AVANCE BIOSCIENCES

Compendial Assays for Drug Substance/ Drug Product Release

United States Pharmacopeia (USP) compendial assays are vital in drug development, ensuring pharmaceutical products meet rigorous standards for quality, safety, and efficacy. These assays guarantee that manufactured drugs consistently adhere to regulatory benchmarks, ensuring batch-to-batch uniformity and optimal bioavailability.

Avance Biosciences offers a portfolio of compendial assays to help our clients meet regulatory and release requirements for their drug substance and/or drug product. These assays include:

Assay Name	Assay Description	Sample Requirements and TAT
Bioburden[1] (USP 61/62)	• Quantitative enumeration of aerobic bacteria and fungi present in the DS/DP to ensure acceptable limits for microbial contamination. • Anaerobic bacteria may also be tested as an option.	Dependent on sample type Note: For samples which require neutralization of inhibitory activity by membrane filtration, only aerobic testing is performed. TAT: 1-2 weeks
Sterility[1] (USP 71)	• Confirms the absence of viable microorganisms in sterile DS/DP to meet safety requirement.	Dependent on sample type and testing method required (direct inoculation vs. membrane filtration). TAT: 2-3 weeks
Mycoplasma Testing	• QPCR-based rapid mycoplasma test covering 17 Mycoplasma species. • Verifies absence of mycoplasma contamination to ensure the safety of DS/DP derived from cell culture. • Includes USP 63 controls.	1 ml test sample; can test pellet, supernatant, or both. TAT: 2 weeks
Endotoxin[1] (USP 85)	• Detects and quantifies endotoxin in DS/DP to safeguard against pyrogenic reactions in parenteral drugs.	100 µl minimum volume TAT: 1-2 weeks
pH (USP 791)	• Ensures the pH of DS/DP falls within acceptable ranges for stability and efficacy.	1 ml minimum volume TAT: 1-2 weeks
Osmolality (USP 785)	• Evaluates DS/DP for biological compatibility to meet safety and potency requirements (product dependent).	1 ml minimum volume TAT: 1-2 weeks
Color and Achromacity (USP 631)	• Assess visual appearance of DS/DP to meet specified color requirements.	Glass vial(s) of DS/DP test sample. TAT: 1-2 weeks
Visible Particle Evaluation (USP 790)	• Sample evaluated for the presence of visible particles in injectable products to ensure safety and quality.	Glass vial(s) of DS/DP test sample. TAT: 1-2 weeks

[1] Based on the nature of the tests, different sample requirements may apply. Some test samples may require suitability evaluation before testing depending on formulation.