PARENTRAL PRODUCT

● DEFINATION:-

Preparation are defined as solution suspension emulsion for injection or infusion, gels for injection and implants. They are sterile preparation intended to be administered directly into the systemic circulation in human and animal body.

● Parenteral preparation can be classified

1-Solution or emulsion of medicament suitable for injection

Example: - Atropine sulphate injection

2-Sterile solids:-

Example- Benzyl penicillin G sodium injection

3-Sterile suspension:-

Example: - Sterile chloramphenicol suspension

4-Transfusion fluids

Example: - Ringer solution, dextrose injection.

● ADVANTAGES OF PARENTRAL PREPARATION:-

1- Onset of action is quick

2- The drugs which cannot be administered by oral route, can be administered by this route

3-The patients who are vomiting or unconscious cannot take drug by oral route

4- The drug action can be prolonged by modifying the formulation.

● DISADVANTAGES OF PARENTRAL PREPARATION:-

1- Injection causes pain at the site of injection
2- The trained person are required to administered the drug
3- The administration of a drug through wrong route of injection may prove to fetal
4- It is difficult to save a patient when over dose is given

● FORMATION OF PARENTRAL PREPARATION:-

The formulation of parenteral preparations need careful planning through knowledge of the medicaments and adjuvants to be used.

● VEHICLES

1- Aqueous vehicle
2- Non aqueous

1. Aqueous vehicle

Water is used as vehicle for majority of injection because water is tolerated wall by the body and the safest to administer.

1. Water for injection
2. Water for injection free from co2
3. Water for injection free from dissolved air

2. Non aqueous

1. The commonly used non aqueous vehicles are oil and alcohol
2. Fixed oils such as arachis oil, cotton seed, and oil are used as vehicle

● ADDITIVES:-

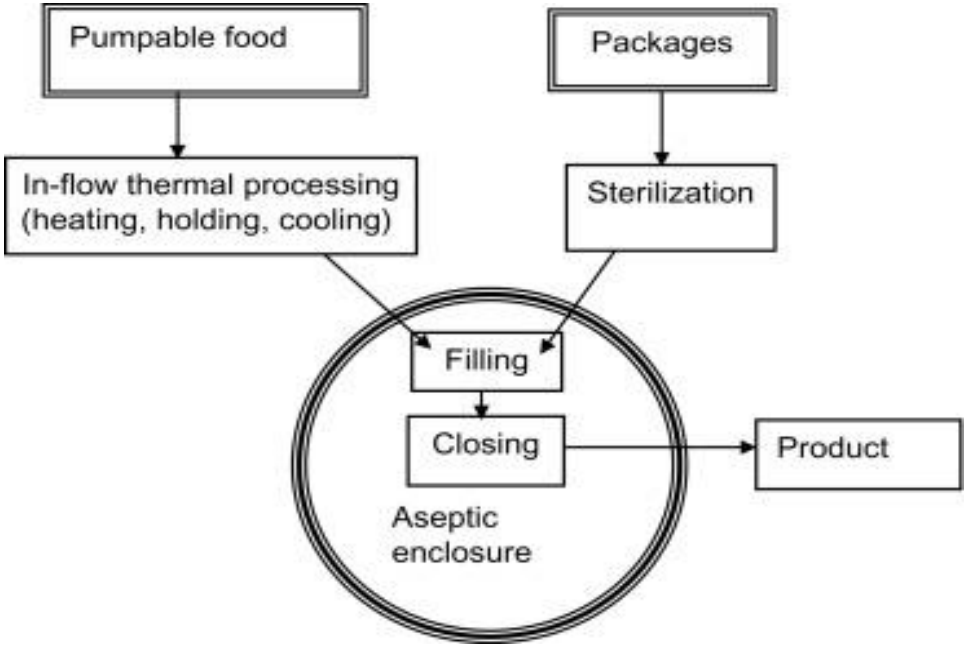
Pharmaceutical additives this are the substance which are added in the formulation among the therapeutic agent so as to impact specific quality in the formulation

1. Solubilizing agents-
   Examples: Polysorbate or by using co-Solvent
2. Stabilizer-
   Examples: Nitrogen and carbon dioxide
3. Buffering agent –
   Example: Citric acid and sodium citrate
4. Antibacterial agent-
   Example: Phenol and cresol
5. Chelating agent-
   Example: Sodium and potassium salt, citric acid
6. Suspending, Emulsifying and Wetting agent –
   Example: Methylcellulose, Carboxymethyl cellulose
7. Tonicity factor
   Example-Sodium chloride, dextrose

● ISOTONICITY:-

Isotonicity is important for parenteral preparation because the possibility that the product may penetrate red blood cells and cause hemolysis is greatly reduced if the solution is isotonic with blood.

● ASEPTIC PROCESS:-



● FORMULATION 0F INJECTION:-

- The formulation of injectable need careful planning through knowledge of the medicaments and adjuvants to be used
- in the preparation of injectable, the following substances added to make a stable preparation
  1. Vehicles
  2. Adjuvant
  3. Solubilizing agent
  4. Stabilizers
  5. Buffering agent

● FORMULATION OF STERILE POWDER:-

- Sterile powder is aseptically added to a sterile vial.
- The dry drug powder is reconstituted with a sterile vehicle before use
- Powder for injection are solid substances distributed in their final container and which, when shaken with the prescribed volume of the appropriate sterile liquid, rapidly form either clear and practically particle free solution or uniform suspension.

● LARGE VOLUME PARENTERAL:-

- These are supplied for single dose having more than 100 ml.
- These are delivered through IV route
- These generally provide electrolytes nutrition to the body

● CLOSURE CONTAINER:-

A container closure system refers to the sum of packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components.

● FILLING AND SEALING OF AMPOULES:-

▪ FILLING OF AMPOULES:-

- The size of the delivery tube of liquids to the container to be used the viscosity and density of the liquid and the speed of delivery desired filling machine parts should be constructed of non-reactive material such as borosilicate glass or stainless steel.

▪ SEALING OF AMPOULES:-

- Container should be sealed in the aseptic area in immediately adjacent to the filling machine.
- It is obvious that a sterile container that has been opened can no longer be consider to sterile therefore, temperature proof sealing is essential

● VIALS:-

- Vial is glass or plastic container closed with a rubber stopper and sealed with an aluminum crimp
- Vials are available for single or multiple dosing.

● INFUSION FLUID:-

- Polyvinyl chloride collapsible bags are used to pack most infusion fluid. It is a part of large volume parenteral product [100ml to 1000ml per day]

● QUALITY CONTROL TEST OF PARENTRAL PRODUCT:-

- Quality control involves testing of unit and determining if they are within the specification for the final product

1- In process QC:-

- Conductivity measurement
- Volume filled
- Temperature for heat sterilized product
- Environmental control test
- Visuals inspection

2- Finished product

- Leaker test
- Clarity test
- Pyrogen test
- Sterility test
- Content uniformity test

● OPTHALMIC PREPARATION:-

A sterile solution, suspension or ointment for instillation into the eye in the form of drops, sprays and ointments.

● FORMULATION OF EYE DROP:-

Eye drops are sterile aqueous or oily suspension of drug for instilling into conjunctiva sac with dropper.

1. Thickening agent
2. Preservative

● EYE OINTMENT:-

Semisolid preparation based on oleaginous water washable bases packed in collapsible tubes for easy transferred into eye cavity by pressure

- **FORMULATION:-**

1- Medicament –water/oil soluble

2- Ointment base

● EYE LOTION:-

Eye lotion this are sterile aqueous solution intended for washing the eyes to remove irritant or foreign body.

1. Drug – NaCl, NaHCO3,boric acid ,borax
2. Vehicle- water
3. Iso-osmotic agent.

● EVALUATION OPTHALMIC PREPARATION:-

1. Sterility test
2. Clarity test
3. Leaker test
4. Metal particles in ophthalmic ointment

REFERENCE: - Leon Lachman, Herbert Lieberman The theory and practice of industrial pharmacy [pg.610-6390]

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