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

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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.

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