

Latex Particle Challenge GLP Report

Test Article: 16-40348/201603200-100
16-40345/201603200-400
20130040-002/201603200-416A
20130040-005/201603200-416B
Purchase Order: 16-000533
Study Number: 889570-S01
Study Received Date: 28 Apr 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0005 Rev 05
Protocol Detail Sheet (PDS) Number: 201601655 Rev 01

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.

Test Side: Outside (16-40348/201603200-100, 16-40345/201603200-400)
Inside (20130040-002/201603200-416A, 20130040-005/201603200-416B)
Area Tested: Entire Mask
Particle Size: 0.1 μ m
Laboratory Conditions: 11 May 2016: 21°C, 27% relative humidity (RH) at 0859;
21°C, 24% RH at 1341; 21°C, 24% RH at 1645
17 May 2016: 21°C, 30% RH at 0837; 21°C, 30% RH at 0911



Study Director

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23 May 2016
Study Completion Date



889570-S01

Results:

16-40348/201603200-100:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	1	13,725	99.9951
2	<1	13,860	>99.9976
3	<1	13,272	>99.9975
4	1	12,391	99.989
5	1	11,456	99.9942

Average Filtration Efficiency: >99.9947%
Standard Deviation: 0.00341

16-40345/201603200-400:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	18	13,555	99.87
2	14	13,688	99.90
3	6	13,206	99.955
4	11	12,686	99.913
5	7	12,366	99.946

Average Filtration Efficiency: 99.915%
Standard Deviation: 0.0361

20130040-002/201603200-416A:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	5	12,060	99.961
2	122	11,117	98.9
3	20	13,300	99.85
4	2	13,114	99.987
5	12	13,440	99.908

Average Filtration Efficiency: 99.722%
Standard Deviation: 0.4597

20130040-005/201603200-416B:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	12	11,944	99.90
2	14	12,655	99.89
3	16	13,666	99.88
4	63	14,359	99.56
5 ^a	12	12,733	99.903
	39	12,849	99.70

Average Filtration Efficiency: 99.81%

Standard Deviation: 0.142

^a Additional testing was conducted for this sample as the original result was determined to be invalid. Only the additional testing results are reported.

Acceptance Criteria: Ambient background particles detected through the test system must be below 1% of the challenge total (<100 particles).

Procedures:

Test Set-up: Testing was conducted in an ISO Class 5 (class 100) HEPA filtered hood. The inlet air to the test system was filtered through a 0.2 µm rated air filter. The particle generator outlet was clamped off and the number of background particles within the test system was verified to be <1 particles at 1 cubic foot per minute (CFM). The flow rate through the test system was maintained at 1 CFM ± 5%.

An aliquot of the PSL aerosolized using a particle generator, mixed with additional filtered air, dried and passed through the test system. The particles delivered were enumerated using a laser based particle counter.

Test Procedure: A test article was placed into the holder and the system was allowed to stabilize. The average number of particles being delivered to the test article was determined (no medium in air stream) as triplicate one-minute control readings were taken prior to and after every test article. Control count averages were maintained at a level of 10,000-15,000 particles per cubic foot. Triplicate one-minute counts were recorded for the test article between the control counts.

The PFE of each test article was determined by using the following equation:

$$\% PFE = \frac{C - T}{C} \times 100$$

Where: C = Combined average of the control counts
T = Average test article counts