

平成 29 年度「日本薬局方の試験法等に関する研究」研究報告 日本薬局方収載医薬品の品質評価に向けた近赤外分光イメージング法の活用 並びにケミカルイメージング技術の標準化に関する研究^{*2}

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Study on Standardization of Near-Infrared Spectroscopic Imaging for
Pharmaceutical Quality Evaluation

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Summary

We examined near-infrared (NIR) imaging as a technique to evaluate the distribution of components in pharmaceutical products for manufacturing process quality control. NIR images of each component on the surface of model products and commercial products were obtained and used to construct distribution images of the components on the tablet surface. Careful control of the measurement conditions, as well as the spectral pre-analytical treatment procedure, was important for valid image construction. Moreover, the constructed images showed large variations of component distribution on the surfaces of tablets. Our results suggest that chemical imaging using NIR may have limited applicability for quantitative estimation of components in whole tablets.

Key words

Near-infrared spectroscopy, Near-infrared imaging, Distribution analysis