Nelson Labs
A Sotera Health company

Bacterial Filtration Efficiency (BFE) at an Increased Challenge Level GLP Report

Summary: This test procedure was performed to evaluate the BFE of test articles at an increased challenge level. A suspension of *Staphylococcus aureus*, ATCC #6538, was delivered to the test article at a challenge level of greater than 10^6 colony forming units (CFU). 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 a 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.

This test procedure was modified from Nelson Laboratories, LLC (NL), standard BFE procedure in order to employ a more severe challenge than would be experienced in normal use. This method was adapted from ASTM F2101. 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. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Challenge Flow Rate:	150 LPM
Area Tested:	Entire Test Article
Side Tested:	Entrance Region Side
Challenge Level:	7.1×10^6 CFU
MPS:	~2.9 µm
Test Monitor Results:	Acceptable

Results:

Test Article	Total CFU Recovered	Filtration Efficiency (%)
01BFE164	18	99.99975
02BFE035	3	99.999958
03BFE029	<1[a]	>99.999986

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

The spherical cells of Staphylococcus aureus are up to 1 µm in diameter*

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.

*Reference: https://www.britannica.com/science/bacteria/Diversity-of-structure-of-bacteria#ref463523