NELSON LABORATORIES

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CZECH REPUBLIC

Viral Filtration Efficiency (VFE) Final Report

Test Article: AntiVirus - Respilon
Laboratory Number: 754320
Study Received Date: 05 May 2014
Test Procedure(s): Standard Test Protocol (STP) Number: STP0007 Rev 09

Summary: The VFE test is performed to determine the filtration efficiency by comparing the viral control counts to test article effluent counts. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This method allows a reproducible challenge to be delivered to the test articles. 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: Sponsor Labeled Side
Area Tested: ~45.6 cm^2
VFE Flow Rate: 28.3 Liters per minute (L/min)

Results:

Test Article Number	Percent VFE (%)
1	99.9
2	99.9
3	99.9
4	99.9
5	99.9

Note: Plate count totals for each stage are available upon request.

Mean Positive Control Count: 2,082 plaque forming units (PFU)
Negative Monitor Count: <1 PFU
Mean Particle Size (MPS): 2.8 µm

Study Director — Sarah Smit, B.S.

22 May 2014
Study Completion Date