



mAb and Protein Testing

Protein-based biotherapeutics such as monoclonal antibodies have revolutionized the treatment of various diseases and continue to be a key area of innovation in the pharmaceutical industry. Avance Biosciences team provides a comprehensive panel of assay solutions for protein-based biotherapeutics from early drug development through final drug product testing to ensure the highest standards of product quality, integrity, safety, purity and potency.

Protein-Based Biotherapeutics Testing

Critical Quality Attributes	Assay	Description
Purity	Residual host cell DNA Quantitation	Quantitation of residual host cell DNA in test sample by QPCR by extraction (PCR inhibition observed when tested by dilution)
	Residual host cell RNA Quantitation	Quantitation of residual host cell RNA in test sample by QPCR by extraction (PCR inhibition observed when tested by dilution)
Content	Protein quantitation	ELISA, MSD and/or Western Blot Analysis using the JESS™ platform
Genetic Integrity	Vector Genome Integrity	Confirm the integrity of the vector genome using QPCR/ddPCR, Bioanalyzer or CE
Safety	Endotoxin	USP <85>
	Bioburden	USP <61>
	Sterility	USP <71>
Other	Appearance	USP <790>
	pH	USP <791>