

## Contract analytical services for biopharmaceuticals



[www.coriolis-pharma.com](http://www.coriolis-pharma.com)

### Corporate overview

Coriolis Pharma is an independent service provider for formulation research and development of biopharmaceutical drugs such as proteins, peptides, monoclonal antibodies, nucleic acids and vaccines. As a fully privately owned company we serve a global client base consisting of both small and large biopharmaceutical companies with molecules in early and late stage development.

An interdisciplinary team of highly qualified scientists with many years of experience in formulation development of biopharmaceuticals is supported by an expert scientific advisory board of leading academic researchers in the field. This structure allows Coriolis Pharma to deliver cutting edge service and know-how related to the formulation development of liquid and lyophilized products to the biopharmaceutical industries.

In addition to the core formulation capabilities, Coriolis Pharma is also specialized in the field of subvisible particle analysis and characterization of protein aggregates. This includes utilization of the latest innovative technologies such as resonant mass measurements (Archimedes), Nanoparticle Tracking Analysis (Nanosight), Micro-Flow Imaging (MFI), asymmetric and hollow fiber flow field flow fractionation (AF4/HF5), as well as provision of cGMP compliant analytics for selected particle measurement and aggregation characterization methods.

# Contract analytical services for biopharmaceuticals

## (Aggregation – Particles – Stability – Structure – Lyophilization analytics)

At Coriolis Pharma, we understand that a successful (formulation) development of biopharmaceutical products requires sensitive and specific analytical techniques for the detection of chemical and physical instabilities.

Our team members are experts in protein analysis, in particular in the field of protein aggregation and degradation.

We have recently published two reviews on analytical methods for particle analysis and protein degradation assessment.

Zölls S, Tantipolphan R, Wiggenhorn M, Winter G, Jiskoot W, Friess W, Hawe A; Particles in therapeutic protein formulations, Part 1: Overview of analytical methods; J Pharm Sci, 101:914-935 (2012)

Filipe V, Hawe A, Carpenter JF, Jiskoot W; Analytical approaches to assess the degradation of therapeutic proteins; Trends in Analytical Chemistry, 49:118–125 (2013)

For the analytical characterization of biopharmaceutical drugs Coriolis Pharma is equipped with modern, state of the art techniques, including:

### Technologies for in-depth aggregate and particle characterization

Analytical ultracentrifugation (AUC), size exclusion chromatography (HP-SEC), asymmetrical flow-field flow fractionation (AF4), hollow fiber flow-field flow fractionation (HF5), dynamic light scattering (DLS), nanoparticle tracking analysis (NTA), Resonant mass measurement (RMM), laser desorption, Flow Cytometry, electrical sensing zone method (Coulter Counter), light obscuration, Micro-Flow Imaging (MFI), optical microscopy with Raman spectroscopy (Morphology G3-ID), (semi-automated) visual inspection

### Structural characterization of proteins

UV-, fluorescence-(intrinsic and with extrinsic dyes), FTIR- and CD-spectroscopy (near-UV and far-UV CD)

### Further analytical techniques for protein stability

HPLC/UPLC methods (e.g. RP-HPLC, HP-SEC, IEX, HIC), SDS-PAGE (gel or chip-based), IEF, cIEF, ELISA, osmolality, turbidity, viscosity, Zeta potential

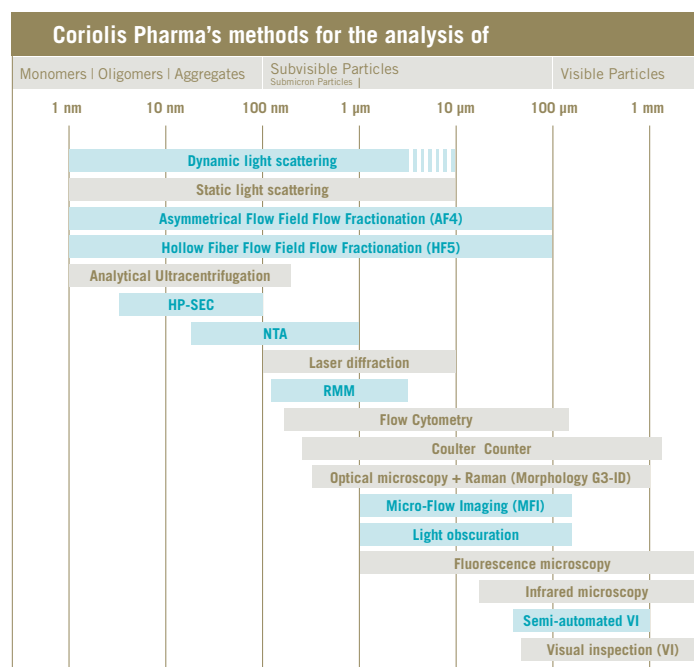
### Determination of melting temperature

Microcalorimetry ( $\mu$ -DSC) and Dynamic Scanning Fluorimetry (DSF)

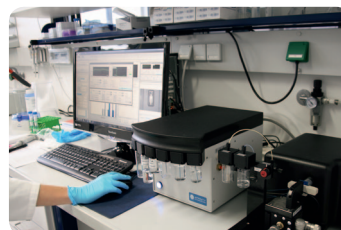
### Lyophilization related analytical testing

Karl-Fischer titration, DSC, freeze-drying microscopy, XRD and BET, Headspace oxygen and moisture

Selected methods are also available in full GMP compliance.



\* also as GMP methods at Coriolis Pharma



Making the subvisible visible

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