### Bacterial Filtration Efficiency (BFE) Final Report

**Test Article:** 95F - 1  
**Purchase Order:** 101818  
**Study Number:** 1112599-S01  
**Study Received Date:** 23 Oct 2018  
**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: STP0004 Rev 15  
**Deviations:** None

### Summary

The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 2.7 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 μm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-14, EN 14683:2014, Annex B, and AS4381:2015.

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.

<table>
<thead>
<tr>
<th>Test Side</th>
<th>BFE Test Area</th>
<th>BFE Flow Rate</th>
<th>Conditioning Parameters</th>
<th>Positive Control Average</th>
<th>Negative Monitor Count</th>
<th>MPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Either</td>
<td>~40 cm²</td>
<td>28.3 Liters per minute (L/min)</td>
<td>85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours</td>
<td>2.5 x 10^3 CFU</td>
<td>&lt;1 CFU</td>
<td>3.0 μm</td>
</tr>
</tbody>
</table>

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**Study Director**  
Janelle R. Bentz, M.S.  
**Study Completion Date**  
31 Oct 2018
Results:

<table>
<thead>
<tr>
<th>Test Article Number</th>
<th>Percent BFE (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&gt;99.9&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>2</td>
<td>&gt;99.9&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>3</td>
<td>&gt;99.9&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>4</td>
<td>&gt;99.9&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>5</td>
<td>&gt;99.9&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup> There were no detected colonies on any of the Andersen sampler plates for this test article.

The filtration efficiency percentages were calculated using the following equation:

\[
\% BFE = \frac{C - T}{C} \times 100
\]

C = Positive control average  
T = Plate count total recovered downstream of the test article  
Note: The plate count total is available upon request