EO 101

Ethylene Oxide Sterilization

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What is Ethylene Oxide?

- A widely used gas for the sterilization of medical devices and instruments.
- Discovered in 1859
- In the 1940's developed as a sterilant.
- It is a colorless and odorless flammable gas.
- The biggest use of EO is in the manufacture of Ethylene Glycol.

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How does it work?

•Ethylene oxide is an alkylating agent that disrupts the DNA of microorganisms, which prevents them from reproducing.

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What is the process?

- Certain conditions must be met at the site of microbial inactivation on and within the product.
- This includes the proper combination of EO concentration, EO exposure time, relative humidity and temperature.

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Conventional EO Sterilization Process

- External Preconditioning
- Sterilization in the chamber
- External Aeration

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External Preconditioning

- Purpose
  - Hydrate spores to make them more susceptible to the lethal effects of EO.
  - Ensure uniformity of the product's relative humidity and temperature so that sterilizing activity is predictable.
- Process
  - Product is placed in a preconditioning room for a determined number of hours to raise the temperature and relative humidity of the load, prior to entering the sterilization chamber.

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Sterilization Cycle

- Purpose
  - To destroy bio burden, resulting in product with desired sterility assurance level. Ensure uniformity of the product's relative humidity and temperature so that sterilizing activity is predictable.
- Process
  - Product is placed in sterilization chamber where it is treated with EO gas in a series of stages under vacuum.
  - Temperature: 100-130 F (38 to 60 C). Every 10 C doubles inactivation rate.

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Cycle Sequence

- Initial Evacuation
- Humidity Injection
- Humidification (Conditioning) Dwell
- Gas (EO) Injection
- Gas (EO) Dwell
- Sterilant Evacuations with N2/Air Washes

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Sterilization Process

- Humidity
  - Water is needed for the alkylation reaction to disrupt cellular components and DNA.
  - A relative humidity of at least 35% is optimal.
  - Humidity also acts as a conduit to get EO through the packaging.
- Gas Concentration
  - Typically 400 – 650 mg/L
- Gas Dwell Time
  - Time range is product specific (2 – 12 hours).

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External Aeration (Degassing)

- Purpose
  - To allow dissipation of remaining gases, resulting in safe residue levels on the product.
- Process
  - Product is placed in aeration room for determined number of hours. Typical temperature is 100-115 F. Time varies with specific products and component materials.

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Benefits of EO Sterilization

- A tried and proven method of sterilization accepted throughout the industry and regulatory bodies.
- Effective for a wide range of product and packaging materials.
- Permeates through plastics and cardboard.

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Factors Affecting Cycle Success

- Bioburden
- Environmental conditions
- Product and package properties
- Loading configuration
- Cycle parameters

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- ISL's mission is to offer specialized, customer-focused Ethylene Oxide (EO) sterilization services to medical device companies.
- Our goal is to provide superior customer service and to help our customers achieve the most efficient and cost-effective means of EO sterilization in compliance with all applicable regulatory and statutory requirements.
- ISL is FDA registered, ISO 13485 certified, JPAL certified.