NELSON LABORATORIES

Viral Filtration Efficiency (VFE) Final Report

Test Article: PTFE Face Mask
Study Number: 892417-S01
Study Received Date: 12 May 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0007 Rev 13

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 1.1 - 3.3 x 10^3 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.

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: Either Side
Area Tested: ~40 cm^2
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: 2.0 x 10^3 PFU
Negative Monitor Count: <1 PFU
MPS: 2.9 µm

Results:

Test Article Number	Percent VFE (%)
1	>99.9[a]
2	>99.9[a]
3	>99.9[a]
4	>99.9[a]
5	>99.9[a]

[a] 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:

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

C = Positive control average

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

Technical Reviewer

ANAB ACCREDITED TESTING LABORATORY

Study Director Trang Truong, B.S.

31 May 2016
Study Completion Date

892417-S01

NELSON LABORATORIES

Dioctyl Phthalate (DOP) Aerosol Test Final Report

Test Article: PTFE Face Mask
Study Number: 895418-S02
Study Received Date: 26 May 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0015 Rev 05

Summary: This procedure was performed to evaluate the particle penetration and airflow resistance properties of filtration materials. A neutralized, polydispersed aerosol of DOP was generated and passed through the test article. The filtration performance and airflow resistance of each test article was calculated.

The filter tester used in this procedure was a TSI® CERTITEST® Model 8130 Automated Filter Tester that is capable of efficiency measurements of up to 99.999%. The tester produces a particle size distribution with a count median diameter of 0.185 ± 0.020 µm and a geometric standard deviation not exceeding 1.60 µm as determined by a scanning mobility particle sizer (SMPS). The mass median diameter is approximately 0.33 µm, which is generally accepted as the most penetrating aerosol size. 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.

Area Tested: Entire Respirator
Airflow Rate: ~28.3 Liters per minute (L/min)
Test Type: Initial Penetration (~1 min. LOAD Test)
Test Side: Outside

Results:

Test Article Number	Airflow Resistance (mm H_2O)	Particle Penetration (%)	Filtration Efficiency (%)
2	2.8	4.64	95.36

Study Director Brandon L. Williams

14 Jun 2016
Study Completion Date

895418-S02