Sterilization Alternatives

Electron Beam Radiation

Electron beam (e-beam) radiation was introduced in the 1950s as a means of sterilizing single-use, disposable healthcare products. The process, however, was not widely accepted due to the unreliable nature of the e-beam equipment.

By the 1970s, advances in technology brought improved operating efficiency and e-beam irradiation became an acceptable method of sterilization for healthcare products.

Today, e-beam irradiation is the method of choice for processing products of high-volume/low-value, such as syringes, or low-volume/high-value, such as cardiothoracic devices.

The Nature of Electron-Beam Radiation

E-beam radiation is a form of ionizing energy that is generally characterized by its low penetration and high dosage rates. The beam, a concentrated, highly charged stream of electrons, is generated by the acceleration and conversion of electricity. The electrons are generated by equipment referred to as accelerators which are capable of producing beams that are either pulsed or continuous.

As the product/material being sterilized passes beneath or in front of the electron beam, energy from the electrons is absorbed. This absorption of energy alters various chemical and biological bonds within the product/material. The energy that is absorbed is referred to as the "absorbed dose." It is this absorption of energy—or "dose delivery"—that destroys the reproductive cells of microorganisms by destroying their DNA chains.

E-beam radiation is similar to gamma processing in that, upon contact with the exposed product, electrons alter various chemical and molecular bonds, including the reproductive cells of microorganisms.

High-Energy Beams for Reliable Penetration

While commercial e-beam accelerators range in energies from 3 MeV to 12 MeV (million electron volts) and usually operate at a single energy, advances in technology have resulted in the development of select e-beam equipment capable of operating at varying energies. For the sterilization of healthcare products, high-energy electron beams are typically required to achieve penetration of the product and packaging.

When evaluating e-beam irradiation for the purpose of sterilization, product density, size, orientation, and packaging must be considered. In general, e-beam irradiation performs best when used on low-density, uniformly packaged products.

Excellent Controls for Consistent Dose Delivery

E-beam sterilization requires the simultaneous control of the beam's current, scan width and energy, as well as the speed of the conveyor transporting the product through the beam. The speed of the conveyor is usually regulated with feedback circuitry from the beam current. If the beam current changes during processing, the conveyor speed correspondingly changes to ensure that the delivered dose is held constant.

Shorter Exposure Time for Favorable Material Compatibility

Most materials manufactured for use in sterile healthcare products are formulated for radiation stability. Although not formulated exclusively for gamma or e-beam sterilization, some materials have demonstrated less degradation when processed with e-beam radiation. This is due to a significant difference in dose rate between the two radiation technologies.

In general, products processed with e-beam radiation experience shorter exposure time, which could result in less oxidative effects on certain materials. Some polypropylene materials, for example, experience less breakdown and long-term aging effects from processing with accelerated electrons.

However, reports published by material experts with leading manufacturers of plastics and resins demonstrate that the vast majority of other materials commonly used in medical and packaging applications perform equally well, assuming treatment with the same dose of radiation.

Dosimetric Release = Immediate Product Release

It is possible to release e-beam-processed product immediately upon certification that the process was completed in conformance to specifications, without the need for conventional sterility testing. This release mechanism, known as dosimetric release, is based solely on the dosage of radiation delivered to the product and is accepted by the FDA (Food and Drug Administration). A description and outline of the process can be found in the American National Standard, ANSI/AAMI/ISO 11137-1994

Key Considerations

	Gamma Radiation	Electron Beam (E-beam)	Ethylene Oxide (EO)
Process Methodology	Continuous or batch	Continuous	Batch
Product Release	Dosimetric release (immediate, no post-sterilization testing is required).	Dosimetric release (immediate, no post-sterilization testing required).	Historically, BIs were required to verify sterility assurance level (SAL). Today, state-of-the-art Parametric Release enables significantly faster product release.
Penetration	Complete penetration	Complete penetration, dependent upon material thickness.	Complete penetration with the use of gas-permeable packaging.
Material Compatibility	Most materials are satisfactory. Considered somewhat incompatible with PVC, PTFE and Acetal.	Most materials are satisfactory.	Nearly all materials are compatible.
Residuals	None	None	Ethylene Chlorohydrin, requiring an aeration period following processing. With advanced CyclEOne technology, separate aeration is not required.

References

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