

Differential Pressure (Delta P) GLP Report

Test Article: BH MEDICAL 3-Ply Medical Mask
Study Number: 1321732-S01
Study Received Date: 17 Jul 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 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
Delta P Flow Rate: 8 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
Test Article Dimensions: ~175 mm x ~174 mm

Results:

Test Article Number	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	5.6	55.2
2	5.2	51.0
3	5.8	56.8
4	5.9	57.9
5	5.8	56.8



Trang Truong electronically approved
Study Director

Trang Truong

14 Aug 2020 21:42 (+00:00)
Study Completion Date and Time

Test Article Preparation: The test articles were conditioned for a minimum of 4 hours at $21 \pm 5^{\circ}\text{C}$ and $85 \pm 5\%$ RH, prior to Delta P testing.

Test Method Acceptance Criteria: The Delta P test flow rate shall be maintained at 8 L/min throughout the testing.

Procedure:

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/cm² and Pa/cm² of test area and calculated using the following equation:

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

Where: \bar{M} = Average mm of water of the test replicates per test article
A = Area of the test article holder (cm²)

The test article holder used in the Delta P test has a test area of 4.9 cm².

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	04 Aug 2020
Phase Inspected by Quality Assurance: Delta P Measurements	10 Aug 2020
Audit Results Reported to Study Director	11 Aug 2020
Audit Results Reported to Management	13 Aug 2020

Scientists	Title
Adrianne Sandall	Supervisor
Trang Truong	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.

Camille Coffey electronically approved
Quality Assurance

14 Aug 2020 21:37 (+00:00)
Date and Time