NELSON LABORATORIES

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Viral Penetration ASTM Method F 1671 GLP Report

Test Article:	Polyurethane sheets with weld seam, treated with a dose of gamma radiation at 25-50 kGy. LOT 19082016
Study Number:	920189-S01
Study Received Date:	03 Oct 2016
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0062 Rev 14

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 ± 5°C and 30-80% 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 ASTM F1671 sampling was at the discretion of the sponsor. All test method acceptance criteria were met.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	32
Test Article Side Tested:	Outside
Test Article Preparation:	Cut from the Seam at Random
Exposure Procedure:	B (Retaining Screen: Woven Polyester Mesh, with >50% Open Area)
Compatibility Ratio:	1.4
Environmental Plate Results:	Acceptable

Results:

Test Article Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
1-32	1.7×10^8	1.6×10^8	<1[a]	None Seen	Pass
Negative Control	1.7×10^8	1.6×10^8	<1[a]	None Seen	Acceptable
Positive Control	1.7×10^8	1.6×10^8	1.1×10^1	Yes	Acceptable

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

Test Method Acceptance Criteria: The negative control must be negative for viral penetration. The positive control must be positive for viral penetration. The post challenge titer must be ≥1.0×10^8 PFU/mL.

ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Study Director — Jennifer Jorgenson, B.S.

01 NOV 2016
Study Completion Date

920189-S01

Procedure: The test articles were loaded into the test cells and the bolts were torqued to 13.6 Newton meters (120 inch pounds) in a criss cross technique. Test articles were challenged with the maximum test cell capacity of approximately 55-60 mL of a ΦX174 bacteriophage suspension for 5 minutes at atmospheric pressure, 1 minute at 2.0 psig (13.8 kPa), then 54 minutes at atmospheric pressure or until liquid penetration was observed. At the conclusion of the test procedure, the bacteriophage suspension was drained from the test cell and collected to determine the post ΦX174 bacteriophage concentration. The observed side of the test article was rinsed with 5 mL of a sterile assay medium and then recovered from the surface of the test article with a sterile pipette. The collected fluid was assayed for the presence of the ΦX174 bacteriophage. The fluid was plated in duplicate using 0.5 mL aliquots. The surface tension of the challenge suspension and the assay medium was adjusted to approximately 40-44 dynes/cm using surfactant-type Tween® 80 at a final concentration of approximately 0.01% by volume.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	13 Oct 2016
Phase Inspected by Quality Assurance: Plating	21 Oct 2016
Audit Results Reported to Study Director	26 Oct 2016
Audit Results Reported to Management	26 Oct 2016

Scientists	Title
Adam Meese	Supervisor
Jennifer Jorgenson	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Quality Assurance

01 Nov 2016
Date