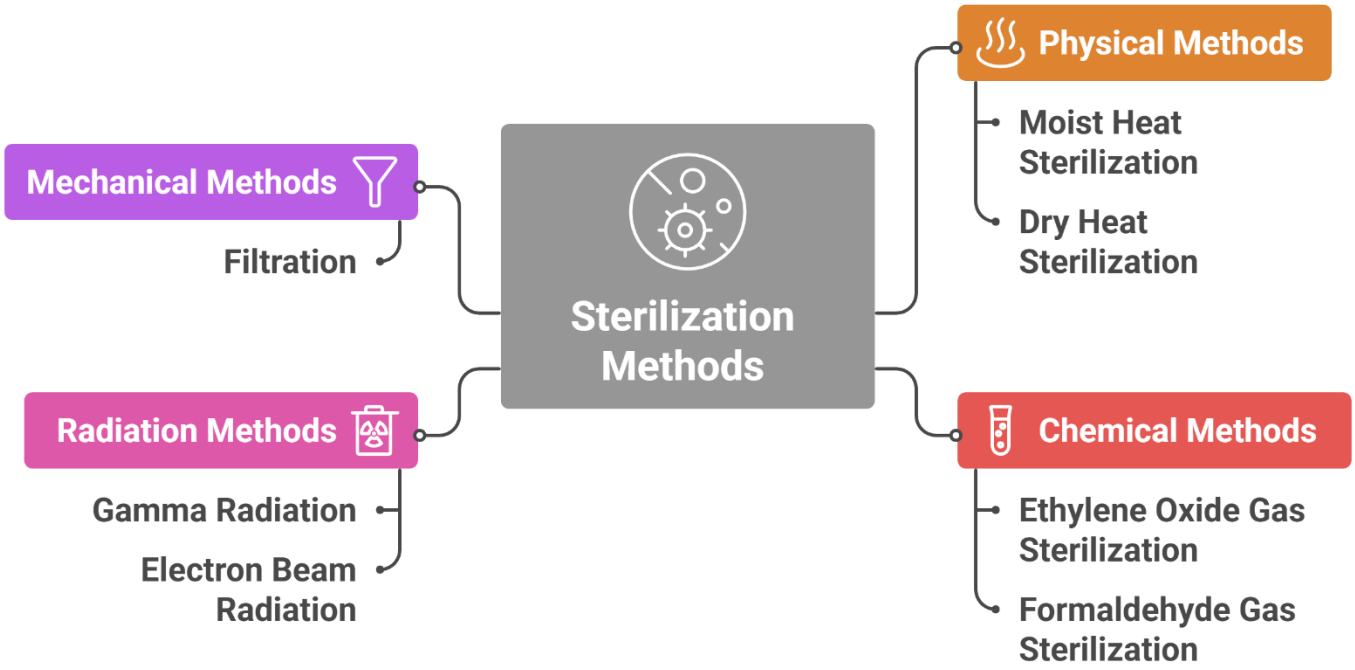
Different Methods of Sterilization

- Sterilization is the process of eliminating all forms of microbial life, including bacteria, viruses, fungi, and spores, from a surface, fluid, medication, or biological culture medium.
- In the pharmaceutical industry, sterilization is crucial to ensure the safety, efficacy, and stability of pharmaceutical products.
- Sterilization methods are broadly classified into:
    1. **Physical Methods**
    2. **Chemical Methods**
    3. **Radiation Methods**
    4. **Mechanical Methods**



Physical Methods of Sterilization

A. Moist Heat Sterilization (Autoclaving)

- **Principle**: Uses steam under pressure to kill microorganisms by denaturing their proteins.
- **Common Conditions**: 121°C at 15 psi for 15–20 minutes.
- **Equipment**: Autoclave.

Applications:

- Aqueous preparations
- Surgical instruments
- Culture media
- Dressings and linens

Merits:

- Efficient and reliable
- Penetrates porous materials
- Non-toxic
- Economical

Demerits:

- Not suitable for heat-sensitive materials
- May cause degradation of some products
- Requires proper packing for effective sterilization

B. Dry Heat Sterilization

- **Principle**: Destroys microorganisms by oxidation of cellular components.
- **Common Conditions**:
  - 160°C for 2 hours
  - 170°C for 1 hour
  - 180°C for 30 minutes
- **Equipment**: Hot air oven

Applications:

- Glassware
- Oily substances
- Powders
- Metal instruments

Merits:

- Suitable for moisture-sensitive materials
- No corrosion of instruments
- Simpler than autoclaves

Demerits:

- Requires higher temperatures and longer exposure time
- May not ensure uniform heating
- Not suitable for thermolabile (heat-sensitive) materials

Chemical Methods of Sterilization+

A. Ethylene Oxide (ETO) Gas Sterilization

- **Principle**: Alkylation of DNA and proteins in microorganisms, inhibiting their replication.
- **Conditions**: 30–60°C, 30–80% relative humidity, exposure time of 2–5 hours.

Applications:

- Heat-sensitive medical devices (e.g., plastics, catheters)
- Surgical instruments
- Electronics

Merits:

- Suitable for thermolabile materials
- Penetrates packaging materials
- Effective against all microorganisms including spores

Demerits:

- Toxic and potentially carcinogenic
- Long aeration time required to remove residual gas
- Expensive setup and operation
- Flammable (requires strict safety protocols)

B. Formaldehyde Gas Sterilization

- **Principle**: Alkylates amino and sulfhydryl groups of proteins and nucleic acids.
- **Conditions**: 70–75°C with 70% relative humidity

Applications:

- Fumigation of rooms and cabinets
- Heat-sensitive equipment

Merits:

- Effective at relatively low temperatures
- Good for room disinfection

Demerits:

- Irritating fumes; potential health hazards
- Carcinogenic
- Slow and may require long exposure

Radiation Sterilization

A. Gamma Radiation

- **Source**: Cobalt-60
- **Mechanism**: Causes ionization leading to DNA damage and microbial death

Applications:

- Disposable medical equipment (syringes, gloves)
- Pharmaceuticals (powders, ointments)
- Tissue grafts

Merits:

- Penetrates deep into materials
- Suitable for heat-sensitive products
- Pre-packaged materials can be sterilized

Demerits:

- Requires shielding due to radiation hazards
- Expensive setup
- May alter physical/chemical properties of some materials

B. Electron Beam (E-Beam) Radiation

- **Source**: Electron accelerators
- **Mechanism**: High-energy electrons disrupt microbial DNA

Applications:

- Similar to gamma radiation but suitable for surface sterilization
- Medical devices and packaging

Merits:

- Fast processing
- No radioactive materials used
- Lower penetration = better control for surface applications

Demerits:

- Limited penetration depth
- Expensive equipment

Filtration (Mechanical Method)

- **Principle**: Physically removes microorganisms using filters with pore sizes typically ≤0.22 µm.
- **Common Filters**: Cellulose acetate, nitrocellulose, polyvinylidene fluoride

Applications:

- Heat-sensitive liquid solutions (e.g., IV fluids, ophthalmic solutions, antibiotics, vaccines)
- Air filtration in cleanrooms

Merits:

- Suitable for thermolabile substances
- Immediate use after filtration
- No heat or chemicals involved

Demerits:

- Cannot remove viruses or pyrogens unless specialized filters are used
- Filter integrity must be verified
- Only applicable to liquids and gases (not solids)

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