PHARM.D • YEAR 3

Advanced Pharmacology

CHAPTER 5

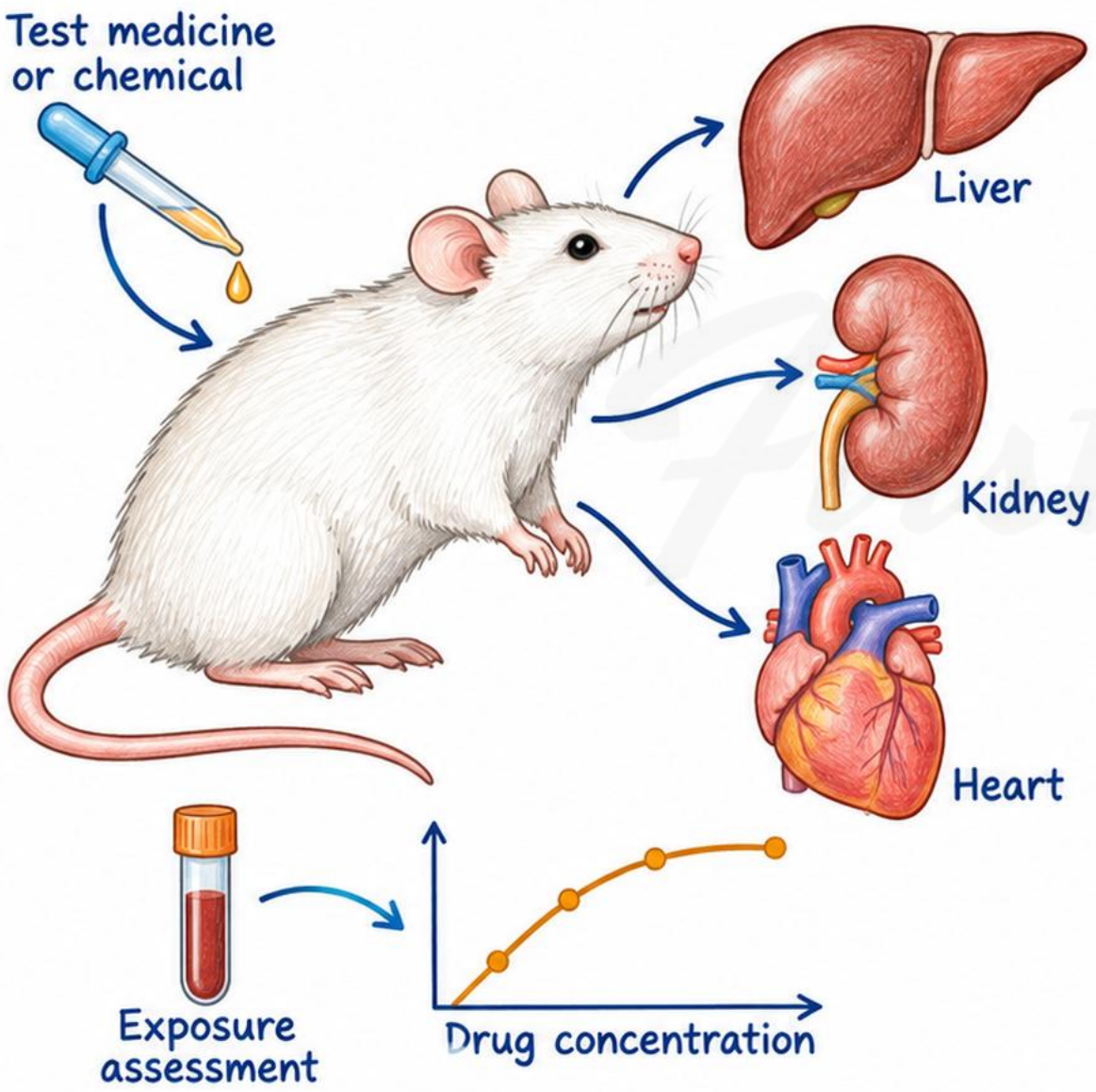
Principles of Animal Toxicology

PPT CHAPTER COVER



DOCTOR OF PHARMACY

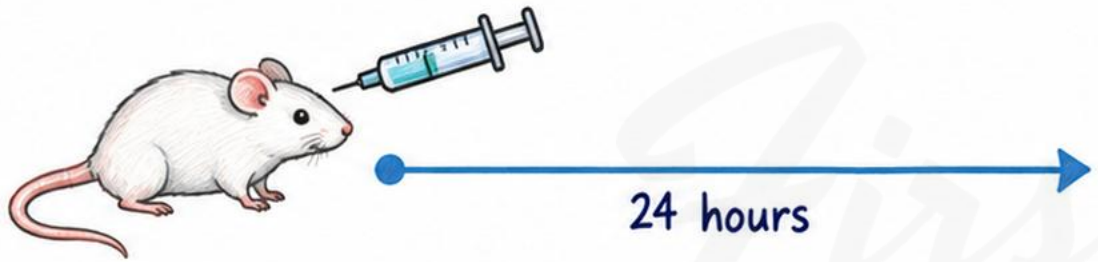
Animal toxicology: what the study asks



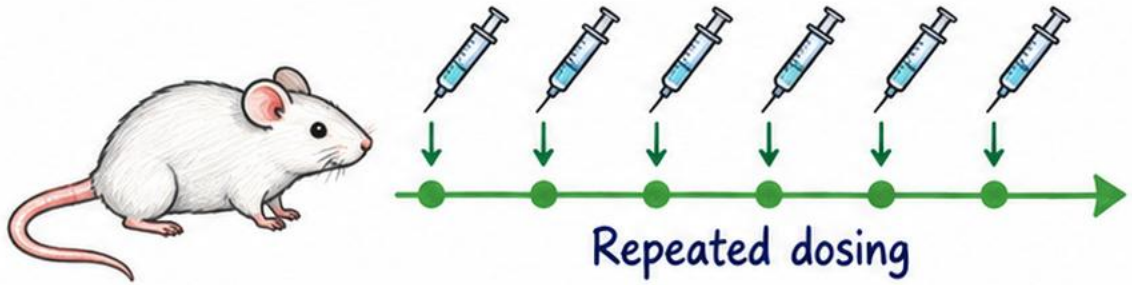
- Animal toxicology studies the harmful effects of medicines and chemicals under defined exposure conditions.
- The central questions concern severity, target organs, dose-response relationships, time course and reversibility.
- Findings help plan further studies, human starting-dose assessment and clinical monitoring; they do not prove complete human safety.
- A hazard is the potential to cause harm. Risk also depends on exposure and the circumstances of use.
- Species, route, formulation, duration and measured drug concentrations affect interpretation. A useful study connects observations to exposure and pathology rather than treating one numerical endpoint as the entire safety profile.

Acute, subacute, subchronic and chronic

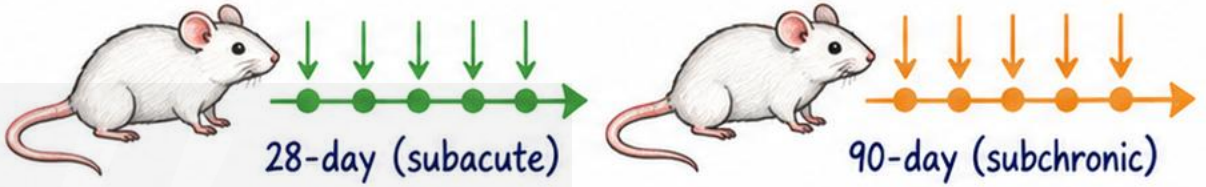
1. Acute studies examine a single exposure or several doses within a short defined period, commonly within 24 hours.



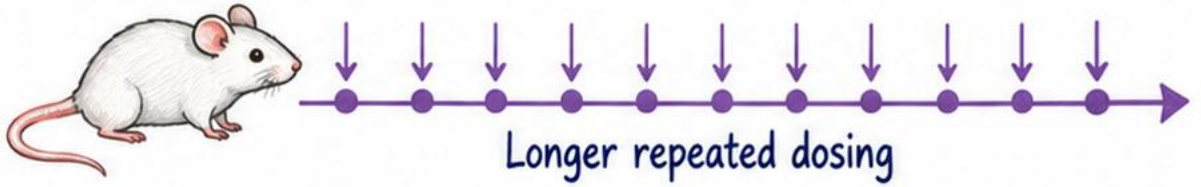
2. Repeated-dose studies assess effects that develop or accumulate during continued exposure.



3. Subacute and subchronic are not identical terms: common guideline models use 28-day and 90-day dosing respectively.



4. Chronic studies extend assessment over longer periods, selected for the development program and intended clinical use.



5. Study duration alone does not establish every endpoint. Carcinogenicity, genotoxicity and reproductive toxicity often require separate tailored studies; a routine chronic study does not automatically answer all three questions.

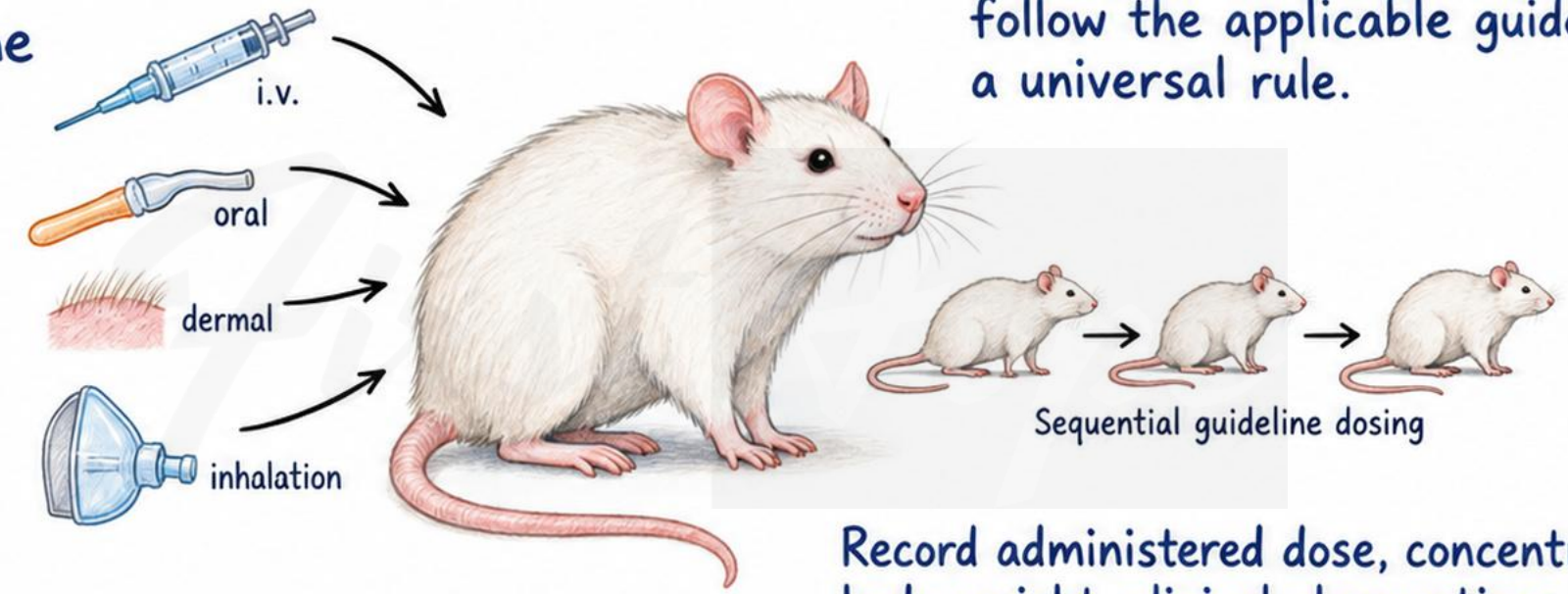
Acute toxicity: objectives and limits



- Acute studies characterize short-term toxic potential, clinical signs and delayed effects after a brief exposure.
- They can identify target-organ concerns and help select doses for subsequent investigations.
- Hazard classification may use mortality information or other guideline-defined evidence; calculating an exact LD50 is not mandatory in every modern acute protocol.
- Observation often continues for approximately 14 days, with humane endpoints and care specified in advance.
- A negative acute result does not exclude cumulative, reproductive or delayed toxicity. Route and species differences also limit direct prediction of a human overdose, so clinical poison management cannot be inferred from an animal result alone.

Acute study design and animal welfare

Choose a scientifically justified species, route, formulation and exposure plan relevant to the question.



Animals should have defined health status, acclimatization and controlled housing; group size and sex selection follow the applicable guideline, not a universal rule.

Modern fixed-dose, acute-toxic-class and up-and-down approaches can reduce animal use compared with large classical lethality studies.

Record administered dose, concentration, body weight, clinical observations and timing accurately.

Prespecified humane endpoints, veterinary oversight and ethical approval are essential. Replacement, reduction and refinement remain priorities even when a regulated animal study is required; death is not a desirable default observation endpoint.

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