Exova
Health Sciences

Trace Metal Analysis / Analytical Development and Validation / Extractables & Leachables Studies / NMR Spectroscopy / Glass and Polymer Container Testing / CMC and Clinical Manufacturing

Leading the way in pharmaceutical and medical device development, compliance and assurance.

Exova is at the forefront of the world's pharmaceutical and medical device testing services. We deliver trusted contract development and quality assurance to our clients across the globe, so they can deliver trusted products to physicians and patients.

Our unrivaled, tailored service is driven by solid partnerships that deliver. Our relationships are built on expertise, partnership and trust. Built on the value we add to our clients' businesses and the assurance we bring them.

Exova's health sciences teams have a proven track record of helping our customers move their products to market faster, solving tough problems and supporting finished product manufacturing with consistently reliable, high quality results.

That is why, from CMC development through finished product release testing and everything in between, the world's leading healthcare brands trust Exova.

TRACE METAL ANALYSIS

The testing of trace metals in drug products, drug substances, biologics, dietary supplements and medical devices is critical in determining the safety of a material and predicting its interactions with other compounds.

Exova is a recognized world leader in trace metal analysis. Testing for elemental impurities by ICPOES and ICPMS, in compliance with USP <233>, EP (2.4.20), and ICH Q3D gives you reliable, independent data for both raw materials and finished products. With ten ICPMS instruments, Exova is a leader in capacity to take on major elemental impurities programs, and has completed over 500 studies in the last 18 months.

Our experts can provide you with the information you need on the presence of a full spectrum of trace and heavy metals.

We have the capability to separate and quantitate inorganic mercury, arsenic, and selenium from their various organic species. We can determine residual catalysts, such as palladium and platinum, in in-process intermediates and final products.

ANALYTICAL METHOD DEVELOPMENT AND VALIDATION

A robust analytical method creates efficiencies and ensures consistent results throughout the life cycle of your product. Methods validated to regulatory guidelines ensure that the procedure is best suited for the intended use at the various stages on the way to market.

Exova offers innovative analytical method development and validation solutions supported by state-of-the-art spectroscopic instrumentation.

We prepare and execute validation protocols based on workable methods in compliance with the Food and Drug Administration (FDA) and the International Conference on Harmonization (ICH) guidelines.

Comprehensive development and validation reports are provided along with method transfer, procedure writing and analyst training services.

Exova

www.exova.com

EXTRACTABLES & LEACHABLES (E&L) STUDIES

Leachable materials may originate from pharmaceutical container closure systems, process equipment, and medical device packaging, and migrate to contaminate products. Extractables and leachables studies identify and quantify these substances, ensuring product quality and effectiveness.

Exova is an industry leader in supplying full-service extractables and leachables testing programs for pharmaceutical packaging and manufacturing equipment as well as medical devices, helping our customers fulfil the regulatory requirements for pharmaceuticals and medical product safety.

We clearly grasp the importance of understanding the customer, tailoring options, scope of work and price to provide the most efficient solutions without compromising the science.

Our risk based approach to E&L consistently shortens time to market and helps ensure sustainability of the product once it is produced commercially.

Exova laboratories comply with Good Manufacturing Practice (cGMP) guidelines. Our scientists have been active participants in working groups that have developed the current extractable and leachable best practices such as PQRI, USP Expert Panels, ELSIE, and BPOG and we regularly hold training sessions with client teams to discuss the best approach to meeting their E&L obligations.

NMR SPECTROSCOPY

Nuclear Magnetic Resonance (NMR) spectroscopy enables verification of chemical synthesis and compound characterization.

It provides information about a molecule's covalent structure, stereochemistry and conformation helping to establish or confirm the identity of pharmaceutical substances or related impurities.

Exova utilizes one of a few cGMP compliant 500 MHz NMR instruments existing in commercial laboratories, for NMR development, consulting and testing services. Our expertise in the field of NMR spectroscopy ranges from small molecule structure elucidation to biological chemistry and structural biochemistry.

We provide NMR structural characterization services to many laboratories in the pharmaceutical and biotechnology industry.

We also assist medical device companies and customers in polymers and coatings, oil and petrochemical industries.

CONTAINER TESTING

Containers must be capable of retaining a drug's therapeutic efficacy from the time of packaging through to administration. Containers that do not meet the specifications of the major compendia can compromise the safety and effectiveness of the drug product.

Exova provides container testing services to various pharmacopeia methods including USP, EP, and JP methods, supported by a state-of-the-art validated autoclave.

We also offer Atomic Absorption Spectrometry with hydride generation to support full EP monograph requirements.

If your package is new or contains modified labels, adhesives or closures, we can supply extractables and leachables testing studies to demonstrate that your package meets the required specifications.

Full package deformulation services are provided, and our clients rely on Exova to assist them in reverse engineering packaging materials to understand the composition of each polymer, inks, resins, coatings, label adhesive, plasticizers, ntioxidants, etc.

CMC AND CLINICAL BATCH MANUFACTURING

Chemistry, Manufacturing, and Controls (CMC) activities form a crucial part of any clinical trial. Drugs can be denied market approval if the quality of the product and the manufacturing process fail to satisfy regulatory requirements. Ensuring that the trial is designed and developed to as near perfection as possible accelerates the drug development process.

Exova SL Pharma has provided full CMC development for several NDA 505-b applications as well as generic drug products (ANDAs) and our work has led directly to the successful regulatory approval and commercialization of parenteral dosage forms, ophthalmics and topicals.

Parenteral solutions and emulsions are complex formulations both in how they release drug into the body and how they are formulated to be effective for their intended use, and remain stable over time. Due to these products bypassing the body's natural defenses, they must be exceptionally pure and free from contaminants, posing a challenge to pharmaceutical companies that manufacture such products.

Exova SL Pharma offers parenteral CMC product development and clinical manufacturing services that help you meet the stringent requirements and specifications enforced by the Food and Drug Administration (FDA). Our formulation and product development services are focused on parenteral products, but also include ophthalmic and topical drug products.

CONTACT

Mississauga Pharma

2395 Speakman Dr.,
Mississauga, ON L5K 1B3

Contact: Stephen McMillan,
Inside Sales Manager
Tel: +1 905 822 4111 (ext. 10324)
Fax: +1 905 823 1446
Email: americas@exova.com

Exova SL Pharma – Wilmington

1300 First State Blvd, Suite C,
Wilmington, DE 19804

Contact: Robyn Woolley,
Business Development Director
Tel: +1 302 367 9807
Fax: +1 302-636-0204
Email: americas@exova.com

Santa Fe Springs Pharma

9240 Santa Fe Springs Road,
Santa Fe Springs, CA 90670

Contact: Louis Albanese,
Inside Sales Manager
Tel: +1 562-948-2225
Fax: +1 562-948-5850
Email: americas@exova.com