

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

Test Article: SXFC10
 Laboratory Number: 791558
 Study Received Date: 01 Dec 2014
 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.

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

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	99.8	3.2	31.6
2	99.8	3.0	29.6
3	99.7	3.0	29.2
4	99.9	2.9	28.8
5	99.8	3.0	29.1

Positive Control Average: 1,971 CFU
 Negative Monitor Count: <1 CFU
 MPS: $3.0 \mu\text{m}$
 Test Article Dimensions: $\sim 153 \text{ mm} \times \sim 150 \text{ mm}$


 Study Director

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10 Dec 2014
 Study Completion Date

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request