

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 $2,200 \pm 500$ colony forming units (CFU) with a mean particle size (MPS) at $3.0 \mu\text{m} \pm 0.3 \mu\text{m}$. 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.

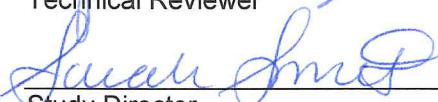
BFE Area Tested: $\sim 45.6 \text{ cm}^2$
 BFE Flow Rate: 28.3 Liters per minute (L/min)
 Delta P Flow Rate: 8 L/min
 Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours.

Results:

Test Article	Percent BFE (%)	Delta P (mm H ₂ O/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


 Technical Reviewer


 Study Director

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12 Feb 2015
 Study Completion Date