

動物用注射劑細菌內毒素檢驗技術探討

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摘要

細菌內毒素被認為是注射劑產品熱原污染的最主要來源。因此，製藥業將細菌內毒素試驗列為常規檢測項目，檢測標的物不僅最終產品，尚包含水、原料、包材甚至生產設備。為了檢測內毒素，科學家在不同時期發展出不同檢測方式，包含體內試驗如兔熱原試驗、管內試驗如蠶血試劑法等，這些方法皆經過長時間的不斷驗證而被藥典收載作為檢測的標準方法。今天的報告內容將介紹目前通用的細菌內毒素檢測技術，包含較傳統的藥典標準檢測方式以及較新穎且符合動物保護精神的替代技術；並討論目前我國動物用藥品執行細菌內毒素檢測現況及未來趨勢。

Bacterial endotoxin testing for veterinary parenteral products

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Abstract

Bacterial endotoxins are considered to be the major cause of pyrogenic response in animals treated with contaminated parenteral products. Bacterial endotoxin testing is routinely required in pharmaceutical industries, not only for the final veterinary products, but also for all of the raw materials, and technical instruments used throughout the production process. For the detection of bacterial endotoxins, various methods have been developed including the *in vivo* rabbit pyrogen test (PRT) and the *in vitro* LAL assay with each method having undergone a rigorous verification process, and eventually adopted into the pharmacopoeia as a standard method. We provide an introductory overview of current techniques used to detect bacterial endotoxins in veterinary pharmaceutical products, including traditional standard testing methods detailed in the pharmacopoeia as well as novel alternative technologies. We also discuss the current status and future trends for bacterial endotoxin testing of veterinary pharmaceuticals in Taiwan.