NITTO AVECIA PHARMA SERVICES

STABILITY TESTING

Analytical Chemistry | Analytical Development | Biopharma | Drug Delivery | Formulation | Manufacturing | Microbiology | Stability | Structural Chemistry

With over 14,000 ft² 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.

PROVIDING HIGH QUALITY TESTING AND RELIABLE STORAGE

• Clinical • Commercial • NDA • BLA • ANDA • IND

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

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.

WWW.AVECIAPHARMA.COM

10 VANDERBILT, IRVINE CA 92618 TEL: 949.951.4425 TOLL FREE: 877.445.6554 FAX: 949.951.4909

Nitto Avecia Pharma Services

STABILITY TESTING

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.

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 INCLUDE

PARENTERAL MANUFACTURING

- Process Validation
- Lyophilization
- Scale-Up Studies

FORMULATION DEVELOPMENT

- Formulation Characterization
- Container/Closure Compatibility Studies

ANALYTICAL CHEMISTRY

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

ANALYTICAL DEVELOPMENT

- Method Development and Validation
- Process Validation Support
- Cleaning Validation and Verification
- Comparator Studies and Reference Standard Qualification

BIOPHARMACEUTICALS

- Method Development and Validation
- Product Characterization and Quality Control 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

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

API OLIGO MANUFACTURING (VIA NITTO DENKO AVECIA)

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

WWW.AVECIAPHARMA.COM

10 VANDERBILT, IRVINE CA 92618 TEL: 949.951.4425 TOLL FREE: 877.445.6554 FAX: 949.951.4909

Nitto Avecia Pharma Services