

# 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

Alt Fechenheim 34 • D-60386 Frankfurt am Main

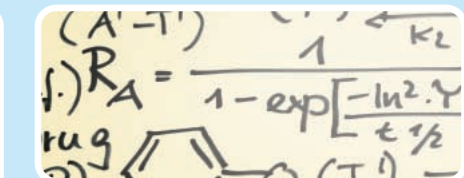
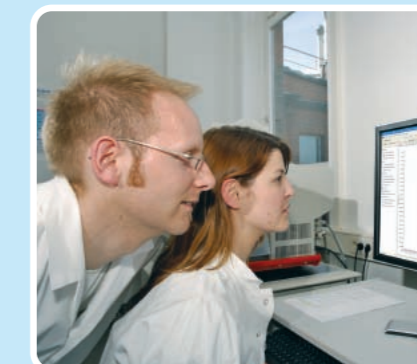
Phone: +49 (0)69 4109 2534 • Fax: +49 (0)69 4269 4784

Internet: [www.prolytic.de](http://www.prolytic.de)

Business Directors: Dr. Dorothee Krone, Peter Romeis

Local Court Frankfurt am Main

Companies register No.: HRB 56529 • USt.-IdNr.: DE226546121



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.

**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, amperometric)  
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)

## 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

$\gamma$ -Counter  
Luminescence-Microtiter-Reader  
ELISA-Microtiter-Reader



»WE ARE EXPERTS IN BIOANALYTICS AND PHARMACOKINETICS«

### 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 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!

