

## Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article: FMPV2020L  
SAMPLE #B1  
SAMPLE #B2  
SAMPLE #B3  
SAMPLE #B4  
SAMPLE #B5  
Purchase Order: NGPO\_0182020  
Study Number: 1274106-S01  
Study Received Date: 05 Mar 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.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

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: Sponsor Labeled Side  
BFE Test Area:  $\sim 40 \text{ cm}^2$   
BFE Flow Rate: 28.3 Liters per minute (L/min)  
Delta P Flow Rate: 8 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  
Positive Control Average:  $1.8 \times 10^3$  CFU  
Negative Monitor Count:  $<1$  CFU  
MPS:  $3.0 \mu\text{m}$

Study Director

  
James W. Luskin

21 Mar 2020  
Study Completion Date



1274106-S01

**Results:**

Test Article Number	Percent BFE (%)
1	99.8
2	99.9
3	99.9
4	99.9
5	>99.9

Test Article Number	Delta P (mm H <sub>2</sub> O/cm <sup>2</sup> )	Delta P (Pa/cm <sup>2</sup> )
1	4.9	48.2
2	4.9	48.3
3	6.0	58.6
4	5.0	48.6
5	5.6	55.2

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

## Viral Filtration Efficiency (VFE) Final Report

Test Article: FMPV2020L  
SAMPLE NO: V1  
SAMPLE NO: V2  
SAMPLE NO: V3  
SAMPLE NO: V4  
SAMPLE NO: V5  
Purchase Order: NGPO\_0182020  
Study Number: 1274107-S01  
Study Received Date: 05 Mar 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: STP0007 Rev 16  
Deviation(s): None

**Summary:** The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage  $\Phi$ X174 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  $1.1 - 3.3 \times 10^3$  plaque forming units (PFU) with a mean particle size (MPS) of  $3.0 \mu\text{m} \pm 0.3 \mu\text{m}$ . The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure was adapted from ASTM F2101.

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: Sponsor Labeled Side  
Test Area:  $\sim 40 \text{ cm}^2$   
VFE 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  
Positive Control Average:  $1.9 \times 10^3$  PFU  
Negative Monitor Count:  $<1$  PFU  
MPS:  $3.2 \mu\text{m}$

  
Study Director

  
James W. Luskin

  
Study Completion Date



1274107-S01



**Results:**

Test Article Number	Percent VFE (%)
V1	99.8
V2	>99.9 <sup>a</sup>
V3	99.9
V4	99.7
V5	99.8

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

The filtration efficiency percentages were calculated using the following equation:

$$\% VFE = \frac{C - T}{C} \times 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request