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Latex Particle Challenge Final Report

Test Article:	TDK-25-II
Study Number:	1111370-S01
Study Received Date:	19 Oct 2018
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 05
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, 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:	Labeled Side
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 31% relative humidity (RH) at 0749; 21°C, 30% RH at 1009; 21°C, 29% RH at 1349
Average Filtration Efficiency:	99.66%
Standard Deviation:	0.070

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Curtis Devan — Study Director

For Brandon L. Williams

29 OCT 2018 — Study Completion Date

1111370-S01

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Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	52	12,327	99.58
2	32	13,739	99.77
3	46	13,437	99.66
4	45	13,156	99.66
5	50	13,020	99.62