NELSON LABORATORIES

Sponsor:
Jim Schumacher
Advanced Global Innovations, Ltd.
28/1 Pridi Banomayong 2,
Sukhumvit 71
Bangkok, 10110
THAILAND

Bacterial Filtration Efficiency (BFE) at an Increased Challenge Level Final Report

Test Article:	SS-99S
Study Number:	974799-S01
Study Received Date:	05 Jul 2017
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: 801-STP0009 Rev 09 Customer Specification Sheet (CSS) Number: 201704251 Rev 01

Summary: This procedure was performed to evaluate the BFE at an increased challenge level of the test article. A suspension of *Staphylococcus aureus*, ATCC #6538, was delivered to the test article to determine filtration efficiency. A challenge level of greater than 10^7 colony forming units (CFU) was pumped through a nebulizer using a peristaltic pump at a controlled flow rate and fixed air pressure. The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) in parallel. The challenge was delivered for a five minute interval and sampling through the AGIs was conducted for six minutes to clear the aerosol chamber.

This test procedure was modified from Nelson Laboratories, LLC (NL), standard BFE procedure in order to employ a more severe challenge than would be experienced in normal use. This method was adapted from ASTM F2101. NL has not performed validation using the challenge interval performed in this testing, however, adequate controls are included to verify the reliability of this study. 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.

Challenge Flow Rate:	30 Liters per Minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Area Tested:	~38.5 cm^2
Side Tested:	Hard Side
Challenge Level:	5.2 x 10^7 CFU
Mean Particle Size (MPS):	~3.1 µm

Results:

Test Article Number	Total CFU Recovered	Filtration Efficiency (%)
1	3.5 x 10^3	99.9932

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Challenge Level
T = Total CFU recovered downstream of the test article

Study Director Trang Truong Trang T. Truong, B.S. 12/Jul/2017 Study Completion Date

974799-S01