563. 标题: Chemical Mapping of Hydration and Dehydration Process of Theophylline in Tablets Using Terahertz Pulsed Imaging
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摘要: The purpose of this research is to investigate the topographical pattern of hydration and dehydration (also known as pseudo-polymorphic change) of drug substance in drug product using terahertz (THz) pulsed imaging. Emphasis is placed on (1) applicability of THz pulsed imaging and (2) kinetic analysis in the pseudo-polymorphic change. Either anhydrous or monohydrated form of theophylline was used as the drug substance, leading to initially anhydrous or monohydrated tablets. These tablets were stored at 25 degrees C to keep the relative humidity constant at 84% (anhydrous tablets) or 45% (monohydrated tablets), respectively. The THz pulsed imaging was confirmed to enable visualization that the hydration of the anhydrous form or the dehydration of the monohydrated form began on the surface of the tablets and gradually progressed to the core side in the tablets with storage. Kinetic studies indicated that these pseudo-polymorphic changes followed the phase boundary mechanism. Since the other imaging techniques has been scarcely achieved to show the topographical pattern of pseudo-polymorphic change of drug substances in drug products directly and visually, it is considered that THz pulsed imaging has a potential ability to solve complicated issues in pharmaceutical development.
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