VISWANADHA INSTITUTE OF PHARMACEUTICAL SCIENCES

GUEST LECTURE

ON

PARENTERAL PROCESS

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Guest lecture includes parenteral formulation process, various types of parenteral dosage forms, characteristics of parenteral dosage forms, Parenteral Drug Manufacturing, Clean room maintenance, Personnel Requirements for Sterile Manufacturing

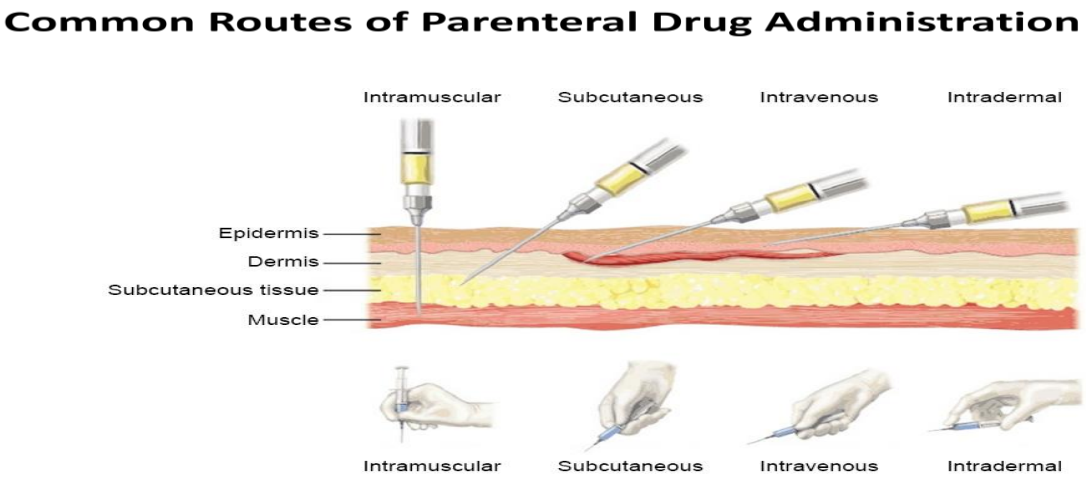

Fig no: 1 Common routes of parenteral drug administration

Characteristics of Parenteral Drug Forms

1. Safety (freedom from adverse toxicological concerns
2. Sterility (freedom from microbial contamination)
3. Non-pyrogenic (freedom from endotoxin contamination)
4. Particle-free (freedom from visible particle contamination)

Fig no: 2 Detection Of Particulate Matter In Vials And Ampoules

5. Stability (chemical, physical, and microbial)

6. Compatibility (formulation, packaging, and other diluents)

7. Isotonicity (isotonic with biological fluid)

Overview of Parenteral Drug Manufacturing

- The parenteral drug manufacturing (Drug Product Manufacturing) process includes compounding, mixing, filtration, filling, terminal sterilization, lyophilization, closing, and sealing, sorting, and inspection, labeling, and final packaging for distribution.
- The manufacturing process is complicated, requiring organization and control to ensure the product meets the quality and the specifications.
- ***Aseptic processing requirement*** adds more complication but assures that all dosage forms manufactured are free from any contamination of microbial, endotoxin, and visible particulate matter.
- The manufacturing process initiates with the procurement of approved raw materials (drug, excipients, vehicles, etc.) and primary packaging materials (containers, closures, etc.) and ends with the sterile product sealed in its dispensing package.
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Fig no: 3 Aseptic processing

- **Clean room maintenance**
  - Carefully planned schedule of cleaning by expertly trained custodians should be implemented. Cleaning tools should be non-linting.

- **Sanitization/disinfection agents** – chemicals reducing the microbial bioburden. **They are not sterilization agents!**
- Quaternary ammonium compounds, phenolic mixtures, alcohols, biguanides, formaldehyde, chloride, peroxide, glutaraldehyde, etc.
- LpH (Steris Corp.) is well known. ***Sanitizing agents are normally not sporocides!***

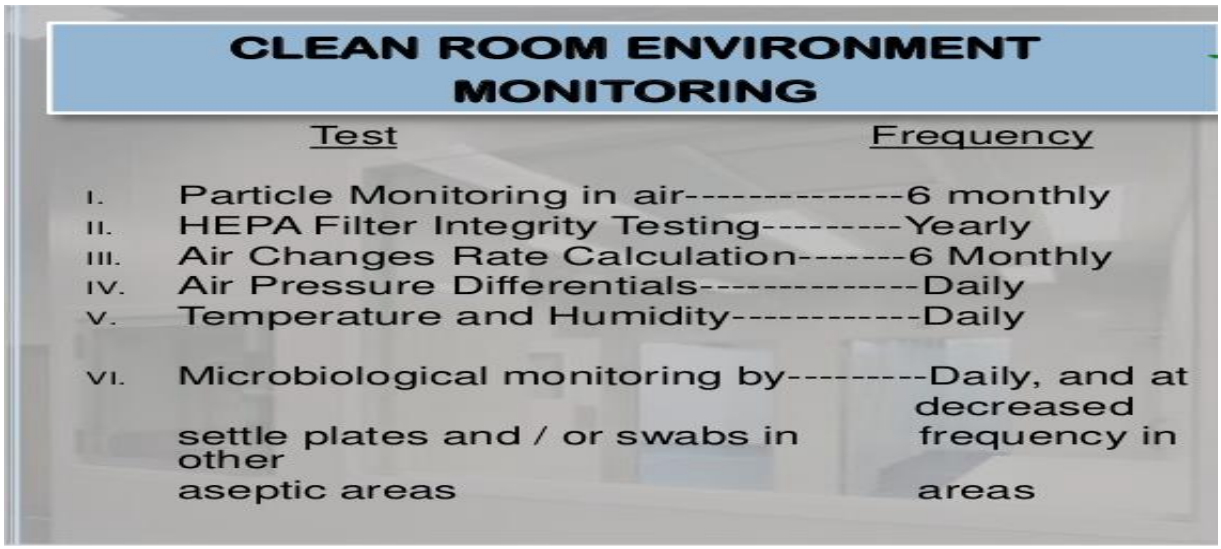

Fig no : 3 Clean room monitoring

Personnel Requirements for Sterile Manufacturing

- People are the worst source of microbial and particle contamination.
- Personnel selected to work in clean room must be neat, orderly, and reliable. They should be in good health and free from dermatological conditions that may increase the microbial load. A person with cold, allergies or other illness should not be permitted in the clean room until their recovery. Effective training and proper gowning can reduce the particle shedding from personnel.
- Bathing removes microorganisms but increases the number of particles emitted from human body. Personnel working in clean room should bathe ***at least 2 hours before they enter clean room***.
- Suntan also dries skin, causing it to flake and peel more easily. Cleanroom personnel are encouraged not to expose their skin to excessive sunlight.
- Friction between clothing and skin also increases the rate of shedding. Therefore, tight clothing should be avoided.

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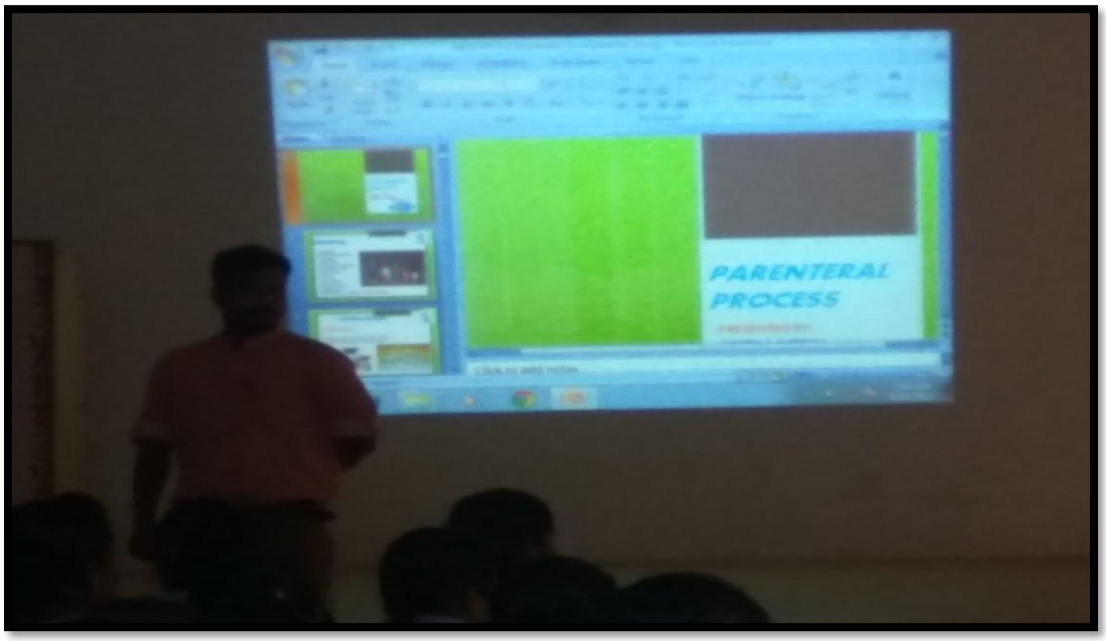

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