AURIGENE
PHARMACEUTICAL SERVICES

Case Study

Pharmacokinetic (PK) study of a compound following single dose intravenous and oral administration to female beagle dogs in a crossover design.

Objective:

In order to understand the PK properties of a compound and study its effect on animal (dog) model:

- Studying PK properties of the compound
- Checking the clearance and bioavailability of the compound
- Assessing the PK properties to understand if the compound can be used for the clinical trials in humans.

Study Design:

- Species/ Gender: Non-naïve beagle dog/female
- Study design: Discrete or crossover with 7 days wash out interval; multiple time points and varying concentrations.
- The compound was injected through cephalic vein into the plasma; via intravenous or oral route.
- Concentration of test article (and/or other analytes) in plasma estimated using a fit-for-purpose bioanalytical methods using LC-MS/MS

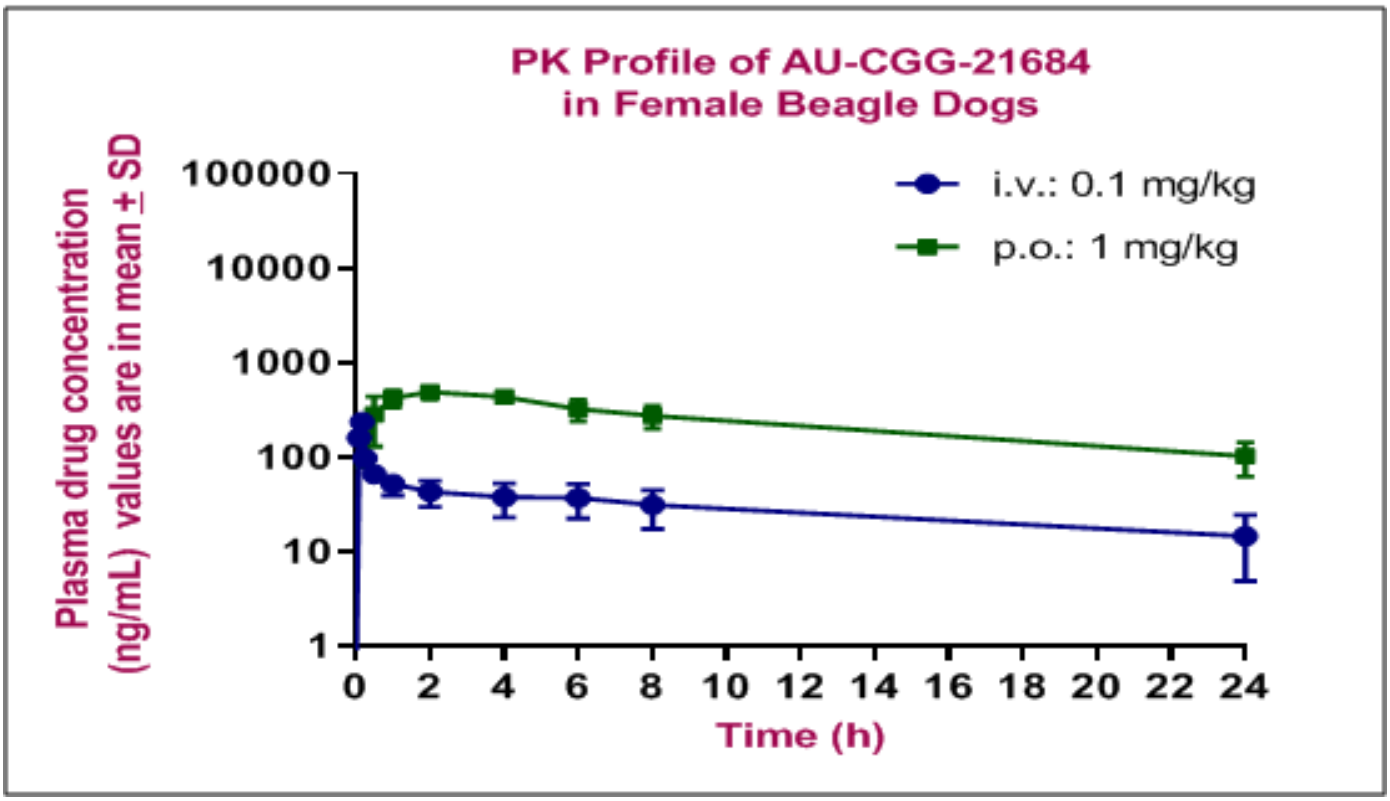
Aurigene solution:

- PK report with study details: individual & mean time vs. concentration profile was plotted, PK parameters were calculated
- No test material related observations were noted.
- After intravenous administration at 0.1 mg/kg, the compound showed low volume of distribution and moderate systemic clearance. After oral administration at 1 mg/kg, the compound showed high oral plasma exposure.
- Observed bioavailability: 87%

Outcomes:

High bioavailability

High clearance of the compound



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