

ヘパリン純度試験に関する研究 (第7報[†])日本薬局方各条ヘパリンナトリウム及びヘパリンカルシウムの
タンパク質及び核酸純度試験法に関する研究

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(受付:平成24年4月4日, 受理:平成24年10月1日)

Study on Heparin Purity Test (Part 7[†])Study on Heparin Purity Tests of Protein and Nucleic Acid for
JP Heparin Sodium and Heparin Calcium Monographs

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Summary

Heparin sodium and heparin calcium are used throughout the world as anticoagulants for the treatment of venous thrombosis and prophylaxis of clotting during extracorporeal circulation. Since the heparin contamination problem that occurred in early 2008, the Japanese Pharmacopoeia (JP) monographs for heparin sodium and heparin calcium have been continually revised to ensure the safety and quality of heparin products. It has been suggested that contaminated heparin is characterized by high concentrations of protein and nucleotidic impurities. The currently available protein limiting tests have poor sensitivity, and the current JP heparin monographs do not include a limiting test for nucleotidic impurities. Therefore, there is an urgent need for additional revision of the limiting test for protein and for addition of a limiting test for nucleotidic impurities in order to ensure the quality of heparin products. In this study, we developed limiting tests for protein and nucleotidic impurities in heparin by referring to the US Pharmacopoeia and European Pharmacopoeia. Furthermore, the suitability of the tests for the JP heparin monographs was evaluated in a collaborative study with Japanese heparin manufacturers and suppliers.

Key words

Heparin sodium, Heparin calcium, Limiting test for protein impurities, Limiting test for nucleotidic impurities