

## Viral Filtration Efficiency (VFE) Final Report

Test Article: CSM.02+V  
 Study Number: 1363975-S01  
 Study Received Date: 17 Nov 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: Inside  
 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:  $1.8 \times 10^3$  PFU  
 Negative Monitor Count:  $<1$  PFU  
 MPS:  $3.3 \mu\text{m}$

### Results:

Test Article Number	Percent VFE (%)
1	99.2
2	99.6
3	99.8
4	99.3
5	99.6



Sean Shepherd electronically approved for  
Study Director

Mikell Goldsberry

21 Dec 2020 20:01 (+00:00)  
Study Completion Date and Time

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