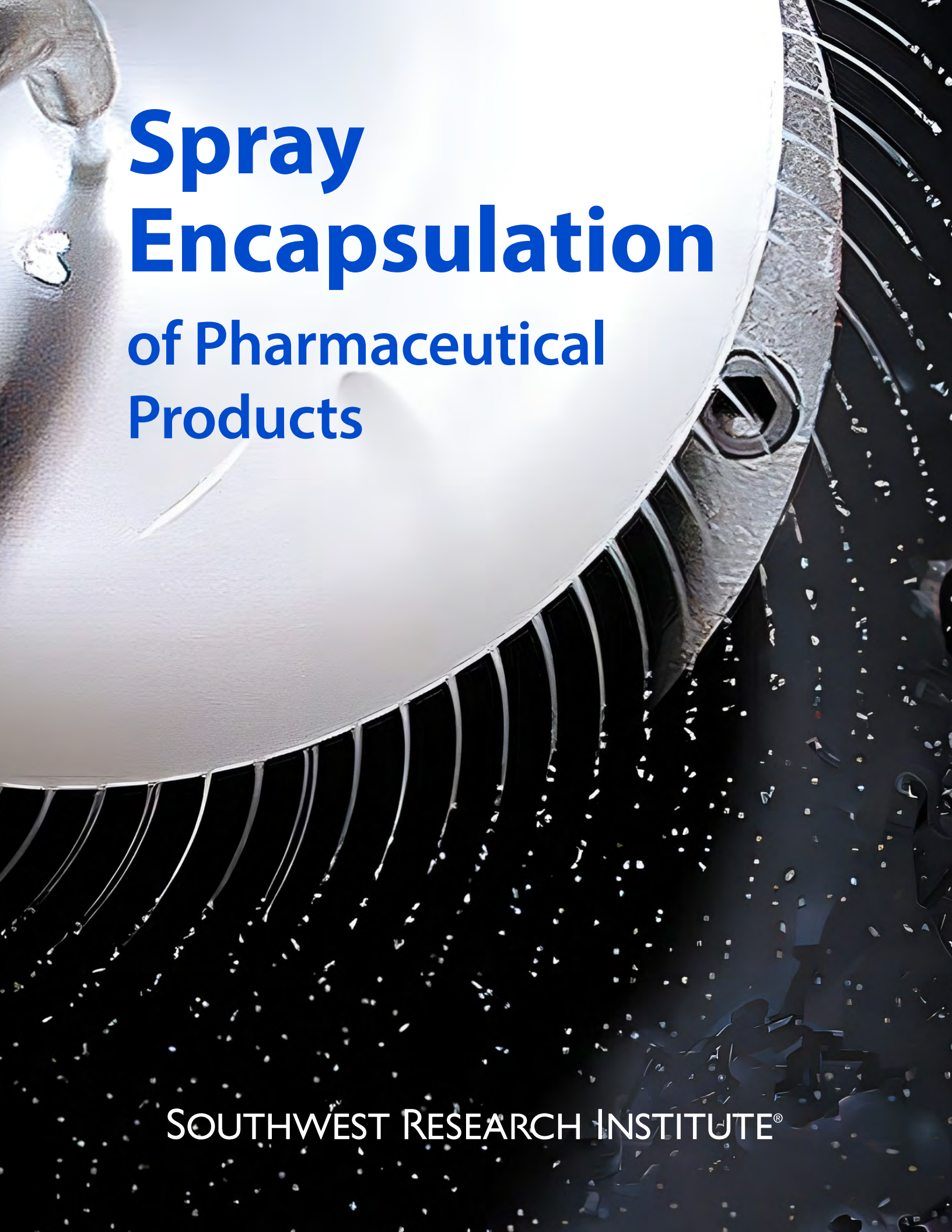


Spray Encapsulation

of Pharmaceutical Products

SOUTHWEST RESEARCH INSTITUTE®

Based on more than half a century of experience in encapsulation technology, Southwest Research Institute (SwRI) offers comprehensive services in developing and characterizing pharmaceutical products for drug delivery. Using their extensive expertise, SwRI scientists obtain desired release-rate characteristics by selecting and developing the optimum formulation by considering shell materials, coatings, particle size, and drug payload.

Particle Development

To improve particle development, the Institute uses innovative and state-of-the art techniques, including spray drying and disk atomization. Using these processes, SwRI scientists design, develop, and prototype a variety of drug-delivery systems.

Spray Drying

Spray drying is suitable for producing heat-sensitive products, with particle size ranging from 1 to 250 micrometers. Spray drying enables small average particle size with a narrow range of particle size distribution.

Characteristics of spray drying include:

- Aqueous feed, and solvent processing available
- Atomization resulting from a rotating wheel, pressure nozzles, two-fluid nozzles, or by sonic energy
- High-speed rotary atomization (5,000 to 30,000 revolutions/minute)
- Outlet temperatures approximately equal to product temperature

The SwRI production minor spray dryer can dry up to 25 kilograms per hour of water with rotary atomization or two-fluid atomization of the feed. Here a two-point collection (chamber and cyclone) system is installed.

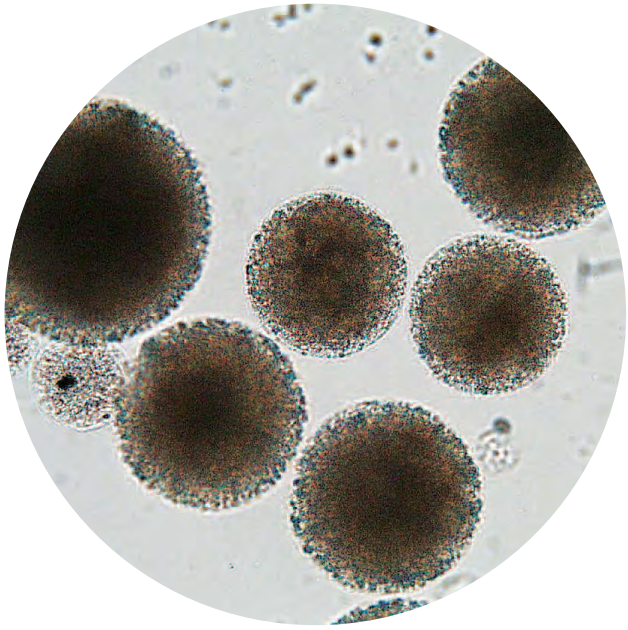
Disk Atomization

Disk atomization uses a rotary atomizer. Disk runs typically use a lower volume of drying air than spray drying, requiring less heat input. Disc atomization can be achieved using the following processes:

- **Hot melt and prilling**. Drugs are dispersed into molten polymer and atomized from a disk.
- **Solvent evaporation**. A product is dissolved into a solvent with a dissolved polymer and atomized.
- **Water evaporation**. A drug is dissolved into water with a shell material and atomized.

Disk atomization possesses the following characteristics:

- Produces particles from 30 to 3,000 micrometers
- Achieves larger particle size in comparison to spray drying
- Uses solvent-based or molten polymer feedstock
- Obtains more spherical particles and better film coating compared to spray drying

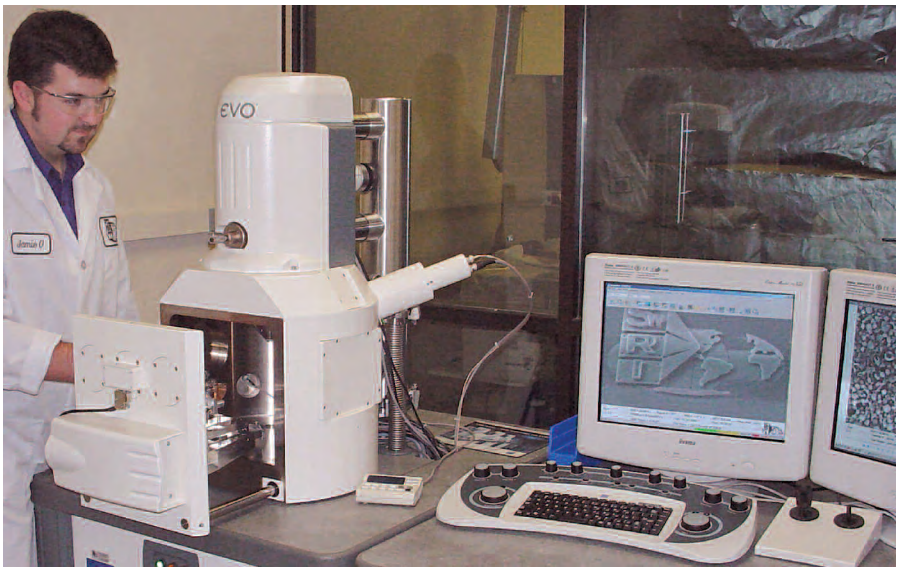


Using visible or scanning electron microscope, SwRI scientists image glyceride hot-melt particles.

About the cover: An SwRI-developed spinning disk provides extremely spherical particles with uniform coating.

Analytical Capabilities

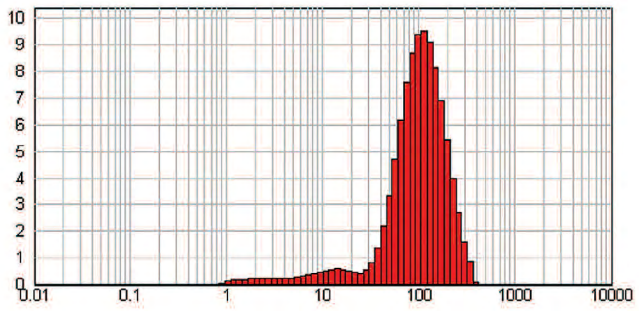
The Institute applies numerous physical and chemical analytical techniques to analyze capsule payload, release kinetics, and particle sizes. Using state-of-the-art support equipment, SwRI scientists analyze and modify particle size and morphology and establish release and stability factors in a formulation matrix.



Particle Analysis and Characterization

Particle size and morphology may be characterized by a variety of methods, including:

- **Optical particle sizer.** Determines distribution between 1 to 500 micrometers and provides number, area, or volume average of wet or dry particles
- **Submicron particle sizer.** Characterizes nanoparticles in solution
- **Optical or electron microscopy**. Determines surface characteristics, morphology, and particle size for particles of 25 nanometers or less
- **Vibratory screener**. Used to sieve kilogram quantities of particles for classification and determining particle size ranges.



The Institute's optical particle sizer is used to determine size distribution for particles manufactured in the SwRI production minor spray dryer. This spray dryer can achieve average particle sizes up to 100 micrometers.

Particle Size Reduction (Milling and Micronization)

The Institute is capable of reducing particle sizes to the nanometer size range. The apparatus includes a ball mill, a centrifugal grinding mill, and a jet mill for gram- or kilogram-scale reduction.

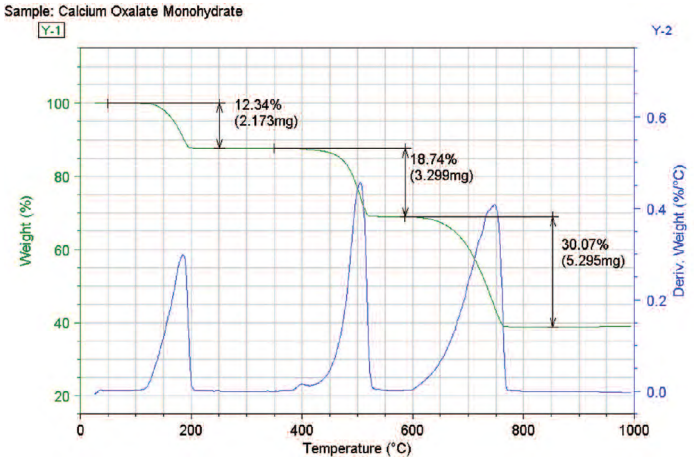
Institute specialists perform milling at low and extremely low temperatures (cryogenic) for processing heat-sensitive polymers and temperature-sensitive drugs.

Stability and Release Testing

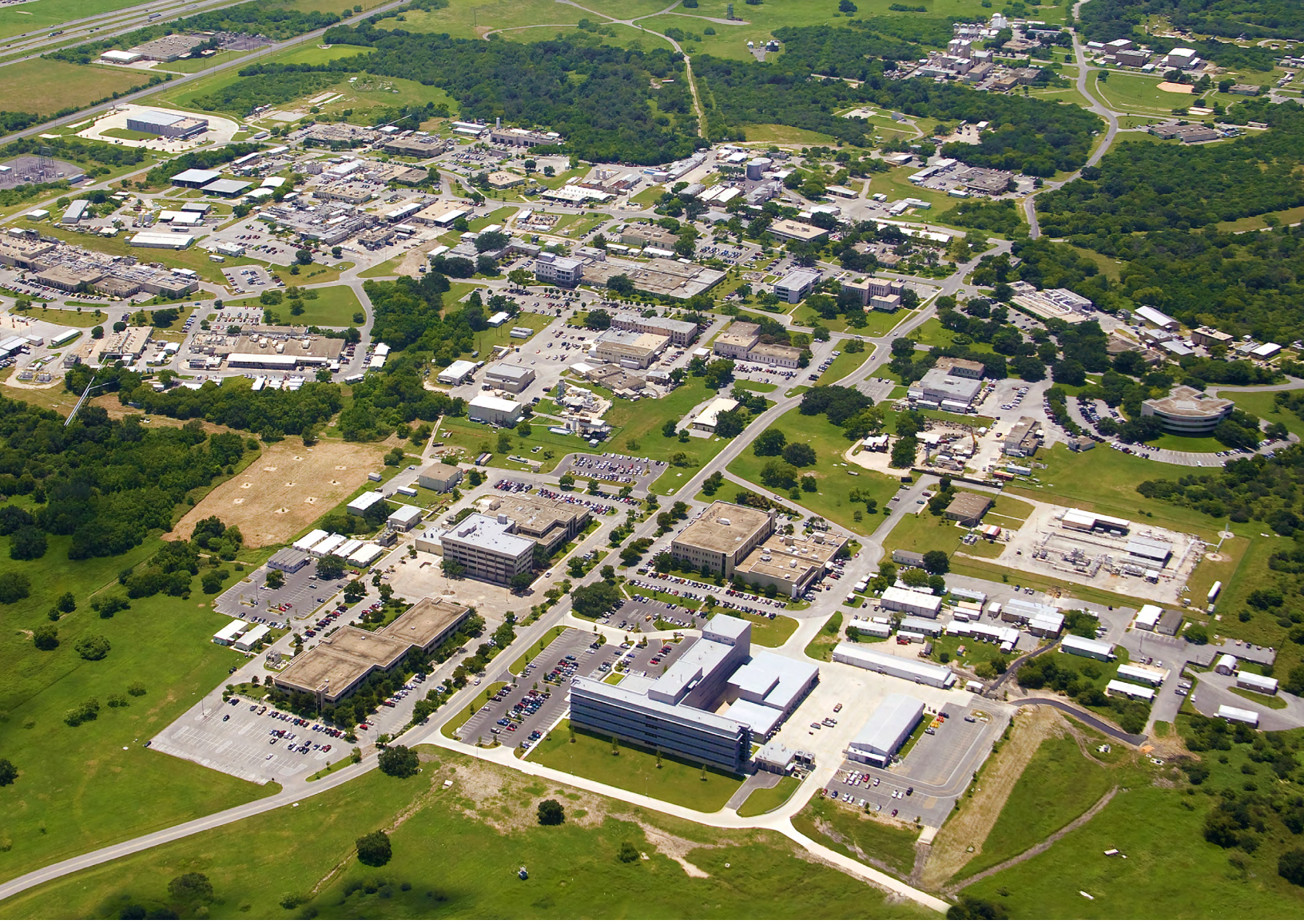
Using thermogravimetric analysis or differential scanning calorimetry, SwRI pharmaceutical specialists measure the thermal stability of drugs in polymer matrices.

Institute chemists are experienced in determining stability and rate of release of drugs from formulation matrices. They use a series of sophisticated techniques and equipment to sample and analyze performance of drug matrices. These techniques include:

- Ultraviolet spectroscopy
- Fourier transform infrared spectroscopy
- Nuclear magnetic resonance
- High-performance liquid chromatography
- Franz cell studies



Thermogravimetric analysis is used to determine the temperatures at which drugs degrade. This process evaluates destabilizing interactions of drugs and polymer matrices.



Southwest Research Institute® is a premier independent, nonprofit research and development organization. With eleven technical divisions, we offer multidisciplinary services leveraging advanced science and applied technologies. Since 1947, we have provided solutions for some of the world's most challenging scientific and engineering problems.

An Equal Employment Opportunity/Affirmative Action Employer
Race/Color/Religion/Sex/Sexual Orientation/Gender Identity/National Origin/Disabled/Veteran
Committed to Diversity in the Workplace

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

Joseph Persyn
Sr. Manager
Chemistry & Chemical Engineering
Microencapsulation
210.522.2691
joseph.persyn@swri.org

microencapsulation.swri.org

210.522.2122

ask@swri.org

Like. Share. Follow. Listen.

swri.org

NSF-ISR

Quality System Registered to ISO 9001:2000

Quality Certification — Chemistry & Chemical Engineering Division
The Chemistry and Chemical Engineering Division of Southwest Research Institute has achieved certification to ISO 9001:2000, an internationally recognized quality standard.

Designed & printed by SwRI MPS 01 0724 272415 tp