Microbiological Methods for Testing the Sterility of Tattoo Inks

Sterility Testing

Tattoo inks contaminated with microorganisms can cause infections and lead to serious health injuries when introduced into the skin during a tattooing procedure, since there is an increased risk of infection any time the skin barrier is broken. To ensure the safety of tattoo inks, the FDA has communicated with the tattoo industry to make them aware of the expectation of sterility for tattoo inks. USP <71> “Sterility Tests” is the principal source used for sterility testing methods for the FDA. Equivalent methods such as European Pharmacopoeia 2.6.1 and Japanese Pharmacopoeia 4.06 are also used for sterility testing worldwide. For detailed information on the methods, please refer to the FDA Guidance for Industry Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/sterile-drug-products-produced-aseptic-processing-current-good-manufacturing-practice