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Viral Filtration Efficiency (VFE) Final Report

Test Article:	AntiMicrobe Web R
Study Number:	1272273-S01
Study Received Date:	28 Feb 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: STP0007 Rev 16
Deviation(s):	None

Summary: The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.1 - 3.3 x 10^3 plaque forming units (PFU) with a mean particle size (MPS) of 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. 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.

Test Side:	Either
Test Area:	~40 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
Positive Control Average:	1.3 x 10^3 PFU
Negative Monitor Count:	<1 PFU
MPS:	3.1 µm

Curtis Gerow FSE — 16 Mar 2020
Study Director: James W. Luskin — Study Completion Date

1272273-S01

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	20	12,610	99.84
2	23	13,655	99.83
3	31	12,495	99.75
4	31	13,291	99.77
5	33	14,085	99.77

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Latex Particle Challenge Final Report

Test Article:	AntiMicrobe Web R
Study Number:	1272275-S01
Study Received Date:	28 Feb 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):	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 (atomized), 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:	Either Side
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 24% relative humidity (RH) at 0854; 21°C, 23% RH at 1200
Average Filtration Efficiency:	99.79%
Standard Deviation:	0.042

Curtis Gerow — 16 Mar 2020
Study Director: Curtis Gerow, B.S. — Study Completion Date

1272275-S01

Results:

Test Article Number	Percent VFE (%)
1	>99.9[a]
2	>99.9[a]
3	>99.9[a]
4	>99.9[a]
5	>99.9[a]

[a] There were no detected plaques on any of the Andersen sampler plates for this test article.

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

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

GECKO MASK

Popis respirační nanoroušky

- Chrání před **bakteriemi** a **viry.**
- Je tvořena sendvičem ze 100% bavlny a nanovlákna, které je složeno vlákny menší než 0,1 µm, tudíž má **99,79% účinnost.**
- **Jedná se o roušku s kapsou s možností výměny nanovlákna.**
- **Rouška vydrží i sedm dní**

Jak se o roušku starat?

- Po 24 hodinách nanovlákno vyjměte, bavlněnou roušku vyperte a vyžehlete.
- Samotné nanovlákno **přežehlete pod bavlněnou látkou** (Pozor! zvolte přiměřeně stupně, nanovlákno nesmí po přežehlení změnit tvar ani barvu).

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