

Bacterial Filtration Efficiency (BFE) Final Report

Test Article: MaiErTe M/B
 Purchase Order: 20181001
 Study Number: 1069727-S01
 Study Received Date: 06 Jul 2018
 Testing Facility: Nelson Laboratories, LLC
 6280 S. Redwood Rd.
 Salt Lake City, UT 84123 U.S.A.
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 15
 Deviation(s): None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at $1.7 - 2.7 \times 10^3$ colony forming units (CFU) with a mean particle size (MPS) of $3.0 \pm 0.3 \mu\text{m}$. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-14, EN 14683:2014, Annex B, and AS4381:2015.

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: Either
 BFE Test Area: $\sim 40 \text{ cm}^2$
 BFE Flow Rate: 28.3 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
 Test Article Preparation: 5 Swatches Cut from Material
 Positive Control Average: 2.1×10^3 CFU
 Negative Monitor Count: <1 CFU
 MPS: $2.7 \mu\text{m}$

Results:

Test Article Number	Percent BFE (%)
1	99.6
2	99.7
3	99.1
4	99.5
5	99.7




 Study Director Janelle R. Bentz, M.S.


 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