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Viral Filtration Efficiency (VFE) Final Report

Test Article: Totobobo F96-2014 / 6A
Laboratory Number: 760987
Study Received Date: 11 Jun 2014
Test Procedure(s): Standard Test Protocol (STP) Number: STP0007 Rev 10

Summary: The VFE test is performed to determine the filtration efficiency by comparing the upstream viral control counts to downstream test article counts. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 2200 ± 500 plaque forming units (PFU) with a mean particle size (MPS) at 3.0 µm ± 0.3 µm. 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.

Area Tested: ~45.6 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.

Results:

Test Article Number	Percent VFE (%)
1	>99.9[a]

Note: Plate count totals for each stage are available upon request.
[a] There were no detected plaques on any of the Andersen sampler plates for this test article.

Positive Control Average: 1,709 PFU
Negative Monitor Count: <1 PFU
MPS: 2.9 µm

Study Director — Sarah Smit, B.S.

23 Jun 2014
Study Completion Date

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