



Formulations and Drug Delivery

Does your drug have:

- Poor solubility
- Low bioavailability
- Short half-life in vitro or in vivo
- High irritation potential to the mucosa

SRI is your solution for product development. Combinatorial libraries and high throughput screening typically produce drug candidates that are not optimized for these parameters. The SRI Department of Pharmaceutical Formulation Design has over 15 years of direct experience solving formulation and delivery problems for commercial and government clients. We have specific expertise in producing shelf-stable, commercially viable formulations utilizing GRAS excipients.

Solubility and Stability

Solubility of drug substance is a major issue for many new chemical entities (NCEs) intended for parenteral administration. Our experience has helped recent clients increase the solubility of their compounds by a hundredfold. Similarly, SRI has helped clients to develop shelf-stable solution dosage forms for compounds that have half lives as short as a few days.

Bioavailability and Pharmacokinetics

Even if drugs are soluble and stable, the commercial viability of certain potent drug candidates is greatly diminished because they are not orally available. Our InForMED approach utilizing iterative in-silico modeling, formulation design, and in vivo testing will help you to develop the desired dosage form very efficiently.



Bridging the drug development gap

Complete Delivery Solutions

PREFORMULATION

Our preformulation services include finger printing the physico-chemical properties of the compound which includes solubility and stability as a function of pH, thermal characteristics, and polymorphism.

FORMULATION DEVELOPMENT

SRI assists clients with the development of a suitable “First in Human” dosage form in the shortest possible time. The dosage forms could range from standard formulations for oral administration to alternative dosage designs. Our expertise includes development of:

- Tablets and Capsules
- Parenteral solutions and Emulsions
- Oral solutions and suspensions
- Topical gels
- Implantable and injectable controlled release formulations

cGMP Clinical Trial Materials

The SRI Pharmaceutical Formulation Development Facility, which includes a new Class 100 clean room maintained under the International Congress of Harmonization guidelines, is designed to provide pharmaceutical and biopharmaceutical companies with a single, quality resource for the manufacture of oral, topical, parenteral, and other Clinical Trial Materials (CTM) for Phase I / II studies.

These drug product manufacturing activities are supported by our Quality Control & Quality Assurance unit, which tests, inspects, and releases the products in full compliance with regulations of the FDA and international regulatory agencies.

The SRI facility also offers primary and secondary packaging services for solid, semi-solid, and liquid dosage forms, including overencapsulation. SRI also can design the labels and kits for secondary packaging.

IND and Beyond

SRI can assist in preparing the Chemistry, Manufacturing and Controls (CMC) data package needed for an investigational new drug (IND) submission by assessing, generating, and compiling the necessary information on both the drug substance and its final drug formulation or drug product.

In formulating new drugs, SRI is very conscious of the cost parameters and regulatory obstacles, and we look for simple, economical solutions to dosage design challenges. Our staff has extensive industry experience relating to all kinds of dosage forms and has worked with new chemical entities, generic products, and life cycle management.

You Make the Call

For further information, contact our Client Services Team:

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