Nitto Avecia Pharma Services

analytical DEVELOPMENT

With over **thousands of methods developed**, validated, and/or transferred supporting IND/ANDA/NDA/BLA applications, Nitto Avecia Pharma Services' **scientific** team has a **proven track record** with nearly all drug forms, substances, and products.

EXTENSIVE ANALYTICAL METHOD DEVELOPMENT AND VALIDATION SERVICES

- Assay and related substances
- Chromatographic purity
- Stability indicating assays
- Forced degradation studies
- Dissolution
- Gap analysis and remedial validation
- Residual solvents
- Extractables/Leachables
- Chiral drugs
- Cleaning procedures
- Characterization of reference standard and drug substances
- Process validation support
- Comparative studies
- Reference standard qualification
- Counterfeit product evaluation
- Vendor qualification
- Method development and phase-appropriate validation

STATE-OF-THE-ART INSTRUMENTATION

- HPLC (UV-Vis, PDA, RI, FI, CAD, and ELSD)
- UPLC/UHPLC
- GC/MS MSD (EI and CI ionization source)
- GC: direct injection and head space capability (range of detectors)
- LC/MS: MSD with APCI and ESI
- IC (conductivity and ECD
- DSC/TGA
- Dissolution (apparatuses I, II, VI)
- MALS
- Karl Fischer
- LC/MS/MS: Quadrupole, triple quadrupole and time-of-flight of mass spectrometers with APCI and ESI
- HIAC

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PARTNER WITH NITTO AVECIA PHARMA SERVICES' ANALYTICAL DEVELOPMENT TEAM

Nitto Avecia Pharma Services' analytical development group has experience in support of various dosage forms within the generic and branded pharmaceutical industries. The team's diverse background has enabled Avecia Pharma to develop an in-depth understanding of all facets of the drug development process. In addition, Avecia Pharma offers extensive experience in gap analysis and remedial validation of existing methodologies to comply with current CDER/ICH guidelines for validation.

As development partners, we design detailed protocols for method development, validation, and technology transfer based on the products phase in the drug development process.

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 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]