

Sponsor: Celine Huang Hubei Wanli Protective Products Co., Ltd Yuanshi, Ganhe Xiantao, Hubei, 433000 CHINA

Latex Particle Challenge Final Report

Test Article: WLM2002

Purchase Order: WL201906-1121T

Study Number: 1253865-S01

Study Received Date:

26 Dec 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: STP0005 Rev 07

Deviation(s): None

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 (atomized), 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, 24% relative humidity (RH) at 0951; 20°C, 24% RH at 1242

Average Filtration Efficiency: 99.920%

Standard Deviation: 0.0358

Study Director

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Study Completion Date

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FRT0005-0001 Rev 6



Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	9	12,401	99.927
2	7	13,042	99.949
3	17	13,496	99.87
4	14	13,570	99.90
5	6	13,926	99.957

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