NELSON LABORATORIES

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Viral Filtration Efficiency (VFE) Final Report

Test Article:	Standard Cambridge Mask w/ Carbon Filter
Laboratory Number:	823624
Study Received Date:	26 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 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 2,200 ± 1,100 plaque forming units (PFU) with a mean particle size (MPS) at 3.0 µm ± 0.3 µm. 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:	Entire Test Article
VFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours.
Positive Control Average:	2,212 PFU
Negative Monitor Count:	<1 PFU
MPS:	3.2 µm

Results:

Test Article Number	Percent VFE (%)
1	99.8
2	99.6
3	99.3
4	99.7
5	99.7

The filtration efficiency percentages were calculated using the following equation:

$$\%\,VFE = \frac{C - T}{C}\ x\ 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

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Study Completion Date