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Latex Particle Challenge Final Report

Test Article: 1. SM3P #1
2. SM3P #2
3. SM3P #3
4. SM3P #4
Purchase Order: 7788
Study Number: 954158-S01
Study Received Date: 03 Feb 2020
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 F2100, 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: ~61 cm²
Particle Size: 0.1 µm
Laboratory Conditions: 10 Feb 2020: 21°C, 23% relative humidity (RH) at 0952;
20°C, 24% RH at 1235
11 Feb 2020: 21°C, 23% RH at 0815; 21°C, 23% RH at 0839
Average Filtration Efficiency: 95.85%
Standard Deviation: 0.068

Study Director

Brandon L. Williams



13 Apr 2017
Study Completion Date



954158-S01

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1 ^a	18	11,138	96.84
	15	12,594	96.88
2 ^a	10	10,141	98.90
	7	14,080	98.948
3 ^a	19	10,651	96.82
	34	12,850	96.74
4	24	13,549	98.82

^a Additional testing results reported. The original results were determined to be invalid due to a mounting error.

ASTM F 2100 – Level 2 Barrier Protection

Characteristic	Testing Methodology	Acceptable Limits
Bacterial Filtration Efficiency (BFE)	ASTM F2101	BFE @ 3.0 µm large Bacteria ≥ 95%
Differential Pressure (ΔP)	MIL-M-36954C	ΔP < 4.0 mm of H ₂ O/cm ²
Particulate Filtration Efficiency (PFE)	ASTM F2299	PFE @ 0.1 µm large Latex particules ≥ 95%
Fluid Resistance	ASTM F1862	Resistant @ 80mmHg
Textile Flammability	16 CFR 1610	Class I flame spread

Characteristic	Specification		
Description	Shingle pleats rectangular face masks with a shapeable nosepiece and two earloops present, one on each side, in order to hold mask in place. (Refer to Appendix 1 Specific Attribute)		
Dimension	Body Size	Length	7" (176 mm)
		Width	3 ½" (89 mm)
	Height of Earloop ⁽¹⁾	2 ½" (63,5mm)	
	Pleat Depth ⁽²⁾	½" (14 mm)	
	Length of Nose-piece	4 ¾" (120 mm)	

Visual

