Irradiation of Fetal Bovine Serum

Guidelines on the Irradiation of Fetal Bovine Serum

Gamma irradiation is the most commonly used method for viral inactivation of fetal bovine serum (FBS) as a means of obtaining a safe but biologically active product.

High-energy photons are emitted from an isotope source that disrupts living cells by damaging DNA and other cellular structures, inactivating any potential microorganisms.

The ability to appropriately irradiate FBS depends on a number of complex factors including characteristics, design of the packaging, and volume of the FBS.

Gamma radiation of frozen FBS presents a unique challenge. Locating a dose measuring or dosimeter on the outside of the package container is not sufficient to determine how much radiation is received throughout the mass of the serum, only what was delivered to that location.

Many dose measuring or dosimetry methods are influenced by temperature making the placement of the measuring device next to frozen bovine serum inaccurate. In addition, the amount of exposure is influenced by the time of radiation exposure near the source, the distance from the radiation source, and amount of shielding created by the packaging and serum itself.

To overcome temperature and shielding issues, a reference dose mapping study is performed to demonstrate that a specified dose is received throughout the mass of the product while maintaining serum performance.

A routine dosimeter system is used to measure to reference dose and determine the reference ratio. The reference ratios are used during routine processing to calculate the dose range that must be delivered to the reference dosimeter to achieve required internal minimum and maximum dose for frozen FBS.

Peak Serum offers full capability to irradiate upon request and meet any specialized dosimeter requirement. We ensure all specifications set forth and are in compliance with EMEA guidelines for use in global markets.