SaniSure®
Solution Based Innovation

Memorandum

SaniSure Standard Bioburden and Particulate Testing Assurance Memo

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

As part of our Bacterial and Endotoxin standards Quality program, we monitor our procedures and products by routinely testing to the USP 85 Standard and have 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 process and monitor for particulates using the validated and approved testing procedures specified in USP <788> and EP2.9.19. We consistently meet these Standards and the criteria for particulates.

SaniSure understands that these general guidelines are not always enough 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).

Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General; Current Good Manufacturing Practice for Finished Pharmaceuticals and ISO 9001:2008 Standard.