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報告書

令和元年度「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開発と分析バリデーションに関する研究[*2]

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Study on the Development and Validation of Raman Spectroscopy-based Analytical Methods for Pharmaceuticals[*2]

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Summary

The purpose of this study was to investigate the applicability of Raman spectroscopy for pharmaceutical quantification, focusing on the selection of analytical methods, classification of risk factors, and analytical validation. The intensity of Raman signals from smaller particles (<38 μm) was decreased, and this impaired the analytical performance of transmission Raman spectroscopy. The effects of differences in other physical properties could be eliminated by means of spectral preprocessing. Analytical validation for transmission Raman spectroscopy was performed using tablets containing 20% acetaminophen in lactose monohydrate. The quantitative results obtained by transmission Raman met the accuracy and precision criteria of the USP draft. These data suggest that Raman spectroscopy, especially transmission spectroscopy, is an effective method for quantification of the content uniformity of solid dosage forms.

Key words

Raman spectroscopy, Methods development, Validation, Transmission, Quantification