Cirrus Pharmaceuticals, Inc. is a contract product development organization providing services to the pharmaceutical and biotech industries. Projects range from sample-based services to feasibility studies to full-scale product development.

Cirrus Pharmaceuticals, Inc. is registered with the United States Food and Drug Administration and is cGMP compliant.
Cirrus Pharmaceuticals, Inc. offers its sponsors a senior scientific staff with over three decades of combined experience in parenteral product development. Our scientists characterize and formulate water-soluble and water-insoluble drugs, making use of a wide range of formulation approaches. Project scope ranges from rapid formulation screening to full development programs.

Backed by a talented analytical group, our parenteral team can address all aspects of product development, including:

- **Preformulation**
- **Formulation Development**
- **Manufacturing Process Development**
- **Sterilization Process Development**
- **Filter Compatibility Studies**
- **Container/Closure and Delivery Component Compatibility Studies**
- **Lyophilization**
- **Drug Product Stability Testing**
- **Scale-up and Technical Transfer**

**Chemical and Physical Characterization**

A variety of tests and services are offered to characterize and select the drug candidate, such as:

- **Solubility Profile**
- **Partition Coefficient**
- **Short-term Stability**
- **Salt Form Selection**
- **Degradation Pathway Elucidation**

**Formulation Development**

Cirrus scientists have successfully formulated numerous products:

- **Water-soluble Compounds (Stable and Unstable)**
- **Water Insoluble Compounds**
- **Proteins/Peptides**

Our parenteral team has experience with essentially all types of parenteral formulations, including:

- **Solutions**
- **Micellar Dispersions**
- **Emulsions**
- **Inclusion Complexes (Cyclodextrins)**
- **Liposomes**
- **Suspensions (IM or subQ)**

Services include feasibility studies to assist in dosage form selection and compatibility studies of active ingredients with excipients, packaging, and delivery components. Formulation selection and optimization are aided by the extensive use of statistical experimental design. Short-term accelerated stability studies are typically employed to challenge the candidate formulations.

**Stability and Release Testing**

Full product release testing and long-term stability testing are available. Key stability tests include:

- **Chromatography, Including LCMS**
- **USP Particulate Testing**
- **Particle Size Analysis (for Emulsions)**
- **pH and Osmolality**
- **Visual Evaluation**

Submission-ready documents will be generated.

**Process Development, Scale-Up and Technical Transfer**

Our formulation scientists and process engineers collaborate to develop a robust and efficient manufacturing process which can be scaled up through careful evaluation of process parameters. To facilitate process transfer, Cirrus typically prepares a manufacturing monograph and master batch record. Elements of the process may include:

- **Blending/Homogenization**
- **Filtration**
- **Filling**
- **Terminal Sterilization**
- **Lyophilization**

If requested, Cirrus can work with the sponsor to select a manufacturing site for full-scale batch production, transfer the manufacturing process, and oversee batch manufacture.

**Experienced Personnel**

Cirrus' senior scientists are supported by an experienced and dedicated staff of scientists who have undergone meticulous, well-documented training. Through a dynamic, structured work environment, we combine the rigor to meet cGMP requirements with the flexibility to meet diverse sponsor needs.

**Microformulation**

In addition to Cirrus' standard parenteral formulation capabilities, we have developed methods for carrying out formulation studies with as little as 2-3 mg of drug substance. These methodologies can be used to formulate new drugs for initial animal experiments when only low milligram quantities of the drug have been synthesized and/or purified.