CERTIFICATE OF ACCREDITATION

ANSI-ASQ National Accreditation Board
500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

Toxikon Corporation
15-25 Wiggins Avenue
Bedford, MA 01730

has been assessed by ANAB
and meets the requirements of international standard

ISO/IEC 17025:2005

while demonstrating technical competence in the field of

TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of tests to which this accreditation applies.

AT-1340
Certificate Number

ANAB Approval

Certificate Valid: 07/03/2018-07/24/2020
Version No. 004 Issued: 07/03/2018

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

ANSI-ASQ National Accreditation Board

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

Toxikon Corporation

15-25 Wiggins Avenue
Bedford, MA 01730

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TESTING

Valid to: **July 24, 2020** Certificate Number: **AT-1340**

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Tests for Genotoxicity	**ISO 10993-3** Bacterial Reverse Mutation (Ames) Test (OECD 471) SOP 6.1.11 In Vitro Mammalian Chromosome Aberration Test (OECD 473) SOP 6.1.32; 6.1.32.1 Mammalian Erythrocyte Micronucleus Test (OECD 474) SOP 6.1.117 SOP 6.1.192 In vitro Mammalian Cell Gene Mutation Test-Mouse Lymphoma Assay (OECD 476) SOP 6.1.142	Finished Medical Devices and Components / Drugs	Colony Counters Microscopes Semi-quantitative BD FACS Flow Cytometer

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Tests for Interaction with Blood	**ISO 10993-4** In Vitro Hemocompatibility (SOP 6.1.153, 3.8.211) WBC. RBC, Platelet Counts, Erythrocyte Indices PT / UPTT /APTT/ Lee and White Coagulation Time (SOP 6.1.63, SOP 6.1.152, SOP 6.1.64, and 6.1.132) Time for platelet aggregation (SOP 6.1.156) Complement Activation (SOP 6.1.150) Thrombogenicity (SOP 6.2.32) Hemolysis (SOP 6.1.51 and SOP 6.1.169)	Finished Medical Devices and Components / Drugs	Advia & hematology counter Start4 Hemostasis Analyzer Packs 4 Aggregometer ELISA, plate reader Spectrophotometer
Tests for In vitro Cytotoxicity	**ISO 10993-5** Mem Elution / Cytotoxicity or Direct Contact (SOP 6.1.53) Agar Diffusion (SOP 6.1.54) MTT Cytotoxicity Assay (SOP 6.1.177) Neutral Red Uptake (NRU) Cytotoxicity Assay (SOP 6.1.178)	Finished Medical Devices and Components / Drugs	Cell culture equipment / microscope Plate reader
Tests for Local Effects after Implantation	**ISO 10993-6** Implant Test (SOP 6.2.13.3) Subcutaneous Implant (SOP 6.2.13.4) Bone Implant (SOP 6.2.46)	Finished Medical Devices and Components / Drugs	Animal system Explant and histological evaluation / pathology

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Tests for Irritation and Sensitization	**ISO 10993-10** Kligman Sensitization (SOP 6.2.20) Buehler Sensitization (SOP 6.2.25.3) Ocular, Vaginal,Buccal, Skin, Penile Irritation (SOPs 6.2.16, 6.2.28, 6.2.27, 6.2.23. 6.2.29) Intracutaneous (SOP 6.2.13.2) Murine Lymph Node Assay (SOP 6.2.54)	Finished Medical Devices and Components / Drugs	Animal systems-Clinical observations and tissue evaluations Scintillation counter
Tests for Systemic Toxicity	**ISO 10993-11** Pyrogen Test (SOP 6.2.14) Systemic Injection Test (SOP 6.2.13.1) 14 Day Intravenous Toxicity (SOP 6.2.40) 21/28 Day Repeat Dose Study (SOP 6.2.37) Systemic Toxicity via Intramuscular or Subcutaneous Implantation (SOP 6.2.62)	Finished Medical Devices and Components / Drugs	Animal Systems Thermometer readings Clinical observations Scoring Tissue Evaluations Advia automatic hematology counter Cobas automatic clinical chemistry analyzer

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ethylene Oxide Sterilization Residuals	**ISO 10993-7** SOP 11.2	Finished Medical Devices and Components / Drugs	Agilent 6890 GC-FID

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Leachables and Extractables Testing	**ISO 10993-18** GC (SOPs 3.7.33, 3.7.38, 11.67, 11.68) GC/MS (SOP 3.7.30, 11.67, 11.68, 11.95) HPLC (SOP 3.8.88) LC/MS (SOP 10.15, 10.19,11.94) TOC and TIC (SOP 3.8.63,3.8.250 11.9) ICP (SOP 3.8.201, 11.96, 11.97) ICP/MS (SOP 3.8.131, 10.15) FTIR (SOP 3.8.115)	Finished Medical Devices and Components / Drugs	(Detection limits vary with analyte & matrix) Agilent 5890 and 6890 GC and GC/MS Agilent 1100 HPLC and LC/MS systems Tekmar Dohrman Phoenix 8000 TOC & Tekmar TOC Fusion Thermo Fisher 6300 ICP Thermo Fisher 61E and X Series ICP w/MS Perkin Elmer IR

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bioburden Testing	**ISO 11737-1** Sterilization of Medical Devices -- Estimation of Organisms on Products SOP 6.1.49 / USP, AAMI	Finished Medical Devices and Components / Drugs	Autoclave, incubators, HEPA hood
Sterility Test Methods	**ISO 11737-2** Sterilization of Medical Devices -- Validation of a Sterilization Process USP, AAMI 6.1.47 and 6.1.2	Finished Medical Devices and Components / Drugs	Sterile Room Autoclave, incubators, HEPA hood

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1340.

Vice President