

# 動物用化學藥品檢驗實務經驗分享

動物用藥品檢定分所

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## 摘要

動物用化學藥品檢驗係依據「動物用藥品管理法」子法「動物用藥品檢驗標準」第二章動物用一般藥品檢驗標準的條文(第4~22條)辦理。行政院農業委員會家畜衛生試驗所動物用藥品檢定分所化學藥品檢定研究系依法執行動物用化學藥品國家檢定，負責各項動物用一般藥品之技術性實驗室檢驗與檢定工作，確保藥品品質的一致性、有效性和安全性，以健全我國動物用藥品管理體系。目前主要工作項目含括動物用一般藥品許可證申請登記、補助飼料(維生素)許可證申請登記、消毒資材、含藥物飼料、市售動物用一般藥品及偽、禁、劣藥等檢驗與鑑定。申請許可證登記檢驗的案件，每年約有100 - 120件，實驗室依樣品的成分及劑型，根據法規進行檢驗；檢驗完成後，依檢驗結果製作成績書，通知主管機關，做為許可證發證之依據，如實務經驗案例：「維克歐米嘉」動物用干擾素以一般藥品檢驗登記與管理介紹。化學藥品檢定研究系未來將秉持檢驗分析方法確效與驗證，維持認證系統運作，提昇實驗室檢驗公正性及公信力。

# **Practical Experience Sharing in the Inspection of Veterinary**

## **Drugs**

Wen-Hua Lin

### **Abstract**

Inspections of veterinary drugs shall be handled in accordance with the Chapter Two Inspection Standards of Veterinary General Drugs (Articles 4 to 22) in the Inspection Standards of Veterinary Drugs Act, the sub-law of Veterinary Drugs Control Act. Department of Chemical Assay and Research, Animal Drugs Inspection Branch, Animal Health Research Institute, Council of Agriculture, Executive Yuan, executes national inspections of veterinary drugs in accordance with the laws and is responsible for the laboratory technical inspections and assays work to ensure the consistency, effectiveness, and safety of the drug quality to improve the national system of the veterinary drugs control. The current primary work includes the registrations and applications for the permits of veterinary general drugs and complementary feed (vitamin), and inspections and assays on the disinfectant, feed containing drugs, veterinary general drugs on the market, fake drugs, prohibited drugs, and substandard drugs. There are about 100-120 inspection cases registered per year for the permit applications. The laboratory executes the inspection in accordance with the components and the form of the sample and relevant regulations. The evaluation report will be produced according to the inspection results, and the competent authority will be notified. The evaluation report will be the basis for the license issuance. For example, “virbagen omega” animal interferon is registered through the veterinary general drug inspection. The Department of Chemical Assay and Research will continue to verify and valid the inspection and assay methods, maintain the operation of the certification system, and improve the fairness and credibility of the inspections.