

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

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Test Article: Oxyphen M3512  
Purchase Order: 152196  
Study Number: 1358338-S01.1 Amended  
Study Received Date: 30 Oct 2020  
Study Completion Date: 02 Dec 2020  
Testing Facility: Nelson Laboratories, LLC  
6280 S. Redwood Rd.  
Salt Lake City, UT 84123 U.S.A.  
Test Procedure(s): Standard Test Protocol (STP) Number: STP0010 Rev 15  
Deviation(s): None

**Summary:** This test procedure was performed to evaluate the VFE of test articles at an increased challenge level. A suspension of  $\Phi$ X174 bacteriophage was delivered to the test article at a challenge level of greater than  $10^6$  plaque-forming units (PFU) to determine the filtration efficiency. The challenge was aerosolized using a nebulizer and delivered to the test article at a fixed air pressure and flow rate of 30 liters per minute (LPM). The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) for collection. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber. The mean particle size (MPS) control was performed at a flow rate of 28.3 LPM using a six-stage, viable particle, Andersen sampler for collection. The 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 procedure 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 LPM  
Area Tested:  $\sim 40 \text{ cm}^2$   
Side Tested: Rough Side  
Challenge Level:  $3.6 \times 10^6$  PFU  
MPS:  $\sim 2.9 \mu\text{m}$   
Test Monitor Results: Acceptable

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James Luskin electronically approved  
Study Director

James Luskin

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04 Jan 2021 20:51 (+00:00)  
Amended Report Date and Time

**Results:**

Test Article Number	Total PFU Recovered	Filtration Efficiency (%)
1	9.0 x 10 <sup>1</sup>	99.9975
2	3.0 x 10 <sup>1</sup>	99.99917
3	1.0 x 10 <sup>1</sup>	99.99972

Note: After inspection of the original tested samples, it was noted that there were small tears present, caused from the initial testing method. Retesting took place, with a more delicate testing holder. The original results were deemed invalid and only the retest results will be reported.

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

**Amendment Justification:** At the request of the sponsor, investigational testing was performed and the retest results were added to the report in place of the original results.