

鴨病毒性肝炎卵黃抗體製劑之研發與製造

製劑研究組

研究員兼組長 陳瑞祥 助理研究員 施雨華

摘要

鴨病毒性肝炎(DVH)為台灣重要的水禽病毒性疾病，鴨病毒性肝炎主要發生在雛鴨，為急性致死性疾病。本所歷經4年研究於2015年度完成，以高度免疫的雞隻生產的蛋製成卵黃抗體製劑之實驗室相關研發、檢測試驗及田間試驗2場。結果顯示本製劑具高度安全性及效力，應用於田間可以有效預防第一血清型鴨肝炎A病毒(DHAV-1)的感染症。本製劑於實驗室及田間水禽場經測試結果均可達到良好的安全性與滿意的保護效果，於2~8°C下保存，保存期可長達1年。依據試驗結果種鴨應於產蛋期前完成市售DHAV-1疫苗免疫，藉由高力價移行抗體來保護雛鴨耐過野外DHAV強毒感染。如果雛鴨來源為免疫不完善之種鴨場，雛鴨應於1日齡及10日齡被動免疫1劑量卵黃抗體以保護雛鴨耐過DHAV野外強毒之感染。本所於2016年3月取得製造動物用藥品許可證(動物藥製字09081號)。該項產品之核准上市，可解決現場對本製劑之殷切需求，有效降低感染鴨病毒性肝炎造成的損失，造福水禽產業。

Development and Manufacture against of Biologics

Duck Viral Hepatitis

Re-Shang Chen Yu-Hua Shih

Abstract

Duck viral hepatitis (DVH) characterized by hepatitis is an acute fatal disease in ducklings. The Animal Health Research Institute used a strain of duck hepatitis A virus (DHAV) to immunize layer hens to produce eggs with high yolk antibody. All laboratory tests and field trials of this biologics development were completed in 2015. The results showed that the biologic was with a high degree of safety and efficacy to target animal. One shot of the biologic could provide protection against in duck farms. This biologic should be stored at 2 - 8 °C and its shelf life is one year. The vaccination is recommended for breeding ducks before the laying period in order to produce maternal antibody through yolk to protect ducklings from virulent DHAV infection. If the breeding ducks were immunized inappropriately, their ducklings should inject two shot on 1-day and 10-days old to receive passive immunization against virulent DHAV infection. Manufacturing license (No. 09081) has been approved by the Bureau of Animal and Plant Health Inspection and Quarantine, Taiwan, in March 2016. With a strong demand by waterfowl industry, the licence approval of this biologics would be effectively reduce economic losses caused by DHAV infection in ducks.