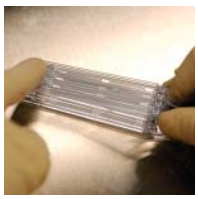

charles river
accelerating drug development. exactly.

Endosafe®-PTS™ in Nuclear Medicine

Charles River's novel endotoxin detection system, the Endosafe® - PTS™, is a rapid, point-of-use test system that performs a kinetic chromogenic assay with a disposable test cartridge and a handheld reader. The PTS™ has been licensed by the FDA for in-process and final product release testing of pharmaceutical products.

The FDA and USP require that a bacterial endotoxins test is performed prior to human IV use of injectable PET drugs. The PTS™ is especially effective for radiopharmaceutical products with short half lives, as quantitative results for batch records are available in about 15 minutes. Additionally, the PTS™ requires only a small amount of product at a non-interfering dilution and requires no preparation of endotoxin standards.

Test Technology

The PTS™ system includes a cartridge containing LAL reagent, chromogenic substrate, and control standard endotoxin (CSE). Each cartridge has duplicate channels for sample analysis and positive product control. The cartridges are manufactured according to rigid quality control procedures promoting test accuracy and product stability.

A calibration code is provided for each batch of cartridges that relates to a batch-specific, two-log standard curve constructed using the log of the reaction time vs. the log of the endotoxin concentration. After the assay reaction occurs, color intensity is measured optically and compared against the internally-archived, batch-specific standard curve. The sample and spike values are calculated by interpolation of the standard curve using the reaction times. By design, the PTS™ performs a duplicate sample/duplicate positive product control LAL test, thereby satisfying the harmonized USP Bacterial Test (BET) and the FDA guideline for LAL testing.

Endosafe® - PTS™ Features

- FDA-licensed
- Quantitative results in about 15 minutes
- Compatible with minimal dilutions of all common PET drugs
- Simple, one button operation
- LAL test components all included
- Stores 100 test results for printing or downloading
- No need to prepare endotoxin standards
- Ability to download data into standard reports and trending software applications for official documentation
- Comes with 1-year warranty; Extended warranty available
- Endosafe Technical Service can provide assistance with qualification and SOP development

Assay Procedure

To perform the test, the user simply pipettes 25 µl of a sample into each of the four sample reservoirs of the cartridge. The reader draws and mixes the sample with the LAL reagent in two channels and with the LAL reagent and positive product control in the other two channels. The sample is incubated and then combined with the chromogenic substrate.

Data Analysis and Acceptance Criteria

At the conclusion of the test, the endotoxin measurement and the assay acceptance criteria are displayed on the screen. The instrument can be used to detect endotoxin levels as high as 10 EU/mL and as low as 0.01 EU/mL.

The PTS™ system is the optimum solution for bacterial endotoxin testing of PET drugs due to its simplicity and speed.

For additional information on the Endosafe® - PTS™, please call 1.877.CRIVER.1 or visit our web site, www.criver.com.

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