



Latex Particle Challenge Final Report

Test Article: AntiVirus - Respilon
Laboratory Number: 754319
Study Received Date: 05 May 2014
Test Procedure(s): Standard Test Protocol (STP) Number: STP0005 Rev 03

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 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: Sponsor Labeled Side
Area Tested: 91.5 cm²
Particle Size: 0.1 µm
Laboratory Conditions: 20°C, 26%relative humidity (RH) at 0925; 20°C, 25%RH at 1025
Average Filtration Efficiency: 99.5%
Standard Deviation: 0.38

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	129	10,260	99.7
2	116	11,840	99.9
3	119	12,880	99.9
4	140	12,937	98.9
5	245	13,150	99.1


Study Director Brandon L. Williams

19 May 2014
Study Completion Date