

Differential Pressure (Delta P) Final Report

Test Article: MKM-2-HC-M-T200
 Purchase Order: MM2022-T1
 Study Number: 1504414-S01
 Study Received Date: 04 Apr 2022
 Test Started Date: 11 Apr 2022
 Test Finished Date: 12 Apr 2022
 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: STP0217 Rev 01
 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+AC:2019, 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: Either
 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/cm ²)
1	1.6	15.5
2	1.6	15.6
3	1.6	15.2
4	1.5	14.9
5	1.7	16.3



James Luskin electronically approved
Study Director

James Luskin

14 Apr 2022 20:10 (+00:00)
Study Completion Date and Time