FORMULATION

Analytical Chemistry | Analytical Development | Biopharma | Drug Delivery | Formulation | Manufacturing | Microbiology | Stability | Structural Chemistry

Nitto Avecia Pharma Services is a cGMP contract development and manufacturing organization. Avecia Pharma's experienced and knowledgeable formulation team can reduce product risk and accelerate the drug development process by providing you with the optimum dosage form selection.

EXPERT FORMULATION TAILORED TO YOUR API AND INVESTIGATIVE NEEDS

- Multiple dosage forms (suspensions, liquids, lyo)
- Fill-finish of drug product
- Container/Closure and solution contact surfaces compatibility
- CMC section preparation
- Technology in-process transfer to CMO

PRE-FORMULATION

- Arrhenius kinetics
- Effect of pH
- Excipient compatibility
- LogD/LogP
- Polymorph screening by DSC
- Solubility/solubilization
- Stability evaluation

COMPREHENSIVE FORMULATION OF STERILE INJECTABLES

- Admixture and container/closure compatibility studies
- Development report in support of CMC
- Emulsions/suspensions, semi solids
- Fill-finish of drug product
- Liposome and microsphere encapsulation
- Liquid and lyophilized dosage forms
- Parenteral dosage forms
- Pilot batch production and stability analysis
- Toxicology supply manufacturing/dosing solutions

DISCIPLINED TECHNOLOGY TRANSFER

- Batch record development
- Critical process parameters evaluation
- Method transfer, development and validation
- Scale-Up from lab to manufacturing

STATE-OF-THE-ART INSTRUMENTATION

- VirTis 25L Genesis EL freeze dryer with sample thief and Maestro software
- TA Instruments Q2000 Differential Scanning Calorimeter with modulated DSC
- TA Instruments TGA Q500 high resolution thermo-gravimetric analyzer
- LYOSTAT2 freeze drying microscope system
- Microfluidics Microfluidizer Model M-110P high shear homogenizer
- Malvern Zetasizer Nano Series ZS-90
- Malvern Mastersizer 2000 with wet and dry modules
- Mettler Toledo DL39 Karl Fischer Coulometer
- Brookfield HBDV-II+Pro cone/plate rheometer
- Agilent 1200 Series HPLCs with a range of detectors
- UPLC
- Brookfield CT3 texture analyzer
- HunterLab ColorQuest XE
- Ross Dual planetary mixer
- Dissolution apparatuses
- Advanced Instrumentation: Micro-osmometer, specialized pH meters, and micro/analytical top loading balances

WWW.AVECIAPHARMA.COM

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Nitto Avecia Pharma Services

FORMULATION

PARTNER WITH NITTO AVECIA PHARMA SERVICES' FORMULATION DEVELOPMENT TEAM

Nitto Avecia Pharma Services' in-depth knowledge covers a diverse range of products, from generics to opthalmics, as well as a wide variety of dosage forms and routes of delivery. Avecia Pharma's preformulation studies are designed with an anticipated formulation strategy, route of administration, and ultimate formulation configuration in mind. Our formulation experts unite a thorough understanding of your needs along with the data on the physicochemical properties of the compounds to ensure the delivery of a stable, high quality product.

In addition to our formulation capabilities and complete CMC support, we also conduct the necessary analyses, container/closure compatibility studies and pilot batch studies required to move your product through the regulatory process.

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 INCLUDE

PARENTERAL MANUFACTURING

- Process Validation
- Lyophilization
- Scale-Up Studies

FORMULATION DEVELOPMENT

- Formulation Characterization
- Container/Closure Compatibility Studies

ANALYTICAL CHEMISTRY

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

ANALYTICAL DEVELOPMENT

- Method Development and Validation
- Process Validation Support
- Cleaning Validation and Verification
- Comparator Studies and Reference Standard Qualification

BIOPHARMACEUTICALS

- Method Development and Validation
- Product Characterization and Quality Control 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

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

API OLIGO MANUFACTURING (VIA NITTO DENKO AVECIA)

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

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