Viral Penetration ASTM Method F 1671 Final Report

Test Article: Set# 1: Grade WL26403, Run# T31513, Lot# 361800174703
Purchase Order: 
Study Number: 
Study Received Date: 20 Jan 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. 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: 8
Number of Test Articles Passed: 8
Test Article Side Tested: Darker Side (Labeled Side)
Test Article Preparation: Cut from the Material at Random
Test Article Sealed: Paraffin Wax
Exposure Procedure: A (No retaining screen)
Compatibility Ratio: 1.0 per sponsor
Environmental Plate Results: Acceptable

Results:

<table>
<thead>
<tr>
<th>Test Article Number</th>
<th>Pre-Challenge Concentration (PFU/mL)</th>
<th>Post-Challenge Concentration (PFU/mL)</th>
<th>Assay Titer (PFU/mL)</th>
<th>Visual Penetration</th>
<th>Test Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-8</td>
<td>$2.5 \times 10^6$</td>
<td>$3.0 \times 10^6$</td>
<td>$&lt;1^a$</td>
<td>None Seen</td>
<td>Pass</td>
</tr>
<tr>
<td>Negative Control</td>
<td>$2.5 \times 10^6$</td>
<td>$3.0 \times 10^6$</td>
<td>$&lt;1^a$</td>
<td>None Seen</td>
<td>Acceptable</td>
</tr>
<tr>
<td>Positive Control</td>
<td>$2.5 \times 10^6$</td>
<td>$3.0 \times 10^6$</td>
<td>$1.5 \times 10^2$</td>
<td>Yes</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

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

Study Director: Jennifer Jorgenson, B.S.

Study Completion Date: 02 Feb 2016