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Viral Filtration Efficiency (VFE) Final Report

Test Article:	ZSTS001
Purchase Order:	ZSTS001
Study Number:	999097-S01
Study Received Date:	27 Oct 2017
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0007 Rev 15
Deviation(s):	None

Summary: The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.1 - 3.3 x 10^3 plaque forming units (PFU) with a mean particle size (MPS) of 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure 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.

Test Side:	Inside
Test Area:	~40 cm^2
VFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Control Average:	3.3 x 10^3 PFU
Negative Monitor Count:	<1 PFU
MPS:	3.1 µm

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Study Director — Janelle R. Bentz, M.S. — Study Completion Date: 06 Nov 2017

999097-S01

Results:

Test Article Number	Percent VFE (%)
1	99.8
2	99.8
3	99.8
4	99.8
5	99.8

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request