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# Repeated-Dose Toxicity Study Records

Practical 14 - Pharmacology simulation and data practical

## Aim

To review an approved toxicity-study report without performing animal exposure.

## Principle

Toxicity interpretation connects exposure, observations, pathology, design and uncertainty. Acute and repeated-dose studies answer different questions; no observed effect at one exposure is not proof of universal safety.

## Materials and Requirements

- Supplied anonymised teaching traces or datasets
- Study design, controls, units and instrument calibration records
- Ethics and welfare records where the original study involved animals
- Approved method or teaching-data pack and a dated record sheet

## Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the study question, experimental unit, controls and original approval or data provenance. This notes exercise uses records or simulation; it is not authorisation to perform animal procedures.
3. Identify oral, dermal or repeated-dose scope and the relevant current guideline and ethics record.
4. Review group rationale, exposure confirmation, humane endpoints, clinical observations and follow-up completeness.
5. Assess body-mass, clinical-pathology and histopathology evidence appropriate to the study and route.
6. Prepare a dose/exposure-response summary, distinguishing observed findings, statistical significance, biological relevance and missing evidence.
7. Summarise independent experimental units, variability, exclusions and limitations; retain all original traces and data.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

## Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

| Group / preparation | Condition / time | Raw endpoint | Derived result / interpretation |
|---|---|---|---|
| Vehicle / baseline | Record | Enter | Evaluate |
| Reference condition | Record | Enter | Evaluate |
| Test condition | Record | Enter | Calculate |

## Calculations

- Body-mass change (%) = (later mass - baseline mass)/baseline mass x 100

### Worked Example

Illustrative baseline 200 g and later mass 190 g give -5.0% change. A toxicity conclusion also needs controls, timing, intake, exposure and other clinical evidence.

### Assigned study scope

• Review the selected repeated-dose guideline, such as the applicable OECD 407 scope, with duration, recovery groups and clinical/pathology endpoints. A NOAEL requires the complete study and adverse-effect judgement.

## Result and Interpretation

• Write an evidence-limited hazard summary and explain why human safe exposure cannot be inferred from a single teaching study.

## Precautions

• Apply replacement, reduction and refinement to study planning.
• Any live work requires the current institutional and Indian CCSEA/IAEC framework, trained staff and an approved protocol.
• Do not convert a teaching calculation into an unapproved animal or patient procedure.

## Viva Questions and Answers

### Does no observed effect mean no risk?

It is limited by the tested design, exposure and detection capability.

### Why confirm exposure?

An apparent negative result may reflect inadequate exposure.

### Why assess biological relevance?

A statistical difference is not automatically an adverse effect.

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