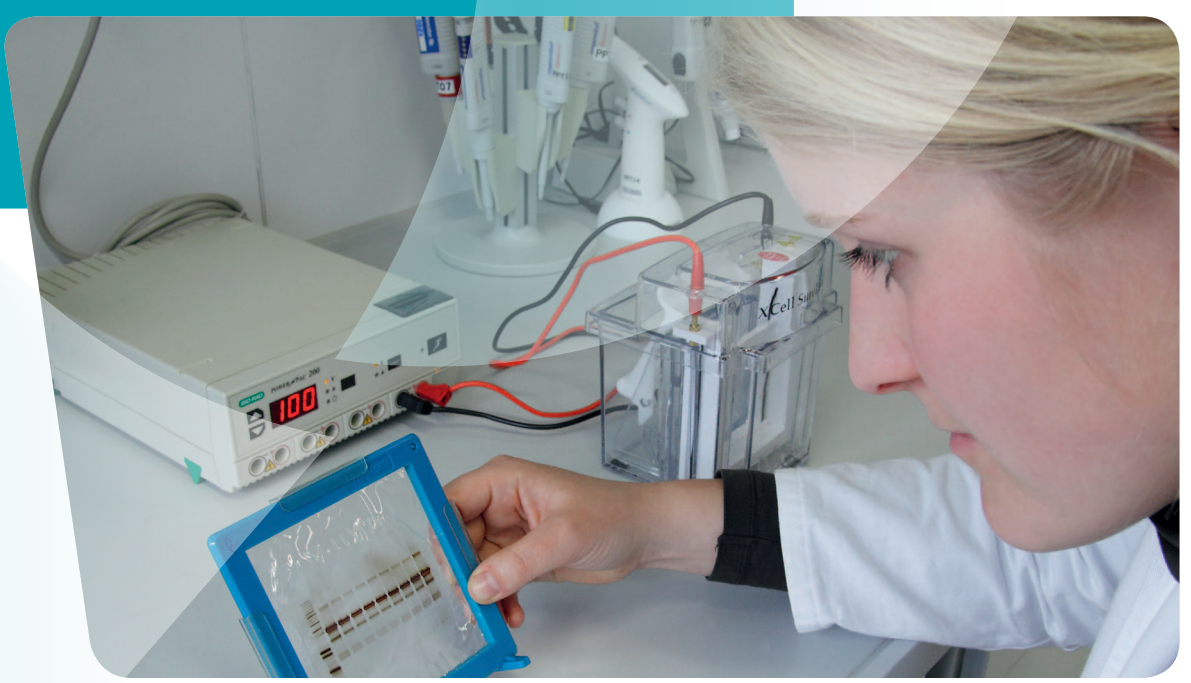
Coriolis Pharma

Biopharmaceutical Research and Development Service

Forced degradation and stability testing of biopharmaceuticals



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.

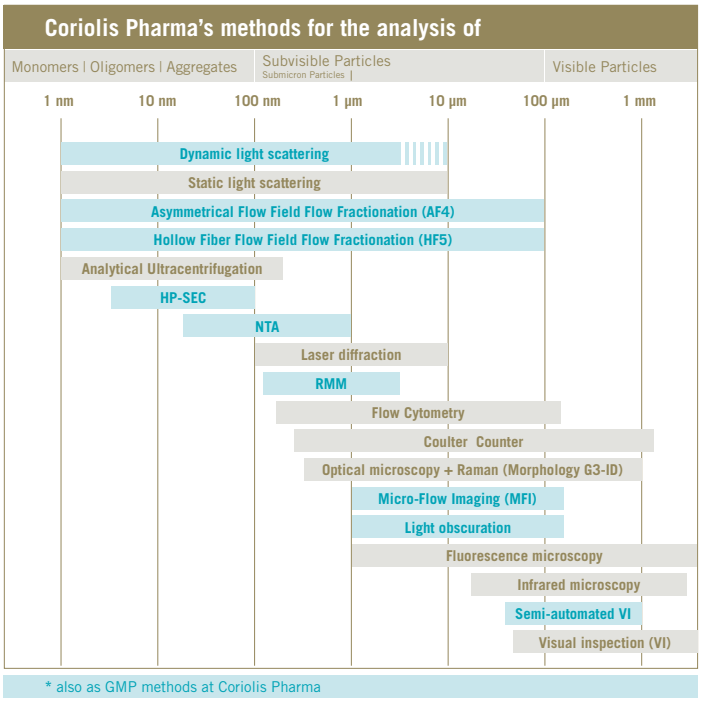
An interdisciplinary team of highly qualified scientists with many years of experience in formulation development of biopharmaceuticals is supported by an expert scientific advisory board of leading academic researchers in the field. This structure allows Coriolis Pharma to deliver cutting edge service 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.

Forced degradation studies and stability testing

Forced degradation studies are an integral part of each biopharmaceutical development for candidate selection, molecule characterization, elucidation of degradation pathways, formulation development, assay development and comparability studies.

At Coriolis Pharma we can select from a full range of stress conditions and apply them specifically to the molecule of interest. These can be monitored and further optimized.



Forced Degradation

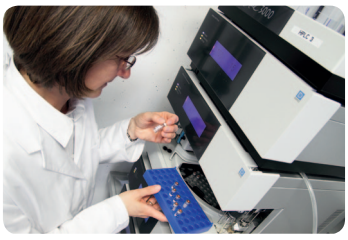
In order to give an overview and guidance on the complex topic of forced degradation studies two review articles have recently been published by Coriolis Pharma in cooperation with experts from academia and industry:

Hawe A, Wiggenhorn M, van de Weert M, Garbe JH, Mahler HC, Jiskoot W; Forced degradation of therapeutic proteins, J Pharm Sci, 101:895-913 (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)

Typical stress conditions can include:

- Intermediate and accelerated testing (ICH and non-ICH)
- Elevated temperature
- Freeze-thawing
- Freeze-freezing
- Various types of mechanical stress, e.g. shaking, stirring, etc.
- Photostability testing (ICH and non-ICH)
- pH stress
- Forced oxidation
- Forced deamindation
- Shipment studies
- In-use stability studies
- Compatibility studies with various materials and the final administration conditions



Stability testing

Stability testing is performed according to the ICH guidelines, in climate chambers of controlled temperature and humidity.

Examples for stability testing:

- -156°C, -80°C, -40°C, -20°C, 2-8°C, 25°C/60% r.h., 40°C/75% r.h.
- Any conditions possible (ICH and non-ICH)
- Arrhenius kinetics

For both, forced degradation studies and stability testing Coriolis Pharma will recommend a tailored analytical package to gain the maximum information on the stability of the molecule of interest from the generated samples.

How stable is your product?

Coriolis Pharma

Biopharmaceutical Research and Development Service

Am Klopferspitz 19 | 82152 Martinsried | Germany

Phone +49 (0) 89 – 5 42 44 98-0
Fax +49 (0) 89 – 5 42 44 98-22

contact@coriolis-pharma.com

www.coriolis-pharma.com