

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

Test Article: Suavel Protec (REF 80-900)
Suavel Comfort (REF 80-400)
Study Number: 912855-S01.1 Amended
Study Received Date: 25 Aug 2016
Study Completion Date: 31 Aug 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 13

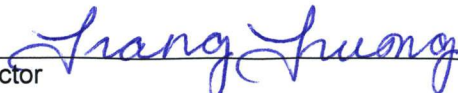
Summary: The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at $1.7 - 2.7 \times 10^3$ 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 F2101-14 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: $\sim 40 \text{ cm}^2$
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.
Test Article Dimensions: $\sim 155 \text{ mm} \times \sim 157 \text{ mm}$
Positive Control Average: 2.1×10^3 CFU
Negative Monitor Count: < 1 CFU
MPS: $2.8 \mu\text{m}$

Study Director



Trang Truong, B.S.



16 JAN 2017
Amended Report Date



912855-S01

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	99.6	1.9	18.3
2	99.7	1.7	16.7
3	99.8	1.8	17.5
4	99.6	1.6	16.0
5	99.5	1.7	16.3

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

Amendment Justification: At the request of the sponsor, " Suavel Comfort (REF 80-400)" was added to the test article ID.