ViriMASK™

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Document:

Release of Nelson Labs® Final Report for Determination of Inhalation and Exhalation Resistance for Air-Purifying Respirators. Released in its entirety according to Nelson Labs' published copyright policies.

Terms:

- 42 CFR Part 84.180. Public Health Law (US) governing approval process and criterion for respiratory protective respirators.
- NIOSH Procedure TEB-APR-STP-003. Testing procedure for respiratory protective respirators.

Summary:

This test procedure is in compliance with FDA good manufacturing practice regulations 21 CFR Parts 210,211 & 820. The procedure evaluates the differential pressure of the ViriMASK Oculo-Respirator Filter and compares it to the 42 CFR Part 84.180 criteria for resistance.

Results:

ViriMASK performed exceptionally well. Average measured resistance to airflow was significantly lower than allowable resistance, during inhalation and exhalation.

"All test method acceptance criteria were met. The test articles [ViriMASK Filters] submitted by the sponsor [ViriMASK] conform to this NIOSH criterion for airflow resistance."

Test Article Number	Inhalation Resistance	Exhalation Resistance
Criterion	≤35 mmH2O@85L/min	≤25 mmH2O@85L/min
Filter #1	8.3	7.1
Filter #2	9.0	7.9
FIlter #3	8.6	7.6

For more information, contact info@virimask.com

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Determination of Inhalation and Exhalation Resistance for Air-Purifying Respirators Final Report

Test Article:	NZ-0100-03-FILTER
Purchase Order:	PO VM1886A
Study Number:	1289142-S01
Study Received Date:	16 Apr 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: STP0145 Rev 05
Deviation(s):	None

Summary: This procedure was performed to evaluate the differential pressure of box with filter respirators in accordance with 42 CFR Part 84.180. The air exchange differential or breathability of respirators was measured for inhalation resistance using NIOSH procedure TEB-APR-STP-0007 and exhalation resistance with NIOSH procedure TEB-APR-STP-0003. The differential pressure technique is a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material, at a constant flow rate.

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.

The inhalation resistance criteria as stated in 42 CFR Part 84.180 is an initial inhalation not exceeding 35 mm water column height pressure. The test articles submitted by the sponsor conform to this NIOSH criterion for airflow resistance.

The exhalation resistance criteria as stated in 42 CFR Part 84.180 is an initial exhalation not exceeding 25 mm water column height pressure. The test articles submitted by the sponsor conform to this NIOSH criterion for airflow resistance.

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.

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Robert Dieker electronically approved for Curtis Gerow
Study Director

28 May 2020 16:21 (+00:00)
Study Completion Date and Time

Results:

Test Article Number	Inhalation Resistance (mm H_2O)	Exhalation Resistance (mm H_2O)
1	8.3	7.1
2	9.0	7.9
3	8.6	7.6

Test Method Acceptance Criteria: The resistance measurement for the reference plate must be within ± 3 standard deviations of the mean established in the control chart.

Procedure: A complete respirator was mounted to a test fixture comprised of a metal plate with an approximate 3.5 inch diameter hole in the center to allow airflow to reach the mask. The sample holder was assembled by placing a Plexiglas collar around the test fixture and topping with another metal disc with a 3.5 inch opening in the center. The sample holder is held tightly together with clamps and connected to an air source. The manometer is attached to the sample holder by a connection port on the Plexiglas collar.

Before testing, the manometer was zeroed and the back pressure in the sample holder checked and verified to be acceptable. Resistance measurements were taken with a manometer capable of measuring at least 6 inches of water. For inhalation testing, a negative airflow (vacuum) was applied. For exhalation testing, a positive airflow (compressed air) was used. Airflow was passed through the sample holder at approximately 85 ± 2 liters per minute (L/min).