

Viral Filtration Efficiency (VFE) at an Increased Challenge Level Final Report

Test Article: NIOX NOVA Patient Filter, Art. No. 13-1018
 NIOX VERO Patient Filter, Art. No. 12-1018
 Laboratory Number: 762327.1 Amended
 Study Received Date: 18 Jun 2014
 Study Completion Date: 01 Jul 2014
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0010 Rev 06

Summary: This procedure was performed to evaluate the VFE at an increased challenge level of the test article. A suspension of ΦX174 bacteriophage was delivered to the test article to determine filtration efficiency. A challenge level of greater than 10⁶ plaque-forming units (PFU) was pumped through a nebulizer using a peristaltic pump at a controlled flow rate and a fixed air pressure. The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) in parallel. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber.

This test procedure was modified from Nelson Laboratories, Inc., standard VFE test in order to employ a more severe challenge than would be experienced in normal use. 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 Liters per minute (L/min)
 Area Tested: Entire Test Article
 Side Tested: Oval Port (NOVA), ~14 mm OD Port (VERO)

Results:

NIOX NOVA Patient Filter, Art. No. 13-1018:

Test Article Number	Total PFU Recovered	Filtration Efficiency (%)
1	5.9 x 10 ²	99.981
2	4.6 x 10 ²	99.985
3	3.5 x 10 ²	99.989

Challenge Level: 3.2 x 10⁶ PFU
 Mean Particle Size (MPS): 3.0 μm

NIOX VERO Patient Filter, Art. No. 12-1018:

Test Article Number	Total PFU Recovered	Filtration Efficiency (%)
1	8.7 x 10 ²	99.972
2	9.3 x 10 ²	99.971
3	7.3 x 10 ²	99.977

Challenge Level: 3.2 x 10⁶ PFU
 MPS: 3.0 μm

Amendment Justification: At the request of the sponsor, the test article identification was changed from "NIOX NOVA Patient Filter NIOX VERO Patient Filter" to "NIOX NOVA Patient Filter, Art. No. 13-1018 NIOX VERO Patient Filter, Art. No. 12-1018" throughout the report.



Study Director

Sarah Smit, B.S.

03 Jul 2014
 Amended Report Date