NELSON LABORATORIES

Sponsor:
Billy Liang
Saykia Corporation
No 32-19 Pucai Rd
Puyan Township
Changhua, 51649
TAIWAN ROC

Viral Filtration Efficiency (VFE) at an Increased Challenge Level Final Report

Test Article:	SK203 Lot #20170606
Purchase Order:	SKNL080617
Study Number:	970196-S01
Study Received Date:	12 Jun 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-STP0010 Rev 10

Summary: This procedure was performed to evaluate the VFE at an increased challenge level of the test article. A suspension of ΦX174 bacteriophage was delivered to the test article to determine filtration efficiency. A challenge level of greater than 10^7 plaque-forming units (PFU) was pumped through a nebulizer using a peristaltic pump at a controlled flow rate and a 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 one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber. VFE at an Increased Challenge Level test procedure was adapted from ASTM F2101.

This test procedure was modified from Nelson Laboratories, LLC (NL), standard VFE test in order to employ a more severe challenge than would be experienced in normal use. 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)
Area Tested:	Entire Test Article
Side Tested:	~26 mm OD Port
Challenge Level:	3.2×10^7 PFU
Negative Monitor Count:	<1 PFU
Mean Particle Size (MPS):	~3.0 µm

Results:

Test Article Number	Total PFU Recovered	Filtration Efficiency (%)
1	5.8×10^2	99.9982
2	5.3×10^2	99.9984
3	2.3×10^3	99.9930

Study Director Trang Truong Trang T. Truong, B.S.

26JUN2017
Study Completion Date

970196-S01

The filtration efficiency percentages were calculated using the following equation:

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

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