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MIAN Garments - Fashion
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Xuan Linh Hamlet,
Thuy Xuan Tien Commune,
Chuong My District,
Hanoi,
VIETNAM

Viral Filtration Efficiency (VFE) Final Report

Test Article: MIAN Careplus Face Mask
Study Number: 932652-S01
Study Received Date: 14 Mar 2020
Test Procedure(s): Standard Test Protocol (STP) Number: 801-STP0007 Rev 13

Summary: The VFE test is performed to determine the filtration efficiency by comparing the upstream viral control counts to downstream test article counts. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 1.1 - 3.3 x 10^3 plaque forming units (PFU) with a mean particle size (MPS) at 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This method allows a reproducible challenge to be delivered to the test articles. 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: Inside
Area Tested: ~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: 2.5 x 10^3 PFU
Negative Monitor Count: <1 PFU
MPS: 3.0 µm

Results:

Test Article Number	Percent VFE (%)
1	99.9
2	>99.9
3	>99.9
4	99.9
5	>99.9

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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Trang Truong
Study Director Trang T. Truong, B.S.

16 Mar 2017
Study Completion Date

932652-S01

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Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	MIAN Careplus Face Mask
Sample Source:	MIAN Garments - Fashion Production Co., Ltd
Study Number:	912551-S01
Study Received Date:	14 Mar 2020
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 13

Summary: The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 1.7 - 2.7 x 10^3 colony forming units (CFU) with a mean particle size (MPS) at 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with ASTM F2101-14 and EN 14683:2014, Annex B.

The Delta P test determines the breathability 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 was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

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 Area Tested:	~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.
Test Article Dimensions:	~148 mm x ~165 mm
Positive Control Average:	2.0 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.7 µm

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Trang Truong
Study Director — Trang Truong, B.S.

09sep2016
Study Completion Date

912551-S01

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	>99.9	4.2	41.0
2	>99.9	4.1	39.7
3	99.8	4.0	39.3
4	>99.9	4.1	40.6
5	99.8	4.1	40.2

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: MIAN Careplus Face Mask
Study Number: 949385-S01
Study Received Date: 14 Mar 2020
Test Procedure(s): Standard Test Protocol (STP) Number: 801-STP0005 Rev 05

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, dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

Three one-minute counts were performed, with the test article in the system, and the results averaged. Three one-minute control counts were 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 average 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: Inside
Area Tested: 91.5 cm^2
Particle Size: 0.1 µm
Laboratory Conditions: 20°C, 24% relative humidity (RH) at 1120; 21°C, 24% RH at 1405
Average Filtration Efficiency: 99.82%
Standard Deviation: 0.018

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	25	13,735	99.82
2	31	14,918	99.79
3	19	10,649	99.82
4	21	12,442	99.83

ANAB ACCREDITED TESTING LABORATORY

Study Director Brandon L. Williams

12 Apr 2017
Study Completion Date

949385-S01

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Synthetic Blood Penetration Resistance Final Report

Test Article:	MIAN Careplus Face Mask
Study Number:	969654-S01
Study Received Date:	14 Mar 2020
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: 801-STP0012 Rev 07

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the canula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2014) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

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.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	30
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	21.2°C and 30% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 160 mmHg (21.3 kPa)

Test Article Number	Synthetic Blood Penetration
1-5, 7-12, 14-32	None Seen
6, 13	Yes

Study Director: Thang Thuong for Brandon L. Williams — Study Completion Date: 14 Jul 2017

969654-S01

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Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	MIAN Careplus Face Mask
Study Number:	969123-S01
Study Received Date:	14 Mar 2020
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: 801-STP0004 Rev 14

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 - 2.7 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 F2101-14 and EN 14683:2014, 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 was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

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)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~176 mm x ~165 mm
Positive Control Average:	1.9 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Trang Truong
Study Director — Trang T. Truong, B.S.

17/11/2017
Study Completion Date

969123-S01

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	99.5	2.9	28.0
2	99.6	3.0	29.3
3	99.5	2.9	28.5
4	99.6	2.9	28.3
5	99.0	2.8	27.2

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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Viral Filtration Efficiency (VFE) Final Report

Test Article:	Type A: MIAN Careplus Face Mask Sample Source: MIAN Garments - Fashion Production Co., Ltd
Study Number:	876428-S01
Study Received Date:	14 Mar 2020
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0007 Rev 12

Summary: The VFE test is performed to determine the filtration efficiency by comparing the upstream viral control counts to downstream test article counts. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 1.1 - 3.3 x 10^3 plaque forming units (PFU) with a mean particle size (MPS) at 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This method allows a reproducible challenge to be delivered to the test articles. The VFE test procedure was adapted from ASTM F2101-07.

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
Area Tested:	~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:	2.9 µm

Results:

Test Article Number	Percent VFE (%)
1	97.6
2	96.9
3	97.2
4	98.2
5	98.0
Average	97.6

ANAB ACCREDITED TESTING LABORATORY

Janelle Bentz
Study Director — Janelle R. Bentz, M.S.

15 Mar 2016
Study Completion Date

876428-S01

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