



MED-CON (THAILAND) CO., LTD.

20 Soi Ruammit, Rama 6 Road, Samsennai, Phayathai, Bangkok 10400 Thailand.

Tel: +66 2 271 0983-4 Fax: +66 2 271 0985

E-mail: info@medconthai.com, Website: www.medconthai.com

Bacterial Filtration Efficiency (BFE) Final Report

Test Article: AVMB18
Study Number: 1027459-S01
Study Received Date: 05 Mar 2018

Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 15
Deviation(s): None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* 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 $1.7 - 2.7 \times 10^3$ colony forming units (CFU) with a mean particle size (MPS) of $3.0 \pm 0.3 \mu\text{m}$. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-14, EN 14683:2014, Annex B, and AS4381:2015.

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
BFE Test Area: $\sim 40 \text{ cm}^2$
BFE Flow Rate: 28.3 Liters per minute (L/min)
Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours
Positive Control Average: 2.6×10^3 CFU
Negative Monitor Count: <1 CFU
MPS: $3.0 \mu\text{m}$

Results:

Test Article Number	Percent BFE (%)
1	99.5

The filtration efficiency percentages were calculated using the following equation:

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

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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Latex Particle Challenge Final Report

Test Article: PJJ1704PF
Study Number: 965600-S01
Study Received Date: 18 May 2017

Test Procedure(s): Standard Test Protocol (STP) Number: 801-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: Inside
Area Tested: 91.5 cm²
Particle Size: 0.1 µm
Laboratory Conditions: 20°C, 32% relative humidity (RH) at 1035; 20°C, 32% RH at 1550
Average Filtration Efficiency: 99.79%
Standard Deviation: 0.066

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	37	13,689	99.73
2	42	14,671	99.71
3	24	11,259	99.79
4	15	11,996	99.87
5	22	12,998	99.83



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Synthetic Blood Penetration Resistance Final Report

Test Article: CB1711SB
Study Number: 1010970-S01
Study Received Date: 21 Dec 2017

Test Procedure(s): Standard Test Protocol (STP) Number: STP0012 Rev 08
Deviation(s): None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2014 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of $21 \pm 5^\circ\text{C}$ and a relative humidity of $85 \pm 10\%$. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

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.

Number of Test Articles Tested: 32
Number of Test Articles Passed: 32
Test Side: Outside
Pre-Conditioning: Minimum of 4 hours at $21 \pm 5^\circ\text{C}$ and $85 \pm 5\%$ relative humidity (RH)
Test Conditions: 21.7°C and 21% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥ 29 of 32 test articles show passing results.

Test Pressure: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen



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Viral Filtration Efficiency (VFE) Final Report

Test Article: PTJ1704VF
Study Number: 965599-S01
Study Received Date: 18 May 2017

Test Procedure(s): Standard Test Protocol (STP) Number: 801-STP0007 Rev 14

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 Φ X174 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 $1.1 - 3.3 \times 10^3$ plaque forming units (PFU) with a mean particle size (MPS) of $3.0 \mu\text{m} \pm 0.3 \mu\text{m}$. 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: Inside
Test Area: $\sim 40 \text{ cm}^2$
VFE Flow Rate: 28.3 Liters per minute (L/min)
Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours.
Positive Control Average: 1.2×10^3 PFU
Negative Monitor Count: <1 PFU
MPS: $3.0 \mu\text{m}$

Results:

Test Article Number	Percent VFE (%)
1	99.5
2	99.1
3	99.7
4	99.2
5	99.4

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request