

## Viral Filtration Efficiency (VFE) at an Increased Challenge Level Final Report

Test Article: 40920 / 1234.1803.20  
 Study Number: 1356229-S01  
 Study Received Date: 27 Oct 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: STP0010 Rev 15  
 Deviation(s): None

**Summary:** This test procedure was performed to evaluate the VFE of test articles at an increased challenge level. A suspension of ΦX174 bacteriophage was delivered to the test article at a challenge level of greater than  $10^6$  plaque-forming units (PFU) to determine the filtration efficiency. The challenge was aerosolized using a nebulizer and delivered to the test article at a fixed air pressure and flow rate of 30 liters per minute (LPM). The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) for collection. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber. The mean particle size (MPS) control was performed at a flow rate of 28.3 LPM using a six-stage, viable particle, Andersen sampler for collection. The VFE at an Increased Challenge Level test procedure was adapted from ASTM F2101.

This test procedure was modified from Nelson Laboratories, LLC (NL), standard VFE test procedure in order to employ a more severe challenge than would be experienced in normal use. 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.

Challenge Flow Rate: 30 LPM  
 Area Tested: Entire Test Article  
 Side Tested: Side with Blue Cap  
 Challenge Level:  $8.6 \times 10^6$  PFU  
 MPS:  $\sim 2.9 \mu\text{m}$   
 Test Monitor Results: Acceptable

### Results:

Test Article Number	Total PFU Recovered	Filtration Efficiency (%)
1	$6.6 \times 10^2$	99.9923
2	$9.7 \times 10^2$	99.989
3	$5.8 \times 10^2$	99.9933

James Luskin electronically approved  
 Study Director

James Luskin

30 Nov 2020 18:52 (+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 = Challenge Level

T = Total PFU recovered downstream of the test article