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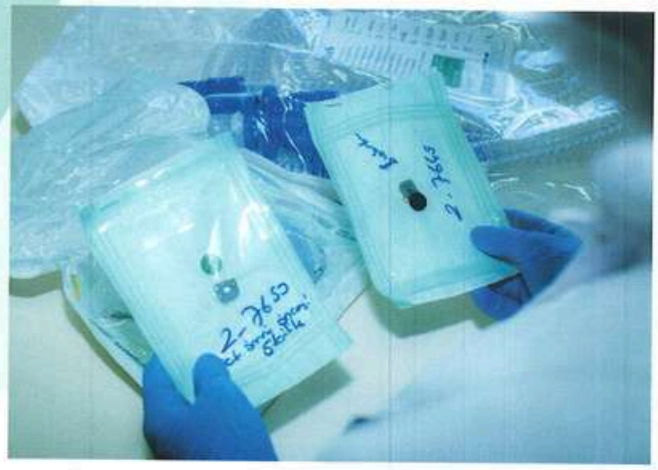
Medical Product Analyses

Ethylene Oxide Residue Test



Conducted to determine the amount of Ethylene Oxide residue on your products after sterilization with ethylene oxide.
ISO 10993-7
3 Days
Analyses to be conducted:
Ethylene Oxide (EtO)
Ethylene Chlorohydrin (EtCH)
Ethylene Glycol (EtG)

Cleaning Validation Tests
(Grease, Residue, and Detergent Residue Testing)

These tests are conducted to determine whether the cleaning validation of your products has been properly performed.
Analysis Duration: 3 Days

- **Analysis Methods:**
  Grease Test: SM 5520B
  Detergent Residue Test: ISO 2271

Leak Test

This test is conducted to verify the sealing integrity of product packaging.

- **Analysis Method: ASTM F 1929**
- **Analysis Duration: 2 Days**

Cleanroom Bio-contamination Tests

Cleanroom microbiological tests are conducted to ensure that the cleanrooms where your products are manufactured comply with the ISO 14698 standard for microbiological controls.

- **Air Microbial Counting: ISO 14698-1-2**
- **Personnel Hand Hygiene: ISO 14698-1-2**
- **Equipment Hygiene: ISO 14698-1-2**
- **Air Particle Counting: ISO 14644-1**
- **Analysis Duration: 7 Days**

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Bioburden Test (Biological Load Quantity Test)

- The Bioburden Validation is conducted to detect the biological bacterial load present on your products.
- Analysis Method: ISO 11737-1
- Analysis Duration: 7 Days

Tests to be Conducted:

- Aerobic Mesophilic Bacteria
- Anaerobic Mesophilic Bacteria
- Yeast and Mold

Sterility Test

The Sterility Test is conducted to verify the sterility of your products.

- Analysis Method: ISO 11737-2
- Analysis Duration: 14 Days
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Tests to be Conducted:

- Aerobic Mesophilic Bacteria / Anaerobic Mesophilic Bacteria
- Negative Control
- Positive Control

Stability Test

The Stability Test is conducted to verify that your products maintain their stability throughout the designated real-time shelf life.

Analysis Method: ASTM F 1980
Analysis Duration: Varies depending on the test temperature.

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