Sterilization

Lecture (2)

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Sterilization by filtration:

- **Definition:**

Filtration process consists of the passage of a liquid/gas through a screen like material with pores small enough to retain microorganism. It is capable of preventing the passage of both viable and non viable particles.

Applications

- Solutions containing heat-sensitive substances.
- biological products (blood and animal products, vaccines)
- Separation of bacteria from their toxins and enzymes.
- Air and other gases for supply to aseptic areas.

Advantages

- Non-thermal process so suitable for thermolabile medicaments
- Both dead and living organisms can be removed

Disadvantages

- Strict aseptic techniques need to be observed (sterile equipments and sterile atmosphere).
- Used only for liquids.
- Viruses cannot be removed because of their smaller size
- Adsorption of medicament may occur to a lesser extent with some types of filters.

Types of filters

1. **Sintered ceramics :**

- Made from finely ground porcelain fused together to make porous mass.
- Reusable and sterilized by hot air oven or by autoclaving.
- Used for filtration of large volumes
- **Disadv.:**
  - ✓ Leaking is possible.
  - ✓ May adsorb some of the medicament to be filtered.
  - ✓ Difficult to clean.

2-Sintered glass:

- Made from high grade borosillicate glass.
- Reusable and sterilized by autoclaving.
- Used for filtration of small volumes
- **Adv:**

  - No leakage - Less medicament adsorption - Easily cleaned
- **Disadv:**

  - Filters clog rapidly - Slow flow rate

3- Fibrous pads:

- Composed of compressed asbestos blended with wood cellulose.
- One use and then discarded.
- Sterilized by autoclaving.
- **Adv:**

  - Clog less easily - suitable for viscous solutions.
- **Disadv:**

- Loose fibers may separate and contaminate the filtrate.
- Significant medicament adsorption may occur.

4. Membrane filters:

- Thin, strong and homogeneous filters made of cellulose acetate, cellulose nitrate, polycarbonate, and polyvinylidene fluoride, or other polymers.
- Today the method of choice for sterilization by filtration.
- Remove particles and microbes efficiently while retaining very little products.
- Disposable. Sterilized by cold sterilization.
- Use of a prefilter can avoid blocking of the membrane filter.
- **Adv:**
  - ✓ No danger of microbial leakage.
  - ✓ medicament adsorption is insignificant.
  - ✓ High flow rate.
  - ✓ Used in sterility testing

5. HEPA filters:

- Used for sterilization of gases.
- HEPA (High efficiency particulate air) filters can remove up to 99.97% of particles >0.3 micrometer in diameter.
- Air is first passed through prefilters to remove larger particles and then passed through HEPA filters.
- **Application:** laminar flow cabinet.

Sterilization by Radiation

Types of radiation used for sterilization:

1. Electromagnetic radiation (e.g. gamma rays and UV light)
2. Particulate radiation (e.g. accelerated electrons).

Mechanism of action

- The major target for these radiation is microbial DNA:

  Gamma rays and electrons cause ionization and free radical production.

  UV light causes excitation.

N.B. Excitation process is less damaging and less lethal than ionization, and so UV irradiation is not as efficient a sterilization method as electron or gamma-irradiation.

- Vegetative bacteria generally prove to be the most sensitive to irradiation followed by moulds and yeasts, with bacterial spores and viruses as the most resistant

Applications

- Ionizing radiation sterilization is generally applied to articles in the dry state; including surgical instruments, sutures, unit dose ointments, plastic syringes and dry pharmaceutical products.
- UV light, with its much lower energy, and poor penetrability finds uses in the sterilization of air, for surface sterilization of aseptic work areas, for improvement of bacteriological quality of water, but is not suitable for sterilization of pharmaceutical dosage forms.

Advantages:

- Useful method for the industrial sterilization of heat sensitive products.

Disadvantages:

- Undesirable changes can occur in irradiated preparations, e.g.:
  - ✓ Aqueous solution where radiolysis of water occurs.
  - ✓ Certain glass or plastic materials used for packaging or for medical devices can suffer damage.

Gaseous sterilization

Examples:

1. Formaldehyde
2. Ethylene oxide

Mechanism of action

- Alkylating agents causing alkylation of sulphydryl, amino, hydroxyl and carboxyl groups on proteins and amino groups of nucleic acids.

Applications

Have found application in the sterilization of:

- Re-usable surgical instruments.
- Certain medical, diagnostic and electrical equipment.
- Surface sterilization of powders.
- Disinfection of all or a part of building.

Advantages:

- Cold sterilization for heat sensitive products.

Disadvantages:

- Sterilize only exposed surfaces except objects made of porous or permeable materials.
- Being alkylating agents are potentially mutagenic and carcinogenic.
- They also produce acute toxicity including irritation of the skin, conjunctiva and nasal mucosa.

1. Ethylene oxide sterilizer

- An ethylene oxide sterilizer consists of a chamber surrounded by a water jacket.
- Air is removed from sterilizer by evacuation.
- 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.

2. Low temperature steam formaldehyde (LTSF) sterilizer

- Formaldehyde gas for use in sterilization 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.
- An LTSF sterilizer operates with sub atmospheric pressure steam. At first, air is removed by evacuation and formaldehyde steam is admitted to the chamber.
- The chamber temperature is maintained by a thermostatically controlled water-jacket, and steam and condensate are removed via a drain channel.

Liquid sterilization

Examples:

1. **Peracetic Acid liquid**
2. **Hydrogen Peroxide**