

Diocetyl Phthalate (DOP) Aerosol Test GLP Report

Test Article: Ref: 1790 Lot: 30909595
 Ref: 1745 Lot: 31004742
 Ref: 1744S Lot: 30913809
 Purchase Order: 21261
 Laboratory Number: 530924
 Study Received Date: 02 Jun 2010
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0015 Rev 05
 Protocol Detail Sheet (PDS) Number: 201001876 Rev 01

Summary: This procedure was performed to evaluate the particle penetration and airflow resistance properties of filtration materials. A neutralized, polydispersed aerosol of dioctyl phthalate (DOP) was generated and passed through the test article. The filtration performance and airflow resistance of each test article was calculated. All test method acceptance criteria were met.

Area Tested: Entire Filter

Results:

Ref: 1744S

Test Article Number	Airflow Rate (L/min)	Corrected ^a Airflow Resistance (mm H ₂ O)	Filtration Efficiency (%)
1	29.9	16.0	99.995
2	30.0	16.5	99.995
3	30.0	16.9	99.994

^a The final airflow resistance value for each test article was determined by subtracting out the background resistance from the system.

Ref: 1745

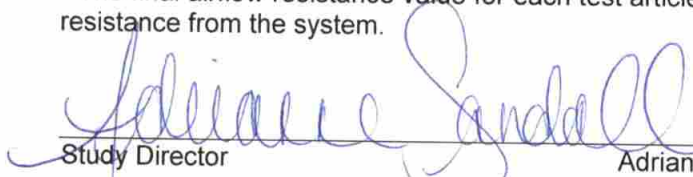
Test Article Number	Airflow Rate (L/min)	Corrected ^a Airflow Resistance (mm H ₂ O)	Filtration Efficiency (%)
1	30.0	14.4	99.994
2	30.0	14.2	99.995
3	30.0	14.2	99.995

^a The final airflow resistance value for each test article was determined by subtracting out the background resistance from the system.

Ref: 1790

Test Article Number	Airflow Rate (L/min)	Corrected ^a Airflow Resistance (mm H ₂ O)	Filtration Efficiency (%)
1	30.0	9.3	99.999
2	30.0	9.2	99.999
3	29.9	9.6	99.999

^a The final airflow resistance value for each test article was determined by subtracting out the background resistance from the system.


 Study Director Adrienne Sandall, B.S.

25 Jun 2010
 Study Completion Date

Acceptance Criteria: Filter tester must pass the "TESTER SET-UP" procedure. The airflow resistance and particle penetration of the reference material must be within the limits set by the manufacturer.

Procedure:

Test Set-Up: The filter tester used in this procedure was a TSI® CERTITEST® Model 8130 Automated Filter Tester that is capable of efficiency measurements of up to 99.999%. The tester produces a particle size distribution with a count median diameter of $0.185 \pm 0.020 \mu\text{m}$ and a geometric standard deviation not exceeding $1.60 \mu\text{m}$ as determined by a scanning mobility particle sizer (SMPS). The mass median diameter is approximately $0.33 \mu\text{m}$, which is generally accepted as the most penetrating aerosol size.

The reservoir of the oil generator was filled with DOP and the instrument allowed a minimum warm-up time of 30 minutes. The main regulator pressure was set to 75 ± 5 pounds per square inch (psi). The filter holder regulator pressure was set to approximately 35 psi. The DOP aerosol generator pressure was set to approximately 30 psi and the make-up air flow rate was set to approximately 50 Liters per minute (L/min).

With the filter holder empty, the transducer and photometer zeros, the aerosol concentration level and the photometer correlation factor (CF) were checked and determined to be acceptable. The CF is used to correlate upstream photometer measurements with those made downstream.

Filter Test: Each test article was placed into the sample holder and the DOP aerosol passed through the test article at an airflow rate of approximately 30.0 L/min. Instantaneous airflow resistance and penetration results for each test article were given.

A reference material was tested before and after every test set to verify the test system was within acceptable control limits.

Quality Assurance Statement

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

Activity	Date
Study Initiation	15 Jun 2010
Audit Performed by Quality Assurance	21 Jun 2010
Audit Results Reported to Study Director	24 Jun 2010
Audit Results Reported to Management	24 Jun 2010

Scientists	Title
Todd Hillam	Supervisor
Adrienne 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

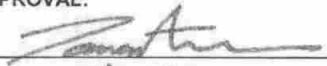
30 Jun 2010

Date

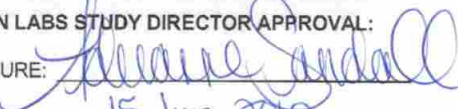
NELSON LABORATORIES	FORM TITLE: PDS Approval Form	PDS NUMBER: 201001876
		PDS REVISION: 1
PREPARED FOR SPONSOR		LABORATORY / CONTRACTOR
CONTACT:	James Annan or Nynke Goodman	Nelson Laboratories, Inc. P.O. Box 17577 SALT LAKE CITY, UT. 84117-0557 8280 SOUTH REDWOOD ROAD SALT LAKE CITY, UT. 84123-6600 Tel: 801-290-7500 Fax: 801-290-7998 Web Site: www.nelsonlabs.com
COMPANY:	Intersurgical	
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FAX:	N/A	
PROTOCOL SPECIFICATIONS		
PARENTAL DOCUMENT:	Diocetyl Phthalate (DOP) Aerosol Test, STP0015, 5	
SECTION:	Aerobiology	
PDS INITIATION DATE:	11-Jun-2010	EXPIRATION DATE: 11-Jun-2012
JUSTIFICATION:		
No changes to the Standard Testing Protocol.		
PROTOCOL SPECIFICATIONS:		
Test according to Standard Test Protocol.		
<input type="radio"/> Additional pages attached for protocol specifications <input checked="" type="radio"/> 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: 
 DATE: 14th JUNE 2010
 PRINT NAME: JAMES ANNAN

NELSON LABS STUDY DIRECTOR APPROVAL:

SIGNATURE: 
 DATE: 15 Jun 2010
 PRINT NAME: Adhane 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

FOR OFFICE USE ONLY	See sample submission form	<input checked="" type="checkbox"/> FDA GLP	<input type="checkbox"/> NON-GLP
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