

令和2年度「日本薬局方の試験法等に関する研究」研究報告 ラマン分光法を用いた医薬品の試験法におけるシステム適合性の 導入に関する研究*²

小出 達夫*^{1, #}

Study on System Suitability for Pharmaceutical Quantification Test Using Raman Spectroscopy

Tatsuo KOIDE *^{1, #}

Summary

The purpose of this study was to investigate system suitability requirements for pharmaceutical quantification tests using Raman spectroscopy. Successive daily measurements showed that changes in Raman peak position caused by day-to-day variations in the condition of the instrument had a significant effect on the determined quantitative values. Therefore, it is necessary to specify that the spectrum of the substance to be tested should be confirmed to ensure system suitability. It is also necessary to specify the reproducibility of the scattering peak intensity in the spectrum, though in most cases the variation of the intensity is considered to be reduced by spectral pre-treatment and multivariate analysis. However, in the case of univariate analysis, it is necessary to set a stricter specification to take account of the effect of noise on the measured peak intensity. Appropriate management of samples for system suitability evaluation is also considered to be important.

Key words

Raman spectroscopy, System suitability, Transmission, Quantification