

## 平成24年度「日本薬局方の試験法等に関する研究」研究報告\*2

## ラマン分光法の医薬品品質試験への適用に関する研究

小出 達夫\*1, #, 香取 典子\*1

Suitability of Raman Spectroscopy for Quality Tests in Pharmaceutical Manufacturing

Tatsuo KOIDE\*1, # and Noriko KATORI\*1

**Summary**

The purpose of this study was to investigate the performance of Raman spectroscopy as a tool for quality evaluation in pharmaceutical manufacturing. Three kinds of polymorphism and eleven kinds of pharmaceutical additives, including lactose, starch and seven kinds of magnesium stearate and calcium stearate, were chosen for this study. Samples were placed in polyethylene bags for measurement of Raman spectra.

Raman spectroscopy was effective for discriminating polymorphism. However, some additives were not suitable for Raman spectral analysis because they showed weak Raman scattering and fluoresced strongly during measurement. Discrimination analysis using multivariate analysis, such as principal component analysis (PCA), of spectra enabled us to classify six kinds of magnesium stearate and calcium stearate. However, near-infrared spectral analysis led to different classifications of some kinds of magnesium stearate, as compared with those derived from Raman spectral analysis. Further work is needed to investigate the relationships among spectra, physical properties and quality of compounds.

**Key words**

Raman spectroscopy, Discrimination analysis, Polymorphism, Additive, Near-Infrared Spectroscopy