NELSON LABORATORIES

Sponsor:
James Hurlman, Daniel Consaga
Dynarex Corporation
10 Glenshaw St.
Orangeburg NY 10962

Bacterial Filtration Efficiency and Differential Pressure GLP Report

Purchase Order:
Laboratory Number: 609430.1 Amended
Study Received Date: 22 Nov 2011
Study Completion Date: 14 Dec 2011
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 05
Protocol Detail Sheet (PDS) Number: 201104318 Rev 01

Summary: The bacterial filtration efficiency (BFE) test is performed to determine the filtration efficiency by comparing the bacterial control counts to test article effluent counts. A suspension of *Staphylococcus aureus* 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 procedure allows a reproducible bacterial challenge to be delivered to test materials. This method complies with ASTM F2101.

The differential pressure (ΔP or Delta P) test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate.

All test method acceptance criteria were met.

Test Side: Outside Surface
BFE Area Tested: ~3.0 inches (75 mm) diameter
BFE Flow Rate: 28.3 L/min (1 cubic foot per minute(CFM))
Delta P Flow Rate: 8 L/min

Study Director

Sarah Smit, B.S.

05 Apr 2012
Amended Report Date

P.O. Box 571830 | Murray, UT 84157-1830 U.S.A. · 6280 South Redwood Road | Salt Lake City, UT 84123-6600 U.S.A.
www.nelsonlabs.com · Telephone 801 290 7500 · Fax 801 290 7998 · sales@nelsonlabs.com

rp   FRT0004-0001 Rev 5
Page 1 of 4

Results:

Unit Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)
1	99.8	3.6
2	99.5	3.3
3	99.5	3.2

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

Mean Positive Control Count: 2,446 colony forming units (CFU)
Negative Control Count: <1 CFU
Mean Particle Size (MPS): 3.2 μm

Unit Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)
1	99.4	4.4
2	99.3	4.4

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

Mean Positive Control Count: 2,446 CFU
Negative Control Count: <1 CFU
Mean Particle Size (MPS): 3.2 μm

Test Article Preparation: The BFE test articles were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity, prior to testing.

Acceptance Criteria: The BFE control average must be 2,200 ± 500 CFU. A BFE run with a control average of less than 1,700 shall be unacceptable. Challenges greater than 2,700, but less than 3,000, are, in our experience, valid. Acceptance of runs with control averages exceeding 2,700 shall be at the sponsor's approval.

The average MPS of the challenge aerosol must be maintained at 3.0 ± 0.3 μm.

The average % BFE for the reference material must be within the upper and lower control limits established for the BFE test.

The Delta P result for each reference material must be within the upper and lower control limits established for the Delta P test.

P.O. Box 571830 | Murray, UT 84157-1830 U.S.A. · 6280 South Redwood Road | Salt Lake City, UT 84123-6600 U.S.A.
www.nelsonlabs.com · Telephone 801 290 7500 · Fax 801 290 7998 · sales@nelsonlabs.com

rp

FRT0004-0001 Rev 5
Page 2 of 4

Procedure:

BFE: A culture of *Staphylococcus aureus*, ATCC #6538, was diluted in 1.5% peptone water (PEPW) to a precise concentration to yield challenge level counts of 2,200 ± 500 CFU per test article. The bacterial culture suspension was pumped through a nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPS of approximately 3.0 μm. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. Test articles, positive controls, and reference material received a one minute challenge followed by a one minute vacuum cycle.

The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six soybean casein digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 48 ± 4 hours and the colonies formed by each bacteria laden aerosol droplet were counted and converted to probable hit values using the hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test articles. The distribution ratio of colonies for each of the six agar plates was used to calculate the MPS of the challenge aerosol.

The filtration efficiencies were calculated as a percent difference between test article runs and the control average using the following equation:

$$\% \, BFE = \frac{C - T}{C} \; x \; 100$$

Where: C = Average of control values.
         T = Count total for test material.

Delta P: The ΔP test simply measured the differential air pressure on either side of the test article using an incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 Lpm (volumetric). At least one reference material is included with each set of test articles.

The ΔP values were reported in mm water/cm^2 of test area and calculated using the following equation:

$$Delta \, P \, (\Delta P) = \frac{\bar{M}}{Test \, Area}$$

Where: $\bar{M}$ = Average mm water of test replicates.

The test article holder used in the ΔP test has a test area of 4.9 cm^2.

Amendment Justification: At the request of the sponsor, a portion of the test article identification was changed

rp   FRT0004-0001 Rev 5

NELSON LABORATORIES

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Part 58) Regulations.

Activity	Date
Study Initiation	28 Nov 2011
Audit Performed by Quality Assurance	12 Dec 2011
Audit Results Reported to Study Director	13 Dec 2011
Audit Results Reported to Management	13 Dec 2011

Scientists	Title
Todd Hillam	Supervisor
Sarah Smit	Study Director

Data Disposition: The raw data and final report from this study are archived at NLI or an approved off-site location.

Katie Swenson
Quality Assurance

05Apr2012
Date

P.O. Box 571830 | Murray, UT 84157-1830 U.S.A. · 6280 South Redwood Road | Salt Lake City, UT 84123-6600 U.S.A.
www.nelsonlabs.com · Telephone 801 290 7500 · Fax 801 290 7998 · sales@nelsonlabs.com

rp   FRT0004-0001 Rev 5
Page 4 of 4