Nelson Labs
A Sotera Health company

Sponsor:

Makana Mask Inc.
651 Critchlow Dr., Ste. 2
Ogden, UT 84404

Latex Particle Challenge Final Report

Test Article:	Sample PFE1T, Sample PFE2T, Sample PFE3T, Sample PFE4T, Sample PFE5T (lot # 1)
Purchase Order:	MM2T200BVPFE01
Study Number:	1512647-S01
Study Received Date:	03 May 2022
Test Started Date:	12 May 2022
Test Finished Date:	19 May 2022
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.

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Lisa Bonner electronically approved — 23 May 2022 16:48 (+00:00)

Study Director Lisa Bonner — Study Completion Date and Time

Test Side:	Sponsor Labeled Side
Area Tested:	~70.9 cm^2
Particle Size:	0.1 µm (Sample PFE1T and Sample PFE5T) 0.3 µm (Sample PFE2T) 0.5 µm (Sample PFE3T) 1.0 µm (Sample PFE4T)
Laboratory Conditions:	Sample PFE1T and Sample PFE5T: 20.6°C, 22% relative humidity (RH) at 1156; 20.2°C, 22% RH at 1257 Sample PFE2T: 20.5°C, 22% RH at 1338; 20.5°C, 22% RH at 1402; 20.6°C, 22% RH at 1416 Sample PFE3T: 20.5°C, 22% RH at 1430; 20.6°C, 22% RH at 1445 Sample PFE4T: 20.6°C, 22% RH at 1508; 20.7°C, 22% RH at 1527

Results:

Sample PFE1T:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	2	12,587	99.984

Sample PFE2T:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	1	13,058	99.9923

Sample PFE3T:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	<1	14,386	>99.9977

Sample PFE4T:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	<1	13,110	>99.9975

Sample PFE5T:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	8	12,988	99.938