



Accredited Laboratory

A2LA has accredited

GIBRALTAR LABORATORIES, INC.

Fairfield, NJ

for technical competence in the field of

Biological Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).



Presented this 10th day of December 2018.

A handwritten signature in black ink, written over a horizontal line.

President and CEO
For the Accreditation Council
Certificate Number 56.01
Valid to December 31, 2020

For the tests to which this accreditation applies, please refer to the laboratory's Biological Scope of Accreditation.



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

GIBRALTAR LABORATORIES, INC.
16 Montesano Rd
Fairfield, NJ 07004
Chuck Weibel Phone: 973 227 6882

BIOLOGICAL

Valid To: December 31, 2020

Certificate Number: 0056.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following biological tests on raw materials, excipients, intermediate and finished product pharmaceuticals, dietary supplements, human cells, tissues, tissue products and medical devices:

Monograph Testing Employing the Following:

<u>Technology</u>	<u>Reference Method(s)</u>	<u>SOP(s)</u>
Antibiotics – Microbial Assays	USP <81>	165M, 167M
Antimicrobial Effectiveness Test (AET)	USP <51>; EP 5.01.03 CTFA M3, M6	5M
Antiviral Efficacy	9CFR 113.47; 40CFR 158	64M, 90M, 110M
Bacterial Endotoxins Test (Gel Clot and Kinetic Chromogenic LAL)	USP <85>; EP 2.06.14; ANSI/AAMI ST 72	160M
Bioburden	ISO 11737-1, -2, -3; ISO 11137-1, -2, -3	60M
Cytotoxicity - Elution, Agar Overlay and Agar Diffusion Methods	USP <87>; ISO 10993-5	159M
Detection Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	ASTM F2096-11	177M
Disinfectant Testing: - Virucidal - Tuberculocidal - Bactericidal - Available Chlorine - Germicidal - Fungicidal - Sporicidal	AOAC Chapter 6, 21 CFR 610.12; ANSI/AAMI ST 58; 9 CFR 113; AOAC, EPA 40 CFR 158	90M, 56M, 20M, 7M, 39M, 35M 57M
Dye Penetration Testing	ASTM F1929-15	122M

<u>Technology</u>	<u>Reference Method(s)</u>	<u>SOP(s)</u>
Enumeration of Organisms in Water: - Total Heterotrophic Plate Count - Coliforms	USP<1231>; Standard Methods for the Examination of Water and Wastewater	19M
Environmental Monitoring	USP <1116>; ISO 14644-1, -2; ISO 14698-1; ISO 8573	153M, 130M, 161M
Identification of Organisms	Vitek 2 Compact Systems	42M, 106M, 162M
Immunological Test Method – Enzyme Linked Immunosorbent Assay (ELISA)	USP<1103>	171M
Microbial Aerosol Challenge Test for Packages	ISO 11607	158M
Microbial Content (Qualitative Tests) - <i>Klebsiella</i> spp. - <i>Listeria monocytogenes</i> and <i>Listeria</i> spp. - <i>Shigella</i> - <i>Cronobacter Sakazakii</i> - <i>Enterobacteriaceae</i> - <i>Salmonella</i> spp. - Coagulase Positive <i>Staphylococcus</i>	BAM CMMEF; ISO 11290 BAM ISO/TS 22964 ISO 21528 ISO 6579 ISO 6888	21M, 172 M
Microbial Limits. Microbiological Examination of Nonsterile Products, Microbial Enumeration Tests	USP <61>, <62>, <2021>, <2022>; EP 2.06.12; EP 2.06.13	150M, 172M
Mycoplasma Tests	USP<63>; EP 2.06.07; 9 CFR 113.28; 21 CFR 610	6M
Nucleic Acid Based Technique – Polymerase Chain Reaction (PCR)	USP<1127>	169M
Protein Analysis by SDS-PAGE and Western Blot	USP<1045>; USP<1049>	170M
Quantitative Analysis for Hemoglobin, Protein, and Carbohydrate Residue on Reusable Medical Devices	ANSI/AAMI TIR 30; ANSI/AAMI TIR 12; ANSI/AAMI ST 70; ISO 10995-5, 10993-12	174M
Sterility Tests	USP <71>; EP 2.06.01; ANSI/AAMI ST 77, ST 79; ISO 11137-1, -2, -3; ISO 11737-1, -2, -3; ISO 17665	8M
Validation of Microbial Recovery from Pharmaceutical Articles	USP <1227>	-----



Accredited Laboratory

A2LA has accredited

GIBRALTAR LABORATORIES, INC.

Fairfield, NJ

for technical competence in the field of

Chemical Testing

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Presented this 10th day of December 2018.

A handwritten signature in black ink, written over a horizontal line.

President and CEO
For the Accreditation Council
Certificate Number 56.02
Valid to December 31, 2020

For the tests to which this accreditation applies, please refer to the laboratory's Chemical Scope of Accreditation.



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

GIBRALTAR LABORATORIES, INC.
122 Fairfield Road
Fairfield, NJ 07004
Chuck Weibel Phone: 973 227 6882

CHEMICAL

Valid To: December 31, 2020

Certificate Number: 0056.02

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following chemical tests on raw materials, excipients, intermediate and finished product pharmaceuticals, dietary supplements, human cells, tissues, tissue products and medical devices:

Monograph Testing Employing the Following:

<u>Test/Technology</u>	<u>Reference Method</u>	<u>SOP</u>
Arsenic Limit Test	USP <211>	27C
Chloride and Sulfate Limit Test	USP <221>	-----
Chromatography (GC and HPLC)	USP <621>	-----
Dissolution	USP <711>	-----
Ethylene Oxide Sterilization Residuals	ISO 10993 Part 7	30C
Heavy Metals Limit Test	USP <231>	55C
Identification Tests - General	USP <191>	-----
Iron Limit Test	USP <241>	24C
Lead Limit Test	USP <251>	25C
Loss on Drying	USP <731>	-----
Loss on Ignition	USP <733>	-----
Melting Range	USP <741>	-----
Nitrogen and Oxygen Determination in Nitrogen	USP-NF	45C
Optical Rotation	USP <781>	100C
Particulate Matter in Injections	USP <788>	53C
pH	USP <791>	2G
Readily Carbonizable Substances Limit Test	USP <271>	-----
Refractive Index	USP <831>	75C
Residual Solvents (Organic Volatile Impurities)	USP <467>	18C
Residue on Ignition Limit Test	USP <281>	23C
Specific Gravity	USP <841>	32C
Spectrophotometric Identification Tests (FTIR, UV/VIS)	USP <197>	-----
Thin Layer Chromatography Identification Tests	USP <201>	-----
Total Organic Carbon	USP <643>	40C
Validation of Compendial Methods, GC/HPLC	USP <1225>	-----
Water Conductivity	USP <645>	43C
Water Determination by Karl Fischer	USP <921>	67C