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Drug Metabolism and Pharmacokinetics (DMPK) Service

WuXi AppTec DMPK

Drug Metabolism and Pharmacokinetics (DMPK) Service

DMPK studies characterize the absorption, distribution, metabolism, and excretion (ADME) properties of compounds, to help identify drugs with better safety and potency against a target, reduce the risk of drug-drug interactions, and provide a basis for clinical dosage and frequency setting.

The DMPK Service Department is one of the business units under the Laboratory Testing Division. It is primarily responsible for *in vivo* and *in vitro* pharmacokinetic studies. When you partner with WuXi AppTec for drug discovery and development services, you gain access to an integrated worldwide network of facilities that offer a full range of discovery screening, preclinical development, clinical drug metabolism, and pharmacokinetic platforms and services.

The DMPK Service Department has a diverse client community, covering more than 90% of the world's large pharmaceutical companies and more than 1,500 small and medium-sized biopharmaceutical companies, virtual companies, non-profit organizations, and academic institutions. As a global DMPK service provider, we are committed to delivering all clients with high-quality data, fast turn-around times, precise R&D strategies, and excellent services to meet the unique needs of every client and become the preferred partner for DMPK studies.

15+
Years of experience

1,000+
Employees

1,500+
Global clients

1,200+
Successful IND filings supported

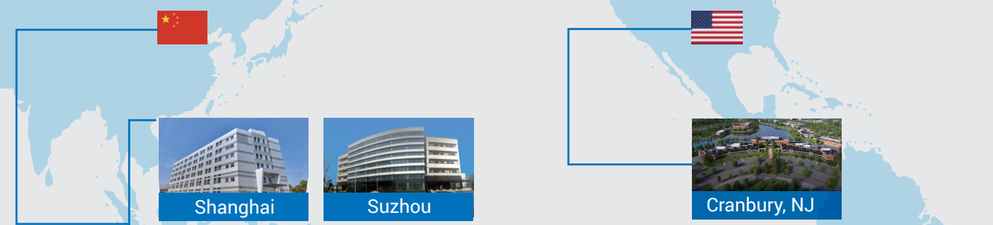
200+
Assay types

300k+
In vitro studies each year

20k+
In vivo studies each year

180k+
Samples analyzed per week

Global Operation with 5 R&D Centers in China and the United States



Our Strengths

Comprehensive Service
- Screening to IND filing
- *In vitro* and *in vivo*
- Routine small molecules and new modalities

Fast Data Delivery
- No lead time for *in vitro* and *in vivo* assays
- Less than five working days for screening assays
- 4 months for standard IND-enabling package

Experienced and Professional Teams
- Professional teams dedicated to project management, experimental design and implementation, and report delivery

Digital Operations
- Precise and intelligent operation system, efficient and safe data delivery

High Standard Instruments and Facilities
- AAALAC accredited and smart animal facilities
- High-precision bioanalytical instruments

High-throughput Automation Platform
- Fully automated *in vitro* ADME workstation
- Fully automated bioanalysis sample pretreatment system

Reliable Experimental Results
- Meet IND and NDA requirements of FDA, NMPA and EMA 15+ years of surveillance/audit
- 150+ NMPA inspections

DMPK Services

- New Modalities & Therapeutics Platforms
- *In Vitro* ADME Study
- Rodent PK Study
- Non-Rodent PK Study
- Metabolite Profiling and Identification
- Radiolabeled *In Vivo* PK/ADME Study
- Non-GLP Bioanalysis
- Compound Management & Import and Export Support

New Modalities & Therapeutics Platforms

▶ New Modalities

PROTAC* ADC OLIGO PDC PEPTIDE mRNA

Our dedicated R&D team established comprehensive pharmacokinetic research strategies and test systems from *in vitro* to *in vivo* for different new drug modalities. The team consists of experts in different fields covering *in vitro* and *in vivo* ADME, metabolite identification, QWBA and radiolabeled mass balance, and bioanalysis.

We have collaborated with pharmaceutical and biotech companies focusing on new drug modalities. We have successfully supported thousands of projects and conducted extensive testing on tens of thousands of drug molecules, including peptides, antibodies, oligonucleotides, PROTACs, ADCs.

*PROTAC refers to Proteolysis-Targeting Chimera

▶ Therapeutics

Ophthalmic Drugs | Transdermal Drugs | Respiratory Drugs | Neurosciences Drugs | Anti-Infection Drugs | Anti-Tumor Drugs

Therapeutic drugs often exhibit unique pharmacokinetic profiles in different disease areas. We have gained extensive experience through years of research projects that cover various therapeutic areas such as anti-tumor, anti-infection, ophthalmic, transdermal, respiratory, and neurosciences. Our dedicated research teams for each therapeutic area, including study directors, experiment scientists, and analysts, have developed customized research strategies, optimized and validated suitable study protocols, and mastered demanding study techniques. In addition, we have established advanced instrument platforms for sample collection, processing, and analysis.

We are capable of assisting our clients in all stages of research needs, including compound screening, optimization, and clinical filing. We have accumulated extensive experience in providing integrated solutions for our clients by collaborating with many internal departments, including pharmacodynamics, formulation, and toxicology.

In Vitro ADME Study

▶ Overview

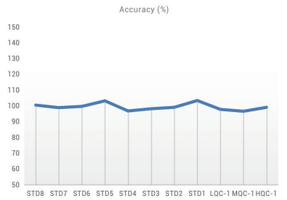
In vitro pharmacokinetic studies characterize the ADME properties of drugs via a high-throughput platform, providing data support for *in vivo* and clinical studies. We have dedicated*in vitro* ADME teams for both experiments and analysis, each offering first-class capabilities, project throughput, and rapid, high quality data delivery. The standard ADME assays are validated to ensure the accuracy and reliability of our experimental data.

▶ Capabilities

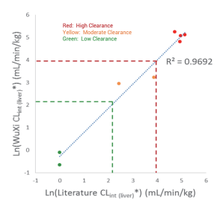
Physicochemical Property	▪ Solubility (KS, TS), pKa, logD, logP
Permeability	▪ Cell models: Caco-2, MDCK I, MDR1-MDCK I, MDCK II, MDR1-MDCK II ▪ Non-cell models: PAMPA
Whole Blood/Plasma Distribution and Protein Binding	▪ Whole blood/plasma distribution: B/P Ratio ▪ Protein binding: Dialysis, ultracentrifugation, ultrafiltration, etc.
Stability	▪ Matrix stability: Tissue, plasma, SGF/SIF, buffer, whole blood, GSH reaction, etc. ▪ Metabolic stability: Microsomes, S9, hepatocytes, lysosome, mitochondria, recombinase, etc.
Drug-drug Interaction	▪ Drug-metabolizing enzyme: CYP, UGT, AO, FMO, CES Inhibition, induction, and substrate studies. ▪ Transporters: ABC transporters and substrate and inhibition studies (BCRP, P-gp, BSEP, MRP1, MRP2, MRP3, MRP4), SLC transporters substrate and inhibition studies (OATP1B1, OATP1B3, OATP2B1, OAT1, OAT3, OCT1, OCT2, NTCP, PEPT1, PEPT2, MATE1, MATE2-K), hepatic uptake and hepatic uptake clearance experiments on multiple species.

▶ High-Throughput Integrated Automated Workstation

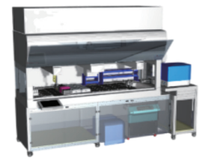
High accuracy and good reproducibility, covering major types of *in vitro* experiments.



Accuracy of workstation standard curve

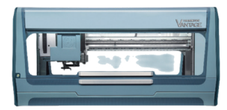


Comparison of WuXi AppTec vs. Literature Values in HLM



Tecan FLUENT 1080

Tecan EVO200



Hamilton VANTAGE

Hamilton STAR Plus

Rodent PK Study

▶Overview

Rodent PK studies have the advantage of easy-to-build *in vivo-in vitro* relationships, lower demand for compounds, shorter TAT at a lower cost, diverse animal models, and mature *in vivo* technologies. Our DMPK rodent facilities, located in Shanghai, Suzhou, Nanjing, and New Jersey, are all accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). In addition, animal facilities in Shanghai and Suzhou have PHS Animal Welfare Assurance. The facility has an independent Institutional Animal Care and Use Committee (IACUC), veterinary care team, and engineering team to ensure the health and welfare of animals.

▶ Capabilities

Animal Species

Mouse CD1, C57BL/6, BALB/c, C3H, CB17-SCID, FVB, NU/ NU, BALB/c Nude, C57BL/6J DIO, BCRP KO, P-gp-KO, DBA/1, etc.

Rat Wistar Han, Wistar, Lewis, SD, Nude, F344, Brown Norway, etc.

Other Hamster, Guinea pig, etc.

▶ Dosing Routes

IV/PO/SC/IP/IM, transdermal (*in vivo* & *in vitro*), intestinal (*in vivo* & *in vitro*), respiratory (intranasal, intratracheal, inhalation), ocular (eye drop, intravitreal, intraconjunctival), etc.

▶ Surgical Models

Cannulation in carotid artery, jugular vein, portal vein, bile duct, intestine lymphatic duct (mesenteric lymph duct, thoracic duct), cerebroventricular, cistern magna, etc.

▶ Preclinical Formulation Screening

- Drug properties optimization: pKa /Log P/ Log D, solubility, stability, etc.
- Formulation forms and optimization: solution, suspension, emulsion, SEDDS, micronization, solid dispersion, capsule, osmosis pump, nano-suspension, etc.

▶ Advanced Capabilities

Ophthalmic PK (*in vitro* ophthalmology platform, ocular drug delivery and sample collection), transdermal drug PK (IVPT, TDDS, skin damage model), CNS PK (microdialysis, ICV), *in vitro* and *in vivo* absorption model (SPIP, ussing chamber, everted gut sac), and respiratory PK (solution, powder), etc.

Non-Rodent PK Study

▶ Overview

Our non-rodent PK facilities are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC International). The facility in Suzhou also has an Office of Laboratory Animal Welfare (OLAW)-approved Animal Welfare Assurance that is required by the Public Health Service (PHS). WuXi AppTec has an Institutional Animal Care and Use Committee (IACUC), engineering team, veterinary team, and husbandry team to ensure our facility is well maintained, complies with guidance requirements, and provides good animal welfare and management.

▶ Capabilities

Animal Species

Dog Beagle

NHP Cynomolgus and Rhesus

Other Rabbit, Mini-pig, Ferret

▶ Dosing Routes

IV/PO/SC/IP/IM, transdermal, gastrointestinal, intra-portal, ocular, buccal, sublingual, intraosseous, CNS administration, etc.

▶ Surgical Models

Cannulation in portal vein, bile duct, intestine, thoracic duct, lumbar vertebra, cerebroventricular, cistern magna, etc.

▶ Preclinical Formulation Screening

The team has experienced experts in preclinical formulation screening studies and advanced instruments, which can screen suitable preclinical formulations within 24 hours.

▶ High Standard Animal Facilities & Welfare

Meets the standards of China, the United States and Europe.

Fruit Storage Room

Enrichment

Feed Storage Room

Animal Cages

Metabolite Profiling and Identification

▶ Overview

We provide comprehensive metabolite profiling and structural characterization services, covering lead compound optimization from drug discovery to clinical development, including radiolabeled metabolite profiling and identification. In addition, our extensive experience in metabolite biosynthesis provides our clients with more convenient and efficient synthesis methods to support drug discovery and safety assessment. We also offer customized services based on the client's research needs. Our global research centers and departments collaborate to ensure a timely delivery of high-quality reports that meet the requirements of regulatory authorities (NMPA, FDA, EMA, etc.).

▶ Capabilities

Drug Discovery Stage	▪ Metabolic soft spot screening ▪ *In vitro* species comparison	▪ Reactive metabolite trapping ▪ *In vitro* and *in vivo* correlation
Pre-clinical Development-IND Stage	▪ *In vitro* species comparison ▪ [^{3}H]- or [^{14}C]-ADME studies in animals (mouse, rat, dog, monkey)	▪ *In vivo* MetID in rodent and non-rodent PK/TK studies
Clinical Development-NDA Stage	▪ Phase I: MetID in human SAD/MAD samples ▪ Phase II or III: Radiolabeled human mass balance study and metabolite identification	▪ Phase I: Metabolites in Safety Testing (MIST)
Metabolite Biosynthesis	Utilizing preparative LC, HRMS, and NMR technology, we have established a biosynthesis platform for targeted metabolites under a biotransformation system of*in vitro* incubation and*in vivo* animal administration. The platform can efficiently synthesize metabolites at the milligram (mg) level and accurately identify their precise structures.	

Advanced Instruments and Software


Thermo Orbitrap Eclipse™ Tribrid™


Thermo Orbitrap Exploris™ 480


Thermo Q-Exactive™ HF


Waters VION™ IMS QTof


Thermo Q-Exactive™Plus


Thermo Q-Exactive™


Thermo LTQ Orbitrap XL


Waters Xevo®G2 QTof

- Thermo Compound Discoverer
- Thermo Mass Frontier
- Thermo Networks
- Waters Metabolynx
- Waters UNIFI
- Molecular Discovery Mass-MetaSite
- Thermo BioPharma Finder

For small molecule metabolite identification

For biological large molecule metabolite identification

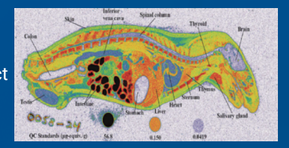
Radiolabeled *In Vivo* PK/ADME Study

▶ Overview

We provide radiolabeled compound synthesis, [^{14}C] and [^{3}H] -labeled compound preclinical *in vivo* ADME (rat/mouse/dog/monkey/mini-pig), and human AME study service. Based on nearly 15 years of experience and more than 500 IND and NDA filings, we provide customized study designs based on compound characteristics and assay needs.

▶ Capabilities

Preclinical Stage	[^{14}C]-labeled compound synthesis	[^{14}C] & [^{3}H]-labeled compound mass balance (excretion studies)	[^{14}C] & [^{3}H]-labeled tissue distribution assays (anatomical method)	Radiolabeled whole blood/plasma PK study	Radiolabeled metabolite profiling and identification
QWBA	Quantitative Whole-body Autoradiography (QWBA) provides a complete and detailed tissue distribution by scanning the whole body of animals, this can be used to predict the drug efficacy and accumulation in the body more comprehensively to support the clinical dosimetry calculation.				
Clinical Stage	[^{14}C]-labeled mass balance	Radiolabeled whole blood/plasma PK study	Radiolabeled metabolite profiling and identification		



▶ Advanced Instruments and Equipment


Cryostat Microtome


Typhoon RGB Imager


Liquid Scintillation Counter


β-counter Solid Scintillation Counter


β-RAM Online Radioactivity Detector

Bruker-400 1H NMR

Non-GLP Bioanalysis

▶ Overview

With an experienced professional analysis team, advanced analytical instruments, whole-process electronic management, and reliable quality control systems, we continuously empower our customers with high-efficiency and high-quality bioanalytical services from screening to clinical. We provide high-quality customized services for the specific needs of customers in large and small molecule drugs, biomarkers, immunogenicity, and cell-based assays.

▶ Capabilities

Multiple Molecular Types

- Small molecules: Fatty acids, chiral compounds, macrolides, metal-containing compounds, PROTACs, siRNAs, ASOs.
- Macromolecule biopharmaceuticals: peptides, proteins, antibodies, glycans, ADCs, AOCs, nucleic acids.
- Drug carriers: AAVs, LNPs, liposomes, polymers, DNA nanostructures.
- Biomarkers: amino acids and neurotransmitters, bile acids, vitamins, hormones, glucose metabolism, lipids, tricarboxylic acid cycle.

100+ Biological Matrices and Micro Sample Bioanalysis

- Various conventional soft and hard tissues
- Cerebrospinal fluid, microdialysis, PBMC, ophthalmic tissue, etc.
- Dry blood/plasma spots, capillary sampling, and VAMS (volumetric absorptive microsampling),etc.

▶ Bioanalytical Instrument Platform

Mass Spectrometer

Waters Vion™ QTof

Thermo Orbitrap Eclipse Tribrid/QE Plus/QE HF

Sciex Triple Quad™ 7500+

PE NexION 2000

Ligand Binding

MESO QuickPlex SQ 120

Molecular Devices SpectraMax M5e

BD LSRFortessa™ X-20

Nucleic Acid Detection qPCR

QIAcube HT

QuantStudio™ 7 Flex Real-Time PCR System

QIAgility

Full Automation, High-throughput

Apricot Designs Dual Arm

High-throughput intelligent delivery system (Night Watcher)

Compound Management & Import and Export Support

▶ Compound Management

Integrated automatic storage devices with compound management systems are used to provide secure and accurate services.

Storage	Metage	Separation and Preparation
▪ 1,000,000+ storage capacity, supporting multiple storage conditions. ▪ Based on robotic arms and intelligent algorithms for positioning, compound automatic access.	▪ Mosaic system is integrated with high-precision scales for real-time transmission of weighing data.	▪ Mosaic interfaces with Hamilton automatic workstation for automatic calculation, preparation, and separation. ▪ Precise calculations and real-time data synchronization.

Full Life-Cycle Management

▶ Import and Export Support

DMPK has established a comprehensive import and export service platform based on years of practical experience. Every year, we help global customers complete thousands of import and export operations, including the import of 100+ special items. Our professionals provide one-on-one assistance, promoting the smooth progress of projects.

Simplified Import & Export Process

Assist with Customs Documentation

Assist with Permits Handling