Model Name
Pharmacokinetics (PK) Study, Plasma, In-life and Bioanalysis, Mouse

Item Number
515555

Introduction
This study is to bring early stage pharmacokinetic (PK) data for evaluating new molecular entity and is prerequisite for interpreting preclinical efficacy and toxicology results.

Procedure Summary
Test compound is administered i.v. (2 mg/kg) or p.o. (10 mg/kg) to groups of 3 animals. At designed time points post test compound administration, the animals are euthanized and plasma samples are obtained and stored at -70°C. Plasma samples are sent back to the sponsor, or are processed using the extraction procedure and then analyzed using the HPLC MS/MS or HPLC MS method.

Suggested Testing
• n=3/time point or 3 in total
• A dose of 2 mg/kg for i.v. and 10 mg/kg for p.o.
• Dosing volume at 5 mL/kg for i.v and 10 mL/kg for p.o.
• Sampling time points: 3, 10, 30, 60, 120, 240, 360 and 1,440 minutes post i.v. dosing or 10, 30, 60, 120, 240, 360, 480 and 1,440 minutes post p.o. dosing

Turnaround Time(s)
• Acute Assay: In-Life completion in 2-4 weeks from sample receipt
• For Subacute Assays: 6 weeks to 3 months

Literature
Prof. Dr. med, Dr. s.c. H, Springer-Verlag Berlin Heidelberg, p.728-731, 1997

Related Assay(s)  (Item # - Assay Name - Species)
509500 - Behavior, Modified Irwin Screen, Safety non-GLP - Mouse
560000 - Maximum Tolerated Dose, Autonomic Signs - Mouse
515580 - Pharmacokinetics (PK) Study, BBB, In-life and Bioanalysis - Mouse
515570 - Pharmacokinetics (PK) Study, BBB, In-life - Mouse
515550 - Pharmacokinetics (PK) Study, Plasma, In-life - Mouse

Modified Protocols
We will readily accommodate client-specified alterations.

Laboratory
These assays are performed at our AAALAC accredited laboratory in Taipei.

Animal Welfare
All aspects of this work is performed in general accordance with the Guide for the Care and Use of laboratory animals (National Academy Press, Washington, DC, 2011). The study protocol was approved by the Pharmacology Discovery Services IACUC and is performed with the oversight of veterinarians to assure the humane treatment of laboratory animals.

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