

WHAT ARE THE BENEFITS OF WASHED, READY TO STERILIZE VIAL STOPPERS FOR PHARMACEUTICAL CLIENTS?



Pre-Washed, CFU and BET Tested Vial Stoppers

QCVIALZ offers 13mm 20mm and 30mm vial stoppers that are pre-washed, then packaged into autoclave ready bags. CFU Bioburden and Endotoxin testing of our washed vial stoppers is then conducted by a US FDA and ISO 17025 certified facility in the USA. Once a batch of vial stoppers has been tested and approved, the RTS/RFS (Ready to Sterilize / Ready for Sterilization) vial stoppers are offered for sale with lot traceability and documented testing results for facilities that require cGMP documentation compliance.

Why is Bioburden Testing of vial stoppers important?

Bioburden Testing determines the number of colony forming units (CFU / microorganisms) present on a surface that has not yet been sterilized (autoclave sterilization, Ethylene Oxide, gamma-irradiation, etc).

What is Bacterial Endotoxin Testing?

Bacterial Endotoxin Testing (BET) is an in vitro assay for detection and quantification of bacterial endotoxins, which are a component of the cell wall of gram-negative bacteria. The BET **must be performed** for medical devices with direct or indirect contact to the cardiovascular system, lymphatic system, or cerebrospinal fluid.



Ready to sterilize vial stoppers and complete pharmaceutical vial packaging shipped worldwide by

QCVIALZ

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