

Non-Clinical Services: Pharmacokinetic Study

Full-scale ADME, PK and TK studies for more than 100 new drugs have been successfully completed in areas of ophthalmic, chiral, prodrug with special formulations and various delivery routes.



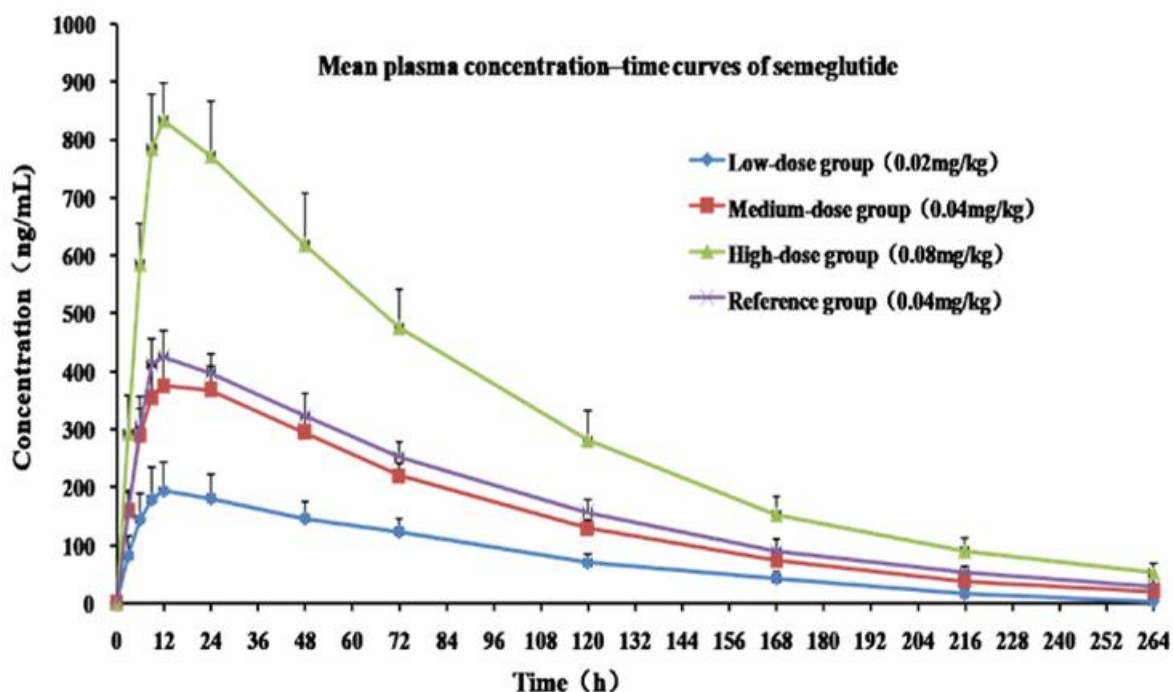
In vitro ADME study

- Hepatic microsomes / hepatocytes / hepatic S9 metabolic stability and metabolite identification studies (human, monkey, canine, rat, mouse)
- Metabolic phenotyping studies (chemical inhibition and recombinant enzyme metabolism)
- CYP enzyme inhibition / induction studies
- Plasma protein binding rate
- Caco-2 permeability assay
- Melanin binding assay
- In vitro transdermal absorption study

In vivo ADME study

- Absorption and blood concentration-time curve
- Tissue distribution
- Metabolite identification and quantitative analysis

- Excretion
- Bioequivalence studies
- Drug interaction studies
- Blood brain barrier (cerebrospinal fluid) permeability



Toxicokinetic Study

- TK in single dose toxicity studies
- TK in repeated dose toxicity studies
- TK in genotoxicity studies
- TK in reproductive toxicity studies
- TK in carcinogenicity (oncogenicity) studies
- Biodistribution studies

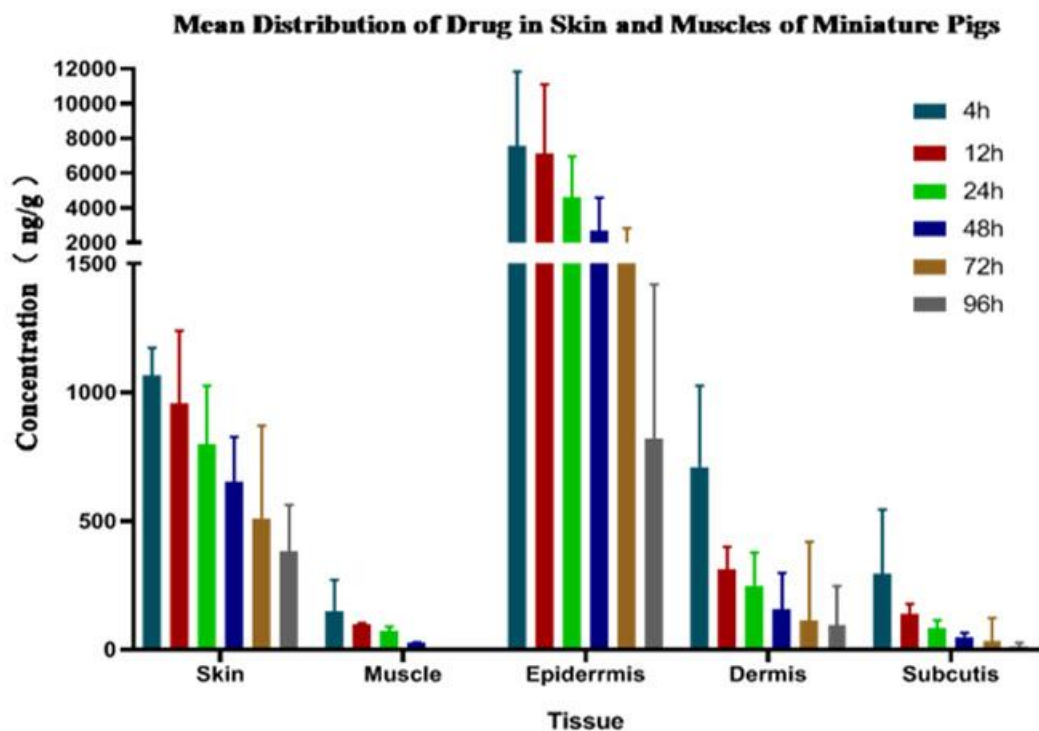
Project Experience

We have conducted PK research and bioanalytical studies for over 100 new drug candidates and developed validated detection methods for more than 200 molecules. All projects have

successfully passed regulatory review, demonstrating our robust technical capabilities and compliance with international standards.

Our successes include the following:

- ✓ Full-scale ADME and TK studies of innovative drugs from early drug screening to new drug submission
- ✓ Pharmacokinetic and toxicokinetic studies of ophthalmic drugs / chiral drugs / prodrugs
- ✓ Pharmacokinetic studies of special formulations (micelles, liposomes, microspheres)
- ✓ Pharmacokinetic studies of transdermal / inhalation / mucosal / joint cavity / nasal drug delivery formulations
- ✓ Bioanalytical determination of endogenous substances, ultra-low drug concentration analysis, multi-analyte analysis, complex matrix sample analysis



Featured Studies:**(1) Ophthalmic drug PK study**

We have established advanced platform technologies for ocular tissue isolation, in vivo aqueous and vitreous sampling, and localized ocular drug delivery (including subconjunctival capsules, intravitreal injection, anterior chamber injection, and vitreous implantation). In addition, we developed robust ocular tissue homogenization and analytical methods and successfully completed PK studies for more than 10 innovative ophthalmic drugs.

(2) Transdermal drug PK study

- **Whole-body exposure PK study:** Measurement of systemic exposure by detecting drug levels in blood
- **Topical skin exposure PK study:** Layer-specific assessment of drug distribution, with skin separated into epidermis, dermis, subcutaneous tissue, and subcutaneous muscle for exposure testing

(3) PK study of dynamic inhalation of oral and nasal exposure

Plasma concentration–time profiles and tissue distribution studies of multiple drugs were conducted using a dynamic oronasal inhalation exposure system. Because the inhaled volume delivered through oral and nasal routes in animals is inherently limited, bioanalytical methods with high sensitivity are essential to ensure accurate detection of drug levels in biological samples.

(4) PK/TK study of polypeptide drug

We have completed PK/TK studies using LC-MS/MS bioanalysis for many polypeptide drugs including semaglutide, liraglutide, Integritin, Insulin degludec, Insulin aspart, and leuprolide—all with successful regulatory review outcomes.

(5) PK/TK study of natural product

We conduct comprehensive studies on natural products, including metabolite identification in vivo and in vitro, toxicogenesis evaluation, and multi-component herbal formulation analysis.

(6) Bioanalysis of chiral drugs

We have completed 20+ bioanalyses project of chiral drugs by UPCC-MS/MS.



5776 Stoneridge Mall Road, Pleasanton, CA
95488 USA
+01 (925) 297-5123
info@hilandbiosciences.com