



With **over 10 years industry experience** per structural scientist, Nitto Avecia Pharma Services' strategic, systematic approach provides **high quality solutions** for identification, characterization, and development of highly sensitive methodologies.

INDUSTRY-LEADING STRUCTURAL CHEMISTRY SERVICES

- Extractables/leachables studies
- Reference standard/drug substance characterization
- Structural elucidation of target/lead compounds
- Elemental analysis
- Structural elucidation of unknowns
- Purification of impurities and degradation products
- Amino acid analysis
- Peptide mapping
- Glycan analysis
- Enantiomeric studies
- Residual analysis in support of biotechnology-derived products
- Residual Solvent Screening by GC/MS
- Melamine analysis by GC/MS and LC/MS
- Structural characterization of protein variants and isoforms

LEADING-EDGE INSTRUMENTATION

- LC/MS/MS: Quadrupole, triple quadrupole of mass spectrometers with APCI and ESI
- LC/MS-QTOF
- GC/MS (EI and CI ionization)
- UPLC-MS/MS
- GC (multiple detectors)
- HPLC (multiple detectors)
- ICP-MS
- ICP-OES
- Flame AA
- GFAA
- IC
- FTIR
- DSC/TGA
- TOC

PARTNER WITH NITTO AVECIA PHARMA SERVICES' STRUCTURAL CHEMISTRY TEAM

With a multidisciplinary team including biochemists, synthetic organic chemists, and analytical chemists, Avecia Pharma offers an array of approaches and techniques to characterize drug structures and analyze their purity at every step of the development process. In addition, Avecia Pharma's integrated team approach unites our structural chemists with scientists from other departments to provide a comprehensive set of capabilities and expertise that will efficiently accelerate and strengthen the process of characterizing and identifying complex chemical and protein compounds.

Nitto Avecia Pharma Services' structural chemistry team has expertise that goes beyond chemical characterizations to include a deep understanding of all facets of drug development that can impact the successful development and launch of a product. This includes experience analyzing different routes of administration, meeting regulatory requirements, solving packaging issues, and identifying potential problems in manufacturing. With in-depth academic history, diverse industry experience, and influential industry involvement, Avecia Pharma's structural chemists are unsurpassed.

OUR PROJECT MANAGEMENT TEAM SERVES YOU BETTER

Our signature service assigns you a single, dependable point of contact who guarantees all of the benefits of valued partnership such as strategic planning meetings, weekly reports, high quality data, and detailed post-project follow-up.

We invite you to visit us, audit our facilities, discover our insight, and learn more about our commitment to excellence. Visit www.aveciapharma.com or call 877-445-6554.

AVECIA PHARMA'S COMPLETE PACKAGE OF SERVICES

PARENTERAL MANUFACTURING

- CGMP Fill/Finish
- Aseptic Filling/Lyo
- Pre-Clinical through Commercial

FORMULATION/PROCESS DEVELOPMENT

- Formulation Characterization
- Container/Closure Compatibility Studies

ANALYTICAL CHEMISTRY

- USP/NF, EP, BP, JP, ACS, AOAC, and Client Methods

ANALYTICAL DEVELOPMENT

- Phase Appropriate Validation
- Process Validation Support
- Cleaning Validation and Verification
- Comparator Studies and Reference Standard Qualification

BIOPHARMACEUTICALS

- Cell-Based Bioassays
- Phase Appropriate Validation
- Product Characterization and QC Testing

DRUG DELIVERY TECHNOLOGIES

- Inhalation/Nasal Product Testing
- Transdermal Product Testing
- Device Evaluation

MICROBIOLOGY

- Quality Control Testing
- Research and Development

STABILITY STORAGE

- Standard ICH and Custom Storage Conditions

STRUCTURAL CHEMISTRY

- Extractables/Leachables
- Reference Standard Characterization
- Structural Elucidation of Unknowns
- Investigational Studies

OLIGO MANUFACTURING (API) VIA NITTO DENKO AVECIA

- Pre-Clinical, Clinical and Commercial Supply
- Small Scale [mg] to Large Scale [multi kg]