

Bacterial Filtration Efficiency (BFE) Final Report

Test Article: Surgical Masks
 Brand: CrossCare
 CH1040AB-02 / CH1040AB-BS
 Study Number: 957175-S01
 Study Received Date: 06 Apr 2017
 Testing Facility: Nelson Laboratories, LLC, a Business Unit of Sterigenics International
 6280 S. Redwood Rd.
 Salt Lake City, UT 84123 U.S.A.
 Test Procedure(s): Standard Test Protocol (STP) Number: 801-STP0004 Rev 14

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 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: Inside
 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: 1.9×10^3 CFU
 Negative Monitor Count: <1 CFU
 MPS: $3.0 \mu\text{m}$

Results:

Test Article Number	Percent BFE (%)
1	99.7
2	99.5
3	99.6
4	99.8
5	99.7



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Study Completion Date 01 May 2017



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The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request