

TOXIKON AT A GLANCE

Services

DEVICES



BIOTECH



PHARMA



CUSTOM



Capabilities

- » GC, GC/MS
- » HPLC
- » LC / MS, LC / MS / MS
- » LC / ELSD
- » Inductively Coupled Plasma C /CP
- » Spectroscopy
- » ICP/MS
- » Particle Size Analysis
- » Method Development / Transfer / Validation

Locations:

Corporate Headquarters

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Toxikon provides comprehensive analytical services for all stages of product development, from concept to final product. The scientific approach of our experienced chemists provides comprehensive techniques for the medical device, pharmaceutical and biotechnology industries, including method development and validation, stability studies, extractables and leachables and bioanalytical services.

Our facilities and experienced laboratory management can offer the highest quality of work in compliance with ICH, OECD, ISO 17025 and many other globally-recognized standards. With decades of experience, our team will collaborate with you as an extension of your firm to facilitate drug and device development, achieve product safety and regulatory compliance, as well as maintain the highest levels of laboratory quality control. Toxikon can offer you services that will facilitate product development by reducing the potential for product and process failure. By partnering with us and learning your application, Toxikon provides specific solutions and results that will facilitate development.

Toxikon: Your Team of Experts

At Toxikon, we understand the importance of sound science for drug and medical device development, and we are committed to supporting you through the entire product development cycle, from concept to final product. Our approach involves three main values. First, we are committed to quality and scientific excellence. Second, our client-centric, collaborative approach will give you confidence knowing that our scientists understand your application, and third, the know-how to navigate the regulatory landscape for your product's development path.



Analytical and Bioanalytical Chemistry Overview

Services at a Glance

Toxikon is an ISO/IEC 17025-accredited Contract Research Organization (CRO) registered with the FDA for drug, biologic, and medical device testing. With approximately 200 employees, Toxikon is committed to staying at the forefront of life science product development. Toxikon's safety services include toxicology (acute, subchronic, and chronic toxicity, reproductive toxicity, genetic toxicology, carcinogenicity), pharmacokinetics, toxicokinetics, bioavailability, ADME, chemical characterization, impurities analysis and synthesis, bioanalysis, and microbiology. Additionally, full IND/NDA enabling studies are performed with a multidisciplinary approach to program management. Toxikon's extensive certifications and licenses allow it to meet international regulatory requirements for data acceptability and harmonization.

To meet all applicable international GxP requirements, Toxikon's facilities are fully registered with FDA and USDA, and accredited with the Association for the Assessment and Accreditation of Laboratory and Animal Care International (AAALAC), and the International Organization for Standardization (ISO). Toxikon also has assurance with the National Institutes of Health so federally funded work can be performed at our facilities in compliance with NIH's Public Health Service Policy on Human Care and Use of Laboratory Animals (PHS Policy).

Analytical Chemistry Services

- » Test Article Characterization
- » ICH Stability Testing
- » Routine Formulation Analysis
- » Method Development/Transfer/Validation
- » Sample Analysis
- » ISO 10993, Parts 9, 13, 14, 15, and 18 Protocol and Support Services
- » Raw and Finished Product Testing
- » Physicochemical studies (European Pharmacopoeia, USP and JP)
- » Accelerated Aging
- » Forced Degradation
- » Photostability
- » Particle Size Analysis
- » Degradate quantitation
- » Manufacturing Residual Analysis
- » Extractables and Leachables
- » Sterilization Residual Analysis (EO, EC, and EG)

Extractables and Leachables

- » Inhalants/MD
- » Parenterals/Injectibles
- » Drug Delivery Systems
- » Implants
- » Primary/Secondary Container Closure Systems
- » Raw Material/Polymers
- » Material Comparison
- » Residual Analysis

Other services

- » Compendia Testing
 - Physicochemical
 - Residue on Ignition
 - Non-Volatile Residue
 - Heavy Metal Analysis
- » Residual Solvent Testing
- » Total Organic Carbon
- » Total Inorganic Carbon

Bioanalytical Chemistry Services

- » Method Development/Transfer/Validation
- » Dose Formulation Analysis
- » Preclinical and Clinical Sample Analysis
- » Toxicokinetics / Pharmacokinetics
- » LC / MS/ MS and Immunoassays
- » Metabolite Isolation/Identification

Rapid Turnaround Non-GLP Discovery Services

- » Protein-Binding Assays
- » Non-GLP Studies
- » Screening
- » Rapid PK

Synthesis and Formulation

- » Custom Synthesis
- » Specialty Studies

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To learn more about Toxikon and our development capabilities, please visit us at www.toxikon.com