



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

LexaMed, Ltd.

**705 Front Street
Toledo, OH 43605**

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: 01 July 2023

Certificate Number: AT-2689



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

LexaMed, Ltd.

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TESTING

Valid to: **July 1, 2023**

Certificate Number: **AT-2689**

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Antimicrobial Preservative Effectiveness	SOP LEXLP-072 based on USP <51>	Antimicrobial Preservatives	ISO Class 5 LAF Hood Incubators
Bacterial Endotoxin (Gel-clot)	SOP LEXLP-004 and LEXLP-003 based on: USP <85>; USP <161>; ANSI/AAMI ST72	Medical Devices, Pharmaceuticals	Depyrogenation oven
Bacterial Endotoxin (Kinetic Turbidimetric)	SOP LEXLP-085 and LEXLP-091 based on: USP <85>; USP <161>; ANSI/AAMI ST72	Medical Devices, Pharmaceuticals	Depyrogenation oven Microplate reader
Bioburden	SOP LEXLP-014 and LEXLP-037 based on: ANSI/AAMI/ISO 11737-1; USP <61>; USP <1111>	Medical Devices, Pharmaceuticals	ISO Class 5 LAF Hood Incubators
Cytotoxicity (MEM)	SOP LEXLP-047 based on: USP <87>; ISO 10993-5	Medical Devices	ISO Class 5 LAF Hood Microscope Incubators
Cytotoxicity (Agar Overlay)	LEXLP-048 based on: USP <87>; ISO 10993-5	Medical Devices	ISO Class 5 LAF Hood Microscope Incubators

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Particulates	SOP LEXLP-092 and LEXLP-026 based on: USP <788>; USP <789>; USP <1788>	Medical Devices, Pharmaceuticals (ophthalmic solutions/injectables)	Liquid Particle Counter Microscope
Microbiological Examination of Non-Sterile Products – Microbial Limits (Enumeration and Specified Organisms)	LEXLP-038 based on: USP <61>; USP <62>	Pharmaceuticals	ISO Class 5 LAF Hood Incubators
Biological Indicator Population Verification	LEXLP-101 based on: ISO 1138-1	Biological Indicators	ISO Class 5 LAF Hood Incubators
Sterility and B/F Testing	SOP LEXLP-017 and SOP LEXLP-021 based on: USP <71>; ISO 11737-2	Medical Devices, Pharmaceuticals, BIs	ISO Class 5 Cleanrooms and LAF Hoods Incubators

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Container Closure Integrity (CCI) Testing (Dye Immersion)	SOP LEXLP-073 based on: USP <1207>	Pharmaceutical Containers	Pressure/Vacuum Vessel, UV/Vis Spectrophotometer
Ethylene Oxide (EO) Residual Analysis	SOP LEXLP-039 and LEXLP-040 based on: ISO 10993-7	Medical Devices	Gas Chromatograph (GC)
Protein	SOP LEXLP-033	Medical Devices	UV/Vis Spectrophotometer
Hemoglobin	SOP LEXLP-081	Medical Devices	UV/Vis Spectrophotometer
Carbohydrate	SOP LEXLP-084	Medical Devices	UV/Vis Spectrophotometer

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT -2689.



R. Douglas Leonard Jr., VP, PILR SBU