Nelson Labs
A Sotera Health company

Sponsor:
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Latex Particle Challenge GLP Report

Test Article:	BH MEDICAL 3-Ply Medical Mask
Study Number:	1321728-S01
Study Received Date:	17 Jul 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 08
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. During testing and controls, the air flow rate is maintained at 1 cubic foot per minute (CFM) ± 5%.

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:	21°C, 31% relative humidity (RH) at 0949; 21°C, 29% RH at 1039
Average Filtration Efficiency:	99.956%
Standard Deviation:	0.0181

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Trang Truong electronically approved — 20 Aug 2020 22:03 (+00:00)
Study Director — Trang Truong — Study Completion Date and Time

Results:

Test Article	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	6	11,844	99.949
2	8	11,792	99.932
3	3	11,640	99.974
4	3	11,596	99.974
5	6	11,908	99.950

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 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:

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

Where: C = Combined average of the control counts
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	04 Aug 2020
Phase Inspected by Quality Assurance: Latex Test	14 Aug 2020
Audit Results Reported to Study Director	14 Aug 2020
Audit Results Reported to Management	17 Aug 2020

Scientists	Title
Adrianne Sandall	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

20 Aug 2020 17:11 (+00:00)
Date and Time