

Development & Testing



Focused on Faster

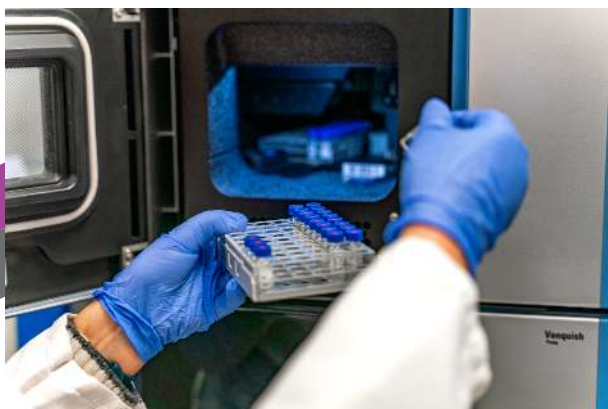
Development & Analytical Services

- **Preclinical Development**
 - Pre-formulation, excipient, and formulation studies of parenteral and lyophilized formulations
 - Solubility, degradation, potency, thermal analysis
 - Non-clinical reference standard hand fills
- **Process Development**
 - Lyophilization cycle development/optimization
 - Technology transfer
- **Analytical Method Work**
 - Method transfer/validation
 - Method development/optimization
 - Examples include: (U)HPLC, UV-Vis, CE, moisture, endotoxin, particulate matter, etc
- **Testing**
 - Release testing
 - Stability Testing
 - CoA Generation



GMP Testing Services

- **GMP Testing**
 - ICH thermal stability test programs
 - Compendial testing (USP/EP)
 - Raw material testing for manufacturing use
 - Release and Certificate of Analysis generation
 - Trials for solubility, pH, degradation, potency, purity, reconstitution
 - Testing of cytotoxic compounds
 - Thermal cycling and excursion testing
 - Material compatibility testing (e.g.: infusion sets, IV bags, stoppers, etc.)
- **Microbiology**
 - Microbial enumeration tests
 - Tests for specified microorganisms
 - Bacterial Endotoxin
 - Sterility



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