AVANCE BIOSCIENCES

Stability Testing Services

A biotherapeutic stability testing study is a comprehensive assessment designed to evaluate how the quality, safety, and efficacy of a biotherapeutic product changes over time. Regulatory guidance documents, including the International Council for Harmonization (ICH) guidelines Q1A(R2) on stability testing and the U.S. Food and Drug Administration (FDA) guidelines, mandate such studies to standardize procedures and ensure that biotherapeutic products meet stringent quality standards throughout their lifecycle.

Our Expertise

Combining cutting-edge analytical methods and instrumentation, significant background in assay development and validation, with stringent GMP/GLP regulatory guidance and support, Avance scientists have the tools to successfully support your stability program to ensure precise and reliable assessment of the shelf-life, potency, and safety of your biotherapeutic product.

Our Services

1. Study Design: Our Project Management will work with Customer to define the scope, objectives, and parameters of the study, including selecting the product batches, storage conditions, and duration of the study.
2. Storage and Monitoring: Samples are stored in the defined controlled environment with 24/7 monitoring to ensure compliance with the study design.
3. Analytical Testing: Testing is performed at the established time points to evaluate physical, biological, and microbiological attributes of the product. Common tests include potency assays, purity tests, and degradation product analysis.
4. Documentation and Reporting: All procedures, observations, and results are documented in a comprehensive report.

Methods Supporting Stability Testing

Tests	Description
Custom assays based on ddPCR, QPCR, NGS, Flow cytometry, ELISA, etc	Assays designed for characterize client's product for a specific feature

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Methods Supporting Stability Testing (Cont.)

Tests	Description
UV-Visible Spectroscopy (UV-Vis)	Concentration, purity, and detection of specific absorbance changes
Capillary Electrophoresis (CE/CE-SDS)	Purity, MW, and/or Integrity analysis
Enzyme-Linked Immuno-sorbent Assay (ELISA)	Protein quantification
Sterility Testing	USP 71 Compendial Assay
Visible Particle Evaluation	USP 790 Compendial Assay (Visual Assessment)
Appearance	USP 631 Color and Achromicity
pH Measurement	pH stability and potential for degradation under different pH conditions
Osmolality Testing	Osmolality, ensuring isotonicity and stability in biological conditions