

## Viral Filtration Efficiency (VFE) Final Report

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Test Article: NnF MBRANE® BreaSAFE PA6  
Study Number: 1366181-S01.1 Amended  
Study Received Date: 23 Nov 2020  
Study Completion Date: 29 Dec 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 ΦX174 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: Either  
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:  $1.3 \times 10^3$  PFU  
Negative Monitor Count:  $< 1$  PFU  
MPS:  $2.9 \mu\text{m}$



Mikell Goldsberry electronically approved  
Study Director

Mikell Goldsberry

09 Jan 2021 00:00 (+00:00)

Amended Report Date and Time

**Results:**

Test Article Number	Percent VFE (%)
1	>99.9 <sup>a</sup>
2	>99.9 <sup>a</sup>

<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

**Amendment Justification:** At the request of the sponsor, the test article was changed from "NnF MBRANE® PA6+Ag" to "NnF MBRANE® BreaSAFE PA6".