Pharm.D - Year 3

Pharmaceutical Formulations

Complete subject manual: 8 practicals and activities. Each chapter includes a student observation or work record.

Use the PDF bookmarks to navigate. The table gives each practical's content-page count; the combined manual has continuous page numbers.

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Preparation of Tablets

Experiment 1 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare and compare the assigned wet-granulated, directly compressed, soluble and chewable tablets.

Principle

Tablet manufacture requires a blend with suitable flow, compressibility and content uniformity. Formulation and processing affect tablet performance.

Requirements

- Institution-approved tablet master formulas and non-hazardous teaching ingredients.
- Mixing, granulation, drying, sieving and supervised tablet-compression equipment.

Procedure

1. Calculate and identify roles

Record active ingredient, diluent, binder, disintegrant, lubricant and any sweetener/flavour. State the assigned tablet type and batch size.

2. Wet-granulated option

Mix the assigned powders, form the specified granules with binder, dry and size under the master formula, then blend the designated final ingredients.

3. Direct-compression option

Use the prescribed directly compressible ingredients; blend and lubricate as specified without introducing a wet-granulation stage.

4. Soluble and chewable options

Use the distinct assigned formula: assess dissolution in the specified medium for soluble tablets and appropriate mechanical/palatability-design checks for chewable tablets. Do not ingest a teaching batch.

5. Compress and evaluate

Record compression settings provided by the supervisor and inspect appearance, mass, mechanical strength and the assigned release/performance tests.

Observations and Record

Tablet type	Method / yield	Quality observation
Wet granulation	_____	_____
Direct compression	_____	_____
Soluble	_____	_____
Chewable	_____	_____

Worked Example

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

- Theoretical batch mass = number of tablets × target mass per tablet.
- Example: 100 units × 0.50 g = 50 g. A total recovery of 47.5 g gives 95% mass yield; this does not establish content uniformity.

Result

Record the completed observations, calculations and conclusion with units. State any limitation of the observation.

Precautions

- Use trained supervision for compression machinery and avoid changing the master formula without authorisation.
- Evaluate each tablet type against its own prescribed tests and limits.

Viva Questions and Answers

1. Why granulate?

It can improve flow and processing of a suitable powder blend.

2. Why is mass uniformity not content uniformity?

An ingredient may be unevenly distributed even when total tablet masses are similar.

Hard Gelatin Capsules

Experiment 2 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To fill and evaluate an assigned hard gelatin capsule formulation.

Principle

Capsule shell size, powder bulk properties and fill uniformity determine the amount that can be delivered. Capsule shell mass must be separated from fill mass where required.

Requirements

- Assigned capsule shells and master-formula ingredients, balance, mixing tools and supervised capsule-filling equipment.

Procedure

1. Calculate

Enter target fill per capsule, number of units, shell size and ingredient quantities.

2. Blend

Reduce lumps and mix ingredients by the prescribed method; evaluate the assigned flow/bulk-density information.

3. Fill and close

Use the supervised filling method, maintain consistent fill and close shells without damage.

4. Check masses

Record empty-shell and filled-capsule masses where the assigned method requires them.

5. Evaluate

Assess appearance, fill uniformity and the required disintegration/dissolution or other performance test.

Observations and Record

Capsule	Empty shell mass	Filled mass / net fill
1	_____	_____
2	_____	_____
3	_____	_____

Worked Example

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

- Net fill mass = filled capsule mass − empty shell mass.
- Example: 0.420 g − 0.070 g = 0.350 g net fill.
- Mean fill = sum of net fills / number of capsules assessed.

Result

Record the completed observations, calculations and conclusion with units. State any limitation of the observation.

Precautions

- Keep shell moisture and handling conditions suitable for the assigned material.
- Do not infer drug content solely from total capsule mass.

Viva Questions and Answers

1. Why choose an appropriate shell size?

It must accommodate the required fill volume and material properties.

2. Why record shell mass?

It can affect the apparent fill-mass calculation.

Parenteral Formulations - Supervised Manufacturing Demonstration

Experiment 3 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To document the formulation and quality-control principles of the assigned parenteral products.

Principle

Parenterals require a validated manufacturing process that addresses composition, particles, sterility assurance, endotoxin-related requirements where applicable and container integrity. A clear solution is not evidence of injectable safety.

Requirements

- Approved demonstration records or non-administered training preparations for ascorbic acid injection, calcium gluconate injection, sodium chloride infusion and dextrose-sodium chloride injection.
- Institution-prescribed master formula and validated process flow.

Procedure

1. Identify formulations

Record active ingredient(s), concentration basis, vehicle quality, container and intended official product title for each demonstration.

2. Read the process flow

Trace solution preparation, specified filtration, filling/closure and sterilisation or aseptic-processing stages as appropriate to the validated product process. Not every product uses the same sequence.

3. Inspect the batch record

Identify critical checks, yield reconciliation and the process-release responsibilities.

4. Review quality evidence

Record supplied identity/assay, pH, visible/subvisible particles, sterility, applicable endotoxin and integrity test findings against the prescribed product requirements.

5. Conclude

State which product records are complete, invalid or require review. Training preparations are never administered.

Observations and Record

Product	Formula / process code	Quality evidence
Ascorbic acid injection	_____	_____
Calcium gluconate injection	_____	_____
Sodium chloride infusion	_____	_____
Dextrose-sodium chloride injection	_____	_____

Worked Example

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

- For w/v composition, ingredient mass = stated grams per 100 mL × required final volume / 100.
- Illustration only: a 1% w/v teaching concentration in 100 mL corresponds to 1 g in the final 100 mL. It is not an authorised formulation or patient instruction.

Result

Record the completed observations, calculations and conclusion with units. State any limitation of the observation.

Precautions

- Use the assigned supervised demonstration and validated process record.
- Do not assume filtration removes every contaminant or substitutes for all sterility-assurance requirements.

Viva Questions and Answers

1. Does clarity prove sterility?

No. Sterility and particulate quality are different attributes.

2. Why distinguish terminal sterilisation from aseptic processing?

They use different validated process controls and cannot be substituted without product-specific justification.

Quality-control Tests for Tablets Capsules and Injections

Experiment 4 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To record and assess the assigned dosage-form quality tests.

Principle

Quality tests examine defined attributes of a dosage form. Identity, content, physical uniformity, performance and microbiological quality are related but distinct.

Requirements

- Assigned dosage forms, prescribed test methods and limits, suitable calibrated equipment and supplied sterile-product test records.

Procedure

1. Map the tests

List the method and specification for each product before recording results.

2. Tablets

Measure the assigned mass variation, dimensions/mechanical strength, friability, disintegration, dissolution and content-related tests as required by the product.

3. Capsules

Record net fill and the prescribed disintegration/dissolution and content-related tests.

4. Injections

Interpret assigned assay, pH, particle, sterility, applicable endotoxin and integrity records; no infectious challenge test is performed.

5. Decide

Separate a valid failure from an invalid measurement and record the authorised quality-review decision.

Observations and Record

Product / test	Observed value	Assigned requirement / outcome
Tablet	_____	_____
Capsule	_____	_____
Injection	_____	_____

Worked Example

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

- Friability mass loss (%) = (initial mass − final mass) / initial mass × 100, using the specified cleaned/dedusted test basis.
- Example: 6.50 g to 6.47 g gives 0.462%. Apply the actual product-specific acceptance criterion.

Result

Record the completed observations, calculations and conclusion with units. State any limitation of the observation.

Precautions

- Do not apply one numerical limit to all dosage forms or product types.
- A passing physical test does not replace an assay or sterility requirement.

Viva Questions and Answers

1. Are disintegration and dissolution identical?

No. Break-up and release of dissolved drug are different endpoints.

2. What accompanies a pass/fail statement?

The product, method, result, units and assigned acceptance requirement.

Oral Liquid Formulations

Experiment 5 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

1. Paracetamol Syrup

Aim

To prepare and evaluate paracetamol syrup using the assigned master formula.

Principle

Solvent composition and concentration must keep the prescribed paracetamol uniformly incorporated throughout storage.

Requirements

- Paracetamol and the assigned solvent/sweetener system
- Prescribed flavour/preservative where applicable
- Purified water and compatible oral container
- Balance, suitable mixing equipment, measuring glassware and compatible packaging.

Procedure

1. Read and calculate the assigned formula

Confirm the prescribed monograph or college master formula, ingredient grades, concentration basis and final batch size. Calculate a scale factor and record each ingredient quantity.

2. Prepare the ingredients

Dissolve the ingredient in the solvent portion stated in the authorised master formula.

3. Combine in the stated sequence

Combine gradually with the sweetened vehicle; avoid conditions that cause precipitation.

4. Complete the preparation

Cool where required and make up the final volume; inspect again after the assigned standing period.

5. Evaluate and package

Assess clarity or intended dispersion state; absence of delayed crystallisation; concentration and final volume. Record the actual yield. Use the compatible container, route label and storage conditions assigned for the preparation.

Observations and Record

Ingredient / check	Quantity or observation	Recorded value
Paracetamol and the assigned solvent/sweetener system	As assigned / observed	_____
Prescribed flavour/preservative where applicable	As assigned / observed	_____
Purified water and compatible oral container	As assigned / observed	_____
Final yield / appearance	oral liquid; clarity or intended dispersion state	_____

Worked Example

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

- Scale factor = required batch size ÷ master-formula batch size.
- Example only: scaling a 100 mL formula to 25 mL gives a factor of 0.25. An ingredient stated as 4 g becomes 1 g. This is a scaling example, not the official composition.

Result

Preparation: ____. Batch basis: ____. Actual yield: ____. Quality observations: ____. Packaging and label: ____.

Precautions

- Use the assigned formulation and prescribed concentration basis; similar product names can represent different strengths.
- Evaluate the preparation after the specified equilibration or cooling stage.
- A teaching preparation is not released for patient use. Apply the assigned route, storage and use-period label.

Viva Questions and Answers

1. Why use a master formula?

It fixes the composition, processing sequence, tests and final quantity basis.

2. Why measure the yield?

Transfer loss or final adjustment can change the amount and concentration delivered.

3. How is the preparation evaluated?

clarity or intended dispersion state, absence of delayed crystallisation, concentration and final volume.

2. Aluminium Hydroxide Gel Antacid Suspension

Aim

To prepare and evaluate aluminium hydroxide gel antacid suspension using the assigned master formula.

Principle

A structured dispersion must redisperse consistently to support a uniform measured dose.

Requirements

- Assigned aluminium hydroxide gel
- Prescribed suspending/wetting components
- Oral vehicle and container
- Balance, suitable mixing equipment, measuring glassware and compatible packaging.

Procedure

1. Read and calculate the assigned formula

Confirm the prescribed monograph or college master formula, ingredient grades, concentration basis and final batch size. Calculate a scale factor and record each ingredient quantity.

2. Prepare the ingredients

Disperse the specified gel and any vehicle components separately as required.

3. Combine in the stated sequence

Blend the gel uniformly into the vehicle without persistent lumps.

4. Complete the preparation

Complete the volume, mix and assess settling and redispersion.

5. Evaluate and package

Assess homogeneity; redispersibility; assigned acid-neutralising performance. Record the actual yield. Use the compatible container, route label and storage conditions assigned for the preparation.

Observations and Record

Ingredient / check	Quantity or observation	Recorded value
Assigned aluminium hydroxide gel	As assigned / observed	_____
Prescribed suspending/wetting components	As assigned / observed	_____
Oral vehicle and container	As assigned / observed	_____
Final yield / appearance	oral suspension; homogeneity	_____

Worked Example

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

- Scale factor = required batch size ÷ master-formula batch size.
- Example only: scaling a 100 mL formula to 25 mL gives a factor of 0.25. An ingredient stated as 4 g becomes 1 g. This is a scaling example, not the official composition.

Result

Preparation: ____. Batch basis: ____. Actual yield: ____. Quality observations: ____. Packaging and label: ____.

Precautions

- Use the assigned formulation and prescribed concentration basis; similar product names can represent different strengths.
- Evaluate the preparation after the specified equilibration or cooling stage.
- A teaching preparation is not released for patient use. Apply the assigned route, storage and use-period label.

Viva Questions and Answers

1. Why use a master formula?

It fixes the composition, processing sequence, tests and final quantity basis.

2. Why measure the yield?

Transfer loss or final adjustment can change the amount and concentration delivered.

3. How is the preparation evaluated?

homogeneity, redispersibility, assigned acid-neutralising performance.

Ointment and Gel Formulations

Experiment 6 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

1. Salicylic Acid and Benzoic Acid Ointment

Aim

To prepare and evaluate salicylic acid and benzoic acid ointment using the assigned master formula.

Principle

Uniform dispersion of the assigned acids in a compatible base is needed for consistent external application.

Requirements

- Salicylic acid
- Benzoic acid
- Assigned ointment base and levigating agent
- Balance, suitable mixing equipment, measuring glassware and compatible packaging.

Procedure

1. Read and calculate the assigned formula

Confirm the prescribed monograph or college master formula, ingredient grades, concentration basis and final batch size. Calculate a scale factor and record each ingredient quantity.

2. Prepare the ingredients

Reduce the assigned powder size and levigate with the prescribed compatible agent.

3. Combine in the stated sequence

Incorporate the powders into the base by geometric dilution.

4. Complete the preparation

Mix to uniformity and transfer without entrapped coarse particles.

5. Evaluate and package

Assess smoothness; uniformity; absence of grit; external-use label. Record the actual yield. Use the compatible container, route label and storage conditions assigned for the preparation.

Observations and Record

Ingredient / check	Quantity or observation	Recorded value
Salicylic acid	As assigned / observed	_____
Benzoic acid	As assigned / observed	_____
Assigned ointment base and levigating agent	As assigned / observed	_____
Final yield / appearance	external ointment; smoothness	_____

Worked Example

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

- Scale factor = required batch size ÷ master-formula batch size.
- Example only: scaling a 100 mL formula to 25 mL gives a factor of 0.25. An ingredient stated as 4 g becomes 1 g. This is a scaling example, not the official composition.

Result

Preparation: ____. Batch basis: ____. Actual yield: ____. Quality observations: ____. Packaging and label: ____.

Precautions

- Use the assigned formulation and prescribed concentration basis; similar product names can represent different strengths.
- Evaluate the preparation after the specified equilibration or cooling stage.
- A teaching preparation is not released for patient use. Apply the assigned route, storage and use-period label.

Viva Questions and Answers

1. Why use a master formula?

It fixes the composition, processing sequence, tests and final quantity basis.

2. Why measure the yield?

Transfer loss or final adjustment can change the amount and concentration delivered.

3. How is the preparation evaluated?

smoothness, uniformity, absence of grit, external-use label.

2. Diclofenac Gel

Aim

To prepare and evaluate diclofenac gel using the assigned master formula.

Principle

The assigned polymer system forms a gel whose pH, viscosity and drug compatibility depend on the master formula.

Requirements

- Assigned diclofenac form
- Prescribed gel-forming polymer
- Vehicle and formula-specific pH-adjusting component
- Balance, suitable mixing equipment, measuring glassware and compatible packaging.

Procedure

1. Read and calculate the assigned formula

Confirm the prescribed monograph or college master formula, ingredient grades, concentration basis and final batch size. Calculate a scale factor and record each ingredient quantity.

2. Prepare the ingredients

Disperse and hydrate the polymer in the prescribed vehicle without persistent clumps.

3. Combine in the stated sequence

Prepare and incorporate the drug component using the assigned solvent/chemical form.

4. Complete the preparation

Apply the prescribed pH/consistency adjustment and allow the specified equilibration before assessment.

5. Evaluate and package

Assess uniformity; pH; consistency; absence of visible precipitate. Record the actual yield. Use the compatible container, route label and storage conditions assigned for the preparation.

Observations and Record

Ingredient / check	Quantity or observation	Recorded value
Assigned diclofenac form	As assigned / observed	_____
Prescribed gel-forming polymer	As assigned / observed	_____
Vehicle and formula-specific pH-adjusting component	As assigned / observed	_____
Final yield / appearance	external gel; uniformity	_____

Worked Example

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

- Scale factor = required batch size ÷ master-formula batch size.

- Example only: scaling a 100 mL formula to 25 mL gives a factor of 0.25. An ingredient stated as 4 g becomes 1 g. This is a scaling example, not the official composition.

Result

Preparation: ____. Batch basis: ____. Actual yield: ____. Quality observations: ____. Packaging and label: ____.

Precautions

- Use the assigned formulation and prescribed concentration basis; similar product names can represent different strengths.
- Evaluate the preparation after the specified equilibration or cooling stage.
- A teaching preparation is not released for patient use. Apply the assigned route, storage and use-period label.

Viva Questions and Answers

1. Why use a master formula?

It fixes the composition, processing sequence, tests and final quantity basis.

2. Why measure the yield?

Transfer loss or final adjustment can change the amount and concentration delivered.

3. How is the preparation evaluated?

uniformity, pH, consistency, absence of visible precipitate.

Cosmetic Formulations

Experiment 7 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To prepare and compare the assigned lipstick, creams, shampoo and dentifrice teaching products.

Principle

Cosmetic performance depends on the dosage-form structure, ingredient compatibility, processing and intended site of application.

Requirements

- Institution-approved cosmetic master formulas, permitted teaching ingredients, suitable mixing equipment and containers.

Procedure

1. Calculate and identify roles

Record emollient, wax, emulsifier, surfactant, humectant, abrasive or other role for each ingredient.

2. Lipstick

Prepare the assigned wax/oil base, disperse pigment uniformly and mould under the prescribed temperature sequence; assess surface and consistency.

3. Cold and vanishing creams

Prepare separate assigned phases, combine at the prescribed conditions and mix during cooling; record each cream formula and its own intended emulsion structure.

4. Clear shampoo

Dissolve/blend the assigned surfactant system and other components while limiting foam; adjust only as the formula permits and assess clarity and pH.

5. Toothpaste / tooth powder

Prepare a uniform blend with the specified abrasive and other components; for paste, incorporate the binder/humectant vehicle as assigned.

6. Evaluate and package

Record appearance, homogeneity, consistency and the product-specific checks. Teaching products are not used on people.

Observations and Record

Product	Formula / yield	Assigned evaluation
Lipstick	_____	_____
Cold cream	_____	_____
Vanishing cream	_____	_____
Clear shampoo	_____	_____
Toothpaste / tooth powder	_____	_____

Worked Example

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

- Mass yield (%) = recovered product mass / theoretical batch mass × 100.
- Example: 19 g recovered from a 20 g batch basis gives 95%.

Result

Record the completed observations, calculations and conclusion with units. State any limitation of the observation.

Precautions

- Use permitted ingredients and product-specific pH/quality requirements.
- Do not describe every cold or vanishing cream with one universal composition or emulsion type.

Viva Questions and Answers

1. Why control cooling in creams?

It influences the emulsion and consistency of the finished preparation.

2. Why limit entrapped air?

It affects appearance, packing and some consistency measurements.

Tablet Coating - Process Demonstration

Experiment 8 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To document the supplied tablet-coating demonstration and its quality checks.

Principle

A coating process deposits a controlled layer on a tablet core. Coating type and composition determine its intended appearance, protection or release function.

Requirements

- Instructor-provided labelled diagrams, traces or data for this activity.
- Calculator, graph paper or spreadsheet, and the activity record.

Procedure

1. Identify the coating

Record the assigned film, sugar or other coating system and its intended function.

2. Trace the equipment

Label the pan or fluid-bed system, application system, air handling and process monitoring shown.

3. Read process data

Record supplied spray/bed/air conditions as observations, not as an invented coating recipe.

4. Inspect the product

Compare coating uniformity, defects and the required product performance tests.

5. Conclude

Relate any observed defect to a possible process/material issue for supervisor investigation.

Observations and Record

Record item	Entry
Activity / material identifier	_____
Measurement or visible feature	_____
Comparison / calculated outcome	_____
Interpretation and limitation	_____

Worked Example

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

- Coating mass gain (%) = (coated tablet mass − core mass) / core mass × 100.
- Example: 500 mg core to 525 mg coated unit gives 5% gain; this is not a universal coating target.

Result

The recorded finding is ____; the supporting observation or calculation is ____. The main limitation is ____.

Precautions

- Use the supplied teaching material; distinguish a measured observation from an assumed value.
- Keep units, axes, labels and measurement conditions consistent.
- Record limitations and seek instructor review before applying a conclusion to a live case.

Viva Questions and Answers

1. Does every film coat alter drug release?

No. The coating composition and purpose determine its function.

2. Why test performance after coating?

A coating can affect disintegration, dissolution and other product attributes.

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