Nitto Avecia Pharma Services

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

PROTEIN ANTIBODY

Nitto Avecia Pharma Services provides direct access to our scientists and leadership who will partner with you no matter the size of your organization.

COMPREHENSIVE PLATFORM TO SUPPORT PROCESS DEVELOPMENT, MANUFACTURING, AND REGULATORY FILINGS

- Physico-chemical characterization to support CMC/IND submission
- Reference standard testing
- Method development and phase-appropriate validation
- Pre-clinical to commercial phase release and stability programs to support IND and BLA submission
- Biosimilar product testing

Quality Attributes	Method	Test
Identity	Microplate-FIr	Enzyme kinetics, Km/Kcat
Identity	AAA – AccQTag, Pickering	AA composition, Extinction Coefficient
Identity	icIEF	pI/Charge heterogeneity
Identity/Characterization	HILIC-FIr	N-glycan profile
Identity/Characterization	IEX-UV	Charge heterogeneity
Purity	CE-SDS/SEC-MALS	Size/subunit
Impurity	qPCR	Residual DNA
Strength	SoloVPE	Protein concentration
Potency	HIC/RPLC	Unconjugated Ab, ADC DAR values
Identity	MS	Intact Mass/Glycoforms
Identity	MS/MS	Peptide mapping/sequencing
Identity/Product Impurities	Multiple Attribute Monitoring (MAM)/MRM	Sequence Variants/Isoforms/PTMs
Residual Analysis for downstream Drug Substance	Various Technologies (LC/MS/MS, GC/MS and ICP/MS), qPCR and ELISA	IPTG, Antibiotics, Antifoams, Surfactants, Residual DNA, and HCP
Excipient	Various Technologies and Compendial procedures	Polysorbate 20, 80, Sugars, Amino Acids
Safety	USP <71>, <85>, USP <61> and <62> USP <1227>	Sterility, Endotoxin and Bioburden

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PROTEIN ANTIBODY

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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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