IFIN-HH

Center for Technology Transfer and Marketing

CTTM

ENDOTOXIN DETECTION

DESCRIPTION

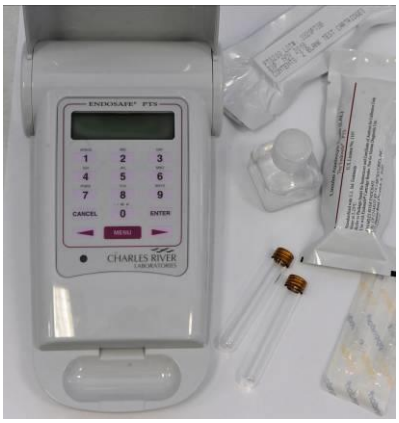
Endotoxin from Gram-negative bacteria are the most common cause of toxic reaction resulting from contamination with pyrogens. Detection of bacterial endotoxins contamination is esential to ensure the safety of sterile pharmaceutical product and medical devices.
The Bacterial Endotoxins Test is an in vitro assay for detection and quantification of a component of the cell wall of Gram negative bacteria.
The samples extraction is performed using water free of detectable endotoxins. The test involves analyzing the sample extract using Limulus Amebocyte Lysate, a reagent made from blood of horseshoe crab. In the presence of bacterial endotoxins, the lysate reacts to cause changing depending on the technique.

APPLICATION DOMAINS

Any product that is labeled as nonpyrogenic must be tested to verify that claim. Bacterial Endotoxins Test is performed as part of the batch release testing for medical devices and injectable pharmaceuticals.

MAIN ADVANTAGES

The tests are performed on routine basis or for research purposes. Validation is performed for each product type. The Bacterial Endotoxins Test is included in the GMP license of IRASM laboratory.



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POTENTIAL CUSTOMERS OR COMMERCIAL APPLICATIONS

Pharmaceutical and medical devices manufacturers seeking for routine or exploratory (R&D) microbiological tests.

KEYWORDS

Bacterial endotoxins, medicinal products, medical devices, in vitro assay.