

動物用一般藥品品質監測結果與分析

動物用藥品檢定中心化學藥品檢定研究系

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摘要

我國動物用藥品之管理流程，涵蓋許可申請、成分審查、核准上市，以及後續之品質監測與使用管理，形成一套藥品全生命週期之管理架構；其中，又以上市後藥品的品質監測，為維護用藥安全之關鍵管制措施。動物用藥品檢定中心歷年來皆配合藥品主管機關，執行市售動物用一般藥品品質檢驗工作，以確保掌握藥品市場品質現況。彙整近十年之抽樣藥品檢驗資料顯示，樣品來源以國內製造廠生產之藥品為主，約占 73%，劑型分佈則以注射液最多，約占 37%，檢驗成分以 Amoxicillin 最為常見，其次為 Lincomycin。各年度品質檢驗結果均呈現穩定，平均合格率達 96%；於不合格藥品部分，則以含 Penicillin G 類成分之滅菌懸浮注射液為多，顯示此類產品於品質管制上有加強之必要性。

Analysis of Quality Surveillance Results for Veterinary

Chemical Drugs

Chen Yu Lin

Abstract

The management process of veterinary drugs in Taiwan includes licensing applications, ingredient evaluations, marketing authorizations, as well as subsequent quality monitoring and usage management, thereby establishing a comprehensive life-cycle management framework for veterinary drugs. Among these, post-market quality monitoring is a key regulatory measure for safeguarding drug safety. Over the years, the Animal Drugs Inspection Branch has cooperated with the competent authority to conduct quality inspections of marketed veterinary chemical drugs, in order to ensure effective oversight of marketed drug quality. Analysis of sampling inspection results over the past decade indicates that the majority of samples were products manufactured by domestic producers, accounting for approximately 73% of the samples. Injectable preparations were the most common dosage form, comprising about 37% of the samples. The most frequently inspected active ingredient was amoxicillin, followed by lincomycin. Overall quality inspection results were stable across years, with an average pass rate of 96%. Non-compliant products were predominantly penicillin G-containing sterile injectable suspensions, indicating that further strengthening of quality control measures is necessary for this category of products.