

LIMULUS AMEBOCYTE LYSATE (LAL) TEST RESULTS
Characterization - Gel-Clot Method

Report Date: 3/25/2008
Customer Number: ST062
IC Number: 0308-119

Pyrotell®: Lot Number 507-09-433; Sensitivity (λ) = 0.03 EU/mL

LAL Reagent Water (LRW): Lot Number 308-475

Control Standard Endotoxin (CSE): Lot number 108, *Escherichia coli* O113:H10. The potency is 5 EU/ng when compared with the Reference Standard Endotoxin (RSE), EC-6-3 (Food and Drug Administration, CBER) using Pyrotell® lot number 507-09-433. CSE was diluted with LRW to obtain concentrations that bracketed the labeled sensitivity of the LAL reagent (2λ , λ , 0.5λ , and 0.25λ).

LAL Reagent Water (LRW): LRW was used to reconstitute Pyrotell® and endotoxin, prepare dilutions of endotoxin and samples, and serve as the negative control.

Procedure: The samples were tested undiluted in a two-fold dilution scheme in duplicate. The positive product controls were the undiluted samples fortified with CSE equivalent to 2λ .

Results: The Characterization assay is used to determine the amount of endotoxin present in a sample. The sensitivity of the reagent was confirmed to be 0.03 EU/mL. The negative control was included in duplicate and had less than 0.03 EU/mL. The error of the gel-clot method is plus or minus one two-fold dilution. Testing was conducted in compliance with USP 30 <85> *Bacterial Endotoxins Test* and FDA GMP.

Test Date: 3/24/2008

Sample Identification	Endotoxin Concentration	Inhibition
1. Background Water Lot Number 3/20/08-1	0.125 EU/mL	None
2. Concentrated Endotoxin Lot Number 3/20/08-2	8 EU/mL	None
3. 0.2 μ Nylon Charged Pharma Lot Number 3/20/08-3	0.03 EU/mL	None
4. 0.03 μ PES Lot Number 3/20/08-4	0.5 EU/mL	None

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