

日本薬局方ヘパリンナトリウム各条のナトリウム定性試験 及び定量試験に関する研究

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Study on Qualitative Tests and Assay for Sodium in Heparin Sodium Monograph
of Japanese Pharmacopoeia

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Summary

A qualitative test and an assay for sodium have been adopted in the Heparin Sodium monographs of the United States Pharmacopeia (USP) and European Pharmacopoeia (EP), respectively. Although calcium assays have been adopted in the Heparin Calcium monograph of Japanese Pharmacopoeia (JP) XVII, a sodium test has not yet been adopted in the JP Heparin Sodium monograph. Therefore, a test for sodium is required to ensure the quality of pharmaceutical heparin sodium products that are distributed in Japan and to improve international harmonization. Our study demonstrates the applicability of the JP General Test, Qualitative Test (sodium salt) <1.09>, and Atomic Absorption Spectrophotometry <2.23> as the test for sodium in the JP Heparin Sodium monograph.

Key words

Heparin sodium, Qualitative test, JP Qualitative Test (sodium salt) <1.09>, Assay for sodium, JP Atomic Absorption Spectrophotometry <2.23>