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**QUESTION:** Sterilization is an essential stage in the processing of any product of destined for parental administration or for contact with broken skin. Discuss? Discuss the importance of sterilization in the production of pharmaceutical products. Explain Gaseous Sterilization. What is Radiation Sterilization

**Sterilization** is necessary for the complete destruction or removal of all microorganism including spore forming and non spore forming bacteria viruses and protozoa that could contaminate pharmaceutical or other materials and thereby constitute a health hazard. The delivery of sterile products for use in patient care depends not only on the effectiveness of the sterilization process but also on the unit design, decontamination, disassembling and packaging of the device, loading the sterilizer, monitoring, sterilant quality and quantity, and the appropriateness of the cycle for the load contents, and other aspects of device reprocessing.

The first step is Cleaning in which in decontamination is thorough cleaning of equipment which primarily is required to lower the bioburden before they are subjected to disinfection or sterilisation. Cleaning of dismantled equipment ensures there is no residue left on any of its parts by washing with cool water with an enzymatic cleaner and detergent. Those involved in cleaning equipment should use gloves to protect themselves from injuries and infection. Whenever feasible, complete protective clothes consisting of head gear, eyewear, mask, fluid repellent gown, and protective foot wear should be worn.

 **Chemical disinfection and sterilization**

This fast and technically easy to carry out method is suitable for equipment likely to get damaged by heat sterilization. Chemical sterilization is achieved by completely immersing equipment in disinfectant containing solution for varying period of time depending on the nature of the item to be disinfected or sterilised. The sterilant acts on the exposed surfaces of the item.

**The importance of sterilization in the production of pharmaceutical products**

Pharmaceutical Importance of Sterilization

1. 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.
2. 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 nonaqueous solvents, Oils, fats, waxes, soft hard paraffin, silicone, Oily injections, implants, ophthalmic ointments and ointment b Gaseous sterilization is used for sterilizing thermolabile substances like; hormones, proteins, various heat sensitive drugs etc.
3. U.V light is perhaps the most lethal component in ordinary sunlight used in sanitation of garments or utensils.
4. Gamma-rays from Cobalt 60 are used to sterilize antibiotic, hormo 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 , sutures, plastics and catheters etc.
5. 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 fermentors, centrifuges, autoclaves and ases etc.

**Gaseous Sterilization**

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 following advantages are noted: sterilization is at low temperatures thus avoiding damage to heat- and moisture-sensitive materials; objects or items can be terminally sterilized in their containers or packages; diffusion of some gaseous sterilants through containers of plastic, paper, or fabric eliminates problems of removal of sterilant; gaseous sterilants penetrate into areas not reached by liquids; sterilization by some gases takes place in the presence of large quantities of

The disadvantages are as follows: the length of time for sterilization and aeration is much greater than with other methods; the flammability of some gases requires special operating procedures; toxicity hazards exist with most sterilizing gases; chemical analyses are occasionally necessary to determine residues or addition products formed during sterilization of some organic materials corrosion or other forms of physical damage can occur from improper sterilizing procedures; and the cost of sterilization is much greater than with moist or dry heat. As a general rule, gaseous sterilization needs close control and supervision to insure effectiveness. All of the compounds most actively employed in gaseous sterilization are alkylating agents. Brief sketches of some of the properties and the necessary requisites for their use as gaseous sterilants are presented for five alkylating agents in their decreasing order of use: (a) Ethylene oxide: C2H40j b.p., 10.4°C.; flammability limits in air, 3.6 to 100 per cent by volume; requires dilution by inert gases, carbon dioxide, or chlorofluorohydrocarbons, for safe use; usual concentrations for sterilizing purposes, 400 to 1000 mg. per I.; requires relative humidity in the range of 25 to 50 per cent j has strong penetrating ability and moderate microbicidal propertiesj most versatile gas for sterilizing purposes. Other compounds which have microbicidal activity and which could be used in gaseous sterilization are epichlorohydrin, epibromohydrin, ethylene imine, ethylene sulfide, glycidaldehyde, propylene imine, chloropicrin, and ozone. Difficulty with commercial availability, increased toxicity, or lower microbicidal activity has prevented their practical development and use. Since most gaseous sterilization is carried out with ethylene oxide, this compound will be the focal point of this review.

**Radiation Sterilization**

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.

One industrial application of non-ionizing radiation is the breakdown of ozone (O3). By adding ozone to water, bacteria are unable to sustain life. Unfortunately, ozone also destroys process media.

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| Advantages: No degradation of media during sterilization, thus it can be used for thermally labile mediaLeaves no chemical residueAdministration of precise dosage and uniform dosage distributionImmediate availability of the media after sterilizationDisadvantages: This method is a more costly alternative to heat sterilizationRequires highly specialized equipment  |