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近赤外分光法を用いた医薬品の規格・基準の設定に関する研究 その 2
— 拡散反射 NIR 分光分析による医薬品の定性的な品質確認に対するアプローチ —

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An Approach for Qualitative Analysis of Pharmaceuticals Using Diffusion Reflectance NIR Spectroscopy

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Summary

Qualitative evaluation of pharmaceuticals on the market by means of diffuse reflectance near infrared spectroscopy (NIRS) was examined using the quinolone antibiotics, levofloxacin (LVFX), ofloxacin (OFLX) and ciprofloxacin hydrochloride (CPFX.HCl) and their tablets. OFLX, which is a racemate, and LVFX, which is the optical isomer of OFLX, showed clearly different spectral patterns in NIRS. Moreover, we examined whether it is possible to distinguish between LVFX, which is used for commercial tablets, and LVFX HCl, which can be purchased cheaply as a reagent and may be used to produce counterfeit drugs. A marked difference in spectral patterns between the two was observed. Furthermore, cluster analysis was used to estimate the spectroscopic heterogeneity of commercial CPFX.HCl tablets. From these studies, we conclude that NIR spectral information may be useful for the comparison of quantitative heterogeneity among pharmaceutical products and to identify products with markedly different quality features.

Key words

NIR, Diffusion reflectance, Quinolone antibiotics, data preprocessing, Cluster analysis