

The Living Fossil (Horseshoe crab)

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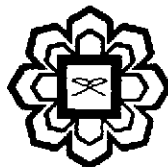
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Environmental and Pharmaceutical applications of Amebocytes Lysate (LAL/TAL) from Horseshoe crabs

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Abstract

It is well known that US Food and Drug Administration (FDA) has made the *Limulus/Tachypleus* Amebocytes Lysate (LAL/TAL) test as a test for the presence of endotoxin in biologicals, pharmaceutical drugs, and medical devices which is currently recognized by various pharmacopoeias and is used worldwide. Since its discovery, LAL/TAL has proven its usefulness not only to detect harmful levels of endotoxin (as pyrogens) in pharmaceutical products, but has become an indispensable tool in controlling endotoxin in processes and equipment used to produce pharmaceuticals. Indeed, the exquisite sensitivity of LAL compared to other assays for endotoxin/pyrogen has proven extremely useful in monitoring high-purity water used as a prime ingredient or processing agent for all biologicals, drugs, and devices. LAL/TAL has also become the assay of choice for researchers studying both the clinical and the environmental effects of endotoxin. To highlight its usefulness, present study was conducted to shed light on various specific applications of LAL/TAL in Pharmaceutical Environmental fields.

Key words: LAL/TAL, Amebocyte lysate, horseshoe crabs, FDA, Endotoxin.

Introduction

The occurrence of bacterial contamination in parenteral drugs, devices, infusion and transfusion solutions need to be quantified before it is being marketed commercially. The advent of LAL has made this step easy and the reliability of LAL/TAL test was recognized by Food and Drug Administration (FDA, 1987) as an 'End product' test, which triggered the biomedical companies to concentrate on LAL/TAL production using horseshoe crabs as a sole source. An economic