



**SNS COLLEGE OF ALLIED HEALTH SCIENCES**

SNS Kalvi Nagar, Coimbatore - 35

Affiliated to Dr MGR Medical University, Chennai



**DEPARTMENT OF CARDIO PULMONARY PERFUSION CARE**  
**TECHNOLOGY**

**COURSE NAME : MICROBIOLOGY**

**TOPIC : ETHYLENE OXIDE STERILIZATION**



# INTRODUCTION

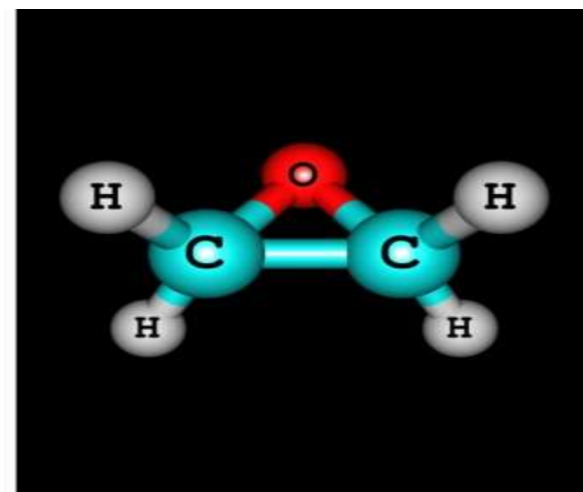
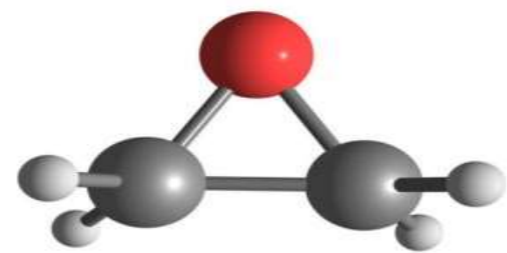


- Sterilization is a process which eliminates, removes or kills all form of microbial life including fungi, bacteria, viruses, etc.
- Various means of sterilization available are:
- Heat, Chemical, Radiation, Pressure and Filtration.
- **ETO sterilization** is one of the most widely used sterilization methods.
- It is a chemical form of sterilization and provides high efficiency with deep penetration power.
- Because of this ETO is preferred for sterilization of Medical and Pharmaceutical Products.



# ETO or Ethylene Oxide

- It is a colorless and flammable gas having a faintly sweet odor.
- The chemical structure of the compound has a strained ring that makes it participate quite readily in the addition reactions causing the ring (of the structure) to open.
- It kills the microorganisms - accumulated during the production or packaging process, also kills the spores.
- It is basically used to sterilize items that are heat or moisture sensitive and is suited for semi-industrial applications.





# Overview



- ETO is a colorless gas that is flammable and explosive.
- The four essential parameters (operational ranges) are:
  - Gas concentration (450 to 1200 mg/l);
  - Temperature (37 to 63°C);
  - Relative humidity (40 to 80%)
  - Water molecules carry ETO to reactive sites
  - Exposure time (1 to 6 hours).
- Two ETO gas mixtures are available to replace ETO-chlorofluorocarbon (CFC) mixtures for large capacity, tank-supplied sterilizers.
- The ETO-carbon dioxide (CO<sub>2</sub>) mixture consists of 8.5% ETO and 91.5% CO<sub>2</sub>.



# ETO Sterilization

- ETO Sterilization, also known as Ethylene Oxide Sterilization, is a chemical process done with the device called [ETO Sterilizer](#).
- The primary factors affecting this process include chemical concentration, humidity, temperature and time.
- ETO is used as a low-temperature sterilant.
- It is considered to provide sterilization as a result of alkylation of protein, DNA and RNA.
- This prevents cellular metabolism in microbial life and also prevents them from replicating.
- ETO gives more effective results by penetrating through most materials including plastics.





# Why and Where



- For industries like Pharmaceuticals, it has become essential to perform sterilization to avoid contamination.
- Even plastics and Electronics industries are praising this method.
- Other methods of sterilization available, for example, steam; is cost-effective but will damage sensitive materials like biological materials, fibre, electronics and plastics.
- For such materials, chemical sterilization methods are preferred which has high penetration power and gives no damage.
- Sterilization of tools and other materials in any medical procedure is very essential.
- As these materials are delicate ***ETO process*** is preferred.
- Similar usage of this process can be seen in different places including hospital, electronics industry, plastic industries, etc



## 5 stages of basic ETO sterilization cycle



- Preconditioning and humidification
- Gas introduction
- Exposure
- Evacuation
- Air washes
- Takes approximately 2 1/2 hrs excluding aeration time.
- Mechanical aeration for 8 to 12 hours at 50 to 60°C allows desorption of the toxic ETO residual contained in exposed absorbent materials.
- Most modern ETO sterilizers combine sterilization and aeration in the same chamber as a continuous process.



# 1. Preconditioning



- Like most other sterilization processes, *ETO sterilization process* starts with preconditioning of products that are to be sterilized.
- Preconditioning is usually done in a separate room or specially designed room for preconditioning.
- In this process, the product is heated and humidified at a stable/Controlled internal temperature and moisture.
- For the sterilizer stage, the system requires an accurate temperature control and pressure & vacuum control.
- The preconditioning step assures that the sterilization process is reproducible regardless of external atmospheric condition.
- After preconditioning, the product is placed in a heated chamber.





## 2.Initial Evacuation



- This step involves removal of most of the air from the chamber.
- It is done to ensure the safe use of **ethylene oxide** and hence safely deliver the results.
- Evacuation of air from the chamber is usually accomplished by performing deep pumping using a vacuum pump.



## 3.Humidification



- During the preconditioning step, the heat was applied to the product.
- This may lead to loss of a significant amount of moisture from the product.
- This loss of moisture can affect the final results hence it is necessary to provide additional moisture.
- The amount of moisture required is determined and the same is injected in form of steam injections.



## 4. Gas Injections



- The next step is an injection of ***ETO gas*** in the chamber.
- Since ETO is available in the liquid state, it has to be heated into gaseous state first, before injecting it into the chamber.
- This step involves a long and complex sterilization cycle and requires a system with:
  - Accurate temperature control
  - Reliable control systems
  - Advance reporting and warning systems
  - Shutdown strategies in critical conditions



## 5. Post-exposure Gas Purge:

- Once the gas injection process is complete, all gas from the chamber is removed.
- This is done because ETO is highly flammable, so to ensure safety the level of gas should be below the flammable limit.

- **6.Aeration:**

- Once the ETO sterilizer completes the sterilization, products are placed in a room with elevated temperatures.
- In this room, airborne residue gases are contained and removed continually.





# ETO Sterilization Process



- **1. Pre-Sterilization Phase**

- Involves the preparation of the medical device for sterilization.
- The device should be cleaned thoroughly.
- The device should also be packaged appropriately to prevent contamination during the sterilization process.

- **2. Sterilization Phase**

- Involves exposing the packaged device to a mixture of ETO and other gases.
- The device is typically placed in a sterilization chamber, where the ETO gas is introduced.
- Subsequently, the gas is circulated throughout the chamber, thereby guaranteeing that all components of the medical device are permeated.

- **3. Post-Sterilization Phase**

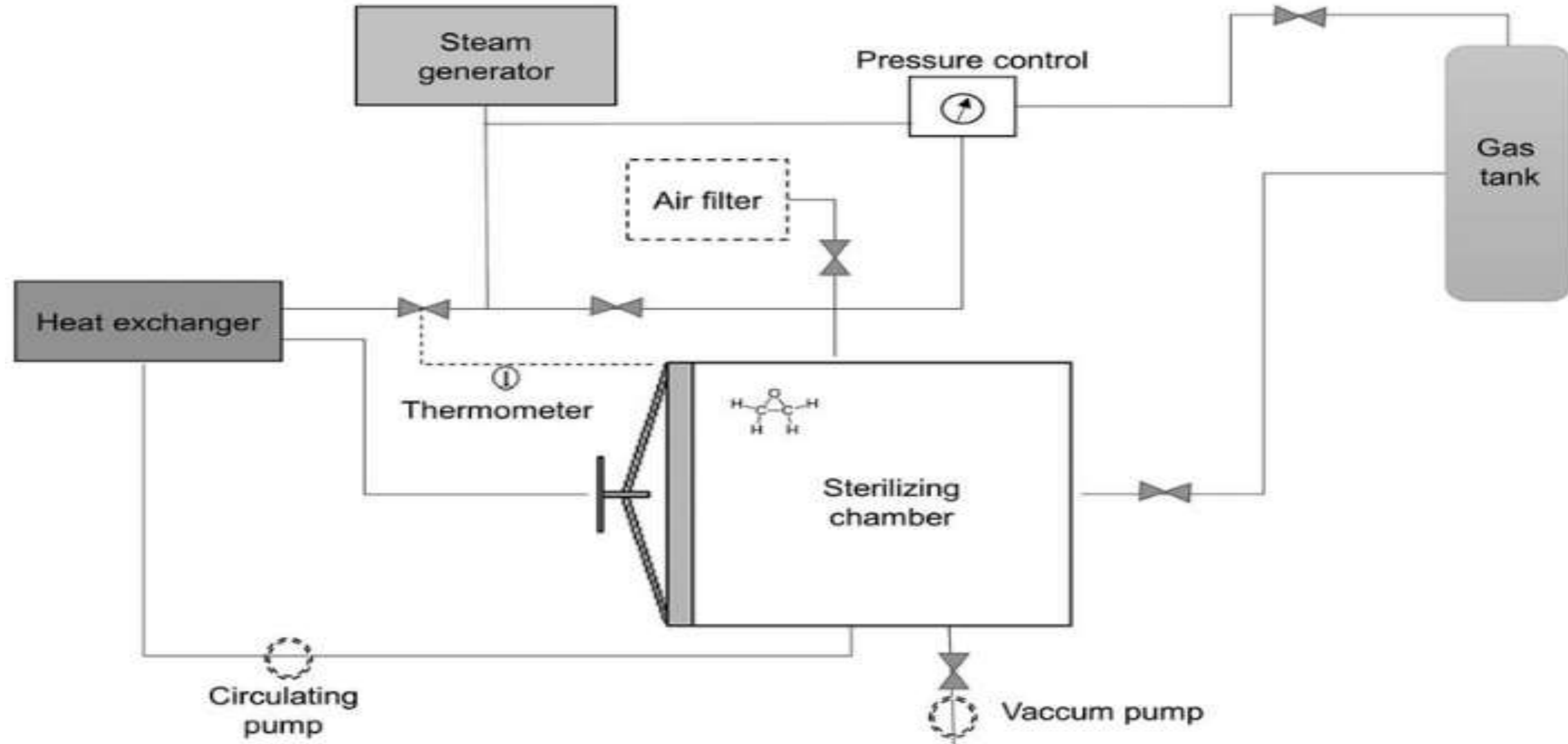
- After the sterilization process is complete, the device must be aerated to remove any residual ETO.



- **Aeration**

- The device is removed from the sterilizer and placed in a designated aeration area.
- The aeration unit is turned on, and the air is circulated around the device to remove any residual ETO.
  
- **Testing**
- The gadget is examined when the aeration procedure is finished to make sure there is no remaining ETO.
- The testing process may involve using specialized equipment to detect ETO levels.
  
- **Packaging and Labeling**
- After testing, the device is packaged and labelled appropriately.
- The packaging should be designed to maintain sterility until the device is used.

# ETO GAS STERILIZATION





# Exposure to ETO



- Can cause eye pain, sore throat, difficulty breathing and blurred vision.
- Also cause dizziness, nausea, headache, convulsions, blisters and vomiting and coughing.
- ETO has been linked to genetic damage, nerve damage, peripheral paralysis, muscle weakness, and impaired thinking and memory





- Acute exposure to ETO may result in irritation (e.g., to skin, eyes, gastrointestinal or respiratory tracts) and
- Central nervous system depression
- Chronic inhalation has been linked to the formation of cataracts, cognitive impairment, neurologic dysfunction, and disabling polyneuropathies.
- ETO should be considered a known human carcinogen.



## Mode of Action

- The microbicidal activity of ETO is considered to be the result of alkylation of protein, DNA, and RNA.
- Alkylation, or the replacement of a hydrogen atom with an alkyl group, within cells prevents normal cellular metabolism and replication.

### Microbicidal Activity

- ETO inactivates all microorganisms although bacterial spores (especially *B. atrophaeus*) are more resistant than other microorganisms.
- For this reason *B. atrophaeus* is the recommended biological indicator.



# Advantages



- It can sterilize heat- or moisture-sensitive medical equipment without deleterious effects on the material used in the medical devices
- This sterilization is carried out at low temperatures.
- Its non-corrosive nature makes it **preferable for sterilizing metal**, plastic and rubber.
- Its high penetration capacity makes it very efficient.
- Used to sterilize a large number of products.
- Highly effective in eliminating microorganisms on complex medical devices.
- Penetrate even the most inaccessible parts of the device, ensuring thorough sterilization.
- Can be performed at low temperatures, minimizing the risk of damage to the device.
- ETO sterilization is an essential sterilization method in the healthcare industry, providing effective sterilization for complex medical devices.



- Used in the pharmaceutical industry to sterilize products sensitive to moisture or heat.
- ETO is used in healthcare facilities to sterilize critical items (and sometimes semicritical items) that are moisture or heat sensitive and cannot be sterilized by steam sterilization.
- Ethylene oxide can penetrate multiple layers of breathable packaging, which makes it ***suitable for the sterilization*** of a wide range of materials:
  - Assembled complex devices
  - Catheters, Syringes
  - Saline bags, Stents
  - Multi-lumen tubing products
  - Products with integrated-electronics
  - Custom procedure packs





- The main disadvantages associated with ETO are the
- Lengthy cycle time
- Cost
- Its potential hazards to patients



# Challenges to be faced during ETO sterilization:



- The chemical used is harmful to humans, so the procedures should be carried out carefully.
- Flammable nature of ETO gas raises safety concerns.
- The time required for the sterilization process is high.
- Requires strict environment causes the overall cost to rise.



# Safety Precautions for ETO Sterilization



- ETO is a toxic gas that can pose health hazards to healthcare workers and patients.
- Strict safety precautions must be taken to ensure that the ETO sterilization process is performed safely.
- **Personal Protective Equipment (PPE)**
- Healthcare workers involved in the ETO sterilization process should wear appropriate PPE, including gloves, masks, and protective clothing.



# Assessment



1. What is the purpose of ETO Sterilization?
2. Steps involved in the process of ETO Sterilization”?
3. 5 advantages of ETO Sterilization”?
4. Which organisms is recommended for biological indicator?
5. When and where does it used?
6. What are the 4 parameters for ETO Sterilization?



# THANK YOU