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M.Pharm Practical Notes

Pharmacognosy Practicals II

Semester 2

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Nucleic-Acid Isolation from Cauliflower

Practical 1 - Approved nucleic-acid isolation practical

Aim

To isolate DNA from an approved plant model and assess recovery and integrity.

Principle

Cell disruption releases nucleic acids; controlled lysis and purification separate DNA from proteins, polysaccharides and other contaminants. Precipitated threads alone do not prove DNA identity or purity.

Materials and Requirements

- Approved nonpathogenic teaching system or supplied anonymised dataset
- Laboratory risk assessment, controls and raw-data 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. Use cauliflower or another authorised plant model; animal-tissue comparisons use supplied records unless separately approved.
3. Record input mass and use the adopted plant-DNA kit or validated lysis and clarification method.
4. Purify through the specified binding/wash/elution or approved precipitation workflow, retaining extraction blanks.
5. Measure DNA concentration and recovered volume and assess integrity by a suitable gel and purity by complementary checks.
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.

Preparation / control	Condition / method	Raw observation	Calculated / interpreted result
Negative / vehicle control	Specify	Record	Evaluate
Positive / reference control	Specify	Record	Evaluate
Test replicates	Specify	Record	Calculate

Calculations

- DNA yield per gram = measured DNA mass / input tissue mass
- DNA mass = concentration x elution volume

Worked Example

Illustrative DNA concentration 80 ng/microlitre in 100 microlitres gives 8,000 ng = 8 micrograms. From 0.20 g plant material, yield is 40 micrograms/g.

Report the actual assay specificity and extraction-blank result.

Result and Interpretation

- Present extraction flow, recovery, purity indicators and gel evidence.
- Report biological and technical replication separately and explain control performance.

Precautions

- Use only the approved biological system, containment and decontamination procedure.
- A teaching dataset does not authorise live animal, human-tissue or unknown-organism work.
- Keep original images and observations; avoid selecting only favourable fields or bands.

Viva Questions and Answers

Why avoid harsh handling after lysis?

It can shear high-molecular-weight DNA.

Why include an extraction blank?

It checks contamination introduced during purification.

Why do plant matrices need care?

Polysaccharides and secondary metabolites can interfere.

RNA Isolation from Yeast

Practical 2 - Approved nucleic-acid isolation practical

Aim

To isolate RNA from approved teaching yeast and assess concentration and integrity.

Principle

RNA purification requires effective nuclease control and separation from DNA, proteins and other matrix components. The extraction method and downstream use determine whether a DNA-removal step is required.

Materials and Requirements

- Approved nonpathogenic teaching system or supplied anonymised dataset
- Laboratory risk assessment, controls and raw-data worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Use approved teaching yeast or supplied extraction records and document starting material.
2. Prepare a nuclease-controlled workspace and apply the adopted yeast-disruption and RNA-purification kit method.
3. Include extraction blanks and apply the justified DNA-removal and cleanup steps.
4. Measure concentration using an RNA-appropriate method and assess integrity by the selected electrophoretic or instrument method.
5. Record yield, purity, integrity and suitability for the planned downstream application.

Observations and Record

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

Preparation / control	Condition / method	Raw observation	Calculated / interpreted result
Negative / vehicle control	Specify	Record	Evaluate
Positive / reference control	Specify	Record	Evaluate
Test replicates	Specify	Record	Calculate

Calculations

- RNA concentration = A260 x 40 micrograms/mL x dilution, for 1 cm-normalised absorbance
- RNA yield = concentration x recovered volume

Worked Example

Illustrative A260 = 0.25 at dilution 5 gives 50 micrograms/mL RNA. A 0.20 mL recovery contains 10 micrograms.

Absorbance alone cannot distinguish residual DNA from the intended RNA.

Result and Interpretation

- Present extraction flow, recovery, purity indicators and gel evidence.
- Report biological and technical replication separately and explain control performance.

Precautions

- Use the approved RNase-control practices and compatible nuclease-free materials.
- Do not treat an acceptable absorbance ratio as proof of intact RNA.
- Retain the RNA-specific quality and DNA-contamination controls.

Viva Questions and Answers

Why control RNases?

RNA can degrade rapidly through nuclease activity.

Why assess DNA contamination?

It can bias concentration and downstream amplification.

What confirms RNA integrity?

A suitable electrophoretic or equivalent integrity method.

Quantitative Estimation of DNA

Practical 3 - Nucleic-acid measurement practical

Aim

To estimate nucleic-acid concentration and assess spectral quality.

Principle

At a 1 cm path length, an absorbance of 1 at 260 nm conventionally corresponds to about 50 micrograms/mL double-stranded DNA or 40 micrograms/mL RNA. These factors depend on nucleic-acid type; absorbance ratios alone do not prove purity or integrity.

Materials and Requirements

- Approved nonpathogenic teaching system or supplied anonymised dataset
- Laboratory risk assessment, controls and raw-data 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. Record nucleic-acid type, path length or instrument normalisation and the matching solvent blank.
3. Measure the full relevant spectrum and dilution within the qualified instrument range.
4. Calculate concentration with the correct factor and dilution; inspect 260/280 and 260/230 ratios with pH and blank context.
5. Use a gel or other orthogonal integrity and specificity check when required.
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.

Preparation / control	Condition / method	Raw observation	Calculated / interpreted result
Negative / vehicle control	Specify	Record	Evaluate
Positive / reference control	Specify	Record	Evaluate
Test replicates	Specify	Record	Calculate

Calculations

- Concentration = A260 x nucleic-acid factor x dilution factor, for absorbance normalised to 1 cm
- Yield = concentration x recovered volume

Worked Example

Illustrative double-stranded DNA: A260 = 0.20 and dilution 10 give 100 micrograms/mL. In 0.50 mL the yield is 50 micrograms.

Using the RNA factor would instead give 80 micrograms/mL. A DNA 260/280 ratio near 1.8 or RNA ratio near 2.0 is only a contextual indicator.

Result and Interpretation

- State nucleic-acid type, concentration, yield, spectral quality and independent integrity evidence.
- Report biological and technical replication separately and explain control performance.

Precautions

- Use only the approved biological system, containment and decontamination procedure.
- A teaching dataset does not authorise live animal, human-tissue or unknown-organism work.
- Keep original images and observations; avoid selecting only favourable fields or bands.

Viva Questions and Answers

Why use the correct factor?

Different nucleic-acid forms have different absorbance relationships.

Does a good ratio prove intact DNA?

Integrity needs another suitable measurement.

Why match the blank?

Buffer and pH can influence spectral measurements.

Immobilisation Techniques

Practical 4 - Biological teaching-data practical

Aim

To evaluate immobilisation of an approved whole-cell or enzyme model.

Principle

Entrapment or attachment retains biological material in a support while permitting transport of substrate and product. Apparent activity reflects loading, viability or enzyme stability and mass-transfer limitations.

Materials and Requirements

- Approved nonpathogenic teaching system or supplied anonymised dataset
- Laboratory risk assessment, controls and raw-data 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. Choose an approved benign model, defined support and an authorised immobilisation procedure.
3. Record input biomass or activity, support quantities and actual preparation and wash conditions.
4. Measure retained activity, leakage and activity in the wash with appropriate free-system and support blanks.
5. Assess repeated-cycle response and distinguish loss of catalyst from transport or chemical limitations.
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.

Preparation / control	Condition / method	Raw observation	Calculated / interpreted result
Negative / vehicle control	Specify	Record	Evaluate
Positive / reference control	Specify	Record	Evaluate
Test replicates	Specify	Record	Calculate

Calculations

- Activity retention (%) = measured immobilised activity / input free-system activity x 100

Worked Example

Illustrative 100 activity units enter the process and 70 units are recovered in the immobilised preparation: retention = 70%.

Compare assays on a consistent activity basis and account for diffusion effects.

Result and Interpretation

- Report loading, retained activity, leakage and reuse performance under stated conditions.
- Report biological and technical replication separately and explain control performance.

Precautions

- Use only the approved biological system, containment and decontamination procedure.
- A teaching dataset does not authorise live animal, human-tissue or unknown-organism work.
- Keep original images and observations; avoid selecting only favourable fields or bands.

Viva Questions and Answers

What can limit immobilised activity?

Diffusion and catalyst changes can both reduce apparent activity.

Why analyse washes?

They reveal nonretained or leaking material.

Does reuse prove indefinite stability?

Performance is established only for the tested cycles and conditions.

Establishment and Assessment of Callus Culture

Practical 5 - Approved plant-culture practical

Aim

To review establishment and assessment of a benign plant callus culture.

Principle

Callus formation depends on explant identity, aseptic technique, medium and growth-regulator balance. Visible growth does not prove genetic stability or the desired secondary-metabolite content.

Materials and Requirements

- Approved nonpathogenic teaching system or supplied anonymised dataset
- Laboratory risk assessment, controls and raw-data 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. Use an approved benign plant culture or supplied records with source identity and contamination checks.
3. Record explant, sterilisation record, medium formulation and authorised environmental programme; do not substitute a universal hormone recipe.
4. Review initiation, contamination, appearance and serial-transfer observations and document losses.
5. Measure fresh and dry biomass by a defined method and assess a relevant marker only with a suitable assay.
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.

Preparation / control	Condition / method	Raw observation	Calculated / interpreted result
Negative / vehicle control	Specify	Record	Evaluate
Positive / reference control	Specify	Record	Evaluate
Test replicates	Specify	Record	Calculate

Calculations

- Growth index = (final biomass - initial biomass)/initial biomass, using a consistent fresh or dry basis

Worked Example

Illustrative initial dry biomass 0.10 g and final 0.30 g give growth index 2.0, corresponding to a threefold final-to-initial mass ratio.

Result and Interpretation

- Provide a culture lineage record, contamination assessment and biomass/marker results.
- Report biological and technical replication separately and explain control performance.

Precautions

- Use only the approved biological system, containment and decontamination procedure.
- A teaching dataset does not authorise live animal, human-tissue or unknown-organism work.
- Keep original images and observations; avoid selecting only favourable fields or bands.

Viva Questions and Answers

Is callus an organised organ?

It is a proliferating tissue mass under the defined culture conditions.

Why keep a lineage record?

Transfers and culture history affect reproducibility.

Does biomass prove marker yield?

Marker content must be measured separately.

Establishment and Assessment of Plant Suspension Culture

Practical 6 - Approved plant-culture practical

Aim

To assess establishment and growth of a benign plant-cell suspension culture.

Principle

A plant suspension disperses cells and aggregates in a liquid medium. Mixing, aggregate size, sampling representativeness and oxygen transfer affect apparent biomass and product formation.

Materials and Requirements

- Approved nonpathogenic teaching system or supplied anonymised dataset
- Laboratory risk assessment, controls and raw-data 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. Use an approved benign plant culture or supplied records with source identity and contamination checks.
3. Record explant, sterilisation record, medium formulation and authorised environmental programme; do not substitute a universal hormone recipe.
4. Review initiation, contamination, appearance and serial-transfer observations and document losses.
5. Measure fresh and dry biomass by a defined method and assess a relevant marker only with a suitable assay.
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.

Preparation / control	Condition / method	Raw observation	Calculated / interpreted result
Negative / vehicle control	Specify	Record	Evaluate
Positive / reference control	Specify	Record	Evaluate
Test replicates	Specify	Record	Calculate

Calculations

- Growth index = (final biomass - initial biomass)/initial biomass, using a consistent fresh or dry basis

Worked Example

Illustrative initial dry biomass 0.10 g and final 0.30 g give growth index 2.0, corresponding to a threefold final-to-initial mass ratio.

Suspension-culture record

• Start from an authenticated, suitable callus under the approved protocol and record medium, vessel, fill and mixing conditions.
• Sample representatively and record cell aggregation, viability, packed-cell volume where relevant and dry biomass. Compare biomass with measured marker concentration.
• Illustrative dry biomass increases from 1 to 3 g/L while marker content decreases from 10 to 5 mg/g. Volumetric marker changes from 10 to 15 mg/L; biomass and cell-specific content tell different stories.

Result and Interpretation

• Provide a culture lineage record, contamination assessment and biomass/marker results.
• Report biological and technical replication separately and explain control performance.

Precautions

• Use only the approved biological system, containment and decontamination procedure.
• A teaching dataset does not authorise live animal, human-tissue or unknown-organism work.
• Keep original images and observations; avoid selecting only favourable fields or bands.

Viva Questions and Answers

Is callus an organised organ?

It is a proliferating tissue mass under the defined culture conditions.

Why keep a lineage record?

Transfers and culture history affect reproducibility.

Does biomass prove marker yield?

Marker content must be measured separately.

Aldehyde Content of Volatile Oils

Practical 7 - Analytical practical

Aim

To determine method-defined aldehyde content in a selected volatile oil.

Principle

A suitable hydroxylamine-based method relates carbonyl reaction to a measured acid/base equivalent, but other carbonyls and matrix components may affect selectivity. The method and equivalent basis must be defined.

The test preparation, blank, calibration or titrant standardisation and independent controls are part of the measurement. State the actual concentration units, test conditions and adopted method before interpreting the result.

Materials and Requirements

- Selected oil and adopted validated carbonyl method
- Standardised titrant, reagent blank and suitable reference
- Controlled reaction and endpoint equipment
- Qualified balance and volumetric equipment
- Controlled method and raw-data worksheet

Procedure

1. Identify the material, intended attribute, method version and acceptance criteria. Record preparation and instrument or reagent identities.
2. Prepare the prescribed blank and reference or standardised reagent. Verify the measurement with an independent check where applicable.
3. Record the aldehyde identity or equivalent basis and method stoichiometry.
4. Run oil, blank and reference under matching reaction conditions.
5. Apply the prescribed blank direction and endpoint procedure and calculate the stated equivalent content.
6. Record individual readings for independently prepared test portions. Keep all raw observations, including unsuccessful measurements and their investigation.
7. Calculate the result on the stated mass, volume or area basis, including dilution, blank and recovery corrections as justified.
8. Compare the evidence with the applicable criteria and write a conclusion limited to the tested preparation and conditions.

Observations and Record

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

Preparation / attribute	Method condition	Raw measurement	Calculated result
Blank	Record	Record	Calculate
Reference	Record	Record	Calculate
Test 1	Record	Record	Calculate
Test 2	Record	Record	Calculate

Calculations

• For a justified 1:1 equivalent method: aldehyde-equivalent amount (mol) = corrected titrant volume (L) x concentration (mol/L)

Worked Example

Illustrative corrected equivalent consumption 2.00 mL of 0.100 mol/L corresponds to 0.200 mmol carbonyl equivalents.

Multiplying by a named aldehyde molar mass is valid only for the specified reporting convention.

Result and Interpretation

• Report method-defined aldehyde equivalents and interference limitations.

• Report replicate variability and the evidence that the method can measure the intended attribute in this matrix.

Precautions

• Use approved reactive-reagent and solvent controls.

• Do not assume all oil carbonyls are the same aldehyde.

• Retain reagent and native-acidity corrections.

• Use the adopted laboratory procedure, suitable controls and the designated waste arrangements.

Viva Questions and Answers

Why use a reagent blank?

The reagents can contribute to titrant consumption.

Does the assay identify the aldehyde?

Identity requires separate selective evidence.

Why state equivalent basis?

Mixed carbonyl compounds can have different masses and responses.

Total Phenolic Content of Herbal Materials

Practical 8 - Analytical practical

Aim

To estimate total phenolic-equivalent content in an authenticated herbal material.

Principle

The Folin-Ciocalteu response reflects reducing capacity and can include nonphenolic interferents. Results must state the chosen reference equivalent and extraction basis.

The test preparation, blank, calibration or titrant standardisation and independent controls are part of the measurement. State the actual concentration units, test conditions and adopted method before interpreting the result.

Materials and Requirements

- Authenticated material and validated class assay
- gallic acid reference and suitable extraction blank
- Calibrated spectrophotometer or selected validated detector
- Qualified balance and volumetric equipment
- Controlled method and raw-data worksheet

Procedure

1. Identify the material, intended attribute, method version and acceptance criteria. Record preparation and instrument or reagent identities.
2. Prepare the prescribed blank and reference or standardised reagent. Verify the measurement with an independent check where applicable.
3. Prepare the extract and reference series using the method-specific reaction and measurement conditions.
4. Evaluate native-colour, reagent and matrix interference and a recovery control.
5. Calculate reference-equivalent concentration and convert to the stated original-material or extract basis.
6. Record individual readings for independently prepared test portions. Keep all raw observations, including unsuccessful measurements and their investigation.
7. Calculate the result on the stated mass, volume or area basis, including dilution, blank and recovery corrections as justified.
8. Compare the evidence with the applicable criteria and write a conclusion limited to the tested preparation and conditions.

Observations and Record

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

Preparation / attribute	Method condition	Raw measurement	Calculated result
Extraction blank	Record	Record	Calculate
Reference series	Record	Record	Calculate
Recovery control	Record	Record	Calculate
Test preparation	Record	Record	Calculate

Calculations

• Equivalent content (mg/g) = calibrated equivalent concentration (mg/mL) x extract volume (mL) x dilution / material mass (g)

Worked Example

Illustrative equivalent concentration 0.10 mg/mL in 25.0 mL from 0.50 g material gives 5.0 mg reference equivalents/g.

This is not automatically 5 mg/g of every constituent in the class.

Result and Interpretation

• Report gallic acid equivalents, method selectivity and mass/moisture basis.

• Report replicate variability and the evidence that the method can measure the intended attribute in this matrix.

Precautions

• Do not omit matrix blanks.

• Control reaction time, temperature and wavelength.

• Do not infer biological efficacy from a class-equivalent assay.

• Use the adopted laboratory procedure, suitable controls and the designated waste arrangements.

Viva Questions and Answers

Why name the reference?

It defines the equivalent response basis.

Why can class assays disagree?

Different chemistries respond to different subsets and interferents.

Does total content identify individual compounds?

Individual constituent analysis is a separate task.

Total Alkaloid Content of Herbal Materials

Practical 9 - Analytical practical

Aim

To estimate method-defined alkaloid-equivalent content in an authenticated herbal material.

Principle

Use a validated class-appropriate extraction and calibrated assay; no single response quantifies every alkaloid equally. Results must state the chosen reference equivalent and extraction basis.

The test preparation, blank, calibration or titrant standardisation and independent controls are part of the measurement. State the actual concentration units, test conditions and adopted method before interpreting the result.

Materials and Requirements

- Authenticated material and validated class assay
- the specified alkaloid standard reference and suitable extraction blank
- Calibrated spectrophotometer or selected validated detector
- Qualified balance and volumetric equipment
- Controlled method and raw-data worksheet

Procedure

1. Identify the material, intended attribute, method version and acceptance criteria. Record preparation and instrument or reagent identities.
2. Prepare the prescribed blank and reference or standardised reagent. Verify the measurement with an independent check where applicable.
3. Prepare the extract and reference series using the method-specific reaction and measurement conditions.
4. Evaluate native-colour, reagent and matrix interference and a recovery control.
5. Calculate reference-equivalent concentration and convert to the stated original-material or extract basis.
6. Record individual readings for independently prepared test portions. Keep all raw observations, including unsuccessful measurements and their investigation.
7. Calculate the result on the stated mass, volume or area basis, including dilution, blank and recovery corrections as justified.
8. Compare the evidence with the applicable criteria and write a conclusion limited to the tested preparation and conditions.

Observations and Record

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

Preparation / attribute	Method condition	Raw measurement	Calculated result
Extraction blank	Record	Record	Calculate
Reference series	Record	Record	Calculate
Recovery control	Record	Record	Calculate
Test preparation	Record	Record	Calculate

Calculations

• Equivalent content (mg/g) = calibrated equivalent concentration (mg/mL) x extract volume (mL) x dilution / material mass (g)

Worked Example

Illustrative equivalent concentration 0.10 mg/mL in 25.0 mL from 0.50 g material gives 5.0 mg reference equivalents/g.

This is not automatically 5 mg/g of every constituent in the class.

Result and Interpretation

• Report the specified alkaloid standard equivalents, method selectivity and mass/moisture basis.

• Report replicate variability and the evidence that the method can measure the intended attribute in this matrix.

Precautions

• Do not omit matrix blanks.

• Control reaction time, temperature and wavelength.

• Do not infer biological efficacy from a class-equivalent assay.

• Use the adopted laboratory procedure, suitable controls and the designated waste arrangements.

Viva Questions and Answers

Why name the reference?

It defines the equivalent response basis.

Why can class assays disagree?

Different chemistries respond to different subsets and interferents.

Does total content identify individual compounds?

Individual constituent analysis is a separate task.

Total Flavonoid Content of Herbal Materials

Practical 10 - Analytical practical

Aim

To estimate method-defined flavonoid-equivalent content in an authenticated herbal material.

Principle

A selected aluminium-complexation method responds differently to different flavonoid classes. Results must state the chosen reference equivalent and extraction basis.

The test preparation, blank, calibration or titrant standardisation and independent controls are part of the measurement. State the actual concentration units, test conditions and adopted method before interpreting the result.

Materials and Requirements

- Authenticated material and validated class assay
- quercetin reference and suitable extraction blank
- Calibrated spectrophotometer or selected validated detector
- Qualified balance and volumetric equipment
- Controlled method and raw-data worksheet

Procedure

1. Identify the material, intended attribute, method version and acceptance criteria. Record preparation and instrument or reagent identities.
2. Prepare the prescribed blank and reference or standardised reagent. Verify the measurement with an independent check where applicable.
3. Prepare the extract and reference series using the method-specific reaction and measurement conditions.
4. Evaluate native-colour, reagent and matrix interference and a recovery control.
5. Calculate reference-equivalent concentration and convert to the stated original-material or extract basis.
6. Record individual readings for independently prepared test portions. Keep all raw observations, including unsuccessful measurements and their investigation.
7. Calculate the result on the stated mass, volume or area basis, including dilution, blank and recovery corrections as justified.
8. Compare the evidence with the applicable criteria and write a conclusion limited to the tested preparation and conditions.

Observations and Record

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

Preparation / attribute	Method condition	Raw measurement	Calculated result
Extraction blank	Record	Record	Calculate
Reference series	Record	Record	Calculate
Recovery control	Record	Record	Calculate
Test preparation	Record	Record	Calculate

Calculations

• Equivalent content (mg/g) = calibrated equivalent concentration (mg/mL) x extract volume (mL) x dilution / material mass (g)

Worked Example

Illustrative equivalent concentration 0.10 mg/mL in 25.0 mL from 0.50 g material gives 5.0 mg reference equivalents/g.

This is not automatically 5 mg/g of every constituent in the class.

Result and Interpretation

• Report quercetin equivalents, method selectivity and mass/moisture basis.

• Report replicate variability and the evidence that the method can measure the intended attribute in this matrix.

Precautions

• Do not omit matrix blanks.

• Control reaction time, temperature and wavelength.

• Do not infer biological efficacy from a class-equivalent assay.

• Use the adopted laboratory procedure, suitable controls and the designated waste arrangements.

Viva Questions and Answers

Why name the reference?

It defines the equivalent response basis.

Why can class assays disagree?

Different chemistries respond to different subsets and interferents.

Does total content identify individual compounds?

Individual constituent analysis is a separate task.

Ayurvedic Siddha Homoeopathic and Unani Formulary Records

Practical 11 - Formulary and quality-record practical

Aim

To prepare separate formulary and standardisation records for Ayurvedic, Siddha, Homoeopathic and Unani examples.

Principle

Each system has distinct official terminology, formulation instructions and quality standards. Manufacturing or identity compliance does not by itself establish clinical efficacy.

Materials and Requirements

- Selected current official pharmacopoeia/formulary entries
- Authenticated ingredient and controlled manufacturing records
- System-specific finished-product test and label templates
- 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. Select one authorised example from each system and copy only the essential identity, ingredient and process requirements into a training record.
3. Map raw-material authentication, quantities, process controls and finished-product attributes separately for all four examples.
4. Review the supplied preparation records and specifications, including dilution or potency notation where relevant.
5. Prepare a comparative quality and labelling matrix, distinguishing official preparation rules from claims needing clinical evidence.
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.

System	Official entry / form	Identity / process controls	Finished-quality evidence
Ayurveda	Select current entry	Record	Assess
Siddha	Select current entry	Record	Assess
Homoeopathy	Select current entry	Record	Assess
Unani	Select current entry	Record	Assess

Calculations

• For serial dilution accounting only: overall dilution fraction is the product of the stage dilution fractions.

Worked Example

Illustrative three sequential 1:10 dilutions give a nominal dilution fraction of 10^-3. This bookkeeping does not establish clinical efficacy or the actual content of an unmeasured preparation.

Result and Interpretation

• Deliver four clearly separated records and identify the applicable standards and missing evidence.

Precautions

• Do not substitute one system terminology for another.
• Do not prepare metal/mineral or hazardous botanical products outside an approved specialist facility.
• Keep teaching formulations out of clinical use.

Viva Questions and Answers

Why use separate records?

The systems have different preparation and quality conventions.

Does formulary compliance prove efficacy?

Clinical evidence is a separate requirement.

Why authenticate every ingredient?

Misidentification undermines both quality and safety.

Preparation and Quality Assessment of Aromatherapy Formulations

Practical 12 - Bench formulation practical

Aim

To prepare and assess an approved aromatic formulation as a laboratory product-development exercise.

Principle

A lotion is a pourable liquid or semiliquid preparation. In an emulsion lotion, droplet structure and continuous-phase rheology influence pouring, creaming 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 oil, emulsifier, humectant and aqueous-phase formula
- Suitable mixer and viscosity measurement 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 two phases through the selected method and combine using controlled mixing.
4. Condition the batch before measuring flow, pH and appearance. Compare readings at the same temperature and shear conditions.
5. Evaluate reversible creaming separately from irreversible phase separation and record container compatibility observations.
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
Pourability	Record the adopted method	Record	Evaluate
pH and viscosity	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Creaming / separation	Record the adopted method	Record	Evaluate
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 100 g formula allocation: oil phase 12%, approved emulsifier system 4% and humectant 3% leave 81% for the specified aqueous phase and other qualified components.
At a 250 g target batch, the oil allocation is 30 g.
A complete formula must also address preservation, stability and container compatibility.

Aromatic-material controls

• Record the botanical or chemical identity, composition specification, intended route and ingredient-specific safe-use basis.
• Select any fragrance level from the current supplier and applicable product evidence; a natural origin does not establish suitability or a universal concentration.
• Assess odour consistency, compatibility, stability and packaging without assigning clinical efficacy from fragrance alone.

Result and Interpretation

• State whether the batch behaves as the intended pourable system over the selected observation period. 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.

Herbal Lip-Balm Formulation and Evaluation

Practical 13 - Bench formulation practical

Aim

To prepare and evaluate a herbal lip-balm model using an approved wax-oil base.

Principle

A lipstick base combines waxes and oils into a structured stick. Wax composition, pigment wetting where relevant, cooling and mould filling affect strength, surface uniformity and payoff.

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 wax and oil blend with a permitted teaching pigment if used
- Controlled heating bath and moulds
- Selected strength, appearance and uniformity 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 the wax and oil fractions and prepare a uniformly wetted pigment dispersion where the exercise includes pigment.
4. Melt and combine through the selected controlled process, staying within ingredient-specific handling conditions.
5. Fill the prepared moulds, cool by the prescribed method and examine the conditioned sticks for cracks, graininess and sweating.
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
Mass and dimensions	Record the adopted method	Record	Evaluate
Appearance and homogeneity	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Mechanical or softening response	Record the adopted method	Record	Evaluate
Payoff by the defined method	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 50 g base: wax fraction 20% gives 10.0 g and oil fraction 80% gives 40.0 g before any separately specified pigment or additive.

If 2% pigment is introduced, the total formula is revised rather than adding it without correcting the other fractions.

Herbal component

• Record the identity, marker or specification and permitted inclusion basis of the chosen botanical component.
• Evaluate compatibility, distribution and stability of the botanical addition instead of assuming that a natural origin establishes suitability.

Result and Interpretation

• Interpret strength and application-related physical tests with the selected composition and conditioning method. 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.

Herbal Lipstick Formulation and Evaluation

Practical 14 - Bench formulation practical

Aim

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

Principle

A lipstick base combines waxes and oils into a structured stick. Wax composition, pigment wetting where relevant, cooling and mould filling affect strength, surface uniformity and payoff.

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 wax and oil blend with a permitted teaching pigment if used
- Controlled heating bath and moulds
- Selected strength, appearance and uniformity 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 the wax and oil fractions and prepare a uniformly wetted pigment dispersion where the exercise includes pigment.
4. Melt and combine through the selected controlled process, staying within ingredient-specific handling conditions.
5. Fill the prepared moulds, cool by the prescribed method and examine the conditioned sticks for cracks, graininess and sweating.
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
Mass and dimensions	Record the adopted method	Record	Evaluate
Appearance and homogeneity	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Mechanical or softening response	Record the adopted method	Record	Evaluate
Payoff by the defined method	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 50 g base: wax fraction 20% gives 10.0 g and oil fraction 80% gives 40.0 g before any separately specified pigment or additive.

If 2% pigment is introduced, the total formula is revised rather than adding it without correcting the other fractions.

Result and Interpretation

• Interpret strength and application-related physical tests with the selected composition and conditioning method. 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.

Herbal Facial-Cream Base

Practical 15 - 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.

Herbal Hair and Nail-Care Formulations

Practical 16 - Bench formulation practical

Aim

To prepare development and evaluation records for approved herbal hair- and nail-care models.

Principle

A lotion is a pourable liquid or semiliquid preparation. In an emulsion lotion, droplet structure and continuous-phase rheology influence pouring, creaming 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 oil, emulsifier, humectant and aqueous-phase formula
- Suitable mixer and viscosity measurement 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 two phases through the selected method and combine using controlled mixing.
4. Condition the batch before measuring flow, pH and appearance. Compare readings at the same temperature and shear conditions.
5. Evaluate reversible creaming separately from irreversible phase separation and record container compatibility observations.
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
Pourability	Record the adopted method	Record	Evaluate
pH and viscosity	Record the adopted method	Record	Evaluate
Creaming / separation	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
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 100 g formula allocation: oil phase 12%, approved emulsifier system 4% and humectant 3% leave 81% for the specified aqueous phase and other qualified components.

At a 250 g target batch, the oil allocation is 30 g.

A complete formula must also address preservation, stability and container compatibility.

Product-specific records

• Define separate objectives and test methods for hair conditioning, scalp products and nail-care preparations.
• Record botanical identity and marker control, base compatibility, physical attributes and the proposed claim-evidence plan.

Result and Interpretation

• State whether the batch behaves as the intended pourable system over the selected observation period. 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.

Quality Evaluation of Herbal Tablets and Capsules

Practical 17 - Bench formulation practical

Aim

To evaluate herbal tablets and capsules using suitable identity, content and physical-quality evidence.

Principle

Capsule quality depends on the shell, fill material and filling process. Powder flow, packing and compatibility can influence filling consistency and subsequent product 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 fill formula and capsule shell specification
- Suitable capsule-filling arrangement
- Balance and required physical, assay and release tests
- 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 target fill composition and choose the shell size through the selected bulk-volume and compatibility assessment.
4. Prepare the blend and assess relevant flow and packing properties before filling.
5. Fill using the specified process and record shell identity, fill mass and process observations.
6. Evaluate mass variation, appearance, content and the disintegration or dissolution characteristics required for the product.
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
Shell and fill identity	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Fill mass	Record the adopted method	Record	Evaluate
Content / physical tests	Record the adopted method	Record	Evaluate
Release evaluation	Record the adopted method	Record	Evaluate

Calculations

• Net fill mass = filled capsule mass - corresponding empty shell mass
• Relative fill deviation (%) = (individual fill - mean fill) / mean fill x 100

Worked Example

Illustrative filled and empty shell masses are 420 and 90 mg: net fill is 330 mg.
For a mean fill of 325 mg, this unit differs by (330-325)/325 x 100 = 1.54%.
Use the relevant method and sample-size requirements when drawing a formal conclusion.

Herbal product panel

• Map tablet and capsule tests separately to the selected product specification.
• Add botanical identity, fingerprint or marker control and appropriate contaminant requirements; mass uniformity alone does not establish botanical-content consistency.

Result and Interpretation

• Distinguish shell variation from fill variation and state the complete quality evidence.
• 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 suitable shell conditioning and approved materials.
• Control segregation and fill handling.
• Avoid inferring drug-content uniformity from fill mass alone.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

Why consider shell compatibility?

Moisture and chemical interactions can affect product stability and function.

What does bulk volume help estimate?

The space required for the selected fill mass.

Does a consistent fill guarantee dissolution?

Release performance requires its own test.

Sunscreen and UV-Protection Formulation Assessment

Practical 18 - Formulation and optical-evaluation practical

Aim

To prepare a sunscreen-base development record and assess suitable optical and physical evidence.

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.

UV-protection evidence

• Record the UV-filter identity, regulatory status for the intended market, concentration and formulation compatibility.
• Measure only through the selected qualified optical method and include substrate, application, blank and stability controls.
• An absorbance screen or an unvalidated classroom SPF calculation is not a substantiated labelled SPF or UVA-protection claim. Use the applicable validated standard for the claimed attribute.

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 and Standardisation of Herbal Cough Syrup

Practical 19 - Bench formulation practical

Aim

To prepare and standardise an approved herbal oral-syrup model for laboratory evaluation.

Principle

A syrup is a concentrated aqueous oral-liquid vehicle containing dissolved sugars or another justified sweetening system. Botanical extracts may contribute insoluble matter, colour and variable marker content; clarity, uniformity, preservation and dose-volume consistency need separate controls.

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

- Authenticated, specified herbal extract and approved syrup formula
- Purified water and suitable vehicle ingredients
- Qualified balance, volume, pH, viscosity and marker-assay 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 extract identity, marker content, solvent residue specification and the approved formulation with all quantities and final-volume basis.
4. Prepare the syrup vehicle through the authorised process; dissolve or disperse each compatible ingredient in the prescribed sequence, avoiding unjustified heat exposure of the extract.
5. Incorporate the extract at its defined stage, adjust to final volume at the specified temperature and fill labelled laboratory containers.
6. Assess appearance, pH, viscosity under stated conditions, delivered volume, marker content and physical uniformity; specify microbial-quality and preservative-effectiveness evidence where applicable.
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 / interval	Record the adopted method	Record	Evaluate
Appearance / pH	Record the adopted method	Record	Evaluate
Viscosity / delivered volume	Record the adopted method	Record	Evaluate
Marker and microbial controls	Record the adopted method	Record	Evaluate

Calculations

• Marker per dose volume = assayed marker concentration x stated dose volume
• Vehicle solids (% w/v) = dissolved solids mass (g) / final volume (mL) x 100

Worked Example

Illustrative 60 g specified dissolved solids in a final volume of 100 mL is 60% w/v. This does not establish microbial preservation.

Illustrative marker assay 0.40 mg/mL corresponds to 2.0 mg in a 5.0 mL analytical portion; this arithmetic is not a recommended patient dose.

Result and Interpretation

• Report formula, botanical identity, marker assay, physical quality and the evidence still needed for shelf life and any proposed claim.
• 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

• Keep the preparation labelled for laboratory evaluation only.
• Use final volume rather than added-water volume for % w/v.
• Do not assume that sweetness, herbal origin or high solids proves safety or preservation.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

Why assay a marker?

It supports consistency of the specified extract and finished preparation.

Why control final volume?

It determines ingredient and marker concentrations.

Does a bench syrup test establish cough treatment?

Clinical claims require suitable product evidence and the applicable regulatory basis.

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