NELSON LABORATORIES

Sponsor:
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Bacterial Filtration Efficiency Test (BFE) at an Increased Challenge Level GLP Report

Test Article:	MicroGard II 190 g/m^2, Respiratory Filter
Purchase Order:	10003754
Laboratory Number:	530459
Study Received Date:	28 May 2010
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0009 Rev 03
	Protocol Detail Sheet (PDS) Number: 201001540 Rev 01

Summary: This procedure was performed to evaluate the bacterial filtration efficiency (BFE) at an increased challenge level of the test article. A challenge level of greater than 10^6 colony-forming units (CFU) was delivered to each test article to determine filtration efficiency. The aerosol challenge flow rate was maintained at 30 liters per minute (LPM). This test procedure was modified from Nelson Laboratories, Inc., standard BFE procedure in order to employ a more severe challenge than would be expected in normal use. This method was adapted from ASTM F2101. All test method acceptance criteria were met.

Results:

Unit Number	Total CFU Recovered	Filtration Efficiency (%)
1	5.2×10^1	99.99959
2	2.7×10^1	99.99979
3	3.7×10^1	99.99971
4	7.2×10^1	99.99944
5	6.0×10^1	99.99953

Challenge Level: 1.3×10^7 CFU
Mean Particle Size (MPS): 3.3 µm

Adrianne Sandall

Study Director Adrianne Sandall, B.S.

11 Jun 2010

Study Completion Date

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Acceptance Criteria: The mean particle size (MPS) of the challenge aerosol must be maintained at 3.0 ± 0.3 µm. The average percent BFE for the reference material must be within the upper and lower control limits established for the BFE test. The BFE challenge level must be ≥ 1 x 10^6 CFU/test article when the flow rate is ≥ 30 LPM.

Procedure: Approximately 100 mL of soybean casein digest broth (SCDB) was inoculated with *Staphylococcus aureus*, ATCC #6538, and incubated with mild shaking for 24 ± 4 hours at 37 ± 2°C. The culture suspension was pumped through a Chicago nebulizer using a peristaltic pump at a controlled flow rate of 30 LPM and fixed air pressure. The challenge level was adjusted to provide a consistent challenge of greater than 10^6 CFU per test article.

The droplets were generated in a glass aerosol chamber and drawn through the test article holder into AGIs in parallel. The AGIs contained 30 mL aliquots of sterile peptone water (PEPW) to collect the aerosol droplets. The challenge was delivered for a 1 minute interval and sampling through the AGIs was conducted for 2 minutes to clear the aerosol chamber. Control runs (no media in test article holder) were performed after every 5-7 test articles to determine the number of viable particles being generated in the challenge aerosol. The MPS of the challenge aerosol was determined using a six-stage Andersen sampler.

The titer of the AGI assay fluid was determined using standard plate count and/or membrane filtration techniques. All plates were incubated at 37 ± 2°C for 48 ± 4 hours prior to counting. The percent BFE was calculated by subtracting the counts of the test article from the average control counts and dividing by the average control counts.

Quality Assurance Statement

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

Activity	Date
Study Initiation	02 Jun 2010
Audit Performed by Quality Assurance	03 Jun 2010
Audit Results Reported to Study Director	09 Jun 2010
Audit Results Reported to Management	09 Jun 2010

Scientists	Title
Todd Hillam	Section Leader
Adrianne Sandall	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

14 Jun 2010
Date

Lab Number: 530459

NELSON LABORATORIES	FORM TITLE: PDS Approval Form	PDS NUMBER: 201001540
		PDS REVISION: 1

PREPARED FOR SPONSOR		LABORATORY / CONTRACTOR
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PROTOCOL SPECIFICATIONS			
PARENTAL DOCUMENT:	BFE at an Increased Challenge Level, STP0009, 3		
SECTION:	Aerobiology		
PDS INITIATION DATE:	13-May-2010	EXPIRATION DATE:	13-May-2012

JUSTIFICATION:

No changes to the Standard Testing Protocol.

PROTOCOL SPECIFICATIONS:

Test according to Standard Test Protocol.

○ Additional pages attached for protocol specifications ◉ No additional pages needed

The sponsor is responsible for test/control article characterization.
This includes, but is not limited to, identity, strength, purity, and stability.

PLEASE SIGN, DATE, & RETURN TO NELSON LABORATORIES

SPONSOR APPROVAL:

*SIGNATURE: H. Sc

DATE: 14.05.2010

PRINT NAME Helmut Scherer

NELSON LABS STUDY DIRECTOR APPROVAL:

SIGNATURE: Adrianne Sandall

DATE: 02 Jun 2010

PRINT NAME: Adrianne Sandall

*SIGNING THIS DOCUMENT SIGNIFIES AN ACCEPTANCE OF THE NELSON LABORATORIES TESTING TERMS AND CONDITIONS AS ATTACHED OR AS LISTED AT WWW.NELSONLABS.COM/PROTOCOLCONDITIONS.JSP

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