Nelson Labs
A Sotera Health company

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Latex Particle Challenge Final Report

Test Article:	MB2.b_120ml_121422_S0011A & S0012A MB2.b_120ml_121422_S0013A & S0014A MB2.b_120ml_121422_S0021A & S0022A MB2.b_120ml_121422_S0023A & S0024A MB2.b_120ml_121422_S0025A & S0026A
Study Number:	1577124-S01
Study Received Date:	27 Dec 2022
Test Started Date:	03 Jan 2023
Test Finished Date:	06 Jan 2023
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:	Either Side
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	20.1°C, 22% relative humidity (RH) at 0825; 20.3°C, 22% RH at 0850
Average Filtration Efficiency:	99.65%
Standard Deviation:	0.194

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Curtis Gerow electronically approved for	10 Jan 2023 17:05 (+00:00)
Study Director Lisa Bonner	Study Completion Date and Time

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	74	13,642	99.46
2	63	13,372	99.53
3	7	13,525	99.948
4	36	13,574	99.73
5	55	13,636	99.60