



oroxcell
biopharmaceutical
partner
for life sciences
industries

Pharmacokinetic studies

Pharmacokinetic studies

1. Authorization and ethics policy

- Respect of legislation and quality
- Respect of a strict ethics policy

2. Pharmacokinetic studies

- Pharmacokinetic studies using laboratory models
- Other support studies
- Surgery applications



The respect of legislation and quality

Legal authorizations

- Government authorization for laboratory models housing and handling
- All PK specialists have experimental authorization (Level II or I)
- Government authorization for use of radiolabeled compounds (^3H , ^{14}C and ^{45}Ca)
- Transport, storage and waste disposal of biological and radioactive materials are in accordance with the legislation
- Liability insurances

High quality service

- Highly skilled staff
- Experimentation building at the cutting edge of the state of the art
- Experimental environment control: temperature, relative humidity, air pressure

The respect of a strict ethics policy

Ethics

- Animal Ethics Charter
- Animal Ethics Committee

3R Principles

- **Replacement**: Use of alternative methods such as cell cultures, human volunteers and computer modelling instead of animals to achieve a scientific aim. **Reconstructed human skin and eye corneal epithelium models are available.**
- **Refinement**: Use of methods that alleviate or minimize potential pain, suffering or distress, and that enhance welfare for those animals that cannot be replaced.
- **Reduction**: Use of methods that enable researchers to obtain comparable amounts of information from fewer animals, or more information from the same number of animals.

Respect of the environment

Pharmacokinetic studies using laboratory models

Administration

- Mice, rats, hamsters, mini-pigs, dogs
- Intravenous, subcutaneous, oral, intraperitoneal, intramuscular, intradermic and intrarectal routes
- Possibility of administering radiolabeled compounds

Sampling

- Blood: exposure and response time course
- Tissues/organs: for histology analysis or determination of CYP450 activity

Dosing

- Bioanalysis and data treatment
- Determination of PK parameters (WinNonlin®)

Other support studies

Pharmacokinetic studies in human healthy volunteers

- Gastro-intestinal perfusion under fed or fasted conditions with intestinal and blood sampling
- Phase I PK studies

Support for toxicological studies

- Toxicokinetic studies
- Repeated dose

Support for induction / inhibition studies

- Determination of CYP450 activity

Mass Balance

Surgery applications

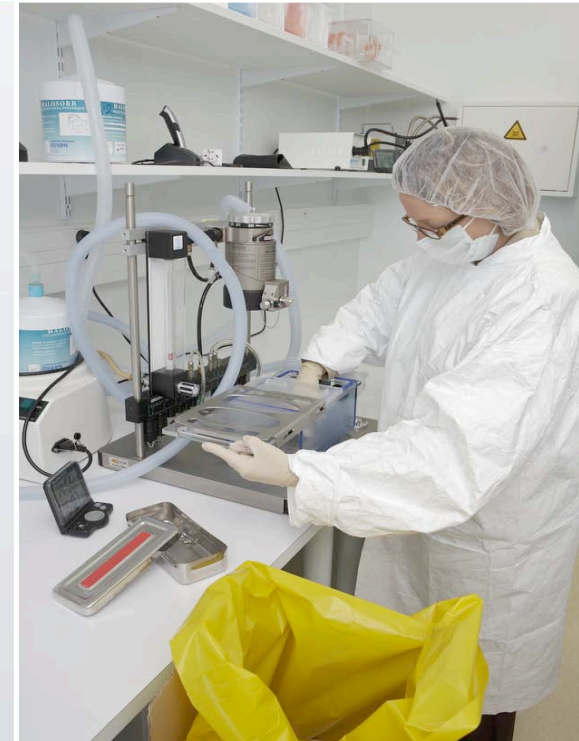
Catheterisation in rat

- Jugular vein
- Femoral vein
- Mesenteric vein

In-situ intestinal perfusion

- Pre-systemic and systemic blood sampling
- Gastro-intestinal sampling

Ussing chambers





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