Nitto Avecia Pharma Services

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

EXTRACTABLES LEACHABLES

Investigate the potentially harmful effects of your container/closure/single-use systems on your drug product by partnering with Nitto Avecia Pharma Services. Our team of structural scientists have over 20 years of experience with polymers, organic and elemental impurities, and an array of pharmaceutical productsto assist in identifying the threat of contamination to your drug products. Let Avecia Pharma leverage this expertise in a thorough examination of impurities in your drug formulation

EXPERTISE SUPPORTING A RANGE OF PRODUCTS & DELIVERY SYSTEMS

- pMDI
- Nasal products
- LDPE ampoules
- PVC blister packs
- Injectables
- Medical devices
- IV bags
- Ophthalmics

OUR COMPREHENSIVE SERVICES

Regulations make extractables and leachables studies an essential part of your drug development process. Our team of skilled scientists is highly experienced in developing and validating new methodologies in support of various container/closure/single-use systems.

Three-phase systematic approach

1. Controlled extraction studies
2. Model extraction studies
3. Leachables studies

- Routine container/closure testing
- Formulation compatibility and testing
- Identification, isolation, and quantification of extractables and leachables

STATE-OF-THE-ART INSTRUMENTATION

- GC/MS and/or GC-FID (including headspace analysis)
- LC/MS/MS or LC/UV
- ICP-MS
- UPLC/MS/MS
- QTOF
- ICP-OES

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EXTRACTABLES LEACHABLES

Nitto Avecia Pharma Services

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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