

Viral Filtration Efficiency (VFE) Final Report

Test Article: VK RespiPro
 Study Number: 1422790-S01
 Study Received Date: 02 Jun 2021
 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: Inside
 Test Area: $\sim 7.8 \text{ cm}^2$
 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: 1.8×10^3 PFU
 Negative Monitor Count: <1 PFU
 MPS: $3.0 \mu\text{m}$

Results:

Test Article Number	Percent VFE (%)
1	99.1

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



Mikell Goldsberry electronically approved
 Study Director

Mikell Goldsberry

16 Jun 2021 04:22 (+00:00)
 Study Completion Date and Time