

## 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  $\Phi$ X174 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.

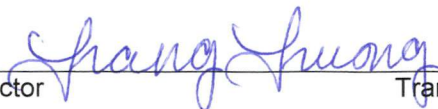
This test procedure was modified from Nelson Laboratories, LLC (NL), standard VFE test in order to employ a more severe challenge than would be experienced in normal use. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 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:  $3.2 \times 10^7$  PFU  
 Negative Monitor Count: <1 PFU  
 Mean Particle Size (MPS): ~3.0  $\mu$ m

**Results:**

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

Study Director



Trang T. Truong, B.S.

Study Completion Date

26 Jun 2017



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The filtration efficiency percentages were calculated using the following equation:

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

C = Challenge Level

T = Total PFU recovered downstream of the test article