

Latex Particle Challenge Final Report

Test Article: 1. HELIX™ 200 #1
2. HELIX™ 200 #2
3. HELIX™ 200 #3
4. HELIX™ 200 #4
Purchase Order: 7788
Study Number: 954158-S01.1 Amended
Study Received Date: 23 Mar 2017
Study Completion Date: 13 Apr 2017
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 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: Either Side
Area Tested: ~61 cm²
Particle Size: 0.1 µm
Laboratory Conditions: 10 Apr 2017: 21°C, 23% relative humidity (RH) at 0952;
20°C, 24% RH at 1235
11 Apr 2017: 21°C, 23% RH at 0815; 21°C, 23% RH at 0839
Average Filtration Efficiency: 99.85%
Standard Deviation: 0.068




Study Director
Brandon L. Williams


Amended Report Date



Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1 ^a	18	11,138	99.84
	15	12,594	99.88
2 ^a	10	10,141	99.90
	7	14,080	99.948
3 ^a	19	10,651	99.82
	34	12,850	99.74
4	24	13,549	99.82

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

Amendment Justification: At the request of the sponsor, the sponsor information was updated. Lanaco Limited (formerly Texus Fibre Limited) organized this test on behalf of Healthy Breath Limited.