

## Bacterial Filtration Efficiency (BFE) Final Report

Test Article: LOT: 47201GC  
Study Number: 1349912-S01  
Study Received Date: 06 Oct 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: STP0004 Rev 18  
Deviation(s): 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  $1.7 - 3.0 \times 10^3$  colony forming units (CFU) with a mean particle size (MPS) of  $3.0 \pm 0.3 \mu\text{m}$ . The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

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.

Test Side: Inside  
BFE Test Area:  $\sim 7.8 \text{ cm}^2$   
BFE Flow Rate: 28.3 Liters per minute (L/min)  
Conditioning Parameters:  $85 \pm 5\%$  relative humidity (RH) and  $21 \pm 5^\circ\text{C}$  for a minimum of 4 hours  
Test Article Dimensions:  $\sim 216 \text{ mm} \times \sim 165 \text{ mm}$   
Positive Control Average:  $2.6 \times 10^3$  CFU  
Negative Monitor Count:  $<1$  CFU  
MPS:  $2.9 \mu\text{m}$



Sean Shepherd electronically approved for  
Study Director

James Luskin

09 Nov 2020 17:19 (+00:00)

Study Completion Date and Time

**Results:**

Test Article Number	Percent BFE (%)
1	99.6
2	99.8
3	99.5
4	99.5
5	99.4

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