



Memorandum

SaniSure Bacterial Endotoxin and Particulate Testing Assurance Memo

SaniSure remains committed to providing our customers complete Quality assurances throughout our processes.

As part of our Bacterial Endotoxin Quality program, we monitor our procedures and products by routinely testing to the USP <85> Standard and has been found to consistently meet the criteria of ≤ 0.25 EU/mL.

This testing is carried out on a regular basis on a multitude of different products and completed assemblies. In addition we monitor our products for subvisible particulates using the validated and approved testing procedures specified in USP <788>. We consistently meet the Standard and the criteria for subvisible particulates.

SaniSure understands that these general guidelines are not always sufficient for some of our customers for their more stringent GMP projects. For these projects, we continue to offer individual lot by lot testing on specific assemblies per our customer's requirements at minimal additional charges.

Our Quality Management System meets the requirements of the Code of Federal Regulations (21 CFR, Parts 210 and 211).

In addition the SaniSure Quality Management Systems is certified to the ISO 9001:2015 Standard.