

Medicinal Products for Human Use

Your Project

Do you need an environmental risk assessment (ERA), e.g. for a new application in Europe?

Our GLP-studies comply in any case with the legal requirements such as

- Directive 2001/83/EC
- EMEA/CHMP/SWP/4447/00.

Our Expertise

You can fully rely on our quality services and our commitment to keep promised timelines.

Our competence comprises

Phase II

- TIER A
- TIER B
- specifically designed higher TIER

laboratory evaluations. We are capable to fulfil all your specific needs and perform all studies at highest level of quality.

Due to our extensive experience with numerous active pharmaceutical ingredients (API) and different formulation types IBACON can support you in selecting the suitable and cost efficient test designs. For specific purposes, tailor-made studies can be established in accordance with international guidelines and authority demands.

Our Support

- **Physical-Chemical Properties**
- **Stability Studies**
- **Analytical Chemistry**
 - Method Development and Validation
 - Residue Analysis, Certificate of Analysis etc.
 - Fully Equipped Analytical Laboratory (LC/MS/MS, HPLC, GC/MS, LSC, TOC etc.)
 - Studies with Radiolabelled Substances
 - Handling of Performance Based Occupational Exposure Limitclassified Substances (PBOEL)
 - Studies with Narcotic Drugs (Permission According to §3 German Narcotics Act)
- **Environmental Fate**
 - Adsorption / Desorption (Soil and Activated Sludge)
 - Ready Biodegradability
 - Aerobic and Anaerobic Transformation in Soil
 - Aerobic and Anaerobic Transformation in Aquatic Sediment Systems
 - Abiotic Degradation (Hydrolysis, Phototransformation)
 - Activated Sludge Respiration Inhibition
 - Bioaccumulation (Fish, Worm, Arthropods)
- **Effects on Biotic Systems / Ecotoxicology**
 - Aquatic Organisms (Algae, Daphnia, Fish etc.)
 - Endocrine Disruption
 - Sediment Dwelling Organisms (*Chironomus Riparius* etc.)
 - Terrestrial Plants
 - Soil Macroorganisms (Earthworm, Collembola, etc.)
 - Soil Microorganisms: Nitrogen Transformation

Our Quality

Our study designs comply with the requirements of official guidelines of organisations such as

- EU
- OPPTS
- EMEA
- OECD
- EPPO
- METI
- ISO
- IOBC
- SETAC

All test procedures fulfil the internationally recognised quality standards of

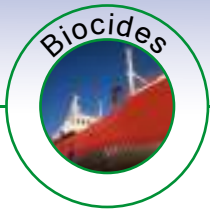
- OECD GLP
- US EPA
- Japanese MAFF

This approach ensures that our study reports can be used for your registration projects - worldwide.

Therefore:

**Test our competence
and let us test your product!**

For more information, please find the contact details of our sales-team on the next page.



Your Partner

for...

- Ecotoxicology
- Environmental Fate
- Physical-Chemical Properties
- Analytical Chemistry

**How You
 Can Benefit
 from IBACON**



- Approved expertise in contract research
- Independent, flexible and customer-oriented
- In-depth experience - more than 1000 GLP studies per year
- Highly qualified and dedicated staff
- Long-term expert knowledge in test development and scientific research
- Excellent network of partner laboratories and consultants

Your Contact



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GLP-STUDIES

Physical-Chemical
 Properties

Environmental Fate

Ecotoxicology
 Effects on Biotic Systems

Analytical Chemistry

Project Management

