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

Test Article:	SQ-1001 / LOT #SQ-1001
Study Number:	1291212-S01
Study Received Date:	21 Apr 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.

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:	~172 mm x ~170 mm
Positive Control Average:	2.9 x 10^3 CFU (Original) 3.0 x 10^3 CFU (Investigation)
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

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Trang Truong electronically approved — 16 Jun 2020 21:46 (+00:00)

Study Director Trang Truong — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	99.9
2[a]	99.9
3	>99.9
4	99.3
5	>99.9

[a] The original result for this test article was unexpected when compared to the other test articles. Investigational testing was performed on the same test article in duplicate and it was determined that the original result was invalid. All valid test results are reported.

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	4.0	39.2
2	3.9	38.5
3	4.1	39.9
4	3.8	37.7
5	3.8	37.7

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

Test Article Preparation: The test articles were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% RH, prior to BFE and Delta P testing.

Test Method Acceptance Criteria: The BFE positive control average shall be maintained at 1.7 – 3.0 x 10^3 CFU.

The MPS control average of the challenge aerosol shall be maintained at 3.0 ± 0.3 µm.

The Delta P test flow rate shall be maintained at 8 L/min throughout the testing.

Procedure:

BFE: A culture of *S. aureus*, ATCC #6538, was diluted in peptone water (PEPW) to yield challenge level counts of 1.7 – 3.0 x 10^3 CFU per test article. The bacterial culture suspension was pumped through a nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPS of approximately 3.0 µm. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. Test articles, positive controls, and reference material received a one minute challenge followed by a one minute vacuum cycle.

The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six soybean casein digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 48 ± 4 hours and the colonies formed by the bacteria laden aerosol droplets were then counted and converted to probable hit values using the positive hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test articles. The distribution ratio of the colonies on each of the six agar plates was used to calculate the MPS of the challenge aerosol.

Delta P: The Delta P test simply measured the differential air pressure on either side of the test article using an incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 L/min (volumetric). At least one reference material is included with each set of test articles.

The Delta P values were reported in mm water/cm^2 and Pa/cm^2 of test area and calculated using the following equation:

$$Delta\ P = \frac{\bar{M}}{A}$$

Where: $\bar{M}$ = Average mm of water of the test replicates per test article
A = Area of the test article holder (cm^2)

The test article holder used in the Delta P test has a test area of 4.9 cm^2.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	04 May 2020
Phase Inspected by Quality Assurance: Delta P Measurements	18 May 2020
Audit Results Reported to Study Director	20 May 2020
Audit Results Reported to Management	21 May 2020

Scientists	Title
Denise Anderson	Supervisor
Trang Truong	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Nicole Widmer electronically approved
Quality Assurance

16 Jun 2020 21:38 (+00:00)
Date and Time

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Latex Particle Challenge GLP Report

Test Article:	SAMPLE ID:SQ-1001 LOT: SQ-1001
Study Number:	1291220-S01
Study Received Date:	21 Apr 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.

Test Side:	Inside
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	22°C, 24% relative humidity (RH) at 1151; 22°C, 24% RH at 1351 22°C, 24% RH at 1513; 22°C, 23% RH at 1601
Average Filtration Efficiency:	99.84%
Standard Deviation:	0.063

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.

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Trang Truong electronically approved — 10 Jun 2020 21:28 (+00:00)

Study Director Trang Truong — Study Completion Date and Time

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	10	10,532	99.905
2	24	11,980	99.80
3	13	12,898	99.90
4	18	12,198	99.85
5	29	12,019	99.76

Test Method Acceptance Criteria: Ambient background particles detected through the test system must be below 1% of the challenge total (<100 particles).

Procedures:

Test Set-up: Testing was conducted in an ISO Class 5 (class 100) HEPA filtered hood. The inlet air to the test system was filtered through a 0.2 µm rated air filter. The particle generator outlet was clamped off and the number of background particles within the test system was verified to be <100 particles at 1 cubic foot per minute (CFM). The flow rate through the test system was maintained at 1 CFM ± 5%.

An aliquot of the PSL was aerosolized using a particle generator, mixed with additional filtered air, dried and passed through the test system. The particles delivered were enumerated using a laser based particle counter.

Test Procedure: A test article was placed into the holder and the system was allowed to stabilize. The number of particles being delivered to the test article was determined (no medium in air stream) as one-minute control readings were taken prior to and after every test article. Control count averages were maintained at a level of 10,000-15,000 particles per cubic foot. One-minute counts were recorded for the test article between the control counts.

The PFE of each test article was determined by using the following equation:

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

Where: C = Combined average of the control counts
T = Average test article counts

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	04 May 2020
Phase Inspected by Quality Assurance: Latex Test	15 May 2020
Audit Results Reported to Study Director	21 May 2020
Audit Results Reported to Management	22 May 2020

Scientists	Title
Denise Anderson	Supervisor
Trang Truong	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Ashley Leverenz electronically approved
Quality Assurance

10 Jun 2020 13:24 (+00:00)
Date and Time

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Synthetic Blood Penetration Resistance GLP Report

Test Article:	SQ-1001 LOT: SQ-1001
Study Number:	1291209-S01
Study Received Date:	21 Apr 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: STP0012 Rev 09
Deviation(s):	None

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 cannula 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 14683:2019 and AS4381:2015) 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.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	32
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	24.1°C and 21% 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: 80 mmHg (10.7 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Trang Truong electronically approved — 06 Jun 2020 01:49 (+00:00)

Study Director Trang Truong — Study Completion Date and Time

Test Method Acceptance Criteria: The output of synthetic blood passing through the targeting hole before and after every set of test articles must be ≤5% (±0.10 g) in difference from the theoretical output of 2 mL.

Procedure: A clean cannula was fixed onto the front of the valve and the reservoir was filled with synthetic blood. The reservoir pressure and timer were set to allow a differential weight of 95-102%. This was achieved by setting the valve timer to 0.5 seconds and 1.5 seconds, collecting and weighing the amount of fluid before and after the targeting hole, and then calculating the weight differences for the deliveries. After the reservoir pressure and timer duration had been adjusted, the 2 mL spray was verified by dispensing three spurts in a row through the targeting hole into a graduated cylinder and weighing. After every 16 test articles, synthetic blood was delivered into a graduated cylinder and weighed to ensure the test apparatus was still delivering 2 mL of synthetic blood.

Each test article was tested within one minute of removal from the conditioning chamber. The facemask was mounted on the test article(s) holding fixture and positioned 305 mm (12 in) from the cannula. The mask was then subjected to the 2 mL volume spray, which moved from the cannula in a horizontal path perpendicular to the facemask. This procedure used a targeting hole that blocked the initial, high-pressure portion of the synthetic blood stream and allowed only the fluid traveling at the target velocity to hit the center of the mask. Each test article was observed for penetration within 10 seconds of dispensing the synthetic blood against the target area.

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Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	04 May 2020
Phase Inspected by Quality Assurance: Penetration Test	13 May 2020
Audit Results Reported to Study Director	13 May 2020
Audit Results Reported to Management	13 May 2020

Scientists	Title
Denise Anderson	Supervisor
Trang Truong	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Nathan Tolman electronically approved
Quality Assurance

05 Jun 2020 22:40 (+00:00)
Date and Time

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Flammability of Clothing Textiles GLP Report

Test Article:	SAMPLE ID:SQ-1001 LOT: SQ-1001
Study Number:	1291202-S01.1 Amended
Study Received Date:	21 Apr 2020
Study Completion Date:	28 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: STP0073 Rev 06
Deviation(s):	None

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. Step 2 - *Refurbishing and testing after refurbishing*, was not performed. All test method acceptance criteria were met.

Test Article Side Tested:	Outside Surface
Orientation:	Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

The 16 CFR Part 1610 standard specifies that 10 replicates are to be tested if, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study.

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Trang Truong electronically approved — 16 Jun 2020 21:25 (+00:00)

Study Director Trang Truong — Amended Report Date and Time

Results:
SAMPLE ID:SQ-1001 Lot # SQ-1001:

Replicate Number	Time of Flame Spread
1	DNI
2	DNI
3	DNI
4	DNI
5	DNI

DNI = Test Article did not ignite

Test Method Acceptance Criteria: Flame length must be approximately 16 mm (~⅝ in) from the flame tip to the opening in the gas nozzle.

Procedure: Test articles were prepared by cutting the material into approximately 50 x 150 mm swatches. Preliminary testing to establish the orientation and side of the test article to test was performed. The side and orientation that burned the fastest was used to test the test articles. Each test article was clamped into the specimen holder and placed in an oven maintained at 105 ± 3°C for 30 ± 2 minutes. The test articles were then placed in a desiccator for a minimum of 15 minutes prior to testing.

The flame length of the flammability tester was adjusted to approximately 16 mm prior to testing. Test articles were placed on the flammability rack and the stop cord was strung through the guides. The flammability timer was zeroed and testing was started. When the flame reached the stop cord, the timer stopped, and the results were recorded. Testing was terminated for test articles that did not exhibit flame spread beyond the initial application of the flame.

Amendment Justification: At the request of the sponsor, the results for each test article ID were separated in to individual reports.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	04 May 2020
Phase Inspected by Quality Assurance: Preliminary Test	18 May 2020
Audit Results Reported to Study Director	19 May 2020
Audit Results Reported to Management	20 May 2020

Scientists	Title
Denise Anderson	Supervisor
Trang Truong	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Eric Stembridge electronically approved
Quality Assurance

15 Jun 2020 22:02 (+00:00)
Date and Time