

Differential Pressure (Delta P) Final Report

Test Article: 11062020-1 Study Number: 1361719-S01 Study Received Date: 10 Nov 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):

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. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Inside

Delta P Flow Rate: 8 Liters per minute (L/min)

Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours

Results:

Test Article Number	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm²)
1	5.2	50.6
2	5.2	51.4
3	4.8	46.9
4	4.6	45.1
5	5.0	49.2





Sean Shepherd electronically approved for

Leah Tiberius

21 Nov 2020 17:58 (+00:00)

Study Completion Date and Time

Study Director

801-290-7500

nelsonlabs.com sales@nelsonlabs.com