Southwest Research Institute

Southwest Research Institute (SwRI) offers comprehensive formulation and drug delivery services. Experienced SwRI scientists have produced multiple publications and received numerous patents in drug formulation and delivery technology. With more than 45 years of experience in micro- and nano-encapsulation technology, Institute scientists can quickly develop solutions to formulation and drug delivery problems such as solubility, stability, controlled delivery, delayed release, taste, and targeting.

SwRI has research, development, and scale-up capabilities and possesses experience in most particle-forming technologies. Institute staff members formulate drugs with the particle size and format the administration route may require. Examples of particle sizes that may be provided with each encapsulation method are shown below.

<table>
<thead>
<tr>
<th>Encapsulation Method</th>
<th>Size Range (µm)</th>
<th>Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single- and twin-screw extrusion</td>
<td>1,000+</td>
<td>Implant</td>
</tr>
<tr>
<td>Submerged nozzle</td>
<td>700 – 6,000</td>
<td>Microcapsule</td>
</tr>
<tr>
<td>Centrifugal extrusion</td>
<td>125 – 3,000</td>
<td>Microcapsule or microsphere</td>
</tr>
<tr>
<td>Rotating disk</td>
<td>35 – 1,000</td>
<td>Microcapsule or microsphere</td>
</tr>
<tr>
<td>Spray drying</td>
<td>5 – 150</td>
<td>Glass, microcapsule, or microsphere</td>
</tr>
<tr>
<td>Suspension coating</td>
<td>100 – 10,000</td>
<td>Microcapsule, coated implants</td>
</tr>
<tr>
<td>Interfacial polymerization</td>
<td>1 – 500</td>
<td>Microcapsule</td>
</tr>
<tr>
<td>Phase separation/coacervation</td>
<td>1 – 500</td>
<td>Microcapsule</td>
</tr>
<tr>
<td>Solvent evaporation</td>
<td>0.1 – 5,000</td>
<td>Nano- or microsphere or capsule</td>
</tr>
<tr>
<td>Nanoprecipitation (pat. pend.)</td>
<td>0.2 – 0.9</td>
<td>Drug particle or nanocapsule</td>
</tr>
</tbody>
</table>

The Institute can test particle formulations with analytical capabilities including:

- Beckman Coulter N4 Plus submicron particle analyzer for characterization of particles ranging from 5 nanometers to 2 micrometers
- Malvern process systems for measuring from 2 to 1,000 micrometers
- ZetaPlus particle electrophoresis systems for surface charge analysis
- Environmental Scanning Electron Microscope (ESEM) for analysis particle morphology
- Differential scanning calorimetry and thermal gravimetric analysis for thermal property evaluation
- X-ray diffraction and confocal Raman spectroscopy for crystalline-amorphous characterization
- AS-400 nuclear magnetic resonance (NMR) for solid-state characterization
- In-vitro ADME assays (Caco-2, MDR/MDCK) for assessing formulation effects on compound permeability and transporter (P-glycoprotein) properties.

About the cover: SwRI scientists use state-of-the-art techniques, including the environmental scanning electron microscope, to view particle and crystal morphology and aggregation.

©2007 Southwest Research Institute. All rights reserved. Southwest Research Institute, SwRI, and SwRI-NASDEL are registered marks in the U.S. Patent and Trademark Office.

An Equal Opportunity Employer M/F/D/V Committed to Diversity in the Workplace

SwRI scientists have created stable taste-masked, enteric-coated and sustained release oral formulations for Institute clients, such as this transparent nanosuspension.

Using the SwRI-NASDEL™ capsule-gel mucosal delivery technology, medical personnel can deliver cytotoxic compounds to the patient without irritating or upsetting the nasal epithelium.
Scientists utilize the SwRI-developed rotating disc process to encapsulate liquids and solids, forming microcapsules or microspheres.

SwRI has experience with a wide range of techniques for drug delivery, including the following:

**Oral** — Using a variety of methods, SwRI scientists create stable taste-masked, enteric-coated and sustained release oral formulations that conform to current Good Manufacturing Practices (cGMP) standards. Using its cGMP suites, Institute scientists can prepare the micro- or nanoparticles for filling into hard gelatin capsules or compression into tablets.

**Ocular** — SwRI-developed controlled-release micro- and nano-particles and implants allow drug delivery in the vitreous, conjunctiva, and anterior portions of the eye.

**Nasal and Mucosal** — The Institute has developed a controlled-release nasal delivery technology (SwRI-NASDEL™) that does not irritate the nasal mucosa.

**Subcutaneous (implant or depot)** — SwRI has developed controlled-release formulations in the form of depot and subcutaneous implants ranging from a fraction of a millimeter to several millimeters. Release rate and duration vary, according to client requirements.

**Topical** — SwRI has experience in developing creams, ointments, and gels for a variety of compounds, including nano-particle-containing gels for cellular delivery of interfering RNA.

**Intravenous and intramuscular (IV and IM)** — SwRI has developed traditional isotonic mixture IV and IM formulations, as well as nanosuspensions not immediately cleared by the reticular endothelial system for controlled release formulations.

The Institute has developed a variety of materials for controlled delivery of therapeutic aids, such as this implantable coated fiber (left). Release rate is modulated by the drug’s physical properties or the implant material or porosity, providing release durations of up to six months.
Southwest Research Institute is an independent, nonprofit, applied engineering and physical sciences research and development organization using multidisciplinary approaches to problem solving. The Institute’s main facility, located in San Antonio, Texas, occupies more than 1,200 acres and provides nearly two million square feet of laboratories, test facilities, workshops, and offices for more than 3,000 employees who perform contract work for industry and government clients.

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

Joseph McDonough, Ph.D., Manager
Synthesis and Drug Delivery Section
Chemistry and Chemical Engineering Division
Southwest Research Institute
6220 Culebra Road • P.O. Drawer 28510
San Antonio, Texas 78228-0510
(210) 522-3670 • Fax: (210) 522-4632
E-mail: joseph.mcdonough@swri.org
Web Site: swri.org
drugdelivery.swri.org

Benefiting government, industry, and the public through innovative science and technology.

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.