

## Sodium Chloride (NaCl) Aerosol Test Final Report

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Test Article: HEPA melt-blown / Model: MH13  
Purchase Order: 21-086N  
Study Number: 1433705-S01  
Study Received Date: 12 Jul 2021  
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  $0.075 \pm 0.020$  microns ( $\mu\text{m}$ ) and a geometric standard deviation not exceeding 1.86  $\mu\text{m}$ . The mass median diameter was approximately 0.26  $\mu\text{m}$ , 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: 100 cm<sup>2</sup>  
Airflow Rate: 32 ± 2 liters per minute (L/min)  
Test Side: Either Side  
Test Type: Instantaneous Penetration (10 sec. FILTER Test)



Cameron Brierley electronically approved for  
Study Director

Curtis Gerow

02 Aug 2021 17:59 (+00:00)  
Study Completion Date and Time

**Results:**

Test Article Number	Airflow Resistance (mm H <sub>2</sub> O)	Particle Penetration (%)	Filtration Efficiency (%)
1	3.3	0.011	99.989
2	3.1	0.015	99.985
3	3.2	0.019	99.981
4	3.0	0.013	99.987
5	3.1	0.012	99.988
6	3.0	0.018	99.982
7	3.2	0.016	99.984
8	3.2	0.002	99.998
9	3.2	0.046	99.954
10	3.4	0.022	99.978
11	3.2	0.016	99.984
12	3.3	0.011	99.989
13	3.4	0.009	99.991
14	3.2	0.013	99.987
15	3.1	0.021	99.979
16	3.3	0.015	99.985
17	3.1	0.031	99.969
18	3.2	0.013	99.987
19	3.3	0.012	99.988
20	3.1	<0.001 <sup>a</sup>	>99.999 <sup>b</sup>

<sup>a</sup> No particle penetration was detected through this test article.

<sup>b</sup> There were no detected particles penetrating this filter during testing.