Nelson Labs.
A Sotera Health company

Sponsor:
Chen Qiaofang
Zhejiang Longterm Medical Tech, Co. Ltd.
Huancheng Rd 493
Huzhou City, Zhejiang, 313200
CHINA

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

Test Article:	SM-1 Lot: 202002296801
Purchase Order:	20200312-01
Study Number:	1277746-S01
Study Received Date:	16 Mar 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: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* 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 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles 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 complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met.

Test Side:	Inside
BFE Test Area:	~40 cm^2
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
Test Article Dimensions:	~175 mm x ~159 mm
Positive Control Average:	2.2 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.2 µm

Study Director James W. Luskin

03 Apr 2020
Study Completion Date

1277746-S01

Results:

Test Article Number	Percent BFE (%)
1	>99.9
2	99.7
3	99.7
4	>99.9
5	>99.9

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	3.2	31.7
2	3.2	31.1
3	3.5	34.7
4	3.3	32.8
5	3.5	34.6

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

Test Article Preparation: The test articles were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% RH, prior to BFE and Delta P testing.

Test Method Acceptance Criteria: The BFE positive control average shall be maintained at 1.7 – 3.0 x 10^3 CFU.

The MPS control average of the challenge aerosol shall be maintained at 3.0 ± 0.3 µm.

The Delta P test flow rate shall be maintained at 8 L/min throughout the testing.

Procedure:

BFE: A culture of *S. aureus*, ATCC #6538, was diluted in peptone water (PEPW) to yield challenge level counts of 1.7 – 3.0 x 10^3 CFU per test article. The bacterial culture suspension was pumped through a nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPS of approximately 3.0 µm. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. Test articles, positive controls, and reference material received a one minute challenge followed by a one minute vacuum cycle.

The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six soybean casein digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 48 ± 4 hours and the colonies formed by the bacteria laden aerosol droplets were then counted and converted to probable hit values using the positive hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test articles. The distribution ratio of the colonies on each of the six agar plates was used to calculate the MPS of the challenge aerosol.

Delta P: The Delta P test simply measured the differential air pressure on either side of the test article using an incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 L/min (volumetric). At least one reference material is included with each set of test articles.

The Delta P values were reported in mm water/cm^2 and Pa/cm^2 of test area and calculated using the following equation:

$$Delta\ P = \frac{\bar{M}}{A}$$

Where: $\bar{M}$ = Average mm of water of the test replicates per test article
A = Area of the test article holder (cm^2)

The test article holder used in the Delta P test has a test area of 4.9 cm^2.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	20 Mar 2020
Phase Inspected by Quality Assurance: Delta P Measurements	25 Mar 2020
Audit Results Reported to Study Director	31 Mar 2020
Audit Results Reported to Management	31 Mar 2020

Scientists	Title
Sarah Smit	Supervisor
James Luskin	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Quality Assurance

03 Apr 2020
Date

Certification of Conformity

Manufacturer: Zhejiang Longterm Medical Technology Co., Ltd.
Address: Huancheng North Road 493, Mo Gan Mountain National High-tech district, Deqing, Zhejiang, People's Republic of China

European Representative: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e Verd,2595AA The Hague,THE NETHERLANDS

Product: Medical face mask
Model Code: Flat,Folding
Classification: I Rule: Rule 1 of MDD
UMDN Code: 12447

All the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

CE

General Applicable Directive:

COUNCIL DIRECTIVE 93/42/EEC

Additional information, clarification about the CE marking
We attest that a TCF for the CE marking process is in place. Whereas the manufacturer is responsible to start the CE marking certification procedure through an appointed Notified Body and perform all the necessary activies, as required by the Directive and accepted by the Notified Body, before placing the CE mark on the product.

President
Kangping Wu

Kangping Wu
Signature

Management Representative
Buchun Qiao

Buchun Qiao
Signature

Date of issue 20 March 2020

Expiry date 19 March 2025