



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Infinity Laboratories
1585 South Perry Street, Suite B
Castle Rock, CO 80104

Fulfills the requirements of

ISO/IEC 17025:2017

In the field of

TESTING

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

A handwritten signature in black ink, appearing to read 'R. Douglas Leonard Jr.', is positioned above a horizontal line.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 02 September 2021
Certificate Number: AT-1982



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017.
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).

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Infinity Laboratories

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Castle Rock, CO 80104

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TESTING

Valid to: **September 2, 2021**

Certificate Number: **AT-1982**

Chemical

| Specific Tests and/or Properties Measured | Specification, Standard, Method, or Test Technique | Items, Materials or Product Tested | Key Equipment or Technology |
|---|--|------------------------------------|---|
| Antimicrobial Agent Content | USP <341> | Pharmaceuticals | Gas Chromatography, High Performance Liquid Chromatography |
| Chemical Identification | USP <197> USP <854> USP <857> | Medical Devices Pharmaceuticals | FT-IR Spectrophotometer, UV/Vis Spectrophotometer |
| Conductivity | USP <645> | USP Water | Conductivity Meter |
| Container Closure Integrity | USP <1207> | Medical Devices Pharmaceuticals | Vacuum Chamber |
| Ethylene Oxide (EtO) Residual Analysis | USP <621> ISO 10993-7 | Medical Devices | Gas Chromatography |
| Particulates | USP <788> USP <789> | Medical Devices Pharmaceuticals | Particle Counter |
| pH | USP <791> | Pharmaceuticals | pH Meter |
| Potency/Purity | USP <621> USP <730> USP <1225> | Pharmaceuticals | Gas Chromatography, High Performance Liquid Chromatography, Inductively Coupled Plasma-Mass Spectrometer, Liquid Chromatography-Mass Spectrometer |
| Total Organic Carbon | USP <643> | USP Water | TOC Analyzer |
| Water Determination | USP <921> | Pharmaceuticals | Karl Fischer Titrator |

Microbiological

| Specific Tests and/or Properties Measured | Specification, Standard, Method, or Test Technique | Items, Materials or Product Tested | Key Equipment or Technology |
|--|--|---|--|
| Antimicrobial Effectiveness | USP <51> | Pharmaceuticals | Biological Safety Cabinets, Incubators |
| Bacterial Endotoxins | USP <85> | Medical Devices, Pharmaceuticals, Tissue | Microplate Reader |
| Bioburden | ISO 11737-1 ISO 11737-2 ISO 11137-1 ISO 11137-2 | Medical Devices, Pharmaceuticals, Tissue | Biological Safety Cabinets, Incubators |
| Biological Indicator Population Verification | USP <55> | Biological Indicators | Biological Safety Cabinets, Incubators |
| Biological Indicator Sterility | ISO 11135 | Biological Indicators | Biological Safety Cabinets, Incubators |
| Coliform Detection | USP <1231> Standard Methods for the Examination of Water and Wastewater | Water | Biological Safety Cabinets, Incubators |
| Heterotrophic Plate Count | USP <1231> Standard Methods for the Examination of Water and Wastewater | Water | Biological Safety Cabinets, Incubators |
| Method Suitability | USP <71> USP <1223> ISO 11737-2 | Medical Devices, Pharmaceuticals | Milliflex Rapid System, Symbio Pump, Biological Safety Cabinets, Incubators |
| Microbiological Examination of Nonsterile Products (Enumeration and Specified Organisms) | USP <61> USP <62> | Pharmaceuticals | Biological Safety Cabinets, Incubators |
| Microorganism Identification (Genetic and Gram Stain) | USP <1113> | Environmental Samples, Medical Devices, Pharmaceuticals | Genetic Analyzer, Thermal Cycler, Incubators, Microscope |
| Product Sterility | USP <71> USP <1223> ISO 11737-2 ISO 11137-1 | Medical Devices, Pharmaceuticals | Milliflex Rapid System, Symbio Pump, ISO Class 7 Cleanroom, ISO Class 5 Biological Safety Cabinets, Incubators |

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1982.



R. Douglas Leonard Jr., VP, PILR SBU

