Nitto Avecia Pharma Services

microbiological TESTING

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

EXPERIENCED MICROBIOLOGICAL SUPPORT

- Microbial limits testing based on USP, EP, JP
- Antimicrobial effectiveness testing
- Bioburden testing
- LAL endotoxin quantification (gel-clot, kinetic chromogenic, and turbidimetric methods)
- Container/Closure Integrity testing (microbial ingression and dye immersion)
- Water quality testing
- Sterility testing
- Environmental monitoring (including 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)
- Disinfectant efficacy testing
- Method development and validation
- Closure integrity testing (microbial ingression and dye immersion)
- Sterilization validations (steam, EO, gamma radiation, chemical)
- Bioburden recovery
- Environmental monitoring

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PARTNER WITH NITTO AVECIA PHARMA SERVICES' MICROBIOLOGY TEAM

As the demand for precision and timeliness of microbiological data increases, trust Nitto Avecia Pharma Services to deliver. We offer a comprehensive range of microbiological testing services supported by our highly experienced microbiology team, including testing according to official compendial methods such as USP, EP, BP, JP, AAMI, ISO standards and client specific methodologies. Our depth of expertise, combined with our novel approach to dedicated project management, and high-quality reporting, ensures well timed execution of your project deliverables.

At Nitto Avecia Pharma Services, our mission is to provide clients with outsourcing solutions that make drug development priorities possible.

OUR PROJECT MANAGEMENT TEAM SERVES YOU BETTER

Our signature service assigns you a single, dependable point of contact who guarantees all of the benefits of valued partnership such as strategic planning meetings, weekly reports, high quality data, and detailed post-project follow-up.

We invite you to visit us, audit our facilities, discover our insight, and learn more about our commitment to excellence. Visit www.aveciapharma.com or call 877-445-6554.

AVECIA PHARMA'S COMPLETE PACKAGE OF SERVICES

PARENTERAL MANUFACTURING

- CGMP Fill/Finish
- Aseptic Filling/Lyo
- Pre-Clinical through Commercial

FORMULATION/PROCESS DEVELOPMENT

- Formulation Characterization
- Container/Closure Compatibility Studies

ANALYTICAL CHEMISTRY

- USP/NF, EP, BP, JP, ACS, AOAC, and Client Methods

ANALYTICAL DEVELOPMENT

- Phase Appropriate Validation
- Process Validation Support
- Cleaning Validation and Verification
- Comparator Studies and Reference Standard Qualification

BIOPHARMACEUTICALS

- Cell-Based Bioassays
- Phase Appropriate Validation
- Product Characterization and QC Testing

DRUG DELIVERY TECHNOLOGIES

- Inhalation/Nasal Product Testing
- Transdermal Product Testing
- Device Evaluation

MICROBIOLOGY

- Quality Control Testing
- Research and Development

STABILITY STORAGE

- Standard ICH and Custom Storage Conditions

STRUCTURAL CHEMISTRY

- Extractables/Leachables
- Reference Standard Characterization
- Structural Elucidation of Unknowns
- Investigational Studies

OLIGO MANUFACTURING (API) VIA NITTO DENKO AVECIA

- Pre-Clinical, Clinical and Commercial Supply
- Small Scale [mg] to Large Scale [multi kg]