

Sodium Chloride (NaCl) Aerosol Test Final Report

Test Article: KandyMask Reusable Face Mask with Micro Filter System - ARSL2110721
Purchase Order: 7862017036
Study Number: 1341363-S01.1 Amended
Study Received Date: 14 Sep 2020
Study Completion Date: 19 Oct 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: STP0014 Rev 09
Deviation(s): None

Summary: This procedure was performed to evaluate the particle penetration and airflow resistance properties of filtration materials. A neutralized, poly-dispersed aerosol of sodium chloride (NaCl) was generated and passed through the test article. The performance of the test article was assessed by measuring the concentration of salt particles penetrating the test article compared to the challenge concentration entering the test article. The filtration performance and airflow resistance of each test article were calculated.

The filter tester used in testing was a TSI® CERTITEST® Model 8130 Automated Filter Tester that is capable of efficiency measurements of up to 99.999%. It produced a particle size distribution with a count median diameter of 0.075 ± 0.020 microns (μm) and a geometric standard deviation not exceeding 1.86 μm . The mass median diameter was approximately 0.26 μm , which is generally accepted as the most penetrating aerosol size. 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.

Area Tested: Entire Respirator
Airflow Rate: 28.3 ± 1 liters per minute (L/min)
Test Side: Outside
Test Type: Initial Penetration (~1 min. LOAD Test)
Conditioning Parameters: $38 \pm 2.5^\circ\text{C}$, $85 \pm 5\%$ relative humidity (RH) for 25 ± 1 hour



Natalie Brady electronically approved for
Study Director

Curtis Gerow

09 Nov 2020 21:15 (+00:00)
Amended Report Date and Time

Results:

Test Article Number	Corrected ^a Airflow Resistance (mm H ₂ O)	Particle Penetration (%)	Filtration Efficiency (%)
1	5.0	3.88	96.12
2	5.0	2.43	97.57
3	5.2	3.22	96.78
4	5.0	2.39	97.61
5	6.3	2.39	97.61

^a The final airflow resistance value for each test article was determined by subtracting out the background resistance from the system.

Amendment Justification: At the request of the sponsor, the test article was changed from "Groupe Kandy -ARSL2089900" to "KandyMask Reusable Face Mask with Micro Filter System - ARSL2110721".