新城病活毒疫苗檢驗標準修正評估

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摘要

依據動物用藥品管理法，國內製造或輸入之新城病活毒疫苗，皆需依農業部公告之新城病活毒疫苗檢驗標準，逐批進行試驗。前述檢驗標準自民國 64 年公告至今，已歷經 4 次的修正沿革。本次檢驗標準修正目的係為導入實驗動物 3Rs（減量、取代及精緻化）原則，評估方式包括參考美國、歐洲、日本、東南亞國家協會、中華人民共和國等檢驗標準，取有效期限內之新城病活毒疫苗共 35 批及新城病、傳染性支氣管炎活毒混合疫苗共 30 批之疫苗樣品進行病毒含有量試驗及效力試驗。病毒含有量試驗係將疫苗序列稀釋並接種至無特定病原雞胚胎蛋後，計算 EID_{50}（50% embryo infective dose）值，效力試驗則是將疫苗免疫無特定病原雞 2 週後，以新城病強毒株（佐藤株）攻毒後，計算雞隻存活率。測試結果為疫苗病毒含量每劑量達到 10^5 EID_{50} 以上，免疫 2 週後攻毒之雞隻存活率皆可達到 80%以上。據此建議效力試驗可以病毒含有量試驗取代，除減少 12 隻雞使用量，並可免去雞隻因攻毒所承受之緊迫；安全試驗則建議修正為免疫疫苗 10 劑量，免疫雞隻數量由原 15 隻減至 10 隻。本次檢驗標準修正後，每批次疫苗檢驗所需雞隻數量，可由 27 隻減低至 10 隻，減少約 63%

雞隻數量，並可選擇不進行攻毒試驗，符合實驗動物之減量及精緻化精神。

Evaluation of revision of the inspection standard for the live Newcastle disease virus vaccine

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Abstract

According to the Animal Drugs Control Act, domestically manufactured or imported Newcastle disease live virus vaccines (NDV) must undergo batch testing in accordance with the Newcastle disease live virus vaccine inspection standards announced by Ministry of Agriculture. The inspection standard was announced in 1975 and has amended four times. The purpose of this amendment of the testing standards is to implant the principles of the 3Rs (Reduction, Replacement, and Refinement) in laboratory animals. It was to refer to inspection standards of the United States, Europe, Japan, the Association of Southeast Asian Nations, and the People's Republic of China to conduct the virus content test and potency test of 35 batches of live NDV vaccines and 30 batches of live NDV and infectious bronchitis virus （IBV） mixed vaccines. The virus content test was to calculate the 50% embryo infective dose value (EID_{50}) after the vaccine virus was diluted and injected into specific pathogen-free (SPF) chicken embryo eggs. The potency test was to calculate the survival rate of chickens after being challenged with the virulent NDV strain (Sato strain) 2 weeks after immunization. The test results showed that the virus titer of the vaccine reached more than 10^5 EID_{50} per dose, and the survival rate of chickens challenged with the virulent NDV coulded reach more than 80%. It was suggested that the virus content test could replace the potency test, which could reduces 12 chickens used for the potency test, and it could prevent the chickens from the stress caused by the virus challenge. The amendment of the safety test suggested that 10 doses of vaccines should be immunized, and the number of immunized chickens should be reduced from 15 to 10. The results of this amendment of the inspection standard were that the number of chickens tested for each batch of the live NDV vaccine could be reduced from 27 to 10, a reduction of about 63% of chickens, which was in line with the spirit of reduction and refinement in the scientific use of experimental animals.