

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article: LK-22-BFE99-1
 LK-22-BFE99-2
 LK-22-BFE99-3
 Laboratory Number: 817694
 Study Received Date: 24 Apr 2015
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 11

Summary: The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* 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 2,200 ± 500 colony forming units (CFU) with a mean particle size (MPS) at 3.0 µm ± 0.3 µm. 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. This test method complies with ASTM F2101-07 and EN 14683:2014, Annex B.

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. The Delta P test was designed to comply with MIL-M-36954C, Section 4 4 1.2 and complies with EN 14683:2014, Annex C.

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.

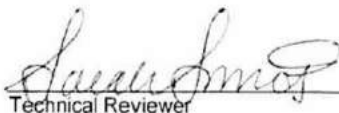
Test Side: Less Patterned Side
 BFE Area Tested: ~45.6 cm²
 BFE Flow Rate: 28.3 Liters per minute (L/min)
 Delta P Flow Rate: 8 L/min
 Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours.

Results:

Test Article	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
LK-22-BFE99-1	>99.9	2.4	23.5
LK-22-BFE99-2	>99.9	2.3	22.2
LK-22-BFE99-3	>99.9 ^a	2.5	24.2

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

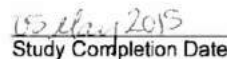
Positive Control Average: 2,086 CFU
 Negative Monitor Count: <1 CFU
 MPS: 2.9 µm


 Technical Reviewer




 Study Director

Janelle R. Bentz, M.S.


 Study Completion Date



The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request

测试汇总

No. SHAHG1405722802

日期: 2014年04月15日 第1页,共4页

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测试结果: 请参见下一页

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测试汇总

No. SHAHG1405722802

日期: 2014年04月15日 第2页,共4页

测试结果:

测试样品描述:

样品编号	SGS样品ID	描述	材质 (客户提供)
SN1	SHA14-057228.001	白色塑料粒子	聚丙烯

FDA 21 CFR 177.1520-熔点

测试要求: 应客户要求, 按照食品与药品管理法规测试与食品接触的聚丙烯的熔点.

测试方法: 参考FDA 21 CFR 177.1520 方法.

测试项目	限值	001
熔点, °C*	160-180	167

备注:

*这项测试由SGS宁波化学实验室检测

FDA 21 CFR 177.1520-密度 (23°C)

测试要求: 应客户要求, 按照食品与药品管理法规测试与食品接触的聚丙烯的密度 (23°C).

测试方法: 参考FDA 21 CFR 177.1520d(1) 或 ASTM D792:2008 方法.

测试项目	限值	001
密度 (23°C), g / cm ³	0.880-0.913	0.887

FDA 21 CFR 177.1520-二甲苯中可溶性

测试要求: 应客户要求, 按照食品与药品管理法规测试与食品接触的聚丙烯的在二甲苯中可溶物含量.

测试方法: 参考FDA 21 CFR 177.1520 方法.



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测试汇总

No. SHAHG1405722802

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测试项目	限值	001
25°C下二甲苯中可溶性, w/w %	9.8	0.9

FDA 21 CFR 177.1520-正己烷中萃取物含量

测试要求: 应客户要求, 按照食品与药品管理法测试与食品接触的聚丙烯的在正己烷中萃取物含量.

测试方法: 参考FDA 21 CFR 177.1520 方法.

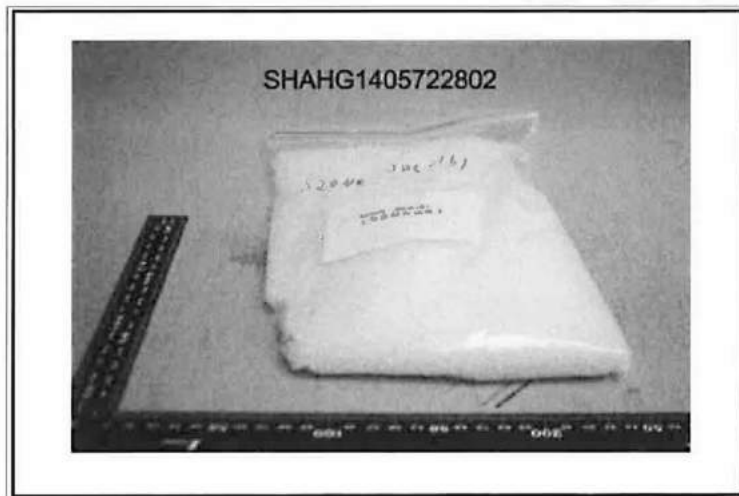
测试项目	限值	001
正己烷中回流萃取, w/w %	6.4	0.7



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