

Latex Particle Challenge Final Report

Test Article: PP30-NF-PE20
PP30-NF-PE20-C
PP30-NF-PE20-C-Weld
Purchase Order: 5616
Study Number: 1298755-S01
Study Received Date: 12 May 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: STP0005 Rev 07
Deviation(s): Quality Event (QE) Number(s): QE22125

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 (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

A one-minute count was performed, with the test article in the system. A one-minute control count was 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 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: Either
Area Tested: 91.5 cm²
Laboratory Conditions: 19°C, 24% relative humidity (RH) at 1103; 20°C, 24% RH at 1239;
20°C, 24% RH at 1346; 20°C, 24% RH at 1456; 20°C, 24% RH at 1516;
20°C, 24% RH at 1536; 20°C, 24% RH at 1611; 20°C, 24% RH at 1703



Christopher Acker electronically approved for
Study Director

Curtis Gerow

30 May 2020 22:57 (+00:00)
Study Completion Date and Time

Deviation Details: Controls and sample counts were conducted for one minute instead of an average of three one minute counts. This change shortens the total test time for each sample but will still provide an accurate determination of the particle counts. An equilibrate is a dwell period where the challenge is being applied to the test article for a certain period of time before test article counts are counted. The equilibrate period was reduced from 2 minutes to a minimum of 30 seconds which is sufficient time to clear the system of any residual particles, and establish a state of stable equilibrium before sample counts are taken. Test method acceptance criteria were met, results are valid.

Results:

Particle Size: 0.1 µm
 Test Article: PP30-NF-PE20

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	70	11,622	99.40

Particle Size: 0.1 µm
 Test Article: PP30-NF-PE20-C

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	65	11,349	99.43

Particle Size: 0.1 µm
 Test Article: PP30-NF-PE20-C-Weld

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	118	11,370	99.0

Particle Size: 0.3 µm
 Test Article: PP30-NF-PE20

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	168	11,437	98.5
2	112	11,976	99.06

Average Filtration Efficiency: 98.80%
 Standard Deviation: 0.377

Particle Size: 0.3 µm
 Test Article: PP30-NF-PE20-C

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	149	12,455	98.8
2	164	12,983	98.7

Average Filtration Efficiency: 98.8%
 Standard Deviation: 0.05

Particle Size: 0.3 µm
 Test Article: PP30-NF-PE20-C-Weld

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	181	13,895	98.7
2	125	11,371	98.9

 Average Filtration Efficiency: 98.8%
 Standard Deviation: 0.14

 Particle Size: 0.5 µm
 Test Article: PP30-NF-PE20

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	293	12,273	97.6

 Particle Size: 0.5 µm
 Test Article: PP30-NF-PE20-C

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	253	12,956	98.0

 Particle Size: 0.5 µm
 Test Article: PP30-NF-PE20-C-Weld

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	336	13,288	97.5

 Particle Size: 1.0 µm
 Test Article: PP30-NF-PE20

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	144	10,460	98.6

 Particle Size: 1.0 µm
 Test Article: PP30-NF-PE20-C

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	251	10,840	97.7

 Particle Size: 1.0 µm
 Test Article: PP30-NF-PE20-C-Weld

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	222	11,031	98.0