Nitto Avecia Pharma Services

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

MICROBIOLOGICAL TESTING

With nearly 30 years' experience in supporting all compendial microbiological testing, Nitto Avecia Pharma Services has the in-depth experience, established quality systems, and expertise to best support your product life cycle at any stage.

EXPERIENCED MICROBIOLOGICAL SUPPORT – USP, EP, JP, CP

- Microbial limits testing based on USP, EP, JP
- Antimicrobial effectiveness testing
- Bioburden testing
- BI studies
- BI population verification
- LAL endotoxin quantification (gel-clot, kinetic chromogenic, turbidimetric methods)
- Utility sampling and testing
- Container/closure integrity testing (microbial ingression and dye immersion)
- Water quality testing
- Sterility testing
- Environmental monitoring (on-site EM support, sampling, and testing services)
- Specialized microbiology testing

PRODUCT VALIDATION/RELEASE TESTING EXPERTISE

- Sterility test validation (bacteriostasis/fungistasis)
- LAL validation (inhibition/enhancement)
- Method suitability
- Hold time study
- Challenge testing
- Disinfectant efficacy testing
- Method development and validation
- Environmental monitoring
- Depyrogenation validation study
- Autoclave validation study
- Closure integrity testing (microbial ingression and dye immersion)
- Mediafill validation
- Sterilization validations (steam, EO, gamma radiation, chemical)
- Bioburden recovery

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MICROBIOLOGICAL TESTING

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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