

## Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article: MEDICAL SURGICAL MASKS /Model: F-Y1-A  
Purchase Order: 20-243A  
Study Number: 1293324-S01  
Study Received Date: 27 Apr 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: STP0004 Rev 18  
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  $1.7 - 3.0 \times 10^3$  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 F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

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)  
Delta P Flow Rate: 8 L/min  
Conditioning Parameters:  $85 \pm 5\%$  relative humidity (RH) and  $21 \pm 5^\circ\text{C}$  for a minimum of 4 hours  
Test Article Dimensions:  $\sim 172 \text{ mm} \times \sim 150 \text{ mm}$   
Positive Control Average:  $2.9 \times 10^3$  CFU  
Negative Monitor Count:  $< 1$  CFU  
MPS:  $2.6 \mu\text{m}$



Reid Jones electronically approved for  
Study Director

James Luskin

15 Jun 2020 13:50 (+00:00)  
Study Completion Date and Time

The mean particle size was out of specification; STP0004 Rev 18 section 6.2 states, "The MPS control average aerosol shall be maintained at  $3.0 \pm 0.3 \mu\text{m}$ ." A lower MPS is a more severe challenging condition to the test articles. The sponsor accepted the lower MPS; the results are valid at the test conditions that occurred.

**Results:**

Test Article Number	Percent BFE (%)
1	99.6
2	99.6
3	99.8
4	99.4
5	99.4

Test Article Number	Delta P (mm H <sub>2</sub> O/cm <sup>2</sup> )	Delta P (Pa/cm <sup>2</sup> )
1	3.4	33.1
2	3.2	31.1
3	3.2	31.3
4	3.4	33.3
5	3.2	31.1

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