INTRODUCTION

- The administration of drugs through the patient by injection under through one or more layer of the skin or mucous membrane.

- The term parenteral derives from the greek word

  1. Para (outside )

  2. Enteron (Intestine)

- It denotes that route of administration other than oral route.
ADVANTAGES

- It provides rapid onset of action
- It provides immediate therapeutic action
- It can be administered accurate dose.
- It can be given to patients who cannot take oral medication.
- It minimize the first pass effect.
- It provides more bioavailability
DISADVANTAGE

- It should be administered aseptically
- It produces pain at the site of injection
- The administration of drug through wrong route may prove fatal effect
- Self administration is not possible
- If pyrogenic preparations lead to very harmful effect.
Routes of administration

- Intra Muscular (IM)
- Intra dermal (ID)
- Intravenous (IV)
- Subcutaneous / Hypodermic (SC)
- Intra articular
- Intra synovial
- Intra spinal
- Intrathecal
- Intrarterial
- Intra cardiac
- Intra cisternal
- Intra peritonial
- Intraplueral
**TYPES OF PARENTERALS**

- Powder for injection - Eg. Cefuroxime for injection
- Colloidal solution - Eg. Iron dextran
- Injectable emulsion - Eg. Propofol USP
- Injectable suspension - Eg. Methylprednisolone acetate
- Oily injection (solution) - Eg. Dimercaprol injection.
- Infusion fluid
PREFORMULATION FACTORS:

It is study about physical & chemical properties of drug substance prior formulation is called as preformulation.

They are
  pH
  Solubility
  pKa
  Dissociation constant
  Compatibility studies- FTIR / DSC
  Oxidation & reduction
  Particle size
FORMULATION OF PARENTERALS

1. Solutes
2. Added substance
   - Antimicrobial agent
   - Buffers
   - Antioxidants
   - Tonicity agent
   - Cryoprotectant
   - Suspending agent
   - Emulsifying agent
3. Vehicle
   - Aqueous - WFI
   - Non- aqueous Eg. arachis oil
GENERAL PROCEDURE

- Cleaning & washing of container, closures
- Preparation of solutions
- Sterilization (Filteration)
- Filling
- Packaging
Lyophilization techniques

- It is a process of removal of solvent from the product or substances is called as lyophilization.

- It consists of three steps:
  - Freezing
  - Primary drying
  - Secondary drying
Criteria for parenterals

- Sterility
- Pyrogen
- Isotonicity
- Stability
- Ph
- Osmotic pressure
Containers & closures

1. Glass
2. Plastic
   - Ampoules (single dose)
   - Vials (multiple dose)
   - Cartridges
   - Automatic injector

3. Rubber closure with aluminium caps
   - Small volume parenterals: less than 100ml
   - Large volume parenterals: more than 100ml
Evaluation test for parenterals

- Test for pyrogen
- Sterility testing
- Rabbit test
- Clarity test
- LAL test
- Leaker test
THANK YOU