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## Study on manufacture and establishment of 1<sup>st</sup> national reference material for cell-derived Japanese Encephalitis vaccine : Reference challenge virus and reference positive serum

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Japanese encephalitis virus(JEV) is a mosquito-born flavivirus that causes public health problems in Asian countries. Until quite recently, the primary JE vaccine used worldwide has been the mouse brain-derived JE vaccine, which is now commonly replaced by cell culture-based JEV vaccines. The Vero cell derived inactivated JE(cJEV) vaccine has been licensed for routine use in Korea in 2013. Unlike chemical drugs, biologics such as vaccines and blood products are produced from organism-origin materials, it is difficult to maintain consistency and safety throughout the manufacturing processes. Also, the reference standard and material are indispensable for the consistent potency management of biologicals. Lately, the 1<sup>st</sup> national reference standard that has esbablished is now in progress with the enrollment as a Korea cJEV national reference standard for our National Lot Release Test for cJEV by plaque neutralization test(PRNT). In this study another 1st National reference candidate materials, challenge virus(CV) and positive control sera(PCS) required for the cJEV PRNT were manufactured at GMP facility, respectively. The candidate CV contents and the candidate PCS neutralization titers were determined by multi-laboratory collaborative study including NCL by cJEV PRNT-based test. After statistical assessment of the collaborative test results, the candidate CV and PCS titers would be set and expected to be used as a national reference material for our national lot release tests with the realtime stability monitoring data. This study results are thought to be helpful for procuring the consistent and reliable national vaccine quality management.

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