Medicilon Toxicology Studies Services

Toxicology studies are used to characterize the toxicity profile of a drug by identifying its impact on functionality and / or organ structure. This includes assessment of the severity and reversibility of toxicity, as well as dose ranges and their relationship to exposure. Toxicology studies aid in determining if, and to what degree, the candidate compound's toxicity is dose-dependent, species-specific, mechanism-related and/or related to the method of administration.

A candidate compound must be assessed in many different kinds of non-clinical toxicity study before it can be administered to the first human volunteer; even more toxicity studies are required thereafter before the candidate compound receives marketing authorisation.

Non-clinical Safety Assessment (GLP & NON-GLP)

Medicilon's state-of-the-art preclinical facilities hold full AAALAC accreditation. With advanced platforms and experienced scientists, Medicilon guarantees the utmost professionalism in drug efficacy and safety assessments services, adhering to global regulatory standards. Offering services from stand-alone preclinical studies to comprehensive IND-enabling packages, Medicilon provides flexible solutions to efficiently support biotech and pharmaceutical clients in reaching their developmental milestones.

We boast professional teams and practical experience in drug safety evaluation and can promise high-quality data and fast turnaround time to support various drug safety evaluations. Our toxicology research can be carried out according to non-GLP or GLP standards.

By the end of 2023, we have served more than 2000 clients globally with more than 300 INDs approved in China and more than 80 INDs approved overseas using toxicology data generated by Medicilon.

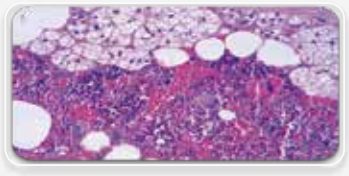
Toxicology studies scope

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

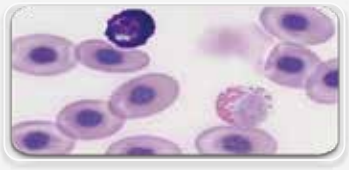
Histopathology Studies

- 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:

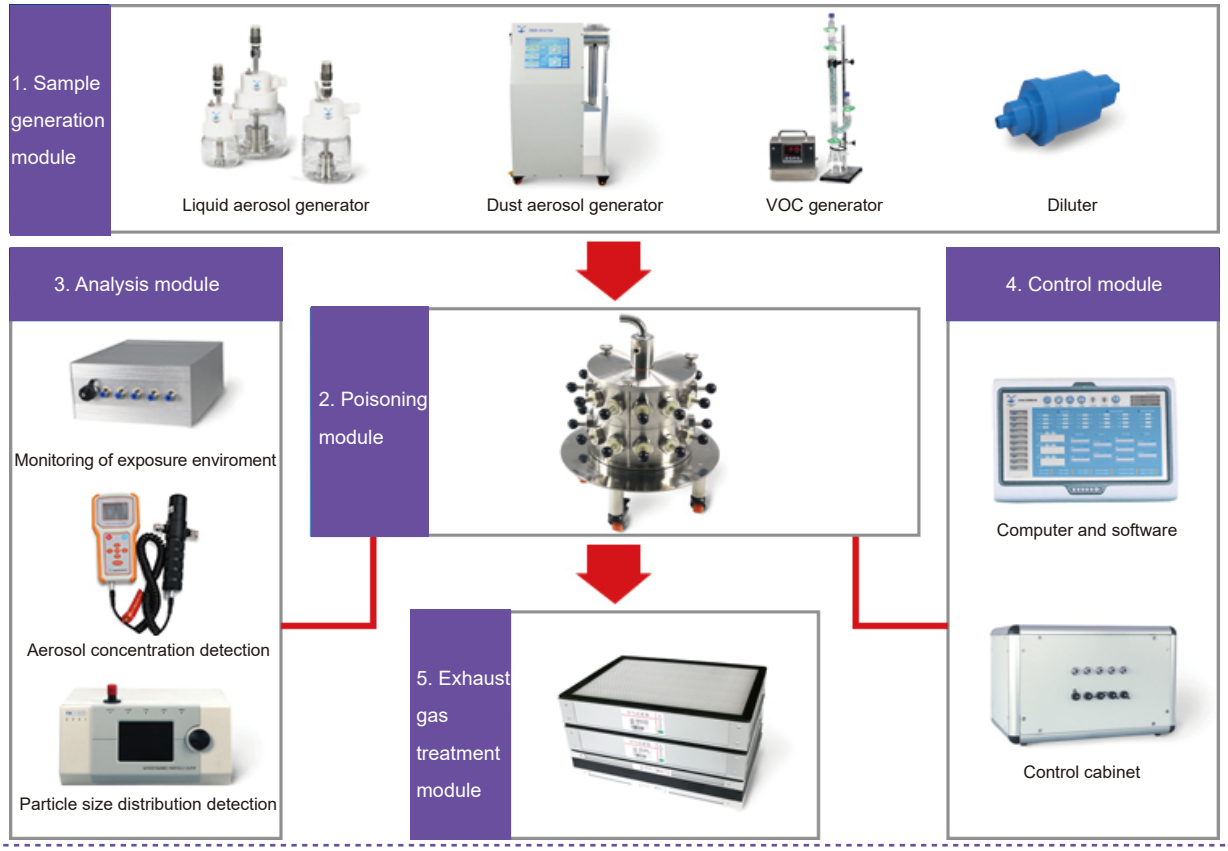
- The inhalation administration platform
- Ophthalmic administration platform
- Intrathecal administration platform
- The skin administration platform
- Sublingual administration platform
- The young animal evaluation platform
- The integrated evaluation technology platform for biological innovative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

Service Advantages

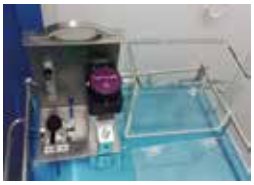
- With a preclinical research institution in line with international standards established earlier in China, Medicilon is proud to be a senior organization with GLP-based laboratories;
- Has cooperated with MPI and followed MPI's quality management system/SOP;
- Features comprehensive quality control measures three-level QC management model;
- Has a comprehensive data management software system;
  - Based on international standards, Medicilon has developed and established Provantis GLP Tox, EMPOWER data acquisition and management system, Chromeleon chromatographic data system and LIMS system to strengthen the standardization and traceability of the research process;
  - With Submit software and own port, Medicilon can independently complete toxicological research data in SEND format for filing items to FDA.
- Features qualities like AAALAC Accreditation and GLP certificate by NMPA, and has passed the on-site inspection by FDA;
- Has successfully completed a number of projects, showing its rich experience in meeting clients' requirements.
  - With rich experience in filing, Medicilon has successfully complete over 100 filing projects based on IND, with contents involving micromolecule drugs and bio-tech-based drugs (including ADC, 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

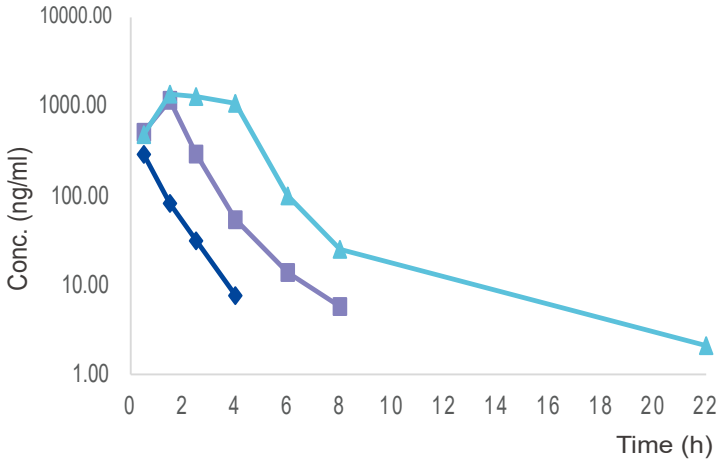
GLP TOX case study: rat and canine mouth and nose exposure

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.



MEDICILON

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

Global Headquarters: 585 Chuanda Road, Pudong, Shanghai, 201299, China

US Laboratory: 50 Soldiers Field Place, Boston, MA 02135, United States