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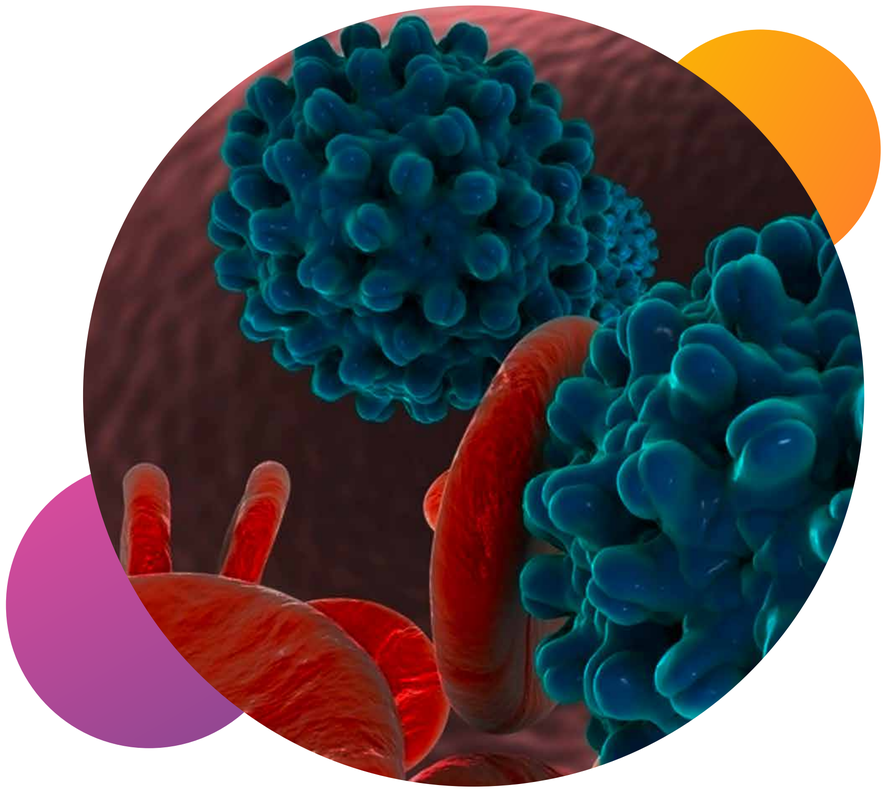

Biopharmaceutical Characterization

Setting the Foundation of Success in Your Drug Development

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Introduction

Biopharmaceuticals are medicinal products manufactured using biotechnology. **Such products are generally complex macromolecular structures and represent a diverse range of drug modalities, including recombinant proteins, PEGylated protein, monoclonal antibodies, vaccines, biosimilars, *etc*.**
These biopharmaceuticals can be therapeutic and/or prophylactic.

A successful biologic medicine development ensures the safety, efficacy, quality, purity, and potency of the biopharmaceutical product.

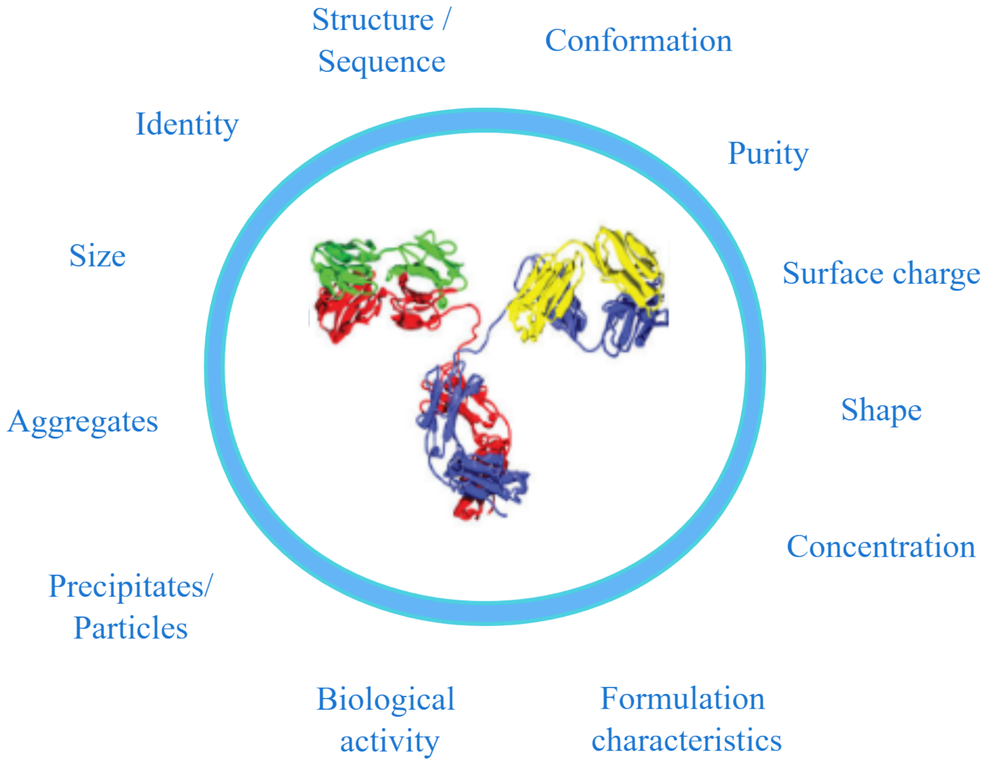
In line with the ICH Q6B Guidance, Creative Proteomics offers biopharmaceutical analysis and characterization services, including structure analysis, physicochemical property, biological activity, immunochemical property, as well as purity and impurity determination to ensure the quality and consistency of your product.

Regulatory Requirements and ICH Q6B

The regulatory guidelines most pertinent to biopharmaceutical characterization are described in the ICH Q6B (Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products).

ICH Q6B Specifically Requests Data on The Following Characterization Parameters:

- Physico-chemical properties
- Biological activity
- Immunochemical properties
- Purity-impurity and contaminants
- Quantity

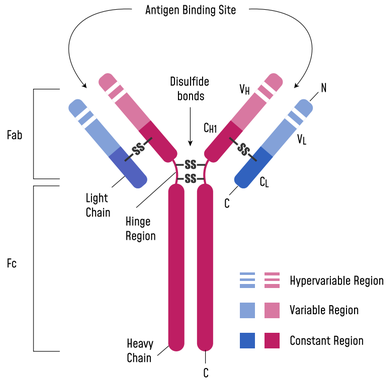


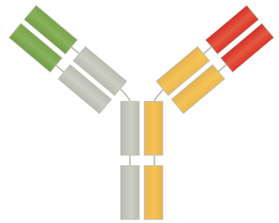
Structure of Antibody Drug

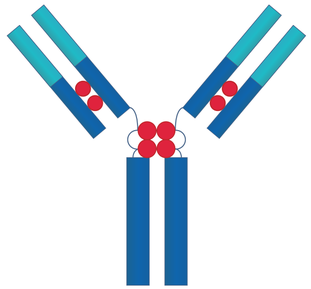
Biopharmaceuticals possessed complex structures and high heterogeneities. Product quality is affected by the production process, storage conditions, *etc.*

- Amino acid sequence and variants
- Glyco-variants
- Charge variant
- Cysteine variants

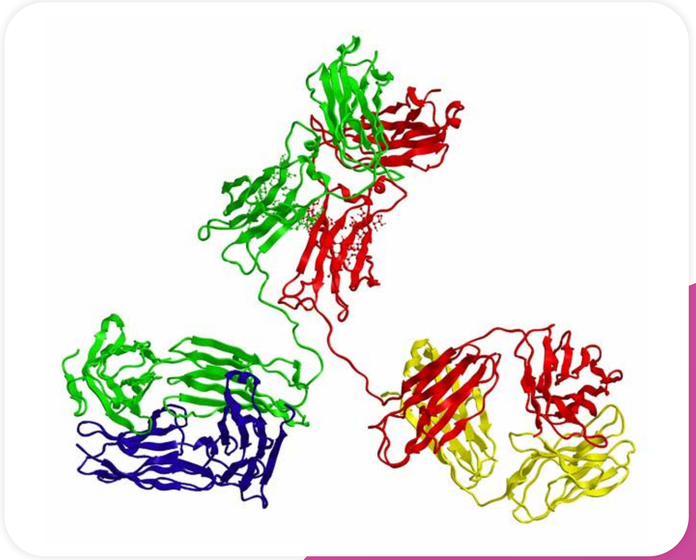
Primary Structure







Advanced Structure



Our Mass Spectrometry Platform

- World-class mass spectrometry platform for biopharmaceuticals
- Experienced Mass Spectrometry Scientists

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Agilent 6530/6545 Q-TOF

Bruker AutoFlex MALDI TOF/TOF

Thermo LTQ Orbitrap Velos

Thermo Q-Exactive Orbitrap

Thermo Q-Exactive Plus Orbitrap

Thermo Orbitrap Fusion

Characterization Capabilities of Mass Spectrometry Platforms

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Protein (Antibody Drug) Characterization	Research Project	Method
Molecular Weight Determination	Intact molecular weight	ESI-Orbitrap MS / MALDI-TOF-MS
	Light and heavy chain molecular weight	ESI-Orbitrap MS
	Fab fragment and Fc fragment molecular weight	ESI-Orbitrap MS
	ADC molecular weight and DAR value analysis	HPLC-MS
Primary Structure Analysis	Peptide mapping (protein amino acid sequence confirmation)	LC-MS/MS
Other Analysis	Charge heterogeneity analysis	IEF/CE-IEF /cIEF
	Protein aggregation analysis	SEC/GPC
Modification Analysis	Disulfide bond analysis	LC-MS/MS
	Glycosylation analysis • Glycan analysis • Glycopeptide analysis	MALDI-TOF / LC-MS/MS
	Phosphorylation analysis	LC-MS/MS
	Deamidation and oxidation	LC-MS/MS
Purity Analysis	Monomer and polymer purity analysis	SEC-HPLC
	Non-glycosylated heavy chain and small molecule fragments	SEC-HPLC / SDS-PAGE / CE-SDS
Binding Assay	Protein binding/inhibition analysis	ELISA（EC50, IC50）
	Cell binding/inhibition analysis	FACS（EC50、IC50）
Impurity Detection and Analysis	HCP assay	2D-DIGE / LC-MS/MS
	Host residual DNA detection	Real-time quantitative PCR

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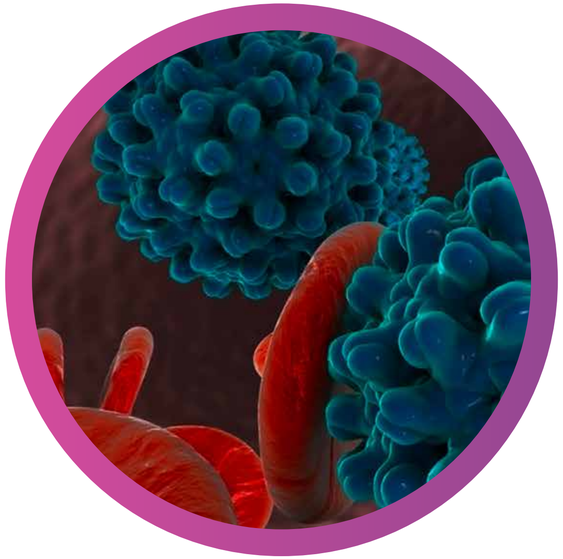
We Reserved In-depth Analytical Service Experiences in Biopharmaceuticals for

- Antibody Drug Conjugates (ADC)
- Antibodies
- Monoclonal Antiboies
- Bispecific Antibodies
- Fab Fragment
- Fusion Proteins



- Glycoprotein/Recombinant Proteins
- PEGylated Proteins
- Biosimilars
- Vaccines
- Therapeutic Enzymes
- Oligonucleotides

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