

anaRIC biologics

Analytical solutions readily delivered

NEW BIOLOGICAL ENTITIES & BIOSIMILARS

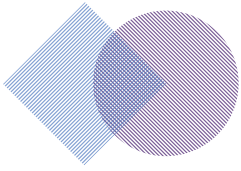


EXPERIENCE

- Monoclonal antibodies (incl. second generation, e.g. fragments, bispecifics)
- Antibody-drug conjugates (ADCs)
- Proteins (e.g. enzymes)
- Vaccines
- Oligonucleotides

ANALYTICAL SOLUTIONS

- Lead selection
- Characterization
- Forced degradation
- Method development & optimization
- Method validation
- Method transfer
- Release & stability (ICH, in-use, cyclic stress)
- Comparability
- Troubleshooting
- Consultancy



NEW BIOLOGICAL ENTITIES & BIOSIMILARS

TESTING CAPABILITIES

Characterization

- Physicochemical properties
- Primary structure
- Higher order structure
- Post-translational modifications
- Aggregates & particulate matter
- Solubility

Identity & purity

- Amino acid sequence & composition
- N- & C-terminal sequence
- Molecular weight
- Size distribution
- Charge variants
- Glycosylation profile
- Disulphide bridges
- Drug-to-antibody ratio (DAR)

Impurities

- Degradation
- Physical modifications
- Chemical modifications

Quantity

- Amino acid analysis
- Total protein content
- In matrix (serum, CSF)

Potency

- Immunoassays
- Enzymatic assays
- Cell-based assays

General quality

- Appearance
- pH
- Osmolality
- Particulate matter
- Moisture content

Process impurities & contaminants

- Host-derived (HCPs, DNA)
- Downstream / cultured derived
- Residual solvents / chemicals / biochemicals / inorganic salts
- Medium components
- Mycoplasma
- Sterility
- Endotoxins

TECHNOLOGIES

- Liquid chromatography
- Gas chromatography
- Mass spectrometry
- Spectrophotometry
- Flow cytometry
- Viscosimetry
- Capillary electrophoresis
- Gel electrophoresis
- Chip electrophoresis
- Karl Fischer titration
- Real-time PCR (qPCR)
- ELISA
- Light obscuration
- Flow imaging analysis
- Dynamic light scattering
- Laser diffraction
- Density
- Osmometry