

DEVELOPMENT & TESTING



DEVELOPMENT & ANALYTICAL SERVICES

Parenteral Formulation Development

- Small and Large Molecules:
Peptides, Proteins, mAbs, Biosimilars, Vaccines, Oligonucleotides/RNA, Small Molecules
- Solubility
- Stability
- pH, Buffer Selection
- Osmolality
- Excipient Selection
- Lyophilization Process Characterization

Pre-Manufacturing Studies

- Temperature Hold
- Hydrogen Peroxide Exposure Degradation
- Pump Parameter Evaluation
- Viscosity Characteristics
- Material Compatibility
- Filter Validation

cGMP TESTING SERVICES

GMP Testing

- Material Identity
- In Process
- Product Release
- Product Specific Assays
- Compendial
- Microbial (Endotoxin, Bioburden, Sterility)
- CoA Generation
- ICH Stability (All ICH Conditions)
- Retention Sample Management, Inspection and Testing
- In-Use Infusion Studies
- Container Closure Integrity testing
- Other Forced Degradation Testing
- Transportation Testing

Method Validation and Qualification Services

- Method Development
- Method Transfer and Validation

