

PURITY TESTING PROTOCOLS FOR SILICONE TUBING

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Silicone tubing products are widely used in critical biopharmaceutical processes including final fill and other aseptic operations that require high purity product contact components.

At Dow we have developed reliable and rigorous methods based on the industry standards for particulates, endotoxins and bioburden to test our Platinum-catalyzed silicone tubing family. The tests were conducted per the USP <788> Particulate Matter in Injection, the USP <85> Bacterial Endotoxins Test, and the ISO 11737-1 Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products.

- Method 2 Microscopic Particle Count Test of USP <788> was used to count particulates collected by extraction from the inner lumen of the tubing followed by membrane filtration: results indicate very low particulate counts well below the compliance limits of USP <788>.
- The gel clot method of USP <85> involved a LAL reagent with low sensitivity (< 0.125 EU/ml) and validated that the endotoxin level of the silicone tubing products is well below this limit.
- The bioburden method per ISO 11737-1 used to measure aerobic bacteria, yeast, molds and spores was validated with excellent recovery efficiency and correction factor. There were no microorganisms detected on the surface of any of the silicone tubing products tested by this rigorous method.

The results obtained demonstrates a high level in cleanliness, exceeding the industry standards, with respect to particulates, endotoxins and bioburden on the surface of the silicone tubing products tested.

This purity is driven by Dow's vertically integrated supply chain for silicone tubing that controls the sourcing of raw materials, and the clean formulation of elastomer involved in the manufacture of the tubing.