Nelson Labs
A Sotera Health company

Sponsor:

Makana Mask Inc.
651 Critchlow Dr., Ste. 2
Ogden, UT 84404

Bacterial Filtration Efficiency (BFE) at an Increased Challenge Level Final Report

Test Article:	(Lot #2) Sample BFE_0_01, Sample BFE_0_02, Sample BFE_0_03, Sample BFE_0_04, Sample BFE_0_05
Purchase Order:	MM2T200BVPFE01
Study Number:	1522141-S01
Study Received Date:	09 Jun 2022
Test Started Date:	16 Jun 2022
Test Finished Date:	22 Jun 2022
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: STP0009 Rev 15
Deviation(s):	None

Summary: This test procedure was performed to evaluate the BFE of test articles at an increased challenge level. A suspension of *Staphylococcus aureus*, ATCC #6538, was delivered to the test article at a challenge level of greater than 10^6 colony forming units (CFU). The challenge was aerosolized using a nebulizer and delivered to the test article at a fixed air pressure and flow rate of 30 liters per minute (LPM). The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) for collection. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber. The mean particle size (MPS) control was performed at a flow rate of 28.3 LPM using a six-stage, viable particle, Andersen sampler for collection.

This test procedure was modified from Nelson Laboratories, LLC (NL), standard BFE procedure in order to employ a more severe challenge than would be experienced in normal use. This method was adapted from ASTM F2101. 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.

Challenge Flow Rate:	30 LPM
Area Tested:	Entire Test Article
Side Tested:	Inside
Challenge Level:	1.5×10^6 CFU
MPS:	~3.0 µm
Test Monitor Results:	Acceptable

James Luskin electronically approved — 24 Jun 2022 14:54 (+00:00)
Study Director James Luskin — Study Completion Date and Time

Results:

Test Article Number	Total CFU Recovered	Filtration Efficiency (%)
1	6.4×10^1	99.9958
2	3.6×10^3	99.77
3	6.5×10^1	99.9958
4	5.5×10^1	99.9964
5	3.2×10^2	99.979

The filtration efficiency percentages were calculated using the following equation:

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

C = Challenge Level
T = Total CFU recovered downstream of the test article