

## Viral Filtration Efficiency (VFE) Final Report

Test Article: 15040822, 15040823, 15040824, 15040825, 15040826  
Purchase Order: NA2410  
Laboratory Number: 823918  
Study Received Date: 27 May 2015  
Test Procedure(s): Standard Test Protocol (STP) Number: STP0007 Rev 11

**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  $\Phi$ X174 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  $2,200 \pm 1,100$  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: Inside  
Area Tested:  $\sim 45.6 \text{ cm}^2$   
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: 2,362 PFU  
Negative Monitor Count:  $<1$  PFU  
MPS:  $3.0 \mu\text{m}$

### Results:

Test Article	Percent VFE (%)
15040822	$>99.9^a$
15040823	$>99.9^a$
15040824	$>99.9^a$
15040825	$>99.9^a$
15040826	$>99.9^a$

<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:

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

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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*09 Jun 2015*  
Study Completion Date