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Everted-Ileum Drug-Absorption Data

Practical 11 - Pharmacology simulation and data practical

Aim

To analyse supplied intestinal-transport data from an everted-ileum model.

Principle

Ex-vivo transport depends on tissue area, orientation, viability, donor concentration, volume and time. Apparent permeability is model-specific and is not a direct measurement of human oral bioavailability.

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. Use supplied records only and review tissue provenance, welfare approval and experimental viability controls without tissue preparation.
4. Reconcile donor and receiver concentrations, chamber volumes, time, area and sampling/replacement corrections.
5. Estimate the linear receiver amount-versus-time slope and assess mass balance and nonspecific loss.
6. Calculate apparent permeability only when the stated sink, concentration and area assumptions are supported.
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

- Papp = (dQ/dt)/(A x Cdonor), using consistent amount, time, area and concentration units

Worked Example

Illustrative dQ/dt = 0.020 microgram/s, area = 2.0 cm^2 and donor = 10 micrograms/cm^3 give Papp = 0.0010 cm/s.

Correct for sampling and confirm the model assumptions before reporting the estimate.

Result and Interpretation

• Report corrected mass balance, viable interval, Papp and model limitations.

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

Why account for sampling?

Removed receiver drug changes cumulative transported amount.

Why check viability?

Damaged tissue can give misleading transport.

Does Papp equal absolute bioavailability?

Absorption and systemic availability require additional processes and evidence.

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