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液体クロマトグラフィーのシステムの再現性試験への ISO 11843-7 の適用に関する研究

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A System Repeatability Test of Liquid Chromatography in the Japanese Pharmacopoeia using ISO 11843-7

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Summary

In general tests using liquid chromatography, the allowable limit of system repeatability is normally defined in terms of the relative standard deviation (RSD) of the response to the analyte in replicate injections of a standard solution. On the other hand, the methodology of ISO 11843 Part 7 (ISO 11843-7), published in 2012, is based on the stochastic properties of instrumental noise. This method provides an SD and RSD of measurements to estimate detection limits by utilizing the stochastic aspects of the noise and signal data of a chromatogram, with no requirement for repetitive chromatographic measurements of real samples. In this study, we examined an assessment strategy based on ISO 11843-7 to evaluate system repeatability. The system repeatability test of HPLC with UV detection (HPLC-UV) for determining zidovudine in the Japanese Pharmacopoeia is shown as an example. The experimentally observed RSD of repeated measurements was 0.16% ($n = 6$). Meanwhile, the RSD evaluated according to ISO 11843-7 was 0.13% ($n = 1$). This value lies within the 95% confidence interval of the experimentally obtained RSD ($n = 6$), ranging from 0.10% to 0.40%. Thus, we conclude that ISO 11843-7 can be applied to evaluate system repeatability of HPLC-UV for determining zidovudine. The present strategy is useful to examine the allowable limit of system repeatability in liquid chromatography, and offers a considerable cost saving in terms of experimental time and consumption of chemicals.

Key words

ISO 11843-7, Liquid chromatography, System repeatability, Precision,