An improved method to detect bacterial endotoxin in vaccines using the LAL cartridge system

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The bacterial endotoxin test is required for all parenteral drugs including vaccines. Limulus Amebocyte Lysate (LAL) derived from the horseshoe crabs is used in the endotoxin test and a variety of LAL assay options are available. The kinetic turbidimetric assay (KTA) and the kinetic chromogenic assay (KCA) are popular quantitative methods. However, these methods require a standard curve using a Control Standard Endotoxin (CSE) in each test, which is influenced by the vortexing time of CSE and by technical ability of each analyst. In this study, we intended to check a suitability of automated cartridge system, based on a kinetic chromogenic LAL as a new method to detect endotoxin in vaccines. A significant feature of this new system is the use of an archived standard curve that provides pre-calibrated reference to the reference standard endotoxin. Variability associated with standard curves generated with liquid reagents and incubating microplate is eliminated. The method validation study was conducted on this new LAL cartridge system according to ICH guideline. All validation parameters including accuracy, precision, specificity and linearity were checked and satisfied the acceptance criteria. And we also conducted the comparative analysis between new LAL cartridge system and the existing methods, KTA and KCA. As a result, the LAL cartridge system is considered to be proper method to detect endotoxin in vaccines. Moreover this technique has several advantages like convenience, simplicity of use and speed of result output. Hence the LAL cartridge system will be able to be used for endotoxin test in vaccines.

Biography

Jong-Mi Lim has completed her master degree (M.D) from University of Seoul. She is working for Korea Food and Drug Administration as a scientific official.

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