Parenterals

Parenteral Introduction

Definition

- "Parenteral" refers to the administration of drugs by injection through the skin or mucous membranes, directly into the body's circulatory system.
- This bypasses the gastrointestinal tract, unlike oral medications.

Purpose of Parenteral Administration

- To achieve rapid onset of action (e.g., emergency drugs like epinephrine).
- For drugs that are poorly absorbed or degraded in the gastrointestinal tract (e.g., insulin).
- For unconscious or uncooperative patients.
- To provide nutrients or fluids when oral intake is not possible (e.g., Total Parenteral Nutrition - TPN).

Types of Parenteral Preparations:

- **Small Volume Parenterals (SVPs):** < 100 mL (e.g., ampoules, vials)
- **Large Volume Parenterals (LVPs):** ≥ 100 mL (e.g., IV infusions)

Routes of Parenteral Administration

1. **Intravenous (IV):** into a vein. Rapid action; 100% bioavailability.
2. **Intramuscular (IM):** into a muscle. Slower absorption than IV; common for vaccines.
3. **Subcutaneous (SC):** under the skin. Used for insulin, heparin.
4. **Intradermal (ID):** into the dermis. Used for allergy testing, TB tests.
5. **Intrathecal:** into the spinal canal (e.g., for spinal anesthesia).
6. **Intra-articular:** into a joint (e.g., for arthritis treatment).

Advantages

- Rapid and predictable drug absorption.
- Useful in emergencies and unconscious patients.
- Precise control over drug dosage.

Disadvantages

- Invasive; risk of pain, infection, or tissue damage.
- Requires trained personnel and sterile techniques.
- More expensive than oral routes.

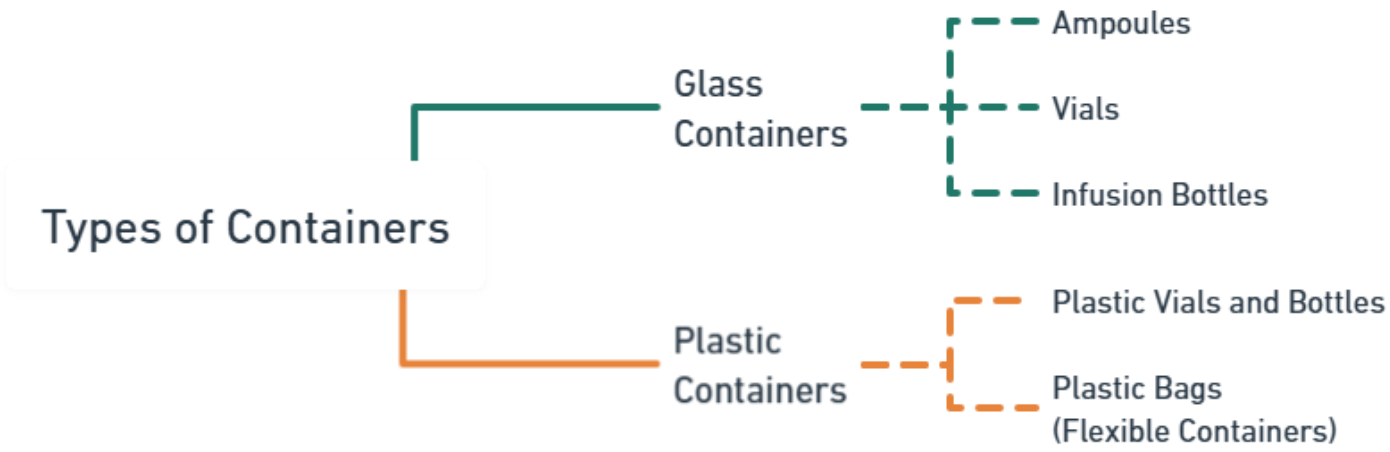
Pharmaceutical Considerations

- **Sterility**: Must be completely free from microorganisms.
- **Pyrogen-Free**: Should not contain fever-inducing agents (bacterial endotoxins).
- **Isotonicity**: Should match the osmotic pressure of body fluids to prevent irritation.
- **pH control**: Close to physiological pH (7.4) to avoid tissue irritation.
- **Particle-Free**: Especially for IV injections, to prevent embolism.

Containers Used for Parenteral (Including Official Tests)

Types of Containers

Parenteral products are packed in **hermetically sealed** containers to maintain sterility and product stability.



A. Glass Containers

1. **Ampoules:**
   - Small, sealed glass vials.
   - Single-dose use only.
   - Broken open at neck to access content.
   - **Advantage**: No interaction with rubber closures.
   - **Disadvantage**: Risk of glass particle contamination.
2. **Vials:**
   - Multi-dose or single-dose containers.
   - Sealed with a rubber stopper and aluminum cap.
   - Can be accessed multiple times using a sterile syringe.
3. **Infusion Bottles:**
   - For Large Volume Parenterals (LVPs).

- Typically made from Type I (borosilicate) or Type II (treated soda-lime) glass.

B. Plastic Containers

1. Plastic Vials and Bottles:

- Made from polyethylene or polypropylene.
- Lightweight and break-resistant.
- Requires careful testing for leaching or interaction.

2. Plastic Bags (Flexible Containers):

- Used for IV infusions (e.g., dextrose, saline).
- Made from PVC, EVA, etc.
- Often include ports for medication addition and infusion sets.

Types of Glass (as per USP / IP):

- **Type I (Borosilicate Glass):** Highly resistant to thermal shock and chemical attack; suitable for all parenteral preparations.
- **Type II (Treated Soda-Lime Glass):** Suitable for buffered aqueous solutions.
- **Type III (Soda-Lime Glass):** For dry substances only.
- **Type NP (General-purpose soda-lime):** Not suitable for parenteral use.

Requirements for Containers:

- Must not interact chemically or physically with the drug
- Should maintain sterility
- Must protect the contents from light, oxygen, and moisture if needed
- Should be compatible with sterilization methods

Official Tests for Parenteral Containers (as per pharmacopeias like IP, USP):

1. Sterility Test:

- Ensures container does not allow entry of microorganisms.
- Performed by incubating sample for 14 days in different media (e.g., Fluid Thioglycollate Medium, Soybean Casein Digest Medium).

2. Pyrogen Test:

- Detects fever-producing substances.
- Classic test: Rabbit test (inject sample and monitor temperature)
- Modern alternative: LAL (Limulus Amebocyte Lysate) test for bacterial endotoxins

3. Leaching Test:

- Ensures that harmful chemicals do not leach into the formulation from plastic or rubber components.

4. **Particulate Matter Test:**
   - Detection of particles using light obscuration or microscopic methods
   - Particularly important for LVPs
5. **Container-Closure Integrity Test:**
   - Ensures no leakage; uses dye ingress, vacuum decay, or pressure methods.
6. **Clarity and Transparency Test:**
   - Especially for SVPs and LVPs in transparent containers; ensures no visible foreign matter or turbidity.
7. **pH and Volume Tests:**
   - Confirms pH range and volume of content is within specified limits.
8. **Chemical Resistance Test (Glass):**
   - **Surface Glass Test** (for Type I, II, III glass): checks the amount of alkali released.
   - **Hydrolytic Resistance Test:** Measures the chemical resistance of the glass to water.

Formulation of Large Volume Parenterals (LVPs)

Definition

- Parenteral solutions with volume greater than 100 mL, typically 250 mL, 500 mL, or 1000 mL.
- Administered by intravenous infusion over a longer period.

Uses

- **Fluid replacement** (e.g., Ringer's Lactate).
- **Electrolyte replenishment** (e.g., sodium chloride injection).
- **Parenteral nutrition** (e.g., amino acids, dextrose).
- **Diluent for drug infusion** (e.g., infusion of antibiotics or chemotherapy drugs).

Formulation Components:

1. **Active Ingredients / Electrolytes:**
   - May contain electrolytes (e.g., Na^+, K^+, Cl^-) or nutrients (e.g., amino acids, glucose)
2. **Solvent:**
   - Always Water for Injection (WFI)
3. **Tonicity Agents:**

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