

## Acute toxicity study in rodents

**Background:** Acute toxicity studies are designed to study adverse effects after administration of a single dose or multiple doses of a test substance given during a period not exceeding 24 hours. Acute toxicity studies in animals are necessary for early stage preclinical molecules to evaluate the perspectives of their further development. The information obtained from such studies is also useful in choosing doses for efficacy studies, providing preliminary identification of the target organs for drug-specific toxicity, and, in some cases, revealing delayed toxicity. Acute toxicity studies in animals are often conducted using two routes of drug administration - the route intended for human therapy as well as intravenous administration. We can run acute toxicology studies of various designs in mice or rats. We can also provide follow-up studies, such as toxicokinetics or histopathology if requested.

**Service Details:** In a simple exemplary study which can be run in preparation for an animal efficacy study, we dose three groups of 10 mice each (5 male/5 female) with 3 selected doses of the test article by oral gavage. A smaller vehicle dosing group (4-6 animals) is typically included. Animals are observed for mortality, signs of gross toxicity and behavioral changes at 30 min, 2, 4 and 6 hours after the administration and thereafter daily for a period of 14 consecutive days. Body weight is recorded prior to dosing, and on days 7 and 14. Gross necropsy is performed on all animals at the terminal sacrifice. Specific tests, such as hematological, urinary and clinical chemistry analysis, in combination with more definitive toxic or gross pathology endpoints are also available on request.

**Deliverable:** A detailed study report including full description of study design, all experimental data and discussion.

**Sample Submission:** Dry compound or compound in a pre-made animal dosing formulation. Amounts depend on the dosing levels and the design of the study.