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

Test Article:	#11 Medical Face Mask, Type IIR	
Purchase Order:	2019-11-13B_PO	
Study Number:	1242371-S01	
Study Received Date:	18 Nov 2019	
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 17
	Protocol Number:	201905709 Rev 01
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 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. 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 BFE test method also complies with EN14683:2014, 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 14683:2014, Annex C and ASTM F2100-11. This followed Protocol 201904572 Rev 01.

EN 14683:2014 Annex B and EN 14683:2019 Annex B BFE methods are essentially the same with the only difference in the bacterial challenge level. The 2019 version expanded the challenge level by a 300 CFU increase, see below:

2014: Bacterial challenge 1.7 - 2.7 x 10^3 CFU per test

2019: Bacterial challenge 1.7 - 3.0 x 10^3 CFU per test

For this testing the bacterial challenge met the 2014 and 2019 versions of the standard.

In addition, clarifications were added in the 2019 version for sample preparation, conditioning, mean particle size equation, test area and Andersen sampler figure for set-up. These clarifications were added to provide more information about the method but none of the clarifications changed the method.

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.

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Curtis Glover For
Study Director — Janelle R. Bentz, M.S.

02 Dec 2019
Study Completion Date

1242371-S01

Test Side:	Inside
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~174 mm x ~182 mm
Positive Control Average:	2.0 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.1 µm

Results:

Test Article Number	Percent BFE (%)
1	99.4
2	98.9
3	99.2
4	99.3
5	99.1

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	2.0	19.7
2	2.0	20.0
3	2.0	19.8
4	2.0	19.8
5	2.0	20.0

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