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M.Pharm Practical Notes

Pharmacology Practicals II

Semester 2

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Agonist Concentration-Response Curve

Practical 1 - Pharmacology simulation and data practical

Aim

To fit an agonist concentration-response curve and interpret potency and maximum response.

Principle

For a simple Hill model E = E0 + (Emax - E0)C^n/(EC50^n + C^n). EC50 is an operational potency measure under the experiment conditions, not automatically a binding affinity.

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 isolated-preparation traces or simulation and verify baseline, calibration, concentration units and viability controls.
4. Extract responses by a consistent rule and plot response against log molar concentration.
5. Fit a justified concentration-response model, assess residuals and estimate EC50, Emax and uncertainty.
6. Evaluate repeated-curve stability, desensitisation and whether the tested range supports a plateau.
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

- pEC50 = -log10(EC50 in mol/L)

Worked Example

Illustrative EC50 = 10^-7 mol/L gives pEC50 = 7.0. For E0 = 0, Emax = 100 and n = 1, concentration equal to EC50 gives response 50.

Result and Interpretation

- Provide fitted and raw curves, parameter units and the evidence supporting the model.

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

What is potency?

The concentration or dose associated with a defined effect under specified conditions.

Is EC50 always Kd?

System response and receptor coupling can make them differ.

Why include a plateau?

It supports estimation of the maximum response.

Antagonism and Potentiation of an Agonist Curve

Practical 2 - Pharmacology simulation and data practical

Aim

To compare agonist curves under antagonist and potentiating conditions.

Principle

For a simple Hill model E = E0 + (Emax - E0)C^n/(EC50^n + C^n). EC50 is an operational potency measure under the experiment conditions, not automatically a binding affinity.

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 isolated-preparation traces or simulation and verify baseline, calibration, concentration units and viability controls.
4. Extract responses by a consistent rule and plot response against log molar concentration.
5. Fit a justified concentration-response model, assess residuals and estimate EC50, Emax and uncertainty.
6. Evaluate repeated-curve stability, desensitisation and whether the tested range supports a plateau.
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

- pEC50 = -log10(EC50 in mol/L)

Worked Example

Illustrative EC50 = 10^-7 mol/L gives pEC50 = 7.0. For E0 = 0, Emax = 100 and n = 1, concentration equal to EC50 gives response 50.

Curve comparison

- Compare baseline, EC50, Emax and slope on the same response basis with appropriate time controls.
- A parallel rightward shift with preserved maximum can be consistent with reversible competitive antagonism under suitable equilibrium conditions. Other mechanisms and experimental artifacts must be considered.
- Illustrative control EC50 10 nM and exposed EC50 30 nM give dose ratio 3; a left shift may indicate potentiation but requires mechanism-specific controls.

Result and Interpretation

- Provide fitted and raw curves, parameter units and the evidence supporting the model.

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

What is potency?

The concentration or dose associated with a defined effect under specified conditions.

Is EC50 always Kd?

System response and receptor coupling can make them differ.

Why include a plateau?

It supports estimation of the maximum response.

Matching Bioassay

Practical 3 - Pharmacology simulation and data practical

Aim

To estimate relative activity by the assigned bioassay method using supplied responses.

Principle

A bioassay compares a test preparation with a reference through a defined biological response. Valid comparison needs suitable dose-response behaviour, preparation stability, randomisation and uncertainty assessment.

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. Map standard and test preparation concentrations, dilutions, timing and independent replicates.
4. Assess blank response, reference-curve stability, carryover and comparability of conditions.
5. Apply the assigned matching, interpolation, bracketing or multiple-point method and test its assumptions.
6. Correct for prior dilution and express relative activity on the stated reference basis with uncertainty or an honest bracket.
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

- Relative potency at an equivalent effect = reference dose / test dose, when expressed on comparable amount bases
- Stock concentration = assay concentration x prior dilution factor

Worked Example

If standard 2 ng/mL and unknown dilution 1:10 give equivalent response, unknown stock is 20 ng/mL under the justified equivalence assumption.

Matching method

• Adjust or compare supplied unknown and standard concentrations until equivalent responses are supported; interpolate locally rather than claiming equality from one noisy trace.

Result and Interpretation

• Report method, reference definition, potency basis and the limits of precision.

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 use a reference?

It provides a defined activity basis for comparison.

Why assess parallelism?

Relative potency may not be constant across effects if curves differ.

Why report uncertainty?

Biological variability affects the potency estimate.

Interpolation Bioassay

Practical 4 - Pharmacology simulation and data practical

Aim

To estimate relative activity by the assigned bioassay method using supplied responses.

Principle

A bioassay compares a test preparation with a reference through a defined biological response. Valid comparison needs suitable dose-response behaviour, preparation stability, randomisation and uncertainty assessment.

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. Map standard and test preparation concentrations, dilutions, timing and independent replicates.
4. Assess blank response, reference-curve stability, carryover and comparability of conditions.
5. Apply the assigned matching, interpolation, bracketing or multiple-point method and test its assumptions.
6. Correct for prior dilution and express relative activity on the stated reference basis with uncertainty or an honest bracket.
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

- Relative potency at an equivalent effect = reference dose / test dose, when expressed on comparable amount bases
- Stock concentration = assay concentration x prior dilution factor

Worked Example

Illustrative response = 20 + 10 x log10(C in ng/mL). Response 30 gives C = 10 ng/mL; a tenfold prior dilution gives stock 100 ng/mL.

Interpolation method

• Use a validated local calibration over a range bracketing the unknown, with comparable preparation and response conditions.

Result and Interpretation

• Report method, reference definition, potency basis and the limits of precision.

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 use a reference?

It provides a defined activity basis for comparison.

Why assess parallelism?

Relative potency may not be constant across effects if curves differ.

Why report uncertainty?

Biological variability affects the potency estimate.

Bracketing Bioassay

Practical 5 - Pharmacology simulation and data practical

Aim

To estimate relative activity by the assigned bioassay method using supplied responses.

Principle

A bioassay compares a test preparation with a reference through a defined biological response. Valid comparison needs suitable dose-response behaviour, preparation stability, randomisation and uncertainty assessment.

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. Map standard and test preparation concentrations, dilutions, timing and independent replicates.
4. Assess blank response, reference-curve stability, carryover and comparability of conditions.
5. Apply the assigned matching, interpolation, bracketing or multiple-point method and test its assumptions.
6. Correct for prior dilution and express relative activity on the stated reference basis with uncertainty or an honest bracket.
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

- Relative potency at an equivalent effect = reference dose / test dose, when expressed on comparable amount bases
- Stock concentration = assay concentration x prior dilution factor

Worked Example

If unknown response lies between valid 2 and 4 ng/mL standard responses, report that bracket unless a justified interpolation model supports a point estimate.

Bracketing method

• Compare unknown response with lower and upper standard responses using a stable preparation and matched sequence controls.

Result and Interpretation

• Report method, reference definition, potency basis and the limits of precision.

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 use a reference?

It provides a defined activity basis for comparison.

Why assess parallelism?

Relative potency may not be constant across effects if curves differ.

Why report uncertainty?

Biological variability affects the potency estimate.

Multiple-Point Bioassay

Practical 6 - Pharmacology simulation and data practical

Aim

To estimate relative activity by the assigned bioassay method using supplied responses.

Principle

A bioassay compares a test preparation with a reference through a defined biological response. Valid comparison needs suitable dose-response behaviour, preparation stability, randomisation and uncertainty assessment.

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. Map standard and test preparation concentrations, dilutions, timing and independent replicates.
4. Assess blank response, reference-curve stability, carryover and comparability of conditions.
5. Apply the assigned matching, interpolation, bracketing or multiple-point method and test its assumptions.
6. Correct for prior dilution and express relative activity on the stated reference basis with uncertainty or an honest bracket.
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

- Relative potency at an equivalent effect = reference dose / test dose, when expressed on comparable amount bases
- Stock concentration = assay concentration x prior dilution factor

Worked Example

If log-response analysis supports equipotent doses 2 units of standard and 4 units of unknown preparation, relative potency of unknown per unit amount is 2/4 = 0.50 of the standard, subject to model validity.

Multiple-point method

• Use replicated standard and unknown doses with a justified parallel-line or other bioassay design, checking linearity, parallelism, preparation stability and uncertainty.

Result and Interpretation

• Report method, reference definition, potency basis and the limits of precision.

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 use a reference?

It provides a defined activity basis for comparison.

Why assess parallelism?

Relative potency may not be constant across effects if curves differ.

Why report uncertainty?

Biological variability affects the potency estimate.

Antagonist pA2 and Schild Analysis

Practical 7 - Pharmacology simulation and data practical

Aim

To estimate antagonist affinity from a justified Schild analysis.

Principle

For simple equilibrium competitive antagonism, dose ratio DR = 1 + [B]/KB, so log10(DR - 1) = log10[B] - log10 KB. An approximately unit slope supports the model; pA2 equals -log10 KB only under the appropriate assumptions.

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 matched agonist curves with several antagonist concentrations and suitable time/viability controls.
4. Estimate EC50 for each curve and calculate DR relative to the matched control.
5. Fit log10(DR - 1) against log10 antagonist concentration in mol/L and assess slope, parallelism and maximum response.
6. Only when justified, estimate KB and pA2; otherwise report the apparent relationship without forcing a unit-slope model.
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

- DR = EC50 with antagonist / control EC50
- KB = [B]/(DR - 1) under the competitive model

• pA2 = -log10 KB when model assumptions hold

Worked Example

Illustrative [B] = 10 nM and DR = 3 give KB = 5 nM = 5 x 10^-9 mol/L and pA2 about 8.30.
One point cannot validate a Schild slope; several concentrations and appropriate diagnostics are required.

Result and Interpretation

• Report the plot, slope and uncertainty and distinguish a valid pA2 from a forced estimate.

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 use molar concentration?

The logarithmic affinity definition requires a defined concentration basis.

What does a non-unit slope suggest?

The simple model, equilibrium or experimental assumptions may not hold.

Why compare Emax?

Changes can challenge a simple surmountable-antagonism interpretation.

Isolated-Heart Trace Interpretation

Practical 8 - Pharmacology simulation and data practical

Aim

To interpret supplied isolated-heart rate and contraction traces.

Principle

An isolated-heart preparation measures responses under its recorded perfusion and experimental conditions. Rate and contractile amplitude are distinct endpoints, and baseline drift can confound apparent effects.

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 traces only; identify species, perfusion record, temperature, calibration and timing without preparing tissue.
4. Measure baseline and defined response windows with matched time and vehicle controls.
5. Calculate rate from the calibrated time axis and amplitude from the appropriate transducer scale.
6. Compare effects with recovery or washout records and discuss preparation viability and model limitations.
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

- Heart rate (beats/min) = counted beats / observed seconds x 60
- Amplitude change (%) = (test - baseline)/baseline x 100

Worked Example

Illustrative 12 beats in 6 s give 120 beats/min. Amplitude changing from 10 to 12 calibrated units gives +20%. Do not infer a patient treatment effect from the trace.

Result and Interpretation

• Provide labelled trace segments, rate and amplitude results and control interpretation.

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

What is chronotropy?

An effect on heart rate.

What is inotropy?

An effect on contractile force under the defined measurement.

Why use time controls?

Preparation behaviour can drift independently of the test condition.

Blood Pressure Heart Rate and ECG Records

Practical 9 - Pharmacology simulation and data practical

Aim

To assess supplied blood-pressure, heart-rate and ECG records.

Principle

Pressure and ECG are different signals. Calibration, baseline, timing, species and measurement method determine valid interpretation; a pressure waveform alone does not identify an arrhythmia.

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. Review supplied traces and calibration, anaesthesia and source-study records without conducting invasive recording.
4. Measure systolic and diastolic pressures and rate over defined stable windows.
5. Identify ECG waves and intervals only where signal quality and the species-specific reference permit.
6. Compare matched conditions and document artifacts, baseline changes and independent-unit variation.
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

- Pulse pressure = systolic - diastolic pressure
- Approximate MAP = diastolic + (systolic - diastolic)/3 when the approximation is appropriate

Worked Example

Illustrative pressure 120/80 mmHg gives pulse pressure 40 mmHg and approximate MAP 93.3 mmHg. The example is arithmetic, not a normal range for an anaesthetised animal or a clinical diagnosis.

Result and Interpretation

• Report the measured signals and limitations rather than applying human reference ranges to all species.

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 calibrate pressure?

Raw transducer output needs a valid pressure conversion.

Is the MAP approximation universal?

Waveform and rate can make it unsuitable; direct integration may be needed.

Why review ECG separately?

Electrical timing and pressure are distinct measurements.

Rat ECG Interpretation

Practical 10 - Pharmacology simulation and data practical

Aim

To measure and interpret supplied rat ECG intervals with species-appropriate context.

Principle

Pressure and ECG are different signals. Calibration, baseline, timing, species and measurement method determine valid interpretation; a pressure waveform alone does not identify an arrhythmia.

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. Review supplied traces and calibration, anaesthesia and source-study records without conducting invasive recording.
4. Measure systolic and diastolic pressures and rate over defined stable windows.
5. Identify ECG waves and intervals only where signal quality and the species-specific reference permit.
6. Compare matched conditions and document artifacts, baseline changes and independent-unit variation.
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

- Pulse pressure = systolic - diastolic pressure
- Approximate MAP = diastolic + (systolic - diastolic)/3 when the approximation is appropriate

Worked Example

Illustrative pressure 120/80 mmHg gives pulse pressure 40 mmHg and approximate MAP 93.3 mmHg. The example is arithmetic, not a normal range for an anaesthetised animal or a clinical diagnosis.

Rat ECG worksheet

- Record lead configuration, time and voltage calibration, source-study anaesthesia, temperature and rate.
- Measure RR, PR, QRS and QT where identifiable; use the justified species- and rate-specific interpretation rather than importing human diagnostic cutoffs.
- Illustrative RR = 0.15 s gives rate 400/min. It is a timing calculation, not a claimed normal value.

Result and Interpretation

- Report the measured signals and limitations rather than applying human reference ranges to all species.

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 calibrate pressure?

Raw transducer output needs a valid pressure conversion.

Is the MAP approximation universal?

Waveform and rate can make it unsuitable; direct integration may be needed.

Why review ECG separately?

Electrical timing and pressure are distinct measurements.

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.

Acute Oral Toxicity Study Records

Practical 12 - 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 current acute-oral guideline, such as OECD 420, 423 or 425, and its actual scope. Do not invent an LD50 from a small teaching table.

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.

Acute Dermal Toxicity Study Records

Practical 13 - 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 current acute-dermal guideline and skin-condition, contact and local/systemic observation records. This is a report appraisal, not an exposure procedure.

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.

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.

Chromosomal-Aberration Study Data

Practical 15 - Pharmacology simulation and data practical

Aim

To score and interpret supplied chromosomal-aberration records.

Principle

Cytogenetic assays assess defined structural or numerical endpoints under a validated method. Cytotoxicity, metaphase quality, exposure and positive/negative controls determine interpretability.

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 blinded metaphase images and the exact approved assay classification rules.
4. Assess image quality and score prespecified independent preparations; distinguish gaps if the method requires separate reporting.
5. Calculate cells with specified aberrations and review cytotoxicity and control performance.
6. Compare groups with the appropriate experimental-unit analysis and identify confirmation needs.
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

- Aberrant-cell frequency (%) = cells with the defined aberration endpoint / cells validly scored x 100

Worked Example

Illustrative 10 aberrant cells among 200 valid metaphases give 5.0%.

Multiple aberrations in one cell do not automatically count as multiple aberrant cells; keep endpoint definitions explicit.

Result and Interpretation

• Provide scoring rules, control results, preparation-level summaries and a limited genotoxicity interpretation.

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 blind scoring?

It reduces expectation bias.

Why track cytotoxicity?

Severe toxicity can confound the assay.

Are gaps always counted identically?

Use the selected guideline and scoring definition.

Parallel-Group Clinical Trial Protocol

Practical 16 - Regulatory documentation practical

Aim

To draft a review-ready fictional clinical study protocol.

Principle

A protocol connects the research question to participant protection, design, procedures, analysis and operational controls. Regulatory permission, ethics approval and registration are separate requirements.

Materials and Requirements

- Fictional product or study case and controlled document templates
- Current official requirements for the specified jurisdiction and product category
- Requirement-to-evidence and gap-assessment worksheet
- 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. Define product category, intended use, jurisdiction, application type and the date of the regulatory check. Keep this as an offline training exercise with no filing, fees or real applicant information.
3. Define a scientifically justified question and one measurable primary endpoint, with a feasible and ethical comparator.
4. Specify design, eligibility, allocation, blinding and study schedule, including withdrawals and safety escalation.
5. Write a justified sample-size and analysis plan with missing-data handling, monitoring, data integrity and consent arrangements.
6. Map the protocol to the assigned jurisdiction and assemble the supporting dossier and review checklist.
7. Perform an independent consistency and completeness check. Record evidence, gaps, owners and the exact approval or permission still required.
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.

Requirement / dossier element	Document / evidence	Gap / responsible role	Readiness decision
Administrative scope	Identify	Assess	Record
Scientific / quality evidence	Map	Assess	Record
Submission / lifecycle	Validate	Assess	Record

Worked Example

Illustrative parallel-group question compares mean change in a defined validated endpoint. A proposed 100 participants per arm is a planning placeholder until supported by effect, variability, type-I error, power and attrition assumptions.

Required protocol sections

• Scientific rationale, objectives, population and primary/secondary endpoints.
• Design, comparator, allocation, blinding, eligibility, study visits and procedures.
• Intervention accountability and product quality; safety monitoring, stopping rules and reporting responsibilities.
• Sample-size justification, analysis population, estimand or question, missing-data and multiplicity handling as appropriate.
• Consent, privacy, participant care, compensation/insurance as required, ethics oversight and dissemination.

Assigned study design

• Parallel design: independent groups receive their assigned strategy. Define allocation concealment, baseline adjustment and a between-group endpoint comparison.

Result and Interpretation

• Deliver a protocol synopsis, schedule of assessments, safety plan and requirement-to-document map.
• A complete training checklist is not an authorisation, licence or guarantee of acceptance.

Precautions

• Distinguish scientific content requirements from electronic-publishing rules.
• Recheck current forms, amendments, scope and local requirements at actual filing.
• Do not invent approval numbers, signatures, fees or deadlines.

Viva Questions and Answers

Why define the application type first?

It determines the legal route and required evidence.

Does a valid file format prove scientific adequacy?

Technical validation and substantive review are separate.

Why retain requirement versions?

Regulations and submission specifications can change.

Crossover Clinical Trial Protocol

Practical 17 - Regulatory documentation practical

Aim

To draft a review-ready fictional clinical study protocol.

Principle

A protocol connects the research question to participant protection, design, procedures, analysis and operational controls. Regulatory permission, ethics approval and registration are separate requirements.

Materials and Requirements

- Fictional product or study case and controlled document templates
- Current official requirements for the specified jurisdiction and product category
- Requirement-to-evidence and gap-assessment worksheet
- 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. Define product category, intended use, jurisdiction, application type and the date of the regulatory check. Keep this as an offline training exercise with no filing, fees or real applicant information.
3. Define a scientifically justified question and one measurable primary endpoint, with a feasible and ethical comparator.
4. Specify design, eligibility, allocation, blinding and study schedule, including withdrawals and safety escalation.
5. Write a justified sample-size and analysis plan with missing-data handling, monitoring, data integrity and consent arrangements.
6. Map the protocol to the assigned jurisdiction and assemble the supporting dossier and review checklist.
7. Perform an independent consistency and completeness check. Record evidence, gaps, owners and the exact approval or permission still required.
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.

Requirement / dossier element	Document / evidence	Gap / responsible role	Readiness decision
Administrative scope	Identify	Assess	Record
Scientific / quality evidence	Map	Assess	Record
Submission / lifecycle	Validate	Assess	Record

Worked Example

Illustrative parallel-group question compares mean change in a defined validated endpoint. A proposed 100 participants per arm is a planning placeholder until supported by effect, variability, type-I error, power and attrition assumptions.

Required protocol sections

• Scientific rationale, objectives, population and primary/secondary endpoints.
• Design, comparator, allocation, blinding, eligibility, study visits and procedures.
• Intervention accountability and product quality; safety monitoring, stopping rules and reporting responsibilities.
• Sample-size justification, analysis population, estimand or question, missing-data and multiplicity handling as appropriate.
• Consent, privacy, participant care, compensation/insurance as required, ethics oversight and dissemination.

Assigned study design

• Crossover design: participants receive sequences across periods. Justify washout and stability, assess period/sequence effects and whether carryover makes the design unsuitable.

Result and Interpretation

• Deliver a protocol synopsis, schedule of assessments, safety plan and requirement-to-document map.
• A complete training checklist is not an authorisation, licence or guarantee of acceptance.

Precautions

• Distinguish scientific content requirements from electronic-publishing rules.
• Recheck current forms, amendments, scope and local requirements at actual filing.
• Do not invent approval numbers, signatures, fees or deadlines.

Viva Questions and Answers

Why define the application type first?

It determines the legal route and required evidence.

Does a valid file format prove scientific adequacy?

Technical validation and substantive review are separate.

Why retain requirement versions?

Regulations and submission specifications can change.

Non-Inferiority Clinical Trial Protocol

Practical 18 - Regulatory documentation practical

Aim

To draft a review-ready fictional clinical study protocol.

Principle

A protocol connects the research question to participant protection, design, procedures, analysis and operational controls. Regulatory permission, ethics approval and registration are separate requirements.

Materials and Requirements

- Fictional product or study case and controlled document templates
- Current official requirements for the specified jurisdiction and product category
- Requirement-to-evidence and gap-assessment worksheet
- 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. Define product category, intended use, jurisdiction, application type and the date of the regulatory check. Keep this as an offline training exercise with no filing, fees or real applicant information.
3. Define a scientifically justified question and one measurable primary endpoint, with a feasible and ethical comparator.
4. Specify design, eligibility, allocation, blinding and study schedule, including withdrawals and safety escalation.
5. Write a justified sample-size and analysis plan with missing-data handling, monitoring, data integrity and consent arrangements.
6. Map the protocol to the assigned jurisdiction and assemble the supporting dossier and review checklist.
7. Perform an independent consistency and completeness check. Record evidence, gaps, owners and the exact approval or permission still required.
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.

Requirement / dossier element	Document / evidence	Gap / responsible role	Readiness decision
Administrative scope	Identify	Assess	Record
Scientific / quality evidence	Map	Assess	Record
Submission / lifecycle	Validate	Assess	Record

Worked Example

Illustrative parallel-group question compares mean change in a defined validated endpoint. A proposed 100 participants per arm is a planning placeholder until supported by effect, variability, type-I error, power and attrition assumptions.

Required protocol sections

• Scientific rationale, objectives, population and primary/secondary endpoints.
• Design, comparator, allocation, blinding, eligibility, study visits and procedures.
• Intervention accountability and product quality; safety monitoring, stopping rules and reporting responsibilities.
• Sample-size justification, analysis population, estimand or question, missing-data and multiplicity handling as appropriate.
• Consent, privacy, participant care, compensation/insurance as required, ethics oversight and dissemination.

Assigned study design

• Non-inferiority design: justify the margin from historical evidence and clinical relevance before the trial. Specify effect direction, assay sensitivity, analysis populations and interval rule; failure of superiority does not establish non-inferiority.

Result and Interpretation

• Deliver a protocol synopsis, schedule of assessments, safety plan and requirement-to-document map.
• A complete training checklist is not an authorisation, licence or guarantee of acceptance.

Precautions

• Distinguish scientific content requirements from electronic-publishing rules.
• Recheck current forms, amendments, scope and local requirements at actual filing.
• Do not invent approval numbers, signatures, fees or deadlines.

Viva Questions and Answers

Why define the application type first?

It determines the legal route and required evidence.

Does a valid file format prove scientific adequacy?

Technical validation and substantive review are separate.

Why retain requirement versions?

Regulations and submission specifications can change.

ADR Monitoring Protocol

Practical 19 - Clinical pharmacy case practical

Aim

To prepare an institutional ADR-monitoring protocol for a fictional clinical service.

Principle

A monitoring protocol defines who is observed, what events are captured, how suspected reactions are assessed and reported, and how confidentiality and clinical follow-up are maintained. Surveillance intensity and the denominator influence reported rates.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- 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 question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Define the service, population, objectives, event definitions, inclusion/exclusion rules and whether capture is prospective, retrospective or spontaneous.
4. Specify clinician escalation, structured case capture, causality/seriousness assessment, follow-up and reporting responsibilities.
5. Prepare consent/ethics and privacy arrangements appropriate to the actual surveillance or research category.
6. Define a data dictionary, duplicate management, quality checks, analysis plan and feedback to the clinical team.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
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.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Calculations

• Affected-patient proportion (%) = unique patients with an event / unique patients observed x 100

Worked Example

Illustrative active surveillance follows 200 unique patients and identifies 10 with at least one suspected ADR: patient proportion = 5.0%. If there are 14 events, the event count is 14; do not report 14/200 as the proportion of patients affected.

Result and Interpretation

• Deliver a monitoring protocol, case form, responsibility map and denominator-aware analysis plan.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

Why distinguish patients from events?

One person may have several events.

Does spontaneous reporting estimate incidence directly?

Exposure denominators and under-reporting usually limit that interpretation.

Why preserve follow-up?

Outcome and alternative-cause information can change the assessment.

Ligand Docking Study

Practical 20 - Molecular modelling practical

Aim

To generate and critically assess ligand poses in a validated benign target structure.

Principle

Docking samples poses and ranks them with an approximate scoring function. Receptor conformation, protonation, waters, cofactors and ligand states influence the result. Docking score is not a measured affinity.

Materials and Requirements

- Benign reference structures with verified stereochemistry and protonation basis
- Institution-approved software with version, parameters and model documentation
- Independent reference or validation dataset
- 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. Define the endpoint and retain unmodified input structures and identifiers. Standardise salts, tautomers and stereochemistry using a documented rule.
3. Check target identity, structure quality, missing regions, relevant cofactors and the intended binding-site evidence.
4. Prepare receptor and ligands with documented state and charge choices and define a justified search region.
5. Validate by an appropriate reference-ligand redocking or other control, inspect clashes and key interactions, and compare multiple plausible poses and repeats.
6. Save input/output files, failures, parameter choices and independent validation results so the analysis can be reproduced.
7. 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.

Molecule / model	Input / settings	Output / diagnostic	Interpretation / limitation
Reference	Document	Record	Evaluate
Test molecules	Document	Record	Evaluate
Independent check	Document	Record	Evaluate

Calculations

- Pose RMSD = sqrt[sum squared distances between corresponding atoms / number of compared atoms], after the justified alignment and atom mapping

Worked Example

Illustrative four corresponding heavy atoms each differ by 1.0 angstrom, giving RMSD = 1.0 angstrom.

A low RMSD supports one aspect of pose recovery; it does not prove ranking accuracy, affinity or correct chemistry.

Result and Interpretation

- Present the preparation record, validation, pose evidence and limitations of ranking.
- Predictions are not measured biological activity, clinical safety or regulatory approval.

Precautions

- Avoid training/test leakage and unsupported extrapolation.
- State software and model version and applicable domain.
- Do not select the best-looking model using the final test set.

Viva Questions and Answers

Does a lower score prove a stronger binder?

Scoring is approximate and needs experimental validation.

Why check protonation?

It changes interactions and charge assignment.

Why inspect atom mapping for RMSD?

Symmetry and atom correspondence can change the numerical result.

Redocking and Docking-Validation Study

Practical 21 - Molecular modelling practical

Aim

To generate and critically assess ligand poses in a validated benign target structure.

Principle

Docking samples poses and ranks them with an approximate scoring function. Receptor conformation, protonation, waters, cofactors and ligand states influence the result. Docking score is not a measured affinity.

Materials and Requirements

- Benign reference structures with verified stereochemistry and protonation basis
- Institution-approved software with version, parameters and model documentation
- Independent reference or validation dataset
- 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. Define the endpoint and retain unmodified input structures and identifiers. Standardise salts, tautomers and stereochemistry using a documented rule.
3. Check target identity, structure quality, missing regions, relevant cofactors and the intended binding-site evidence.
4. Prepare receptor and ligands with documented state and charge choices and define a justified search region.
5. Validate by an appropriate reference-ligand redocking or other control, inspect clashes and key interactions, and compare multiple plausible poses and repeats.
6. Save input/output files, failures, parameter choices and independent validation results so the analysis can be reproduced.
7. 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.

Molecule / model	Input / settings	Output / diagnostic	Interpretation / limitation
Reference	Document	Record	Evaluate
Test molecules	Document	Record	Evaluate
Independent check	Document	Record	Evaluate

Calculations

- Pose RMSD = sqrt[sum squared distances between corresponding atoms / number of compared atoms], after the justified alignment and atom mapping

Worked Example

Illustrative four corresponding heavy atoms each differ by 1.0 angstrom, giving RMSD = 1.0 angstrom.

A low RMSD supports one aspect of pose recovery; it does not prove ranking accuracy, affinity or correct chemistry.

Redocking validation

• Remove the reference ligand from a structurally checked complex and reproduce its pose using documented settings.

• Report receptor alignment, ligand atom mapping, symmetry handling, RMSD, chemical geometry and contact recovery; a single threshold is not complete validation.

Result and Interpretation

• Present the preparation record, validation, pose evidence and limitations of ranking.

• Predictions are not measured biological activity, clinical safety or regulatory approval.

Precautions

• Avoid training/test leakage and unsupported extrapolation.

• State software and model version and applicable domain.

• Do not select the best-looking model using the final test set.

Viva Questions and Answers

Does a lower score prove a stronger binder?

Scoring is approximate and needs experimental validation.

Why check protonation?

It changes interactions and charge assignment.

Why inspect atom mapping for RMSD?

Symmetry and atom correspondence can change the numerical result.

Pharmacophore-Based Screening

Practical 22 - Molecular modelling practical

Aim

To build and validate a ligand- or structure-based pharmacophore hypothesis.

Principle

A pharmacophore describes a spatial arrangement of interaction features proposed to support recognition. Alignment, feature tolerances and reference activity quality influence the hypothesis.

Materials and Requirements

- Benign reference structures with verified stereochemistry and protonation basis
- Institution-approved software with version, parameters and model documentation
- Independent reference or validation dataset
- 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. Define the endpoint and retain unmodified input structures and identifiers. Standardise salts, tautomers and stereochemistry using a documented rule.
3. Select a coherent, documented activity dataset and generate justified conformers and protonation states.
4. Align known ligands or inspect a validated complex to define donor, acceptor, hydrophobic and other justified features.
5. Specify spatial tolerances and excluded volumes where supported; test held-out actives and appropriate decoys without tuning on the final test set.
6. Save input/output files, failures, parameter choices and independent validation results so the analysis can be reproduced.
7. 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.

Molecule / model	Input / settings	Output / diagnostic	Interpretation / limitation
Reference	Document	Record	Evaluate
Test molecules	Document	Record	Evaluate
Independent check	Document	Record	Evaluate

Calculations

- Recall = retrieved known actives / known actives assessed
- Precision = known actives retrieved / all retrieved molecules

Worked Example

Illustrative a screen retrieves 20 compounds including 8 of 10 known actives: recall = 80% and precision = 40%. Performance on these data does not establish experimental activity of the other 12 compounds.

Result and Interpretation

- Present the feature map, selection rationale and independent screening-performance assessment.
- Predictions are not measured biological activity, clinical safety or regulatory approval.

Precautions

- Avoid training/test leakage and unsupported extrapolation.
- State software and model version and applicable domain.
- Do not select the best-looking model using the final test set.

Viva Questions and Answers

What distinguishes a pharmacophore from a molecule?

It is a feature arrangement rather than a full chemical structure.

Why use decoys?

They challenge discrimination beyond recovering known actives.

Why validate conformers?

Feature matching depends on the geometry used.

QSAR Study and External Validation

Practical 23 - Molecular modelling practical

Aim

To construct and externally evaluate a small, interpretable two-dimensional QSAR model.

Principle

QSAR relates a precisely defined measured endpoint to molecular descriptors. Endpoint consistency, data curation, split design and an applicability domain are necessary; a high training R-squared is insufficient.

Materials and Requirements

- Benign reference structures with verified stereochemistry and protonation basis
- Institution-approved software with version, parameters and model documentation
- Independent reference or validation dataset
- 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. Define the endpoint and retain unmodified input structures and identifiers. Standardise salts, tautomers and stereochemistry using a documented rule.
3. Curate duplicate structures, assay units, censored values and activity conditions; transform only by a documented rule.
4. Separate training and external test sets before descriptor selection and preprocessing; consider scaffold grouping to reduce leakage.
5. Fit a parsimonious model with internal validation and response randomisation where appropriate, then evaluate the untouched external set and domain.
6. Save input/output files, failures, parameter choices and independent validation results so the analysis can be reproduced.
7. 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.

Molecule / model	Input / settings	Output / diagnostic	Interpretation / limitation
Reference	Document	Record	Evaluate
Test molecules	Document	Record	Evaluate
Independent check	Document	Record	Evaluate

Calculations

- pIC50 = -log10(IC50 in mol/L)
- RMSE = sqrt[sum(observed - predicted)^2 / number of predictions]

Worked Example

Illustrative IC50 = 10 micromol/L = 10^-5 mol/L gives pIC50 = 5.0. A teaching model pIC50 = 3.0 + 0.5 log P predicts 4.0 at log P = 2.0.

The illustrative equation is not a validated medicinal-chemistry relationship; fit and test an actual curated dataset.

Result and Interpretation

- Report endpoint, split, descriptors, equation, validation metrics and domain, including failures.
- Predictions are not measured biological activity, clinical safety or regulatory approval.

Precautions

- Avoid training/test leakage and unsupported extrapolation.
- State software and model version and applicable domain.
- Do not select the best-looking model using the final test set.

Viva Questions and Answers

Why convert IC50 to mol/L?

The logarithmic endpoint requires a defined concentration unit.

What is leakage?

Information from evaluation data influences model development.

Why test externally?

Training fit does not establish predictive performance.

Adverse Drug Reaction Reporting

Practical 24 - Clinical pharmacy case practical

Aim

To complete a fictional suspected-ADR report through the appropriate reporting framework.

Principle

A valid safety case needs an identifiable patient, identifiable reporter, suspected product and suspected reaction, with enough information for follow-up. Identifiable within a protected reporting system does not mean publishing personal details.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- 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 question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Use the current Indian PvPI healthcare-professional form or equivalent official local framework and keep all training identities fictional.
4. Enter reaction chronology, description, seriousness/outcome, suspected and concomitant medicines, indication, exposure dates and relevant tests.
5. Record dechallenge, alternative causes and missing information without deliberately rechallenging the patient.
6. Check completeness, protect confidentiality and document the intended local ADR-monitoring pathway and follow-up; do not send the training report.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
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.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Worked Example

Fictional report has a suspected medicine and rash but no event dates or reporter contact. Record the missing fields and a follow-up query rather than inventing them.

A suspected reaction may be reported even when causality is uncertain; reporting must not delay urgent clinical care.

Result and Interpretation

• Deliver a clearly labelled fictional report and a completeness/follow-up checklist.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

Is proof required before reporting?

Suspicion can be enough for reporting.

Why include concomitant medicines?

They help assess interactions and alternative explanations.

Can training cases be submitted as real events?

No; the exercise remains fictional and offline.

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