

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

Test Article: Totobobo F96-2014 / 6A
 Laboratory Number: 760988
 Study Received Date: 11 Jun 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 and EN14683, 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 EN14683, 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 Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	>99.9 ^a	1.2	11.4

Note: Plate count totals for each stage are available upon request.

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

Positive Control Average: 2,326 CFU
 Negative Monitor Count: <1 CFU
 MPS: 2.9 μm



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23 Jun 2014
 Study Completion Date