NELSON LABORATORIES

Sponsor:
Josh Torbenson
RZ Mask LLC
3201 County Rd 42 W
Suite 102
Burnsville, MN 55306

Latex Particle Challenge Final Report

Test Article:	F2
Purchase Order:	2507
Study Number:	1017084-S01
Study Received Date:	26 Jan 2018
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0005 Rev 05
Deviation(s):	None

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized, dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

Three one-minute counts were performed, with the test article in the system, and the results averaged. Three one-minute control counts were performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the average number of particles penetrating the test article compared to the average of the control values.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. 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.

Test Side:	Outside
Area Tested:	Entire Mask (Only tested the inner layer of material, not the entire product)
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 24% relative humidity (RH) at 1017; 21°C, 23% RH at 1132
Average Filtration Efficiency:	99.937%
Standard Deviation:	0.0297

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Study Director Brandon L. Williams

07 Feb 2018
Study Completion Date

1017084-S01

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	11	12,463	99.912
2	3	12,709	99.979
3	9	13,244	99.932
4	6	13,342	99.955
5	12	12,817	99.909

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Latex Particle Challenge Final Report

Test Article:	F3
Purchase Order:	2507
Study Number:	1017085-S01
Study Received Date:	26 Jan 2018
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0005 Rev 05
Deviation(s):	None

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized, dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

Three one-minute counts were performed, with the test article in the system, and the results averaged. Three one-minute control counts were performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the average number of particles penetrating the test article compared to the average of the control values.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. 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.

Test Side:	Outside
Area Tested:	Entire Mask (Only tested the inner layer of material, not the entire product)
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 23% relative humidity (RH) at 1132; 22°C, 23% RH at 1417
Average Filtration Efficiency:	>99.963%
Standard Deviation:	0.0223

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Study Director Brandon L. Williams

07 Feb 2018
Study Completion Date

1017085-S01

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	<1[a]	10,724	>99.9969
2	8	12,902	99.935
3	4	13,129	99.967
4	6	13,597	99.956
5	6	14,622	99.959

[a] There were no detected particles penetrating this filter during testing.

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

Test Article:	F2
Purchase Order:	2507
Study Number:	1017082-S01
Study Received Date:	26 Jan 2018
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0145 Rev 04
Deviation(s):	None

Summary: This procedure was performed to evaluate the differential pressure of non-powered air-purifying particulate 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.

Results:

Test Article Number	Inhalation Resistance (mm H_2O)	Exhalation Resistance (mm H_2O)
1	1.4	<0.2
2	1.0	<0.2
3	1.2	<0.2

Study Director Brandon L. Williams

05 Feb 2018
Study Completion Date

1017082-S01

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).

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

Test Article:	F3
Purchase Order:	2507
Study Number:	1017083-S01
Study Received Date:	26 Jan 2018
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0145 Rev 04
Deviation(s):	None

Summary: This procedure was performed to evaluate the differential pressure of non-powered air-purifying particulate 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.

Results:

Test Article Number	Inhalation Resistance (mm H_2O)	Exhalation Resistance (mm H_2O)
1	1.2	<0.2
2	1.9	<0.2
3	2.0	<0.2

Study Director Brandon L. Williams

05 Feb 2018
Study Completion Date

1017083-S01

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).