

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 日本薬局方医薬品の確認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2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 II—

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Summary

In order to evaluate feasibility of applying terahertz (THz) spectroscopy as an JP identification test, THz spectral distinguishability was examined by using Japanese Pharmacopoeia (JP) levofloxacin (LVFX) tablets as test samples. The characteristic THz absorptions of LVFX hemihydrate, which is the active pharmaceutical ingredient (API), were observed in the THz spectra obtained from JP LVFX tablets (the LVFX content in the tablets is approximately 75 w/w%). Moreover, grouping of JP LVFX tablets depending on their source was successfully achieved by means of principal component analysis (PCA) and examination of the PCA score distribution using second-derivative THz spectra. Distinguishability between LVFX (enantiomer) and OFXN (racemate) using THz spectral analysis were also examined. The PCA score distribution clearly distinguished the two compounds. Furthermore, LVFX tablets containing a mixture of LVFX hemihydrate and monohydrate were found by THz spectral analysis, even though only the hemihydrate is the API. These results suggest that THz spectroscopy is applicable not only to confirm the identity of commercial JP pharmaceuticals, but also to detect substandard or suspected counterfeit pharmaceuticals on the market.

Key words

Terahertz spectroscopy, Qualitative analysis, Levofloxacin, Principal component analysis