Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	Disposable Medical Mask Model. 3030, 3031
Study Number:	1404877-S01
Study Received Date:	02 Apr 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 ± 0.3 μm. 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:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	$85 \pm 5\%$ relative humidity (RH) and $21 \pm 5°C$ for a minimum of 4 hours
Test Article Dimensions:	~172 mm x ~163 mm
Positive Control Average:	1.7×10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.2 μm

Mikell Goldsberry electronically approved	17 Apr 2021 02:42 (+00:00)
Study Director	Study Completion Date and Time
	Mikell Goldsberry

Results:

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

[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:

$$\% \, BFE = \frac{C - T}{C} \, x \, 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request