

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.

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