Nelson Labs
A Sotera Health company

Sponsor:

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

Test Article:	MKM-2-HC-M-T200 6A-10A
Purchase Order:	MM2022-T1
Study Number:	1504415-S01
Study Received Date:	04 Apr 2022
Test Started Date:	14 Apr 2022
Test Finish Date:	15 Apr 2022
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 16
Deviation(s):	None

Summary: This test procedure was performed to evaluate the VFE of test articles at an increased challenge level. A suspension of ΦX174 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:	Entire Test Article
Side Tested:	Outside
Challenge Level:	1.9×10^6 PFU
MPS:	~3.3 µm
Test Monitor Results:	Acceptable

James Luskin electronically approved — 19 Apr 2022 17:13 (+00:00)
Study Director James Luskin — Study Completion Date and Time

Results:

Test Article	Total PFU Recovered	Filtration Efficiency (%)
6A	9.4×10^2	99.950
7A	4.6×10^4	97.6
8A	2.0×10^4	98.9
9A	4.8×10^4	97.5
10A	4.9×10^3	99.74

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