

Bacterial Filtration Efficiency (BFE) Final Report

Test Article: Happy Masks Filters
Purchase Order: 1
Study Number: 1365131-S01.1 Amended
Study Received Date: 19 Nov 2020
Study Completion Date: 09 Dec 2020
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: Sponsor Labeled Side
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
Positive Control Average: 2.0×10^3 CFU
Negative Monitor Count: <1 CFU
MPS: $3.1 \mu\text{m}$



Mikell Goldsberry electronically approved
Study Director

Mikell Goldsberry

12 Dec 2020 03:31 (+00:00)
Amended Report Date and Time

Results:

Test Article Number	Percent BFE (%)
1	>99.9 ^a
2	>99.9
3	>99.9
4	>99.9 ^a
5	>99.9

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

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, the address was updated.