

市售動物用一般藥品品質監測

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摘要

動物用藥品生命週期冗長，於生命週期中的品質管制也非常繁複，其中藥品上市後的品質監控，即為動物用藥品品質管制中重要一環。歷年來，我們依循動物用藥品管理法與動物用藥品檢驗標準之規定，配合各地方主管機關抽查藥品之政策，進行市售動物用一般藥品成分、質與量之品質檢驗，並將檢驗結果提供應用於藥品風險管理評估之參考，確保動物用藥品用藥安全。分析近年來成果，市售動物用一般藥品抽查樣品，每年以國內製造藥品所佔比例為多，達 70% 以上；抽查樣品檢驗結果，歷年合格率皆達 95.9% 以上。此外，檢驗不合格樣品中，則以成分為 Penicillin G 為最多。

Post-market safety monitoring of veterinary drugs

Chen Yu-Lin

Abstract

The life cycle of veterinary drugs is lengthy, and quality control during the life cycle of these drugs is also very complicated. Safety monitoring of post-market veterinary drugs is one of the most important aspects of veterinary drug quality control management. Our project is based on the Veterinary Drugs Control Act and standards for inspection of veterinary drugs. In accordance with the policies of the local authorities, we conduct random inspections to determine the quality of pharmaceutical ingredients and test animals. These inspection results are then included as data points for drug risk assessment management, and ultimately ensure veterinary drug safety and the continual safe development of veterinary drugs. Analysis of these inspection results from recent years, showed that more than 70% of sampled veterinary drugs were domestically produced. More than 95.9% of randomly sampled post-market veterinary drugs passed inspection, while penicillin G was found in most samples that failed inspection.