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HOSPITAL MANUFACTURING

The objective of each hospital manufacturing system is to produce the drugs at the lowest price at the quantity that perfectly meets the demands of patient care.

Estimation of demand :

Demand forecasting tells the expected level of demand at some future date on the basis of past and present information. It helped in production planning, new product development, capacity enhancement or new schemes etc. Demand forecasting is generally used for short term estimation as well as long term forecasting.

Formula for Cost Per Unit :

Cost Per Unit = (Total Fixed Costs + Total Variable Costs) / Total Units Produced.

Types of hospital manufacturing :

The hospital manufacturing unit can produce 2 types of products.

1) Strile products
2) Non sterile products

STERILE MANUFACTURE

Drug products that are delivered via the parenteral, ophthalmic, inhaled, or otic route present an increased risk of infection or harm because they bypass many of the body's natural defenses. To ensure patient safety, the FDA requires that drug products delivered via these routes be supplied as sterile products. This designation

includes many complex drug products, including ophthalmic suspensions, sterile injectables, lyophilized powders for injection, and aqueous-based aerosols for inhalation.
In general, there are two ways to manufacture a sterile drug product:

1. Terminal Sterilization: A process that involves filling and sealing product containers under high-quality environmental conditions, then subjecting the product in its final container to a sterilization process such as heat or irradiation.
2. Aseptic Manufacturing and Sterile Fill-Finish: A process in which the drug product, container, and closure are first subjected to sterilization methods separately, as appropriate, and then brought together (aseptic manufacturing). Because there is no process to sterilize the product in its final container, it is critical that containers be filled and sealed in an extremely high-quality environment (sterile fill-finish).

Aseptic processing :

Aseptic processing is uniquely challenging because it requires careful planning, thoroughly trained personnel with the appropriate mindset, and specialized facilities/equipment to properly execute.

Any of the following can be sources of contamination in an aseptic processing and sterile fill-finish operation:

- Drug Product Components and Container Systems
- Cleanroom Facilities
- Equipment and Processes
- Personnel

Considerations for Aseptic Processing and Sterile Fill-Finish :

Any personnel who enter an aseptic manufacturing area must be thoroughly trained in cleanroom procedures and behavior. According to the FDA, personnel are a potentially major source of contamination and a proper training program should cover, at a minimum:

- Aseptic technique
- Cleanroom behavior (e.g., move slowly and deliberately, keep entire body out of the path of unidirectional airflow)
- Microbiology
- Hygiene
- Gowning
- Patient safety hazards posed by nonsterile drug products
- Specific written procedures covering aseptic manufacturing area operations

For sterile manufacture following equipments are necessary to meet the requirements of Drugs and Cosmetics Act.

- Storage equipment for ampoules and vials
- Storage cabinets
- Water still
- Ampoule washing machine
- Ampoule drying machine
- Filling and sealing unit
- Sintered glass funnel
- Filter press
- Hot air oven
- Equipments for evaluation and quality control
- Autoclave
- Labeling and packing units

FUMIGATION

Fumigation is a process of gaseous sterilisation which is used for killing of micro-organisms and prevention of microbial growth in air, surface of wall or floor. It is generally used in the pharmaceuticals, operation theatres, hospitals etc.

Formaldehyde fumigation :

Formaldehyde fumigation has long been an accepted method for areas where microbiological cleanliness is required. Fumigation with formaldehyde vapor is the recognized and most commonly used method because it is a cost-effective procedure.

Procedure for fumigation:

- The windows should be sealed and formaldehyde should be generated either by boiling a solution of formalin 40% or by adding it to potassium permanganate, in a metal vessel on the floor, since heat is also generated. The door is than closed and sealed.

- For a 10 x 10 x 10 ft room - 150 gm potassium permanganate and 280 ml of formalin are used

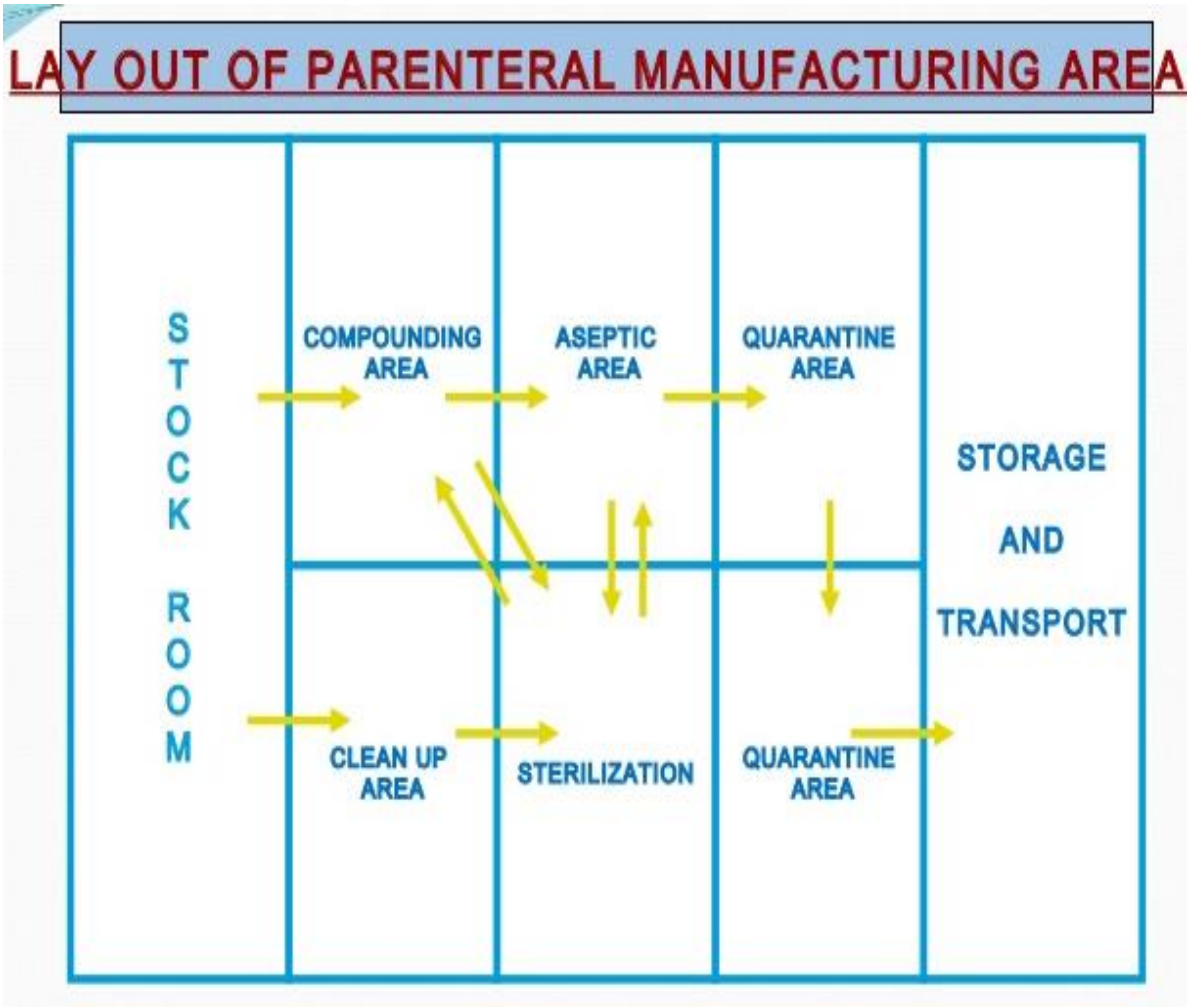
PARENTERAL DRUGS (LVP, SVP)

A Parenteral Drug (LVP, SVP) is defined as one intended for injection through the skin or other external boundary tissue, rather than through the alimentary canal, so that active substances they contain are administered, using gravity or force, directly into a blood vessel, organ, tissue, or lesion. They are infused when administered intravenously (IV), or injected when administered intramuscularly (IM), or subcutaneously into the human body.

A large volume parenteral (LVP) is a unit dose container of greater than 100ml that is terminally sterilized by heat. Small volume parenteral (SVP) is a single or multiple dose container of less than or equal to 100ml that are produced under asceptic filling or terminally sterilized.

Requirements of sterile manufacturing :

- Clean- up area.
- Preparation area
- Aseptic area
- Quarantine area
- Finishing and packaging area



Evalution of parenteral preparation:

The finished parenteral products are subjected to the following test, in order to maintain quality control

1) Sterility test
2) Clarity test
3) Leakage test
4) Pyrogen test

NON STERILE MANUFACTURE

Non-sterile compounding involves creating a medication in a clean environment but does not require the environment to be completely free from all microorganisms. Non-sterile products are those in which the presence of microbial charge is conceptually admitted, although limited, taking into account the characteristics of its use, as is the case of topical and oral cosmetic and pharmaceutical products, which come into contact with areas bearing natural microbial flora. Examples for non sterile products,

- Tablets
- Capsules
- Powders
- Semisolids etc

Stock solutions are prepared in advance to meet the requirements of both inpatient & out patient wards. A stock solution is a concentrated solution that will be diluted to some lower concentration for actual use. Stock solutions are used to save preparation time, conserve materials, reduce storage space, and improve the accuracy with which working lower concentration solutions are prepared.