THERE'S A SCIENCE TO SUCCESS.™

serán

STATE-OF-THE-ART LABORATORIES SUPPORTING EARLY DEVELOPMENT THROUGH COMMERCIAL

Analytical Services & Support

Serán's analytical labs deploy a variety of techniques to assess the physical and chemical properties of drug substances and prototype formulations. Careful collection and evaluation of the right data enables rational scientific choices leading to optimized formulations.

- **Pre-formulation assessment**
- **Fundamental molecular characterization**
- **Method development & validation**
- **Finished product release testing**

Quality Control

Serán's QC lab ensures that raw materials used in cGMP manufacturing, as well as intermediates and dosage forms produced at Serán, consistently meet rigorous quality standards. The QC lab also conducts comprehensive chemical and physical stability assessments of intermediates and drug products to ensure compliance with regulatory and quality requirements.

EXPERIENCE COUNTS

Industry Expertise Our team of experienced scientists, analysts, specialists, and management professionals possess a wealth of knowledge and expertise in pharmaceutical development and manufacturing.

Comprehensive Solutions: We offer end-to-end analytical R&D and QC solutions tailored to meet the unique needs and requirements of CDMO clients across diverse therapeutic areas and dosage forms.

Regulatory Excellence: With a deep understanding of regulatory requirements and industry best practices, we help clients navigate complex regulatory landscapes and achieve regulatory approval efficiently.

Connect & Learn More

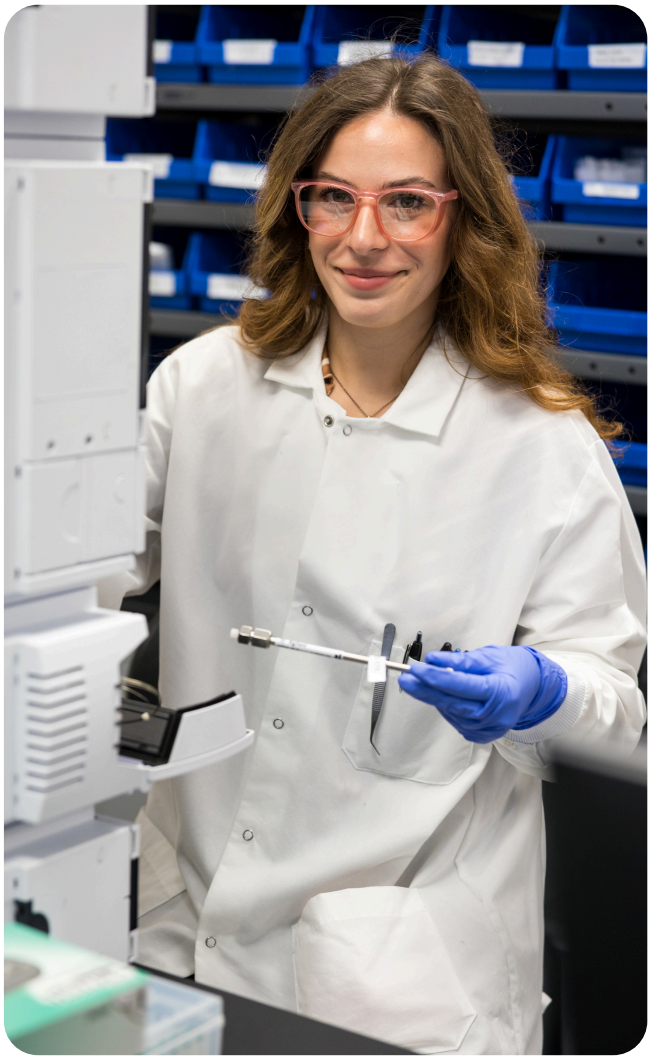
www.seranbio.com
hello@seranbio.com

Comprehensive Analytical R&D and QC Designed to Uphold the Highest Levels of Product Quality and Compliance

Unparalleled Analytical Support

Analytical Services

- Fundamental molecular characterization
- Pre-formulation assessment and formulation screening
- Advanced solid-state characterization
- Exploratory stability
- Dissolution assessment
- Modeling and predictions
- Method Transfer
- Method Development
- Method Optimization
- Method Qualification & Validation
- Development batch stability (IND-enabling)
- Onsite ICH Stability Chambers
- Data Trending & Predictive Modeling
- Cleaning method development and validation



Quality Excellence in Every Step

Quality Control & Quality Assurance

- Raw material testing
- In-process testing
- Finished product testing
- Stability studies
- cGMP compliance
- Document control
- Regulatory Compliance
- Quality Assurance support - document review, audit preparation, and regulatory submission assistance

Equipment

- **Analytical Characterization:** mDSC, XRPD, TGA, DVS, SEM, HPLC, UPLC, HPLC-CAD, cKF, PION µFlux, Type I / Type II Dissolution, biorelevant dissolution
- **Physical Characterization:** Tablet hardness tester, disintegration (auto-endpoint), Geopyc, Accupyc, shear cell, FlowDex, sieve analysis, Texture Analyzer

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