

TOXIKON AT A GLANCE

Services

DEVICES



BIOTECH



PHARMA



CUSTOM



Capabilities

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

Locations:

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Toxikon has developed extensive methodologies for designing studies to identify extractables and leachables in medical devices and pharmaceutical products. The demand for these types of studies by U.S. and other governing bodies is increasing, as data from these assessments identifies potential contaminants that migrate from containers, closure systems, tubing, and other materials, potentially rendering drug products unsafe. These materials include, but are not limited to polymers and other plastics, elastomers, coatings, accelerants, and antioxidants. Degradation products from gamma to e-beam sterilization processes to residual solvents from manufacturing may also be present.

Our team of experts will collaborate with you to learn your application and develop a comprehensive approach to identify compounds extracting from materials under elevated temperatures, extended contact time, or solvent exposure. Likewise, protocols are designed to determine if extractables are leaching into drug products or other materials under normal use conditions. As part of our research and testing portfolio for medical device development and drug discovery, Toxikon offers life science companies highly customizable extractables and leachables programs to meet PQRI, FDA, ISO, EMEA, EP, and USP requirements.

The likelihood of interaction with dosage forms is of particular concern when there are multiple components that comprise the container. This risk increases when the route of administration has high potential for uptake found in metered dose (MDI) and dry powder inhalers (DPI), injectable suspensions (prefilled syringes, IV bags), and ophthalmic solutions. Whatever your product needs, Toxikon provides analytical services applicable to all phases of product development. This includes characterizing raw materials for container/closure and disposable systems, conducting material comparisons, providing ongoing QC validation support for manufacturing residuals and testing for byproducts of sterilization.



Extractables and Leachables 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 Methods

- » Organic analysis via GC, GC/MS, HPLC, HPLC/ELSD, LC/MS
- » Ion chromatography
- » Elemental analysis by ICP, CVAA, and ICP-MS
- » FTIR and UV/VIS Spectroscopy
- » pH, Conductivity, Total Organic/ Inorganic Carbon
- » Particle sizing analysis
- » Karl Fischer

Chemistry Support

- » Test article characterization
- » ICH stability testing
- » Routine formulation analysis
- » Method Development/Transfer/Validation
- » 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, and photostability
- » Manufacturing residual analysis
- » Sterilization residual analysis (EO, EC, and EG)

Other Services

- » USP compendia studies

Plasticizers Analysis (Partial Listing)

- » bis(2-ethylhexyl) phthalate (DEHP)
- » bisphenol A (BPA)
- » Tris (2-Ethylhexyl) Trimellitate (TOTM)
- » Di-isobutyl phthalate
- » Di-n-butyl phthalate
- » Di-n-octyl phthalate
- » Dinonyl phthalate

Antioxidant Analysis (Partial Listing)

- » Butylhydroxytoluene (BHT)
- » Irganox 1010
- » Irganox 1076
- » Irgafos 168

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To learn more about Toxikon and our extractables and leachables services, please visit us at www.toxikon.com