## Latex Particle Challenge GLP Report

Test Article: (2) Sample Lots: F \& L<br>Purchase Order: 89748-13565<br>Study Number: 1364607-S01<br>Study Received Date: 18 Nov 2020<br>Testing Facility: Nelson Laboratories, LLC<br>6280 S. Redwood Rd.<br>Salt Lake City, UT 84123 U.S.A.<br>Test Procedure(s): Standard Test Protocol (STP) Number: STP0005 Rev 08<br>Deviation(s): None

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. 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<br>Area Tested: $91.5 \mathrm{~cm}^{2}$<br>Particle Size: $0.1 \mu \mathrm{~m}$<br>Laboratory Conditions: Lot F: $21.4^{\circ} \mathrm{C}, 22 \%$ relative humidity (RH) at $0253 ; 21.4^{\circ} \mathrm{C}, 22 \% \mathrm{RH}$ at 0348<br>Lot L: $22.6^{\circ} \mathrm{C}, 21 \% \mathrm{RH}$ at $0646 ; 22.2^{\circ} \mathrm{C}, 21 \% \mathrm{RH}$ at 0756



Christopher Acker electronically approved
Study Director

Christopher Acker
14 Jan 2021 23:40 (+00:00)
Study Completion Date and Time

Results:
Lot F:

| Test Article Number | Test Article Counts | Average Control Counts | Filtration Efficiency (\%) |
| :---: | :---: | :---: | :---: |
| 1 | 56 | 13,488 | 99.58 |
| 2 | 44 | 13,244 | 99.67 |
| 3 | 60 | 12,887 | 99.53 |
| 4 | 67 | 13,229 | 99.49 |
| 5 | 56 | 13,293 | 99.58 |
| 6 | 60 | 13,507 | 99.56 |
| 7 | 75 | 13,685 | 99.45 |
| 8 | 56 | 13,663 | 99.59 |
| 9 | 66 | 13,329 | 99.50 |
| 10 | 73 | 13,257 | 99.45 |
| Average Filtration Efficiency: $99.54 \%$ |  |  |  |

Lot L:
Test Article Number
Test Article Counts
Average Control Counts
Filtration Efficiency (\%)

| 1 | 37 |
| :---: | :---: |
| 2 | 52 |
| 3 | 48 |
| 4 | 37 |
| 5 | 47 |
| 6 | 47 |
| 7 | 53 |
| 8 | 44 |
| 9 | 46 |
| 10 | 59 |

14,170
99.74
99.63
99.65

13,869
99.74

14,663
99.68
99.66

13,514
99.61

13,311
99.67

13,815
99.67

Average Filtration Efficiency: 99.66\%
Standard Deviation: 0.050

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 $0.2 \mu \mathrm{~m}$ 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 $\pm 5 \%$.

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 average 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. A one-minute count was recorded for the test article between the control counts.

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

$$
\% P F E=\frac{C-T}{C} \times 100
$$

Where: $\mathrm{C}=$ Combined average of the control counts
$\mathrm{T}=$ 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 | 11 Dec 2020 |
| Phase Inspected by Quality Assurance: |  |
| Sample Preparation | 28 Dec 2020 |
| Audit Results Reported to Study Director | 29 Dec 2020 |
| Audit Results Reported to Management | 29 Dec 2020 |


| Scientists | Title |
| :---: | :---: |
| Adrianne Sandall | Supervisor |
| Chris Acker | 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.

Camille Coffey electronically approved
Quality Assurance

14 Jan 2021 16:06 (+00:00)
Date and Time

