GLP-CERTIFIED

QUALITY IS GUARANTEED

- defined management and responsibility
- planned and monitored projects and processes
- traceability and transparency of data
- reliability of results for the authorities
- internationally recognized data standards

Prolytic GmbH

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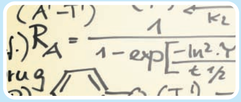
Internet: www.prolytic.de
Business Directors: Dr. Dorothee Krone, Peter Romeis
Local Court Frankfurt am Main
Companies register No.: HRB 56529 • USt.-IdNr.: DE226546121

prolytic GmbH






UNSER UNTERNEHMEN
OUR COMPANY

PROLYTIC is a GLP-certified laboratory with core competences in the fields of bioanalytics and pharmacokinetics. Our highly-qualified employees ensure that our customers receive reliable, excellent analytical work on the highest professional level as well as competent service at all times.

»WE ARE EXPERTS IN BIOANALYTICS AND PHARMACOKINETICS«

OUR AIM is to provide our expertise and support to our customers at different stages of drug testing and development, as well as throughout the planning, evaluation and documentation of animal and human studies. Many years of experience and a dedicated dynamic team make us the perfect partner for quality-conscious clients, not only in the pharmaceutical industry.

PROLYTIC SERVICES

Method development

Sample Processing
- Liquid/liquid extraction (plasma, urine, tissue or other matrices)
- Solid phase extraction (plasma, urine or other matrices)

Analytical Methods
- HPLC
  - UV/VIS detection
  - Fluorescence detection
  - Electrochemical detection (coulometric, amperiometric)
- HPLC - MS/MS

Immunological Methods
- EIA / ELISA / LIA / RIA

Method validation according to FDA / EMEA regulations for medicinal and veterinary medicinal products

- Intra und inter assay accuracy and precision
- Storage stability at different temperatures and time-periods (long term and short term stability)
- Freeze/thaw stability
- Sensitivity (LOD, LOQ)
- Selectivity
- Recovery
- Roughness

Drug analysis in biological matrices

Qualitative and/or quantitative drug and metabolite analysis (blood, plasma, urine, tissue or other matrices)

In vitro investigations

Determination of …
- Distribution coefficient
- Protein binding (ultra filtration method or equilibrium dialysis)
- Antibodies (following chronic treatment)

Stability investigations in …
- Solutions (influence of variables such as salts, concentrations, pH values)
- Liver homogenate
- Intestine homogenate
- Microsome suspension
- Hepatocyte suspension
- Plasma and blood
- Enzyme solution (CYP P450 and various enzymes)

Pharmaceutical analytics

Determination of …
- Content
- Purity
- Molecular weight
- Maximum solubility in different solutions

Pharmacokinetic evaluations

- Non-compartmental and compartmental evaluations
- PK/PD Modelling
- Optimization of dosing schedules

Reporting

- Validation report
- Analytical report
- Pharmacokinetic report
- Toxicokinetic report

Consulting

- Study planning within preclinical and clinical range
- Project preparation and project coordination
- Drug development

Expert reports

On analytics, preclinical and clinical pharmacokinetics:
- IND/CTX for first man studies
- Expert report for FDA / EMEA
- IDB (Investigational Drug Brochure)

PROLYTIC EQUIPMENT

HPLC

Agilent Technologies 1100 / 1200
Thermo Separation Products
Shimadzu

HPLC-MS/MS

TSQ 7000 (Thermo Finnigan)
API 4000 (Applied Biosystems)

Immunological test systems

γ-Counter
Luminescence-Microtiter-Reader
ELISA-Microtiter-Reader

PROLYTIC SUPPORT

Together with our partners in the fields of animal and clinical studies, biometrics, physicochemical analytics and more, we provide full kinetic and toxicological studies.

If you have any requests in the fields of…

- Clinical development
- Preclinical development
- Toxicological development
- Galenics
- Veterinary drug development
- Environmental analytics

…please contact us!