

# 注射劑熱原試驗簡介與動物用注射劑細菌內毒素評估

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## 摘要

本計畫目標為建立國家動物用藥品檢定實驗室具備執行細菌內毒素試驗能力，並對市售動物用注射劑產品進行內毒素調查。試驗結果可做為主管機關做為未來修訂檢驗標準可行性之參考。期盼能符合國際注射劑品質規範並縮小動物用藥及人用藥間差距，並藉此提升國內動物用藥廠對自身產品品質要求。

通過大量手法訓練，本計畫完成訓練執行細菌內毒素所需各步驟：CSE之系列稀釋、LAL試劑標誌靈敏度核驗、樣品抑制或增強性試驗及樣品限量試驗之操作及判讀能力。計畫期間以兩廠牌凝膠法商用試劑對35件動物用注射劑產品進行樣品抑制/增強性試驗及51件(批)次產品進行限量試驗。試驗結果大多數產品皆能通過藥典規範。

# **Brief introduction of pyrogen test and Animal injection bacterial endotoxin test evaluation**

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## **Abstract**

The goal of the project is to establish a national animal drug testing laboratory to perform bacterial endotoxin testing and to conduct endotoxin investigations on animal injections. The results can be used as a reference for the authorities to revised test standards in the future. Looking forward to meet the international injection quality standards and decrease the quality gap between animal and human drugs, in the other hand to enhance domestic animal drugs manufacturers' self-requirements for their own products.

Via large amount training and practice, we completed every step requirements for bacterial endotoxin test: CSE serial dilution, labeled lysate sensitivity test, sample dilution inhibition/enhancement test and sample limit test. In the project, a number of 35 samples of animal injection products were executed inhibition/enhancement tests and 51 samples (lots) executed limited test using two brands of commercial BHT gel-clot reagents. Most of products could pass the pharmacopoeia specification.