

Navigating you through
drug development



Your Premier Partner for API Synthesis and Purification Services

Empower Your Drug Development Journey with Nanologica & Ardena

As industry leaders in API synthesis and purification, we merge advanced technology with unparalleled expertise to offer you a comprehensive solution for your pharmaceutical needs. Beyond conventional purification methods such as crystallization, we bring exceptional expertise in purification by large scale chromatography which is required for complex molecule structures (e.g. semisynthetic natural products and products produced by fermentation).

At Nanologica and Ardena, we understand the critical importance of API synthesis and purification in drug development. Our **holistic approach to API synthesis and purification** ensures that you receive tailored solutions that meet your specific requirements **from small-scale non-GMP exploration to large-scale GMP production**. With a focus on quality, compliance, and efficiency, we empower you to unlock the full potential of your API purification journey.

Discover the difference with Nanologica and Ardena

- Integrated service offering in up and downstream processing
- Scientific expertise combined with state-of-the-art equipment
- Ability to customize suitable chromatographic resins for excellent purification performance

ARDENA
info@ardena.com
www.ardena.com

 **NANOLOGICA**

Our integrated approach to synthesis and purification

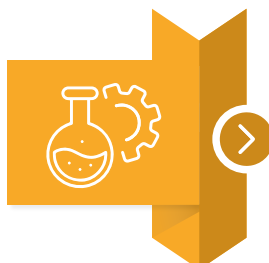
PROOF-OF-CONCEPT STUDIES

- Lead development
- Custom synthesis



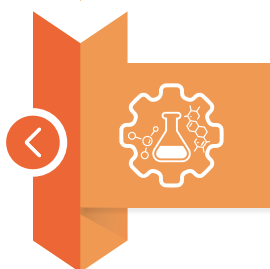
DEVELOPMENT

- Development of synthesis process
- Preparative HPLC method development and loading studies
- Robustness & repeatability
- Analytical method development & validation



CLINICAL MANUFACTURING

- non-GMP and GMP
- Gram to Kilogram scale
- Establishment of control strategy
- In-house manufacturing of HPLC stationary phase
- Impurity profiling and identification



VALIDATION

- Defining process window
- Design space qualification
- Design of experiments



COMMERCIAL MANUFACTURING

- Manufacturing for commercial phase
- Tech transfer for further scale-up
- Support towards commercial phase



DRUG PRODUCT

- Formulation development
- Clinical and commercial manufacturing
- Validation
- Regulatory dossier writing



Contact us to discuss your API project with our experts

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