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Viral Penetration ASTM Method F 1671 Final Report

Test Article: DPT-T4
 DPT-HP
 Purchase Order: 1429
 Laboratory Number: 741704
 Study Received Date: 28 Feb 2014
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0062 Rev 12

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. 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: 2
 Number of Test Articles Passed: 2
 Test Article Side Tested: Either Side
 Test Article Preparation: Cut from Material at Random
 Exposure Procedure: B (Retaining Screen: Woven Polyester Mesh, with >50% Open Area)
 Compatibility Ratio: 24.7 (DPT-T4), 1.0 (DPT-HP)
 Environmental Plate Results: Acceptable

Results:

Test Article	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
DPT-T4	4.1 x 10 ⁹	3.4 x 10 ⁹	<1 ^a	None Seen	Pass
DPT-HP	2.2 x 10 ⁸	1.9 x 10 ⁸	<1 ^a	None Seen	Pass
Negative Control	4.1 x 10 ⁹	3.4 x 10 ⁹	<1 ^a	None Seen	Acceptable
Positive Control	2.2 x 10 ⁸	1.9 x 10 ⁸	TNTC ^b	Yes	Acceptable
Blank Control	N/A	N/A	<1 ^a	None Seen	Acceptable

^a A value of <1 plaque forming unit (PFU)/mL is reported for assay plates showing no plaques.
^b TNTC = PFU were too numerous to count.




 Study Director

Adam Meese, B.S.

19 Mar 2014
 Study Completion Date

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plp FRT0062-0001 Rev 5
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