



THE AMERICAN ASSOCIATION FOR  
LABORATORY ACCREDITATION

## 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 17025:2005 *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 January 2009*).



Presented this 22<sup>nd</sup> day of January 2009.

A handwritten signature in cursive script, appearing to read "Peter Abney".

President

For the Accreditation Council

Certificate Number 0056.01

Valid to December 31, 2010

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

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

GIBRALTAR LABORATORIES, INC.<sup>1</sup>  
 122 Fairfield Road  
 Fairfield, NJ 07004  
 Chuck Weibel Phone: 973 227 6882

BIOLOGICAL

Valid To: December 31, 2010

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:

Monograph Testing Employing the Following:

Technology	Reference Method	SOP
Validation of Microbial Recovery from Pharmacoepial Articles	USP 1227	-
Antimicrobial Effectiveness Test (AET)	USP 51; CTFA M3, M6	5M
Sterility Tests	USP 71 ANSI/AAMI ST77; ANSI/AAMI ISO 11137-1, -2, -3; ANSI/AAMI ST79; ANSI/AAMI ISO 11737-1, -2, -3	8M
Limulus Amebocyte Lysate Test (LAL)	USP 85; ANSI/AAMI ST72	160M
Cytotoxicity - Elution, Agar Overlay and Agar Diffusion Methods	USP 87	159M
Identification of Organisms	Vitek Senior Systems	42M, 106M, 108M
Antiviral Efficacy	AOAC; 40CFR 158	64M, 90M, 110M
Mycoplasma Testing	9 CFR 113; 21 CFR 610	6M
Microbial Content	-	21M
Microbial Limits	USP 61, 62, 2021, 2022	22M, 150M
Bioburden	ANSI/AAMI ISO 11737-1, -2, -3; ANSI/AAMI ISO 11137-1, -2, -3	60M
Antibiotic Assay	USP 81	73M
Disinfectant Testing	AOAC Chapter 6, 21 CFR 610.12; ANSI/AAMI ST 58; 9 CFR 113, AOAC, EPA 40 CFR 158;	90M
Virucidal		56M, 20M,
Bactericidal	AOAC, 40CFR 158	7M, 139M
Fungicidal	AOAC, 40CFR 158	35M
Sporicidal	AOAC, 40CFR 158	57M

Technology	Reference Method	SOP
Enumeration of Organisms in Water Total Heterotrophic Plate Count Coliforms	Standard Methods for the Examination of Water and Wastewater	19M
Environmental Monitoring	USP 1116; ISO 14644-1, -2; ISO 8573	153M, 130M, 160M

<sup>1</sup> The laboratory has a satellite laboratory at the following location:

16 Montesano Rd  
Fairfield, NJ 07004



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## ACCREDITED LABORATORY

A2LA has accredited

**GIBRALTAR LABORATORIES, INC.**

**Fairfield, NJ**

for technical competence in the field of

**Chemical Testing**

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *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 January 2009*).



Presented this 22<sup>nd</sup> day of January 2009.



President

For the Accreditation Council

Certificate Number 0056.02

Valid to December 31, 2010

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

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

GIBRALTAR LABORATORIES, INC.<sup>1</sup>  
122 Fairfield Road  
Fairfield, NJ 07004  
Chuck Weibel Phone: 973 227 6882

CHEMICAL

Valid To: December 31, 2010

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:

Monograph Testing Employing the Following:

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

<sup>1</sup> The laboratory has a satellite laboratory at the following location:

16 Montesano Rd  
Fairfield, NJ 07004  
(A2LA Cert No. 0056.02) 01/26/2009