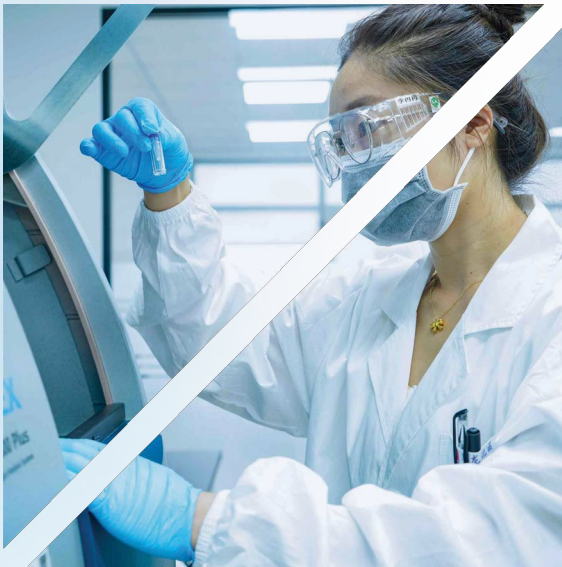


Biologics Analytical Services

Global Partner of Choice for Comprehensive Analytical Characterization of Biological Products from Preclinical Phase through to Commercialization.

Pharmaron is a trusted partner in biologics analytics, offering deep expertise and flexible solutions that support every phase of your project. From method development to regulatory-compliant testing, we ensure your biologic is thoroughly characterized, safe, and market-ready. Our commitment to quality and precision delivers the analytical data you need to make informed decisions and accelerate your product's path to commercialization.



Benefits



Flexible Service Options

Pharmaron offers standalone analytical testing and integrated end-to-end biologics services, providing the flexibility to choose the solution that best fits your project by delivering what you need, when you need it.



Extensive Expertise and Comprehensive Analytical Characterization in Line with ICH Guidelines

Our deep industry experience ensures compliance with regulatory standards for all your product characterisation needs.



Optimized Platform Methods for Consistent and Reproducible Results

Platform methods integrated with state-of-the-art technologies accelerate analytical delivery and ensure accuracy and reliability at every stage.



Tailored Analytical CMC Solutions for Biologics Characterization

Customized approaches for multiple product classes, including, mAbs, multi-specific Abs, ADCs, cytokines, enzymes, VLPs and peptides.



Regulatory Confidence in Submissions for Release Testing of GMP Drug Substance and Drug Product

Comprehensive testing services that ensure your product meets regulatory approval standards.

Pharmaron can support your product development analytics throughout the product lifecycle. Whether you are looking for a complete end-to-end solution or require targeted expertise for specific analytical challenges for your innovator or biosimilar product, our adaptable approach ensures your project's success.

Our Approach:

- **Adaptable Solutions:** Whether it's a full development program or focused support, our services flex to fit your project's needs at any stage.
- **Collaborative Partnership:** We collaborate closely with your team, aligning our expertise with your development goals and timelines for seamless integration.
- **Expertise You Can Trust:** Pharmaron's deep regulatory knowledge and advanced analytics ensure every step of your biologic's journey is backed by reliable, actionable data.

Analytical Service Package to Drive CMC Development (Module 3)

Characterization of Drug Substance

Control of Drug Substance

Drug Substance Stability

Control of Drug Product Excipients

Control of Drug Product

Drug Product Stability

General properties, quantitation

UV, pH, Titer, Excipient (Tween20/80)

Process related impurities

HCD, HCP, residual Protein A, Endotoxin, Mycoplasma

Purity

Size Related Variants:
SEC/CE-SDS/Native
SEC-MS/SEC-MALS
Charge Related Variants:
CEX/iCIEF/CZE/2D-CEX-RP-MS

Bioassay

ELISA binding
Cell-based binding (FACS)
Cell-based assay

Structural characterization

Primary Structure: MW, Sequence coverage, PTMs, N-/O-glycosylation, Sialic acid contents;
High Order Structure: Disulfide bonds, CD, FTIR, DLS, DSF; Others: AAA, Extinction Coefficient, Free thiol

Biological characterization

FcγR, FcRn Affinity (SPR& BLI)
C1q Binding
ADCC/CDC
Enzymatic Activity Assays

Let's Partner to Accelerate Your Analytical CMC Success

To discuss your molecule or request a tailored analytical package contact: bd@pharmaron.com



Laboratory Services



Chemistry, Manufacturing & Control



Clinical Development



Biologics & CGT

BioStaOve0326v1