Endotoxin Testing Proves Extrusion Process Is Pyrogen-Free

Independent statistically significant test results by a leading laboratory have shown that Interface Extrusion extruded solely in a clean room environment is free of pyrogens. Results from three different methods of Limulus Amebocyte Lysate (LAL) testing for endotoxins indicatethe extrusion lines can be classified as “pyrogen free.” The implications of these test results are that catheter manufacturers may potentially eliminate cleaning steps in their own manufacturing process.
LAL chromogenic, turbidimetric, and gel clot analyses were performed by an independent ISO-9001 laboratory registered with the United States Food and Drug Administration (FDA) and the Drug Enforcement Agency. Multiple lots from three extrusion lines passed each method of testing.

Pyrogens are readily detected by Limulus Amebocyte Lysate (LAL) testing systems. The test was accepted by the FDA in 1983 as a standard test for endotoxins. The FDA later established guidelines for LAL testing of pharmaceuticals and medical devices in 1987. The LAL method is effective for measuring endotoxin levels in production processes, product releases, and water systems.

“For many manufacturers, independent testing of vendor tubing is required,” says Andre Noronha, director, medical extrusion for Interface Catheter Solutions. “Our customers count on us for endotoxin-free tubing, which is why we conduct our own rigorous outside testing. Endotoxin testing is necessary to confirm the safe manufacture and release of product. These latest results confirm Interface Catheter Solutions manufactures pyrogen-free tubing directly from our extrusion process and clean room facility, providing higher confidence in our extrusion capabilities for our customers.”

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