

Diocetyl Phthalate (DOP) Aerosol Test Final Report

Test Article: i-Life 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 ₂ O)	Particle Penetration (%)	Filtration Efficiency (%)
2	2.8	4.64	95.36

Study Director

Brandon L. Williams

14 Jun 2016
Study Completion Date



895418-S02