## Pharmaceutical and Medical Device Regulatory Science Society of Japan Pharmaceutical Reference Standards Center

April 2024

## New type of Japanese Pharmacopoeia Endotoxin Reference Standard

In June 2024, new type of JP Endotoxin reference standard (Lot N-ENH01A) will be released. Please note that the usage of the new type of standard products will be changed. The table below shows a comparison of how to use each lot of standard products. If necessary, please consider changing an SOP according to how to use each lot of JP Endotoxin reference standard.

## Comparison of how to use for each lot JP Endotoxin reference standard (RS)

	JP Endotoxin RS	JP Endotoxin RS
	Lot ENH29A	Lot N-ENH01A
Composition	Endotoxin from <i>E. coli</i> O113:H10:K negative	Endotoxin from <i>E. coli</i> O113:H10:K negative
	PEG8000	PEG8000
	Lactose	Lactose
Potency	16000 EU/vial	10000 EU/vial
Storage temp.	≦8°C	-2030°C
Mixing time for reconstitution	5 min.	15 min.
Concentration of Standard Endotoxin Stock Solution	10000 EU/mL	2000 EU/mL
Storage condition for Standard Endotoxin Stock	In a refrigerator (5±3°C) avoiding freezing	In a refrigerator (5±3°C) avoiding freezing
Solution	Use within 14 days	Use within 28 days
Shipping conditions	Domestic (within Japan) : kept refrigerated	Domestic (within Japan) : kept refrigerated
	Overseas : ambient	Overseas : kept refrigerated

For at least one year from June 2024, PMRJ will distribute both lots side by side.



If you have any questions, please do not hesitate to contact us.

https://www.pmrj-rs.jp/en/contact/