

## EN 14683:2005 Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article: AntiVirus - Respilon  
Laboratory Number: 754321  
Study Received Date: 05 May 2014  
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 10

**Summary:** The BFE test is performed to determine the filtration efficiency by comparing the bacterial control counts to test article effluent counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. The Delta P test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. Testing was conducted as directed in Annex B (BFE testing) and Annex C (Delta P testing) of EN 14683:2005. 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: Sponsor Labeled Side  
BFE Area Tested: ~45.6 cm<sup>2</sup>  
BFE Flow Rate: 28.3 Liters per minute (L/min)  
Delta P Flow Rate: 8 Liters per minute (L/min)  
Conditioning Parameters: 65 ± 2% relative humidity (RH) and 20 ± 2°C

**Results:** Test articles with a filtration efficiency greater than or equal to 95% meet the performance requirements of EN 14683:2005 as Type I and/or Type IR. Test articles with a filtration efficiency greater than or equal to 98% meet the performance requirements of EN 14683:2005 as Type II and/or Type IIR.

Test articles with a differential pressure less than 29.4 pascals (Pa)/cm<sup>2</sup> meet the performance requirements of EN 14683:2005 as Type I and/or Type II. Test articles with a differential pressure less than 49.0 Pa/cm<sup>2</sup> meet the performance requirements of EN 14683:2005 as Type IR and/or Type IIR.

| Test Article Number | Percent BFE (%)    | Delta P (Pa/cm <sup>2</sup> ) |
|---------------------|--------------------|-------------------------------|
| 1                   | >99.9 <sup>a</sup> | 46.7                          |
| 2                   | 99.9               | 48.8                          |
| 3                   | 99.9               | 43.5                          |
| 4                   | 99.9               | 46.8                          |
| 5                   | 99.9               | 43.8                          |

<sup>a</sup> There were no detected colonies on any of the Andersen sampler plates for this test article.

Mean Positive Control Count: 1,945 colony forming units (CFU)  
Negative Monitor Count: <1 CFU  
Mean Particle Size (MPS): 2.9 µm  
Test Article Dimensions: ~210 mm x ~210 mm

  
Study Director

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13 May 2014  
Study Completion Date