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

Test Article: AFM015FLY
AFM020FLY
AFM025FMY
AFM025UMY
AFM025SMY
Laboratory Number: 802334
Study Received Date: 04 Feb 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.

BFE Area Tested: ~45.6 cm^2
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 L/min
Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours.

Results:

Test Article	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
AFM015FLY	99.6	1.4	14.0
AFM020FLY	>99.9	1.7	16.9
AFM025FMY	99.5	1.5	14.5
AFM025UMY	99.6	1.6	16.1
AFN025SMY	>99.9	1.3	12.5

Positive Control Average: 2,101 CFU
Negative Monitor Count: <1 CFU
MPS: 2.9 µm

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Technical Reviewer

Sarah Smith
Study Director Sarah Smit, B.S.

ACCREDITED TESTING

12 Feb 2015
Study Completion Date

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