

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

Test Article: 225#1a
 Purchase Order: 7788
 Study Number: 924099-S01.1 Amended
 Study Received Date: 20 Oct 2016
 Study Completion Date: 11 Nov 2016
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0009 Rev 09
 Customer Specification Sheet (CSS) Number: 201604864 Rev 01

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 10⁵ colony forming units (CFU) was pumped through a nebulizer using a peristaltic pump at a flow rate of 28.3 liters per minute (L/min) 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. The mean particle size (MPS) control was performed at a flow rate of 28.3 L/min.

This test procedure was modified from Nelson Laboratories, LLC (NL), 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. NL has not performed validation using the flow rate performed in this testing, however, adequate controls are included to verify the reliability of this study. 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: 28.3 L/min
 Area Tested: ~38.5 cm²
 Side Tested: Either Side
 Challenge Level: 1.0 x 10⁵ CFU
 MPS: ~3.1 μm

Results:

Test Article Number	Total CFU Recovered	Filtration Efficiency (%)
1	<1 ^a	>99.99902

^a There were no detected colonies on any of the assay plates for this test article.

The filtration efficiency percentages were calculated using the following equation:


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

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

Amendment Justification: At the request of the sponsor, the sponsor information was updated. Lanaco Limited (formerly Texus Fibre Limited) organized this test on behalf of Healthy Breath Limited.


 Study Director

 Trang Truong, B.S.


 Amended Report Date

