July 23, 2019

▪TEST REPORT▪

PN 148806

PHARMACEUTICAL SERVICES

Prepared For:

Jacken Cai
Anhui Intco Medical Products Co. Ltd.
No.1 Haitang Road
Suixi District Economic Development Area Huaibei City
Anhui Province
China

Prepared By: _____
Tiffany Heller
Manager, Pharmaceutical Services

Approved By: _____
Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

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July 23, 2019

Jacken Cai
Anhui Intco Medical Products Co. Ltd.

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

RECEIVED: One (1) Blue glove not identified by customer.

TEST CHEMICALS:
Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Blenoxane (Bleomycin), 15 mg/ml (15,000 ppm)	Teva; Lot# 31321906B; Expiration 09/2019
Cyclophosphamide, 20 mg/ml (20,000 ppm)	Sandoz Inc.; Lot# 17101325; Expiration 10/12/2019
Cytarabine, 100 mg/ml (100,000 ppm)	Sigma Aldrich; Lot# LRAA8717; 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)	Intas Pharmaceuticals; Lot# PX04154; Expiration 07/2019
Idarubicin, 1 mg/ml (1,000 ppm)	Sigma Aldrich, Lot# R080E0; Expiration 12/2019
Mesna, 100 mg/ml (100,000 ppm)	Sigma Aldrich; Lot# LRAB9114; Expiration 12/2022
Mitomycin C, 0.5 mg/ml (500 ppm)	Sigma Aldrich; Lot# MKCD6056; Expiration 03/2020
Paclitaxel, 6 mg/ml (6,000 ppm)	Hospira; Lot# F066865AA; Expiration 08/31/2020
Trisenox, 1 mg/ml (1,000 ppm)	Sigma Aldrich; CAS# 1327-53-3; Expiration 11/2020
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	USP; Lot# Y06331; Lot# 05/2020

COLLECTION MEDIA:
Table 2. Collection Media for Test Chemicals

TESTING CHEMOTHERAPY DRUGS	COLLECTION MEDIUM
Blenoxane (Bleomycin), 15 mg/ml (15,000 ppm)	Distilled Water
Cyclophosphamide, 20 mg/ml (20,000 ppm)	Distilled Water
Cytarabine, 100 mg/ml (100,000 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
Idarubicin, 1 mg/ml (1,000 ppm)	Distilled Water
Mesna, 100 mg/ml (100,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Paclitaxel, 6 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Trisenox, 1 mg/ml (1,000 ppm)	Distilled Water
Vincristine Sulfate, 1 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 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area

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)
Blenoxane (Bleomycin), 15 mg/ml (15,000 ppm)	290
Cyclophosphamide, 20 mg/ml (20,000 ppm)	200
Cytarabine, 100 mg/ml (100,000 ppm)	272
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	205
Fluorouracil (5 Flu), 50 mg/ml (50,000 ppm)	269
Idarubicin, 1 mg/ml (1,000 ppm)	257
Mesna, 100 mg/ml (100,000 ppm)	202
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Paclitaxel, 6 mg/ml (6,000 ppm)	231
Trisenox, 1 mg/ml (1,000 ppm)	197
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	220

SAMPLE CHARACTERISTICS:

Table 4. Cuff Thickness characteristics for the tested specimens: Blue Glove.

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Blenoxane (Bleomycin)	0.059	0.061	0.056	0.059
Cyclophosphamide	0.055	0.064	0.052	0.057
Cytarabine	0.058	0.054	0.055	0.056
Etoposide (Toposar)	0.057	0.060	0.059	0.059
Fluorouracil (5 Flu)	0.065	0.060	0.064	0.063
Idarubicin	0.059	0.057	0.056	0.057
Mesna	0.061	0.060	0.054	0.058
Mitomycin C	0.056	0.059	0.052	0.056
Paclitaxel	0.062	0.063	0.058	0.061
Trisenox	0.063	0.055	0.049	0.056
Vincristine Sulfate	0.063	0.053	0.053	0.057
Weight/Unit Area (g/m2)	**59.4**			

RESULTS:

Table 5. Permeation Test Results on: Blue Glove

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
Blenoxane (Bleomycin), 15 mg/ml (15,000 ppm)	>240	N/A	Slight swelling and no degradation
Cyclophosphamide, 20 mg/ml (20,000 ppm)	>240	N/A	Slight swelling and no degradation
Cytarabine, 100 mg/ml (100,000 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
Idarubicin, 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Mesna, 100 mg/ml (100,000 ppm)	>240	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	>240	N/A	Slight swelling and no degradation
Paclitaxel, 6 mg/ml (6,000 ppm)	>240	N/A	Slight swelling and no degradation
Trisenox, 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation

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