Nelson Labs
A Sotera Health company

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

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 10^7 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 150 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 an 10 minute interval and sampling through the AGIs was conducted for 11 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. NL has not performed a validation using the flow rate performed in this testing; however, adequate controls are included to verify the reliability of this study. All test method acceptance criteria were met.

Challenge Flow Rate:	150 LPM
Area Tested:	Entire Test Article
Side Tested:	Entrance Region Side
Challenge Level:	1.2×10^7 PFU
MPS:	2.9 µm
Test Monitor Results:	Acceptable

Results:

Test Article	Total PFU Recovered	Filtration Efficiency (%)
01VFE123	30	99.99976
02VFE121	<1[a]	>99.9999919
03VFE073	<1[a]	>99.9999919

[a] There were no detected plaques on any of the assay plates for this test article.

ΦX174 is a small icosahedral, tailless bacteriophage with a maximum diameter of ~320 Å*

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

*https://www.pnas.org/content/114/52/13708