MEDICILON

Medicilon Non-clinical Toxicology Studies Services
(GLP and non-GLP)

Medicilon offers comprehensive toxicology study services designed to assess the safety profile and potential risks of pharmaceutical compounds. Our expert team collaborates closely with clients to tailor studies according to regulatory requirements and project-specific needs.

Our state-of-the-art facilities, advanced platform, experienced scientists, and commitment to quality ensure that clients receive high quality, reliable, and regulatory-compliant GLP toxicology data to support the development of safe and effective pharmaceutical products.

As of April 2024, Medicilon has proudly served over 2000 clients worldwide, contributing to the successful approval of over 400 IND applications in China and over 70 INDs overseas, demonstrating our commitment to providing high-quality services and supporting the global advancement of pharmaceutical development.

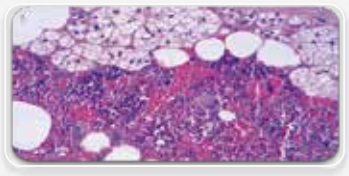
Toxicology studies scope

Toxicology Services (GLP & Non-GLP)

- Single and repeated-dose toxicity studies
- Reproductive/developmental and juvenile toxicity studies
- Genotoxicity studies
- Toxicokinetic studies
- Safety pharmacology research
- Immunogenicity studies
- Local tolerance studies
- Carcinogenicity studies

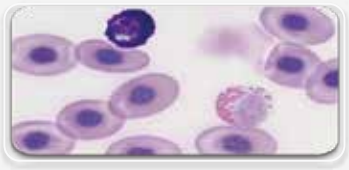
Histopathology Studies

- H&E staining
- Special staining
- Immunohistochemistry (IHC)
- Tissue cross-reactivity (TCR)



Clinical Pathology Studies

- Hematology analysis
- Urinalysis
- Clinical biochemistry analysis
- Hemocoagulation analysis
- Lymphocyte phenotyping



New Drug Delivery Technology

Inhalation formulation safety assessment

Ophthalmology safety assessment

Toxicology research service platforms

In addition to common administration routes such as PO and IV, the following characteristic evaluation platforms are also established:

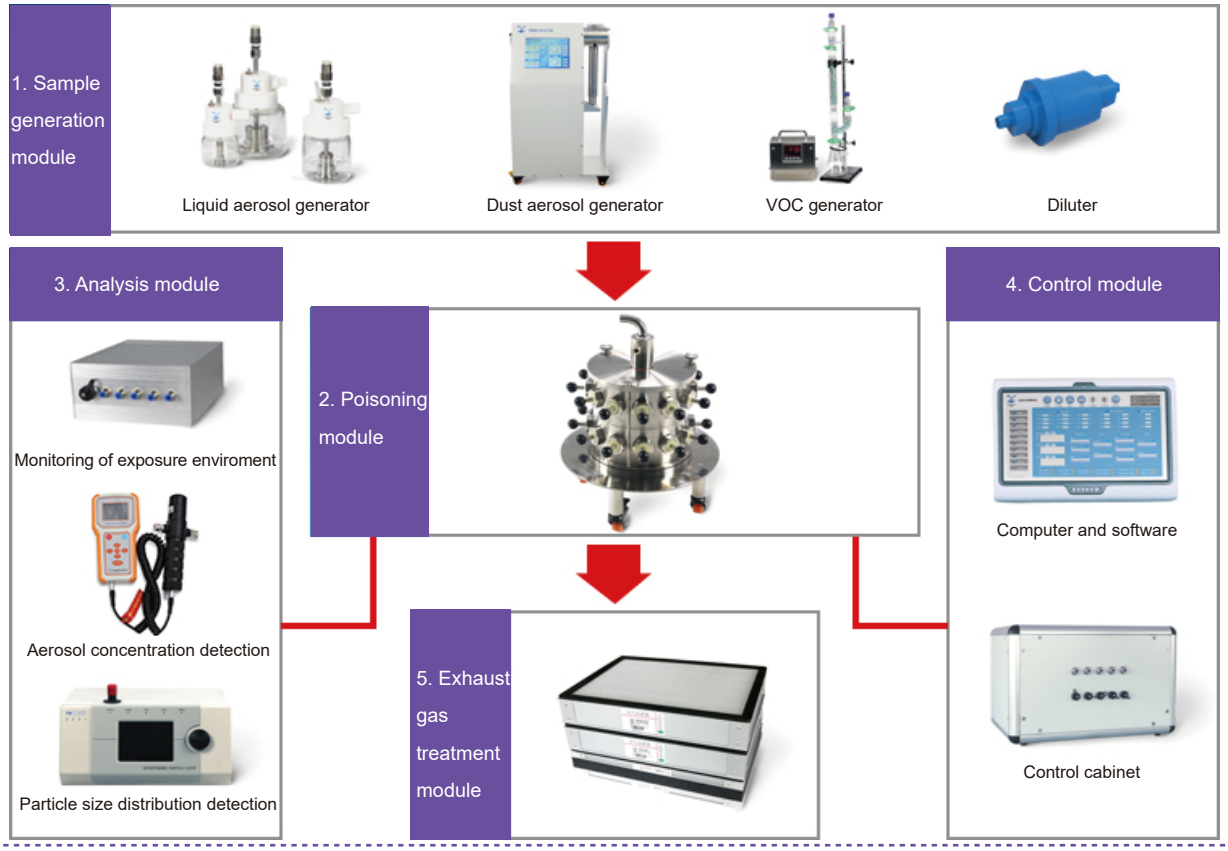
- The inhalation administration platform
- Ophthalmic administration platform
- Intrathecal administration platform
- The skin administration platform
- Sublingual administration platform
- The young animal evaluation platform
- The integrated evaluation technology platform for biological innovative drugs such as antibody, vaccine, siRNA, ADC, and CAR-T cell

Service Advantages

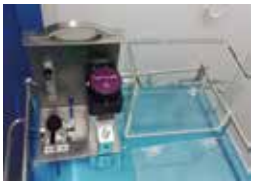
- Medicilon boasts esteemed qualities such as AAALAC Accreditation, on-site inspections conducted by the US FDA, and GLP certification by the China NMPA.
- Medicilon had joint venture with MPI (a leading US tox CRO) and adhered to MPI's quality management system and Standard Operating Procedures (SOPs).
- In alignment with international standards, Medicilon has developed and implemented several key systems to enhance the standardization and traceability of the research process. These include Provantis GLP Tox, EMPOWER data acquisition and management system, Chromeleon chromatographic data system, and Laboratory Information Management System (LIMS).
- Medicilon utilizes Submit software to autonomously generate toxicological research data in the Standard for Exchange of Nonclinical Data (SEND) format, facilitating the submission of regulatory filings to the FDA.
- Medicilon has a proven track record of successfully completing over 400 filing projects for IND applications for our clients, showcasing its extensive experience in fulfilling clients' diverse requirements with excellence. These projects encompass a wide range of contents, including small molecule drugs, as well as biotechnology-based drugs such as ADCs, antibodies, proteins, and polypeptides.

Medicilon Inhalation Study Case Studies

Small animal/canine/NHP nose and mouth exposure system

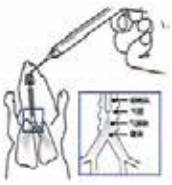


Inhalation delivery methods




Intratracheal instillation

Pressurized Atomization

Micro Intratracheal Atomization

Inhalation formulation quality analysis: key equipments

Anderson Cascade Impactor

Round Disk Impactor

Automatic Air Pump

Breathing Simulator

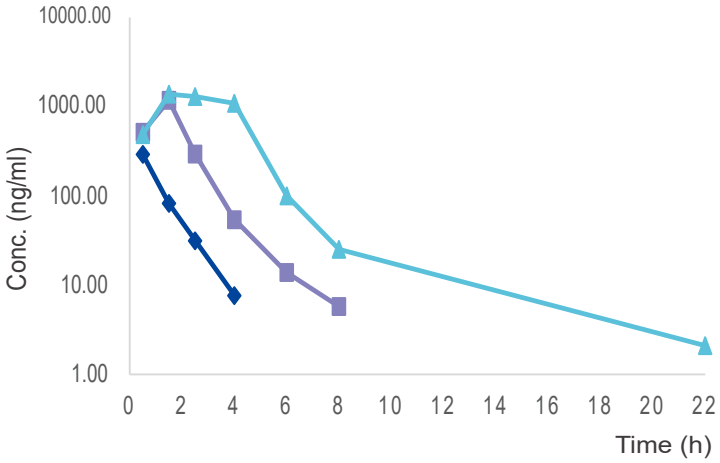
GLP TOX case study: rat and canine mouth and nose exposure

Duration

- Rat: 240min daily for 28 days
- Canine: 240min daily for 28 days

Parameters

- In-life observation: is the animal breathing normally, are there any symptoms such as asthma, coughing, asphyxia, and allergy, whether there is secretion at the mouth and nose region etc.
- Dissection and pathology: focus on any stimulatory reaction such as hyperemia, swelling and necrosis of the animal's tongue, palate, inner check, nose, throat and pharynx, bronchus and lung. Pathological analysis is performed on the above tissues.



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