Nelson Labs
A Sotera Health company

Sponsor:
Prashant Paul
Nirvana India Private Limited
B-1 Extension A-41
Mohan Cooperative Estate, Mathura Rd.
New Delhi, 110044
INDIA

Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	NB101
Study Number:	1300976-S01
Study Received Date:	19 May 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 x 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:	Sponsor Labeled Side (Black Side)
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Control Average:	2.5 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

Reid Jones electronically approved for — 03 Jun 2020 13:08 (+00:00)
Study Director James Luskin — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	98.1
2	98.3
3	98.1
4	98.5
5	98.0

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

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Determination of Inhalation and Exhalation Resistance for Air-Purifying Respirators Final Report

Test Article:	NB101
Study Number:	1300972-S01
Study Received Date:	19 May 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: STP0145 Rev 05
Deviation(s):	None

Summary: This procedure was performed to evaluate the differential pressure of the sponsor supplied product. The air exchange differential or breathability was measured for inhalation resistance using NIOSH procedure TEB-APR-STP-0007 and exhalation resistance with NIOSH procedure TEB-APR-STP-0003 (with the exception that the product was not a respirator). The differential pressure technique is a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material, at a constant flow rate.

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.

Results:

Test Article Number	Inhalation Resistance (mm H_2O)	Exhalation Resistance (mm H_2O)
1	4.1	1.6
2	4.3	1.4
3	4.4	2.2

Test Method Acceptance Criteria: The resistance measurement for the reference plate must be within ± 3 standard deviations of the mean established in the control chart.

Brent Shelley electronically approved for — 11 Jun 2020 15:24 (+00:00)
Study Director Curtis Gerow — Study Completion Date and Time

Procedure: A product was mounted to a test fixture comprised of a metal plate with an approximate 3.5 inch diameter hole in the center to allow airflow to reach the mask. The sample holder was assembled by placing a Plexiglas collar around the test fixture and topping with another metal disc with a 3.5 inch opening in the center. The sample holder is held tightly together with clamps and connected to an air source. The manometer is attached to the sample holder by a connection port on the Plexiglas collar.

Before testing, the manometer was zeroed and the back pressure in the sample holder checked and verified to be acceptable. Resistance measurements were taken with a manometer capable of measuring at least 6 inches of water. For inhalation testing, a negative airflow (vacuum) was applied. For exhalation testing, a positive airflow (compressed air) was used. Airflow was passed through the sample holder at approximately 85 ± 2 liters per minute (L/min).

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Viral Filtration Efficiency (VFE) Final Report

Test Article:	NB101
Study Number:	1300970-S01
Study Received Date:	19 May 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: STP0007 Rev 16
Deviation(s):	None

Summary: The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage ΦX174 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 1.1 - 3.3 x 10^3 plaque forming units (PFU) with a mean particle size (MPS) of 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure 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.

Test Side:	Black Side
Test Area:	~7.1 cm^2
VFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Control Average:	2.8 x 10^3 PFU
Negative Monitor Count:	<1 PFU
MPS:	2.8 µm

Sarah Smit electronically approved for James Luskin — Study Director

31 May 2020 21:57 (+00:00) — Study Completion Date and Time

Results:

Test Article Number	Percent VFE (%)
1	99.7
2	97.0
3	92.0
4	94.8
5	95.2

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request