

## 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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