SNS COLLEGE OF ALLIED HEALTH SCIENCES

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COURSE NAME : CLINICAL MICROBIOLOGY

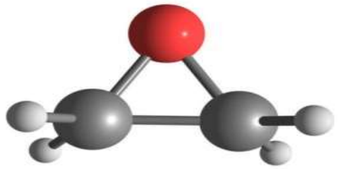
TOPIC : ETHYLENE OXIDE STERILIZATION

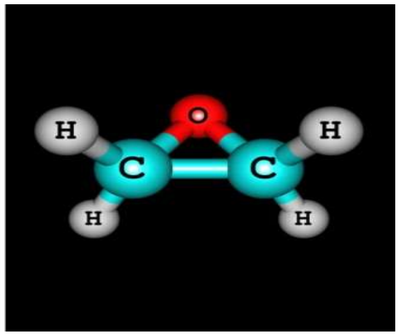
INTRODUCTION

- 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_2) mixture consists of 8.5% ETO and 91.5% CO_2.

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

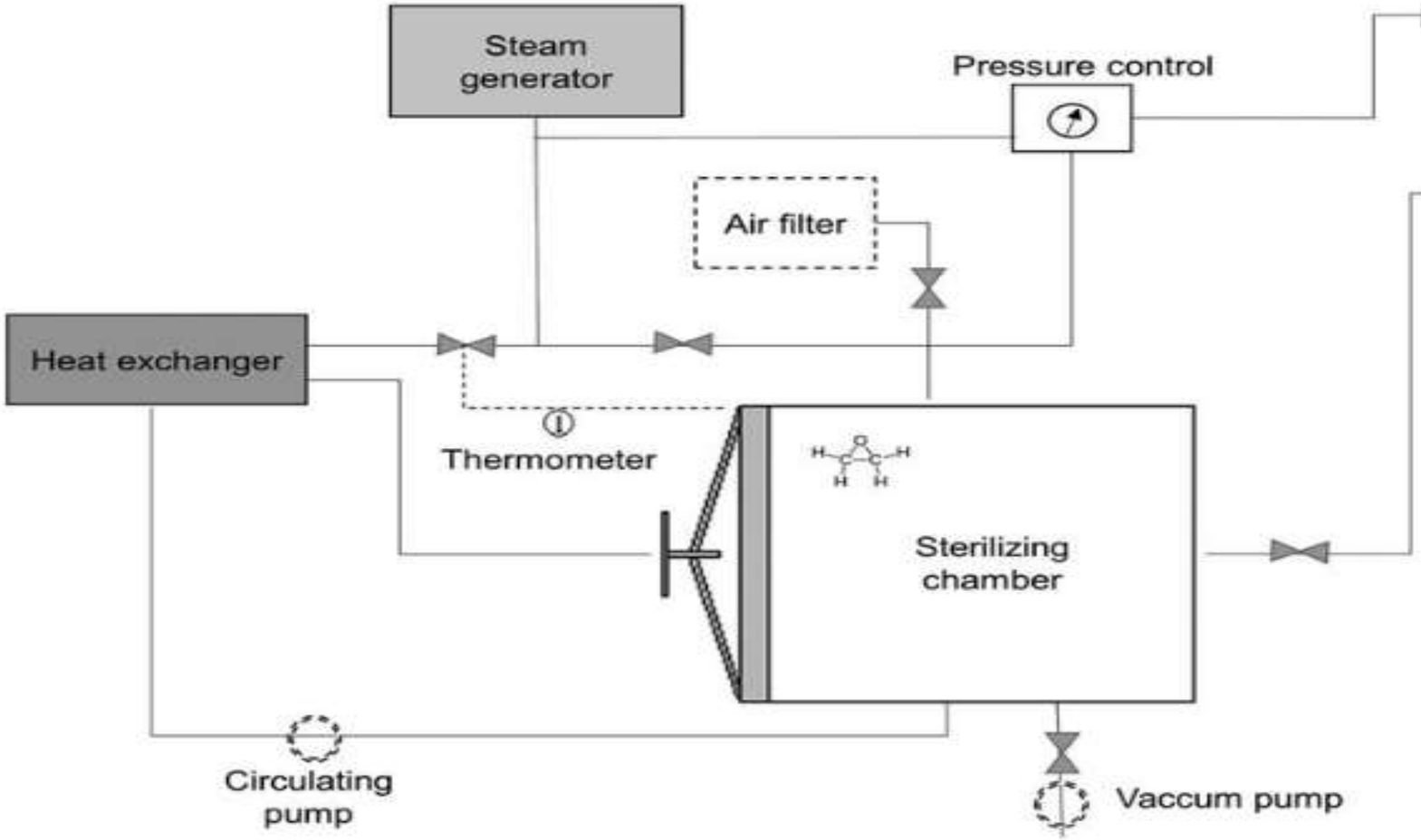
- **1. Pre-Sterilization Phase**
- Involves the preparation of the medical device for sterilization.
- The device should be cleaned thoroughly.
- The device should also be packaged appropriately to prevent contamination during the sterilization process.
- 2. **Sterilization Phase**
- Involves exposing 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