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 facility.
Scientists at Cirrus Pharmaceuticals, Inc. have the experience to lead the characterization, formulation and development of water-soluble or water-insoluble drugs, and bring a wide range of formulation approaches to topical and transdermal product development. Project scope ranges from rapid formulation screening to full development programs.

Backed by a talented analytical group, our topical product development team is prepared to address all aspects of product development, including:

- Physical & Chemical Characterization
- Formulation Development
- Manufacturing Process Development
- Container/Closure and Delivery Component Compatibility
- Drug Product Stability Testing
- Scale-up and Technical Transfer

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

### Chemical and Physical Characterization

A variety of preformulation tests and services are offered to understand the physical and chemical characteristics of the drug substance. These include:

- Solubility
- Partition Coefficient
- Particle Size and Morphology
- Polymorphism
- Surface Tension/Interfacial Tension
- Wettability
- Stability

### Topical and Transdermal Dosage Forms

- Gel
- Cream
- Patch
- Ointment
- Lotion
- Novel Delivery Methods

### Formulation Expertise

- Solubilizing Water-insoluble Drugs
- Excipient Selection & Compatibility
- Particle Size Reduction
- Enhancing Product Performance
- Manufacturing Process Development
- Bioavailability Enhancement
- Improving Product Stability
- Product Performance Evaluation
- Novel Delivery System Development

### Stability and Release Testing

Services for release testing and short- and long-term stability testing are available, including:

- Visual Evaluation
- pH
- Chromatographic Assay
- Particle Size Analysis
- Viscosity
- In Vitro Diffusion Testing (Synthetic Membranes or Dermatomed Skin)

Submission-ready documents will be generated.

### Process Development, Scale-up and Technical Transfer

Our formulation scientists and process engineers collaborate to develop a manufacturing process which can be optimized for robustness and efficiency, then scaled up through careful evaluation of manufacturing parameters. To facilitate the transfer process, Cirrus typically writes the manufacturing monograph and batch records. Elements of the process may include:

- Blending/Homogenization
- Filling
- Container/Closure Components

If requested, Cirrus can work with the client to select a manufacturing site for full-scale batch production, transfer the manufacturing process, and oversee batch manufacture. Cirrus can also perform release testing, if needed.

### Enhancement Approaches for Topical and Transdermal Delivery

Services for passive and active energy-assisted transdermal and topical delivery of small molecules, proteins and peptides are available. Enhancement approaches include:

- Iontophoresis
- Microneedles
- Ultrasound
- Electroporation

Iontophoresis can be utilized to deliver peptide molecules while ultrasound can be utilized for proteins. Optimization services to customize and test these skin transport technologies for a pulsatile or programmed drug delivery are available.