Efficiency Check of Endotoxin Reduction with the LAL Test

Test for pharmaceutical cleaning machines and depyrogenation tunnels

For dry heat sterilization authorities are requiring a 3-log reduction of endotoxins. In case a dry heat sterilization is not possible, the required reduction has to be achieved e.g., by a washing process. In both cases the proof of the reduction is provided by exposing objects inoculated with certified lipopolysaccharides (LPS, endotoxin) to the process and performing a LAL test afterwards, which allows the necessary quantification of the results.

The LAL test (Limulus Amebocyte Lysate test) uses an enzymatic system extracted from amebocytes in the blue blood of the horseshoe crab (Limulus polyphemus), which reacts very sensitively and specifically to lipopolysaccharides by coagulation. The evaluation in the laboratory is done with a kinetic-turbidimetric test, which spectrometrically measures the increasing turbidity in the two replicates of each sample. The calculation of the endotoxin contents is based on a simultaneously measured endotoxin standard row.
Inoculated, but untreated objects are used as recovery samples to calculate the actual log reduction.

Valicare provides the necessary GMP-compliant documentation, like protocols, test documentation and reports.

Our Competence

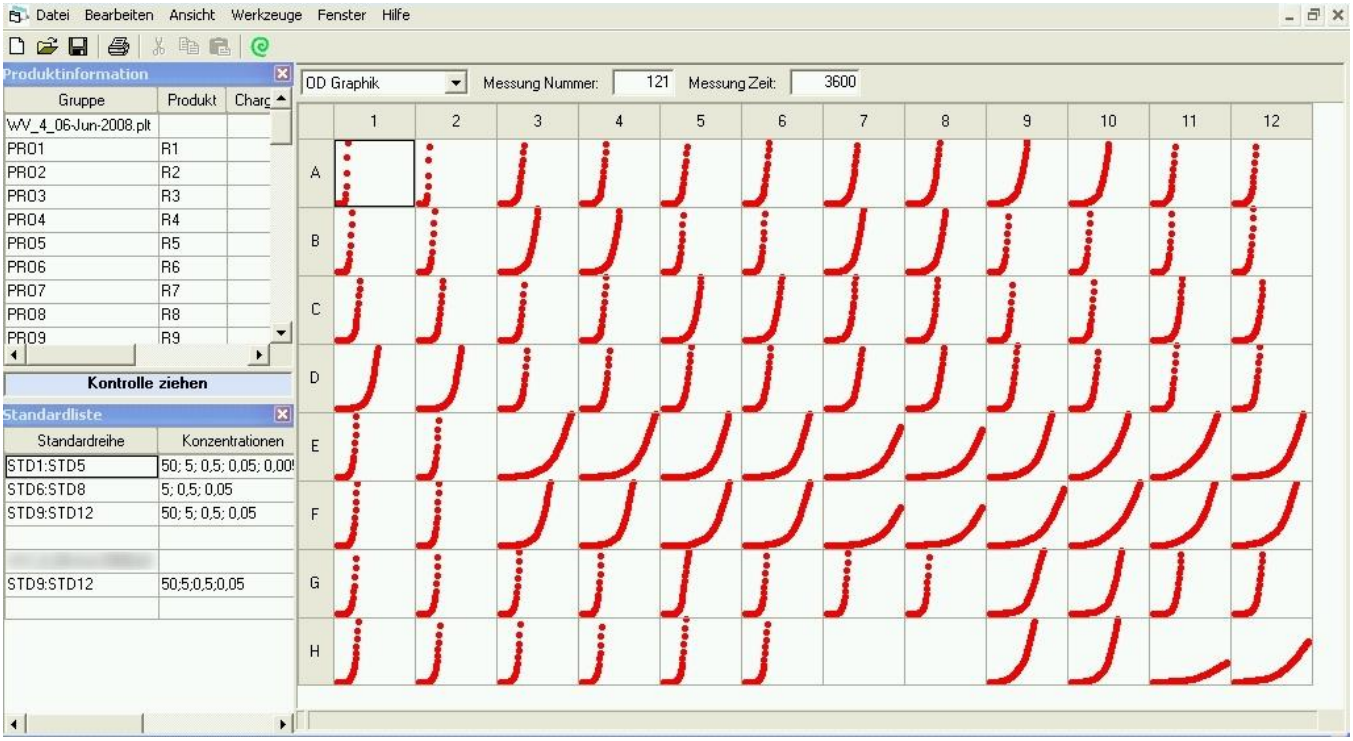
- More than 18 years of experience in execution of kinetic turbidimetric endotoxin testing
- Engineers of various disciplines with technical expertise
- Natural scientists with analytical expertise and laboratory experiences

Our Services & Support

- Preparation of challenge objects (inoculation with lipopolysaccharides)
- Onsite machine runs
- Measurements of the processed objects, determination of recoveries, evaluation by kinetic-turbidimetric method
- Creation of GMP-compliant documents
- Measurement with qualified equipment

Your Benefits

- Personnel relief and time savings by outsourcing the tests to experts
- Significant and reproducible results by the application of SOP-based and competently executed, GMP-compliant methods and laboratory analyses
- GMP-compliant and audit-suitable documentation



End point determination of the kinetic-turbidimetric LAL test by measuring of optical density.

Contact us if you are planning LAL tests for checking the endotoxin reduction. We support you!

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