

Bacterial Filtration Efficiency (BFE) at an Increased Challenge Level Final Report

Test Article: SK203
 Lot #20170606
 Purchase Order: SKNL080617
 Study Number: 970195-S01
 Study Received Date: 12 Jun 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: 801-STP0009 Rev 09

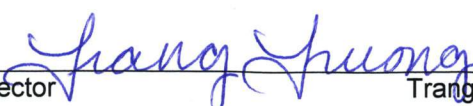
Summary: This procedure was performed to evaluate the BFE at an increased challenge level of the test article. A suspension of *Staphylococcus aureus*, ATCC #6538, was delivered to the test article to determine filtration efficiency. A challenge level of greater than 10⁶ colony forming units (CFU) was 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 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, LLC (NL), 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: ~26 mm OD Port
 Challenge Level: 3.3 x 10⁶ CFU
 Mean Particle Size (MPS): ~3.0 µm

Results:

Test Article Number	Total CFU Recovered	Filtration Efficiency (%)
1	1	99.999969
2	2	99.999939
3	1	99.999969

Study Director:  Trang T. Truong, B.S. Study Completion Date: 26 Jun 2017



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The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} \times 100$$

C = Challenge Level

T = Total CFU recovered downstream of the test article