

Viral Filtration Efficiency (VFE) Final Report

Test Article: Moshi Nanohedron™ filter
Study Number: 1304905-S01
Study Received Date: 29 May 2020
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0007 Rev 16
Deviation(s): None

Summary: The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at $1.1 - 3.3 \times 10^3$ plaque forming units (PFU) with a mean particle size (MPS) of $3.0 \mu\text{m} \pm 0.3 \mu\text{m}$. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure 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.

Test Side: Either Side
Test Area: $\sim 40 \text{ cm}^2$
VFE Flow Rate: 28.3 Liters per minute (L/min)
Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours
Positive Control Average: 2.4×10^3 PFU
Negative Monitor Count: Acceptable
MPS: $2.7 \mu\text{m}$



Trang Truong electronically approved for
Study Director

James Luskin

13 Jul 2020 23:56 (+00:00)

Study Completion Date and Time

Results:

Test Article Number	Percent VFE (%)
1	>99.9 ^a
2	>99.9 ^a
3	>99.9 ^a
4	>99.9 ^a
5	>99.9 ^a

^a There were no detected plaques on any of the Andersen sampler plates for this test article.

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request



TEST REPORT TUCHENG

ORIGINAL

Date: Jun. 15, 2020 Date of Receipt: May. 28, 2020

Report No.: TFF9E618 Quantity: IPC Page Order/Pages: (P1/2) Ref. No.: NIL

Report Title: Aevoe Inc. (Moshi) (T7594) Item: Filter Media

Address: 27F., No. 8, Sec. 5, Zhongxiao E. Rd., Xinyi Dist., Taipei City 110, Taiwan

Test Items		Test Results	Test Methods
Bacterial Filtration	1	> 99.9	ASTM F2101-2019
Efficiency (BFE)(%)	2	> 99.9	
Staphylococcus aureus	3	> 99.9	
ATCC 6538	4	> 99.9	
	5	> 99.9	

Note: Control average: 1866 CFU.

Note: Mean particle size: 2.9 μm.

Note: Testing side: outside of specimen.

Note: Testing area: 39.5 cm².

Note: Flow rate : 28.3 L/min.

Note: Sample description is given by the client: Nanohedron TM filters



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Authorized by president of
Taiwan Textile Research Institute

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Date: Jun. 15, 2020 Date of Receipt: May. 28, 2020

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Report No.: TFF9E618 Quantity: 1PC Page Order/Pages: (P2/2) Ref. No.: NIL

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Test Items	Test Results		Test Methods
Protection Efficiency of Mask(%) (0.075 μm NaCl, CMD)	1	99.95	CNS 14755 Z2125-2011 Flow rate:85.3 (Liter/min)
	2	99.95	
	3	99.95	
	4	99.99	
	5	99.99	
	6	99.99	
	7	99.99	
	8	99.99	
	9	99.99	
	10	99.99	
	Ave.	99.98	

Note: Sample description is given by the client: Nanohedron TM filters

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Test Items		Test Results	Test Methods
Inhalation Resistance (Pa)	1	212.66	CNS 14755 Z2125-2011 Flow rate:85.3 (Liter/min)
	2	207.76	
	3	195.02	
	4	196.00	
	5	200.90	
	6	200.90	
	7	192.08	
	8	201.88	
	9	206.78	
	10	217.56	
	Ave.	203.15	
Exhalation Resistance (Pa)	1	227.36	
	2	220.50	
	3	215.60	
	4	212.66	
	5	214.62	
	6	215.60	
	7	207.76	
	8	215.60	
	9	221.48	
	10	230.30	
	Ave	218.15	

Note: 1mmH₂O=9.8Pa.

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