2024～2025 年生物製劑品質管制檢驗成果與 GMP 製程精進報告

製劑組

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摘要

本所自 1988 年建置符合 GMP 規範之動物用藥品製造廠，製劑組主要負責家畜禽疫苗及診斷試劑之研發改良、生產製造、儲備供應及品質管理工作。目前本所持有 22 張生物製劑製造許可證，主要生產品項包括雞新城病病毒紅血球凝集抗原、雛白痢診斷液、牛流行熱不活化疫苗、水禽雷氏桿菌症不活化菌苗及羊痘活毒疫苗等重要生物製劑。本報告將針對 2024 年至 2025 年間各項生物製劑之生產批次與品管檢驗結果進行彙整分析，藉由檢視製程穩定性、品質趨勢及檢驗數據表現，作為後續製程優化與產品品質精進之依據，以持續提升本所生物製劑之安全性、有效性與供應品質。此外，本所為全面提升動物用疫苗製造品質，並配合農業部「動物用藥品優良製造準則」及歐美藥品確效與品質保證之國際發展趨勢，本所刻正推動 GMP 大樓水系統更新工程，以強化製程用水穩定性與系統確效能力，使整體生產設施更臻符合現行法規及國際標準，進一步提升疫苗供應體系之安全性、可靠性與製造效能。

2024–2025 Report on Biological Product Quality Control Performance and GMP Manufacturing Process Enhancement

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Abstract

Since 1988, our institute has operated an animal pharmaceutical manufacturing facility that complies with Good Manufacturing Practice (GMP) requirements. The Formulation Division is primarily responsible for the research and development, production, stockpiling, supply, and quality management of livestock and poultry vaccines as well as diagnostic reagents. Currently, the institute holds 22 biological product manufacturing licenses. Major products include New Castle Disease Virus H.A Antigen, Pullorum Disease Antigen, Bovine Ephemeral Fever Inactivated Vaccine, Trivalent Inactivated Bacterin Against *Riemerella Anatipestifer* Infection, and Sheep Pox and Goat Pox Attenuated Live Vaccine, among other important biological products. This report presents a comprehensive analysis of the production batches and quality control testing results of various biological products manufactured between 2024 and 2025. By evaluating manufacturing process consistency, quality trends, and analytical performance data, the report aims to provide a scientific basis for subsequent process optimization and continuous product quality improvement, thereby enhancing the safety, efficacy, and supply quality of the institute's biological products. In addition, to further improve the quality of veterinary vaccine manufacturing and align with the Ministry of Agriculture's Veterinary Drug Good Manufacturing Practice (GMP) regulations, as well as international trends in pharmaceutical validation and quality assurance adopted in Europe and North America, the institute is currently implementing a water system upgrade project for its GMP manufacturing building. This initiative is intended to strengthen the stability of process water quality and enhance system validation capabilities, ensuring that the overall production facilities are more fully compliant with current regulatory requirements and international standards. Ultimately, the project is expected to further improve the safety, reliability, and manufacturing efficiency of the veterinary vaccine supply system.