



Nitto Avecia Pharma Services has **in-depth experience** with a **wide range of drug delivery device technologies** to offer your programs **comprehensive technical support.**

INHALATION/NASAL COMPREHENSIVE TESTING STUDIES

- Drug product characterization
- Drug content assay
- Aerodynamic particle size distribution by NGI/ACI
- Deliverable-dose uniformity
- Pressure testing
- Retention of prime
- Valve delivery
- Shot weight
- Leak rate
- Device counters
- Emitted/delivered dose
- Cyr test (storage orientation)
- Primary particle size determination
- Bulk density
- Water content
- Microscopic evaluation
- Spacer evaluations
- Particulate matter
- Rate of delivery/total delivery

INHALATION/NASAL ADVANCED INSTRUMENTATION

- Digital flow meters
- Copley Andersen Cascade Impactors™ (28, 60 LPM) MSP Next Generation Impactor (NGI)™
- Multi-stage liquid impinger
- Dose uniformity sampling apparatus (MDI/DPI)
- Copley Scientific model TPK critical flow controller
- InnovaSystem Mighty-Run Actuator Station
- Malvern Mastersizer 2000
- Malvern Zetasizer ZS90
- Copley Breath Simulator (BRS100)
- Copley Scientific Inhaler Testing Data Analysis Software (CITDAS)

TRANSDERMAL TESTING EXPERTISE

- Assay
- Chromatographic purity
- Drug release profile (dissolution)
- Residual solvents
- Stability studies

TRANSDERMAL INSTRUMENTATION

- HPLC: Waters, Agilent, Dionex (UV/VIS, PDA, FI, RI, CAD, ELSD, EC, and conductivity)
- HIAC
- High resolution chromatography
- LC/MS: MSD with APCI and ESI
- LC/MS/MS: Sciex 3000 and 4000 with ESI and APCI
- GC/MS: Agilent MSD with EI and CI ionization source ionization source
- IC (detectors: conductivity and ECD)
- GC: direct injection and head space capability (range of detectors)
- Dissolution (apparatus VI)

PARTNER WITH NITTO AVECIA PHARMA SERVICES' DRUG DELIVERY TECHNOLOGIES' TEAM

Nitto Avecia Pharma Services is known as a dependable resource throughout the pharmaceutical, biopharmaceutical, and medical device industries for its experience in transdermal and inhalation/nasal product development support, including formulation as well as device evaluation.

We combine our core competencies in drug delivery technologies' development with an ongoing commitment to state-of-the-art instrumentation and technology. Additionally, we provide an innovative approach to cross-functional scientific expertise and experience, high quality systems, and above-and-beyond project management. This culmination makes Avecia Pharma the source to trust for the exceptional quality and reporting your projects demand.

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]