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## Potency determination of the 3<sup>rd</sup> national standard of Japanese encephalitis virus vaccine for *in vivo* & *in vitro* assay

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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 1<sup>st</sup> and 2<sup>nd</sup> 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 3<sup>rd</sup> 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 3<sup>rd</sup> 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 of the reliable virus content with the candidate material.

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