

ISO 16604 Viral Penetration Final Report

Test Article: Demron-C
 Study Number: 1290356-S01
 Study Received Date: 20 Apr 2020
 Testing Facility: Nelson Laboratories, LLC
 6280 S. Redwood Rd.
 Salt Lake City, UT 84123 U.S.A.
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0174 Rev 04
 Deviation(s): None

Summary: This test method was performed to evaluate the barrier performance of protective materials which are intended to protect against blood borne pathogen hazards. Test articles were conditioned for a minimum of 24 hours at $21 \pm 5^\circ\text{C}$ and $60 \pm 10\%$ relative humidity (RH), and then tested for viral penetration using a ΦX174 bacteriophage suspension. At the conclusion of the test, the observed side of the test article was rinsed with a sterile medium and assayed for the presence of ΦX174 bacteriophage. The viral penetration method complies with ISO 16604. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested: 6 (3 per procedure)
 Number of Test Articles Passed: 6
 Test Article Side Tested: Grey Side
 Test Article Preparation: Received Precut
 Test Article Sealed: Paraffin Wax
 Exposure Procedure: A (No retaining screen)
 C (no retaining screen; 0 kPa)
 Compatibility Ratio: 1.1
 Settle Plate Results: Acceptable

Results:

Procedure A (1-3):

Test Article Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
1-3	3.3×10^8	1.8×10^8	$<1^a$	None Seen	Pass
Negative Control	3.3×10^8	1.8×10^8	$<1^a$	None Seen	Acceptable
Positive Control	3.3×10^8	1.8×10^8	TNTC ^b	Yes	Acceptable

^a A value of <1 plaque forming units (PFU)/mL is reported for assay plates showing no plaques.

^b TNTC = PFU were too numerous to count.

Study Director

Jennifer Jorgenson, B.S., RM(NRCM)

30 Apr 2020
Study Completion Date



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Procedure C (1-3):

Test Article Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
1-3	3.3×10^8	1.8×10^8	<1 ^a	None Seen	Pass
Negative Control	3.3×10^8	1.8×10^8	<1 ^a	None Seen	Acceptable
Positive Control	3.3×10^8	1.8×10^8	TNTC ^b	Yes	Acceptable

^a A value of <1 PFU/mL is reported for assay plates showing no plaques.

^b TNTC = PFU were too numerous to count.