

# WHAT IS STERILIZATION:




Sterilization can be defined as any process that effectively kills or eliminates transmissible agents (such as fungi, bacteria, viruses and prions) from a surface, equipment, foods, medications, or biological culture medium.

# METHODS OF STERILIZATION

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- The various methods of sterilization are:
- 1. **Physical Method**
  - a. Thermal (Heat) methods
  - b. Radiation method
  - c. Filtration method
- 2. **Chemical Method**
  - a. Gaseous method




| <b>Sl. No.</b> | <b>Physical Method of Sterilization</b> | <b>Instruments used</b> |
|----------------|---|-------------------------|
| 1              | Dry Heat                                | Oven                    |
| 2              | Moist Heat                              | Autoclave               |
| 3              | Radiation                               | Gamma-ray Chamber       |

# PHYSICAL METHODS:

## 1. HEAT STERILIZATION:


- Heat sterilization is the most widely used and reliable method of sterilization, involving destruction of enzymes and other essential cell constituents.
- This method of sterilization can be applied only to the THERMO STABLE PRODUCTS, but it can be used for MOISTURE-SENSITIVE MATERIALS.
  - i) Dry Heat (160-1800°C) Sterilization for thermo stable products
  - ii) moist heat (121-1340 °C) sterilization is used for moisture- resistant materials.

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- The efficiency with which heat is able to inactivate microorganisms is dependent upon
    - i) the degree of heat, the exposure time and
    - ii) the presence of water.
  - The action of heat will be due to induction of lethal chemical events mediated through the action of water and oxygen.
  - In the presence of water much lower temperature time exposures are required to kill microbe than in the absence of water.

# Dry Heat Sterilization

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- It employs higher temperatures in the range of **160-180°C** and requires exposures time up to 2 hours, depending upon the temperature employed.
- The benefit of dry heat includes **good penetrability** and **non-corrosive nature** which makes it applicable for **sterilizing glass wares and metal surgical instruments**. It is also used for **sterilizing non-aqueous thermo stable liquids and thermo stable powders**.

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- Dry heat destroys bacterial endotoxins (or pyrogens) which are difficult to eliminate by other means and this property makes it applicable for sterilizing glass bottles which are to be filled aseptically

# Moist Heat Sterilization

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- Moist heat sterilization involves the use of steam in the range of **121-134°C**. Steam under pressure is used to generate high temperature needed for sterilization. **Saturated steam acts as an effective sterilizing agent.**



## **HOT AIR OVEN**



**Close View**



**Open View**

# Autoclave

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- Autoclaves use **pressurized steam to destroy microorganisms**, and are the most dependable systems available for the decontamination of laboratory waste and the sterilization of laboratory glassware, media, and reagents. For efficient heat transfer, steam must flush the air out of the autoclave chamber.
- Generally the conditions employed are **Temperature upto 121-134°C for 15-20 min under 15 lbs pressure**, based on type of material used.

# Types of Autoclaves



Pressure Cooker Type



Common Laboratory Autoclave



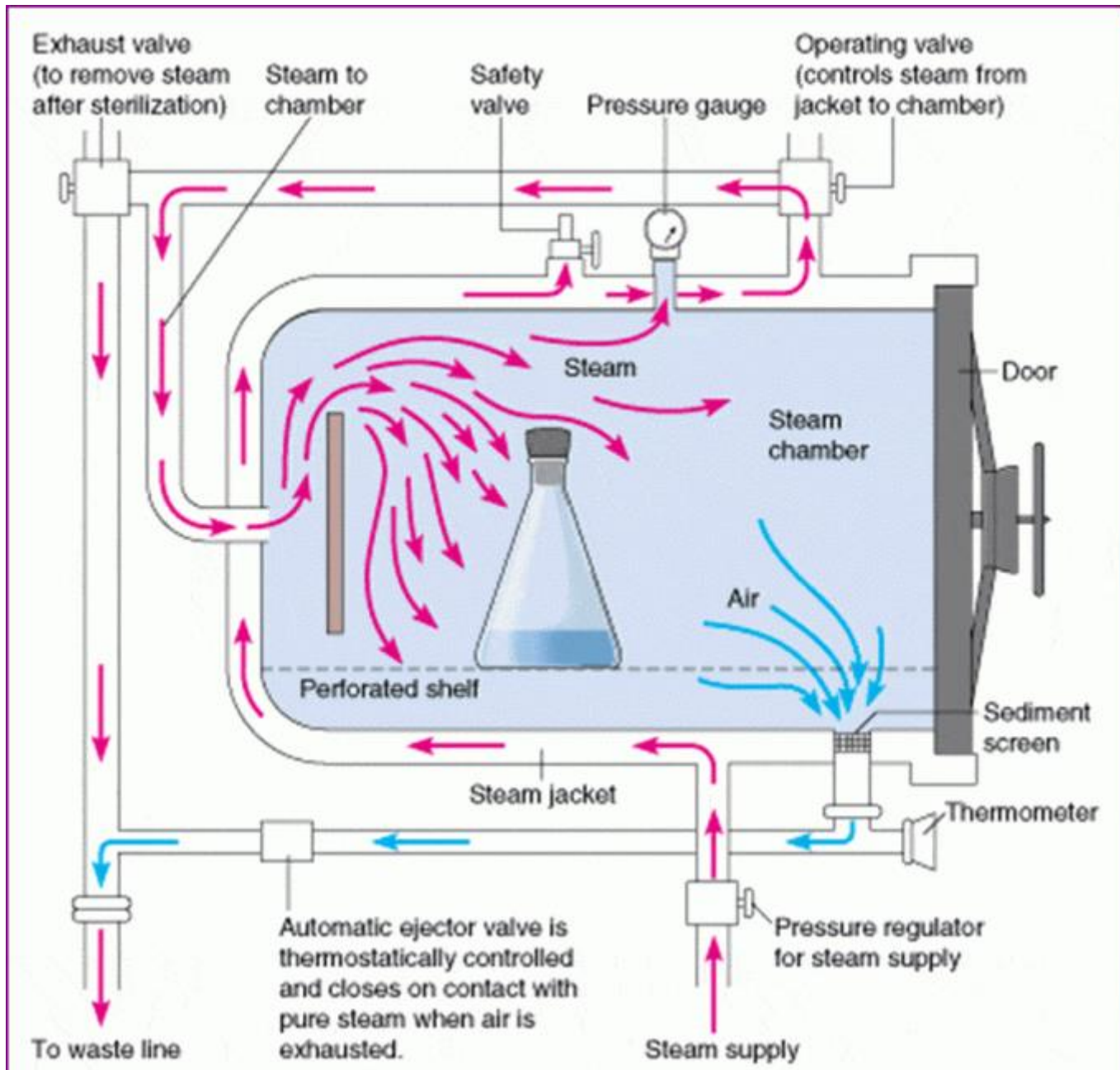
Vertical Autoclave



Horizontal Autoclave




Large Automatic Hospital Autoclave



# Radiation Sterilization

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- Many types of radiation are used for sterilization like electromagnetic radiation (e.g. gamma rays and UV light), particulate radiation (e.g. accelerated electrons). **The major target for these radiation is microbial DNA.**
- Radiation sterilization with high energy gamma rays or accelerated electrons has proven to be a useful method for the industrial sterilization of heat sensitive products.

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- Radiation sterilization is generally applied to articles in the dry state; including **surgical instruments, sutures, prostheses, 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 treatment of manufacturing grade water, but is **not suitable** for sterilization of pharmaceutical dosage forms.

# Filtration Sterilization

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- Filtration process does **not destroy but removes the microorganisms**. It is used for both the **clarification and sterilization of liquids and gases** as it is capable of preventing the **passage of both viable and non viable particles**.
- The major mechanisms of filtration are **sieving, adsorption and trapping within the matrix of the filter material**.
- **Ex:HEPA FILTERS**

# LAMINAR AIR FLOW CHAMBER







# LAMINAR AIR FLOW CHAMBER



LAFs use HEPA FILTERS for filtering bacteria, viruses and other microbes.


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- Sterilizing grade filters are used in the treatment of heat sensitive injections and ophthalmic solutions, biological products and 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 freeze driers. Membrane filters are used for sterility testing

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- There are **two types of filters** used in filtration sterilization:
    - (a) **Depth filters**:
    - (b) **Membrane filters**: These are porous membrane about 0.1 mm thick, made of cellulose acetate, cellulose nitrate, polycarbonate, and polyvinylidene fluoride, or some other synthetic material.

# CHEMICAL STERILIZATION METHOD

## GASEOUS METHOD

- The chemically reactive gases such as formaldehyde, (methanol, H.CHO) and ethylene oxide (CH<sub>2</sub>)<sub>2</sub>O possess biocidal activity. Ethylene oxide is a colorless, odorless, and flammable gas.
- The mechanism of antimicrobial action of the two gases is assumed to be through alkylations of sulphhydryl, amino, hydroxyl and carboxyl groups on proteins and amino groups of nucleic acids.

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- The concentration ranges (weight of gas per unit chamber volume) are usually in range of 800- 1200 mg/L for ethylene oxide and 15-100 mg/L for formaldehyde with **operating temperatures of 45-63 °C and 70-75 °C** respectively.
  - Both of these gases being alkylating agents are potentially mutagenic and carcinogenic. They also produce acute toxicity including irritation of the skin, conjunctiva and nasal mucosa

# MERITS/DEMERITS AND APPLICATION OF DIFFERENT STERILIZATION METHODS

| S.no | METHOD             | MECHANISM                      | MERITS  | DEMERITS  | APPLICATIONS   |
|------|--------------------|--------------------------------|---|---|--|
| 1    | Heat sterilization | Destroys bacterial endo toxins | Most widely used and reliable method of sterilization, involving destruction of enzymes and other essential cell constituents | Can be applied only to the thermo stable products | Dry heat is applicable for sterilizing glass wares and metal surgical instruments and moist heat is the most dependable method for decontamination of laboratory waste and the sterilization of laboratory glassware, media, and reagents. |

# MERITS/DEMERITS AND APPLICATION OF DIFFERENT STERILIZATION METHODS

| S.no | METHOD                  | MECHANISM                   | MERITS  | DEMERITS   | APPLICATIONS  |
|------|-------------------------|-----------------------------|---|--|---|
| 1    | Gaseous sterilization   | Alkylation                  | Penetrating ability of gases.   | Gases being alkylating agents are potentially mutagenic and carcinogenic.  | Ethylene oxide gas has been used widely to process heat-sensitive devices.  |
| 2    | Radiation sterilization | Ionization of nucleic acids | It is a useful method for the industrial sterilization of heat sensitive products | Undesirable changes occur in irradiated products, an example is aqueous solution where radiolysis of water occurs. | Radiation sterilization is generally applied to articles in the dry state; including surgical instruments, sutures, prostheses, unit dose ointments, plastics |


# MERITS/DEMERITS AND APPLICATION OF DIFFERENT STERILIZATION METHODS

| S.no | METHOD                   | MECHANISM                                       | MERITS  | DEMERITS   | APPLICATIONS  |
|------|--------------------------|---|---|--|---|
| 1    | Filtration sterilization | Does not destroy but removes the microorganisms | It is used for both the clarification and sterilization of liquids and gases as it is capable of preventing the passage of both viable and non viable particles | Does not differentiate between viable and non viable particles | This method is Sterilizing grade filters are used in the treatment of heat sensitive injections and ophthalmic solutions, biological products and air and other gases for supply to aseptic areas |



# Pharmaceutical Importance of Sterilization

- • 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.
- • 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 drug in non aqueous solvents, Oils, fats waxes, soft hard paraffin silicone, Oily injections, implants, ophthalmic ointments and ointment bases etc.
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- • 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.
  - • Gamma-rays from Cobalt 60 are used to sterilize antibiotic, hormones, sutures, plastics and catheters etc.

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- 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 freeze driers. Membrane filters are used for sterility testing.