Analysis of Protein Biopharmaceuticals

Comprehensive cGMP Services at Every Stage of Drug Development

Amazing where you can go
At Solvias, we work closely with you...

Solvias provides comprehensive services for protein-based drugs, to biotechnology and pharmaceutical companies, at every stage of drug development.

...TO DESIGN CUSTOMIZED PROGRAMS...
Solvias can help you to solve your most complex analytical challenges by providing expert guidance and by designing flexible and customized programs. Complex projects are coordinated by dedicated professional customer project managers.

...THAT MEET YOUR NEEDS...
Methods destined for use in pharmaceutical release testing are developed with a focus on robustness and reproducibility. The goal of the method development program is to establish a reliable method and carefully describe it in a standard operating procedure (SOP) that can readily be executed at Solvias or transferred to your laboratory of choice. Within the framework of the method development program, critical parameters such as the linearity, reproducibility, and LOQ will be checked to ensure reliable analytical results. A written SOP that includes product specifications is a prerequisite for beginning a method validation program. The method validation program is performed under cGMP according to ICH guidelines and typically includes the following parameters: specificity and selectivity, accuracy and precision, limit of detection (LOD) / limit of quantification (LOQ), linearity and measurement range, robustness, and solution stability.

A milestone-based program can easily be designed and adapted to best fit the needs of your drug development program. All product-specific intellectual property (IP) for methods developed by Solvias is assigned to the customer.

...AND ARE TAILORED TO YOUR DRUG.
The selection of the techniques to be used is based upon the properties of the drug. For example, to establish a stability-indicating method, techniques such as CE and HPLC are applied to samples that have been stressed (e.g. temperature). As both are orthogonal methods with different separation processes, they reveal a complementary picture of product-related degradation forms. The optimal method can then be further developed. We preferentially apply quantitative methods, if quantification is desired (e.g. capillary electrophoresis instead of flat bed electrophoresis).
Services
Bioanalytical programs individually tailored to meet your needs

PRIMARY ACTIVITIES
• Characterization (for regulatory submission)
• Method development and validation (ICH)
• QC Release testing (cGMP)
• Stability studies (cGMP)
• Comparability

ADDITIONAL SERVICES INCLUDE
• Certification, storage and supply of customer-specific reference substances
• Analytical support in process validation
• Analytical support in formulation development
• Extractables and leachables
• Analytical troubleshooting

QUALITY
• FDA-inspected
• cGMP contract laboratory approved by Swissmedic
• ISO 9001-certified QM system
Technology base

A broad range of capabilities allows Solvias to apply the best solution to your problem

- Capillary electrophoresis (CZE, CE-IEF, CE-SDS; UV and LIF detection)
- Chromatography (HPLC, GC, DC, SEC, IEC; many special detectors)
- Electrophoresis (IEF, SDS-PAGE, native gel; standardized and ready gels)
- Amino acid analysis
- Mass spectrometry (ESI, MALDI-TOF/TOF-MS)
- Western blotting
- ELISA
- Hyphenated techniques (LC-MS)
- Quantitative PCR, threshold system
- Spectroscopy (UV/VIS, CD, fluorescence)
- Analytical ultracentrifugation
- Light scattering (MALS, DLS)
- DNA sequencing (cGMP)
Applications
Complete characterization programs according to ICH Guideline Q6B: comprehensiveness is our strength

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PURITY
- Determination of molecular entities composing the drug substance

QUANTITY
- A<sub>280</sub>
- Quantitative amino acid analysis
- Nitrogen determination
- Proteinassay (Lowry)
- Immunoassay (ELISA)

PEG analysis

Glycan analysis

Spectral properties

Liquid chromatographic patterns

Electrophoretic patterns

Extinction coefficient

Isoelectric point

Molecular size

Molecular weight

All classes of molecules

Microbial contamination

Endotoxin

Virus contamination

Heavy metals
Practical solutions to complex problems

Solvias brings years of pharmaceutical experience to solve the most complex analytical and regulatory challenges

- Peptide mapping by LC-MS
- Disulfide bridging by LC-MS
- Determination of oxidative forms by e.g. LC-MS and LC-UV
- Isoelectric focusing by capillary electrophoresis
- PEG substitution by capillary electrophoresis and mass spectrometry
- Carbohydrate analysis by e.g. HPLC and capillary electrophoresis HPAEC-Dionex, MALDI-TOF/TOF mass spectrometry
- Content determination by amino acid analysis
- Determination of extinction coefficient by amino acid analysis and UV/VIS absorbance
- Quantification of Tween®
- Conformational Analysis by FTIR
We focus on reliable and efficient methods for pharmaceutical release testing

**DISULFIDE BRIDGING**
- Enzymatic cleavage of the native protein LC-MS separation and identification of peptide fragments
- Proof of proper folding by presence of species with proper disulfide bridging and absence of improperly bridged fragments
- Reductive alkylation to induce shift of bridged peptides in the chromatogram as a control step

**CARBOHYDRATE ANALYSIS IN RELEASE TESTING**
- Sialic acid by HPLC
- Neutral sugars by HPLC
- Glycosylation with and without sialic acid by capillary electrophoresis
- HPAEC-PAD

**BIOSIMILAR/FOLLOW-ON BIOLOGICS**
- Comprehensive choice of state-of-the-art methodology
- Experience to ensure successful registration
- Dedicated project management
