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Semester 6 - Practical Notes

Pharmacology III

Complete Subject Manual

15 practicals and activities. Use the PDF bookmarks to move between practicals. Page numbers restart within each practical; the page counts below exclude the promotion pages.

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Study of Dose Calculations for Experimental Data

Practical 01 | Pharmacology III

Aim

To study Dose Calculations for Experimental Data, and interpret the recorded observations.

Principle

- This exercise is dimensional arithmetic using an instructor-supplied experimental label. A concentration in mass/volume must not be confused with a dose in mass/body mass.
- This exercise uses a software/video simulation or an instructor-provided dataset.
- A response depends on the model, intervention, controls and observation period; comparisons must use the same endpoint.
- Record only supplied observations. Distinguish illustrative or simulated values from results obtained in an actual study.

Materials and Apparatus

- Assigned software/video, prepared teaching records and completed control/test data.
- Assigned pharmacology simulation/video and completed observation dataset.
- Computer, graphing or calculation software and a structured record sheet.

Method

1. Identify the simulated preparation, control group and response being measured.
2. Record the model settings and treatment labels supplied in the exercise.
3. Review the baseline or control trace before comparing the intervention traces.
4. Read the stated response endpoint using the same definition for every group.
5. Tabulate the completed simulation observations and calculate the assigned comparison.
6. Explain the mechanism, control response and any limitation of the model.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Model label	_____
Given dose unit	_____
Given body mass	_____
Required amount	_____
Supplied concentration	_____
Calculated volume	_____

Calculations and Interpretation

- Required amount = given dose per kg × supplied body mass in kg.
- For the stated data exercise: volume = required amount/supplied concentration.
- Convert g to kg before multiplication; these calculations do not select a clinical dose.

Result

Report the supplied simulated response, its defined comparison and the mechanism supported by the model. Label the observations as simulated.

Finding: _____

Conclusion: _____

Precautions

- Keep software units, treatment labels and endpoint definitions consistent.
- Use supplied simulation data and distinguish an illustration from an observed outcome.
- A model demonstrates an experimental principle; it does not establish an individual patient treatment.

Viva Questions

1. Why use a control response?

It separates the intervention effect from baseline variation in the simulated model.

2. Why define the endpoint before comparison?

Changing the endpoint after reviewing results can bias the interpretation.

Study of Mast-Cell Stabilization Activity

Practical 02 | Pharmacology III

Aim

To study Mast-Cell Stabilization Activity, and interpret the recorded observations.

Principle

- The completed teaching images or counts compare intact and degranulated cells. The effect is interpreted relative to the defined challenge and controls.
- This exercise uses a software/video simulation or an instructor-provided dataset.
- A response depends on the model, intervention, controls and observation period; comparisons must use the same endpoint.
- Record only supplied observations. Distinguish illustrative or simulated values from results obtained in an actual study.

Materials and Apparatus

- Assigned software/video, prepared teaching records and completed control/test data.
- Assigned pharmacology simulation/video and completed observation dataset.
- Computer, graphing or calculation software and a structured record sheet.

Method

1. Identify the simulated preparation, control group and response being measured.
2. Record the model settings and treatment labels supplied in the exercise.
3. Review the baseline or control trace before comparing the intervention traces.
4. Read the stated response endpoint using the same definition for every group.
5. Tabulate the completed simulation observations and calculate the assigned comparison.
6. Explain the mechanism, control response and any limitation of the model.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Group	_____
Cells counted	_____
Intact cells	_____
Degranulated cells	_____
Control status	_____

Calculations and Interpretation

- Intact cells (%) = $\text{intact count} / \text{total counted} \times 100$.
- Degranulated cells (%) = $\text{degranulated count} / \text{total counted} \times 100$.
- State the group and denominator used in each comparison.

Result

Report the supplied simulated response, its defined comparison and the mechanism supported by the model. Label the observations as simulated.

Finding: _____

Conclusion: _____

Precautions

- Keep software units, treatment labels and endpoint definitions consistent.
- Use supplied simulation data and distinguish an illustration from an observed outcome.
- A model demonstrates an experimental principle; it does not establish an individual patient treatment.

Viva Questions

1. Why use a control response?

It separates the intervention effect from baseline variation in the simulated model.

2. Why define the endpoint before comparison?

Changing the endpoint after reviewing results can bias the interpretation.

Study of Anti-Ulcer Activity in SHAY and NSAID Models

Practical 03 | Pharmacology III

Aim

To study Anti-Ulcer Activity in SHAY and NSAID Models, and interpret the recorded observations.

Principle

- The two simulations represent different ulcer-related mechanisms. The endpoint may include a defined ulcer score or gastric-fluid measure; model-specific scoring systems are not interchangeable.
- This exercise uses a software/video simulation or an instructor-provided dataset.
- A response depends on the model, intervention, controls and observation period; comparisons must use the same endpoint.
- Record only supplied observations. Distinguish illustrative or simulated values from results obtained in an actual study.

Materials and Apparatus

- Assigned software/video, prepared teaching records and completed control/test data.
- Assigned pharmacology simulation/video and completed observation dataset.
- Computer, graphing or calculation software and a structured record sheet.

Method

1. Identify the simulated preparation, control group and response being measured.
2. Record the model settings and treatment labels supplied in the exercise.
3. Review the baseline or control trace before comparing the intervention traces.
4. Read the stated response endpoint using the same definition for every group.
5. Tabulate the completed simulation observations and calculate the assigned comparison.
6. Explain the mechanism, control response and any limitation of the model.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Model	_____
Control score	_____
Test score	_____
Scoring definition	_____
Supplied gastric measures	_____

Calculations and Interpretation

- For a nonzero control ulcer index: inhibition (%) = (control index - test index)/control index × 100.
- Use the exact scoring definition supplied for each model.

Result

Report the supplied simulated response, its defined comparison and the mechanism supported by the model. Label the observations as simulated.

Finding: _____

Conclusion: _____

Precautions

- Keep software units, treatment labels and endpoint definitions consistent.
- Use supplied simulation data and distinguish an illustration from an observed outcome.
- A model demonstrates an experimental principle; it does not establish an individual patient treatment.

Viva Questions

1. Why use a control response?

It separates the intervention effect from baseline variation in the simulated model.

2. Why define the endpoint before comparison?

Changing the endpoint after reviewing results can bias the interpretation.

Study of Drug Effects on Gastrointestinal Motility

Practical 04 | Pharmacology III

Aim

To study Drug Effects on Gastrointestinal Motility, and interpret the recorded observations.

Principle

- The simulation follows a marker over a defined intestinal length or compares another stated motility endpoint. A fractional transit measure needs both distances.
- This exercise uses a software/video simulation or an instructor-provided dataset.
- A response depends on the model, intervention, controls and observation period; comparisons must use the same endpoint.
- Record only supplied observations. Distinguish illustrative or simulated values from results obtained in an actual study.

Materials and Apparatus

- Assigned software/video, prepared teaching records and completed control/test data.
- Assigned pharmacology simulation/video and completed observation dataset.
- Computer, graphing or calculation software and a structured record sheet.

Method

1. Identify the simulated preparation, control group and response being measured.
2. Record the model settings and treatment labels supplied in the exercise.
3. Review the baseline or control trace before comparing the intervention traces.
4. Read the stated response endpoint using the same definition for every group.
5. Tabulate the completed simulation observations and calculate the assigned comparison.
6. Explain the mechanism, control response and any limitation of the model.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Treatment	_____
Observation interval	_____
Marker distance	_____
Total segment length	_____
Transit measure	_____

Calculations and Interpretation

- $\text{Transit (\%)} = \text{marker distance} / \text{total measured intestinal length} \times 100$.
- Keep the observation interval and model comparable across groups.

Result

Report the supplied simulated response, its defined comparison and the mechanism supported by the model. Label the observations as simulated.

Finding: _____

Conclusion: _____

Precautions

- Keep software units, treatment labels and endpoint definitions consistent.
- Use supplied simulation data and distinguish an illustration from an observed outcome.
- A model demonstrates an experimental principle; it does not establish an individual patient treatment.

Viva Questions

1. Why use a control response?

It separates the intervention effect from baseline variation in the simulated model.

2. Why define the endpoint before comparison?

Changing the endpoint after reviewing results can bias the interpretation.

Study of Agonist and Antagonist Effects on Guinea Pig Ileum

Practical 05 | Pharmacology III

Aim

To study Agonist and Antagonist Effects on Guinea Pig Ileum, and interpret the recorded observations.

Principle

- Agonists produce graded responses in the simulation. Competitive antagonism may shift the curve, while a reduction in maximum response requires broader interpretation.
- This exercise uses a software/video simulation or an instructor-provided dataset.
- A response depends on the model, intervention, controls and observation period; comparisons must use the same endpoint.
- Record only supplied observations. Distinguish illustrative or simulated values from results obtained in an actual study.

Materials and Apparatus

- Assigned software/video, prepared teaching records and completed control/test data.
- Assigned pharmacology simulation/video and completed observation dataset.
- Computer, graphing or calculation software and a structured record sheet.

Method

1. Identify the simulated preparation, control group and response being measured.
2. Record the model settings and treatment labels supplied in the exercise.
3. Review the baseline or control trace before comparing the intervention traces.
4. Read the stated response endpoint using the same definition for every group.
5. Tabulate the completed simulation observations and calculate the assigned comparison.
6. Explain the mechanism, control response and any limitation of the model.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Agonist concentration	_____
Control response	_____
Antagonist condition	_____
Curve position	_____
Maximum	_____

Calculations and Interpretation

- Dose ratio = EC_{50} with antagonist/ EC_{50} without antagonist when both values are estimable.
- Compare maximum response independently of the EC_{50} shift.

Result

Report the supplied simulated response, its defined comparison and the mechanism supported by the model. Label the observations as simulated.

Finding: _____

Conclusion: _____

Precautions

- Keep software units, treatment labels and endpoint definitions consistent.
- Use supplied simulation data and distinguish an illustration from an observed outcome.
- A model demonstrates an experimental principle; it does not establish an individual patient treatment.

Viva Questions

1. Why use a control response?

It separates the intervention effect from baseline variation in the simulated model.

2. Why define the endpoint before comparison?

Changing the endpoint after reviewing results can bias the interpretation.

Study of Serum Biochemistry with a Semi-Autoanalyzer

Practical 06 | Pharmacology III

Aim

To study Serum Biochemistry with a Semi-Autoanalyzer, and interpret the recorded observations.

Principle

- The analyzer measures a method-dependent optical reaction. Calibration, reagent blank and quality-control records are necessary before a numerical serum result can be interpreted.
- This exercise uses a software/video simulation or an instructor-provided dataset.
- A response depends on the model, intervention, controls and observation period; comparisons must use the same endpoint.
- Record only supplied observations. Distinguish illustrative or simulated values from results obtained in an actual study.

Materials and Apparatus

- Assigned software/video, prepared teaching records and completed control/test data.
- Assigned pharmacology simulation/video and completed observation dataset.
- Computer, graphing or calculation software and a structured record sheet.

Method

1. Identify the simulated preparation, control group and response being measured.
2. Record the model settings and treatment labels supplied in the exercise.
3. Review the baseline or control trace before comparing the intervention traces.
4. Read the stated response endpoint using the same definition for every group.
5. Tabulate the completed simulation observations and calculate the assigned comparison.
6. Explain the mechanism, control response and any limitation of the model.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Analyte	_____
Method/wavelength	_____
Standard response	_____
Test response	_____
Quality control	_____
Calculated result	_____

Calculations and Interpretation

- For a valid blank-corrected single-standard proportional method: test concentration = test response/standard response × standard concentration.
- Use the method-specific calibration when a single-standard relationship is inappropriate.

Result

Report the supplied simulated response, its defined comparison and the mechanism supported by the model. Label the observations as simulated.

Finding: _____

Conclusion: _____

Precautions

- Keep software units, treatment labels and endpoint definitions consistent.
- Use supplied simulation data and distinguish an illustration from an observed outcome.
- A model demonstrates an experimental principle; it does not establish an individual patient treatment.

Viva Questions

1. Why use a control response?

It separates the intervention effect from baseline variation in the simulated model.

2. Why define the endpoint before comparison?

Changing the endpoint after reviewing results can bias the interpretation.

Study of Saline Purgative Effect on Frog Intestine

Practical 07 | Pharmacology III

Aim

To study Saline Purgative Effect on Frog Intestine, and interpret the recorded observations.

Principle

- The supplied model illustrates osmotic movement associated with a poorly absorbed solute. Water movement, net fluid change and motility are distinct endpoints.
- This exercise uses a software/video simulation or an instructor-provided dataset.
- A response depends on the model, intervention, controls and observation period; comparisons must use the same endpoint.
- Record only supplied observations. Distinguish illustrative or simulated values from results obtained in an actual study.

Materials and Apparatus

- Assigned software/video, prepared teaching records and completed control/test data.
- Assigned pharmacology simulation/video and completed observation dataset.
- Computer, graphing or calculation software and a structured record sheet.

Method

1. Identify the simulated preparation, control group and response being measured.
2. Record the model settings and treatment labels supplied in the exercise.
3. Review the baseline or control trace before comparing the intervention traces.
4. Read the stated response endpoint using the same definition for every group.
5. Tabulate the completed simulation observations and calculate the assigned comparison.
6. Explain the mechanism, control response and any limitation of the model.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Model condition	_____
Initial fluid measure	_____
Final fluid measure	_____
Time	_____
Control change	_____

Calculations and Interpretation

- Net fluid change = final measured fluid quantity - initial quantity.
- Compare with the control over the same observation interval.

Result

Report the supplied simulated response, its defined comparison and the mechanism supported by the model. Label the observations as simulated.

Finding: _____

Conclusion: _____

Precautions

- Keep software units, treatment labels and endpoint definitions consistent.
- Use supplied simulation data and distinguish an illustration from an observed outcome.
- A model demonstrates an experimental principle; it does not establish an individual patient treatment.

Viva Questions

1. Why use a control response?

It separates the intervention effect from baseline variation in the simulated model.

2. Why define the endpoint before comparison?

Changing the endpoint after reviewing results can bias the interpretation.

Study of Insulin Hypoglycemic Effect in a Rabbit Model

Practical 08 | Pharmacology III

Aim

To study Insulin Hypoglycemic Effect in a Rabbit Model, and interpret the recorded observations.

Principle

- Insulin can lower the supplied model blood-glucose values. Time course and baseline values are essential to comparison; the simulation does not establish a treatment schedule.
- This exercise uses a software/video simulation or an instructor-provided dataset.
- A response depends on the model, intervention, controls and observation period; comparisons must use the same endpoint.
- Record only supplied observations. Distinguish illustrative or simulated values from results obtained in an actual study.

Materials and Apparatus

- Assigned software/video, prepared teaching records and completed control/test data.
- Assigned pharmacology simulation/video and completed observation dataset.
- Computer, graphing or calculation software and a structured record sheet.

Method

1. Identify the simulated preparation, control group and response being measured.
2. Record the model settings and treatment labels supplied in the exercise.
3. Review the baseline or control trace before comparing the intervention traces.
4. Read the stated response endpoint using the same definition for every group.
5. Tabulate the completed simulation observations and calculate the assigned comparison.
6. Explain the mechanism, control response and any limitation of the model.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Group	_____
Baseline glucose	_____
Time after model intervention	_____
Glucose value	_____
Percentage change	_____

Calculations and Interpretation

- Decrease (%) = (baseline glucose - later glucose)/baseline glucose × 100.
- Preserve the supplied glucose units and time points.

Result

Report the supplied simulated response, its defined comparison and the mechanism supported by the model. Label the observations as simulated.

Finding: _____

Conclusion: _____

Precautions

- Keep software units, treatment labels and endpoint definitions consistent.
- Use supplied simulation data and distinguish an illustration from an observed outcome.
- A model demonstrates an experimental principle; it does not establish an individual patient treatment.

Viva Questions

1. Why use a control response?

It separates the intervention effect from baseline variation in the simulated model.

2. Why define the endpoint before comparison?

Changing the endpoint after reviewing results can bias the interpretation.

Study of Rabbit Pyrogen Test - Historical Data Interpretation

Practical 09 | Pharmacology III

Aim

To study Rabbit Pyrogen Test - Historical Data Interpretation, and interpret the recorded observations.

Principle

- The historical model examines a temperature response to a defined test preparation. Pyrogen testing and sterility testing evaluate different properties.
- This exercise uses a software/video simulation or an instructor-provided dataset.
- A response depends on the model, intervention, controls and observation period; comparisons must use the same endpoint.
- Record only supplied observations. Distinguish illustrative or simulated values from results obtained in an actual study.

Materials and Apparatus

- Assigned software/video, prepared teaching records and completed control/test data.
- Assigned pharmacology simulation/video and completed observation dataset.
- Computer, graphing or calculation software and a structured record sheet.

Method

1. Identify the simulated preparation, control group and response being measured.
2. Record the model settings and treatment labels supplied in the exercise.
3. Review the baseline or control trace before comparing the intervention traces.
4. Read the stated response endpoint using the same definition for every group.
5. Tabulate the completed simulation observations and calculate the assigned comparison.
6. Explain the mechanism, control response and any limitation of the model.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Record label	_____
Baseline temperature	_____
Post-test readings	_____
Maximum rise	_____
Method rule	_____

Calculations and Interpretation

- Maximum rise = highest relevant post-test temperature - the method-defined baseline.
- Apply the supplied method's individual and total-rise rule; do not invent a universal pass limit.

Result

Report the supplied simulated response, its defined comparison and the mechanism supported by the model. Label the observations as simulated.

Finding: _____

Conclusion: _____

Precautions

- Keep software units, treatment labels and endpoint definitions consistent.
- Use supplied simulation data and distinguish an illustration from an observed outcome.
- A model demonstrates an experimental principle; it does not establish an individual patient treatment.

Viva Questions

1. Why use a control response?

It separates the intervention effect from baseline variation in the simulated model.

2. Why define the endpoint before comparison?

Changing the endpoint after reviewing results can bias the interpretation.

Study of Acute Oral Toxicity from a Provided Dataset

Practical 10 | Pharmacology III

Aim

To study Acute Oral Toxicity from a Provided Dataset, and interpret the recorded observations.

Principle

- LD50 is a model estimate of a dose associated with mortality in half a population under stated conditions. A limit-test or toxicity-class result need not supply a precise LD50.
- This exercise uses a software/video simulation or an instructor-provided dataset.
- A response depends on the model, intervention, controls and observation period; comparisons must use the same endpoint.
- Record only supplied observations. Distinguish illustrative or simulated values from results obtained in an actual study.

Materials and Apparatus

- Assigned software/video, prepared teaching records and completed control/test data.
- Assigned pharmacology simulation/video and completed observation dataset.
- Computer, graphing or calculation software and a structured record sheet.

Method

1. Identify the simulated preparation, control group and response being measured.
2. Record the model settings and treatment labels supplied in the exercise.
3. Review the baseline or control trace before comparing the intervention traces.
4. Read the stated response endpoint using the same definition for every group.
5. Tabulate the completed simulation observations and calculate the assigned comparison.
6. Explain the mechanism, control response and any limitation of the model.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Provided dose labels	_____
Number represented	_____
Observed outcomes	_____
Model/assumption	_____
Estimate or class	_____

Calculations and Interpretation

- Outcome proportion = relevant outcome count/number represented.
- Estimate LD50 only by the appropriate fitted model for the supplied data; report uncertainty and do not infer it from a single group.

Result

Report the supplied simulated response, its defined comparison and the mechanism supported by the model. Label the observations as simulated.

Finding: _____

Conclusion: _____

Precautions

- Keep software units, treatment labels and endpoint definitions consistent.
- Use supplied simulation data and distinguish an illustration from an observed outcome.
- A model demonstrates an experimental principle; it does not establish an individual patient treatment.

Viva Questions

1. Why use a control response?

It separates the intervention effect from baseline variation in the simulated model.

2. Why define the endpoint before comparison?

Changing the endpoint after reviewing results can bias the interpretation.

Study of Skin Irritation and Corrosion - Dataset Interpretation

Practical 11 | Pharmacology III

Aim

To study Skin Irritation and Corrosion - Dataset Interpretation, and interpret the recorded observations.

Principle

- Irritation and corrosion describe different severity/reversibility concepts. Completed scores must be interpreted using the specified test and observation times.
- This exercise uses a software/video simulation or an instructor-provided dataset.
- A response depends on the model, intervention, controls and observation period; comparisons must use the same endpoint.
- Record only supplied observations. Distinguish illustrative or simulated values from results obtained in an actual study.

Materials and Apparatus

- Assigned software/video, prepared teaching records and completed control/test data.
- Assigned pharmacology simulation/video and completed observation dataset.
- Computer, graphing or calculation software and a structured record sheet.

Method

1. Identify the simulated preparation, control group and response being measured.
2. Record the model settings and treatment labels supplied in the exercise.
3. Review the baseline or control trace before comparing the intervention traces.
4. Read the stated response endpoint using the same definition for every group.
5. Tabulate the completed simulation observations and calculate the assigned comparison.
6. Explain the mechanism, control response and any limitation of the model.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Method label	_____
Observation time	_____
Supplied scores	_____
Reversibility evidence	_____
Method classification	_____

Calculations and Interpretation

- Calculate a summary score only where the supplied test method specifies it.
- Do not replace the method's classification rules with an unvalidated average.

Result

Report the supplied simulated response, its defined comparison and the mechanism supported by the model. Label the observations as simulated.

Finding: _____

Conclusion: _____

Precautions

- Keep software units, treatment labels and endpoint definitions consistent.
- Use supplied simulation data and distinguish an illustration from an observed outcome.
- A model demonstrates an experimental principle; it does not establish an individual patient treatment.

Viva Questions

1. Why use a control response?

It separates the intervention effect from baseline variation in the simulated model.

2. Why define the endpoint before comparison?

Changing the endpoint after reviewing results can bias the interpretation.

Study of Eye Irritation and Corrosion - Dataset Interpretation

Practical 12 | Pharmacology III

Aim

To study Eye Irritation and Corrosion - Dataset Interpretation, and interpret the recorded observations.

Principle

- Eye-response data can include corneal, iris and conjunctival observations. The timing and reversibility of effects matter to the method-specific classification.
- This exercise uses a software/video simulation or an instructor-provided dataset.
- A response depends on the model, intervention, controls and observation period; comparisons must use the same endpoint.
- Record only supplied observations. Distinguish illustrative or simulated values from results obtained in an actual study.

Materials and Apparatus

- Assigned software/video, prepared teaching records and completed control/test data.
- Assigned pharmacology simulation/video and completed observation dataset.
- Computer, graphing or calculation software and a structured record sheet.

Method

1. Identify the simulated preparation, control group and response being measured.
2. Record the model settings and treatment labels supplied in the exercise.
3. Review the baseline or control trace before comparing the intervention traces.
4. Read the stated response endpoint using the same definition for every group.
5. Tabulate the completed simulation observations and calculate the assigned comparison.
6. Explain the mechanism, control response and any limitation of the model.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Observation time	_____
Corneal score	_____
Iris score	_____
Conjunctival scores	_____
Reversibility/classification	_____

Calculations and Interpretation

- Use the scoring and classification rules supplied for the dataset.
- Keep separate tissue endpoints separate unless the stated method directs their combination.

Result

Report the supplied simulated response, its defined comparison and the mechanism supported by the model. Label the observations as simulated.

Finding: _____

Conclusion: _____

Precautions

- Keep software units, treatment labels and endpoint definitions consistent.
- Use supplied simulation data and distinguish an illustration from an observed outcome.
- A model demonstrates an experimental principle; it does not establish an individual patient treatment.

Viva Questions

1. Why use a control response?

It separates the intervention effect from baseline variation in the simulated model.

2. Why define the endpoint before comparison?

Changing the endpoint after reviewing results can bias the interpretation.

Pharmacokinetic Parameters from a Given Dataset

Practical 13 | Pharmacology III

Aim

To study Pharmacokinetic Parameters from a Given Dataset, and interpret the recorded observations.

Principle

- Time-concentration data support pharmacokinetic calculations only within the stated route and model. The one-compartment IV-bolus first-order model differs from oral absorption and multicompartment models.
- Choose the calculation or statistical model appropriate to the data structure and assumptions.
- Units, paired or independent observations, and the direction of the measured effect must be explicit.

Materials and Apparatus

- Provided concentration-time data, dose and route information, calculation/plotting software.
- Instructor-provided dataset and the stated study/model assumptions.
- Calculator or spreadsheet/statistical software and a record sheet.

Method

1. Confirm the route, dose, units and model assumptions stated with the data.
2. Plot concentration against time and inspect the proposed elimination interval.
3. For an appropriate log-linear interval, fit $\ln(\text{concentration})$ against time and obtain the elimination slope.
4. Calculate half-life and integrate the area under the curve with the chosen method.
5. Calculate clearance and apparent distribution measures only with the necessary route/model information.
6. Report parameters with units, assumptions and any extrapolated AUC portion.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Time	_____
Concentration	_____
Log concentration	_____
AUC intervals	_____
Model parameters	_____

Calculations and Interpretation

- For log-linear elimination: $\ln(C) = \ln(C_0) - kt$; half-life = $0.693/k$.
- Trapezoidal AUC interval = $(C_i + C_{i+1})/2 \times (t_{i+1} - t_i)$.
- When justified by terminal first-order data: residual AUC = C_{last}/k .
- After an IV dose, clearance = dose/AUC to infinity; for an oral dose without known bioavailability the result is CL/F .
- For the stated one-compartment IV-bolus model, $V = \text{dose}/C_0$ and clearance = kV .

Worked Illustration

Illustration: a valid elimination slope of -0.20 per hour gives $k = 0.20$ per hour and half-life = 3.47 hours.

The values in this illustration are for calculation practice.

Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: _____

Conclusion: _____

Precautions

- Do not interchange paired and independent analyses.
- Keep unit conversions explicit and round at the final reporting stage.
- A model estimate or p-value does not by itself establish a causal or clinical conclusion.

Viva Questions

1. Why is oral dose/AUC called CL/F when F is unknown?

The observed exposure includes incomplete bioavailability, so clearance and bioavailability cannot be separated from that expression alone.

2. Why state assumptions?

An equation or test can give a misleading answer when its underlying assumptions do not hold.

Student t Test and One-Way ANOVA

Practical 14 | Pharmacology III

Aim

To study Student t Test and One-Way ANOVA, and interpret the recorded observations.

Principle

- A t test examines a defined mean comparison, while one-way ANOVA examines a mean difference across independent groups under its model. Paired and independent data require different analyses.
- Choose the calculation or statistical model appropriate to the data structure and assumptions.
- Units, paired or independent observations, and the direction of the measured effect must be explicit.
- Standard independent-group ANOVA assumes independent errors and an appropriate common-variance/normal-error model; use a suitable alternative when those conditions are unsuitable.
- An omnibus ANOVA result does not identify which individual groups differ. Any follow-up comparisons need the planned multiplicity approach.

Materials and Apparatus

- Provided grouped or paired dataset and statistical software.
- Instructor-provided dataset and the stated study/model assumptions.
- Calculator or spreadsheet/statistical software and a record sheet.

Method

1. Identify whether observations are paired or independent and define the comparison.
2. Check missing values, distributions and the relevant model assumptions.
3. Summarize each group with its size, mean and standard deviation.
4. Use an appropriate t test for two-group/paired data or an appropriate ANOVA for the stated multiple-group design.
5. Record the statistic, degrees of freedom, p-value and the estimated difference or group means.
6. Interpret against the pre-specified significance level and distinguish statistical significance from effect size.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Data structure	_____
Group size	_____
Mean and variability	_____
Test statistic	_____
Degrees of freedom	_____
p-value and effect	_____

Calculations and Interpretation

- Independent unequal-variance comparison: $t = (\text{mean1} - \text{mean2}) / \sqrt{s_1^2/n_1 + s_2^2/n_2}$, with Welch-Satterthwaite degrees of freedom.
- Paired comparison: $t = \text{mean difference} / (\text{SD of differences} / \sqrt{n})$; degrees of freedom = $n - 1$.
- One-way ANOVA: $F = \text{mean square between groups} / \text{mean square within groups}$.

Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: _____

Conclusion: _____

Precautions

- Do not interchange paired and independent analyses.
- Keep unit conversions explicit and round at the final reporting stage.
- A model estimate or p-value does not by itself establish a causal or clinical conclusion.

Viva Questions

1. Why is repeatedly using unadjusted t tests across many groups problematic?

It can inflate the chance of false positive conclusions across the collection of comparisons.

2. Why state assumptions?

An equation or test can give a misleading answer when its underlying assumptions do not hold.

3. Why keep intermediate calculations?

They make the result reproducible and expose unit or transcription errors.

Chi-Square and Wilcoxon Signed-Rank Tests

Practical 15 | Pharmacology III

Aim

To study Chi-Square and Wilcoxon Signed-Rank Tests, and interpret the recorded observations.

Principle

- A chi-square independence test analyzes categorical counts. A Wilcoxon signed-rank test uses ranks of paired differences and requires the appropriate paired-data and symmetry assumptions for a location-shift interpretation.
- Choose the calculation or statistical model appropriate to the data structure and assumptions.
- Units, paired or independent observations, and the direction of the measured effect must be explicit.

Materials and Apparatus

- Provided contingency table or paired measurements and statistical software.
- Instructor-provided dataset and the stated study/model assumptions.
- Calculator or spreadsheet/statistical software and a record sheet.

Method

1. Choose the test from the data structure and the stated question.
2. For chi-square, construct the count table and calculate expected counts under independence.
3. Check expected-count adequacy and consider a suitable exact alternative where needed.
4. For signed ranks, compute paired differences, handle zeros by the specified convention and rank nonzero absolute differences with averaged ties.
5. Calculate the statistic or obtain it with verified software settings and record the exact/asymptotic approach.
6. Report the result and the assumptions supporting the interpretation.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Observed/expected counts	_____
Paired differences	_____
Ranks and ties	_____
Statistic	_____
Degrees of freedom or method	_____
p-value	_____

Calculations and Interpretation

- Expected cell count = row total $\times$ column total/grand total.
- Chi-square = $\sum[(\text{observed} - \text{expected})^2 / \text{expected}]$; table degrees of freedom = (rows - 1)(columns - 1).
- Wilcoxon: sum ranks separately for positive and negative nonzero differences; state the statistic convention used by the software.

Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: _____

Conclusion: _____

Precautions

- Do not interchange paired and independent analyses.
- Keep unit conversions explicit and round at the final reporting stage.
- A model estimate or p-value does not by itself establish a causal or clinical conclusion.

Viva Questions

1. Is the Wilcoxon signed-rank test the same as the rank-sum test?

No. Signed ranks analyze paired differences; rank-sum methods compare independent groups.

2. Why state assumptions?

An equation or test can give a misleading answer when its underlying assumptions do not hold.

3. Why keep intermediate calculations?

They make the result reproducible and expose unit or transcription errors.

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