

Latex Particle Challenge GLP Report

Test Article: SAMPLE ID : BYD N95 DE2322 Lot #6200522
Study Number: 1305387-S01
Study Received Date: 01 Jun 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 cm²
Particle Size: 0.1 µm
Laboratory Conditions: 21°C, 32% relative humidity (RH) at 0759; 21°C, 32% RH at 0925
Average Filtration Efficiency: >99.944%
Standard Deviation: 0.0997



Sarah Guzman electronically approved
Study Director

Sarah Guzman

22 Jul 2020 15:50 (+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:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	25	10,768	99.77
2	<1 ^a	10,347	>99.9968
3	<1 ^a	10,090	>99.9967
4	<1 ^a	10,779	>99.9969
5	4	11,129	99.964

^a There were no detected particles penetrating this filter during testing.

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:

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

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	23 Jun 2020
Phase Inspected by Quality Assurance: Latex Test	25 Jun 2020
Audit Results Reported to Study Director	08 Jul 2020
Audit Results Reported to Management	13 Jul 2020

Scientists	Title
Sarah Smit	Supervisor
Sarah Guzman	Study Director
Benjamin Sipes	Scientist
Christopher Acker	Scientist

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.

Robert De Vargas electronically approved
Quality Assurance

22 Jul 2020 15:49 (+00:00)
Date and Time