January 2024

Purity One Quality Management System and Manufacturing Requirements:

Quality Management System

- Quality Management System meets the requirements of, and is certified to, ISO 13485:2016.
- Quality Management System complies with applicable sections of 21 CFR Part 820.

Cleanroom Certification

- Products are produced in a certified cleanroom meeting ISO 14644-1: 2015 Class 7 requirements.

Product Materials

- All product contact materials are USP Class VI and are made from and processed with materials that are free from animal-derived ingredients/products (ADI/APD) or meet the requirements of the CHMP Note for Guidance EMA/410/01/Rev 3.

Manufacturing Requirements

- Dose audits are performed quarterly on simulated product to ensure continued gamma irradiation compliance.
- Endotoxin and particulate testing are performed quarterly on simulated product to ensure production processes are in control. Endotoxins are tested per USP <85>. Particulates are tested in alignment with USP <788> and USP <790>.

Shelf Life and Storage Conditions

- Shelf life is from the date of manufacture to the date of expiration and is currently calculated at 2 years.
- Store the product in a dry inside environment with an ambient temperature below 77°F and humidity of less than 65%. The product should be free from exposure to direct sunlight. The area should be free from volatile solvents, corrosive gases, or other potentially harmful vapors.

195 Industrial Drive, Northampton, MA 01060
Ph: 413-320-4650