VALIDATION OF AN ETHYLENE OXIDE STERILIZATION CYCLE

Demonstration of the effectiveness of an ethylene oxide sterilization cycle is achieved through the validation process. Validation is the total process starting with commissioning, followed by performance qualification.

Commissioning demonstrates that the sterilization equipment intended for use will maintain operational specifications and will perform within the required parameters necessary to achieve sterilization of the specific product item. Process Qualification provides assurance by obtaining, documenting, and interpreting the results; thereby showing continued compliance to the predetermined specifications.

Most often, the validation of an EtO cycle follows the half-cycle or "over-kill" method using Biological Indicators (BI's) and product. This method demonstrates that the resistance of the microbiological challenge test system is equal to or greater than the product bioburden.

The appropriateness of the Biological Indicator (10^6 Bacillus atrophaeus) should be evaluated. This can be done by characterization of the natural bioburden and using this information to determine D-values; determining that the bioburden level is ≤100 CFU (colony forming units), indicating a lesser challenge than the BI; or, if characterization is not performed and the bioburden level is >100 CFU, by performance of a fractional exposure cycle using BI's and product, followed by testing for comparison of any positive response(s) yielded from the BI's vs. the product.

A half-cycle, the minimum exposure to ethylene oxide which yields no surviving microorganisms with all process parameters – except time – remaining the same, demonstrates a 6 log reduction. Two additional half-cycle experiments are performed as confirmation. A full cycle, providing a 12 log reduction (10^{-6}), is performed for product release purposes.

Continued assurance that the original indicated process parameters remain effective is shown through revalidation, usually performed on an annual basis. Typical revalidation is shown by performing one half-cycle and one full cycle, as well as a review of the original validation data and any subsequent revalidation records to confirm that no changes have taken place.

A schedule of routine bioburden testing monitors any changes in product components, environment, packaging, or manufacturing process that could have potential impact on the product bioburden and its resistance to the sterilization process

TESTING, TO BE CONSIDERED WHEN VALIDATING AN ETO STERILIZATION CYCLE, INCLUDES:

- Bioburden
- Bioburden Validation for Recovery Efficiency
- Test of Sterility
- Bacteriostasis-Fungistasis – Validation of a product test of sterility
- Ethylene Oxide Residuals
- Bacterial Endotoxin Test
- Inhibition Enhancement – Validation of the BET

References:

- ANSI/AAMI/ISO 11135--1: Sterilization of health care products– Ethylene oxide – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
- AAMI/ISO 14161: Sterilization of health care products – Biological Indicators – Guidance for the selection, use, and interpretation of results
- ANSI/AAMI/ISO 11737-1: Sterilization of health care products – Microbiological methods - Part 1: Determination of population of microorganisms on product
- ANSI/AAMI/ISO 11737-2: Sterilization of medical devices – Microbiological methods - Part 2: Tests of sterility performed in the validation of a sterilization process
- USP <1211> - Sterilization and Sterility Assurance of Compendial Articles

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