

平成 25 年度「日本薬局方の試験法等に関する研究」研究報告<sup>\*2</sup>

## ラマン分光法の医薬品確認試験への適用に関する研究

小出 達夫<sup>\*1, #</sup>, 香取 典子<sup>\*1</sup>, 合田 幸広<sup>\*1</sup>Study on the Pharmaceutical Quality Test for Identification  
by Using Raman SpectroscopyTatsuo KOIDE<sup>\*1, #</sup>, Noriko KATORI<sup>\*1</sup> and Yukihiro GODA<sup>\*1</sup>**Summary**

The purpose of this study was to investigate the performance of Raman spectroscopy for distinguishing pseudopolymorphic forms, and to establish pharmaceutical quality evaluation methods using Raman spectroscopy.

Commercial "magnesium stearate" has a wide variety of physical properties, for example, pseudopolymorphism, relative content of stearate and palmitate, and particle size. These properties influence the manufacturing processes of products containing magnesium stearate as an additive and their quality, and therefore, it is necessary to control the quality of magnesium stearate itself.

Ten kinds of magnesium stearate were obtained from different vendors and subjected to Raman spectrometry in the conventional and low frequency ranges. We investigated the relationship between the Raman spectra and pseudopolymorphic form. As a result, the samples were categorized into four types: namely, mono-, di-, and tri-hydrate, and their mixture. Raman spectra in the conventional range (more than 200  $\text{cm}^{-1}$ ) were not able to completely distinguish mixtures of pseudopolymorphic forms, whereas Raman spectra in the low frequency range (less than 200  $\text{cm}^{-1}$ ) could do so. Our data indicate that Raman spectroscopy, especially in the low frequency range, is an effective method for discriminating pseudopolymorphism of magnesium stearate.

**Key words**

Raman spectroscopy, Magnesium stearate, Low frequency raman, Pseudopolymorphism