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**QUESTION;**

1. Sterilization is an essential stage in the processing of any product destined for parenteral administration or for contact with broken skin. Discuss?
2. Discuss the importance of sterilization in the production of Pharmaceutical products.
3. Explain Gaseous Sterilization, its Sterilizer design, and operation.
4. What is Radiation Sterilization?

**ANSWER;**

1. Sterilization is an essential stage in the processing of any product destined for parenteral administration, or for contact with broken skin, mucosal surfaces, or internal organs, where the threat of infection exists. In addition, the sterilization of microbiological materials, soiled dressings and other contaminated items is necessary to minimize the health hazard associated with these products.

Sterilization processes involve the application of a biocidal agent or physical microbial removal process to a product or preparation with the object of killing or removing all microorganisms. These processes may involve elevated temperature, reactive gas, irradiation or filtration through a microorganism-proof filter. The success of the process depends on a suitable choice of treatment conditions, e.g. temperature and duration of exposure. Thus, there is a need to achieve a balance between the maximum acceptable risk of failing to achieve sterility and the maximum level of product damage that is acceptable. This is best determined from a knowledge of the properties of the sterilizing agent, the properties of the product to be sterilized and the nature of the likely contaminants. A suitable sterilization process may then be selected to ensure maximum microbial kill/removal with minimum product deterioration.

1. 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. Pharmaceutical Importance of Sterilization;

* 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 non-aqueous solvents, Oils, fats, waxes, soft hard paraffin, silicone, Oily injections, implants, ophthalmic ointments and ointment bases etc.
* Gaseous sterilization is used for sterilizing thermo labile substances like hormones, proteins, various heat sensitive drugs etc.
* U.V lights are 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.

1. Gaseous sterilization is the treatment of objects or materials with a chemical in the gaseous or vapor state to destroy all microorganisms with which they have been contaminated. The need for such a method of sterilization has developed from the use of many items that cannot be subjected to heat, radiation, or liquid chemical sterilization. The most common gases used for sterilization include ethylene oxide (EO), ozone, mixed oxides of nitrogen, and chlorine dioxide. Ethylene oxide (also known as EO or EtO) is a low temperature gaseous process widely used to sterilize a variety of healthcare products, such as single-use medical devices. Through the use of a vacuum-based process, EO sterilization can efficiently penetrate surfaces of most medical devices and its lower temperature makes it an ideal process for a wide variety of materials

EO is suitable for the sterilization of a wide range of materials not compatible with other methods of sterilization. Products commonly processed with ethylene oxide include:

* Assembled complex devices
* Catheters
* Custom procedure packs
* Equipment with integrated electronics
* Multi-lumen tubing products
* Stents
* Wound care dressings.

1. Sterilization can be achieved using electromagnetic radiation, such as electron beams, X-rays, gamma rays, or irradiation by subatomic particles. Electromagnetic or particulate radiation can be energetic enough to ionize atoms or molecules (ionizing radiation), or less energetic (non-ionizing radiation). There are 2 general types of radiation used for sterilization, ionizing radiation and non-ionizing radiation. Ionizing radiation is the use of short wavelength, high-intensity radiation to destroy microorganisms. This radiation can come in the form of gamma or X-rays that react with DNA resulting in a damaged cell. Non-ionizing radiation uses longer wavelength and lower energy. As a result, non-ionizing radiation loses the ability to penetrate substances, and can only be used for sterilizing surfaces. The most common form of non-ionizing radiation is ultraviolet light, which is used in a variety of manners throughout industry.