STABILITY

We're dedicated to advancing your analytical development needs with a wide range of cutting-edge testing services.

With over 14,000 square feet storage capacity and over 14 ICH and custom conditions, Nitto Avecia Pharma Services has the capacity 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 condition-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

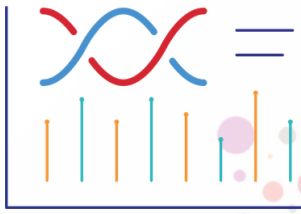
RANGE OF STORAGE CONDITIONS INCLUDING ALL ICH CONDITIONS

- 25°C/60% RH
- 30°C/65% RH
- 30°C/75% RH
- 40°C/75% RH
- 5°C, refrigerator
- -20°C, freezer
- -70°C, Ultimate freezer
- Photostability chambers ICH options
- Customized conditions

10 Vanderbilt Ave | Irvine, CA 92618 | Tel 949.951.4425 | aveciapharma.com

STABILITY

THE TRUE PARTNERSHIP DIFFERENCE



We make your goals achievable through a dedicated approach. Every project is led by a **single point of contact**, ensuring seamless communication, strategic planning, consistent reporting, and high-quality data from start to finish.

Partner with Nitto Avecia Pharma Services for reliable, high-quality analytical chemistry support across all stages of drug development. Since 1988, we have built a strong reputation for delivering flexible outsourcing solutions tailored to your development priorities.

OUR CORE CAPABILITIES

COMPREHENSIVE COMPENDIAL TESTING

Cost-effective analysis (USP/NF, EP, BP, ACS, and custom monographs) for raw materials, in-process samples, and finished products.

STABILITY PROGRAM MANAGEMENT

Let us help with the logistics for your stability programs, including storage in a wide range of ICH-listed conditions.

BROAD EXPERTISE

Drug substances, drug products, diverse dosage forms, and vendor qualification.

EXTRACTABLES & LEACHABLES

Broad expertise in PVC blister packs, injectables, medical device, IV bags, and single-use systems.

DEDICATED PROJECT MANAGEMENT TEAM

A single, dependable point of contact who guides and runs meetings, generates agendas and minutes, provides high-quality data and metrics, and conducts detailed post-project follow-up.

MICROBIOLOGY

Comprehensive cGMP microbiological testing for sterility, endotoxins, bioburden, and environmental monitoring.

PACKAGING & DEVICE TESTING

Expert analysis of elastomers, glass, and plastics. We can assist with navigating extractables and leachables.

BIOPHARMA

Integrated analytical support to enable development and commercialization of complex biologics.

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