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平成26年度「日本薬局方の試験法等に関する研究」研究報告[*3]
ラマン分光法の定量試験への適用に関する研究

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Study on the Pharmaceutical Quantification Test Using Raman Spectroscopy

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Summary

The purpose of this study was to investigate the performance of Raman spectroscopy in the pharmaceutical quantification test.

Acetaminophen, as an active pharmaceutical ingredient, and lactose monohydrate, as an excipient, were mixed in a blender, in a ratio of 20 : 80. The mixed powder was compressed into experimental tablets by hand using 300 mg of the mixture and 20 MPa pressure. Raman spectra of the tablets were measured using backscattering, transmission and PhAT probe modes. A calibration curve was created by using the peak ratio values of acetaminophen and lactose, in order to cancel out the influence of variability of fluorescence and light path length.

The quantitative results obtained in the transmission mode exhibited the highest correlation to those obtained by the usual UV method among the three kinds of measurement mode, and showed sufficient accuracy and precision for application as a pharmaceutical quantification method in process analytical technology (PAT). Our data suggest that Raman spectroscopy, especially in the transmission mode, is an effective method for quantification of content uniformity of solid dosage forms.

Key words

Raman spectroscopy, Transmission, Quantification