

FACILITY FACTS

- 67.6 acres with 38 buildings, offering approximately 1 million sq. feet of manufacturing and packaging space
- Manufacturing space: 565,900 sq. feet
- Packaging space: 65,000 sq. feet
- Warehouse space: 129,400 sq. feet
- Lab space: 63,600 sq. feet
- Gated complex; fenced perimeter, proximity badge readers and security cameras throughout
- All buildings are continuously reviewed and are compliant with worldwide cGMPs

PRODUCT CAPABILITIES

- Aqueous and solvent-based bulk granulations
- Sustained-release spheroids; coated and uncoated spheroids
- Compressed tablets; film and sugar-coated tablets
- Hard gelatin capsules
- Oral and nasal liquids
- Bulk lyophilization
- Creams, gels and ointments
- Solvent processing capability via a thermal oxidizer
- Packaging of bottles, blister packs and tubes
- Extensive experience in technology transfer, technology development and manufacturing site transfers
- Lab scale/bench scale development center for solid oral dosage forms

DEVELOPMENT SERVICES

Pre-formulation and Formulation Development

Our customized development programs integrate process development and scale-up, thereby removing costly reformulation in later stages. Akrimax can carry your molecule through development to the market with our complete range of formulation and analytical development capabilities.

- Characterization of physical properties
- Chemical reactivity and forced degradation studies
- Excipient compatibility studies
- Formulation development for early safety studies
- Prototype formulations for clinical trials
- Preliminary process identification
- Commercial formulation development
- Process development optimization

Analytical Development

We provide analytical development services focused on speeding up the product development cycle. Our experts develop and authenticate lab methodologies for your new pharmaceutical product, monitor its ongoing stability, and support the formulation and clinical manufacturing process all the way through commercialization.

Analytical development services include:

- Method development and validation
- Cleaning residuals development and validation
- Dissolution and drug release profiling
- Forced degradation studies
- Specifications development
- Stability monitoring to ICH guidelines

Akrimax Clinical Express

Our experienced team of development scientists will formulate and produce the necessary quantities of clinical trial materials for every stage of your molecule's clinical development plan.

The Akrimax Clinical Express (ACE) program accelerates your molecule to first time in human studies utilizing the least amount of active pharmaceutical ingredients.

ACE includes:

- Phase I, II, III and registration clinical supplies
- Complete ACE formulation, manufacturing, packaging and discharge testing
- Investigative new drug application support documentation
- Stability support for all clinical materials

Clinical Packaging Services

Our clinical packaging services allow us to take your project directly to clinical studies. Akrimax's Clinical Packaging services include:

- Clinical packaging for solid, liquid, cream and ointment dosage forms
- Primary and secondary packaging formats
- Comparator product procurement
- Clinical trial manufacturing storage capabilities including ambient and refrigerated temperatures
- Drug destruction services

All of our packaging services are conducted by our experienced professionals at our cGMP-compliant facility. Akrimax has packaging capabilities available for solid, liquid, cream and ointment forms. Akrimax can store products on site at controlled temperature conditions, including refrigerated and ambient. Akrimax can destroy your excess and expired materials and provide you with a certificate of destruction.

Direct Scalability to Commercialization

Akrimax's Development Services (ADS) scientists maintain a close working relationship with our manufacturing groups throughout the development process, allowing them to ensure their formulations are fully scalable. Akrimax provides the following product registration support services:

- Manufacturing, packaging and release testing of registration batches
- Stability study design and monitoring
- Validation master plan, protocols and reports
- Regulatory guidance from development through to commercialization
- Documentation provided in submission-ready format
 - > IND/CTX
 - > CMC section of NDA/PL
 - > Customized reports

SPECIALIZED SERVICES

Controlled-Release Formulations

Akrimax recognizes the need for sophisticated controlled-release formulation options for a range of product and molecule types.

And with considerable experience in controlled release formulation development, our formulation scientists utilize strategies such as:

- Matrix systems
 - > Hydrogels
 - > Polymeric matrix
 - > Wax matrix

Controlled-Release Formulations, cont.

- Multi-particulate systems
 - > Granulates
 - > Pellets
 - > Beads
- Polymeric film coating
- Ion-exchange resins
- pH-dependant release methods such as enteric coating

Akrimax's fully equipped formulation laboratories use scalable equipment that saves customers time and money during the scale-up process. Akrimax Development Services (ADS) are incorporated into our world-class manufacturing facility, allowing us to take your controlled-release product from pre-formulation all the way to a commercialized product. Our site has equipment to accommodate processes for controlled-release manufacturing that include:

- Top spray/Wurster spray coating
- Granulations
- Extrusion/spheronization
- Hot-melt granulation

High-Potency

Akrimax offers many development services for high-potency compounds in solid, semi-solid, and liquid dosage forms, including fast-dissolve and controlled-release tablets.

ADS scientists are skilled in formulation development, Akrimax Clinical Express (ACE) manufacturing, and scaling up of high-potency products, and they are supported with a broad range of analytical services.

Project Development

Our dedicated technical project managers will guide your project through each process and ensure it meets your timeline. Your technical project manager will plan your project with you and follow its progression through our system, informing you regularly and consistently along the way.

Akrimax's project managers:

- Cooperate with clients on project implementation
- Pursue cost and time-saving strategies
- Monitor and communicate project status with clients
- Respond to client questions
- Manage project change planning

Conventional Dosage Forms

ADS offer product development services for an array of solid dosage forms including tablets, capsules and powders. Akrimax's capabilities also cover a number of liquid and semi-solid formulations: suspensions, solutions, drops, ointments and creams.

Akrimax can provide packaging in a variety of formats, and by tying in our manufacturing capabilities, we can offer customized primary packaging solutions for production from clinical trials to commercial manufacturing.

DOSAGE FORM

Solid

- Capsules
- Tablets
- Powders
- Granules

Liquid & Semi-Solid

- Solutions
- Suspensions
- Sprays
- Drops
- Creams
- Ointments

PROCESS

Solid

- Blending
- Coating
- Compression
- Encapsulation
- Extrusion/Spheronization
- Fluid bed drying
- High-shear granulation
- Tablet printing
- Roller compaction

Liquid & Semi-solid

- Homogenizing
- Alcohol processing
- Milling

Packaging

- Blister packaging (aluminum coldform & thermoform)
- Liquid bottle (glass & plastic)
- Solid bottle filling
- Can/jar filling
- Tube filling (plastic and laminate)
- Metered-dose pumps

MANUFACTURING AND PACKAGING EQUIPMENT

This is a partial list and does not include all manufacturing capabilities:

- Granulation/Drying: Lodige/Processalls, Diosna and Glatt Fluid Bed Dryers
- Milling: Fitzmills (Hammer and Auger)
- Mixers/Blenders: PK Blenders
- Tablet Compression: Manesty MK IV, Stokes and Kikusui tablet presses
- Coating: Sugar coating pans, Accela-cota coating pans and Glatt-Wurster coaters (solvent capable)
- Branding: Ackley&Hartnett branders
- Capsules: H&K encapsulators, spheronizers and extruders
- Packaging: Fully automated high-speed blister lines and bottling lines