

動物用一般藥品品質檢測與監控

動物用藥品檢定中心化學藥品檢定研究系

陳玉林 助理研究員

摘要

動物用藥品管理制度，包含藥品許可登記、成分查驗、上市許可、上市後藥品品質監控，以及使用監管等管制環節，用以確保動物用藥品在整個生命週期中的品質和安全性。在其中，又以上市後動物用藥品的品質監控，為藥品品質管制中重要一環。歷年來，我們配合主管機關動物用藥品管理政策，進行市售動物用一般藥品成分、質與量檢驗，以確保其品質和安全。分析近年的檢測結果，市售動物用一般藥品的抽查樣品來源，主要為國內製造，佔比約 75%，注射液則是最常見的劑型，佔比達到 38.9%。而在檢測結果方面，平均合格率為 96.2%，其中 Amoxicillin 是最常見的成分。另外，在檢驗不合格的樣品中，則以 Penicillin G 類藥品為最多。

Quality testing and monitoring of general veterinary drug

Chen Yu-Lin

Abstract

The control points of the veterinary drugs management system include drug registration, ingredient inspection, marketing authorization, post-market drug quality monitoring, and use surveillance. These control points ensure the safety and quality of veterinary drugs throughout their life cycle. The post-market quality control of veterinary drugs is especially important among these control points. We have cooperated with the competent authorities' policies to conduct quality inspections on the post-market of general veterinary drugs, focusing on drug composition, quality, and quantity. These inspections ensure veterinary drugs' quality and safety. The results of the last ten years showed that domestically produced drugs accounted for 75% of the total inspected drugs. Injections were found to be the most common dosage form, comprising 38.9% of the total. The average pass rate was 96.2% and amoxicillin was the most common ingredient. In addition, penicillin G drugs were commonly found in non-passed samples.