

August 6, 2019

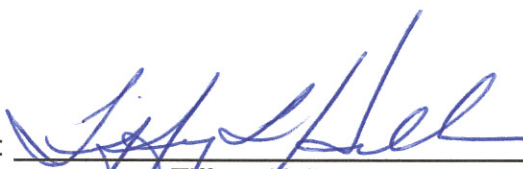
TEST REPORT


PN 149079

PHARMACEUTICAL SERVICES

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Tian's International, Inc.

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

RECEIVED: Two (2) Gowns identified as; USP800 Barrier Gown.

TEST CHEMICALS:

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	Sigma Aldrich; Lot # 018M4057V; Expiration 04/2020
Thiotepa (THT), 10 mg/ml (10,000 ppm)	Sigma Aldrich; Lot# SLBZ3176, Expiration 05/2020

COLLECTION MEDIA:

Table 2. Collection Media for Test Chemicals

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Thiotepa (THT), 10 mg/ml (10,000 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:	Seam 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 DRUG	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Thiotepa (THT), 10 mg/ml (10,000 ppm)	199

SAMPLE CHARACTERISTICS:

Table 4. Seam Thickness characteristics for the tested: USP800 Barrier Gown.


Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Carmustine (BCNU)	0.485	0.539	0.276	0.433
Thiotepa (THT)	0.484	0.551	0.533	0.523
Weight/Unit Area (g/m²)	148.0			

RESULTS:

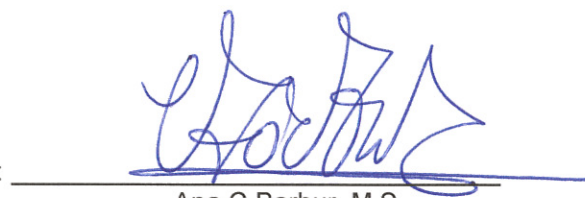
Table 5. Permeation Test Results on Seam Testing of: USP800 Barrier Gown.

TEST CHEMOTHERAPY DRUGS	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
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	27.6 (27.6,27.6,28.4)	0.01 (0.01,0.01,0.01)	No significant changes
Thiotepa (THT), 10 mg/ml (10,000 ppm)	>240 min.	0	No significant changes

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