



With **over 14,000 ft<sup>2</sup> storage capacity** and **over 14 ICH** and **custom conditions**, Nitto Avecia Pharma Services has the capability to help design **stability studies tailored** to product needs.

## COMPREHENSIVE STABILITY STUDIES AND SERVICES

- Stability protocol generation
- Stability testing
- Stability storage
- Stability summary report generation
- Freeze/thaw studies
- Stability time points and conditions specific report generation
- Preclinical stability
- Clinical stability
- Stability indicating method development and validation
- Release testing
- Method transfer and analyses qualification
- Assay, impurities, dissolution, water content, etc. of various formulations

## RANGE OF STORAGE CONDITIONS INCLUDING ALL ICH CONDITIONS

- 25°C/60% RH
- 30°C/65% RH
- 30°C/75% RH
- 40°C/75% RH
- 25°C
- 50° C
- 5°C, Refrigerator
- -20°C, Freezer
- -70°C, Ultimate freezer
- Photostability chambers – ICH options I and II
- Customized conditions

## PARTNER WITH ANITTO AVECIA PHARMA SERVICES' STABILITY TESTING TEAM

For the quality control and security your projects demand, all cGMP validated environmental and photostability chambers are monitored 24 hours a day by a computer-based Environmental Monitoring System. Our walk-in, reach-in, UV/visible and fluorescent photostability chambers are supported by back-up chambers, a reserve generator and an electronic notification system.

We have the latest Stability Laboratory Information Management System (LIMS) to ensure compliance. The system accommodates sophisticated sample management, as well as allows the stability department to generate cumulative reports.

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]