Nitto Avecia Pharma Services

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

ELEMENTAL IMPURITIES

In an effort to improve and modernize the USP General Chapter <231>, Heavy Metals, USP has added two new General Chapters and one Supplemental General Chapter.

- <233> Elemental Impurities – Procedures
- <232> Elemental Impurities – Limits
- <2232> Elemental Contaminants in Dietary Supplements

The updated USP methodologies (harmonized with ICH Q3D) utilize modern technologies to provide better precision, sensitivity, and accuracy. To comply with these changes, drug products will be required to fall within the proposed limits.

Pharmaceutical, biopharmaceutical, medical device, and nutraceuticals organizations must be in compliance.

UTILIZING MODERN, PRECISE INSTRUMENTATION

- ICP-MS
- ICP-OES

HOW CAN NITTO AVECIA PHARMA SERVICES HELP?

Nitto Avecia Pharma Services has nearly 30 years of analytical experience with Heavy Metals analysis. Additionally, Avecia Pharma has actively participated in the industry since the early 2000s on this subject matter via technical posters, papers, presentations, and through collaborating with clients.

Our experience staff can help you:

- Develop/transfer, validate and test elements listed in <232> and beyond
- Perform a general screening for elements listed in <232> and beyond (for informational purposes only)

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ELEMENTAL IMPURITIES

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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