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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?

1. **Importance of sterilization in parenteral products**

Sterilization, which is any process, physical or chemical, that destroys all forms of life, is used especially to destroy microorganisms, spores, and [viruses](https://www.britannica.com/science/virus). Parenteral routes, which does not involve the [gastrointestinal tract](https://www.britannica.com/science/gastrointestinal-tract), include injection into a [vein](https://www.britannica.com/science/vein-blood-vessel), injection under the skin, injection into a muscle, infusion through the [lungs](https://www.britannica.com/science/lung), and absorption through intact skin. Parenteral products are commonly sterilized after filling and sealing in the final containers and the process is called terminal sterilization.

Injections are sterilized by following methods:

* Moist heat sterilization
* Dry heat sterilization
* Filtration through bacteria proof filters
* Using aseptic techniques

Parenteral drug products are required to be free from three things—viable microorganisms, pyrogenic substances (which essentially means a low-level of bacterial endotoxin), and visible particulates. Terminal sterilization is the preferred method for drug products because, in this process, sterilization takes place after the product has been filled into the primary packaging. As a result of this, there is no further opportunity for contamination due to human intervention. As mentioned above, terminal sterilization with moist heat is recommended by all pharmacopeias, typically with heating to 121 °C at 15 psi for 15 minutes. Sterility assurance is of paramount importance in parenteral drug manufacturing. These products are administered directly into the bloodstream, bypassing the body’s natural defenses. Contamination of parenteral drug products, therefore, can have serious consequences on the patient.

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

Sterilization process of pharmaceutical products ensures sterilization of products in its final container. The aim of sterilization is to eradicate all form of live microorganism from a substance. This procedure done particularly for the articles have direct application on human or animals. Hence, it is imperative to preserve a substance for a long time without decay. If not sterilized, then microbes can cause infection. It is an important process as it ensures the product remains sterile.

1. **Explain gaseous sterilization**.

Gaseous sterilization is sterilization by means of a bactericidal gas, frequently used for items that are heat and moisture sensitive. Ethylene oxide is the gas most often used; it is highly explosive and flammable in the presence of air, but these hazards are reduced by diluting it with carbon dioxide or fluorinated hydrocarbons. Gaseous sterilization is a chemical process resulting from reaction of chemical groups in the bacterial cell with the gas. Factors influencing gas sterilization include time of exposure, gas concentration, penetration of the gas, and temperature and humidity in the sterilizing chamber. The chemically reactive gases ethylene oxide and formaldehyde possess broad spectrum biocidal activity, and have found application in the sterilization of reusable surgical instruments, certain medical, diagnostic and electrical equipment, and the surface sterilization of powders.

* **Sterilizer design and operation of ethylene oxide**: An ethylene oxide sterilizer consists of a leak-proof and explosion-proof steel chamber, normally of 100–300 L capacity, which can be surrounded by a hot-water jacket to provide a uniform chamber temperature. Successful operation of the sterilizer requires removal of air from the chamber by evacuation, humidification and conditioning of the load by passage of sub atmospheric-pressure steam followed by a further evacuation period and the admission of preheated vaporized ethylene oxide from external pressurized canisters or single-charge cartridges. Forced gas circulation is often employed to minimize variations in conditions throughout the sterilizer chamber. Packaging materials must be air, steam-and gas-permeable to permit suitable conditions for sterilization to be achieved within individual articles in the load. Absorption of ethylene oxide by the load is compensated for by the introduction of excess gas at the beginning or by the addition of more gas as the pressure drops during the sterilization process. The same may also be true for moisture absorption, which is compensated for by supplementary addition of water to maintain appropriate relative humidity. After treatment, the gases are evacuated either directly to the outside atmosphere or through a special exhaust system. Filtered, sterile air is then admitted either for a repeat of the vacuum/air cycle or for air purging until the chamber is opened. In this way, safe removal of the ethylene oxide is achieved, reducing the toxic hazard to the operator. Sterilized articles are removed directly from the chamber and arranged for desorption. The operation of an ethylene oxide sterilizer should be monitored and controlled automatically.
* **Sterilizer design and operation of formaldehyde:** An 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 (in a vaporizer with a steam jacket) and continues through either a simple holding stage or through a series of pulsed evacuations and steam and formaldehyde admission cycles. The chamber temperature is maintained by a thermostatically controlled water jacket, and steam and condensate are removed via a drain channel and an evacuated condenser. At the end of the treatment period formaldehyde vapor is expelled by steam flushing and the load is dried by alternating stages of evacuation and admission of sterile, filtered air.

1. **What is radiation sterilization**

Radiation sterilization is a type of sterilization that relies on ionizing radiation, primarily gamma, X-ray or electron radiation, to deactivate microorganisms such as bacteria, fungi, viruses and spores. Due to numerous advantages over heat or chemical based sterilization techniques, this method is particularly attractive in medicine and healthcare-related fields. For example, radiation sterilization is readily applied during tissue allograft preparation, pharmaceutical packaging and medical device manufacturing.