

動物用一般藥品之品質監測

化學藥品檢定研究系

陳玉林 助理研究員

摘要

動物用藥品生命週期冗長，其中以藥品上市後的品質監控，為動物用藥品品質管制中重要一環。歷年來，我們配合主管機關抽查藥品之政策，並依循動物用藥品檢驗標準之規定，進行市售動物用一般藥品成分、質與量之品質檢驗，以確保動物用藥品品質與用藥安全。分析近年來成果，可見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 71 % 以上，樣品劑型則以注射劑為多，達 39 % 以上。於抽查樣品檢驗結果，歷年合格率皆可達 95 % 以上。此外，檢驗不合格樣品中，成分以 Penicillin G 類藥品為最多。

Quality control monitoring of general veterinary drugs

Chen Yu-Lin

Abstract

Veterinary drugs have a long life-cycle, and the quality control monitoring of post-market veterinary drugs is one of the most important parts of this life-cycle within the quality assurance and control measure protocols for each product. Our quality control protocols are based on national veterinary drug inspection standards and we regularly conduct random quality control inspections within the veterinary pharmaceutical market that is focused on drug composition, quality and quantity. These inspection results will ensure veterinary drug quality and safety. The results of the post-market veterinary general pharmaceutical inspections from recent years, demonstrate that >71% of sampled drugs were domestic products, and >39% were drug solutions for injection. >95% of inspected drugs passed inspection while the product Penicillin G comprised most of the inspections that did not pass quality control standards.