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.

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