

Sodium Chloride (NaCl) Aerosol Test Final Report

Test Article: Standard Cambridge Mask w/ Carbon Filter
 Laboratory Number: 822960
 Study Received Date: 21 May 2015
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0014 Rev 07

Summary: This procedure was performed to evaluate particulate filter penetration as specified in 42 CFR Part 84 and TEB-APR-STP-0059 for requirements on a N95 respirator. Respirators were conditioned then tested for particle penetration against a polydispersed, sodium chloride (NaCl) particulate aerosol. The challenge aerosol was dried, neutralized, and passed through the test article at a concentration not exceeding 200 mg/m³. The initial airflow resistance and particle penetration for each respirator was determined.

According to 42 CFR Part 84.64, pretesting must be performed by all applicants as part of the application process with NIOSH. Results seen below are part of that pretesting and must be submitted to and accepted by NIOSH for respirator approval.

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.

Results: The NIOSH N95 filter efficiency as stated in 42 CFR Part 84.181 is a minimum efficiency for each filter of ≥95% (≤5% penetration). The test articles submitted by the sponsor conform to the NIOSH N95 criteria for filter efficiency.

Test Article Number	Initial Airflow Resistance (mm H ₂ O)	Particle Penetration (%)	Filtration Efficiency (%)
1	15.1	0.222	99.778
2	14.8	0.274	99.726
3	16.7	0.322	99.678
4	14.7	0.533	99.467
5	11.9	0.139	99.861
6	17.0	0.264	99.736
7	11.7	0.188	99.812
8	15.4	0.334	99.666
9	13.7	0.139	99.861
10	19.0	0.348	99.652
11	16.7	0.153	99.847
12	12.8	0.487	99.513
13	18.3	0.230	99.770
14	17.7	0.380	99.620
15	20.7	0.396	99.604
16	18.5	0.194	99.806
17	16.9	0.248	99.752
18	17.9	0.453	99.547
19	17.3	0.241	99.759
20	12.6	0.201	99.799


 Study Director Brandon L. Williams

15 Jun 2015
 Study Completion Date

Acceptance Criteria: The filter tester must pass the "Tester Set Up" procedure. The airflow resistance and particle penetration of the reference material must be within the limits set by the manufacturer.

Filter Test Procedure: Prior to testing, respirators were taken out of their packaging and placed in an environment of $85 \pm 5\%$ relative humidity (RH) and $38 \pm 2.5^\circ\text{C}$ for 25 ± 1 hrs.

The filter tester used in this procedure was a TSI® CERTITEST® Model 8130 Automated Filter Tester that is capable of efficiency measurements of up to 99.999%. It produces a particle size distribution with a count median diameter of $0.075 \pm 0.020 \mu\text{m}$ and a geometric standard deviation not exceeding $1.86 \mu\text{m}$. The mass median diameter is approximately $0.26 \mu\text{m}$, which is generally accepted as the most penetrating aerosol size. The reservoir was filled with a 2% NaCl solution and the instrument allowed a minimum warm-up time of 30 min. The main regulator pressure was set to 75 ± 5 pounds per square inch (psi). The filter holder regulator pressure was set to approximately 35 pounds psi. The NaCl aerosol generator pressure was set to approximately 30 psi and the make-up airflow rate was set to approximately 70 liters per minute (L/min).

The neutralized NaCl test aerosol was verified to be at $25 \pm 5^\circ\text{C}$ and $30 \pm 10\%$ RH by the acceptance of the manufacturer's reference material. The NaCl concentration of the test aerosol was determined in mg/m^3 by a gravimetric method prior to the load test assessment.

An entire respirator was mounted on a test fixture, placed into the test article holder, and the NaCl aerosol passed through the outside surface of the test article at a continuous airflow rate of 85 ± 4 L/min. In accordance with NIOSH policy, three respirators were challenged until 200 ± 5 mg of NaCl had contacted the filter. Based upon the load pattern of NIOSH Type 2, the initial penetration reading of the remaining 17 filters was recorded.