Medicilon

美迪西生物医药

Integrated Preclinical Drug Discovery Services

SHANGHAI MEDICILON INC.

Company Profile

Shanghai Medicilon Inc. is one of the top contract research organizations (CRO) in China. Since its establishment in 2004, Medicilon has been striving to offer fully integrated pharmaceutical services for the global scientific community. Our services span across chemistry, biology, formulation and precilinical studies. Therefore, we have the capability to help our clients to develop their researches and discovery programs from the stage of initial ideas to the Investigational New Drug (IND) filing phase.

Our headquarters is located in Zhangjiang High-Tech Park in Shanghai, China, with an additional facility in Chuansha Economic Park, Shanghai, China. We occupy over 300,000 sq. ft. in lab space and have over 800 employees cross biology, chemistry and preclinical research. Over 30% of our employees have M.S. and Ph. D. degrees.

Medicilon is one of the first CRO in China to provide integrated services, including compound synthesis, biological activity screening, structural biology, pharmacodynamics, pharmacokinetics, toxicology, and IND filing. Our high quality services are well-recognized internationally.

Medicilon is fully accredited by the International Laboratory Animal Assessment and Accreditation (AAALAC) and in compliance with the US Food and Drug Administration's (US FDA) Good Laboratory Practice (GLP). The standard of laboratories is certified by the China Food and Drug Administration (CFDA) for GLP compliance. Therefore, experimental reports generated at Medicilon can be used for China and USA dual filing to facilitate the evaluation of the safety and marketing of life-changing compounds for our clients.

SHANGHAI MEDICILON INC.

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Innovation Platform

- The GLP for Safety Evaluation Platform
- The Protein and Antibody Pharmacokinetic Platform
- The Animal Disease Models Platform
- The Isotopic Platform
- The Protein Crystallography Platform
- The New Drug Formulations and The Generic Drug Platform

Why Choose Medicilon?

- A CRO to Provide Full Set of Preclinical Research Which Comply with Both China and US GLP Standards
- A CRO to Provide Structural Biology and Chemical Biology Services
- A CRO to Provide "Foreign Pharmaceutical Company - CRO - Domestic Pharmaceutical Company" Three Parties Collaboration
- One of the Largest Preclinical Drug Safety Evaluation CRO in Shanghai

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CAPABILITIES

Integrated and Comprehensive Drug Research and Development Service Platform

Target Validation → Hit-to-Lead Screening → Lead Optimization → Druggability Test → IND Enabling Study

Chemistry Services

Medicinal Chemistry: Drug Design, Structure-Activity Relationship Campaign, Lead Optimization and Druggability Test
Synthetic Chemistry: Intermediates, Reference Compounds, Metabolites, Impurities, and Other Small Molecule Chemicals
Process Development: Development and Optimization of Synthetic Process, Quality Analysis

Biology Services

Recombinant Protein Expression and Purification, Crystallization and Structure Determination, Discovery Biology, SeMET Growth Media Kits and Packages, Computational Biology and Molecular Modeling, Isotope Experiments and Biomarker Testing

Formulation:

Solid Formulation: Tablets, Capsules, Granules, Injectable Powder
Semi-Solid Formulation: Ointments, Creams, Gels
Liquid Formulation: Injections, Oral Liquid Preparations, Sprays, Tinctures
Innovative Dosage Forms: Slow Release Formulations, Nano Preparations, Pellets, Fat Emulsions

Pharmaceutical Analysis

API Analysis, Formulation Analysis, Analytical Method Development and Validation, Impurity Studies, Regular Chemical Analysis

Preclinical Services

Pharmacokinetics: In Vivo Assays, In Vitro Assays, BE Research, A Full Set of Studies for IND (CFDA & US FDA)
Drug Safety Evaluation: Single Dose Toxicity Test, Repeated Dose Toxicity Test, Safe Pharmacology Study, Immunogenicity Test, Toxicokinetics, Reproductive Toxicology Study, Genotoxicity Study
Pharmacology: Oncology, Digestive Diseases, Endocrine and Metabolic Diseases, Inflammation and Immune Diseases, Nervous System Disease Models
Bioanalysis: Small Molecule Drugs, Biologics (Proteins & Antibody)

FORMULATION

Our CMC department focuses on establishing large-scale synthetic routes along with formulation development and quality control for both proprietary and generic drugs. We provide solid, semi-solid, liquid, and sterilization preparations for a broad range of formulation, including slow release formulation, micro particles, protein and peptide pharmaceutical formulations. All studies are complied with ICH and CFDA guidelines. Our CMC experts have decades of experience in helping clients to complete their pre-formulation and formulation studies. We have already successfully assisted many clients with their submission new drug application to FDA, CFDA, and EMEA.

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Formulation Development

- Solid Formulations: Tablets, Capsules, Granules, Injectable Powder
- Semi-Solid Formulations: Ointments, Creams, Gels
- Liquid Formulations: Injections, Oral Liquid Preparations, Sprays, Tinctures
- Innovative Dosage Forms: Slow Release Formulations, Nano Preparations, Pellets, Fat Emulsions

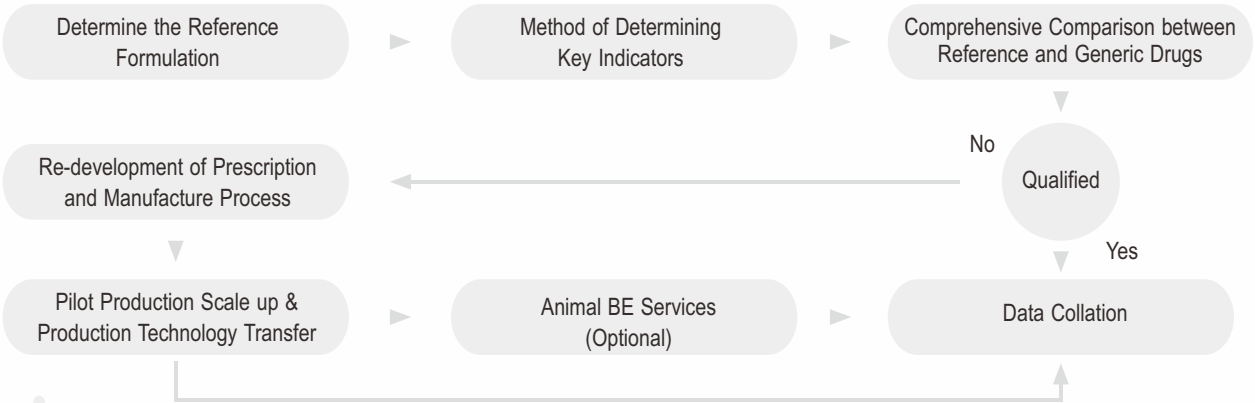
Formulation Quality Development

Our facilities are fully complied with the GMP guidelines to ensure product quality stable and reliable.

Generic Drug Evaluation of Consistency Quality

- Comparison of the Quality of Reference Formulation and Generic Drugs
- Re-development of Prescription and Manufacture Process
- Animal BE Service

Medicilon Provide Generic Drug Quality Consistency Workflow



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