

## 日本薬局方ヘパリンナトリウム各条のエンドトキシン試験法 に関する研究

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Study on Bacterial Endotoxins Test for JP Heparin Sodium Monograph

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### Summary

The bacterial endotoxins test is adopted in the Japanese Pharmacopoeia (JP) Heparin Calcium and Heparin Sodium Injection monographs, as well as the United States Pharmacopoeia and European Pharmacopoeia Heparin Sodium monographs, whereas the pyrogen test is still adopted in the JP XVI Heparin Sodium monograph. Replacement of the pyrogen test with the bacterial endotoxins test is required both as an alternative to animal experiments and for international harmonization. In this study, we evaluated the applicability of JP bacterial endotoxins test <4.01> to JP Heparin Sodium monograph by examining the interfering effect of heparin sodium on the bacterial endotoxins test with commercially available lysate reagents.

### Key words

Heparin sodium, Japanese Pharmacopoeia, Bacterial endotoxin test, Lysate reagent