



CASE STUDY

VACUUM PUMP SOLUTIONS FOR ETHYLENE OXIDE STERILIZATION

PROJECT OVERVIEW

Ethylene oxide (EtO) and propylene oxide treatment methods have been used for decades throughout the pharmaceutical and low-moisture food industries to safely eliminate pathogens like salmonella and e. coli. In order to effectively remove pathogens from product, a rugged yet flexible vacuum solution is required to operate throughout the four critical factors of EtO sterilization: gas concentration, humidity, temperature, and time. Ethylene oxide gas is toxic, flammable, and carcinogenic in order to chemically attack the DNA of microorganisms.

INDUSTRY SIC CODES

2834 - Pharmaceutical Preparations

Key players in this market:

- Johnson & Johnson
- Novartis Pharmaceuticals Corp.
- Bristol-Myers Squibb Co.
- Abbvie Inc.
- Merck & Co. Inc.

87349906 - Industrial Sterilization Service

Key players in this market:

- Eestech, Inc.
- G3 Medical, Inc.
- Sterigenics U.S.

ETHYLENE OXIDE STERILIZATION

Ethylene oxide sterilization is highly effective but requires careful handling because of its hazardous nature. The EtO may be 100% concentrated or mixed with inert gas diluents such as Nitrogen or Carbon Dioxide, and the level of effectiveness depends upon the concentration, temperature, humidity, and exposure time. Similar to steam sterilization, the atmospheric air must be removed to ensure better penetration and contact with the microorganisms, while also reducing the air content below the EtO flammable limit of 3-100% in air.

This process normally requires the products be preconditioned in a controlled environment of temperature and humidity whether outside or inside the chamber. The chamber is then evacuated to approximately 1.5-2" Hg A. In some cases, evacuation of the air is followed by inert gas (normally Nitrogen) injections and re-evacuations to ensure air removal through dilution. A leakup test may also be performed to check chamber leak integrity before introduction of the EtO. Temperature and humidity are controlled depending upon the products being sterilized with maximum temperatures, normally less than 60°C. The gaseous phase EtO is injected into the chamber and is then removed through successive evacuation and aeration processes.

ETO STERILIZATION VACUUM SYSTEM

The typical vacuum system used in the sterilization process is a water-sealed liquid ring vacuum pump. Because EtO is completely miscible with water, it can dissolve in the sealant water during discharge and outgas during exposure to the pump suction, reducing the net pumping capacity at lower pressures. In some cases, a booster/liquid ring may be used to enhance the low pressure pumping capacity.

Kinney has designed and manufactured liquid ring, booster/liquid ring, and gas ejector/liquid ring vacuum systems for ethylene oxide sterilization applications with specialized materials of construction in order to meet the specific demands of these industries.