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Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	15040808, 15040809, 15040810, 15040811, 15040812
Purchase Order:	NA2410
Laboratory Number:	823921
Study Received Date:	27 May 2015
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 11

Summary: The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* 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 ± 500 colony forming units (CFU) 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 procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with ASTM F2101-07 and EN 14683:2014, Annex B.

The Delta P test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

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.

Test Side:	Inside
BFE Area Tested:	~45.6 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours.
Positive Control Average:	2,639 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm
Test Article Dimensions:	~105 mm x ~160 mm

ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Janelle Bentz
Study Director Janelle R. Bentz, M.S.

08 Jun 2015
Study Completion Date

Results:

Test Article	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
15040808	>99.9[a]	4.9	48.5
15040809	>99.9[a]	4.8	47.4
15040810	>99.9[a]	4.8	47.2
15040811	>99.9[a]	4.8	47.0
15040812	>99.9[a]	4.8	46.9

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request