

Bacterial Filtration Efficiency (BFE) 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: 762326
Study Received Date: 18 Jun 2014
Test Procedure(s): Standard Test Protocol (STP) Number: STP0009 Rev 06

Summary: This procedure was performed to evaluate the BFE at an increased challenge level of the test article. A suspension of *Staphylococcus aureus*, ATCC #6538, was delivered to the test article to determine filtration efficiency. A challenge level of greater than 10^7 colony forming units (CFU) was pumped through a nebulizer using a peristaltic pump at a controlled flow rate and 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 1 minute interval and sampling through the AGIs was conducted for 2 minutes to clear the aerosol chamber.

This test procedure was modified from Nelson Laboratories, Inc., 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 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 CFU Recovered	Filtration Efficiency (%)
1	4.9×10^1	99.99961
2	4.7×10^1	99.99962
3	5.2×10^1	99.99958

Challenge Level: 1.2×10^7 CFU
Mean Particle Size (MPS): 3.1 μ m

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

Test Article Number	Total CFU Recovered	Filtration Efficiency (%)
1	1.1×10^2	99.99914
2	6.5×10^1	99.99948
3	1.6×10^2	99.9987

Challenge Level: 1.2×10^7 CFU
MPS: 3.1 μ m



Study Director

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Study Completion Date