



Sterility assurance level (SAL)

Sterility assurance level (SAL) is a term used in microbiology to describe the [probability](#) of a single unit being non-sterile after it has been subjected to the [sterilization](#) process. For example, medical device manufacturers design their sterilization processes for an extremely low SAL - "one in a million" devices should be nonsterile. **SAL** is also used to describe the killing efficacy of a sterilization process, where a very effective sterilization process has a very high SAL.

In microbiology it's impossible to prove that all organisms have been destroyed because: 1) they could be present but undetectable simply because they're not being incubated in their preferred environment and 2) they could be present but undetectable because their existence has never been discovered. Therefore SALs are used to describe the probability that a given sterilization process has destroyed all of the microorganisms.

SALs can be used to describe the microbial population that was destroyed by the sterilization process. Each [log](#) reduction (10^{-1}) represents a 90% reduction in microbial population. So a process shown to achieve a "6-log reduction" (10^{-6}) will reduce a population from a million organisms (10^6) to very close to zero, theoretically.

The sterility assurance levels of manufactured pharmaceuticals is controlled by using only sterile components both inside and out during aseptic processing. Compounded sterile products in many cases use the pharmaceutical products created in septic processing in the form of vials, ampoules and IV bags. The exterior of these items are not sterile and until the development of Advanced Aseptic Compounding by CTG had no way of effectively and repeatably decontaminating the surfaces of these components.

The Advanced Aseptic Compounding technology of the MIC-EDU provides a consistent and repeatable means of decontaminating of not only the components but also the interior surfaces of the MIC. The decontamination cycles developed for the MIC-EDU systems has been validated to a 6-log reduction of a known population of *Geobacillus stearothermophilus*. Each load uses chemical indicators to verify that VHP is present during decontamination of the MIC and it's contents.