MYCENAX

Analytical Method Development

Mycenax provides one-stop analytical services covering antibodies, enzymes, recombinant proteins, ADCs, plasmid DNA, stem cells, and exosomes. All validated methods comply with ICH Q2 (R2) guidelines to ensure consistent and reproducible results.

The key features of our services are as follows:

- End-to-end solutions and phase-specific approach
- Analytical services for a variety of biopharmaceuticals
- Full in-house analytical capabilities for lot release and product characterization

Comprehensive In-House Analytics

Method Development/ Method Validation

Lot Release

Product Characterization

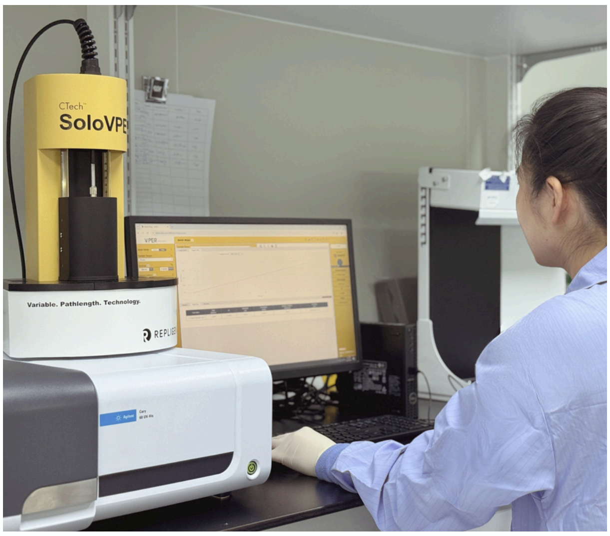
Stability Testing

Analytical Services

For more information, please scan the QR code.

Characterization Services

Analysis of physicochemical properties and biological activity. Please scan the QR code for details.



Biosimilars:

The Similarity Assessment Tools

Mycenax manages CQAs from cell line development to fill-finish, controlling glycosylation, charge variants, potency, and purity throughout development to produce biosimilars with close similarity.

Analytical Assessment in Biosimilar Development

Cell Line Development

- Charge Variant
- Glycosylation
- Primary Sequence Identification

USP Process Development

- Aggregation
- Charge Variants
- Glycosylation
- Potency

DSP Process Development

- Aggregation
- Charge Variants
- Glycosylation
- HCP/HCD
- Potency

Formulation

- Molecular Weight
- PTMs
- Product and process related Impurities
- Potency
- Sequence
- Stability Study

Critical Quality Attributes (CQAs)

Mycenax monitors CQAs throughout development, ensuring biologics align with critical specifications.

Primary Structure

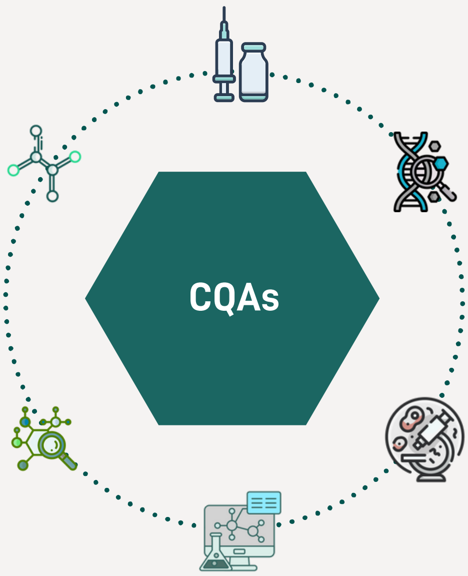
- Amino Acid Sequence
- Disulfide Bridge
- Molecular Weight

High Order Structure

- Conformation Stability
- Secondary Structure
- Tertiary Structure

Post-Translational Modification

- Deamidation
- Glycosylation
- Oxidation



Process Related Impurity

- Host Cell Protein
- Host Cell DNA

Product Related Variants

- Aggregates
- Charge Variants
- Fragments

Biological Activity

- ADCC/CDC
- Binding Affinity
- Cell-based Activity