Our scientists have the experience to lead the characterization and development of water-soluble or water-insoluble drugs, and apply 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 and chemical characterization
- Manufacturing process development
- Drug product stability testing
- Formulation development
- Container/ Closure and delivery component compatibility
- Scale-up and technical transfer

Services include feasibility studies 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
- Improving product stability
- Enhancing product performance
- Bioavailability enhancement
- Particle size reduction
- Novel delivery system development
- Excipient selection and compatibility
- Product performance evaluation
- Manufacturing process development

STABILITY AND RELEASE TESTING

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

- pH
- Visual evaluation
- Chromatographic assay
- In vitro release testing (synthetic membranes or dermatomed skin)
- Particle size analysis
- Viscosity

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, we typically write the manufacturing monograph and batch records. Elements of the process may include:

- Blending/ Homogenization
- Filling
- Container/ Closure components

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

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

Development and optimization services to customize and test these skin transport technologies for a pulsatile or programmed drug delivery are available.

ABOUT CIRRUS, A KEMWELL COMPANY

Cirrus is a contract product development organization based in RTP, NC, USA, and was acquired by Kemwell in 2013. Kemwell is a 100% CDMO, servicing pharmaceutical and biopharmaceutical organizations worldwide for over 30 years. Cirrus and Kemwell provide full product development and manufacturing as well as task-based services to customers across the globe. Our scientists offer proven expertise in all dosage form development, including inhaled, nasal, oral, parenteral, and topical.

To get customized solutions for your project, get in touch with us today.

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