eurofins | BioPharma Product Testing



Raw Materials Testing for Biologics

Evaluating the quality and efficacy of materials used in bioprocesses is critical in biologics manufacturing. There are many factors that make testing particularly challenging, including the diverse range of materials used in bioprocesses, varying approaches to manufacturing and specific control strategies used to ensure quality.

Eurofins BioPharma Product Testing is well-versed in evaluating the identity, purity, potency and quality of a diverse range of materials used in a wide array of bioprocesses, using established GMP methods, as well as customized methods developed to fit unique client needs. Our 20 years of biopharmaceutical experience, dedicated teams of scientists and state-of-the-art instrumentation heighten our comprehensive lab capacity and testing capabilities to proficiently advance projects of any size or complexity.

Why Choose Eurofins BioPharma Product Testing?

- We provide a comprehensive biologic raw materials testing package to support all testing needs.
- We can develop and validate unique methods to test biologic materials, as well as support platform methods for many of the techniques offered.
- We have the ability to test non-monographed materials to satisfy agency scrutiny.
- We provide 24/7 online access to data and flexible service models such as Fee-For-Service, Full-Time-Equivalent and Professional Scientific Services® programs.

Testing Capabilities

Chemically Defined Media

- Amino Acid Content and Profile for Pre- and Post-Column AAA
- Sugar Profile
- Vitamin Profile
- pH, Osmolality, Solubility, and Appearance
- Trace Metals

Cell Preservation Media, Animal Sera, and Metabolic Growth Factors (e.g. insulin, interleukins, etc.)

- Quality and Functionality Testing per USP <90> and the EP monograph for Fetal Bovine Sera
- Total protein content by UV-VIS
- Hemoglobin level
- IgG and species confirmation (immunochemical assays)
- Electrophoretic profile and various assays
- pH and Osmolality
- Insulin Testing per USP and EP Monographs
- Development of various metabolic protein assays

Enzymes (e.g. proteases, nucleases, etc.)

- SDS-PAGE Identification & Purity
- pH and Osmolality
- Specific Activity and Kinetics
- Methods can be developed with extremely low sample requirements



Chromatographic Resins

- Resin Identification – Photoacoustic Spectroscopy (FTIR-PAS)

Surfactants / Buffers

- Fingerprint ID by FTIR
- Assay and Identification by HPLC-CAD
- pH/Osmolality
- Ion Identification
- Simethicone Testing
- RNAse and DNAse detection

Instrumentation

- Agilent 1200
- Agilent 1260
- Agilent VWD, MWD
- Agilent 1290 UHPLC
- Agilent 7890 & 6890 GC with 1888 & 7679A model Headspaces
- Agilent 8453 UV/Vis Spectrophotometer
- Waters Alliance HPLC System
- Waters Acquity UPLC System
- Waters PDA, TUV
- Waters Acquity UPLC Systems deactivated for AccQ Tag Derivatization
- Waters 2414 RI Detector
- Thermo Corona Ultra, Plus, and Veo CAD
- SpectraMax UV/Vis Plate Reader (96-well and cuvette)
- Thermo Nicolet 6700 FTIR Spectrophotometer
- Thermo Dionex ICS-5000+ HPIC
- MTEC PAC 300 Photoacoustic Detector
- Pickering Pinnacle PCX Post-Column Derivatizers
- Eldex H/D Workstations
- Invitrogen Xcell SureLock™ Mine-Cell
- Helena QuickGel System
- BioRad GS-900 Densitometer