alcami®

Critical Considerations For Formulation Success In Drug Product

ProForm Select™
Take No Chances.

Our ProForm Select™ integrated offering for solid-state chemistry and formulation development ensures that you avoid missing important clinical milestones and process instability. From development to clinical and commercial supply, our integrated service offers the unique ability to address both the API process and formulation in parallel. A single project manager will help ensure seamless technical and quality alignment, as well as continual focus on proactive solutions to develop solid-state chemistry and formulation development together. The result is faster time through the clinic, improved process stability, elimination of transfer implications, and mitigated risk.

Key Benefits of ProForm Select™ Program

Integration
A single solution provider for API and Drug Product development, with seamless quality and technical alignment.

Attention
Cross-functional project management, providing one point of contact for you and supporting technical alignment and cross-functional coordination.

Speed
RFP to program commencement in less than a month. A single contract and project team for the entire program contributes to timeline compression by eliminating handoff time, and parallel activities create further efficiencies.

Ease of Use
ProForm Select™ aligns our solid-state and formulation development groups to design an efficient, robust, and competitive approach to take your API to its finished dosage form. An early selection profile is established to mitigate risk in form variation and development, resulting in a scalable, targeted to dosage form.

API Solutions
- Appropriate salt selection
  - Crystal consistency
  - Polymorph selectivity
  - Reproducible API
- Robust process chemistry
  - Clinical: Specify and define critical quality attributes
  - Commercial: Specify and measure critical quality attributes
- Commercial consistency with raw material and manufacturing equipment changes
- Second Supplier Qualification

Drug Product Solutions
- Dissolution profile
- Bioavailability
- Stability and impurity profile consistency
- Consistent solubility
- Robust formulation process
- Robust manufacturing process
  - Clinical: Specify and define critical quality attributes
  - Commercial: Specify and measure critical quality attributes
- Commercial consistency with raw material and manufacturing equipment changes
- Second Supplier Qualification

ProForm Select™ Program Phases

Concept Through Clinic Solutions

28–30 weeks, more than 50% faster than industry standard

From concept to clinic, our scientists help our customers develop a scalable synthesis route and molecular characterization including solid-state chemistry. We perform an in-depth assessment of the target product profile for the drug molecule and potential drug product, and a GAP analysis of client needs to support your regulatory filing.

Program Offerings

API	Solid State Development on API "Drugability of API"	Drug Product
Process Development, Including Solid State Development on Intermediates	Initial API Characterization	Development of Prototype Dosage Form
API Analytical Development and Reference Standard Production and Qualification	Risk Assessment of Molecule and Program	Drug Product Analytical Development
	Solubility, Salt and Polymorph Screening and Characterization	

ProForm Select™ Program Phases

Commercial Level Control

Successful commercial supply depends not only on establishing a scalable synthesis route but also molecular characterization, including a solid state dosage form. Our fully integrated teams and a single point of project management will help reduce timelines and costs associated with handoff and transition times. De-risk your molecule through development of the most stable form and appropriate crystallization solution to gain right first time solutions with ProForm Select™.

34-36 weeks, more than 53% faster than industry standard

Program Offerings

API	Solid State Development on API	Drug Product
Supply Chain Support	API Characterization	Technical & Risk Assessment
Process Development, Including Solid State Development on Intermediates	Solubility, Salt and Polymorph Screening and Characterization	
Analytical Full Validation Packages	Crystal Engineering DOE Parametric Control Study	Supporting DOE studies
	Demonstration and Characterization	

ProForm Select™ Program Phases

Commercial & Secondary Supply Success

Our commercial level and secondary supply service provides a SUPAC Guidance-compliant drug substance/drug product package. We apply QbD and continuous improvement principles to provide a reduced risk molecule with higher yields, lower costs, and a reliable uninterrupted process. The result is an optimized and validated large-scale process.

20-22 weeks, more than 80% faster than industry standard

Program Offerings

API	Solid State Development on API	Final Drug Product
Supply Chain Support		Supply Chain Support
Process Development, Including Transfer Package and dFMEA Control Strategy Assessment	API Characterization	Technical & Risk Assessment
Analytical Full Transfer Packages		Analytical Full Transfer Packages

Connected At Every Level

AAIPharma Services Corporation and Cambridge Major Laboratories, Inc. have joined to form Alcami, a world-class supplier of comprehensive pharmaceutical development and manufacturing services headquartered in Wilmington, NC. With nearly 1,000 employees operating at seven sites in the United States and Europe, our combined capabilities include API development and manufacturing, solid state chemistry, formulation development, analytical development and testing services, clinical and commercial finished dosage form manufacturing (oral solid dose and parenteral), packaging, and stability services.

Company Snapshot

- Combined staff of nearly 1000
- 740,000 square feet across U.S. and European facilities
- State-of-the-art technology and infrastructure
- FDA and EU compliant operations
- DEA-licensed for controlled drug products

ProForm Select™ Target Molecules

An ideal candidate for this program is a small molecule with an Occupational Exposure Limit (OEL) as low as to 1mg/m^3. ProForm Select™ is best used for solid oral dosage forms, crystalline and amorphous drug product forms. There are no limitations on dosage forms for our project teams. Whether you need capsules, minitabs, or any other release form, ProForm Select™ can provide it.

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