

放射性医薬品基準に記載される有害試薬を
用いる試験についての代替試験法の開発

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**Development of Alternative Methods without Harmful
Reagents for Radiochemical Purity Tests in the Minimum
Requirements of Radiopharmaceuticals**

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Summary

Following the policy of replacing test methods using harmful reagents described in the monograph drafting guide for the Japanese Pharmacopoeia XV, we have developed 14 modified purity-test methods without harmful reagents for 11 radiopharmaceuticals in the Minimum Requirements of Radiopharmaceuticals in Japan. For analytical validation of these test methods, their specificity, precision, and detection limit were evaluated and compared with those of the corresponding current methods. No significant differences were found between the results obtained with the modified methods and the current methods. These findings suggest that the proposed methods will be suitable as alternatives to the current methods.

Key words

Minimum Requirements of Radiopharmaceuticals, Alternative methods without harmful reagents, Radiopharmaceuticals, Radiochemical purity test, Specificity, Precision, Detection Limit