財団 Information ▶報告書

令和２年度「日本薬局方の試験法等に関する研究」研究報告
日本薬局方医薬品の各条試験及び製造工程試験への適用を目指した遠赤外／テラヘルツ分光法の標準化に関する研究
―遠赤外／テラヘルツスペクトルを用いた市販医薬品（錠剤）の識別性評価（第３報）*4―

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Study on Standardization of Far-infrared / Terahertz (THz) Spectroscopy for Application as an Identification Test of Japanese Pharmacopoeia Pharmaceuticals
― Spectral Distinguishability among Commercial Pharmaceuticals (Tablets) Using Far-infrared / THz Spectroscopy III *4 ―

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Summary

In order to evaluate the applicability of terahertz spectroscopy to the Japanese Pharmacopoeia (JP) identification test, the distinctiveness of the terahertz (THz) spectra among four Japanese Pharmacopoeia levofloxacin (LVFX) tablets was examined. As a result, although it is stated in the package insert that LVFX hemihydrate is used, a commercially available formulation was found to contain a mixture of hemihydrate and monohydrate by THz spectral analysis. An analysis of the dehydration process of LVFX hemihydrate and monohydrate in a dry environment and comparison with the dehydration process of tablets having similar components suggested that polymorphic conversion from hemihydrate to monohydrate had occurred in LVFX tablets D during the manufacturing or storage process. The coexistence of monohydrate may promote dehydration under a drying environment in general THz spectral measurements. Our findings suggest that THz spectroscopy, which can sensitively detect pseudo-polymorphism, would be applicable for use not only as a JP identification test, but also to check substandard drugs on the market.

Keywords

Terahertz spectroscopy, Qualitative analysis, Levofloxacin, Pseudo-polymorphs, Dehydration