Nelson Labs
A Sotera Health company

Sponsor:
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Bacterial Filtration Efficiency (BFE) at an Increased Challenge Level Final Report

Test Article:	Oxyphen M3512
Purchase Order:	152196
Study Number:	1358337-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: STP0009 Rev 14
Deviation(s):	None

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 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.

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. 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:	~ 40 cm^2
Side Tested:	Rough Side
Challenge Level:	2.4 x 10^6 CFU
MPS:	~ 2.9 µm
Test Monitor Results:	Acceptable

James Luskin electronically approved — 04 Jan 2021 20:52 (+00:00)
Study Director James Luskin — Amended Report Date and Time

Results:

Test Article Number	Total CFU Recovered	Filtration Efficiency (%)
1	2.9×10^1	99.9988
2	2	99.999916
3	5.9×10^1	99.9975

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:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Challenge Level
T = Total CFU 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.