

Bacterial Filtration Efficiency (BFE) Final Report

Test Article: MMSample-NWPPx3
Study Number: 1389894-S01
Study Received Date: 16 Feb 2021
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 18
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 $1.7 - 3.0 \times 10^3$ 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 F2101-19 and EN 14683:2019, Annex B.

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 Test Area: $\sim 7.8 \text{ cm}^2$
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
Positive Control Average: 2.4×10^3 CFU (Test Article 1)
 2.3×10^3 CFU (Test Articles 2-5)
Negative Monitor Count: <1 CFU
MPS: $2.7 \mu\text{m}$ (Test Article 1)
 $3.1 \mu\text{m}$ (Test Articles 2-5)



Mikell Goldsberry electronically approved
Study Director

Mikell Goldsberry

03 Apr 2021 00:05 (+00:00)
Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	72
2	63
3	66
4	69
5	60

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