## Insoluble Innovative Drug Technology Platform

In the process of drug formulation development, there are more and more drugs with low solubility, and about 70% of new drug candidate compounds are poorly soluble drugs. Medicilon Formulation Department solves the problems of drug solubility and permeability through unique technologies, improves the success rate of drug development, shortens the development time, and promotes compounds to become truly valuable new drugs. Medicilon has established and perfected technical platforms such as solid dispersion (such as hot melt extrusion, spray drying, etc.), micronization, clathrate, emulsions, *in vitro* dissolution/*in vivo* PK comprehensive evaluation, etc.

### Our services

- Solubilization of insoluble drugs
- Improvement of bioavailability

### Medicilon cases

Azithromycin Tablets, Mosapride Citrate Granules, Domperidone Suspension, Canagliflozin Tablets, Ivermectin Tablets, etc

### Device configuration

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## Pharmaceutical Research CDMO Service Platform

The oral solid preparation workshop of Medicilon Pharmaceutical Department complies with GMP, which can carry out generic drug research and development and testing, as well as clinical phase I and II research and development, production, packaging, testing and stability research of innovative drugs. The service capacity has been expanded from CRO to CDMO to meet customer needs and facilitate innovative drug research and development.

### Our services

- Preparation can be flexibly developed in different production processes and production batches (1kg-40kg)

### Device configuration

Conform to the requirements of GMP oral solid preparation workshop equipped with advanced equipment and fully functional facilities, major equipment including hot melt extrusion machine, spraying machine, dryer, granulator, pulverizer, dry granulator granulation machine, multi-function fluidized bed, mixing machine, tablet press, capsule filling machine, coating machine, emulsifying machine with high efficiency, grain packaging machines, blister packaging machine and others.

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## Perfect Quality Management System

Medicilon GMP preparation Analysis Laboratory has established a perfect quality management system, which can not only meet the QC inspection and release work of GMP workshop, but also meet the requirements of long-term stability and accelerated stability research under GMP conditions for generic drug conformance evaluation.

### Our services

The system covers institutions and personnel, laboratories and equipment, materials, verification, documents and records, inspection, calibration, quality assurance, etc. It specifies the responsibilities of departments and corresponding management personnel, and establishes personnel training and experimental record filling, auditing, documentation, change control, deviation and OOS/OOT processing procedures, CAPA management, reference preparation and control substance management, chromatography data processing, software authority management and other systems.

### Device configuration

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# Medicilon CMC Sector
# Preparation Department

**Advantages and Features**
CDMO service platform
Insoluble innovative drug technology platform
High-end preparations technology platform
Perfect quality management system

## Advantages & Features

Medicilon's preparation laboratory and workshop area is about 4,000 square meters, with 100 professional R&D teams, of which more than 40% are masters/doctors, and more than 95% are undergraduates. The team has rich experience in successful research and development of innovative drugs, consistency evaluation, and improved new drugs, and experience in China-US dual filing and project management. The Medicilon pharmaceutical preparation R&D team has successfully cooperated with well-known large and medium-sized pharmaceutical companies worldwide, and has accumulated 18 years of experience in the research and application of innovative drugs and generic drugs. We provide one-stop and systematic preparation R&D services covering innovative drugs and generic drugs to meet the needs of customers at different stages of R&D.

### Provide one-stop preparation development services

Medicilon can undertake a full set of preparation research (including research and development, clinical sample production, stability), safety evaluation, packaging material compatibility, filter membrane verification, packaging sealing, pre-BE and BE research and other services to meet all your needs for on-site preparation development services.

### From CRO to CDMO

Medicilon built a new GMP-compliant oral solid preparation workshop, and improved the level of drug production and quality management systems. Medicilon can carry out the research and development, inspection and stability research of generic drugs, as well as the research and development, production, packaging, inspection and stability research of clinical phase I and II of innovative drugs, and our service capabilities have expanded from CRO to CDMO.

### Rich instrument and equipment configuration

- The main preparation equipment includes jet mill, Thermo hot melt extruder, Spray dryer, Multifunctional fluidized bed (granulation, Wurster column pellet coating), Wet granulator, Dry granulator, Hopper mixer, Rotary tablet press, Automatic capsule filling machine, High-efficiency coating machine, Granule packaging machine, aluminum-plastic packaging machine, Emulsifier machine, Colloid-grinder, Soft capsule making machine and freeze dryer, etc.
- The main analytical instruments include chromatographic analyzers such as UPLC, HPLC, GC, IC, LC-MS and GC-MS, and Laser particle size analyzer, Auto Dissolution Tester, constant temperature and humidity test chamber, differential scanning calorimeter (DSC), Thermal Gravimetric Analyzer (TGA), X-ray Powder Diffraction (XRPD), Nuclear Magnetic Resonance (NMR), Fourier Transform Infrared Spectroscopy (FT-IR) and ICP-MS, etc.

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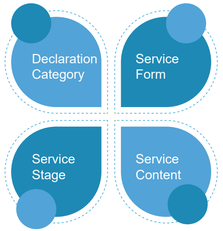
## Our services

- Class 1 innovative drugs
- Class 2 improved new drugs
- Class 3 and 4 generic drugs
- Consistency evaluation
- Supplementary application




- Oral formulations (Tablets, Capsules, Granules, Oral Solutions/Suspensions, Syrups)
- Injectable preparations (injection solutions, sterile powders for injection (aseptically dispensed or lyophilized), concentrated solutions for injection)
- External preparations (ointments, creams, tinctures)
- Other formulations (Eye Drops, Sprays, Inhalants, Sustained Release)

- New Drug IND Application (China-US dual filing)
- Phase II/III clinical trials of new drugs
- NDA Application
- Post-marketing changes

- Preformulation
- Formulation process development
- Pilot scale-up
- Quality research and stability research
- Writing application materials

## Formulation research of innovative drugs

| Preformulation | Formulation & Preparation Process Research | IND, Phase I Clinical Trial | Phase II, III Clinical Trial | NDA |
|---|---|---|---|---|
| Feasibility assessment<br>Dosage form selection<br>Compatibility of raw materials | Formulation process development<br>Formulation optimization<br>Quality development | Pilot scale-up<br>Quality research and stability research<br>Phase I clinical samples | Prescription and manufacture process scale-up & change | Prescription process confirmation<br>Quality research<br>Process validation |

## Generic Drug Formulation Studies (QbD)

Target Product Quality Profile QTPP

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Critical Quality Attributes CQAs

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Risk Assessment, Critical Material Attributes CMAs, Critical Process Parameters CPPs, DoE, Design Space DS

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Control Strategy

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## High-end Preparations Technology Platform

Medicilon Formulation Department not only has outstanding performance in the development and research of traditional dosage forms, but also established Inhalation Drug Delivery, Ophthalmic Drug Delivery, Transdermal Drug Delivery, Sustained-and Controlled-Release Drug Delivery, Microparticle Drug Delivery and other High-end preparations technology platforms in recent years.

## Inhalation Drug Delivery

Medicilon is familiar with the development process of various inhalation preparations, especially in the field of Dry Powder Inhaler (DPI), Nebulizer and Nasal Spray preparations. During the research process, the research work is fully complied with the requirements of regulations and guiding principles. Medicilon is equipped with related equipment such as COPLEY's Next Generation Impactor (NGI), COPLEY's BRS 2100 Breath Simulator, Particle Size Analyzer from Sympatec and other equipment, which can meet the quality research of various inhalation preparations and *in vitro* assessment. So far, Medicilon has cooperated with a number of companies that carry out research on inhalation preparations, and has completed a number of quality research work on protein inhalation preparations, inhalation solutions and nebulizers, all of which have been received unanimos praise.

### Our services

- Nebulizer
- Nasal Spray
- Research and development of Dry Powder Inhaler (DPI)
- Quality study of various inhalation preparations

### Device configuration

### Medicilon cases

Acetylcysteine Solution for Inhalation, Mometasone Furoate Aqueous Nasal Spray, etc.

## Ophthalmic Drug Delivery

Due to aging population, widespread use of electronic products, and changes in living habits such as improper eye use, the incidence of eye diseases such as Eye Infection, Conjunctivitis, Macular Degeneration, and Dry Eye Syndrome has increased significantly. Medicilon has accumulated many project experience in solution, suspension and semi-solid ophthalmic preparations, and is familiar with various packaging forms and BFS technology.

### Our services

- Ophthalmic liquid preparations (solutions, suspensions, etc.)
- Research and development of ophthalmic semi-solid preparations (eye ointment, gel, etc.)

### Medicilon cases

Moxifloxacin Hydrochloride Ophthalmic Solution, Atropine Sulfate Eye Drops, New drug suspension eye drops, etc.

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## Transdermal Drug Delivery

Transdermal Therapeutic System (TTS) or Transdermal Delivery System (TDS) refers to a new dosage form in which a drug enters the circulatory system through the skin surface at a constant rate (or near-constant rate) to produce systemic or local therapeutic effects. Transdermal dosage forms are patches, ointments, plasters, liniments and aerosols, etc. *In vitro* Release Test (IVRT) and *In vitro* Penetration Test (IVPT) are important means to evaluate the dosage forms and prescriptions of external preparations (such as creams, ointments, gels, patches, liniments, etc.). Medicilon has rich experience in evaluation of transdermal drug delivery preparations, and is equipped with corresponding transdermal and detection instruments (LC-MS/MS), which can be used in compound screening, new drug application, pharmaceutical changes and consistency of listed chemicals. We provide professional and efficient service for projects involving *in vitro* evaluation.

### Our services

- Research and development of creams, ointments, gels, liniments, etc.
- Research of *in vitro* release test and *in vitro* penetration test.

### Device configuration

### Medicilon cases

Tacrolimus Ointment, Minoxidil Tincture, Clindamycin Phosphate and Benzoyl Peroxide Gel, Progesterone Sustained-release vaginal gel, Metronidazole Vaginal Gel, Triamcinolone Acetonide Acetate Ointment, Neticonazole Hydrochloride, etc.

## Sustained-and Controlled-Release Drug Delivery

Medicilon has a variety of sustained and controlled release drug delivery technologies, such as water dispersion coated sustained-release pellets technology, Laser drilling osmotic pump controlled-release technology, and matrix-type sustained-release technology. Sustained-and controlled-release preparation technology platform is dedicated to the development and scale-up research of sustained-and controlled-release preparations, innovated and improved the platform technology of matrix-type and reservoir-type sustained- and controlled-release drug delivery systems, established and improved the *in vitro* test methods and related standards of various oral sustained- and controlled-release preparations.

### Our services

- Development and scale-up of matrix-type and depot-type sustained and controlled release preparations
- Quality evaluation of matrix-type and depot-type sustained and controlled release preparations

### Medicilon cases

Oxycodone Hydrochloride Prolonged-release Tablets, Quetiapine Fumarate Extended-Release Tablets, Paroxetine Hydrochloride Enteric-Coated Sustained-Release Tablets.

## Microparticle Drug Delivery

Microparticle Drug Delivery Systems (MDDS) can increase the solubility of insoluble drugs, improve the stability of drug particles in the medium, and has the characteristics of sustained release and targeting. MDDS has the advantages of high drug loading, high bioavailability, less local and systemic side effects, less fluctuation of blood drug concentration, and high efficacy and patient compliance. In recent years, research hotspots have focused on formulations such as microemulsions, liposomes, nanoparticles, and microspheres.

### Our services

- Pre-prescribing of Microparticle Drug Delivery
- Formulation process research
- Analytical method development, etc.