

Latex Particle Challenge Final Report

Test Article: (B) Enro – Tech 3D Masks (After 100 machine washes and Tumble dry low)
Study Number: 1371065-S01B.1 Amended
Study Received Date: 10 Dec 2020
Study Completion Date: 31 Dec 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) \pm 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. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Either Side
Area Tested: 91.5 cm²
Particle Size: 0.1 μ m
Laboratory Conditions: 21.1°C, 22% relative humidity (RH) at 1024; 21.1°C, 22% RH at 1116
Average Filtration Efficiency: 99.02%
Standard Deviation: 0.125




Study Director

Chris Acker

14 JAN 2021
Amended Report Date



1371065-S01

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	158	13,204	98.8
2	131	13,538	99.03
3	126	13,867	99.09
4	133	13,907	99.04
5	121	13,765	99.12

Amendment Justification: At the request of the sponsor, the report was separated into an A and B report by test article.