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M.Pharm Practical Notes

Pharmaceutics Practicals II

Semester 2

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Microcapsule Formation by Coacervation

Practical 1 - Bench formulation practical

Aim

To compare phase-separation conditions during microcapsule formation.

Principle

Coacervation or phase separation produces a polymer-rich phase that may deposit around a dispersed core. Temperature change, non-solvent addition and an incompatible polymer can alter polymer solvation and separation.

Formation of a polymer-rich phase does not by itself establish a complete capsule wall; morphology and core retention must be evaluated.

A formulation comparison is meaningful when the raw-material grades, batch size and evaluation conditions are recorded. Change one planned factor at a time or use a documented experimental design, and compare independently prepared batches rather than only repeated readings from one batch.

Materials and Requirements

- Approved core material and coating polymer
- Selected solvent and non-solvent system
- Temperature-controlled mixing and microscopy
- Calibrated balance, suitable containers and identified evaluation equipment
- Controlled batch sheet and raw-data forms

Procedure

1. Define the purpose, formula, batch size, material grades and comparison conditions. Calculate all quantities before weighing.
2. Check equipment readiness and record material identities and actual quantities. Reconcile theoretical and actual batch mass.
3. Select the prescribed baseline formulation and keep core loading and mixing conditions fixed across the comparison.
4. Apply one approved phase-separation trigger at a time: temperature change, non-solvent addition or incompatible-polymer addition.
5. Record the addition order, conditions and onset of phase separation using microscopy or other suitable observations.
6. Recover and stabilise the preparation through the adopted process, then assess morphology, size, core retention and release.
7. Evaluate the stated quality attributes on representative portions using the same method for all comparison batches. Record individual readings and any excluded observations with reasons.
8. Calculate the specified response, variability and material balance. Compare with predefined teaching or product criteria and discuss sources of variation.
9. Label retained preparations and dispose of remaining material through the laboratory procedure. Keep the complete preparation and evaluation record together.

Observations and Record

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

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Trigger and conditions	Record the adopted method	Record	Evaluate
Phase-separation observation	Record the adopted method	Record	Evaluate
Size / morphology	Record the adopted method	Record	Evaluate
Core retention	Record the adopted method	Record	Evaluate

Calculations

• Core retention (%) = measured retained core / input core x 100
• Dry recovery (%) = recovered dry mass / theoretical input solids x 100

Worked Example

Illustrative dry input solids 2.00 g and recovered material 1.60 g give 80.0% dry recovery.

Measured retained core 0.36 g from 0.50 g input gives 72.0% core retention.

Report morphology as well as these mass-based values; a precipitate may have high recovery without having the intended microcapsule structure.

Result and Interpretation

• Compare trigger conditions and morphology using predefined descriptors. Explain the distinction between precipitation, microsphere formation and encapsulation.
• State the preparation conditions and the evidence supporting the result. A satisfactory physical observation alone does not establish long-term stability, clinical performance or suitability for administration.

Precautions

• Use the approved solvent system and ventilation.
• Avoid changing multiple phase-separation factors unintentionally.
• Use the specified stabilisation process rather than introducing an unqualified reactive cross-linker.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

What is a coacervate?

A polymer-rich liquid phase formed under suitable phase-separation conditions.

Why examine morphology?

Mass recovery alone does not prove the intended capsule structure.

Why control mixing?

It affects dispersion and the contact between phases.

Preparation and Evaluation of Alginate Beads

Practical 2 - Bench formulation practical

Aim

To prepare calcium-alginate beads and evaluate formation, size, recovery and marker release.

Principle

Alginate chains form an ionically cross-linked gel in the presence of suitable calcium ions. Droplet formation controls initial size, while polymer grade, solution viscosity, cross-linking and subsequent handling affect the bead structure.

A formulation comparison is meaningful when the raw-material grades, batch size and evaluation conditions are recorded. Change one planned factor at a time or use a documented experimental design, and compare independently prepared batches rather than only repeated readings from one batch.

Materials and Requirements

- Sodium alginate and calcium chloride solutions prepared by the approved method
- Benign marker or approved model drug
- Controlled dispensing device, stirrer and bead-sizing method
- Calibrated balance, suitable containers and identified evaluation equipment
- Controlled batch sheet and raw-data forms

Procedure

1. Define the purpose, formula, batch size, material grades and comparison conditions. Calculate all quantities before weighing.
2. Check equipment readiness and record material identities and actual quantities. Reconcile theoretical and actual batch mass.
3. Hydrate the selected alginate grade and document its concentration, viscosity condition and marker content.
4. Introduce controlled droplets into the prescribed calcium bath with the approved nozzle and mixing conditions.
5. Maintain the chosen curing procedure, then recover and rinse the beads using the stated method.
6. Measure wet size and the defined dry or wet recovery basis. Assess marker content and release using validated separation and assay steps.
7. Evaluate the stated quality attributes on representative portions using the same method for all comparison batches. Record individual readings and any excluded observations with reasons.
8. Calculate the specified response, variability and material balance. Compare with predefined teaching or product criteria and discuss sources of variation.
9. Label retained preparations and dispose of remaining material through the laboratory procedure. Keep the complete preparation and evaluation record together.

Observations and Record

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

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Droplet and bath conditions	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Bead size distribution	Record the adopted method	Record	Evaluate
Recovered mass	Record the adopted method	Record	Evaluate
Marker content and release	Record the adopted method	Record	Evaluate

Calculations

• Encapsulation efficiency (%) = entrapped marker / input marker x 100
• Drug loading (%) = entrapped marker / recovered dry bead mass x 100

Worked Example

Illustrative input marker is 100 mg and the validated measurement of free marker is 20 mg.
Entrapped marker is 80 mg and encapsulation efficiency is 80.0%. If recovered dry beads weigh 400 mg, loading is 20.0% w/w.
Account for recovery and assay losses before assigning all unmeasured marker to encapsulation.

Result and Interpretation

• Relate bead size and release to the actual process conditions. State whether mass and size were measured wet or dry.
• State the preparation conditions and the evidence supporting the result. A satisfactory physical observation alone does not establish long-term stability, clinical performance or suitability for administration.

Precautions

• Control the dispensing geometry and solution condition.
• Prevent contamination during curing and recovery.
• Do not compare wet-yield and dry-yield percentages as equivalent quantities.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

What forms the gel?

Ionic cross-linking of alginate by calcium ions.

Why record alginate grade?

Polymer characteristics influence viscosity and gel behaviour.

Are loading and encapsulation efficiency identical?

No; they use different denominator quantities.

Gelatin and Albumin Microspheres

Practical 3 - Bench formulation practical

Aim

To prepare and characterise a gelatin, albumin or other approved polymeric microsphere model.

Principle

Coacervation or phase separation produces a polymer-rich phase that may deposit around a dispersed core. Temperature change, non-solvent addition and an incompatible polymer can alter polymer solvation and separation.

Formation of a polymer-rich phase does not by itself establish a complete capsule wall; morphology and core retention must be evaluated.

A formulation comparison is meaningful when the raw-material grades, batch size and evaluation conditions are recorded. Change one planned factor at a time or use a documented experimental design, and compare independently prepared batches rather than only repeated readings from one batch.

Materials and Requirements

- Approved core material and coating polymer
- Selected solvent and non-solvent system
- Temperature-controlled mixing and microscopy
- Calibrated balance, suitable containers and identified evaluation equipment
- Controlled batch sheet and raw-data forms

Procedure

1. Define the purpose, formula, batch size, material grades and comparison conditions. Calculate all quantities before weighing.
2. Check equipment readiness and record material identities and actual quantities. Reconcile theoretical and actual batch mass.
3. Select the prescribed baseline formulation and keep core loading and mixing conditions fixed across the comparison.
4. Apply one approved phase-separation trigger at a time: temperature change, non-solvent addition or incompatible-polymer addition.
5. Record the addition order, conditions and onset of phase separation using microscopy or other suitable observations.
6. Recover and stabilise the preparation through the adopted process, then assess morphology, size, core retention and release.
7. Evaluate the stated quality attributes on representative portions using the same method for all comparison batches. Record individual readings and any excluded observations with reasons.
8. Calculate the specified response, variability and material balance. Compare with predefined teaching or product criteria and discuss sources of variation.
9. Label retained preparations and dispose of remaining material through the laboratory procedure. Keep the complete preparation and evaluation record together.

Observations and Record

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

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Trigger and conditions	Record the adopted method	Record	Evaluate
Phase-separation observation	Record the adopted method	Record	Evaluate
Size / morphology	Record the adopted method	Record	Evaluate
Core retention	Record the adopted method	Record	Evaluate

Calculations

• Core retention (%) = measured retained core / input core x 100

• Dry recovery (%) = recovered dry mass / theoretical input solids x 100

Worked Example

Illustrative dry input solids 2.00 g and recovered material 1.60 g give 80.0% dry recovery.

Measured retained core 0.36 g from 0.50 g input gives 72.0% core retention.

Report morphology as well as these mass-based values; a precipitate may have high recovery without having the intended microcapsule structure.

Microsphere-specific record

• Use the selected protein-polymer process and document the hardening method, recovery, size distribution and marker content.

• Microspheres contain material within a matrix; microcapsules have a core-wall architecture. Confirm the observed morphology instead of assigning the structure from the recipe alone.

Result and Interpretation

• Compare trigger conditions and morphology using predefined descriptors. Explain the distinction between precipitation, microsphere formation and encapsulation.

• State the preparation conditions and the evidence supporting the result. A satisfactory physical observation alone does not establish long-term stability, clinical performance or suitability for administration.

Precautions

• Use the approved solvent system and ventilation.

• Avoid changing multiple phase-separation factors unintentionally.

• Use the specified stabilisation process rather than introducing an unqualified reactive cross-linker.

• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

What is a coacervate?

A polymer-rich liquid phase formed under suitable phase-separation conditions.

Why examine morphology?

Mass recovery alone does not prove the intended capsule structure.

Why control mixing?

It affects dispersion and the contact between phases.

Liposomes and Niosomes

Practical 4 - Bench formulation practical

Aim

To prepare a liposome or niosome model and evaluate vesicle properties and marker entrapment.

Principle

Liposomes form bilayer structures from suitable phospholipids, whereas niosomes commonly use selected nonionic surfactant systems. Hydrophilic and lipophilic materials associate differently with aqueous compartments and bilayer regions.

A formulation comparison is meaningful when the raw-material grades, batch size and evaluation conditions are recorded. Change one planned factor at a time or use a documented experimental design, and compare independently prepared batches rather than only repeated readings from one batch.

Materials and Requirements

- Approved lipid or nonionic-surfactant system and marker
- Controlled film-hydration or other selected preparation arrangement
- Qualified size-characterisation and separation methods
- Calibrated balance, suitable containers and identified evaluation equipment
- Controlled batch sheet and raw-data forms

Procedure

1. Define the purpose, formula, batch size, material grades and comparison conditions. Calculate all quantities before weighing.
2. Check equipment readiness and record material identities and actual quantities. Reconcile theoretical and actual batch mass.
3. Record component identity, ratio, marker amount and the selected preparation method.
4. Prepare and hydrate the film or use the approved alternative process, documenting hydration and size-control conditions.
5. Separate free from vesicle-associated marker using a qualified technique and verify recovery through the separation.
6. Measure size distribution, dispersity where applicable, morphology or supporting evidence, entrapment and changes during the defined storage observation.
7. Evaluate the stated quality attributes on representative portions using the same method for all comparison batches. Record individual readings and any excluded observations with reasons.
8. Calculate the specified response, variability and material balance. Compare with predefined teaching or product criteria and discuss sources of variation.
9. Label retained preparations and dispose of remaining material through the laboratory procedure. Keep the complete preparation and evaluation record together.

Observations and Record

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

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Composition / method	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Size distribution	Record the adopted method	Record	Evaluate
Free and associated marker	Record the adopted method	Record	Evaluate
Storage observation	Record the adopted method	Record	Evaluate

Calculations

• Entrapment efficiency (%) = associated marker / input marker x 100
• State the separation recovery and whether the result is apparent or recovery-corrected.

Worked Example

Illustrative input marker 10.0 mg and validated free-marker amount 2.0 mg give an apparent associated amount of 8.0 mg and 80.0% entrapment.
If separation recovers only 85% of an independent marker control, investigate that loss before interpreting the entrapment result.
A size result of 150 nm alone does not establish a uniform unilamellar population.

Result and Interpretation

• Report composition, method and the full characterisation evidence. Distinguish size, dispersity, morphology and encapsulation.
• State the preparation conditions and the evidence supporting the result. A satisfactory physical observation alone does not establish long-term stability, clinical performance or suitability for administration.

Precautions

• Control oxidation and storage conditions for sensitive components.
• Use the qualified separation method.
• Handle organic solvents and sonication equipment through the laboratory procedure.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

How do liposomes and niosomes differ?

Their main bilayer-forming components differ.

Why validate free-marker separation?

Separation losses or leakage can bias entrapment estimates.

Does one mean diameter describe the whole population?

No; distribution and supporting characterisation are important.

Preparation and Evaluation of Spherules

Practical 5 - Bench formulation practical

Aim

To prepare pellets by a selected spheronisation process and assess their shape, size and recovery.

Principle

A suitably plastic wet mass is formed and rounded through controlled processing. Material composition, wetness, extrusion conditions and spheronisation energy affect pellet shape and size distribution.

A formulation comparison is meaningful when the raw-material grades, batch size and evaluation conditions are recorded. Change one planned factor at a time or use a documented experimental design, and compare independently prepared batches rather than only repeated readings from one batch.

Materials and Requirements

- Approved pellet-forming powder blend and binder liquid
- Extrusion-spheronisation equipment operated by trained staff
- Drying arrangement, sieves and image-analysis method
- Calibrated balance, suitable containers and identified evaluation equipment
- Controlled batch sheet and raw-data forms

Procedure

1. Define the purpose, formula, batch size, material grades and comparison conditions. Calculate all quantities before weighing.
2. Check equipment readiness and record material identities and actual quantities. Reconcile theoretical and actual batch mass.
3. Prepare the specified powder blend and add the selected liquid through the documented wet-massing process.
4. Record wet-mass condition and have the trained operator perform extrusion and spheronisation at the planned settings.
5. Dry through the prescribed method and determine the chosen size fractions.
6. Measure pellet shape using a defined image-analysis approach and assess mechanical behaviour and marker distribution where required.
7. Evaluate the stated quality attributes on representative portions using the same method for all comparison batches. Record individual readings and any excluded observations with reasons.
8. Calculate the specified response, variability and material balance. Compare with predefined teaching or product criteria and discuss sources of variation.
9. Label retained preparations and dispose of remaining material through the laboratory procedure. Keep the complete preparation and evaluation record together.

Observations and Record

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

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Wet-mass and process condition	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Sieve fractions	Record the adopted method	Record	Evaluate
Shape measurements	Record the adopted method	Record	Evaluate
Recovery / marker content	Record the adopted method	Record	Evaluate

Calculations

• Usable yield (%) = recovered mass in target fraction / total input solids x 100
• Aspect ratio = major dimension / minor dimension; define the measurement method.

Worked Example

Illustrative input solids 100 g and recovered target-size fraction 72 g give 72% usable yield.
A pellet with measured major and minor dimensions 1.10 and 1.00 mm has aspect ratio 1.10.
Interpret the distribution of shape measurements rather than one selected pellet.

Result and Interpretation

• Discuss size, shape and usable yield together. Explain any effect of wet-mass condition and processing on the result.
• State the preparation conditions and the evidence supporting the result. A satisfactory physical observation alone does not establish long-term stability, clinical performance or suitability for administration.

Precautions

• Operate guarded equipment through the trained operator.
• Record liquid addition and drying losses.
• Use representative images rather than selecting only the most spherical units.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

Why does wetness matter?

It influences plasticity, extrusion and rounding.

What does an aspect ratio near one suggest?

A more equidimensional outline under the stated measurement method.

Why report usable yield?

Total recovery may include material outside the desired size range.

Dissolution Improvement by Solid Dispersion

Practical 6 - Bench formulation practical

Aim

To prepare a drug-carrier dispersion and compare dissolution with the untreated drug and a physical mixture.

Principle

A solid dispersion distributes drug within a solid carrier. Dissolution may change through wetting, size reduction, altered crystallinity or other drug-carrier interactions. Improved release does not automatically establish an amorphous product.

A formulation comparison is meaningful when the raw-material grades, batch size and evaluation conditions are recorded. Change one planned factor at a time or use a documented experimental design, and compare independently prepared batches rather than only repeated readings from one batch.

Materials and Requirements

- Approved slightly soluble model drug and carrier
- Selected fusion or solvent-removal arrangement
- Assay, dissolution and suitable solid-state characterisation methods
- Calibrated balance, suitable containers and identified evaluation equipment
- Controlled batch sheet and raw-data forms

Procedure

1. Define the purpose, formula, batch size, material grades and comparison conditions. Calculate all quantities before weighing.
2. Check equipment readiness and record material identities and actual quantities. Reconcile theoretical and actual batch mass.
3. Define the drug-to-carrier ratio and prepare untreated-drug and physical-mixture controls.
4. Use the approved fusion or solvent-removal method, recording temperatures or solvent-removal conditions relevant to material stability.
5. Recover, condition and size the preparation by the specified method, documenting yield and content uniformity.
6. Compare dissolution under identical conditions and use appropriate solid-state evidence when discussing the mechanism.
7. Evaluate the stated quality attributes on representative portions using the same method for all comparison batches. Record individual readings and any excluded observations with reasons.
8. Calculate the specified response, variability and material balance. Compare with predefined teaching or product criteria and discuss sources of variation.
9. Label retained preparations and dispose of remaining material through the laboratory procedure. Keep the complete preparation and evaluation record together.

Observations and Record

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

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Preparation	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Drug and carrier ratio	Record the adopted method	Record	Evaluate
Measured content	Record the adopted method	Record	Evaluate
Dissolution / solid-state evidence	Record the adopted method	Record	Evaluate

Calculations

• Theoretical loading (%) = input drug mass / total input solids x 100
• Drug recovery (%) = measured recovered drug / input drug x 100

Worked Example

Illustrative input: 1.00 g drug and 4.00 g carrier give 20.0% theoretical loading.
If the recovered material contains 0.95 g drug, drug recovery is 95.0%.
Compare the dispersion with the physical mixture as well as the untreated drug to distinguish process effects from simple carrier addition.

Result and Interpretation

• Report recovery, content, dissolution and the evidence supporting the proposed physical state.
• State the preparation conditions and the evidence supporting the result. A satisfactory physical observation alone does not establish long-term stability, clinical performance or suitability for administration.

Precautions

• Choose a process within the drug and carrier stability limits.
• Evaluate residual solvent when relevant.
• Avoid equating a missing thermal peak alone with proven amorphisation.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

Why include a physical mixture?

It separates the effects of carrier addition from the preparation process.

Must every dispersion be amorphous?

No; dispersions can contain different material states.

Does faster dissolution prove better clinical exposure?

That requires additional evidence.

Comparison of Dissolution Profiles Between Brands

Practical 7 - Bench practical

Aim

To compare two product release profiles using matched conditions and an appropriate comparison method.

Principle

A dissolution test measures transfer of drug into a defined medium under controlled hydrodynamic conditions. A profile provides information across time and may reveal lag, burst release or incomplete release.

Temperature, apparatus, medium, speed, sampling and analytical method are selected for the product and study purpose. An in-vitro profile alone does not establish a clinical duration of action.

Materials and Requirements

- Qualified dissolution apparatus and the specified vessels
- Product-specific medium and calibrated temperature measurement
- Validated sampling and assay arrangement
- Reference standard and dosage units

Procedure

1. Record product, batch, dose, apparatus, medium composition and volume, agitation, temperature and sampling schedule.
2. Verify apparatus readiness and the method-required medium preparation and deaeration conditions.
3. Introduce units using the prescribed technique and collect individual-vessel samples at the planned times.
4. Use the validated sampling location and filtration procedure. Replace withdrawn volume where specified and document the exact scheme.
5. Measure concentrations within the established assay range using appropriate standards and blanks.
6. Correct for removed drug and dilution. Plot individual and mean cumulative release, retain variability and compare with the applicable criteria.

Observations and Record

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

Time	Measured concentration	Corrected released mass	Release percentage
Initial	Record baseline	Calculate	Calculate
Time point 1	Record	Calculate	Calculate
Time point 2	Record	Calculate	Calculate
Final planned point	Record	Calculate	Calculate

Calculations

- For equal-volume replacement: Mn = V x Cn + v x sum(Ci for earlier samples)
- Release (%) = Mn / initial drug amount x 100

Worked Example

Illustrative V = 900 mL and replacement sample volume v = 10 mL. Concentrations at three times are 0.010, 0.020 and 0.030 mg/mL.

Corrected mass at the third point = 900 x 0.030 + 10 x (0.010 + 0.020) = 27.3 mg.

For a 50.0 mg initial amount, release is 54.6%. This calculation assumes the stated replacement scheme and a stable dissolved analyte.

Profile comparison

- Use the same sampling schedule and method, and retain individual-vessel data for both products.
- For a valid conventional f2 comparison, apply the relevant guidance on unit numbers, variability and late time points. Product-specific conditions take priority.
- f2 = 50 log10(100 / sqrt(1 + mean((R - T)^2))). A value within the conventional similarity range is interpreted only when the prerequisites for that comparison are met.

Result and Interpretation

- Report the entire profile, individual-unit variability and the actual conditions.
- Compare controlled-release products using an appropriate product-specific design and acceptance approach.
- Distinguish incomplete release from analytical loss or an unsuitable test condition.

Precautions

- Maintain method-specified temperature and hydrodynamics.
- Control sampling time, filter recovery and volume replacement.
- Avoid treating pooled samples as evidence of individual-unit uniformity.
- Investigate apparatus or assay failures before interpreting the profile.

Viva Questions and Answers

Why correct for sampling?

Withdrawn fluid removes drug that contributes to cumulative release.

Why examine individual units?

A similar mean can conceal large unit-to-unit variation.

Does faster dissolution always mean a better controlled-release product?

No; performance must match the intended release target.

Comparison of Protein Binding Between Two Drugs

Practical 8 - Practical study

Aim

To compare unbound fractions of two model drugs using an approved equilibrium-dialysis or ultrafiltration dataset.

Principle

Only unbound concentration is used in the binding-fraction calculation. Membrane adsorption, volume shifts, equilibration and nonspecific losses can bias a separation; measured recovery must therefore accompany the binding estimate.

Materials and Requirements

- Supplied total and unbound concentration data or an approved nonclinical model
- Qualified separation system, protein matrix and protein-free controls
- Suitable assay and recovery controls
- 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. Record protein concentration, buffer, pH, temperature, incubation condition and separation method for both drugs.
3. Measure total concentration and the separated unbound fraction, correcting for dilution and volume changes according to the method.
4. Evaluate membrane adsorption and mass balance with appropriate protein-free and recovery controls.
5. Calculate unbound and bound fractions for independent preparations at matched total concentrations.
6. 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.

Drug / control	Total concentration	Unbound concentration	Unbound / bound fraction
Drug A	Enter mg/L	Enter mg/L	Calculate
Drug B	Enter mg/L	Enter mg/L	Calculate
Protein-free recovery	Input amount	Recovered amount	Calculate

Calculations

- Unbound fraction fu = Cu / Ctotal
- Bound fraction = 1 - fu; bound (%) = 100 x (1 - fu)

Worked Example

Illustrative A: total 10 mg/L, unbound 1 mg/L gives fu = 0.10 and 90% bound. B: total 10 mg/L, unbound 3 mg/L gives fu = 0.30 and 70% bound.

These comparisons apply to the measured conditions. Concentration-dependent binding and different clinical matrices can change the result.

Result and Interpretation

- Report replicate variability, recovery and the conditions of the comparison.
- Do not convert a binding result directly into a clinical dose recommendation.

Precautions

- Check for protein leakage and membrane adsorption.
- Avoid interpreting poor recovery as binding.
- Keep protein and separation conditions matched.

Viva Questions and Answers

What is fu?

The unbound concentration divided by the total concentration.

Why use a protein-free control?

It helps detect nonspecific losses to the device.

Is binding always concentration independent?

Saturable binding can make the fraction change with concentration.

Paracetamol Bioavailability Data Analysis

Practical 9 - Dataset-based practical

Aim

To calculate dose-normalised paracetamol bioavailability from a supplied animal-study teaching dataset.

Principle

Noncompartmental analysis estimates exposure from the concentration-time profile without first assuming a fixed compartmental structure. Terminal extrapolation requires a defensible terminal phase. IVIVC additionally needs an appropriate relationship between in-vitro release and in-vivo input or response; two similar-looking curves do not establish it.

Keep the supplied data, transformations, software version, analysis settings and complete output together. Record units explicitly and distinguish assumptions from observations.

Materials and Requirements

- Supplied concentration-time data, dose, route and subject identifiers
- Dissolution profiles where an IVIVC investigation is intended
- Spreadsheet or institution-approved analysis software
- Raw-data dictionary and analysis worksheet

Procedure

1. Define the analysis question and the variables, units, identifiers and missing-data conventions in the dataset.
2. Import a working copy and check values against the original file. Inspect ranges, duplicates, timing and unit consistency.
3. Map concentration, time, dose and subject columns and select the intended route and exposure calculation.
4. Inspect the profile and choose the integration method, terminal observations and treatment of below-quantitation values through the stated analysis plan.
5. Calculate Cmax, Tmax, AUC, terminal rate where justified, half-life and extrapolated fraction. Review terminal-fit diagnostics.
6. In WinNonlin or the selected implementation, preserve the model and settings report. For IVIVC, identify the development and validation datasets and the appropriate input-estimation method.
7. Retain diagnostics, intermediate calculations and the selected analysis settings. Explain exclusions and sensitivity checks.
8. Write a conclusion that addresses the stated question and the limitations of the design rather than relying on one fitted statistic.

Observations and Record

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

Parameter	Input or method	Calculated value	Diagnostic / units
Cmax and Tmax	Observed profile	Record	State units
AUC	Selected integration	Record	Check sampling
Terminal slope	Justified points	Record	Review fit

Parameter	Input or method	Calculated value	Diagnostic / units
IVIVC	Development and validation design	Record	State evidence

Calculations

- Linear trapezoid area = (C1 + C2)/2 x (t2 - t1)
- AUC_infinity = AUC_last + C_last/lambda_z, where terminal extrapolation is justified
- Half-life = ln(2)/lambda_z
- After extravascular dosing, dose/AUC estimates CL/F rather than true clearance unless F is known.

Worked Example

Illustrative oral profile: times 0, 1, 2, 4, 6 and 8 h; concentrations 0, 8, 4, 2, 1 and 0.5 mg/L.

Linear trapezoidal AUC to 8 h is 20.5 mg.h/L. The illustrated terminal decline from 2 to 8 h halves every 2 h, giving lambda_z = 0.3466 h^-1.

Tail area = 0.5/0.3466 = 1.443 mg.h/L; AUC_infinity is about 21.943 mg.h/L and half-life is 2.00 h.

A formal analysis uses adequate observations, prespecified methods and appropriate terminal-fit assessment.

Bioavailability record

- Use institution-supplied or explicitly simulated concentration-time data; the record does not require student animal dosing.
- Record study approvals, species, preparation, dose units, sampling plan and validated analytical method when reviewing a real authorised study.
- Illustrative dose-normalised AUC values are 0.18 and 0.24 exposure units per dose unit for oral and intravenous routes. Absolute bioavailability = 0.18/0.24 x 100 = 75.0%.

Result and Interpretation

- Report the exposure parameters and their data basis. Evaluate extrapolated exposure and the adequacy of terminal sampling.
- State separately whether an IVIVC was developed, tested or only proposed.

Precautions

- Do not mix concentration or time units.
- Distinguish observed from model-derived values.
- A regression between dissolution and plasma concentration is not automatically a validated Level A IVIVC.
- Preserve the original dataset and a reproducible record of the analysis.

Viva Questions and Answers

Why select the terminal phase carefully?

The selected slope affects half-life and extrapolated exposure.

What is CL/F?

Apparent clearance after an extravascular dose when absolute bioavailability is not established.

Why use separate IVIVC validation evidence?

The fitted relationship must predict data beyond the observations used to develop it.

Pharmacokinetic and IVIVC Analysis in WinNonlin

Practical 10 - Software and data-analysis practical

Aim

To perform noncompartmental pharmacokinetic calculations and evaluate the evidence needed for an IVIVC analysis.

Principle

Noncompartmental analysis estimates exposure from the concentration-time profile without first assuming a fixed compartmental structure. Terminal extrapolation requires a defensible terminal phase. IVIVC additionally needs an appropriate relationship between in-vitro release and in-vivo input or response; two similar-looking curves do not establish it.

Keep the supplied data, transformations, software version, analysis settings and complete output together. Record units explicitly and distinguish assumptions from observations.

Materials and Requirements

- Supplied concentration-time data, dose, route and subject identifiers
- Dissolution profiles where an IVIVC investigation is intended
- Spreadsheet or institution-approved analysis software
- Raw-data dictionary and analysis worksheet

Procedure

1. Define the analysis question and the variables, units, identifiers and missing-data conventions in the dataset.
2. Import a working copy and check values against the original file. Inspect ranges, duplicates, timing and unit consistency.
3. Map concentration, time, dose and subject columns and select the intended route and exposure calculation.
4. Inspect the profile and choose the integration method, terminal observations and treatment of below-quantitation values through the stated analysis plan.
5. Calculate Cmax, Tmax, AUC, terminal rate where justified, half-life and extrapolated fraction. Review terminal-fit diagnostics.
6. In WinNonlin or the selected implementation, preserve the model and settings report. For IVIVC, identify the development and validation datasets and the appropriate input-estimation method.
7. Retain diagnostics, intermediate calculations and the selected analysis settings. Explain exclusions and sensitivity checks.
8. Write a conclusion that addresses the stated question and the limitations of the design rather than relying on one fitted statistic.

Observations and Record

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

Parameter	Input or method	Calculated value	Diagnostic / units
Cmax and Tmax	Observed profile	Record	State units
AUC	Selected integration	Record	Check sampling

Parameter	Input or method	Calculated value	Diagnostic / units
Terminal slope	Justified points	Record	Review fit
IVIVC	Development and validation design	Record	State evidence

Calculations

- Linear trapezoid area = (C1 + C2)/2 x (t2 - t1)
- AUC_infinity = AUC_last + C_last/lambda_z, where terminal extrapolation is justified
- Half-life = ln(2)/lambda_z
- After extravascular dosing, dose/AUC estimates CL/F rather than true clearance unless F is known.

Worked Example

Illustrative oral profile: times 0, 1, 2, 4, 6 and 8 h; concentrations 0, 8, 4, 2, 1 and 0.5 mg/L.

Linear trapezoidal AUC to 8 h is 20.5 mg.h/L. The illustrated terminal decline from 2 to 8 h halves every 2 h, giving lambda_z = 0.3466 h^-1.

Tail area = 0.5/0.3466 = 1.443 mg.h/L; AUC_infinity is about 21.943 mg.h/L and half-life is 2.00 h.

A formal analysis uses adequate observations, prespecified methods and appropriate terminal-fit assessment.

Result and Interpretation

- Report the exposure parameters and their data basis. Evaluate extrapolated exposure and the adequacy of terminal sampling.
- State separately whether an IVIVC was developed, tested or only proposed.

Precautions

- Do not mix concentration or time units.
- Distinguish observed from model-derived values.
- A regression between dissolution and plasma concentration is not automatically a validated Level A IVIVC.
- Preserve the original dataset and a reproducible record of the analysis.

Viva Questions and Answers

Why select the terminal phase carefully?

The selected slope affects half-life and extrapolated exposure.

What is CL/F?

Apparent clearance after an extravascular dose when absolute bioavailability is not established.

Why use separate IVIVC validation evidence?

The fitted relationship must predict data beyond the observations used to develop it.

Cell Permeability and Metabolism Data Interpretation

Practical 11 - Software and data-analysis practical

Aim

To calculate apparent permeability and interpret cell-based metabolism observations from a supplied approved dataset.

Principle

A permeability experiment measures transport across a defined barrier under controlled donor and receiver conditions. Apparent permeability reflects the chosen system and requires area, concentration, time, recovery and barrier-integrity information. Disappearance of parent compound alone does not establish metabolism. Keep the supplied data, transformations, software version, analysis settings and complete output together. Record units explicitly and distinguish assumptions from observations.

Materials and Requirements

- Institution-supplied permeability or metabolism dataset
- Membrane or authorised cell-system description, area and donor concentration
- Integrity controls and analytical recovery information
- Spreadsheet or institution-approved analysis software
- Raw-data dictionary and analysis worksheet

Procedure

1. Define the analysis question and the variables, units, identifiers and missing-data conventions in the dataset.
2. Import a working copy and check values against the original file. Inspect ranges, duplicates, timing and unit consistency.
3. Record the barrier system, direction, area, concentrations and sampling and replacement scheme.
4. Verify that the dataset includes appropriate blanks, integrity evidence, donor and receiver measurements and recovery checks.
5. Identify a justified approximately linear transport interval and calculate the transported amount per unit time.
6. Calculate apparent permeability with the correct area and concentration units. Compare reverse-direction or control data only when the design supports it.
7. For metabolism observations, examine parent and metabolite evidence, binding and recovery before attributing loss to enzymatic conversion.
8. Retain diagnostics, intermediate calculations and the selected analysis settings. Explain exclusions and sensitivity checks.
9. Write a conclusion that addresses the stated question and the limitations of the design rather than relying on one fitted statistic.

Observations and Record

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

Interval / preparation	Transported amount	Integrity / recovery	Calculated response
Control	Record	Record	Assess
Test interval 1	Record	Record	Calculate
Test interval 2	Record	Record	Calculate
Reverse direction if supplied	Record	Record	Compare

Calculations

- Papp = (dQ/dt) / (A x Cdonor)
- For consistent units, nmol/s divided by cm^2 x nmol/cm^3 gives cm/s.

Worked Example

Illustrative dQ/dt = 0.020 nmol/s, area = 1.00 cm^2 and maintained donor concentration = 100 nmol/cm^3.
Papp = 0.020/(1.00 x 100) = 2.0 x 10^-4 cm/s.
Interpret with barrier integrity, recovery and the interval assumptions. This value does not directly specify human absorption.

Result and Interpretation

- State system-specific limitations and distinguish transport, binding, degradation and metabolism evidence.

Precautions

- Use supplied or institution-approved data and systems.
- Correct sampling and concentration units.
- Avoid biological interpretation when barrier integrity or recovery is inadequate.
- Preserve the original dataset and a reproducible record of the analysis.

Viva Questions and Answers

Why assess barrier integrity?

A damaged barrier can produce misleadingly high transport.

Why measure recovery?

Material can bind, degrade or be lost during handling.

Does parent loss prove metabolism?

No; other processes can also reduce parent concentration.

Experimental Design in Design-Expert

Practical 12 - Software and data-analysis practical

Aim

To construct a controlled experimental design for a pharmaceutical formulation question.

Principle

Design of experiments varies selected factors systematically so that their effects and interactions can be estimated. Factor coding, randomisation, replication and a defined response are essential to interpretation. An unreplicated saturated design cannot independently estimate experimental error.

Keep the supplied data, transformations, software version, analysis settings and complete output together. Record units explicitly and distinguish assumptions from observations.

Materials and Requirements

- Defined formulation factors and feasible ranges
- Critical response definitions and measurement methods
- Design-Expert or institution-approved design software
- Spreadsheet or institution-approved analysis software
- Raw-data dictionary and analysis worksheet

Procedure

1. Define the analysis question and the variables, units, identifiers and missing-data conventions in the dataset.
2. Import a working copy and check values against the original file. Inspect ranges, duplicates, timing and unit consistency.
3. Define the formulation question, critical quality attributes, factor types and feasible ranges.
4. Choose an appropriate factorial, response-surface or mixture design and justify the choice.
5. Add replication, centre points or other elements needed to estimate variability and assess model adequacy.
6. Randomise the practical run order where appropriate and issue controlled run sheets with coded and actual settings.
7. Check the design for infeasible combinations and specify how process deviations and missing observations will be handled.
8. Retain diagnostics, intermediate calculations and the selected analysis settings. Explain exclusions and sensitivity checks.
9. Write a conclusion that addresses the stated question and the limitations of the design rather than relying on one fitted statistic.

Observations and Record

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

Run	Coded factor X1	Coded factor X2	Measured response
1	-1	-1	Record
2	+1	-1	Record
3	-1	+1	Record
4	+1	+1	Record

Run	Coded factor X1	Coded factor X2	Measured response
Additional replicates / centre points	State	State	Record

Calculations

• Coded factor = (actual value - centre value) / half-range
• For a two-factor model, y = b0 + b1X1 + b2X2 + b12X1X2

Worked Example

Illustrative responses for the four listed factor combinations are 40, 60, 50 and 90 units.
The fitted coefficients are b0 = 60, b1 = 15, b2 = 10 and b12 = 5.
The four-point model exactly fits these four values. Additional evidence is needed for an error estimate, adequacy test and confirmation.

Result and Interpretation

• Present the rationale, randomised run plan and response definitions. A design is complete only when the measurement and execution plan are clear.

Precautions

• Use feasible, scientifically meaningful factor ranges.
• Plan replication before conducting the experiment.
• Avoid confusing mixture fractions, which sum to a constraint, with independent factorial factors.
• Preserve the original dataset and a reproducible record of the analysis.

Viva Questions and Answers

Why randomise run order?

It helps reduce confounding with time-related changes.

What is an interaction?

The effect of one factor depends on the level of another.

Why use replication?

It provides information on experimental variability.

Formulation Data Analysis in Design-Expert

Practical 13 - Software and data-analysis practical

Aim

To analyse formulation-design data and evaluate the proposed response model.

Principle

Design of experiments varies selected factors systematically so that their effects and interactions can be estimated. Factor coding, randomisation, replication and a defined response are essential to interpretation. An unreplicated saturated design cannot independently estimate experimental error.

Keep the supplied data, transformations, software version, analysis settings and complete output together. Record units explicitly and distinguish assumptions from observations.

Materials and Requirements

- Defined formulation factors and feasible ranges
- Critical response definitions and measurement methods
- Design-Expert or institution-approved design software
- Spreadsheet or institution-approved analysis software
- Raw-data dictionary and analysis worksheet

Procedure

1. Define the analysis question and the variables, units, identifiers and missing-data conventions in the dataset.
2. Import a working copy and check values against the original file. Inspect ranges, duplicates, timing and unit consistency.
3. Define the formulation question, critical quality attributes, factor types and feasible ranges.
4. Choose an appropriate factorial, response-surface or mixture design and justify the choice.
5. Add replication, centre points or other elements needed to estimate variability and assess model adequacy.
6. Randomise the practical run order where appropriate and issue controlled run sheets with coded and actual settings.
7. Check the design for infeasible combinations and specify how process deviations and missing observations will be handled.
8. Retain diagnostics, intermediate calculations and the selected analysis settings. Explain exclusions and sensitivity checks.
9. Write a conclusion that addresses the stated question and the limitations of the design rather than relying on one fitted statistic.

Observations and Record

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

Run	Coded factor X1	Coded factor X2	Measured response
1	-1	-1	Record
2	+1	-1	Record
3	-1	+1	Record
4	+1	+1	Record

Run	Coded factor X1	Coded factor X2	Measured response
Additional replicates / centre points	State	State	Record

Calculations

• Coded factor = (actual value - centre value) / half-range
• For a two-factor model, y = b0 + b1X1 + b2X2 + b12X1X2

Worked Example

Illustrative responses for the four listed factor combinations are 40, 60, 50 and 90 units.
The fitted coefficients are b0 = 60, b1 = 15, b2 = 10 and b12 = 5.
The four-point model exactly fits these four values. Additional evidence is needed for an error estimate, adequacy test and confirmation.

Analysis and confirmation

• Import the controlled run data and review deviations and missing values before fitting.
• Assess model hierarchy, residuals, uncertainty and lack of fit when the design permits its estimation. A saturated four-point fit alone does not support a meaningful residual-error F test.
• Define an optimisation objective with justified constraints, then evaluate independently prepared confirmation runs at the selected settings.

Result and Interpretation

• Present the rationale, randomised run plan and response definitions. A design is complete only when the measurement and execution plan are clear.

Precautions

• Use feasible, scientifically meaningful factor ranges.
• Plan replication before conducting the experiment.
• Avoid confusing mixture fractions, which sum to a constraint, with independent factorial factors.
• Preserve the original dataset and a reproducible record of the analysis.

Viva Questions and Answers

Why randomise run order?

It helps reduce confounding with time-related changes.

What is an interaction?

The effect of one factor depends on the level of another.

Why use replication?

It provides information on experimental variability.

Quality by Design in Pharmaceutical Development

Practical 14 - Software and data-analysis practical

Aim

To prepare a quality-by-design case linking a product target, risks, experiments and a control strategy.

Principle

Quality by design begins with the intended product performance and uses scientific understanding and risk management to identify important quality attributes, material attributes and process parameters. Experimental evidence supports the control strategy; a risk table alone is not a design space.

Keep the supplied data, transformations, software version, analysis settings and complete output together. Record units explicitly and distinguish assumptions from observations.

Materials and Requirements

- Defined target product profile and product-use context
- Material and process knowledge
- Risk assessment, experiment plan and control-strategy template
- Spreadsheet or institution-approved analysis software
- Raw-data dictionary and analysis worksheet

Procedure

1. Define the analysis question and the variables, units, identifiers and missing-data conventions in the dataset.
2. Import a working copy and check values against the original file. Inspect ranges, duplicates, timing and unit consistency.
3. State the intended route, dosage form, strength and relevant performance targets in the quality target product profile.
4. Identify critical quality attributes and explain how each relates to patient or product performance.
5. Map potentially influential material attributes and process parameters and assess the available knowledge and uncertainty.
6. Plan experiments and measurements that address important uncertainties and interactions.
7. Use the resulting evidence to propose justified operating controls, material controls and monitoring. Update the risk assessment with new knowledge.
8. Retain diagnostics, intermediate calculations and the selected analysis settings. Explain exclusions and sensitivity checks.
9. Write a conclusion that addresses the stated question and the limitations of the design rather than relying on one fitted statistic.

Observations and Record

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

Target / attribute	Risk and rationale	Evidence or study	Proposed control
Drug release	Record	Record	Propose
Content uniformity	Record	Record	Propose

Target / attribute	Risk and rationale	Evidence or study	Proposed control
Relevant impurity or stability attribute	Record	Record	Propose
Manufacturing attribute	Record	Record	Propose

Calculations

• For a declared classroom FMEA, risk-priority number = severity x occurrence x detectability. Define each scoring scale; this is one prioritisation tool, not a universal regulatory requirement.

Worked Example

Illustrative binder-level risk has severity 4, occurrence 3 and detectability 2 on the specified five-point classroom scales.

RPN = 24. A control proposal should explain the underlying risk and evidence, rather than simply targeting a smaller number.

Independent confirmation of a proposed formulation setting supports the decision more than an unverified optimisation output.

Result and Interpretation

• Show a traceable connection from the product target to the proposed controls and remaining uncertainty.

Precautions

• Keep risk-scoring definitions consistent.
• Use scientific evidence for the control strategy.
• Avoid presenting an unvalidated acceptable region as an established regulatory design space.
• Preserve the original dataset and a reproducible record of the analysis.

Viva Questions and Answers

What is a critical quality attribute?

An attribute that needs appropriate control to support the intended product quality.

Is an RPN a universal acceptance criterion?

No; it depends on the selected risk tool and context.

What makes a control strategy credible?

A justified link to product and process understanding and appropriate evidence.

Computer Simulation of Pharmacokinetics and Pharmacodynamics

Practical 15 - Software and data-analysis practical

Aim

To simulate a concentration-time profile and connect exposure to an explicit pharmacodynamic model.

Principle

A pharmacokinetic model describes drug disposition, while a pharmacodynamic model relates concentration or exposure to a measured response. The model assumptions determine which quantities can be interpreted. Hysteresis or delayed responses may require more than a direct concentration-effect relationship.

Keep the supplied data, transformations, software version, analysis settings and complete output together. Record units explicitly and distinguish assumptions from observations.

Materials and Requirements

- Declared model parameters and initial conditions
- Supplied or simulated concentration and response data
- Spreadsheet or institution-approved analysis software
- Raw-data dictionary and analysis worksheet

Procedure

1. Define the analysis question and the variables, units, identifiers and missing-data conventions in the dataset.
2. Import a working copy and check values against the original file. Inspect ranges, duplicates, timing and unit consistency.
3. Specify the route, model structure, parameter units and whether the task is simulation or fitting.
4. Construct a time grid suitable for the processes being represented and simulate the concentration profile.
5. Apply the selected response relationship and inspect how changes in clearance, volume, Emax or EC50 alter the output.
6. Compare predictions with any provided observations and review residuals and parameter identifiability.
7. Retain diagnostics, intermediate calculations and the selected analysis settings. Explain exclusions and sensitivity checks.
8. Write a conclusion that addresses the stated question and the limitations of the design rather than relying on one fitted statistic.

Observations and Record

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

Model component	Parameter / units	Input value	Prediction / sensitivity
PK model	Clearance and volume	Record	Concentration profile
PD model	Emax and EC50	Record	Response profile
Scenario	One changed parameter	Record	Compare outputs

Calculations

- For a simple one-compartment IV-bolus model, $C(t) = \text{Dose}/V \times \exp(-CL \times t/V)$

• Direct Emax model: E = E0 + Emax x C/(EC50 + C)

Worked Example

Illustrative direct-response model: E0 = 0, Emax = 100 response units and EC50 = 5 concentration units.
At C = 5, E = 50 units. At C = 15, E = 75 units.
These are model outputs. They do not define a patient dosing regimen or prove that a real biological system follows the selected equation.

Result and Interpretation

• Present the model, parameters and outputs together. Explain what the simulation can and cannot answer.

Precautions

• State model and unit assumptions.
• Inspect predictions over plausible parameter ranges.
• Separate fitting quality from biological plausibility.
• Preserve the original dataset and a reproducible record of the analysis.

Viva Questions and Answers

What does EC50 represent?

The concentration giving half the modelled maximal increment in response.

Why perform sensitivity analysis?

It shows how parameter changes influence model predictions.

Can a model be fitted well but interpreted poorly?

Yes; structure and parameter identifiability still require assessment.

Computational Modelling of Drug Disposition

Practical 16 - Software and data-analysis practical

Aim

To compare compartmental or physiologically motivated models of drug disposition.

Principle

Disposition models describe distribution and elimination using defined structures and parameter relationships. Additional compartments can improve description but also increase the evidence needed to estimate parameters reliably.

Keep the supplied data, transformations, software version, analysis settings and complete output together. Record units explicitly and distinguish assumptions from observations.

Materials and Requirements

- Supplied concentration-time data and model candidates
- Dose, route, physiological assumptions and parameter bounds
- Spreadsheet or institution-approved analysis software
- Raw-data dictionary and analysis worksheet

Procedure

1. Define the analysis question and the variables, units, identifiers and missing-data conventions in the dataset.
2. Import a working copy and check values against the original file. Inspect ranges, duplicates, timing and unit consistency.
3. Draw the proposed structure and state which data inform absorption, distribution and elimination.
4. Fit or simulate the selected structures with consistent units and meaningful parameter bounds.
5. Inspect residual patterns, uncertainty and parameter correlations rather than selecting only the smallest residual sum.
6. Compare candidates using the prespecified model-selection approach and interpret the model parameters within that structure.
7. Retain diagnostics, intermediate calculations and the selected analysis settings. Explain exclusions and sensitivity checks.
8. Write a conclusion that addresses the stated question and the limitations of the design rather than relying on one fitted statistic.

Observations and Record

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

Candidate model	Assumptions	Fit / prediction evidence	Reason for selection
One-compartment	Record	Record	Assess
Two-compartment or other candidate	Record	Record	Assess
Sensitivity or validation scenario	Record	Record	Assess

Calculations

• For a one-compartment linear model, elimination rate constant = CL/V
• Changing model structure changes the interpretation of fitted rate constants and volumes.

Worked Example

Illustrative CL = 4 L/h and V = 20 L give elimination rate constant 0.20 h^-1 and half-life ln(2)/0.20 = 3.466 h. A second model may fit better because it represents a distribution phase. Compare the supporting diagnostics and parameter uncertainty before interpreting that improvement.

Result and Interpretation

• Explain the selected structure and the observations supporting it. Treat simulations outside the data range as extrapolations.

Precautions

• Avoid mixing rate constants with clearance units.
• Use independent validation where available.
• Do not interpret a compartment as a literal organ without the model supporting that meaning.
• Preserve the original dataset and a reproducible record of the analysis.

Viva Questions and Answers

Is every compartment an organ?

No; many compartmental models are mathematical descriptions.

Why can too many parameters be a problem?

The data may not identify them reliably.

Why inspect residuals?

They can reveal systematic model inadequacy.

Clinical Data Collection Manual

Practical 17 - Regulatory documentation practical

Aim

To compile a clinical data-collection and management manual.

Principle

A data manual defines how protocol observations become attributable, traceable and analysable records. Good data management preserves source provenance and corrections rather than replacing inconvenient values.

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. Create a schedule-linked case-report form and dictionary with variable names, units, permitted values and missingness codes.
4. Define source transcription, access controls, query generation/resolution, audit trail and coding conventions.
5. Specify adverse-event capture, reconciliation with safety records, confidentiality and secure transfer.
6. Define review, cleaning, database freeze/lock, exports and retention with roles and documented approvals.
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 weight is entered as 700 kg for a case whose source says 70.0 kg. Issue a traceable query and preserve the correction history; do not overwrite the record without attribution.

Result and Interpretation

- Deliver a manual, example CRF, data dictionary and a completed query-resolution example.
- 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.

Sensitivity Analysis and Population Pharmacokinetics

Practical 18 - Software and data-analysis practical

Aim

To examine covariate effects, variability and sensitivity in a population pharmacokinetic dataset.

Principle

Population models separate typical parameter values, between-subject variability and residual variability. Covariates can explain part of the variation, but association within a model requires assessment of design, confounding and predictive performance.

Keep the supplied data, transformations, software version, analysis settings and complete output together. Record units explicitly and distinguish assumptions from observations.

Materials and Requirements

- Supplied subject-level dosing and concentration data
- Covariates, units, sampling times and analysis plan
- Spreadsheet or institution-approved analysis software
- Raw-data dictionary and analysis worksheet

Procedure

1. Define the analysis question and the variables, units, identifiers and missing-data conventions in the dataset.
2. Import a working copy and check values against the original file. Inspect ranges, duplicates, timing and unit consistency.
3. Verify subject identifiers, dosing events, actual sampling times and covariate definitions.
4. Specify the structural and variability models and identify covariates justified by the question.
5. Compare prespecified parameter scenarios and examine changes in clinically relevant model outputs.
6. Assess diagnostic plots, uncertainty and predictive checks appropriate to the software and dataset. Record covariate-selection decisions transparently.
7. Retain diagnostics, intermediate calculations and the selected analysis settings. Explain exclusions and sensitivity checks.
8. Write a conclusion that addresses the stated question and the limitations of the design rather than relying on one fitted statistic.

Observations and Record

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

Model / scenario	Covariate or parameter	Output change	Diagnostic / interpretation
Base model	Record	Record	Assess
Covariate model	Record	Record	Assess
Sensitivity scenario	Record	Record	Assess

Calculations

• Relative sensitivity can be expressed as percentage change in output / percentage change in the chosen input, over a stated perturbation.
• A covariate relationship must state its units, reference value and functional form.

Worked Example

Illustrative typical clearance changes from 5.0 to 4.0 L/h in a declared parameter scenario.
For the same dose and a linear model, AUC proportional to 1/CL increases by 5.0/4.0 - 1 = 25%.
This is a model sensitivity result, not an automatic dose-adjustment instruction.

Result and Interpretation

• Distinguish explained covariate effects from remaining variability and uncertainty. Describe the population represented by the data.

Precautions

• Keep actual event timing and units intact.
• Avoid selecting covariates solely for a convenient p value.
• Check overfitting and predictions for poorly represented groups.
• Preserve the original dataset and a reproducible record of the analysis.

Viva Questions and Answers

What is between-subject variability?

Variation in model parameters across individuals beyond the stated typical relationships.

Why record reference covariate values?

They define the interpretation of the typical parameter.

Why use predictive checks?

They assess whether the model reproduces important features of the data.

Development and Evaluation of a Cream Base

Practical 19 - Bench formulation practical

Aim

To prepare and evaluate a cream base using a controlled laboratory formula.

Principle

An oil-in-water cream contains dispersed oil droplets in a structured continuous aqueous phase. Emulsifier identity, phase ratio, cooling and rheology influence consistency and physical stability.

A formulation comparison is meaningful when the raw-material grades, batch size and evaluation conditions are recorded. Change one planned factor at a time or use a documented experimental design, and compare independently prepared batches rather than only repeated readings from one batch.

Materials and Requirements

- Approved self-emulsifying wax, oil phase, humectant and purified water
- Balance, controlled heating and mixing arrangement
- Suitable mixing, temperature and measurement equipment
- Calibrated balance, suitable containers and identified evaluation equipment
- Controlled batch sheet and raw-data forms

Procedure

1. Define the purpose, formula, batch size, material grades and comparison conditions. Calculate all quantities before weighing.
2. Check equipment readiness and record material identities and actual quantities. Reconcile theoretical and actual batch mass.
3. Prepare the specified oil and water phases and heat each only within the material-specific process range.
4. Combine in the approved order with controlled mixing, then cool as specified. Add heat-sensitive ingredients only at their qualified process stage.
5. Measure the pH through the selected method and compare consistency, homogeneity and phase behaviour after the defined conditioning period.
6. Evaluate the stated quality attributes on representative portions using the same method for all comparison batches. Record individual readings and any excluded observations with reasons.
7. Calculate the specified response, variability and material balance. Compare with predefined teaching or product criteria and discuss sources of variation.
8. Label retained preparations and dispose of remaining material through the laboratory procedure. Keep the complete preparation and evaluation record together.

Observations and Record

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

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Appearance and homogeneity	Record the adopted method	Record	Evaluate
pH and measurement method	Record the adopted method	Record	Evaluate
Consistency or viscosity	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Phase behaviour and mass recovery	Record the adopted method	Record	Evaluate

Calculations

• Component mass = total target batch mass x percentage / 100
• Batch recovery (%) = recovered mass / theoretical batch mass x 100

Worked Example

Illustrative same-session 100 g bench base: self-emulsifying wax 6 g, liquid paraffin 10 g, glycerol 5 g and purified water to 100 g.
The theoretical water quantity before process adjustment is 79 g. Any process-loss adjustment and additional ingredient must be documented.
This simple teaching composition requires formulation-specific development and preservation evidence for storage or use.

Result and Interpretation

• Explain the emulsion type and the effect of preparation conditions. Use product-specific targets rather than a universal pH or viscosity limit. Record appearance, homogeneity, relevant physical measurements and the defined observation period.
• State the preparation conditions and the evidence supporting the result. A satisfactory physical observation alone does not establish long-term stability, clinical performance or suitability for administration.

Precautions

• Prepare only the authorised teaching batch and identify it for laboratory evaluation.
• Follow ingredient-specific handling and disposal requirements.
• Record the need for a validated preservation system before any stored or distributed product is considered.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

Why calculate all quantities first?

It identifies inconsistencies in the formula and establishes the material balance.

Why use a controlled method?

Mixing, temperature and ingredient order can change the resulting structure.

Does a visually acceptable batch establish stability?

No; stability and microbiological quality need appropriate evidence.

Development and Evaluation of a Shampoo Base

Practical 20 - Bench formulation practical

Aim

To prepare and evaluate a shampoo base using a controlled laboratory formula.

Principle

Shampoo performance depends on a compatible surfactant system, formulation rheology, cleaning and foaming properties and the intended scalp and hair-use context. Foam height is one test attribute and is not a direct measurement of all cleaning performance.

A formulation comparison is meaningful when the raw-material grades, batch size and evaluation conditions are recorded. Change one planned factor at a time or use a documented experimental design, and compare independently prepared batches rather than only repeated readings from one batch.

Materials and Requirements

- Approved surfactant blend, viscosity modifier and aqueous base
- pH meter and defined foam and viscosity test methods
- Suitable mixing, temperature and measurement equipment
- Calibrated balance, suitable containers and identified evaluation equipment
- Controlled batch sheet and raw-data forms

Procedure

1. Define the purpose, formula, batch size, material grades and comparison conditions. Calculate all quantities before weighing.
2. Check equipment readiness and record material identities and actual quantities. Reconcile theoretical and actual batch mass.
3. Calculate surfactant addition on an active-matter basis, accounting for the concentration of each supplied ingredient.
4. Mix using the defined order and shear conditions, controlling entrained air. Add viscosity modifiers through the adopted process.
5. Measure pH, viscosity and foam behaviour using specified dilution, water and test geometry. Compare replicate measurements under identical conditions.
6. Evaluate the stated quality attributes on representative portions using the same method for all comparison batches. Record individual readings and any excluded observations with reasons.
7. Calculate the specified response, variability and material balance. Compare with predefined teaching or product criteria and discuss sources of variation.
8. Label retained preparations and dispose of remaining material through the laboratory procedure. Keep the complete preparation and evaluation record together.

Observations and Record

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

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Surfactant active matter	Record the adopted method	Record	Evaluate
pH and viscosity	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Foam height and persistence	Record the adopted method	Record	Evaluate
Appearance and homogeneity	Record the adopted method	Record	Evaluate

Calculations

• Component mass = total target batch mass x percentage / 100
• Batch recovery (%) = recovered mass / theoretical batch mass x 100

Worked Example

Illustrative target: 5.0 g active surfactant is needed in a 100 g teaching batch. If the supplied surfactant solution is 25.0% active, required supplied material = 5.0/0.25 = 20.0 g.

The 15.0 g nonactive fraction is part of the total formula mass and must be included in the water and ingredient balance.

Result and Interpretation

• Distinguish supplied surfactant mass from active content and interpret foam in the context of the chosen test. Record appearance, homogeneity, relevant physical measurements and the defined observation period.
• State the preparation conditions and the evidence supporting the result. A satisfactory physical observation alone does not establish long-term stability, clinical performance or suitability for administration.

Precautions

• Prepare only the authorised teaching batch and identify it for laboratory evaluation.
• Follow ingredient-specific handling and disposal requirements.
• Record the need for a validated preservation system before any stored or distributed product is considered.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

Why calculate all quantities first?

It identifies inconsistencies in the formula and establishes the material balance.

Why use a controlled method?

Mixing, temperature and ingredient order can change the resulting structure.

Does a visually acceptable batch establish stability?

No; stability and microbiological quality need appropriate evidence.

Development and Evaluation of a Toothpaste Base

Practical 21 - Bench formulation practical

Aim

To prepare and evaluate a toothpaste base using a controlled laboratory formula.

Principle

A toothpaste base suspends an approved abrasive in a structured humectant and aqueous system. Abrasive properties, binder hydration, mixing and surfactant incorporation influence extrudability and uniformity.

A formulation comparison is meaningful when the raw-material grades, batch size and evaluation conditions are recorded. Change one planned factor at a time or use a documented experimental design, and compare independently prepared batches rather than only repeated readings from one batch.

Materials and Requirements

- Approved abrasive, humectant, binder and aqueous-phase formula
- Controlled mixer, extrusion arrangement and evaluation methods
- Suitable mixing, temperature and measurement equipment
- Calibrated balance, suitable containers and identified evaluation equipment
- Controlled batch sheet and raw-data forms

Procedure

1. Define the purpose, formula, batch size, material grades and comparison conditions. Calculate all quantities before weighing.
2. Check equipment readiness and record material identities and actual quantities. Reconcile theoretical and actual batch mass.
3. Hydrate the selected binder using the approved sequence and incorporate humectant and abrasive with controlled mixing.
4. Add the specified surfactant and flavour system at the qualified stage, controlling aeration and mass balance.
5. Evaluate homogeneity, pH by the prescribed dispersion method, extrusion and phase behaviour. Assess active compatibility separately where an active is included.
6. Evaluate the stated quality attributes on representative portions using the same method for all comparison batches. Record individual readings and any excluded observations with reasons.
7. Calculate the specified response, variability and material balance. Compare with predefined teaching or product criteria and discuss sources of variation.
8. Label retained preparations and dispose of remaining material through the laboratory procedure. Keep the complete preparation and evaluation record together.

Observations and Record

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

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Dispersion pH	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Extrudability	Record the adopted method	Record	Evaluate
Homogeneity and phase behaviour	Record the adopted method	Record	Evaluate
Abrasive and active compatibility record	Record the adopted method	Record	Evaluate

Calculations

- Component mass = total target batch mass x percentage / 100
- Batch recovery (%) = recovered mass / theoretical batch mass x 100

Worked Example

Illustrative allocation for 100 g base: 35 g abrasive, 30 g humectant and 1 g binder leave 34 g for the defined aqueous phase and other approved ingredients.

If an active is added, adjust the complete formula and assess its compatibility and analytical recovery.

Result and Interpretation

- Evaluate the defined laboratory base. Therapeutic and abrasivity claims require their appropriate tests and product evidence. Record appearance, homogeneity, relevant physical measurements and the defined observation period.
- State the preparation conditions and the evidence supporting the result. A satisfactory physical observation alone does not establish long-term stability, clinical performance or suitability for administration.

Precautions

- Prepare only the authorised teaching batch and identify it for laboratory evaluation.
- Follow ingredient-specific handling and disposal requirements.
- Record the need for a validated preservation system before any stored or distributed product is considered.
- Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

Why calculate all quantities first?

It identifies inconsistencies in the formula and establishes the material balance.

Why use a controlled method?

Mixing, temperature and ingredient order can change the resulting structure.

Does a visually acceptable batch establish stability?

No; stability and microbiological quality need appropriate evidence.

Incorporation of Herbal and Chemical Actives

Practical 22 - Bench formulation practical

Aim

To incorporate a specified herbal or chemical active into a compatible formulation base and evaluate distribution and quality.

Principle

An oil-in-water cream contains dispersed oil droplets in a structured continuous aqueous phase. Emulsifier identity, phase ratio, cooling and rheology influence consistency and physical stability.

A formulation comparison is meaningful when the raw-material grades, batch size and evaluation conditions are recorded. Change one planned factor at a time or use a documented experimental design, and compare independently prepared batches rather than only repeated readings from one batch.

Materials and Requirements

- Approved self-emulsifying wax, oil phase, humectant and purified water
- Balance, controlled heating and mixing arrangement
- Suitable mixing, temperature and measurement equipment
- Calibrated balance, suitable containers and identified evaluation equipment
- Controlled batch sheet and raw-data forms

Procedure

1. Define the purpose, formula, batch size, material grades and comparison conditions. Calculate all quantities before weighing.
2. Check equipment readiness and record material identities and actual quantities. Reconcile theoretical and actual batch mass.
3. Prepare the specified oil and water phases and heat each only within the material-specific process range.
4. Combine in the approved order with controlled mixing, then cool as specified. Add heat-sensitive ingredients only at their qualified process stage.
5. Measure the pH through the selected method and compare consistency, homogeneity and phase behaviour after the defined conditioning period.
6. Evaluate the stated quality attributes on representative portions using the same method for all comparison batches. Record individual readings and any excluded observations with reasons.
7. Calculate the specified response, variability and material balance. Compare with predefined teaching or product criteria and discuss sources of variation.
8. Label retained preparations and dispose of remaining material through the laboratory procedure. Keep the complete preparation and evaluation record together.

Observations and Record

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

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Appearance and homogeneity	Record the adopted method	Record	Evaluate
pH and measurement method	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Consistency or viscosity	Record the adopted method	Record	Evaluate
Phase behaviour and mass recovery	Record the adopted method	Record	Evaluate

Calculations

• Component mass = total target batch mass x percentage / 100
• Batch recovery (%) = recovered mass / theoretical batch mass x 100

Worked Example

Illustrative same-session 100 g bench base: self-emulsifying wax 6 g, liquid paraffin 10 g, glycerol 5 g and purified water to 100 g.

The theoretical water quantity before process adjustment is 79 g. Any process-loss adjustment and additional ingredient must be documented.

This simple teaching composition requires formulation-specific development and preservation evidence for storage or use.

Active-incorporation study

• Record identity, potency or marker specification, solubility and stability of the active. Establish the justified incorporation stage and concentration.
• For a target 0.50 g active from material with 80.0% active content, supplied amount is 0.625 g; revise the full formula mass accordingly.
• Evaluate content uniformity, compatibility, pH and relevant performance. Ingredient inclusion alone does not establish a therapeutic claim.

Result and Interpretation

• Explain the emulsion type and the effect of preparation conditions. Use product-specific targets rather than a universal pH or viscosity limit. Record appearance, homogeneity, relevant physical measurements and the defined observation period.
• State the preparation conditions and the evidence supporting the result. A satisfactory physical observation alone does not establish long-term stability, clinical performance or suitability for administration.

Precautions

• Prepare only the authorised teaching batch and identify it for laboratory evaluation.
• Follow ingredient-specific handling and disposal requirements.
• Record the need for a validated preservation system before any stored or distributed product is considered.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

Why calculate all quantities first?

It identifies inconsistencies in the formula and establishes the material balance.

Why use a controlled method?

Mixing, temperature and ingredient order can change the resulting structure.

Does a visually acceptable batch establish stability?

No; stability and microbiological quality need appropriate evidence.

Formulation Design for Skin Hair and Oral-Care Concerns

Practical 23 - Case-based formulation practical

Aim

To develop separate formulation and evaluation plans for six skin, hair and oral-care concerns.

Principle

A development plan connects the intended product claim to a suitable base, ingredient compatibility, quality attributes and claim evidence. A cream, cleanser and toothpaste have different process and evaluation requirements; a visually acceptable base does not establish a therapeutic effect.

Materials and Requirements

- Six fictional product briefs and approved ingredient specifications
- Suitable cream, cleanser and oral-care base procedures
- Physical, analytical, microbial-quality and stability methods
- 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 intended cosmetic or medicinal claim and assess whether clinical or dental referral is relevant to the concern.
3. Choose a justified product type and ingredient role separately for each case; calculate a complete formula and identify compatible incorporation stages.
4. Use the appropriate approved base procedure for the selected model, recording quantities, order, temperature and mixing rather than applying a cream process to every product.
5. Assess physical quality, content/distribution where relevant, microbial controls, stability and packaging with methods matched to each product.
6. Prepare a claim-evidence plan and distinguish bench quality observations from clinical efficacy.
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.

Concern	Development concept	Quality focus	Evidence / referral
Dry skin	Moisturising cream or lotion	Humectant/base compatibility, pH and stability	Substantiate the moisturising claim
Acne	Suitable cleansing or authorised active-product concept	Tolerability, content and base compatibility	Review medicine/cosmetic claim status

Concern	Development concept	Quality focus	Evidence / referral
Blemish appearance	Defined cosmetic appearance endpoint	Colour, uniformity and stability	Controlled claim evaluation
Wrinkle appearance	Defined moisturising/appearance concept	Physical stability and endpoint consistency	Substantiate the intended claim
Bleeding gums	Oral-care development record	Oral-base quality and ingredient compatibility	Dental assessment; no treatment claim from base tests
Dandruff	Scalp cleanser or authorised active concept	Surfactant system, content and stability	Product-specific claim and regulatory evidence

Calculations

- Required supplied ingredient = target ingredient amount / specified potency fraction
- Formula total must equal the declared final mass or volume basis.

Worked Example

Illustrative analytical marker target 0.50 g from a preparation containing 80.0% marker requires 0.625 g supplied material. Rebalance the remaining formula to its declared total.
The example is a formulation calculation, not a recommended treatment ingredient or concentration.

Result and Interpretation

- Present six separate concept, formula, process and evaluation records with the evidence still needed for each claim.

Precautions

- Use only approved laboratory formulations and label them for evaluation.
- Do not infer treatment of acne, gingival bleeding or other disease from a base test.
- Check actual ingredient suitability and claim status for the intended route and market.

Viva Questions and Answers

Why use different product procedures?

The bases and intended routes have different structure and quality needs.

Does including an active establish efficacy?

The complete product and proposed claim need appropriate evidence.

Why refer bleeding gums?

An oral-care base study cannot diagnose or treat its underlying cause.

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