



BIOANALYTICS

AURIGON – YOUR CONTRACT RESEARCH PARTNER

BIOANALYTICS

WE OFFER YOU FULL SUPPORT FOR NON-CLINICAL AND CLINICAL STUDIES

Bioanalysis (determination of substance concentration in biological samples) is an essential element of the drug development process in the pharmaceutical industry. The quantitative measurement of the active compound and/or its metabolite(s) provides data for pharmacokinetic/toxicokinetic evaluation in order to assess systemic exposure.

The data are used – among other things – in the interpretation of toxicology findings and in assessing their relevance in terms of clinical safety issues.

Validation in accordance with GLP requirements is carried out in compliance with the latest FDA, EMA, and ICH guidelines. These requirements apply to all development stages.



We can offer you full support for non-clinical and clinical studies as well as our expertise and a wide range of bioanalytical platforms for small and large molecules:

- Method development / method transfer using the most appropriate techniques: LC-MS/MS, HPLC-UV, ELISA
- Analysis of solutes in various matrices (plasma, tissues, excreta, etc.) of different species
- Pharmacokinetic and toxicokinetic evaluation with acknowledged and validated tools (WinNonLin®)

Reliable support for clinical trials with contribution to Phase I to IV trials with

- Operational manual for sample handling
- Analysis of the active substance and/or its metabolite(s) in human plasma or other matrices for pharmacokinetic and exposure assessments in humans
 - Bioavailability and bioequivalence
 - Food interaction
 - Drug-drug interaction
 - Special patient population studies

Additionally, we are able to support you with our experience in complex methods, difficult-to-analyze solutes and analytically challenging compounds e.g.,

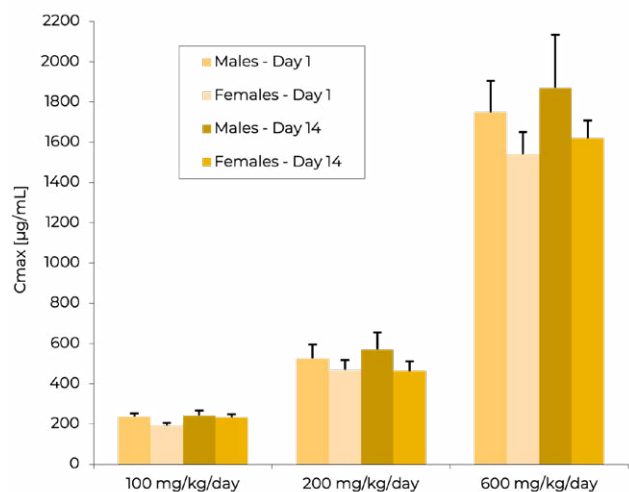
- Amphipathic compounds containing long alkyl chains
- Highly polar or highly basic compounds
- Peptide derivatives with hydrophobic moieties

CONTACT US

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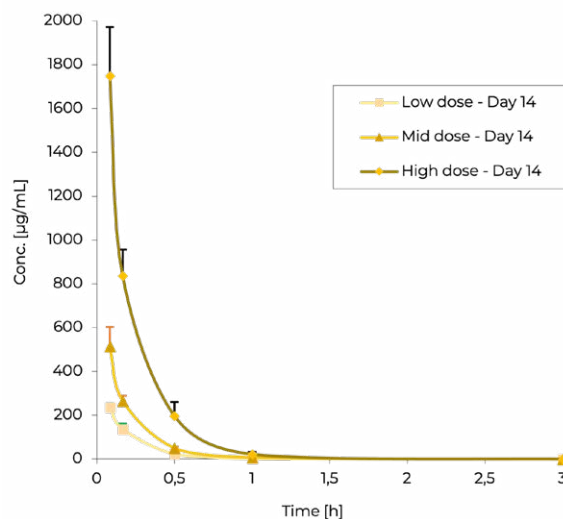
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C_{MAX}

Comparison of the C_{max} values of test item in male and female Wistar rats following bolus intravenous administration.



TOTAL MEAN PLASMA LEVEL CURVES – DAY 14

Comparison of the total mean plasma level curves of test item in Wistar rats following bolus intravenous administration on Day 14.

PRODUCT LIST

BIOANALYTICAL ACTIVITIES

- Bioanalytical method development
- Bioanalytical method validation
- Bioanalytical support of toxicokinetic studies
- Bioanalytical support of clinical trials

PHARMACOKINETIC STUDIES

- Single and multiple dose pharmacokinetic studies
- Bioequivalence studies in animals
- Pharmacokinetic support of pharmacological/toxicity studies
- Calculation and evaluation of pharmacokinetic parameters (WinNonLin®)
- Bioavailability studies
- Providing blank samples for bioanalytical activities

QUALITY CONTROL ACTIVITIES

- Formulation analytical method development
- Formulation analytical method validation
- Formulation analysis of dose formulations in toxicity studies

AVAILABLE PLATFORMS

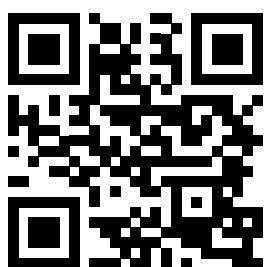
- LC-MS/MS
- HPLC-UV
- Spectrophotometry (ELISA)

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If you need additional information please contact us. We truly hope that the provided information brings you ...

... a wing stroke ahead.



Scan the QR code to get access to our scientific knowledge pool.