

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.

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R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 01 July 2023 Certificate Number: AT-2689





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 | Specificat <mark>ion, Standard,</mark> 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

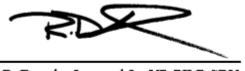
| Specific Tests and/or Properties Measured | Specification, Standard, Method, or Test Technique | Items, Materials or Product Tested | Key Equipment or Technology |
|--|--|---|---|
| Particulates | SOP LEXLP-092 and LEXLP-026 based on: USP <788>; USP <789>; USP <1788> | Medical Devices, Pharmaceuticals (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.



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