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Viral Filtration Efficiency (VFE) Final Report

Test Article: i-Life 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:

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

C = Positive control average

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

Technical Reviewer

ANAB ACCREDITED TESTING LABORATORY

Study Director Trang Truong, B.S.

31 May 2016
Study Completion Date

892417-S01