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.

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