



DEVELOPMENTAL SERVICES

Alpha Research Inc. offers a full range of services to meet the varying needs of its partners during the development of their API's, including:

Process Synthetic Development:

- Synthetic route development
- Process optimization and development
- Process Validation

Custom Synthesis:

- Non-GMP and cGMP
- mg to 100 kg scale
- Compounds to support lead optimization efforts
- Final API's, intermediates
- Reference compounds, related compounds, impurities, metabolites

Stability Testing:

- Stability chambers to ICH requirements. Photostability equipped.
- Forced Degradation (Stress) Testing
- Development of stability indicating analytical methods

Analytical Development:

- Pharmaceutical specification development
- Method development
- Method validation
- Method Transfer

Technology Transfer:

- Demonstration of synthesis at the kilogram scale
- Preparation of fully transferable technology package
- Technology transfer services to sites throughout the world

CMC Documentation:

- Preparation of supporting data
- Preparation of DMF and CMC documentation
- Regulatory support in advance of and during submissions
- Regulatory Submissions

Alpha Research Inc.

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