

Differential Pressure (Delta P) Final Report

Test Article: Yomask YM-99
 Study Number: 1328769-S01.1 Amended
 Study Received Date: 07 Aug 2020
 Study Completion Date: 26 Aug 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. 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/cm ²)
1	5.2	50.6
2	5.3	51.9
3	4.6	45.1
4	5.1	50.0
5	5.3	52.5

Amendment Justification: At the request of the sponsor, the sponsor's address was changed.



James Luskin electronically approved
Study Director

James Luskin

05 Aug 2021 18:04 (+00:00)
Amended Report Date and Time