

Preclinical Services/

Medicilon provides fully integrated pharmaceutical services to pharmaceutical community.

discovery programs from the initial idea stage to the IND filing phase.

professional knowledge in drug metabolism/pharmacokinetics, pharmacology studies as well as toxicology. We offer the high-quality and cost-effective data with rapid turnaround time to support clinical research. Our



Our pharmacokinetics department offers the clients a broad spectrum of high quality of services in the areas of ADME, pharmacokinetics and bioanalysis services, ranging from small molecules to large molecules, such as protein and antibody. The animal species involved in our services are non-human primate, canine, mice, rat, rabbit and hamster. Meanwhile, non-human primate experimental platform and isotope platform for protein/antibody are certified by the Shanghai government.

ADME

/

➤ Preclinical Pharmacokinetics



Method development and validation (GLP & Non-GLP)

GLP Non-GL

Pharmacokinetics (Tumor bearing rodents,
Crossover studies, Cassette

(N in 1) dosing and analysis, Effect
acokinetics, BBB penetration)

Drug interaction studies

CYP 450 inhibition/induction

CYP450

Distribution studies

Excretion studies

Prediction and identification of major metabolites

Toxicokinetics analysis



➤ Pharmacokinetics with Radiolabelled Compounds ➤

- Protein/ant body drug with ^{125}I labeled for PK
- Tissue distribut on

➤ Pharmacokinetics Package for IND Filing ➤

DMPK package for CFDA and FDA IND filing

FDA CFDA

- Chemical compounds
- Tradi tional chinese medicine
- Ant body

We have successfully helped many clients to prepare the DMPK package for CFDA and US FDA IND filing and have passed all audits smoothly.

我们已经成功地帮助很多客户向CFDA和FDA递交符合新药注册要求的药代申报资料，并已接受多次核查，且顺利通过所有核查。

Quick study initiation and scheduling flexibility will help you make your decisions faster and reduce your total research costs!

实验的快速启动和安排的灵活性将帮助您做出更快的决定和减少总的研究费用！

➤ Cancer Xenograft Models/ /

Head and Neck Cancer	KB, FaDu
Nasopharyngeal Carcinoma Stem Cell	S18, S26
Lung Cancer	DMS114, NCI-H69, NCI-H146, NCI-H209, NCI-H446, NCI-H526, NCI-H1688,95-D, A549, Calu-1, Calu-3, Calu-6, HCC827, NCI-H226, NCI-H292, NCI-H358, NCI-H441, NCI-H460, NCI-H520, NCI-H522, NCI-H1299, NCI-H1437, NCI-H1650, NCI-H1975, NCI-H1993, NCI-H2009, NCI-H2122, NCI-H2126, NCI-H2228, PC-10, QG-56, LLC
Breast Cancer	Bcap-37, BT-474, 2LMP, MCF7, MDA-MB-231, MDA-MB-435s, SUM159, MDA-MB-468, ZR-75-1, ZR-75-30
Gastric Cancer	BGC-823, HGC-27, MKN-28, MKN-45, NCI-N87, NUGC-3, SCH, SGC-7901, SNU-5, SNU-16, MGC-803
Pancreatic Cancer	AsPC-1, BxPC-3, Capan-1, Capan-2, CFPAC-1, HPAF-II, MIAPaCa-2, PANC-1, SU.86.86
Renal Cancer	ACHN, OS-RC-2, 786-O
Hepatocellular Carcinoma	Bel-7402, Hep-3B, Huh-7, PLC/PRF/5, QGY-7703, SK-HEP-1, SMMC-7721
Glioblastoma	U87-MG
Colon and Cecum Cancer	COLO 201, COLO 205, COLO 320 DM, CW-2, DLD-1, HCT-8, HCT-15, HCT116, HCT116 P53 K0(-/-), HT-29, LoVo, LS1034, LS174T, SW610, NCI-H187, NCI-H1975, NCI-H209, NCI-H2122, NCI-H2126, NCI-H2228, NCI-H226, NCI-H292, NCI-H358, NCI-H441, NCI-H460, NCI-H520, NCI-H522, NCI-H1299, NCI-H1437, NCI-H1650, NCI-H1975, NCI-H1993, NCI-H2009, NCI-H2122, NCI-H2126, NCI-H2228, PC-10, QG-56, LLC

Medicilon also offers primary tumor models.

美迪西也提供原代肿瘤模型用于药物筛选。



➤ Metabolic Disease Models/

Disease	Model	Species
D		R
	G t	D D
		DIO DIO
	A	R
O	G t	D D

➤ Inflammation & Immunological Disease Models/



Our toxicology department has professional teams with rich experience in toxicology studies. We offer high-quality data and rapid turnaround period to support drug discovery and development. Our toxicological study is conducted in various kinds of animal species. The toxicological evaluation from dose design, in-life studies to histology and pathology testing along with toxicokinetics studies are all complied with non-GLP or GLP standard. Our study platform is certified as one of Shanghai Public Service Research Platforms.

GLP GLP

➤ Drug Preclinical Safety Evaluations (CFDA, FDA GLP Compliance) ➤

- Repeated dose toxicity study
- Genotoxicity study
- Reproductive toxicity study
- Immunogenicity study
- Toxicokinetic study

➤ Histopathology Capabilities ➤

- Routine and special staining techniques
- Preparation of slides with high quality
 - Slide and cassette printing (Leica)
 - Tissue processing (Leica)
 - Hematoxylin & eosin staining (Leica)

domestic and

international pathologists



➤ Clinical Pathology Capabilities

Leukocyte count (total and 5 part differential), Erythrocyte count, Hemoglobin, Hematocrit, Mean corpuscular hemoglobin, Mean corpuscular volume, Mean corpuscular hemoglobin concentration, Absolute and percent reticulocytes, Platelet count, Blood cell morphology

- Urinalysis

Volume, Specific gravity, pH, Color and appearance, Protein, Glucose, Bilirubin, Ketones, Blood, Urobilinogen, Nitrite, Leukocyte, Microscopy of centrifuged sediment

- Clinical Chemistry

Alkaline phosphatase, Total bilirubin, Direct bilirubin, Indirect bilirubin, ALT, AST, Gamma glutamyl transferase, Urea nitrogen, Creatinine, Total protein, Albumin, Globulin, Glucose, Total cholesterol, Triglycerides, Electrolytes(sodium, potassium, chloride), Calcium, Phosphorus, Creatine kinase, High density lipoprotein cholesterol, Low density lipoprotein cholesterol, Bicarbonate

- Coagulation

Prothrombin time, Activated partial thromboplastin time, Thrombin time, Fibrinogen



pH

Y -



➤ Preparation of Toxicity Package Compliance with FDA and CFDA IND Registration Requirements

FDA CFDA

Animal Facilities and Capability

- Totally 50,000 SF
- 12,500 SF of function area
- 12,500 SF of Canine housing: maximum capability for 350 animals
- 12,500 SF of NHP housing: maximum capability for 400 animals
- 12,500 SF of Barrier system for Rodent housing: Separate SPF and non-SPF area; maximum capability for 2400 animals of SPF area and 500 animals of non-SPF area
- Design and Operation of the facility is under international and Chinese re

总设施面积5,000平方米
 功能区域1,250平方米
 犬动物房1,250平方米：最多可容纳350只
 非人类灵长动物房1,250平方米：
 最多可容纳400只
 啮齿类屏障系统动物房1,250平方米：SPF和
 非SPF区域；SPF区域最多可容纳5000只；
 非SPF区域最多可容纳500只
 设施的设计和运营均符合国际和国内的标准



Clean hallway in barrier system
屏障系统洁净走廊



Non-clean hallway in barrier system
屏障系统非洁净走廊



标本室



Wet tissue storage
湿标本室



Rodent room
大(小)鼠饲养室



Dog room
犬类饲养室



NHP room
非人灵长类饲养室



Animal dissecting table
解剖台



Drug evaluation research completed from 2008 to 2012

More than 1000 per year preclinical researches have been completed, including single-dose toxicity studies, repeated-dose toxicity studies, topical toxicity studies, toxicokinetic studies and pharmacokinetic studies, now the company has been expanding the safety evaluation to safety pharmacology study, immunogenicity study, genotoxicity and reproductive toxicity study. At present, evaluation and research of four IND packages are being conducted and will be submitted to FDA soon.

每年完成超过1000项药物临床前安全评价研究，包括单次给药毒性试验、反复给药毒性试验、局部毒性试验、毒代动力学试验和药代动力学试验。公司现将药物安全评价能力扩展至安全药理试验、免疫原性试验、遗传毒性和生殖毒性试验。目前公司正开展4个新药全套临床前评价和研究的项目用于申报FDA。

Provantis and LIMS are used in data collection, analysis, storage and format reporting. All instruments used in GLP studies have been validated including software.

Provantis和LIMS软件用于数据采集、分析、储存和格式化报告 所有的设备和仪器已验证或正在验证包括跟数据生成有关的设备和仪器软件。

From Sponsors Evaluations ()/选自客户的评估报告

"The results of an intensive three days audit onsite of GLP systems and procedures, as well as site and personnel, operating systems and procedures, and raw data and final report from one non-GLP study lead to the conclusion that Medicilon is qualified and capable of conducting non-clinical GLP studies in compliance with the US FDA GLP's. The personnel who participated the audit were knowledgeable and professional."

Please contact us for more information on how we can help move your drug along the development pathway.