Viral Filtration Efficiency (VFE) at an Increased Challenge Level Final Report

Test Article:
Purchase Order: T18B02172
Study Number: 1104770-S01
Study Received Date: 03 Oct 2018
Testing Facility:

Test Procedure(s): Standard Test Protocol (STP) Number: STP0010 Rev 12
Deviation(s): None

Summary: This test procedure was performed to evaluate the VFE of test articles at an increased challenge level. A suspension of ΦX174 bacteriophage was delivered to the test article at a challenge level of greater than 10^7 plaque-forming units (PFU) to determine the filtration efficiency. The challenge was aerosolized using a nebulizer and delivered to the test article at a fixed air pressure and flow rate of 30 liters per minute (LPM). The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) for collection. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber. The mean particle size (MPS) control was performed at a flow rate of 28.3 LPM using a six-stage, viable particle, Andersen sampler for collection. The VFE at an Increased Challenge Level test procedure was adapted from ASTM F2101.

This test procedure was modified from   ), standard VFE test procedure in order to employ a more severe challenge than would be experienced in normal use. 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.

Challenge Flow Rate: 30 LPM
Area Tested: ~40 cm^2
Side Tested: Smooth, Flat Side
Challenge Level: 6.4×10^7 PFU
MPS: ~2.7 μm
Test Monitor Results: Acceptable

Study Director

For Janelle R. Bentz, M.S.

16 Oct 2018
Study Completion Date

Results:

Test Article Number	Total PFU Recovered	Filtration Efficiency (%)
1	2.1×10^4	99.968
2	1.2×10^4	99.981
3	3.5×10^4	99.945
4	1.1×10^4	99.982
5	1.6×10^4	99.976

The filtration efficiency percentages were calculated using the following equation:

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

C = Challenge Level
T = Total PFU recovered downstream of the test article

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Bacterial Filtration Efficiency (BFE) at an Increased Challenge Level Final Report

Test Article:
Purchase Order: T18B02172
Study Number: 1104771-S01
Study Received Date: 03 Oct 2018
Testing Facility:

Test Procedure(s): Standard Test Protocol (STP) Number: STP0009 Rev 11
Deviation(s): None

Summary: This test procedure was performed to evaluate the BFE of test articles at an increased challenge level. A suspension of *Staphylococcus aureus*, ATCC #6538, was delivered to the test article at a challenge level of greater than 10^7 colony forming units (CFU). The challenge was aerosolized using a nebulizer and delivered to the test article at a fixed air pressure and flow rate of 30 liters per minute (LPM). The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) for collection. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber. The mean particle size (MPS) control was performed at a flow rate of 28.3 LPM using a six-stage, viable particle, Andersen sampler for collection.

This test procedure was modified from   , standard BFE procedure in order to employ a more severe challenge than would be experienced in normal use. This method 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.

Challenge Flow Rate: 30 LPM
Area Tested: ~40 cm^2
Side Tested: Smooth, Flat Side
Challenge Level: 1.6×10^7 CFU
MPS: ~2.7 μm
Test Monitor Results: Acceptable

_____ For _16 Oct 2018_
Study Director   Janelle R. Bentz, M.S. Study Completion Date

Results:

Test Article Number	Total CFU Recovered	Filtration Efficiency (%)
1	3.8×10^1	99.99977
2	6.7×10^1	99.99959
3	2.0×10^2	99.9988
4	1.2×10^2	99.99924
5	3.4×10^1	99.99979

The filtration efficiency percentages were calculated using the following equation:

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

C = Challenge Level
T = Total CFU recovered downstream of the test article