

Parenteral Products



Parenteral dosage form

- **Parenteral dosage form are the irreversible dosage form which are given or administered by other than oral routes I.e. directly into the systemic circulation.**
- **Parenteral term is derived from two Words – para (outside) and enteron(intestine).**
- **Injected directly into the body tissue through the primary protective systems of human body, the skin and the mucous membrane.**
- **Parenteral dosage is a sterile drug product, which is presented in the form of solution, suspension, emulsion, or reconstituted lyophilized powder, suitable for administration by injection.**



- **Certain Pharmaceutical agents, particularly peptides, Proteins and many chemotherapeutic agents can only be given parenteral because they are inactivated in the gastrointestinal tract when given by oral route.**
- **Parenteral administering drugs are relatively unstable and generally highly potent drugs that require strict control of administration to the patient.**

Need of parenteral dosage form

Due to Following criteria, parenteral dosage form is necessary in Pharmaceutical and health services field.

- 1. Time of action is very low.**
- 2. Fast action**
- 3. No first pass metabolism**
- 4. No effect of GIT fluids**
- 5. First choice in emergency**
- 6. Patient convenience**
- 7. Costly drugs and potent drug easily administered**

Characteristics of Parenterals

Parenteral products are unique from any other type of pharmaceutical dosage form for the following reasons:

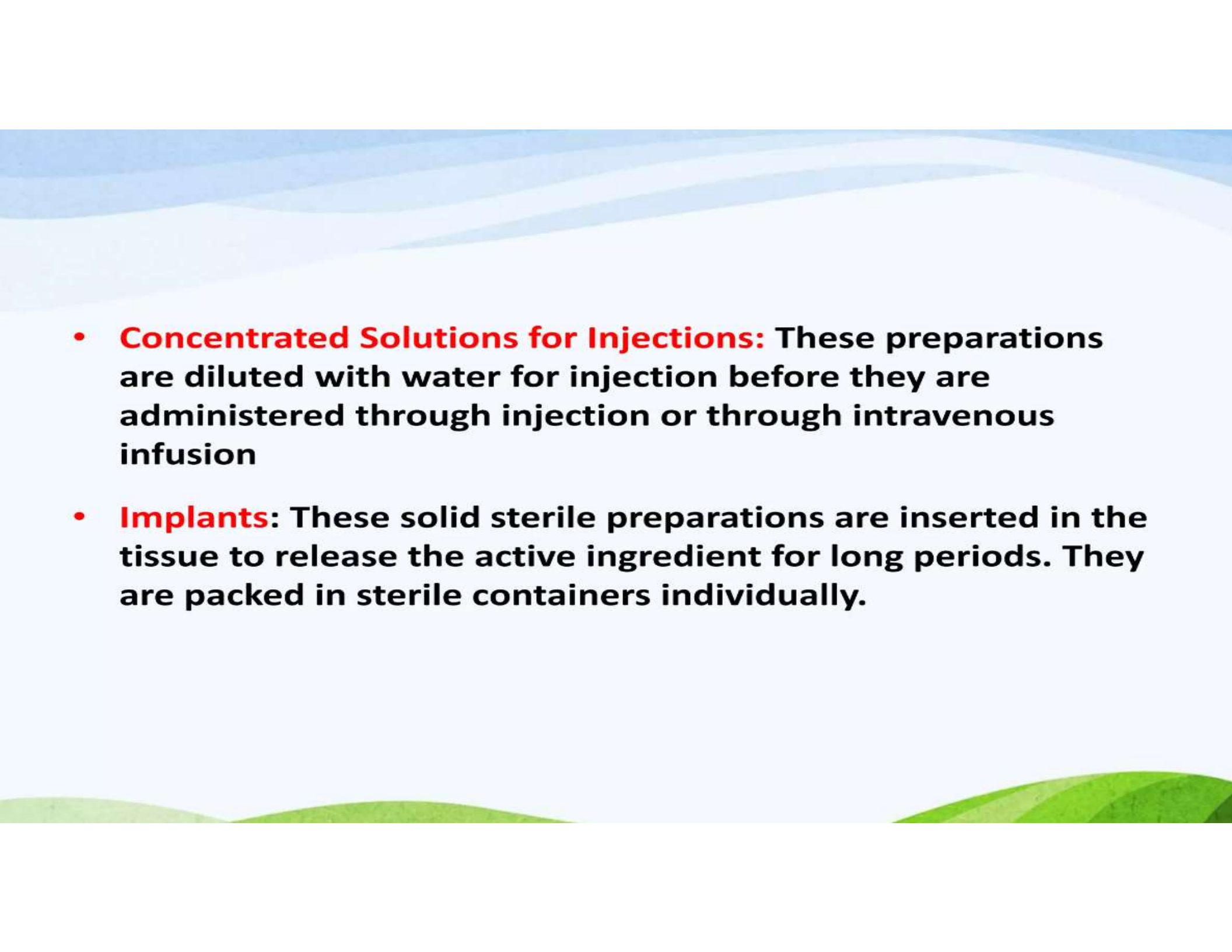
1. **must be sterile.**
2. **must be free from pyrogenic (endotoxin) contamination.**
3. **Injectable solutions must be free from visible particulate matter.**
4. **constituted sterile powders.**
5. **should isotonic, although strictness of isotonicity depends on the route of administration.**
6. **All products must be stable, chemically, physically and microbiologically.**

Types of Parenteral dosage Form

- 1. Injection**
- 2. Infusion**
- 3. Powder for injection**
- 4. Concentrated solution for injection**
- 5. Implants**

TYPE OF PARENTERALS

- **Injection:** Injections contain sterile solutions or suspension and are prepared by dissolving the active ingredient and other substances in Water for Injection or other suitable non-aqueous base or a mixture of both.
- **Infusions** These parenteral preparations are composed of a sterile aqueous solution with water as a continuous phase. The preparations are free of bacterial endotoxins or pyrogens. They contain no antimicrobial preservatives
- **Powder for Injection:** These are sterile solid preparations that are mixed or reconstituted with a diluent (usually 5% dextrose solution, normal saline, bacteriostatic water, or sterile water for injection) before administration. These preparations are preferred when drugs are not stable in solution.

- 
- **Concentrated Solutions for Injections:** These preparations are diluted with water for injection before they are administered through injection or through intravenous infusion
 - **Implants:** These solid sterile preparations are inserted in the tissue to release the active ingredient for long periods. They are packed in sterile containers individually.

Advantages

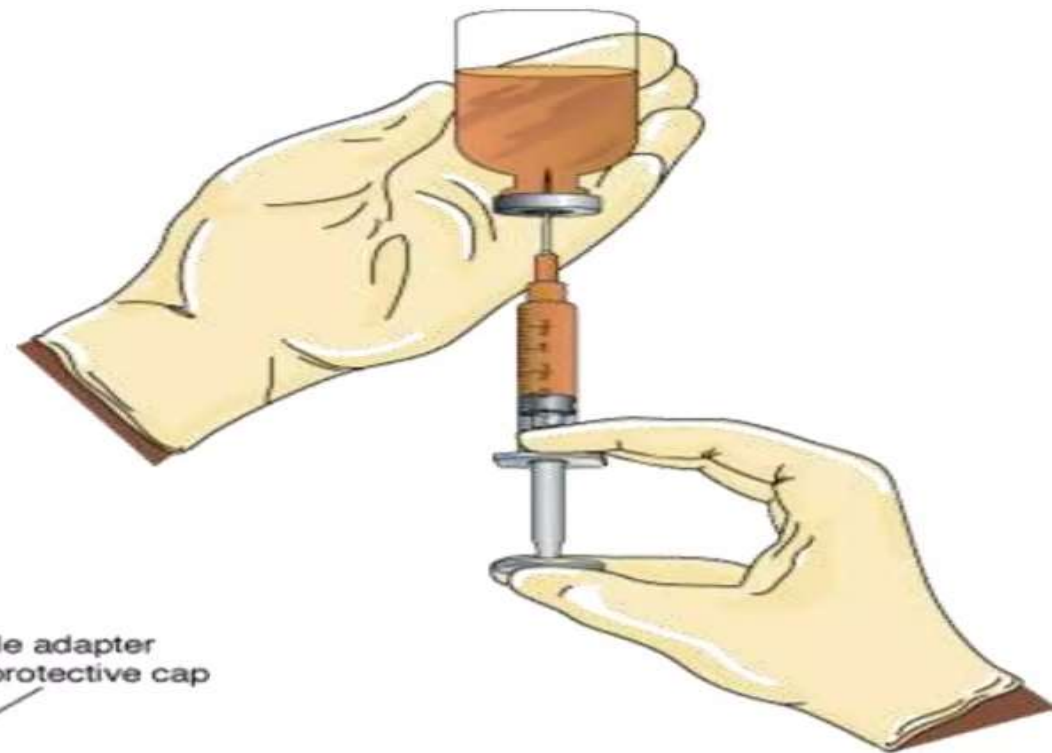
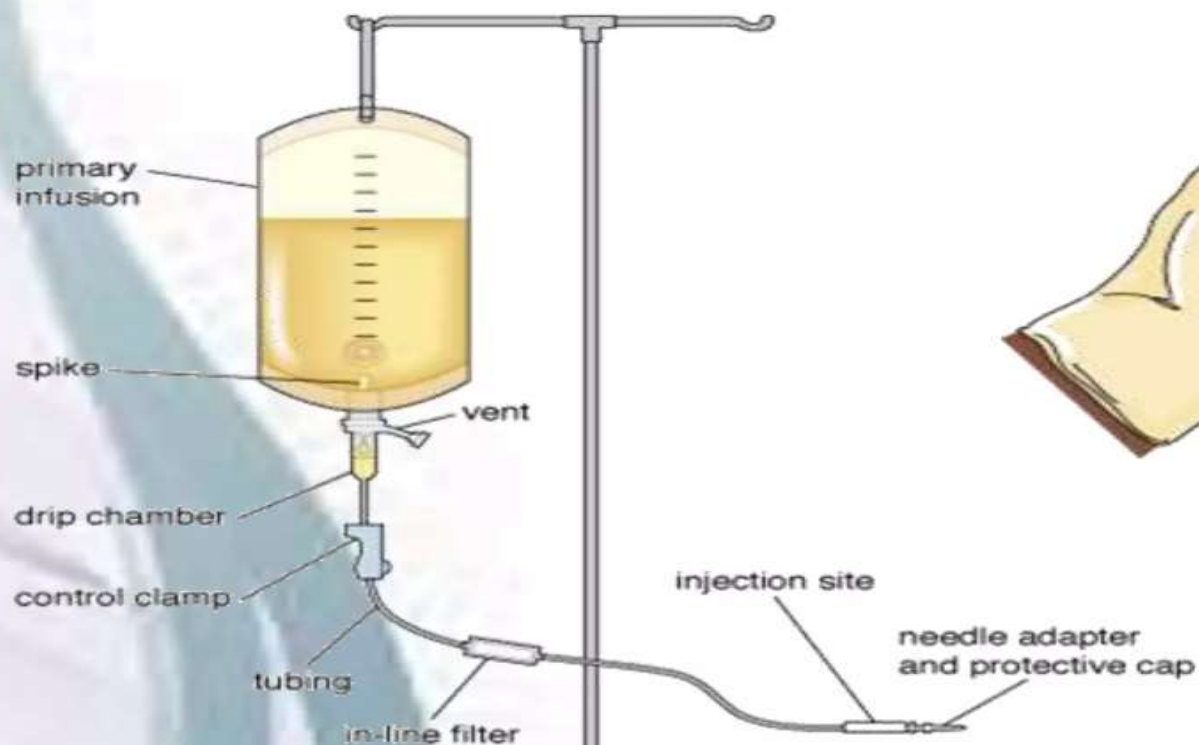
- **poorly absorbed, inactive or ineffective destroyed in GIT can be administered by parenteral route.**
- **Parenteral preparations provides immediate onset of action.**
- **To achieve slow or delayed onset can be used. action, intramuscular and subcutaneous routes.**
- **This route is most suitable the patient is unconscious difficult to swallow drug etc. pass effect.**
- **This route avoid hepatic first chance of missing dose.**
- **The drug is directly released into blood stream by injection so minimum drug is needed to produce the effect as there is no wastage.**
- **Useful for emergency situations**
- **Providing sustained drug delivery (implants, im depot inj)**
- **Avoid first pass metabolism**
- **Can inject drug directly in to a tissue (target drug delivery)**
- **Useful for delivering fluids, electrolytes, or nutrients (TPN)**
- **Can be done in hospitals, ambulatory infusion centers and Complete bioavailability**

DISADVANTAGES

- 1. Injectable drugs are expensive as they need the instruments like syringe.**
- 2. Needs a skilled person.**
- 3. Drug once given cannot be controlled if there are adverse effects or poisoning. It is difficult to control adverse effects leading to death.**
- 4. Chances of pain and injury at site of injection.**
- 5. Sterilization is required.**
- 6. Pain on injection**
- 7. Difficult to reverse an administered drug's effect. Sensitivity or allergic reaction at the site of injection.**

CLASSIFICATION

1. Small volume parenterals (SVP)
2. Large volume parenterals (LVP)



Small volume parenterals

USP defn: An injection that is packed in containers labeled as containing 100 ml or less.

Large volume parenterals

Defn: LVP are parenterals designed to provide :-

- Fluid
- Calories (dextrose solution)
- Electrolytes
- Combination of these
- Volume 101- 1000 ml



DIFFERENCE BETWEEN SVP & LVP

parameter	SVP	LVP
volume	100 ml or less	101-1000 ml
Routes	IV, IM & SC	IV- LVP & non IV- LVP
Dosage unit	Single or multiple	Single
preservative	Used	Not used
Buffers	Used	Not used
Formulation	Soln, emulsion,suspension.	Soln & o/w nutrient emulsion
Isotonicity	Not essential	must
Pyrogenicity	Not essential	must
use	Therapeutic & diagnostic	Nutrition,detoxification, And during surgery

