# Defining cleanliness parameters

It's easy to assume that the particular parameters used to define cleanliness are easily understood; however, with so many terms and complexities, they can quickly become ambiguous. While the main drivers behind selecting a particular product are often functions with definitions such as low-particulate and low-pyrogen, there are additional aspects that may require clarification. Does irradiating or autoclaving, for example, mean that a product is sterile?

What does steam or gamma sterilization achieve? Often there can be more than one answer to these queries and thus defining these terms is important for maintaining critical environments. Different applications will often require different processes in order to achieve the required levels of cleanliness.

| Process | Definition |
|---|---|
| Irradiation | The application of a dose of radiation in an attempt to destroy all viable forms of life, including bacterial spores. The typical radiation dose required to reach the desired sterility assurance level (SAL) of $10^{-6}$ is 25–40 kGy. Simply being "irradiated" is not a guarantee of sterility (see "Sterile" below). |
| Autoclaving | The application of steam, heat, and pressure in an attempt to destroy all viable forms of life, including bacterial spores. The amount of time, heat, and pressure can vary depending upon several factors. Simply being "autoclaved" is not a guarantee of sterility (see "Sterile" below). |
| Sterile | Sterilization involves the application of steam, heat, and pressure (autoclaving), irradiation (e.g., gamma radiation, electron beam), or chemicals (e.g., EtOH, $H_2O_2$) to destroy all viable forms of life, including bacterial spores, to an acceptable sterility assurance level (SAL) of $10^{-6}$ that has been fully validated. Validation generally includes a statistically significant sampling plan, multiple lots, and the use of validated equipment and processes. |
| Particulate cleaning | Water filtered to submicron levels (USP water or WFI, for example) is used for the particulate-cleaning process. Water is heated and used to "wash" items in multiple cycles. Materials are then dried and packaged, all in clean-room environments to keep particulates low. Simply being "particulate washed" is not a guarantee of sterility (see "USP <788>" below). |
| USP <788> | Compliance to USP <788> requires that either a product is produced in a clean environment or a product is particulate washed, such that you can achieve a validation of this low-particulate limit. Validation generally includes a statistically significant sampling plan, multiple lots, and the use of validated equipment and processes. |

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