Nelson Labs
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(生物相容性測試報告)

Latex Particle Challenge Final Report

Test Article:	MWPTFE95	
Study Number:	1294770-S01	
Study Received Date:	30 Apr 2020	
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):	Quality Event (QE) Number(s):	QE22125

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.

A one-minute count was performed, with the test article in the system. A one-minute control count was 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 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:	White Side (Inside)
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	20°C, 32% relative humidity (RH) at 0955; 20°C, 32% RH at 1106; 21°C, 32% RH at 1253; 21°C, 31% RH at 1408;
Average Filtration Efficiency:	>99.3762%
Standard Deviation:	0.85388

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Sarah Guzman electronically approved for — 23 Jun 2020 19:03 (+00:00)

Study Director — Curtis Gerow — Study Completion Date and Time

Deviation Details: Controls and sample counts were conducted for one minute instead of an average of three one minute counts. This change shortens the total test time for each sample but will still provide an accurate determination of the particle counts. An equilibrate is a dwell period where the challenge is being applied to the test article for a certain period of time before test article counts are counted. The equilibrate period was reduced from 2 minutes to a minimum of 30 seconds which is sufficient time to clear the system of any residual particles, and establish a state of stable equilibrium before sample counts are taken. Test method acceptance criteria were met, results are valid.

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1-1[a]	212	11,463	98.2
1-2[a]	<1	12,947	>99.9974
2	<1	12,028	>99.9972
3[b]	188	11,686	98.4
3-1[b]	205	13,798	98.5
3-2[b]	1	12,319	99.9919
4	4	13,131	99.970
5	<1	12,769	>99.9974

[a] The original result for this test article was unexpected when compared to the other test articles. Investigational testing was performed on the same test article in duplicate and it was determined that the original result was invalid. All valid test results are reported.

[b] The original result for this test article was unexpected when compared to the other test articles. Investigational testing was performed on the same test article in duplicate and it was determined that the original result was valid. All valid test results are reported.