Strengths and Features

The process department currently has a total area of about 6000 m^2, including 2000 m^2 of R&D lab, 800 m^2 of non-GMP pilot scale up workshop, 1000 m^2 of GMP API workshop and 1000 m^2 of analysis and testing center, 800 m^2 of GMP compliant QC lab, and 200 m^2 of microbiology lab. A strong R&D team supports API process development services covering areas such as synthesis, analysis, microbiology, project management and QA and QC. The team has rich experience in innovative drugs, consistency evaluation, successful R&D of improved new drugs, in China-US dual filing and in project management. From pre-clinical trial synthesis, process development to commercial production stage and the whole supply chain system of R&D, procurement and production of enterprises, we provide innovative process development and large-scale production services for enterprises. With the establishment of GMP-compliant API workshops and the upgrading level of pharmaceutical production and quality management systems, we are able to provide customized services for GMP production, helping more R&D-oriented companies to carry out practical technology transformation, shorten time-to-market and promote commercialization.

One-stop Process R&D Service

Medicilon's Process Department aims to meet customers' needs for a one-stop service for API development, and to utilize our extensive medicinal chemistry experience to efficiently drive our customers' drug development projects, to facilitate the development of new drug to enter earlier into the clinical phase, and to effectively help our customers to control the cost of new drug development.

From CRO to CDMO

With years of experience and the construction of laboratories, Medicilon Process Department can not only perform R&D, testing and stability studies of generic drugs for customers, but also R&D, production, testing and stability studies of innovative drugs in clinical phase I and phase II, gradually developing from process R&D to industrial commercial production and transforming from CRO to CDMO

Rich Configuration of Equipment

The experimental equipment are well equipped and our technology is advanced, and the main equipment include different types of glass reactors, rotary evaporators, stainless steel reactor, vacuum drying oven, blast oven, temperature control unit, precision filter, two-in-one filter, centrifuge, airflow pulverizer, turbo pulverizer, etc. The main analytical instruments include UPLC, HPLC, GC, IC, LC-MS, GC-MS and other chromatographic analyzers, as well as laser particle size sizer (PSD), constant temperature and humidity test chamber, differential scanning calorimeter (DSC), thermogravimetric analyzer (TGA), X-ray powder diffraction (XRPD), nuclear magnetic resonance (NMR), Fourier transform infrared spectroscopy (FT-IR) UV spectrophotometer, cyclometer, muffle furnace, melting point meter, moisture meter (KF) conductivity meter, TOC and ICP-MS, etc.

Through continuous investment in laboratory instrumentation and the establishment of GMP workshops, we are committed to providing customers with high-quality products and services through productive, rapid, problem solving and active communication and to realize the shift from CRO to CDMO. We have expanded the scope of pharmacy services while enhancing the capability and level of pharmacy services.

MEDICILON

Innovative Drug Process Research & Declaration

We provide preclinical and clinical stage API process development, optimization, manufacturing and filing services in both China and the US. We have established a GMP-compliant API research platform and have successfully developed APIs for innovative drugs for several pharmaceutical companies in accordance with the latest regulations and guidelines. we also have developed GMP APIs for preclinical trials for innovative drug companies.

Our services

- Customized starting materials
- Synthesis process research

Route design and determination | Process optimization | Impurity/specimen preparation (or purchase) and standardization | Laboratory process confirmation 1 batch | Pilot scale up production 2 batches (pilot batch (non-GMP)) | Safety assessment 1 batch (toxicology batch (non-GMP)) | GMP production 1 batch (cGMP batch production)

- Quality Studies

Establishment of material quality standards | Development and optimization of analytical method | Material testing and release | Central control analysis | Validation of analytical method

- Stability Studies

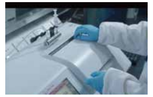
Influencing factors experiment (1 month) | Accelerated stability (6 months) | Long-term stability (tentative 24 months)

- Crystal Structure Screening & Process Development

Crystal Structure Screening | Crystal Structure Process Study

- Filing Services In Both China & U.S.

Reports and information: Process Optimization Report | Pilot test production report | Method validation report | Stability report | CTD format reporting materials, etc.



MEDICILON

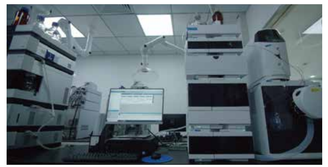
Process Route Screening

Medicilon provides customization of starting materials and design and confirmation of synthesis process routes. We conduct research on the product to be developed, review a large amount of data, analyze the synthesis route and the original source of synthesis, and analyze the synthesis equipment and synthesis cost to understand whether the synthesis route has intellectual property issues, whether the production cost is acceptable, whether it can meet the green chemistry, etc. We conduct route screening, process optimization, quality research, and process validation.

Our services

- Route design & screening
- Salt screening, crystal structure study and crystal process development
- Salt Screening
- Crystal structure screening
- Crystal structure process studies (laboratory test processes, kilo-scale processes)
- Statistics and experimental design by using quality by design (QbD) and multivariate data analysis Quality studies of APIs and intermediates
- Development and validation of analytical method
- Technology transfer and process validation

Whether it is an emergency route screening at the pre-development stage or a cost-effective route screening at the formal drug development stage, Medicilon helps customers to select the API process routes which is stable, quality reliable, low cost, process safe, environment friendly and suitable for large-scale production by evaluating the technical feasibility, equipment availability, availability of principles and reagents, number of reaction steps, patent protection and environmental impact, etc.



MEDICILON

Generic Drug Process Research & Declaration

Provide generic API manufacturing process development, optimization, production and declaration (DMF) services

Our Services

- Design intellectual property and cost-competitive synthetic routes
- Route screening
- Confirmation of API crystal structure
- Optimization of process
- Quality studies
- Three batches of laboratory test & pilot tests and at least three batches of cGMP process validation
- API stability testing
- Development & validation of API analytical method
- Preparation and writing of API declaration, Medicilon provides all API work and CTD format declaration information required for generic API declaration (DMF)
- Declaration services for both China and US

Establish a database of key process parameters by continuously optimizing the process to obtain a mature and easy-to-industrial process route. According to the characteristics of the process route, to establish the complete impurity spectrometry of starting materials, intermediates and APIs, so that the prepared APIs can meet the requirements of generic formulations and thus the industrial production of a certain scale can be practiced.

Optimization of API Production Process

Medicilon Process Department applies the concept of QbD to the R&D of API process, devotes itself to creating a suitable process route tailored for customers, and optimizes the API production process to improve product quality and process efficiency.

Our Services

- Establishment of API quality standards
- Establishment of intermediate control standards
- Optimization and determination of process parameters
- Optimization and determination of post-treatment methods
- Optimization and determination of purification methods
- Process risk assessment and control (assessment of the risk level of the process)
- Safety evaluation of the process
- Establishment of quality standards for raw materials, intermediates and final products
- Impurity spectrometry studies
- CTD documentation writing

Solids Screening Platform of Process Department

The solids screening platform of Medicilon's process department strictly follows the registration regulations and regulatory requirements of the NMPA in China and the FDA in the U.S. to study and control the solid forms of drug molecules in APIs and formulations, and is able to develop the most effective screening strategies based on the characteristics of the substances, including but not limited to crystallization methods, selection of solvent, selection of the suitable salt-forming acid and base.

Our Services

- **Discovery** — Various salt forms/crystal structure /co-crystal of APIs
- **Evaluation** — The drug-forming properties of different crystal structure of APIs
- **Development** — API crystallization production process to obtain target crystal structure, morphology and particle size

Salt Screening

Goal
- Improve the drug properties
- Discover the most suitable salt form for development
- Ensure the protection of the effective patent
- Circumventing the prior technology patents

Technology package
- Characterization of free state properties
- Solubility in different solvents
- Selection of the suitable salt-forming acid and base
- Multiple salt formation techniques
- Characterization of physicochemical properties
- Studies of solid state and solution stability
- Salt form selection and recommendation
- Patent deliverables

Salt Screening Process

Characterization » Program Design » Preliminary confirmation of salt formation » Scale-up » Assessment » Patent Report

MEDICILON

Co-crystal Screening

Goal
- Improve the defects of the free state
- Discover the most suitable cocrystal for development
- Ensure the protection of the effective patent
- Circumventing the prior technology patents

Polymorph Screening

Goal
- Discover the most suitable crystal structure for development
- Ensure the protection of the effective patent
- Circumventing the prior technology patents

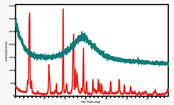
Technology package
- Analysis of existing technology
- Technologies of multiple crystallization
- Characterization of physicochemical properties
- Studies of solid state and solution stability
- Analysis of the relative stability of polymorph
- Crystal structure selection and recommendation
- Patent deliverables

Polymorph Screening Process

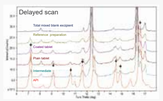
Characterization » Program Design » Screening » Scale-up » Assessment » Patent Report

Qualitative, quantitative and limit analysis method development and validation

- Analysis of raw material crystallinity or impurity crystal structure
- Qualitative and quantitative analysis of raw material crystal structure in formulations
- Development & validation of particle size distribution analysis method

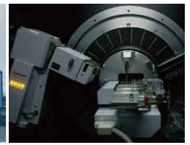


Verification of crystallinity



Qualitative Analysis of crystal structure of APIs in formulations

X-Ray Powder Diffraction (XRPD)



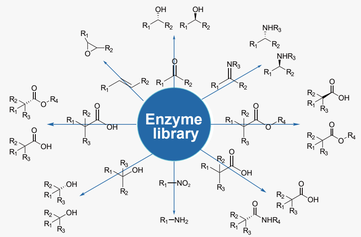
MEDICILON

Biotechnology Platform

Medicilon's process department has established a biotechnology platform with corresponding chemical technology platform, testing platform and GMP production platform. The biotechnology platform focuses on the combination of chemical synthesis and bioenzyme-catalyzed synthesis, on the research, development and application of bioenzymes, on the R&D and production of pharmaceutical intermediates and APIs in using green biotechnology, and on providing high-end CRO and CDMO services and testing and quality research services for pharmaceutical companies. Biological enzyme catalysis is characterized by high efficiency, specificity, versatility and variability, and mildness of reaction conditions. At present, the biotechnology platform has established dozens of large bioenzyme libraries, such as ketone reductases (KRED), esterase, imine reductase (IRED), nitroreductase (NTR), cyclooxygenase (COX), amidase, etc. In addition, we will also carry out research in the direction of immobilized enzymes and coenzymes.

Our Services

- Study of enzyme-catalyzed conversion process
- Development and validation of analytical methods
- Research, development and application of bioenzymes



MEDICILON

Email: marketing@medicilon.com

Address: 50 Soldiers Field Place, Boston, MA 02135

Website: www.medicilon.com **Tel:** +1(626)986-9880

Medicilon CMC Sector
Process Department

One-stop API Process R&D Platform

- Process Route Screening
- Optimization of API production process
- Research & declaration of innovative drug
- Research & declaration of generic drug process
- Process Department Solid Screening Platform
- Biotechnology Platform