

## Viral Filtration Efficiency (VFE) Final Report

Test Article: PTFE Face Mask  
 Study Number: 892417-S01  
 Study Received Date: 12 May 2016  
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0007 Rev 13

**Summary:** The VFE test is performed to determine the filtration efficiency by comparing the upstream viral control counts to downstream test article counts. A suspension of bacteriophage  $\Phi$ X174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at  $1.1 - 3.3 \times 10^3$  plaque forming units (PFU) with a mean particle size (MPS) at  $3.0 \mu\text{m} \pm 0.3 \mu\text{m}$ . The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This method allows a reproducible challenge to be delivered to the test articles. 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  
 Area Tested:  $\sim 40 \text{ cm}^2$   
 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:  $2.0 \times 10^3$  PFU  
 Negative Monitor Count:  $<1$  PFU  
 MPS:  $2.9 \mu\text{m}$

### Results:

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

<sup>a</sup> 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:

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

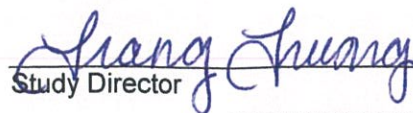
C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request



Technical Reviewer



Study Director

Trang Truong, B.S.



31 May 2016

Study Completion Date



892417-S01

## Diocetyl Phthalate (DOP) Aerosol Test Final Report

Test Article: PTFE Face Mask  
 Study Number: 895418-S02  
 Study Received Date: 26 May 2016  
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0015 Rev 05


**Summary:** This procedure was performed to evaluate the particle penetration and airflow resistance properties of filtration materials. A neutralized, polydispersed aerosol of DOP was generated and passed through the test article. The filtration performance and airflow resistance of each test article was calculated.

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. 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.

Area Tested: Entire Respirator  
 Airflow Rate: ~28.3 Liters per minute (L/min)  
 Test Type: Initial Penetration (~1 min. LOAD Test)  
 Test Side: Outside

**Results:**

Test Article Number	Airflow Resistance (mm H <sub>2</sub> O)	Particle Penetration (%)	Filtration Efficiency (%)
2	2.8	4.64	95.36

  
 Study Director Brandon L. Williams

14 Jun 2016  
 Study Completion Date

