Nelson Labs
A Sotera Health company

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Viral Filtration Efficiency (VFE) Final Report

Test Article:	PP30-NF-PE20 PP30-NF-PE20-C PP30-NF-PE20-C-Weld
Purchase Order:	5616
Study Number:	1298754-S01
Study Received Date:	12 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:	Either
Test Area:	~40 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:	2.2 x 10^3 PFU
Negative Monitor Count:	<1 PFU
MPS:	2.8 µm

Reid Jones electronically approved for — 04 Jun 2020 15:53 (+00:00)
Study Director James Luskin — Study Completion Date and Time

Results:

PP30-NF-PE20:

Test Article Number	Percent VFE (%)
1	99.1
2	98.8
3	96.6
4	97.3
5	97.7

PP30-NF-PE20-C:

Test Article Number	Percent VFE (%)
1	99.0
2	99.5
3	99.6
4	97.8
5	98.9

PP30-NF-PE20-C-Weld:

Test Article Number	Percent VFE (%)
1	97.6
2	99.1
3	98.5
4	99.1
5	97.8

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

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INDIA

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
Study Director Curtis Gerow

11 Jun 2020 15:24 (+00:00)
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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Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	PP30-NF-PE20 PP30-NF-PE20-C PP30-NF-PE20-C-Weld
Purchase Order:	5616
Study Number:	1298749-S01
Study Received Date:	12 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.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

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:	Either
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Control Average:	2.9 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.0 µm

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Reid Jones electronically approved for James Luskin
Study Director

08 Jun 2020 20:50 (+00:00)
Study Completion Date and Time

Results:

PP30-NF-PE20:

Test Article Number	Percent BFE (%)
1	98.8
2	99.2

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	1.5	14.3
2	1.3	12.9

PP30-NF-PE20-C:

Test Article Number	Percent BFE (%)
1	98.8
2	98.7

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	1.9	19.0
2	1.5	15.0

PP30-NF-PE20-C-Weld:

Test Article Number	Percent BFE (%)
1	98.5
2	99.0

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	2.5	24.1
2	1.8	17.5

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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Latex Particle Challenge Final Report

Test Article:	PP30-NF-PE20 PP30-NF-PE20-C PP30-NF-PE20-C-Weld
Purchase Order:	5616
Study Number:	1298755-S01
Study Received Date:	12 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: STP0005 Rev 07
Deviation(s):	Quality Event (QE) Number(s): QE22125

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. 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:	Either
Area Tested:	91.5 cm^2
Laboratory Conditions:	19°C, 24% relative humidity (RH) at 1103; 20°C, 24% RH at 1239; 20°C, 24% RH at 1346; 20°C, 24% RH at 1456; 20°C, 24% RH at 1516; 20°C, 24% RH at 1536; 20°C, 24% RH at 1611; 20°C, 24% RH at 1703

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Christopher Acker electronically approved for Curtis Gerow
Study Director

30 May 2020 22:57 (+00:00)
Study Completion Date and Time

Deviation Details: Controls and sample counts were conducted for one minute instead of an average of three one minute counts. This change shortens the total test time for each sample but will still provide an accurate determination of the particle counts. An equilibrate is a dwell period where the challenge is being applied to the test article for a certain period of time before test article counts are counted. The equilibrate period was reduced from 2 minutes to a minimum of 30 seconds which is sufficient time to clear the system of any residual particles, and establish a state of stable equilibrium before sample counts are taken. Test method acceptance criteria were met, results are valid.

Results:

Particle Size: 0.1 µm
Test Article: PP30-NF-PE20

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	70	11,622	99.40

Particle Size: 0.1 µm
Test Article: PP30-NF-PE20-C

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	65	11,349	99.43

Particle Size: 0.1 µm
Test Article: PP30-NF-PE20-C-Weld

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	118	11,370	99.0

Particle Size: 0.3 µm
Test Article: PP30-NF-PE20

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	168	11,437	98.5
2	112	11,976	99.06

Average Filtration Efficiency: 98.80%
Standard Deviation: 0.377

Particle Size: 0.3 µm
Test Article: PP30-NF-PE20-C

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	149	12,455	98.8
2	164	12,983	98.7

Average Filtration Efficiency: 98.8%
Standard Deviation: 0.05

Particle Size: 0.3 µm
Test Article: PP30-NF-PE20-C-Weld

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	181	13,895	98.7
2	125	11,371	98.9

Average Filtration Efficiency: 98.8%
Standard Deviation: 0.14

Particle Size: 0.5 µm
Test Article: PP30-NF-PE20

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	293	12,273	97.6

Particle Size: 0.5 µm
Test Article: PP30-NF-PE20-C

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	253	12,956	98.0

Particle Size: 0.5 µm
Test Article: PP30-NF-PE20-C-Weld

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	336	13,288	97.5

Particle Size: 1.0 µm
Test Article: PP30-NF-PE20

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	144	10,460	98.6

Particle Size: 1.0 µm
Test Article: PP30-NF-PE20-C

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	251	10,840	97.7

Particle Size: 1.0 µm
Test Article: PP30-NF-PE20-C-Weld

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	222	11,031	98.0

Multi disciplinary Laboratory with International presence
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M.: 09911659800, 09958849764, 07210888634

TEST REPORT

Face Mask Analysis

Report Code: MS-270320-01 **Issue Date: 31/03/2020**

Issued To : M/s NIRVANA INDIA PVT. LTD.
B1 EXTENSION, A-41, MOHAN COOPERATIVE ESTATE MATHURA ROAD, NEW DELHI-110044

PART A: Particulars of Sample submitted

A.	Sample Description	:	AIRIFIC FACE MASK
B.	Date of Sample Received	:	27/03/2020
C.	Date of Commencement of Testing	:	27/03/2020
D.	Date of completion of Testing	:	31/03/2020
E.	Test Method	:	NIOSH & IS:9473:2002
F.	Sample submitted By	:	Customer
G.	Instrument Used	:	Laminar Air Flow Cabinet, Aerosol Generator, Pressure Probe etc. Flame Photometer

TEST RESULT

1. Filter Efficiency as per NIOSH Standard

Summary: This procedure was performed to evaluate particulate filter penetration as specified in 42 CFR Part 84 for requirements on a N95 respirator. Respirators were conditioned then tested for particle penetration against a polydispersed, sodium chloride (NaCl) particulate aerosol. The challenge aerosol was dried, neutralized, and passed through the test article at a concentration not exceeding 200 mg/m^3 the initial airflow resistance and particle penetration for each respirator was determined.

According to 42 CFR Part 84.64, pretesting must be performed by all applicants as part of the application process with NIOSH. Results seen below are part of that pretesting and must be submitted to and accepted by NIOSH for respirator approval.

TEST RESULT

Article Number	Initial Airflow Resistance (mm H_2O)	Particle Penetration (%)	Filtration Efficiency (%)
1	**16.1**	**2.84**	**97.16**
2	**15.7**	**3.21**	**96.79**
3	**15.0**	**2.84**	**97.16**
4	**15.9**	**2.85**	**97.15**
5	**16.4**	**3.56**	**96.44**

Results: The NIOSH N95 filter efficiency as stated in 42 CFR Part 84.181 is a minimum efficiency of filter is 95.0 %. The test articles submitted by the customer meets the NIOSH N95 and FFP2 criteria for filter efficiency.

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Laboratory: A-91, Sector 80, Phase-2, Noida-201301, (U.P)
M.: 09911659800, 09958849764, 07210888634

2. Bacterial Filtration Efficiency (BFE)

S.No.	Name of test Bacteria	Recovered Bacteria After Filtration	Bacterial Before Filtration Through Mask	Percent Reduction compared to Control Sample
1.	*Pseudomonas aeruginosa* (MTCC 424)	1.2×10^3	2.43×10^5	99.50
2.	*E.Coli* (MTCC 443)	2.41×10^3	3.62×10^5	99.33
3.	*Aspergillus niger* (MTCC 282)	2.61×10^3	2.82×10^5	99.07

NOTES : Test Method: ASTM F 2101
Flow rate: 28.3 LPM
Area Tested: 36 cm^2
Side Tested: Both Side

Remarks: On the basis of above tested parameter it is concluded that sample having Anti bacterial Filtration Efficiency compared to control sample. So removes bacteria & fungi during process of filtration with >99% filtration efficiency.

Notes:
1. **The results given above are related to the tested sample, as received & mentioned Parameters.**
2. **Responsibility of the Laboratory is limited to the invoiced amount only.**
3. **This test report will not be generated again, either wholly or in part, without prior written Permission of the laboratory.**

V.KP
Checked by

Authorized Signatory