

PRODUCT NAME: PANODYNE MEDICAL MASK 3 PLY
SAMPLE QUANTITY: 60 PCS
DATE OF MANUFACTURE: MAR-2020
DATE OF RECEIPT: 18-MAR-2020
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BATCH NO: PO11887
REPORT NO: RPM20200326
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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 $1.7-3.0 \times 10^3$ colony forming units (CFU) with a mean particle size (MPS) OF $3.0 \pm 0.3 \mu\text{m}$. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM, F2101-19 and EN14683:2019 Annex B.

The Delta P test is performed to determine the breathable ability 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 F2101-19.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulation 21CFR Parts 210, 211 and 820.

Test Side: Inside
 BFE Test Area: ~40 cm²
 BFE Flow Rate: 28.4 Liters per minute (L/min)
 Delta P Flow Rate: 8L/min
 Conditioning Parameters: 85±5% relative humidity (RH) and 21±5°C for a minimum of 4 hours
 Test Article Dimensions: 176 mm x 156 mm
 Positive Control Average: 2.6 x 10³ CFU
 Negative Monitor Count: <1 CFU
 MPS: 3.1 µm

RESULTS:

TEST ARTICLE NUMBER	Percent BFE (%)
1	99.5
2	99.3
3	99.4
4	99.5
5	99.5

TEST ARTICLE NUMBER	DELTA P (mm H ₂ O/ cm ²)	DELTA P (Pa/ cm ²)	Fluid Resistance (mm Hg)	Flammability
1	4.0	39.0	160	Class 1
2	4.1	39.9	160	Class 1
3	4.2	40.5	160	Class 1
4	4.1	39.7	160	Class 1
5	4.4	42.9	160	Class 1

The filtration efficiency percentages were calculated using the following equation

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

C=Positive control average

T=Plate count total recovered downstream of the test article

Note: The plate count total is available upon request