Year 1 - Practical Notes

Pharmaceutics

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Using Pharmacopoeias and Formularies

Experiment 1 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To retrieve an official formula and prepare an accurate working formula.

Principle

A pharmacopoeia defines identity, purity and quality standards; a formulary supplies preparation and use information. A monograph is read as a whole, including its general notices.

Key Points

- Record the edition and exact monograph title.
- Separate ingredient identity, quantity, method, tests, limits, storage and labelling.
- A named preparation may differ between editions; do not combine quantities from different editions.

Practice Scenario

Calculation exercise: a master formula is for 1,000 mL and the required batch is 50 mL. The factor is 0.05; 200 g of a master ingredient becomes 10 g.

Activity Procedure

1. Locate the preparation

Find the assigned monograph and check its official name and strength.

2. Extract the formula

Copy ingredient grades, units and target batch size into a working sheet.

3. Scale

Calculate required/master batch size and apply that factor to all ingredients.

4. Plan evaluation

List required tests and acceptance limits before preparing the product.

5. Check the record

Have the working formula checked and note packaging and label requirements.

Record and Observations

Field	Record
Edition / monograph	_____
Master / working size	_____
Scaling factor	_____
Test / acceptance limit	_____
Storage / container	_____

Result

Complete the record using your activity, then state the findings, the action required and the reason for that action.

Viva Questions and Answers

1. What is a monograph?

An official description and standard for a named pharmaceutical substance or preparation.

2. What is the scaling factor?

Required batch size divided by the master batch size.

3. Does a clear liquid prove quality?

No; the required identity, strength and other tests are also needed.

Preparation of Simple Syrup

Experiment 2 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare a sucrose syrup by the prescribed method and distinguish percentage by mass from percentage by volume.

Principle

Syrup is a concentrated aqueous solution of sucrose. Concentration affects viscosity, crystallisation and susceptibility to microbial growth. A 66.7% w/w teaching syrup means 66.7 g sucrose in 100 g of final syrup, not in 100 mL.

Requirements

- Sucrose, purified water and prescribed IP formula.
- Balance, beaker, stirring rod, controlled water bath and suitable clean bottle.

Procedure

1. Weigh ingredients

Use the final-mass basis in the assigned formula. Weigh the sucrose and an initial water quantity accurately.

2. Dissolve

Stir with gentle controlled warming if the prescribed method allows heating. Avoid prolonged boiling and scorching.

3. Cool and adjust

Cool to the measuring temperature. Replace evaporative loss by adjustment to the prescribed final mass, not by an estimated splash of water.

4. Inspect

Check for undissolved sugar, crystals, clarity and uniformity. Record the mass obtained and temperature when measured.

5. Package

Transfer to a tightly closed clean bottle. Label the preparation, batch and laboratory-specified storage and use period.

Observations and Record

Item	Teaching quantity for 100 g	Record
Sucrose	66.7 g	_____
Purified water	q.s. to 100 g final mass	_____
Appearance / final mass	Clear, uniform syrup / weighed mass	_____

Worked Example

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

- For a 30 g batch at 66.7% w/w: sucrose = 30 × 0.667 = 20.01 g. Water is adjusted so the final mass is 30 g.
- If the final mass before adjustment is 29.20 g, add water to obtain 30.00 g; required addition is 0.80 g.
- Do not convert this formula into % w/v without knowing the density. The prescribed IP edition remains the basis for official composition.

Result

Record the observed outcome and calculated value, with units. State whether the stated laboratory specification was met; do not copy the worked example as your result.

Precautions

- Avoid prolonged heat, which can cause sucrose inversion and colour changes.
- Do not assume concentrated syrup is sterile or indefinitely stable.
- Keep closures and utensils clean; dilution changes preservation behaviour.

Viva Questions and Answers

1. Why adjust after cooling?

Heating may evaporate water; final adjustment restores the intended mass concentration.

2. Why can crystals form?

Loss of water or an unsuitable concentration or temperature can produce supersaturation.

3. How does w/w differ from w/v?

w/w uses final preparation mass; w/v uses final preparation volume.

Preparation of Piperazine Citrate Elixir

Experiment 3 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label a piperazine citrate elixir.

Principle

An elixir is a sweetened hydroalcoholic oral liquid. Solubility and mixing order are important because adding water changes the solvent environment.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Piperazine citrate	Active ingredient	_____
Prescribed alcohol / co-solvent	Solvent	_____
Syrup / flavour	Palatability	_____
Purified water	Vehicle	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Read the formula

Check the assigned strength and solvent system; calculate the working quantities.

2. Dissolve separately

Prepare the water-soluble and alcohol-soluble portions in their assigned solvents.

3. Combine

Add the aqueous portion gradually to the alcoholic portion with stirring.

4. Complete

Add flavour and sweetening ingredients as assigned; bring to final volume.

5. Evaluate and dispense

Check clarity and final volume; package in the prescribed closure and label as an oral training preparation.

Evaluation and Label

- Check clarity, precipitation on standing, final volume, assigned strength and the suitability of the oral label.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- For a 25-unit batch from a 100-unit master formula, multiply every ingredient quantity by 0.25.
- Enter the actual final yield and compare it with the target batch size.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- Avoid ignition sources when handling alcohol.
- Do not change the solvent ratio to remove precipitate without checking the formula.
- The clinical dose belongs to the prescription, not the preparation exercise.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Check clarity, precipitation on standing, final volume, assigned strength and the suitability of the oral label.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Aqueous Iodine Solution

Experiment 4 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare an aqueous iodine-potassium iodide solution and explain why iodine dissolves more readily in the presence of iodide.

Principle

Iodide forms soluble polyiodide species with iodine: I2 + I− □ I3−. Dissolving potassium iodide first therefore helps incorporate iodine into water. The preparation is brown and must not be confused with tincture of iodine, which uses an alcoholic system.

Requirements

- Iodine, potassium iodide, purified water and the prescribed BPC formula.
- Balance, glass mortar or beaker, measuring cylinder and amber glass bottle.

Procedure

1. Calculate quantities

Check the assigned formula and final-volume basis. For the strong 5% iodine / 10% potassium iodide teaching composition below, calculate quantities for the batch.

2. Dissolve iodide

Dissolve potassium iodide in a small portion of purified water. Retain enough vehicle for final adjustment.

3. Incorporate iodine

Add iodine gradually and mix until dissolved. Use the prescribed ventilation and avoid unnecessary warming that could increase iodine loss.

4. Adjust and mix

Transfer quantitatively, rinse the working vessel with vehicle and make up to final volume. Mix thoroughly.

5. Evaluate and label

Observe the deep-brown solution for visible particles. Package in a tightly closed light-resistant container. Apply route and use instructions from the assigned formulation; iodine preparations are not interchangeable.

Observations and Record

Ingredient	Teaching quantity for 100 mL	Quantity for assigned batch
Iodine	5 g	_____
Potassium iodide	10 g	_____
Purified water	q.s. to 100 mL	_____

Worked Example

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

- For 20 mL of the stated teaching composition: iodine = 5 × 20/100 = 1 g; potassium iodide = 10 × 20/100 = 2 g; water q.s. to 20 mL.
- Iodine concentration = 1 g ÷ 20 mL × 100 = 5% w/v.
- This commonly used strong composition explains the method. Use the college-prescribed BPC formulation if its specified strength differs.

Result

Record the observed outcome and calculated value, with units. State whether the stated laboratory specification was met; do not copy the worked example as your result.

Precautions

- Do not add 100 mL water to the solids when the formula says q.s. to 100 mL.
- Keep the container closed to limit iodine loss and protect from light.
- Avoid skin contact and do not use the teaching preparation clinically.

Viva Questions and Answers

1. Why dissolve potassium iodide before iodine?

Iodide promotes the formation of more soluble iodine complexes.

2. Why use an amber bottle?

It limits light exposure; tight closure also limits loss of volatile iodine.

3. Is Lugols solution an alcoholic tincture?

No; it is an aqueous iodine-iodide preparation.

Preparation of Castor Oil Emulsion

Experiment 5 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label an oil-in-water emulsion.

Principle

An emulsifier stabilises dispersed oil droplets in a continuous aqueous phase. In the dry-gum method, a primary emulsion is formed before dilution.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Castor oil	Dispersed oil phase	_____
Acacia	Emulsifier	_____
Purified water	Continuous phase	_____
Assigned sweetener / flavour	Palatability	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Calculate

Use the assigned formula. For a fixed-oil dry-gum demonstration, the oil:water:gum primary ratio is commonly 4:2:1.

2. Form the primary emulsion

Triturate gum with oil in a dry mortar; add the calculated primary water and triturate briskly until a uniform primary emulsion forms.

3. Dilute gradually

Add remaining aqueous ingredients in small portions while mixing.

4. Complete

Transfer, rinse the mortar with vehicle and make to final volume.

5. Evaluate

Check uniformity and redispersibility; compare dilution and microscopy observations.

6. Package

Use the assigned container; include Shake well and the prescribed route.

Evaluation and Label

- Observe creaming, cracking, droplet appearance and dilution behaviour; irreversible separation differs from reversible creaming.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- Example: 10 mL fixed oil needs 5 mL water and 2.5 g gum for the primary emulsion; additional vehicle is added to the assigned final volume.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- Primary-emulsion water is not the whole final water quantity.
- Use a dry mortar for the initial dry-gum stage.
- Protect oxidation-sensitive oils from unsuitable storage.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Observe creaming, cracking, droplet appearance and dilution behaviour; irreversible separation differs from reversible creaming.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Cod Liver Oil Emulsion

Experiment 6 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label an oil-in-water emulsion.

Principle

An emulsifier stabilises dispersed oil droplets in a continuous aqueous phase. In the dry-gum method, a primary emulsion is formed before dilution.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Cod liver oil	Dispersed oil phase	_____
Acacia	Emulsifier	_____
Purified water	Continuous phase	_____
Assigned sweetener / flavour	Palatability	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Calculate

Use the assigned formula. For a fixed-oil dry-gum demonstration, the oil:water:gum primary ratio is commonly 4:2:1.

2. Form the primary emulsion

Triturate gum with oil in a dry mortar; add the calculated primary water and triturate briskly until a uniform primary emulsion forms.

3. Dilute gradually

Add remaining aqueous ingredients in small portions while mixing.

4. Complete

Transfer, rinse the mortar with vehicle and make to final volume.

5. Evaluate

Check uniformity and redispersibility; compare dilution and microscopy observations.

6. Package

Use the assigned container; include Shake well and the prescribed route.

Evaluation and Label

- Observe creaming, cracking, droplet appearance and dilution behaviour; irreversible separation differs from reversible creaming.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- Example: 10 mL fixed oil needs 5 mL water and 2.5 g gum for the primary emulsion; additional vehicle is added to the assigned final volume.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- Primary-emulsion water is not the whole final water quantity.
- Use a dry mortar for the initial dry-gum stage.
- Protect oxidation-sensitive oils from unsuitable storage.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Observe creaming, cracking, droplet appearance and dilution behaviour; irreversible separation differs from reversible creaming.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Calamine Lotion

Experiment 7 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label a calamine suspension lotion.

Principle

Insoluble solid particles are dispersed in a liquid vehicle. Wetting and controlled particle size support easy redistribution after settling.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Calamine	Dispersed solid	_____
Zinc oxide if specified	Protective solid	_____
Glycerol	Wetting agent	_____
Assigned suspending medium	Vehicle	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Calculate and inspect

Record the assigned formula and inspect powders for lumps.

2. Levigation

Triturate powders with the wetting liquid to make a smooth paste.

3. Dispersion

Add the suspending vehicle gradually with mixing.

4. Complete

Transfer quantitatively and bring to final volume.

5. Evaluate and label

Observe sedimentation and redispersion; label Shake well and For external use.

Evaluation and Label

- Inspect grit, uniformity, sedimentation and the number of gentle inversions needed for redispersion.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- For a 25-unit batch from a 100-unit master formula, multiply every ingredient quantity by 0.25.
- Enter the actual final yield and compare it with the target batch size.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- Do not label the lotion for oral use.
- Avoid inhaling fine powders.
- A hard sediment that cannot be redispersed is undesirable.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Inspect grit, uniformity, sedimentation and the number of gentle inversions needed for redispersion.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Magnesium Hydroxide Mixture

Experiment 8 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label a magnesium hydroxide suspension.

Principle

Magnesium hydroxide is poorly soluble; the preparation is a dispersed solid mixture whose dose uniformity depends on redispersion.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Magnesium hydroxide	Active dispersed solid	_____
Assigned stabiliser	Suspension stability	_____
Purified water	Vehicle	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Calculate

Check whether the assigned formula uses the solid or prepares it by precipitation.

2. Disperse

Wet and disperse the assigned solid with gradual addition of vehicle.

3. Mix

Obtain a smooth, uniform dispersion using the approved method.

4. Complete

Bring to volume and package.

5. Evaluate

Record settling, redispersion and assigned pH or assay checks.

Evaluation and Label

- Check the appearance, ease of redistribution, final volume and assigned monograph tests.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- For a 25-unit batch from a 100-unit master formula, multiply every ingredient quantity by 0.25.
- Enter the actual final yield and compare it with the target batch size.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- Use only the designated grade of ingredients.
- Do not infer antacid strength from appearance.
- Include Shake well when required.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Check the appearance, ease of redistribution, final volume and assigned monograph tests.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Simple Ointment Base

Experiment 9 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label a simple ointment base.

Principle

Fusion distributes the higher-melting components through the soft base. Stirring during cooling helps maintain a uniform consistency.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Hard paraffin	Stiffening	_____
Cetostearyl alcohol	Consistency	_____
Wool fat	Water absorption	_____
White soft paraffin	Base	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Weigh

Record each ingredient and the working quantity.

2. Fuse

Melt the higher-melting components on a controlled water bath and add the softer base.

3. Cool with stirring

Mix gently as the mass cools; avoid entrapping air.

4. Fill

Transfer to the assigned wide-mouth container.

5. Evaluate

Record uniformity, smoothness, consistency and final mass.

Evaluation and Label

- Check homogeneity, absence of grit, spreadability and final yield.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- Teaching composition per 100 g: hard paraffin 5 g, cetostearyl alcohol 5 g, wool fat 5 g and white soft paraffin 85 g.
- For 20 g, the corresponding quantities are 1 g, 1 g, 1 g and 17 g; confirm the assigned official formula.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- Avoid direct flame or overheating.
- Use dry equipment.
- The base is not a sterile ophthalmic preparation.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Check homogeneity, absence of grit, spreadability and final yield.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Sulphur Ointment

Experiment 10 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare a smooth sulphur ointment by incorporation and evaluate its uniformity.

Principle

Sulphur is dispersed as a solid in an ointment base. Levigation with a suitable portion of the base or prescribed levigating agent reduces grittiness; geometric incorporation distributes the powder through the remaining base.

Requirements

- Sulphur of the specified grade, prescribed IP ointment base and formula.
- Balance, mortar or slab, spatula and compatible ointment container.

Procedure

1. Calculate the formula

Identify sulphur concentration on the mass basis and the required final ointment mass. Check whether the base is supplied or must first be prepared.

2. Prepare sulphur

Reduce permissible agglomerates without exposing yourself to dust. Levigate with the prescribed compatible material to obtain a smooth paste.

3. Incorporate the base

Add the base in portions comparable to the paste amount, then progressively add the remainder. Scrape the working surface to recover all material.

4. Evaluate

Inspect colour and texture, spread a small portion on a clean inspection surface, and look for visible gritty particles or separated liquid.

5. Fill and label

Transfer to a suitable well-closed container. Record net mass and apply external-use, strength and storage details from the laboratory formula.

Observations and Record

Characteristic	Assessment	Record
Texture	Smoothness and visible particles	_____
Uniformity	Colour and consistency throughout	_____
Net mass	Weighed container minus tare	___ g

Worked Example

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

- Illustrative 10% w/w exercise: 25 g final ointment requires 2.5 g sulphur and enough prescribed base to make 25 g.
- If the base is the only other ingredient, calculated base = 25 - 2.5 = 22.5 g.
- Yield: if 24.0 g is recovered, percentage recovery = 24.0 ÷ 25.0 × 100 = 96%. The assigned IP formula determines the actual strength.

Result

Record the observed outcome and calculated value, with units. State whether the stated laboratory specification was met; do not copy the worked example as your result.

Precautions

- A levigating liquid must be compatible with the base and permitted by the formula.
- Avoid excess heating and uncontrolled addition of vehicle.
- Do not use fingers to inspect texture; use a clean surface or spatula.

Viva Questions and Answers

1. Is sulphur usually dissolved in the base?

No; it is dispersed as a solid in this type of ointment.

2. What is the purpose of levigation?

To obtain a smoother dispersion and reduce agglomerates.

3. Why fill by net mass?

Container tare must be excluded from the amount of preparation.

Preparation of Cetrimide Cream

Experiment 11 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label the assigned cetrimide cream.

Principle

A cream combines an oil phase and an aqueous phase with emulsification. Cetrimide is a cationic ingredient; incompatible anionic materials may affect it.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Cetrimide	Assigned antiseptic	_____
Cetostearyl alcohol	Consistency / emulsification	_____
Liquid paraffin	Oil phase	_____
Purified water	Aqueous phase	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Prepare phases

Prepare the oil and aqueous phases according to the assigned formula.

2. Emulsify

Bring both phases to the specified conditions and combine with continuous mixing.

3. Cool

Stir as the cream cools; add any temperature-sensitive ingredients at the assigned stage.

4. Evaluate and pack

Check texture, uniformity and separation; package as an external training cream.

Evaluation and Label

- Inspect emulsion uniformity, consistency, pH where assigned and separation.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- For a 25-unit batch from a 100-unit master formula, multiply every ingredient quantity by 0.25.
- Enter the actual final yield and compare it with the target batch size.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- Use the named formula and ingredient grades.
- Avoid contamination and inappropriate heating.
- Record actual results rather than assuming that appearance proves compliance.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Inspect emulsion uniformity, consistency, pH where assigned and separation.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Sodium Alginate Gel

Experiment 12 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label the assigned sodium alginate gel.

Principle

Hydrated alginate chains produce a viscous gel. Gradual dispersion avoids a dry core trapped inside lumps.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Sodium alginate	Gelling polymer	_____
Assigned humectant	Wetting / moisture retention	_____
Purified water	Vehicle	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Disperse

Sprinkle polymer slowly into the vehicle while stirring, or pre-wet it as the formula directs.

2. Hydrate

Allow the assigned hydration period and stir gently until smooth.

3. Complete

Add other assigned ingredients and make to mass or volume.

4. Evaluate

Record clarity, lumps, consistency and spreadability.

Evaluation and Label

- Check smoothness, hydration, viscosity comparison and final quantity.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- For a 25-unit batch from a 100-unit master formula, multiply every ingredient quantity by 0.25.
- Enter the actual final yield and compare it with the target batch size.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- Use the named formula and ingredient grades.
- Avoid contamination and inappropriate heating.
- Record actual results rather than assuming that appearance proves compliance.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Check smoothness, hydration, viscosity comparison and final quantity.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Turpentine Liniment

Experiment 13 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label the assigned turpentine liniment.

Principle

A liniment is a liquid or semi-liquid external preparation intended for application to skin. The assigned soap or emulsifier helps distribute the oil phase.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Turpentine oil	Oil phase	_____
Assigned camphor / soap	Monograph ingredients	_____
Purified water	Vehicle	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Read the formula

Distinguish the named liniment from similarly named preparations.

2. Prepare portions

Dissolve or disperse ingredients in the assigned phase.

3. Combine

Mix the phases in the specified sequence.

4. Evaluate and pack

Observe uniformity and redistribution; label For external use and the assigned warnings.

Evaluation and Label

- Record phase behaviour, uniformity and the correct external label.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- For a 25-unit batch from a 100-unit master formula, multiply every ingredient quantity by 0.25.
- Enter the actual final yield and compare it with the target batch size.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- Use the named formula and ingredient grades.
- Avoid contamination and inappropriate heating.
- Record actual results rather than assuming that appearance proves compliance.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Record phase behaviour, uniformity and the correct external label.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of White Liniment BPC

Experiment 14 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label the assigned white liniment bpc.

Principle

The formulation uses an assigned soap-emulsification system to disperse oily material in an aqueous phase.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Assigned oil / oleic component	Oil / soap-forming ingredient	_____
Assigned alkaline solution	Emulsification component	_____
Purified water	Vehicle	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Scale

Use the named BPC formula and record the edition-specific ingredients.

2. Mix portions

Prepare the required oily and aqueous portions.

3. Emulsify

Combine in the assigned order with thorough mixing.

4. Dispense

Record uniformity; use the correct container and external label.

Evaluation and Label

- Check separation, redistributability and the specified appearance.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- For a 25-unit batch from a 100-unit master formula, multiply every ingredient quantity by 0.25.
- Enter the actual final yield and compare it with the target batch size.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- Use the named formula and ingredient grades.
- Avoid contamination and inappropriate heating.
- Record actual results rather than assuming that appearance proves compliance.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Check separation, redistributability and the specified appearance.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Effervescent Powder Granules

Experiment 15 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare free-flowing effervescent granules and relate moisture control to their stability.

Principle

An acid reacts with a carbonate or bicarbonate in water to release carbon dioxide. Citric acid, tartaric acid and sodium bicarbonate are commonly used in teaching formulations. Granulation improves handling, but moisture during manufacture or storage can start the reaction too early.

Requirements

- Prescribed acid-bicarbonate formula, with any assigned drug and vehicle.
- Balance, dry mortar, sieve, granulation tray, controlled drying equipment and moisture-resistant container.

Procedure

1. Check the formula

Identify the acid forms and bicarbonate quantity. Calculate the batch and verify that the selected method is suitable for any drug present.

2. Prepare powders

Reduce permitted lumps, sieve the dry materials separately and mix in the specified sequence. Avoid generating excessive dust.

3. Granulate

Use the prescribed fusion or solvent-assisted method. For a fusion method, controlled release of crystal water helps produce a coherent mass; do not overheat or allow vigorous premature reaction.

4. Size and dry

Pass the suitable damp mass through the assigned sieve. Dry under the prescribed conditions, cool in a dry environment and resieve if required.

5. Evaluate and pack

Record granule appearance, flow and behaviour when a measured teaching portion is added to water. Pack promptly in a tightly closed moisture-resistant container.

Observations and Record

Check	Record	Observation
Granulation / drying	Method, sieve and drying condition	_____
Appearance / yield	Granule size, final dry mass	_____
Effervescence test	Test portion and water volume	_____

Worked Example

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

- Reaction: $H^+ + HCO_3^- \rightarrow CO_2 + H_2O$. One mole of bicarbonate consumes one mole of acid equivalents.
- If a teaching formula assigns 1 part citric acid, 2 parts tartaric acid and 3.4 parts sodium bicarbonate, total parts = 6.4. For 32 g, the calculated masses are 5 g, 10 g and 17 g.
- That parts ratio is an illustrative scaling exercise, not a universal official formula. Hydrate form and acid equivalents must be considered.

Result

Record the observed outcome and calculated value, with units. State whether the stated laboratory specification was met; do not copy the worked example as your result.

Precautions

- Keep water and humid air away until the dissolution test.
- Do not use uncontrolled heat to force granulation.
- Record drying conditions and final mass; apparent good flow alone does not prove stability.

Viva Questions and Answers

1. What causes effervescence?

Carbon dioxide is released when acid and bicarbonate react in water.

2. Why package immediately after cooling?

The exposed granules can take up moisture and react prematurely.

3. Why use both citric and tartaric acids in some formulas?

They can improve granulation and handling compared with either acid alone, depending on the method.

Preparation of Dusting Powder

Experiment 16 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare a fine, uniform dusting powder and evaluate its suitability for the assigned external application.

Principle

Dusting powders are dry external preparations. Uniform particle size and mixing help produce smooth application. An ordinary compounded powder is not automatically sterile and must not be described as suitable for an open wound unless its specified formulation and processing support that use.

Requirements

- Prescribed IP powder formula and dry ingredients.
- Balance, mortar, assigned sieve and clean sifter container.

Procedure

1. Read the formula

Identify the intended site of application, ingredient quantities and required grade and fineness. Calculate the final mass.

2. Prepare individual powders

Reduce allowable agglomerates and sieve ingredients as prescribed. Handle fine powders to minimise airborne dust.

3. Mix

Use geometric dilution for low-level ingredients. Add powders of similar size progressively and mix consistently.

4. Evaluate

Check texture on a clean inspection surface, visible particles, uniformity and delivery through the assigned container. Do not test an unapproved preparation on skin.

5. Package and label

Transfer with minimal loss to a suitable sifter container. Record net mass and label external use and the prescribed application restrictions.

Observations and Record

Characteristic	Method of assessment	Record
Fineness / texture	Prescribed sieve and visual inspection	_____
Uniformity	Appearance across the mixed batch	_____
Net yield / delivery	Final mass and sifter operation	_____

Worked Example

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

- Illustrative 20 g teaching blend: 10% zinc oxide, 20% starch and 70% specified inert base gives 2 g, 4 g and 14 g.
- Check: 2 + 4 + 14 = 20 g. If 19.4 g is recovered, yield = 19.4 ÷ 20 × 100 = 97%.
- This example demonstrates mixing calculations. Use the assigned IP composition and material grades for the actual practical.

Result

Record the observed outcome and calculated value, with units. State whether the stated laboratory specification was met; do not copy the worked example as your result.

Precautions

- Do not infer sterility from dryness or fine particle size.
- Avoid inhalation and contamination during mixing and filling.
- Do not substitute mineral powders or grades without instructor approval.

Viva Questions and Answers

1. Why is fineness important?

Coarse particles can make application unpleasant and non-uniform.

2. Why use a sifter container?

It supports controlled external distribution of the powder.

3. What is geometric dilution?

Progressively mixing a smaller quantity with comparable quantities of a larger component.

Study and Preparation Record of Normal Saline Injection

Experiment 17 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label a supervised injectable-formulation training record.

Principle

An injectable preparation requires the prescribed identity and strength, particulate control, appropriate pH, sterility and endotoxin compliance. Clear appearance alone cannot establish injectable quality.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Sodium chloride	Assigned active solute	_____
Water for injections	Compendial vehicle	_____
Other prescribed ingredients	Only if in the assigned formula	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Review the monograph

List the official composition, container, pH range and required tests.

2. Calculate

Scale the assigned formula and independently check each concentration calculation.

3. Observe preparation

Document the instructor demonstration of dissolution, clarification and the validated sterilisation or aseptic process.

4. Record controls

Identify water quality, container-closure integrity and process validation checks.

5. Evaluate the training record

Record visual inspection and assigned analytical results; identify the separate sterility and endotoxin requirements.

6. Label training material

Use the institution-approved training label; bench demonstration material is not released for patient administration.

Evaluation and Label

- Separate strength and pH testing from particulate, sterility, endotoxin and container-closure requirements.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- Concentration calculation: 0.9% w/v means 0.9 g of sodium chloride in 100 mL final solution.
- For 50 mL of that teaching concentration, the calculated solute mass is 0.45 g; use the monograph-assigned target for the actual exercise.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- Injectable manufacture uses a validated facility and process.
- Do not substitute purified water for water for injections.
- Do not use demonstration material in people.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Separate strength and pH testing from particulate, sterility, endotoxin and container-closure requirements.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Study and Preparation Record of Calcium Gluconate Injection

Experiment 18 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label a supervised injectable-formulation training record.

Principle

An injectable preparation requires the prescribed identity and strength, particulate control, appropriate pH, sterility and endotoxin compliance. Clear appearance alone cannot establish injectable quality.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Calcium gluconate	Assigned active solute	_____
Water for injections	Compendial vehicle	_____
Other prescribed ingredients	Only if in the assigned formula	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Review the monograph

List the official composition, container, pH range and required tests.

2. Calculate

Scale the assigned formula and independently check each concentration calculation.

3. Observe preparation

Document the instructor demonstration of dissolution, clarification and the validated sterilisation or aseptic process.

4. Record controls

Identify water quality, container-closure integrity and process validation checks.

5. Evaluate the training record

Record visual inspection and assigned analytical results; identify the separate sterility and endotoxin requirements.

6. Label training material

Use the institution-approved training label; bench demonstration material is not released for patient administration.

Evaluation and Label

- Separate strength and pH testing from particulate, sterility, endotoxin and container-closure requirements.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- Concentration calculation: 10% w/v means 10 g of calcium gluconate in 100 mL final solution.
- For 50 mL of that teaching concentration, the calculated solute mass is 5 g; use the monograph-assigned target for the actual exercise.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- Injectable manufacture uses a validated facility and process.
- Do not substitute purified water for water for injections.
- Do not use demonstration material in people.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Separate strength and pH testing from particulate, sterility, endotoxin and container-closure requirements.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Tetracycline Hard Gelatine Capsules

Experiment 19 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label a hard-gelatine capsule training batch.

Principle

A uniform powder blend is divided into capsule shells. Fill mass alone does not establish drug-content uniformity.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Assigned tetracycline material / dummy blend	Training fill	_____
Assigned diluent / glidant	Blend and filling properties	_____
Hard gelatine shells	Container	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Calculate

Record target strength, number of capsules and the specified potency adjustment.

2. Prepare the blend

Sieve as assigned and use geometric dilution for a uniform blend.

3. Fill

Select the prescribed shell size and divide the blend using the approved filling technique.

4. Close and inspect

Check shell closure, damaged capsules and powder loss.

5. Evaluate

Record fill masses and identify the separate content, disintegration and other monograph checks.

Evaluation and Label

- Check fill-mass variation, appearance, closure and the distinction between mass and drug-content uniformity.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- Example only: 20 capsules containing 250 mg labelled drug each need 5,000 mg = 5 g drug before any specified potency correction or process allowance.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- Control powder exposure and use the assigned training material.
- Do not infer clinical strength from total capsule mass.
- Keep shells protected from excess heat and moisture.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Check fill-mass variation, appearance, closure and the distinction between mass and drug-content uniformity.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Paracetamol Tablets

Experiment 20 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label a tablet-formulation training batch.

Principle

Granulation and compression convert a blend into a solid unit. Binder, disintegrant and lubricant influence strength and release behaviour.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Paracetamol / designated dummy material	Assigned drug	_____
Diluent	Bulk	_____
Binder	Granule strength	_____
Disintegrant	Break-up	_____
Lubricant	Compression and ejection	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Weigh and mix

Scale the master formula and blend the assigned powders.

2. Granulate

Add binder as directed to form a suitable wet mass and screen it.

3. Dry and size

Dry using the validated teaching conditions and size the granules.

4. Final blend

Add disintegrant and lubricant in the specified sequence.

5. Compress

Observe the supervised press settings and collect tablets.

6. Evaluate

Record appearance, mass, hardness and assigned disintegration or dissolution tests.

Evaluation and Label

- Assess mass variation, friability, disintegration and the specified analytical tests; hardness is not a substitute for dissolution.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- Example only: 10 tablets with 500 mg labelled paracetamol each require 5 g active drug; total tablet mass also includes excipients.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- Use the tablet press only under trained supervision.
- Avoid over-lubrication.
- Document the training batch and losses.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Assess mass variation, friability, disintegration and the specified analytical tests; hardness is not a substitute for dissolution.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Cosmetic Cold Cream

Experiment 21 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label a cosmetic cold cream.

Principle

An emulsion-based cosmetic that usually has a substantial oily phase.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Assigned wax	Structure	_____
Liquid paraffin / assigned oil	Emollient	_____
Assigned emulsifier	Emulsion stability	_____
Purified water	Aqueous phase	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Read the formula

Record the assigned cosmetic formula, batch size and ingredient grade.

2. Prepare

Prepare the oil and aqueous phases, combine at the assigned conditions and stir while cooling.

3. Complete

Add any heat-sensitive ingredients at the assigned stage and bring to final mass.

4. Evaluate

Inspect texture, separation, pH where assigned and spreading or pouring behaviour.

5. Package and label

Use a suitable training container and record the composition and external route.

Evaluation and Label

- Record the appearance, consistency, phase stability, assigned pH and final yield.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- For a 25-unit batch from a 100-unit master formula, multiply every ingredient quantity by 0.25.
- Enter the actual final yield and compare it with the target batch size.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- A pleasant appearance does not establish skin compatibility or preservative effectiveness.
- Avoid strong fragrance or sensitising additions outside the assigned formula.
- Label as a training preparation.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Record the appearance, consistency, phase stability, assigned pH and final yield.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Cosmetic Shampoo

Experiment 22 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label a cosmetic shampoo.

Principle

Surfactants remove soil and oil; viscosity and pH influence application.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Assigned surfactant	Cleansing	_____
Co-surfactant / thickener	Foam and consistency	_____
Purified water	Vehicle	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Read the formula

Record the assigned cosmetic formula, batch size and ingredient grade.

2. Prepare

Dissolve the assigned surfactants with gentle mixing, add viscosity modifiers as directed and avoid excessive foam.

3. Complete

Add any heat-sensitive ingredients at the assigned stage and bring to final mass.

4. Evaluate

Inspect texture, separation, pH where assigned and spreading or pouring behaviour.

5. Package and label

Use a suitable training container and record the composition and external route.

Evaluation and Label

- Record the appearance, consistency, phase stability, assigned pH and final yield.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- For a 25-unit batch from a 100-unit master formula, multiply every ingredient quantity by 0.25.
- Enter the actual final yield and compare it with the target batch size.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- A pleasant appearance does not establish skin compatibility or preservative effectiveness.
- Avoid strong fragrance or sensitising additions outside the assigned formula.
- Label as a training preparation.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Record the appearance, consistency, phase stability, assigned pH and final yield.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Cosmetic Body Lotion

Experiment 23 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label a cosmetic body lotion.

Principle

An emulsion spreads oil and humectant over skin in a pourable vehicle.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Assigned oil	Emollient	_____
Emulsifier	Stability	_____
Humectant	Moisture retention	_____
Purified water	Vehicle	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Read the formula

Record the assigned cosmetic formula, batch size and ingredient grade.

2. Prepare

Prepare both phases, emulsify, cool with stirring and adjust to the assigned final mass.

3. Complete

Add any heat-sensitive ingredients at the assigned stage and bring to final mass.

4. Evaluate

Inspect texture, separation, pH where assigned and spreading or pouring behaviour.

5. Package and label

Use a suitable training container and record the composition and external route.

Evaluation and Label

- Record the appearance, consistency, phase stability, assigned pH and final yield.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- For a 25-unit batch from a 100-unit master formula, multiply every ingredient quantity by 0.25.
- Enter the actual final yield and compare it with the target batch size.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- A pleasant appearance does not establish skin compatibility or preservative effectiveness.
- Avoid strong fragrance or sensitising additions outside the assigned formula.
- Label as a training preparation.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Record the appearance, consistency, phase stability, assigned pH and final yield.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Cosmetic Toothpaste

Experiment 24 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label a cosmetic toothpaste.

Principle

A paste combines an abrasive, humectant, binder and appropriate vehicle.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Assigned abrasive	Cleaning	_____
Humectant	Prevents drying	_____
Binder / surfactant	Texture and dispersion	_____
Purified water	Vehicle	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Read the formula

Record the assigned cosmetic formula, batch size and ingredient grade.

2. Prepare

Hydrate the binder, levigate the abrasive into humectant and incorporate other ingredients without excessive aeration.

3. Complete

Add any heat-sensitive ingredients at the assigned stage and bring to final mass.

4. Evaluate

Inspect texture, separation, pH where assigned and spreading or pouring behaviour.

5. Package and label

Use a suitable training container and record the composition and external route.

Evaluation and Label

- Record the appearance, consistency, phase stability, assigned pH and final yield.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- For a 25-unit batch from a 100-unit master formula, multiply every ingredient quantity by 0.25.
- Enter the actual final yield and compare it with the target batch size.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- A pleasant appearance does not establish skin compatibility or preservative effectiveness.
- Avoid strong fragrance or sensitising additions outside the assigned formula.
- Label as a training preparation.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Record the appearance, consistency, phase stability, assigned pH and final yield.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Preparation of Cosmetic Vanishing Cream

Experiment 25 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare, evaluate, package and label a cosmetic vanishing cream.

Principle

An emulsified stearic-acid based cosmetic spreads as a thin film.

Working Formula

Use the assigned current monograph for ingredient grades, amounts and specifications. Enter the working quantities before starting.

Ingredient	Purpose	Working quantity
Assigned stearic component	Cream structure	_____
Assigned alkaline / emulsifying ingredient	Emulsion system	_____
Humectant	Moisture retention	_____
Purified water	Vehicle	_____

Scaling factor = required batch size / master batch size. Working ingredient amount = master amount × scaling factor.

Requirements

- Assigned master formula and ingredients
- Balance, measuring glassware and suitable mixing equipment
- Appropriate clean container and label

Procedure

1. Read the formula

Record the assigned cosmetic formula, batch size and ingredient grade.

2. Prepare

Prepare the assigned phases and combine under controlled conditions, then stir through cooling.

3. Complete

Add any heat-sensitive ingredients at the assigned stage and bring to final mass.

4. Evaluate

Inspect texture, separation, pH where assigned and spreading or pouring behaviour.

5. Package and label

Use a suitable training container and record the composition and external route.

Evaluation and Label

- Record the appearance, consistency, phase stability, assigned pH and final yield.
- Label the name, strength where relevant, route, batch/date, storage and institution-assigned use period. Mark laboratory preparations as training material.

Observations and Record

Check	Observation
Appearance / consistency	_____
Final mass or volume	_____
pH or other assigned test	_____
Packaging / label check	_____

Worked Example

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

- For a 25-unit batch from a 100-unit master formula, multiply every ingredient quantity by 0.25.
- Enter the actual final yield and compare it with the target batch size.

Result

The training preparation was obtained as _____. Final yield: _____. Assigned quality checks: _____. It was packaged and labelled for the intended route.

Precautions

- A pleasant appearance does not establish skin compatibility or preservative effectiveness.
- Avoid strong fragrance or sensitising additions outside the assigned formula.
- Label as a training preparation.

Viva Questions and Answers

1. Why scale every ingredient?

The proportions must remain constant when batch size changes.

2. Why record the method?

Mixing order, temperature and technique affect the product.

3. Which quality checks are needed?

Record the appearance, consistency, phase stability, assigned pH and final yield.

4. Why is a label required?

It identifies the product, route, directions, storage and the training batch.

Stages of Tablet Manufacturing

Experiment 26 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To identify each stage of tablet manufacture and its quality controls.

Principle

A manufacturing process links material properties, controlled operations and finished-product quality.

Key Points

- Direct compression and wet granulation are different routes.
- Blending, granulation, drying, sizing, lubrication and compression each have a purpose.
- In-process controls detect variation before the batch is completed.

Activity Procedure

1. Map the route

Create a flow chart for the assigned direct-compression or wet-granulation route.

2. Observe equipment

Identify mixer, granulator, dryer, sieve and press using the teaching demonstration.

3. Link each stage to a risk

Relate poor blend uniformity, excess moisture and over-lubrication to quality.

4. Record controls

Enter material checks, process settings and tablet observations from the demonstration.

Record and Observations

Stage	Purpose / observation
Blending	_____
Granulation / drying	_____
Sizing / lubrication	_____
Compression	_____
In-process checks	_____

Result

Complete the record using your activity, then state the findings, the action required and the reason for that action.

Viva Questions and Answers

1. Why dry granules?

To bring residual moisture to the assigned process target.

2. Why add lubricant late?

Excess mixing with lubricant can change compression and release behaviour.

3. What is an in-process control?

A check during manufacture that helps maintain the specified process and product quality.

Use and Storage of Dosage Forms and Devices

Experiment 27 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To demonstrate correct use and storage of common dosage forms and delivery devices.

Principle

The route, product design and manufacturer instructions determine administration and storage.

Key Points

- Measure oral liquids with a calibrated device.
- Distinguish immediate-release, modified-release and enteric-coated tablets before crushing.
- Check the exact inhaler, spacer and insulin-pen instructions; device steps differ.
- Storage requirements include the labelled temperature, moisture protection and in-use period.

Activity Procedure

1. Inspect

Read route, strength, expiry, storage and patient instructions on dummy products.

2. Demonstrate

Show a measured oral dose, correct tablet handling and external-product labelling.

3. Practise devices

Use a dummy inhaler with spacer and an insulin-pen trainer; explain preparation, administration and after-use steps.

4. Teach back

Ask a partner to repeat the demonstration and correct observed errors.

Record and Observations

Product / device	Correct use and storage
Oral liquid	_____
Tablet / capsule	_____
Inhaler / spacer	_____
Insulin pen	_____
Topical preparation	_____

Result

Complete the record using your activity, then state the findings, the action required and the reason for that action.

Viva Questions and Answers

1. Why avoid a kitchen spoon?

Its volume is not a reliable medication measure.

2. Can every tablet be crushed?

No; formulation and manufacturer instructions must be checked.

3. Why check the in-use period?

A product may have a shorter permitted life after opening than its unopened expiry date.

Quality Control of Tablets Capsules Emulsions and Injections

Experiment 28 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To relate common dosage forms to their required evaluation tests.

Principle

Quality testing examines identity, strength, performance and suitability for the route; no single test proves all aspects.

Key Points

- Tablets: appearance, mass variation, friability, disintegration, dissolution and specified content tests.
- Capsules: shell integrity, mass/content tests, disintegration and dissolution where applicable.
- Emulsions: droplet/phase observations, redispersion, viscosity and assigned assay.
- Injections: clarity and particulates, strength, pH, sterility, endotoxins and container integrity as applicable.

Activity Procedure

1. Select tests

Read the assigned monograph and identify method, instrument and acceptance limits.

2. Observe the demonstration

Record tablet, capsule, emulsion and injectable test demonstrations.

3. Calculate

Show any individual or mean mass calculations using units.

4. Report

Compare actual observations with the stated limit and distinguish a screening observation from a release test.

Record and Observations

Dosage form	Test / result / assigned limit
Tablet	_____
Capsule	_____
Emulsion	_____
Injection	_____

Result

Complete the record using your activity, then state the findings, the action required and the reason for that action.

Viva Questions and Answers

1. Is disintegration the same as dissolution?

No; breaking apart is different from the drug dissolving.

2. What does friability examine?

Mechanical resistance to abrasion under the defined test.

3. Can an injection be released after visual inspection alone?

No; the complete assigned quality and process requirements are needed.

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