



Providing analytical chemistry services **since 1988**, Nitto Avecia Pharma Services has established **streamlined** processes supported by **experienced staff** to provide **reliable, expedited testing** for nearly all drug substances, products, and components.

## EXPANSIVE SERVICES

- Dissolution
- Disintegration
- Total organic carbon
- Thermal analysis (DSC/TGA)
- Mercury analysis
- Moisture determination (Karl Fischer, TGA, direct/coulometric titration)
- Water activity
- Inorganic impurity profile
- Container/Closure testing
- Atomic absorption (flame AA, GFAA)
- Friability, disintegration
- Analytical Method Remediation
- Particle size distribution
- Osmolality
- Melting point determination
- Residual solvents
- Organic volatile impurities
- Viscosity determination
- Nitrogen analysis
- Gas analysis (oxygen, carbon dioxide, etc.)
- Specific gravity
- Limit test
- Identification test
- Amino acid profile
- Impurities profile
- Particulate Matter (Methods I/II)
- Specific Rotation
- Glass grain test

## STATE-OF-THE-ART INSTRUMENTATION

- HPLC (UV-Vis, PDA, RI, FI, CAD, ELSD, EC, and conductivity)
- ICP-MS
- ICP-OES
- LC/MS: Quadrupole, triple quadrupole and quadrupole-time-of-flight of mass spectrometers with APCI and ESI
- GC: direct injection and head space capability (FID, TCD and NPD)
- GC/MS MSD with EI and CI ionization source
- Malvern Zetasizer Z690
- Malvern Mastersizer 2000
- Brookfield HBDV-II+Pro cone/plate rheometer
- HunterLab ColorQuest XE colorimeter
- AccuSizer
- GFAA
- Flame AA
- FTIR
- Polarimeter
- UV-Vis spectrophotometer
- Fluorescent spectrophotometer
- TGA
- DSC/TGA
- IC
- CE
- UPLC
- Total organic carbon (TOC) analyzer

## PARTNER WITH NITTO AVECIA PHARMA SERVICES' ANALYTICAL CHEMISTRY TEAM

Nitto Avecia Pharma Services' long-standing team is committed to providing expert and timely analytical chemistry support. We offer high quality, affordable compendial testing according to USP/NF, EP, BP, JP, ACS and customer-specified monographs in support of raw materials, in-process analysis, and finished product release testing including controlled substances (Schedules I-V)

We specialize in handling drug substances, drug products, and nearly all dosage forms including tablets, capsules, semi-solids, parenterals, sterile, transdermal, and inhalation products. Our device specialists oversee routine chemical and functional testing of packaging (elastomers, glass, plastics) and component testing. We also assist with vendor and contract manufacturer qualification. These essential services are why Nitto Avecia Pharma Services has earned a solid reputation in the industry since 1988.

At Nitto Avecia Pharma Services, our mission is to provide our clients with outsourcing solutions that make their drug development priorities possible.

## 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](http://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]