

## Viral Filtration Efficiency (VFE) Final Report

Test Article: NL Virus Filtration  
Purchase Order: NANO0027  
Study Number: 858972-S01  
Study Received Date: 20 Nov 2015  
Test Procedure(s): Standard Test Protocol (STP) Number: STP0007 Rev 12

**Summary:** The VFE test is performed to determine the filtration efficiency by comparing the upstream viral control counts to downstream test article counts. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at  $1.1 - 3.3 \times 10^3$  plaque forming units (PFU) with a mean particle size (MPS) at  $3.0 \mu\text{m} \pm 0.3 \mu\text{m}$ . The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This method allows a reproducible challenge to be delivered to the test articles. The VFE test procedure was adapted from ASTM F2101-07.

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 Side  
Area Tested:  $\sim 40 \text{ cm}^2$   
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:  $1.5 \times 10^3$  PFU  
Negative Monitor Count:  $<1$  PFU  
MPS:  $2.8 \mu\text{m}$

### Results:

Test Article Number	Percent VFE (%)
1	>99.9
2	99.9
3	99.9
4	99.7
5	99.9

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



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