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Sterilization refers to any process that eliminates, removes, kills, or deactivates all forms of life (in particular referring to microorganisms such as fungi, bacteria, viruses, spores, unicellular eukaryotic organisms such as Plasmodium, etc.) and other biological agents like prions present in a specific surface, object or fluid, for example food or biological culture media. Sterilization can be achieved through various means, including heat, chemicals, irradiation, high pressure, and filtration. Sterilization is distinct from disinfection, sanitization, and pasteurization, in that those methods reduce rather than eliminate all forms of life and biological agents present. After sterilization, an object is referred to as being sterile or aseptic.

1. Sterilization is an essential stage in the processing of any product destined for administration, or for contact with broken skin because sterilization stages involve application of biocidal agent or physical microbial removal process to a product with the object of removing all microorganisms. The process depends on a suitable choice of treatment conditions. The articles to be sterilized they is a potential risk of product damage, which for the pharmaceutical preparation may result to reducing

therapeutic efficacy, stability or patient acceptability. With terminal methods of sterilization of a parenteral product, particularly steam under pressure, a probability of no more than one nonsterile unit in a million (10-6) is readily achievable. Even greater levels of assurance can be achieved with current technology.

2. Discuss the importance of sterilization in the production of pharmaceutical products.

- Moist heat sterilization is the most efficient biocidal agent. In the pharmaceutical industry it is used for: Surgical dressings, Sheets, Surgical and diagnostic equipment, Containers, Closures, Aqueous injections, Ophthalmic preparations and Irrigation fluids etc.

- Dry heat sterilization can only be used for thermostable, moisture sensitive or moisture impermeable pharmaceutical and medicinal. These include products like; Dry powdered drugs, Suspensions of drug in no aqueous solvents, Oils, fats, waxes, soft hard paraffin, silicone, Oily injections, implants, ophthalmic ointments and ointment bases etc.

- Gaseous sterilization is used for sterilizing thermolabile substances like; hormones, proteins,

various heat sensitive drugs etc.

- U.V light is perhaps the most lethal component in ordinary sunlight used in sanitation of garments or utensils.

- Gamma-rays from Cobalt 60 are used to sterilize antibiotic, hormones, sutures, plastics and catheters etc.

- Filtration sterilizations are used in the treatment of heat sensitive injections and ophthalmic solutions, biological products, air and other gases for supply to aseptic areas. They are also used in industry as part of the venting systems on fermenters, centrifuges, autoclaves and freeze driers. Membrane filters are used for sterility testing.

3. Explain gaseous sterilization, its sterilizer design, and operation.

- Gaseous Sterilization method: The chemically reactive gases such as formaldehyde, (methanol, H.CHO) and ethylene oxide (CH2)2O possess biocidal activity. Ethylene oxide is a colorless, odorless, and flammable gas. The mechanism of antimicrobial action of the two gases is assumed to be through

alkylation of sulfhydryl, amino, hydroxyl and carboxyl groups on proteins and amino groups of nucleic acids. The concentration ranges (weight of gas per unit chamber volume) are usually in range of 800-1200 mg/L for ethylene oxide and 15-100 mg/L for formaldehyde with operating temperatures of 45-63°C and 70-75°C respectively. Both of these gases being alkylating agents are potentially mutagenic and carcinogenic. They also produce acute toxicity including irritation of the skin, conjunctiva and nasal mucosa.

A. Ethylene oxide sterilizer: An ethylene oxide sterilizer consists of a chamber of 100-300-Litre capacity and surrounded by a water jacket. Air is removed from sterilizer by evacuation, humidification and conditioning of the load is done by passing sub-atmospheric pressure steam, then evacuation is done again and preheated vaporized ethylene oxide is passed. After treatment, the gases are evacuated either directly to the outside atmosphere or through a special exhaust system. Ethylene oxide gas has been used widely to process heat-sensitive devices, but the aeration times needed at the end of the cycle to eliminate the gas made this method slow.

B. Low temperature steam formaldehyde (LTSF) sterilizer: An LTSF sterilizer operates with sub atmospheric pressure steam. At first, air is removed by evacuation and steam is admitted to the chamber.

Sterilizer designs and operation

An ethylene oxide sterilizer consist of a leak proof and explosion proof steal chamber normally of 100-300 liter capacity.

- The chamber temperature is maintained by a thermostatically controlled water jacket and steam and condensate is removed and drain channel evacuated condenser
- At the end of the treatment period formaldehyde vapor is expelled by steam flushing and the bad is dried by alternating stages of evacuation and admission of sterile filtered air.
- A LTSF sterilizer is designed to operate with sub atmospheric pressure steam.
- Air is removed by evacuation and steam is admitted to the chamber to allow heating of the load and to assist in air removal
- The sterilization period starts with the release of formaldehyde by vaporization from formalin
- After treatment, the gases are evacuated either directly to the outside atmosphere or through the special exhaust system
- Filtered sterile air is then admitted either for a repeat of the vacuum or for air purging until the chamber is opened
- In this way safe removal of the ethylene oxide is

achieved reducing the toxic hazards to the operator

- Forced gas circulation is often employed to minimize variations in conditions throughout the sterilizer chamber
- Absorption of the ethylene oxide by the load is enhanced by the introduction of excess gas at the beginning or by the addition of more gas as the pressure drops during the sterilization process
- This can be surrounded by a hot water jacket to provide uniform chamber temperature
- Successful operation of the sterilizer requires removal of air from the chamber by evaporation, humidification and conditioning of the load by passage of sub atmospheric pressure steam.

4. What is radiation sterilization?

Radiation sterilization: This method involves exposing the packed materials to radiation (UV, X-rays, gamma rays) for sterilization. The main difference between different radiation types is their penetration and hence their effectiveness. UV rays have low penetration and thus are less effective, but it is relatively safe and can be used for small area sterilization. X-rays and gamma rays have far more penetrating power and thus are more effective for sterilization on a large scale. It is, however, more dangerous and thus needs special attention. UV irradiation is routinely used to sterilize the interiors of biological

safety cabinets between uses. X-rays are used for sterilizing large packages and pallet loads of medical devices. Gamma radiation is commonly used for sterilization of disposable medical equipment, such as syringes, needles, cannulas and IV sets, and food.