NELSON LABORATORIES

Sponsor:
Helmut Scherer
CareFusion Germany 234 GmbH
Leibnizstrasse 7
Hoechberg 97204
GERMANY

Virus Filtration Efficiency Test (VFE) at an Increased Challenge Level GLP Report

Test Article:	MicroGard II 190 g/m^2, Respiratory Filter
Purchase Order:	10003754
Laboratory Number:	530460
Study Received Date:	28 May 2010
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0010 Rev 03
	Protocol Detail Sheet (PDS) Number: 201001539 Rev 01

Summary: This procedure was performed to evaluate the virus filtration efficiency (VFE) at an increased challenge level of the test article. A challenge level of greater than 10^6 plaque-forming units (PFU) 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 VFE 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 PFU Recovered	Filtration Efficiency %
1	9.0×10^1	99.9966
2	3.6×10^1	99.9986
3	9.9×10^1	99.9962
4	1.4×10^2	99.9949
5	2.0×10^2	99.9924

Challenge Level: 2.6×10^6 PFU
Mean Particle Size (MPS): 3.2 µm

Adrianne Sandall

Study Director — Adrianne Sandall, B.S.

11 Jun 2010

Study Completion Date

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

Challenge Procedure: The stock bacteriophage ΦX174 was prepared by inoculation of ΦX174 into a log phase culture of *E. coli*. The culture was shaken at 37 ± 2°C until bacterial turbidity cleared. The virus stock was centrifuged to remove large cellular debris and then filtered through a 0.2 µm membrane filter to remove remaining host cell debris. The stock culture was stored at 2-8°C.

The challenge suspension was pumped through a Chicago nebulizer using a peristaltic pump at a controlled flow rate of 30 LPM and a fixed air pressure. The challenge level was adjusted to provide a consistent challenge of at least 10^6 PFU per test article.

The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article holder into AGIs in parallel. Each AGI 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 AGI fluid was assayed using standard plaque assay techniques. All plates were incubated at 37 ± 2°C for 12-24 hours. The percent VFE 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	07 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: 530460

NELSON LABORATORIES	FORM TITLE: PDS Approval Form	PDS NUMBER: 201001539
		PDS REVISION: 1

PREPARED FOR SPONSOR		LABORATORY / CONTRACTOR
CONTACT:	Helmut Scherer	Nelson Laboratories, Inc. P.O. Box 17577 SALT LAKE CITY, UT. 84117-0557 6280 SOUTH REDWOOD ROAD SALT LAKE CITY, UT. 84123-6600 Tel: 801-290-7500 Fax: 801-290-7998 Web Site: www.nelsonlabs.com
COMPANY:	CareFusion Germany 234 GmbH	
EMAIL:	helmut.scherer@CareFusion.com	
PHONE:	+49 931 4972 784	
FAX:	+49 931 4972 62784	

PROTOCOL SPECIFICATIONS			
PARENTAL DOCUMENT:	VFE at an Increased Challenge Level, STP0010, 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. [signature]

DATE: 14.05.2010

PRINT NAME Helmut Scherer

NELSON LABS STUDY DIRECTOR APPROVAL:

SIGNATURE: [signature]

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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