Analytical & Regulated Projects

Pharmaceutical Analysis Laboratories

SwRI's laboratories are fully compliant in support of cGMP development and manufacturing. Drug products and processes are characterized and tested under industry standard chemical analysis procedures in adherence with cGMP and cGLP standards.

We support researchers, startups, manufacturers, and other companies across the drug development supply chain in our laboratories, including:

- Stability Studies
- cGMP Manufacturing
- CMC Chemistry Manufacturing Control Services
- Chemical Analysis Services
- Microencapsulation



Pharmaceutical extruder system in a clean room

About Us

Pharmaceutical testing laboratories at Southwest Research Institute[®] (SwRI[®]) provide analytical services used in the formulation of drug products for clinical trials and scale-up for manufacturing.

We welcome your inquiries. For more information, please contact:

Sandra Drabik, PhD Analytical & Regulated Projects 210.522.6419 sandra.drabik@swri.org

Pharmaceuticals & Bioengineering Chemistry & Chemical Engineering Division

pharmtest.swri.org



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Southwest Research Institute®



Drug dissolution equipment

Analytical & Regulated Projects

Working With Us

Multidisciplinary Problem-Solving Services

As an independent and impartial nonprofit performing applied contract research and development, we are focused on pursuing innovation and excellence for the benefit of our clients. We strive to ensure that our products and services conform to the highest quality standards and have achieved multiple quality accreditations and certifications.



400 MHz Varian NMR spectrometer

Serving Industry, Government, Academia, and the Public

SwRI maintains contract vehicles and teaming structures that help your organization advance its goals.

The goal of the Chemistry and Chemical Engineering Division is to strive for continuous improvement in providing the highest quality services and products to meet or exceed the client's expectations.

Integrated Pharmaceutical Services

- FDA-inspected facilities
- ISO 9001:2008 quality system
- Clean rooms and pilot plants (Class 10,000 and 100,000)
- High-potency plant-scale isolator and laboratory
- DEA-controlled substances (I-V)
- CGMP clinical supplies, storage, and distribution
- ICH stability for API and drug product

Capabilities

SwRI will develop and validate methods needed for your drug product / dosage form to include in your CMC section to include:

- Assay and impurity test
- HPLC drug testing
- Residual solvent analysis
- Drug dissolution testing
- ICH stability studies
- Particle size analysis
- TGA and DSC analysis

Additional Services

Zeta potential, light degradation, impurity ID, API, raw material, product release, reference standard characterization, cGMP NMR analysis



Thermal analysis: TA Instruments SDT Q600 and MDSC Q100; FTIR Nicolet iS50