PHARMACEUTICAL AND BIOTHERAPEUTIC DEVELOPMENT AND TESTING.

FORMULATION AND METHOD DEVELOPMENT.

At Alcami, our formulation and method development teams are ready to solve your most difficult formulation challenges for new chemical entities (NCEs) and design high performance dosage forms. We offer early phase accelerated programs for new drug development for both human and animal health applications.

Our chemistry manufacturing and control (CMC) scientists support drug candidates of all biopharmaceutical classification system (BCS) schemes from BCS Class I through Class IV.

ANALYTICAL DEVELOPMENT AND VALIDATION CAPABILITIES.

- Drug substance and drug product methods
- Assays, related substances, chiral purity, elemental impurity, and residual solvent analysis
- Dissolution testing with UV and HPLC backend
- Phospholipid and fatty acid analysis
- Physical and structural chemistry
- Remedial method validation / method lifecycle evaluation studies
- Drug substance and reference standard material characterization and qualification
- Drug product comparator studies
- Abuse-deterrent and food compatibility studies
- Extractables and leachables studies
- Heavy metals, trace metal impurities, and elemental impurity testing

FORMULATION DEVELOPMENT CAPABILITIES.

- Drug substance preformulation studies
  - API and excipients
- Support from preclinical to commercial
  - Branded and generic drug products
- Pharmaceutical process development and optimization
- Pouching
- Trial kit assembly

MICROBIOLOGY.

Alcami is committed to the safety, efficacy, and timely completion of your project. We combine microbiological expertise developed from serving the biotech, pharmaceutical, and medical device industries to provide the most current and effective methodologies for developing your products. Alcami offers a full range of compendial compliance microbiological testing per the USP, EP, JP, and BP.

SOLUTIONS FOR YOUR TOUGHEST CHALLENGES.

- Microbial identification by MicroSEQ®
  - Genetic sequencing
- Suitability of compendial microbiological methods
  - USP, EP, JP, and BP microbiology testing
  - Full monograph testing
- Sterility testing using isolator
- Harmonized microbial enumeration testing and tests for specified microorganisms
- Turbidimetric and cylinder plate assays
- Particulate matter testing by light obscuration and microscopy
- Endotoxin testing by gel clot, photometric quantitative techniques (Turbidimetric and chromogenic methods) on standard plate readers and Multi Cartridge Systems (MCS)
- Strain typing by DiversiLab® rep-PCR system
- Total viable spore count, purity, and post-exposure testing of biological indicators
- Admixture studies

ENVIRONMENTAL MONITORING.

- Environmental Monitoring Performance qualification for clean rooms in manufacturing and laboratory areas
- Utility Systems Performance Qualification (WFI, Clean Steam and Compressed gases)
- Environmental Monitoring and Utility Sytems routine sampling support
- Disinfectant Efficacy / Qualification studies
  - Direct inoculation and surface methods

DRUG PRODUCT SUPPORT.

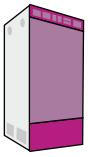
- Microbial retention filter validation
- Cleaning validation using validated analytical methods
- Container closure integrity testing
- Microbial cleaning validation recovery studies

ANTIBIOTIC ANALYSIS.

- Antimicrobial preservative effectiveness testing
- Antibiotic potency and residual antibiotics

STABILITY.

Alcami has a world-class stability program to further its integrated service offerings. Stability capabilities support drug product development and manufacturing for clinical trial supply and commercial programs.



ANALYTICAL TESTING.

Your analytical testing needs can be achieved through our comprehensive testing services for new drug entities, generic drugs, animal health products, over the counter medications, chemicals, and biopharmaceuticals. Alcami has a network of cGMP centers in Missouri and North Carolina to deliver responsive, quality service.

To further Alcami's end-to-end service offering, its analytical capabilities support drug product development and manufacturing for clinical trial supply and commercial programs. Areas of expertise include analytical development and validation for small molecule, biotech and large molecule analytical development and validation, physical chemistry and material characterization, stability storage and analysis, and compendial raw materials testing.

CAPABILITIES.

- Analytical development and validation for small molecule
- Biotech and large molecule analytical development and validation
- Physical chemistry and material characterization
- Stability storage and analysis
- Compendial raw materials testing

BIOPHARMACEUTICAL DEVELOPMENT AND TESTING.

- Binding / Potency
  - Enzyme Activity
    - ELISA
    - Cell-Based Assay
    - Endotoxin (LAL)
  - Residual Host Cell Protein
    - Sterility
    - Protein Content
    - Western Blot
    - Bradford Assay
- Identification
  - Western Blot
    - SDS-PAGE
    - Sequencing by LC / MS
    - Unknown Peak ID
    - Accurate Mass
  - iCE™ Capillary IEF
    - Mass Spectrometry
- Structural Characterization
  - Peptide Map
    - AAA
    - Oligosaccharide Analysis
    - Glycosylation Profile
    - Extinction Coefficient
  - CE-LIF ProteomeLab™ PA800
    - Q-TOF LC-MS (ESI, MALDI)
    - PE SCIEX™ API 4000 / 5000
    - Agilent™-GC MS
- Purity
  - UV-VIS
    - Process Impurities
    - Product Impurities
    - Micro-Flow Imaging
  - RP-HPLC
    - IEX-HPLC
    - SEC-HPLC
    - Gel Permeability

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