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## Latex Particle Challenge Final Report

Test Article: DFM3L-PFE115

Purchase Order: 1002

Study Number: 1334039-S01 Study Received Date: 21 Aug 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.

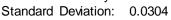
A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article. Control counts were performed to determine the average number of particles delivered to the test article. The filtration 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. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

> Test Side: Inside Area Tested: 91.5 cm<sup>2</sup> Particle Size: 0.1 µm

Laboratory Conditions: 21°C, 28% relative humidity (RH) at 1558; 21°C, 29% RH at 1704

Average Filtration Efficiency: 99.924%







Christopher Acker electronically approved for

Curtis Gerow

These results apply to the samples as received and relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NL terms and conditions at www.nelsonlabs.com.

23 Sep 2020 03:58 (+00:00)

Study Director

Study Completion Date and Time

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FRT0005-0001 Rev 7



## Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	10	13,324	99.925
2	7	12,598	99.944
3	16	12,395	99.87
4	8	13,400	99.940
5	8	12,974	99.938

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