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Viral Filtration Efficiency (VFE) Final Report

Test Article: AFM015FLY
AFM020FLY
AFM025FMY
AFM025UMY
AFM025SMY
Laboratory Number: 802333
Study Received Date: 04 Feb 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.

Area Tested: ~45.6 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.

Results:

Test Article	Percent VFE (%)
AFM015FLY	99.5
AFM020FLY	99.6
AFM025FMY	99.2
AFM025UMY	99.8
AFM025SMY	99.3

Positive Control Average: 1,630 PFU
Negative Monitor Count: <1 PFU
MPS: 2.9 µm

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

Study Director Sarah Smit, B.S.

13 Feb 2015
Study Completion Date