



Eurofins BioPharma Product Testing San Diego's Services

Eurofins BioPharma Product Testing San Diego provides analytical and formulation development for small molecules through biologics, including peptides, proteins, oligonucleotides and RNAs. The cGMP and GLP compliant lab services encompass Pre-formulation & Formulation, Analytical Method Development & Validation, Routine QC & Monograph Testing, Clinical Material Labeling/Packaging, and Sterile Fill/Finish. Eurofins BioPharma Product Testing San Diego also provides 1,500 ft² of non-sterile manufacturing capabilities.

Formulation Development & Optimization

- Liquids (solutions, suspensions, emulsions)
- Topicals (creams, ointments, gels, lotions)
- Comparator Testing
- Compatibility Testing (bags/sets, ports, etc.)
- Solubility and Stability Screening
- Toxicology Formulation and Test Article Preparation
- Lyophilization Formulation Development

Analytical Development & Validation

- Method Development, Qualification & Validation
- Method Optimization & Remediation
- Analytical Support of Pre-Formulation & Dose Stability
- Residual Solvents Analysis
- Forced Degradation Studies
- Stability Study, Storage and Release Testing
- Topical *in vitro* assays

GMP Manufacturing (Non-Sterile)

- Dosage Forms (topicals, solutions, reagents, powders)
- Technology Transfer
- Process Development
- Active Pharmaceutical Ingredients (Atypical APIs)
- Clinical Trial Materials

GMP Manufacturing (Sterile)

- Sterile clinical supplies for Phase I and II
- Compounding, sterile filtration, clinical packaging and distribution

Routine QC & Monograph Testing

- Raw Material & Excipient Screening
- Intermediates & API Characterization
- In-process and Finished Product Testing
- Toxicology Test Article Dose Verification & Short-term Stability
- Degradent, Impurity and Related Substance Identification
- Reference Standard Characterization & Stability
- High Potency Testing capabilities for cytotoxics, B-lactams, and mutagens
- LCMS & ELISA Quantitative Assays
- BSL-2 containment to isolate dangerous biological agents

Clinical Material Labeling & Packaging

- Kitting
- Labeling
- Storage & Distribution
- Reconciliation & Destruction