

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article: SAMPLE ID : HSD-TYP2
 LOT #191121
 Purchase Order: 20191121
 Study Number: 1244612-S01
 Study Received Date: 25 Nov 2019
 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: STP0036 Rev 15
 Customer Specification Sheet (CSS) Number: 201905892 Rev 01
 Deviation(s): None

Summary: The testing was conducted in accordance with EN 14683:2019, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	2.4	62	3	65.0	27.1
2	2.5	3	3	6.1	2.5
3	2.5	17	3	20.1	8.1
4	2.5	9	6 ^a	14.6	5.9
5	2.4	22 ^a	3	25.0	10.4
Recovery Efficiency		87.4%			

< = No Organisms Detected

Note: The results are reported as colony forming units (CFU) per mask.

^a Spreader. Count is considered a minimum estimate due to swarming of certain colonies on the membrane.



Robert Putnam electronically approved
 Study Director

Robert Putnam

16 Dec 2019 17:54 (+00:00)
 Study Completion Date and Time

Method Suitability:

Organism	Percentage
<i>Bacillus atrophaeus</i>	91%

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results. The number of masks to be tested shall be a minimum of 5 or more to meet an acceptable quality level of 4%. The bioburden of the medical mask shall be < 30 CFU/g tested.

Procedure:

Positive Controls/Monitors: *Bacillus atrophaeus*
 Extract Fluid: Peptone Tween[®]
 Extract Fluid Volume: ~300 mL
 Extract Method: Orbital Shaking for 15 minutes at 250 rpm
 Plating Method: Membrane Filtration
 Agar Medium: Potato Dextrose Agar
 Tryptic Soy Agar
 Recovery Efficiency: Exhaustive Rinse Method
 Aerobic Bacteria: Plates were incubated 3 - 7 days at 30-35°C, then enumerated.
 Fungal: Plates were incubated 5 - 7 days at 20-25°C, then enumerated.