STABILITY STUDIES AND SERVICES

- **Stability storage**
- **Stability protocol preparation**
- **Stability testing**
- **Stability summary report generation**
- **Stability indicating method development and validation**
- **Release testing**
- **Assay, impurity, dissolution, water content, and other testing of various formulations**
- **Range of Storage Conditions including ICH conditions**
  - 25°C/60% RH
  - 30°C/60% RH
  - 30°C/65% RH
  - 30°C/75% RH
  - 40°C/75% RH
  - 25°C/40% RH
  - 5°C
  - Customized Storage Conditions

COMPETITIVE ADVANTAGE

Innovative and out-of-the-box thinking to solve complex problems.

Fast decision making with quick solutions.

Competitive drug development costs

Excellent network of industrial experts and advisors.

Direct, day-to-day interaction for technical management, ensuring transparency.

BIOLINK LIFESCIENCES

250 Quade Drive Cary, NC 27513

www.biolinkonline.com

919-678-9478

BIOLINK LifeSciences

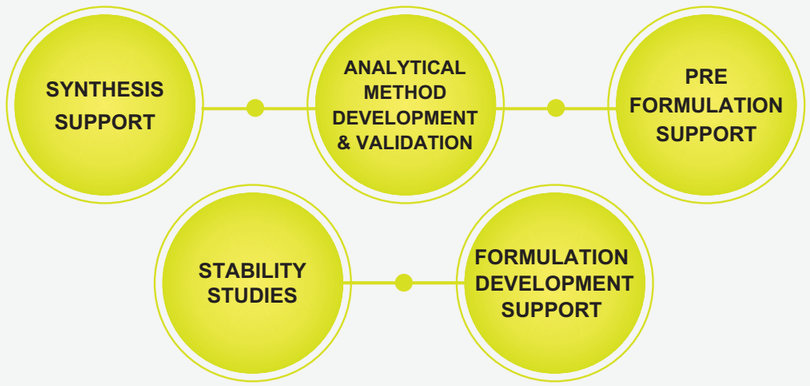
CONTRACT RESEARCH ORGANIZATION

Biolink LifeSciences is a premier contract research organization offering a comprehensive range of services including synthesis, characterization, formulation development and analytical services for small to large molecules for nearly all dosage forms. Our strength resides with our highly experienced team in synthetic chemistry, analytical method development & validation and formulation development to solve difficult problems.

MISSION STATEMENT

Established in 2001, Biolink LifeSciences offers a full range of services including custom synthesis, process development, analytical method development & validation, stability studies, GMP release of API and drug products, reference standard synthesis & characterization, and pre-formulation and formulation development services. State-of-the-art instruments, cutting edge technologies, and experienced scientific staff ensure high quality and efficient services to support the development needs for all dosage forms. We strive to provide our clients with the data and knowledge necessary to meet project requirements during the development process.

SERVICES & CAPABILITIES



PRE-FORMULATION DEVELOPMENT

- **Physical Characterization**
  - Polymorph screening, hygroscopicity testing, particle size, shape, and surface area, and flow properties testing
- **Solubility Analysis**
  - Solubilization studies, partition coefficient studies, dissolution studies, pH solubility profile, and pKa determination
- **Stability Analysis**
  - Solid-state stability, solution-phase stability, excipient compatibility studies

FORMULATION DEVELOPMENT

- **Immediate release solid dosage prototype development**
  - Tablets, capsules, powders and multi-particulate
- **Technical services**
  - Formulation & manufacturing processes consulting
  - Scale-up / Technical transfer assistance
  - Formulation optimization
- **Modified release prototype development**
  - Tablets and/or multi-particulates beads
- **Liquid and Semi-solids prototype development**
  - Solutions, suspensions and semi-solids

ANALYTICAL SUPPORT

- Analytical Method Development and Validation (i.e. assay/ related substances & dissolution)
- Clinical Trial Support (i.e. method development & batch release)
- Stability Studies
- Pharmacopoeia Testing of raw materials & finish products (USP/NF, EP, BP, JP, & Client Methods)
- Cleaning validation and Verification

SYNTHESIS SUPPORT

- Custom synthesis of new molecules (mg to kg scale)
- Route design for proprietary molecules
- Structural identification of metabolites & degradants
- Synthesis of analogues, metabolites and/or degradants
- Synthesis of stable isotope-labeled compounds as reference standards
- Process development and scale-up
- Technology transfer