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# Semester 5 - Practical Notes

## Industrial Pharmacy I

### Complete Subject Manual

11 practicals and activities. Use the PDF bookmarks to move between practicals. Page numbers restart within each practical; the page counts below exclude the promotion pages.

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# Preformulation Studies of an Assigned Drug

Practical 01 | Industrial Pharmacy I

## Aim

To study Preformulation Studies of an Assigned Drug, and interpret the recorded observations.

## Principle

- Preformulation links the properties of the drug substance to dosage-form choices. Paracetamol, aspirin or another assigned drug can be compared for solubility, particle properties, moisture behaviour and compatibility.
- The property is obtained from a defined observable under controlled conditions.
- Replicate measurements, instrument checks and consistent units are needed before comparison.
- Aspirin can hydrolyse in the presence of moisture; any increase in apparent dissolution must not be mistaken for unchanged-drug stability.
- Poor powder flow can affect filling, while slow dissolution may require a separate formulation strategy.

## Materials and Apparatus

- Assigned drug, balance, pH meter, microscopy or particle-size apparatus, solubility assay and prepared compatibility records.
- Assigned test material and calibration or comparison material.
- The apparatus specified for this property, a balance or volumetric equipment where relevant, and a record sheet.

## Method

1. Identify the drug form and the dosage form being considered.
2. Measure the assigned physical properties under stated conditions.
3. Study solubility in the specified media and record pH and temperature.
4. Review the assigned thermal, spectral or other compatibility comparisons with excipients.
5. Tabulate property results and link each to a processing, stability or release concern.
6. Propose a dosage-form approach supported by the observations.

## Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

| Observation / parameter    | Record / finding |
|----------------------------|------------------|
| Drug identity              | _____            |
| Solubility and pH          | _____            |
| Particle characteristics   | _____            |
| Moisture result            | _____            |
| Compatibility observations | _____            |

## Calculations and Interpretation

- Report each measured property with its method and units.
- For an assay-based solubility result, correct the measured concentration for all dilution steps.

## Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: \_\_\_\_\_

Conclusion: \_\_\_\_\_

## Precautions

- Keep temperature and test conditions consistent across comparative readings.
- Record raw readings before rounding calculated values.
- Do not compare results obtained with different methods as if they were interchangeable.

## Viva Questions

### 1. What is the purpose of preformulation?

To understand drug properties before selecting the formulation and manufacturing approach.

### 2. Why control the test conditions?

A change in conditions may alter the measured property independently of the intended variable.

### 3. Why retain replicate readings?

They show repeatability and help identify an anomalous measurement.

# Preparation and Evaluation of Paracetamol Tablets

Practical 02 | Industrial Pharmacy I

## Aim

To study Preparation and Evaluation of Paracetamol Tablets, and interpret the recorded observations.

## Principle

- A tablet formulation balances flow, compressibility, disintegration and drug release. Paracetamol content must be assessed separately from tablet mass.
- A dosage form combines an active ingredient with excipients selected for processing, stability and performance.
- Preparation and evaluation are linked: changes in composition or process can alter the product quality attributes.
- Identify the function of the diluent, binder, disintegrant and lubricant.
- Prepare and evaluate granules or the assigned direct-compression blend.
- Observe compression settings and record tablet defects or dimensional changes.
- Evaluate mass, mechanical strength, disintegration, assay and release with the assigned methods.

## Materials and Apparatus

- Paracetamol, assigned diluent, binder, disintegrant and lubricant; granulation/compression equipment and tablet test apparatus.
- Assigned active ingredient, excipients and the instructor-approved master formula.
- Balance, mixing/preparation equipment, packaging materials and the assigned evaluation apparatus.

## Method

1. Read the master formula and identify the purpose of each ingredient.
2. Calculate the quantities for the assigned laboratory batch and check ingredient identity.
3. Follow the specified order of addition and preparation process, recording actual quantities and process observations.
4. Measure the yield or finished quantity and package the laboratory preparation as specified.
5. Evaluate the product attributes listed for this dosage form with documented methods.
6. Compare the observations with the assigned specification and explain any difference.

## Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

| Observation / parameter    | Record / finding |
|----------------------------|------------------|
| Formula and batch size     | _____            |
| Granule properties         | _____            |
| Mean tablet mass           | _____            |
| Strength/friability        | _____            |
| Disintegration/dissolution | _____            |
| Assay                      | _____            |

## Calculations and Interpretation

- Batch scale factor = desired quantity/master-formula quantity.
- Scale each ingredient by the same factor unless the approved formula specifies otherwise.
- Assay (%) = measured active amount/declared active amount × 100, on the same unit and product basis.

## Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: \_\_\_\_\_

Conclusion: \_\_\_\_\_

## Precautions

- Record changes in process or composition; do not conceal a deviation.
- Use the specification assigned to the exact product and dosage form.
- A teaching batch is for laboratory evaluation and is not released for patient use.

## Viva Questions

### 1. Why identify excipient functions?

Each excipient can influence processing, stability, release or acceptability.

### 2. Why is appearance alone insufficient for evaluation?

It does not establish content, performance, stability or microbiological quality.

# Preparation and Evaluation of Aspirin Tablets

Practical 03 | Industrial Pharmacy I

## Aim

To study Preparation and Evaluation of Aspirin Tablets, and interpret the recorded observations.

## Principle

- Aspirin tablet processing must consider moisture-associated hydrolysis as well as compressibility and release. A tablet can retain its mass while its chemical quality changes.
- A dosage form combines an active ingredient with excipients selected for processing, stability and performance.
- Preparation and evaluation are linked: changes in composition or process can alter the product quality attributes.
- Record the moisture and temperature exposure of the assigned process.
- Prepare the approved blend or granulation and observe compression.
- Evaluate tablet properties and distinguish physical defects from chemical deterioration.
- Interpret aspirin assay using the assigned analytical method and analyte basis.

## Materials and Apparatus

- Aspirin and the approved tablet excipients, compression equipment and the assigned assay/quality tests.
- Assigned active ingredient, excipients and the instructor-approved master formula.
- Balance, mixing/preparation equipment, packaging materials and the assigned evaluation apparatus.

## Method

1. Read the master formula and identify the purpose of each ingredient.
2. Calculate the quantities for the assigned laboratory batch and check ingredient identity.
3. Follow the specified order of addition and preparation process, recording actual quantities and process observations.
4. Measure the yield or finished quantity and package the laboratory preparation as specified.
5. Evaluate the product attributes listed for this dosage form with documented methods.
6. Compare the observations with the assigned specification and explain any difference.

## Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

| Observation / parameter   | Record / finding |
|---------------------------|------------------|
| Batch formula             | _____            |
| Process moisture exposure | _____            |
| Tablet mass               | _____            |
| Mechanical tests          | _____            |
| Disintegration/release    | _____            |
| Assay                     | _____            |

## Calculations and Interpretation

- Batch scale factor = desired quantity/master-formula quantity.
- Scale each ingredient by the same factor unless the approved formula specifies otherwise.
- Assay (%) = measured active amount/declared active amount × 100, on the same unit and product basis.

## Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: \_\_\_\_\_

Conclusion: \_\_\_\_\_

## Precautions

- Record changes in process or composition; do not conceal a deviation.
- Use the specification assigned to the exact product and dosage form.
- A teaching batch is for laboratory evaluation and is not released for patient use.

## Viva Questions

### 1. Why identify excipient functions?

Each excipient can influence processing, stability, release or acceptability.

### 2. Why is appearance alone insufficient for evaluation?

It does not establish content, performance, stability or microbiological quality.

# Preparation and Evaluation of Film Coating of Tablets or Granules

Practical 04 | Industrial Pharmacy I

## Aim

To study Preparation and Evaluation of Film Coating of Tablets or Granules, and interpret the recorded observations.

## Principle

- Film coating deposits a polymer-based layer. Polymer, plasticizer and process conditions influence film continuity, adhesion and the effect on release.
- A dosage form combines an active ingredient with excipients selected for processing, stability and performance.
- Preparation and evaluation are linked: changes in composition or process can alter the product quality attributes.
- Identify the role of the polymer, plasticizer and vehicle.
- Review the coating-feed and drying balance demonstrated by the instructor.
- Observe coating distribution, sticking, picking or roughness during the assigned run.
- Measure dry mass gain and assess the film and relevant release behaviour.

## Materials and Apparatus

- Assigned cores, film former, plasticizer and coating vehicle; supervised coating equipment.
- Assigned active ingredient, excipients and the instructor-approved master formula.
- Balance, mixing/preparation equipment, packaging materials and the assigned evaluation apparatus.

## Method

1. Read the master formula and identify the purpose of each ingredient.
2. Calculate the quantities for the assigned laboratory batch and check ingredient identity.
3. Follow the specified order of addition and preparation process, recording actual quantities and process observations.
4. Measure the yield or finished quantity and package the laboratory preparation as specified.
5. Evaluate the product attributes listed for this dosage form with documented methods.
6. Compare the observations with the assigned specification and explain any difference.

## Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

| Observation / parameter | Record / finding |
|-------------------------|------------------|
| Core mass               | _____            |
| Coating composition     | _____            |
| Process observations    | _____            |
| Dry coated mass         | _____            |
| Film appearance         | _____            |
| Release effect          | _____            |

## Calculations and Interpretation

- Dry coating gain (%) = (coated dry mass - initial core mass)/initial core mass × 100.

## Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: \_\_\_\_\_

Conclusion: \_\_\_\_\_

## Precautions

- Record changes in process or composition; do not conceal a deviation.
- Use the specification assigned to the exact product and dosage form.
- A teaching batch is for laboratory evaluation and is not released for patient use.

## Viva Questions

### 1. Why identify excipient functions?

Each excipient can influence processing, stability, release or acceptability.

### 2. Why is appearance alone insufficient for evaluation?

It does not establish content, performance, stability or microbiological quality.

# Preparation and Evaluation of Tetracycline Capsules

Practical 05 | Industrial Pharmacy I

## Aim

To study Preparation and Evaluation of Tetracycline Capsules, and interpret the recorded observations.

## Principle

- Capsule filling depends on a uniform, suitable-flowing powder blend. Capsule-shell properties and tetracycline stability must be considered separately from fill mass.
- A dosage form combines an active ingredient with excipients selected for processing, stability and performance.
- Preparation and evaluation are linked: changes in composition or process can alter the product quality attributes.
- Identify the exact tetracycline form and the approved blend composition.
- Calculate the assigned fill quantity and observe uniform blending and filling.
- Record shell closure and appearance together with individual fill masses.
- Evaluate the finished capsules by the specified mass/content, disintegration and release tests.

## Materials and Apparatus

- Assigned tetracycline form and excipients, capsule shells, filling demonstration and quality-test equipment.
- Assigned active ingredient, excipients and the instructor-approved master formula.
- Balance, mixing/preparation equipment, packaging materials and the assigned evaluation apparatus.

## Method

1. Read the master formula and identify the purpose of each ingredient.
2. Calculate the quantities for the assigned laboratory batch and check ingredient identity.
3. Follow the specified order of addition and preparation process, recording actual quantities and process observations.
4. Measure the yield or finished quantity and package the laboratory preparation as specified.
5. Evaluate the product attributes listed for this dosage form with documented methods.
6. Compare the observations with the assigned specification and explain any difference.

## Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

| Observation / parameter | Record / finding |
|-------------------------|------------------|
| Drug form               | _____            |
| Blend uniformity        | _____            |
| Shell size              | _____            |
| Fill mass               | _____            |
| Disintegration          | _____            |
| Assay and release       | _____            |

## Calculations and Interpretation

- Batch scale factor = desired quantity/master-formula quantity.
- Scale each ingredient by the same factor unless the approved formula specifies otherwise.
- Assay (%) = measured active amount/declared active amount × 100, on the same unit and product basis.

## Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: \_\_\_\_\_

Conclusion: \_\_\_\_\_

## Precautions

- Record changes in process or composition; do not conceal a deviation.
- Use the specification assigned to the exact product and dosage form.
- A teaching batch is for laboratory evaluation and is not released for patient use.

## Viva Questions

### 1. Why identify excipient functions?

Each excipient can influence processing, stability, release or acceptability.

### 2. Why is appearance alone insufficient for evaluation?

It does not establish content, performance, stability or microbiological quality.

# Preparation and Evaluation of Calcium Gluconate Injection

Practical 06 | Industrial Pharmacy I

## Aim

To study Preparation and Evaluation of Calcium Gluconate Injection, and interpret the recorded observations.

## Principle

- An injectable solution must satisfy chemical quality, particle control, sterility and container-closure requirements. Clear appearance alone does not establish suitability.
- A dosage form combines an active ingredient with excipients selected for processing, stability and performance.
- Preparation and evaluation are linked: changes in composition or process can alter the product quality attributes.
- Review the drug and excipient roles in the approved injectable formula.
- Observe the trained demonstration of solution preparation and its process records.
- Distinguish a filtration step from a validated sterilization or aseptic process.
- Review assay, clarity/particles, pH and applicable sterility/endotoxin and closure records.

## Materials and Apparatus

- Instructor-prepared calcium gluconate injection demonstration, approved formula and completed sterile-process/quality records.
- Assigned active ingredient, excipients and the instructor-approved master formula.
- Balance, mixing/preparation equipment, packaging materials and the assigned evaluation apparatus.

## Method

1. Read the master formula and identify the purpose of each ingredient.
2. Calculate the quantities for the assigned laboratory batch and check ingredient identity.
3. Follow the specified order of addition and preparation process, recording actual quantities and process observations.
4. Measure the yield or finished quantity and package the laboratory preparation as specified.
5. Evaluate the product attributes listed for this dosage form with documented methods.
6. Compare the observations with the assigned specification and explain any difference.

## Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

| Observation / parameter             | Record / finding |
|-------------------------------------|------------------|
| Formula basis                       | _____            |
| Solution clarity                    | _____            |
| pH                                  | _____            |
| Particulate observation             | _____            |
| Assay                               | _____            |
| Sterile-process and closure records | _____            |

## Calculations and Interpretation

- Batch scale factor = desired quantity/master-formula quantity.
- Scale each ingredient by the same factor unless the approved formula specifies otherwise.
- Assay (%) = measured active amount/declared active amount × 100, on the same unit and product basis.

## Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: \_\_\_\_\_

Conclusion: \_\_\_\_\_

## Precautions

- Record changes in process or composition; do not conceal a deviation.
- Use the specification assigned to the exact product and dosage form.
- A teaching batch is for laboratory evaluation and is not released for patient use.

## Viva Questions

### 1. Why identify excipient functions?

Each excipient can influence processing, stability, release or acceptability.

### 2. Why is appearance alone insufficient for evaluation?

It does not establish content, performance, stability or microbiological quality.

# Preparation and Evaluation of Ascorbic Acid Injection

Practical 07 | Industrial Pharmacy I

## Aim

To study Preparation and Evaluation of Ascorbic Acid Injection, and interpret the recorded observations.

## Principle

- Ascorbic acid is susceptible to oxidation. The formulation and packaging are studied for control of oxygen, light, pH and chemical stability alongside injectable-product requirements.
- A dosage form combines an active ingredient with excipients selected for processing, stability and performance.
- Preparation and evaluation are linked: changes in composition or process can alter the product quality attributes.
- Identify the approved stability-control approach and the role of each ingredient.
- Observe the instructor demonstration and record relevant exposure/packaging conditions.
- Review the assigned stability-indicating assay and distinguish colour change from quantitative potency.
- Interpret the chemical, particulate and sterile-quality records for the exact demonstration product.

## Materials and Apparatus

- Prepared ascorbic acid injection demonstration, approved formula and completed chemical/sterile-quality records.
- Assigned active ingredient, excipients and the instructor-approved master formula.
- Balance, mixing/preparation equipment, packaging materials and the assigned evaluation apparatus.

## Method

1. Read the master formula and identify the purpose of each ingredient.
2. Calculate the quantities for the assigned laboratory batch and check ingredient identity.
3. Follow the specified order of addition and preparation process, recording actual quantities and process observations.
4. Measure the yield or finished quantity and package the laboratory preparation as specified.
5. Evaluate the product attributes listed for this dosage form with documented methods.
6. Compare the observations with the assigned specification and explain any difference.

## Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

| Observation / parameter        | Record / finding |
|--------------------------------|------------------|
| Drug and excipient roles       | _____            |
| Oxidation-related observations | _____            |
| pH                             | _____            |
| Assay                          | _____            |
| Particles                      | _____            |
| Packaging and process records  | _____            |

## Calculations and Interpretation

- Batch scale factor = desired quantity/master-formula quantity.
- Scale each ingredient by the same factor unless the approved formula specifies otherwise.
- Assay (%) = measured active amount/declared active amount × 100, on the same unit and product basis.

## Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: \_\_\_\_\_

Conclusion: \_\_\_\_\_

## Precautions

- Record changes in process or composition; do not conceal a deviation.
- Use the specification assigned to the exact product and dosage form.
- A teaching batch is for laboratory evaluation and is not released for patient use.

## Viva Questions

### 1. Why identify excipient functions?

Each excipient can influence processing, stability, release or acceptability.

### 2. Why is appearance alone insufficient for evaluation?

It does not establish content, performance, stability or microbiological quality.

# Preparation and Evaluation of Eye Drops and Eye Ointments

Practical 08 | Industrial Pharmacy I

## Aim

To study Preparation and Evaluation of Eye Drops and Eye Ointments, and interpret the recorded observations.

## Principle

- Ophthalmic solutions and ointments have different vehicles and release behaviour. Both require appropriate sterile processing, container integrity and ocular-product quality controls.
- A dosage form combines an active ingredient with excipients selected for processing, stability and performance.
- Preparation and evaluation are linked: changes in composition or process can alter the product quality attributes.
- Compare the roles of aqueous vehicles in drops and semisolid bases in ointments.
- Observe the approved preparation demonstrations and record the process controls.
- Review clarity and pH for drops, and uniformity and particle/grittiness observations for ointments.
- Examine assay, container integrity and the applicable completed sterile-quality records.

## Materials and Apparatus

- Prepared ophthalmic teaching products, approved formulae and completed sterility, particle and product-quality records.
- Assigned active ingredient, excipients and the instructor-approved master formula.
- Balance, mixing/preparation equipment, packaging materials and the assigned evaluation apparatus.

## Method

1. Read the master formula and identify the purpose of each ingredient.
2. Calculate the quantities for the assigned laboratory batch and check ingredient identity.
3. Follow the specified order of addition and preparation process, recording actual quantities and process observations.
4. Measure the yield or finished quantity and package the laboratory preparation as specified.
5. Evaluate the product attributes listed for this dosage form with documented methods.
6. Compare the observations with the assigned specification and explain any difference.

## Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

| Observation / parameter         | Record / finding |
|---------------------------------|------------------|
| Dosage form                     | _____            |
| Vehicle and ingredient roles    | _____            |
| pH or consistency               | _____            |
| Particles/grittiness            | _____            |
| Drug content                    | _____            |
| Closure/sterile-process records | _____            |

## Calculations and Interpretation

- Batch scale factor = desired quantity/master-formula quantity.
- Scale each ingredient by the same factor unless the approved formula specifies otherwise.
- Assay (%) = measured active amount/declared active amount × 100, on the same unit and product basis.

## Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: \_\_\_\_\_

Conclusion: \_\_\_\_\_

## Precautions

- Record changes in process or composition; do not conceal a deviation.
- Use the specification assigned to the exact product and dosage form.
- A teaching batch is for laboratory evaluation and is not released for patient use.

## Viva Questions

### 1. Why identify excipient functions?

Each excipient can influence processing, stability, release or acceptability.

### 2. Why is appearance alone insufficient for evaluation?

It does not establish content, performance, stability or microbiological quality.

# Preparation and Evaluation of Cold Cream and Vanishing Cream

Practical 09 | Industrial Pharmacy I

## Aim

To study Preparation and Evaluation of Cold Cream and Vanishing Cream, and interpret the recorded observations.

## Principle

- Cold cream commonly illustrates a water-in-oil emulsion, while vanishing cream commonly illustrates an oil-in-water system. The assigned composition and an identification test determine the actual emulsion type.
- A dosage form combines an active ingredient with excipients selected for processing, stability and performance.
- Preparation and evaluation are linked: changes in composition or process can alter the product quality attributes.
- Identify the oil, aqueous, emulsifying and consistency-building ingredients.
- Observe preparation of the phases and their combination in the approved order.
- Record cooling/mixing observations and appearance after preparation.
- Compare emulsion type, spreadability, consistency and stability with the assigned tests.

## Materials and Apparatus

- Approved cream formulae, mixing apparatus and evaluation equipment.
- Assigned active ingredient, excipients and the instructor-approved master formula.
- Balance, mixing/preparation equipment, packaging materials and the assigned evaluation apparatus.

## Method

1. Read the master formula and identify the purpose of each ingredient.
2. Calculate the quantities for the assigned laboratory batch and check ingredient identity.
3. Follow the specified order of addition and preparation process, recording actual quantities and process observations.
4. Measure the yield or finished quantity and package the laboratory preparation as specified.
5. Evaluate the product attributes listed for this dosage form with documented methods.
6. Compare the observations with the assigned specification and explain any difference.

## Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

| Observation / parameter           | Record / finding |
|-----------------------------------|------------------|
| Ingredient roles                  | _____            |
| Emulsion type                     | _____            |
| Appearance                        | _____            |
| pH where applicable               | _____            |
| Spreadability                     | _____            |
| Separation/stability observations | _____            |

## Calculations and Interpretation

- Batch scale factor = desired quantity/master-formula quantity.
- Scale each ingredient by the same factor unless the approved formula specifies otherwise.
- Assay (%) = measured active amount/declared active amount × 100, on the same unit and product basis.

## Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: \_\_\_\_\_

Conclusion: \_\_\_\_\_

## Precautions

- Record changes in process or composition; do not conceal a deviation.
- Use the specification assigned to the exact product and dosage form.
- A teaching batch is for laboratory evaluation and is not released for patient use.

## Viva Questions

### 1. Why identify excipient functions?

Each excipient can influence processing, stability, release or acceptability.

### 2. Why is appearance alone insufficient for evaluation?

It does not establish content, performance, stability or microbiological quality.

# Quality Control of Marketed Tablets and Capsules

Practical 10 | Industrial Pharmacy I

## Aim

To study Quality Control of Marketed Tablets and Capsules, and interpret the recorded observations.

## Principle

- Pharmacopoeial quality control applies the relevant general chapter and product monograph to the exact dosage form. Mass uniformity, content uniformity, assay, disintegration and dissolution answer different questions.
- The property is obtained from a defined observable under controlled conditions.
- Replicate measurements, instrument checks and consistent units are needed before comparison.

## Materials and Apparatus

- Marketed tablet/capsule records and the assigned applicable pharmacopoeial methods and apparatus.
- Assigned test material and calibration or comparison material.
- The apparatus specified for this property, a balance or volumetric equipment where relevant, and a record sheet.

## Method

1. Record product identity, strength, dosage form and the pharmacopoeial edition used.
2. Identify the tests and limits applicable to that product rather than copying a universal limit.
3. Perform or review the assigned measurements and retain individual unit readings.
4. Calculate mass variation, assay or release on the correct product basis.
5. Compare each result with its own acceptance criterion and required stage rules.
6. Report compliance only for the tests actually completed.

## Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

| Observation / parameter | Record / finding |
|-------------------------|------------------|
| Product and dosage form | _____            |
| Test name               | _____            |
| Individual readings     | _____            |
| Calculated value        | _____            |
| Applicable limit        | _____            |
| Interpretation          | _____            |

## Calculations and Interpretation

- Mass deviation (%) =  $(\text{individual mass} - \text{mean mass}) / \text{mean mass} \times 100$ .
- Drug released (%) =  $\text{corrected cumulative drug amount} / \text{declared dose} \times 100$ .
- Apply the assigned content-uniformity calculation separately; mass variation does not automatically establish content uniformity.

## Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: \_\_\_\_\_

Conclusion: \_\_\_\_\_

## Precautions

- Keep temperature and test conditions consistent across comparative readings.
- Record raw readings before rounding calculated values.
- Do not compare results obtained with different methods as if they were interchangeable.

## Viva Questions

### 1. Is disintegration the same as dissolution?

No. Disintegration is physical breakup; dissolution measures drug entering the specified medium.

### 2. Why control the test conditions?

A change in conditions may alter the measured property independently of the intended variable.

### 3. Why retain replicate readings?

They show repeatability and help identify an anomalous measurement.

# Pharmacopoeial Evaluation of Glass Containers

Practical 11 | Industrial Pharmacy I

## Aim

To study Pharmacopoeial Evaluation of Glass Containers, and interpret the recorded observations.

## Principle

- Glass-container suitability includes resistance to aqueous chemical attack and the characteristics required for its intended product. Surface and crushed-glass tests are distinct assessments.
- The property is obtained from a defined observable under controlled conditions.
- Replicate measurements, instrument checks and consistent units are needed before comparison.

## Materials and Apparatus

- Assigned glass containers, instructor-demonstrated pharmacopoeial tests and completed extraction/titration records.
- Assigned test material and calibration or comparison material.
- The apparatus specified for this property, a balance or volumetric equipment where relevant, and a record sheet.

## Method

1. Identify the container and the intended pharmaceutical use.
2. Read the assigned method and distinguish the surface test from the glass-grains test.
3. Review the instructor-prepared test and reagent-blank records.
4. Calculate the endpoint or corrected titration result on the specified basis.
5. Compare with the exact method/category limit supplied for the exercise.
6. Report only the tested property and state the container category used.

## Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

| Observation / parameter | Record / finding |
|-------------------------|------------------|
| Container type and use  | _____            |
| Test method             | _____            |
| Blank reading           | _____            |
| Test reading            | _____            |
| Applicable criterion    | _____            |
| Conclusion              | _____            |

## Calculations and Interpretation

- Corrected titration result = test result minus applicable blank result, on the stated method basis.
- Use the category-specific criterion; there is no single limit suitable for every glass test.

## Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: \_\_\_\_\_

Conclusion: \_\_\_\_\_

## Precautions

- Keep temperature and test conditions consistent across comparative readings.
- Record raw readings before rounding calculated values.
- Do not compare results obtained with different methods as if they were interchangeable.

## Viva Questions

### 1. Why distinguish surface and glass-grains tests?

They assess different aspects of the container surface and glass material and have method-specific criteria.

### 2. Why control the test conditions?

A change in conditions may alter the measured property independently of the intended variable.

### 3. Why retain replicate readings?

They show repeatability and help identify an anomalous measurement.

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