

# Seven Star Pharmaceutical Services



## Who We Are

At Seven Star Pharmaceutical Services, we are dedicated to advancing the science of solid-state chemistry and material characterization through precision, innovation, and deep scientific insight. Based in Malvern, Pennsylvania, we specialize in analytical development, material characterization, pre-formulation, and formulation development services for small molecules. Our expertise spans the pharmaceutical, chemical, and materials science sectors, providing a comprehensive spectrum of services that support research, development, and commercialization.

We combine scientific rigor with innovative methodologies to help our clients understand, optimize, and control their materials—from early discovery to product realization.



## Our work is guided by six interconnected areas of expertise

- **Solid Form Screening and Selection** – identifying optimal salt, co-crystal, and polymorphic forms to ensure material stability and performance.
- **Crystallization Process Development** – designing robust and reproducible crystallization processes to achieve consistent solid-state outcomes.
- **Preformulation and Formulation Development** – transforming solid-state understanding into practical dosage form design, including tablet compaction, dry granulation, lyophilization, and spray drying, to address diverse developability challenges and enable reliable product advancement.
- **Analytical Development** – developing and validating analytical methods to support product development, stability studies, and regulatory submissions.
- **Intellectual Property Support** – providing analytical evidence and expert interpretation to strengthen patents, support data validation, and assist in litigation.
- **Routine Analytical Testing** – delivering accurate and reliable results using advanced techniques including XRPD, SCXRD, DSC, TGA, DVS, FTIR-Raman, particle size analysis, powder rheometry, and more.

More than a testing laboratory, we act as scientific partners, offering data interpretation, insight, and problem-solving expertise.

Our mission is to provide scientifically rigorous, transparent, and reliable results that empower innovation and accelerate development.

With a steadfast commitment to quality, precision, and integrity, Seven Star Pharmaceutical Services continues to illuminate the path from molecule to material to market.

## Our Commitment

At Seven Star Pharmaceutical Services, every analysis, study, and report reflects our dedication to scientific precision, data integrity, and meaningful interpretation. We take pride in bridging analytical science with material understanding—helping our clients make confident, informed decisions that advance their products from concept to reality.



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# Routine Material Characterization and Analytical Testing

At Seven Star Pharmaceutical Services, our routine material characterization and analytical testing capabilities provide essential insights into the composition, solid-state form, thermal behavior, and physical properties of materials.

These standardized and validated methods form the foundation of reliable data generation, supporting solid-state, formulation, and stability studies throughout the drug development process.

By combining chemical analysis with physical and structural characterization, we deliver a complete understanding of how materials behave under varying environmental and processing conditions.

Our routine studies are performed using established compendial methods or client-validated procedures, ensuring accuracy, reproducibility, and regulatory alignment—whether assessing an API, excipient, or formulated product.

## Typical services include

- X-ray Powder Diffraction (XRPD)
- Differential Scanning Calorimetry (DSC)
- Modulated Differential Scanning Calorimetry (mDSC)
- Thermogravimetric Analysis (TGA)
- Dynamic Vapor Sorption (DVS)
- Polarized Light Microscopy (PLM)
- Hot Stage Polarized Light Microscopy (HS-PLM)
- Melting point determination with video recording
- Karl Fischer Titration (KFT)
- Particle Size Distribution (PSD)
- Fourier Transform Infrared (FTIR) Spectroscopy
- Raman Spectroscopy
- UV-Visible Spectroscopy
- Helium Gas Pycnometry (Powder Density)
- Geopyc (Envelope density)
- BET surface area analyses
- SEM with XRF capability
- Empirical Powder Flow Tests – Angle of repose, Carr's index, Hausner ratio, and tap density measurements for comparative flowability screening.
- Tablet disintegration, hardness, and friability testing
- Assay determination using compendial or client-validated methods
- Dissolution testing performed using compendial or client-validated methods



# Analytical Development and Advanced Capabilities

Our analytical development and advanced capabilities are designed to address complex scientific and developability challenges, enabling in-depth understanding of material properties, process behavior, and product performance.

These specialized studies combine method design, optimization, and interpretation to support development programs from early research through scale-up and commercialization.

We focus on creating scientifically sound and application-oriented solutions—helping clients interpret data, identify root causes, and implement meaningful strategies that enhance formulation robustness, stability, and manufacturability.

## Capabilities include

- **Temperature and Humidity Dependent XRPD** – Environmental control studies using the Empyrean XRPD system to evaluate phase behavior and stability under variable conditions.
- **Single Crystal X-ray Diffraction (SCXRD)** – Structure elucidation and confirmation of molecular arrangement and polymorphic identity.
- **pKa and log P/log D Measurements** – Conducted using the Sirius T3 instrument to support solubility and ionization profiling.
- **FT4 Powder Rheometry** – Advanced powder flow characterization involving multiple, scientifically selected tests to assess flowability, compressibility, permeability, and shear behavior. Each study is tailored to the material and objective, providing detailed insights beyond empirical indices.
- **HPLC / UPLC Method Development and Validation** – Design, optimization, and validation of analytical methods to support product development, stability studies, and regulatory submissions.
- **Development of Discriminatory Dissolution Methods** – Formulation-specific design and optimization of dissolution conditions to enable sensitive assessment of formulation or process differences.
- **Tablet Compaction and Dry Granulation Studies** – Using the Natoli NP-RD10A R&D Tablet Press to evaluate tableting feasibility and mechanical performance.
- **Lyophilization (Freeze Drying)** – Feasibility and optimization studies to enhance material stability and process robustness.
- **Spray Drying** – Applied for solubility enhancement, particle engineering, and amorphous dispersion development.
- **Environmental Stability Studies** – Controlled studies assessing the impact of humidity, temperature, and time on material form and integrity using XRPD, DVS, DSC, and complementary techniques.

