Nitto Avecia Pharma Services

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

RESIDUAL SOLVENTS TESTING

Nitto Avecia Pharma Services provides expert, rapid analysis of all three classes of residual solvents. Our USP/ICH compliant, state-of-the-art laboratory, and experienced team of scientists allow you to manage the large number of methods that may be involved in identification and quantification of impurities, including residual solvents.

We remain committed to ongoing, effective software and instrumentation upgrades. You benefit from faster, more selective and sensitive testing – with reduced number of separation phases.

OUR EXPERTISE ENCOMPASSES

- Detection, profiling and control support of residual solvents in drug substances, excipients, and drug products
- Water-Soluble/water-Insoluble raw materials and APIs
- Screening for potential interference
- Screening for identification of unknown peaks
- Feasibility studies
- Strict compliance of ICH guidelines
- Development and validation of analytical methods
- Assistance in regulatory reporting
- Comprehensive and accurate reports
- Remediation of existing materials and products

OUR MULTIPLE POINTS OF INTERACTION

- Joint review of DMF/physico-chemical properties of the API and excipients
- Meeting to ensure appropriate:
  - Technology - GC-FID/TCD/ECD or GC/MS via direct injection or head-space sample introduction
  - Limits, e.g., TDI
  - Procedures for method transfer/validation
  - Process - prescreening, routine testing, API qualification

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

RESIDUAL SOLVENTS TESTING

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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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