



Product Information:

GMP compliant Protein Analysis and Characterization

GMP-compliant Protein Analysis

Founded in 1997, Protagen Protein Services GmbH (PPS) has established and successfully expanded a fee-for-service business in protein and peptide analysis. The service platform now comprises method development, qualification and validation, comparability of biologics, complete protein characterization and release testing and GMP-compliant protein analysis for quality control of biotherapeutics.

The strong commitment to quality is reflected in the established and authority approved Quality Management system of Protagen Protein Services, and in the experienced staff.

Protagen Protein Services is continuously expanding its customer base and offers customized solutions for the producing pharma industries and contract manufacturing organizations (CMO).

Quality Assurance and Regulatory Affairs



Quality control (QC) and quality assurance (QA) according to GMP standards are decisive to process analysis and batch release analysis. The analytic workflow for all technologies employed for protein analysis is documented in standard operation procedures (SOP), risk analysis, and documentation guidelines. All study results are internally peer-reviewed by our experts providing the customer with a precise evaluation and conclusion.

ICH Q6B - Biotechnological and biological products

Biotechnological and biological products need to be characterized in accordance with ICH-guidelines. Quality guideline Q6B specifies test procedures and acceptance criteria for the analysis of proteins.

Protagen Protein Services provides a comprehensive analytical service package depending on the customers' needs.



Technology overview: Expertise and capabilities



Our services range from intensive laboratory research support over routine basic analytical testing to full product characterization and release testing. We support our customers with a wide range of analytical methods which are individually combined to give the best possible results.

Analytical Methods

Amino Acid Sequence

- ▶ Peptide Mapping by LC-ESI-MS/MS, MALDI-MS/MS, UV
- ▶ Quantitative PTM Analysis (Deamidation, oxidation, glycation ...)
- ▶ Disulfide Bridging analysis
- ▶ N/O-Glycosylation Site determination
- ▶ N/C-terminal sequencing of entire proteins
- ▶ Intact molecular weight MALDI or LCESI
- ▶ N-terminal sequencing by Edman
- ▶ De novo Sequencing of monoclonal antibodies (mAb)

Glycan Analysis

- ▶ Monosaccharide Content
- ▶ Sialic Acid Content
- ▶ Glycan Mapping –MALDI, HPAEC or NP-HPLC
- ▶ Linkage Analysis GC-MS
- ▶ Glycopeptide mapping

Physicochemical Properties/Purity

- ▶ Amino Acid Analysis – Content and Composition
Modified Amino Acids (eg. Hydroxyproline, Norvaline)
- ▶ Extinction coefficient/ UV VIS - Quantity
- ▶ IEF gel/cIEF – Charge Variants
- ▶ CZE- Charge/ Size Variants
- ▶ SDS-PAGE/cSDS – Size *Reducing/ non reducing*
- ▶ RP-HPLC/IEX-HPLC - Purity
- ▶ CD - Conformation
- ▶ Fluorescence - Conformation
- ▶ SEC-MALLS/AUC - Aggregation
- ▶ 2D PAGE – Purity *High resolution protein separation (up to 40 x 30 cm (16x12 in))*
- ▶ HCP Analysis *2D PAGE, Western Blot, Mass Spectrometry*
- ▶ HDX-MS - Conformation *Top Down and Bottom Up Approach*

Bioassays

- ▶ Cell-based bioassays
- ▶ ELISA: antibody selection

Comprehensive testing and analysis procedures are our specialty

Protagen Protein Services provides comprehensive support for the Life Science Industry. The excellent knowledge in protein analysis has already served numerous customers in R&D of biosimilars and biotherapeutics. Protagen Protein Services is also prepared to establish and to perform the methods required by the Pharmacopoeia.

If you think about outsourcing all of your GMP-release analytics, if you want to avoid intensive investments in costly analytical equipment, or if you simply try to cope with capacity overloads, Protagen Protein Services will provide the solution.

We offer the following services:

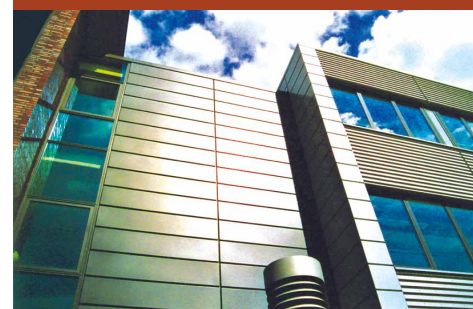
- ▶ *Validation of assays*
- ▶ *Release and lot testing*
- ▶ *Full protein reference standard characterization*
- ▶ *Stability testing (e.g. Oxidation, Freeze/Thaw-Cycles, Elevated temperatures, UV-Radiation)*
- ▶ *Method development, qualification and validation*
- ▶ *Comparability of Biologics*
- ▶ *Complete protein characterization and release testing*
- ▶ *Regulatory support*
- ▶ *Method development transfer*

Additionally, we provide a customized method development or service packages to meet your company's needs. Please contact us to discuss your specific requirements.

Key advantages and customer benefits at a glance

Advantage	Customer Benefit
Fast and flexible partner	<ul style="list-style-type: none"> ▶ Shorter time-to-market for your products ▶ Long-term partnership
Access to a broad range of protein analytical methods	<ul style="list-style-type: none"> ▶ Reliable solutions for routine analyses as well as for special analyses
Ability to develop state-of-the-art analytical methods	<ul style="list-style-type: none"> ▶ Custom-tailored and validated analytical solutions ▶ Dedicated partner for development of new products
Transfer of methods in or out according to customer needs	<ul style="list-style-type: none"> ▶ Flexible business models to manage costs efficiently
Comprehensive and stringent project management	<ul style="list-style-type: none"> ▶ Clear and well-defined communication on project progress ▶ Detailed project plan with defined milestones to meet your desired deadlines
Long-lasting industrial experience	<ul style="list-style-type: none"> ▶ Ability to understand customers' needs
Guaranteed compliance with current GMP regulations	<ul style="list-style-type: none"> ▶ Safety for your business
Experience with regulatory authorities	<ul style="list-style-type: none"> ▶ Support and accompaniment at regulatory authorities during market authorization (e.g. EMA) ▶ Focus on your core business and competencies

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