# SEMINAR ON

# PARENTRALS



1

# **CONTENTS**

- Introduction
- Routes of administration
- Advantages
- Disadvantages
- Preliminary stages
- Formulation
- Manufacture
- Filling
- Packaging
- Sealing
- Sterilization
- Quality control
- Conclusion
- References



# INTRODUCTION



## DEFINITION

• According to USP :

an injection that is packaged in containers which are sterile and pyrogen free in nature"



"







#### **A BRIEF ABOUT PARENTERALS :**

- para: outside enteron: intestine
- Any drug or fluid whose delivery does not utilize the alimentary canal for entry into body tissues.
- Parenteral products are injected through the skin or mucous membranes into the internal body compartments.
- These are the preparations which are given other than oral routes.

# **ROUTES OF ADMINISTRATION**



Three primary routes of parenteral administration are commonly employed :

- Subcutaneous
- Intramuscular
- Intravenous

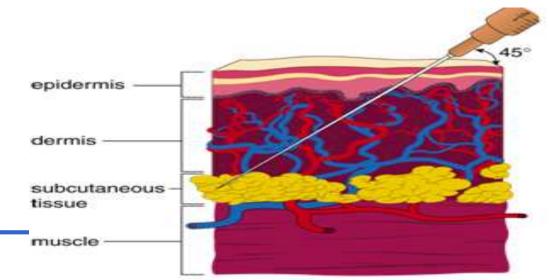
Other routes :

- Intra arterial
- Intra thecal
- Intra articular
- Intra cardial
- Intra ceribral
- Intra peridural
- Intra cisternal

# Subcutaneous



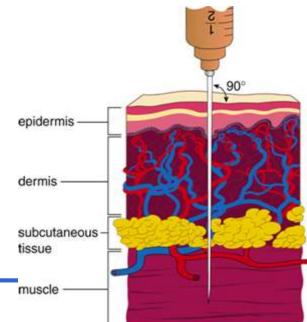
- Administer medications below the skin into the subcutaneous fat
- Often have a longer onset of action and a longer duration of action compared with IM or IV injection
- Given at a 45-degree angle
  - 25- or 26-gauge needle, 3/8 to 5/8 inch length
- No more than 1 ml should be injected into the site to avoid pressure on sensory nerves causing pain and discomfort



# Intramuscular Injections



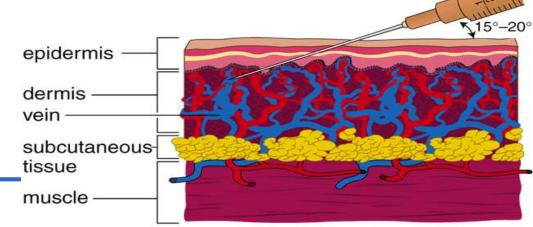
- In adults, IM injections are given into upper, outer portion of the gluteus maximus
- For children and some adults, IM injections are given into the deltoid muscles of the shoulders
- Typical needle is 22- 25 gauge <sup>1</sup>/<sub>2</sub>- to 1-inch needle
- IM injections are administered at a 90<sup>0</sup> angle
  - volume limited to less than 2 ml



# Intravenous Injections



- Fast-acting route because the drug goes directly into the bloodstream
- often used in the emergency department and in critical care areas
- Commonly used
  - for fluid and electrolyte replacement
  - to provide necessary nutrition to the patient who is critically ill
- Intravenous (IV) injections are administered at a 15- to 20-degree angle
- Volume NMT 1 litre.



## Intra-arterial injection

The injection are given directly in to the artery

Intracardiac injection

These are given into the heart muscle or ventricle at the time of emergency only.

## Intrathecal injection

These are given into the subachonoid space the surround the spinal cord. This route is used for spinal anesthesia.



#### Intracisternal injection

- These are given in b/w first & second cervical nerve.
- Used for CSF for diagnostic purpose.

### **Peridural injection**

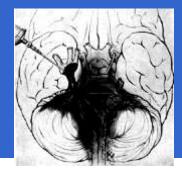
- These are given in b/w the dura matter & inner aspect of vertebra.
- Used for given spinal anesthesia.

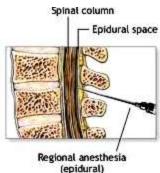
### Intra-articular injection

- These are given in into the articulating ends of bones in a joint.
- Used for lubricating the joints.

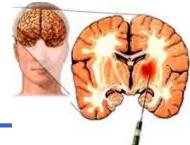
Intracerebral injection

These are given into the cerebrum.







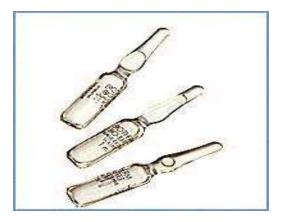




- Parentrals are classified into two types. They are
- 1. Small Volume Parenterals (upto 100ml)

#### **Primary uses of SVP**

- Therapeutic injections
- Opthalmic products
- Diagnostic agents
- Allergenic extracts





### 2. Large Volume Parenterals (100-1000ml)

## **Clinical Utilization of LVP**

- Basic Nutrition
- Restoration of Electrolyte balance
- Fluid replacement
- Blood and blood products
- Drug carriers



# **ADVANTAGES**



- Quick onset of action
- Suitable for the drugs which are not administered by oral route
- Useful for unconscious or vomiting patients.
- Useful for patients who cannot take drugs orally
- Useful for emergency situations
- Duration of action can be prolonged by modifying formulation.
- Can be done in hospitals, ambulatory infusion centers, and home health care

# DISADVANTAGES



- Pain on injection.
- Difficult to reverse an administered drug's effects.
- Sensitivity or allergic reaction at the site of injection.
- Requires strict control of sterility & non pyrogenicity than other formulation.
- Only trained person is required
- Require specialized equipment, devices, and techniques to prepare and administer drugs.
- More expensive and costly to produce.

# FORMULATION



### Aqueous vehicle :

## Water For Injection(WFI) USP :

- Highly purified water used as a vehicle for injectable preparations which will be subsequently sterilized.
- USP requirement include not more than 10 parts per million of total solids.
- pH of 5.0 to 7.0
- WFI may prepared by either distillation or reverse osmosis.
- Stored in chemically resistant tank.



### **Bacteriostatic Water for Injection (BWFI):**

- This type of water used for making parenteral solutions prepared under aseptic conditions and not terminally sterilized.
- Need to meet USP sterility test.
- It can contain an added bacteriostatic agent when in containers of 30ml or
  less



### **Sterile Water for Injection USP**

- SWFI containing one or more suitable bacteriostatic agents.
- Multiple-dose containers not exceeding 30 ml.
- They are permitted to contain higher levels of solid than WFI because of the possible leaching .
- Used for Washing wounds, surgical incisions, or body tissues.



### Water-miscible vehicles :

• primarily to effect solubility of drugs and/or reduce hydrolysis

### Non-aqueous vehicles :

Fixed oils (vegetable origin, liquid, and rancid resistance, unsaturated, free fatty acid content)

- Peanut oil
- Corn oil
- Cotton seed oil (depo-testosterone)
- Sesame oil
- Soybean oil (source of fat in intralipid)
- Ethyl oleate
- Isopropyl myristate

# **OTHER ADDITIVES**

#### **Antibacterial Agents**

- Required to prevent microorganism growth
- Limited concentration of agents
  - Phenylmercuric nitrate and Thiomersol 0.01%
  - Benzethonium chloride and benzalkonium chloride 0.01%
  - Phenol or cresol 0.5%
  - Chlorobutanol 0.5%

#### **Buffers**

- Added to maintain pH
- Results in stability
- Effective range, concentration, chemical effect
  - Citrate and Acetate buffer
  - Sodium benzoate and benzoic acid
  - Sodium titrate and tartaric acid
  - Phosphate buffer

## Antioxidant -

• Included to the formulation to protect from oxidation

Two types

- Reducing agent.eg- ascorbic acid, sodium bisulfite,thiourea
- Blocking agent.eg- BHT, Tocopherol

## Surfactants-

Included to solublise the active ingredient

- polyoxyethylene sorbitan monooleate
- sorbitan monooleate

#### **Tonicity Agents**

#### **Chelating agent**

- contribute to isotonicity of product
- Reduce pain of injection
  - Sodium chloride
  - Potassium chloride
  - Dextrose
  - mannitol
  - sorbitol

ethylenediamine tetraacetic acid