



Testing. Development. Problem Solving.

May 4, 2023

TEST REPORT

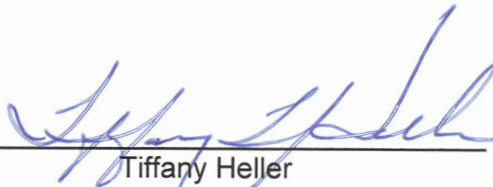
PN 169302D
PO# 1388

PHARMACEUTICAL SERVICES

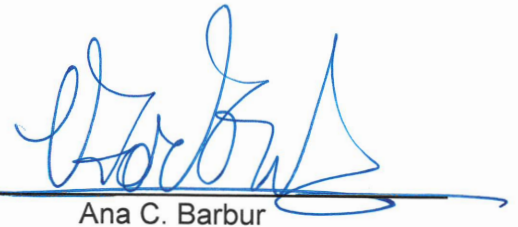
Prepared For:

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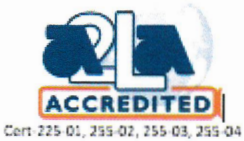
Prepared By:


Tiffany Heller
Manager, Pharmaceutical Services

Approved By:


Ana C. Barbur
Vice President, Analytical & Chemical Services

DCN 1176



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TrueCare BiomedixPage 2 of 5
PN 169302D**SUBJECT:** Permeation Testing per ASTM F739-20 on samples submitted by the above company.**RECEIVED:** One (1) sample type identified by customer as; TCBAFST – Bouffant, Lot Number 13880323-2.**TEST CHEMICALS:**

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Cisplatin, 1 mg/ml (1,000 ppm)	Accord; Lot# P2106582; Expiration 09/2023
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	Hikma; Lot# BJ01110; Expiration 08/2023

COLLECTION MEDIA:

Table 2. Collection Media for Test Drug

TESTING CHEMOTHERAPY DRUGS	COLLECTION MEDIA
Cisplatin, 1 mg/ml (1,000 ppm)	Distilled Water
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM F739-20
Permeation Test Cell Size:	1" Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	27.0°C ± 1.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm ²
Selected Data Points:	49/test
Number of Specimens Tested:	3/test
Location Sampled From:	At random from material

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PN 169302D**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 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)
Cisplatin, 1 mg/ml (1,000 ppm)	199
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	232

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested: TCBAFST – Bouffant, Lot Number 13880323-2.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Cisplatin	0.208	0.187	0.205	0.200
Doxorubicin HCl	0.209	0.216	0.191	0.206
Weight/Unit Area (g/m²)	55.5			

RESULTS:

Table 5. Permeation Test Results on testing of: TCBAFST – Bouffant, Lot Number 13880323-2.

TESTING CHEMOTHERAPY DRUGS	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	AVERAGE STANDARDIZED BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	AVERAGE CUMULATIVE PERMATION (Specimen 1/2/3) (µg/cm ²)	AVERAGE STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm ² /min)	OTHER OBSERVATIONS
Cisplatin, 1 mg/ml (1,000 ppm)	>480 min.	>480 min.	<0.1	<0.1	No significant changes
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	>480 min.	>480 min.	<0.1	<0.1	No significant changes

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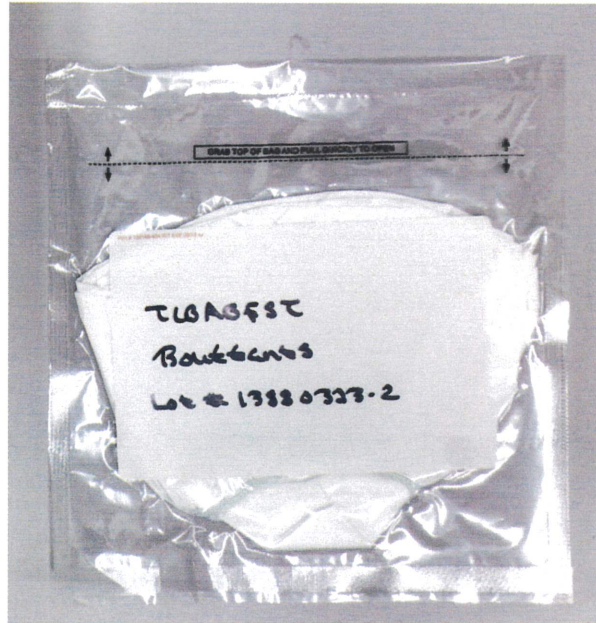
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SAMPLES RECEIVED:

TCBABFST – Bouffant,
Lot Number 13880323-2



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APPENDIX

Testing Location: 2887 Gilchrist Road, Akron Ohio 44305

Decision Rules

Customer Selected Decision Rule: Decision Rule 1

RULE 1.

This is the way test results have traditionally been reported by ARDL. If ARDL runs a test for you that has pass/fail requirements, ARDL will report the values observed and then state "Pass" or "Fail", based on those values only. By default, ARDL will apply this rule to all Category I tests and those tests which are not on ARDL's Scope of Accreditation.

RULE 2.

This rule takes into account the calculated measurement uncertainty of test results generated. Every test and piece of test equipment has an inherent amount of measurement uncertainty associated with it. Rule 2 establishes "Guard Bands", where the measurement uncertainty value is added to the Minimum Passing requirement and is subtracted from the Maximum Passing requirement. The Pass/Fail requirements thus become tighter and customers may be more "Certain" of their Pass/Fail result.

RULE 3.

This rule also takes into account measurement uncertainty but does not set up guard bands. Rule 3 may be used when values are reported, but there is no Pass/Fail requirement called out in the test specification. Rule 3 simply states that the measurement uncertainty is reported to the customer, along with the testing result generated, and the customer decides if the results are suitable for their purposes.

REPORT REVISIONS:

DATE

05/04/2023

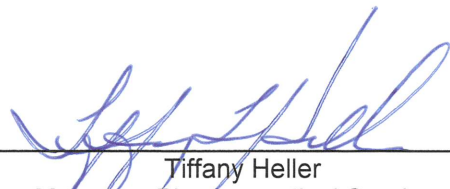
REVISION #

N/A

DETAILS


Original Final Report

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Approved By:



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Vice President, Analytical & Chemical Services

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