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Study on establishment of reference antiserum for immunogenicity assay of acellular pertussis vaccines

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Regulatory authority performs the lot release test including a potency test before the vaccine products release on the market. Immunogenicity assay is used for the potency test of acellular pertussis (aP) vaccine. In Korea, the immunogenicity assay is currently tested for imported aP vaccines and performed using in-house reference materials. Therefore, domestic supply problem of in-house materials occasionally causes delay of national lot release. The aim of the present study is establishment of pertussis antiserum as a national reference material. The candidate antiserum was obtained by immunizing ICR mice with a three component acellular pertussis vaccine: Pertussis Toxin (PT), Filamentous Hemagglutinin (FHA) and Pertactin (PRN). Immunoglobulins were purified by chromatography and dialyzed against phosphate buffered saline. Immunoglobulin solution was diluted in 10% normal mouse serum in PBS. The solution was dispensed in 0.5 ml aliquots into glass vials and freeze dried under vacuum (1,500 vials). Further analysis of the outcome of collaborative study enabled to assign to the pertussis candidate antiserum a potency of 57,338 and 45 ELISA unit/ml, respectively, to its anti-PT, anti-FHA and anti-PRN antibody contents. Thus, the antiserum might be used for lot release test of acellular pertussis vaccine products in Korea.

Biography

Joon Ik Ahn has completed his PhD from Hanyang University in South Korea. He is a Scientific Officer of Vaccine Division, NIFDS and MFDS. He has been working to approve vaccine lot release in vaccine division since 2013.

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