

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

Test Article: 3.1
 3.2
 3.3
 Laboratory Number: 813177B.1 Amended
 Study Received Date: 01 Apr 2015
 Study Completion Date: 13 Apr 2015
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0009 Rev 07



Nelson Laboratories
 H2-Filtermundstücke Tr
 3.1, 3.2, 3.3 (BFE)
 27.04.2015
 20.05.2015

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: Lip Side
 Appendix A Number of Pages: 1

Results:

Test Article	Total CFU Recovered	Filtration Efficiency (%)
3.1	$\sim 8.6 \times 10^2$	~ 99.9939
3.2	$\sim 9.9 \times 10^2$	~ 99.9930
3.3	2.7×10^3	99.981

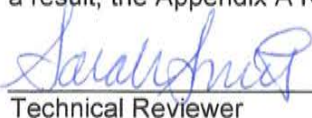
Challenge Level: 1.4×10^7 CFU
 Mean Particle Size (MPS): $\sim 3.0 \mu\text{m}$

The filtration efficiency percentages were calculated using the following equation:

$$\% \text{ BFE} = \frac{C - T}{C} \times 100$$

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

Amendment Justification: At the request of the sponsor, Appendix A was added to the initial report. As a result, the Appendix A Number of Pages was added to the summary section.


 Technical Reviewer


 Study Director

Janelle R. Bentz, M.S.

27 Apr 2015

Amended Report Date



Appendix A

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

Test Article: 3.1
 3.2
 3.3
 Laboratory Number: 813177B
 Study Received Date: 01 Apr 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.

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 Technical Reviewer



 Study Director

Janelle R. Bentz, M.S.

13 Apr 2015

 Study Completion Date

Test Article Description: The test articles were referred to as "mouthpieces with bacterial/viral filter for hydrogen breath test analyser LactoFAN2" by the sponsor. The test articles were made up of a yellow plastic housing that was ~55 mm long and ~25 mm in diameter, conically shaped. The filter material was contained within this tight housing construction inside of the mouthpiece. Per sponsor, the applied flow rate of 30 L/min during testing was chosen based on data from testing performed by the sponsor which determined the maximum exhalation power with several test subjects was 30 L/min.

