protein & ANTIBODY

Avecia Pharma Services provides direct access to our Scientists and Leadership who will partner with you no matter the size of your organization.

Comprehensive platform and flexible programs to support Process Development, Manufacturing and Regulatory Filings

- Physico-Chemical Characterization to support CMC/IND submission
- Reference Standard Testing
- Method Development and Phase-Appropriate Validation
- Pre-clinical to Commercial phase Release and Stability programs to support IND and BLA submission
- Biosimilar Product Testing

Quality Attributes	Method	Test
Identity	Microplate-Flr	Enzyme kinetics, Km/Kcat
Identity	AAA ñ AccQTag, Pickering	AA composition, Extinction Coefficient
Identity	icIEF	pI/Charge heterogeneity
Identity/Characterization	HILIC-Flr	N-glycan profile
Identity/Characterization	IEX-UV	Charge heterogeneity
Purity	CE-SDS/SEC-MALS	Size/subunit
Impurity	qPCR	Residual DNA
Strength	SoloVPE	Protein concentration
Potency	HIC/RPLC	Unconjugated Ab, ADC DAR values
Identity	MS	Intact Mass/Glycoforms
Identity	MS/MS	Peptide mapping/sequencing
Identity/Product Impurities	Multiple Attribute Monitoring (MAM)/MRM	Sequence Variants/Isoforms/PTMs
Residual Analysis for downstream Drug Substance	Various Technologies (LC/MS/MS, GC/MS and ICP/MS), qPCR and ELISA	IPTG, Antibiotics, Antifoams, Surfactants, Residual DNA, and HCP
Excipient	Various Technologies and Compendial procedures	Polysorbate 20, 80, Sugars, Amino Acids
Safety	USP <71>, <85>, USP <61> and <62> USP <1227>	Sterility, Endotoxin and Bioburden

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