Pharm.D - Year 4

Biopharmaceutics and Pharmacokinetics

Complete subject manual: 16 practicals and activities. Each chapter includes a student observation or work record.

Use the PDF bookmarks to navigate. The table gives each practical's content-page count; the combined manual has continuous page numbers.

Contents

No.	Practical / activity	Content pages
1	Dissolution Improvement Methods	2
2	Dissolution Comparison of Two Dosage Forms	2
3	Polymorphism and Dissolution	2
4	High and Low Protein Binding	2
5	Protein Binding at Different Concentrations	2
6	Bioavailability from Supplied Animal or Human Data	2
7	Ka Ke Half-life Cmax AUC AUMC and MRT	2
8	Bioavailability from Urinary Excretion	2
9	AUC and Bioequivalence Assessment	2
10	In-vitro Absorption and Permeability	2
11	Bioequivalence Review of Marketed Products	2
12	Inverted Intestine - Supplied Absorption Data	2
13	Protein Binding at Different Contact Times	2
14	Metabolic Pathways and Drug Elimination	2
15	Half-life from Blood and Urine Data	2
16	Renal Clearance Calculation	2

Dissolution Improvement Methods

Experiment 1 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned dissolution improvement methods experiment or teaching dataset.

Principle

Particle size, wetting, solid state and formulation can change dissolution. An improved laboratory curve must be assessed under matched test conditions.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Design the comparison

Choose the assigned control and an authorised particle-size, wetting or formulation modification; state what is held constant.

2. Read the dissolution test

Record apparatus, medium, temperature, agitation and sampling schedule from the prescribed method.

3. Measure

Use calibrated concentration readings and record sampling/replacement corrections.

4. Compare

Plot percentage dissolved over time and assess the observed effect and variation.

Observations and Record

Record component	Value
Preparation / control	_____
Assigned test conditions	_____
Times / concentrations	_____
Corrected percent dissolved	_____
Comparison / limitation	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- Percentage dissolved = corrected dissolved mass / stated drug amount × 100.
- Example: 25 mg in solution from a 50 mg stated amount gives 50%, provided cumulative sampling is accounted for.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

Dissolution Comparison of Two Dosage Forms

Experiment 2 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned dissolution comparison of two dosage forms experiment or teaching dataset.

Principle

Two dissolution curves must use a common suitable method, amount basis and sampling corrections. A visual difference is not automatically an in-vivo bioavailability difference.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Identify products

Record formulation, strength, batch and labelled drug amount.

2. Run or review matched tests

Use the assigned apparatus and medium; preserve replicate measurements rather than averaging prematurely.

3. Correct concentrations

Apply dilution and cumulative removed-drug corrections where samples are replaced.

4. Plot and interpret

Compare time profiles and the assigned comparison metric; discuss method applicability.

Observations and Record

Record component	Value
Product / amount basis	_____
Test conditions / replicates	_____
Concentration and correction	_____
Percent dissolved by time	_____
Comparison metric	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- With equal-volume withdrawal v replaced by blank medium: cumulative mass at time n = Cn V + v × sum of earlier measured concentrations; V is constant vessel volume.
- Example: V = 900 mL, v = 5 mL, C1 = 0.01 and C2 = 0.02 mg/mL. At time 2, mass = 0.02 × 900 + 5 × 0.01 = 18.05 mg.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

Polymorphism and Dissolution

Experiment 3 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned polymorphism and dissolution experiment or teaching dataset.

Principle

Different crystal forms of the same substance can differ in dissolution and stability. A dissolved concentration curve does not by itself identify the crystal form.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Identify assigned forms

Read the supplied form identifiers and solid-state characterisation evidence.

2. Match the comparison

Check particle size, amount, method and other formulation variables that could confound the comparison.

3. Analyse profiles

Plot dissolution for the supplied forms using the same units and sampling corrections.

4. Assess

Relate the observation to the characterisation record without assuming the faster form is always the more stable form.

Observations and Record

Record component	Value
Form code / identity evidence	_____
Particle size / method basis	_____
Time-profile readings	_____
Observed difference	_____
Confounding / stability question	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- Use matched percentage-dissolved values or an assigned rate model; a fitted rate requires its stated validity range.
- Illustration: 40% versus 25% at the same assigned time is a 15 percentage-point difference, not a 15% relative increase.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

High and Low Protein Binding

Experiment 4 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned high and low protein binding experiment or teaching dataset.

Principle

Protein binding is expressed as the bound or unbound fraction on a defined concentration basis. A high bound fraction alone does not determine the total clinical effect.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Read the method

Identify the supplied binding method and total/free concentration measurements.

2. Calculate fractions

Subtract free from total on the same fluid-concentration basis.

3. Compare drugs

Record bound and unbound fractions separately for the assigned high/low-binding examples.

4. Interpret

Discuss concentration, protein and method context rather than ranking efficacy from binding alone.

Observations and Record

Record component	Value
Drug / method	_____
Total and free concentration	_____
Bound concentration	_____
Bound / unbound fraction	_____
Interpretation	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- fu = Cfree/Ctotal; fb = 1 − fu; bound (%) = fb × 100.
- Example: total = 10 and free = 1 microgram/mL give fu = 0.10 and binding = 90%.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

Protein Binding at Different Concentrations

Experiment 5 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned protein binding at different concentrations experiment or teaching dataset.

Principle

Binding can depend on drug and protein concentrations and the applicable affinity/capacity model. Different total concentrations must not be compared without calculating fractions.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Read concentrations

Enter matched total/free readings and the protein basis for each assigned level.

2. Calculate

Compute unbound and bound fractions at each level.

3. Plot

Plot fraction or bound concentration against the chosen concentration basis and inspect the trend.

4. Interpret

Discuss saturable binding only when the pattern and model support it; consider method artefacts.

Observations and Record

Record component	Value
Total concentration levels	_____
Free concentrations	_____
Protein basis	_____
fu / bound fraction	_____
Trend / limitation	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- For each level, fu = Cfree/Ctotal.
- Example: total/free pairs 10/1 and 20/4 micrograms/mL give fu values 0.10 and 0.20; the fractions differ, but the mechanism needs further evidence.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

Bioavailability from Supplied Animal or Human Data

Experiment 6 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned bioavailability from supplied animal or human data experiment or teaching dataset.

Principle

Bioavailability compares systemic exposure on a dose-normalised basis when clearance and the model conditions are appropriately comparable.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Identify routes and datasets

Record administered amounts, route, concentration units and sampling coverage from the supplied study.

2. Calculate exposure

Use the assigned AUC method and assess terminal extrapolation.

3. Normalise

Use dose-normalised exposure and clearly identify an intravenous or other comparator.

4. Report

Distinguish absolute from relative bioavailability and state assumptions and variability.

Observations and Record

Record component	Value
Route / dose	_____
AUC and unit	_____
Comparator	_____
Dose-normalised ratio	_____
Assumptions	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- Absolute F = (AUCextravascular × DoseIV)/(AUCIV × Doseextravascular).
- Example: AUCextravascular = 20, AUCIV = 25, DoseIV = 50 and Doseextravascular = 100 in matched units give F = 0.40, or 40%.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

Ka Ke Half-life Cmax AUC AUMC and MRT

Experiment 7 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned ka ke half-life cmax auc aumc and mrt experiment or teaching dataset.

Principle

A concentration-time profile provides observed and model-derived parameters. Estimating absorption/elimination constants requires an appropriate model and sufficient sampling.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Plot data

Plot concentration versus time and terminal log concentration versus time; identify observed Cmax and its sampling time.

2. Estimate Ke and half-life

Fit an appropriate terminal region and calculate Ke from its natural-log slope.

3. Assess Ka

For the assigned one-compartment first-order oral model, use the prescribed residual or fitting method; do not call the terminal slope Ka without justification.

4. Calculate areas

Use the assigned integration method for AUC and AUMC, showing measured and extrapolated components.

5. Report MRT

Divide AUMC by AUC on the same integration basis and state the route/model interpretation.

Observations and Record

Record component	Value
Observed Cmax / Tmax	_____
Terminal slope / Ke	_____
Ka and model	_____
AUC / AUMC	_____
Half-life / MRT	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- Ke = −slope of ln(C) versus t; t1/2 = ln(2)/Ke. For terminal log10(C), Ke = −2.303 × slope.
- Linear-trapezoidal AUC segment = (Ci + Ci+1)/2 × (ti+1 − ti). AUMC applies the same stated integration approach to tC.
- For monoexponential terminal extrapolation: AUCtail = Clast/Ke; AUMCtail = tlast Clast/Ke + Clast/Ke^2. MRT = AUMC/AUC.
- For the applicable first-order one-compartment oral model: Tmax = ln(Ka/Ke)/(Ka − Ke), when Ka and Ke differ.
- Examples: Ke = 0.2 h−1 gives t1/2 = 3.466 h. AUC = 40 mg·h/L and AUMC = 120 mg·h^2/L give MRT = 3 h. A segment from 0 h/0 mg/L to 1 h/4 mg/L gives 2 mg·h/L.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

Bioavailability from Urinary Excretion

Experiment 8 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned bioavailability from urinary excretion experiment or teaching dataset.

Principle

Cumulative unchanged drug recovered in urine can compare availability only when collection is adequate and the fraction excreted unchanged is comparable under the stated assumptions.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Read collection data

Record interval times, volumes, unchanged-drug concentrations and missing collections.

2. Calculate amount

Multiply each interval concentration by its volume and sum recovered unchanged drug.

3. Normalise

Compare dose-normalised recovery with the specified comparator.

4. Assess limits

Discuss incomplete collection, metabolism and renal changes before attributing a recovery difference to absorption.

Observations and Record

Record component	Value
Interval / volume / concentration	_____
Unchanged amount by interval	_____
Total recovered amount	_____
Dose-normalised comparison	_____
Collection / renal limitations	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- Ae,total = sum of Ci × Vi. Relative F estimate = (Ae,test/Dosetest)/(Ae,reference/Dosereference), under the stated unchanged-excretion assumptions.
- Example: equal doses with recoveries of 30 and 40 mg give a relative estimate of 0.75; incomplete collection would invalidate that conclusion.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

AUC and Bioequivalence Assessment

Experiment 9 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned auc and bioequivalence assessment experiment or teaching dataset.

Principle

AUC measures exposure; bioequivalence assessment evaluates appropriate pharmacokinetic endpoints with a defined study design and statistical method. A simple mean ratio alone does not establish bioequivalence.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Review design

Record test/reference products, study design, sampling and the applicable regulatory/product-specific scope.

2. Calculate exposure

Apply the specified AUC integration and terminal rules consistently.

3. Read statistics

Use supplied log-scale analysis and the 90% confidence intervals for the applicable geometric mean ratios.

4. Conclude

For the standard applicable immediate-release systemic setting, compare the complete relevant intervals with 80.00–125.00%; use the assigned current product-specific criteria where they differ.

Observations and Record

Record component	Value
Products / applicable guidance	_____
AUC / Cmax	_____
Geometric mean ratio	_____
90% confidence interval	_____
Criterion and supported conclusion	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- Geometric mean ratio (%) = exp(mean log(test) − mean log(reference)) × 100, under the assigned statistical model.
- Illustration: a ratio of 100% with a 90% interval of 92–109% is within an assigned 80–125% range; a mean ratio of 100% with an interval of 78–128% is not.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

In-vitro Absorption and Permeability

Experiment 10 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned in-vitro absorption and permeability experiment or teaching dataset.

Principle

An in-vitro transport model measures appearance across a defined barrier. Apparent permeability depends on area, donor concentration and the model assumptions.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Read model data

Record donor/receiver system, barrier area and initial donor concentration supplied.

2. Calculate transport

Obtain receiver-side cumulative amount with sampling correction and identify the applicable linear time region.

3. Calculate Papp

Use dQ/dt, area and donor concentration with consistent units.

4. Assess

Check mass recovery, concentration assumptions and barrier suitability before generalising to in-vivo absorption.

Observations and Record

Record component	Value
Model / area	_____
Donor concentration	_____
Time / receiver amount	_____
Slope / Papp	_____
Recovery and limitation	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- Papp = (dQ/dt)/(A × C0). If dQ/dt is micrograms/s, A cm^2 and C0 micrograms/cm^3, Papp is cm/s.
- Example: 0.01 microgram/s divided by (1 cm^2 × 100 micrograms/cm^3) gives 0.0001 cm/s.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

Bioequivalence Review of Marketed Products

Experiment 11 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned bioequivalence review of marketed products experiment or teaching dataset.

Principle

A marketed-product comparison must distinguish dissolution, a pharmacokinetic comparison and a formal bioequivalence conclusion. The evidence needed depends on the product and permitted study pathway.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Identify products

Record dosage form, strength, batch and comparator status from the assigned records.

2. Map evidence

Separate pharmaceutical quality, dissolution and supplied pharmacokinetic/statistical evidence.

3. Evaluate the comparison

Check method suitability, design and current product-specific criteria; do not infer BE from a similar dissolution graph alone.

4. Report

State what the supplied evidence supports and which required evidence is missing.

Observations and Record

Record component	Value
Product / comparator	_____
Quality and dissolution evidence	_____
PK/statistical evidence	_____
Applicable criterion	_____
Supported claim / gap	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- If an assigned dissolution comparison uses f2, apply its validity conditions and prescribed sampling basis before calculating it.
- Illustration: two similar curves may support the assigned in-vitro comparison, while a formal in-vivo BE claim still needs its applicable evidence.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

Inverted Intestine - Supplied Absorption Data

Experiment 12 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned inverted intestine - supplied absorption data experiment or teaching dataset.

Principle

The syllabus model estimates transport across an intestinal preparation. This activity interprets supplied demonstration data; no animal dissection or tissue preparation is performed.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Read the demonstration

Record assigned donor/receiver compartments, timing and model limitations from the diagram.

2. Calculate amounts

Use supplied concentrations and receiver volumes, with the stated sampling correction.

3. Compare transport

Calculate the assigned transport rate or fractional transfer on a common basis.

4. Assess the model

Discuss tissue integrity, recovery and the limitation of extrapolating a prepared-tissue result to a patient.

Observations and Record

Record component	Value
Supplied model code	_____
Concentration / volume / time	_____
Transferred amount	_____
Rate or fraction	_____
Integrity / recovery limitation	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- Transferred amount = concentration × receiver volume. Fraction transferred = transferred amount / initial donor amount.
- Example: 2 micrograms/mL × 5 mL = 10 micrograms; from an initial 100 micrograms this is 10%, before any required correction.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

Protein Binding at Different Contact Times

Experiment 13 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned protein binding at different contact times experiment or teaching dataset.

Principle

A time-dependent binding measurement must be assessed for approach to equilibrium and sample/method effects. An early fraction is not automatically an equilibrium binding fraction.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Read time records

Enter supplied contact times and matched total/free measurements.

2. Calculate fractions

Use the same method and concentration basis for every time point.

3. Plot

Plot unbound/bound fraction against time and assess whether the readings approach a stable region.

4. Interpret

Discuss whether the assigned record supports equilibrium and identify the remaining method limitations.

Observations and Record

Record component	Value
Contact time	_____
Total / free concentration	_____
fu / bound fraction	_____
Plateau assessment	_____
Method limitation	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- Bound fraction = 1 − Cfree/Ctotal.
- Example: constant total 10 with free readings 3, 2 and 2 micrograms/mL gives binding of 70%, 80% and 80%; the apparent plateau needs the stated validity checks.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

Metabolic Pathways and Drug Elimination

Experiment 14 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned metabolic pathways and drug elimination experiment or teaching dataset.

Principle

Elimination includes removal of unchanged drug and formation/removal of metabolites. A concentration decline alone does not identify one metabolic pathway.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Map the supplied pathway

Label parent compound and assigned metabolites and identify the stated transformation classes.

2. Read recovery data

Record parent/metabolite amounts and the collection basis.

3. Assess kinetics

Compare concentration-time and recovery observations using the assigned model.

4. Conclude

Distinguish measured recovery from unmeasured pathways and avoid assuming complete mass balance when the data are incomplete.

Observations and Record

Record component	Value
Parent / metabolite identifiers	_____
Pathway classes	_____
Recovery basis	_____
Measured fraction	_____
Unmeasured or uncertain fraction	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- Measured recovery (%) = sum of correctly equivalent recovered amounts / administered amount × 100; use a common parent-equivalent or molar basis.
- Example: 40% parent-equivalent recovery plus 30% metabolite-equivalent recovery totals 70%; the remaining 30% is unaccounted for in that record.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

Half-life from Blood and Urine Data

Experiment 15 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned half-life from blood and urine data experiment or teaching dataset.

Principle

A terminal blood-concentration slope and urinary unchanged-drug excretion-rate slope can estimate elimination under appropriate assumptions. Urine concentration alone is not an excretion rate.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Blood dataset

Fit the valid terminal ln(concentration)-time region and record its slope.

2. Urine dataset

Calculate interval unchanged amount and excretion rate; assign it to the interval midpoint as the specified method requires.

3. Estimate

Fit the appropriate terminal log-rate region and compare constants with the blood result.

4. Assess differences

Consider collection, model and measurement limitations before attributing a difference to a real biological change.

Observations and Record

Record component	Value
Terminal blood slope	_____
Urine interval amount / duration	_____
Terminal excretion-rate slope	_____
Ke / half-life	_____
Agreement / limitation	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- Interval excretion rate = interval unchanged amount / interval duration. For the appropriate terminal first-order region, Ke = −slope of ln(rate) versus time. t1/2 = 0.693/Ke.
- Example: unchanged amount 4 mg over 2 h gives 2 mg/h. A valid terminal slope of −0.1 h−1 gives a half-life of 6.93 h.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

Renal Clearance Calculation

Experiment 16 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned renal clearance calculation experiment or teaching dataset.

Principle

Renal clearance relates unchanged-drug excretion rate to plasma concentration on a matching time basis. It differs from the total elimination clearance.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Read records

Enter urinary concentration, collection volume/duration and the matching plasma concentration.

2. Calculate urine flow

Divide collection volume by duration using suitable units.

3. Calculate clearance

Divide the unchanged-drug excretion rate by the matched plasma concentration.

4. Assess

Check timing, completeness, units and whether the drug was measured unchanged before interpreting the value.

Observations and Record

Record component	Value
Urine concentration	_____
Collection volume / duration	_____
Plasma concentration / timing	_____
Excretion rate	_____
Renal clearance	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- CLrenal = Curine × urine flow / Cplasma. Concentration units must match.
- Example: Curine = 0.10 mg/mL, flow = 1 mL/min and Cplasma = 0.002 mg/mL give CLrenal = 50 mL/min.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

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