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Providing Sterilisation & Laboratory Services for the World's Most Innovative Healthcare Companies.

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Ethylene Oxide Residual Analysis - Medistri

🚀 Ethylene Oxide Residual Analysis

Ensuring patient safety is paramount when sterilizing medical devices. Among sterilization methods, ethylene oxide (EO) is widely used due to its compatibility with a broad range of materials. However, residuals such as ethylene oxide, ethylene chlorohydrin (ECH), and ethylene glycol (EG) can remain on the devices post-sterilization. These residues must be minimized to prevent harm during product use.

Ethylene oxide sterilization is a common method used for thermosensitive medical devices. The process involves exposing devices to EO gas, which effectively eliminates microorganisms without compromising material integrity. Despite its effectiveness, EO can interact with materials, leading to residual byproducts:

- **Ethylene Oxide (EO):** The sterilizing agent itself may remain as a residue.
- **Ethylene Chlorohydrin (ECH):** Formed when EO interacts with free chloride ions.
- **Ethylene Glycol (EG):** Created when EO reacts with water.

Residual EO, ECH, or EG can persist in medical devices for several reasons:

1. **Material Properties:** Certain materials, such as cellulose, cotton, or specific plastics, absorb and retain EO more than others.
2. **Packaging:** Breathable materials like Tyvek or medical-grade paper are essential for EO sterilization. Packaging with restricted airflow may hinder gas release.
3. **Load Characteristics:** The density, volume, and arrangement of products on a pallet can influence residual retention.

Conducting EO residual analysis ensures that these byproducts are reduced to safe levels, maintaining device safety and compliance with international standards.

The evaluation of ethylene oxide (EO) residues is governed by ISO 10993-7:2008, which outlines the permissible levels of residues based on how long a medical device is used, the methods for effectively extracting and testing these residues, and the stringent quality control measures required for analytical procedures.

At Medistri, our GMP-certified laboratory employs advanced gas chromatography (GC/FID) technology to precisely measure the presence of ethylene oxide, ethylene glycol, and ethylene chlorohydrin residues, ensuring accuracy and reliability in every analysis.

Medistri adheres to ISO 10993-7:2008 and ISO 17025 standards, ensuring our processes meet stringent quality requirements. Our in-house laboratory infrastructure is fully integrated with our sterilization services, streamlining workflows for our partners and enabling seamless product development.

Ethylene oxide sterilization is an invaluable method for ensuring the safety of medical devices. However, it’s essential to manage and minimize residual byproducts through robust analysis and compliance with international standards. At Medistri, our state-of-the-art facilities and integrated approach simplify your processes, helping you focus on innovation and growth while prioritizing patient safety.

🎯 To learn more about Medistri’s Ethylene Oxide Residual Analysis, visit on our website here or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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