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NIR 光を用いた製錠プロセスにおける品質特性解析アプローチの一例

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Application of Near Infra-red Spectroscopy for Analysis
of Product Quality Characteristics of Pharmaceutical Manufacturing Processes

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Summary

The product quality characteristics of pharmaceutical granules made by three kinds of production processes (direct compaction, shear granulation and fluidized-bed granulation) were examined using near-infrared, mid-infrared and far-infrared/terahertz spectroscopies. The samples contain 10 w/w% of theophylline as an active pharmaceutical ingredient (API). There were significant differences of C-H stretching and CH₂ deformation absorptions in the mid-infrared region among the products of the three production processes, and these appeared to be due to differences in the interaction between the API and the binding agent. We suggest that vibrational analysis in the infra-red region would contribute not only to an understanding of the product quality attributes of pharmaceutical production processes, but may also be applicable for quality control of pharmaceutical products.

Key words

NIR, Granulation process, Wet granulation, PAT, Theophylline, HPC, ATR-MIR, Far-IR, Terahertz