

Sodium Chloride (NaCl) Aerosol Test GLP Report

Test Article: Blox Respirator
Lot # BLX-F36R-003
Purchase Order: 00008715
Study Number: 1404015-S01
Study Received Date: 31 Mar 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 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.



Curtis Gerow electronically approved
Study Director

Curtis Gerow

22 Apr 2021 22:41 (+00:00)
Study Completion Date and Time

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

| Test Article Number | Corrected ^a Initial Airflow Resistance (mm H ₂ O) | Maximum Particle Penetration (%) | Filtration Efficiency (%) |
|---------------------|---|----------------------------------|---------------------------|
| 1 | 13.4 | 0.874 | 99.126 |
| 2 | 17.9 | 0.763 | 99.237 |
| 3 | 13.8 | 0.787 | 99.213 |
| 4 | 12.9 | 0.398 | 99.602 |
| 5 | 12.6 | 0.364 | 99.636 |
| 6 | 14.5 | 0.333 | 99.667 |
| 7 | 13.1 | 0.275 | 99.725 |
| 8 | 13.3 | 0.518 | 99.482 |
| 9 | 12.8 | 0.400 | 99.600 |
| 10 | 13.4 | 0.375 | 99.625 |
| 11 | 15.8 | 0.607 | 99.393 |
| 12 | 13.5 | 0.399 | 99.601 |
| 13 | 12.6 | 0.432 | 99.568 |
| 14 | 13.7 | 0.476 | 99.524 |
| 15 | 14.2 | 0.536 | 99.464 |
| 16 | 14.7 | 0.424 | 99.576 |
| 17 | 13.3 | 0.554 | 99.446 |
| 18 | 13.9 | 0.500 | 99.500 |
| 19 | 16.3 | 0.581 | 99.419 |
| 20 | 16.8 | 0.486 | 99.514 |

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

Test Method 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 hours.

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 produces a particle size distribution with a count median diameter of 0.075 ± 0.020 microns (μm) and a geometric standard deviation not exceeding $1.86 \mu\text{m}$. The mass median diameter was 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 minutes. The main regulator pressure was set to 75 ± 5 pounds per square inch (psi). The filter holder regulator pressure was set to approximately 35 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 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 filter 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 each test article. Based upon the load pattern of NIOSH Type 2, the initial penetration reading of the remaining 17 respirators was recorded.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

| Activity | Date |
|--|-------------|
| Study Initiation | 02 Apr 2021 |
| Phase Inspected by Quality Assurance: Load Test | 09 Apr 2021 |
| Audit Results Reported to Study Director | 09 Apr 2021 |
| Audit Results Reported to Management | 12 Apr 2021 |

| Scientists | Title |
|------------------|----------------|
| Adrienne Sandall | Supervisor |
| Curtis Gerow | Study Director |

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Jennifer Coons electronically approved
Quality Assurance

22 Apr 2021 22:36 (+00:00)
Date and Time