OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Conference on
Vaccines & Vaccination
July 29-31, 2013 Embassy Suites Las Vegas, NV, USA

Establishment of the 3rd national standard for *in vitro* potency assay of Japanese encephalitis virus vaccine

Byung Chul Kim, Hyung-sil Moon, DoKeun Kim, Tae Moo Yoo, Sung Hwa Hong, Naery Lee, Jong-Mi Lim, Donghee Kim, Seokkee Chang, Jiyoung Hong, Jooyeon Lee and Ho Jung Oh
National Institute of Food and Drug Safety Evaluation, Korea

Traditionally, the quality control for Japanese Encephalitis Virus (JEV) vaccine has performed *in vivo* potency assay using animals. The Ministry of Food and Drug Safety (MFDS) established alternative *in vitro* assay (ELISA) replacing the *in vivo* assay requiring animals and many times as an official quality control method of potency test for the JEV vaccine. The *in vitro* potency assay showed it's faster and easy to perform without pre-treatment such as a mouse immunization. Also it had better precision and reproducibility comparing to the conventional *in vivo* assay.

The reference material is essential in order to evaluate potency test for the JEV vaccine. The 1st and 2nd national standard for *in vivo* potency assay of JEV vaccine had manufactured, each established in 2001 and 2007, and have been using for the manufacturer's quality control and national lot release since then. As the need of the national standard for *in vitro* potency assay, this study was initiated by MFDS in 2013 to manufacture and establish the 3rd national standard for *in vitro* and *in vivo* potency assay of JEV vaccine. The *in vitro* and *in vivo* potency results of the candidate material for 3rd national standard, each were measured 1.077 and 2.761. In the study hereafter, the collaborative study of the MFDS and manufacturers will be conducted to estimate the reliable virus content with the candidate material.

happysea@korea.kr