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Latex Particle Challenge Final Report

Test Article:	Nanoxin (nanofiber mask)
Purchase Order:	OSE-267-46818-C7S9X3
Study Number:	928870-S01
Study Received Date:	14 Nov 2016
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0005 Rev 05

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
Particle Size:	0.3 µm
Laboratory Conditions:	21°C, 27% relative humidity (RH) at 1031; 21°C, 25% RH at 1328

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	98	10,378	99.05

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Study Director Brandon L. Williams

28 Nov 2016
Study Completion Date

928870-S01

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Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	Nanoxin (nanofiber mask)
Purchase Order:	OSE-267-46818-C7S9X3
Study Number:	928869-S01
Study Received Date:	14 Nov 2016
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 13

Summary: The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* 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 1.7 - 2.7 x 10^3 colony forming units (CFU) 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 procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with ASTM F2101-14 and EN 14683:2014, Annex B.

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
BFE Area Tested:	~7.1 cm^2
BFE 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.
Test Article Dimensions:	~210 mm x ~190 mm
Positive Control Average:	2.1 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

Results:

Test Article Number	Percent BFE (%)
1	99.3

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

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29 Nov 2016
Study Completion Date

928869-S01

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