Water |
| Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm) | Distilled Water |
| Epirubicin (Ellence), 2 mg/ml (2,000 ppm) | Distilled Water |
| Etoposide (Toposar), 20.0 mg/ml (20,000 ppm) | Distilled Water |
| Fludarabine, 25.0 mg/ml (25,000 ppm) | Distilled Water |
| Fluorouracil, 50.0 mg/ml (50,000 ppm) | 9.20 pH Sodium Hydroxide Solution |
| Idarubicin, 1.0 mg/ml (1,000 ppm) | Distilled Water |
| Ifosfamide, 50.0 mg/ml (50,000 ppm) | Distilled Water |
| Mechlorethamine HCl, 1.0 mg/ml (1,000ppm) | 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 |
| Mitoxantrone, 2.0 mg/ml (2,000 ppm) | Distilled Water |
| Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm) | 30% Methanol Aqueous Solution |
| Paraplatin, 10 mg/ml (10,000 ppm) | Distilled Water |
| Rituximab, 10 mg/ml (10,000 ppm) | Distilled Water |
| Thiotepa, 10.0 mg/ml (10,000 ppm) | Distilled Water |
| Vincristine Sulfate, 1.0 mg/ml (1,000 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 |

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, 15 mg/ml (15,000 ppm) | 290 |
| Busulfan, 6 mg/ml (6,000 ppm) | 197 |
| Carboplatin, 10.0 mg/ml (10,000 ppm) | 192 |
| Carmustine (BCNU), 3.3 mg/ml (3,300 ppm) | 229 |
| Cisplatin, 1.0 mg/ml (1,000 ppm) | 199 |
| Cyclophosphamide (Cytosan), 20 mg/ml (20,000 ppm) | 200 |
| Cytarabine, 100 mg/ml (100,000 ppm) | 272 |
| Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm) | 320 |
| Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm) | 232 |
| Epirubicin (Ellence), 2 mg/ml (2,000 ppm) | 233 & 253 |
| Etoposide (Toposar), 20.0 mg/ml (20,000 ppm) | 205 |
| Fludarabine, 25.0 mg/ml (25,000 ppm) | 261 |
| Fluorouracil, 50.0 mg/ml (50,000 ppm) | 269 |
| Idarubicin, 1.0 mg/ml (1,000 ppm) | 257 |
| Ifosfamide, 50.0 mg/ml (50,000 ppm) | 200 |
| Mechlorethamine HCl, 1.0 mg/ml (1,000ppm) | 194 |
| 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 |
| Mitoxantrone, 2.0 mg/ml (2,000 ppm) | 242 |
| Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm) | 231 |
| Paraplatin, 10 mg/ml (10,000 ppm) | 192 |
| Rituximab, 10 mg/ml (10,000 ppm) | 192 |
| Thiotepa, 10.0 mg/ml (10,000 ppm) | 199 |
| Vincristine Sulfate, 1.0 mg/ml (1,000 ppm) | 220 |

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested: Sensicare Neoprene.

| Testing Chemotherapy Drugs | Thickness (mm) | | | Average (mm) |
|---|----------------|----------|----------|--------------|
| | Sample 1 | Sample 2 | Sample 3 | |
| Bleomycin | 0.239 | 0.144 | 0.153 | 0.179 |
| Busulfan | 0.145 | 0.140 | 0.140 | 0.142 |
| Carboplatin | 0.142 | 0.123 | 0.144 | 0.137 |
| Carmustine (BCNU) | 0.138 | 0.127 | 0.135 | 0.134 |
| Cisplatin | 0.142 | 0.143 | 0.132 | 0.139 |
| Cyclophosphamide (Cytosan) | 0.147 | 0.144 | 0.126 | 0.139 |
| Cytarabine | 0.134 | 0.151 | 0.128 | 0.138 |
| Dacarbazine (DTIC) | 0.142 | 0.136 | 0.127 | 0.135 |
| Doxorubicin Hydrochloride | 0.128 | 0.137 | 0.162 | 0.142 |
| Epirubicin (Ellence) | 0.124 | 0.139 | 0.131 | 0.131 |
| Etoposide (Toposar) | 0.139 | 0.143 | 0.139 | 0.140 |
| Fludarabine | 0.132 | 0.144 | 0.140 | 0.139 |
| Fluorouracil | 0.125 | 0.124 | 0.143 | 0.131 |
| Idarubicin | 0.125 | 0.133 | 0.152 | 0.137 |
| Ifosfamide | 0.134 | 0.138 | 0.164 | 0.146 |
| Mechlorethamine HCl | 0.144 | 0.132 | 0.165 | 0.147 |
| Melphalan | 0.140 | 0.121 | 0.147 | 0.136 |
| Methotrexate | 0.141 | 0.127 | 0.141 | 0.136 |
| Mitomycin C | 0.141 | 0.146 | 0.144 | 0.144 |
| Mitoxantrone | 0.137 | 0.141 | 0.134 | 0.137 |
| Paclitaxel (Taxol) | 0.152 | 0.139 | 0.130 | 0.140 |
| Paraplatin | 0.138 | 0.124 | 0.133 | 0.132 |
| Rituximab | 0.133 | 0.123 | 0.123 | 0.126 |
| Thiotepa | 0.139 | 0.126 | 0.143 | 0.136 |
| Vincristine Sulfate | 0.139 | 0.122 | 0.126 | 0.129 |
| Weight/Unit Area (g/m²) | 194.5 | | | |

RESULTS:

Table 5.1 Permeation Test Results on testing of: Sensicare Neoprene.

| TEST CHEMOTHERAPY 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 |
|--|--|---|--------------------------------------|
| Bleomycin, 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 |
| Carboplatin, 10.0 mg/ml (10,000 ppm) | No breakthrough up to 240 min. | N/A | Slight swelling and no degradation |
| Carmustine (BCNU) 3.3 mg/ml (3,300 ppm) | 36.3 (36.3,37.4,38.4) | 0.1 (0.1,0.1,0.1) | Moderate swelling and no degradation |

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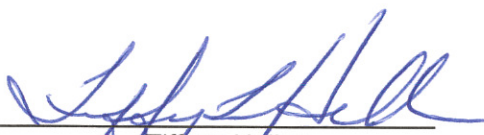
NOTE: Non-ISO 17025 accredited test methods are designated with the ^ symbol to differentiate from ISO 17025 accredited methods in the body of the test report.*

RESULTS cont.:

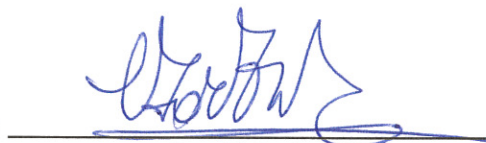
Table 5.2 Permeation Test Results on testing of: Sensicare Neoprene.

| TEST CHEMOTHERAPY DRUG AND CONCENTRATION | MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes) | AVERAGE STEADY STATE PERM. RATE (Specimen 1/2/3) ($\mu\text{g}/\text{cm}^2/\text{minute}$) | OTHER OBSERVATIONS |
|---|--|--|--------------------------------------|
| Cisplatin 1.0 mg/ml (1,000 ppm) | No breakthrough up to 240 min. | N/A | Slight swelling and no degradation |
| Cyclophosphamide (Cytosan) 20 mg/ml (20,000 ppm) | No breakthrough up to 240 min. | N/A | Slight swelling and no degradation |
| Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm) | No breakthrough up to 240 min. | N/A | Slight swelling and no degradation |
| Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm) | No breakthrough up to 240 min. | N/A | Slight swelling and no degradation |
| Epirubicin (Ellence), 2 mg/ml (2,000 ppm) | No breakthrough up to 240 min. | N/A | Slight swelling and no degradation |
| Etoposide (Toposar) 20.0 mg/ml (20,000 ppm) | No breakthrough up to 240 min. | N/A | Slight swelling and no degradation |
| Fludarabine, 25.0 mg/ml (25,000 ppm) | No breakthrough up to 240 min. | N/A | Slight swelling and no degradation |
| Fluorouracil 50.0 mg/ml (50,000 ppm) | No breakthrough up to 240 min. | N/A | Slight swelling and no degradation |
| Idarubicin, 1.0 mg/ml (1,000 ppm) | No breakthrough up to 240 min. | N/A | Slight swelling and no degradation |
| Ifosfamide, 50.0 mg/ml (50,000 ppm) | No breakthrough up to 240 min. | N/A | Slight swelling and no degradation |
| Mechlorethamine HCl, 1.0 mg/ml (1,000ppm) | 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 |
| Mitoxantrone, 2.0mg/ml (2,000ppm) | No breakthrough up to 240 min. | N/A | Slight swelling and no degradation |
| Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm) | No breakthrough up to 240 min. | N/A | Moderate swelling and no degradation |
| Paraplatin, 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 |
| Thiotepa 10.0 mg/ml (10,000 ppm) | 49.2 (56.0,49.2,78.5) | 0.4 (0.4,0.4,0.3) | Slight swelling and no degradation |
| Vincristine Sulfate 1.0 mg/ml (1,000 ppm) | No breakthrough up to 240 min. | N/A | Slight swelling and no degradation |

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