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**Questions**

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?

**Answers**

1. **–** Since **sterilization** describes a process that destroys or eliminates all forms of microbial life and is carried out by physical or chemical methods, therefore, sterilization is essential 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 in order to minimize health hazards (such as burns to the skin, reddish skin, and terrible reactions that could worsen the situation of the individual using unsterile product)
* Products designed for contact with broken skin should be sterilized properly if not, a major risk of all such procedures will lead to the introduction of pathogens which can then cause infections.
* Sterilization is suitable for supplies and items; in contact with broken skin or mucous membrane, that penetrates the skin or enters sterile body areas, contaminated with readily transmittable organisms and medium to high infection risk.
* 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. It must be remembered, however, that with all articles to be sterilized there is a potential risk of product damage, which for a pharmaceutical preparation may result in reduced therapeutic efficacy, stability or patient acceptability. 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. It is important to sterilize in the production of pharmaceutical products. The importance is stated below;
* Sterilization provides an environment free from living microorganisms.
* It prevents the growth of disease.
* It prevents the spread of disease.
* Prevents the loss of Productivity.
* Moist heat sterilization is the most efficient biocidal agent. In pharmaceutical industry, it is used for surgical dressings, containers, closures, aqueous injections, ophthalmic preparations and irrigation fluids etc
* Dry heat sterilization can only be used for thermo stable, moisture sensitive or moisture impermeable pharmaceutical and medicinal. These include products like; dry powdered drugs, suspensions of drugs in non-aqueous solvents, oils, fats waxes, soft hard paraffin silicone, oily injections, implants, ophthalmic ointments and ointment bases etc.
* Gamma-rays from Cobalt 60 are used to sterilize antibiotics, hormones, sutures, plastics and catheters 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.
1. **Gaseous Sterilization is the treatment of objects or materials with a chemical in the gaseous or vapor state to destroy all micro organisms with which they have been contaminated.** Gaseous sterilization is used for sterilizing thermolabile substances like; hormones, proteins, various heat sensitive drugs etc. 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.

**Ethylene oxide**: used in the sterilization of heat sensitive materials. In air, this gas is highly flammable, and in practice it is mixed with 90% carbon dioxide to prevent it from igniting.It needs appropriate aeration after sterilization to avoid toxicity to the user and other handler.

•Its cost and the problem of its flammability preclude its more widespread use.

**Sterilizer design** **and Operation**

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.

**Formaldehyde:** This gas is produced by heating formalin (37% w/v aqueous solution of formaldehyde) to a temperature of 70–75 °C with steam, leading to the process known as LTSF. Formaldehyde has a similar toxicity to ethylene oxide and although absorption to materials appears to be lower, similar desorption routines are recommended. A major disadvantage of formaldehyde is low penetrating power, and this limits the packaging materials that can be employed to principally paper and cotton fabric.

•Formaldehyde mixed with sub-atmospheric steam can also be used as an sterilant gas.

**Sterilizer design and Operation**

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 generally applied to articles in dry states; including surgical instruments, sutures, prostheses, unit dose ointments, plastics syringes and dry pharmaceutical products.

**Types**:

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 while 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.

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