



Coriolis Pharma

Biopharmaceutical Research and Development Service

Outstanding solutions for biopharmaceuticals



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Corporate overview

Coriolis Pharma is a globally operating independent service provider for formulation research and development of (bio)pharmaceutical drugs (proteins, peptides, monoclonal antibodies, RNA/DNA etc.) and vaccines.

An interdisciplinary team of highly qualified scientists with many years of experience in the development of (bio)pharmaceuticals supported by an expert scientific advisory board provides cutting-edge service and know-how related to the formulation development of (bio)pharmaceuticals.

This may involve for example formulation development of (pre-)clinical material through to commercial products, lyophilization processes, stability testing, supply of pre-clinical material, and analytical services using innovative analytical technologies (GMP analytics for MFI, light obscuration and AF4/HF5).

- **formulations for early clinical development**, e.g. liquid or dried formulations for phase I, IIa and IIb
- **formulations for late clinical development (phase III) and commercial application**

Stability testing and forced degradation studies

Within Coriolis Pharma suitable stress conditions for the molecule of interest are selected and optimized to be used during analytical and formulation development. Typical stress conditions are elevated temperature, e.g. intermediate and accelerated testing according to ICH, freeze-thawing, freeze-freezing, mechanical stress, photostability testing according to ICH or compatibility studies with various materials and the final administration conditions. Stability testing is performed according to the ICH guidelines, in climate chambers of controlled temperature and humidity.

Lyophilization cycle development, optimization and scale-up

Coriolis Pharma is highly experienced in the development, optimization, scale-up and transfer of lyophilization processes for biopharmaceutical drugs. The company is equipped with several freeze-driers from lab-scale to pilot scale, as well as the necessary analytical methods for the physico-chemical characterization of liquid and dried state (Karl-Fischer titration for residual moisture, differential scanning calorimetry and X-ray powder diffraction for the morphology). For the development of economical freeze-drying cycles suitable process parameters for freezing, primary and secondary drying are selected based on physico-chemical characterization of the freezing behavior of the formulations. When selecting process parameters the suitability for the later transfer to the client and scale up will already be considered. Freeze-drying processes are monitored by modern process analytical tools and it is possible to extract samples from the running processes by a sample thief and individual shelf closure.

Key expertise and service

Analytical development for biopharmaceutical drugs

For the analytical characterization of biopharmaceutical drugs Coriolis Pharma is equipped with modern, state-of-the-art techniques to assess different aspects of protein degradation. Next to standard techniques for protein stability testing (various HPLC methods, SDS-PAGE, DLS, cIEF, etc.) the company is specialized in aggregate and particulate characterization. For this purpose highly innovative technologies such as asymmetrical flow field flow fraction (AF4), hollow fiber flow field flow fractionation (HF5), nanoparticle tracking analysis (Nanosight®), microflow imaging (MFI), Coulter Counter and Archimedes are operational and included in the projects. For the structural characterization of proteins, Coriolis Pharma is equipped with a wide selection of spectroscopic techniques, e.g. UV, fluorescence, FTIR and CD.

The service for the customers includes:

- development, optimization and validation of analytical methods
- identification and selection of stability indicating methods
- transfer of analytical methods to the clients
- cGMP analytics for AF4, HF5, MFI and light obscuration

Formulation research and development

A strategic and systematic formulation development of biopharmaceutical drugs and vaccines is a key expertise of Coriolis Pharma. As service for the customers, liquid and dried formulations (especially freeze-dried and spray-dried formulations) are developed for all phases of development, including:

- **pre-formulation screening**, e.g. identifying suitable formulation composition with respect to pH, ionic strength, protein concentration, excipients; high throughput formulation approach is possible; identifying degradation products and selecting a set of stability indicating methods
- **pre-clinical formulation development**, e.g. liquid, frozen or dried formulations for tox-studies



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