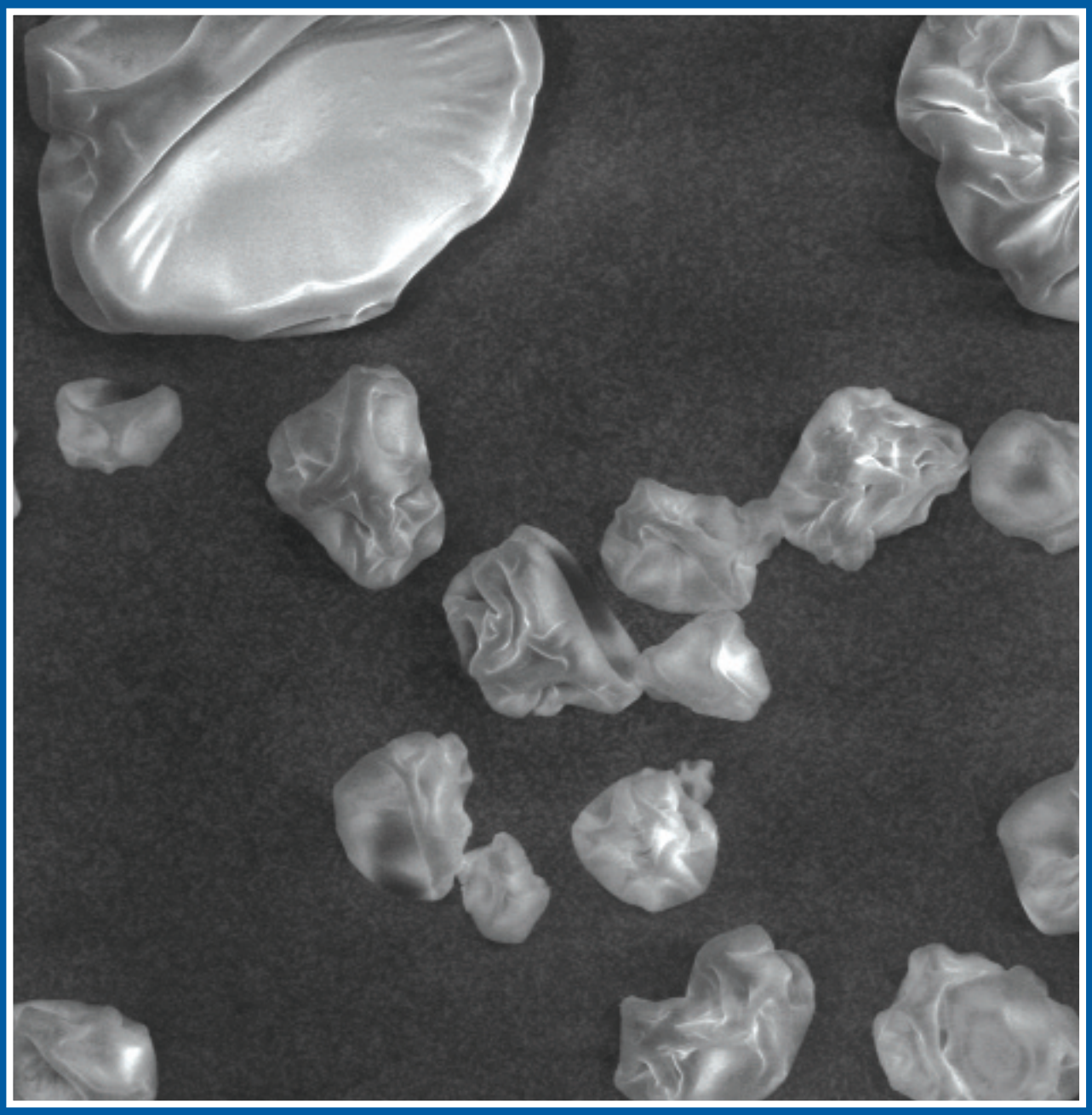
Drug Formulation
and Delivery Services



Southwest Research Institute®
San Antonio, Texas

Southwest Research Institute

Founded in 1947 as an independent, nonprofit research and development organization, Southwest Research Institute provides significant research, engineering, and testing resources for industry, business, and government. With 11 technical divisions and state-of-the-art laboratories, the Institute uses a multidisciplinary, integrated approach to solving complex problems in science and applied technology. Subject to the client's wishes, programs are kept confidential. As part of a long-held tradition, patent rights arising from sponsored research at the Institute are often assigned to the client. SwRI generally retains the rights to Institute-funded advancements.

Related Publications

S.R. Kleppner, R. Patel, J. McDonough, and L.C. Costantini, In-vitro and in-vivo characterization of a buprenorphine delivery system, *JPP*, 58, pp. 295–302, 2006.

J.T. Persyn, J.A. McDonough, J.A. Nino, H. Dixon, and E.J. Boland, Mucosal delivery of cytotoxic therapeutic agents: Response of rat nasal mucosa to microencapsulated ethopropazine HCl enantiomer, *J. Microencapsulation*, 22:7, pp. 737–744, November 2005.

L.C. Costantini, S.R. Kleppner, J. McDonough, M.R. Azar, and R. Patel, Implantable technology for long-term delivery of nalmefene for treatment of alcoholism, *Int. J. Pharm.*, 283:1, pp. 35–44, 2004.

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.*

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.

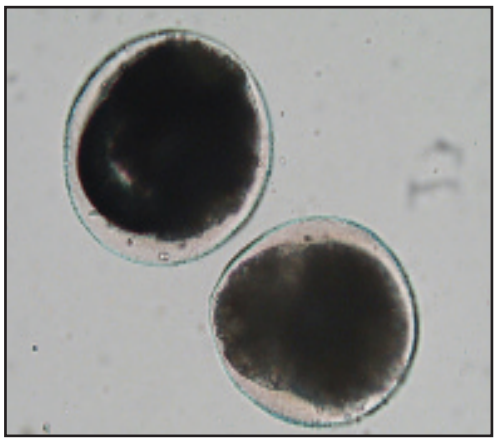
Encapsulation Method	Size Range (µm)	Format
Single- and twin-screw extrusion	1,000+	Implant
Submerged nozzle	700 – 6,000	Microcapsule
Centrifugal extrusion	125 – 3,000	Microcapsule or microsphere
Rotating disk	35 – 1,000	Microcapsule or microsphere
Spray drying	5 – 150	Glass, microcapsule, or microsphere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

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.

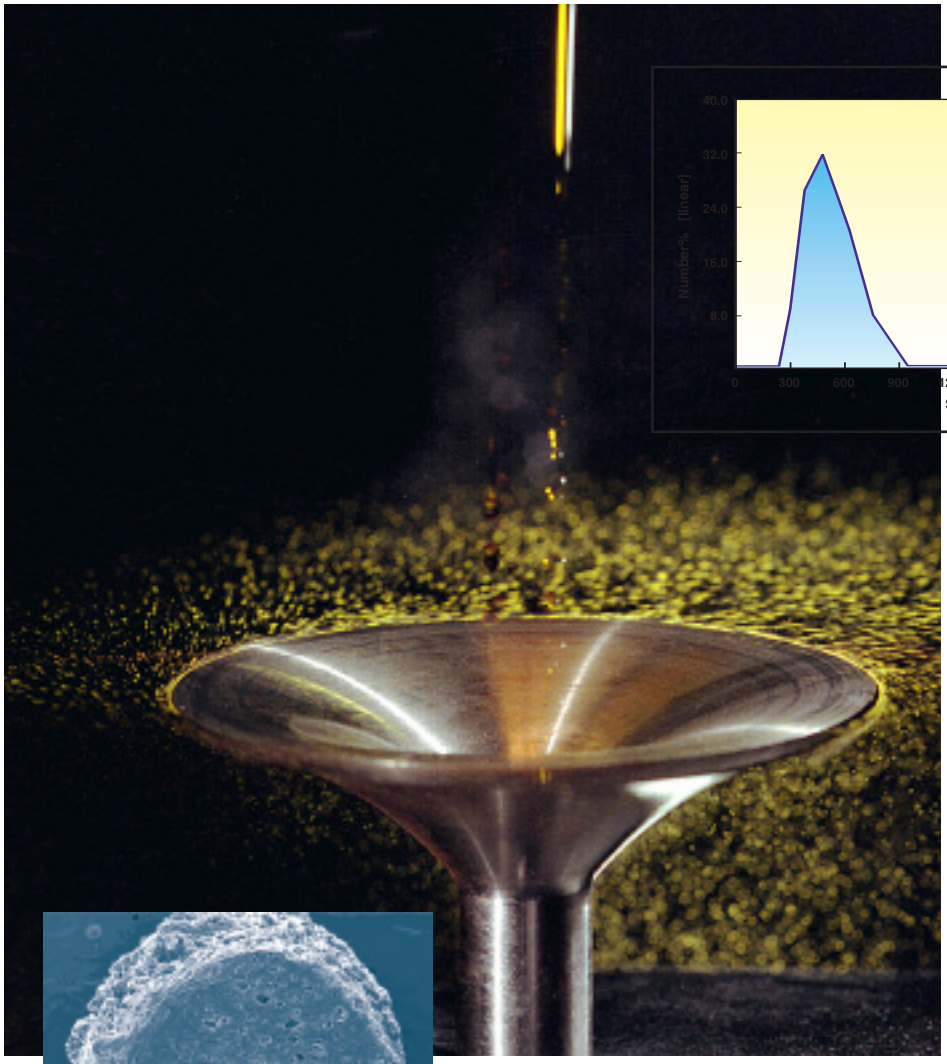
D1M015605

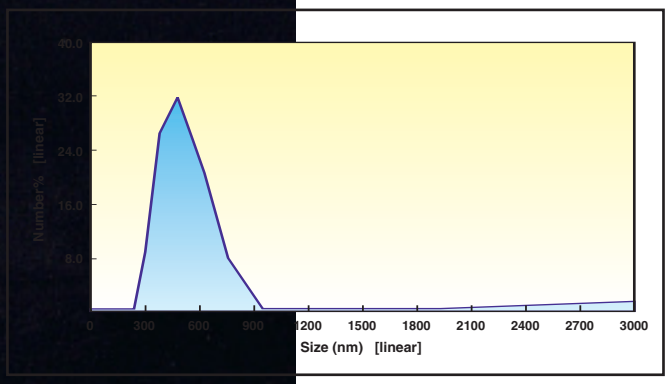
SwRI scientists have created stable taste-masked, enteric-coated and sustained release oral formulations for Institute clients, such as this transparent nanosuspension.



DO15606

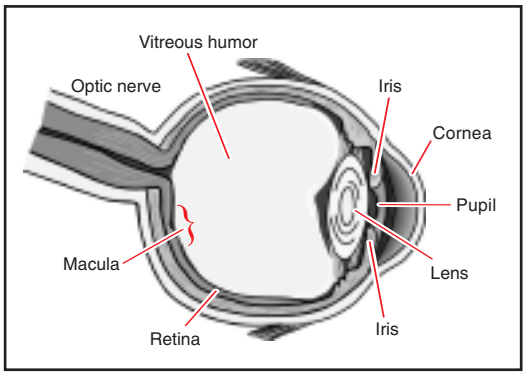
Using the SwRI-NASDEL™ capsule-gel mucosal delivery technology, medical personnel can deliver cytotoxic compounds to the patient without irritating or upsetting the nasal epithelium.





DO15607

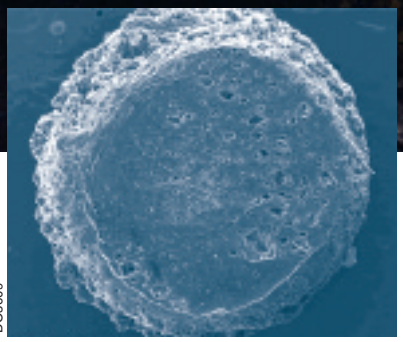
Scientists developed innovative techniques for surfactant-free nano-precipitation.



DO15608

Institute scientists develop a variety of formulations capable of delivering therapeutic drugs via ocular pathways. Transparent nanosuspensions of coated particles or pure drug can be applied to the vitreous humor without disturbing the field of vision.

DE82310



DO5609

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.

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.

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.

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

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

Darrel Johnston, Director
Drug Discovery & Development Section

Chemistry & Chemical Engineering Division
Southwest Research Institute
6220 Culebra Road
San Antonio, Texas 78238-5166
210.522.2160 • Fax: 210.522.5895
E-mail: darrel.johnston@swri.org
Web Site: swri.org

drugdelivery.swri.org

01-0662-1 JCN 272350

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.