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

Test Article: VR 010 Lot # SY1502007
Laboratory Number: 809059
Study Received Date: 11 Mar 2015
Test Procedure(s): Standard Test Protocol (STP) Number: STP0009 Rev 07

Summary: This procedure was performed to evaluate the BFE at an increased challenge level of the test article. A suspension of *Staphylococcus aureus*, ATCC #6538, was delivered to the test article to determine filtration efficiency. A challenge level of greater than 10^7 colony forming units (CFU) was pumped through a nebulizer using a peristaltic pump at a controlled flow rate and fixed air pressure. The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) in parallel. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber.

This test procedure was modified from Nelson Laboratories, Inc. (NLI), 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 Liters per Minute (L/min)
Area Tested: Entire Test Article
Side Tested: ~22 mm OD Port

Results:

Test Article Number	Total CFU Recovered	Filtration Efficiency (%)
1	1.0×10^2	99.99934
2	5.6×10^1	99.99963
3	4.5×10^1	99.99970

Challenge Level: 1.5×10^7 CFU
Mean Particle Size (MPS): ~3.2 µm

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

Technical Reviewer

Study Director Janelle R. Bentz, M.S.

16 Mar 2015
Study Completion Date

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

Test Article: VR 010 Lot # SY1502007
Laboratory Number: 809058
Study Received Date: 11 Mar 2015
Test Procedure(s): Standard Test Protocol (STP) Number: STP0010 Rev 07

Summary: This procedure was performed to evaluate the VFE at an increased challenge level of the test article. A suspension of ΦX174 bacteriophage was delivered to the test article to determine filtration efficiency. A challenge level of greater than 10^6 plaque-forming units (PFU) was pumped through a nebulizer using a peristaltic pump at a controlled flow rate and a fixed air pressure. The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) in parallel. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber.

This test procedure was modified from Nelson Laboratories, Inc. (NLI), standard VFE test 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 Liters per minute (L/min)
Area Tested: Entire Test Article
Side Tested: ~22 mm OD Port

Results:

Test Article Number	Total PFU Recovered	Filtration Efficiency (%)
1	1.4×10^2	99.9977
2	2.4×10^2	99.9962
3	1.8×10^2	99.9972

Challenge Level: 6.3×10^6 PFU
Mean Particle Size (MPS): ~3.2 µm

The filtration efficiency percentages were calculated using the following equation:

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

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

Technical Reviewer

Study Director Janelle R. Bentz, M.S.

26 Mar 2015
Study Completion Date