Sponsor:
Sarinda Kwok
Profit Royal Pharmaceutical Limited
RM 1211, 12/F, Sunbeam Centre
27 Shing Yip St.
Kwun Tong, Kowloon, Hong Kong
CHINA

Nano and Advanced Materials Institute Limited
Unit 517, 5/F, Lakeside 1
No. 8 Science Park West Ave.
Hong Kong Science Park, Shatin
Hong Kong
CHINA

Latex Particle Challenge Final Report

Test Article: 15040815, 15040816, 15040817, 15040818, 15040819
Purchase Order: NA2410
Laboratory Number: 823922
Study Received Date: 27 May 2015
Test Procedure(s): Standard Test Protocol (STP) Number: STP0005 Rev 04

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: Inside
Area Tested: Entire Mask
Particle Size: 0.1 µm
Laboratory Conditions: 21°C, 32% relative humidity (RH) at 1236; 21°C, 33% RH at 1603
Average Filtration Efficiency: >99.976%
Standard Deviation: 0.0245

Results:

Test Article	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
15040815	3	10,198	99.974
15040816	1	11,250	99.9941
15040817	8	11,938	99.936
15040818	<1	12,317	>99.9973
15040819	3	12,451	99.979

ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Study Director Brandon L. Williams

5 Jun 2015
Study Completion Date