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Latex Particle Challenge Final Report

Test Article: Totobobo F96-2014 /6A
Laboratory Number: 760989
Study Received Date: 11 Jun 2014
Test Procedure(s): Standard Test Protocol (STP) Number: STP0005 Rev 03

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: Inside
Area Tested: 91.5 cm^2
Particle Size: 0.1 µm
Laboratory Conditions: 21°C, 33%relative humidity (RH) at 1035; 20°C, 32%RH at 1136

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	17	12,336	99.86

Study Director Brandon L. Williams

24 Jun 2014
Study Completion Date

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Viral Filtration Efficiency (VFE) Final Report

Test Article: Totobobo F96-2014 / 6A
Laboratory Number: 760987
Study Received Date: 11 Jun 2014
Test Procedure(s): Standard Test Protocol (STP) Number: STP0007 Rev 10

Summary: The VFE test is performed to determine the filtration efficiency by comparing the upstream viral control counts to downstream test article counts. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 2200 ± 500 plaque forming units (PFU) with a mean particle size (MPS) at 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This method allows a reproducible challenge to be delivered to the test articles. The VFE test procedure was adapted from ASTM F2101.

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.

Area Tested: ~45.6 cm^2
VFE Flow Rate: 28.3 Liters per minute (L/min)
Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours.

Results:

Test Article Number	Percent VFE (%)
1	>99.9[a]

Note: Plate count totals for each stage are available upon request.
[a] There were no detected plaques on any of the Andersen sampler plates for this test article.

Positive Control Average: 1,709 PFU
Negative Monitor Count: <1 PFU
MPS: 2.9 µm

Study Director — Sarah Smit, B.S.

23 Jun 2014
Study Completion Date

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